Online Controlled Substances Summit 2025
Virtual Meeting
September 11, 2025 | 12:30-3:30pm *(eastern)*

Transcript

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

Susan Winckler (00:00:32):

Hello, and welcome. Thank you for joining us virtually for this important public health discussion. I am Susan Winckler and I serve as chief executive officer for the Reagan-Udall Foundation for the FDA. And we are pleased to collaborate with FDA to host the 2025 Online Controlled Substances Summit.

(00:00:51):

As we dive into the agenda, I thank our FDA collaborators for their partnership in planning this summit. So, let's talk about our time together. We are gathered to talk about the misuse of the online ecosystem, social media and other web-based platforms that are misused by criminal enterprises to create access points for obtaining controlled substances outside of the legal structure and delivery of healthcare. We will hear perspectives from regulators, including the U.S. Food and Drug Administration, researchers and academics, from family members who have suffered loss, and from digital platform representatives from search, social media, and e-commerce.

(00:01:36):

Throughout the day, we will learn from these experts about how the illegal sale and purchase of controlled substances online exacerbates the ongoing public health problem of misuse of these products, as well as explore strategies for actions that each of us can take to fight back against this criminal enterprise.

Evolving Threat Part 1
Sangeeta Vaswani Chatterjee, PharmD, Acting Director, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Susan Winckler (00:01:58):

To open our meeting today, I am pleased to turn to Dr. Sangeeta Chatterjee, who is acting director of the Office of Drug Security, Integrity, and Response within FDA's Center for Drug Evaluation and Research's Office of Compliance.

(00:02:15):

Dr. Chatterjee, it's been a pleasure to work with you in planning this event, and I am happy to turn the virtual stage over to you.

Dr. Sangeeta Vaswani Chatterjee (00:02:24):

Great. Thank you so much, Susan. So, good afternoon, everyone. I want to thank the Reagan-Udall Foundation, my esteemed colleagues at FDA, and most importantly, all of you for attending today's sixth Online Controlled Substance Summit meeting.

(00:02:38):

And your presence here today really demonstrates your genuine commitment to addressing the drug overdose crisis that's taken so many lives. And in the digital realm, specifically, what we're seeing is that drug traffickers and criminal website operators are illegally abusing internet platforms and services to fuel the crisis, and they're heartlessly preying on millions of Americans struggling with substance abuse disorders. And so, having been involved with these summits since their inception in 2018, I can say with certainty that this type of engagement has the power to drive real change. And we really applaud the meaningful actions that the stakeholders have taken to prevent the illegal sales of controlled substances through their platforms and services. And we really need to keep the momentum going, so at today's summit, we look forward to building upon these successes and identifying additional opportunities for intervention and risk reduction.

(00:03:37):

The human cost. This is really the reason we are here today. So, on the left, this is Ryan Haight. In February 2001, 18-year-old Ryan from California died after purchasing Vicodin online from a pharmacy that did not require a prescription. Ryan's preventable death led to the passage of the 2008 Ryan Haight Online Pharmacy Consumer Protection Act, which amended the Controlled Substance Act. And I'll talk a little bit more about later in the presentation.

(00:04:07):

More recently, we lost Charlie Ternan on March 14th 2020, at just the age of 22 years old. Charlie died after ingesting a counterfeit Percocet pill laced with fentanyl. And as part of today's summit, we will hear directly from Charlie's father, Ed Ternan, about how this tragedy has affected their family.

(00:04:28):

These are not isolated incidents. The crisis knows no boundaries. We are seeing heartbreaking impacts that cut across various segments of society and age ranges. And some of the victims are even younger. They are not even yet in high school.

(00:04:46):

So, I work in CDER's Office of Compliance. Our mission is to shield the public from poor quality, unsafe, and ineffective drugs. And we do this through proactive compliance strategies and risk-based enforcement actions. So, we take a multi-pronged approach to addressing the online component of the drug overdose crisis, and one of the tools that we have in our toolbox are warning letters. And we send these to operators of websites that illegally sell these dangerous products to U.S. consumers. So, despite the fact that the Federal Food, Drug, and Cosmetic Act prohibits the introduction of prescription drugs in interstate commerce, without prescriptions or approval including controlled substances, we see these types of products that are offered for sale online continuously. And since January of this year alone, we issued 15 warning letters for the sale of controlled substances online, and one as recently as yesterday. Since 2017, we have issued over 70 warning letters citing more than 600 sites.

(00:05:54):

So, I want to note that the Controlled Substance Act, which is enforced by our DEA colleagues, prohibits the illegal distribution and dispensing of controlled substances online and establishes requirements for the legal distribution. So, under current law, no entity is registered with the DEA to dispense or distribute controlled substances online. And what that means is that anyone selling controlled substances through the internet is breaking federal law while putting patients at grave risk. So, FDA has partnered with DEA to also issue joint warning letters that cite both of our authorities.

(00:06:32):

In terms of the current landscape, we're definitely seeing that many of these sites are selling these controlled substances without requiring a prescription, making it really easy to access these dangerous drugs. A variety of controlled substances are being sold, including opioids, benzodiazepines, Schedule II stimulants. And these substances are frequently misused or abused together, so the risk is further heightened when they're available on the same site. And this really can even lead to overdose and death in many circumstances.

(00:07:04):

Non-medical use of these substances is widespread, and what we're also seeing is that non-medical use of Schedule II stimulants is frequently occurring with young adults and college students. And with more and more youth having access to devices and social media, it's really critical to protect this population.

(00:07:29):

So, I would just like to take a moment to provide some historical perspective and describe our journey since 2018. So, the earlier summits focused on building the foundation for concrete stakeholder actions, and that included both social media as well as search engines, and they also included the role of registries and the registrars. And for those of you who have been involved with these summits from the very beginning, you'll remember that they used to be called the Online Opioid Summits, and we changed the name to the Online Controlled Substances Summits. And the reason for that is that the problem has really morphed from the opioid crisis to the drug overdose crisis, and we had to adapt to that and make sure that we were evolving with the landscape.

(00:08:13):

We also had to continue to evaluate the evolving landscape in terms of the stakeholders that had to be involved as part of the solution. And so, we expanded participation. Four recurring themes emerged collaboration, education, barriers, and continuity. And it also became very apparent to us that this is a multi-platform problem where the marketing and sale is occurring across multiple sites. So, there is a recognition that successful compliance strategies requires coordination across all stakeholders who have the greatest sphere of influence.

(00:08:52):

So, a holistic approach is critical. We underscore the importance of convening representatives from both the public and private sector. And as you can see here, the prior summits have included broad multi-sector engagement, each playing a key role advancing innovative solutions.

(00:09:15):

And I would like to highlight some of the major successes that we've seen in terms of actions that have been taken to protect users of the internet. So, we saw that search engines started to de-index websites named in FDA warning letters, making them so that they don't appear in the organic search results. We also saw some search engines displaying pop-up warnings to websites identified in FDA warning letters, alerting consumers to the potential dangers. Some of the social media platforms have redirected users searching for controlled substances to educational and treatment resources.

(00:09:51):

FDA completed a successful pilot process with the Department of Commerce and domain name registries related to opioids. And as a result of which, nearly 30 websites illegally offering opioids for sale became inaccessible to the public. And this was through voluntary registry actions that were based on FDA's warning letters. And this was a proven framework, so we continue to work with registries in this manner for other controlled substances as well. Our summits have also catalyzed similar initiatives around the globe, expanding our impact beyond the U.S. borders.

(00:10:26):

So, these are significant wins for public health, and we need to remain laser focused on the problem, recognizing that the threat continues to evolve based on the way that these products are sold, as well as the new and emerging platforms that we're seeing.

(00:10:42):

So, fast-forward to last year's summit in 2024, four critical insights emerged, consumer access challenges and opportunities, communication strategies and messaging, partnership development and trust building, compliance barriers and solutions. The conversation did not stop at the summit. These critical insights have served as the cornerstone for our ongoing dialogues and have laid the groundwork for meaningful action.

(00:11:09):

So, I would like to conclude by underscoring that collaboration is essential. We recognize that the availability of controlled substances online is not a problem that was created by the internet industry, but we do need the help of the internet ecosystem to find innovative solutions. We appreciate that so many key stakeholders have joined us at today's event, who we trust are equally concerned about the drug overdose crisis and are committed to making a profound impact. The stakes are really high, the lives that we save matter, and that's why this work matters. Thank you so much, and I'll turn it over to Susan.

Susan Winckler (00:11:49):

Thank you so much, Dr. Chatterjee, for reminding us of the history of these conversations and the importance thereof.

FDA Remarks

Grace Graham, MPP, Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration

Susan Winckler (00:11:59):

I want to turn to an additional FDA official. We have two more in our set of opening remarks here. So, thank you, Dr. Chatterjee. I'd like now to turn to Deputy Commissioner Grace Graham. She serves as deputy commissioner for policy, legislation, and international affairs at FDA.

(00:12:19):

And Deputy Commissioner Graham, we'd love your thoughts as you think about your broad portfolio and the importance of this topic and our conversation today. I'll turn it over to you.

Grace Graham (00:12:31):

Thank you, Susan. And it was great to get to hear Dr. Chatterjee's presentation and some of the background.

(00:12:38):

Unfortunately, for most of my time on the Hill and in government since 2011, the opioid crisis has been front and center, substance use disorder crisis. I've been at FDA now as deputy commissioner a little over six months and very excited to be here today, and thank you and the team for convening this summit. And thanks to the speakers, panelists, and attendees for participating in what is an important meeting and interesting conversation.

(00:13:08):

As I mentioned, throughout my time on Capitol Hill, I got to see how devastating the overdose and poisoning crisis is, not just individuals, entire families and communities. The number of parents that I met with who every day started like another day, they go to get their teenage son, daughter out of bed, up for school, and then finds them not alive. And often, when it's investigated, that pill that led to the tragic outcome was ordered online through an app, delivered nearby or to the door of their home.

(00:13:46):

And while the federal government has taken action, and I've been fortunate to work with FDA and the federal government throughout my career on many pieces of legislation, there's still much more that needs to be done. Drug overdoses and poisonings remain the leading cause of death among Americans aged 18 to 44. And addressing this crisis is one of the many critical priorities of this administration and working to make America healthy again.

(00:14:14):

When I first started in 2011, pill mills of prescription medications were a top concern. Since then, the crisis has expanded beyond prescription opioids. Now fatal overdoses often involve illicit synthetic opioids such as fentanyl or its analogs. We've seen opioids used in combination with other controlled substances, including benzodiazepines, stimulants, xylazine, and polysubstance use, as was mentioned, is increasing. And just this week there's reports of emerging threats such as nitazenes coming out of New York.

(00:14:49):

FDA has taken bold action to try to warn the public about emerging threats, recently announcing efforts to combat concentrated synthetic 7-hydroxy, which is a concentrated byproduct of the kratom plant and is too often easily purchased in gas stations, convenience stores, vape shops, and online. And some of these products may appeal to kids and when they're in the gas station, parents and others may not even realize that these are illegal and that they are an opioid.

(00:15:22):

FDA continues to be committed to working with state, local, and federal government partners, physicians, families, to address known and emerging threats. Another part of that role is doing our part to help ensure a safe supply chain for prescription medications and making sure the public is aware of the safest channels from which to get their medications. Patients and families may not realize that some online pharmacies are unlicensed or that a cheaper prescription medication dispensed through this illegitimate online pharmacy may be unsafe and ineffective.

(00:15:53):

FDA can also help facilitate innovation to reduce reliance on controlled substances and help those who may have a substance use disorder achieve recovery. Prescribed controlled substances are an important treatment option for patients who need them, but that doesn't mean we shouldn't work together to try

to have more options for patients. Just yesterday, FDA released draft guidance to help innovators who want to bring novel non-opioid treatments for chronic pain, and there's more that can be done to help those with substance use disorder have more options to help on their path to recovery.

(00:16:25):

So, while FDA is working more broadly than just looking at controlled substances available online, I am glad that today's summit and everyone's taking the time to participate today, will explore innovative strategies to curb the illegal online sale of these products. The spread of prescription drugs illegally sold to consumers, including kids, through unsafe websites and social media platforms, present unique challenges for regulators, law enforcement, policymakers, families, doctors, and others who are working to prevent these dangerous products from harming the American public.

(00:16:59):

As you've already heard, we have a great three colleagues from FDA and you've heard from Dr. Chatterjee already, from CDER, and you'll also be hearing from Marta Sokolowska and Jake Ellis, that will highlight this evolving threat and what FDA is doing to help combat it and protect the public. As we work to open the sixth summit, also hear from stakeholders, public and private sector, academia, regulatory, to help navigate these challenges and help develop strategic and effective solutions because it will take more than FDA by itself. And so, I'm just so grateful that everyone took the time to participate today.

(00:17:37):

I'm looking forward to the conversations and collective actions continuing beyond today and through innovation, collaboration, hoping we can further alter the trajectory of this crisis, preventing overdoses and poisonings. Thank you.

Susan Winckler (00:17:50):

Thanks so much, Deputy Commissioner Graham, and very helpful to remind us that there are the efforts that we're talking about today and then broader efforts to continue to address the challenge of substance use disorder and misuse of controlled substances.

Evolving Threat Part 2

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

Susan Winckler (00:18:09):

So, we appreciate your engagement with us, and as you noted, we're now going to turn to a third colleague from FDA in our opening remarks, and I am going to turn now to hear from Mr. Jake Ellis, who serves as the senior operations manager in the agency's Office of Criminal Investigations. Jake, would you share with us your thoughts on this evolving threat?

Jake Ellis (00:18:32):

Thank you very much. Thank you very much for the Reagan-Udall Foundation for organizing this and for Sangeeta to always inviting me to speak with her. We don't catch up as often as I'd like to, but when we do, it's always great to hear what both our sides of this fight are doing.

(00:18:46):

Our mission here at FDA OCI is pretty clear. We're here to protect the public by investigating and bringing to justice those who violate federal laws involving FDA-regulated products, and that includes criminals who traffic in counterfeit opioids and illegally distribute controlled substances online.

(00:19:02):

It's a constantly evolving threat. I've worked in the cyberspace of these investigations here at FDA for approximately the past seven years. A lot of my time has been spent investigating counterfeit opioids, counterfeit Adderall, counterfeit Xanax investigations, which perpetrated on the dark web, rogue online pharmacies, and now encrypted chat applications. These are complicated investigations because of the technology involved, so it is a very, very tough mission for us.

(00:19:34):

Our approach in this is typically twofold. One is enforcement and the other is collaboration. We utilize our experience, techniques that we've developed, as well as software and contracted software to combat this fight. We also collaborate with our federal, state, and international partners because no single agency can investigate this on its own. And we recognize that behind every seizure, every case, every person that we put in jail, these are families that are being affected by these horrible drugs and on this evolving threat that we're constantly chasing and always feel we're a little behind the eight-ball on what is the next thing that's going to be coming.

(00:20:12):

So, over at FDA OCI, we have our Cyber Investigations Program. Their mission is investigating these crimes across the entire internet landscape, as I mentioned, rogue online pharmacies, dark web marketplaces, social media, encrypted chat applications. Our focus of that unit, counterfeit pills, it is the now synthetic opioids. We started out with a lot of the fentanyl. It's moved into, as deputy commissioner mentioned, nitazenes coming out of Asian countries and us trying to chase down what they are and where they're being pressed into pills.

(00:20:53):

One of our biggest successes in collaboration I'll talk about is with the FBI's JCODE Unit, the Joint Criminal Opioid and Darknet Enforcement Group. While darknet is in there, they're now expanding their mission to combat a lot of different aspects of the internet, but it started with a darknet focus. This latest iteration was Operation Raptor. They always use the word tor because the Darknet you're accessed with the Tor browser.

(00:21:21):

As you see at the bottom here, these are the different investigating agencies, including Europol, but a lot of the domestic ones from the U.S. that were involved in this operation. And the operation culminated with approximately 270 darknet traffickers being arrested, 200 million in cash and virtual currency seized, 2.3 metric tons of illicit drug, that's raw powder that had not yet been pressed into pills, adulterants that are put into the pills like xylazine, things like that, and 181 firearms. And you can see the international footprint of all the countries that were involved here throughout Europe, Asia, and South America. So, a real one- team effort of a lot of government agencies and law enforcement coming together to combat this very, very difficult threat.

(00:22:09):

Another initiative that we're just starting up, again, as the deputy commissioner mentioned, is combating the 7-OH threat, this synthetic kratom. So we've named that Operation 007. What we're going to be targeting is just getting off the ground, but what we're going to be targeting is high-risk internet pharmacies and dark web marketplaces that are marketing this, specifically marketing it as

natural extract, all natural, herbal blends, mood enhancers, things like that. Clearly lying to the public about what this is. We are conducting undercover purchases. I'm going to be getting it over to our lab so that we can understand a little bit more about the footprint of this 7-OH, and then conducting our normal criminal investigations after that.

(00:22:55):

When we started first looking into it after Commissioner Makary mentioned it one morning, I heard it on the news, we started investigating what it was and what the threat was. And one thing that we noticed was the explosion of usage online, and you can see that Reddit online posts in the last 12 months, how much they've gone up. 187 mentions in June of 2024 compared to 19,744 mentions just one year later. So, everybody's talking about it on the internet. Now everybody's going to be talking about it for law enforcement to be going after this threat and understanding where our best angle of approach is.

(00:23:37):

So, that's the end that I have. I'm not going to be able to stay for the entire summit today due to other needs, but my email address is right here if anybody does need to reach out. And again, thank you very much to CDER, to Sangeeta, Deputy Commissioner, and the Reagan-Udall Foundation.

Susan Winckler (00:23:54):

Jake, we greatly appreciate your remarks in that update of what ... Well, just really the incredibly important work that you and others in the Office of Criminal Investigations are pursuing. So, thanks for joining us today and providing that overview.

Session 1: Research Updates and Trends

Saleem Alhabash, PhD, Professor & Associate Chair, Department of Advertising and Public Relations, Associate Director of Research, Center for Anti-Counterfeiting and Product Protection, Michigan State University
John Hertig, PharmD, Founder, Hertig Healthcare Advising, LLC
Angie Hoth, PharmD, MPH, Research Consultant, Reagan-Udall Foundation for the FDA

Susan Winckler (00:24:10):

With that, we'll turn from the FDA perspective to an update on some of the research in this space. So, in our next session, we want to ground today's conversation with updated research on trends in this space. We have three speakers and I'm going to turn first to Dr. Saleem Alhabash from Michigan State University's Department of Advertising and Public Relations, where Dr. Alhabash serves as the associate chair of the department. And we're looking forward to hearing from you, sharing some of your research findings on who buys these illicit medications and why.

(00:24:50):

With that, I'm going to step out of the way and let you pick it up, and we look forward to your information.

Dr. Saleem Alhabash (00:24:55):

Thank you so much, Susan, for having me today, and thanks for the warm introduction. I'm thrilled to participate today on behalf of Michigan State University and its A-CAPP Center, which is the first and only academic center that is dedicated to research, education, and outreach on trademark counterfeiting and intellectual property protection.

(00:25:17):

I'd like to dive right in by examining the problem of counterfeit medications within a broader context. The counterfeit product ecosystem has profound impacts on the global economy, communities around the world, and most critically, the health and wellbeing of consumers.

(00:25:37):

The problem, as you know, is mushrooming in magnitude. Counterfeiting is valued globally at about $467 billion, accounting for approximately 2.3% of all global trade. With the growth of e-commerce and social commerce marketplaces this issue will continue to expand. When it comes to multiple stakeholders are seeking solutions from law enforcement, actions that are technology-driven, such as track and trace technologies, blockchain and AI, but the sheer volume and velocity of this issue complicates supply chains and make enforcement feel like a daily game of Whac-A-Mole.

(00:26:24):

So, with that said, there's profound impacts on the health and wellbeing of consumers. We know that the counterfeit medication market is evolving and growing. For example, the CBP in 2023 reported seizing 1.5 million units of counterfeit medications. And in addition, there is tons of counterfeit medications that are available online. The WHO reports that about half of all medications sold online are counterfeit with the majority of online pharmacies operating illegally. And the human cost is staggering with multiple human deaths that are attributed to buying counterfeit medications.

(00:27:03):

So, this begs the question for us to ask today. Who are the counterfeit consumers and why do they buy counterfeits? So, this problem exists with a broader landscape of online risks. Most of us have engaged in these risks and engage in them on a daily basis, from accepting a friend request from someone on social media to sharing our private information and having it misused by different stakeholders.

(00:27:34):

It is safe to say that online risks are everywhere. And this raises the question of whether this is an issue of information availability or is it fundamentally a problem of human behavior? From a data perspective, the scale is quite overwhelming. Seagate has estimated that by 2025, this year, the global digital data sphere will reach about 175 zettabytes. And to put that in perspective, if we saved this data on Blu-ray DVDs and stacked them, the pile would reach the Moon 23 times and circle the Earth 222 times, and it would take one person, 1.8 billion years to save all these data, or 81 days if every person on Earth pitched in.

(00:28:24):

Each connected individual now experiences more than 4,900 digital touch points every single day, highlighting the sheer volume of information that is shared online. And amid this, bad actors exploit vulnerabilities, undermining consumer trust and the integrity of marketplaces.

(00:28:44):

From a consumer behavior standpoint, it is important to understand why the digital environment makes these risks so difficult to resist. I'm going to share a few findings from our research. Number one, every platform evolves beyond its intended purpose. Once launched, platforms take on lives of their own, and especially in how people use and shape them.

(00:29:09):

The second important thing to highlight is that people form deep psychological connections to digital platforms. Despite majority of them being free, platforms become so embedded that people assign

them immense value. For example, the large amounts of money people say they would require to give up their Facebook account that you're seeing on the screen.

(00:29:32):

Number three, digital technology use has become so embedded in our life that it's become automatic, habitual, and passively addictive. In one study that I led, we have found that people switched between segments every 10 seconds when they were using social media, which is just one second longer than the average attention span of a goldfish. Psychophysiological data further show that simple actions, such as pressing the like button, activate unconscious cognitive and emotional mechanisms. The fourth observation deals with the fact that what happens online does not really stay online. In one study, participants exposed to beer ads reported greater intentions to drink alcohol than those who were shown water ads.

(00:30:24):

When later we offered them a choice between a coffee shop or a bar gift card as an incentive, 73% of them, especially those who were exposed to beer ads, chose the bar gift card compared to about a 50-50 split in the control group.

(00:30:42):

And the last observation, AI adds new risks. Emerging technologies have now been influencing people's lives in troubling ways, from recommending divorce, to suggesting suicide to individuals struggling with mental illness.

(00:30:57):

Let's bring it back to counterfeit medications. We conducted a study of about 4,000 consumers from eight countries, and here are some of the findings. What we found is that the majority have bought medications from brick-and-mortar pharmacies, and about half of them have bought medications online.

(00:31:19):

When we asked them about buying counterfeit medications, about one-fifth to one quarter of the sample reported that they have bought counterfeit medications, both knowingly and unknowingly.

(00:31:33):

Men were more likely than women to buy counterfeit medications, and younger consumers, particularly Gen Zs, were more frequent buyers of counterfeit over-the-counter medications, vitamins, and supplements, while Millennials led in prescription medication purchases.

(00:31:55):

Health literacy was a key factor. Participants with lower health literacy were significantly more likely to purchase counterfeit medications compared to those with higher levels of health literacy.

(00:32:09):

Finally, we also asked people why they buy medications online. Responses fell into two broad categories, convenience and accessibility, and necessity. And necessity dealt with lack of prescriptions or unavailability of medications locally.

(00:32:25):

While convenience was cited more often among the participants, our statistical analyses showed that necessity was a far stronger predictor of counterfeit medication purchases.

(00:32:38):

To close, the evolving digital environment holds immense promise, but also creates new risks. Among them, the purchase of counterfeit medications. While digital platforms provide convenience, gaps in healthcare access and medication availability might push consumers toward risky behaviors. Addressing this issue requires situating it within broader socio-political context and developing consumer-centered solutions. Thank you for having me today.

Susan Winckler (00:33:06):

Dr. Alhabash, thank you so much. I always learn quite a bit in these presentations, but I did not expect to learn about the attention span of a goldfish today. And the other information you presented was far more important and very helpful as we just think about this ecosystem and continually evolving ecosystem that can be misused by the criminal enterprise. So thank you so much for sharing your expertise in such a compelling way.

(00:33:39):

With that, I'm going to turn to our next speaker who is Dr. John Hertig, founder of Hertig Healthcare Advising, and also an adjunct assistant professor at Purdue University. Dr. Hertig, I am sorry that you have to follow Dr. Alhabash in that compelling presentation, but I know that you are going to be just as informative. I'll turn it to you.

Dr. John Hertig (00:34:01):

Thank you, Susan, and thank you to the Reagan-Udall Foundation for the invitation to this really important event. I'm used to following Dr. Alhabash, so I'm totally comfortable with this and looking forward to building on his wonderful work.

(00:34:15):

What I'm going to present for you in the next few minutes is really focused on our patients and consumers, and what and how they are behaving when they go online, with a particular focus on online controlled substances. As Dr. Alhabash suggested, there are a variety of different ways as to why our consumers and our patients do use the internet, social media and other platforms to buy prescription medicines. One of the ones that's most obvious is likely cost, where our consumers feel they're getting a better deal online, they go hunt for a better deal. Just like we use Amazon or Amazon Prime, or other ways to buy products, they're looking for that better cost.

(00:34:53):

But the two that are growing most, and you saw that in the previous work are convenience and access. We are a convenience- driven society, and it makes sense that we would go online for the convenience factor to buy prescription medicines including controlled substances, but access is growing and access takes many different forms. It may be access, because as Dr. Alhabash suggested, there's a necessity because they can't access prescription medicines.

(00:35:20):

There are many parts of our country that are in pharmacy and healthcare deserts, and so the internet is their only option to access. We then have access when it comes to wanting to remain anonymous, perhaps because of bias or other judgments. "I don't want to go into a particular clinic. I don't want to go into a doctor's office, so I'm using the internet to access products." Unfortunately, the more our consumers and our patients use the internet, the more comfortable they become, and you end up developing essentially this false confidence, where consumers feel that they can identify in a legal site or a dangerous site, when in most cases, they really cannot, putting themselves at jeopardy from a patient safety issue.

(00:36:04):

There are many contributing trends that are leading to a growth in access of prescription medicines online. We have this historic shift to buying medicine online, where we see year-over-year growth. My research confirms Dr. Alhabash's research as well, where we have about 50% of US adults that have used an online or internet-based pharmacy in some way. We simultaneously see a rise in patient harm, where 24% of Americans who have purchased medicine online report receiving harmful, counterfeit or substandard products.

(00:36:36):

In many cases, our own policy has normalized remote access. For example, telemedicine, although very important, has normalized access to controlled substances via telehealth platforms, which under controlled circumstances is fine, but when we go beyond those safeguards, we put ourselves as consumers and patients at risks. We have shortages that continue to occur, along with other access gaps. There's persistent stimulant supply disruptions, for example, with lack of access to Adderall, for example. And our sales channels continue to keep shifting, where we have an increasing use of social media and other platforms to access prescription products.

(00:37:20):

In the most recent research that we have, about 15% of our patients are accessing controlled substances via social media and digital platforms. This was highlighted in a research study that I conducted along actually with Dr. Alhabash and our colleagues, where we specifically looked at how controlled substances were being purchased on social media. Where we had just over 1,000 participants, 730 were actually included due to inclusion and exclusion criteria. You can see the demographic breakdown here.

(00:37:54):

Of note, a vast majority of those included in this study had insurance. And so oftentimes, this isn't an issue of insurance, but it could be an issue of under insurance where they're accessing out of necessity. The younger population included in our study was again validated by how often they use social media. And when we asked them what they purchase online in the past 12 months, and this was a percentage of the full sample, you see an alarming number of people buying narcotics, with over 50% are stimulants, as we just went over with Adderall, and sedatives like our benzodiazepines that are listed here. Many, many, many of our participants are purchasing via social media, as well as messaging and other digital platforms.

(00:38:39):

Knowing this, there are a number of contemporary consumer considerations that our research has bared out. We have a series of macro-level forces that are driving continual growth, as well as the sophistication of illegal online drug sellers. We have our tariffs and other trade that are creating increased costs driving people online. We have a loss of insurance as well as under insurance, where our patients aren't able to access products maybe via traditional pathways, and so they're going online to access them. We have an incredible growth in AI and artificial intelligence that enables rapid creation of fake and misleading websites that are involved in search engine optimization manipulation, as well as the use of chatbots that are driving people to illegal and dangerous sources.

(00:39:25):

We have a continued barrage of influencer ads, and actually there's some recent research that suggests a 10 to 20% influence of influencers or celebrities that push products on what people buy. We've talked about drug shortages already. Cross border importation leverages these foreign jurisdictional shields, where so many of these bad actors are actually ex-US or outside the United States making it very

difficult for law enforcement to track and shut down. And then we have this evolving modern payment schemes, where we have crypto peer-to-peer transfers, these other ways to buy particular products. Much of that is happening on the dark net, but we're seeing that creep into the front net as well.

(00:40:10):

So as I conclude today, I want to make sure I emphasize a few key points. One is, there is a rapid and continued increase in e-commerce and online controlled substance purchasing, because of many of those macro as well as micro trends and the easy availability of these products online. Online pharmacies can be safe and potentially cost-effective for patients. Unfortunately, it's the minority of what's available online. Only about 5% of online pharmacies are legal in some way, but we shouldn't shut down everything, because again, they can be a way that our patients access medication, particularly those that struggle with going into brick and mortar pharmacies.

(00:40:53):

However, healthcare professionals, pharmacists, physicians, others need to be involved in this type of care, and these online sources must be thoroughly vetted. Educated consumers as well as our health professionals take less risks. Unfortunately, more education is needed. We have this really dangerous intersection where our consumers feel that they can tease out or they can identify safe sources, when in fact, they really cannot, which puts themselves of significant risk.

(00:41:25):

If you are a health provider, asking simple questions can make a world of difference for our patients. For example, "Where are you getting your medication from? Are you getting it from the pharmacy across the street, the independent down the road, or are you just Googling it?" Just Googling it is not enough to stay safe online, particularly as we have emerging digital platforms and social media that are selling prescription medicines, oftentimes risky medicines like controlled substances and other products.

(00:41:55):

This is indeed a global issue. I'm so pleased that the Reagan-Udall Foundation is putting on and continues to put on these events in collaboration with the FDA. More work needs to be done because this issue results in a severe negative impact on public health, patient safety, and especially is dangerous with controlled substances. I know we're going to be hearing from families who have been directly impacted in just horrific ways by this, and I'm happy to be part of the solution and working with many of you on this call to continue to move the needle in a positive direction. So thank you again, Susan. Thank you for the invitation, and I look forward to learning more throughout the day today.

Susan Winckler (00:42:34):

Dr. Hertig, Thank you so much. I was struck in your presentation about the thoroughness in helping us to get a picture, not only a picture of what is happening, but some of the picture of why and the importance of that. And you even took care of some of the questions that were submitted online related to individual behavior, so greatly appreciate that. Thank you for joining us today.

(00:43:03):

With that, I will turn to our third researcher who is going to help us learn more about what is happening and then the evolution of the availability of controlled substances illegally via the misuse of various digital platforms. For our third presentation, I'm going to turn to Dr. Angie Hoth, who is a research consultant for the foundation. Dr. Hoth, the virtual stage is yours.

Dr. Angie Hoth (00:43:33):

Thank you, Susan, and good afternoon everybody. I think what you're going to find with my presentation is it echoes a lot of what Dr. Alhabash and Dr. Hertig has already told you. So I will start in.

(00:43:49):

So today, I'm going to provide you with some information about how consumers are purchasing controlled substances through social media, via research that was conducted by the foundation and research partners.

(00:44:02):

We conducted an observational assessment of social media interactions related to the selling and purchases of online controlled substances, namely opioids like oxycodone, fentanyl, and hydromorphone, stimulants such as amphetamines, Adderall and Ritalin, and benzodiazepines like Xanax and Valium, and included where and how sales were advertised, initiated and conducted. This is an update of a social media scan that we conducted in 2023, and platforms were chosen based on their popularity, the purpose of the site, and some prior research that had been done on where purchases were occurring.

(00:44:46):

This slide shows some of the search terms that are used to find controlled substances online. Searching drug brand names, common slang terms and seller terms yielded the most results in being able to find controlled substances online. Slang terms with common language such as using berries or juice resulted in a lot of non-drug related posts and weren't very useful in finding specific controlled substances.

(00:45:16):

Some of the workarounds used to search for controlled substances include intentionally misspelling the drug brand or generic name, or using numbers in place of letters. Some of the terms shown in red on this slide indicate that the person is looking to buy or sell a controlled substances. Purchasers may add buy in front of a slang term or even an emoji, and sellers might add plug to the end.

(00:45:44):

So searches do also include emojis, and they include a lot of emojis. This is not an exhaustive list that are being used in searches, but these are very popular, and especially popular with younger users on platforms in order to get around search restrictions. So from our research, four takeaways emerged from the research work that was done related to safety, motivations for purchasing online, platform functions, and the actual purchase itself. The safety of the product was generally not discussed at all regarding on the sites that were selling the specific controlled substances.

(00:46:29):

And they were not discussed in advertisements or during public interactions, but some strategies increase the perception of safety, such as sellers using the word drugstore or pharmacy in their site or seller names, which can be very misleading.

(00:46:46):

Searches resulted in a mix of legitimate ads and illicit content popping up when people were searching for a controlled substance, which made it very difficult to determine what information was true and what information was not. And as you already heard, common motivations for purchasing online include fast and discreet delivery, that there was no prescription required, and ease of access. Some users also cited taking control of their health as a reason for bypassing traditional medical channels.

(00:47:20):

Policies on all platforms restrict the purchase or sale of controlled substances, and many policies have evolved since 2023, with some becoming more restrictive and some becoming somewhat less restrictive. What our research has found was that search functions may facilitate or block access to sale information, and consumers and sellers are very savvy to create workarounds to get around new policies or search functions that may block access.

(00:47:49):

And finally, similar to what we saw in 2023 and 2024, was that purchasers typically use social media to identify sellers, move to a second platform for communication about a sale, and then move to a third platform for the financial transaction. In addition, payment details were rarely discussed in posts.

(00:48:15):

So top takeaways from our research are that despite platform policies prohibiting the sale of controlled substances, purchasers and users can still locate sellers through very creative search terms.

(00:48:28):

Common motivations for purchasing controlled substances through social media include fast discreet access without needing a prescription, and overall safety information tends to be lacking.

(00:48:40):

Massive amounts of information and constantly evolving terminology make assessment of the problem and regulation extremely difficult. And one consideration is how can harm reduction messaging be woven into searches in order to alert people to potential risks and offer mitigation strategies.

(00:49:02):

Some platforms offer warning or safety statements, but general harm reduction information overall was limited, so how can we keep people safe at the time that they're actually doing their searches? And so those were the findings from our social media, delving into social media, and I will turn it back to you, Susan.

Susan Winckler (00:49:25):

Excellent. Thank you so much, Angie. I can see your slide with the visual presentation of the search terms and the emojis, and that's just helpful to continue to learn about the language and the mechanisms that are used for individuals to pursue these searches, and then unfortunately, get drawn into the criminal enterprise on the other side that is evading the legal system. So thank you. We appreciate the update on the research and learning more about this environment and consumer behavior so that we might better provide better information and better protection for all around us. So thank you.

Session 2: Human Impact of Online Access to Controlled Substances

Jennifer Frink, Family Representative
Ed Ternan, President & Co-Founder, Song for Charlie

Susan Winckler (00:50:14):

We'll close out that research update and turn now to a session to remind us of the human toll of this criminal activity. We're going to hear from two families who have been directly impacted by the illegal online sale of controlled substances. And their experiences drive our urgency in responding and reminding us why the work that we are all doing, why this work, and we need others to engage in it, why

it is so critical. I'm first going to turn to Ms. Jennifer Frink and then to Ed Tiernan. So Jennifer, may I turn to you and thank you for investing your time and trusting us with the story that you're about to share?

Jennifer Frink (00:51:05):

Thank you, Susan. Thank you for the opportunity to tell my family's story. It is not easy for me, but my hope is that sharing this information will help others. There are three things I'd like to start off telling you about my son, Tasman William Frink. First, he was highly intelligent.

(00:51:24):

Second, he was a digital native, born in 2002. He grew up in the digital age, comfortable with computers and the internet from toddlerhood. Laptops were standard issue in grade school and getting a smartphone when you turn 13 was a rite of passage.

(00:51:44):

Third, he had a very normal suburban upbringing in Portland, Oregon. He had good schools, friends, vacations to beaches and mountains, boy scouts, swim team, lacrosse, races, birthday parties, beloved pets, big family gatherings at all of the major holidays, and parents who deeply loved him.

(00:52:09):

Tasman was a precocious child who could read and write fluently by the time he was three years old. He loved Thomas the Tank Engine and he could rattle off over 100 different trained names and numbers. He had a photographic memory. And by the time he was in preschool, he could solve simple algebra problems. He shocked his kindergarten teacher on the first day of school by writing down that he wanted to learn to spell big words in kindergarten like disestablishmentarianism. I can only imagine how disappointed he was when he saw the actual curriculum for kindergarten that year.

(00:52:49):

School quickly bored him. He acted up and he developed a reputation as a prankster. He was a nonconformist with a fierce independent streak who liked to be in control. It was not uncommon to get a call from the principal when he got into trouble for random acts of mischief, especially in middle school. The kids all had smartphones in middle school, and misuse of this privilege was a problem.

(00:53:15):

I have strong opinions about our kids' early exposure to technology. We now know that it affects their emotional wellbeing and that that constant stimulation impairs their attention span. And then equally troubling is the unrestricted access to inappropriate content.

(00:53:34):

But despite the distraction of having a cell phone, Tasman earned good grades in his Talented and Gifted program, he had a loyal friend group, and he planned to attend college after high school. Around age 15, he established a pattern of working and saving, and he began investing in the stock market.

(00:53:54):

He put his smarts and his internet savvy to work, and before long was making substantial gains, trading options, and cryptocurrency. He graduated from high school in 2021 with a concentration in business and the senior superlative award, biggest prankster.

(00:54:13):

The next stop was University of Colorado Boulder. In the fall of 2022, my son was a college sophomore at Boulder. He developed close friends. He had a girlfriend. He earned good grades and a spot in the very competitive business school at Boulder.

(00:54:32):

My husband Jason and I were relieved. After the challenges of parenting a smart kid with a penchant for getting into trouble, our son was maturing and he was thriving, but our relief was short-lived. His second year at Boulder was a year of rough transitions. He had a bad breakup, a less than ideal housing situation, and he had a skateboarding accident that led to a broken arm and a prescription for oxycodone. We saw him twice during the fall of 2022, once in October for parents' weekend and again when he came home for Thanksgiving. He was not himself. We thought he was depressed. We planned to dig into how we could help when he came home at winter break,. We were oblivious as to what was really going on.

(00:55:27):

On December 12th, 2022, a high school friend of my son's called me with news that would change my life, "Tasman's drug use is out of control." We had caught Tasman with weed in high school and knew that he experimented with alcohol. Neither was acceptable, and unfortunately, neither was unusual for a high school aged male.

(00:55:52):

We didn't see any harmful or excessive drinking or any hard drug use, so what his friend told me on that call came as a complete shock. We learned that during fall semester, his sophomore year, he had developed dependencies on cocaine, benzodiazepines, and opioids, "The gas and the brakes," one drug counselor would later tell me.

(00:56:17):

His source, we learned much later, was the dark web. For the next 10 months, Jason and I were consumed with trying to get our son help. After considerable reluctance, we persuaded him to leave college and return home. He ultimately spent 30 days in a rehab program that he would tell me was one of the greatest, most memorable experiences of his life.

(00:56:41):

Once out of rehab, we about him relapsing if he lived anywhere but under our roof. He reassured Jason that it didn't matter where he lived. He said, "Dad, I can buy drugs online anywhere." But he told us that he had no desire to touch drugs or alcohol ever again.

(00:56:58):

By the fall of 2023, 3 months after completing rehab, he seemed to be in a much better place. He wanted to become an EMT and firefighter and enrolled in community college. We were surprised by our entrepreneurial money-loving son seeking a profession in a field where he'd previously shown no interest, but encouraged this new endeavor.

(00:57:22):

He no longer saw himself sitting behind a desk in his future career. He liked the excitement and the prospect of doing good in the world. We loved hearing about his ambulance and hospital shifts and seeing pictures of him in his uniform. He loved the program.

(00:57:39):

He committed a new path as he began EMT school. He moved into a sober living house where weekly random drug tests were administered with zero tolerance for a failed test. He pledged to attend 90 Narcotics Anonymous meetings in 90 days, and he had a sponsor, NNA.

(00:57:57):

We were in close touch and he had strong family support. At the end of April 2024, the extended family was looking forward to celebrating his graduation in May. Instead, on April 24th, 2024, Tasman died from an accidental overdose. He was 21 years old and one week from successfully completing the EMT program.

(00:58:25):

He ordered the drugs that killed him through the dark web and had them delivered to his sober living residence. From what we can gather, Tasman thought he could take a break from sobriety and somehow got a hold of what turned out to be fake pain medication. He died from a lethal combination of four substances, one being oxycodone, the same thing he was prescribed for his broken arm 21 months prior.

(00:58:50):

The coroner described the other three substances as counterfeits, in his words, "Dark web stuff that you're not going to find in any pharmacy." A detective was assigned to our son's case. They took his laptop, his cell phone, and his notebook. The detective cautioned us that these cases are rarely solved.

(00:59:09):

Sure enough, around a month after Tasman's death, the case was closed with no resolution. Whoever sold him the drugs was untraceable and would go unpunished. My son did not want to die. His advisor confirmed to us that he was on track to graduate from his EMT program, and he had plans. But this is a problem I've since learned with smart people and addiction, they think they can outsmart the addiction.

(00:59:38):

Several months after Tasman died, I discovered a file he maintained containing his login and password credentials for a long list of websites. Some of the passwords were under a header that he called Onions. I was not ignorant about the dark web. I knew that it's a hidden part of the internet that's intentionally kept out of reach of traditional search engines like Google and Bing. I had even read the book American Kingpin about Ross Ulbricht and the dark web marketplace he founded called the Silk Road. I knew of Tor, the software that popularized the dark web by hiding your IP address, making it difficult for websites or surveillance systems to track you. What I didn't know is how it works. Data sent through Tor is wrapped in multiple layers of encryption, just like the layers of an onion. This is why it is called The Onion Router, T-O- R. I also didn't know that Tor launched on September 20th, 2002, one month before my son, the digital native, was born. The Tor browser can access special domain names with the suffix onion. Tasman's list of onions in his password file seemed to sum up his dark web activities. I don't pretend to be an expert on using the dark web to buy drugs, and I can just hear my son's voice telling me that me talking about the dark web is cringe, but here I go.

(01:01:06):

The first onion on his list was Archetyp, a dark web marketplace. In June of this year, police across Europe dismantled Archetyp, taking down the platform's infrastructure and arresting the 30-year-old German administrator. Gratifying news, but too late for Tasman. Two other dark web marketplaces on my son's list were BohemiaMarket and IncognitoMarket, both of which I understand have been taken down. Another item in his password list was for Monero, a cryptocurrency designed to be confidential and untraceable. The majority of existing cryptocurrencies, including Bitcoin and Ethereum have transparent blockchains. Transactions can be verified and or traced by anyone in the world. This means that sending and receiving addresses of these transactions could potentially be linked to real world identities. Monero, on the other hand, uses various technologies to ensure the privacy of its users. Tasman's experience dating back to high school where he learned to trade cryptocurrency came in handy when transacting on the dark web.

(01:02:10):

His list also referenced the website called Dread, which I learned as a Reddit-like dark web discussion forum. It offers a space for users to exchange information, reviews and opinions about hidden online markets. The last onion on his list was Kleopatra, a free and open source encryption software that provides a user-friendly interface for encrypting and decrypting files. At the heart of Kleopatra is a standard known as OpenPGP. PGP stands for pretty good privacy, which is universally respected in the tech world for providing robust security measures. By converting his money to crypto, using Cleopatra to send and receive messages and signing onto dark web marketplaces like Archetyp, Tasman was able to have drugs delivered to his door just as he might call up an Uber or have takeout from DoorDash. I find it shocking that packages of legal drugs can be easily sent through the US Postal Service and delivered by your friendly mail carrier. My son was an adult making his own, albeit terrible decisions. He was also moving on with his life, about to graduate from a program he loved doing noble work he was passionate about, but once he knew how to tap into the dark web, he had the keys to the pharmacy. An overpowering temptation.

Susan Winckler (01:03:39):

Jennifer, thank you. The ability to share your story is just incredibly powerful and helpful to the community to understand and so thank you for sharing with us information that may help others. And I think we all wish that we had known the boy who wanted to spell disestablishmentarianism, which I will now challenge my teenagers to learn how to spell it. Before we turn from you, is there something that you wish you had known or a lesson that you'd like to leave with us?

Jennifer Frink (01:04:23):

Yes, thank you, Susan. It's been 16 months since Tasman died, so I've had a lot of time to reflect and there are a lot of things that I wish were different. Starting with childhood, I wish that his teachers and counselors had been better equipped to engage his smart brain and harness his talents. And I wish I understood that there were root causes that led my son to get into trouble at school, and I wish his teachers and counselors hadn't just taken his misbehavior at face value. I wish I understood his brain and what led him to self-medicate and what personality traits might have created this pathway to addiction. And then in terms of smartphones, I wish that we knew how to navigate the introduction of smartphones and technology to young people to ensure their overall development and their wellbeing. I wish he had never broken his arm, or at least that he hadn't been prescribed oxycodone.

(01:05:19):

I am grateful for his friend that gave me the heads-up, but I wish his friends had spoken out sooner about his substance abuse. I wish there were better sources of information on what to do when a loved one develops substance abuse issues because it was incredibly difficult to get help for him. I wish I better understood the nature of addiction and the perilous state he was in at the beginning of 2024, so fresh out of rehab. I wish we had known to delete his dark web onions and passwords, at least creating some sort of a barrier to temptation. I wish we lived in a world where you couldn't simply order drugs online and have them delivered through the US Postal Service, but more than anything, I wish I had my kid back. So my hope is that in sharing our family's story, we can help spark change and ultimately create a world where fewer families face this heartbreak of addiction. Thank you.

Susan Winckler (01:06:15):

And thank you, Jennifer. You are making a difference and I hope that we can. We know we can't address all those wishes, but I hope that we can address them. Thank you.

Jennifer Frink (01:06:29):

Thank you.

Susan Winckler (01:06:32):

We have another story to hear and to, I shouldn't say hear, another story to experience. And so allow me to turn to Ed Ternan. Ed, we are turning to you for what we want to hear your experience and your thoughts on how we might do better.

Ed Ternan (01:07:00):

Thank you, Susan, and I hope you can all hear me okay.

Susan Winckler (01:07:03):

We can.

Ed Ternan (01:07:04):

I want to start... Good. Good. I want to start by thanking the Reagan-Udall Foundation and for all of the partners here who are in this meeting, but I specifically excuse my emotions. I specifically want to acknowledge Jennifer Frank and thank her for sharing her story. I've recently been introduced to Jen. My understanding is that this is the first time Jen has shared her personal story and it's so important. And as someone who has probably told Charlie's story, I was trying to add it up without exaggeration, a couple of hundred times, I still can't get through it easily, so I appreciate you Jen. Thanks for sharing. One of the things that has struck me and my wife, Mary, since our son Charlie died, is the groundswell of grassroots activism among bereaved parents and family members who have kind of rung the bell around this new chemical drug landscape that came on the scene in the mid-twenties and then was just accelerated by the ease of access through online channels causing a complete new kind of profile of the overdose crisis and its victims.

(01:08:26):

And so I always like to start by acknowledging and respecting all those families who have the courage to speak up. I will tell you Charlie's story and then I will tell you what we've done at Song for Charlie in response to the tragedy that my family suffered specifically and the approach that we've taken. And then I'd like to kind of just put ourselves out there to see how we might be able to join this coalition and strengthen even some of the existing relationships we have because we firmly believe in collaboration and team building and building this network to take on a network. That kind of idea is going to be critical to saving lives from similar tragedies.

(01:09:12):

So Charlie was a 22-year-old college senior when he died in May of 2020, and he was just a month shy of graduating from Santa Clara University, which is in Silicon Valley in California. If you remember back to those times, it was COVID and it was very early in the COVID crisis. So Mary and I have an interesting experience with that in that Charlie came home for spring break in March and the university shut down and as a result, he stayed with us for a couple of months in our home, just the three of us, his two older siblings had graduated and had moved on with their lives. And I say that because we were with Charlie and we had eyes on him and we were interacting with him and we did not see any signs of addiction or mental crisis. We thought he was coping pretty well given that he was a college senior.

(01:10:10):

The world seemed to be collapsing around him. He's got to find a job. He's thinking about his future. So he's having that kind of normal, I think, existential crisis that a young man goes through and they call it seniors go through. We all remember that. But he was doing okay and about a month before he and his classmates were due to graduate, they decided that despite the fact that the university was closed, they would go back to campus and be together for their last month of their senior year. Charlie drove up from Southern California where we lived to the Silicon Valley where he was going to school. He's 6'2", he has a little Jetta, he had a back surgery. He was complaining to Mary and I on the phone once he got up there, "My back's killing me." He decided to go, he asked a friend or his friends in the fraternity house one afternoon, a few days after getting up there, whether anybody had any Xanax.

(01:11:14):

The story was that, and while his fraternity brothers were going to go out and do some running around and do some day drinking or senioritis stuff, whatever they were going to do, Charlie had a telephone job interview that afternoon. And his thinking was, and we know this from talking to his fraternity brothers that he would stay home and wait for that phone call and just play video games. Nobody in the house had any Xanax and taking a Xanax, I guess, and playing some video games somewhat normalized, like maybe smoking a little bit of a joint, was in the seventies and eighties when I was coming up. Nobody had any. And so they found a plug on Snapchat who they did not know, and they bought some pills and Charlie opportunistically bought a Perc while they were at it. We know this because they used the friend's phone, not Charlie's.

(01:12:05):

So we were able to access the friend's phone and we know exactly what they purchased. And we also know that they found all of the fake Xanax that they purchased, and the only thing that was gone was one M-thirty that they had bought. So we know that Charlie took one pill on an afternoon playing video games, waiting for a job interview. It was a medication he'd been prescribed before for his back surgery. He was familiar with it. He took it as prescribed one tablet and he died within about 15 minutes because it was a counterfeit. So Charlie was lied to by this dealer who misrepresented his product on a social media app. And one of the things that's changed, we talk a lot at Song for Charlie about the new chemical drug landscape and the changes to the substances and the potency of these synthetics and the implications that has for younger drug users earlier on in their substance use journey.

(01:13:04):

The other thing that's changed that's relevant to this conversation that we've already heard is the online environment. So back in the day, if you wanted to buy some drugs, like somebody had to vouch for you, you probably had to go somewhere in person. You paid in cash, you made eye contact with the dealer. Those days are over. The transactions these days, first of all, the access is immediate and instantaneous and delivery is part of the deal. But also, Charlie never laid eyes on the kid who sold him the pill, who that killed him. He wasn't part of the transaction, his friend was. So the new way of transacting drug deals now is very anonymous, it's arm's length. It's very transactional. There is no kind of relationship at all between the seller and the purchaser oftentimes, especially of these counterfeit pills. So when Mary and I went through this tragedy, we looked at each other and said, "Well, what can we do about this? We're just literally a little old couple from Pasadena, so we can't boil the ocean."

(01:14:15):

But we asked ourselves, who's warning the kids? And in late 2020, the answer to that question really was nobody, not really, not effectively. We did some searching online around the time of Charlie's death, and we discovered that the local DEA website had a warning up in Santa Clara County where Charlie did, as did the local sheriff's department. That was a newspaper article buried in the San Jose

Mercury News about a high school girl who had died six weeks before Charlie, and maybe one story on the evening, thirty-minute newscast out of San Francisco in the three months leading up to Charlie's death. And Mary and I looked at each other and said, " You could put that information in those places for the next 20 years, and Charlie and his generation will never see it there. That's not where they get their information."

(01:15:09):

So we took what some in our position might call the road less travel, which is we decided that we would seek to collaborate with the social media companies. And so we started to reach out. We just felt like that was the clearest path to our objective, which was to prevent the next death. And so we very early on started working with Snap and then Meta and Google and YouTube. We have ongoing relationships and partnerships with those organizations now. We really believe that we need to come together to take on this new national crisis that's affecting Americans across the demographic and age range. And so that requires new kinds of alliances and partnerships and collaborations. Even sometimes among strange bedfellows like competitors like Snap and Meta. Interagency, different agencies need to come together and share information on a deeper level.

(01:16:19):

People in the traditional drug kind of conversation in the areas of supply reduction, law and order, demand reduction, drug education, harm reduction need to come together and talk about what works where we're encouraged in doing this work over the last five or so years in seeing some of those, this coalition coming together. This is happening, we're seeing it and we think it's having a positive impact. I mean, just in the context of this meeting here, I can tell you that at Song for Charlie, in addition to the social media and tech companies I mentioned, we also have strong working relationships and or have worked in the past with DEA recently, FBI JCODE, the National Association of Boards of Pharmacy, the Alliance for Safe Online Pharmacies. We have a very strong relationship with Major League Baseball who are helping us get the word out through their iconic American brand and their platform.

(01:17:16):

These are the kinds of things that we need to do and pull together to do and cooperate and collaborate on ways that in the past might've been kind of outside the norm. I'll do a quick plug for the HIDTA program. I'm a big fan of the HIDTAs. They have opened their doors to us, as has DEA. I recently, as I was touring around the country, going to different major league baseball stadiums, was able to visit with several field offices, DEA Laboratories and HIDTA headquarters and meet with staff. And I would encourage anyone involved in the political process to think about ways to keep HIDTA active and independent. Their collaborative model, it's really impactful and works. That's a shameless plug for HIDTA. I'll close by just saying here's what Song for Charlie's doing now in 2025, we see ourselves as the creators and distributors of educational content addressing the fentanyl crisis and its impact on American families.

(01:18:21):

We think we can contribute by expanding our scope. We're being pulled this way by questions we get from our audiences about new high-potency THC products and Kratom and the other emerging threats that are happening out there on the illicit market and even the legal market. So we will expand our scope into probably additional substances. And we see ourselves as stepping into the drug education space for say, between fifth, sixth graders, up until senior year, maybe freshman year in college, addressing the substances and risks that they may come across. And we empower them with useful information. We say, "Just say know," but we spell it K-N-O-W. In order for us to do that and become the

trusted source in this information age of so much noise and misinformation out there, we need to rely on experts like yourself to make sure that we're standing firmly on a foundation of fact.

(01:19:23):

And that's why we appreciate our working relationships, to understand how the platforms work, how search works, what's going to happen with AI chatbots, but also emerging threats and substances in the changing drug landscape. So we think that Song for Charlie as an established, we're in our fifth year now, an established unaffiliated, apolitical nonprofit, can play a role as a distributor of this health promotion, health literacy information, working with all of you to spread the word and educate the American youth and families about these new drug threats that include the access issue related to tech and social media. So I mean, I can stop there. You might be able to tell I could go on forever, but I know Susan, you want your meeting back. Thank you all for having me and for all you do, and we are happy to help in any little way that we can.

Susan Winckler (01:20:24):

So Ed, thank you. The help that you and Jennifer gave us by trusting us with your information is impossible to quantify. And thank you for the work that you're doing for the efforts of Song for Charlie. As we think about our next steps forward, I just say thank you for grounding us in this reality, and I am confident energizing each of us to do more to, as you said, to just say know, the K-N-O-W. Thank you, Ed.

(01:21:16):

So when we think about what we've just heard, we know that part of the danger that's created here is from the dark web and some of those components, but the problems are also present across mainstream platforms that the misuse of the criminals who wish to provide the illegal products to individuals, they misuse rather, mainstream platforms as well. And so we want to think through that broader impact.

Session 3: Strategies for Intervention/Disruption

Michael Carson, Senior Director, Regulatory Policy, eBay
Jim Crotty, JD, Law Enforcement Outreach Manager, Meta
Nate Feltner, JD, Principal Corporate Counsel, Microsoft
Stephen Dufresne, Manager, Safety Operations Outreach, Snap Inc.

Susan Winckler (01:22:02):

And I do just want to say again to add, and Jen, how important it was and the extraordinary investment that you have made in sharing your story today. I know that there are colleagues in the digital community are working to make the experiences that your families have had the exception and in a future world, the exception that no longer occurs. And so I want to turn to a bit of that. What can we do together? How can we do that collaborative work and bring us to our third session of the summit. So as we think about how to take those experiences off the table to protect against them happening again, I'm really happy to have joining us to talk about strategies for intervention and disruption, colleagues from across the digital platforms, each representing a different element of the ecosystem. We know it's not the entire ecosystem, but we have a broad swath here.

(01:23:14):

And so let's bring those panelists onto the virtual stage and start to that conversation. So I'll invite Mike, Jim, Stephen, and Nate to please come on the virtual stage and let's have a conversation. So thank you

first for joining us today as we think about what it is, well, we want to hear from you the efforts that you're taking to disrupt the criminal network and think about how we might better collaborate and opportunities to do better. So I want to start, I was thinking as I reflected on Jen and Ed's stories, let's think about that online journey that I would think about too, where I might be looking for something when I'm looking for something online. I use a search function. Now it often ends up being a query that generates a response from artificial intelligence. So I'm going to start at the end of our ecosystem with Nate Feltner. Now Nate, you are principal corporate counsel at Microsoft. I would imagine that at least some portion of your workload is spent thinking about the search and the AI function. Could you tell us a bit about that work and how Microsoft might work to support consumers in their searches, but also help protect those same consumers against the elements who are misusing your tools to mislead them?

Nate Feltner (01:24:51):

So first of all, hi, Susan mentioned my name is Nate Feltner, and I support the Microsoft engineers that are working on our consumer web products, focusing specifically on Bing Search and Copilot Search. On behalf of Microsoft and myself, I want to say thank you for the opportunity to share here. I want to say thank you to the presenters before us for sharing their stories. Yeah, so not a small part of my job is spent on the digital safety and content moderation space, which also includes strategies for responding to illicit pharmacies and pharmaceuticals online. We take these issues super seriously. We understand that many users may not fully understand the very real risks that are associated with purchasing drugs online, especially in light of the opioid crisis in the US coming off the pandemic, be digitally native users and society just generally moving more purchasing online. So before I get to our general approaches for illicit pharma, I just want to provide a quick reminder about what search engines are. And this applies generally to generative technologies as well, because how they operate is pretty critical to the safety strategies that they use.

(01:26:29):

As most here probably know search engines are not the internet, but rather there are tools for accessing content published by third parties on the open web. Bing and search engines in general use automated web crawlers to create an index of the publicly available web content published on the open internet. We have complex algorithms then in the background that rank and return the most relevant and helpful material that matches the user's search or query in a list of results. What this means is that search engines don't actually host or control the content that they provide access to. And in most cases, we won't ever have actual knowledge of the content in our indexes or indices. So we need to make sure our interventions towards pharma and digital safety harms, digital harms, scale with the scale of the internet and its reality. We have a multilayered intervention approach to elicit pharma and pharmaceuticals.

(01:27:41):

Some of the strategies were touched on earlier, we use a combination of both reactive and proactive interventions. So I'll just start from the reactive standpoint, pretty straightforward there. We remove access to sites that are reported to us by local authorities. Governments interested in flaggers being unlawful. So just a notice that a site or content in the site is unlawful, that's sufficient for us to justify removing it. In the US, we block all rogue online pharmacies that are listed on the FDA's Warning Letter Site, and we make sure that those are removed from the Bing index entirely so they can't be accessed in results. We also provide several different reporting channels for users, trusted flaggers, local authorities, where they can notify us about unsafe material or illegal content, and we'll take action there too. We also have a number of proactive approaches, which really is how search is able to scale its interventions.

(01:28:51):

First, I'll start with ranking. So we prioritize high authority results in response to riskier types of searches, riskier queries, and I'll get to what that means. So Bing tries to provide very responsive and relevant results, but unfortunately sometimes the most relevant results for a query are very low quality or low authority. And that's sort of an algorithmic phrase. It's a phrase that is a proxy for stuff that can be disreputable, unsafe, conspiracy stuff. So low authority content is generally the stuff that is the most dangerous. We don't want to provide results that are unexpectedly harmful, meaning that in some cases, for some very high-risk queries. We index much higher on high quality or high authority signals. And then of course, some queries are so dangerous, we only provide high authority like news content and helpful resources. We also provide PSAs and notices providing access to local resources in response to some queries. This is sort of like instead of censoring information, we want to provide more helpful information for people that are entering higher risk queries.

(01:30:18):

We also provide public safety answers in some circumstances that provides information about how to purchase online safely, since, again, a lot of purchasing just is moving online as a general matter.

(01:30:35):

We also want to avoid making the problem worse. So we don't want to provide auto suggestions or display related searches to users when they're searching for harmful content. For example, if somebody is searching for counterfeit drugs, we don't want to help them by giving them better or different types of searches to use. So we will remove autosuggest and related searches for queries like that.

(01:31:03):

And then with AI search, with our Copilot products, we have a much higher standard there because we're providing a summarized answer for a user. So we make sure that that is, I think the phrase that our engineers use is kind of like PG by default. We have a lot of classifiers and Meta prompts that are working in the background to assess the queries and the output, and we make sure that when we're summarizing, we only summarize very high quality, high authority sources.

(01:31:34):

We also have a number of policies for ad content. We prohibit marketing illegal or prescription drugs and controlled substances and other types of fraudulent activities.

(01:31:48):

So yeah, that's our general approach to illicit pharma, how we try to handle this at scale and how we try to balance access to information with keeping users safe.

Susan Winckler (01:32:02):

Yeah. Nate, that's very helpful. And I can see the visual that you created for me with the defensive kind of when we know it's bad to block it, and the more proactive in saying, how do we help provide the high quality information versus allowing those who are misusing platforms to get a higher profile. So that's very helpful.

(01:32:33):

And I heard just this morning from my 15-year-old how very smart Microsoft Bing is in helping her get her work done. So we know. I'll just underscore, we know that the prevalence in using search to try and find answers.

(01:32:51):

So let me take us to the next natural step in our journey. Then sometimes it might be the first step when something might've caught our eye, and I want to step in to move from search and AI and think more in the social media. So I'm going to turn now to Jim Crotty.

(01:33:13):

Jim as the law enforcement outreach manager at Meta, where have you seen some success in facilitating consumer journeys to legal and safe virtual destinations?

Jim Crotty (01:33:27):

Yeah, thanks Susan. And thanks to the Reagan-Udall Foundation and the FDA for convening this summit again, for including me, for including Meta as part of this really important conversation and keeping the conversation going, because there's no finish line in this race to combat this type of illicit activity. And so we've all got to keep working together.

(01:33:54):

I think what you're going to hear me say is going to be reflective of some of what other folks have already said. There's several common themes running throughout this event about it being an ecosystem, about no one platform or one industry, or the government being able to do it on their own.

(01:34:16):

I also wanted to just take a moment to acknowledge the fact that it is 9/11 and sort of the weight of that day. It's hard to believe that it's been 24 years. Teaching a class tonight, and none of my students were born back then. So aging myself, I guess. And I also want to thank Jen and Ed for sharing their stories. Ed is a friend. We've worked together in the past and continue to do so with Meta and Song for Charlie.

(01:34:40):

So very unique perspective having been with the federal government at the DEA, now with Meta, I also work on a nonprofit, so sort of sitting at the intersection of all these different groups and the importance of information sharing and collaboration. That's what we're doing today.

(01:34:59):

So to answer your question, I think at the onset, it's important to note that this is an adversarial space, and I think all my colleagues across the tech industry will know this and recognize this, but the bad actors are constantly adapting and evolving and probing, trying to evade our detection systems.

(01:35:24):

Now, that said, at Meta, we've had a lot of really good success in this space, combating that type of activity. We continue to prioritize it. It is one of our top priorities, high risk harms at Meta, and we continue to make significant investments into our integrity, trust, and safety programs.

(01:35:45):

In terms of the how, what are the interventions or strategies that we employ? Meta for every one of our, we call it the family of applications, Facebook, WhatsApp, Messenger, others, there's 3.4 billion daily active users across all of those platforms every single day. So about the third of the world is logging on to one of our platforms. So it's an immense challenge. It's a massive scale. And so as a result, we have to employ a multilayered approach, kind of as I sort of use the term, defense in depth. And so there are a few different ways that we do that.

(01:36:23):

So first of all, because it is such a massive scale, we have to leverage technology. Like everybody else, we're investing heavily into AI and machine learning, and we're not just using that to build products for a consumer. We're also using it in our internal tooling so we can keep the users safe.

(01:36:46):

So what does that look like? We will gather what we refer to as signal from a variety of sources. One of course is going to be what is it that we are seeing on our own platforms that shouldn't be there? That's going to inform how we develop our systems. We also want to consult with external partners and leaders in this space to better understand what are the emojis, what are the slang terms, what are the latest techniques that bad actors are using to try to circumvent our systems? And then that includes information from places like the FDA, the DEA, INCB, International Narcotics Control Board, UNODC, so a whole host of sources.

(01:37:29):

And then the third piece is reporting that we get from users. When somebody on our platform sees something that shouldn't be there, when they report that, that's extremely valuable to us because one, we know we want to take that down and remove it, whatever it is. And two, if we missed it the first time around, we can then go back and tweak our systems to do better the next time. So that's how we use sort of automation and technology to find and remove violating content. But we also know that there's ... The machines are getting better every day, but there's still not always 100% accurate. And so there's still a need for human reviewers to be in the loop, right? Machines are good at a lot of things. They're not so good at things like nuance and context and humor. And so that's where the human review teams come in. If the technology's unable to make a determination, what we have, literally thousands of people around the world reviewing that content every day.

(01:38:35):

We also work very closely with law enforcement. One, of course is responding to legal process requests. We have a very robust system to do that. Law enforcement comes to us with subpoena, a search warrant, et cetera. We will provide the data that they've requested.

(01:38:52):

But we're also trying to be more proactive. And it is good to see Stephen here on the panel with me. He and I have been out on the road together with DEA providing training to their investigators in various field divisions around the country. That's in close partnership with DEA. So I think that's a great example of that partnership, public-private partnership that we're talking about. And it's not just limited to the federal government. Of course, there's also our state and local partners. I know Ed gave a nice shout-out to the HIDTA program, and they're a really good convener of all the law enforcement authorities. On that theme of partnership, and I hope I'm not stealing too much of Stephen's thunder here, but we also-

Susan Winckler (01:39:39):

Well, we're going to turn to him next, so don't steal at all. It's all right.

Jim Crotty (01:39:43):

But signal sharing between industry partners too. Snap was among the first to join. We have an illicit drug threat exchange, and we audit, this is all like an automated thing where they're sharing signals with us and we're sharing signals with them constantly because we know that bad guys will exploit multiple different platforms and we want to try to prevent that.

(01:40:07):

Another example at a global level, and again, Snap is part of this too, but the Alliance to Prevent Drug Harms. This is a department of state UNODC-led initiative along with the tech industry launched last summer. The website should be launching here shortly, which will have additional resources and again, another sort of venue to bring folks together.

(01:40:33):

And then I think lastly, I just want to note the importance of these communities. So a lot of these parent organizations like Song for Charlie, a lot of them started on our platforms. That's how they found their community. They made these connections in the first place.

(01:40:51):

And with that reach that we have, we want to be able to leverage it for good and we want to amplify the positive messages of prevention and treatment and recovery. And so we also partner, Song for Charlie, I referenced a couple of times, but there are a lot of other leading nonprofits that we work with to do that. So with that, I will yield my time back. Thanks.

Susan Winckler (01:41:18):

Jim, that was great and helpful for us as we think about, as you were talking about deploying technology and the interventions and then recognizing that there's folks on the other side who are deploying it for the opposite. But you mentioned continuing our online journey and your colleague Stephen Dufresne from Snapchat, who's here.

(01:41:42):

Stephen, you have a title that conveys your importance and engagement in this topic as well as Safety Operations Team Manager. So what would you highlight if we think about the process of what happens in the misuse of your ecosystem? Tell us about your efforts at Snapchat.

Stephen Dufresne (01:42:04):

Yeah, absolutely. Hi Susan. Thank you for having me. It's an honor to be here, especially with these amazing industry experts. Jim, great to see you. I also want to extend my condolences to the Frank and Turnan families and thank them for their strength and being willing to share their story. I've met Ed in person, I've shared tears with Ed, and I had tears for the Frank family in that moment. It's very sad to see. So as far as what we're doing here at Snap, I work with our outreach team, which is a part of our safety operations organization. So that includes our trust and safety organization, as well as our law enforcement operations team. And so it's a wide variety of data that we're receiving about what's going on Snapchat.

(01:42:48):

So from our trust and safety team, as Jim had mentioned on the MediSight, or not MediSight, sorry. Yeah, MediSight they're receiving in-app reports from their users just like we are. So we're receiving in-app reports from users about content on the application. We also have proactive detection. So one thing we have in the application is we're able to proactively detect 90% or over 90% of drug content before it gets reported to our safety operations team. So that's an area for proactive detection that we've invested heavily in and continue to improve as the ecosystem and environment shifts.

(01:43:27):

Additionally, we have our law enforcement operations team, which handles legitimate law enforcement requests for user data across the world. So that's also another signal as far as potential bad actors and

drug proliferating on the platform. So we use that for potential further investigation and proactive escalation to organizations like the DEA.

(01:43:49):

So on top of, some of the efforts we're doing operationally, Snapchat as an app was designed with privacy and safety in mind. And so there are key privacy settings that are set to strict standards by default. So for example, we don't allow anyone to be messaged directly by anyone who they haven't already added as a friend or isn't in their phone contacts. So in order for you to communicate with someone, they have to accept your friend request.

(01:44:17):

Additionally, we also have in-app resources for when users are searching for some of these drug-related keywords or terms or emojis. That's called heads up and that's our in-app portal that distributes expert resources to Snapchatters or who are searching for these, a range of drug-related terms and slang. And as John Hurtick noted before, more education is needed. So this is a really valuable part of the application that we are continuously updating.

(01:44:43):

On the parent side, and so I think that's a really important side too, for parents, we continue to enhance what we call family center. And so this is the suite of parental tools that provides parents and caregivers insight into their teens' activity on Snapchat. So for example, who they may be communicating with in a one-to-one or group chat, who some of their new friends are, and also offers a parent an option to easily report that account to our team for further review and action.

(01:45:10):

So those are some of the actions we've taken to keep Snap, make Snap a safe environment and protect our community.

Susan Winckler (01:45:18):

Stephen, that's equally instructive in thinking about the built-in upfront controls and then the listening that you're doing and the use of the signals that you get to intervene and then to helping with that. What was Ed's phrase? Just say no with the K-N-O-W to help with the no.

(01:45:43):

Let's move to the final stage in our journey and then we'll continue the conversation. We know whether seeking products and being kind of drawn into the illicit web or intentionally seeking controlled substances outside of the system, that the purpose of the journey is a purchase. And so I want to turn now to Michael Carson, who's Senior Director for Regulatory Policy at eBay to talk about that e-commerce function. I was struck in some of the earlier commentary about that the purchase of drugs illegally has been become a pristine transaction versus where it had been before, and that's absolutely a misuse of eBay's functionality, which is vital to so many.

(01:46:38):

So tell us about the eBay component and your efforts to disrupt the illegal network that we've been talking about today.

Michael Carson (01:46:47):

Thank you, Susan. Thank you to the Reagan-Udall Foundation and the FDA as well. I've had the pleasure of participating in each of these summits dating back to 2018, so it's always a great opportunity to share,

but to learn as well. And also, I just wanted to also express my thanks to Ed and Jennifer for their very impactful stories.

(01:47:06):

Just a quick reminder of what eBay is and how it operates. We are a marketplace that allows buyers and sellers to come together and engage in commerce. We don't touch the items ourselves, but that said, we take our responsibility very seriously to make sure that unsafe or illegal products are not available on our site. And we attack that in a variety of ways.

(01:47:28):

We start with education through our policy pages, but also through direct messages to both buyers and sellers, either in the selling or the listing or the purchasing flow, and in some cases with recalled items or other harmful products, we'll even message buyers after a purchase is made if different things come to light. We want to make them aware of what the issue is.

(01:47:50):

But we don't stop there. We actively enforce these policies. And with a site that has over 2 billion listings at any one time, to echo Jim's comments, we use a combination of technology, obviously you have to use technology, but you do need that human element. You have to train that technology right the first time or you'll be going off down the wrong road, and then you use that technology to sustain yourself going.

(01:48:15):

And a good example of how we've done both of that is with an issue that's been [inaudible 01:48:21] already today with recent warnings around Cratom, highly concentrated Cratom products, the 7-OH products that came out in July from the FDA this year.

(01:48:33):

I've been at the company for 20 years and we've had a long-term relationship with the FDA, and I was fortunate enough to get a heads-up before the public announcement was made that this was a growing issue. And that allowed us to quickly use both of those tools, the human element, because we didn't have necessarily for these new types of product. Cratom itself is something we have prohibited for a while, but these new designer types of products with different names that we maybe weren't aware of, we were able to quickly deploy our teams to manually search the site, identify those listings, obviously take them down, but use that information to then feed into our technology going forward to understand what we want to tackle in the future. And so that allowed us to get a head start on things.

(01:49:14):

And often, while these public announcements are great and it gets the word out and makes people aware, it can also change behaviors of people too. It can create a bit of a feeding frenzy, a supply and demand of people that have the product and say, "Oh my gosh, this is going to be illegal soon. I better get rid of it." Or buyers that weren't even aware of it and maybe are curious about things, or sellers starting to change the way that they're listing them using different keywords.

(01:49:39):

So being able to just get ahead, even if it's a couple of days or a couple of weeks, was really fortunate. And so that's one of the things I think we can think about going forward is how we get that information when these new issues crop up and we can be as on top of it as possible.

Susan Winckler (01:49:56):

Yeah, Mike, I appreciate that particularly the idea, this is, as FDA and others would frequently do on any other public health issue, you think about who do we need to communicate with first so they're prepared to respond to the question. I think you're observing that the action to better protect against those products is stronger when this group, you have the heads-up and can protect against, as you said, that I could only imagine like a fire sale deep discount.

Michael Carson (01:50:36):

We have the tools that we can deploy. We just need to know where to point those tools.

Susan Winckler (01:50:42):

Right, right. As well as the importance of recognizing that it's important to share some resources publicly and then recognize that all resources that are shared publicly are then available for the people who are on the other side trying to misuse everything to kind of find the loopholes and figure a way out of it. That's very helpful.

(01:51:10):

You've all shared what I would capture is kind of what's going well in your efforts and really helpful to hear the diligence with which each of you is approaching the protection of your users and protecting against the misuse of your platforms. But we know we also still have a problem and are trying to keep ahead of the criminal network on the other side.

(01:51:41):

But could we talk a bit about what are some of the challenges that you're facing? And I'll let you kind of volunteer and jump in here, but if nobody on mute, Jim, I'm going to turn to you first to say, would you open up a bit about those challenges?

Jim Crotty (01:51:59):

Well, I'll volunteer before I'm selected. And I think you said Susan, it's diligence, it's vigilance. I mentioned that this is an adversarial space and it's constantly evolving. That's true of the drug trade and it's also true of the online ecosystem. And so we've got to continue to evolve and improve our own systems.

(01:52:26):

Stephen mentioned they find and remove upwards of 90% of the violating content before it's reported. I think it's about the same for us, maybe even a bit higher. But we also know that that 2, 3, 4%, whatever it is that we're missing can be really bad stuff.

(01:52:45):

So as I said, there's never going to be this moment where we say, "Oh, okay, we're done. We've fixed it." It's just that continuous process improvement and all the things that we're discussing here today.

Susan Winckler (01:53:02):

Thanks, Jim. And oh, Mike, you jumped in before I had to even call on anybody else.

Michael Carson (01:53:07):

I'll take the second, yeah, the second round. And I think it's really a two-way street between industry and regulators and law enforcement. We can each teach each other things. Jim and Stephen talked about training them, but they can also obviously give us the information on new trends that they're

seeing, like new warnings coming out or other things that they're aware of if they're doing investigations.

(01:53:29):

Maybe it's not even on one of our platforms in particular, but it could migrate to one of our platforms or even that information that they're finding elsewhere could be very helpful to us.

(01:53:38):

So I think not looking at it as either relying on government to tell us what to do or us telling them about technology, it's really that two-way street and sharing that information and figuring out the best way to quickly do it and not get bogged down in things that may, privacy concerns or other things that may slow down things. What can we do quickly that everybody can just agree on and start from there and not make perfect the enemy of the good in this case.

Susan Winckler (01:54:08):

Right. Because I think you all are experts in your systems that you run every single day. And so it's about the information that you need to keep pace with the misuse of your systems. So then say, "All right, how do we bring that in?"

(01:54:25):

Steven, do you want to say anything about the challenges? What is it you're thinking? Yeah, we're going to do better on that.

Stephen Dufresne (01:54:36):

Yeah. Yeah. I think as Jim and Mike had mentioned, detection and evasion is something that we're constantly evolving and trying to address. So when we remove a bad actor from the platform, how can we keep them off the platform?

(01:54:53):

So from a tech perspective, in addition to some of the keyword filtering and the new data that we receive from industry and law enforcement, there's also tech efforts that we have as well.

(01:55:05):

One thing, we were an early adopter of Google's device recall beta program, so that helped us prevent block bad actors after we've removed them from the service, even if they've restored their device. So there's new technology that's coming out as well to help us address some of these bad actors that keep coming back.

Susan Winckler (01:55:26):

Thanks, Stephen.

(01:55:27):

Nate, anything you want to chime in on there?

Nate Feltner (01:55:32):

Yeah, sure. Yeah. Some of these things have been mentioned before, but identifying new slang and unique keywords to help us trigger our interventions is always something that we are trying to catch up to. And for that, we really do look to experts in industry and in government to help fill that. And in search, again, we really try to balance our respect for assistive information and third party publishing

rights with all the protecting users from harms that they're not expecting to encounter, but also harms that they are looking for.

(01:56:27):

And again, working with outside groups is really helpful there. So it's not Microsoft telling the users what to ... We don't want to editorialize the internet, but we need to keep users safe. And that's a very real tension that it's very useful to partner with other groups and other companies for that stuff.

(01:56:51):

And one final thing that is kind of a challenge I think for us is our expanding our deterrent messaging and PSAs to other markets. As we all know, this problem isn't just limited to the US and it's not just limited to one service or another. Bad actors are really good at exploiting the gaps in between nations and in between services. So we want to make sure that we expand our defensive tactics as wide as we can.

(01:57:21):

With new markets, we want to make sure that again, we are not being the authority, we're pointing to local resources and providing stuff that is relevant for those users where they are.

(01:57:38):

So yeah, I would say that that's probably a good summarization of our challenges and how we look to solve those.

Susan Winckler (01:57:46):

Yeah. And Nate, what I heard there is not only the underscoring of the need for collaboration and getting folks to work together, but it's not only about the information that you might share share, but the collective intelligence that you gain by talking about it and sharing. And then it's not that you are the experts per se, but you're pointing to the experts and can use that information.

(01:58:14):

We have time for one last rapid fire question. I'll warn you. I'll give you the long wind up that I'm going to ask for one step or one element of information or one partner that might make a difference and strengthen our collaborative efforts here. And when I say collaborative efforts, I'm thinking about the description we've had in some of the conversations that it's a little bit of whack-a-mole, that there's a bad actor, so you take them down and then you're doing the proactive things. And each of you said that collaboration was essential to defeat the criminal network on the other side.

(01:58:59):

So I'll turn to you each for that. What's one step or one element of information or one partner that might make a difference as we try to pursue these collaborative efforts? And I'm going to tell you the order I'm going to call on you. I'm going to say Mike, Stephen, Nate, and we'll close with Jim. So Mike, you get to run at it first.

Michael Carson (01:59:23):

Sure. I would say a forum on a regular basis where both companies that are in this ecosystem, and even like I said, you look at us as the tech panel, but our companies are all vastly different. So we even made subgroups of tech companies in the ecosystem with like-minded approaches to this and with law enforcement and/or regulators at the table sharing information more consistently, whether that's keywords, trends, things that we're seeing, things that they're seeing, having that as a regular forum that we can share that information quickly and effectively.

Susan Winckler (02:00:03):

Noted. Thank you, Mike. Stephen, turning to you.

Stephen Dufresne (02:00:04):

My turn. Okay. So just reiterating again, collaboration is key, and whether that is consistent enforcement of issues that we're seeing across our platforms or intelligence sharing, that type of collaboration is key. I'm going to echo what Jim had shared before. Snap's a member of the Alliance to Prevent Drug Harms. This is a public-private partnership focused on disrupting illegal online drug activity.

(02:00:32):

And so we're doubling down on awareness raising and educational efforts, both online and off. And so I believe this is a collaboration with the State Department, UNODC, Meta, X. And so this is something that we continue to advance, so that collaboration is key. And like Mike had said, with both industry and law, government and so on, everyone needs to come to the table for this type of collaboration.

Susan Winckler (02:00:59):

Excellent. So we have thoughts on what's a productive collaboration, how to have those conversations, and then additional sense of what should be shared in those. Not that we're taking all the content off the table, but Nate, what would you add to that? And then, Jim, you're going to have the hardest part going last. Nate? Oh, Nate, I need you to unmute.

Nate Feltner (02:01:21):

That'd be helpful. I would just echo the public and private partnerships piece. Having somebody in our client group that is focused on those partnerships has been really helpful building trust with not just governments, but NGOs and other companies too.

(02:01:43):

The trust thing is important. I would say we've had good success working with Meta in the past and their ThreatExchange and info sharing from them. So that's been great. I think finding what works best for your service and then having an open mind because we're here with a shared purpose.

Susan Winckler (02:02:09):

Yeah. Nate, that's instructive in thinking about the approach and the shared purpose. Thank you on that. Jim, I'm going to let you close it out.

Jim Crotty (02:02:25):

Yeah, thanks. No pressure. I think you're all right. The reality is it's probably not going to be just one step or one partner or one element, right? It's going to take a lot of different things to keep moving forward, but I think everyone has said in a different way how important it is to bring us all together to one, so everyone has a seat at the table, and then so we have a way to share that information amongst ourselves.

(02:02:58):

And so I don't know exactly what that looks like. Maybe it's the ThreatExchange, maybe it's more FDA roundtables, maybe it's the Alliance to Prevent Drug Harms. Maybe it's all the above or something

completely different. But there certainly seems to be that need, as I think everyone has expressed here today.

Susan Winckler (02:03:19):

And that underscores, Jim, all of that activity that you've described helps with the trust that Nate mentioned. Because I think we know in any of these types of collaborations, trust isn't built by an outreach that says, "Hey, can we work together?" It's built by having the conversations, approaching it with intentionality, and working together through challenges.

(02:03:48):

So I will note I observed in the Q&A that there was a great question about perhaps using youth as a source to help identify those search terms and emojis. So I'll just throw that all to you as an idea rather than a question. And it's probably an idea that many in your teams have been thinking about.

Stephen Dufresne (02:04:07):

Can I actually jump in and answer that?

Susan Winckler (02:04:08):

Absolutely.

Stephen Dufresne (02:04:09):

Yeah. Yeah. So actually, Snap does have a Safety Advisory Board where we have a number of experts across education, technology, and including some of the youth voice that are the Snapchat generation. So they're sharing their feedback about what they're seeing online, what they're experiencing firsthand. And so part of that is part of the drug talk and the exploitation side. So definitely something we get that information or we get that feedback from members of that generation.

Nate Feltner (02:04:42):

And I have one point too on that. In Search, we do something called social listening where we mine the places where youth are and how they're talking and then find connections and look through the data.

Susan Winckler (02:04:53):

Yeah. That's, I'm sure, very helpful to your efforts. And I think about it as the technology application of the social listening that every parent does when they have teenagers in the car and are encouraging them to speak freely so that we know what they're talking about. I have to say, Mike, Nate, Stephen, Jim, this was so helpful to learn from you and think through what are some of the things that we can do collaboratively to address the criminal element on the other side. So thank you for joining.

Session 4: Global Perspective

Carrie Harney, JD, Vice President, U.S. Government and Regulatory Affairs, US Pharmacopeia
Vladimir Kostic, Data Analyst, United Nations International Narcotics Control Board
Laila Sofia Mouawad, Technical Officer, International Cooperation Unit, Brazilian Health Regulatory Agency (Anvisa)

Susan Winckler (02:05:31):

We are grateful for your engagement and partnership. We know it'll take all of us working together to get ahead of the bad actors. So thanks for investing your time, and we're actually going to turn to that global market question that Nate raised. So thank you. We'll turn now to our next session because as we noted in some of the conversations so far, the illegal online sales of controlled substances is not unique to the United States or to any one geography. It's a battle that's playing out in a number of countries around the globe. And so we want to learn from others about how the crisis is playing out globally as well as efforts that are being taken to address it.

(02:06:20):

So we have three speakers who are going to help us do that, and I will introduce each in turn. But you'll see here, we'll be joined by three individuals to speak to different dimensions of the global dynamic. So I'm first going to turn to Carrie Harney, who is with the US Pharmacopeia. Many would think that US Pharmacopeia is focused only on the US market, but USP addresses a number of global issues including fighting illegal online sales and counterfeits around the world.

(02:06:54):

So I am just thrilled that we have Carrie Harney, who is vice president for US Government and Regulatory Affairs at USP, here to share some thoughts with us. Carrie, I'm going to turn the stage over to you.

Carrie Harne (02:07:09):

Well, thank you, Susan, and thank you everybody for the invitation to be here today. Certainly, it is very important to USP this conversation, and we appreciate the opportunity to participate today and learn from all of the great panelists. As Susan said, I do work at USP or US Pharmacopeia. For those who are not as familiar with USP, USP is a private scientific nonprofit organization founded in 1820 with a mission to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

(02:07:54):

We work to strengthen the supply chain, and as Susan mentioned, not just the US supply chain, but really the global supply chain for medicines so that the medicines that people rely on for their health are available when they're needed and work as intended.

(02:08:12):

So as this slide shows, USP develops and publishes standards for drug products, including controlled substances. These standards are used in more than 140 countries across the world, and they help to ensure that medicines are safe, high quality, and are of the correct identity. And as you can see on this slide, standards span the supply chain. So we have standards that apply to raw ingredients before they're even in the medicines, all the way up to standards that help dispense medicines to patients and ensure that patients are getting quality medicines.

(02:08:55):

And in the realm of controlled substances, we do have standards that help promote the safe handling and use of controlled substances in the home and healthcare settings. And collectively, these standards help ensure that legitimately obtained and regulated controlled substances are used as safely as possible. So while we certainly think it's important to continue to work to strengthen the supply chain through quality standards, we also recognize the fact that the issues that we're talking about today aren't part of the regulated supply chain, especially when we're talking about patients obtaining controlled substances online.

(02:09:41):

And indeed, we find that according to sources, 95% of online sellers, or those purporting to be pharmacies online, are actually operating illegally across the globe and in violation of local laws and relevant pharmacy practice standards. And when a patient is in this world of being outside of the regulated supply chain, that means that they are acting with these sellers without the protections of that supply chain.

(02:10:13):

And so when we think about what those protections typically are, that's the relationship with the healthcare provider, the relationship with the pharmacy and the pharmacist, and more broadly operating within a world that is under the jurisdiction of their national regulatory agency. And in the US, that's FDA, and FDA works to authorize drug manufacturers, ensure the quality of products, and help prevent counterfeit and substandard medicines. When a patient is outside of this system, they are in a space that really can present significant risk to their health.

(02:10:53):

So it's not uncommon, for example, for these online pharmacies to sell substandard and falsified medicines, products that contain too much or too little of the active ingredient or that are contaminated with other harmful ingredients. And of course, many also sell controlled substances, as we've heard about today.

(02:11:16):

Consistent with what we've heard today, I did want to note recent consumer survey research from the Alliance for Safe Online Pharmacies that indicates while consumers are buying a variety of medicines online, controlled substances, and Dr. Hertig referred to this in his presentation, but including opioids, benzodiazepines, as well as stimulants are among the classes of medicines that are being purchased online.

(02:11:46):

And I think it's also important to note that the ASOP data indicates that a substantial share of Americans who have purchased medicines online have done this knowingly, that these medicines are being shipped from outside the US or that are intended for sale outside of the US. And so I think this helps to illustrate the fact that this really is a global issue and isn't limited to any one country, and also the fact that a global response is needed to address this issue.

(02:12:21):

And so just to maybe give a little bit of insight into one response that is underway now, and one that USP helps to support is the APEC Supply Chain Security Toolkit. In 2013, to enhance medical product quality and supply chain globally, the Asia-Pacific Economic Cooperation, or APEC, commissioned the development of the Supply Chain Security Toolkit. And this final product is a 10-part toolkit outlining harmonized best practices for preventing, detecting and responding to substandard and falsified medical products at every step of the life cycle for pharmaceutical products.

(02:13:03):

And this toolkit focuses on developing and implementing through training programs, processes, procedures, and tools directed at enhancing global medical product quality and supply chain security. And so we've worked very closely with FDA and other partners, and we serve as a center of excellence as part of an APEC Center of Excellence. And part of our role, as that center of excellence, is to develop content and deliver quality trainings based on the toolkit materials.

(02:13:38):

So particularly relevant, I think, to the conversation today is the part of the toolkit that's directed at internet sales. And so this is what we refer to as the Internet Sales Toolkit. This part of the toolkit is intended to address the illegal online sales of medical products globally. And this does address the sale of controlled substances.

(02:14:01):

And what this toolkit is intended to do is to provide information for a wide variety of stakeholders, including industry stakeholders, national regulatory authorities, healthcare practitioners and consumers to really help them understand the scope of the problem and also provide recommendations on what can be done to help combat the problem and to protect patients across the world.

(02:14:32):

I just wanted to provide an overview of the recommendations from the Internet Sales Toolkit. I think we've actually, in the discussions today, heard presentations that reflect many of these recommendations, but I wanted to highlight a couple for the audience today. First, is the recommendation to develop public awareness campaigns for patients and healthcare practitioners on safe online purchasing. I think this issue of public awareness, as we've heard from others, continues to be so important.

(02:15:07):

And focusing on the United States, the ASOP consumer data continues to indicate a relatively low level of overall knowledge about safe and unsafe sellers. And in fact, the most recent data that we have indicates that 65% of Americans falsely believe that all websites offering prescription medicines online have been reviewed and approved by the FDA and by state regulators to ensure compliance with all applicable laws. Unfortunately, we know that that is not the case for these online pharmacies, but I think the fact that so many Americans believe it to be, really illustrates the importance and the urgency of these public awareness campaigns.

(02:15:52):

As another recommendation, there's a recommendation to strengthen laws and policies against online substandard and falsified products, and the toolkit does provide some recommendations on what such laws and policies can be. Apropos of our last panel, the toolkit does talk about voluntary protocols for internet commerce companies, and I think really underscores the importance for these voluntary actions and this collaboration to think about what can be done to make these platforms safe for patients.

(02:16:27):

And finally, I think I wanted to highlight the recommendation for stakeholders to participate in cooperative international activities in fora. These really, I think, provide opportunities for the stakeholders to share valuable insights, learnings, maybe some innovative tools and approaches that have been successful in various jurisdictions that can be shared.

(02:16:51):

So USP continues to deliver APEC Center of Excellence trainings across the world and as well as other partners too, who deliver these trainings. And in fact, I think a year or so ago, there was just a training in collaboration with Health Canada on the Internet Sales Toolkit recommendations that I think was very impactful in that jurisdiction.

(02:17:16):

So moving forward, I think it's important that we continue to support trainings and implementation of this toolkit. It's certainly not the answer to all of these issues, but I think it really can help support best

practices among different governments and economies. It can educate the public, encourage voluntary action from key stakeholders in this environment and help coordinate enforcement mechanisms.

(02:17:44):

And hopefully, over time, and with the other efforts that we've heard about today, can really make a difference in protecting patients and public health. So thank you again for the opportunity to be here, and I look forward to the rest of the discussion.

Susan Winckler (02:18:00):

Carrie, thank you so much. What I'm struck is that we were just hearing from among the technology sector about the importance of public-private partnerships and the collaboration, and you've helped us expand and assure that we're thinking about that on a global scale as well. So really appreciate you sharing that information.

(02:18:21):

And so let's continue our conversation about the global scale. I want to turn to Vladimir Kostic, who is a data analyst with the International Narcotics Control Board at the United Nations, to talk about the GRIDS Programme. And I'll say, Vladimir, we first need the explanation of what GRIDS stands for, and so I'm glad it's on your first slide there. I'll turn to you.

Vladimir Kostic (02:18:49):

Thank you, Susan. We love acronyms at the United Nations. We even have acronyms within acronyms. I'll try to point all of those out as I go through the presentation. I wanted to start by saying a big thank you to the foundation and to the FDA for convening us. I also wanted to say thank you to Jennifer and Ed for sharing the stories of Tasmyn and Charlie.

(02:19:13):

I like to say that one of the goals of our program is to disrupt trafficking, but essentially it really is to protect families and our societies from these deadly threats. So go back to the presentation, which now I regret doing because there's been so many interesting topics and points the other speakers have talked about that I would've spent the next 10 minutes just tying into those. But let's go through it.

(02:19:40):

My name is Vladimir Kostic or Vladi Kostic, and I work for the United Nations International Narcotics Control Board and its GRIDS Programme or the Global Rapid Interdiction of Dangerous Substances. I'll try to offer a global perspective on what we're doing to support governments and the private sector in disrupting trafficking of deadly substances both online and offline, especially when it comes to synthetic opioids through data tech and partnerships.

(02:20:09):

Jim said that today's the 24th anniversary of 9/11. I remember like yesterday when I was a kid watching on one of these big fat cathode tube TVs live when it was happening. Just to give you a scale, I think last year we had, what? Maybe 33 times as many victims of overdoses because of synthetic opioids as on 9/11. And that's just a crazy number, and that's only in the United States, right? When you expand it on a global level, that number becomes even much, much, much higher. So I'll just try to click through the presentation. Perfect.

(02:20:49):

So not many people know what the INCB is. It is a UN treaty mandated body established in 1961. Its roots are even before the League of Nations, so think opium conventions. We're based in Vienna,

Austria, in Europe, so it's 9:00 PM here almost. The board's mandate is twofold. On the one side, we ensure legitimate access to narcotic drugs, psychotropic substances, and precursor chemicals for medical, scientific, and industrial use.

(02:21:22):

And on the other hand, we work to prevent the diversion of these legitimate substances that are used into illegal channels. And my program focuses on counter-trafficking of dangerous substances in general. The International Drug Control Conventions of 1961 on narcotic drugs, 71 on psychotropic substances and 88 on precursor chemicals are almost universally acceded tool. What does that mean? That means that we can work with pretty much every single government in the world. We don't need any MOUs or any Memorandum of Understandings, any agreements signed with those agencies or governments to work with them because they have already agreed to that through the drug control conventions.

(02:22:15):

Briefly, the GRIDS Programme focuses on counter-trafficking of dangerous substances. Through our officers deployed in nine locations around the world, where we developed a pretty sizable global network of enforcement officers that work in the space of counter-trafficking. And now I think Ed said building a network to fight the network, right? This enforcement network is not only police. It includes customs officers, it includes postal security officers, veterinary inspectors, because one of the cutting agents, Xylazine, that was mentioned earlier, is a veterinary medicine as well.

(02:22:54):

So we're really trying to use all of government approach, if I can say it like that. Our officers in these locations, their primary task is to build capacity within their regions. They also support investigations and coordinate them, but a big part of their work is building these networks out, building trust within their regions, both on the enforcement side and the public or the private side within industry. The enforcement network is then obviously complemented by the private sector partners that we engage on a voluntary basis through their respective governments, as well as partnerships with basically every international partner that exists, Interpol, Europol, World Customs Organization, Universal Postal Union, just to name a few.

(02:23:49):

My program, our HQ is in Vienna, Austria. There we have our GRIDS Cyber-Communication Center, which you can see there on screen. It hosts a suite of operational tools that we offer to governments at the great cost of zero, and I'll talk about them in a second. Our approach consists of two different operational synchronized streams. On the left is the enforcement side, and there, through structured training, cooperation and secure access to our tools, we enable timely information exchange, which is very, very important among, again, different agencies around the world.

(02:24:33):

That data is mined both by analysts at HQ in the field as well as other governments into consolidated intelligence. We then package that intelligence and route it out through the appropriate channels for actioning, with the idea not to only have more seizures, but to actually have dismantling of these criminal organizations.

(02:24:55):

On the right side, equally as important is the private sector stream. And there, again, through governments and based on a voluntary basis, we partner with, we call these the four Ms, with marketing, movement, monetization, and manufacturing partners to work with them, to support them

in preventing exploitation of the legitimate services. And it's a pleasure seeing these tech companies here. These are just a few of the ones we work on a global level with.

(02:25:26):

And whether online or offline, both of these streams are designed to support governments with the same goal, to detect bad actors, deny them access to consumers, disrupt their supply chains, and ultimately dismantle their organizations. There's a lot of animations here. Let's see if they'll run. Perfect.

(02:25:48):

Again, I said we focus on these emerging new psychoactive substances. What are these? Think small chemical variations of controlled substances that are either purposely modified to have the same effects or even many times more potent effects while circumventing existing controls or other substances that may have not yet been placed on their national or regional or international control. Here, to put a bit of humor into it, it's like playing a cat and mouse game with these bad guys. The bad guys are very fast and sneaky mouse that can design a new chemical or use some fringe chemical that was designed 50 years ago to circumvent control.

(02:26:31):

And we are a very fat cat that is very slow, and has to ask around 190 other cats to see whether we can chase the mouse. So by the time a substance is controlled, many, many more pop up. Just another slide to illustrate my graph, I guess, is the huge volume of synthetic opioids we're seeing around the world. Really, the amounts of seizures across the globe are staggering. The other panelists have spoken about controlled substances a lot throughout the summit, and while a lot of those deadly substances are controlled in the United States, a lot of them are not controlled in other countries. Think South Asia, Southeast Asia, Africa, where manufacturers can legitimately make these pharmaceuticals and ship them freely with no export restrictions from their countries.

(02:27:32):

And obviously, they are illegal in the United States and they're being seized, but there's so many of these shipments because it's very cost-effective for them to just keep sending more and more and more of these pharmaceuticals to consumers. Online, we're even seeing basically bad guys who are essentially dropshippers. They'll get orders of various pharmaceuticals, and then they'll identify suppliers who will ship straight to the end consumer. These are just some of the images from seizures and open source intelligence of different pharmaceuticals that have all been laced with many, many different very potent drugs, whether it's Xylazine, again, a veterinary product, whether it's nitazenes, these substances that can be many, many more times potent than fentanyl and just being put in there.

(02:28:24):

And these are the most concerning because the end consumer does not really understand or know what they're taking. They're taking a Percocet or Xanax or an Adderall, but what is really inside of it? It could be anything. A lot has been spoken about technology. We're invested heavily in a number of different systems. At the core of everything is IONICS. We like to call it, basically, Felony Facebook. It is essentially accessible by every single government around the world, and it is designed to exchange seizure information on emerging synthetic drugs, opioids, NPS, falsified pharmaceuticals.

(02:29:05):

What makes it different than most platforms is that it contains very detailed information on who is exporting, who is sending the drugs, and who is importing, who is ordering the drugs. This includes street address information, contact numbers, tracking numbers, all these different data points, signals

that are very useful for investigations, risk profiling, targeting, and finding the true source of where the drugs are coming from for backtracking.

(02:29:35):

What's really cool about IONICS is again, it does not care about what agency you're from. As long as you're a government agency that has a role to play in counter-trafficking, you can get access to it. Basically, every single government sees more or less the same data, so that, let's say I'm originally from Serbia, let's say, drugs are coming from Serbia to the United States. They are seized by the Customs and Border Protection there. CBP will communicate that information through IONICS where the officers in Serbia will be notified, and hopefully they will either start an investigation or find out where these drugs are coming from and then stop them from ever coming again. So again, goal is not just more seizures, it's actually finding the true source of the drugs. It is designed to allow countries to push out their borders to conduct investigations on the outbound side, on the origin side. On top of IONICS, we have a number of different targeting tools built there that assist law enforcement in targeting, profiling, and again, protecting their communities. Very, I think, important for this conversation today is a new tool we've been working on. It's, again, another acronym, SNOOP. We start from something that sounds cool, Snoop Dogg and then work back in acronym. It stands for Scanning Novel Opioids on Online Platforms. And essentially, the idea is to look for bad substances. So these are drugs that have no legitimate uses but are very deadly that will only be used as drugs of abuse, and find bad guys selling on legitimate platforms. Think about... eBay is extremely good at taking these offline and not allowing them to ever be posted. But you'll have hundreds of different smaller e-commerce platforms that don't have the same resources or knowledge.

(02:31:29):

We use machine learning and many other different algorithms to collect this data, mine it into actionable intelligence, and then either distribute it to the e-commerce platforms, distribute it to other partners, such as monetization, marketing, social media companies at the same time, because these bad guys are extremely good at optimizing how they reach the largest amount of consumer. The same bad guy advertising on a small regional e-commerce platform in Southeast Asia will also have a Meta account, Twitter, X, streaming platform accounts and whatnot. Now, this is just how one of these intelligence packages looks like.

(02:32:11):

We work with a large number of private sector partners. I just wanted to show you these. These are very important tools. This is a list of basically substances that I was talking about that have no legitimate uses with a number of different keywords associated to them. These are shared with governments and private sector partners to assist them in figuring out what emerging drugs are there that they should be on the lookout.

(02:32:37):

And finally, I think I have one more slide there, just I think Mike was talking about a venue to bring different players together. We organized last year Tech Against Trafficking with, I think, more than 70 experts from across the world, industry leaders over there to share best practices, ideas and actionable next steps. We look forward to organizing it again. Next year, I think most of the tech companies that were here will again be invited if they're available. We would love to host them in Vienna and find more solutions. I'm sorry if I went over time. I have so many more things to say, but thank you again for having me here.

Susan Winckler (02:33:13):

That was so informative. Vladimir, thank you so much. And everything from your really helpful analogies in helping us think about the cat and the mouse, and then just as substantively thinking through all of the different variations of resources about the changes in chemicals and things that are made available. And thanks, also, for your efforts in the Tech against Trafficking.

(02:33:42):

With that, let's turn to a specific regulator in our assessment of looking at interventions around the world. And for that, we are going to turn to Laila Sofia Mouawad, who is the Technical Officer International Cooperation Unit for the Brazilian Regulatory Health Agency or ANVISA. Laila, we would love to hear from you some of your experience with the implementation of an internet scrubbing tool, a digital surveillance tool. I'll turn the stage to you.

Laila Sofia Mouawad (02:34:18):

Thank you, Susan. And thank you so much for inviting ANVISA to participate on this summit. So I will speak a little bit about our experience in Brazil with the use of a digital surveillance tool to search for irregular products that are distributed online.

(02:34:47):

So the background is the big challenge that all regulators are currently facing with the massive expansion of e-commerce. Also, the growing volume and anonymity of online transactions, the lack of harmonized global regulations on this field, the proliferation of counterfeit and substandard products. So basically what we have is illegal products frequently advertised and sold on social media platforms and online marketplaces. And the use of encrypted messaging apps and cryptocurrency for transactions further complicates the surveillance and enforcement actions and consequently complicates our missions.

(02:35:53):

So to try to tackle these challenges, we started a technical cooperation project with the United Nations Development Program in order to hire a specialized private company to develop the digital surveillance tool for us. This tool was named EPINET. It's not an acronym, and I don't know why they chose this name. But yes. So basically, we hired a company to develop this tool which was designed to monitor online sales in Brazil. And the searches are based on models of artificial intelligence using several factors, URLs and contents to classify signals and threats. So the tool covers all Brazilian websites and e-commerce platforms. The contract was signed in 2021, and it became effective from November 2021 to December 2024. So basically, we had a three-year pilot project, which generated a lot of data, very useful data for us. And our goal now is to continue to resume the use of this tool. But right now, we are working on the internal process to rehire the tool.

(02:37:43):

This is a very simplistic and summarized description of how the tool works. So basically, we, ANVISA, selected the keywords we could use up to 800 keywords at a time. So we were currently updating the list of keywords based on observed trends. We also defined criteria that were additionally needed for the validation steps. And then the tool performed the searches and the signals using these keywords and these criteria, and the signals captured were sent to the first validation step, which was an automated step. And then the possible threats were submitted to a second validation step that could be also again automated, or we could even need to have a human verification before the irregular products were identified.

(02:39:16):

After that, once the system identifies the irregular products, it automatically sent warning letters on behalf of ANVISA. So we worked with the contractor on a template. So basically, the system also searches for the information of the owners of the websites and then it fills in the blanks in the template and automatically send these warning letters on behalf of ANVISA requesting the takedowns. And then after that, the system regularly checks whether the advertisements were removed, and it also generates effectiveness data.

(02:40:11):

So here are some numbers of the pilot project. So during the three-year project, the system captured more than 128 million signals, which were narrowed down into more than 220,000 warning letters issued, of which had a 98% effectiveness. So we had takedowns of 98% of the warning letters issued. During the last stage of the pilot project, we also performed some investigations into the Deep and Darkweb. We used this potential to search for controlled substances. One example was to search for the Vyvanse product, which is Lisdexamfetamine. We searched for this substance for six months, and the system detected more than 54,000 mentions. So basically, what we could see is that what the system found is prescription falsification, so they sell falsified prescriptions. Also direct sales letters and strategies also included digital marketing.

(02:42:20):

I apologize for the text in Portuguese. I just wanted to add this graph to show that the software also gathers data and it is also able to design trend lines, just to show few findings of this investigation. These are examples of advertisements of prescription sales and also direct sales.

(02:43:07):

To conclude my presentation and now reflecting on the global perspectives for regulatory authorities, in ANVISA, we strongly believe that it is necessary to invest in advanced digital surveillance tools. This is something we are working on now, strengthen international cooperation as well, enhance public awareness about the dangers of purchasing medicines from unverified sources. I believe this was already mentioned by other speakers too. And also, collaboration with internet service providers, payment processors and tech companies are also essential in dismantling online networks that facilitate the illegal drug trade. So that was all. Thank you very much again.

Susan Winckler (02:44:15):

Laila, that was excellent and always helpful to see a practical resource and the learnings from a regulatory agency. So thank you for sharing your insights and the learnings that you have. We appreciate it. And that finishes our global tour as we are continuing our movement through this topic.

(02:44:39):

So with that, I am going to bring us to our last session of the day. And we'll note that as we've had various discussions with leaders across the digital ecosystem, there were some common practices that emerged that many of the digital platforms employ as they shape strategies to prevent the illegal sale of controlled substances online. So I'll note that we just have some of those common practices there, because as some of you have noted in comments and in the chat, that there are a number of players in the digital ecosystem who are not yet involved in these efforts. And this is just some basic information that can help them to take steps to better protect consumers, and as we heard earlier, to better protect our children.

(02:45:37):

We also heard from the digital leaders, and you heard it again today, about the need for trusted resources to help redirect consumers. And to that end, we are going to be posting an introductory list of resources to help those working in this space, striking that balance of providing the resources that are helpful without in any way empowering the criminal network on the other side. So I'll just note that those resources are now available on the Foundation's website, and we are pleased to provide that information.

Closing Remarks

Sangeeta Vaswani Chatterjee, PharmD, Acting Director, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

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

Susan Winckler (02:46:09):

So let me turn now to our concluding remarks. And for that, we are going to welcome Dr. Sangeeta Chatterjee back to the stage and introduce Dr. Marta Sokolowska for our closing conversation. For those of you who have not yet worked with her, Dr. Sokolowska is the deputy center director for substance use and behavioral health in the Center for Drug Evaluation and research at FDA where she sets the strategic leadership for the center's work related to controlled substances and substance use.

(02:46:41):

So I want to welcome to the stage, our virtual stage, Dr. Sokolowska and Chatterjee. What a powerful program. I just have to say it's such a privilege to have the opportunity to listen to the experts and the personal testimony that we heard today and then learning about intervention and disruption strategies from a number of different platforms and then thinking through the global dynamics. So if we think back to all that we've heard in the last two and a half hours, two hours and 45 minutes, my question to you, it would help our audience, what are the two main takeaways you would like the audience to remember from this meeting? What do you want to underline for them? And Dr. Chatterjee, let's turn to you first.

Dr. Sangeeta Vaswani Chatterjee (02:47:39):

Sure. Thank you so much, Susan. And I agree with you that this has been a really great discussion and a very dynamic and open and candid dialogue. So we really appreciate that everyone has been so willing to share information. So I think my first takeaway is really that we are functioning in an environment where evolving public health threat needs evolving technology. That's kind of the way I think to kind of sum up today's discussion. So I think that we need to be equally dynamic and collaborative and holistic in our approach. So we heard some really great updates from the researchers about purchasing patterns. We heard the global perspective, and we also heard about some of the great interventions that the platforms are taking to protect their users. And I think that those are really critical. So I think that the human stories are really powerful reminders that, behind every data point, there's a family that's been changed forever. So I think that the technical solutions do need to be matched by the social responsibility. So I think that that's the first takeaway.

(02:48:47):

The second takeaway, and I'll keep it brief, is that I'm really glad to see these common practices. And I just want to reflect a little bit that I think that these are really concrete and meaningful steps. And I think the development of these practices really creates a comprehensive and multilayered defense system

based on proactive prevention. And I think that intercepting users at critical moments when they're about to search or make a purchase of an illegal controlled substance that's being offered for sale illegally is really critical and can be really transformative moments. And so I also really appreciate the availability of resources for the internet ecosystem stakeholders to use as appropriate.

Susan Winckler (02:49:36):

I am struck that as you described it, we need a dynamic and collaborative regulator, which is the posture that FDA has been showing here, but a key component. So thanks for highlighting those two components and resources we heard throughout the day always important. So Dr. Sokolowska, Sangeeta was comprehensive, but I bet there's two more things that you want to flag.

Dr. Marta Sokolowska (02:50:07):

Well, first of all, thank you very much everyone for joining this really informative meeting, and Susan and the REF team, thank you very much for moderating this really great discussion. And I just want to say specific thank you to Jennifer and Ed for sharing your stories.

(02:50:24):

I've been working on trying to address the overdose crisis for many, many years, and we see now decreases in the overdose crisis for the last while. And as we are celebrating those successes, it's really critical that we keep in mind that our job is far from being done, that there are way too many people, too many kids, too many parents, too many communities that are still impacted. And it just motivates me to continue working, because I know that there is more that we have to work on. And this landscape is evolving so quickly that every time we think that we turn a corner there is new innovation. And that's why I really value this discussion that we had today.

(02:51:16):

And throughout the six years, it's the sixth time that we've had this meeting. What I really value is how we continue the evolution of learning both on the demand and the supply side of this online access to controlled substances, overall understanding, recognizing the fact that online access is here to stay and we have to figure out how can we fit our messaging to inform the demand appropriately and control the supply as much as possible in appropriate format. So I really appreciate that, understanding how we evolve our understanding of the motives, why people are turning to online platforms to get access to variety of products, including controlled substances sometimes when it's not listed. It's really important, because that helps us to tailor our messaging appropriately.

(02:52:16):

And also, what I found really intriguing and very encouraging is the discussion regarding the innovation collaboration between the different platforms and how that discussion has evolved over the last six years and how more agile and really trying to address the issue at hand our partners have been both on the technology side and internationally. So I'll just leave with that. I really appreciate that.

Susan Winckler (02:52:46):

Really important underscoring both of those points. We are getting to the last few minutes that we have together, and so I want to give you each an opportunity to think about a consistent concept of today. And each of you mentioned it is it takes a network to defeat a network that we have to have this collaboration on each side. So I want to give you each a chance to give a quick response to, are there additional collaborators who could strengthen our network response? And what might a successful

future look like? All right, you both unmuted at the same time, so Sangeeta, go, but make sure you leave time for Marta.

Dr. Sangeeta Vaswani Chatterjee (02:53:28):

I'm going to make it really short. So I think that what today's session really underscored that platforms are emerging and the threat is emerging, right? So I think that with each of these summits and in each of these conversations, it's really critical to see what new platforms are out there. And also what are the types of internet platforms that youth are accessing? So I think that that's really important. And in terms of academia, there's really great research that's coming out, machine learning AI capabilities. So I think it would be good to continue to bring them in the conversation in terms of proactive threat detection, as well as content moderation. So I think I'm going to leave time for Marta.

Dr. Marta Sokolowska (02:54:15):

Well, so I'll turn it a bit around, since you talked about the supply and how we can control that better, I would say let's also try to figure out how we can better address the demand issue, better inform the consumers on what it is that they might or might not be getting online. And also, as we are thinking about the messaging, also trying to figure out how we can put into that prevention and also focus on educating the consumers on creating drug-free environments that may be very well stop seeking these products online that might be risky for them. So we still have room to grow.

Susan Winckler (02:55:01):

Absolutely. And Marta, what I'm struck by that is it brings me back to the very eloquent wishes that Jen gave us, wishing that she knew more about her son and about the use of controlled substances and the risks of those and the environment in which they can be purchased now. And those are things that we can address, so looking at the demand side and doing more there. I don't think that any of us could say it any better than Dr. Chatterjee and Sokolowska did to close us out today.

(02:55:42):

So I will simply say thank you to all of our speakers who provided such great and helpful insight. We hope they've answered some of the questions that you may have about the sale and purchase of controlled substances online, the risks, and what the future might look like as we take on additional work. Thank you for joining us today, and thank you for your efforts to make the online ecosystem a safer place and stop the illegal sale of controlled substances. Take care.