Public Meeting on Patient-Focused Drug Development for Stimulant Use Disorder

Moderated by Robyn Bent and Lyna Merzoug

Tuesday, October 6, 2020

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Virtual Event

Silver Spring, Maryland 20910

Reported by: Irene Gray

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A P P E A R A N C E S

List of Attendees:

Ms. Robyn Bent, OCD, CDER, FDA

Dr. Brett Giroir, U.S. Department of Health and Human Services

Dr. Theresa Mullin, OCD, CDER, FDA

Dr. Maryam Afshar, Division of Anesthesiology, Addiction Medicine and Pain Medicine

Dr. Marta Sokolowska, OCD, CDER, FDA

Dr. Celia Winchell, Division of Anesthesiology, Addiction Medicine and Pain Medicine

Dr. Tiffany Farchione, Division of Psychiatry

Dr. Javier Muniz, Division of Psychiatry

Dr. Jana McAninch, Division of Epidemiology

Lyna Merzoug

Shannon Cole

Jessica Hulsey

Brendan Welsh

Scott Sheldon

Pam L.

Paula Walsh

Brandee Izquierdo

Philip Rutherford,

Michael Galipeau

Kevin F.

Charles Smith

Amy Griesel

David

C O N T E N T S

P R O C E E D I N G S

MS. BENT: Good afternoon. Good afternoon, everybody, and thank you for joining us for this FDA-led patient-focused drug development meeting on stimulant use disorder. My name is Robyn Bent. I'm the director of patient-focused drug development with the Center for Drug Evaluation and Research here at FDA. I'll serve as the discussions facilitator for today's meeting, which is part of the FDA initiative called patient-focused drug development.

We have a really full agenda today and I'm going to briefly walk you through it. We're going to start off with opening remarks from Admiral Brett Giroir, the assistant secretary of health. And he'll be providing opening remarks in just a few minutes.

After Admiral Giroir's opening remarks, we'll hear from Dr. Theresa Mullin, Associate Director for Strategic Initiatives in the Center for Drug Evaluation and Research -- who will talk a little bit more about FDA's patient-focused drug development efforts.

We'll then spend some time hearing from Dr. Maryam Afshar from the Division of Anesthesiology, Addiction Medicine, and Pain Medicine, who will provide us with a background on stimulant use disorder. The use of stimulants such as cocaine, methamphetamine, crystal meth, or the misuse of prescriptions like Adderall or Ritalin. Then we'll move onto our discussion with individuals who are living with stimulant use disorder and their loved ones or advocates.

We'll have three sessions. Our first session will focus on the health effects and daily impacts of stimulant use disorder that matter really most to individuals. Our second session will focus on your thoughts about current approaches to managing stimulant use disorder. And then our third session will focus on the impact of COVID-19 on stimulant use disorder.

I'll better explain the meeting format and the process right before we get into our first panel.

Logistics. So a few logistics and housekeeping points. This meeting is taking place in a fully virtual setting and is focused on hearing from people who have personal experiences with stimulant use disorder. Throughout the day, we'll have polling questions and you'll have the opportunity to share your experiences by either using the chat feature in the bottom right corner of the meeting screen or by calling the phone number that we'll be putting up on the screen throughout the meeting.

Recording. This meeting will be webcast and the live webcast is being recorded. Both the webcast and transcripts of today's meeting will be archived on our website.

So I'm going to start now -- we're going to start with opening remarks, and it will be my pleasure to introduce Admiral Brett Giroir who will provide these opening remarks to us. Admiral Giroir is the 16th Assistant Secretary for Health -- or the ASH -- at the U.S. Department of Health and Human Services, and leads more than 6,000 officers in the

U.S. Public Health Service Commissioned Corps. As the secretary's principal public health and science advisor, the ASH is leading America to healthier lives through promoting vaccination across a lifespan, developing the nation's report card for health, called Healthy People 2030, working to end America's HIV epidemic, working to improve the lives of those suffering health disparities, and bringing a spotlight to the importance of preventing and treating substance use disorders. In addition to his role at the ASH, Admiral Giroir represents the United States to the World Health Organization Executive Board and was appointed on March 12th to lead the coordination of COVID-19 testing efforts across health and human services. He has served in numerous leadership positions in the federal government and in academic institutions. Most notably serving as the acting FDA commissioner in 2019, and the first position to serve as an office director at the Defensive Advanced Research Projects Agency in 2007. As a pediatric critical care physician, Admiral Giroir brings that

hands-on patient-centered perspective to his work at the ASH.

Admiral Giroir, thank you for joining us today. The floor is yours, sir.

DR. GIROIR: So good afternoon to everyone and thank you, Captain Bent, for that very kind introduction and for all the great work that you and your team are doing.

I think as all of us know in the virtual world, we are in unprecedented times as we deal with COVID-19. And while we continue to face such tremendous challenges with COVID, our efforts to address substance use disorders and overdose deaths is even more critical now as people face new barriers to care and treatment.

Indeed our nation's substance abuse crisis has been one of the most pressing public health challenges we have faced, and the crisis continues to evolve.

While we have made great strides against prescription opioids, more and more people are

impacted by prescription and elicit stimulant misuse and addiction.

I wanted to be clear how we view substance use disorders so there is no misunderstanding or disagreement. Substance use disorder is a chronic brain disease. It is not a moral flaw. This is a public health crisis and we are committed to addressing it in that way. That is precisely why Secretary Azar declared this a public health emergency.

Our goal is not to make bad people good, but to help sick people get better. Today, we focus on stimulants such as prescription stimulants, cocaine and methamphetamine. Some of the most potently addictive substances on the planet. They trigger rushes of dopamine and other neurotransmitters like nothing else. Household survey data from 2019 show that nearly 4.9 million people, Americans, misused prescription stimulants in that past year, and on average 2,500 people a day, aged 12 or older, initiated prescription stimulant misuse. In the same

survey, two million people reported methamphetamine use and 5.5 million people reported cocaine use in just the past year.

Recent CDC data show increasing overdose deaths related to psychostimulants like methamphetamines and cocaine, with a 28 percent increase in methamphetamine-related overdose deaths and a 13 percent increase in cocaine-related overdose deaths for the 12 months ending in February 2020.

We don't know the exact reasons for the increase, but there have been significant increases in drug supply across the border by Mexican drug cartels. Much more polysubstance use among those with use disorders and dangerous trends in toxicity and mixing of drugs, like methamphetamine and fentanyl.

For instance, in 2017, almost 73 percent of cocaine-involved deaths also involved opioids. And the data suggests that increases in cocaine-involved overdose deaths from 2012 to 2017 were driven primarily by co-use of synthetic opioids like fentanyl.

A study published earlier this year of over one million urine drug test results from 2013 to 2019 found a 14-fold increase in the rate at which samples testing positive for fentanyl also tested positive for methamphetamines, and more than a six-fold increase in cocaine. And the study my team published last month in JAMA, comparing urine drug tests before and after the COVID-19 emergency declaration showed significant increases in positivity rates for cocaine, methamphetamine and fentanyl among people diagnosed with or at risk for substance use disorder.

HHS, our department, has expanded our efforts for prevention treatment and recovery services, and to strengthen our research capacity and data surveillance systems to understand trends in stimulant use. To effectively coordinate activities around the department, together with SAMHSA, my office established an interagency methamphetamine task force that aims to expertly inform HHS efforts related to methamphetamine use. CDC is continuing to conduct

research to understand trends in methamphetamine and cocaine-related morbidity and mortality, including how these trends are similar to opioids and how they're different. NIH is leading several research projects to develop new treatments. We're at least fortunate for opioid use disorder to have medication-assisted treatment, many forms. We don't have that for cocaine or methamphetamines. Some of the exciting new treatments, including a monoclonal antibody, that could alter methamphetamine disposition.

HHS agencies continue to expand flexibilities across programs. This has been very important. The state opioid response program, which is literally billions of dollars, did not allow that opioid money to be used for stimulant misuse. But after working with congress, we now have that flexibility for states to use these billions of dollars to focus on people who are suffering primarily from cocaine or methamphetamine misuse. And through the combined efforts from FDA, like today's meeting, HHS will ensure the patient's perspective and input is

understood as we continue with our effort. Your input is indeed the most important. It's what matter. How can we help you? What is your experience? What do you consider to be a success with a new treatment recommendation? And I want to say how much I respect you and admire all of you for your courage to have your voices heard today.

In closing, I want to reaffirm that HHS is committed to addressing stimulant use disorders and build a sustainable system for prevention and treatment of all substance use disorders. And imperative to our success in addressing stimulant use disorder is your input. The individual perspective and experience is critical to the work that we do, so I would like to extend my gratitude to everyone speaking today for your willingness to share your stories. Our strategy will continue to be grounded in evidence and have a whole of government, whole of society, patient-centered approach.

Again, thank you to the individuals participating in today's meeting and for the FDA

housing this forum. I welcome you to increase your engagement with the federal government as we all continue to push hard for sustainable holistic solutions that help everyone.

MS. BENT: Thank you, sir. And thank you so much for taking your time to remind us why we're here today and for putting the weight of your office behind the prevention and treatment of substance use disorders, including stimulant use disorder. We really appreciate it, so thank you very much.

With that, I would now like to invite Dr. Theresa Mullin to unmute and turn on her video to provide a little background on the FDA patient-focused drug development program, because it really is a program unique among FDA public meetings. Dr. Mullin?

DR. MULLIN: Thank you, Robyn. And --

MS. BENT: Thank you.

DR. MULLIN: -- thank you. It's an honor to follow the admiral's remarks. And I'm going to give you a quick overview. Hopefully you can hear

me. Hopefully you can hear me at this point in --

MS. BENT: Yes, we can. I'm sorry. I -- yes, we can hear you.

DR. MULLIN: Robyn will tell me if we can't. Yes. Thank you. And I'm going to give you a brief overview of our patient-focused drug development initiative at FDA. This meeting is a patient-focused drug development meeting.

So next slide, please. And so to begin with -- and I hope you all can see this and it's much bigger on your screen than it is on my screen right now -- but I want to begin by giving you a little bit of background about FDA's role in medical product development and evaluation. FDA's mission overall is to protect and promote the public health. And part of that is to evaluate the safety and effectiveness of new drugs. And while we play an important oversight role in drug development, we're just part of that process. We do not -- FDA does not develop drugs and we do not conduct clinical trials for the development of drugs. Instead, we have our review divisions of

medical specialists, statisticians, clinical pharmacologists, toxicologists, chemical engineers and so on. And we provide regulatory oversight during drug development, and we make decisions on whether a drug can be approved for marketing based on the evidence that's submitted to us from that development program.

Next slide, please. And so how does patient-focused drug development fit into this? Well, patient-focused drug development, we define that as a systematic approach to help ensure that patients' experiences, perspectives, their needs and priorities are being captured and meaningfully incorporated into drug development and drug evaluation. And so this program helps us to do that.

Next slide, please. And so the voice of the patient is very critical to FDA's understanding and ability to make those kinds of assessments and oversee this process. Patients are uniquely positioned to inform us in our understanding of the clinical context and what matters to them, and that is

important to us in our decision-making and our assessment of this evidence that we receive about drugs and whether they can be approved for marketing. Before we had these PFDD, as we call them, meetings that the only mechanism we really had for obtaining input from patients would be limited to those discussions that would occur around a particular application or particular product -- such as an advisory committee. And only a few patient representatives typically would be involved in that and because it would be about a particular product, there would be extensive conflict of interest screening that would have to occur in order to even have those people participate.

PFDD meetings have allowed us to open it up and get a much wider view of the community. And it's been a more systematic way for us to get patients' perspectives on the severity of the condition and the impact of their condition on their daily life and their views on how well the currently available treatments are working for them.

Next slide, please. This gives you a little bit of a timeline for the patient-focused drug development effort and initiative. We began having these meetings and established this in 2012. And since that time and over those years, we've had -- as of now, FDA's conducted over 25 of these disease-specific meetings and we have also established an externally-led PFDD option because we found that many disease areas where people wanted to have these kinds of meetings, it kind of was greater than FDA's capacity to conduct and plan the meetings. And so the externally-led's been a really valuable addition to the program. And we greatly value the input that we get from patients and their caregivers and family during these meetings. And so we continue to have them and continue to greatly benefit.

Next slide, please. This just gives you a quick sort of overview of the many and very different disease areas that we -- some of them that we've had to date. And as you can see, there is really quite a large range here of conditions that --

and many, many more that we need to hear from. There have been already over 30 -- in addition to the ones listed here, over 30 externally-led meetings as well that patient advocates have organized and run.

And next slide, please. And so this is to give you a sense of how these meetings are done. And the patient-focused drug development meetings are really different from what's our normal federal agency approach to a meeting, and they're really more like a townhall-style format. And we begin these meetings with having an overview and we have our senior clinical staff provide a clinical overview of the condition and the currently available options for treatment. That's followed by a focus on the symptoms and daily impacts of this condition on patients and people close to them that usually starts off with a panel of patients and caregivers that reflect on their own experiences -- directly on their own experiences -- with the condition. And that provides a good launchpad, if you will, for a discussion involving everybody else in the meeting and their experiences,

and how what they've experienced with regard to the impact of the condition. And then that's followed by a session on current treatment options. And again, we start off with a panel of patients and caregivers talking about their firsthand experience with different treatment options and how that's worked for them, or where it's fallen short. And that's followed and provides a good basis for that facilitated discussion that follows, to build on that and hear from others and how -- what their experience has been. How it's been similar or different, and it provides a useful kind of springboard for us.

Next slide, please. So each of these patient-focused drug development meetings is tailored to the specific needs of the disease area, although they do tend to follow that standard format. And we do encourage that patient advocates, researchers, drug developers, healthcare providers and other government officials attend these meetings, but our focus is to hear directly from patients and their caregivers. So we ask that others remain silent and in listening mode

during these discussions because the meetings are really a platform for us to hear directly from patients and caregivers and patient representatives with the disease. And after these meetings, we develop a voice of the patient report where we try to capture very faithfully what we've heard and the way it's been described to us in the meetings, and that input that has been shared with us by patients and caregivers.

Next slide, please. And so with that, I thank you again for joining us today. We really look forward to hearing from you, hearing your perspective on stimulant use. And I'd like to now turn it over to Robyn, actually, who's going to introduce the next speaker. So thank you very much.

MS. BENT: Thank you so much, Dr. Mullin. Obviously, I'm a bit biased, but I think the PFDD meetings really hold an important place in incorporating the patient voice into the medical product development process, and I really appreciate you taking your time to kind of share that overview

with us.

Now, I would like to ask Dr. Maryam Afshar to unmute and turn on her video to begin her presentation that will provide us with kind of an overview of stimulant use disorder. Dr. Afshar?

DR. AFSHAR: Good afternoon, everyone, and thank you for joining us today. I'm Maryam Afshar. I'm a medical reviewer in the Division of Anesthesiology, Addiction Medicine and Pain Medicine.

Since our audience have varying degree of experience and understanding of stimulants use disorder, I was asked to provide a brief overview. The slides you will see contain more information than we can review in 10 minutes, but they will be available on the FDA website for your reference.

I would like to first go over some general definitions and then talk about definition of stimulant use disorder. Misuse is the intentional use of the drug by an individual in a way other than prescribed. Misuse is in the context of therapeutic use. Drug abuse is in the context of non-therapeutic

use and is using the drug in order to experience psychological or physical effects. Tolerance is needing to use more of a substance to get the desired effect, or experiencing a weaker effect while using the same amount. Withdrawal is experiencing psychological or physical symptoms in absence of the drug, or using the drug to avoid the symptoms. Dependence can be physical or psychological. By physical dependence, we mean that if the drug is decreased or stopped, the individual will experience withdrawal symptoms. Psychological dependence is when the individual has lost control over drug use or experiences psychological distress if not able to use. This corresponds to the familiar term, addiction. The currently used general medical term is substance use disorder.

Over the years, some of the terms that we have been using have changed. The Diagnostic and Statistical Manual of Mental Health Disorders, or DSM-4, that was published in 1994 had substance use disorders categorized under two groups: substance

abuse and substance dependence. The criteria for substance abuse was one or more symptoms out of three social problems due to substance use or risky use. The criteria for substance dependence were three or more symptoms out of seven, including tolerance and/or withdrawal.

In DSM-5, substance use disorder is a single diagnosis with different severities that are based on the number of symptoms that are present. Similar to use disorder is substance use disorder involving use of substances such as cocaine, methamphetamine and prescription stimulants. In DSM-5, stimulant use disorders is a single diagnosis with different severities that are based on the number of symptoms that are present. Also craving or strong desire or urge to use a substance was added as a criterion.

Another change in DSM-5 is amphetamine use disorder and cocaine use disorder were combined into a single stimulant use disorder diagnosis.

In general, the signs of any substance

use disorder are categorized into four groups: loss of control, risky use, social problems and drug effects.

Examples for loss of control are: using more than intended, spending a lot of time getting the drug, using and recovering from the effects, a strong -- sorry. A strong urge to use, repeated attempts to stop or cut down, and risky use or using stimulants when it can be physically dangerous, continuing to use despite experiencing physical or psychological problems.

Symptoms of social impairment are: not being able to take care of responsibilities at work, school or home because of stimulant use, using stimulants despite problems in relationships and socially, or not attending social or recreational activities because of stimulant use.

Drug effects are tolerance or withdrawal, which we already talked about.

Stimulant use disorder can be diagnosed when 2 of 11 symptoms are present in a year. Mild

stimulant use disorder can be diagnosed with two to three symptoms, but it's important to know that if those two symptoms are withdrawal and tolerance, that does not qualify for a diagnosis if the individual is taking a prescription stimulant medication as directed. Patients who are on stimulant medications can develop tolerance, and if the medication is stopped, they can experience withdrawal, but this does not mean they have stimulant use disorder.

Moderate to severe stimulant use disorder is diagnosed if more than four criteria are met and corresponds to roughly what we think of as stimulant dependence or addiction. As mentioned, stimulants include cocaine, methamphetamine and prescription stimulants. Stimulants release monoamine neurotransmitters and result in increase in activity, euphoria, talkativeness, decreased appetite and cardiovascular symptoms such as changes in heart rate and blood pressure.

Withdrawal symptoms include dysphoric mood, fatigue, vivid and unpleasant dreams, and

increased appetite.

Signs of stimulant intoxication include nausea, vomiting, psychosis such as auditory or tactile hallucinations or paranoid ideation, irritability, anger, aggressive behavior, seizure, confusion and coma.

As mentioned, DSM-5 puts all stimulant use disorders in one category, but it doesn't seem like it all can be the same. Individuals using stimulants use for different reasons. Some use for social reasons. It's not to cope or to enhance their energy, to perform better at work or school, or to enhance sexual performance. People use stimulants for very different reasons. As a result, the response to pharmacological treatment can vary. If someone is using stimulants to be socially accepted, we don't expect pharmacological treatment to be helpful. On the other hand, if one uses stimulants to cope with depressed mood, pharmacological treatment and therapy to improve coping skills can be beneficial.

What is the role of agonist or

antagonist treatment based on the reasons to use? Also, all stimulants are not the same. This class of drugs include prescription stimulants, cocaine and methamphetamine. Let's look at methamphetamine and cocaine first. As you can see, there are several differences. Methamphetamine is highly addictive, more potent and has longer-lasting effects. Initially, results in desirable effects like euphoria, increase in attention, wakefulness and self-confidence. There can be risk of infection because of risky sexual behavior or injection practices, can result in severe dental problems, weight loss or cognitive problems and psychosis. Signs of overdose can include hyperthermia, convulsions, arrythmia, stroke and even death. Years ago, methamphetamine use increased due to production in -- labs. After 2005 when congress passed a Combat Methamphetamine Epidemic Act, the precursor chemicals such as ephedrine and pseudoephedrine that were used in production of methamphetamine were regular, and now much of the U.S. methamphetamine supply is from outside.

Cocaine is plant-based and different preparations have very different potencies, has similar desirable effects as methamphetamine, such as increase in energy and sexuality, decrease in appetite, and euphoria. There is risk of cardiac problems, including heart attack and arrythmia. In case of overdose, it can cause seizures, cardiac arrythmia, respiratory failure or stroke.

The other group is prescription stimulants that includes substances such as amphetamine, dextroamphetamine like Adderall and Dexedrine, and methylphenidate like Ritalin and Concerta. All are classified as schedule II and misuse can result in stimulant use disorder. Stimulants are prescribed in treatment of ADHD, narcolepsy and obesity.

Stimulants, including methamphetamine, are the world's second most used illicit drug class. There's region of variability and overdose deaths involving stimulants, including methamphetamine and cocaine, have increased in the recent years.

Stimulant use disorder is a multifaceted problem resulting in social, legal, economical, physical and mental health problems. Treatment options include different behavioral treatments. There are currently no pharmacological treatment that have shown to be effective. There is ongoing research for medications, vaccines and devices including non-invasive brain stimulation.

Some of the challenges in medication development are the population to enroll in the clinical trials, ways to measure the response to treatment and how long to measure. As we discuss people who use methamphetamine, cocaine and prescription stimulants are different, and the reasons for use vary widely that suggest they can't be combined all into a single study.

Can people who use a same substance by different routes be combined in one study? Considering the heterogeneity of the population, the response to the same treatment can be different.

What are the best methods of detecting

response to treatment? For example, a test that detects any and all use could be useful for a treatment to stop using the drug, but not suitable for treatments that the goal is use in moderation.

What are the problems that bring individuals into treatment? What is considered treatment success? Just based on drug use or other parameters, like clinical or functional improvement and how the individual is doing? How long should the studies be to see a response to treatment? Can we see response in a short-term study if there is sporadic use? What else should be considered that would be important to patients and caregivers? The answers to these questions will help us better assess treatment options from a regulatory perspective. We are looking forward to your comments.

MS. BENT: Okay. Thank you so much, Dr. Afshar. I think that it's really helpful for us to hear from someone at FDA who represents the division that will be reviewing any medicines developed to treat stimulant use disorder, and for us

to really understand the type of information that FDA thinks will be necessary to make those decisions, so thank you for that.

Moving on, I'd like to share with you a little bit about how this meeting mainly will proceed and you can see from this slide up here that we're going to talk first about topic one, and then move on to topic two and topic three. And for those of you who need to jump on and off of the webinar, please be aware that topic one is going to -- or session one is going to start as soon as I stop talking. And then we'll move on to session two around 2:50 this afternoon. And so I wanted to start out by saying that it's really been truly an honor to work with the panelists that you'll meet in just a moment as we prepare for today's meeting. And thank you to Doctors Mullin and Afshar for the really helpful presentations that give us some context to think about what the next part of the meeting -- which is really all yours -- is going to discuss.

If you're new to this area of what FDA

does and what medical product development is, then I hope we gave you a little bit of background on that, and especially some of the key terms and words that we'll be using today.

But before we kickoff this next part where those of you with lived experiences with stimulant use are really kind of the stars of the show, I just want to share a little bit of information in terms of kind of an orientation to help you understand the meeting structure and why we set it up this way -- and kind of build on what Dr. Mullin said because it's really -- what we've done is really very purposeful and intentional so that those of you who are here representing yourselves or your loved ones with lived experience of stimulant use disorder, you're really the experts. And the expertise that you have is what we're really here today to hear.

And so we kind of flipped the script on the kind of meetings that most of you go to where you have a lot of medical professionals giving presentations and having discussions while you listen.

Today, we've reversed that. We've heard some opening remarks from some experts in their fields, but you are the experts in your field. You're the ones who know what stimulant use is like to live with. And so we setup this meeting, like I said, in kind of three pieces. And we'll have two panels of your fellow experts who are going to share their experiences. And let me tell you what a courageous act this is. Not only in terms of sitting up and kind of being the first to speak and share their truths and their stories, but also in all of the preparation that has gone into these remarks.

And so first we're going to focus on what it's like to live with stimulant use disorder. In particular, the health effects and the daily impacts, how stimulant use disorder affects day to day life. Kind of life on the best days, life on the worst days, how it's changed over time and what really worries you the most.

And then we come back after a little break and we're going to focus on current approaches

to treatment for stimulant use disorder. Your experiences and your perspectives on that, what you'd like to see in an ideal treatment, if future treatments could be better, how could they be better. Starting again with the panel of experts, but in-between these panels, we're going to break these open and we've got a number of polling questions and discussion questions that we really hope that you will call in or send us comments through the internet about. And finally, we're going to finish up with a discussion of how COVID-19 has impacted you or your loved ones' stimulant use disorder because as the ASH mentioned, you know, we're seeing some things changing because of COVID-19 and it would really be helpful for us to understand from you what you're seeing changing.

And so throughout the day, polling will be done by a computer or cell phone and, as I mentioned previously, we're taking comments from online through the meeting chat feature and via telephone if you've got something to add. So this is your opportunity to build on the kind of invitation

that the panel creates to open up what's really kind of a tough subject matter. And we know that -- so just feel the empowerment that you have in this meeting today to be heard, not only by the FDA, but by representatives from medical product developers, researchers and policy makers about stimulant use disorder and what you'd like to see happen for those with stimulant use disorder. So please, again, take this opportunity and we hope that this will be your invitation to participate with us in this discussion.

With that being said, there are a few things that will help us. One is if when you call or present your comments, if we can stay on the topic that we're discussing -- whatever topic we're talking about. If we're talking about symptoms or if we're talking about daily impact. So try to think about what that topic is and stay close to that topic. It's going to be a little challenging in the virtual setting just because there's about a 20-second delay between when I speak and when you hear me speak. It's also helpful if you can keep your points to maybe just

two or three things so that we can go to as many people who want to speak as possible.

And when speaking, you can remain anonymous if you want. I mean, you don't have to give us your names. You can state your names if you want, but what's important to us isn't what your name is. What's important to us is really what your experience is. And so if you're submitting comments via the webcast, you can provide whatever name you'd like. Don't worry about us being overwhelmed by comments or by phone calls, we can handle it. We'll try to summarize them as much as possible. We'll also encourage you to, again, call via phone to share your comments because, again, you don't need to share your name if you don't want to.

You can also send your comments after the meeting as well. We have a website. It's called a public docket through the federal register which is really just the way that people in the real world can talk to FDA. And the docket is open until December 7th. So you have about two months to comment on

something if something was really interesting or if you have more to say, you can send it in. If you have friends or loved ones or others who you think have something to say, you can encourage them. Anyone is welcome to comment, so you don't have to be an individual or family member to submit comments to the docket. You can also submit your comment as anonymous. And I want you to keep in mind that if you submit to the public docket, that is the word public is there for a reason. This will go to the website. So please think about how much personal information you want to share. We don't need your personal information. Again, we don't care -- it's not important to us what your name is or where you live. We care about your experience. So please keep that in mind. We really want you to share this information with us. When you get to the form, you can just say anonymous, anonymous, or leave the part empty where they may ask what your name is.

Okay. So there's a few rules that are important to go through, and I say this with all

seriousness about the meeting today. We want to hear from individuals and family members and we really hope that you will feel comfortable lending your voices.

Advocates -- we have a lot of individuals online, and so advocates are going to ask you to kind of play it by ear. If you're an advocate and I know you wear many hats, we all kind of wear many hats, but if you also have personal experiences, we're going to ask that you put kind of your personal experience hat on and speak from your lived experience with stimulant use disorder or with a family member or someone with stimulant use. Everyone else really is here to listen. And that means our FDA panelists, who I'll introduce them in a minute. We'll be turning to them periodically to see if they have any follow-up questions, but we're really here in a listening mode. And you may have questions for us and we may not be able to answer all of them, but we are making a note of all of your questions.

If you're viewing as a medical product developer or a healthcare provider or other interested

person, we ask you to just kind of stay in listening mode. And moving on, I think the views expressed today are personal opinions. And they're not just opinions, but they're personal stories. And everyone has their own story and their own perspective, and we respect that. And throughout this meeting, really, respect for one another is paramount. We have different views on things today and differing experiences, and we'll listen respectfully. We'll try not to spend too much time on one given perspective, so we will keep the conversation kind of moving along.

Our discussion is going to focus on health effects and treatments. We know that this is a very, very complicated issue and there are many concerns and many questions that you have, and things you have to think about living with stimulant use disorder and getting the support you need. And those are all important. As it's been described, our discussion today is focused on stimulant use disorder effects, daily impacts and management approaches. And we understand that there are several important issues

to ensuring that individuals get healthcare, treatment and support that they need. Today, we want to focus on the topics that FDA needs most input on so that we can best fulfill our role in medical product development and decision-making. Our discussion may touch upon specific treatments, however, the discussion of specific treatment should be done in a way that helps us understand the broader issues such as what aspects of your stimulant use disorder are being addressed and how meaningful that is to you and your family.

And so now on the screen, you can see information on how to submit comments or call in. And while you're taking in this information or maybe jotting down that phone number, I'd like to take this opportunity to ask my FDA colleagues on the FDA panel to turn on their video and introduce themselves. And I'm going to start with Dr. Sokolowska.

DR. SOKOLOWSKA: Good afternoon, everyone. My name is Marta Sokolowska and I lead the controlled substances program at the Center for Drugs

at the FDA. Our group advises for center director of policies in initiatives to address control -- controlled substances and to relate it to public health consequences and to facilitate development of treatment of -- for substance use disorder. I want to take the opportunity to thank everyone, especially the patients, the family members and the -- and the -- action groups that are on the call who will help us to learn about this disease. So thank you very much, everyone.

MS. BENT: Thank you. Dr. Winchell?

DR. WINCHELL: Hi, I'm Celia Winchell. I lead the team that reviews applications for drugs to treat all types of drug addiction in the Division of Anesthesiology, Addiction Medicine and Pain Medicine at FDA.

MS. BENT: Thank you. Dr. Afshar, once again?

DR. AFSHAR: Hi, I'm Maryam Afshar. I'm a medical reviewer in the Division of Anesthesiology, Addiction Medicine and Pain Medicine.

MS. BENT: Dr. Farchione?

DR. FARCHIONE: Hi, I'm Tiffany Farchione. I am the acting director of the Division of Psychiatry at FDA, and we're the division that approves the stimulant drugs for treatment of ADHD, narcolepsy, things of that nature.

MS. BENT: Dr. Muniz?

DR. MUNIZ: Hi, good afternoon. I am Javier Muniz. I'm a psychiatrist and I work for Dr. Farchione in the Division of Psychiatry products.

MS. BENT: Thank you. Dr. McAninch?

DR. MCANINCH: Hi, good afternoon. I'm Jana McAninch. I'm a senior medical epidemiologist in the Division of Epidemiology. And I work with the non-medical use team, so we work on issues of drug safety that involve things like drug misuse, abuse, addiction and overdose. So I'm very honored to have the opportunity to participate today. Thanks.

MS. BENT: Great. Thank you so much. And we'll also be joined a little bit later by Dr. Michelle Campbell, our senior clinical analyst for

stakeholder engagement in clinical outcomes from the Division of Neurology products here in the Center for Drug Evaluation and Research.

And so now, as I previously mentioned, from time to time during the meeting, we're going to turn back to our FDA panelists to see if they have any follow-up questions. I'd also at this time like to introduce my colleague, Lyna Merzoug, who will be keeping an eye out for comments that come through the internet. She'll be sharing those comments throughout the meeting and she'll be coordinating with our other colleague, Shannon Cole, who you'll speak with if you call to provide comments via phone. Lyna?

MS. MERZOUG: Hello, everyone. Good afternoon. Thank you all for joining today and I'm definitely looking forward to this meeting.

MS. BENT: Great. Thanks so much. And so as I mentioned before, we will have some polling questions today and we're using a third party application, Mentimeter, to run our polling. Polling on Mentimeter's site, menti.com, is anonymous and can

be done via cell phone or on your laptop or tablet. Please note that we're not tracking individual people's answers and we'll only see the responses grouped by option.

You can access the Mentimeter poll in two ways. You can use your cell phone camera to view the QR code that's on the slide, which will take you to the survey, or you can go to www.menti.com and use the digital code on this slide to enter the survey.

For some questions, you'll have one answer. For others, you may have multiple answers. These polling questions are really meant to just be a discussion aid today. They're not meant to be a scientific survey.

And so with that, let's begin with a polling question just to kind of get things going. So please get your cell phone ready. All right. So for question one, we're going to start with just some basic demographic questions that can get you familiar with the polling platform. And the first question is, "Where do you live?" And it looks like -- because

there's a little bit of a delay and people responding, we're going to give us a few minutes to kind of get responses. But already, from the responses we're seeing, I think we're really seeing the advantage of virtual meeting because, you know, a lot of times we hold these public meetings and we have a large contingent of people -- a large contingent of people who are from the local area, and sometimes we don't get as many people from outside of the national area. And so I think that this is really an informative kind of poll, even though completely unscientific. Just getting an idea of where people are joining us from. And so this is great to see. So thanks so much, everybody, for this. And we'll just give it another few seconds to really get people's feedback on this.

Hopefully you guys are able to access the poll. It looks like we have climbing numbers, so that's great. All right. All right, great. So this is really helpful and it doesn't look like we're having any challenges with the application, other than just a little bit of lag time.

So with that being said, let's move on to the next question. And we're asking the next question to really get an idea of who we have participating in the meeting. I understand that many of you may fit into more than one category, so please choose the category that you most closely identify with. Okay. So question two, "Which statement best describes your experience with stimulant use?" And unfortunately, it's showing up a little blurry on my screen, so I'm not 100 percent sure that I can share the results with you. Let me see. I'll try and make it a little bit bigger. I am not able to see the results. Okay. So that's a challenge. I hope that you guys can -- I know you're also able to see the results, so I hope that you can see the results on your screen. Hopefully that will be easier for you to see than for me to see.

But from this point on, we're going to ask that each polling question be answered only by individuals with stimulant use disorder, or family member on behalf of a loved one who uses stimulants.

And so question number three, "How old are you or how old is your loved one who uses stimulants?" And good news, I can tell I'm going to be able to see the answers to this one. Okay. It doesn't look like we're getting any responses to this question, so we'll give it just another minute. We might be having some technical difficulty, so we'll just move on to the next question.

"How long have you or your loved one used stimulants?" And really, this is kind of a complicated question. We're trying to understand how long you've used stimulants, but if you were prescribed something like Ritalin or Adderall as a child, please don't include that time unless you were misusing your prescription. If you're no longer using stimulants, please let us know how long you actively used for. And if you've had times where you've started using and then stopped and then started again, please just give us an estimate of how many months or years you actually actively took stimulants for.

Okay. And so we're seeing responses

and it looks like, you know, we have a great variety of people on the call today -- on the webinar today, ranging from one to two years, to 20 to 30 years. Some people not exactly sure. Really, it looks like right now, we have a majority of people in the three to four year use range. And so that is -- that's really helpful for us to know and thank you so much for providing us with these responses. It's also really great for us to see that we have a good number of people online who have personal experience with stimulant use disorder, and I hope that you guys will consider, in addition to answering the polling questions, also giving us a call or sharing with us your thoughts as we move forward today. So thanks so much for that.

And we have just one more question before we move on to our first panel discussion. And the question is, "Which region of the United States do you live in?" I know that we asked earlier about the demographics from inside D.C., outside D.C., but this gives us a better idea of kind of where in the U.S. or

where in the world you really are coming from. And that's really helpful for us because we know that, you know -- we know that stimulant use is really a problem that is crossing the United States. And so this gives us a good kind of idea of what our demographics for this meeting in particular look like.

And it looks like we've got a strong contingence on the northeast and some from the west. It looks like more people from the Midwest are joining and we thank you for that. We try to make the meeting late enough in the afternoon that nobody had to wake up at the crack of dawn. So we're really grateful that you were able to -- or are able to participate with us. So thank you.

This was really great and I think that you'll see as we go through the meeting, we're going to kind of bring in some other polling just to really set the context for the conversation.

And so with that, I'd like to start our first panel now. And so I think this is why we're kind of all here and we're really excited about this.

So as I mentioned, topic one will focus on the health effects and daily impacts of stimulant use disorder. And we'll have five panelists who will start off the session by sharing their experiences. And in about 25 or 30 minutes, when our panelists are done sharing their experiences, we'll move on to the interactive portion of the meeting by asking you about your experiences. So if there's something that you hear from our panelists that really resonates with you or you want to share a bit of your experience, please consider, again, sharing your comments via the web, or closer to the end of the 25-minute period -- maybe around 1:50, 1:55 -- maybe give us a call at the 1-800-527-1401 phone number to share.

And so I'd like to start by inviting Jessica to share -- to turn on her video and unmute, and to share her experiences as a loved one of a person with stimulant use disorder.

MS. HULSEY: Thank you so much for having me today, and a very big thank you to the FDA for focusing on and building a PFDD on stimulant use

disorder. All I've really wanted for Christmas for a couple decades is a medication to treat stimulant use disorder, so all of these efforts to learn more and hear from patients, we really care about.

My name is Jessica Hulsey and I'm an impacted family member, and I'm also the founder of Addiction Policy Forum. We advocate for patients and families impacted by addiction, and I'm very grateful to our members who are joining -- either participating in the meeting or as panelists today. Thank you for your courage and sharing your experiences so we can advance our treatment of this illness.

Both my parents struggled with stimulant use disorder. My dad struggled with crack cocaine and opioids and my mom struggled with heroin and cocaine. I've lost both of them, so I can share a little bit of my experiences as a loved one, and a little bit of my hopes for how we can advance our approach to this illness.

I think first and foremost, you know, we had a very good overview of the physical effects of

methamphetamine and cocaine and other stimulants, but they are very profound. And how difficult the physical effects, the side effects, the long-term consequences are really create a lot of challenges for our patients. Whether it's the intense cravings which come on very quickly and are hard to manage. Withdrawal lasts much longer than it seems like for other substances. Some of the health effects that are cognitive, whether it's paranoia or psychosis, the mood swings can have a very dramatic impact on patients. It can hurt relationships with family and friends. It can create unfortunate situations where there's criminal justice involvement. And then as our patients get help and are in recovery, sort of picking up the pieces from those consequences is really difficult. And we work and try to do all we can to help with the self-stigma that's around stimulant use disorder, of helping people learn how to forgive themselves, and understanding some of the behaviors and changed priorities that come from addiction, and stimulant use disorder, and understanding how that

happened, to really learn how you find that self-forgiveness.

We talk about the hijacker as a metaphor to describe addiction, and how it hijacks the brain and that list of priorities that you have, and how you behave and conduct yourself. I would say that when it comes to stimulants, the hijacker's a little bit meaner. It comes on quicker. It's harder to get rid of. It does more damage in your life and then you're left picking up those pieces.

I also think that there are long-term effects that we don't talk about. My mom was in recovery when I lost her, but between cocaine and heroin use, she had not only suffered opioid overdoses, but several heart attacks as a result of cocaine use. And that created some very significant issues with her heart.

Similarly, my father struggling with crack cocaine, huge impact on his lungs and other health systems that it ended up creating a lot of issues long-term. Whether it's diabetes or lung

cancer, heart disease, arrythmia. Managing those while you're also trying to manage all the pieces you need for your recovery plan can be really very difficult.

And two other things. I'm trying to stick in my three to five minutes. Success for our patients isn't about abstinence. Slips are a part of any chronic health condition. I have asthma and no one sort of monitors me or I don't sort of lose ground or feel embarrassed if I have to use a rescue inhaler because I'm not managing my symptoms. And similarly, this is a chronic health condition and slips happen. Success is returning to your life. Success is working. Success is taking care of your children. Positive relationships and getting back to sort of prosocial activities. It's sleeping well. It's sleeping through the night on your own and managing those such difficult symptoms of insomnia that are so hard to manage. Success is being heathy and having overall wellbeing.

And I think the last two things I would

add is I think the stigma around stimulant use disorder, particularly when we talk about individuals struggling with methamphetamine, with crystal meth, with cocaine, it feels greater than other substances. And stigma hurts our patients. It keeps us in the shadows. It keeps us from coming forward to seek help because stigma's just a fancy word for discrimination. And not treating those who struggle with this illness with the empathy and compassion that they really deserve.

And so I think that when we better explain the symptoms, even the really tough ones -- whether that's increased aggression or psychosis, or some of the cognitive pieces to some of the nervous ticks and things that we don't understand in the physical symptoms. If we really break those down and we reassure families and the public and patients that there is a way through, that we're working on medications, that we can treat this illness and we can get better, we need to address that stigma. And I feel like it has potentially been made worse by, you

know, when you compare this with the opioid epidemic. We have this narrative that so much of opioid use was about prescribed medications that went off the rails. And then our patients that are struggling with stimulants feel that we end up in the category of other where there's more stigma and more blame on us and our behaviors than there is for others that are even struggling with a different type of substance use disorder. And I think it's really important that we tackle that.

And then last, I would just say that -- I'm not sure it really matters why we started using stimulants. Whether you are trying to fit in or being social, you're managing your own anxiety, you're using this for some type of enhancement or a sexual reason, at some point when you start to actually develop a stimulant use disorder -- when you're developing a moderate to severe addiction to a stimulant, our symptoms are very similar. Our struggles are very similar. We need more help to make those tools in the toolbox be more readily available so we can find them.

And I do think that we can sort of build together ways to share those success stories with our patients and families that are really struggling with this illness.

MS. BENT: Thanks. Thank you so much, Jessica. Thanks for being the first one to speak, but also to kind of sharing a little bit about your mom's experience and your dad's experience.

We're now going to move on to Brendan, who is going to share with us his experience. Brendan?

(End Media 1.)

(Begin Media 2.)

MS. BENT: Thanks so much.

MR. WELSH: Thank you. Good afternoon, everybody. First, I want to share my thanks both to the FDA and Captain Bent for this opportunity. My name's Brendan Welsh. I'm a person in long-term recovery. What that means to me is that I've not found it necessary to use drugs or alcohol in coming up on nearly 10 years now. And honestly, as a direct result of that recovery, I have the pleasure and honor

of joining you guys today to really share some of that firsthand experience of what it was like to live with a stimulant use disorder. Again, I actually grew up with a stimulant use disorder. And the reason I say grew up with is because I was introduced to stimulants at a fairly early age, in my teenage years in high school through parties with friends where cocaine was available. And while I will tell you that introduction to cocaine was something that I remember as clear as yesterday and I remember the instant energy rush and the mania that came along with that.

Because of the lack of availability of cocaine, my true addiction or misuse of stimulants wouldn't come until a few years later when I met a doctor who I said the right things to and introduced me to Adderall through prescription. And what I can tell you now is looking back, I can see that time period where I went from using my Adderall as prescribed to really help me focus in school and I started noticing what would happen if maybe I didn't take one Adderall the day I was supposed to, but then

double up the next day. And the mania that came along with that that I chased after.

And looking back now, I even realize in high school that there were times that I was starting to go through that physical withdrawal that they were talking about in the clinical presentation where my mood plummeted. My energy plummeted. I wanted to isolate and be around no one else until I had that substance again.

And what I will tell you is from the time that I was in high school through my early 20s I chased that feeling of euphoria and rush that came every time I would take one of those Adderall. And I desperately, desperately wanted to avoid not only the physical exhaustion, but the mental and emotional exhaustion that would come with the withdrawal if I didn't have my medication that I was trying to utilize.

I will tell you as far as daily impacts of my drug use, my life became a constant chase because what started as a prescription would

eventually be taken away from me because my doctor noticed signs of my abuse because of my extreme weight loss. And so then I had to go find that prescription out on the streets. So whereas energy could have been focused on my career and profession, I was using that time and energy to go find my drug that I needed to get through work. And ultimately what would happen is I would lose any sort of employment that I had as a result of that chase. And being a person that, at that time, needed those substances, I did what I knew I needed to do in order to make money and that was my introduction to sex work. And what I will tell you is my drug use directly impacted those choices that led me to that work.

And while that all was unfolding, the rest of my life was, too. My relationship with family and friends were becoming more and more distant because if I couldn't use my substances in those settings or around those people, I just chose not to be around those people.

And so looking back now, after being in

recovery for some time, at the health impacts that were going on in my life then, I can clearly see where the constant grinding of my teeth and other oral issues that I left to neglect caused extreme dental problems in the years that would be my early recovery that I would have to then correct.

Additionally, at the time during my active use, one of the major health impacts that I didn't realize was I had been -- or I had become HIV positive, but was not yet diagnosed. And early in my recovery, as a matter of fact within the first six months of being introduced to recovery, I had to come to terms with all of those health impacts. And looking back now, I mean, the positive that has come as a result of the recovery is amazing. I'm more healthy today than I've ever been, but looking back, I know directly that my use of substances, specifically stimulants, led me to situations and behaviors that would ultimately have life-long impacts on my health. And knowing now that there's a possibility for some sort of medication to intervene in people that are

abusing substances, specifically stimulants, it really just -- it gives me a lot of hope for people that are out there that are still using and having those health impacts on a daily basis that they won't have to have the same long-term effects that myself or other people that have come before them have.

So again, my gratitude to the FDA and Captain Bent for this opportunity. Thank you very much.

MS. BENT: Thanks so much, Brendan. I suspect that many of the experiences that you mentioned here are going to resonate with a lot of our meeting participants, and we're going to touch a little bit more on a lot of these topics during the panel discussion.

Now, we're going to turn to Scott to share his experiences. Scott?

MR. SHELDON: Hello. Hopefully you can hear me all right.

MS. BENT: We can, thank you.

MR. SHELDON: My name is Scott Sheldon.

I am in abstinent recovery for just over five years now and I want to thank you for asking me to participate in this. I think finding something that addresses specifically stimulant use disorder will be extremely beneficial to anyone who has had to deal with this.

I started experimenting with alcohol, marijuana and hallucinogens as a young teenager and that very quickly gained me introduction to stimulants through cocaine and crystal meth, much like Brendan, mentioned, going to parties and kind of utilizing them for staying up and for a lot of the traveling involved in that. We would kind of use it -- use stimulants like crystal meth to stay up for 6 to 10 hours while we were at these warehouse parties, and then driving up and down the east coast. And cocaine was often utilized. We kind of saw it as a status, you know, a status symbol based on the cost and the complications of acquiring it. And then for a long time, I would use it in combination with other drugs and often I would utilize opioids in order to help quell the

cravings that came with my stimulant use. I found that I would not go through hundreds of dollars' worth of cocaine or crystal meth if I also combined it with opioids. And soon that led into kind of multiple problems at the same time and the cost of that use became the focus of all of my energy. You know, like doing things to get more money, to get more drugs. And then often times that would lead to my incarceration. And in the later period of my using, that often came offered with treatment for the opioid aspect, whether it was methadone or buprenorphine. You know, there was some way that they would want to help me address my opioid use disorder, but that didn't kind of change my cravings and desire for continued stimulant use. And that continued use kind of took center stage in my problems and in my development of, my thinking and my motivations. It wasn't till I was finally about 37 when I finally decided that, you know, like, I couldn't make things work, but up to that point, I'd been incarcerated in like 14 different institutions. My average use got up

to over $200 a day with cocaine, crystal meth and heroin all combined. And it went from, you know, like swallowing ecstasy pills to snorting crystal meth and cocaine, to then smoking it, to then IV use and all those things led to a number of health problems. None of these -- I have entirely store-bought teeth. I don't have any more teeth left. I lost -- I was down to about 11 by the time I decided to just kind of replace them. And most of that was as a result of, you know, continued damage through my use and the constant dry mouth that comes with the use that prevents your mouth from kind of taking care of itself. And the IV use led to multiple infections and abscesses. I had a number of hospitalizations related to that specifically. I lost more than one dear friend to overdose related to stimulants. One person, she didn't know that she had heart problems until -- well, I guess we all found out kind of after the fact, but the stimulant use kind of exposed that. A little too late to do something positive about it. But, you know, the -- along with that came the kind of

depression of if I wasn't in the pursuit of acquiring more money and more coke or crack or crystal meth, then I also felt kind of lost. And so I would relate it to kind of a depressive state as well. So, you know, I stayed distracted in my use. I stayed avoiding dealing with myself and other responsibilities and problems. And so on a regular daily basis, I was dealing with several issues. Infections, depression, all related to my stimulant use and the fact that there was a lot of development focusing on opioids. You know, like, I would actually utilize that sometimes because I did have a problem with that as well, but I also found that that was more a path of me managing my stimulant use. And so it took me a lot longer to find help and direction to get out of that cycle.

And I hope that through shared experiences and ideas, that some more focus can be turned back towards stimulant use treatment and I appreciate your time. Thanks for letting me share.

MS. BENT: Thanks so much, Scott. We

really appreciate you sharing your story and you brought up more topics that I think we're going to need to kind of unpack during our panelist discussion. So, thanks so much for that.

We're now going to turn to Pam. And so, Pam, thank you so much for joining us today.

PAM: Thank you so much for the event as well as inviting me. Thank you. Good afternoon. My name is Pam and I work in the field of addiction, primarily in harm reduction. I started an organization that works throughout the state, it's called Harm Reduction Michigan. I'm here today though because I came to talk about the using of injection cocaine for 22 years of my life. Predominantly to manage ADHD, unbeknownst to me at the time.

Due to adverse childhood experiences, I had a significant problem with depression and also had ADHD, both of which were unmedicated. I started snorting cocaine, much like the gentlemen who have shared before me, in high school when I was 17, but like one of the gentleman shared, where I lived,

cocaine was not really available. But I went to U of M in Ann Arbor, and in Ann Arbor and the Detroit area, it was readily available.

And in my senior year at the University of Michigan, I began to inject. Some of the people in my peer group started to experiment with injection. Because cocaine, like other stimulants such as methamphetamine has a very harsh come down and very strong cravings -- as all of our panelists have spoken about -- I began to add heroin into my cocaine injections. Of course I then became opiate dependent. Twenty-two years of an injection drug problem led to significant and expensive health problems such as MRSA. I was twice hospitalized with sepsis and septic arthritis. I now have 18 years in long-term recovery, and two years ago, I finally allowed myself to be prescribed medication for ADHD.

Because I am still very afraid of ever being drug dependent again, I prefer to attempt to manage my continued issues with depression through exercise. As a person who has both personal and

professional experience, I would ask that we be cautious in focusing our efforts in addiction on one substance or category of substances. The stimulant use disorder panel is very panel. Please, I'm not trying to diminish that; however, if people don't have the luxury afforded to get at the underlying causes of addiction, which is really in its root emotional, it will simply move to a different substance or sometimes a behavior.

I think I have observed, as a professional in this field in the last decade, as we as a country demonized heroin and opiates, I have seen many of my patients in clinic who are addicted to heroin or opiates switch to readily available methamphetamine, which certainly provided the dopamine spike that their brains were looking for.

It was interesting to me to hear the other panelists because I think, you know, our paths were in ways different, but so many of the same things that were a part of my path as well. The chase, the time people spend chasing down the substances in the

street, and so it's really life-changing. It's hard when asked to click which of these buttons I mostly closely identify with, but because I think so many people like myself and some of the other panelists, when you live through something like a heroin or a cocaine or a methamphetamine addiction, it's such a significant impact on your life that it's really hard to identify primarily as anything else.

So I'm grateful for this summit and I'm very grateful for all the expertise that we have here today. And I'm very grateful for the opportunity to share my comments. Thank you very much for your time today.

MS. BENT: Thanks, Pam. And I now that we're really kind of hoping to get to the point where we kind of talk about the polysubstance use and the challenges because it doesn't -- it isn't something that packs nicely and neatly up into little boxes.

So as our final panelist, we're going to hear from Paula who's going to share her experience as a family member. Paula?

MS. WALSH: Hello. Hi, my name is Paula Walsh. I actually live in Boston, Mass. I'm actually a mother who has already buried a child to overdose four years ago. My son Mark passed away from a fentanyl overdose.

So three months after my son Mark passed away, my only other son who's 27 years old now started using drugs to get rid of his pain of losing his only brother and his best friend.

So Joey first started out by using cocaine and then Joey went on to using meth. So about a month before the COVID started, my son, Joey, started doing meth. To me, that was a whole different ball of wax. That was something that I've never seen in my entire life. I didn't know how to deal with it. I didn't know how to cope with it. I didn't know how to help him. So every time he would use meth, he would go into a psychosis. He would hallucinate. He would see things and it made me really scared for my son and his life. And I felt like he wasn't Joey anymore. He became somebody else. He was suicidal

quite a few times, so there were many times that I've had to actually call the police to my house in the past four months just so they could help my son get into an ambulance because he wouldn't go on his own to the hospital, so that he could be brought down from his psychosis.

Sometimes they would give him Haldol, sometimes they would give him Thorazine. Sometimes they would send him back out the door and give him nothing and put him back into the streets with no treatment. And that made me very sad.

So, you know, my son, also, his heartrate would go extremely high. It would go up to 160 and my son actually had a prior stroke. So he was at risk of death when he does these drugs. When he was high one time, he threatened to jump in front of a commuter rail train because he was not Joey anymore. He did not know what he was doing. He thinks he can walk on water, you know? And he could walk across a highway and not even realize the dangers that he's putting his life in.

Also, actually on one occasion when my son was brought to the hospital, he was actually tased by the police because he started to get agitated. So they tased him instead of treating him in a human way for his stimulant use disorder. Another time, my son was found at 5:00 in the morning overdosed in the middle of the street, right around the corner from a hospital. And they brought him to the hospital and the hospital actually gave my son a couple Ativan pills and -- to help him crash, and it actually worked. I felt -- to me, I felt that was the most humane treatment that my son received at a hospital in a psychosis.

So I've had many issues where they won't accept my son into a detox because detox is, you know, they say methamphetamines and stimulants are not addictive, and they are addictive. But the problem is the detoxes do not have the medications that they need to give these patients who are on stimulants. So that they -- the patients that are on stimulants can't get treated like anybody else who has a disease. The SUD,

substance use order and the stimulant use disorder, I feel like it goes hand in hand. And, you know, my son should be able to walk into a detox and get a medical treatment, so that's why I'm hoping that they can come up with a medical treatment for meth and any stimulants so that they won't have the desire to use them anymore, just like they have suboxone and naltrexone and vivitrol for people that do opiates. Like, something similar to that that will take away their urge to even -- in their brain, so they won't even consider going in that direction.

I also -- I've done a lot of research online and I've found that like California, where methamphetamines and stimulants really started up, I found that they have a lot of treatment centers out there for stimulants. And I've even tried to get my son a scholarship because he didn't have the insurance to go to treatment out there so he could get a medical treatment for stimulants and meth, and to no avail. I could not find that for my son.

And basically, you know, as the mother

who's already had to bury one child, I'm going to continue to advocate for people who have a stimulant use disorder. I want them to get the medical treatments that they need. I want them to be able to stop using. I want to save their lives. I just want to thank you for letting me speak.

MS. BENT: Thanks so much, Paula. There's a lot to unpack in these experiences and we really need to thank Jessica, Brendan, Scott, Pam and Paula, not only for just sharing their experiences, but also for going back to a place and a time that I understand is really, really difficult for a lot of people to go. And they really -- they've done this to help us move the field of stimulant use disorder treatment forward. So thank you so much for that.

And for those of you who would like to call or submit comments to be shared, as a reminder, at the bottom -- as a reminder, here's how to do it. You can either add -- click on the comment box on the corner of your screen, or you can call into the 1-800-527-1401 number to share your experiences.

So again, I'll ask you guys kind of, how many of you heard your or your loved ones' own experiences reflected in the comments shared by the last ones of our speakers? Obviously in a virtual setting, it's not really possible for me to see you nodding or applauding in the way that we usually see during our patient-focused drug development meetings. So we're going to use more polling questions to kind of get feedback from all of you who are joining us online.

Again, polling is limited to participants who have a lived experience with stimulant use. Whether it's users or family members or loved ones, we're not really defining what family members or loved one means, you define it for us. If you have someone that you cared about and you have experiences that you want to share and reflect in the polling, then please do.

So now we're going to just kind of move on to the polling. And we're going to start with just a pretty basic kind of straightforward question.

"Which stimulant did you or your loved one start using first?" Okay. And we have some different options. Cocaine, methamphetamine, crystal meth, prescriptions, other stimulant not mentioned, and I'm not sure. And so we'll just give it a minute for everybody to be able to respond as well as just to kind of think about the experiences that we just heard about from our panelists.

Okay. So we see that we have some responses coming in and it looks like a number of people started using cocaine first, as well as prescription stimulants and methamphetamine. Just give it another moment. Okay, great. And so it looks like a lot of people have started using -- started with using cocaine. And that's really -- that's helpful for us to know. It looks like just a few people started with something -- another stimulant not mentioned.

And so before we move onto the next question, let me just turn to any of our panelists who may have touched a little bit about this in their

talk. But let me see if there's anybody who has anything they'd like to add to this before we move onto kind of current -- talking about what people are currently using.

So to any of our panelists, did you have -- any of our panelists, do you have any questions or anything to add that you wanted to touch on? Okay. So -- and I think -- I mean, I think that makes sense because we've heard from your talks, you kind of shared those experiences.

So let's move onto our next question which is, "If you or your loved ones are currently using stimulants, which stimulants are you or your loved ones currently using?" And again, it looks like we have the same options, but this is really kind of to help us understand what -- kind of the progression of the stimulant use. We'll just give it a few minutes. It's great to see that a lot of people are not currently using stimulants. We'll just give it a few minutes because, like I said, there's a little bit of a lag time between what I see and what you hear.

Okay. All right. So it looks like -- while we saw a number of people start with cocaine, it looks like a lot of people are either no longer using or are using methamphetamine. A few people are using crystal meth and prescription stimulants. And so that's really helpful.

Lyna or Shannon, let me turn to you and see -- do we have any comments related to this or anything that anybody would like to share online yet?

MS. MERZOUG: Hi, Robyn. Thanks. Yeah. We have gotten some responses online to Jessica who is -- this comment's directed to our panelist, Jessica, just basically saying thank you so much for sharing. You were spot on on pretty much everything you shared. I really appreciate the fact that you brought some awareness to addicts being discriminated against when it comes to their disease. It is hard for people to understand how and why addiction is a disease and not a choice. Again, like, educating them on the effects of -- be part of the solution.

MS. BENT: Great. Thanks, Lyna. That

was a great comment. Do you have others or is that what we've got for now?

MS. MERZOUG: It looks like that's what we have for now. Oh, we just got one more. So we have Jennifer who shared a comment just saying, "I appreciate all the comments and commitment to people with substance use disorder. Thanking all of our panelists for speaking up and speaking out. And this community's committed to listening and making a difference in order to support these experiences." So thank you, Jennifer, for sharing.

MS. BENT: Great. Thank you. All right. So let's -- at this point, let's kind of move onto our next question -- our next polling question. "If you or your loved ones are currently using a stimulant, how frequently are you using that stimulant?" And so we have multiple options from daily to not currently using to other. We'll give it just a few more seconds.

And just as we're waiting for the results to come in, I think that I'm also going to

switch up this question just a little bit and maybe turn to our panelists and ask when you were using, like, did the frequency of use kind of change over time? It would be really helpful for us to kind of understand what that looks like. Did your frequency of use change over time? For the people who use more than one stimulant, was the frequency of use different depending on the stimulant that was being used?

And so looking at this, we have -- I mean, we have a small number of responses, but it looks like a majority of people who are currently using are using daily. Some are using more than once a day and we did not do a good job of guessing what their -- what their frequency of use was when we gave these options.

So that's really good information for us to know. And I wonder now if any of our current panelists, would you be willing to talk about kind of the frequency of Use and how that might have changed over time. Do we have anybody who might be willing to talk to us a little bit about that?

PAM: Hi, this is Pam. I'm willing to talk a little bit about it. Initially, I used very, very occasionally because, again, I did not live in a part of the country that cocaine was readily available. But as soon as I moved to Ann Arbor and it was more readily available, I used it as frequently as I could afford to. And then I heard somebody else talking about Adderall for school and I really used it for procrastinating. I would wait until about the last month of school and then I would try to stay up for about a month straight on cocaine to do all of the work from the entire semester.

But anyways, long story short, then once I began injecting, it just went straight downhill from there. You know, having ben addicted to both opiates and cocaine. Cocaine, by far, had for me a much stronger component of craving, never enough. It just has a level of viciousness that, I mean -- yes. It was awful to be drug sick from opiates. That's a really awful experience that I've had a lot of times; however, the cocaine cravings were just a different

level of -- like I tell my clients, people on cocaine you know what you're about to do is really crummy and you know you're going to hate yourself for I don't know whether it's, you know, hocking your favorite jewelry or whatever it is that you're going to go do to afford the cocaine, you're going to hate yourself for having done it, but you're going to do it anyway. And so there's something really vicious about that whole feeling.

And so then it became just every day, all day, as much as I could possibly get until I was hospitalized with sepsis. And even then, you know, the nurse from our program was saying, "Well, you know, you don't really have to go to the hospital." Meaning you will die if you don't. But at that point, the septic arthritis had gotten to the point that I really couldn't even continue to inject. So that was really what pushed me to go on into the hospital. But yes, it increased.

And I guess I also wanted to make the point that I now am on a prescription stimulant, but

I'm very, very careful with it because I don't ever want to be dependent on something to the point that I can't stop. So even though I didn't have the choice to select a couple times a week, I will sometimes make myself go a day without it because I'm just afraid to not -- to just be that dependent. And yes, if I go a day without it, I'll feel the tiredness at about, you know, 3:00 in the afternoon, I'll be very, very tired if I haven't had my stimulants. But I just wait it out, I get through it. And so, you know, I just want to know I can do that and so that's why I do it that way sometimes. So just wanted to share that.

MS. BENT: Thanks, Pam. I think that that was really helpful and it really gave us a lot of good information.

Do I have any other of our current panelists who would be interested in sharing a little bit more information about that?

MR. SHELDON: I would be happy to.

MS. BENT: Okay, great. Thank you.

MR. SHELDON: And this is specifically

about the usage, like, the amount of usage.

MS. BENT: Yeah. The usage, if it's changed over time. Maybe even kind of what drives that frequency. Is it the cravings? Is it the access? And anything kind of related to that, yeah.

MR. SHELDON: Well, I know for myself, initially, it was very sporadic, you know, and kind of on a whim. And then, you know, that was -- whether it was ecstasy or MDMA and occasional crystal meth use in order to just stay up, you know, like, it wasn't something that I felt like I needed. But it eventually with cocaine, you know, like at the time of the use, I would want whatever I could get, but then, you know, as long as there was like a night of sleep or some time, then it wouldn't necessarily kind of take over my thoughts. But then eventually, over the years, there was less time in-between using to the point of where I was literally only limited by how much money I could access and how much -- you know, how much drugs I could access. So like based on the availability of it and whatever finances I could

acquire, which eventually became almost by any means.

So there was, you know -- I guess in the growing years of my use, it was for a while recreational and occasional, and then eventually it became obsessive and daily. Almost, you know, like only ever, like -- I guess there was only ever any ceasing to it when I would pass out or be required to do some things in order to get money. You know, like so my -- my time and my energy all became focused on the acquiring of it. In areas where I lived, right between Baltimore and D.C., there's pretty much no clock or limit to the availability of it. There's a lot of open air drug markets, even when I was in Seattle. I moved there for a few years and the crack and heroin problem that are on the streets of Baltimore, it's more like crystal meth and heroin is the problem in Seattle, but it's just available on the streets. You know, like, all you have to do is head for certain areas and you don't have to know anyone. It doesn't matter what time of day. You know, and so that kind of availability and understanding that I

could just go somewhere and make eye contact with somebody and possibly have it offered to me made it so there was really no limit other than what I was willing to do to get the money to get it.

And yeah, so really incarcerations or incapacitation were really my only limits eventually. And, you know, whenever I would get clean usually by force, like by being incarcerated, I would get out and have the intention of not getting back into that cycle and chase. But without getting a full grasp on how to deal with it, seeing others who would recreationally use or others who didn't have the problem that I did would make it easier for me to think maybe -- maybe if I just did it a little bit differently this time, it wouldn't turn out the same. And that wasn't the case. You know, like, I would kind of turn it back on just by exposing myself to it. And even if I did other drugs, stimulants were always my favorite. So anything else that I did would simply kind of spark the desire and the craving for the stimulants. So, you know, there was no kind of picking a different

path or finding something else. It was always leading back to that somehow. Sometimes right away and sometimes over periods of time, but eventually back to daily use and empty bank accounts and various other problems related to that.

MS. BENT: Thanks, Scott. That was really helpful information. Brendan, did you want to say something? I see your video on.

MR. WELSH: Yeah. I was listening.

MS. BENT: I didn't mean to put you on the spot, I was just interpreting that to mean that you would like to say something.

MR. WELSH: Yeah -- the format leads itself perfectly for that. So thank you. Listening to Scott talk about frequency and even some of the other people, I mean, the pattern I keep hearing over and over again is -- specifically with stimulants in my experience was there was never enough. And the frequency was just more.

And I was thinking back specifically to my Adderall use when I was -- where I could actually

see my use progressing into misuse and beyond. And I remember getting my 180 Adderall and it was supposed to be three a day. Or I'm sorry, it was 90. Three a day for 30 days. And I would, in the beginning, like, take as much as I could while allowing myself to have one pill for each day to avoid withdrawal. But even then, my addiction would overcome that and I would end up taking the ones that I had laid out to prevent withdrawal and just more, more, more. And it was just interesting to hear that across all the panelists that have spoke.

MS. BENT: That's really helpful information. And I think actually that might tie into some of the comments that we're seeing online. So thank you for that. And, Lyna, let me turn to you and say -- find out if we're really -- if we're seeing some comments that are similar in nature to that, or really kind of touch on something similar.

MS. MERZOUG: Yes. Thank you, Robyn. Yeah. I see a comment that came in from Dina [ph]. She's saying, "I go to CNA meetings, the 12-step

meetings, and one of our -- what started out as a weekend use gradually became daily use. My experience was I ended up using all day long, every day I could. I've been in recovery 12 years now. I never imagined I would go 12 minutes without crystal meth." We have that one from Dina.

And then based off of what actually our panelist, Pam, was talking about earlier, we have a comment from Liz about stimulant prescription in childhood. I think it would be very important to find out how many people who have stimulant use disorder as adults were prescribed stimulants, like Ritalin, as children. And if it may have predisposed their -- of desired stimulants to be able to feel normal.

So just touching on -- or following up on two of the comments from our panelists.

MS. BENT: Great. Thanks, Lyna. And so please, everybody who is watching online, please be aware that we are monitoring both the phones and the any comments that you submit. And we will be happy to share them to really kind of include you in the

discussion to the extent possible.

Now I'm going to take a little bit of a turn and I think that I'm going to turn to our FDA panelists, and particularly maybe to Dr. Sokolowska. I think that she might have a question that she would like to follow-up on, ask our panelists, and anybody online to kind of follow-up on something that we heard from Jessica. So, Dr. Sokolowska?

DR. SOKOLOWSKA: Thank you. Jessica, in an earlier comment you mentioned and you spoke quite passionately regarding the impact of stigma on substance use disorder, especially on stimulants use disorder. Could you speak more regarding that and could others maybe provide additional breakdown and framework on how FDA can address the issue of stigma. And to what -- and some of the aspect of stigma that we should be more conscience about.

MS. HULSEY: Absolutely. You know, just from personal experience with my own loved ones and then doing this work at my current position, you know, stigma comes in many forms, right? And I think

when we really dig into sort of empathy and compassion, you know, willingness to engage with our patient population, and I don't think we fully understand the differences between different types of SUD and different opinions or attitudes that are attached to them. I feel just as loving people who've struggled with stimulant use disorder and opiate use disorder and lots of other things, that we seem to have more blame that gets focused on us when we have a stimulant use disorder. I think that opioids, there's so much narrative around -- in a way, like, we've somehow, in some ways, improved stigma by sort of focusing on prescription opioids and leading to dependence and sort of getting out of control, but then all the rest of us that are struggling with non-prescription -- of our use patterns, I feel like it makes stigma worse for us in a way. And I think that was an unintended consequence of how we've organized and approached patients that are struggling with different types of SUD. And that doesn't even really get into -- we've found within our patient community

that three out of four are struggling with polysubstance use. Individuals just don't typically struggle with one particular drug over the other. It ends up being a polysubstance use disorder. But I think we've pit some of these diseases against one another and I feel like I worry. You asked earlier about what keeps us up at night or what's on our worry list. I, in many cases, worry the most about our patients that are struggling with methamphetamine and cocaine and crystal meth because there can be more blame. There can be more misunderstanding of their symptoms. Some of our symptoms are hard, right? Sort of psychosis or aggression, mood swings. Some of the physical differences of being really thin and losing our appetite and being agitated or dental problems. So this can physically make us look differently and I feel like we are treated less than, even within the patient community, of substance use disorders.

So I think we need to have more understanding. I firmly believe -- and we're about to launch a really big project around how we stop stigma

around addiction, but I firmly believe that education is the key to that. Addiction literacy. When you take the time to teach everyone from our family members to healthcare providers to criminal justice professionals, about what addiction is. How it affects the brain. How it changes our priorities and our behaviors. We build empathy and compassion and we help people understand this as a health condition rather than a moral failing. And I think that's incredibly important, particularly in the context of those struggling with stimulants. Because I think that we get treated the worst out of the bunch.

MS. BENT: Thanks, Jessica. Again, very insightful and really, really helpful information.

Lyna, did we have -- before we return back to kind of our panelists to see if they have any thoughts on this as well, did we have any comments from people who are participating online, or I mean viewing the meeting online?

MS. MERZOUG: Yes, we do. Thanks,

Robyn. So we have a comment from Jay [ph] and it's about stigma. So, and he's saying that a major way stigma plays out is in hiring. So many organizations that pledge themselves to do great work stigmatize use by hiring only or majority of those with learned experience over lived experience. And then we have another comment from -- also on stigma. "The scare tactics used as a prevention strategy, especially -- get hard by -- crisis, have really done a lot of damage. Not only by reinforcing stigma, but also by the invisibility of early -- use." So those are the two comments we have right now on stigma.

MS. BENT: Okay. Great. So did we have any of our other panelists who wanted to kind of share their thoughts on stigma? And at this point, I think I'm going to open it up a little bit. And so if you are scheduled to be a panelist in our next treatment session and you have something that you want to share related to stigma, please feel free to turn on your video and share that if you would like. Okay? So I see Brandee and then we see Phil. So I'm going

to start with Brandee because I saw her video first, and then move onto Phil. And then we'll reassess. Thank you, guys.

MS. IZQUIERDO: Phil looks like he's in a big city. I love it. Phil and I go back a ways. No, thank you. I appreciate you opening that up. I think one thing -- one component we miss when we're talking about stimulant use disorder, specifically around stigma, is the stigma internally to the recovering community. So we often talk about external stigma. We talk about internal stigma, but there's also stigma associated with the recovery community that one drug is better than the other, one drug is worse than the other. You can get treatment for one drug, but you can't get treatment for another drug.

We tend to also minimize stimulant use disorder in numerous ways, that it's not that bad. Sorry. I have puppies in the background. My apologies. But that it's not that bad, that you can get over this hump, that you know, it's not as addictive. So I think there's a lot of myth and

misconception in the recovering community, which definitely adds to the stigma associated with stimulant use disorder. And I also think that quite often we pinpoint specific drugs within this disorder framework. And I'm going to leave it at that for right now because I'm the next panelist, so I'll bring a little bit of that up and how that progresses over time, but we have to take a look at how we stigmatize each other or the negative public perception as people in recovery.

MS. BENT: Great. Thanks, Brandee. And I'm going to turn to Phil. And then after Phil, I think we've got a comment from somebody online that Lyna can read for us. So, Phil, please go ahead.

MR. RUTHERFORD: Thanks. And I'm going to do my best not to go into the subject area that I'm going to talk about in the next panel, but I was just thinking about a fun exercise that we could all take and that is if you think about if you think about who's more likely to break your window and steal some stuff out of your house, a crackhead or a person with

a Percocet problem? Which of those two is more likely in your head to break in and steal some stuff? A meth addict or someone with an OxyContin problem? There -- we have stigmatized stimulant use disorder specifically to be more violent and more likely to commit crime than opioid use disorder. Now I'm not trying to say which is worse or one gets a better ride than the other, but some of the -- we're here to talk about stimulants. Some of the specific stigma around stimulants is the criminalization of people with stimulant use disorder. And unfortunately, the crime data doesn't bear that out. It doesn't -- it turns out use disorder is an equal opportunity offender in terms of criminal acts.

So when you said stigma, that kind of popped into my head and I've got some other stuff on that this afternoon -- or in the next session.

MS. BENT: Great. Thanks so much. And I'm going to turn to Lyna for comments that we received online, and then I think, Jessica, you had your video back on which I'm taking as an indicator

that you'd like to add something else. So maybe once Lyna has the opportunity to speak, we'll go to Jessica. And then Michael also has his video on, which I am again interpreting to mean comment. So, Lyna, go ahead.

MS. MERZOUG: Yeah. Thanks, Robyn. So Lisa's actually responding to what Jessica said so well and it's that even within the addiction culture, she's saying that "I feel terrible biases. As a current care specialist, I am -- by all the biases I see in the professionals against us. People still feel it's a choice. Once using, it is not a -- once using, it is not a choice. We cannot stop, that's why we need a substance to get off and back on our feet. We need to learn how to be back on our feet again." So that was -- thank you, Lisa, for your comment. That was really, really important.

MS. BENT: Thanks, Lyna. And I know that we're coming kind of up on the end of our time. We have about 10 minutes left and we have a few more questions that we want to get to, so I'm going to go

to Jessica and then kind of back to Michael. And then I'm going to have us move forward with some of our next questions. And if there's other people who want to share their comments online or submit them to the docket, that would be really helpful to us.

So, Jessica, please go ahead.

MS. HULSEY: And thank you, Lisa, for your comment. I'll try to make this really quick, but I just also wanted to share that -- sorry. Dogs and teenagers in the backyard. It's hard to find a quiet space these days with tele-school, etcetera. But even sort of the term stimulant use disorder can be sometimes confusing to our patients, to our individuals in recovery, our families. If we -- we have done a few small research projects with our community and if you ask about stimulant use, most will talk about their caffeine use. So I do think that this is going to be sort of an important organizer for how we describe this disorder. In the community of patients and individuals in recovery and families, we sort of more self-identify as struggling

with cocaine or methamphetamine or crystal meth or prescription stimulants. And sometimes when we say stimulants, we sort of think of that in the prescription category. And so sometimes it might be helpful to explain that and sort of break it down, and also make sure that we are acknowledging the substances that are really tough to struggle with, like methamphetamine and crystal meth and cocaine. And including and using the words, and using language that our folks identify with. So it's sort of a one off, but I was reading some comments just among the panelists that I think sometimes even the term stimulants can make us feel like we're not included.

MS. BENT: I think that that's a really good point and I know that one that we kind of talked about internally as we're talking about this meeting and really kind of sharing information about this meeting where we kind of created a meeting where people didn't really know what we were talking about because the clinical term isn't so -- as related to real life. And I think that's a really good point.

So, thank you. And let me now turn to Michael.

MR. GALIPEAU: Yeah. Thank you. And I appreciate you guys welcoming our input today. And I just wanted to add a little bit to the conversation, especially around the topic of caffeine and nicotine and other legal, more regulated, more widely accepted stimulants. You know, we don't often put stimulant use disorder or stimulant use in general into like a normative spectrum of use that ranges from infrequent, casual, recreational to daily use, to severe, persistent and chronic use. And we don't include the full scope of stimulant-related activities, like coffee shops and places where people go to smoke cigarettes, which are all stimulants. And you'd probably see a similar pattern of drug-seeking behavior from a large number of people if we were to suddenly ban coffee shops and ban coffees from markets and deny people, you know, basic consumer rights, basic consumer protections. You know, access to a safe and regulated supply. Access to product testing and accountability for manufacturing. And I think

this points back to the impact of stigma, which is really discrimination and how it impacts our social determinants -- I mean, even just looking at the stratification of stimulant users themselves in our criminal justice system, we see a vast difference between the crack cocaine user and how they're treated by the criminal justice system as opposed to somebody who uses powder cocaine, which is, you know, very similar drug with a lot of very similarly presenting qualities in terms of problematic use.

And so it's really unfortunate that, you know, kind of the backseat driver of this experience is this stigma that creates a false dichotomy or a false set of associations that doesn't really look at a full spectrum of human behavior that we have in most other chronic health management disorders.

MS. BENT: I think that is a really good point. And I think we have one more comment from somebody online, and then we're going to move onto our next discussion question. But thank you so much,

Michael, and thank you to all of you who kind of help us really kind of get a better understanding of what's going on with stigma. And I think we probably will touch a little bit on that as so mentioned in our next session as well. So, Lyna?

MS. MERZOUG: All right. Thanks, Robyn. We have a comment from Adam about stigma. And he's saying that, "I think one thing that needs to be understood about internal stigma is it plays into the denial aspect of the disease. Individuals begin to contemplate their use, but do not speak out due to the stigma attached to stimulant use." So thank you, Adam, for sharing that.

MS. BENT: Okay. Thanks, Lyna. And so that was a really great conversation and we're now going to move onto our next question which is really, "If you or your loved ones are currently using a stimulant, are you also using any other illicit drug?" And so we'll get that up on the screen in just a minute. I gave the producers a little bit of a curveball with the question about stigma, so we'll

give them a second to kind of catch up and move us onto the next question.

Okay. There we go. So -- perfect. We're seeing the -- okay. We see a few people saying they're also using other illicit drugs. We don't really have anybody saying that they're using -- oh, okay. So now I'm seeing one person who says they're only using stimulants, but it does look like -- and I think some of our panelists touched on this a little bit earlier, that there really is -- there is kind of a combination where people are using more than one substance. More than just a stimulant, but maybe using something else. And so I would love for somebody to kind of give us a call and help us to really understand why -- what does that look like? Can you tell us a little bit more about why you or your loved ones are using drugs in addition to stimulants? Maybe share a little bit about that with us because it does look like -- now we're looking at -- I don't want to really do math real time, but we're looking at maybe about 60 percent of people saying

they're using more than one. And about 40 percent saying just a stimulant. So maybe if we have -- Lyna, do we have any comments online about that? I know we're kind of early, but do you have any thoughts? And if not, maybe do we have any thoughts from our panelists on that? Lyna, you're muted.

MS. MERZOUG: Sorry about that. No comments yet from online.

MS. BENT: Okay. I am asking for very rapid typing I think. So -- and I think that maybe one thing that we can do is just kind of -- again, kind of adjust on the fly and if you do -- if you guys do have comments, because there is that lag time that we don't really see in the face to face meetings that we're seeing kind of in this virtual setting, I think maybe what we can do is kind of -- or I think when we start session two, we can kind of go back and recap any comments that we received related to some of the topics that we've asked about in this session. Just to give people the time and opportunity to kind of get to the typing and share that.

So let me see. So actually, because we don't really have anybody online to kind of answer this question, Lyna, did you have some kind of -- comments about stigma that you wanted to share with us?

MS. MERZOUG: I'm happy to jump back on with another comment about stigma. We have a comment from Jamie basically saying that she'd like to underline what Jessica said, exactly true. So there's another one for Jessica. And education as well, even healthcare work is extremely important. The nation did with depression, so surely there are ways that people can get the information out in a similar way.

Additionally, impacting substance use disorders, adding to the stigma is incarceration and criminalization around it. Once those were battling through -- disorder and other substance use disorders -- the criminal justice system, they're now not only labeled as addicts, but criminals. So thank you, Jamie, for sharing that.

MS. BENT: Great, great. Thanks, Lyna.

I think in the interest of time, because we are about at our break, I just -- I wanted to kind of -- we are right at the break, right? Sorry. My ability to memorize our schedule is a little -- is a little impaired. So yes, 2:35 is our break and I know that we didn't get to kind of all of the questions that we had hoped to get through in this session, but I think that we heard a lot from our panelists, and we learned a lot. And so I think maybe this was a heavy session and I think that we are going to go to break now. We'll kind of keep an eye on incoming comments. And depending on how our treatment talk goes, we might come back to some of our questions.

So with that being said, it is now 2:35 eastern time. We'll go to break until 2:50 I believe, at which point we will reconvene for session number two. So let me just, once again, give a huge thank you to all of our first session panelists, and to our second session panelists who jumped in early and kind of shared their experiences and thoughts on stigma with us. And we'll see you guys back here in about 15

minutes. Thanks so much, guys.

(End Media 2.)

(Begin Media 3.)

MS. BENT: Hello. Welcome back, everyone. Thanks so much for returning. I hope that you were able to make good use of the break and maybe grab a snack or something. I just -- I wanted to take this opportunity as we were returning to really kind of touch on something that I think we mentioned, but I didn't really properly emphasize. And that's really -- all of the comments that we hear today, all of the comments from our panelists, all of the comments that have been submitted electronically. If anybody wants to call in, any comments that we hear from online -- from people who called in, as well as any comments that are submitted to the federal docket will be summarized and included in our report, which we call the voice of the patient report, that will really be a meeting summary that can be used by people as they're working -- as they're looking at drug development efforts or even -- or for our FDA reviewers to review.

So please, even if you don't feel like you want to call in today or even if you don't feel like you want to submit a comment today, please remember to take this opportunity and to really kind of share your thoughts and share your experiences with us. Because all of that is really helpful to us and will be captured as part of this report that will live -- I don't want to say forever, but will live for a really long time and be used by a large number of people as they move, you know, treatments and policies and things forward. So, please do take the opportunity to share your thoughts.

And again, the docket is open through December 7th, so there's no rush. And, you know, just -- and we would just very much appreciate it.

So having said that, we're still kind of reviewing some of the comments that we received online. And so before we talk a little bit about that, we're going to move onto topic two, which is really meant to focus on the current approaches to treatment for stimulant disorder. Your experiences

and your perspectives on that. What you'd like to see in an ideal treatment, if future treatments could be better? How could they be? And we have six panelists who will start us off -- start off our discussion by sharing their experiences.

And before we launch into our panelists' experiences, I want to let you know that our first question for the open discussion session is going to be, "What prompted your journey to recovery?"

So we're about 30 minutes away from people kind of sharing their answers to that, but if you're interested in responding to that question, please consider sharing it through the comments or by calling the 1-800-527-1401. But with that being said, we're now going to launch into panel two and I'm going to invite Phil to share his experiences. Phil?

MR. RUTHERFORD: Okay. Volume good?

MS. BENT: Perfect.

MR. RUTHERFORD: Okay. So I want to thank you guys for having me on the call. I appreciate the opportunity. Away we go.

My name is Philip Rutherford. I'm a black man living in long-term recovery. What that means to me is today I'm living my best life. Every facet of my life has been enhanced by recovery. I have three beautiful daughters and recovery has enabled me to be a part of the entire spectrum of their lives. Now my wife will tell you that recovery is the key to a happy marriage. My parents will tell you that recovery is the key to a good relationship. Employers, community members, probably even law enforcement -- well, you get the idea. They'll all tell you recovery's good for me.

You probably also noticed that I introduced myself as a black man in long-term recovery and since this is a video meeting, if you're looking at your screen, you probably figured that out all by yourself. I introduced myself that way for a very important reason. Today, we're here talking about stimulant use disorder and seeking treatment methodologies that will be successful. Not too long ago, almost an entire generation of people who look

like me were vilified, demonized and locked away under the guise of public good. Many of these people simply suffered from untreated stimulant use disorder. A condition that I am living proof of the fact that treatment is effective, and more importantly, that long-term recovery is possible.

Recovery has also enabled me to lift my voice and advocate for social justice of which recovery justice is a part. As a matter of fact, for me, there's no separation of the two. Recovery doesn't occur in a vacuum. I recovered in a world that bored stigma to my disorder and bias to the color of my skin.

Now, like many people, I sought treatment for my illness as a last resort. And I say that because rarely, at least in my case, seeking treatment was not a starting point. It was clear pretty quick that my reaction to the substance was abnormal, but a lot of people around me had similar responses. And I think there's a leveling thing that happens where you attempt to justify your use by

saying things like, "Well, I'm not as bad as that guy."

Sometimes you'll hear people say that treatment wasn't successful. I couldn't disagree more. I went to seven treatments. Every single one of them was wildly successful in that I survived. And I picked up enough information and fortitude to make it through to the next one.

I'd also like to dispel the myth that a return to use is a failure. My returns to use taught me a lot about my ability to manage the use of the substance. Now, I believe that there are people out there perfectly capable of recreational stimulant use. I have no opinion on that, but my personal returns to use made it clear to me that I wasn't.

I also said that my treatments were successful. I did not say they were effective. Many of them lacked cultural responsiveness and an understanding of an intersectionality of recovery. What I mean by that is what I said earlier that recovery pathways don't always look the same for

different groups. In my case, I -- there were some differences that probably needed some attention. And that was a while ago, but these days we're at least moving along that path.

I was able eventually to navigate a pathway that included mutual aid groups, those are 12-step, smart recovery, that kind of stuff. And I practiced that pathway in addition to a number of other wellness practices. These approaches worked particularly well once I found a place to fit in. And fitting in is a really important point as all of the use disorders thrive on isolation. It's really important to find a place to fit in. And it's appropriate for me to talk about recovery capital here which is a set of tools that I had available to achieve treatment, remission and recovery. Because whatever we talk about, it happens within the frame of recovery capital. For example, I had stable housing, I had some financial resources, I had a supportive environment, I had reliable healthcare. And by the way, that includes psychiatric care. And I found a

community of recovery where I could fit in. On a number of previous attempts, I had some of these things, but not always all of them. And I think the sum of all of these components is greater than the individual parts. You know, obviously not everyone has all of these resources, but until we begin including this sort of -- this perspective in treatment and recovery planning, I think we're not operating at full capacity. So I think that's a key component to looking at treatment and obviously, if we're talking about medication, that fits into that frame.

In general, I believe as a country, we could benefit from the overhaul of the acute care approach to treatment which is sort of the 14 to 28 day stay with some after care follow-up to a more holistic chronic care model that engages acute treatment when necessary, but provides longitudinal or sort of treatment along the path of recovery. That's all I've got.

MS. BENT: Great. Thanks so much,

Phil. And I know that -- I think that our FDA panelists are going to have some follow-up thoughts or questions to kind of dive deeper as we move forward. But for now, we're going to move onto Brandee who is going to share her experience. So, Brandee?

MS. IZQUIERDO: Thank you very much, Robyn. And Phil, great job as usual. I wouldn't expect anything less and I appreciate that.

I just want to take you along the small path of my journey into treatment and recovery, and I am a person in long-term recovery. For me, as I prefaced -- or as I talked about earlier about stigma, you know, my specific stimulant use disorder started with a prescription drug, and it wasn't any of your typical or normal -- into these conversations. It was actually phentermine. And it was a weight loss drug. And one of the issues with the weight loss drug is that, you know, I would do everything that I possibly could. It was the doctor hustle or the doctor shopping hustle. And not, you know -- for me, my past experience was in contract negotiations and all of

that, so I knew how to negotiate with doctors where they would actually prescribe me in bulk. So those particular prescription pills that I was taking, I was only supposed to take three of them a day, but I was up to at least 10 a day. And coupling that with NoDoz.

What really brought me to my knees and my addiction was not the stimulant disorder, it was the criminal justice system as Phil had mentioned. I had no idea that I had a problem. I didn't think I had a problem. But really, you know, from the phentermine and moving into the cocaine use and the partying and the ecstasy, to come down from that, I had to use alcohol.

So when I entered into the jail system, it was my gateway into treatment and it wasn't a pleasant gateway. Because again, I still didn't recognize that I had a problem. I just thought that I was getting in trouble for -- and realize now that it was an indirect result of my using. In the jail system, the first thing that they treated me for was

the alcohol. Obviously, you know, with detox and the possibility of death with alcohol, that was what they treated me for. And when I was shipped over from -- and I say shipped because that is literally what it was. I was shipped in a van over from the jail -- the prison in Pennsylvania over to a Maryland-based treatment center, I learned about the disease of addiction. But I, again, still thought I only had an alcohol problem. So it wasn't until I got to a point where I said, "Okay. I can no longer use alcohol, but I can surely still use cocaine because cocaine's not the problem. It was the alcohol." And that's where my thoughts began. And I never really got treated properly for the cocaine or the thoughts on the cocaine. It was more the cravings and really figuring out the system. I knew that, for example, cocaine would stay in my system for about three days, so that if I could manipulate the system and move around probation and drug testing and all of that, I could still continue my cocaine use.

And, you know, what I've found through

these systems specifically is stimulant use disorder is not a crisis. So if it's not a crisis, I'm not going to get the proper treatment that I need for that particular substance use disorder. And quite often, especially right now, we're having more of an issue with the opioid use disorders. So there's quicker access into treatment if you either have an opioid use disorder, an alcohol disorder. And the only reason for the alcohol disorder is because there's liability attached to that should you die from the detox.

So I never truly got to the bottom or the root cause of -- or the root part of my stimulant use disorder. And I say that because I am a person in long-term recovery and I'm coming up on 10 years. And one of the -- there were a couple of reasons I used stimulants to begin with, and one was not feeling good about myself. So I'm not a thin woman. I prefer to call myself juicy. Little big boned. And there's always been issue or a complex for me that I needed to stay thin, so that was one of the reasons that I initially started using the phentermine. So that

coupled with the fact that I have four children, which I did lose during my active addiction to Child Protective Services and then eventually their father, you know, I was -- I needed to run circles around people. I felt like I needed to run circles and stay as busy as possible. So I don't even use typically the word stimulant use. It's more of the uppers. I'm not a downer as much as I am an upper. Not realizing that I'm actually countering the upper with alcohol. So it's a complex disease. And there was never a talk about that.

So I can tell you right now, I'm going to be honest and open about this. Caffeine is a huge part of my life at this point and I am a smoker. So I didn't start smoking till I was 30 and in my active addiction. So it's not like it's gone and it's not like I haven't tried to use or utilize resources to stop or curb my cravings, but they still manifest. My addiction still manifests in different ways.

So just trying to find the treatment. I mean, I know there are specific prescriptions out

there for smoking. I haven't used them because I know the side effects can cause anxiety and depression which is something else I deal with on a daily basis.

So I have to remain vigilant at all times in my recovery. And even working with individuals in a direct service capacity, it's extremely difficult because we're seeing a shift to the stimulants. Methamphetamine, cocaine, crack. And it's the barriers associated with accessing treatment are exponential. I mean, you just -- you can't seem to get people in unless they're dealing with an opioid crisis. So it's an extremely frustrating piece.

And like I said, you know, with the treatment component, it's not just about treating one specific substance, but we have to really take a look at all substances because just -- I may be able to arrest my cravings for one specific substance, but then again, you know, it moves onto something else and can manifest. So I'm hoping that we can do better. So, thank you.

MS. BENT: Thank you so much, Brandee.

Again, I think we're going to come back to you and kind of maybe ask you a few more questions maybe a little bit later, but for now, we're going to move onto Kevin who is going to share his experiences. So, Kevin, go ahead. Thanks so much.

KEVIN: Good afternoon and thanks, Robyn, for asking me to participate. My name is Kevin and I'm a recovering crystal meth addict. I last used crystal meth in May of 2018.

As a little bit of background, I first started using crystal meth in my late 20s. For the first 10 years, I mostly used on weekends. At most, maybe once or twice a month. However, by 2014, my use had intensified and the consequences had started to build, as we've heard from many other people, too.

My then partner found out that I was using and reasonably demanded that I stop. I sought an evaluation and was referred to an IOP program based on the progression of my disease. I was unwilling to admit the problem -- that my problem was this bad and I declined that offer. Instead, I started working

with a counselor and I attended weekly recovery support group meetings. I kept this up for about six months, but I could not stop using. And so instead, I ended that relationship. I moved to a new city with the hopes of leaving meth behind that way. It's commonly called a geographic.

From 2015 to 2018, my meth use increased to nearly daily use. My addiction impacted my job performance and spawned a vicious cycle of using. During my last eight months, I went from leading a team of 40 to injecting meth daily. I lost my job and my health, I started dealing drugs and I became completely isolated from my family and friends.

In May of 2018, I was arrested on drug distribution charges. This turned out to be a good thing for me because it made me get serious about quitting. And I was ready to quit, but I had no idea how to do it. I'd been too embarrassed to ask for help. My legal situation meant that I could no longer hide my problem though, and that I had to stop or I would face additional serious consequences.

During these early days of recovery, I really struggled to figure out what to do. My habit use limited my ability to think clearly. I still carried a lot of shame that prevented me from picking up the phone and getting into an inpatient treatment program. I was extremely isolated. All of my friends, and I use that in quotation marks, at the time were using friends. My primary care physician couldn't offer much help. There weren't any prescriptions he could write and he struggled to recommend good treatment programs.

Once I was honest about my situation though, I had a group of non-using friends who were willing to step forward and help. I still had access to health insurance, some savings and a stable place to live. One of my friends was a drug counselor and he helped me find a therapist with experience treating gay men with crystal meth addiction. I started meeting with that therapist weekly and I still check in with him regularly.

My former partner also introduced me to

a sober coworker of his, and this friend introduced me to Crystal Meth Anonymous, a 12-step program focused on meth recovery. He took me to my first meeting the day after we met. And in that meeting for the first time, I encountered a group of people who had actually achieved long-term sobriety from this drug. In pretty short order, I threw myself into a robust program of recovery centered on the steps. I did this because, really, nothing else I had tried had worked and I was desperate enough by this point in time to try anything. I attended meetings daily. I made new sober friends which ended the isolation I felt as a gay man that had helped fuel my addiction. I found a sponsor and started to work the steps. This helped me deal with the spiritual nature of my disease. I found two different part-time jobs which allowed me to focus on recovery and put some money in my pocket, gave me a sense of purpose again, and most importantly, kept me busy. Pretty quickly I became involved in service work. I started sponsoring other men in the program. I started volunteering. It was a lot of work, but

it's what I needed to do to keep me sober.

In hindsight, I would probably do a lot of things differently with regards to treatment if I knew then what I know now.

I would have asked for help a lot sooner and treated this disease as the serious matter it is. I would have enrolled in an IOP program that was first suggested to me. And when my therapist suggested maybe trying out a CMA meeting as part of my treatment, I maybe would have been brave enough to go into that first meeting instead of standing outside and being afraid to do that because everyone inside was laughing and having a good time.

But with addiction, I found that my denial, lack of readiness to change, shame and stigma of this disease are huge barriers to overcome to start the road to recovery. But with the help of many others, I found a path to long-term abstinence from a drug that I had given up any hope of quitting.

I still don't completely understand why it worked this time, but it has worked and I'm

grateful that it has and continues to work. Thanks. That's all I have.

MS. BENT: Thank you so much, Kevin. We're now going to hear from Charles.

MR. SMITH: Hello. My names Charles. I'm 43 years old in long-term recovery. I've struggled with stimulant use disorder and alcohol use disorder since before I was 18 years old. That's over 25 years for those who don't want to do the math.

Today, I've been free from drugs and alcohol for 20 months. I first sought treatment at the age of 22 at a charity residential treatment center as my personal life was spiraling out of control. I was facing a divorce and custody battle, I was kicked out of the home I was living in and I had mounting legal troubles. Since then, I've been in and out of a dozen treatment centers with programs ranging from 30 days to one year. Some programs I completed, others I did not.

I've been arrested many times. I've also had several inpatient psychiatric interventions.

I participated in intensive outpatient programs, group therapy sessions, and 12-step programs.

I've used therapists covered by my insurance provider and paid out of pocket for therapists. I tried neurofeedback therapy and medication-assisted treatment. I will not say that these approaches did not work for me, more likely I needed a well-rounded education in treatment. I will not -- to get to where I am today.

Today, I use smart recovery and naltrexone for my alcohol use to manage my cravings. I've been practicing smart recovery for six years now and it has done wonders in reducing, even stopping my drug and alcohol use. I also maintain a daily meditation practice.

The difference I see in the smart recovery program as opposed to all the other methods I've tried is the fact that it empowers me to make my own decisions regarding my drug usage. It uses a science-based approach to teach me to retrain my thinking to processes more useful to me rather than

trying to teach me what to think.

Methods that empower me to make my own decisions and offer concrete techniques work best for me. In other words, I'm looking for help and setting and maintaining my own goals.

Also useful to me has been the refuge recovery program which utilizes Buddhist principles as a recovery approach. I do not consider myself a Buddhist nor do I recommend a strictly spiritual approach to recovery, but the meditations and teachings have been helpful to me.

What has not been helpful to me has been the one size fits all treatment approach consisting of substance abuse education and mandatory 12-step meetings. Too many times I've walked into a treatment facility and have been offered the same treatment program. Long lectures on how drugs affect my dopamine levels, the dangers of being hungry, angry, lonely or tired, and the importance of building a support network. Then I'm handed a list of meetings and told how many I need to attend per week and off I

go.

Sometimes I'm assigned a case worker, a counselor, who makes vague references to a treatment team that I never meet that makes decisions concerning my program based on economic factors.

This is expected and almost forgivable in low or no-cost charity providers, but for large healthcare providers, I expect better. My recovery should not depend on how many people you can fit into a room to lecture.

Another obstacle to my recovery has been access to quality programs based on my insurance status. At times when I'm in most need of intervention and treatment, I have the least insurance coverage. During these times, my only available options are charity spiritual-based programs which have proven to be the least effective for me. Science-based programs seem to be in short supply.

Since the beginning of the COVID-19 pandemic, access to my recovery programs -- choice has gotten easier. Smart recovery has expanded their

online services and moved in-person meetings to Zoom. I have greater access to more meetings than ever before. Because of this change, I have taken online training to become a meeting facilitator and I now run an online meeting.

There's a bright side to a global pandemic. It has increased access to resources. Zoom meetings may not be enough for everyone, but at this stage in my recovery, it's just what I need. Thank you.

MS. BENT: Thanks so much, Charles. And we may kind of come back to you and ask you a little bit more during the COVID panel, if you're -- or the COVID section if you're up for that, because I think we want to kind of do a -- learn a little bit more about the impacts of COVID. And so hopefully we will see you soon.

So now we're going to move onto Amy. Okay.

MS. GRIESEL: All right. Hi. My name is Amy Grisel. I'm honored to share with you my story

in hope that it'll better help other people that are suffering.

So I am grateful and fortunate to be alive today. With my addiction, with the stimulants, it really started when I was in my 30s, but I believe that if I would have gotten help with my opiate use disorder, that the stimulants never would have came.

So in my 20s, I had gained a -- gained, whatever you want to call it, an addiction to opiates by getting a prescription. And throughout that 10 years, it just got worse and worse, and to the point where I was shooting up heroin.

I overdosed and at that point, I knew I had to stop. And when I quit shooting up heroin, I had a horrible mental break. I didn't realize I was suffering from mental illness that was untreated. So I turned to stimulants. And these, at first for me, actually made me better. It took away all the paranoia, the things that I was seeing and hearing, and then all the sudden it got much worse to the point where my kids were taken away from me. And at that

moment, I knew I needed to seek treatment.

I am in a city, but it seems like a small town because the way it's set up. And my location, I'm kind of away from everybody. So I wasn't able to really connect with the treatment centers that were in town.

My family did help me find one treatment center, unbeknownst to me that it was not a cooccurring. So I spent about a week in that facility, and within that week, they realized that they didn't want me because I was a cooccurring person and they kicked me out on the street. And that night, it happened to be Christmas Eve, and I came home and I decided I was done with the world. I decided that I was not worth anything and I didn't deserve to live, so I attempted suicide by fire. And at that point, I was put in jail and charged with arson. And once they put me through their system, they let me out and put me into a mental health facility. At that point, that's where I was able to be diagnosed with my mental health diagnoses and start to get treatment.

And another thing that was beneficial about that court encounter was I had the opportunity to participate in the felony therapeutic mental health court and kind of just really get rehabilitated. And that's where I think treatment is so important. I was able to get wraparound care. I was able to get a therapist. I was able to get connected to different group settings, cognitive behavioral therapy, DVT and wellness recovery action plan. I also got inpatient treatment and then -- for my substance use, and outpatient treatment. They also connected me with different support groups throughout the community. And just like a previous panelist said, the one that he really enjoyed was refuge recovery. That is what connected to me also just because of all my anxiety. That meditation was able to make it so that I was able to participate in the support groups because it slowed my mind and calmed me down.

Throughout that process, I really realized that creating a foundation for someone that has stimulant use disorder is important. I now have

my children back. I have a great relationship with my now husband and I'm thriving in my recovery. I work as a peer support specialist. I went back to the same court system that I did a two-year program with and became a peer counselor through them in order to show the participants that what worked for me and connecting them to their foundations that work best for them.

Some of the things that I noticed that were barriers throughout that process, for one, that first facility that kicked me out on the street just because I didn't fit for them. I didn't think that was right. Other places that I had been through with inpatient and outpatient treatment, including hospitals, the way they also have that stigma. You know, where they're judging me because of my meth use. And it made me feel uncomfortable. That's another reason why now I work in the hospital as a peer in order to normalize and have that non-judgmental approach. I really feel that trauma-informed care is important -- really important. Being able to connect

with individuals and let them know that you're there. With stimulant use also being able to have that time away from the drug, I think that's one big reason inpatient is important, and those skills. I remember a point where I was curled up on my couch crying, calling my prescriber telling them I need something, I need something. I'm either going to die -- kill myself -- or go to the hospital. There's only two options because of the anxiety that I had. I did receive disability for a couple years while I was able to just really focus on my mental health and getting better. So I thought that was a really good benefit for me. But I just really -- I'm really hoping that these type of things are going to help other people connect to the same type of services that I was able to connect to.

And same with the last participant, COVID really sucks, but these support groups and how people are so openminded and able to create new systems and create new things, I also facilitate a very low barrier support group over the phone. It's

not over a Zoom so that anybody with a phone can just call in. And the people that do have that anxiety disorder and they need to stay home, they can now participate even if their screens are off. So knowing that there are some things that have came out of it that is good, but that's all I have. So thank you.

MS. BENT: Thanks so much, Amy. That was a really -- thank you for sharing your really, really powerful experience. And now we're going to turn to Michael who is going to share his experience. Michael?

MR. GALIPEAU: Yes. Good afternoon and thank you everybody for being here, and thank you to the FDA for, you know, hosting this wonderful feedback call.

So my experience with stimulant use really started nearly as early as I can remember. Very early on in life, I was put onto prescription drugs for a number of cooccurring mental health and physical health disorders that I was dealing with simultaneously. Among those was a diagnosis which

was, you know, later on overturned for bipolar disorder, ADHD, Tourette's Syndrome. Later on I was finally diagnosed with ankylosing spondylitis, which is a rare kind of genetic condition that affects inflammation and just kind of causes, like, general discomfort throughout the body. It can make sleep very difficult. And then in addition to that, more recently I've finally been diagnosed with sleep apnea. So all of these conditions fed in a variety of ways to the role that stimulants have played in my life. And depending on the stimulant, I would say that the role of stimulants in my life have not been one dimensional. I would say certainly my relationship with crack cocaine much farther down the line when my social determinants of health were at probably an all-time low, I was much different than the recreational use of methamphetamines or MDMA or other stimulants in my life more recently that is much less problematic in nature.

And so I do identify as a person in long-term recovery. I also identify as a person who

uses drugs. And the pathway that I practice is moderation management in combination with a whole variety of whole held strategies that includes yoga, it includes -- it includes some history doing 12-step work. When I first got involved in my 12-step experience, I recognized that this was going to look very different for me because at the time, I had been a very long participating patient in the state's medical cannabis programs. And part of the reason that I still identify as a person who uses drugs centers around the human rights and continuity of care conversation that still needs to be had about treatment with medical cannabis.

Going back to my journey, so very early in life, you know, I was, you know, committed to one of the group home institutions as, you know, what I call myself a drug war orphan because of cannabis use that was supplementing the -- just the lack of adequate care that I was receiving from traditional pharmacotherapies. And so when I was institutionalized, I spent about four and a half years

of my life, from the age of 12 until the age of 17, being heavily medicated in an environment that was completely full of traumatic experiences.

And so I was being forced to take, you know, as much as 13 pills a day. Staff would pin you to the ground and force you to take medications that were ordered by a doctor. And if your behavior was non-compliant, they would simply up your dose. And so this is what really planted the seed for what I felt was a fertile ground for problematic use later in life because what I had learned was that if there was some way in which I could not be compliant or manage my behavior, that there was a drug that could sufficiently do that for me. And so all I needed to do was to find the right drug.

And so this kind of pattern of drug seeking really began early on. And when combined with traumatic experience, I had been involved in an environment where young men were routinely sexually assaulted, where people who, like myself, were violently assaulted. Often times the only physical

contact we ever had with any human being was with a staff member being restrained physically for violence. And there was no contact with the outside world. There was no contact with people of the opposite gender, of our age group. It was a really bizarre and insulated bubble in which my life experience was shaped and formed.

And so by the time I had reached the armed forces, I was definitely shaped in a way that had changed my life and shifted the trajectory that I would take for a number of years. And so as I was discharged, you know, fully, honorably from the armed forces for those disclosures -- the treatment records that were found from my DCYF time, as I had, you know, entered the service from a homeless shelter at the age of 17, then turning 18 throughout the process. You know, I found myself discharging into the streets. I was literally homeless again. The armed forces had lost my records, and so kind of my first introduction to street stimulants occurred during that period of homelessness right after I found out that my unit had

been ambushed in Iraq just after I had gotten literally pushed out the doors, they were being deployed just a few months earlier. And I found myself with nowhere to stay. No way to prove that I could be employed. No access to benefits. No access to any kind of a meaningful opportunity. Because the assumption is that if you don't have a DD 214 or documentation that you've been discharged or a way to obtain that, then you're presumed to be AWOL and you're not actually legally allowed to do most things that a human being would need to do for survival.

And so the role of stimulants was always twofold at this point in my life because it was both a financial support and survival mechanism. In addition to a way of coping with the distress of my environment and being able to stay awake for long hours on the streets when I felt like it was unsafe to relax.

And so this led to kind of a cementing of problematic use patterns that persisted for pretty much the entire duration of my chronic homelessness,

which is a little bit over four years.

It wasn't until my family had held an intervention and had sent me to California where I encountered the state's first medical cannabis program in 2006 that I found another way forward. Because of the lack of federal oversight, I was able to get gainful employment through the medical dispensary. I started working again. I got housing. I became stabilized. I became a patient in the state's cannabis program. And that was a big turning point for me. And it was something that I had learned, you know, through self-medicating when I was using stimulants that as I was withdrawing, I could use cannabis to help manage the cravings and the withdrawals and some of the discomfort. And so I realized that I could use that as a strategy even without using stimulants intermittently, right? So that was one way of effectively addressing the cravings.

Now, much later on into, you know, my journey towards wellness, I realized that there aren't

a lot of, you know, licit alternatives that were mild in their effect that I could use to address the functional conditions that I was trying to treat with stimulants. I use coffee. You can see the last of my cup here, you know? And that was something that I started doing while I was incarcerated. And a lot of folks that were incarcerated who struggled with stimulant use had substitute black coffee similarly. So this is widely accepted.

So, you know, being a person who's a Native American, I have a big belief in plant medicine. And so cannabis fits really well into my beliefs around treatment. And I feel that, you know, there are other alternatives that are available. You know, we have teas and coffees, and then whole plant cocoa which really has largely been unexplored. We've really only looked at the cocaine salts, but the role of coca in indigenous societies as a medicine and as a social agent and a talking aid has not produced the kind of addictive patterns of seeking behavior that cocaine salts have. And with a very good reason. We

have what is called the entourage effect in whole plant medicine which is very well researched at this point in the realm of cannabis, but remains largely unexplored in terms of whole plant coca. And so having these times of licit, like, low threshold, low risk alternatives that are widely available in the community, even in non-medical settings, circumvents a lot of the barriers to treatment that I encountered when I was chronically homeless and was not legally entitled to access any benefits. So thank you guys for inviting me here today.

MS. BENT: Thanks so much, Michael. That was really -- that was really a lot to kind of take in and I'm so sorry that you had a lot of these experiences that you shared with us. But I thank you for sharing them.

And at this point, I'd like to kind of turn to our FDA panelists and just see if you have any questions that have come up -- any clarifying questions or anything that you'd like to dig a little deeper into for any of our panelists, and that may

possibly be for -- opening it up to our panelists from the previous session as well.

So, yeah. I see that Dr. Winchell, I see that your camera has come on, and so I'm interpreting that to mean yes, you have some questions. So please, go ahead. You are muted again. Yes. Hey, guys. Can we unmute Dr. Winchell? There is the little phone in the corner, hopefully you can see it. Okay. All right. So it looks like -- I guess it looks like the phone call dropped and she's going to call back in. So let me take this opportunity to ask maybe one of my other FDA colleagues if they have any questions that they would like to ask. Please go ahead. Great. Go ahead. You are unmuted.

DR. MCANINCH: Hi. This is Jana McAninch. Can you hear me okay?

MS. BENT: Yes.

DR. MCANINCH: Okay. Thanks. First, I just want to thank all the panelists for sharing your stories. This is so helpful for us. I wanted to

follow-up on a comment that Kevin made. I think that you said, "I wish I would have asked for help sooner." And this sort of -- I guess it's a question about early intervention. A lot of you described your lives really spiraling out of control and having some really awful, painful experiences. And I'm wondering if you have thoughts about if there was some point earlier on in your course where someone may have recognized a problem and helped you to seek treatment, and engage in treatment and enter into recovery sooner and avoid some of those consequences. And what that might have looked like for you at that early stage versus later in the course of your illness.

And so Kevin, or really any of the panelists, I would love to hear your thoughts on that. Thank you.

KEVIN: Sure.

MS. BENT: So let's start with Kevin and then I see Michael has a comment. And so we'll start with Michael -- or Kevin, and then go to Michael. Thanks. Go ahead, Kevin.

KEVIN: Sure. Thanks. That's a great question, you know? And it's actually something that I've thought about a lot. You know, I think one of the challenges for me with my addiction was, one, not wanting to admit that I had a problem. And that it really had progressed into something. You know, I think as a gay kid who grew up in Southern Indiana, a town of 500, you know, I learned from a very young age how to take care of myself and figure things out on my own. And for a long time, you know, that was a skill that, like, really helped me. But, you know, then as I moved along into my addiction, you know, sometimes things that are assets that kind of like help you get through life actually become real liabilities.

And so for me, that asking for help or even just admitting that I had a problem was like a really long struggle. And I don't know. I don't know what it would have taken to have gotten me to stop earlier. I'd like to think that if someone had really said something or sat down, but you know, it -- I'm not sure, you know? I think sometimes you just have

to get to a certain point with it, you know, where you've suffered enough and you are tired of suffering. But it's a -- it's a really good question that I don't have an answer to, but I think there are a lot of things there that, like, work against asking for early help. Definitely a lot of it the stigma of, you know, admitting that you have a problem played a huge role for me and wanting to hide it for a long time. And I hid it very well.

You know, I think a gay man, I had a lot of experience with compartmentalizing things and, like, keeping things very hidden from other people. So, thanks.

MS. BENT: Great. Great. Thank you. So it looks like Brandee has also turned on her screen. So we're going to start with Michael for a minute or two and then move onto Brandee.

MR. GALIPEAU: Yeah. I would say for me, that journey was nonlinear. Like, there was certainly periods of chaotic and problematic use that certainly qualifies the most severe disorder into the

spectrum, but I would say all along that journey, there were different varieties of help that were available.

I mean, I think back to my first -- I had two overdose experiences related to stimulant use. One of them is due to fentanyl contamination, the other one was just using way too much crack cocaine. And it was other drug users who were in the room with me in the motel who, like, convinced me, even though I couldn't remember what happened, that I was having seizures and, like, it would be really unsafe for me to continue to use. Like, I probably would not survive that. And so there was help along the way, but I feel like the engagement with formal systems and the linkages to some of the social determinants of health, which really were a defining characteristic in my recovery trajectory. Those linkages were not low threshold enough to really meet me where I was at when I was in patterns of use. And the history of recurrence in my experience of us has also largely been tied to traumatic events. You know, I had a

girlfriend that I found dead at one point, and that was literally the last major period of recurrence that I had. Of course, you know, all of those involving some degree of polysubstance use.

But really, I've said this over and over, that trauma was my gateway drug. And so having treatment systems that were truly trauma-informed and low threshold I think really are the key to defining features of the current shift in my own work, serving people in our community.

MS. BENT: Great. Thanks so much. And Brandee?

MS. IZQUIERDO: Yeah. Just quickly, for me, being a woman in recovery, I think, you know, gender, sex, race, all of that plays a contributing factor in when and where and why and how we reach out for help. And I think we definitely need to consider that. As I mentioned, you know, prescription -- the prescription use. I didn't think I had a problem because I was prescribed. From there, moving into the cocaine. Still didn't think I had a problem. Alcohol

brought me to my knees only through the jail and prison systems. But more importantly, and I don't think we emphasize this enough specifically around treatment options -- kids. There are not a lot of treatment centers that either will work with women and children or men and children, or families and children. And underneath of all of it, there is a huge fear based piece for me because I -- I didn't want to lose my kids. That was the only thing in my world that I -- for a while, had the sense of entitlement as a parent and felt like I was a failure with guilt and shame. And telling anyone that I had a problem would immediately -- I'd immediately lose my kids. And again, I think one of the issues or barriers or challenges within our public behavioral health system are there are not enough facilities that allow children or families.

MS. BENT: Great. Thank you. I think that brings up something that we haven't actually talked about. And actually, just before we go back to Dr. Winchell, I wanted to kind of just quickly jump

over to Lyna because I think we had a comment earlier in the day that kind of talked a little bit about pregnancy. And I know, I don't think I told you I was going to jump back to this, but it just really builds so cleanly into what Brandee was just saying.

So, Lyna, would you mind kind of sharing that comment with us?

MS. MERZOUG: Sure. Yeah. So like Robyn mentioned, we did get a comment earlier about pregnancy. And it's from a young lady who didn't put her name, but she did mention that "I'm interested in whether pregnant individuals are being considered in your approach to developing new treatment medications for stimulant use disorder.

I work at a syringe access program in Northern Michigan and I've noticed that the lack of treatment options for methamphetamine use, which is such a heartbreaking situation for our pregnant women. That was the comment about pregnancy, yeah.

MS. BENT: Great. Thank you. And I think while I have you on the line, I think that we

received some comments about treatments that people have submitted? So maybe you can share those and then we'll turn back to Dr. Winchell to ask some more clarifying questions.

MS. MERZOUG: Sure. Yeah. So I actually have comments that kind of hit on a lot of the points that our panelists talked about. And so I have one individual saying that "I work with Mountain Area Health Education Center in Ashville, North Carolina. We are working to spread a hub and -- model for addiction treatment in the state by connecting health departments and community health centers. I just want to affirm that what we are hearing across North Carolina is that -- is the need for treatment for stimulant use disorder, contingency management and effective care for folks experiencing stimulant use disorder." And again, giving a big thank you to Jessica for her courageously telling her story and talking about all the work that she has done. So definitely a big thank you to Jessica.

Another comment that I see is about a

current approach, about -- actually has experience with -- themselves. And saying that "I was almost turned away for detox from crystal meth. I was able to get into a recovery program called Add Care [ph] which doesn't focus on harm reduction. I was paired with a clinician that works, but it's been only mental health-based." That's about -- that was a current approach.

And then I actually have a comment from a gentleman named Jonathan [ph] regarding the homelessness point that actually Michael made. And also talking about his experience and saying that just a little portion of people around him are using stimulants, and that his experience has showed that in many cases, homelessness actually makes it more difficult for people to make any changes.

MS. BENT: Okay. Great. Thanks so much, Lyna. And now, before we move on to kind of our polling session, I did just want to turn back to Dr. Winchell who I understand has fixed any audio issues and give her the opportunity to ask her -- any

clarifying questions that she might have.

DR. WINCHELL: Hi. I have a lot of questions, but I'll try to keep it short. So I -- this has been so helpful and so enlightening, and also very hard to hear because it's a very difficult situation that people are in. And access to treatment is a major issue. And a broader issue of our treatment system and our healthcare delivery system in the United States is well outside the scope of anything we, in my division, can do. But what we do have a chance to do is really think about how one would go about designing a study to test a new medication to see whether it would be helpful to people who have these disorders.

First, I want to make sure I understand correctly. It sounds like most people do think that lumping all stimulant use disorder together, as if Adderall and methamphetamine and intravenous cocaine are kind of all the same problem. That doesn't seem to be the case. We hear -- in people who have opioid use disorder that they freely substitute whatever --

they might have a favorite, but they'll use whatever new agonist they can get their hands on. So that was one issue I heard. And another issue I heard related to polysubstance abuse is that many of you seem to say that you actually -- the underlying issue for you was stimulants. And somehow, the opioid use disorder developed as some attempt to manage some of the symptoms of your stimulant disorder. And then others who had started with an opioid problem and the stimulant was layered on top of that.

So in these situations, we're often asked how would we go about developing a drug for polysubstance use. It sounds as if perhaps there's a way to drilldown and if -- if you receive good treatment for the cocaine problem, maybe there wouldn't have been an opiate problem, or the opiate problem would have taken care of itself eventually.

I just wanted to check if I'm understanding correctly these messages. Thanks.

MS. BENT: Great. Thanks. So, Phil, did you want to kind of kick off a response to Dr.

Winchell's comment or question?

MR. RUTHERFORD: Sure. And I appreciate the sort of narrowing of the focus that you -- we can't solve all of the world's healthcare challenges in this narrow space.

On the subject of medication, yes. I think there is reason to focus narrowly on a substance, but I was just thinking about -- the reason I turned on my camera was I was thinking about the distinction between what happens with distribution of buprenorphine versus the distribution of methadone. So what my thought would be, whatever the substance is, it would be critical that that is freely available. Because like right now, buprenorphine is narrowly available whereas methadone is much more widely available in urban settings.

So whatever it is that you do from a medication standpoint, I would think that we would want to make sure that it is not limited to socioeconomic strata. Because right now, that is precisely what is happening with buprenorphine. And

again, I recognize that you're not necessarily in charge of what happens with drug costing, but the fact of the matter is the -- it is a fairly effective treatment and there's a large group of people that simply don't have access to it. That is all.

MS. BENT: Thanks so much, Phil. And, Michael, do you want to add a minute or two on your thoughts? That would be great.

MR. GALIPEAU: Yeah, sure. I mean, for me, there's kind of like two things that are being managed, right? There's like, you know, somebody's underlying reason for taking stimulants and then managing this come down period or, you know, sometimes accompanied by periods of really intense anxiety. And I think that those are managed by much different medications.

That's kind of the intersection where I found, you know, medical cannabis treatment to be really effective because I can take like a really low intensity stimulant, like drink coffee or in the past, you know, more smoking cigarettes to really, you know,

give me some of those compensatory, you know, deficit overcoming effects without the very long-term effects of some of the stimulant medications.

A lot of the medications on the market are not as mild and much longer-acting, and tend to aggravate my Tourette's. So there's some interactivity with my neurological disorder that makes it very uncomfortable for me to take most of those medications.

But I find a more milder effect, something that has a more limited duration that's a little bit more user friendly, controllable, that's helped me to manage a much more recovery-oriented lifestyle and actually have a better quality of life than I would have had on traditional pharmacotherapies.

MS. BENT: Great. Thanks so much, Michael. And Dr. Winchell, I don't know if you have further questions or Dr. Muniz has a question? Okay. So go ahead, Dr. Muniz.

DR. MUNIZ: Okay. Good afternoon again

and thank you very much for sharing all your experiences. It's been very enlightening to me as well. I want to preface this because I want you to understand where I'm coming from. When I was -- I used to be in the Air Force and I had a -- one of the largest treatment facilities in the Air Force for substance abuse, but our experience was very limited because you may have maybe one chance, maybe a second chance if a command was particularly permissive to let you go back to treatment, otherwise, you get kicked out of the military. So my perspective was very limited in that sense. I could try to help someone once, maybe twice, and that was about where my experience stopped. And I've heard that there were struggles, that there were -- your ability to fight against the disease and that you guys went through a variety of treatment. And I was wondering about what was the most transformative thing in your treatment? The most transformative experience that made you change for that treatment to kind of maybe grab hold? Or what was the most helpful thing when it came to

treatment? So I was wondering if you guys could share something with us that could help me understand a little more of that.

MS. BENT: Okay. So why don't we -- do we have -- and, Michael, I'm going to go to you, but I just wondered -- because we want to hear kind of a diversity of voices as well, if we have anybody else who kind of wanted to start by responding to this question. But -- okay. Jessica, I see you up in the corner. Sorry, it's hard to manage all of the Brady Bunch look on the screen. Thanks.

MS. HULSEY: So responding again as a family member and also just folks that we work with who struggle, the difficulty is that we don't have enough treatment options available. You know, we have so many amazing, brave individuals that are our panelists today, sharing experiences and writing in comments, but for far too many, when you reach out for treatment, there can be a lot of misinformation or wrong numbers. And we heard one person share they were kicked out of programs because there's a myth

that this is hard to treat or harder to treat. And we don't have medications like we have for opioid use disorder. We don't have medications like we have for alcohol use disorder and nicotine use disorder. That's why today's meeting is so important and sort of pivotal for all of us in this community to dream of more tools in the toolbox to treat -- and treat and intervene early with stimulant use disorder is a dream -- and something just so critical.

I think right now, far too few individuals in healthcare and folks that you work with use a matrix model or use contingency management or the things that we know work in treating methamphetamine or cocaine use disorder. So I think it's about understanding which combination of therapies. Even listening to individuals today, the benefit of mutual aid support group is so important. And scientifically, the components that you get from that which is healthy attachment and prosocial engagement and the spiritual components of recovery that are so important are critical. We know that

works for prevention. We know those are really important for managing chronic health conditions. And I think thinking through how medications could be supportive for this. And not just for my interest area, it's not just the cravings and those acute needs, but the long-term health effects that our patients are trying to manage over time. Whether cognitive or impact on other organs, whether it's your lungs or your heart, I think that there's so many dimensions within our patients that we can look towards healthcare and pharmacotherapy development to potentially have some new solutions for us. I think CBT and DBT are such critical components combined with some of the social areas of recovery that we need. And I think that our -- this is a tricky illness. And we've even heard today that it's the layering effect of these behavioral therapies that end up being so useful to our patients. Having additional tools in that toolbox, again, for layering, is really what we want to sort of turn our attention to.

(End Media 3.)

(Begin Media 4.)

MS. BENT: Great. Thanks so much, Jessica. So we'll turn to Michael and then Kevin, and then I think we're going to move onto some of our polling questions as well to kind of bring the audience or the viewers back in.

So go ahead, Michael, and then we'll go to Kevin.

MR. GALIPEAU: Yeah. Thank you, Javier, for sharing that. And it really just refreshed, you know, some of my own memory with my experiences in the armed forces. And ultimately what led to my discharge, which was disclosure that was made during treatment I was receiving to address, you know, some early signs of an alcohol use and substance use disorder that led to the uncovering of my traumatic experiences at DCYF. And my really untimely discharge just before getting deployed with my unit probably saved my life looking back on it because many of them did not survive that deployment.

But thinking about what has been less

effective or not present and also has been more effective, certainly there were not any meaningful role models that would show me what moderation management pathway would look like. And certainly nobody who was speaking out about that as non-abstinence being its own path to recovery. And also, there was no mutual aid societies. Now there fortunately are a couple. Harm Reduction Works which is founded by my friend, Jess Tilley. And, you know, what used to be the -- Positive Change Group which is now the Substantial Improvement Group, that people are now meeting and providing this kind of basic support.

And one of the really kind of essential, pivotal parts of my change process -- recovery housing. Just having that kind of supportive environment. Again, improving upon my social determinants of health, giving me a really basic foundation of stability as I was being released from incarceration gave me something that I could build from. I was even able to go back to college, start working on a social work degree, start working a

regular job. And that really began my current period, a very longstanding and upward trajectory in terms of my quality of life and global health improvement.

MS. BENT: Excellent. Thank you. And, Kevin?

KEVIN: You know, who knows what will work. I mean, and I think that's the thing with stimulant use disorder or with my journey. You know, unfortunately, like with this, there are no medications or anything you can do to deal with the cravings that you have that cause you to use. There's really no medication that will deal with, like, the crash that you're feeling when you stop using and kind of, like, crash out. And there's nothing that really, you know -- like, can relieve, like, the feeling of that rush that you get when you first use as well, too. You know, that brings you kind of back to -- you know, that brings you back to those cravings.

And I think really from my experience, it was really, you know -- it was really a lot of trial and error. You know, of like, you know -- of

going back out and relapsing again, trying to stop. And, you know, finally, you know, was there, like -- what was this transformative thing in my treatment? It was honestly watching, like, the sun rise over the holding cell over Lake Michigan as I was waiting to be booked in, you know, into the court system. And, you know, just having this like epiphany, and I don't know what happened, but it was just like, wait. I don't have to live like this anymore. And I don't want to live anything like this anymore.

And then for me, it was like really a two or three-week very -- very confusing period of trying to figure out what to do next. And I do think, you know, when I walked into my first 12-step meeting and met a bunch of other -- mostly gay men who had been exactly where I was and were happy and sober and had put their lives back together, that I first found, like, a hope that I might actually be able to get better and beat this. And then, you know, the social networks that I was able to build kind of like -- and utilize that network for support was really, like,

that transformative impact for me. Thanks.

DR. MUNIZ: Thank you very much to all of you.

MS. BENT: Okay. So now I understand -- thank you so much. And did you have additional questions, Dr. Muniz or no? Okay. I'm going to take the video turning off as cue that you're good to go. And so I just -- I wanted to turn now -- we actually have a few callers on the phone. And so we're going to take a caller on the phone. We're going to start with David who has been patiently waiting for a little while I think to talk about approaches to treatment, and maybe his thoughts on approaches to treatment.

And so, David, I know that you've been very patiently waiting, but if you could kind of give us a high level idea of your -- what you'd like to say now, go ahead.

DAVID: Sure. Thank you so much. Do you hear me well enough? I'm actually --

MS. BENT: Yes.

DAVID: -- calling in from not a great

spot. There's a internet, so just was checking. Great. You know, I just wanted to chime in. I'm actually -- I have not had stimulant use disorder or any substance use disorder. I've been fortunate about that, but actually, I wanted to talk to you about coca leaves. And so even though I haven't had an issue with it, my father actually has been in and out of recurrences for his entire life. And that has led me to be very, you know, focused on understanding alternatives. And in South America, in particular in Columbia, Peru and Bolivia, there are a number of psychiatrists as well as therapeutic communities that have started using coca leaves as a way of supporting people particularly with craving relief, as well as in terms of how -- build communities around this plant.

So and I think why that is probably requires a tiny bit of explanation. The coca leaf is the source of the molecules with which you produce cocaine hydrochloride as well as cocaine sulphate. In South America, the typical substance of use is called basuco. It's a smoked form of coca paste. But in

general, what these kind of innovative experts are trying to do is use the leaf, both in its full plant format as well as the culture around the leaf. The leaf is used in a number of traditional practices and basically getting together and telling stories and, you know, discussing what the problems for the community are.

So using those concepts as part of their treatment strategies to build these communities that seem to be such a big part of all the narratives that have been shared today. So I think that's something that is very interesting and that deserves taking a look at. You know, coca leaf is not associated with any form of health risk or of addiction. It is -- it's a very effective stimulant, but it's very mild and only lasts as long as it is being held in the mouth in the way that indigenous people of South America use it.

And once people, you know, are finished using the leaves, the effects of coca just wears away within minutes. You know, and people can go to sleep

or what have you.

So the pharmacology of it as well as all the practices that surround the coca leaf or the cultivation -- the making of the different product formats which tend to happen in a community setting I think are really interesting input for this discussion. You know, cocaine wasn't --

MS. BENT: Yes. Thank you so much, David. That is really something that is -- I think Michael may have touched a little bit upon that earlier, so thank you so much and I'm sorry to cut you off, but we need to move onto some of our other callers as well. But we do very much appreciate your feedback and that will certainly be included as part of the voice of the patient report.

I think that we're now going to go -- I don't think I have a name, but we're going to go to somebody who would like to share their experiences as a family member. So, please go ahead.

UNIDENTIFIED SPEAKER: Is it -- can you hear me?

MS. BENT: Yes, we can hear you.

UNIDENTIFIED SPEAKER: Okay. Yeah. So actually this is -- I was keyed onto this discussion from a family member a little while ago because for myself, personally, I actually have found that, you know, I struggled early in life growing up without prescription medication because I had no idea I had an ADHD disorder. I also did not -- I also had a vision problem which I've had corrected with Lasik in a similar aspect.

Actually, both of those things come together into a beautiful hue that I can actually see the world clearly with each of those aspects of mind and actual vision. But, like, growing up, I quickly -- you know, I was a straight A kid up until hormones came around and, like, I could not -- like, my grades started slipping. I started to act up, be the class clown, you know? Get, you know -- just -- I just started to go down the wrong path. I was always -- I started to become the bad kid, you know? And drinking and finding -- and I ended up going down the substance

road because I didn't have any direction. And then eventually, you know, for whatever reason, I even made it through living in foreign exchange in Spain for a year without being able to see because I wouldn't wear my glasses, and also ADHD. But with a totally different culture or, you know, like a freer aspect of life where, you know, like coming back to the United States, I felt more restricted because the kids over there were able to do things. Like, they were given a larger lead on their rope, I would say, earlier. So it was a big -- you know, it was a big thing. And I wish I had had something like that for that experience because now that I'm currently a nurse working through COVID, you know, I've been working with other nurses and dealing with situations that I have to be -- I have, you know, a code going on in one corner of my floor, you know? And then I have, you know, vent alarms going off, bed alarms going off, and I have to constantly reprioritize in my mind, you know, A, B, C. And it's forever changing.

So the fact that I'm able -- like, I'm

blessed. Like, that the doctor that first put me on it found the prescription that, for me, it's just Adderall. And obviously, if there was a better alternative, like, that would be great. But for me, I have -- I found the right dose and it actually settles me out. So I find a total benefit from the stimulant. So I see where there is abuse potential, but just as the same with opiates and all that, you end up with, you know, there's treatment options which I also deal with as a nurse with patients and I have to beg for, you know, somebody that's got multiple fractures and they're, you know, given half a -- like a tramadol. I'm like, I don't think that's going to cut it -- it's 45 or something. But --

MS. BENT: Right. Right. So I'm sorry, but I'm going to have to just ask you to kind of finish up what you're saying so that we can make sure that we hear from as many people as possible. But I think that what you're sharing is very important, so please go ahead and just finish it up.

UNIDENTIFIED SPEAKER: Yes.

MS. BENT: I don't really want to break you off. Sorry.

UNIDENTIFIED SPEAKER: Oh, I'm sorry. Yeah. I'm sorry. I didn't mean to go off course there, but that's basically what I wanted to say was that it does have a place. Like, it -- for me, it's -- without it, it's the same as if I hadn't had, like, the laser surgery for my eyes. Like, where I can see 20/20 now, and before I was 20 -- I forget, 320 and 20 -- 280? So I was legally blind and I would have never been able to fly a helicopter. And that was always one of my dreams and I still plan on doing it. So why not?

MS. BENT: Great. Thank you so much. Thank you for calling in and thank you for sharing your experience. And we're now going to move onto -- I think right now our final caller for this section, who we are apparently calling a family member, so please go ahead.

UNIDENTIFIED SPEAKER: Yes. Can you hear me okay? Hello?

MS. BENT: I think so. It was a little faint, but now it's getting better.

UNIDENTIFIED SPEAKER: Oh, okay. Yes. I'm a family member of a cocaine addict who had been in relapse over many, many years. And she basically was put on modafinil. And let me preface my remarks by saying I attended a summit conference in Miami on stimulant disorder. I think it's like an annual meeting -- and it had experts from all over. And there was some question, even though the point was made, there's no approved drugs for stimulant disorder, but maybe there was some studies that were indicating possible benefits from off-label of existing drugs, particularly of the stimulant category. And I, again, you know, would want to know if any of these members on the panel now have any experience with the use of stimulants to treat the stimulant disorder, prefacing my remarks again, you know, that there are no accepted forms of treatment.

Let me say one other thing in -- conditions just in generally, there's off-label uses

of medications that are not, you know, specifically approved for one condition. And there's so many people with stimulant disorders that may not be able to manage their condition with just support groups and the cognitive therapy, and other forms of treatment, and might be willing to try, you know, promising drugs again off-label. Thank you.

MS. BENT: So thank you. And actually, we did not ask this gentleman to call in, but it actually leads us very, very well into our next polling question which is, "Have you or your loved ones ever used any of the following to manage stimulant use." And so if we can go to our polling questions and maybe use that as a jumping off point to kind of talk a little bit more about what the gentleman just asked, that would be really helpful. So are we able to go to our polling questions? Okay. Great. So we're going to the polling question now and you'll see that there are multiple responses that are available to us. Honestly, I'm not sure I can read them, unfortunately. So give me -- just give me a

second while you guys are responding and I'm going to try and pull them up from previously and just see if there's any way -- to our producers, are we able to zoom in on that at all to get a little bit more clarity? Or if not, that would be -- that's fine as well. And what we can do is just go into our -- we can put the results in as part of the voice of the patient report. And we can kind of just turn briefly to our panelists and ask them briefly to kind of touch on what they've used. Of course, they have spoken to us a lot about their choices in treatment. So let me -- apologies while I just kind of get to this point.

So complimentary alternative therapies is the big blue, lifestyle changes right here is in green, peer support or counseling is in red. And do we have anybody who uses -- it looks like medications is -- is this yellow or other approaches not mentioned is yellow.

And so -- okay. So that looks like the results that we have. And so I guess that brings up a question to maybe some of our panelists if you've used

-- if you haven't already kind of shared with us your approaches to treatment or if you've used any other treatments, if you have any thoughts about this question, please go ahead and turn on your video and we'd be happy to hear from you. Okay. Go ahead, Michael.

MR. GALIPEAU: Yeah, sure. I mean, I've spoken a little bit about, you know, obviously medical maintenance with medical cannabis. Another really important turning point in my story was actually a brief period of self-experimentation where I was kind of trying to use, like, yoga and guided meditation with like a low dose of psychedelics. Particularly, psilocybin mushrooms. And it was actually after that period of self-experimentation, since that time -- quite literally since that time, I have not had problematic substance use with any of the substances that I've had issues with. Even when I've gone out into self-experimentation with the same substances, my relationship to myself and the substances fundamentally changed. And I can't explain

exactly what it is that happened in that process, but I don't have the same experience when I use substances now. And really, it's been pivotal in terms of being able to have control over my life and not feel completely powerless in the face of a substance use disorder.

MS. BENT: Great. Thanks. Let me now turn to Amy.

MS. GRIESEL: Yes. I've used multiple of these. I really -- like I said before, I am a peer support. Well, before I became a peer support, I got assistance from my peers. So I went to something that was called -- and it's called a clubhouse. There's one for behavioral health. So it's a place that you go to kind of feel normal -- if that's the way I should put it -- with other individuals that are suffering from the same things. So the behavioral health one I would either -- you know, each person has a job duty. So you can work in the café. You can work in the business unit. You can work in the boutique. And it's kind of just working together,

showing that, you know what? I have skills, you have skills. Let's motivate and empower each other. There's another place that is for my substance use that I went through that is a peer-led, peer-ran. It's called the Recovery Café. And they've got support groups there. They serve lunch. They have job training things that go on. And it's really like a family environment. You get people that have lived experience that is able to empower you. So with peer support, that really is what I thought was important to be able to give back.

Lifestyle changes, obviously that is a huge thing. Avoiding triggers, learning how to cope with triggers. I place myself in treatment centers as an employee so that I can continue the healing process and keep those present in my mind. Because I am someone that forgets those really easily. So seeing that every day will -- it helps me.

And then the other approaches I mentioned during my share was cognitive behavioral therapy. I think that was one of the really big ones

because being bipolar and having some other diagnoses that my emotional wellbeing is -- I'd get off a lot. So being able to learn how to, for one, have mindfulness, calm myself down, figure out how to be rationale and kind of just have emotional regulation was really, really important to me and having that perspective.

So those were ones that really made it so that I could be on this journey of recovery.

MS. BENT: Great. Thank you so much. So let me turn to Phil. And I hope, Phil, while you're sharing, I would also like to -- because we are running out of time, is it okay if I move onto the next polling question while you're sharing? I don't mean to be at all disrespectful, I just -- I want to hear what you have to say and also kind of get the answer to the next polling question. I'm so sorry.

MR. RUTHERFORD: Well, I'll be quick. I just wanted to say --

MS. BENT: Okay.

MR. RUTHERFORD: I just wanted to say

the -- so that was always the things that we -- the tense of it was things that we have used to manage stimulant use disorder. And as it is a chronic condition or as it is an ongoing thing, I just wanted to point out that there are plenty of things that I continue to use on the path of recovery. I continue to use peer support. I continue to use holistic wellness. I continue to use -- my pathway is abstinence. I continue to use these things to stay in recovery, so it's not that a long time ago I did some stuff and that's what worked. It is the continuation of those processes that allow me to continue to have the quality of life that I've come to enjoy.

MS. BENT: I think that's a really important point, and I think that maybe we could have done a better job of wording that question in a way that it wasn't a single point in time. That really -- that it was more of kind of an ongoing process. So thank you for bringing that to our attention and really just bringing it up because I think that it was really, really important.

And so the next polling question that we had was, "If you're considering a new treatment for stimulant use, which of the following benefits would you consider the most meaningful?" And so we can see here -- we can see very clearly here that there is a diversity of opinions, I mean in a good way, which really kind of focuses mostly on a decreased craving for stimulants and also just the ability to stop using stimulants all together. And so I think that this is a really helpful kind of discussion -- way to start the discussion. And I know that we're kind of moving -- easing a little bit into our time for our COVID -- the impact of COVID. And so I want to just kind of turn to our panel briefly and just get their thoughts on what an ideal treatment would look like if it hasn't been mentioned. Are there benefits that you would look for in a treatment that we really haven't touched on? Is there anything specific that you think that we're just kind of -- that we haven't really talked about yet that you think would be really, really important for us to think about? Okay. So I'm

not seeing a lot of responses, which I mean is kind of great. And -- kind of.

So let me turn now to my FDA colleagues and see if before we move into the -- into talking a little bit about COVID and the experiences of COVID, if you have any additional questions that you'd like us to ask or any other questions that you're kind of waiting for me to get to that I am forgetting. So anyone from FDA? Okay. So I think that one of my colleagues from FDA is typing a question, and so I'm just waiting.

So just to the -- just to give our colleagues kind of an idea of what we were seeing if you're considering new treatments for stimulant use, which would be the which of the following benefits would you consider to be the most meaningful. We had about -- I want to say about 25 percent of people say stop using altogether, 25 percent say decrease the use. We have about -- I'm ballparking, maybe about 20 or 15 percent saying reduce effective stimulant withdrawal. About the same number saying help me

control my use of stimulants so that I can function better. And a few people said other benefits that were not mentioned.

So I think that -- so let me just give them a second to think about if they have any additional questions. And while I'm doing that, please know that we're kind of teeing up the talk about COVID-19 and the impacts. So for those of you who are watching who could call in and kind of share any impacts of COVID-19, how it's affected maybe your stimulant use or maybe your recovery or your treatment, that would be really helpful for us to hear.

So, Michael, did you have something to add?

MR. GALIPEAU: Yeah, sure. I mean --

MS. BENT: Okay.

MR. GALIPEAU: -- just from, you know, my personal experience during COVID, really it's been very difficult to access providers. And I've honestly been very resistant to even seeking routine care,

whether it's dental, primary care, routine preventive care. Anything that I can, you know, possibly delay without having to go into a doctor's office. I just fundamentally feel like it's just not a safe place to be where people are congregating and potentially being treated for COVID. Certainly any kind of elective procedures or hospitalization. But some of the things that I've seen done really well during COVID, I mean, the transition to telehealth and making, you know, buprenorphine more widely available in our community here in Dutchess.

And also, deploying, you know, basic market regulatory tools, like fentanyl testing. So people are aware of what's in the drug supply that's out on the streets that's making people unsafe.

And so that combination of response during COVID, the real community-centered work has really been remarkable in terms of increasing access, increasing engagement, increasing retention. And I think those are important lessons learned in how we design a system that looks to meet people where

they're at with stimulant use disorder and other existing treatments, like methadone.

We had released a national statement through the union making some pretty scoping reform recommendation that you can find on the Urban Survivors' Union website, specifically pertaining to methadone. But a lot of those recommendations really apply broadly to what low threshold access to services could or should look like for people who use drugs.

MS. BENT: Great. Thanks so much. Sorry. I kind of locked my cursor there for a moment. So that's really, really helpful. Dr. Muniz, did you have any questions? Okay. So while we're waiting for people to respond, I think that we're going to turn to Lyna and, again, we're having a little bit of a delay between kind of getting the comments and being able to share them. And so this kind of takes us back I think to our last question, our pre-COVID question, about treatments. And so -- but I think it's a really -- it's a good comment or comment to hear. So, Lyna, if you wouldn't mind sharing it with us, that would be

great.

MS. MERZOUG: Sure. Thanks, Robyn. Okay. So we have a comment from Mindy [ph] on addiction and mental health. And she's saying, "In thinking about treating addiction, it's helpful to remember that there are many different underlying reasons why addicts use, such as taking away pain, both physical and emotional, shame, low self-esteem, self-efficacy, unaddressed mental health and so many other reasons. As you know, it's important to address all of these issues based on each patient's needs. As an addiction professional and a woman in recovery, I have realized that everyone is different and treatment needs to be different for each individual. Also, treatment is short-term and a way to teach patients the tools they need for their long-term recovery, which is for a lifetime, that is very helpful in blocking the cravings and urges to use. So patients can focus on getting the tools they will need long-term. More and more, I am seeing many patients are not able to have the mental health component addressed

because they do not qualify based on the assessment they received. It might be helpful to come up with an assessment that includes patient's mental health as well as their substance use disorder so they can qualify and those issue can all be addressed simultaneously. As a treatment provider, we do assist clients with a warm handoff to mental health services; however, many of those clients are turned away. They are also being turned away from certain treatment programs because of their insurance -- or not having insurance which can be detrimental to these patients." Thanks, Mindy, for sharing your experience.

MS. BENT: Yes. Thank you so much. And now let me turn to Dr. Muniz.

DR. MUNIZ: Hi. I hope you can hear me okay. This question's for Michael. I am -- you know, we, as an agency, we've received a lot of -- and we've read in the media about a lot of interesting -- using psychedelic substances to treat a variety of mental health conditions, such as depression, PTSD, substance abuse. And I similarly read a number of cases where

people have totally lost an interest in perhaps using substances and so on. And I want to be careful with what I'm saying because I don't want to imply that these drugs work, the only thing is we certainly don't know if these drugs are safe and effective, which is what we're supposed to do.

But I wanted to ask you, Michael, a little bit if you don't mind sharing. And I don't know how much you can say here, but in terms of how did that experience change you in this context? If you can. Thank you.

MR. GALIPEAU: Yeah. Absolutely. I'd love to talk about that. There's actually an emerging community of folks that identify with having experience using psychedelics as part of their path into recovery. And for me in particular, it really held kind of a central position in helping me to heal from a lot of the traumatic experience. I had been experiencing really horrible night terrors and not being able to get a consistent night's sleep was really throwing me into survival mode and a very

reactionary state on a day to day basis. And it was really easy to fall into patterns of use when my really basic daily rhythms and body regulation was so horrible dysregulated by my mental health. And so that was really a big driving force. And why I keep bringing up, like, this really intricate relationship between trauma and substance use that, from my experience, was central to what was driving the disordered use. And I differentiate that because there is such a thing as non-disordered use and it doesn't necessarily mean that once a person has acquired a disorder, that it is always lifelong, right? That every single case is different.

And so what works for each case, what psychedelics work or do not work, are going to be, you know, uniquely tailored to that person's individual needs, their complex bio and psychosocial health, and their social determinants of health at the time that they receive those kinds of services.

So it may have been a combination of being at a particular turning point in my life when I

had that experience, but there were certainly some biological changes and changes in my brain that were perceivable immediately that allowed me to lead a more manageable lifestyle and really get a handle on some of the other things that I was being asked to do. Like how to figure out doing step work. You know, when you're in a completely dysregulated state and you're day to day just trying to figure out how to survive your own internal body conditions. It's really hard to focus on the kinds of, you know, concrete steps of doing, like -- you know, I need to come up with a list of like all these things that I'm resentful about and figure out what that looks like. And there was like a lot of really, like, deep, internal work that as somebody wo was living with complex trauma, it was really hard for me to go through that where I was. And having participated in the Horizon Psychedelics conference and having been trained in, you know, psychedelics 101 by Doctors Elizabeth and Ingmar Gorman. And a lot of the really incredible research work that's out there, I would

really, you know, strongly encourage a second look. Because these therapies -- again, it's not a one size fit all solution for everybody.

If it even alleviates a significant portion of the distress for a part of our population that's really struggling to get recovery, then it's important to look at our objective evidence that's available. And there's a very good body of it at this point. You know, we're talking multiple decades of really high quality research that can be reviewed and considered.

DR. MUNIZ: Thank you, Michael.

MS. BENT: Thank you. And so did you have other questions or do we want to kind of turn back to our panel and hear a little bit about the impacts of COVID or their thoughts on COVID?

MR. RUTHERFORD: No, thank you. Appreciate it.

MS. BENT: Okay. Great. Thanks. So now I'm going to turn back to -- I kind of gave away what I was going to do. We're going to turn back to

our panel now. And when I say our panel, I mean both our first panel and our second panel, to really kind of share any thoughts that you have on the impact of COVID on your -- on stimulant use, on access to treatment, people choosing or accessing treatment. Really, anything. And I know that not to call anybody out, but Jessica, I know that you and I, when we were talking, you had had some thoughts on the matter. And so I don't know if you would be comfortable or willing to kind of talk to us a little bit about your thoughts on the impact of COVID? So if so, we would appreciate it. But if not or if you kind of turned away from the meeting a little bit just because I know that you weren't on this panel, we would completely understand.

MS. HULSEY: I'm still here. Happy to check in.

MS. BENT: Great. Great. Thanks so much.

MS. HULSEY: So right when the sort of shutdown began, we did a survey of our patients and families and people that we work with. We had a

little over 1,000 respondents and it confirmed what a lot of us on this call and this meeting already know, that there was quite a lot of disruption and needed services.

We had I think three out of four folks that we worked with reported disruptions and there was a significant impact on substance use and recovery. Four percent report an overdose since the pandemic had begun. And a lot of difficulty switching to, you know, virtual options and sort of disrupting the systems that so many of our individuals in recovery, including long-term recovery, have set up that really builds the components that they need for recovery and for health and wellbeing.

I think Phil put this really beautifully, that these are the pieces that he built into his life that he relies on every day. And we've heard the same. And even individuals who have been in recovery for a long time, sort of seeing as the length in recovery as protective, still really struggled with sort of changing access. Whether it's counseling not

available, the biggest sort of reported frustration was with all of the mutual aid and tall step groups not being accessible, that there were Zoom options, but worried about anonymity. There were, you know, folks joining Zoom sessions to be disruptive, which was really hard. And also just missing that sense of community that you get from participating in mutual aid groups.

And one of our people we work with had such an, I thought, appropriate observation. They said that it's frustrating to have all of our meetings shut down when they're keeping liquor stores and dispensaries open. Our society is so twisted. And I think it was really difficult. I think we should prioritize needed recovery services much higher. It's a combination of we're all in the middle of a pandemic. It's stressful. The news is stressful. People have lost jobs. We've lost friends and families to this illness, so we know that there are more stressors and triggers in 2020. And taking away the safety nets that our individuals in recovery from

substance use disorder or are patients need to stay healthy and strong is just really problematic.

We also heard from our community that about 20 percent were reporting increased use since the pandemic began. Whether they were family members or friends and allies, or individuals in recovery who reported more slips and relapses using alcohol and other substances really as sort of coping mechanisms during this difficult time.

So I think in terms of next steps on this, we've, you know, really focused on how do we get better at telehealth and Zoom and virtual options? How do we keep other services open? How do we make sure that we're keeping SUD services as safe as possible so people don't have disrupted treatment in recovery support because we shouldn't let that safety net decay during such a stressful time.

MS. BENT: Great. Thank you so much, Jessica. That was really helpful and I think that the results of the survey are certainly very interesting.

I think we actually now have somebody

on the phone that we'd like to go to. I think that they're going to speak very briefly about their experiences during COVID, and then we'll come back to our panelists for any kind of closing thoughts. So, caller on the phone, if you want to go ahead and kind of share your experiences with stimulant use disorder in the context of COVID-19, we would very much appreciate it.

UNIDENTIFIED SPEAKER: Yeah. And this is a sidenote real quick, I am a huge advocate for mindfulness, meditation, all that. That is a big component of what I've done throughout my life. Finding that was an amazing experience and has helped me.

But as far as COVID goes, the one thing I can say from the other side, the perspective -- I was the one that called earlier and, like, I'm a nurse and I work nightshift and it would be, like, some of the regulation has gotten so stringent on the medication that I would be hard-pressed to be trying to figure out what day I'm going to have to be at the

pharmacy and what shift I'm going to be working so that, you know -- there's been several occasions over the course of my nightshift that I have just not been able to go to sleep, so that I make sure that I get my Adderall prescription refilled because otherwise, those -- with COVID, the lines would get so long. The -- you know, the pharmacy would be out of the stock and then they would say they'd have to have a pharmacist send it to another one.

So essentially, as a frontline worker and if I'm a charge nurse and I have five other nurses underneath me, or four, and we have, you know, say whatever -- however many patients, 24, 28 beds. You're, like -- you have a guy then that's essentially has -- is without the medication that he does need. So sometimes that has been pretty tough where there's no wiggle room as far as, like, a day early or a day late or whatever. It's -- that -- impact me, but that's where I'm coming from. But I'll support anybody, you know, that's going through, you know, substance abuse disorder. I mean, that's tough. I

see plenty of it.

MS. BENT: Thank you. Yeah. Thank you. Thank you for sharing that. So let me turn briefly to Michael, and then Phil, and then Kevin. And then we will turn to the comments that we have online. And I think that that will take us pretty close to the end of the meeting. So, Michael, please go ahead.

MR. GALIPEAU: Yeah. I think in a little bit broader lens than personal experience, I want to bring in, you know, some of my professional experience here regarding specifically COVID. Because I think there's some really valuable insight in what I've experienced. And I actually wrote a paper -- I would encourage anybody who's interested in reading it, I co-authored a paper with William White and Ryan Hampton, both very well known in the recovery community, just a few months ago discussing some of the concerns around COVID-19 and the small business program. And just acted, like, institutionalized discrimination towards people with substance use

histories and criminality around the substance use histories.

It really is, you know, this idea of, like, how the social determinants of health, people having access to meaningful employment and studies that were conducted very recently on, you know, plant closures throughout the Midwest. I mean, literally right before the pandemic hit, they released a really widely scoping research study on the impact of loss of employment and a whole host of other factors that we're now seeing played out in terms of overdose death amongst not only the typical populations. We have, like, the early recoveries, recurrence, people in and out of incarceration, forced abstinence. They did a lot of research on that in Rhode Island, looking at people who were at risk for overdose getting released from incarceration. But also amongst now, people with longer terms of sobriety that, you know, due to the sudden uncertainty about basic needs, downward economic mobility, we're seeing increased rates of recurrence and also subsequently, because of increased

unsafe conditions in the market, increases in overdose death from a whole different population than we're used to seeing turn up in our medical examiner's office.

And this is, you know -- we're trying to keep up with this, you know, because this is obviously changing very, very rapidly. But the last six months have been extremely distressful and there's ripple effects in how that trauma affects our community widely. And now you're compounding it with people who are experiencing sudden losses due to COVID-19. So I just --

MS. BENT: Right, right, right.

MR. GALIPEAU: -- that we really need to be proactive in, like, the variety and the widespread access to healing modalities and different pathways to recovery because it's needed more than ever by so many people.

MS. BENT: Okay. All right. Thanks so much, Michael. I'm going to now move onto Phil.

MR. RUTHERFORD: Yep. I think in a

real simple way, COVID is the big bad wolf. And when I think about the effect on the recovery community -- and I -- there's a little bit of kind of morality in the big bad wolf analogy in that, you know, the pigs built their house with straw or sticks or stone, and that's like their own personal choice. I don't think that's -- that's not the measure that I want to use, but for whatever reason, there are people within recovery that their only defense is straw, right? And they don't have some of the recovery capital tools that I described earlier. So the big bad wolf, COVID, shows up and knocks the crap out of them, right? So the effects of it are horrific.

And then I think people with more moderate defense against the big bad wolf, the people in the house with sticks, they fear better. And people with much more support, much more tools -- like I think of -- in my own personal experience, we simply moved online, right? We simply moved -- I have access to highspeed internet. I've got a community of people around. We simply moved our meeting online and within

a week of deciding that we couldn't go to our meeting place, we were online and then over time, as the city has opened up again, we occasionally will go out for coffee in an outdoor space and meet in a safe, socially distanced way.

So I have protection there, but I think the concern that I have is the broader recover community at large, there are systemic things in place that -- where people are completely vulnerable to the effects of COVID. Not just the illness, but what it has done to societal interaction and the -- I believe that we're going to pay the price for that over the next 5, 10 years.

MS. BENT: Thanks so much, Phil. And I am told that I went out of order, so my apologies to you, Kevin. I did not mean to go out of order. But please go ahead.

KEVIN: No problem, Robyn. And, you know, I just wanted to reiterate, too, a lot of what Phil said actually -- he kind of took a little bit of my thunder. You know, I'm always interested in what

the recovery community here in Chicago where I live is, you know, we basically, you know, lockdown pretty quickly. And within, like -- actually, within three or four days, we had more 12-step CMA meetings going on online than we actually did in person meetings. So, you know, I think one of the things that those of us in recovery should give ourselves a little bit of credit for is we are resilient.

And, you know, but I think gong back to what Phil said as well, you know, there are a lot of people who are new to recovery I think who are really struggling to come into recovery, you know, in this online format. You know, people who are having to do IOP virtually. I've got a couple of men that I sponsor early in recovery, you know? And the complaints about that and just the experience that it is for them, you know, is just not the same. And I think we have to just acknowledge that and accept that.

You know, and I think, too, the other thing with -- that I think about with this is, you

know, in some ways, you know, for me, I suffered from a disease of isolation. And, you know, when we all had to go into lockdown, you know, we all had to isolate out of our community's health and out of our own health. And, you know, I think that has hit a lot of us really hard. So yeah, thanks.

MS. BENT: Great. Thanks so much for sharing that, Kevin. And we're now going to turn in our last -- perhaps for our final comments from our online viewers, we're going to turn to Lyna to kind of share some of these final comments, and then we'll move onto our closing remarks.

But before we do that, I just want to thank everybody who has participated in the meeting today. So go ahead, Lyna.

MS. MERZOUG: Thanks, Robyn. All right. So we have the final comment from someone who wishes to remain anonymous. And that is that, "I know that COVID has created difficult situations for many; however, a silver lining for those who are not comfortable in social settings, which is a push for

many recovery programs, and does not fit a portion of the population -- because not everyone is naturally social -- has allowed people who are not social to thrive in this new social setting online." So thank you so much for that comment. I think it definitely wraps up what our panelists were just talking about.

MS. BENT: Great. Thanks so much, Lyna. I really appreciate you kind of sharing that. And so everyone, thank you so much for an amazing meeting. What you shared really provided us with valuable insight. And again, if we weren't able to get to your comments today, that doesn't mean that they aren't valuable. So please consider sharing them to the federal register and we will include them in the voice of the patient report.

I'm now going to turn over to Dr. Marta Sokolowska, Associate Director for Controlled Substances in the Center for Drug Evaluation and Research, who's really kind of the driving force behind today's meeting for closing remarks. So please, go ahead.

DR. SOKOLOWSKA: Robyn, thank you very much for leading this meeting. I just wanted to take the last few minutes to really thank everyone for making this an insightful and interesting afternoon.

In these closing remarks, I want to summarize some of what we have heard today from our panelists and audience members, highlight the FDA's commitment to advancing drug development for substance use disorder and stimulant use disorder specifically, and thank the people who have made this event possible.

We have had the opportunity today to learn more about the impact of stimulant use disorder, the challenges of seeking treatment and the need to develop effective treatments. We heard from the individuals who are struggling or have struggled with the use of cocaine, crystal meth, methamphetamines and misuse of prescription stimulants.

We also heard from family members, advocates, caregivers, and other individuals who have seen the impact of misuse and stimulant use disorder

firsthand.

We heard that there are a number of reasons why individuals might begin -- taking stimulants. You mentioned participating in social activities, increasing focus, treating diagnosed and undiagnosed mental health conditions, and coping with pain and trauma, among others. You also talked at length about the polysubstance use, including cocaine, methamphetamine or other stimulants, and opioids.

We heard about how stimulant use disorder affect health and wellbeing. You brought up short-term physical effects such as overdose, psychosis, mood swings, intense cravings and withdrawal. But you also mentioned longer term physical health impacts such as issues related to oral health, infectious diseases, health conditions.

We heard that stimulant use disorder affect major activities of your daily living. You told us about difficulties in participating fully in work and school and maintaining stable housing, as well as experiences with the criminal justice system.

So you further discussed the impacts of stimulant use disorder on families and friends such as damage relationships and limiting the ability to care for children.

We heard about your preferred approaches to managing your stimulant use disorder. You talked about the need for a broader perspective on treatment and recovery. Planning that goes beyond just acute medical care.

You mentioned the metrics model, contingency management, trauma-informed behavioral health effects, healthcare, and treatment of other underlying health conditions, including other substance use disorder.

You also discussed self-management, such as drinking coffee and participating in 12-step programs. And the role of pure relationships and support in helping you find a voice and seeking to improve overall care for -- stimulant use disorder.

And you emphasize the need for pharmacological treatment for stimulants that are

similar to what we already have for opiates.

We heard the importance of language and the need to understand that stimulant use disorder must be part of a broader societal conversation about addiction.

You told us that the word stimulants means different things to different people. And that relapse should be, but often isn't, characterized as part of chronic condition rather than a sign of failure.

You discussed how characteristics, such as gender, race, sexual orientation and social economic status can impact experiences of stimulant use disorder and why they require a more intersectional approach to care.

And you spoke about frequent challenges with stigma, whether from healthcare providers or from individuals with other kinds of substance use disorder.

We heard about how COVID-19 has impacted substance use disorder, including broader

access to services via telehealth.

You also told us about distractions in switching in person care and support to virtual options, as well as challenges in filling prescriptions.

You also mentioned a potential silver lining, that people who were uncomfortable participating in person may be more comfortable participating in online support groups.

All of the insights you have shared at this patient-focused drug development meeting, a critical part of FDA's ongoing effort to advance drug development for stimulant use disorder.

I want to take a moment to tell you what else we've been doing to address stimulant use disorder as this meeting is part of our broader strategy that address this disease.

For instance, FDA is working closely with National Institute on Drug Abuse. And last year, we participated in two NIDA-led workshops. One on target identification for stimulant use disorder

treatment. And the other one on drug/drug interactions between opiates and methamphetamines, to better understand the risk associated with --

In December of 2019, FDA held a public workshop with Duke-Margolis Group to obtain input from clinical and academic experts, as well as harm reduction groups, about complexities of stimulant use disorder and various new treatment development.

In two days, we'll have a public advisory meeting to discuss a new drug application for a potential ADHD amphetamine treatment that hasn't been formulated with properties that are intended to deter non-oral abuse.

And off note, just last week, FDA published a final guidance for industry on endpoints for demonstrating effectiveness of drugs for treatment of opiate use disorders. We are hoping to do more in this space.

As you can see, we have had many discussions with FDA staff about how best to address substance use disorder. We look forward to continue

our work on stimulant use disorder within the agency and collaborating with other stakeholders.

On behalf of FDA, I want to conclude by thanking everyone for participating in today's meeting. We are particularly grateful to the individuals with stimulant use disorder and the family members, advocates, caregivers who have attended and shared their perspectives, as well as panelists and audience members.

We recognize that speaking publicly about your experiences with stimulant use disorder may have been a difficult decision. We heard examples today about the ways that stimulant use disorder is stigmatized, perhaps more than some other types of substance use disorders. And how those -- added to it can make seeking care even more challenging.

FDA is committed to doing our part to destigmatize stimulant use disorder so that individuals can receive the confident and compassionate care.

We also appreciate all of our entities

from the FDA and other federal agencies -- and the press for listening this afternoon.

Finally, I would like to thank Robyn Bent and Lyna Merzoug from the patient-focused drug development staff for moderating and leading this discussion. We couldn't have done it without you.

And I wanted to thank Admiral Giroir for his opening remarks, as well as for all the FDA panelists for the hard work in organizing and facilitating this event. Have a wonderful evening. Good night.

(Whereupon, the meeting concluded at 5:02 p.m.)

CERTIFICATE OF NOTARY PUBLIC

I, IRENE GRAY, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

IRENE GRAY

Notary Public in and for the

State of Maryland

CERTIFICATE OF TRANSCRIBER

I, JACOBEY RADTKE, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

JACOBEY RADTKE

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