

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

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4 Moderated by Robyn Bent and Lyna Merzoug

5 Tuesday, October 6, 2020

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9 Virtual Event

10 Silver Spring, Maryland 20910

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20 Reported by: Irene Gray

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1 A P P E A R A N C E S

2 List of Attendees:

3 Ms. Robyn Bent, OCD, CDER, FDA

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

6 Dr. Theresa Mullin, OCD, CDER, FDA

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

9 Dr. Marta Sokolowska, OCD, CDER, FDA

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

12 Dr. Tiffany Farchione, Division of Psychiatry

13 Dr. Javier Muniz, Division of Psychiatry

14 Dr. Jana McAninch, Division of Epidemiology

15 Lyna Merzoug

16 Shannon Cole

17 Jessica Hulsey

18 Brendan Welsh

19 Scott Sheldon

20 Pam L.

21 Paula Walsh

1 Brandee Izquierdo
2 Philip Rutherford,
3 Michael Galipeau
4 Kevin F.
5 Charles Smith
6 Amy Griesel
7 David

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P R O C E E D I N G S

1
2 MS. BENT: Good afternoon. Good
3 afternoon, everybody, and thank you for joining us for
4 this FDA-led patient-focused drug development meeting
5 on stimulant use disorder. My name is Robyn Bent.
6 I'm the director of patient-focused drug development
7 with the Center for Drug Evaluation and Research here
8 at FDA. I'll serve as the discussions facilitator for
9 today's meeting, which is part of the FDA initiative
10 called patient-focused drug development.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 impacted by prescription and illicit stimulant misuse
2 and addiction.

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

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

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

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

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

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

1 A study published earlier this year of
2 over one million urine drug test results from 2013 to
3 2019 found a 14-fold increase in the rate at which
4 samples testing positive for fentanyl also tested
5 positive for methamphetamines, and more than a six-
6 fold increase in cocaine. And the study my team
7 published last month in JAMA, comparing urine drug
8 tests before and after the COVID-19 emergency
9 declaration showed significant increases in positivity
10 rates for cocaine, methamphetamine and fentanyl among
11 people diagnosed with or at risk for substance use
12 disorder.

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

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

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

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

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

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

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

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

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

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

18 MS. BENT: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 with us.

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

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

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

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

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

17 Over the years, some of the terms that
18 we have been using have changed. The Diagnostic and
19 Statistical Manual of Mental Health Disorders, or DSM-
20 4, that was published in 1994 had substance use
21 disorders categorized under two groups: substance

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

7 In DSM-5, substance use disorder is a
8 single diagnosis with different severities that are
9 based on the number of symptoms that are present.
10 Similar to use disorder is substance use disorder
11 involving use of substances such as cocaine,
12 methamphetamine and prescription stimulants. In DSM-
13 5, stimulant use disorders is a single diagnosis with
14 different severities that are based on the number of
15 symptoms that are present. Also craving or strong
16 desire or urge to use a substance was added as a
17 criterion.

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

21 In general, the signs of any substance

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

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

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

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

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

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

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

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

1 increased appetite.

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

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

21 What is the role of agonist or

1 antagonist treatment based on the reasons to use?

2 Also, all stimulants are not the same. This class of

3 drugs include prescription stimulants, cocaine and

4 methamphetamine. Let's look at methamphetamine and

5 cocaine first. As you can see, there are several

6 differences. Methamphetamine is highly addictive,

7 more potent and has longer-lasting effects.

8 Initially, results in desirable effects like euphoria,

9 increase in attention, wakefulness and self-

10 confidence. There can be risk of infection because of

11 risky sexual behavior or injection practices, can

12 result in severe dental problems, weight loss or

13 cognitive problems and psychosis. Signs of overdose

14 can include hyperthermia, convulsions, arrhythmia,

15 stroke and even death. Years ago, methamphetamine use

16 increased due to production in -- labs. After 2005

17 when congress passed a Combat Methamphetamine Epidemic

18 Act, the precursor chemicals such as ephedrine and

19 pseudoephedrine that were used in production of

20 methamphetamine were regular, and now much of the U.S.

21 methamphetamine supply is from outside.

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

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

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

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

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

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

21 What are the best methods of detecting

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

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

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

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

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

21 If you're new to this area of what FDA

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

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

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

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

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

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

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

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

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

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

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

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

16 You can also send your comments after
17 the meeting as well. We have a website. It's called
18 a public docket through the federal register which is
19 really just the way that people in the real world can
20 talk to FDA. And the docket is open until December
21 7th. So you have about two months to comment on

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

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

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

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

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

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

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

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

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

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

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

11 MS. BENT: Thank you. Dr. Winchell?

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

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

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

1 MS. BENT: Dr. Farchione?

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

7 MS. BENT: Dr. Muniz?

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

11 MS. BENT: Thank you. Dr. McAninch?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 Okay. And so we're seeing responses

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

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

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

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

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

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

1 So as I mentioned, topic one will focus
2 on the health effects and daily impacts of stimulant
3 use disorder. And we'll have five panelists who will
4 start off the session by sharing their experiences.
5 And in about 25 or 30 minutes, when our panelists are
6 done sharing their experiences, we'll move on to the
7 interactive portion of the meeting by asking you about
8 your experiences. So if there's something that you
9 hear from our panelists that really resonates with you
10 or you want to share a bit of your experience, please
11 consider, again, sharing your comments via the web, or
12 closer to the end of the 25-minute period -- maybe
13 around 1:50, 1:55 -- maybe give us a call at the 1-
14 800-527-1401 phone number to share.

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

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

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

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

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

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

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

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

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

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

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

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

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

21 And I think the last two things I would

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

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

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

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

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

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

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

10 Brendan?

11 (End Media 1.)

12 (Begin Media 2.)

13 MS. BENT: Thanks so much.

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

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

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

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

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

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

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

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

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

21 And so looking back now, after being in

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

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

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

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

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

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

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

20 MS. BENT: We can, thank you.

21 MR. SHELDON: My name is Scott Sheldon.

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

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

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

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

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

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

21 MS. BENT: Thanks so much, Scott. We

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 So, you know, my son, also, his
13 heartrate would go extremely high. It would go up to
14 160 and my son actually had a prior stroke. So he was
15 at risk of death when he does these drugs. When he
16 was high one time, he threatened to jump in front of a
17 commuter rail train because he was not Joey anymore.
18 He did not know what he was doing. He thinks he can
19 walk on water, you know? And he could walk across a
20 highway and not even realize the dangers that he's
21 putting his life in.

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

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

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

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

21 And basically, you know, as the mother

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

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

16 And for those of you who would like to
17 call or submit comments to be shared, as a reminder,
18 at the bottom -- as a reminder, here's how to do it.
19 You can either add -- click on the comment box on the
20 corner of your screen, or you can call into the 1-800-
21 527-1401 number to share your experiences.

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

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

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

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

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

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

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

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

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

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

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

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

21 MS. BENT: Great. Thanks, Lyna. That

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 MR. SHELDON: I would be happy to.

20 MS. BENT: Okay, great. Thank you.

21 MR. SHELDON: And this is specifically

1 about the usage, like, the amount of usage.

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

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

1 acquire, which eventually became almost by any means.

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

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

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

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

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

9 MR. WELSH: Yeah. I was listening.

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

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

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

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

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

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

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

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

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

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

1 discussion to the extent possible.

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

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

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

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

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

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

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

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

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

21 MS. MERZOUG: Yes, we do. Thanks,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 So, Jessica, please go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 minutes. Thanks so much, guys.

2 (End Media 2.)

3 (Begin Media 3.)

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

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

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

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

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

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

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

17 MR. RUTHERFORD: Okay. Volume good?

18 MS. BENT: Perfect.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 MS. BENT: Great. Thanks so much,

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

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

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

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

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

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

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

21 And, you know, what I've found through

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

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

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

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

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

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

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

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

21 MS. BENT: Thank you so much, Brandee.

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

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

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

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

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

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

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

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

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

21 My former partner also introduced me to

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

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

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

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

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

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

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

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

5 MR. SMITH: Hello. My names Charles.
6 I'm 43 years old in long-term recovery. I've
7 struggled with stimulant use disorder and alcohol use
8 disorder since before I was 18 years old. That's over
9 25 years for those who don't want to do the math.

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

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

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

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

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

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

1 trying to teach me what to think.

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

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

12 What has not been helpful to me has
13 been the one size fits all treatment approach
14 consisting of substance abuse education and mandatory
15 12-step meetings. Too many times I've walked into a
16 treatment facility and have been offered the same
17 treatment program. Long lectures on how drugs affect
18 my dopamine levels, the dangers of being hungry,
19 angry, lonely or tired, and the importance of building
20 a support network. Then I'm handed a list of meetings
21 and told how many I need to attend per week and off I

1 go.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 moment, I knew I needed to seek treatment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 which is a little bit over four years.

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

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

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

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

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

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

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

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

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

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

18 MS. BENT: Yes.

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

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

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

17 KEVIN: Sure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 Another comment that I see is about a

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

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

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

1 clarifying questions that she might have.

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

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

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

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

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

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

1 Winchell's comment or question?

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

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

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

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

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

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

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

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

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

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

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

21 DR. MUNIZ: Okay. Good afternoon again

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

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

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

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

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

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

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

21 (End Media 3.)

1 (Begin Media 4.)

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

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

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

21 But thinking about what has been less

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

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

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

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

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

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

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

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

1 that transformative impact for me. Thanks.

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

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

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

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

20 MS. BENT: Yes.

21 DAVID: -- calling in from not a great

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

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

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

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

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

1 or what have you.

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

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

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

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

1 MS. BENT: Yes, we can hear you.

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

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

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

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

1 blessed. Like, that the doctor that first put me on
2 it found the prescription that, for me, it's just
3 Adderall. And obviously, if there was a better
4 alternative, like, that would be great. But for me, I
5 have -- I found the right dose and it actually settles
6 me out. So I find a total benefit from the stimulant.
7 So I see where there is abuse potential, but just as
8 the same with opiates and all that, you end up with,
9 you know, there's treatment options which I also deal
10 with as a nurse with patients and I have to beg for,
11 you know, somebody that's got multiple fractures and
12 they're, you know, given half a -- like a tramadol.
13 I'm like, I don't think that's going to cut it -- it's
14 45 or something. But --

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

21 UNIDENTIFIED SPEAKER: Yes.

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

3 UNIDENTIFIED SPEAKER: Oh, I'm sorry.
4 Yeah. I'm sorry. I didn't mean to go off course
5 there, but that's basically what I wanted to say was
6 that it does have a place. Like, it -- for me, it's -
7 - without it, it's the same as if I hadn't had, like,
8 the laser surgery for my eyes. Like, where I can see
9 20/20 now, and before I was 20 -- I forget, 320 and 20
10 -- 280? So I was legally blind and I would have never
11 been able to fly a helicopter. And that was always
12 one of my dreams and I still plan on doing it. So why
13 not?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 MS. BENT: Okay.

21 MR. RUTHERFORD: I just wanted to say

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

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

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

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

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

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

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

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

14 So, Michael, did you have something to
15 add?

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

17 MS. BENT: Okay.

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

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

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

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

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

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

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

1 great.

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

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

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

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

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

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

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

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

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

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

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

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

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

12 DR. MUNIZ: Thank you, Michael.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 I think we actually now have somebody

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

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

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

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

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

1 see plenty of it.

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

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

1 histories and criminality around the substance use
2 histories.

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

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

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

13 MS. BENT: Right, right, right.

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

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

21 MR. RUTHERFORD: Yep. I think in a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 firsthand.

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

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

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

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

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

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

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

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

1 similar to what we already have for opiates.

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

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

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

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

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

1 access to services via telehealth.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 We also appreciate all of our entities

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

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

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

12 (Whereupon, the meeting concluded at
13 5:02 p.m.)

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, IRENE GRAY, the officer before whom the
3 foregoing proceedings were taken, do hereby certify
4 that any witness(es) in the foregoing proceedings,
5 prior to testifying, were duly sworn; that the
6 proceedings were recorded by me and thereafter reduced
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12 action in which this was taken; and, further, that I
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14 attorney employed by the parties hereto, nor
15 financially or otherwise interested in the outcome of
16 this action.

17

A handwritten signature in black ink, appearing to read 'IRENE GRAY', is written on a white rectangular background. The signature is positioned between two horizontal lines that serve as a signature line.

18

IRENE GRAY

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Notary Public in and for the

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JACOB EY RADTKE

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