U.S. FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

PATIENT-FOCUSED DRUG DEVELOPMENT PUBLIC MEETING FOR OPIOID USE DISORDER (OUD)

10903 New Hampshire Avenue Room,

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C O N T E N T S

C O N T E N T S

P R O C E E D I N G S

WELCOME

DR. EGGERS: -- and get started in a few minutes. I do notice that the best (technical difficulty) the planning team, who have worked very hard to put this meeting together. We have Pujita Vaidya, Graham Thompson, Meghana Chalasani, Shanon Woodward, Leila Lackey, Blake Bannister and Arianna Hughes (phonetic).

And so, please, if there's anything you need, let us know. If we have a name tag, we can help you out throughout the day.

We have a full agenda for this day -- can everyone hear me? If anyone can't hear me, please raise your hand? Okay. We have a full agenda for the day. Can I go through the slides?

SPEAKER: Yes.

DR. EGGERS: It works? Okay. After Theresa says some opening remarks, we'll have a bit of background. But our background is brief so that we can get to what the real purpose of the discussion today, is to listen to individuals with opioid use disorder as

well as family members and advocates.

So we will have two discussion topics. One will focus on health effects of opioid use disorder. And then we'll have a lunch. And then we'll come back and have a topic on treatment approaches.

There is time set aside for what we call open public comment later this afternoon. So while the primary purpose of our discussion throughout the day is to hear from individuals, families and advocates about the topics that we have on the table today, we do recognize that there may be others who want to provide a comment or that you in the room may have a comment on a different topic that you'd like to provide.

So if you want to participate in that open public comment, there's a registration sign up form at our registration table. Participation is first come, first serve. And we'll close the registration at the end of the break. The time allotted for each speaker will be two minutes for that.

Okay. Lunch is an important topic. Our -- one of the patient advocacy groups, Addiction Policy Forum, has kindly offered lunch for people who are not

federal, so for people who are individuals, family members and others. There is -- so I believe they'll have that setup in the hallway.

There's also a kiosk at the -- behind this room, where you can preorder lunch for purchase. And we suggest do preorder that and -- at a break or during the discussion sometime find a time to go out and do that if you would like to buy lunch.

Okay. We ask you to please silence your phones. This meeting is being audio recorded. So we are streaming a live audio recording of the meeting, and that will have the presentation slides.

So for you in the webcast, if you're participating, your participation is extremely important. We value your input. We will have every chance for you to participate. You can't see in the room, but I am looking out at a room that is packed with people here to share their experiences. So just know that even if you can't see.

The audio recording and the slides along with the meeting transcript and a summary report will be made publicly available after the meeting.

And because of the sensitive nature of this meeting topic and the importance of gathering candid, meaningful input from individuals who have come forward courageously to speak about living with opioid use disorder, no other audio recording, video recording or photography will be allowed at this patient-focused drug development meetings, that means cell phones as well. So please keep your cameras quiet today.

We ask for your cooperation and strongly request that you respect the privacy of all individuals. If we see anyone recording or taking photos, we will ask you to stop. And if participants do not comply with this request, we will need to stop the meeting. So very much ask for your respect of the people who have courageously attended this meeting.

With that, I would like to turn it to Theresa for some opening remarks.

OPENING REMARKS

DR. MULLIN: Thank you, Sara. And again, good morning and welcome to this meeting. We are very, very happy to have so many individuals and family members and advocates here in the room with us today and we

know that many more are joining us remotely on our webcast. And we thank you very much for making the time to come here today and to share with us and help us understand better kind of what you're experiencing and that we can learn and do better by knowing that directly.

And we're also very happy to have you join us if you're here from other stakeholder groups, if you're here from industry and you want to understand what patients are experiencing directly.

We want to learn more about what the impact of opioid use disorder is for you on your life, you know, what experiences you've had, the challenges you had accessing treatments, your experience with treatment. We understand that opioid use disorder is a very serious condition with physical, emotional and social impacts, that this is a big unmet need for patients.

And we are responsible in our work for weighing the benefits and risks of drugs that companies want to market to patients, and so our getting a better understanding from you of what it's like to live with this condition will help us in doing that kind of

assessment and helping us figure how to encourage the best and most effective drug development in this area to help treat people who are experiencing opioid use disorder.

I also want to thank and acknowledge that we have a lot of representatives, as I said, from industry, other government partners. I especially want to thank our NIDA colleagues for their great help in making this meeting so well attended. Their outreach and planning with us are going to ensure our success today in trying to hear as much we can from as many of you as we can. And the other partners and others who have come here today to hear what experiences people have had.

You know, FDA plays a critical role, but we're not the only player in drug development. And so it's important that we see this high level of interest that we have here today in the room.

And I'm going to just go over a few slides that we have here. You hear us using this term patient-focused drug development. I'm just going to spend a minute to talk about what do we mean by that,

okay.

Well, part of FDA's mission -- we regulate a lot of things, that includes drugs, and part of that job is for us to ensure that a drug that a company wants to market is safe and effective for the use that the company wants to put it out there. And so how do we do that?

Well, we take -- we are very systematic in how we look at these drugs and we need to make sure that the benefits outweigh the risk. So we look at: how bad is the condition that people are experiencing? Are there other drugs available that are really taking care of it, are they meeting their needs? How does this drug -- what benefits does it offer? What are the risks? Could we manage the risks somehow so the benefit outweighs the risk? You know, that's what we have to look at.

And what we find is that people who have the condition are really, like, uniquely positioned to tell us what it's like to live with disease, how bad is it, how well do the drugs that are available work. So they really help to understand those first two areas of

unmet need and severity of the condition. More than the literature or doctors treating the patients, patients directly can tell you things nobody else can say.

So that's really what we understand better now. And we've been trying to systematically collect this kind of information from people who have different diseases and we're learning a lot every time we do this. And we've been calling it patient-focused drug development.

Here's a list -- so as you can see, over the past five years we've been trying to ask questions like this from people with a variety of different diseases which don't have good treatments today. And, you know, people are suffering and they can tell us what it's like in ways that help us be better about making that assessment process and give better advice to companies who are trying to develop drugs to treat those conditions.

And so what we've been learning is people who have the condition are experts in what it's like to live with the condition. This is an industry -- like,

the drug industry and medical product industry, you know, they consult with experts all the time, right? But what we realize now is patients and individuals who are living with the condition, they're experts.

So hearing from them we'll also hear what's not being captured in those development programs, what are we not looking at that we should be because those people are experiencing these things.

And that's really -- we've learned a lot. We've learned sometimes with a progressive condition people would just like to get a good treatment which will stop the condition from progressing any further. In some cases that a relevant kind of a benefit that they would like to have.

We also understand hearing from people lots of time people want to participate and help however they can. You know, there are limits to how much people who have a condition can help, but they want to help as much as they can.

So you're helping us enormously today by being here in this meeting and being on this webcast because you're going to help us better understand, and we're

going to make better and wiser decisions as a result. So thank you again for joining us here today.

And just one more thing I'll mention is that, you know, one of the things we've been looking at as we've been trying to figure out what can we do to help with people who are living with opioid use disorder is also people have asked, "Well, how can you help more with people who are living with chronic pain?" And so this is another condition.

So in mid-July -- on July 9th we're now -- we're going to plan a meeting and we'll have more information about it in the future. But that meeting is going to focus on obtaining the perspectives of people who are living with chronic pain and how is that like for the -- what's that life like for them and what is their experience with using drugs that are available to treat chronic pain and how much more can be done there.

So that's a similar kind of an engagement, but with people who have chronic pain. And we're planning for the future.

And with that, I just want to thank you again

for being here today. We're very much looking forward to hearing what you're going to be able to tell us. Thank you. And I'm going to turn it over now to Maryam.

BACKGROUND ON OPIOID USE DISORDER AND TREATMENT

DR. AFSHAR: Good morning, everyone. Thank you for being here. I am Maryam Afshar. I'm a medical reviewer in the Division of -- better? -- in the Division of Anesthesia, Analgesia, and Addiction Products.

Given the diversity of understanding of the opioid use disorders, I'm going to provide a brief overview of the diagnosis, the impact of the disease and currently available treatment options.

The slides you will see contain more information than what we can cover in 10 minutes, but they will be available on the FDA website for your reference.

I would like to first go over some general definitions and then talk about the definition of opioid use disorder. Opioids are a class of drugs that include heroin, opioid pain medication and synthetic

opioids such as Fentanyl.

Drug abuse is using a drug not as it was prescribed or a substance in order to experience psychological or physical effects. Tolerance is needing to use more of a substance to get the desired effect or experiencing a weaker effect when using the same amount.

Withdrawal is experiencing psychological signs such as irritability or physical signs such as cramps or flu-like symptoms when not using a drug or using a drug to avoid symptoms of withdrawal.

Dependence can be physical or psychological. By physical dependence, we mean that if the drug is decreased or stopped the individual will experience withdrawal symptoms.

Physiological dependence is when the individual has lost control over drug use or experiences psychological distress if not able to use. This corresponds to the familiar term addiction.

The currently used medical term is opioid use disorder. Over the years, some of the terms that we have been using have changed.

The Diagnostic and Substance -- and Statistical Manual of Mental Health Disorder, or DSM-IV, that was published in 1994 had opioid use disorder categorized under two groups, opioid abuse and opioid dependence.

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

Almost 20 years later, according to DSM-V, opioid use disorder is now a single diagnosis with different severities based on the number of symptoms that are present. The signs are categorized into four groups: loss of control, risky use, social problems and drug effects.

Examples for loss of control are using more than intended; spending a lot of time obtaining, using or recovering from the effects of the drug; a strong urge to use; repeated attempts to stop or cut down.

Risky use is using opioids when it is -- it can be physically dangerous to use or continuing to use

despite experiencing physical or psychological problems.

Symptoms of social impairment are like not being able to take care of responsibilities at work, school or home because of opioid use; using opioid despite problems in relations; and not attending to social or recreational activities because of opioid use.

Drug effects are tolerance and withdrawal, which we just talked about.

Opioid use disorder can be diagnosed when two of 11 symptoms are present in a 12 month period.

Mild opioid use disorder can be diagnosed with two to three symptoms. But it's important to note that if those two symptoms are withdrawal and tolerance, that doesn't qualify for a diagnosis if the individual is taking opioid pain medication as directed.

Patients who are on pain medication can develop tolerance, and if the medication is stopped, they can experience withdrawal symptoms. But that does not mean that they have opioid use disorder.

Moderate to severe opioid use disorder

corresponds roughly to what we think of as opioid dependence or addiction and can benefit from medication treatment.

Based on a 2016 national survey on drug use and health, almost 12 million individuals had opioid misuse and over 2 million people were diagnosed with opioid use disorder. As you can see, different surveys use different terms such as misuse, but the bottom line is that lots of people are affected by opioid use disorder.

This is a multifaceted problem affecting many aspects of the individuals' lives, including medical and psychological problems, social and financial problems, even overdose and premature death.

Treatment is categorized in two main groups, behavioral and medication treatment. This is not an exhaustive list of behavioral treatments, but some include cognitive behavioral therapy and peer support groups.

The currently available medication treatments are categorized based on the mechanism of action and includes agonist-antagonist and partial agonist.

Methadone is an agonist, meaning it activates the opioid receptors. It has been available since the early 1970s through federally certified opioid treatment programs or OTPs.

Individuals in OTP will have counseling and regular urine drug screens and initially must show up daily to receive their dose.

Methadone comes in different forms, liquid, powder, diskette and tablet. The tablet form is mainly used in pain management. Like any other medication, there are side effects with methadone. It can cause cardiac arrhythmia. It can also cause drug-drug interactions with other medications. If used with alcohol and benzodiazepine, there is a high risk of respiratory depression and there's also a high risk of overdose when the treatment is stopped.

Now, Trazodone is an antagonist, meaning it blocks the opioid receptors. The extended release form is a monthly intramuscular injection that can be given by the patient's healthcare provider, which can improve access.

Before starting the injection, the individual

must be opioid free 7 to 14 days depending on the type of the opioid that they have been using. Otherwise, it can cause significant withdrawal symptoms.

Now, Trazodone also can cause injection site reaction and there is a risk of overdose after stopping the treatment because of loss of tolerance.

Buprenorphine is a partial agonist, meaning it activates opioid receptors, but it does so to a certain limit. It is prescribed by healthcare providers who receive special training in the office space to improve access. The oral form has been available since 2002. It comes as tablet and film and is absorbed through the lining of the mouth.

A six month implant was approved in 2016 and most recently a monthly injection was approved in 2017. There is risk of overdose after stopping the treatment and also if it's used with alcohol and/or benzodiazepines.

We know medication treatment reduces relapse, improves retention and treatment and decreases drug use; whilst stopping treatment increases the risk of overdose. With treatment, some patients will stop drug

use completely and some will use less.

Opioid use disorder is not simply the use of opioid, but also functional and/or clinical problems due to opioid use. Even though opioid use is characterized by problems due to opioid use, the outcome of treatment has been assessed by looking at the drug use behavior and not the problems and consequences.

Because drug use behavior is not a direct measure of how the individual is doing clinically, meaning how they are feeling or functioning, it is considered a surrogate endpoint.

One thing we are here to understand is: what are the ways individuals decide whether a treatment is working for them, so we can use that in understanding whether or not a new treatment is working.

What brings individuals into treatment? What do individuals, families and clinicians consider treatment success? How do we determine if treatment is successful? Answers to these questions will help us better assess treatment options from a regulatory perspective. We're looking forward to your comments.

Thank you.

(Applause)

THE ROAD FROM PFDD MEETINGS TO CLINICAL TRIAL ENDPOINTS

DR. PAPADOPOLOUS: Good morning again. I'm Elektra Papadopoulos and I led the Clinical Outcome Assessment Staff here in CDER. Our staff serves as consultants to each of the therapeutic area review divisions on their clinical outcome assessments, including patient questionnaires to show clinical benefit in drug development.

So where do we go from our patient-focused drug development meetings? What do we do with this wealth of very important information that we obtain during these meetings? And I hope to be able to answer some of these questions in the next few slides.

So patient-focused drug development meetings are really important opportunity for us to hear from the patients in their own words what symptoms and impacts matter to them most, what they value in treatment and also what amount of change in these impacts would be meaningful in their daily lives.

Drug companies can also benefit from the information that we obtain when they're going about selecting what to measure in their drug developments programs, as well as the FDA, where we can actually confirm whether the outcome assessments that we use truly capture -- truly and faithfully capture the patient's priorities.

Now, importantly, these meetings are a starting point for selecting and developing patient questionnaires and other types of clinical outcome assessments that we use in clinical trials to show benefits of drugs. We strongly recommend that there be further input from patients in the form of qualitative research, and this includes in-depth patient interviews and focus groups, really using rigorous scientific methods.

Now, what is a clinical study endpoint? The term endpoint refers to how a specific outcome will be measured and analyzed in a clinical study. So, for example, an endpoint might be a change in a symptom score using a specific questionnaire, say, at six weeks compared with baseline.

And so this is really important to understand when we're trying to assess clinical benefit. So anytime you read a scientific publication or you're trying to understand the benefit in drug labeling, this is important to understand.

Now, we're going to hear a lot of very important concerns that you have expressed at this meeting, and I wanted to say that not everything that is important will lend itself to measurement as a clinical endpoint in our trials.

So some things that might come out of this meeting could be extremely important, say, as an example, the impact of health on patient's finance -- extremely important, but not really able to show change and really demonstrate a drug effect within the context of a clinical trial.

So here at FDA we have to uphold our rules and regulations and our laws, and within our regulations, are the requirement that our study endpoints need to be well-defined and reliable. And so what do we mean by this?

Essentially, what we mean is that we have

evidence that the assessment is measuring the right thing, which we call the concept, in the right way in a defined population of patients and that the score can accurately and reliably quantify changes that can be interpreted as a clear benefit to patients. So the tool needs to be able to detect change.

It's important to know that a lot of questionnaires that we might fill out in our doctor's offices may or may not be appropriate for use in clinical trials, and so we need to evaluate those through the specific lens of clinical trial endpoints and what is really fit for purpose. It's a specific purpose.

So, you know, I wanted to say also that endpoint development can be a lengthy and expensive process, and I think this really provides an important opportunity for patient groups and stakeholders to come together and support this process outside the context of specific drug development programs so that at the end of the day we can have tools that are publicly available and can be used across drug development more broadly.

So some key takeaways. The outcome of the patient-focused drug development meetings will really support and guide FDA risk/benefit assessments and drug reviews by helping us to understand what symptoms and impacts are important to patients and what they value in treatment.

The information from patients and caregivers ultimately will help us to determine what to measure to provide evidence of clinical benefit, how best to measure the important symptoms and impacts and how much change in those impacts is meaningful to patients.

So in closing, many stakeholders, including drug developers, researchers, clinicians, patient stakeholders can play an important role in developing clinical outcome assessments, including things like patient questionnaires, and there are multiple pathways by which these stakeholders can engage with the FDA. My final slide will show some weblinks alluding to some of these pathways.

And finally, patient-focused drug development meetings are the starting point for developing patient-focused outcome measures and endpoints.

And with that, thank you very much for your attention.

(Applause)

OVERVIEW OF DISCUSSION FORMAT

DR. EGGERS: Okay, I'm back. Again, Sara Eggers. I hope that those background presentations gave you a sense. If you're new to this area of what FDA does and what drug development is, then I hope we gave you a little bit of background on that and especially some of the key terms and words we'll be using today. So thank you very much for that.

I'm now going to kickoff what is the main feature of today's discussion. And I'm going to also -- before saying that, you know, feel free to at any point get up, stretch your legs. If you're meaning to pre-purchase lunch from the kiosk, especially if you're a federal worker and you need to do that, please do so.

The restrooms -- I don't think I mentioned this earlier -- they're located behind this building and then off -- in a hallway to the right you'll find the restrooms there.

But please, this is an open -- as much as we

can make, a federal agency -- be welcoming, we're trying to, so get up and walk around please. Thanks.

Okay. We've been talking about this. There are two main topics we want to cover today. I know there's a lot of words on these slides. But the first topic that will be in the morning is really what's it like to live with opioid use disorder and in particular the health effects and the daily impacts, how it affects -- how opioid use disorder affects day to day life, life on the best days and the worst days and how it has changed over time and what worries you most.

Then when we come back after lunch in the afternoon it's really on current approaches to treatment of opioid use disorder; your experiences and your perspectives on that; what you would like to see in an ideal treatment; if future treatments could be better, how could they be better.

And what factors would you consider if you would ever consider participating in a clinical trial. Clinical trials are very important to drug development and so we would like to know your thinking on those as well.

So here's how it works. For each of these two discussions, we're going to kickoff our discussion with comments from a panel of individuals with OUD. And I'm going to ask Andrew and Amanda to come up at this point.

We have two other participants who are participating on the phone. We are going to try to do as much as we can going to the people on the webcast and we're also using the phone as much as we can today.

So the purpose of the panelist is just to give a story, an experience with opioid use disorder that will help us kickoff a discussion with all of you who identify as individuals with OUD or opioid use disorder or opioid addiction, family and advocates.

Okay. And so it's -- I'll be coming out in the front with a microphone and we're going to have my colleagues have microphones and they will come to you. So if it's -- if you have something to say, raise your hand. We are going to try to get to as many people in the room as we can.

There's a couple of things that help us. One is if you stay -- whatever topic we're talking about,

if we're talking about symptoms or if we're talking about daily impact, to try to think about what that topic is and stay as close to that topic and try to keep your points to just maybe one or two things so that we can go on to as many people who want to speak as possible.

When speaking you may remain anonymous. I mean, you don't have to give us your names. You may state your names if you want. But we don't care what your name is. We care what your experience is. And so that's what's important. The same if you're on the webcast or if you're calling in on the phone.

Okay. Now, you'll see these funny little disks on your tables. This is to give us a chance to do something we call polling questions. And you can -- we encourage you to participate if you're an individual or a family member. They really aid our discussion, because we can't get -- can't -- no one can speak on everything and so you have a chance to raise your hand in some ways by answering polling questions. So you'll use these clickers.

And can everyone click their clicker and just

see that it buzzes? You should feel a little buzz. All buzzing? If no one -- if something doesn't buzz, raise your hand and we'll come with a new clicker. I hear that their battery life is getting to about the point where we need batteries on some.

Okay. So we're going to ask for individual or family members only please. And web participants, there's a chance for you to use your computer to answer these questions too. Web participants please type in. You aren't here to be in person to lend your voice, but we want to hear your comments on the web. Don't worry about us being overwhelmed by comments. We can handle it. We'll try to summarize them as much as possible.

We will occasionally, as time permits, go to the phones to give you another opportunity. Again, please if you're participating on the phone, keep it to one or two things that are on the topic we're discussing.

Okay. You can send us your comments too. We have a website. It's called a public docket through the federal register, which is just the way that people in the real world can talk to people at FDA.

It's open until June 18. So you have two months for you to comment on something if something really was interesting, you got more to say, you can send it in. Or if you have friends, loved ones, others who you think have something to say, you can encourage them. Anyone is welcome to comment, so you don't have to be an individual or a family member.

But I'm going to -- you can submit as anonymous. And I want you to keep in mind that if you submit to the public docket -- that is -- the word public is there for a reason -- this will go on the website. So please think about how much personal information you want to share. And we don't need your personal information. Again, we don't care who -- what your name is or where you live. We care about what your experience is. So keep that in mind.

And so by -- you can just say anonymous, anonymous, or just leave the blank parts for what -- when they ask what your name is.

Okay. So here's how you do it. You can go to this website and click now. And if you go to our webpage -- we hopefully have simplified things a bit as

much as we can.

Okay. There's a few rules that are very important to go through, and I say this with all seriousness about this meeting today. We want to hear from individuals and family members and we really hope that we have made this as welcoming as possible so you feel comfortable lending your voices.

Advocates -- we have a lot of individuals in the room and so advocates we're going to ask you to play it by ear. If you're an advocate and you wear -- we all wear many hates -- if you also have personal experiences, please put that hat on and speak from your personal experiences living with OUD or having a family member.

Everyone else is here to listen. That means FDA and our colleagues from NIDA, they may have some follow-up questions. You might have questions for us and we may not be able to answer all of them, but we are noting all of your questions. And if you come up to us individually, we can take your information and try to answer your question individually, even if we can't answer them all today.

If you're here from a drug developer or a healthcare provider or other interested person, we ask you to just stay in listening mode. Remember that open public comment at the end of the day is where you can comment on other topics.

The views expressed today are personal opinions -- they are not just opinions, they are personal stories. And everyone has their own story and their own perspectives and we respect that. Respect for one another is paramount.

We will have differing views on things today and differing experiences and we will listen to it respectfully. We will not spend too much time on any one given perspective, so we'll be moving along.

Our discussion is going to focus on health effects and treatments. We know that this is a very complicated issue and there are many concerns and many things that -- questions you have and things you have to think about living with OUD and getting the support you need. Those are all important.

We will be focusing, though, on health effects and impacts and treatments. Again, there's the docket

too. You know, you can send us comments through the website for other things.

Okay. Again, for the respect of our participants who are showing great courage in coming here today, no audio recording, video recording or photography.

And please complete evaluation form. We have done 25 meetings that are sort of -- that are very similar to this. We learned from every single one of them, and so your feedback is important.

Okay. So with that said, I'm going to ask you to get your clickers out. Advocates, you can answer the first clicker questions, the first couple of clicker questions too. And I'll then ask you to put them down after a few minutes.

So here's how the -- I will read the questions out, because it can sometimes be wordy. And as you feel comfortable, you're going to click whatever letter I say for that.

So where do you live? Do you live in the DC area, the Metropolitan area, including Virginia and Maryland suburbs? I'm going to guess, Baltimore, you

don't consider yourself a suburb of DC, so you don't have to answer within Washington, DC. So if you live within DC, A. And if you live outside of DC, B.

And I don't see any responses happening. Has anyone -- someone has clicked, right? Okay, so let's see. Okay. You know what? We will come back -- okay, hold -- okay, so we're going to skip the first one. That was -- okay, all we can do -- okay. Try again. We learn from every meeting.

Where do you live, inside DC? Or outside of DC, you will click B. Let me see if we're getting -- I'm not seeing any responses.

SPEAKER: I was thinking about it.

DR. EGGERS: Is it thinking? No. Okay, you know what we're going to do? We're going to skip on the polling questions. We have a lot of ground we want to cover. We'll come back to those if we can them up.

And remember this is a federal government agency, so sometimes our --

(Laughter)

DR. EGGERS: -- technology is -- so let's start with our panel commenters. Just don't pay any

attention to the screens.

(Laughter)

DR. EGGERS: So we have two in person and two over the phone. And I'm going to -- and again, they're going to share their stories to kickoff our discussion. So I'm going to ask Andrew to start. They've prepared about three minutes of comments. And, Andrew, click the red button, bring that microphone as close as you can. You guys will let us know if you can't hear. Okay. So thank you.

PANEL #1 DISCUSSION ON TOPIC 1: HEALTH EFFECTS AND DAILY IMPACTS OF OUD

ANDREW: Thank you very much. So my name is Andrew Kasoulis (phonetic) and I am a person who is long-term recovering from OUD. That's mean, first and foremost, as in "mom has her son back." And I literally still can't even write that without almost crying.

Our family continues to heal. And I've come to understand that where you find recovering people, you find recovering families, you find recovering communities as well. Mom's not the only one that

benefits in the family.

I'm also a grad student at the University of Southern Maine, where I'm pursuing a master's degree in policy planning and management after achieving bachelor of chemistry this past May.

While at USM, I helped co-found the Recovery Oriented Campus Center, the ROCC -- at USM, we are rock stars, rocking our way to college degrees -- and the first of eight main chapters of Young People in Recovery, YPR.

In 2007, however, I developed OUD under the care of a healthcare provider following a work-related back injury that would forever change my life. Nearly four years were spent in and out of physical therapy, undergoing two back surgeries that they don't even do anymore because they have been so unsuccessful.

Often plagued with so much pain that I would sometimes have to actually crawl to the bathroom just to get there. I was quickly prescribed high doses of opioids.

Once a high school lacrosse captain and three times sports all-star and a collegiate football player,

I became restricted to the living room essentially and became a slave to my OUD.

My physicians, like many other physicians, were ill equipped to prevent, identify and/or address OUD. There was no mention that the opioids also treat the emotional and mental trauma that goes along with an injury and I had no idea that there was a component of that. A physical injury that changed my life, you know, had an emotional shift and a mental shift, an emotional trauma and mental trauma.

And then months into my OUD, I was abruptly cut off by my prescriber. With no discharge plan and no insight into other possible services, I experienced intense physical withdrawals, some which were mentioned, which of course included diarrhea and vomiting.

What I was not expecting was the insomnia. I was unable to sleep. And additionally, the feeling of these bugs like crawling underneath my skin and chewing their way through my body, that was something that even if I was told about it, I don't think I could have been prepared for. And far worse were the intense emotional

cravings.

Without opioids I was a failure, I was a loser in my head and I was a roller coaster of rage and depression in my heart. I seemed just completely useless and worthless, weak and pathetic. And what a waste of time and space I was. That was kind of my internal monologue.

Again, I felt a prisoner in my own home and my own mind and I was unable to leave either without the assistance of opioids. And please understand what I mean.

With opioids I was more physically able, sometimes mentally unstoppable and always at a minimum I was emotionally invincible. I was just unfazed by things. My best days were spent laughing and engaging and connecting with friends and people in my community.

I would temporarily feel free and desperately sought that sense of security in any way possible. The opioids indeed became my best friend and my partner.

And at that point, I'm not sure which, you know, life someone would choose. You hear that term choose a lot. And which life would you choose if you're

faced with those options?

Logically, I turned to illicit avenues of satisfying and supporting my physical, mental and emotional cravings. I purchased illicit opioids drugs and developed a criminal lifestyle -- the only community with which I actually felt welcomed, curiously, and a part of, a real part of -- a sense of community there.

I could not keep jobs or relationships. And I became so desperate to find relief from all this pain that I eventually turned to heroin. My worst days included crimes that I'm reluctant to talk about here. I would maybe say them and then say allegedly.

(Laughter)

ANDREW: In short, the use and the lifestyle became incredibly traumatic in and of itself. Emotionally bankrupt and mentally exhausted, I came to a place where the only thing resembling relief came in not living.

Unaware that I had developed a very, very severe depression along with OUD, I attempted suicide through intentional overdose.

What still certainly holds me in terror is the idea of needing further back surgeries, which is almost guaranteed with my condition. Chronic pain is a huge part of my story. I do a lot of yoga and meditation and stretching to manage that.

I certainly hope I can stay on the path of recovery and find effective non-opioid based pain medications, but what most concerns me is the discrimination and stigma that people with OUD face on a daily basis.

And I can tell you about, you know, how I was chained to my past and told, you know, that my present defiance is defined by my past, i.e., the tail wags the dog. If there's not a dog with a tail -- the tail wags the dog; the wake steers the ship.

I think this is best summed up with an experience of a friend of mine and a colleague who landed a fellowship at the White House Office of National Drug Control Policy. He literally went through an NSA clearance, a full NSA clearance, had a badge that said executive office of the president and he could not rent an apartment right here in DC because

he's a person with a felony drug conviction due to his OUD.

He actually had to pay someone -- transfer money to a friend of a friend of a friend in California to sublet a room. And I think that kind of really sums up in a very tangible way what -- you know, some of the things we're dealing with.

Lack of prescriber and public education around OUD continues to prove very negatively, impactful on the lives of millions of Americans.

Fortunately, I am just one of millions of pretty awesome and incredible and aspiring recovery stories, which I really hope that we can elevate and celebrate. And I beg of you in this room to identify as recovery allies. If you're not personally in recovery, to your family, to your friends and in your communities to help raise those stories and elevated those -- that inspiration and that hope because it's happening all over the place.

Again, I'd like to strongly support the FDA's recent initiatives related to OUD and hope that the patient perspective continues to be well represented.

And I appreciate your consideration of my experience and offer myself for any questions that anyone might have here or later. And thank you very, very much.

DR. EGGERS: Thank you, Andrew. Thank you.

(Applause)

DR. EGGERS: We'll save questions for now, but then we'll have the -- facilitate a discussion. I'm going to see if we could have Pamela on the phone.

PAMELA: Hi. I'm here. Can you hear me?

DR. EGGERS: Hi, Pamela. Thank you so much. Yes.

PAMELA: Thank you for the opportunity. Hi, everyone. I am a person also in long-term recovery from opioid dependency. When opioid dependent, opioid used to -- sort of drove my daily activities as I would be drug sick if I didn't first attend to my opioid dependency.

Opioids do not cause confusion if you're taking in appropriate amounts. Most opioids addicts don't use excessively because they know they have to have a continual supply of opioids or they're going to be sick. So you don't ever have extra. Extra is a

foreign concept in terms of opioid use disorder.

The effects of opioid withdrawal were insurmountable. I could not function in my home life or work life if I was in withdrawal. I threw up a lot and then got very dehydrated and was usually requiring a hospital stay to withdraw toward the end.

I remember once trying to stop using opioids while living and working in Paris. I presented at an ER and they quickly whisked me off to a cardiac unit reminding me that I had heart valve problems from having been an injector for so long.

I craved opioids and tried to use before work and after work only, but sometimes would use at lunch or would sneak around to different floors' bathrooms to inject within my workplace.

When someone has an opioid dependency such that they are going to be drug-sick when they don't use, nothing will take precedence over finding some opiates to get unsick. Once unsick, I could perform my job responsibilities and my daily living activities. I had minimal relationships with my family members when I was opiate dependent because they did not approve of my

heroin use. They were not mean, but I was ashamed and could not stop although I wanted to. I decided I would rather die than continue to live a slave to addiction. So I attempted suicide, obviously unsuccessfully.

I had a lot of medical problems from my injecting heroin and cocaine. I was diagnosed with a level IV staph infection and could not walk from sepsis in my knees and back. I had an abscess that had floated to my spine which was also very painful. Because doctors were fearful I would use a PICC line for drugs, they would not put one in to administer the IV antibiotics that I needed. I also had no insurance at the time, so that may have been why they wouldn't put in a PICC line.

They kept having to redo peripheral sites to administer the IV antibiotics which was difficult because of how heavily vena compromised I am. It took me a long time to get rid of the MRSA completely. I had stopped using and got a mosquito bite which turned into a MRSA abscess. I had an ingrown hair which also turned into a MRSA abscess.

I am a reasonably intelligent human being. I

graduated University of Michigan-Ann Arbor, speak 4 languages and hold a master's degree. However, nursing and medical staff often treated me as stupid because of ignorance about the emotional roots of this disease. Establishment needs to stop tying addiction to the intellectual realm. Addiction has nothing to do with intellect.

If anything, strong intellect is a risk factor for the disease of addiction because people who are strong intellectually believe that they can outthink the disease of addiction, which you cannot.

Last week I went to the doctor for an annual physical. I was so excited and proud of the fact that she had no idea that I had been cocaine and opiate dependent for nearly 30 years of my adult life. However, I have advocated doing the lab draws -- I'm sorry, however I have avoided doing the lab draws that they required because I know that once I go to the lab and they can't draw blood out of my arms, 15 years into recovery, I will then be treated completely differently as an addict.

I now am a person in long-term recovery and it

took me really 30 years to get 15 consistent years away from cocaine and opiate use. I am one of the most fortunate. I have a loving family and a mother that never gave up. I come from privilege, education and resources and I was therefore empowered enough to find harm reduction early on, 1994, and believe that the changes in thinking that harm reduction programming provided me were essential to my long-term success and overcoming a traumatic and chaotic addition to opiates and cocaine.

I have broken the generational cycle of chemical dependency in my family. Both my father and grandfather used alcohol. What worries me most about my condition now is the fact that my children are living with the effects of heavily altered genes. I didn't realize that by waiting to have children when I was fairly confident that I was finished using I was then giving my children genes that had been heavily impacted by my very heavy drug use. The cocaine did the most damage, I believe.

I also worry about how much stress I put on my heart with the years of heavy cocaine injection. I

worry most about my children being discriminated against if people where we live were to know my true addiction history. Thank you again for your time today and for the opportunity to speak.

(Applause)

DR. EGGERS: Thank you, Pamela. You can't see us, but there have been -- you've got a lot of head noddings and just reactions that mean that people know what you're talking about and the story you're sharing, so thank you.

Before we let Pamela off the phone I just want to see if there is any clarifying questions from our FDA experts. Okay, all right, then Pamela, thank you so much. Again, you can participate through the webcast and we hope that you keep commenting. That was a very powerful story.

PAMELA: Thank you.

DR. EGGERS: Thank you. Okay, now we're going to go back into the room and we will have Amanda to bring that mike as close as you -- there you go.

AMANDA: I think I'm good, I'm pretty loud. Hi, my name is Amanda. I am a peer recovery outreach

worker for Baltimore County Department of Health, Bureau of Behavioral Health. I am also a person in long-term recovery from opioid use disorder and I am living with and the caretaker of a person with chronic pain that has now begun to acknowledge that they have an opioid use disorder as well.

I started using opioids when I was about 16 years old. I was prescribed them for a wisdom tooth removal and there were a lot of medications in my house and used, started off purely recreationally. By the time I went to college I was a weekend partier, I would say first year of college it became a daily thing.

After a bad relationship I moved from simply using prescription opioids to being an active IV drug user. I had convinced myself that I was the safest IV drug user you have ever seen in your life. I had been able to swindle Sam's Club into giving me those giant boxes of needles. I never used the same needle twice. I had a pill filter. I understood the uses of Narcan and naloxone and I kept them and I always used with a buddy.

And that made me feel like I had it completely

under control. I did have gate (phonetic) shots, so I knew exactly how much I needed in order to function. I was using pharmaceutical pain medication as well as heroin at the same time. I also was using benzos on muscle relaxants. Most of those medications were used when I wasn't able to get a hold of an opioid and I wanted to be able to manage my withdrawal and continue going to school and work, which I was doing full time.

My bad decisions buddy decided to go pick up with me and the person that she used heroin with first had just come back from rehab. The person did not have any money and was willing to do things in order to get heroin that I was not comfortable with and I was watching the car of that transaction happen. I realized that I didn't know how long it was going to be until I decided that that was something I was willing to do.

I went home, I used, I called my parents and that was it. My parents knew that something was going on. I don't think that they thought it was opioid dependency. I believe they thought it was probably alcohol and marijuana and I feel that they had gotten a

hint within the past 6 months that a good quantity prescription medication was coming from my parent's house. I went into treatment, I detoxed and I decided that the only way that I was going to survive was if I was extremely open and public about my substance use and my recovery from the very beginning. I was open and public about the fact that I had gone into treatment. I was open and public about the fact that I was in IOP. I was open with my employer as to why I needed to change my work schedule. So I've never lived anonymously.

It took a very long time for the person that I care for to recognize the similarities between my story and their story. It was -- I would say it was within the past 6 months and it was through the conversation of preparing to come here that they were actually able to sit down and look at what was being on these opioids costing.

They are on an intrathecal spinal morphine pump in addition to oral medication. The pump has been wonderful and when there is no crisis, very little oral medication is taken. The oral medication that they

take is contraindicated to the opioids though. It's a lot of muscle relaxers and benzos.

When it's bad, it's very bad. When the pump isn't enough, when the medication needs to be increased, when we're in the emergency room and they are in full crisis they experience full body muscle spasms. For all of you out there if you've had a Charley horse now imagine your whole body is Charley horsing simultaneously at the same time and it does not stop. We've let them go for 4-1/2 hours. Then you're watching someone scream for 4-1/2 hours.

The new thing that's happened over the past couple of years is that they will actually pass out and stop breathing which is great because we can straighten them out, it's bad because they're not breathing. They will come back around, take that deep breath like they're coming out of water and then seize up again. Large amounts of medication is now needed in order to get those spasms under control because of the tolerance that has built up from years of opioid use. The fear that I have is what happens when I'm not strong enough to not go to the lockbox that I know I'm smart enough

to crack and decide to use again and what do I do if the reason why I'm using is because I'm experiencing the trauma of that person in the emergency room in crisis again. And what do I do when a hospital doesn't do what I know is needed to keep that person out of crisis because they have decided that that pump just magically makes pain disappear, that when they see the amount of medication that this person is on that they don't need anymore.

And now I'm in the hospital for 3 weeks and now I'm watching them scream. It's a vicious cycle. And hearing that person finally admit that being stuck in that vicious cycle of pain has a lot to do with why so much medication is needed. Hearing them say that what happens when the body's tolerance level finally breaks and they just OD. What do we do when that happens and that pump is running and we have no ability to turn it off? What do we do when the pump does stop working because we've watched that happen too and the withdrawal is almost instant because you have a stream, a steady drip of morphine going into someone's spine. I have seen this person try to find the balance between

managing pain, embracing a child with substance use disorder and being strong enough to do what's needed, to do the bio feedback treatment, to do the counseling that's necessary, to constantly be talking to doctors about their condition and find a way to be the best patient advocate they can and sometimes that means sitting in an ER and saying yes, you can try that 1 mg of Dilaudid and know it will do nothing. Thank you.

DR. EGGERS: Thank you, Amanda.

(Applause.)

DR. EGGERS: And now we're going to go back to the phone and have Jody.

JODY: Hi, can you hear me?

DR. EGGERS: Yes, we can. Thank you, Jody.

JODY: Okay, am I loud enough for--?

DR. EGGERS: You are, and you've got a lot of people here welcoming your comments.

JODY: Great, okay, good morning. My interest in the comments today in this topic might be a little bit unique in that it stems from three different view points. One is as an opioid user myself, sometimes scared, angry, confused, about the treatment I receive

as a patient in today's climate being told I need to get off the opioids that I've taken for years as a way to treat my pain and other symptoms, but not given an alternative and left to deal with not only the pain, but now also the withdrawal.

Added to this is suddenly trying to come to terms with hearing things like I'm an addict and an abuser and the disrespect that goes with it when I have been more familiar with people describing me instead as a go-getter and a professorial and other terms. Second is also as an opioid user, but this point of view is one is someone who is often worried that I might be the next one to unwittingly take a lethal combination of prescribed medications or prescribed meds with something like, you know, for a cold and not wake up the next morning and becoming the next statistic.

The third point of view is as the mother of a child who became an addict after being treated with opioids following an automobile accident. She hid her addiction from everyone except a couple of her co-addicted friends and went on to get married, to have two children, get her master's degree and in fact was

working on her Ph.D. when she died of an accidental overdose at the age of 37 after taking methadone and an opioid.

She never asked those who loved her for help, but she was finally looking for it. So I'm tired of the drugs taking away my stamina, making my speech slow, making everything foggy. I could sleep all day, I've gained weight. I've got a constant headache and I never really want to do anything.

I've got scabs from itching and scratching all the time. But without the drugs I can't treat the effects of my medical conditions. I can't perform the functions of my job because I am unable to get to a lengthy meeting or make presentations. I can't go to the dentist, the eye surgeon, which I need to do on a monthly basis for a condition. I can't go to a movie or a concert, take my grandchildren to the zoo or take a long flight to see the ones that aren't local.

My husband has to sleep in another room so at least one of us can get some rest. I've begun tapering off my opioids on my own at the urging of my primary care physician, my pharmacist, my health insurance

company because everyone is making it more difficult to get the prescription, even though the prescribing specialist don't feel that they have a good pain management plan or any other drugs to replace it.

I've had some success doing this on my own. For instance, one dosage was 75 mg daily that I was taking and now I'm down to 30 mg of that drug a week, but sometimes I don't know if the unsettled feeling, the anxiety, the craving, the crawlings and other such things that I often have is from the opioid withdrawal or just from trying to deal with pain. The feelings are there, I just don't know what's causing them more. So now I as a self-proclaimed control freak am not only unable to control my pain, which drives me nuts, but I also can't control my pain control medication either. It's controlling me.

The government regulations are controlling me. The pharmacies are controlling me. Some providers, everybody else is trying to drive my bus and that something that I have always, you know, really held close to my vest as being a control freak trying to do it myself.

So I'm hoping there is a way to work through this crisis providing respect to everybody who has so far been shown so much disrespect in all of this, but only helped to return to a stable, meaningful life and I'm fearful that otherwise too many of us will choose no life instead of a life where we're left trying to navigate without adequate support and assistance where needed because it really does feel that helpless and that hopeless.

DR. EGGERS: Thank you very much, Jody.

(Applause)

DR. EGGERS: Can we -- had you finished your comments, Jody? You were -- okay. Jody, you couldn't see us in here, but again you had a lot of head nods, there are a lot of people who share similar experiences or perspectives as you do and I think we'll -- were there any clarifying questions for Jody. Okay. So can we give another round of applause for our panel members?

(Applause)

LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 1

DR. EGGERS: Thanks. You can sit up here or

you can go back to the table if you like. Okay. Hopefully you heard some of your own experiences and perspectives shared in that. Can I have a -- if you feel comfortable I'm going to ask for show of hands, so however you feel comfortable, whether you're a family member or an individual or even an advocate, speaking on behalf of others, did you hear yourselves, okay I'm getting head nods, so we will take that as yes.

We started a little bit late so we're little bit short on time. I'm going to do a time check at 12:00 o'clock. We might go a little bit over 12:00 because I think we can have lunch in 45. But again, if you need to go use the restroom or any time get up, please do.

We had some polling questions that we tried earlier and so we're going to try them again. I think it should be working. So if you can get those clickers out. These are important to us. Please, if you're looking at the results of these polling questions, they are not a scientific survey in any way, we do not treat them as such. They are just a chance for us to get a sense of who is in the room and who is on the web.

And so it's a -- and so this helps us understand where you're coming from literally and what your experiences are. So where do you live, if you can get to clickers, and we'll try it again. If you live inside D.C. area A and outside the D.C. area B. I'm seeing the numbers go up. That's great.

And if you're on the web, if you haven't taken the polling, then you should be able to do so too. Okay, all right. So I don't see the numbers go up anymore. So we can take this answer. That's a tricky button. I think I saw the majority of people were not from the D.C. area, so, okay, all right. Okay.

So before I -- before you click your buzzers on here I'm going to -- let me read through this, okay, so let's go back to the -- okay. So we thank you for traversing the beltway. And for those of you who had taken the Red Line this morning, a special thank you. I heard there was a fire on the Red Line.

Okay, so next question. Okay. Which statement best describes you? An individual who currently struggles or struggled in the past with opioid use disorder or opioid addiction or abuse, a

family member or caregiver of such an individual or an advocate for individuals who struggle with opioid addiction or abuse.

If you wear two hats, I hope you feel comfortable that you can share that you are that individual or family member. So you can only choose one, so if you wear two, think about choosing A or B.

SPEAKER: Sara, we're going to have to continue this question. This is not going to be as accurate. This only captured some of the responses --

DR. EGGERS: Okay, all right, well let me just make a point here. There are a lot of individuals struggling with opioid abuse and addiction in person and on the phone and we thank you from the bottom of our hearts. We also have family members and people who are advocates. So let's move on, okay.

Now -- from now on I want you to think about yourself or that loved one who has opioid use disorder, one person, so advocates if you only wear that hat then please don't answer these questions. I want you to think of one person, yourself or someone else and how old, what is your age? A younger than 18, B if you're

in the 18 to 29, C if you are in 30 to 39, D if you're in your '40s, E if you're in your 50s, and C if you're 60s or better -- F, yeah, sorry, sorry.

Okay, let's go on to see what we get.

SPEAKER: Okay, okay, okay, okay. We don't have kids represented in the room. Hopefully if there are parents or adolescents on the webcast and you can write in, but otherwise it shows that opioid use disorder doesn't care how old or young you are and so we have a spectrum here. Okay, let's move on. We'll get all the web in a second. Okay. So that's fine. Okay.

So do you or your loved one identify as male -- female -- sorry, female A, B male or C other? Okay. Again it doesn't -- and we have a mix here, let's move on. Okay, how long has it been since you or your loved one first started using opioids of any kind or okay, now start clicking, A less than 5 years ago, B 5 to 10 years ago, C 11 to 20 years ago, D 20 to 30 years ago, E more than 30 years ago, or F you're not sure. And exact numbers don't matter. Just trying to get a sense. Okay. Okay, we have a range of experiences

here and years living with this condition. Okay, I think is that the last polling question? One more, okay.

Have you or your loved one ever been diagnosed by a healthcare professional as having an opioid use disorder or addiction? Okay. What this shows, we have 75% of you in the room have been diagnosed, there is 25% who have not been part of the healthcare system for opioid use disorder, have not been diagnosed for addiction in the room. Can we have a summary of what's on -- okay, we have one more polling question.

Sorry, there is supposed to be a break in between some of these, so. Okay, have you or your loved one ever had the following conditions, acute pain for which a medical treatment was sought. This would be something, broken bones, dental work post surgery. I think Amanda that's -- chronic pain, neuropathic pain, cancer posttraumatic. C, other substance use disorder, alcohol, amphetamines, cocaine, hallucinogens. D, psychiatric or mental health conditions, depression, anxiety, mood disorders or others or E, other health conditions that you think are

relevant to what we're talking about today. You can do more than one, all that apply. While we're doing -- while we're waiting for that, can we have a summary of what's on the web?

GRAHAM: Yeah, we have about 65% saying acute pain for medical treatment, 37% chronic pain, 45% other substance use disorder, 51% psychiatric or other mental health conditions and then 21% other health conditions.

DR. EGGERS: And generally for the other demographic questions were they similar?

GRAHAM: It's very similar, yes.

DR. EGGERS: Were there any pediatric, any kids?

GRAHAM: There were no pediatrics, but there was 37% between 18 and 29.

DR. EGGERS: Okay, all right, okay, thank you. So what this does -- so again it's across the board of the other conditions that you are having to manage and live with at the same time. Okay. What this has done, it's been very helpful for us, even though it's been probably a bit tedious for you to do the polling. It gives us a sense of again who you are without saying

your names and what your experiences are.

Now, let's talk about our -- what we're here to talk about which is what it's like to live with opioid use disorder. We're going to -- I'm going to have to have you do one more polling question for -- but then we'll get into raising your hands and speaking. And the first polling question asks you, I think, about making tradeoffs about the big -- the general bothersome health effects that you are facing and then we're going to get into more specifics.

So if I ask you in general what are the most bothersome health effects related to your or your loved one's opioid use disorder, you can choose up to two things. So it can be the health effects associated with the use of opioids, like we heard Jody talk about some of those. It could be symptoms associated with opioid withdrawal or drug sick as we heard. Symptoms associated with the cravings -- however you think of the word cravings, symptoms associated with that or health effects. Symptoms related to your underlying health condition that we just asked you about or some other big bucket of health effects that we haven't

mentioned.

Okay. Okay. Let's see. And on the web get a summary.

GRAHAM: On the web we have about 70% for health effect associated with use of opioids, about 38% for symptoms associated with withdrawal and cravings and about 27% on symptoms because of an underlying condition.

DR. EGGERS: Okay. All right. So you're dealing with everything and you're having to balance these effects. We heard that nicely from our panelists.

Would anyone like to start with -- anyone like to share more stories about health effects with the use of opioids like we heard Jody talk about one the phone? Anyone like to share some experience about the effects of using opioids that are the most bothersome to you. And we'll go right back with --

ANONYMOUS: Okay. My name is --

DR. EGGERS: And you can state your name if you want.

SHARON: Okay. My name is Sharon and as far

as health effects of using heroin for myself, I used heroin for 40-plus years. I'm now on methadone maintenance program. Thank God. And I still have scars from my injecting heroin, you know, and people notice it. And there was one time I wouldn't leave the house without long sleeves on, 102 degrees I had on long sleeves but I've gotten a lot better about it now, you know. I mean I did it to myself. It is what it is, it's not going to change. So I'm dealing with it and people who don't care to look don't look, you know, so -- you know --

DR. EGGERS: Thank you so much.

ANONYMOUS: You know.

DR. EGGERS: Thanks. One other -- so, right here.

MONICA: Thank you. My name is Monica. I'm a person in long-term recovery. What that means is that I haven't had a mind or mood altering substance since over 12 years. The effects that I still have from the effects of the use of opioids, I have chronic constipation even after being in recovery for 12 years. I still have to take something to assist me in being

able to go bathroom normally. On average I sleep about 4 to 5 hours a night. When I first became a person in recovery I didn't sleep for 62 days even with the help of mental health medications like Trazodone and Seroquel to help me sleep. I may have slept maybe 2 hours per night. So now on average I may sleep about 5 hours. So these are some of the long-term effects of me using heroin. I did use heroin for over 24 years and even being in recovery for 12 years these are some of the long-lasting effects that I still deal with on daily basis after using -- after not using heroin for that amount of time.

DR. EGGERS: So great comments about the -- that the effects can last -- the effects of the opioid use can last well beyond the use of the opioids.

Let's move on and talk about cravings. And first I want to ask, you know, we struggled with this term and so we would like to know how -- what does this term mean to you, this idea, and what words do you use to describe whatever feelings you might consider to be cravings?

AMANDA: Do you want to know in the beginning

like right when you -- like while you were in active use? Or do you want to know what it's like now? Or you want to know both?

DR. EGGERS: Both is good.

MS. AMANDA: It is feeling uncomfortable in your own skin and in the pit of your chest. And in your mind it is the occupying force that is driving you. It is everything hurts and you know that once you get that first bit in it's going to make everything released. It's you're going to not be locked up, you're going to be able to finally relax. That feeling of fight or flight is going to subside, that's in active use.

Today, you know, I'm 7 years in and it's -- a lot of it has to do with when I am put into a fight or flight feeling when I have that feeling of being on edge and I am getting tied again and feeling that push in my chest my brain goes, you need drugs, that's what you need, that's going to solve this problem, and that's the first response. And that's the first response that's going to be in my head probably for the rest of my life. It's quiet but it's there and I have

to use other tools to help deal with that. And the more stressful a situation is, the more physically painful a situation is, the worst that craving feeling has.

When I was getting ready to have my first child, you know, you've got moms that are concerned about everything under the sun when they're about to have a baby. My concern was how am I going to handle being in pain because it's going to cause craving and I know that, and can I do this without an epidural and without pain medication afterwards because I am petrified of putting that in my body. Not because of the baby but because is that going to be the thing that sets me off.

DR. EGGERS: Thank you, Amanda. A lot of head nods, agree with that distinction. But anyone else like to follow-up on that?

ANONYMOUS: I have a question.

DR. EGGERS: Yeah.

ANONYMOUS: I want to know why -- how do I put this -- I feel as though if we have something -- if we have something as beneficial to the cocaine as we do to

the heroin, I don't think we will have as many users on cocaine. You know what I mean? To buying 1 cap of heroin you would buy 10 things of cocaine, you understand what I'm saying? I'm saying is that if you use both heroin and cocaine, right, I think if we have something just as equal to the heroin as we did to the cocaine, I don't think it could be justified. You know what I mean?

DR. EGGERS: That's a very important point. I think it's a bit beyond what we'll be able to talk about in-depth today but we've noted that you've raised the point about the challenges of having them both together and the challenges of fixing either one of them. So thank you for the comment.

DR. HERTZ: Sara?

DR. EGGERS: Yes.

DR. HERTZ: Hi. This is Sharon Hertz. I can say that, well, today we're focused on opioid use disorder. We are concerned about the fact that we don't have treatments for other types of substances with similar problems. And it is something that we're working on with a number of other groups as well to try

and see what we can do to help facilitate management of those disorders as well.

DR. EGGERS: Thank you. Okay. One other person about cravings, we have right up here.

DENISE: Hi. I am Denise REDACTED, a parent, caregiver. So I just thought I'd get a little insight as to what that looks like for us to see our child with cravings. In the beginning we can't wrap our minds around it, but as we travel that journey it was the first time that I looked at that desperation and really understood what my son was going through. So those behaviors instead of me saying how could he do this to me, I realized that it was a symptom of their illness and it allowed me to really put myself in their shoes and allowed me to be part of that solution. So instead of judging him and shaming him I did a better job of understanding what he was going through in trying to lift him up, and that was really important for us. So I hope that makes sense from a caregiver perspective.

DR. EGGERS: Thank you. Very important perspective. Okay. Yes, go ahead, Andrew.

ANDREW: I just want to share a story, kind of

experience I had a few years ago that smashed me in the face one day. So I appreciate fitness, I try to stay, you know, physically in shape. When I don't take care of my body it degrades very, very, very quickly and I end up in a lot of pain and bad things happen.

So I was meal-prepping, trying to eat healthy as well and one day, you know, life happened and I couldn't bring my lunch to school and so I was walking down to the local pizza joint thinking I'm going to get grilled chicken Caesar salad, you know, because it's, you know, because fitness and I want to stay in the track of health and wellness and I didn't even get to the door and I started like sniffing in the air and I was just like, oh, gees. You have a grilled chicken Caesar salad because fitness and then as I opened the door it like really hit me square in the face, this intoxicating scent of pizza, right?

And then I looked over and I saw glistening in a case under this warm heat lamp, and it was summer time but I still wanted to just kind of like curl up underneath that heat lamp with a pepperoni pizza and just kind of like snuggle with it and all of a sudden I

was like off to the races in my head battling just like, no, I'll be -- you know, fitness and you're doing so good and you know what happens, Andrew, you know, you eat one slice of pepperoni pizza and then you're like getting buff chick wraps and, you know, you're into the cookies and --

DR. EGGERS: I think it's a parallel story.

ANDREW: Yeah. And as I'm sitting there, and by the way I got up to the line and I was like I'll have a grilled chicken Caesar salad, while I wait I'm going to have a slice of pepperoni pizza because I'm not as strong as I'd like to think I am. But as I am standing in the line waiting for my food it hit me that is lunch, one afternoon. You want to talk about cravings. That was just one afternoon lunch.

DR. EGGERS: Yeah, that resonate, that resonate, yeah.

ANDREW: And I was like, whoa, this might apply a little bit and I shared that story with law enforcement, doing trainings with law enforcement because they seem to be able to relate to that story quite a bit.

DR. EGGERS: Thank you, Andrew.

ANDREW: Thank you.

DR. EGGERS: I'd like to see if there's any webcast comments on craving?

GRAHAM: We don't have webcast comments on cravings. We see people who are just echoing what we're hearing in the room.

DR. EGGERS: Okay. Great.

GRAHAM: We have a couple on some of the other health effects like social and emotional effects that they're feeling and experiencing.

MS. EGGER: Okay. Great. We will be talking about the social and emotional effects in a little bit. Right now I'd like to go on to -- yes, Elektra. I'll turn you, right.

DR. PAPADOPOLOUS: So I was wondering if maybe we could see a show of hands of, you know, how many think that cravings is the sort of most accurate term and the one that you use the most and -- or how many would use a different term to describe that sensation.

DR. EGGERS: So if you know -- you or your family member or your -- in your support group use the

term cravings, can you raise your hand? Okay. Do you use a different term, raise your hand? Okay. Let's just go quick round. Yell out what you --

SPEAKER: Obsession.

DR. EGGERS: Obsessions, okay. Here, what do you -- triggers. Okay. Other words?

SPEAKER: Urges.

DR. EGGERS: Urges. Okay. Great. Thanks.

ANONYMOUS: Feening is one that comes to mind.

DR. EGGERS: Oh, someone --

SPEAKER: Oh, okay.

DR. EGGERS: Okay, which, what word?

ANONYMOUS: Feening, as in feen, yeah.

DR. EGGERS: Feen, okay, okay. Great. Yell out another one? Okay. Go with the microphone.

ANONYMOUS: (Inaudible)

DR. EGGERS: Yes, go ahead.

ANONYMOUS: It's more the process, it's not just the substance craving itself. It's the act of doing it, preparing it, consuming it, the immediate relief afterward. You know what I mean? Like it's this huge build-up and then, you know, volcanic

eruption type of thing. It's like -- that all alludes to the craving, I guess, that goes with it.

DR. EGGERS: Great. Thank you so much. Okay. One more, one more here.

ANONYMOUS: Got to have it mean you got to have money and you got to scrub. Suppose you don't have money to get it, you're going to go get sick.

DR. EGGERS: Okay. Yes.

ANONYMOUS: As simple as that.

DR. EGGERS: Thank you. That's an important point. One more here.

ANONYMOUS: Anticipation.

DR. EGGERS: Anticipation. Okay. Okay. All right. One more. One more and then we're going to go onto withdrawal or drug sick.

ANONYMOUS: I just want to point out the craving thing when it comes to methadone is similar to opioid cravings with methadone and it can be described in a different manner.

DR. EGGERS: Okay. All right. We're going to talk about methadone in the afternoon, and please raise your hand again. There's two same hats so I am going

to -- you should have worn different hats. Okay. Let's move on to thinking specifically about reducing use or abstaining from opioids. Whatever terms, we've heard terms withdrawal, we've heard term drug sick, it could be things in here that look like cravings to you. But of these effects here we'd like to know what are the most bothersome symptoms for you -- effects for you. So if it's fatigue or lack of energy. Oh, you could choose up to three things. Okay.

Fatigue or lack of energy, A. If it's cognitive effects, so things that happen -- your brain's not working the way you want it to be, you know, you can't concentrate or we call brain fog. Is that working? Okay. That's B. Anxiety, irritability or jitteriness, and I think this might be the first time we've used jitteriness as an FDA term but I think you get the point, that's C.

Depression, apathy, boredom, D. E would be insomnia or sleep issues like we heard about. F is nausea, vomiting, or diarrhea. G is flu-like symptoms such as fever or body aches. H is pain of any kind. And I would be something else. So again what bothers

you the most? This is what we want to know. All of them. Okay. We'll take that point that if you could choose all of them you would. What are we seeing on the web for this? Just generally, what's the most?

GRAHAM: Sorry. It looks like it's -- come back in a second.

DR. EGGERS: Okay. I'll come back. Okay. I think we can close out the polling here. Okay. Okay. It's all of them, right. Okay. It's all of them, F. Interestingly nausea, vomiting, and diarrhea has the -- is amongst the lesser things that you're experiencing. It's outweighed by -- here in the room by anxiety, irritability, jitteriness, depression, apathy, boredom, or insomnia and sleep issues. Okay. And on the web did you want to --

GRAHAM: The top right now is cognitive effects, anxiety and irritability and then flu-like symptoms and the rest are roughly around the same.

DR. EGGERS: Okay. So very similar to here.

Let's take something -- let's take anxiety and in here who -- for someone who picked that, can you explain that feeling to us? Right there. Okay. We'll

go with the microphone.

ANONYMOUS: It feels like -- like if you're going to get it, I mean if you're going to get the drug or something like that.

DR. EGGERS: Okay. So it's anxiety overall, yeah.

ANONYMOUS: Overall, yeah.

DR. EGGERS: Overall. Okay. Anyone else? Okay. So the -- in the cap?

ANONYMOUS: Yeah, it's like if you don't have the money you can go through anxiety and then the jittery part is like when like somebody described feeling something crawling through your skin and it's just -- and being irritable.

DR. EGGERS: Okay.

ANONYMOUS: It's just -- it's overwhelming.

DR. EGGERS: So you're really tying in the -- how difficult it is to tease apart feelings you get about when am I going to have -- when am I going to have the next chance to use versus the feelings that you get that are symptoms that's probably hard to tease out, it sounds like.

ANONYMOUS: No. It's more about like being scared that you're not going to get it and that brings the anxiety in because you don't want to be sick.

DR. EGGERS: Okay. Okay. We'll go here and then we have to --

ANONYMOUS: You can also have anxiety attack --

DR. EGGERS: Okay.

ANONYMOUS: -- like a bomb, bombing. You know what I mean?

DR. EGGERS: Yeah, yeah.

ANONYMOUS: Because I scared a lady half to death on a train one day.

DR. EGGERS: Okay.

ANONYMOUS: And all what I spit out was (inaudible).

DR. EGGERS: Okay. Uh-huh.

ANONYMOUS: And it was shaking.

DR. EGGERS: Uh-huh.

ANONYMOUS: Scared her half to death.

DR. EGGERS: Yeah.

ANONYMOUS: She thought I was dying.

DR. EGGERS: So there are times when a panic attack can happen that goes beyond just --

ANONYMOUS: Right.

DR. EGGERS: -- the anxiety you feel every day. I think we have Mitra who has a question.

DR. AHADPOUR: Just some clarification. So you have the anxiety because you're thinking of -- maybe because the question says reducing use. So you have that anxiety that you want to get the opioids. What about anxiety before the opioids? Did you have anxiety before using the opioids and you kind of self-medicated yourself with the opioids?

DR. EGGERS: Okay. Getting a lot of head nods. Anyone to explain and we'll go here and then we'll go back in the back.

ANONYMOUS: So my experiences is that prior to getting clean and staying clean, those instances of trying to stop and stay stopped, you handle anxiety because you're familiar with the feeling of anxiety that, you know, when you're starting a new job, when life is good, when life -- you know, you're doing different things, you feel this and experience anxiety

in your body.

However for the addict mind it is resemblance of withdrawal symptoms. So even though I may not be drug sick, even though I may have not used in 30, 60, 90 days because my body does not understand -- well, rather my mind does not understand that my body will experience anxiety the same way I experience withdrawal my mind will tell my body that I need drugs to manage the anxiety that I'm feeling which leads me back to using. So it's the miscommunication between mind and body because habitually when I feel that it's associated with the fact that I'm about to go (inaudible). But when you're not using for long periods of time and you feel those anxiety feelings or you feel just the irritability, the jitteriness, the mind associates it with the fact that I'm in withdrawal and because my mind can be stronger than my body it will direct me to go use when that's not even my purpose of going outside that day.

DR. EGGERS: Thank you so much. Thank you. We'll go back there.

ANONYMOUS: Yeah, I would kind of characterize

my anxiety as just the symptom of the underlying trauma that I experience which is actually something I'm a little shocked that I haven't heard yet as trauma being a huge predictor of developing a substance use disorder particularly an opioid use disorder and that's my experience. As 16 years old I was physically assaulted by older man. And when I was 23 years old I was assaulted while under police custody by court officers of the Nassau County prison system. So my anxiety is directly associated with the trauma that I experienced and I constantly relied on self-medication through cannabis to deal with that anxiety successfully but without developing any other health coping mechanisms my substance experimentation gravitated towards opioids eventually which were far better at alleviating anxiety in the short-term than cannabis was but once they stopped working they stopped working and that's all I wanted to continue to do, was figure out a way to get them to work again.

DR. EGGERS: Thank you. You're making this very important point about how complex the issue. If you can address your OUD there may have been a reason

that you had OUD and so the needing to understand what is what and address both of those at the same time.

Okay. We have lots of hands up. We're going to go here and then -- and then I want to -- if there are people on the phone who would like to talk about a health effect that you haven't heard much about or your experience -- or it's really, really bothersome to you, please feel free to join the phone. There's some instructions on the webcast. Okay.

SHARON: Okay. This is Sharon again. I had anxiety as a child. I was shy as a child which when I got like about 14 it led me to alcohol because the alcohol like kept me from being shy, I became more outgoing. And the first time I tried heroin I didn't graduate from one to the other, I went from alcohol to heroin and the heroin seem to have done a better job with my being, you know, shy, you know, I became the life of the party.

So I tended to stick with that because I didn't like being withdrawn, you know, and hating to go out of the house not wanting to be around people, feeling that everybody was looking at me. So the

heroin took care of that.

DR. EGGERS: Thank you. Thank you. Okay. Do we have anyone on the phone?

GRAHAM: We are showing no comments from the phone line.

DR. EGGERS: Okay. If you want to come on the phone then just dial in. There was some -- okay, in the back there, Shanon. Thanks.

ANONYMOUS: So I was diagnosed with depression and anxiety before my drug use and that manifested into eating disorder which then manifested into opioid for me. So my anxiety before was a black hole and then the using and also the withdrawal exacerbated that issue as well. So anxiety for me is like a deep, dark hole, wanting of something I can't quite understand and then nothing in this world would satiate that anxiety, and trying to reach for something but wanting nothing to do with the process of fixing it. So, yeah, that's about -- that's about anxiety for me.

DR. EGGERS: Thanks. Any other symptoms that you want to follow-up on before -- yeah, go ahead, Elektra.

DR. PAPADOPOLOUS: I just wanted to hear a little bit more about the insomnia or sleep issues peoples experience and whether that's related to any other symptoms, perhaps anxiety, just, you know.

DR. EGGERS: Okay. So is your fatigue or sleep issue a symptom of something else that keeps you up at night or other thing?

DR. PAPADOPOLOUS: Well, it was sort of -- it was kind of a chicken and the egg problem, is sleep related to the anxiety and then the fatigue after that.

DR. EGGERS: Okay. Any comment? We'll go back there.

ANONYMOUS: As far as anxiety, as a survivor from being molested at a young age and I suffered with anxiety and then couldn't figure out what I wanted to do in life, I was dealing with death and using drugs was the anxiety got ever worse. I didn't even know I was going through that till I was diagnosed from a doctor, you know. So relating to what the young lady over there said if I'm a child, you know, just you grow up with it. You don't know how to feel, what you're feeling, you know, you just don't know.

DR. EGGERS: Yes, over here. Shanon?

ANONYMOUS: I think -- been thinking about reducing or abstaining from opioids. My mind goes to having to think about, you know, the trauma that I went into. So, you know, not being able to use is meaning having to -- having my life in my face again and in the past experienced maybe PTSD or something, depression, boredom when I'm not going to be able to have drugs I'm just going to have to really be back into with the trauma.

DR. EGGERS: Thank you. Thanks. Okay. So I do need to take a time check because we are at 12:00 o'clock. Can I go 15 minutes into lunch? We'll let lunch go a couple minutes after, is that okay? Are we -- okay. This is an important topic.

All right. We're going to take a few more and then I do want to get to another polling question that very important. So we'll go here, we'll go with you and then you and then we'll --

STEVEN: Yes, how are you doing? My name is Steven (phonetic). During my drug use sleeping was hard for me. I would have naps. I wouldn't sleep. It

will be more so as naps and that led me having more anxiety.

DR. EGGERS: Okay.

ANONYMOUS: You know. So it was very, very hard for me because I just like, I could not sleep, right now I still suffer from it.

DR. EGGERS: Okay.

ANONYMOUS: I cannot sleep. I had to go through various tests, you know, trying to find out why couldn't I sleep a whole night. I take naps, I take 15, 20-minute naps.

DR. EGGERS: Okay.

ANONYMOUS: Every night.

DR. EGGERS: Short naps. Yeah. Okay.

ANONYMOUS: Short naps.

DR. EGGERS: Okay. Right here. And then I understand we have someone on the phone -- two people on the phone. Okay.

YVONNE: Good morning. Yvonne. You asked about the anxiety and how it effects the sleepness. I used to be anxious and also have the racing thoughts, so that would keep me awoke with my thoughts racing on

back then what's going to happen, what I'm going to have to do, all that kept me -- the thoughts wouldn't stop. So that's how my anxiety affected my sleepness.

DR. EGGERS: Thank you very much. We have on the phone -- operator, can we have a caller, please?

GRAHAM: Our first caller is caller number one. Your line is now open.

DR. EGGERS: Thanks.

ANONYMOUS: Yes, thank you for the opportunity to share. I just wanted to say the protracted withdrawals, the long-term withdrawals are the things that made it so hard for me and even now after being on methadone and then Suboxone for years. I reducing my dose I still have issues, but like I detoxed a bunch of different times. And I could get through that first week of being sick, but I couldn't function the longest ever when it was like 5 months and still I will have nights of what I call are skin crawls where you can't lay still, you never mind, go to sleep, your body just jerks and, you know, anxiety, anxiety attacks. You feel like a cat on a hot tin roof and it went on and on and it never did get better. I know some people get

off of opioids and apparently they do get better but I had to go in medically assisted treatment to get my life back.

DR. EGGERS: Thank you very much. Thank you. And we have one more caller. Operator?

GRAHAM: Next comment comes from caller number two. Your line is now open.

GERI: Hi, my name is Geri Lynn Utter, I am actually a doctor of clinical psychology and, I guess, a caregiver. My mother has suffered with opioid use disorder for 20 years. So just to kind of, you know, in listening to everything, I feel like I am listening to my mom and then as a professional, somebody that specializes in addiction, I can just really empathize and what I just wanted to kind of reiterate as far as the comorbidity with posttraumatic stress disorder, anxiety, it's something that we see very commonly, depression.

And, you know, when you have years of drug abuse I just kind of want to reiterate to you that there is actual brain chemistry that changes and the way that your brain function, functions changes. So

it's not a matter of, you know, of will power and, you know, polling yourself up your bootstrap, this is an actual brain disease. So everything that you are talking about as far as trauma, anxiety, depression, it's all symptomatic and reflective of the disease of addiction. So medication-assisted treatment somebody mentioned and if it works for you, if Buprenorphine or methadone, if it's something that works for you and helps to manage, you know, cravings, anxiety, then, you know, it's something that's actually helping with your brain neural transmission.

So, you know, just to kind of echo what folks are saying, I just want you to know that, you know, as somebody in the field, but also as a child of somebody who is addicted, I empathize with you and I think, you know, from a care standpoint, you know, we can't just look at opioid use disorder linearly we have to look at all of the mental health issues that come on top of either being addicted for many years or using opioids to self-medicate depression, anxiety and trauma.

So when you do enter into treatment, you know, opioid use disorder is just one thing that you are

going to work on, you are going to have to really work on everything in order to feel whole or whatever your normal is again

DR. EGGERS: Yeah. Thank you.

GERI: So I just kind of wanted to share that and thank everybody here today for participating because I really empathize and understand your pains.

DR. EGGERS: Thank you so much. There were a lot of head nods in the room, you know, you can't see us. It's going to be a nice transition to our discussion on treatment approaches and what you look for out of treatments in the afternoon. I do want to make sure that we get to one more polling question because that's important. It's not thinking so much about symptoms, but about how these -- what OUD has, that there are bigger impacts. We have -- yeah, just we will take one question -- one comment and then we will -- you can -- we will do the polling questions.

ANONYMOUS: To be in recovery, it didn't take us overnight to get like this, so when you get cleaned it's going to take you some time --

DR. EGGERS: Yes, yes.

ANONYMOUS: -- to get the brain back and that normal feeling because some of us don't even know what normal feels like.

DR. EGGERS: That's right.

ANONYMOUS: Because we was polluted with drugs for many years and I say that because with me when I got cleaned a lot of health issues fell into play.

DR. EGGERS: Yeah.

ANONYMOUS: They were there all along, but self-medicating --

DR. EGGERS: Yes, thank you.

ANONYMOUS: And sleeping is one other thing you go through.

DR. EGGERS: Okay. Thank you so much for that. So then transitioning into these impacts on your or your loved ones daily life, okay, you can chose up to three things. So this is what's the most -- what were the -- where are the biggest impacts for you, okay. A, your ability to carry out important activities like go to school, work, do hobbies that are really important to you, be on the sports teams. B, ability to care for yourself or your family. C, having

days when I am barely able to function at all. D, concerns about risks to -- risks to safety of self or others. E, impact on relationships with family and friends. F, stigma or discrimination. G, worry about the future such as worrying about relapse or overdose or other things such as your family. H, emotional impacts such as self-esteem, self-identity or I, other impacts not mentioned. This is a hard question and I promise, we will stop and have a break in lunch after -- after this.

You have a question? There were -- let's just see what the polling questions come and then I will come to you. Okay. So let's -- is anyone still working, still thinking? Okay. Yeah, okay, let's give a few more minutes.

ANDREW: Okay. Can I share something?

DR. EGGERS: Yeah, go ahead, Andrew.

ANDREW: So it's really interesting that trauma came up and I love that it did, I have this, I don't know if it's my own or if it's just -- if it came from somewhere else, but I just wildly, you know, radical idea that recovery actually starts with the use

posttraumatic event and you hear this a lot, you know, sexual abuse, physical abuse or some traumatic event that kicks off, seeking a relief from that.

The chemistry degree, my capstone I actually did around the brain chemistry of trauma and how it has very causal links to, you know, neurodegenerative diseases such as ALS, Parkinson's, Alzheimer's, but also a lot of substance use depression, anxiety, I was really curious to see how that same biological process is playing out in other ways in our body and come to find out that your skin cells actually react to the sunlight in a similar fashion.

The UV light breaks apart the skin cells creating free radical oxidatives that go on and just kind of bond with anything and react with anything in its path and creating a lot of nasty toxic things including sunburns. And if you get repeated overexposure, cancers, skin cancers. Trauma is in short the sunburn of the brain.

DR. EGGERS: Okay.

ANDREW: And we are finding our sunscreen in drugs and alcohol, it just so happens that it's not an

effective or sustainable, you know, solution. And so we are really like I really hope we can tease out some, you know, productive and positive sunscreens for this brain trauma --

DR. EGGERS: Thank you for the analogy.

ANDREW: Thank you.

DR. EGGERS: Thank you. Okay. So thinking about the big impacts, it's everything, you have identified everything and nothing stands out more than -- it sounds like it would be -- this was probably a very difficult question, so we appreciate you answering it. But the emotional impacts, the stigma or discrimination which we heard about, the ability to function, having days where you are barely able to function at all, let alone go to work. I would like to hear what the effects are, the impacts on the phone are.

GRAHAM: Yeah, so very wide dispersion of results, we have about 46 percent for ability to carry out important activities, 42 percent with having days not being able to function, 50 percent family and friends and then about 30 to 35 percent for stigma,

worry about the future and emotional impacts.

DR. EGGERS: Okay. So I want to -- I am going to close with one question which is it surprises me that, B, ability to care for myself or family was not as high of a choice for the folks in the room. Does anyone have, from your experience, a possible reason why you didn't put that -- you put other things, but not that one as your top. We'll go back there and we will take one more and then we'll close up for lunch. Go ahead.

ANONYOMOUS: Particularly these other things were a little more salient, I mean, I wouldn't deny that the ability to care for myself and family is an important thing, but in particular I identified stigma as the most important thing because quite frankly opioid use disorder is not going to make a tremendous progress towards a solution until we remove the criminal justice component from it. Sure there are crimes that are committed during the process, but if by definition certain characteristics of this disorder are inherently criminal, that's never going to end without that criminal justice component removed.

DR. EGGERS: Okay. Thank you. Good point, good point. We will go back here and then we will take two more because you had your hand up and then we will go to you and then we will -- and then we will have to go to lunch.

ANONYOMOUS: I am designing a program to educate judges --

DR. EGGERS: Okay.

ANONYOMOUS: -- about opioid use and so I would be interested if you can have a chance to ask the people in this room who have used or are using opioids whether they ever had experience with the law, whether -- an arrest for example.

DR. EGGERS: Okay. Can we do this, just to show a hands, are you comfortable raising your hands if you have had an experience with the law?

AMANDA: And you should come talk to me when you are done this because, yes, you should come talk to me.

DR. EGGERS: Okay. Okay. All right. So we are going to move on. We have -- we're going to go with you and then we'll close with you, go ahead.

Right here the -- no, with the dark shirt on.

ANONYOMOUS: Yeah, my question is the ability to care for my family when actually watching my mom trying to raise nine kids by herself being abused by my father and that led me to go out and sell drugs and being in prison, so.

DR. EGGERS: Okay. All right. So that's a different perspective on being able to take care of yourself and family. We're going to have -- we're going to go there.

ANONYOMOUS: No, I think you are absolutely right, you know, when you said that, you are right that it should be A, but for me it was not being able to have meaningful relationships. But maybe it's part of the opioid use disorder disease that, my brain disease doesn't even make me think, I need to take care of myself, you know what I mean, I am just wondering if that's a part of it, that it should be A, but it's not, you know.

DR. EGGERS: Well, there was no judgment in my question, it was just an observation. Okay. Let's see. Since we have heard from, I am going to go to

this gentleman, we haven't heard from and then we'll go summarize anything on the webcast.

WAYNE: My name Wayne. The reason why I had the ability to consume, I was addicted to dope. I let my mother, I gave her the assets, my bank account, so --

DR. EGGERS: Yeah, yeah, thank you. Yes. Okay. So we have one question, then we'll summarize one quick follow up.

DR. AHADPOUR: So one quick question before lunch. Worry about overdose, can I see a show of hands who are worried, I mean, just individuals, caregivers that are worried about overdose.

DR. EGGERS: Even if you are in recovery. Okay.

DR. AHADPOUR: And any solutions for it. May be afterwards.

DR. EGGERS: Let's -- we can see if we can come afterwards. Here is what I wanted -- there is a couple of things, if you feel comfortable on the webcast typing this in over the lunch time or some time or if you feel comfortable submitting comments to our

public website, what we haven't talked about was relapse and your experiences with it and what -- maybe we can get to that a little bit of that this afternoon. We also haven't talked about OUD during pregnancy. If you have experiences or perspectives on that, please share those. And then what worries you most about living, I think we've gotten through that in the conversation. So summary of the webcast, please.

GRAHAM: So we heard several people talking about why they didn't chose ability to care for myself or family, they said they had other things they consider more important such as their worries about work and staying employed. Other people said that they just chose options that they felt actually defined caring for self and family such as days not being able to function or inability to go to school or work and for a lot of other people talking about some of the trauma that they had experienced and what they started using opioids for to try and deal with it and then other people also echoing some of the incidents with the law and other types of issues like that.

DR. EGGERS: Okay. Thank you. You can keep

the webcast coming in. We're going to close for lunch now. We will give you the full hour. And so we will start promptly at 1:15 and we'll make up time in the afternoon.

First though, can I have the -- everyone give a round of applause for just fantastic input today this morning.

(Applause)

DR. EGGERS: Thank you very much. If you have any questions, come find Pujita or myself and we can answer them. Thank you.

LUNCH

AFTERNOON WELCOME

DR. EGGERS: Okay. All right. Thank you everyone for a fantastic morning discussion that covered a lot of issues that are very difficult to talk about and especially when we say you have got an hour go. So I want to thank you for the rich insight you gave at that meeting, for that discussion.

I also wanted to point out and just as a reminder that we did talk about sensitive issues such as suicide attempts and suicide thinking and I just

want to remind everyone that there is help, seek help if you need it, this is the suicide prevention lifeline, it is very important. And I also wanted to remind you about sending comments to the public docket, to the website, again you can submit without putting any names associated with it or any -- you don't have to give us any personal information about yourself.

But you have more to say and I know this about the first topic. And if you are on the webcast, we know you have more to say about that. So please consider doing that. You have until June 18. Okay.

PANEL #2 DISCUSSION ON TOPIC 2: CURRENT APPROACHES TO TREATMENT OF OUD

DR. EGGERS: And now we are going to move into a discussion on current approaches to treating opioid use disorder. And that is there are some -- there are the medications that we will talk about, we will also talk about other treatment or therapies that you do and how they work together. We won't be able to get into every aspect of the management of OUD. We will be focusing primarily on the medical treatments and we would like to know how well those are working for you

and what the biggest problems you faced in using these treatments.

We'd also hope to get out of this afternoon what you find to be the most effective in helping to manage your OUD, again with a lot of focus on medical treatments and the aspects of medical treatments but also other things knowing that it is a very -- that it takes a village to help. And what you think about when you are making decisions about seeking out or using treatments or not using treatments.

I understand we have particularly some people on the webcast who are not currently utilizing treatments and so if you are on the webcast listening, please type in -- type in your thoughts as we get to those.

I am going to ask the panelists to come up, Paul, Carol, Jan and David is on the phone. Oh yes, I am sorry, and Daniel, I was reading David twice, so. You can make your way up, it's the same setup for topic two. We do have a break at around 2:20 and I want to say one other thing that I am -- that I imagine it doesn't get set off in an FDA. I want to -- I want to

apologize, we did not inform you about the no smoking policy here.

So for those of you who needed to, we are surprised that you had to walk all the way down to the stop sign -- stop lights, I apologize that, A, that we didn't inform you and, B, that that street is so long. So I joke a little bit, but I do apologize for not informing you of that in advance. We appreciate your patience with that. Okay.

We are going to actually start with David who is on the phone with the first panel of comments. And so operator, can we have David?

GRAHAM: Your line is open.

DAVID: Hello.

DR. EGGERS: Hi David.

DAVID: Hi, how are you?

DR. EGGERS: Good, thank you. I am glad you are able to participate on the phone. Again you can't see, we know you can't see the room, but it is -- there are many people in here and they show their agreement with you by nodding their heads which you can't see, but we can see it and so we know that what folks who

are saying on the phone is resonating with folks in the room, so. So with that please go ahead.

DAVID: All right. Great. And I wanted to say a big hello to the IBR Reach folks from Baltimore, I am sorry I couldn't be with you guys. I took some sushi that was on sale yesterday and I am paying for it today. So my apologies, but nevertheless I still felt it was very important that I would be able to speak and my gratitude to you, Sara, also for setting this up and letting me spent a couple of minutes talking about myself.

Basically nothing really special as far as drug use, I enjoyed using drugs as a teenager, mainly social, you know, social drug, I was never really into heavy drugs. So amongst my friends, we enjoyed smoking pot, we did LSD and MDMA, you know, stuff like that, mushrooms and just one day somebody suggested to snort some heroin and I never heard about snorting heroin, the only times I thought about heroin was, you know, when you saw it in the movies, people injecting it and dying.

So I -- in my mind I never thought it would be

possible, but nevertheless I figured, well, it can't be that bad if you are only snorting it. So I gave it a try and, you know, truth be told, I didn't like it, I vomited, I had a real bad reaction to it, but, you know, as much as I didn't like it for some reason the next time it came around I tried it again and, you know, off went the boat, so to speak, and it lead to me to places I have never expected to be in my life and, you know, life was very difficult for me at that point.

I lost -- most of my family members turned their backs on me, most of the friends that I so called had, they just, you know, they had wanted nothing to do with me and I ended up being homeless in Baltimore panhandling, living on a mattress at an apartment complex and it was very difficult also for me to get syringes.

Every time I went to the pharmacy, they refused to sell syringes to me, you know, they played games with me, well, what do you need them for, for diabetes, well, what kind of insulin do you take, you know. So there would always be some trick questions that I didn't know the answer to and it was very

difficult for me to get syringes.

So one thing led to another and I heard about the needle exchange program they had in Baltimore. There was a van that would go around in the city and they would basically take your old syringes and give you clean ones. And so I signed up and I was about 22 at that time and one day I came to pick up new needles and the guys there on the van said, listen, there is a mayor's initiative program and it's a program for folks that, you know, are drugs users that are trying to get some help. If you like the next time we arrive, whoever is first in line we'll give that treatment blotched (phonetic). Excuse me.

And so I figured, you know, let's give it a shot, I tried detox before, I tried rehabs, I tried 12 Step programs, I could never get clean for longer than may be a couple of weeks. I would constantly relapse and no matter if it was jail or hospitals, I mean, there were plenty of times where, you know, I ran out of drugs and money I will just go to the ER and tell them that I was -- that I was suicidal because I knew that they would take me in and at least give me some

kind of medicine, so I won't be sick.

So I had to manipulate my way in order to be able to just receive some sort of treatment so I won't be on the street going through withdrawals. And so sure enough that day I came and they gave me a treatment slot and I went to a program, it was a van, a big mobile van that would drive around in the city and they would dispense LAAM, for folks that don't know LAAM is similar to methadone but instead of taking it every day you would only take it three times a week.

And so, you know, I decided, sure, why not, so I started taking the medication, I kept using drugs and after about a month or two when I was -- decided to use I didn't feel it anymore. When I bought the heroin and I injected, I just had no euphoric rush whatsoever. And so I guess the medication kicked in and it started working and let's see.

March of 2000 was the last time that I did any kind of illegal substances after that. And the medication just started working and, you know, I would go to the program, I would comply with their rules and surely enough I was able to get my life back in order.

And in about 2003 they decided to switch most of the folks to methadone. I guess, some folks were having issues with the LAAM, with having QTs and issues with their heart and we would have to get regular EKGs and I was always fine with it, but I guess, they decided to take it offline and just switch everybody to methadone. So, you know, it was no problem for me, the dosage was fine and, you know, after a while I was able to earn (inaudible) and at this point, you know, around 2010 I qualified for a monthly take home where they will give me a methadone hydrochloride tablets for suspension and, you know, I would take those and just, you know, what they do is instead of the liquid you actually have to mix it with water and you would just drink it and it has been fine, I mean, you know, I was able to get my life in order, I was able to arrest the cravings and the compulsiveness around the disease and the chasing and, you know, the insanity of it.

And, you know, life was slowly but surely getting back to normal. I was able to go back to school. I was able to expunge my criminal record which I never thought would be possible and to get my U.S.

citizenship, so just the stuff that I prayed for and thankful for, you know. So just the thing is with the medication, you know, of course with methadone like any medicine it works great, but, you know, there are issues with the two, I have to take other medications because certainly with the methadone there are some side-effects that I have, some weight gain, certainly the constipation, the low testosterone and so, you know, I was prescribed Constulose for the constipation, AndroGel for the low testosterone, Glycopyrrolate for the sweating, you know, I am sure a folks they know.

When you are on methadone you sweat a lot and it can -- it can come out of nowhere, you know, it doesn't have to be even hot outside, you could just be sitting in a normal room and then out of nowhere you just start sweating really hard. So, you know, there are certainly some side-effects that come with it, but it's like with any medication, you know.

So for sure if there are other stuff in the future that, you know, would, you know, would benefit me in as far as switching to another medication, I would be very interested to, you know, to volunteer and

see if there are other stuff, you know, other treatments available. But as far as the dosage goes, you know, my sensitivity is extremely low, you know, I have tried to taper off methadone before and I was always unsuccessful where it was just -- the withdrawal symptoms were extremely high and my tolerance was very low.

So, you know, some people say you might have to stay on it for the rest of your life which, you know, I guess, in terms of living life, yeah, you know, my life is definitely better, but for sure I would like a life without any kind of medication in the future, that will be the ideal situation. So I am not going to take up more time, but again, you know, the medication definitely saved my life.

DR. EGGERS: Thank you.

DAVID: And I probably wouldn't be here without it, but, you know, for sure I would be very interested in future discoveries and anything I can do to volunteer. You know, if there is anything that could be gained from the years that I have been on this medication I would love to share it with the world. So

thank you.

DR. EGGERS: Okay. Thank you, David. Thank you.

(Applause)

DR. EGGERS: Thank you very much. We are so thankful for you sharing your story. And so now we are going to go down the line and we will go with Paul.

PAUL: Okay. Hi, my name is Paul REDACTED, I am a 54 year old man from Boston, Massachusetts and I have substance use disorder and I kind of thinking back when I was preparing this I thought about when did I know that I liked opioids and I think I was 12 years old and I had some -- the teeth worked on and I can remember sitting at home and liking the feeling and watching TV being on an opioid and I remember taking the whole prescription, you know, not all the same day, but so 12 years old and that's when I -- well, I really like the way this feels, kind of tune out in the world. So go through life and went to college and went to high school and came out as a gay man and then when I was 32 years old I had a surgery for gynecomastia which is breast tissue enlargement and so after that I was

treated for the pain, the acute pain and then I was like, this is just too good to give up and I was treated for that surgery for three years for the pain and at the end I had this doctor writing me prescriptions for injectable Demerol and getting Dilaudid and Oxycodone and all the rest of it, and that's when I really just knew that I just needed this medication, so I would doctor shop and even to the point of everything, you know, even trying heroin and I was injecting medicine.

If it wasn't for the needle exchange van in our neighborhood, I would have had HIV or hepatitis C, but thank God, you know, I sought out that. So then I -- and I still wanted, you know, at this point it had been, you know, 3 years and I lost my family. I still have my job. I work as a social worker. I took FMLA. I think that I thought I was dying of something, they had no idea why I never came to work, but I was almost fired many times. So I would go to detoxes and I went to at least 10 different detoxes and then I would come home and then -- and then relapse again and then relapse and relapse and relapse and then I would do 90

days programs, 90 meetings in 90 days and then relapse.

And then finally a doctor said to me, well, you know, you are just too hard, we can't figure you out, maybe you need to go into the world of liquid handcuffs and go on to a methadone treatment and I did. And it was really hard though because I made an appointment, took 8 weeks to get the appointment, okay, and then I get there and I only had a check or credit card or cash, they needed a money order, so they sent me off to the bank. By the time I got back my appointment was over. They said, well, you have used up your time, you need to come back in another 8 weeks.

So then I came back in 8 weeks and they said, you need to have a positive opioid, so I think, what, I had made it through these 8 weeks and I had to go out and score heroin in order to get into a methadone program. So I scored the heroin, then got an overdose and I got into a methadone program and all of a sudden they say, if we know what I had they are doing take homes and I was -- I was going to work and I would go to Christmas and Thanksgiving and had my family back, meaningful relationships and it was just incredible and

then I did have some of the side effects that David mentioned, you know, the sweating and sexual dysfunction. And I said, you know what, in 2003, buprenorphine came on the market. And I said, "I am going to try this." So I got into buprenorphine. And it's been pretty good since then. I went on to a pretty high dose of that. I mean, not high dose. I am on 24 milligrams. And now I am on 16 milligrams. And it's an easier drug to manage. I think the hardest part of being on methadone was going to the treatment programs. They are always in bad neighborhoods. You couldn't talk to people. What kind of a medical treatment do you have to leave as soon as you get it? Well, if you hug somebody, you could lose your take-homes or if you talk to other people -- I mean, it didn't seem like it was a part of any kind of medication system or a medical system that was integrated.

Now, I see a doctor in a primary care setting. The people sitting in the chair next to me are there for diabetes and hypertension. You know it's my most scary moment on methadone was going into the clinics to

pick up my take-homes that someone might jump me because they might be new in recovery, and want to take my take-homes.

So now, nobody knows why I am at the doctor's office to see my doctor, who I see once a month. And they have a nurse model. I go to office based opioid program in Boston. And is so lucky that in Boston, we have such progressive medicine. And we don't have to, you know, go down some dirt road, that's on the way (phonetic) to get your methadone treatment. And I don't mean to trash methadone because it saved my life. It's a wonderful drug. I just think that it's too bad that we have to have it so by itself and not a part of any other part of the system.

So I am also want to tell you I am with the National Guidelines for Medication-Assisted Treatment. They actually help me a lot. There's a lot of things online that help me with methadone discussion group that we had like three people, now there's 8,000 methadone patients that are on Facebook that help each other out, and if it wasn't for that. So the medication was huge but other biggest piece for me,

peer recovery centers. I went to a peer recovery center and meeting other people in recovery and them helping me, in having you know, people in recovery help each other. And I think that really made my recovery strong.

And then at the methadone clinic, I know there's one in New York that they do actually have a methadone -- a peer recovery center at the clinic. But most of them, they don't have that. And I think if they had more treatment like that or things like that, you know if they had coaching back then it would have been helpful for me.

DR. EGGERS: Any final thoughts as you wrap up on what you'd like to see the future of treatments look like?

PAUL: I think that we need to integrate methadone into primary care.

DR. EGGERS: Okay.

PAUL: And we need to change these regulations. There's just too much autonomy, I mean just whatever the state wants to do, they can do. And some states don't give out any take-homes. And we've

got to deal with this stigma thing. If people don't meet people like the people in this room, they are going to not ever accept this form of treatment. They are going to see the people that aren't doing well on methadone and Suboxone and think everyone is passed out in a corner, which isn't true. There are so many of us in recovery, and we are never going to get rid of this stigma until we can go out there and show the face of this. And I know people can do it because it's -- you know that's their own decision and I am not saying that you need to divulge your medical history to people.

But I just think that's whatever that'd be my ideal thing is to get rid of this stigma, and not understand why people don't know about this. I met a mom, a couple weeks ago, whose son had died and she never heard of Suboxone. He was in four, 30-day programs, and nobody ever told her that she could have put him on a medication, that would have had the most science base behind it to treat him, and no one, another abstinence-based program. He went home. And she found him dead in his room and she was pissed. So thank you.

DR. EGGERS: Thank, Paul.

(Applause)

DR. EGGERS: Paul, you raised a lot of --

SPEAKER: So what are take homes?

PAUL: After 90 days, you're allowed to have one take-home. Some states, they let you have a take-home on Sunday; Massachusetts, they don't give you any take-homes. So that means you have to have --

DR. EGGERS: So is it you have the medication you can bring.

PAUL: Bring home with you. So every day, you have to come and pick it up. I actually was lucky that my methadone clinic was at the police station. So I get to go to the police station every morning. So my neighbors would say, "Why are you at the police station every morning?" It was very confidential, in the parking lots, so we go there. And a -- so a take-home after you have had 90 days. And you know what, the people said they were clean. None of us are dirty. We don't have to say clean. Stop the language.

(Applause)

PAUL: You know we have a positive year, and

we are not dirty people. Whoever made us think we were dirty, all of this has got to stop in order for us to get rid of the stigma. I am sorry, to be so passionate here.

DR. EGGERS: You know the issue of stigma underlies everything we are talking about today. And so even though it's going to be hard for medical treatments to address stigma as a clinical benefit --

PAUL: Yeah.

DR. EGGERS: -- we do recognize the importance of that even if we don't get to delve into it quite as much today. So thank you, Paul.

PAUL: Thank you.

DR. EGGERS: And I know that others -- let's applaud if you feel the same way about the importance of stigma.

(Applause)

DR. EGGERS: So there you have driven home that point. Let's move on to Carol to keep the moving -- the meeting moving.

CAROL: Great. Hi, everybody. My name is Carol REDACATED and I am woman in long-term recovery.

I started using drugs at age 13. I was genetically predisposed to addiction on both sides of my family, as a first generation Irish-American. I started using as a way -- I started using opioids when I was like 18 or 19. And I am old, so I will be 58 in May. So just to give you a sense of how things changed in the drug world. I started using opioids as a way to come down off cocaine, when I was I in college. And opioids had a much worst stigma, I think, than they do today on college campuses, where pain pills and heroin is fairly unfortunately not stigmatized. It caused great shame. There were partiers and then there were those junkies, and when I started using heroin, that's sort of I got that stigma.

My experience as a person in long-term recovery, a treatment and recovery advocate as part of my job and my career. I have worked and helped startup recovery community organization in Richmond, Virginia. And I am a part of organizations like Young People in Recovery. And a big shout-out to Young People in Recovery across the country who might be listening in online. What I've learned is that there's no wrong

door to recovery. And you know my experience is that I was on methadone treatment. Unfortunately, I did not have as positive as an experience back in the early '80s as David has, and maybe Paul. And please don't send me hate mail. I am not grinding on methadone. I am just sharing my story here.

For me, I was following a boyfriend who was on a methadone program. It was in a part of town where you could cop other drugs at the same time and kind of learn you know who was doing what to -- I was the -- yeah, who was boosting what at places around town to get money to use. And because I looked kind of sweet and innocent like the Campbell's Soup girl, I was the return lady for stolen goods at stores. It was not great recovery pathway for me, just leave it at that. And I had some of the same side-effects from that particular treatment modality as some others have talked about, not really dainty or feminine to be sweating profusely in the summer. And all of your clothes have these big stains all over them. Yeah, it's not lovely.

So I also have used medicalized detox and

residential treatment twice that use bio-cycle social model for recovery. And today, I manage my recovery using recovery management techniques that include a lot of things. But that can include -- does include 12 sub-meetings and active participation. Being an active member of a recover community organization, I give and receive peer supports from other women. I also use counseling. I use antidepressant to manage anxiety. And I use exercise, meditation, yoga, and therapeutic message, all to help manage my recovery.

But patience, experience, and the needs about while there is no wrong door to recovery, patience, experience, and their needs about which door works for them and has worked for them, and that they have been exposed to really matters. And I think it's often ignored. One particular pathway appears to get pushed in this country at any particular time rather than kind of creating a climate and incentives for all options to be viable for people, and that it -- they should be accessible, and it should be based on the patient's needs and experience with other treatments.

In recognition of the reality, frankly that we

don't have data in this country that purpose perfectly matches an individual to the exact intervention that works for them and until we have that, which I hope we do, people ought to be able to choose pathways and not kind of get forced down to one and shamed if that one pathway doesn't work for you.

I think outstanding areas in my recovery that I would like help with, whether through drug interventions or devices or other interventions that are still lacking for me are a really good tool for managing stress. You know stress is a trigger. Even with 20 years clean -- 20 years in recovery -- excuse me -- I still don't have stress management down. And it definitely triggers addictive feelings in me. Today, I have co-occurring addictions. And when I first got into recovery, I remember almost being kicked out of a recovery program because I had co-occurring bulimia and eating disorder. And they were like, "Oh, no, no, no we only deal with drugs and alcohol. We are going to have to ask you to leave." And I kind of begged and pleaded my way into staying. But a person with a substance use disorder that shows up in

different areas of their life should not be shamed and be told that you get kicked out because you have more than one way that your substance use disorder expresses itself. And it affects areas of the brain, where it's going to show up in different ways. I think the -- it can also show up for me, on like overspending of money. The feeling of wanting more of anything that changes my mood it's quieted down with 20 years of recovery. But it's not been cured. And it impacts my self-esteem because at this age, I think -- well, or this amount of recovery, or I should have this all together by now, right? Like, "Come on, Carol. Get with a program. You're supposed to be like in a better spot."

An addiction is a chronic thing. And we have to teach people that, and that not to shame themselves. As I age, managing chronic and acute pain poses challenges for me in my recovery. Clinicians still push opioids on me, despite me revealing my opioid use disorder and are often unwilling to use non-opioid alternatives, and often there aren't, when I've had to get surgery, call me, or tell my husband that I am hysterical about opioids.

Healthcare professionals need to discuss an opioid management plan with their patient who self-identifies having an opioid use disorder, and what works for me, and how I do my opioid plan, but I don't think everybody has to do it this way. Because remember, I am hysterical about the way that I manage it. Is that what works for me is having others handle the medication for me or we've had it in my house and not get a little text and go on a treasure hunt every 4 hours or whatever prescribed as. Having an accountability partner. For me, I've talked to sponsor about it, but it could be a loved one or a friend or whatever. And I have a plan for the period that I am taking them.

And during recent rotator cuff surgery, I had to stay on opioids for two weeks and I could feel myself becoming -- just counting the footsteps of the person managing the medicine and all of that kind of stuff.

So quickly as I finish up, just a couple of systemic suggestions perhaps to leave with people, I think the FDA should use a REMS process more

aggressively to require -- those they regulate to help with public education campaigns for individuals, families, and communities. I think we should have medical professional and pure education curricula that they do -- already do and are good at and could do more of. I think that they could use REMS for more strategies and use the FDA for more than just like a black box warning on a drug. I think there's a lot more authority there that could be used.

I think price should be looked at for MAT to treat addictions. And in particular if you're going to recommend non-opioid pain alternatives, make sure there's actually insurance reimbursement and coverage of them. Because a lot of times, people will say, "Yes, of course." Like go get the such and such. And I will try to get Toradol and my plan will say, it's not covered. So that doesn't make sense.

DR. EGGERS: Any final thoughts, final words?

CAROL: Yeah. I think that there is also workforce shortage. And while this isn't necessarily in the FDA's purview, I think that people have to realize that our people who treat addiction don't get

reimbursed like other chronic medical conditions. And that is something that payers and others in our community can and should fix, especially since the government is one of the biggest payers for addiction services. Thank you.

DR. EGGERS: Thank you very much, Carol.

(Applause)

DR. EGGERS: And we have Jan.

JAN: My name is Jan. I am a woman in long-term recovery, which means for me that I haven't used drugs or alcohol for the past 31 years. Sustaining my recovery allows me to be the founder and executive director of SpiritWorks, which is a recovery community organization in Williamsburg, Virginia, an ordained deacon in the Episcopal Church, earning an advanced masters of science in addiction studies, a board member of Faces & Voices of Recovery, and a consultant and subject matter expert on issues of addiction and recovery.

I've been invited to share my perspectives, specifically my experience with naltrexone. Back in the day, for me, it was called ReVia. I took it for

about 7 years, subsequent to sustaining a traumatic brain injury. What was happening was I was participating in rehab to recover for my brain injury and I wanted to maintain abstinence. The treatment worked well for me as I was able to maintain abstinence during a very stressful period of time in my life. Success for me looked like I did not return to active addiction, and I also experienced no cravings.

The biggest problems that I experienced were associated with stigma as has been mentioned. It happened for me when I went to pick up my medications at the pharmacy until I developed a relationship with my pharmacy and my pharmacist, ensuring that the medication was available was a huge problem. ReVia was something that was not kept in stock, which meant that some months it needed to be ordered and required me to wait for a few days, which meant that there were periods of time when I didn't have it.

Also, there was a period of time when the cost of the medication was prohibitive. I think that's better now. I used to pay $1,000 a month for it many, many, many years ago. I do not currently use

prescription medical treatments to address my opioid use disorder. Instead, I attend mutual support meetings. I use my faith tradition friends and family support. Doing so continues to work very well. I also maintain a healthy lifestyle which includes proper nutrition, sleep, and other aspects of health and wellness. Maintaining what I call a culture of recovery is critical to my recovery as it means that my recovery is the most important aspect of my life. Without it, as somebody has said earlier, I cannot sustain life.

The treatments, therapies, and supports that I have found most effective, I consider in two different ways. One was the -- in the short term, I needed medication, I needed counseling, mutual support meetings, my faith tradition, family and friends' support. Long term, I continue again with mutual support meetings, faith traditions, and family and friends' support.

The three major factors that I take into account when making decisions about seeking out or using treatments for OUD -- so the first one is that it

depends upon the specific treatment outcome that I am looking for. In other words, that I need to know what the reason is that I am taking a medication or seeking a different type of treatment. I also need to know, as Carol said, who are the people that will support my decision. And I need to include them as accountability partners. And also, accountability partners but to also help me with my decision-making process in the first place so that I know what my motives are and I am doing things for the right reason. The other one that I need, I think Carol also mentioned, I need a specific plan as I engage in a particular treatment in order to protect my recovery.

An ideal treatment for OUD, I believe, includes medication for the biological piece. If it is medically necessary, I think that therapy, some type of counseling and recovery support services are critical. Each of these components is necessary in order to facilitate the achievement and maintenance of long-term recovery. Their dose, frequency, and strength will depend based upon the specific needs of the individual. No one size of treatment fits all.

I think for me, and I was talking about it with somebody at the table earlier that there were time periods when -- I mean, recovery is not static. And so what I needed in the beginning didn't necessarily look like what I needed further down the road. I took ReVia for about 7 years and I no longer take it. I needed it during that time period. It's not something that I required any more. I am grateful for the use of naloxone -- excuse me, naltrexone during the period of years, when I was experiencing a challenging time in my life. Giving my success in using it, I would do it again if the need presented itself. As I am very motivated to maintain an abstinence-based recovery program, taking naltrexone in pill form was effective for me.

I do know of others who take VIVITROL injections and that that has been a better method for them, because it doesn't allow them to change their mind for at least 30 days. And I also have been told of people and worked with people who in their desperation have removed their implants in order to use -- so knowing -- as Carol said, knowing the best

patient for whom treatment is indicated is definitely something that needs to be considered.

DR. EGGERS: Thank you so much, Jan.

JAN: Thank you.

(Applause)

DR. EGGERS: And finally, we have Daniel.

DANIEL: Hello. I am Daniel from Brooklyn, New York. Thank you very much for having me. So I just want to set the scene for a second here. So picture this, that you're in a jail cell, by yourself. You're about $1 million in debt. You have no idea where you are. Your girlfriend, at the time, comes to pick you up, and it's about 3:00 a.m. in the morning and you're in the middle of nowhere. And you get -- you know stumble your way into the car and you forget who she is, like you didn't realize that that's your girlfriend. So that was me about 5 years ago. Today, I am 100 percent, I guess, clean or in recovery yeah, for about 3 years. And that girlfriend at the time, she is my wife now. So that's -- so I did that using Suboxone treatment. So I guess I am the proof that that treatment works. I am currently not on any

substance at all, haven't been for about 3 years, like I said.

So essentially what happened with me is after that scene that I just mentioned to you. I was put into pretrial intervention program. I had good lawyers who put me into that program. And basically I elected to do the Suboxone treatment because that was one of conditions for being a part of that. And you had to kind of get your life together, get a job, et cetera. So I did that. And why the Suboxone treatment works, in my opinion, and I only share my opinion and what worked for me because there are a lot of different ways of getting there. But I can only share what worked for me. And hopefully that helps the experts here figure out what to do.

So the Suboxone works in my opinion because it curbs the withdrawal, which is probably the roots of the crisis because as you know those in -- who have OUD will probably do anything to not experience the effects of withdrawal or the sickness that comes with that. So that's what leads to the criminal activity, et cetera, in order to obtain more substances. So that's one

factor that's very important.

Another factor with regards to successful treatment outcome would probably be the right social environment, social setting. In my experience, it was finding a -- it was being lucky enough to get a very good job where I had a very strong support system with the right people around me who supported me. I am not sure if they even knew about my past. I guess it doesn't matter. I felt very comfortable there. And I think that that's essential. So that's the second aspect.

And the third is creating a situation of stability. So the job is one aspect of the stability factor. With me, I think faith works for me. I am not going to go tell you to become a priest, but it works for me, or a rabbi but it works for me. So I found a bigger connection to God. And like I said, I am not pushing that because I know everybody has their own relationship with regards to relations. So that's kind of where I am at with that.

So I ended up tapering myself off the Suboxone. I am not advocating that because I think

that if you are taking the pills or, by the way, I was up to about 50 pills a day on my worst. So I was bad. I was really bad. This was 5 years ago. So if you're taking the pills, and then you got to stem the Suboxone or whatever treatment to keep yourself off that, I would say you should stay on that for the rest of your life. But I elected to get off the Suboxone and I tapered myself off eventually. So that's what -- that's my situation. And we got to help each other, obviously. We all got to -- we're all on this together. We got to help each other. I started a website. It's called Dan's Recovery Team, dansrecoveryteam.com. Check it out when you get a chance. And hopefully -- we will beat this, we'll beat this. All right. Thank you.

(Applause)

LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 2

DR. EGGERS: Thank you to all the -- can everyone hear me? Thank you to all of the panelists. We hope that we found panelists who -- people who had experiences with a number of different treatments that we wanted to discuss today. And I thought that you've

all very well-articulated your journey, your experiences recognizing that they are your own experiences. And so what we are going to do now is to see how we can expand upon those experiences. We'll also get into some of the downsides of treatment in a -- in another -- in a little bit. But first, first of all, let me just ask one -- I usually do a show of hands about how did you hear your own stories here. But let me just talk about your journeys to recovery and how they started. I thought you all articulated that very well.

And did you see, it was a similar journeys to recovery for you to -- okay. I appreciate how much you had conveyed to us and reminded us of the complexity and the difficulty of that. But now we are going to focus in on medications and I have a polling question. There aren't as nearly as many now, but I would like you to answer a polling question so we get a sense of the experiences with treatments in the room and on the web. So if you can get the clickers handy.

This is -- check all that apply. So have you ever used any of the following -- you or your loved

one? Okay. So the opioid agonist, that would be methadone; the opioid antagonist, such as naltrexone, which we heard about; the opioid partial agonist, such as buprenorphine or buprenorphine naloxone; and that is -- is that Suboxone -- and that's Suboxone; other prescription or over the counter medications that you have used to address your opioid use disorder. Other medications that aren't mentioned, again, to address your opioid use disorder? Or F, I've never used any medications to address opioid use disorder. Okay. And so we encourage you on the web to participate as well.

Okay, anyone still working -- okay, let's see what -- okay. So we have -- basically we have all the medications represented in the room. Methadone and buprenorphine or Suboxone are the most represented. Other prescription over the counter meds. And some of you in here have never used any medications. Can we see what the responses on the webcast were?

GRAHAM: Very similar. Almost the same actually.

DR. EGGERS: Okay, I think there's one group that has several people, who may have not used

medications. Let's start there actually and take a few comments on, for those of you who are comfortable sharing why you have not used any medications and on the web as well. So we will come here -- you take, Amanda.

AMANDA: Question what is Narcan, does it fall anywhere on that list? So I mean --

DR. EGGERS: Narcan is just Naloxone. It's not on the list of --

ANONYMOUS: No, because it's not a treatment. It is an antidote to an opioid overdose.

DR. EGGERS: So go ahead.

AMANDA: Naloxone is part of the Suboxone medication, so when you look at your Suboxone and you see that there is a milligramage and then a slash and then another milligramage, that's the naloxone portion of the Suboxone medication.

ANONYMOUS: I chose to not use medicines to recovery partially because of the amount of time that I was in the inpatient detox. The other part was, I was using opioids and Clonopin at the same time and normally within the same quantities and because they

were so paired, they chose to taper me off and that did kind of help-ish with my withdrawal. It handled the mental portion of withdrawal and by the time I got into other therapies like DVT and the length of time that I stayed in intensive treatment, I was in treatment for 180 days. That kind of support and community engagement of just recovery made it so that I didn't feel that the medication was necessary. If I were to relapse tomorrow, I probably would choose to do medicine-assisted recovery, because a, I know that my likelihood of maintaining recovery is higher if I use medicine-assisted recovery and b, it is a safety net, I have a child, I have responsibilities, I have a job, and I want the dependency or the reliability that that medication would provide me and I also know that second relapse has much higher -- that relapse has a much higher chance of me dying, and that and right now is, you know, the shot I would have today is not the shot I would have had seven years ago.

ANONYMOUS: Thanks very much.

DR. EGGERS: Any -- okay one so one more back there and then we will get a summary, if there is any

web comments on this.

ANONYMOUS: I just want to first make the comment that I'm a little troubled that this panel is only made up of people who have used medication-assisted treatments approved by the FDA and sold by drug companies. There are a lot of other treatments that work, that are not medication-assisted therapies that the pharmaceutical industry profits of off. I spent seven years trying Suboxone, methadone, 12 Step programs, various rehabs and what finally worked for me was a substance called ibogaine that is Schedule 1 illegal substance in this country, thank you, and it is not currently under investigation by the FDA. And I want to ask why are we not talking about things like ibogaine, why are we only focusing on long-term opioid maintenance, not to just qualify anyone's valuable experiences because I know those do work for lot of people, but there are other options and I am little troubled that this panel is only people advocating for medication-assisted treatments. What about these other options, not just ibogaine, but other things that aren't even medication at all, why aren't we talking

about that. But something like ibogaine, which is the only substance that removes opioid withdrawal that is not another opioid, that you do not have to keep taking. I did ibogaine six and half years ago and I have not touched a single substance since and I do not use medication treatments. And I just want to bring this up and I want to have an answer as to why the FDA is not putting any other resources they have to invest getting this treatment. Yes they are death associated with it, but there are deaths associated with any medications. You have to follow a safety protocol for any medication, so I would like to hear someone address my comment about what I began.

PAUL: You know, I would've tried ibogaine if it was available. I have to agree with you and I didn't know that at least they're keeping the plants alive, so they haven't killed it off completely in this country, but it needs to be -- I almost went to Mexico and did it, but I think, you have -- make a great point that ibogaine is something that we don't talk about enough.

(Applause)

ANONYMOUS: So the point --

DR. WINCHELL: Sure I will try to answer your question very generally. I think most people probably know that FDA doesn't actually do the research. We provide some oversight, regulatory oversight to people doing research and if people want to develop drugs that they could bring to market, we provide them with guidance and advice on how to design their trials and when it's all finished they submit that application to us and we vet the results and information about how they make the product and so forth and eventually it can come to market. That's why we are having this meeting because we really want to understand how a medication could be evaluated for effectiveness that might be completely different from anything that we already have available.

If something completely new, something totally out of left field that wasn't an agonist, it wasn't an antagonist, it wasn't a partial agonist or maybe another other version of one of those, how should we evaluate that drug and assess whether it's doing what patients need it to do, and that's what wanted to

understand what you wanted to do. So FDA is quite open to all different types of treatments and we just need to get a better handle on how to evaluate them.

DR. EGGERS: So we probably won't be -- have time to get too much of the experience with that particular medication, but with the amount of clapping that went on, I think there might be other experiences, so please if you're on the web, feel free to write in and this might be something consider putting a docket comment with your experiences in your perspectives on that.

Okay, so are there are any -- somebody is on the web particularly about using any of the medications any.

GRAHAM: Just a lot of people echoing what they have been hearing in the room, and mentioning they are using similar treatments.

DR. EGGERS: Great that is a great sign if we can see echoing from the people on the webcast because we know that it's difficult to make it here to the FDA and so the fact that we are hearing echoes demonstrates that there are a lot of -- that what we are hearing

here is shared with others. Okay, let me -- go head -- wait till we get the microphone.

ANONYMOUS: I'm a long term recovering addict and for me, I had to treat my addiction when I was once I got on the methadone, like if I had diabetes because I used my (inaudible) of my choice to put faith, you know, to have faith, knowing I can do all things, but when I would try to get off the methadone I relapse sometimes and it wasn't good. I would find myself back out there, back in jail and I didn't want that. So I said -- somebody told me, a counselor said try to treat it. It's a disease, number one, you have a disease and no matter what you have to face it, deal with it and do what's best for you, you can do what nobody else do. You have to do what is the best for you and that's what I have done and it's has been 22 years today.

(Applause)

DR. EGGERS: Okay, thank you, we'll go back there.

LOUISE: So I just -- my name is Louise and I'm here as an patient and patient advocate and I am here with Urban Survivors Union and we are a user

union. And some of my -- one of my questions is why are we only looking at abstinence, as the only angle. It seems that that's you know if we can only be completely well or completely sick and there's a lot of room in the middle and sometimes it takes a long time to get from one place to another and sometimes we don't want to get to the other place. So I think we need to show some -- you know it would be interesting to me and it would be part of, you know, what would help a lot of the people that I know and work with, if there was some, you know, some discussion about that.

DR. EGGERS: Okay, can I turn this question around? Okay, let me ask you -- because we are going to -- we are skipping ahead a little bit, you had good insight into what we wanted to learn today. No, keep the microphone there, what if it is not abstinence or addressing withdrawal, what would you like, what would you like it to do, a medication?

LOUISE: I would like to be able to manage my use --

DR. EGGERS: Okay.

LOUISE: -- so that I can have the best

possible life you know, so I can show I am able to have the best possible life I can have.

DR. EGGERS: And what is manage use, you mean.

LOUISE: Excuse me.

DR. EGGERS: And what is manage use. Describe that to us.

LOUISE: Manage would mean, I am able to -- to go to work and function and do what I need to do. If I hadn't found drugs then I feel I would have probably killed myself. So the alternative to what some other people have said, they were using drugs and the drug use made them want to kill themselves.

DR. EGGERS: Okay, can I get a -- do you feel comfortable with a show of hands about how many people -- you said I don't want to repeat your name for --

LOUISE: Louise.

DR. EGGERS: Louise okay, show of hands or claps if you share Louise's perspective knowing that not everyone shares it, but some do, okay. Any questions you want for follow-up, any questions on follow-up on that.

DR. AHADPOUR: So Louise hi, so I have talked

to you before, I'm glad you're here, this is Mitra and we are looking at all aspects. I mean I think that's one of the reasons, we are having this meeting that we know recovery has different meanings to different people and there is -- as someone said there is no wrong door and there is no wrong approach. Everyone has their own approach and some people want that total abstinent, which is great, but at the same time it's great to have not total abstinent. It could be that you decrease your illicit drug use. You are on medication, you're fully functioning, you have the right relationships, you are working. So I mean you are looking at all aspects because there is no one size that fits all.

DR. EGGERS: So what I will do then, I will suggest and we have to go back to a question, but so as not lose this topic, I don't think we can spend too much more time on that, but this is another great thing for the docket or if you are on the website and you share this perspective about wanting to manage your use, try to be as concrete as possible about what that looks like. Is it that you use only at certain times

of the week, is it that you need to only use at certain times of the day that you can -- when you don't -- when you absolutely can't use it that you're able to not use it for a period, so be as concrete like that and write in your comments, that is something that would be extremely useful for our docket and for the webcast. Okay and with that I am going to move to -- let me ask -- I think there's a question from Allen one of our -- one of -- a person, who has been instrumental in our planning. He is an FDA expert by the way.

DR. TRACHTENBERG: Thanks everyone for coming up. I am finding your comments incredibly helpful. This is the question initially for Paul because he mentioned this other drug at the break, but anyone else as well. What role do you see to be played or being played by clonidine also known as Catapres in opioid use disorder.

PAUL: I have only known clonidine to be used in detoxes and to used to get high when you're methadone. Does anyone else ever used it to get high when there are on methadone, anyone in the room. I am the only person.

DR. EGGERS: Okay, you got another hand right beside you.

PAUL: How about because it intensifies -- and I never knew you could do that until I tried it because they are selling it outside the parking lot, but clonidine and (inaudible) intensifies itself, but by itself I had used it for detox and it was quite effective.

DR. EGGERS: So we will take one more. Is this comment about this? Is your -- no, okay.

ANONYMOUS: I mean with all these alternates, you know what for me the methadone was the alternate for the heroin and which worked good for me, you know, through the years, but my question is somewhat in view of this is, what is the ultimate answer for someone to get to the abstinent point, was it another drug and as in that falls behind the methadone process. Or if you want to -- in order to get to the abstinent goal, to come off methadone all together.

DR. EGGERS: So the question I think, is your question what, the question is your raising is if you don't want to be a methadone, what's your -- what do

you do next, what's your next.

ANONYMOUS: What's the next move, yeah.

DR. EGGERS: Okay. So I don't know if we have the answers, but sure some I -- maybe a few ideas.

ANONYMOUS: You don't have to get on methadone if you're heroin, you can get on heroin maintenance and if it is prescribed and regulated dose like they do in Switzerland, the U.K. and several other countries in Europe, you don't ever have to transfer your dependency to methadone, you can stay on heroin become stabilized more quickly and even better if they offered a supervised injection facility for folks to come in be monitored so they don't overdose and die. That's the way that works since its proven to be effective in Canada and other countries, so we need that in United States.

DR. EGGERS: Let me ask in a different -- let me ask this a slightly different way, what would you like if you are on methadone and want to get -- not to be using -- what would you need to see for your health benefits if you were to go onto a different treatment, what you need to see. Let's go here, we one here and

then one in the back there and then we are going to take a break, a 15-minute break.

ANONYMOUS: Well I on methadone and I think the outcome is that once you stabilize your life like I have and you can go back to start doing things to implement yourself in society again, then take a long term detox off. You don't rush off methadone, but you can take a long term detox, that eases your way down, eases your way down to where become un-dependent on it.

DR. EGGERS: So that would be your goal. So that's your goal too. We have one, okay anyway we got a couple different same goals, one more over there and then we will take a break.

ANONYMOUS: Okay you stay on treatment, stay on treatment and you keep going to groups and you listen that's how you get off.

DR. EGGERS: Okay, all right, so it sounds like this you guys will have -- there will be some break conversations at your table. I think this has stirred up a lot of great insight and sounds like of interest to you. We are going to take a break and then we are going to have keep moving on. We have a few

other questions that we want to get to, so we will be for 15 minutes. Please come back at 2:35.

BREAK

LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 2

CONTINUED

DR. EGGERS: There is the bus that's going to Union Station so taking the downtown DC, has plenty of space on it. Its leaving at 4:00 o'clock and our meeting will end by 4:00. So if you in the downtown DC area, then please feel free to take the shuttle and I don't even know the name of the woman in the red blazer, but she is the one who told me. So you have more information right, if people need it.

Okay let me just go get my microphone and get myself situated. I think we were wishing we would have planned like a two-day retreat for as much as there is to talk about and share regarding your experiences with opioid use disorder.

Unfortunately, we have you know about 40 minutes left and what we really want to focus in on is how can we make medical treatments better and have them have the end -- have them achieve. You heard it early

this morning a lecture I talked about end points and what that means is a drug has to show that it can have benefit for you and it has to show in a very concrete specific way. You have to be able to say, "I know this drug shows benefit in people," and so what our job is to translate the things that you're really caring about into those concrete things that can be measured at the end of the day, such as we were talking the woman in the shirt -- about reducing use, and so we want to get in to more of those aspects. What does this look like?

Okay, so I first want to, I am just doing a little bit of real time math here. It's so hard when you have 200 people looking at you doing math, yes. Let's skip the next polling question and go on to the third -- the polling question we are going to skip was about the downsides of treatment and I think you have been very clear in the downsides. Do you have something you would like to -- okay we will let you go and then I will go with the polling question.

STEVEN: Hello my name is Steven, once again I am here with Mend a Life program and what works for me was, I have been on the program for nine years and what

works for me was the methadone as well, but today is I can say that this my first year of actually being clean.

DR. EGGERS: Okay, okay.

STEVEN: Now, what I was saying --

DR. EGGERS: And by that you just mean that you are not using.

STEVEN: Nothing at all, right, but what I saying that the time it took so long for me to get to this year was that I had needed mental health to help me realize and to come out of denial about being on drugs and other things such as abuse coming up and everything that goes into mental health. I believe that if there was more mental health accessibility in programs, it would help out a lot.

DR. EGGERS: Okay so I want to clap, so a show of hands if you agree with what you just heard.

(Applause)

DR. EGGERS: Okay and I think -- yes okay, all of the FDA people are clapping too. I think that has been made crystal clear and I think that it's well understood the need for the -- who said it up here and

so nice that the three things that are needed together the supports, the counseling, the medical treatments if that's necessary. And what we want to do moving forward is -- let me do a show of hands, how many of you believe that medical treatments is a necessary part of your OUD, even if you don't use them now, it might be a necessary part of your OUD to manage your condition. I think medical treatment in terms of the type of medicine that you would get from your doctor.

DR. HERTZ: Yes so the traditional medication assisted therapies.

DR. EGGERS: Yeah. Okay so raise your hand if you believe that medication assisted therapies as Sharon just described are a part of -- you can see as being part of your management needs. Okay then show of hands of those who do not. Okay, so we do have some. What we are going to go through now and we're going to assume that someday there will be newly -- the FDA will be able to approve new medications to help you manage your OUD in all the ways we been talking about today. Okay, so can we go -- we will go on, okay one more, keep going. Next polling question. Okay so here's

what we want to think about, is what would any -- if you are --even if its currently approved drug and you could consider taking it of any treatment, when considering a new treatment even one that's not yet -- even one that's not yet here for opioid use disorder, which of the following benefits would you consider to be most meaningful in your current life situation. So a, help me control my use of opioids better so that I can function that was what we heard back at the table over there, okay. B, help me achieve complete abstinence of opioids. C, reduce effects of opioids withdrawal. D, reduce the effects of opioids cravings. E, reduce how often I have to take the treatment. B, allow me the ability to take my medication at home or G, some other benefit that's not up here, we are going to explore these benefits.

So you can choose up to two things. Is anything unclear about the question? What's most important to you about a treatment, what will it do for you, is there a question, do you have a question. Okay, we will wait till we see the results. And on the web on please chime in this is -- it's got a big

highlight on my sheet here. This is probably the most important question that that many of my colleagues would want to hear. Okay, do some people need clickers and they don't have them. We will bring clickers to you. Okay let's go to the results okay. Okay you've made our discussion difficult because you picked everything. So let's start with the most, the one that got the most in the room and on the web what results are we getting?

GRAHAM: Actually quite different from the web. We have about 73% saying reduced opioid cravings and then about 40% controlled use of opioids, 30% for complete abstinence and reducing withdrawal and in less than 20% for the rest.

DR. EGGERS: Okay, now from here on out, let's try not to speak about specific medications because they are moving for -- we don't care about what medication it is, we just care about what you really are looking for out of a treatment, and I noted at the beginning that there are differing perspectives in here and so we want to take both of these together because hopefully someday, there will be medications that meet

whatever your needs are.

Let's take here B because it was most -- slightly more in the room. How many achieved complete abstinence of opioids. First let me -- is there is any clarification, any question from my FDA colleagues about a type of endpoint that you would like to ask about here. While they're thinking -- what just -- what is it if it is different than what you have already because I have to ask and recognize a lot of you here in the room are currently abstinent from opioids. So you might have to go back into your memories about when it was more difficult or think about potential for relapse.

Okay, what would you want to get out of that, what would -- what would it -- how would you describe what you're looking for there. We will start with Amanda and then we will go here.

AMANDA: Think of it similar to when you're talking to a patient with chronic depression and you're hitting some of the points. So you may have an medication that handles the cravings okay, but it has some serious side effects that are similar to when you

were in active use and understanding that we found a couple of medications that work really well, but there needs to be a combination of things and there also needs to be an understanding that if you have opioid use dependency or you have opioid depression and you are treating that with a medication that's derived from opioids, the depression is still there.

So it would be nice if there was a way to have a medication that would make our brains not crave the drug and also have something similar to that SSRI to help handle some of the anxiety, help handle some of the depression. I think a good chunk of us in this room have experienced the benefits of Trazodone because it does help us go to sleep with a nonnarcotic component and have that be something that kind of prolongs, you so you can hit two birds with one stone.

DR. EGGERS: And you're saying decrease the stigma.

AMANDA: Yeah.

DR. EGGERS: Okay so back here we had okay yes.

SHARON: Excuse me, it's Sharon again. My

question is does -- is there any research into medications that are not opioid based for withdrawal, because to me it's like somewhat like exchanging one opioid addiction for another.

DR. EGGERS: Okay I'll let -- see if Sharon wants to answer the question.

DR. HERTZ: I have a couple of comments on that. We just heard two comments about replacing one opioid with another and I'd like us to follow up on seeing how much people really believe that being on medication assisted therapy with something like methadone or buprenorphine is simply replacing one drug with another versus is it an active treatment for a condition, but in terms of what's available to manage withdrawal we recently had an advisory committee meeting. So I can tell you about this because it's public. For a drug that was being developed to help reduce the symptoms associated with a fairly rapid detox. Now the pros and cons of rapid detox and what was going to happen next were not the question, but so there is a drug that is under review to help reduce those symptoms.

One of the questions that came up during the committee was about longer-term slower detox and that's an outstanding question. So there is some research in there, but that's what I can speak about in terms of what's been public.

DR. EGGERS: Okay. So let me just do a show of hands to Sharon's question about -- let me frame it as a goal. How many of you would, as a goal, for those of you that are currently on one of those products we've been talking about or your goal is to not be on it. How many of you -- show your hands, would be willing to take a medication for up to the remainder of your life to address your OUD? Show of hands.

Yet if you have to take a medic, you -- so maybe it's not the medications that we're talking about the ones that you think are might be replacing one for the other, but it was some other medication. Are you willing to take a medic? So it's not the fact that you're not willing to take a medication for the rest of your life. Are you -- show of hands if you'd be willing to take the medication? Okay that -- we're getting a lot of head nods that, yes, you'd be willing

to take a medication. Now how many of you would rather -- your goal is to be able to get off one of the treatments that we've been talking about?

Okay, you're willing to take some other medication for the rest of your life, but maybe you'd prefer to not be on this one. Okay. So we're not going to discuss that. But we do note that that is then a perspective that's out there. You can make one comment -- yes, sure. Let's let like a brief one.

DANIEL: Yes, super brief. Just with regards to that, how the -- if being on something like Buprenorphine is replacing one substance for another or one drug for another, I guess, technically it is.

But I feel like Suboxone, for whatever reason, because of its chemically designed to do so, it allows you to reenter society and become a functioning part of society again. And I think that that's essential with regards to maintaining a basically -- in recovery that's essential.

So if that requires you to stay on it for the rest of your life, in my opinion, I think that that's better than any alternative. And obviously, I think

it's probably a extra to get off this -- the Buprenorphine, that's an extra step. Right? So if you want to attain that, I guess, "higher level", I don't know what you want to call it, but I don't think it's -- I think it's best to stay on that.

DR. EGGERS: Okay. So then you're -- so you're adding -- so again, this is a very complicated issue, because you're adding then to say that if you need it you need it, right. And so that's what it sounds like we're hearing from a lot of you in the room.

Okay. We're going to take a maybe, what might be a couple other perspectives, just a few of you, and then we're going to move on and talk. Okay, go ahead. Let's see, the woman back, yes.

ANONYMOUS: I just -- I'm struck by the way that we talk about this kind of treatment for substance use related problems that's so different than every other kind of treatment that we talk about.

So if you had problems with anxiety and you went to see a therapist they would say, you know, we have different options. We can give -- we have

medication that we can give you. We can do behavioral intervention and you -- teach you breathing techniques. We can do talk therapy and delve into your childhood trauma and see where this came from. And some combination of that will probably be helpful to you.

But if they said, if you follow our treatment plan you will never ever be anxious again in your life. You would say, "You're crazy. That's ridiculous." But that's what we do with drug treatment as we say, if you follow this plan, the goal is that this problem is going to be completely gone when -- you know the reality is that it's like most other things in life that they are -- sometimes you deal with it better and there are periods where it doesn't go as well. But we see it as this completely discrete other thing. And I think that's one of the big problems --

DR. EGGERS: Okay. Are you speaking of abstinence right now that if you follow our plan you won't use again or --

ANONYMOUS: So, I mean, you might have somebody.

DR. EGGERS: Yes.

ANONYMOUS: You might have somebody who, in fact, is able to never ever have another episode of anxiety in their life, but that's highly unlikely. That for most people it's a treatment plan for dealing with anxiety disorder.

Usually, looks like client will reduce number of panic attacks per week, will learn strategies for coping with feelings of anxiety and a typical treatment plan for substance use disorder, having seen many of them in my life, is something like client will refrain from any illegal drug use. Client will not relapse to illegal drug use.

DR. EGGERS: So give me another one. Give me -- what do you wanted to -- give me something you'll say client -- individual will what -- give me another -- give us an alternative and then I think we can work with that.

ANONYMOUS: Yes. Well -- I mean, I think, people have said this. What you -- I mean, I work for a syringe exchange program and when I look at the data that we've had in terms of what drugs people use and people who say that they use Suboxone, over half of the

people who report that they use Suboxone, say they use it sometimes, not daily.

So, obviously, it's something that's helpful to people, but not necessarily exclusive to -- to the exclusion of other drugs. And I mean I know there's been research that shows that people who use illegal drugs, but also use Suboxone do better than people who don't use Suboxone and use illegal drugs.

So, I think, as for everybody, people want to have some control over the unpleasant symptoms in their life, which are various and they're different for different people. And so I think looking at that piece of it -- that if -- I think about what I've read about naltrexone use -- occasional naltrexone use for alcohol. That people who say when I want to drink I take naltrexone and I don't drink as much and that works for me.

That if there are ways that -- I mean, that the end point, the goal in all of the discussion has been zero you -- not using any of a certain kind of drug. And if you back that up and look it like we use -- you know most other behaviors that goal is how to do

-- how to be able to manage things yourself so that you function in the way you want to better.

DR. EGGERS: Okay. So let's then transition to A, to help me control my use of opioids -- help me control my use of opioids so that I can better function, I think that's one area you're going into.

What is it -- I'm going to throw out an example that's probably wrong, okay, so you can correct me and then give me a better one. But to say that I have my family visiting for the next two weeks and I would be able to not use or cut down or something like that while they're here. And I fully plan on using, again, to some higher level, after my family is gone, because it's probably the wrong example, you can tell me that and then tell me something better. Anyone, anyone? So we'll go there. Amanda, first and the while you are thinking we'll go to --

AMANDA: I totally did that. You have functions -- you need to appear normal, so you think about setting yourself up. That was normally when I would pay more money for prescription medication, because I would need it in such a high quantity to

equal the kind my tolerance that I had gotten at that point on heroin.

That would be kind of the land also where I would think about going out and grabbing Suboxone as well, because that -- I could do that for a short period of time and then taper myself back on to whatever I was using. That was what it was --

DR. EGGERS: And then back there -- couple.

ANONYMOUS: So I was just thinking like I'm going to work all week long. And then when it comes to the weekend, because I'm an adult, I'm going to do what most Americans do, which is have a drink or if that's not so what should I do, I'm going to use opiates. So that would be sort of the way I see this.

DR. EGGERS: So control it for some period of the -- now what -- can I ask -- what would it take to do that? So how -- what would it take for you to be able to control it during the week and allow you to then use more and then be able to control it again?

Can you think of would it have to reduce your cravings during the week or would it have to affect your withdrawal during the week?

ANONYMOUS: Right. So it would have to affect a lot of things. But it would certainly have to affect withdrawal. It would affect anxiety, depression, maybe obsessive thinking.

DR. EGGERS: Okay.

ANONYMOUS: That's sort of the best -- sort of a negative self-talk kind of dialog, so it would have to affect all of that.

DR. EGGERS: So let me ask another one. I'm going to throw out again probably the wrong example, but you can correct me. Imagine you have gotten yourself to a point where you don't like how much you're using, but you don't want to -- you want to go down all across the board. You want to go down a bit.

Talk about that, is that a realistic type of point that you'd like you'd be able to cut it in half, because it's getting -- you're doing dangerous amounts or you're worried about overdose or other risky behaviors. Okay, go ahead. We'll let you answer or --

ANONYMOUS: I think people do that all the time with either through kratom, marijuana, meth use like cocaine. People use in a way that makes it so you

maintain your own self.

And the reality is people don't go to methadone or Suboxone, because we decide to put so many barriers in their way to make it so hard to engage those systems that -- like, legal -- like, I live in Washington and so legalized marijuana has been more of a treatment seems to be for opiate users even though it's not scientific or anything like that.

And like -- for example, kratom, people will use kratom during the week and they'll shoot heroin in the weekends. And so all of these things that people are using because the medical field has been locked out, because we've decided to make it too hard to get these medications.

DR. EGGERS: So let me -- keep that -- keep the microphone. Let me ask you, so again we don't want to talk about specific treatments and I -- and not all treatments can become FDA approved.

ANONYMOUS: Sorry.

DR. EGGERS: What is it -- how is it helping people -- what would you want it to see to say, I'm at a level that's too high for me. I'm going to -- I want

just to cut back. Tell me in concrete terms what that would do for you? Does it take a little edge off? Does it reduce your cravings, but -- so that you don't crave as much? Okay.

ANONYMOUS: I can give an example through methamphetamine. So we -- I run a needle exchange and we gave out meth pipes, and a huge portion of meth injectors switched to meth smoking. And the number one thing they said is now they can make their appointments. Now they can meet their doctors. They can see their family. They can do all these things while still using -- and all they did was change the mode of how they ingest the drug and not change anything around what drug they're using.

DR. EGGERS: So if I can make parallel -- so maybe it's changing to safer forms or less potent forms -- I may come to that. Okay. So those are the types of outcomes. So I think we're going to move on from -- okay, go ahead. Yes, please.

ANONYMOUS: I just want to say back when I first started using methadone it was like maybe come to that point which is like, if you use all week -- right?

I was wishing that it was a methadone program, where you could just go on a weekend like -- like you say you want to get to a certain stage, maybe you go and it will hold you for that weekend or something. Then you wouldn't have to use it every day where it becomes dependent on methadone. You see, that was to me a good solution in the beginning. But like you said, you got to -- in all the way or you're not in at all.

DR. EGGERS: Okay. Thank you for that. I want to move on to craving because we talked about what craving means and what struck me was how craving can still affect, can still be a problem even if you've been in recovery for a long time.

So tell me about that. What does it -- what could a medication do that could help -- I'm -- okay, I'm going to give again the wrong example. But imagine that you are worried about relapsing, that's maybe a big concern you have and something that could help you get through periods of -- you know that there's going to be some high anxiety or stress that or maybe you're going to be in a situation where you're going back to a type of situation that you might have used before in

that type of situation.

If something could help with this idea of cravings, however you think of it. What would that do? Would it take the edge off? Would it -- how could it help you cope through those situations that can be very challenging? Anyone? Does that question makes sense? Okay, go over there and then we'll come over here.

KEVIN: Hi. It's Kevin again. So I relapsed a year and a half ago after almost 6 years of sustained abstinence and recovery. And I am 12 years -- 12 days since arresting that relapse. So basically the position that I found myself in was a highly traumatic life event that happened at a period where I had no support structure around me. I had abandoned everything that had worked thus far.

So the one example that I was personally affected by was death of a loved one. My father passed away. And even though my family knew I was in recovery, I didn't tell them that I was -- all of a sudden in a highly vulnerable state.

DR. EGGERS: Yes. Okay.

KEVIN: So perhaps we as a society might

recognize that if I had -- and I had relationships with a therapist, my primary care physician. They know my condition. They knew about my father's passing, but nobody really asked me, what's your craving level right now? Do you want to go out and go get high? And most people would assume that that might happen.

The other example I'll give is not my personal example, but it's been echoed a lot of concern about people going in for medical treatments, surgery. If I have to go to surgery and I'm going to be in a lot of pain, I'm asking for opiates. I don't care. Opiates work very well at mitigating pain and if I'm under the care of a doctor, I can trust those around me that I can get through that without relapsing.

However, the current state of affairs today is a very similar situation. I read a report in STAT News by Seth Mnookin -- not Seth Mnuchin. Seth Mnookin, who went to Mass General Hospital to receive surgery for kidney stones, and even though his PCP knew he was 20 years in recovery from injection drug use, his wife knew, no doctor at any point ever gave him a consultation about the take home pills that they were

handing him and all of a sudden he found himself physically dependent two weeks later not having had experienced that in decades.

So we need to recognize these highly vulnerable states that people with opioid use disorders will encounter in their life and they need to be given the proper outreach and support throughout those decisions, whatever they make.

DR. EGGERS: So think about FDA's rule. Sorry, I'm going so off script. I'm sorry. Can medications help with that? So I am think -- so what comes to mind is the idea of the rescue. But so you -- and we've all acknowledged the need for support, but would you want a medication that could help you help get through that traumatic lifetime that could reduce your risk of going back, of relapsing abusing again? Okay, so right here we have Jane.

ANONYMOUS: Sure. So, yes, that was my experience. I was having a very difficult time after having a traumatic brain injury and wanting to make sure that I didn't start using opiates again. And so that's why I took naltrexone.

The other thing is, after having a surgery I do have a really wise doctor who knows my condition. And so I went in and had detox and was inpatient in residence, while I needed to do that, so that I didn't just get put back out on the street. And I have a really tight opioid use plan and so it includes all of those things.

I mean recovery planning is -- for me a part of my recovery supports and makes a difference and it does allow me to be in control even when I'm not in control. So it's like a -- what do you call it, a medical advance directive. So I made my plan when I was in a really good place. And so when I'm taking a medication that doesn't allow me to make decisions for myself. I have people who are allowed to step in and make decisions for me at that time.

DR. EGGERS: Okay. So, yes, right.

ANONYMOUS: Yes. I think that having some type of intervention -- I'm not sure that I agree with the notion that all FDA can do is produce medication.

DR. EGGERS: No I just think of one role that we do.

ANONYMOUS: Yes. I do think you have other authorities that you could use to help in this area. But that being said, I think some type of intervention to help manage stressful situations, maybe they're drug related and maybe it can be devices and apps and other things. I think that I am very visual and when I see products that I was formerly addicted to, it can set off and trigger cravings.

And I think it's important that these cravings are for more than things other than just opioids and that drug development or device or app development that can target that reward system in the brain. And I'll give you an example about physical craving. With 10 years in recovery, when I put my ATM -- my credit card in an ATM, because I used to use all night and I would go to the ATMs and maybe there was money in there and maybe there wasn't, for many, many, many, many, years. I was a working person, so I was lucky. But you'd run out, obviously.

And my stomach after -- even 10 years in recovery, would still flip when I was at that ATM machine. I would get that -- there's that 20 seconds

before you know whether cash is coming back out or not, and your card is coming back out. And I would still feel physical sickness about that longing and that craving after 10 years.

So don't think that physical craving isn't a problem. And I can get that where I can get the taste of alcohol when I'm -- in my job there's a lot around, and I can actually get the taste of it when I'm stressed and seeing it everywhere. So things that could address that that are really brain oriented, I think, or gut oriented or heart, I don't know, but some organ.

DR. EGGERS: And would you consider a medic -- so if this -- I don't -- not say that it rises to the level of a challenge -- sorry, go ahead.

DR. WINCHELL: I do have a follow up on that, because in particular, many people are interested in this concept of craving. If there was some type of medication that could prevent you from feeling that experience, is that something you would find helpful all by itself. It wouldn't necessarily change anything about the way you use drugs or any other aspect, but

just that one symptom, would be beneficial.

ANONYMOUS: Absolutely, I will take it, yes. For me -- and this is not the way it is for everyone, if it's mood altering it tends to trigger me wanting more mood altering medication. If it's simply cure cravings, I'd be first in line, because I still over 20 years have problems with various kinds of cravings.

DR. EGGERS: Hand raises if you agree with this perspective. Okay. So we will come right here --

DR. WINCHELL: Can I?

DR. EGGERS: Yes, of course.

DR. WINCHELL: So that's a very interesting perspective from someone in long term recovery who still struggles with those very unpleasant experiences of craving. Suppose someone who is in an early phase trying to get control of their drug use had a medication that made them experience the cravings less intensely, but didn't -- that didn't translate into any modification of how much they use medications. Would people in early recovery or people actively using and looking to gain control would they find that helpful? Just this is part of what --

DR. EGGERS: Might like to be for the dockets, so I think we have lot of people in --

DR. WINCHELL: Yes.

DR. EGGERS: -- sort of long-term recovery. But if you are on the web, please do and if -- and on the docket, unless someone wants to talk about that. You -- did you want to address this question? Okay, you want to address this question?

RICHARD: In a general sense, yes.

DR. EGGERS: Okay. We will let you go first and then we'll go back.

RICHARD: Yes. My name is Richard REDACTED. I'm a professional documentary filmmaker from Baltimore. And my wife Margaret REDACTED is an associate professor in psychiatry at Johns Hopkins University School of Medicine. She's an addiction certified researcher and educator. Today, she's taking care of patients and I will be representing excerpts from her written comments on behalf of our family.

We are the parents of a 25 year old son with opioid use disorder. My wife heard about this meeting from her colleagues and decided to comment because she

cares as a mother and an addiction professional. I'm here at my own time and expense, because I see what kratom has meant to our son and our family and hope that he and others will have access to this drug, which we came across in the last year because of his use of it. So her statement and I'm going to read her statement.

DR. EGGERS: We only have a few more minutes left. Is this something we do it at public comment?

RICHAHRD: I just arrived here. I'm sorry if I'm not in the right place at the right time.

DR. EGGERS: No, no, that's fine. If you could just keep it brief.

RICHARD: I'll consolidate it. So he's been struggling with opioid use disorder for the last 4 or 5 years, in and out of college, in and out of treatment. He was on buprenorphine for 2.5 years and he was unable to work and lethargic during that time. And so we've been through the mill as many people and many families have.

And after he was -- a few relapses and after he was living in Seattle in a sober living facility, he

started using kratom, I guess he heard about it. He was sober. He was going to meetings and he started smoking kratom to stave off his cravings.

And because living facility tested for kratom and kicked him out, he was almost homeless briefly and then he decided to go back to college. He now smokes kratom occasionally as a maintenance for the craving. He has a girlfriend. He's back in college. He just visited us and he's in better shape than he's ever been.

And so as a family we're concerned about kratom becoming inaccessible to people like him, because it's been sort of a -- if not a lifesaver, it's been a very, very efficacious way for him to have survive.

DR. EGGERS: We want to hear all experiences about -- we welcome experiences about all products and especially through the docket or through the webcast. And so thank you for sharing your experiences. We won't be able to get into that discussion in any depth.

There was one more answer about the -- on the question that Celia posed about reducing craving.

ANONYMOUS: So I think we need to think of drug use a little differently. I think we need think of the chaotic drug use and stable drug use and how can we get as many chaotic drug users into stable drug users, because, I think, the concept of recovery that can be their form of recovery. And I also think that if we could get more people on to stable use then we can start engaging them in myriad of other health related issues. And I think that's how we really need to see this.

DR. EGGERS: Okay.

ANONYMOUS: And I think we have a lot of people in recovery here and so it's been very kind of recovery focused. But I think it's really important that we, like, really get in depth of defining chaotic use compared to stable drug use and how we can support people on stable drug use and how we can get as many chaotic drug users into stable drug use.

DR. EGGERS: Okay. We aren't going to able to follow up that now, but you promised to send in a docket comment, define chronic stable drug use and chaotic and what it means. Go ahead, Sharon.

DR. HERTZ: So I would just like to ask this is really interesting for us and I would like to encourage people as much as possible to send in comments to the docket so we can hear as much about that as possible. But that's I think very important.

DR. EGGERS: Okay. We are --

DR. TARVER: I'd like to ask one more question too.

DR. EGGERS: Yes.

DR. TARVER: You also mentioned that some of you are reluctant to want to use medication. I'm just curious as to whether anyone in the audience has used a device or an app to help manage their condition?

DR. EGGERS: Okay. First let's split out, an app -- some sort of app, okay. Another kind of device. Okay. Let's just get a -- can we get a quick -- just quick what it was?

ANONYMOUS: Yes. I used the Calm and Headspace meditation app to chill out anxiety and help manage stressful situations. And I've used a device that monitors my sleep, because lack of sleep makes me start craving and basically just be off.

DR. EGGERS: Anyone else device? Anybody here?

ANONYMOUS: I've used the Spire device and so it monitors your heart rate variability and can identify when you're having anxiety attacks.

DR. EGGERS: Anyone? And then we'll go to Amanda.

ANONYMOUS: I'd used device for -- since I was an orthopedic client to be replaced with (inaudible) purchased through my doctor what they call (inaudible) and this is an alternate for pain control without taking anything by mouth or any other way. And I used it temporarily.

DR. EGGERS: Finally, Amanda.

AMANDA: The Alpha-Stim.

DR. EGGERS: Okay. So I've already begged and borrowed from the people who are doing closing remarks to go a few minutes longer, we'll go till 3:25. Again, we -- I mean, we wish this was -- we had more time. It's really important. A summary on the webcast and we can take one phone caller and a phone caller, if you're in line for the phone and you've -- what we've --

you've heard your issue discussed, we're going to -- please have -- let someone else who has a new issue. Go ahead -- yeah and webcast summary.

GRAHAM: It is on now. So on the webcast a lot of people talking about some of the issues that they've run into seeking treatment for themselves. That addiction doesn't show up on a list of topics when they talk to some of their medical professionals. That when they're looking at what they would want in the treatment that it's not necessarily just managing symptoms, like one at a time, like things like craving, but they'd like a more comprehensive solution, other similar sorts of comments like that.

DR. EGGERS: Thank you. All right. Before we go to the phone, Mitra wants to ask a follow up question.

DR. AHADPOUR: So this is what we were discussing before we went to lunch. I noticed in one of the pollings, the majority of people said they're not concerned for opioid overdose or relapse. Can you just briefly talk about why you are not concerned for an opioid overdose? We are seeing an epidemic of it

all across the nation and what are you doing? I mean, is there something -- and I don't want to put any -- my comments, put my ideas into your discussion, but what are you doing that you're not concerned?

DR. EGGERS: Okay. First let's get a show of hands. I know it's a tough question. How many of you are concerned about relapse and overdose in your situation? You are concerned. Okay. And how many of you are for whatever reason, you are not concerned about that? Okay, so do have some varying perspectives. Let's hear a couple of comments to answer Mitra's question and then we'll move on to the phone.

SHARON: Again, Sharon, I'm not concerned about overdose, because having used drugs as far back as I -- I know there are no -- there's no heroin and I know that what they're selling out here today is everything but, so that's what really got me on a drug withdrawal program, so I don't have any desire to drive what they're selling today, so that's what keeps me away.

DR. EGGERS: Okay. One more back there in the

red.

ANONYMOUS: I would disagree with that because what they're giving out today that's what's previous ordained from, so there's no such thing as non-concern for overdose. We've had more overdose with this thing here that's out than we had when a real one was out.

DR. EGGERS: Can I --

ANONYMOUS: And we just got a training the other day from these guys right here with the (inaudible) to nose, we just had a training for that. There's no such thing as no overdose, we're not candid about it.

DR. EGGERS: Can I ask a follow-up?

ANONYMOUS: I mean -- I mean I might be saying it won't, but I want to say that overdose academic is fully out here today. What they're using to date, you're ODing more from that than you would with the real stuff.

DR. EGGERS: Thank you very much.

ANONYMOUS: Come on now, being -- isn't no joke. It's so --

DR. EGGERS: Can I have a show of hand

questions? How many of you who expressed some concern about possible relapse and then overdoses, are you carrying the lock-zone (phonetic) Narcan -- are you carrying it on you now? Okay. Okay. Okay, one -- okay, thank you for demonstrating. Okay, final comment, then we're going to the phone.

ANONYMOUS: We -- be more power. We are very concerned. We're doing our can training in and out -- in a city and what we do, we meet people on their own terms wherever they're at, whether they're using or not. We just want you to practice harm reduction. Do not isolate yourself. Do not let anybody take your self-esteem away where you're somewhere isolated in a -- oh, how it's using, an overdose and no one's data help you save your life.

DR. EGGERS: Thank you.

ANONYMOUS: We are very concerned and we won't stop being concerned.

DR. EGGERS: Great. Thanks. Okay. I am going to have to go to the phone, so are there any callers on the phone? Operator, can we have a caller? Again if we don't have, it's just important to allow

our webcast participants to be able to chime in a little, but if we don't have any callers, that's fine.

SPEAKER: Stanley's line is open.

DR. EGGERS: Okay. Okay. We're going to ask you to keep it brief because we're running really short on time, but your comment's important.

STANLEY: Okay. Can you hear me now?

DR. EGGERS: Yes, thank you.

STANLEY: Okay, great. Thanks for the forum to sit in on. My name is Stanley REDACTED. I live in Northwest Ohio and I will make this brief. I'm a 62-year-old husband, father, grandfather, even a great grandfather and a long time business-owner and until 30 days ago, I was addicted to opioid pain medication because of an initial 1987 spine surgery. I've had four surgeries since, and 30 days ago -- literally 30 years on opioids, until 30 days ago I was treated with Ibogaine hydrochloride. Within 6 hours, it snapped. I have never had another craving, no dope sickness, nothing.

Again I'm not a 30-year-old junkie, I am a 62-year-old man who has experienced this and the FDA, I

understand you mentioned earlier does not do what the pharmaceutical companies does, put money into research, but somebody should, because this works. I had to travel out of the country to get this done, but Ibogaine saved my life.

DR. EGGERS: Great. Thank you. And again we want to hear all experiences with everything that you think is helping you manage your opioid use disorder. Please talk about that through the webcast as we close up or in the docket. We read all the docket comments.

STANLEY: Okay. I sure will. I appreciate your time.

DR. EGGERS: Thank you. Thank you.

STANLEY: But there is no more management. I don't have it anymore thanks to Ibogaine. Thank you.

DR. EGGERS: Okay, thank you. Okay. I know there are still hands raised, but if we don't, I'm -- I'm worried about these buses that need to head back downtown or back to their places and so we do need to move on, but you are showing that there is still more to the conversation to have. Again, we have the docket. Do we have -- do we put out the website -- the

slide for the docket website? This is -- we've touched upon really important issues and we really only got to the surface and we know that -- we knew that that's what we would get. The conversation will continue and I want to thank you all very much for your participation in the meeting today. I think we heard from almost everyone and that is a real measure of success in our book. Can we give a round of applause for the courage --

(Applause.)

DR. EGGERS: -- and the forthcomingness you had? Okay. So that's the end of the facilitate discussion. Again there are evaluation forms. Please, we really want to know how we've done.

OPEN PUBLIC COMMENT

DR. EGGERS: We're going to move into the open public comment part and so if you signed up for that, you will hear what we're going to move into there. Thank you very much.

DR. WOODWARD: Hi everyone. My name is Shanon Woodward, and right now we're transitioning to the open public comment session of the meeting. So this part of

the meeting allows an opportunity for people to comment on topics other than our two main discussion topics. This is also a chance for stakeholders other than individuals and families to speak. Keep in mind that FDA or NIDA will not address comments that we hear during this session, but all the comments are being transcribed and part of the public record.

We'd like this to be a transparent process, so we encourage you to note any financial interest that may be relevant to your comment. This also may include things such as travel stipends as well. If you don't have any such interest, you may want to state that for the record. And if you prefer not to provide this information, you can still provide your comment. So we collected signups when the meeting began. Right now, we have 12 speakers signed up. I'm apologizing in advance if I butcher your name. Just correct me, I won't take any offense, and also if I get to your name and you share during the meeting today and you feel that you don't need to provide a comment during this time, just let me know, and I can accommodate you as well.

The time for the comments is 2 minutes for each person. We don't have a timer or buzzer, anything like that, so as you get to the end of your time, I may just gently urge you and let you know. So first we have Jack Henningfield. Is Jack Henningfield still in the room? Okay.

MR. HENNINGFIELD: Did you say 2 minutes or 10 minutes?

DR. WOODWARD: Two, two.

MR. HENNINGFIELD: I'm Jack Henningfield. I provide consulting through Pinney Associates on addiction, control medicines, pain medicines. I've worked on most of the addiction medicines since methadone. I think I'm proud of that. I think we've come a long way, but listening to people today, we have a lot further to go and I hope you are listening to people today. One of my mentors was former Surgeon General Koop. He was dedicated to making Addiction Science -- Advancing Addiction Science and making treatments as easy it is to get drugs. And we've come a long way, but not nearly far enough. I think he'd be happy with the opioid report from the White House and

crushed that it's not being implemented. So what we have is not available to a lot of the people.

As you heard today, most people on opioids, it's not just an opioid problem, it's broader mental health problem, it's a societal problem and our treatments have to fit in the context of those problems. There is no one size fits all. We've got to address the needs that people have when they have them with treatments that are acceptable to them and treatments that aren't acceptable, aren't affordable, are no good.

I want to make a few comments on Kratom which is used by 3 to 5 million Americans and 4 surveys show that many people are using it as a lifeline away from opioids because it helps with their withdrawal. I think they are telling people that we're going to take it away, it's like telling somebody that's falling into the ocean and struggling with life preservers they were going to take your life preservers away because they're not Coast Guard-approved. That doesn't make any sense. This is a lifeline.

And finally the four surveys show that many

people who are using Kratom and their families are terrified that FDA and DEA may ban Kratom. What they would like and the surveys show is for FDA to regulate Kratom, help ensure that what they buy is clean and pure and packaged properly. I'll be submitting a longer comment from the record, but I really appreciate what you've done and I really appreciate all the people that have come here today, families and people that have problems, just an incredible eye opener for people like me. I have family members with addiction too, so I can relate to a lot of this at a very personal level. Thank you.

(Applause.)

DR. WOODWARD: Thank you Jack. We have Richard REDACTED, I know you just shared with us briefly. Next we have Maureen Boyle (phonetic). Maureen Boyle? Okay.

MS. BOYLE: So I'm Maureen Boyle. I'm with the Addiction Policy Forum. And I just wanted to first thank FDA for doing this. It's incredibly important. You know, both from the perspective of making sure that we facilitate the development of new medications and

facilitate a larger investment in this, but, you know, I think it's also important to remember the message that the abstinence only end-points sends, right, but, you know, if you've managed to cut down by 75 percent that, you know, if you use again, that that's not success, that's failure, right, so instead of celebrating the fact that you were able to stop for that long or cut down to that amount, you're telling people that they failed.

And I think that sends a really important and really bad message to patients. And so getting to a place where, you know, other outcomes that are more meaningful to people are an acceptable end-point is really important. And I -- you know, I come from this both as a scientist, as an advocate, but also as a family member. So I have a sister who is in active addiction and has been for decades. And I can tell you that my family does not care what she ingests. Like, we don't care what she's putting into her body. We care about whether she can take care of herself and whether she can hold a job and whether she shows up. And you know, however she can get there, I think is the

important thing.

And I think if we can look at things like I said other than abstinence, and you know, even if we're looking at like losing the diagnosis, right, like, you know, you talked about before how the diagnosis is made up of compulsion to use and social impacts and physical withdrawal symptoms, so -- but we're not looking at people who, you know, still use occasionally or, you know, still even, you know, if they don't want to and even if they mess up occasionally. But you know, they've managed to reclaim their lives and we don't count that as success, that's insane.

(Applause.)

DR. WOODWARD: Thank you. Now we have Carol REDACTED.

CAROL: Hello. My name is Carol REDACTED and I wanted to just use this period for two issues. One, I came here today to advocate that there's no wrong door to recovery and just because I have taken a particular path which ultimately was absent in space, wasn't always that way, but I kind of feel like that -- that there are -- you're put in this box and that

somehow if you choose to have abstinence-based recovery, then that means that you're anti people who can manage effective drug use or that you're anti-science or you're anti-MAT, and I think sometimes some of the agencies and others in the field put us in that -- those boxes and try to pit us against one another because it fits their various interest.

And I know I am one of many thousands and tens and thousands of people who believe there is no wrong door to recovery and that people get to define their recovery the way that they want to and there is no judgment for many of us. I know the bad actors or people who are loud on social media sometimes get to typecast all of us, but we're good. This is just my pathway. It doesn't mean I judge people who have another pathway. And I think a lot of times at least in policy circles in Washington, which I'm familiar with, somehow, you know, we've gotten shunned as that people who have abstinence-based or bad actors that judge other people and it's just, I've spent my life working to help people recover in any way that they can.

The second thing I wanted to talk about was the use of taxpayer dollars to help develop or market or whatever drug abuse-deterrent formulations of medications. I know at least in Congress, you know, a law passed that gives tax credits for the development of drug-deterrent formulations and my personal experience in working with a lot of people in or seeking recovery is that there is a recipe on the Internet to beat every single drug abuse-deterrent formulation. There are people who are clever and smart that have figured out a way to get around all of them.

And that continued funding for that instead of putting it into any number of other things, whether it's in a lock-zone or treatment or just education or safe syringe injection sites, whatever, might be a better use of federal policy efforts than drug abuse-deterrent formulations which can be gotten around. Thank you.

DR. WOODWARD: Thank you Carol. Next we have Stevenson (phonetic). Is Stevenson --

MR. SUN: My name is Steven sun. I'm a physician and vice president and head of Quality Risk

Management at Syneos Health. We're an international contract research organization that serves the biopharma company and also serves -- and also has a great interest in serving public health. Thank you for seeking the input of public stakeholders as the development of products for opioid use disorder. And it's part of Syneos Health's commitment to the improvement of public health.

And a 2017 research collaboration agreement of a risk repository system with the FDA for providing a systematic risk assessment of a multi-stakeholder journey for opioid use disorder as is demonstration of the system's risk repository capability which we've deposited in the FDA docket for public read and share to intend for such analysis to provide decision-makers and governing industry an efficient platform for understanding complex issues that involve a multitude of stakeholders that could be achieved through the systematic mapping of each stakeholder's perspective.

And in this case for opioid use disorder, we acknowledged the numerous questions that are asked specifically from the patient's perspective and we made

an attempt to highlight the patient journey in the broader perspective that details of the stakeholder as well as others associated with OUD.

As a former medical officer of the U.S. FDA seeders division risk management controlled substances, I experienced repeated challenges to access experts on the short timelines for evaluating products as part of developing a comprehensive risk assessment. And from this need, a framework emerged to develop a continuous learning system so that each unique bolus of new information and lessons learned could be additive and compound to a growing and intelligent knowledge-base. And we do believe many stakeholders lack the access to see each other's perspectives.

So multi-stakeholder risk assessment would be a cooperative solution to help support many stakeholders including patients, providers, government associates in the industry who are also likely developing from scratch very similar or overlapping risk assessments. We're also advancing this expansion to include an engineering-grade failure mode and effects analysis for common share. Thank you for the

time.

DR. WOODWARD: Thank you Steven. Now we have Kevin REDACTED.

KEVIN: So I wanted to just bring up two points, first their kind of preface I thought I saw in the slide from one of the representatives from NIDA quote about drug abuse being taking a substance that changes mood or mind-altering effects and that struck me as a little odd. I think all of us as human beings inherently want to experience a range of states of consciousness. Otherwise we wouldn't fall asleep and dream.

The other thing I heard a very consistent theme about people developing an opioid use disorder from a legitimate prescription during a medical procedure. I kind of want to draw attention to some data that wasn't reflected. I don't want to deny anybody's experience, but that tends to be the exception and not the norm, most people who get prescribed opioids for chronic pain do not become addicted, but again that's not to deny anybody's experience who spoke today.

The second thing I want to say is that as healthcare providers, as scientists, as advocates, as individuals and families, I would love if we could all agree that the criminal justice component of this issue needs to be removed completely.

(Applause.)

KEVIN: If I drive under the influence of a substance and a policeman pulls me over, I deserve to be prosecuted to the fullest extent of the law, but if I am "exhibiting drug-seeking behavior", sorry, I'm exhibiting the characteristic of a person with an opioid use disorder, I would prefer if I can walk into a hospital and get a measured dose of Oxycodone, then I could have a fentanyl-soaked bag of (expletive) that I had to get from my dealer in Brooklyn every other day.

So this is just the plug to end the drug war, vote for a formal end to district attorneys. If any sheriffs refused to equip their officers with Narcan, vote them out of office. This is not a moral failing. It's a learning disorder. We could catch it early with people -- with young people that are exhibiting effects of trauma, effects lacking resources and family

support, we could intervene on these people early enough that we could perhaps save them from this affliction. Thank you.

DR. WOODWARD: Thank you Kevin. Now we have Juliana REDACTED.

JULIANA: Hi, I just want to first say that I don't want to disqualify anybody's personal experience to my opinion. I believe that there is a million -- more than a million different paths toward recovery or whatever you want to call it, and different things work for different people, but in my personal experience, I found the use of the disease concept of addiction very unhelpful. I do not believe that it is a disease. It actually does not fit the definition of a disease. It's a not a science-based definition, and I stopped using opioids 6-1/2 years ago with Ibogaine.

I don't consider myself an addict, I do not have a disease, and I don't consider myself powerless. I feel that the disease concept of addiction eliminates possibility for the exploration of the many unique experiences, emotional conditions that every person has. It's like a blanket statement saying you have a

disease, and it does not leave room for investigating the many different diverse paths that lead a person to use substances. So I would just like to advocate for transition away from that concept, and the embracing of the fact that everybody suffers in some way. The fact that I chose to deal with it with a substance doesn't make me different from a person that chooses to deal with it through shopping, or through television, or through gambling. We all suffer in different ways and find different ways to deal with it.

For some reason, substance users have been designated as this other population. Why is it that when you use a substance to deal with a difficult emotional situation, that's different than dealing with a difficult emotional situation in a socially acceptable way? I think that that's bullshit. I also just want to go on to say that since using Ibogaine 6-1/2 years ago, I do not have opioid cravings. I am not at risk for relapse, that is not even a possibility in my horizon.

After doing Ibogaine, I stepped out of that life, and I am no longer in the realm of risk and I do

not consider myself at risk for any of these things that we have been talking about. I'm not saying that's what's going to happen to anyone that uses Ibogaine, but the fact that that's happened for me and this person that called in and many other people that I have help treat with Ibogaine, that is significant. It is a huge deal that this is the only drug that gets rid off -- that attenuates opioid --

DR. WOODWARD: Thank you Juliana. Any final thoughts?

JULIANA: I have a final thing to say. I just -- we really want to talk about helping people, we need to talk about total decriminalization of drugs because that is the one thing that would immediately save thousands, if not millions of lives right now.

DR. WOODWARD: Thank you Juliana.

(Applause.)

DR. WOODWARD: Our next speaker is Shilo REDACTED

SHILO: Hi, I have a little list, I'm sorry. I am a 42-year-old lifelong drug user who -- I'm the founder of the Urban Survivors Union and I don't get a

lot of chance to talk to the FDA, so one of things I want to talk about is Naloxone. You keep -- you -- recently, you just led a auto injector through that's $1,000. We are just trying to get Narcan in people's hands. It's unhelpful to keep reinventing the wheel to make drugs more costly than it is to just getting more generics out there for like liquid-based or injectable Naloxone. The other thing I want to talk about is with Medicaid-assisted treatment for opioids, we have nothing for stimulants.

We don't have anything for methamphetamine, we don't have anything for cocaine, and in the West Coast, more people use stimulants than use opioids, and we still have no plan for treatment for them. The only thing that I've ever seen is people prescribing anti-depressants a month before they're considering stopping which is very unhelpful and hard to gauge. The other thing is it's really important that we get better control and quality for Kratom, and we do not make it illegal, and we do not make it hard to get. People -- thousands of people are being forced to use Kratom because we've made methadone clinics so inaccessible,

we've made Suboxone clinics so inaccessible. To be perfectly honest, I think the DEA does more harm to getting treatment in people's hands than it does helping them.

I also think stigma -- I think we really need to get away from this idea of bad drug users, good drug users because to be perfectly honest, I've used drugs my whole life and the only drug that has been the most detrimental to my body has been sugar and it's the only one that people have always commented. That's why I have a round belly. And so --

DR. WOODWARD: Thank you Shilo. And if any final comments, final thoughts?

SHILO: Yes, I think it's really important that we start doing more research for Ibogaine. I think it's very successful, and we've seen large amounts of success in Seattle using it, and I think we -- and also we need to do more research for methamphetamine in general.

(Applause.)

DR. WOODWARD: Thank you. I'm going to turn over to our next speaker Reginald REDACTED. Also in

terms of timing, I just want to do a quick time-check, let everyone know we're getting close to the 3:45 mark, so if you need to be on one of those buses, we don't mind if you have to step out.

REGINALD: Thank you very much. I don't. I'm aware of this meeting being to develop something for opioids, but as a drug user myself, not even as an opioid drug user, I recognize the end-point should be the goal, right? I'm from the other Washington. While opioid use there is, as it is throughout the nation, again the end-point focus should be shifted so the criminalization of it is removed. If I wanted to use whatever drug, decriminalizing and making available alternative medication to manage, you know, anyone's drug use with the end-point being happier, healthier drug use if used. Try that as the end-point of patient-focused drug development. Thank you.

(Applause.)

DR. WOODWARD: Thank you, Reginald. Now we have Alice REDACTED. Alice REDACTED? Okay. Next we have Dennis REDACTED. Dennis REDACTED. She's still -- okay.

DENNIS: So I had an opportunity to interact this morning and I thank you for that. So I'll make it real brief. I think I was able to talk about the family caregiver piece a lot. There's many of us, millions out here, so I want to preface this saying it's not about me, but what the landscape looks like for millions of us is finding out your child is sick and having no support systems, being denied treatment for 2, 3 years with insurance, with private insurance, with employer insurance, having no real good resources that empower that parent to be part of that recovery or wellness toolkit and oftentimes, you know, just financial room.

My son's in recovery, and I think of all the above, and I know that I'm one of the lucky ones, but I know that the 30 e-mails I get today from -- on social media, I know that the hundreds of calls we get at the partnership for peer supports, there is a lot of people that look just like me still on this journey.

So part of when we were discussing things today, I think of the medication -- treatment side of it, right, so not were we just denied treatment, were

denied treatment medications, we're denied everything. So I think that's a real big hurdle for us, and I don' know what that looks like to help people that are denied. The other thing is, is that I think that consumer-faced education is really important.

Again, when you have lack of resources in education to know that our son -- you know, we paid $700 a week and that's fine for Suboxone, but to know that he was giving him Xanax at the same time, early on in the journey, I don't know that that's paid off. I'm just happy that maybe he's not craving, so that consumer-facing education is really important, especially for families.

And I also think what Carol (phonetic) said, just other means, so whether it's that app that supports you, that consumer-face application and really just not -- just the script, right, because when we learned about medication-assisted treatment, we heard a whole lot about continuum supports, right, and getting them healthy and well and that individual recovery because it's so much more than substances. So we don't see that. So a lot of questions were asked today like

would you like that pill. I think we all would, but we would like the support system surrounding it as well. I think it's really important for that wellness piece of it. So thank you.

DR. WOODWARD: Thank you Denise. Next we have Megan Polanin. Megan Polanin?

DR. POLANIN: Thank you. My name is Dr. Megan Polanin from the National Center for Health Research. Our center analyses scientific and medical data, promotes consumer-oriented health policy and legislation, and focuses on patient-centered research and treatment. We do not accept funding from industry, so I have no conflicts of interest to report. We thank the FDA and NIDA for convening today's meeting to elevate patient stories. It's critical to know patient's perspectives on opioid use disorder and this meeting is a positive step at initiating a productive dialogue. We know that the FDA has made a commitment to finding ways to reduce opioid use and addiction including improving more treatments for opioid use disorder.

We also know that drug companies are eager to

get patients who want more treatments to talk with FDA officials. Kaiser Health News recently published their prescription for Power database and reported that in 2015, pharmaceutical companies gave at least $116 million to patient advocacy groups. We want the FDA to hear from patients and are concerned that they're not hearing perspectives that represent the wide range of patients and their loved ones affected by opioid use disorder. Patients who aren't involved with these form of funded patient groups may not know how to engage with the FDA.

If they know about public meetings like this one, they may not have the means to attend and many don't know about opportunities to send written public comments to the FDA docket. Patients often ask as if it's worth their time and expense to come to an FDA meeting when they're given only a few minutes to speak and can only register to speak the morning of the meeting. We've heard from patients that they don't want to come to the FDA meeting at their own expense without a guarantee that they will have a chance to speak and be heard.

DR. WOODWARD: Thank you. Any final thoughts?

DR. POLANIN: Yes. So to ensure that the patient perspective is well represented, the patient engagement process should be inclusive and transparent, and we would encourage the FDA to continue to do so and make even more efforts. So thank you to the patients who've shared their stories today, and we appreciate the opportunity to express our views.

DR. WOODWARD: Thank you.

DR. POLANIN: Thank you.

DR. WOODWARD: I'll now be turning it over to one of my colleagues for some closing remarks and also just for a time-check, it's 3:53, if you are taking one of the shuttles back.

CLOSING REMARKS

DR. AHADPOUR: We just wanted to briefly take this opportunity to thank all of you for those who came, some came long distances and anyone who joined us virtually. You shared your stories, we have listened and we have learned a great deal, so we are grateful for it.

I also wanted to thank all the individuals who

were involved in the planning, the panelists from FDA; NIDA; Office of Center Director; control substance staff and PACE Office of Communications (phonetic); Office of Media Affairs; Office of Minority Health; Office of New Drugs; Division of Anesthesia, Analgesia and Addiction products and Clinical Outcome Assessment Staff; Office of Strategic Programs; senior FDA leadership and/or NIDA colleagues and advocacy and support groups.

I really wanted to just really end it by saying thank you, a big thank you, and also just to mention that opioid uses, so there is a chronic illness, it is treatable. There is evidence-based treatment, and I just wanted to give the -- there was a lot of discussions about trauma, mental illness and addiction. There is treatment available. The SAMHSA treatment locator is one good place to go to find a treatment that is close to you, and I also wanted to give the number for the suicide prevention hotline, 1-800-273-8255. So thank you so much and safe trip back home.

(Applause.)

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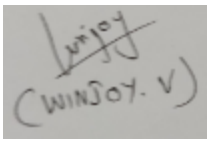

April 30, 2018

Date WINJOY VIJAYAN

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