

The Voice of the Patient

A series of reports from the U.S. Food and Drug Administration's (FDA's)
Patient-Focused Drug Development Initiative

Stimulant Use Disorder

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Introduction

On October 6, 2020, the U.S. Food and Drug Administration (FDA) held a public meeting to hear individual perspectives on stimulant use disorder. The meeting provided FDA with the opportunity to hear directly from individuals with stimulant use disorder. This includes individuals who are struggling or have struggled with the use of cocaine, crystal meth, methamphetamine, or misuse of prescription stimulants such as Adderall or Ritalin. Family members and caregivers were also encouraged to participate and share their experiences. FDA was particularly interested in hearing perspectives on the:

- Health effects and daily impacts of stimulant use disorder
- Impact (if any) of opioid and polysubstance use¹ on participants daily life
- Treatment and management goals
- Decision factors considered when seeking out or selecting an approach to manage stimulant use disorder

FDA conducted the meeting as part of the Agency's Patient-Focused Drug Development (PFDD) Program, an effort to systematically gather individuals' perspectives on their condition, and therapies available to treat the condition.

More information on FDA's PFDD Program can be found at:

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm579400.htm>.

Overview of Stimulant Use Disorder

According to the [Substance Abuse and Mental Health Services Administration](#), the term "stimulant use disorder" describes a range of problems associated with the use of illicit stimulant drugs, including methamphetamine, cocaine, and amphetamines, but not including caffeine or nicotine. A diagnosis of stimulant use disorder is made when a clinician identifies a pattern of use of amphetamine-type substance, cocaine, or other stimulant that leads to clinically significant impairment or distress, including an inability to reduce or control consumption, cravings to use a stimulant, continued use of a stimulant despite it causing negative consequences, and the need to use increased amounts of a stimulant to achieve the desired effect. No medications are FDA-approved to treat stimulant use disorder.

Some of the most well-known stimulants are:

- Cocaine, a drug made from the coca plant that is often snorted or smoked.
- Methamphetamine, a particularly potent amphetamine drug.
- Prescription stimulants such as Adderall, Dexedrine, Ritalin and Concerta, which are used to treat Attention Deficit Hyperactivity Disorder (ADHD).

¹ Polysubstance use – The [Center for Disease Control \(CDC\)](#) defines polysubstance use as two or more drugs that are taken together or within a short period of time, either intentionally or unintentionally.

According to the [2020 National Survey on Drug Use and Health²](#), in 2020:

- 1.3 million people aged 12 or older had a cocaine use disorder.
- 1.5 million people aged 12 or older had a methamphetamine use disorder.
- An estimated 758,000 people aged 12 or older had a prescription stimulant use disorder.

The use of illicit stimulants continues to increase in the United States.³

Meeting Overview

This virtual (online only) meeting provided FDA the opportunity to hear directly from individuals with stimulant use disorder and their family members. These participants were encouraged to engage in the facilitated discussion during the meeting by submitting comments via the meeting site or calling in via phone to share their experiences. The discussion focused on two key topics: (1) health effects and daily impacts of stimulant use disorder and (2) patients' perspectives on current approaches to treating stimulant use disorder. The questions for the meeting discussion (Appendix 1) were published in a [Federal Register notice](#) that announced the meeting. In this document, the term 'meeting participant' or 'participant' will be used to describe individuals with stimulant use disorder or impacted family members who shared their experiences or perspectives during the meeting.

For each topic, a panel of participants (Appendix 2) shared comments to begin the dialogue. The panel for Topic 1 included individuals who are in recovery from stimulant use disorder and impacted family members. The panel for Topic 2 included individuals who are in recovery from stimulant use disorder and one individual who was actively using stimulants. Panelists were diverse in gender, age, and race.

Panel comments were followed by large group facilitated discussions inviting other participants to call in and submit written comments through the webcast platform. An FDA facilitator led the discussion and a panel of FDA staff (Appendix 2) asked follow-up questions. Participants were periodically invited to respond to polling questions (Appendix 3), which provided a sense of the demographic makeup of participants, and the proportion of participants who shared a particular perspective on a given topic.

Approximately 500 people registered to attend the virtual meeting through the live webcast, with around 60 registrants identifying themselves as individuals with stimulant use disorder or an impacted family member or caregiver. The remaining registrants represented healthcare, academia, the medical product industry, other government agencies, and patient/advocacy organizations. Registration for the meeting was recommended but not required, therefore the characteristics of meeting registrants may differ from those of meeting attendees.

² The methodology of how these figures were calculated is discussed in more detail here: Center for Behavioral Health Statistics and Quality. (2021). 2020 National Survey on Drug Use and Health: Methodological summary and definitions. Retrieved from: <https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFR1PDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf>

³ Center for Behavioral Health Statistics and Quality. (2021). 2020 National Survey on Drug Use and Health: Methodological summary and definitions. Retrieved from: <https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFR1PDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf>

Meeting participants varied in gender, race, age, history of stimulant use disorder, and experiences with stimulant use disorder. They also varied in their overarching perspectives on substance use and treatment. Although participants at this meeting may not fully represent the overall population of individuals with stimulant use disorder, the input received reflected a range of experiences and perspectives on the effects of stimulant use and its management approaches.

All meeting attendees were invited to answer the first two polling questions on demographics. Attendees represented a range of experiences with stimulant use, with 22% indicating they are currently misusing or have misused stimulants in the past, 17% indicating they are a family member or caregiver of an individual(s) currently misusing or who previously misused stimulants, and 60% indicating they are an advocate for individuals who are misusing or previously misused stimulants. Approximately 87% of these participants reported living outside the Washington D.C. area.

For all subsequent polling questions, only attendees who identified as an individual with stimulant use disorder or as an impacted family member or caregiver (i.e., meeting participants) were asked to respond. Ages of these meeting participants ranged from 12 to over 60 years of age, with roughly half reporting an age over 40. The majority of meeting participants reported living in the Midwest, Northeast, or Southern regions of the United States. Approximately 31% of respondents indicated they or a family member started stimulant use with cocaine, 26% indicated they or a family member started stimulant use with prescription stimulants, and 28% of respondents reported that they or a family member started stimulant use with methamphetamine or crystal meth. Approximately 8% of respondents reported they or a family member started stimulant use with other stimulants not mentioned in the polling question while the remaining 8% of the respondents were not sure which stimulant they or a family member started using first.

More information, including the archived webcast and meeting transcript, is available on the meeting website: <https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-stimulant-use-disorder-10062020-10062020>.

To supplement the input gathered at the meeting, individuals with stimulant use disorder and their representatives were encouraged to submit comments on the topic to a public docket⁴, which was open until December 7, 2020⁵. Four comments were submitted to the public docket. Comments were received from an individual in recovery from misusing prescription stimulants, an individual in recovery from using methamphetamine, an individual who is currently using prescription stimulants for a medical condition, and a patient advocacy organization focused on recovery, that works with communities.

Report Overview and Key Themes

⁴ A *docket* is a repository through which the public can submit electronic and written comments on specific topics to U.S. federal agencies such as FDA. More information can be found at www.regulations.gov.

⁵ This meeting was originally scheduled for March 10, 2020 and was rescheduled to October 6, 2020. The docket for this public meeting was open for two periods of time. It was first opened for public commenting and closed on May 11, 2020 when the meeting was scheduled for March 10, 2020. The docket re-opened from September 30, 2020 to December 7, 2020 for public commenting to support the October 6th meeting.

This report summarizes the input shared by individuals with stimulant use disorder, their loved ones, and other stakeholders during the virtual meeting. It also includes a summary of comments submitted to the public docket. To the extent possible, the terms used in this report to describe specific health effects, impacts, approaches to management experiences, and perspectives reflect the words used by participants or docket commenters. The report is not meant to be representative of the views and experiences of any specific group of individuals or entities. There may be health effects, impacts, treatments, or other aspects of stimulant use disorder not included in this report.

The input from the meeting and docket comments underscores the diversity in experiences with stimulant use disorder, the complexity of selecting and accessing a management approach, and the broader challenges individuals face in accessing care and support from the community. Several key themes emerged from this meeting:

- Participants described a feeling of euphoria and a rush when using stimulants. They also described continuing to use stimulants to avoid a feeling of mental and physical exhaustion that they associated with withdrawal.
- Some participants reported using one type of stimulant at a time, while others reported using multiple types. A few participants reported that they started to experiment and use illicit stimulants, such as cocaine, methamphetamine, and crystal meth, after experiencing the effects of a prescription stimulant like Adderall or Ritalin.
- Stimulant use affects careers, education, relationships, and other aspects of daily living. Some participants reported losing custody of their children, losing jobs, and missing out on educational opportunities. They also reported multiple encounters with the criminal justice system because of their stimulant use. Participants shared that in some cases, encounters with the criminal justice system led to them gaining access to recovery and mental health programs.
- Participants spoke about how the use of stimulants was both criminalized and stigmatized and described the impact of stigma on their interactions with healthcare providers.
- Participants described the lack of treatment options for stimulant use disorder as an obstacle and barrier to recovery, particularly when compared to existing treatment options for opioid use disorder (OUD).
- Participants emphasized that effective management of stimulant use disorder was only achieved after a lot of “trial and error.”
- Participants discussed impacts of the COVID-19 pandemic on long-term recovery. Some experiences with disruptions in gaining access to recovery programs in a virtual environment were shared. However, most participants highlighted the benefits in switching to virtual programs.

Participants stressed the need for greater awareness of the underlying causes and impacts of stimulant use disorder among families, communities, health professionals, and the criminal justice system. They shared that having increased awareness of the underlying causes that lead individuals to start using stimulants could result in better health outcomes and opportunities for resources that would benefit this population. Participants also emphasized the importance of increasing understanding of the health

care needs of individuals with stimulant use disorder and the need for communities to have better access to resources and management approaches. Participants emphasized that stimulant use disorder is often not seen as a chronic health condition. They offered insights on how to better help individuals with stimulant use disorder achieve recovery and how recovery might look different for each individual. Based on the shared experiences, there was no consensus on the definition of what a “successful recovery” looks like.

The patient input generated through this PFDD meeting and the public docket strengthens FDA’s understanding of the impact of stimulant use disorder on individuals, and the management strategies currently used by these individuals to manage this condition. FDA staff will carefully consider this input during the medical product development process, including when advising sponsors on their drug development programs and when assessing products under review for marketing approval. This input may also be of value to medical product development more broadly. For example, it may be useful to medical product developers as they explore treatments more specific to symptoms of stimulant use disorder, or in designing interventions that can facilitate its enhanced management.

Topic 1: Health Effects and Daily Impacts

Topic 1 focused on gathering perspectives on the impacts of stimulant use disorder on individuals' health and daily lives. FDA was particularly interested in understanding how participants describe the health effects, in their own words. FDA was also interested in learning how stimulant use disorder affects individuals' ability to perform daily activities as normally and fully as they would like.

To start the dialogue, five panelists provided comments. Panelists included:

- A woman, whose deceased parents both struggled with cocaine use, shared her experience as an impacted family member. She emphasized the profound side effects and long-term consequences – such as long-lasting withdrawal, intense cravings, and cognitive health effects like paranoia or psychosis – on individuals with stimulant use disorder.
- A man in long-term recovery who started using prescription Adderall and cocaine as a teenager in high school and started misusing his Adderall prescription in his early twenties. Stimulant use disorder disrupted his career and education. He shared that the choices he made while using stimulants led to him becoming infected with HIV.
- A man in recovery who previously experimented with cocaine and methamphetamine use in combination with opiates and other drugs. He focused most of his energy on financially supporting his addiction, which eventually impacted his family relationships, dental health, and overall well-being.
- A woman in long-term recovery after using cocaine as a college student. She expressed that her unmedicated depression, ADHD, and adolescent trauma drove her use of stimulants. She shared her ongoing challenges of trying to stay on task or be organized without using a prescription stimulant to treat her ADHD.
- A woman who described her son's journey with stimulant use disorder as being catastrophic. She expressed her frustration with the lack of medical treatment available for stimulant use disorder. She also highlighted the challenges her son has faced due to the criminalization of stimulant use disorder.

The panelists' opening comments provided a range of perspectives on the health effects and daily impacts of stimulant use disorder. Their stories provided rich insight into the physical, social, mental, and financial impacts. During the large group facilitated discussion that followed, panelists and meeting participants discussed additional impacts of the condition.

The remainder of this section summarizes in more depth the input from participants on the topics related to the health effects and impacts of stimulant use disorder.

Perspectives on Health Effects of Stimulant Use Disorder

Participants described their paths to developing stimulant use disorder. The experiences ranged from individuals who struggled with the misuse of prescription stimulants in their adolescence and eventually became addicted to illicit stimulants (cocaine, methamphetamine, and crystal meth) to individuals who developed stimulant use disorder following recreational use, to individuals who began using stimulants

to manage the side effects of opioids and untreated mental illness. These varying histories highlight the complexity of stimulant use, misuse, addiction, and recovery. They also provide insight on how experiences and perspectives of stimulant use disorder and management of the condition may be shaped by individuals' personal situations and motives.

In a polling question (Appendix 3, Q6), participants were asked to identify which stimulant they started using first. A total of 39 participants responded to the question. About 30% of the participants noted starting with cocaine use. In the following polling question, participants who were using stimulants at the time of the meeting were asked which stimulants they were currently using. While most participants shared that they were not currently using stimulants, others selected currently using cocaine, methamphetamine, crystal meth, prescription stimulants, or other stimulants not mentioned in the poll.

In a polling question (Appendix 3, Q10), participants were asked to identify the most negative effects of stimulant use. In response, participants shared that several physical effects (such as rapid or irregular heart rate, difficulty breathing, increased blood pressure), mental effects (such as paranoia, confusion, hallucinations), and effects of stimulant withdrawal (such as fatigue, depression, inability to focus) were the most negative effects related to stimulant use.

Throughout the meeting, participants discussed the significant impacts of stimulant use on their health.

- Several participants noted issues with **dental health**. They highlighted that, even in recovery, they experience oral issues such as “meth mouth” and tooth decay.
- FDA was interested in understanding whether meeting participants used **stimulants along with other substances** such as opioids, and how the use may have evolved over time. One participant described the impact of polysubstance use, stating, “I believe that if I would have gotten help with my opioid use disorder, that the stimulants [stimulant use disorder] never would have come.” Many meeting participants described using opioids to balance the intense symptoms of stimulant use disorder. For example, one participant described his polysubstance use, sharing, “And then for a long time, I would use it [cocaine] in combination with other drugs and often I would utilize opioids in order to help quell the cravings that came with my stimulant use.” Another meeting participant who shared his experiences on the health effects and impacts of both stimulant use disorder and OUD explained that although he was able to receive treatment for OUD, it didn't address his stimulant use. He stated, “You know, there was some way that they would want to help me address my opioid use disorder, but that didn't kind of change my cravings and desire for continued stimulant use.”
- Many participants shared the **health effects** they experienced. One participant shared that his intravenous drug use led to multiple infections and abscesses resulting in “a number of hospitalizations related to that specifically.” Another participant described long-term health effects, stating, “Twenty-two years of an injection drug problem led to significant and expensive health problems such as MRSA [Methicillin-resistant Staphylococcus aureus].” She continued to share that she was “twice hospitalized with sepsis and septic arthritis.” A mother also touched on the effects that meth use had on her son's heart, sharing that “his heart rate would go extremely high” and “he was at risk of dying when he does these drugs.”
- Participants attributed undiagnosed **mental health conditions** as one reason for starting the use of stimulants. They noted that mental health issues often went untreated until they stopped

using stimulants and found treatment for their mental health condition. One participant shared, "At that point, that's where I was able to be diagnosed with my mental health diagnosis and start to get treatment." Participants also highlighted the impacts that stimulants had on mental health. A mother of an individual with stimulant use disorder shared that her son experienced a psychotic episode sharing, "so every time he would use meth, he would go into psychosis."

Impacts of Stimulant Use Disorder on Daily Life

Participants described stimulant use disorder as having a significant impact on their daily lives. They described difficulties in maintaining stable housing and participating fully in work and school. Many participants shared their experiences with the criminal justice system and further discussed the impacts of their stimulant use on families and friends. Participants recalled how their use of stimulants limited their ability to care for their children and damaged their relationships.

Participants described withdrawal as consisting of multiple symptoms such as mental and physical exhaustion, inability to focus, and sleeping for long periods of time. A participant described his experience by sharing, "from the time that I was in high school through my early 20s, I chased that feeling of euphoria and rush that came every time I would take one of those Adderall. And I desperately, desperately, wanted to avoid not only the physical exhaustion, but the mental and emotional exhaustion that would come with the withdrawal if I didn't have the medication that I was trying to utilize." One participant compared the symptoms of withdrawal from stimulants to withdrawal from other substances, stating, "Withdrawal lasts much longer than it seems like for other substances." Another participant described his experience with withdrawal by sharing, "And looking back now, I even realize in high school that there were times that I was starting to go through that physical withdrawal that they were talking about in the clinical presentation where my mood plummeted. My energy plummeted. I wanted to isolate and be around no one else until I had that substance again."

While concern of stigma from criminalization of stimulant use disorder was a prominent topic of discussion during the meeting, several participants identified positive impacts of their encounters with the criminal justice system. When speaking about their ability to control their stimulant use, one participant shared, "So really, incarcerations or incapacitation were really my only limits eventually." Other participants also described incarceration as being the reason why they "got clean." A participant shared about her time in jail and how it impacted her recovery journey, stating, "Another thing that was beneficial about the court encounter was I had the opportunity to participate in the Felony Therapeutic Mental Health Court and just really get rehabilitated. And that's where I think treatment is so important. I was able to get wraparound care. I was able to get a therapist. I was able to get connected to different group settings, cognitive behavioral therapy, DBT [dialectical behavior therapy], and wellness recovery action plan." Another participant shared the experience he received from being incarcerated, highlighting, "And one of the really kind of essential, pivotal parts of my change process [was] recovery housing. Just having that kind of supportive environment. Again, improving upon my social determinants of health, giving me a really basic foundation of stability as I was being released from incarceration gave me something that I could build from. I was even able to go back to college, start working on a social work degree, start working a regular job."

Effects of Stigma

As mentioned above, throughout the meeting, individuals and representatives described the effects of stigma on stimulant use.

Participants described the stigma that surrounds stimulant use disorder and impacts people who use stimulants. One participant noted that stigma not only exists in the broader community but within the recovery community as well. Within the recovery community, some drugs tend to be considered “better” or “worse” than others and often people minimize stimulant use disorder as being “not that bad” when compared to other types of addiction.

Meeting participants expressed how the criminalization of stimulant use often adds to the stigma. One participant described how individuals with stimulant use disorder are labeled by society, stating, “they’re now not only labeled as addicts, but criminals.” A participant also shared that society stereotypes people with stimulant use disorder as being more violent and more likely to commit crimes than people with OUD. Another participant felt that, compared to individuals who use opioids, individuals who use stimulants face a greater degree of stigma. He asked rhetorically, “Which of these two is more likely to break in and steal some stuff [from your house]? A meth addict or someone with a[n] OxyContin problem?” Other panelists agreed and shared that they believed that this stereotype stemmed from the criminalization of stimulant use. Another participant shared that they felt that different types of stimulants carried different stigmas, saying, “even just looking at the stratification of stimulant users themselves in our criminal justice system, we see a vast difference between the crack cocaine user and how they’re treated by the criminal justice system as opposed to somebody who uses powder cocaine, which is, you know, [a] very similar drug with a lot of very similarly presenting qualities in terms of problematic use.”

One participant explained that education is the key to battling addiction stigma. She discussed that when time is taken to teach family members, healthcare providers, and criminal justice professionals about what addiction is and how it affects the brain and changes behaviors, it will help build empathy and compassion that will help the community understand that stimulant use disorder is a health condition. Lastly, a participant emphasized the need to help with the “self-stigma” that’s around stimulant use disorder. She noted ongoing efforts in the space that are geared towards helping individuals with the condition deal with the self-stigma, sharing, “we work and try to do all we can to help with the self-stigma that’s around stimulant use disorder, of helping people learn how to forgive themselves, and understanding some of the behaviors and changed priorities that come from addiction, and stimulant use disorder, and understanding how that happened, to really learn how you find that self-forgiveness.”

Additional Impacts

Participants described in detail the impact that stimulant use disorder has on daily life, including:

- **Impact on Relationships.** Many participants discussed how the condition impacted their relationships with family and friends. Throughout the discussion, they described damaged relationships and their inability to care for their children when they were using stimulants.
- **Impact on Work Life.** Many participants discussed experiencing hardships at work and school due to stimulant use disorder. One participant shared his experience, stating, “My addiction impacted my job performance and spawned a vicious cycle of using. During my last eight months [of using stimulants] I went from leading a team of 40 to injecting meth daily. I lost my job and my health.” Another participant stated, “So whereas energy could have been focused on

my career and profession, I was using that time and energy to go find my drug that I needed to get through work. And ultimately what would happen is I would lose any sort of employment that I had as a result of that chase.”

- **Financial Impacts.** A few participants touched on the financial impacts. A participant shared, “I found that I would not go through hundreds of dollars’ worth of cocaine or crystal meth if I also combined it with opioids” and “doing things to get more money, to get more drugs.” Another participant shared his experiences on the financial impact, stating, “being a person that, at the time, needed those substances, I did what I knew I needed to do in order to make money, and that was my introduction to sex work. And what I will tell you is my drug use directly impacted those choices that led to that work.”

Topic 2: Perspectives on Current Approaches to Management

During the second panel discussion, panelists shared their experiences, not only on the management approaches they used, but also the factors they considered when making decisions about their recovery. Six panelists (Appendix 2) provided comments to start the dialogue.

The panelists included:

- A man in long-term recovery who first started using cocaine in the late 1980's. He shared how stimulant use negatively impacted every single area of his life. After seven attempts, he is now in long-term recovery.
- A woman whose journey with stimulant use disorder first started by negotiating with doctors, which she described as "doctor shopping," to gain access to prescription stimulants. She entered recovery after an encounter with the criminal justice system and participation in a recovery program.
- A man in recovery who shared his experience with participating in a 12-step program focused on meth recovery. With the help of loved ones, he found a path to long-term abstinence from a drug that he had given up any hope of quitting.
- A man who struggled with stimulant use disorder for over 25 years and has been in and out of a dozen treatment centers with recovery programs ranging from 30 days to one year. He now participates in a recovery program that supports individuals who have chosen to abstain or are considering abstinence from addictive behaviors.
- A woman who started using illicit stimulants at the age of 30 after she experienced opiate withdrawal and an undiagnosed mental health condition. After an encounter with the criminal justice system, she was given the opportunity to participate in a felony therapeutic mental health program and was connected to many community resources, including inpatient and outpatient treatment programs. After a year and a half in the felony therapeutic program, she began her journey to recovery.
- A man who shared his experience as an individual who uses stimulants and practices a harm reduction pathway to manage stimulant use disorder. His management approaches include moderation management combined with pharmacotherapy, mindfulness-based practices, and holistic wellness.

In the facilitated discussion that followed, individuals with stimulant use disorder and representatives discussed experiences with recovery programs, therapy sessions, and effects of treatments. Overall, many participants expressed that there is no single approach to treatment that will work for everyone and that the journey to recovery requires addressing not only the short-term cravings and symptoms of withdrawal but also the underlying issues that led to addiction in the first place. Participants also shared differing views on how they defined recovery.

In a polling question (Appendix 3, Question 13), participants were asked if they had used any of the listed approaches to manage stimulant use disorder. Participants described a variety of approaches as part of their recovery which included peer support, counseling, behavioral therapy, and lifestyle changes

(such as complete abstinence and avoiding “triggers”). Throughout the discussion, participants shared that their approach to recovery was often dependent on the resources and community support systems that were available to them. Several participants stressed that their comments represent the management approaches which worked best for them personally and may not be applicable to all individuals with stimulant use disorder.

Perspectives on Approaches to Management

Participants described utilizing a range of approaches to manage the symptoms of their stimulant use disorder. Some approaches that worked for panelists included 12-step recovery programs, SMART recovery programs, and cannabis. Participants also discussed the importance of addressing the underlying causes of their addiction through social support and mental health services. Overall, meeting participants stressed that participating in a recovery program that fit their individual needs, where they felt they ‘fit in’, and that was available to them when they were ready to enter recovery, was the preferable management approach for stimulant use disorder. Many shared their wish that there was a medication available to help treat the effects of withdrawal from stimulants. They also stressed the need for increased counseling and behavioral support services.

Obstacles and Barriers for Recovery

Participants described the obstacles and barriers to seeking recovery, including lack of access and lack of awareness of quality treatment programs. Shame and stigma surrounding stimulant use disorder were also mentioned as barriers to treatment. Examples of treatment barriers they encountered are captured in the statements below:

- “My primary care physician couldn’t offer much help. There weren’t any prescriptions he could write, and he struggled to recommend good treatment programs. Once I was honest about my situation though, I had a group of non-using friends who were willing to step forward and help.”
- “What I’ve found through these [criminal justice] systems specifically is stimulant use disorder is not a crisis. So, if it’s not a crisis, I’m not going to get the proper treatment that I need for that particular substance use disorder. And quite often, especially right now, we’re having more of an issue with the opioid use disorder. So there’s quicker access into treatment if you either have an opioid use disorder, an alcohol disorder.”
- “With addiction, I found that my denial, lack of readiness to change, shame and stigma of this disease are huge barriers to overcome to start the road to recovery.”
- “What has not been helpful to me has been the one-size-fits-all treatment approach consisting of substance abuse education and mandatory 12-step meetings.”
- “Another obstacle to my recovery has been access to quality programs based on my insurance status. At times when I’m in most need of intervention and treatment, I have the least insurance coverage.”
- “I think one of the challenges for me with my addiction was, one, not wanting to admit that I had a problem.”

- “I sought an evaluation and was referred to an Intensive Outpatient Program based on the progression of my disease. I was unwilling to admit that my problem was this bad and I declined that offer.”

Desires for Treatment

Throughout the meeting, participants shared desires for effective treatments to be made available to people with stimulant use disorder. They frequently referenced the treatment programs available to people who struggle with opioid use as successful models. Participants discussed that they may choose to continuously participate in recovery programs to manage their condition.

One participant explained that treating stimulant use disorder is not only about treating the effects of the specific addictive substances, but also looking to treat the effects of the underlying cause of addiction. She expressed, “I may be able to arrest my cravings for one specific substance, but then again, it moves onto something else and can manifest.”

Participants described that experiencing homelessness makes it challenging to access care for stimulant use disorder. One participant also noted, “homelessness actually makes it more difficult for people to make any changes.”

Meeting participants identified barriers to care that impacted their ability to manage stimulant use disorder, which included cost of treatment programs, overall access to treatment, and stigma associated with receiving treatment for an addiction condition.

Meeting participants shared their experiences with using other therapies beyond 12-step and SMART recovery programs. They stressed that when seeking recovery, there is “not a one size fit all solution for everybody.” Participants described how characteristics, such as gender, race, sexual orientation, and social and economic status can impact experiences of stimulant use disorder and stressed the need for a more intersectional approach to care. One meeting participant described recovery as a process that encompassed a combination of several therapies, which for him included cannabis and the coca leaf. Specific therapies discussed are described in further detail below.

- Several meeting participants described their experiences utilizing different types of health services to manage stimulant use disorder. Types of health services mentioned included individual and group counseling services, residential treatment programs, weekly recovery meetings, and other recovery-focused programs such as 12-step programs and SMART recovery. Several participants shared the impact of therapy and counseling in addressing the mental health issues associated with their recovery. In describing their experiences with 12-step programs, many focused on the benefits they gained from participating in the program. Several pointed out the 12-step program as the reason they got their “life back.” Participants commented on other programs to reduce their desire to use stimulants and enhance their ability to withstand withdrawal and cravings. One participant shared, “I’ve been practicing SMART recovery for six years now and it has done wonders in reducing, even stopping my drug and alcohol use.”

- Many meeting participants stressed support from peers, family, and friends as critical to their recovery. In addition to family and friends, participants described their support networks as including community organizations and accountability partners. Participants stressed the value in interacting with others in recovery as important to staying committed to managing their condition.

Participants also shared experiences using other methods to manage their stimulant use disorder. A participant who is in recovery described being dependent on caffeine, sharing, “Caffeine is a huge part of my life at this point, and I’m a smoker,” and explaining that her addiction still “manifests in different ways.”

Some participants identified other substances, to support their management of stimulant use disorder. A few participants shared experiences with using cannabis to help manage the cravings, withdrawals, and discomfort. One participant highlighted this, stating, “And so I realized that I could use that [cannabis] as a strategy even without using stimulants intermittently. So that was one way of effectively addressing the cravings.”

Participants provided a range of perspectives on areas that could lead to improved management of stimulant use disorder. Meeting participants stressed that enhanced management begins by increasing awareness, for both the medical community and criminal justice system, of the severity of the condition.

Participants stressed that stimulant use disorder is a chronic condition and needs to be managed as such.

When discussing an ideal treatment, participants stressed the desire for treatment options and the need for continued research on polysubstance use. Participants also expressed a desire to reduce stigma around stimulant use disorder and raise awareness about the condition. In response, an FDA panel member agreed and spoke of the Agency’s commitment to doing its part to, “destigmatize stimulant use disorder so that individuals can receive the competent and compassionate care.”

Meeting participants also stressed the importance of ensuring the availability of support networks to meet the needs of individuals who are interested in recovery. Participants noted that recovery is not one-size-fits-all and that management should be tailored to individual treatment goals. Participants discussed that treatment goals change, and a personalized approach is needed to sustain recovery. Several participants highlighted managing cravings, emotional issues, and personal traumas; navigating stigma; and restoring meaningful relationships as key areas of their recovery which are challenging to address holistically without changes in overall approaches to management of stimulant use disorder.

Topic 3: Impact of COVID-19 Pandemic on Stimulant Use Disorder

During this session, individuals with stimulant use disorder and family members provided a range of perspectives on the impacts of the COVID-19 pandemic on stimulant use disorder.

Many meeting participants shared that since the COVID-19 pandemic, access to recovery programs had gotten easier. Some recovery programs have expanded their online services and converted in-person meetings to Zoom.

Participants described:

- “I have greater access to more meetings than ever before. Because of this change, I have taken an online training to become a meeting facilitator and I now run an online meeting.”
- “There’s a bright side to a global pandemic. It has increased access to resources. Zoom meetings may not be enough for everyone, but at this stage in my recovery, it’s just what I need.”
- “Within three or four days [of lockdown], we had more 12-step Crystal Meth Anonymous Meetings going online than we actually did in-person meetings.”
- “I know that COVID has created difficult situations for many; however, a silver lining for those who are not comfortable in social settings, which is a push for many recovery programs, and does not fit a portion of the population because not everyone is naturally social. It has allowed people who are not social to thrive in this new social setting online.”

Conversely, some meeting participants shared that it is difficult for those who are new to recovery to access providers and recovery programs online.

Participants also discussed that the COVID-19 pandemic has caused individuals with stimulant use disorder to feel “triggered”, “stressed” and “isolated.” A participant shared, “It’s stressful. The news is stressful. People have lost jobs. We’ve lost friends and families to this illness [COVID-19], so we know that there are more stressors and triggers in 2020.” A participant also discussed their experience with feeling isolated during the pandemic, expressing, “For me, I suffered from a disease of isolation. And, you know, when we all had to go into lockdown, you know, we all had to isolate out of our community’s health and out of our own health. And, you know, I think that has hit a lot of us really hard.”

They shared that lockdowns and the shuttering of support services is problematic to those who rely on them, sharing, “taking away the safety nets that our individuals in recovery from substance use disorder or our patients need to stay healthy and strong is just really problematic.”

Summary of Comments Submitted to the Public Docket

Four comments were submitted to the public docket that supplemented the Patient-Focused Drug Development Meeting on Stimulant Use Disorder. The docket comments reiterated the significant and burdensome health effects of stimulant use disorder. Comments were submitted by an individual in recovery from misusing prescription stimulants, an individual in recovery from using methamphetamine, an individual who is currently using prescription stimulants for a medical condition, and a patient advocacy organization working with recovery communities.

Overall, the comments received reflected experiences and perspectives similar to those shared during the public meeting. The following highlights of these submitted comments focus on the experiences shared by the commenters.

Submitted Comments on the Effects of Withdrawal from Stimulant Use Disorder

The effects of withdrawal described by commenters were generally consistent with those discussed at the meeting and included impacts on physical and emotional well-being. Symptoms of methamphetamine withdrawal mentioned by a docket commenter included feeling “rundown,” “wiped out,” and “want[ing] to do nothing but sleep for days.” The commenter described significant impacts of experiencing withdrawal from stimulants, sharing, “I would have to say the most significant impact would be emotionally due to the isolation, guilt, and shame. Not to mention the lack of drugs now which throws your brain into a whirlwind of emotions as it tries to reregulate all your chemicals like dopamine.”

Submitted Comments on the Effects of Stimulant Use Disorder on Daily Life and Relationships

A commenter shared that stimulant use impacted their ability to keep a job, stating, “Quitting with a job was hard as I missed many days due to not wanting to get out of bed, [it] cost me a few jobs. Being I just wanted to sleep, family life was cut short as I couldn’t keep my eyes open long enough to function” and “I missed a lot of work because of my use [methamphetamine]. If I ran out [of methamphetamine], I wouldn’t wake up or felt like trash, so I was either late or didn’t go at all. That’s not who I am so it was embarrassing.” They also discussed family life being affected by their methamphetamine use, sharing, “family responsibilities didn’t receive the attention they deserved.”

The commenter stressed the impact of methamphetamine use on their ability to carry out important daily activities. They commented, “On a good day my use would get me through work and home to clean, laundry was folded, it gave great energy. I got things done. On days of no [methamphetamine]use which would be my worst, due to being out of meth, I got nothing done, missed work, spent countless pointless hours over my journey trying to get meth.”

A docket commenter also described other health effects due to misusing prescription stimulants. The commenter highlighted the effects on sleep, sharing, “I manipulated my doctor to prescribe me 3x30 mg a day. One prescription lasted 4 days with no sleep.”

Submitted Comments on Current Approaches to Management of Stimulant Use Disorder

The submitted comments reflected the challenges of managing stimulant use disorder. Commentors discussed their paths to recovery which included participating in recovery programs, rehabilitation

centers, outpatient treatment centers, and different types of behavioral therapy. One individual wrote that “finding a recovery path that works for you” is important. The commenter also stressed the need for mental health support to manage their stimulant use disorder. They attributed their success with recovery to receiving Dialectical Behavioral Therapy (DBT). They shared those sessions allowed them to learn emotion regulation and distress tolerance skills since they identified as an emotional user. They also reiterated the importance of a recovery program that involves follow-up care and assistance with finding housing and employment if need be.

Impacts of COVID-19 Pandemic

Similar to comments from meeting participants, one commenter described the impacts of the COVID-19 pandemic, stating, “COVID has put a lot of stress on my recovery due to the fact we were forced to be in isolation which can be very triggering for a user.”

Suggestions to enhance management of stimulant use disorder included access to recovery and therapy programs and focus on both substance use and mental health.

Conclusion

The perspectives shared by participants at this meeting and through the docket illustrated the impacts of stimulant use disorder and the challenges of seeking treatment and managing stimulant use disorder. FDA recognizes that individuals with stimulant use disorder and their family members have a unique ability to contribute to our understanding of their condition and approaches to management. FDA is grateful to all the participants for attending the meeting and sharing their experiences with the use of cocaine, crystal meth, methamphetamines, and misuse of prescription stimulants. This Patient-Focused Drug Development meeting provided FDA the opportunity to hear the impact of stimulant use disorder, firsthand.

FDA is thankful to the individuals and impacted family members who thoughtfully and bravely provided such personal insight into their experiences. Through this meeting, FDA learned that there are many reasons why individuals might begin using stimulants. FDA recognizes the importance of supporting those with stimulant use disorder by using their personal experiences to inform drug development. The Agency shares the desire and commitment expressed by meeting participants to advance the development and appropriate use of safe and effective treatment options for managing stimulant use disorder.

Appendix 1: Meeting Agenda and Discussion Questions

Center for Drug Evaluation and Research (CDER)
Public Meeting on Patient-Focused Drug Development for Stimulant Use Disorder
Tuesday, October 6, 2020
12:30 pm – 5:00 pm EDT
AGENDA

- Welcome**
12:30 – 12:35 pm Robyn Bent, RN, MS, CAPT, US Public Health Service, *Office of the Center Director (OCD), Center for Drug Evaluation and Research (CDER), FDA*
- Opening Remarks**
12:35 – 12:40 pm ADM Brett P. Giroir, M.D.
Assistant Secretary for Health, United States Department of Health and Human Services
- Overview of FDA’s Patient-Focused Drug Development Initiative**
12:40 – 12:50 pm Theresa Mullin, PhD
OCD, CDER, FDA
- Background on Stimulant Use Disorder**
12:50 – 1:00 pm Maryam Afshar, MD
Division of Anesthesiology, Addiction Medicine, and Pain Medicine, OND, CDER, FDA
- Overview of Discussion Format**
1:00 – 1:05 pm Robyn Bent, RN, MS, CAPT, US Public Health Service
OCD, CDER, FDA
- Topic 1: Health Effects and Daily Impacts**
1:05 – 1:35 pm Panelists will share their experiences with stimulant use, and the health effects and daily impacts of stimulant use disorder.
- Large-Group Facilitated Discussion on Topic 1**
1:35 – 2:35 pm Individuals with stimulant use disorder and impacted family members in the audience will be invited to add to the dialogue.
- Break**
2:35 – 2:50 pm
- Topic 2: Current Approaches to Management**
2:50 – 3:20 pm Panelists will start off the discussion on treatment goals and decision factors considered when seeking a treatment for stimulant use disorder.
- Large-Group Facilitated Discussion on Topic 2**
3:20 – 4:20 pm Individuals with stimulant use disorder and impacted family members in the audience will be invited to add to the dialogue.

4:20 – 4:50 pm **Impact of COVID-19 Pandemic on Stimulant Use Disorder**

4:50 – 5:00 pm **Closing Remarks**
Marta Sokolowska, PhD *OCD, CDER, FDA*

DISCUSSION QUESTIONS

Topic 1: Health Effects and Daily Impacts

1. How would you describe your journey with stimulant use disorder?
 - a. Which stimulant(s) did you start using first?
 - b. What stimulant(s) are you using now?
 - c. Did you use any other illicit or prescription drugs before you started using the stimulant that you are currently using?
 - d. How are you using stimulants? How has your stimulant(s) use changed over time? Are you using more frequently or at higher doses?
 - e. Do you use stimulants in combination with other drug(s)? If so, what other drugs do you use and why?
 - f. Have you used a stimulant(s) as treatment for opioid withdrawal and/or overdose?

2. Of all the ways that stimulant use disorder impacts your health and well-being, which effects have the most significant impact on your daily life and the daily life of your family and/or friends? *Examples may include physical and mental effects of using stimulants (effects on your body and thinking), effects of stimulant withdrawal, effects of cravings, impacts on your ability to function in personal or professional life, or emotional or social effects.*
 - a. What drives your use of stimulants?
 - b. Are there certain activities that you can only do if you take a stimulant? If so, what are those activities?
 - c. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your stimulant use? *Examples of activities may include daily hygiene; meeting school, work, or family responsibilities; participation in social activities.*
 - d. How does your stimulant use affect daily life on your best days? On your worst days?
 - e. What worries you most about your condition?

Topic 2: Current Approaches to Management

1. Have you considered seeking treatment? Why or why not?
2. What are you currently doing to help manage your stimulant use?
 - a. How well have these management approaches worked for you?
 - b. How well have they helped address the effects of stimulant use that are most troubling to you?
 - c. What are the biggest problems you have faced in using these approaches? *Examples may include bothersome side effects, challenges or barriers to access, concern about stigma.*
3. What are the biggest factors that you consider when making decisions about seeking out or engaging in treatment for stimulant use disorder?
4. What specific things would you look for in a treatment for stimulant use disorder?

5. If you had the opportunity to participate in a clinical study to test an experimental treatment for stimulant use disorder, what factors would you consider when deciding whether you would participate?

Topic 3: Impact of COVID-19

1. Has the COVID-19 pandemic impacted your substance use or your desire to seek treatment? If yes, please describe how.

Appendix 2: Patient and FDA Panel Participants

Patient Panel, Topic 1

- Jessica Hulseley
- Brendan Welsh
- Scott Sheldon
- Pam L.
- Paula Walsh

Patient Panel, Topic 2

- Philip Rutherford
- Brandee Izquierdo
- Kevin F.
- Charles Smith
- Amy Griesel
- Michael Galipeau

FDA Panel

- Marta Sokolowska, PhD, Controlled Substances Program, Office of the Center Director, CDER
- Celia Winchell, MD, Division of Anesthesiology, Addiction Medicine, and Pain Medicine, Office of New Drugs, CDER
- Maryam Afshar, MD, Division of Anesthesiology, Addiction Medicine, and Pain Medicine, Office of New Drugs, CDER
- Tiffany Farchione, MD, Division of Psychiatry, Office of New Drugs, CDER
- Javier Muniz, MD, Division of Psychiatry, Office of New Drugs, CDER
- Jana McAninch, MD, MPH, MS, Division of Epidemiology II, Office of Surveillance and Epidemiology, CDER

Appendix 3: Meeting Polling Questions

Patient-Focused Drug Development Meeting for Stimulant Use Disorder

Demographic Questions

1. Where do you live?
 - a. Within Washington, D.C. metropolitan area (including the Virginia and Maryland suburbs)
 - b. Outside of the Washington, D.C. metropolitan area

2. Which statement best describes your experience with stimulant use (e.g., methamphetamine, crystal meth, cocaine, prescription stimulants)?
 - a. An individual who is currently misusing OR has misused stimulants in the past
 - b. A family member or caregiver of an individual(s) who is currently misusing OR has misused stimulants in the past
 - c. An advocate for individuals who are misusing OR have misused stimulants in the past

We will ask that the remainder of the questions be answered individuals with stimulant use disorder or a family member or caregiver on behalf of an individual with stimulant use disorder

3. What is you/your loved one's age?
 - a. Younger than 12 years old
 - b. 12 – 17 years old
 - c. 18 – 24 years old
 - d. 25 – 29 years old
 - e. 30 –39 years old
 - f. 40 –49 years old
 - g. 50 –59 years old
 - h. 60 years old or older

4. For how long have you/your loved one used stimulants (e.g., methamphetamine, crystal meth, cocaine, prescription stimulants)?
 - a. Less than 1 year
 - b. 1-2 years
 - c. 3-4 years
 - d. 5-10 years
 - e. 11 – 20 years
 - f. 21 – 30 years
 - g. More than 30 years
 - h. I'm not sure
 - i. I am no longer using

5. Which region of the United States do you live in?
 - a. Midwest
 - b. Northeast
 - c. South
 - d. West
 - e. I live outside of the United States
 - f. Other

Questions for Topic 1: Health Effects and Daily Impacts

6. Which stimulant(s) did you/your loved one start using first? **Select all that apply.**
- Cocaine
 - Methamphetamine
 - Crystal Meth
 - Prescription stimulant(s) (such as Adderall, Dexedrine, Ritalin, Concerta)
 - Other stimulant(s) not mentioned
 - I'm not sure
7. If you/your loved one are currently using a stimulant(s), which stimulant(s) are you/your loved one currently using? **Select all that apply.**
- Cocaine
 - Methamphetamine
 - Crystal Meth
 - Prescription stimulant(s) (such as Adderall, Dexedrine, Ritalin, Concerta)
 - Other stimulant(s) not mentioned
 - I am not currently using a stimulant
8. If you/your loved one are currently using a stimulant(s), how frequently do you/your loved one use the stimulant(s)?
- Daily
 - More than once a day
 - Weekly
 - Monthly
 - Other
 - Not currently using a stimulant
 - Not sure
9. If you/your loved one are currently using a stimulant(s), are you/your loved one also using any other illicit drug(s)?
- Yes
 - No
 - I am not currently using a stimulant
 - I am not using a stimulant(s), but I am using an illicit drug(s)
10. In general, what are the most negative effects related to your/your loved one's use of stimulants? **Please choose up to three answers.**
- Physical effects of using stimulants (such as rapid or irregular heart rate, difficulty breathing, increased blood pressure)
 - Mental effects of using stimulants (such as paranoia, confusion, hallucinations)
 - Effects of stimulant withdrawal (such as fatigue, depression, inability to focus)
 - Effects of "cravings"
 - Symptoms related to a health condition
 - Other effects not mentioned
 - I do not have negative effects related to my use of stimulants

11. Thinking specifically of a time when you reduced or abstained from using stimulants, what have been the most negative impacts? **Please choose up to three answers.**

- a. Physical limitations on activities (such as work, school, sports, hobbies)
- b. Cognitive limitations related to work or school activities
- c. Ability to concentrate or stay focused
- d. Fatigue or lack of energy
- e. Insomnia or sleep issues
- f. Impact on relationships
- g. Impact on sexual intimacy
- h. Depression or emotional impacts (such as self-esteem)
- i. Other impacts not mentioned

12. What do you find to be the most significant impacts of your/your loved one's stimulant use on your/your loved one's daily life? **Please choose up to three answers.**

- a. Ability to carry out important activities (such as work, school, sports, hobbies)
- b. Ability to care for myself or family
- c. Ability to concentrate or stay focused
- d. Impact on relationships with family and friends
- e. Risks to safety of self or others
- f. Stigma or discrimination
- g. Worry about the future (such as relapse, overdose)
- h. Emotional impacts (such as self-esteem, self-identify)
- i. Other impacts not mentioned

Questions for Topic 2: Current Approaches to Management

13. Have you/your loved one ever used any of the following to manage stimulant use? **Check all that apply.**

- a. Medications for ongoing addiction treatment
- b. Medical devices (such as electric nerve stimulators)
- c. Lifestyle changes (such as complete abstinence, avoiding "triggers")
- d. Peer support, counseling or behavioral therapy
- e. Mobile apps
- f. Complementary or alternative therapies (such as acupuncture, meditation)
- g. Other approaches not mentioned
- h. I am not using any approaches to manage my stimulant use but I want to
- i. I'm not trying to manage my stimulant use

14. If you are considering a new treatment for stimulant use, which of the following benefits would you consider to be most meaningful? **Please choose up to three answers.**

- a. Help me control my use of stimulants so that I can function better
- b. To stop using stimulant all together
- c. Reduce effects of stimulant withdrawal
- d. Decrease cravings for stimulants
- e. Reduce how often I have to take the stimulant
- f. Other benefit not mentioned

15. If you are interested in decreasing or stopping stimulant use, what challenges or barriers are keeping you from do so?

- a. How the treatment is administered (such as a pill or injection)
- b. The frequency and length of the management approach
- c. Insurance or cost burden
- d. Side effects of the treatment
- e. Stigma
- f. Other challenges or barriers not mentioned

16. If there was a clinical trial to study an experimental treatment, would you consider participating?

- a. **Yes:** I would want to know more, but I am generally willing to consider participating
- b. **No:** I would probably not consider participating
- c. **Maybe:** I am not sure whether I would be willing to consider participating or not
- d. I'm not interested in decreasing my stimulant use