U.S. FOOD & DRUG ADMINISTRATION

Patient-Focused Drug Development Meeting on
Opioid Use Disorder

April 17, 2018

FDA will be streaming a live audio recording of the meeting with the presentation slides, which is open to the public at: https://collaboration.fda.gov/pfdd041718/. The audio recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting.

Because of the sensitive nature of the meeting topic, and the importance of gathering candid, meaningful input from individuals who have come forward to speak about living with opioid use disorder, **no other audio recording, video recording, and/or photography will be allowed** at this Patient-Focused Drug Development meeting. FDA is asking for your cooperation and strongly requests that you respect the privacy of all attendees.

#PFDD

Wi-Fi Network: FDA-Public Password: publicaccess

U.S. FOOD & DRUG ADMINISTRATION

Welcome

Sara Eggers, PhD

Office of Strategic Programs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

April 17, 2018

Agenda

- Opening Remarks
- Setting the context
  - Overview of Opioid Use Disorder
  - Road from PFDD Meetings to Clinical Trial Endpoints
  - Overview of Discussion Format
- Discussion Topic 1
- Lunch
- Discussion Topic 2 (with a short break)
- Open Public Comment
- Closing Remarks

No Recording or Photography

- FDA is streaming a live audio recording of the meeting with the presentation slides, which is open to the public
  - Access the live stream: https://collaboration.fda.gov/pfdd041718/.
  - The audio recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting.
- Because of the sensitive nature of the meeting topic, and the importance of gathering candid, meaningful input from individuals who have come forward to speak about living with opioid use disorder, **no other audio recording, video recording, and/or photography will be allowed at this Patient-Focused Drug Development meeting.**
- FDA is asking for your cooperation and strongly requests that you respect the privacy of all attendees.

U.S. FOOD & DRUG ADMINISTRATION

Opening Remarks

Theresa Mullin, PhD

Associate Director for Strategic Initiatives

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

April 17, 2018

FDA is responsible for assessing expected benefit versus risk of new drugs to determine if they can be approved for marketing

Decision Factor	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition	**Sets the context for the weighing of benefits and risks:**	
Current Treatment Options	• How serious is this indicated condition, and why? • How well is the patient population's medical need being met by currently available therapies?	
Benefit	**Characterize and assess the evidence of benefit:** • How meaningful is the benefit, and for whom? • How compelling is the expected benefit in the post-market setting?	
Risk	**Characterize and assess the safety concerns:** • How serious are the safety signals identified in the submitted data? • What potential risks could emerge in the post-market setting?	
Risk Management	**Assess what risk management (e.g., labeling, REMS) may be necessary to address the identified safety concerns**	
Benefit-Risk Summary and Assessment		

Individuals living with a condition are uniquely positioned to inform FDA understanding of the clinical context

- FDA has been working to more systematically obtain those individuals' point of view on the severity of their condition, its impact on daily life, and their assessments of available treatment options
- Patient-Focused Drug Development Meetings offer a more systematic way of gathering patient perspective on their condition and treatment options
  - FDA committed to convene at least 20 meetings on specific disease areas over the past five years
  - Meetings help advance a systematic approach to gathering input

FDA has conducted Patient-Focused Drug Development meetings for over 20 conditions in the past 5 years

Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
• Chronic fatigue syndrome/ myalgic encephalomyelitis • HIV • Lung cancer • Narcolepsy	• Sickle cell disease • Fibromyalgia • Pulmonary arterial hypertension • Inborn errors of metabolism • Hemophilia A, B, and other heritable bleeding disorders • Idiopathic pulmonary fibrosis	• Female sexual dysfunction • Breast cancer • Chagas disease • Functional gastrointestinal disorders • Parkinson's disease and Huntington's disease • Alpha-1 antitrypsin deficiency	• Non-tuberculous mycobacterial lung infections • Psoriasis • Neuropathic pain associated with peripheral neuropathy • Patients who have received an organ transplant	• Sarcopenia • Autism • Alopecia Areata • Hereditary angioedema

Some FDA “Learnings” to Date

- Individuals with serious chronic conditions are experts on what it’s like to live with their condition
- Their “chief complaints” may not be factored explicitly into drug development plans, including measures of drug benefit planned in trials
- For progressive degenerative diseases many individuals and their loved ones may feel an ideal treatment would at minimum stop progression of their/their loved one’s loss of function
- Individuals living with a condition often want to be active in the work to develop and evaluate new treatments; they and caregivers are able and willing to engage via Internet, social media, and other means

An Overview of Opioid Use Disorder

Maryam Afshar, MD

Division of Anesthesia, Analgesia and Addiction Products

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

April 17, 2018

Definitions

- Opioids: A class of drugs that include heroin, prescription pain medications such as morphine and oxycodone, and synthetic opioid such as fentanyl.
- Drug abuse is defined as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect. (1)

(1) Assessment of Abuse Potential of Drugs Guidance for Industry (FDA)

Definitions, continued

- Tolerance: is a state that develops as a result of physiological adaptation characterized by a reduced response to a specific dose of drug after repeated administration of the drug (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose). (1)
- Withdrawal: experiencing psychological or physical symptoms in absence of the drug or using the drug to avoid the symptoms

(1) Assessment of Abuse Potential of Drugs, Guidance for Industry, FDA

Definitions, continued

- Dependence refers to physical or psychological dependence.
  - *Physical dependence* is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.
  - *Psychological (or psychic) dependence* refers to a state in which individuals have impaired control over drug use based on the rewarding properties of the drug (ability to produce positive sensations that increase the likelihood of drug use) or the psychological distress produced in the absence of the drug. (1)
  - The term "psychological dependence" conveys a similar state to that of "addiction" (American Society for Addiction Medicine (ASAM), 2011) and "substance dependence" (American Society for Addiction Medicine (DSM)-IV-TR, 2000).

(1) Assessment of Abuse Potential of Drugs, Guidance for Industry, FDA

Opioid Use Disorder

Based on (DSM) IV, OUD was categorized in 2 groups:

- Opioid Abuse: 1 or more symptoms of social problems or risky use.
- Opioid Dependence: 3 or more symptoms including tolerance and/or withdrawal.

Based on DSM 5 (2013), OUD is a single diagnosis, with severity determined by the number of symptoms present.

Symptoms can be categorized into:

- Loss of control
- Risky use
- Social problems
- Drug effects

OUD Symptoms

- Loss of control:
  - Opioids are taken in larger amounts or over a longer period than was intended.
  - Persistent desire or unsuccessful attempts to cut down or control opioid use.
  - Craving, or a strong desire or urge to use opioids.
  - A great deal of time is spent in activities to obtain, use, or recover from the effects of opioids.
- Risky use:
  - Recurrent opioid use in situations in which it is physically hazardous.
  - Continued opioid use despite physical or psychological problem that is likely to have been caused or exacerbated by the substance.

OUD Symptoms, continued

- Social impairment:
  - Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
  - Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
  - Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- Pharmacological criteria:
  - Tolerance
  - Withdrawal

Diagnosis

- OUD can be diagnosed if at least 2 of 11 symptoms are present in a 12-month period.
- Severity Criteria
  - Mild: 2-3 symptoms*
  - Moderate: 4-5 symptoms
  - Severe: 6 or more symptoms

*Patients who are taking opioid pain medications as directed can be physically dependent, meaning they can experience tolerance and if the medication is discontinued they can experience withdrawal symptoms, ***but this does not mean that they have OUD.***

Epidemiology

- 11.8 million people (age 12 years or older) with opioid misuse in the United States (4.4 percent of the population in the age group) (2)
  - 11.5 million people misused prescription pain relievers in the past year compared with 948,000 people who used heroin (Results from the 2016 National Survey on Drug Use and Health, SAMSHA)
- In 2016, an estimated 2.1 million people aged 12 or older had an opioid use disorder, or 0.8 percent of people aged 12 or older. (2)
  - 1.8 million people aged 12 or older had a pain reliever use disorder, which represents 0.7 percent of people aged 12 or older
- U.S. opioid overdose deaths increased 200% between 2000 and 2014 (CDC)
- In 2016 opioids were involved in 42,249 deaths (HHS.gov)

(2) 2016 National Survey on Drug Use and Health, SAMSHA

The Impact of Opioid Use Disorder

- OUD is a chronic, relapsing disease
- Health problems including infectious disease (hepatitis and HIV)
- Psychological problems
- Overdose
- Loss of productivity and economic burden for the individual and society
- Legal problems
- Accidents, trauma and premature death
- Disabilities
- Child welfare

Treatment Options

- Behavioral treatment
  - Motivational enhancement therapy
  - Cognitive-behavioral Therapy (CBT)
  - 12 step program and peer support groups
  - Individual and family therapy
  - Case management
- Pharmacotherapy
  - Agonist
  - Antagonist
  - Partial Agonist

Available Medications For Treatment of OUD

- Methadone (agonist)
  - Available only through federally certified Opioid Treatment Programs (OTPs) since 1972. It is provided in combination with counselling and urine drug testing.
    - Liquid concentrate
    - Powder (dissolved in water)
    - Diskettes (dissolved in water)
    - Tablets (mainly used in pain management)
  - Initially is dispensed daily with take-home doses allowed with adherence to the program.
  - Potential risk of QT prolongation that can result in cardiac arrhythmia
  - Risk of overdose with benzodiazepine or alcohol use and after discontinuation of treatment.
  - Risk of interactions with other medications.

Available Medications, continued

- Naltrexone (antagonist)
  - Blocks the effect of opioids
  - Oral naltrexone (approved in 1984): Use has been limited due to compliance issues and poor treatment outcomes
  - Vivitrol, extended release naltrexone (approved in 2010): Monthly intramuscular injection
  - Patients must be opioid free for at least 7 to 14 days
  - Due to loss of tolerance to opioid, the risk of overdose increases if discontinued
  - Can cause injection site reaction
  - Can precipitate opioid withdrawal symptoms

Available Medications, continued

- Buprenorphine (partial agonist)
  - Office based treatment can improve access
  - Sublingual buprenorphine and naloxone: approved in 2002
    - Sublingual tablet (Zubsolv, Suboxone, generic)
    - Buccal film (Bunavail)
    - Sublingual film (Suboxone)
    - Buprenorphine only tablet (Subutex and generics)
  - Buprenorphine implant (Probuphine): approved in 2016
  - Buprenorphine extended release injection (Sublocade): approved in 2017
  - Risk of overdose with benzodiazepine or alcohol use and after discontinuation of treatment.
  - Can precipitate withdrawal
  - Healthcare providers must receive special training, get a SAMSHA waiver and DEA number.

Treatment Outcome

- Medication treatment reduces relapse
- Continuing the medication when patient is stabilized (maintenance therapy) can improve retention in treatment and suppress drug use
- Discontinuation of treatment increases the risk of relapse and overdose

Some Challenges to Medication Development

- What do affected individuals, families and clinicians consider treatment success?
- What is the goal of treatment?
- What bring individuals into treatment?
- How long does it take to see changes?
- What are the best ways to measure clinical or functional improvement?
- What are the best endpoints to measure: drug use or clinical improvement?

U.S. FOOD & DRUG ADMINISTRATION

The Road from Patient-Focused Drug Development Public Meetings to Clinical Study Endpoints

Elektra J. Papadopoulos, MD, MPH
Associate Director, Clinical Outcome Assessments Staff
Office of New Drugs
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

April 17, 2018

Disclaimer

The views expressed in this presentation are those of the speaker, and do not necessarily represent an official FDA position.

PATIENT-FOCUSED DRUG DEVELOPMENT MEETINGS

Patient-Focused Drug Development Meetings

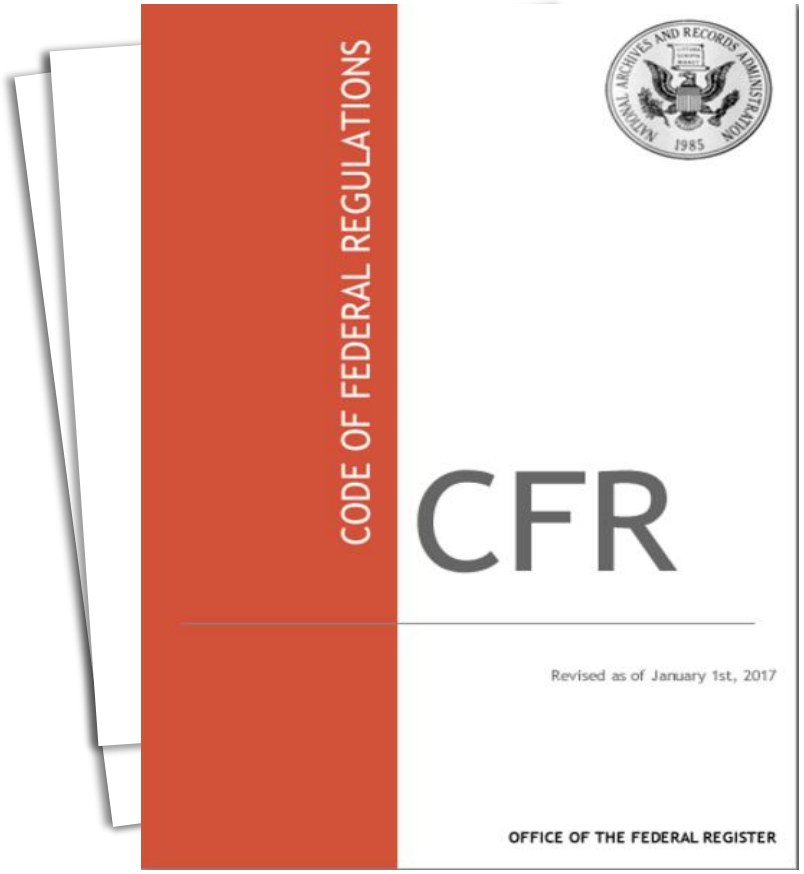
- Provide the opportunity for patients' and caregivers' voices to be heard
  - What symptoms and impacts matter most?
  - What amount of change matters to patients?
- Can be a starting point for selecting or developing patient questionnaires and other types of clinical outcome assessments

Clinical Study Endpoints

- ***Endpoint*** refers to how a specific outcome will be measured and analyzed in a clinical study
  - Example: Change in symptom questionnaire score at 6 weeks compared with baseline
- Understanding the endpoint is assessing is critical to understanding the benefit of the treatment

FDA's Regulatory Standards

- Well-defined and reliable assessments (21 CFR 314.126)
  - Evidence that the assessment is measuring:
    - The ***right thing (concept)***
    - In the ***right way***
    - In a ***defined patient population***
    - A ***score*** that ***accurately and reliably quantifies*** changes that can be interpreted as a clear improvement due to treatment (***clinical benefit***)



Key Takeaways

- The outcomes of PFDD meetings will support and guide FDA risk-benefit assessments in drug reviews by understanding what symptoms and impacts are important to patients and what they value in a treatment
- Patient and caregiver input ultimately helps determine:
  - WHAT to measure to provide evidence of clinical benefit
  - HOW best to measure the important symptoms or impacts
  - HOW MUCH change in the symptom or impact is meaningful

In closing

- Many stakeholders – drug developers, researchers, patient stakeholders – can play a part in developing COAs
- Multiple pathways to engage with FDA exist
- Patient-focused drug development meetings are a “starting point” for developing patient-focused outcome measures and endpoints

Resources

- **FDA COA Staff Website:** http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm349031.htm#Endpoints
- **PRO Guidance:** http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf
- **DDT COA Qualification Guidance:** http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM230597.pdf
- **DDT COA Qualification Website:** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm284077.htm
- **Critical Path Innovation Meeting Website & Guidance:** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm395888.htm

U.S. FOOD & DRUG ADMINISTRATION

Overview of Discussion Format

Sara Eggers, PhD

Office of Strategic Programs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

April 17, 2018

Discussion Overview

Topic 1: Health Effects and Daily Impacts of Opioid Use Disorder

- Health effects of OUD have the most significant impact on your daily life
- How OUD affects daily life on your best days. On your worst days
- How your OUD has changed over time
- What worries you most about your condition

Topic 2: Current Approaches to Treatment of Opioid Use Disorder

- Your experiences with medical treatments
- Other treatments or therapies you currently use to address your OUD
- What have you found to be most effective in helping you manage your OUD
- What specific things would you look for in an ideal treatment for OUD
- What factors would you consider when deciding whether or not to participate in a clinical trial

Discussion Format

We will kick off our discussion with comments from a panel of individuals with OUD

- The purpose is to set context for a broader discussion with the audience
- Panel commenters reflect a range of experiences with OUD
- Some panelists are affiliated with advocacy or support organizations

We will then broaden the dialogue to include individuals and family members in the audience

- The purpose is to build on the experiences shared by the panel
- We will ask questions and invite you to raise your hand to respond
- When speaking, you may remain anonymous or state your first name

Discussion Format, continued

You'll have a chance to answer "polling" questions

- Their purpose is to aid our discussion
- In-person participants, use the "clickers" to respond
- Web participants, answer the questions through the webcast
- Individuals or family members only, please

Web participants can add comments through the webcast

- Although they may not all be read or summarized today, your comments will be incorporated into our summary report
- We'll occasionally go to the phones to give you another opportunity to contribute

Send us your comments!

You can send us comments through the "public docket"

- The docket will be open until June 18, 2018
- Comments will be incorporated into our summary report
- Anyone is welcome to comment
- You can submit as anonymous

Visit:
https://www.regulations.gov/document?D=FDA-2018-N-0987-0001

Or Search "patient focused OUD" on
www.regulations.gov

And **Click Comment Now!**

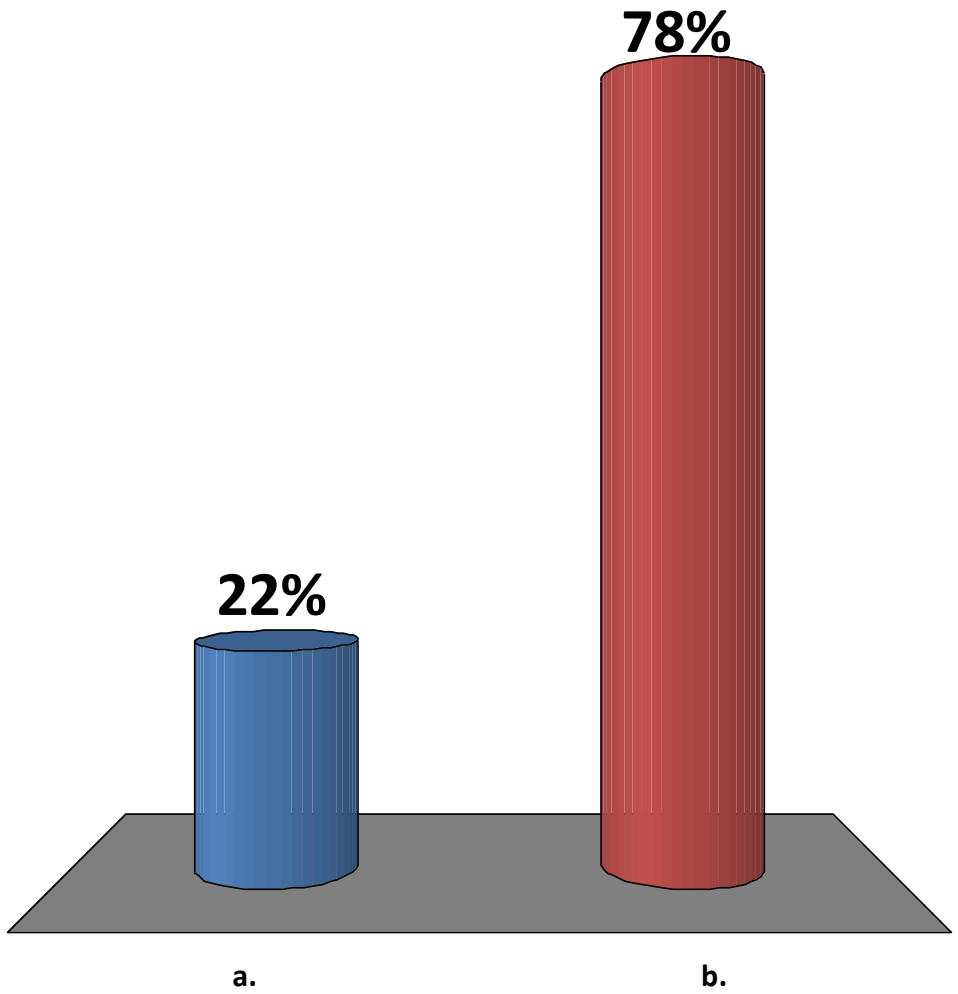
Discussion Ground Rules

- We encourage all individuals and family members to contribute to the dialogue
- FDA and NIDA are here to listen
- Discussion will focus on OUD health effects and treatments
  - Open Public Comment Period is available to comment on other topics
- The views expressed today are personal opinions
- Respect for one another is paramount
- No audio recording, video recording, or photography is allowed at this meeting.
- Complete an evaluation form to let us know how the meeting went today

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



Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

Which statement best describes you?

a. An individual who currently struggles with OR has struggled in the past with opioid addiction or abuse

b. A family member or caregiver of an individual(s) who currently struggles with or has struggled in the past with opioid addiction or abuse

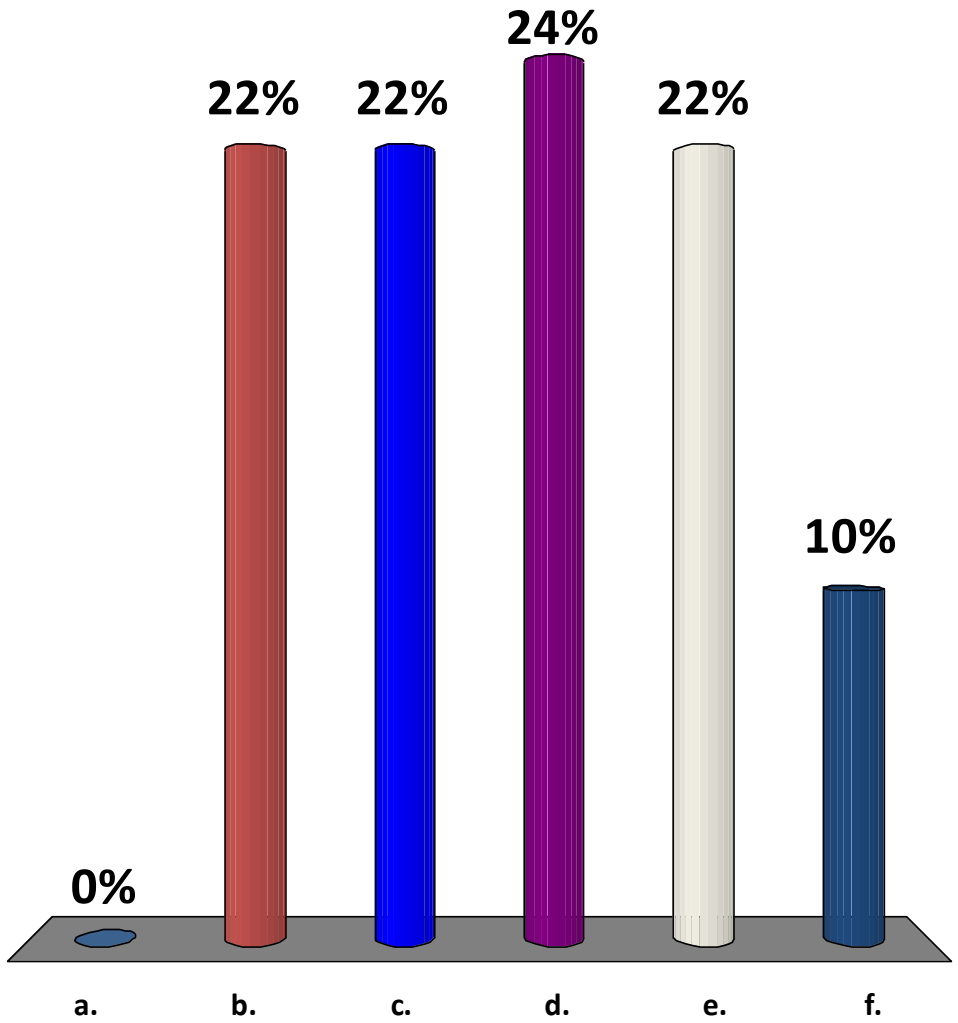
c. An advocate for individuals who struggle with opioid addiction or abuse

NOTE: FDA's Polling Software experienced technical difficulties for this question and results are not displayed.

Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

What is your/your loved one's age?

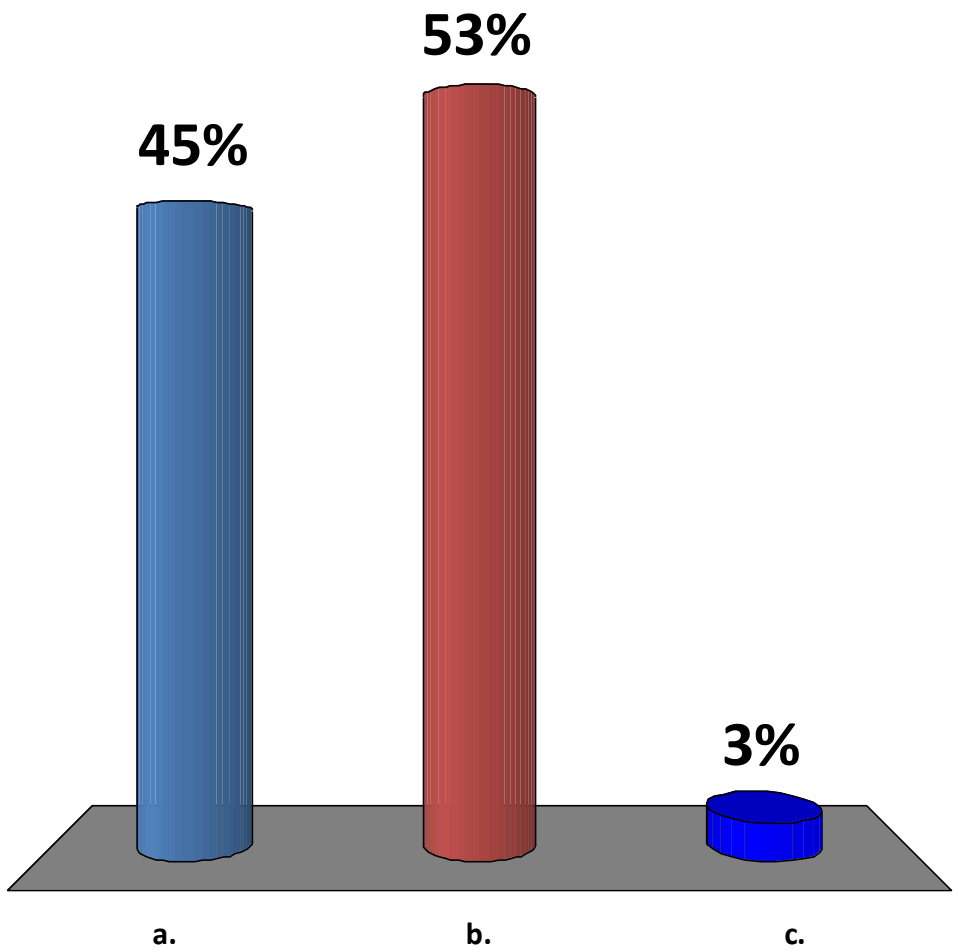
a. Younger than 18 years old
b. 18 – 29 years old
c. 30 – 39 years old
d. 40 – 49 years old
e. 50 – 59 years old
f. 60 years old or older



Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

Do you/your loved one identify as:

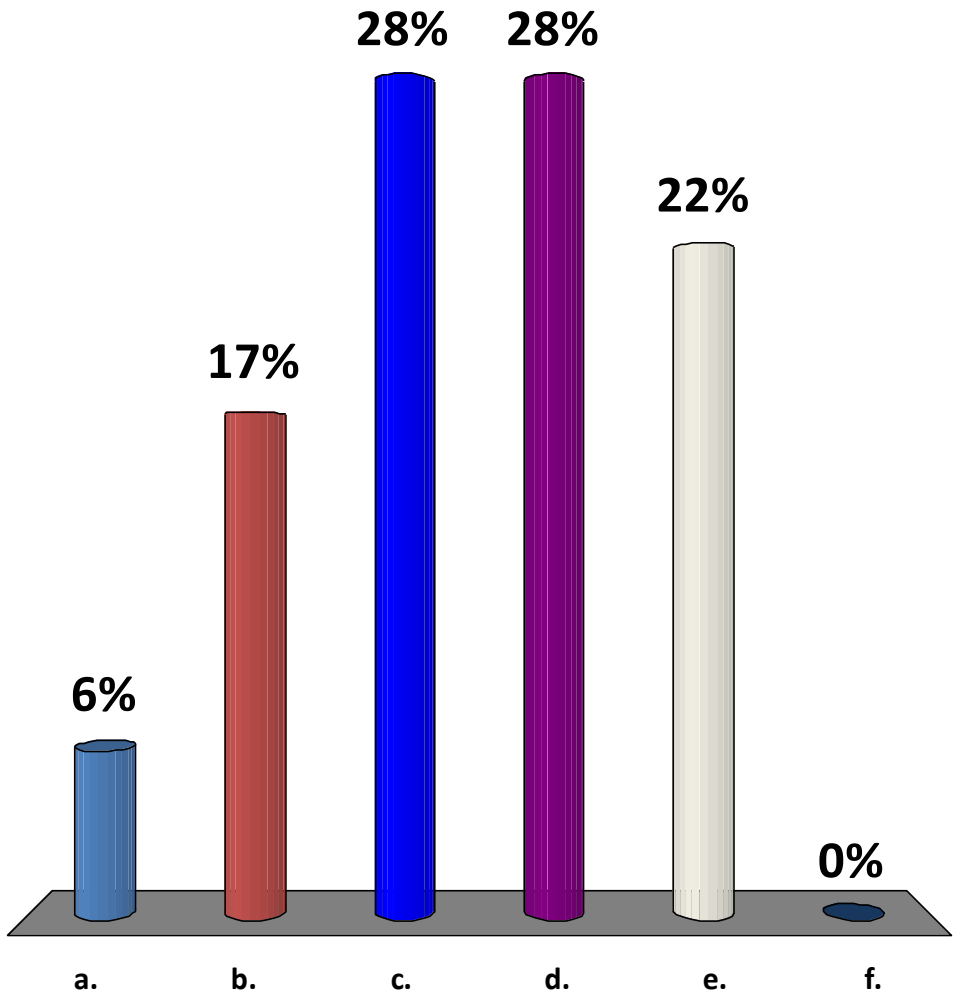
a. Female
b. Male
c. Other



Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

How long has it been since you/your loved one first started using opioids, of any kind?

a. Less than 5 years ago
b. 5-10 years ago
c. 11 – 20 years ago
d. 21 – 30 years ago
e. More than 30 years ago
f. I'm not sure

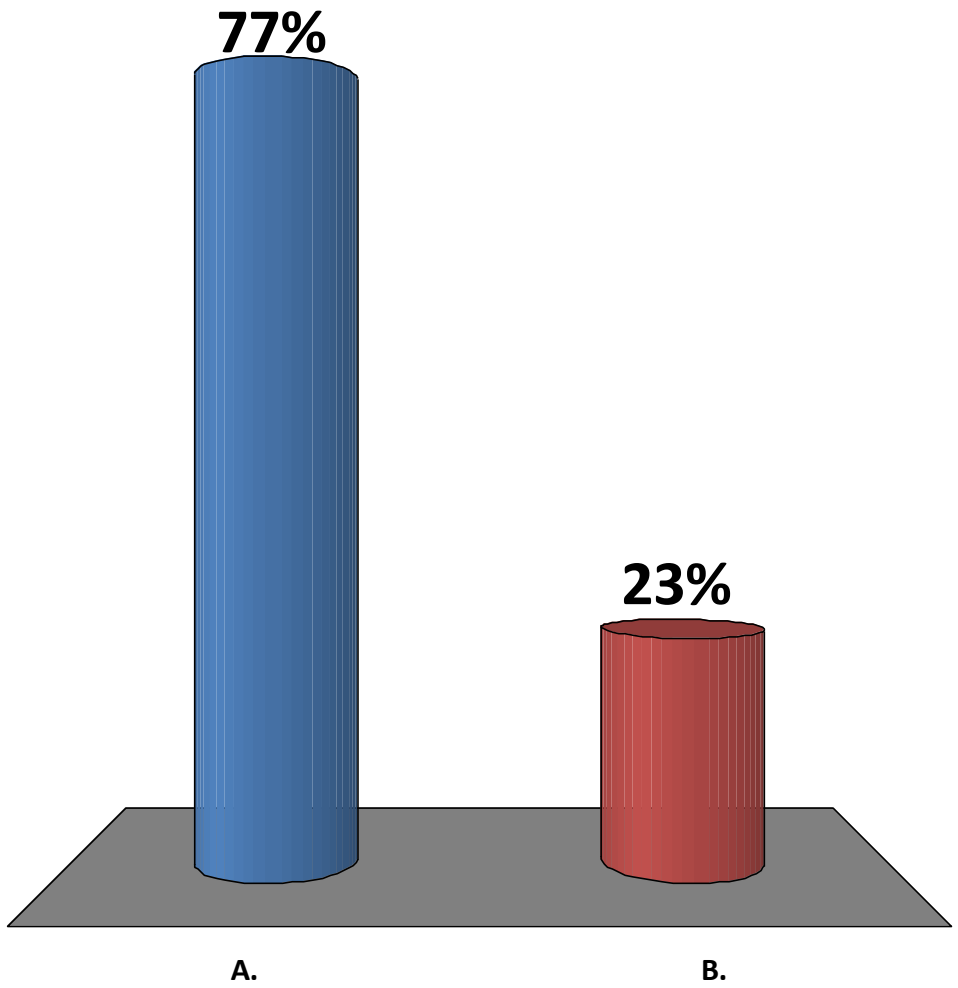


Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

Have you/your loved one ever been diagnosed by a healthcare professional as having opioid use disorder or addiction?

A. Yes

B. No



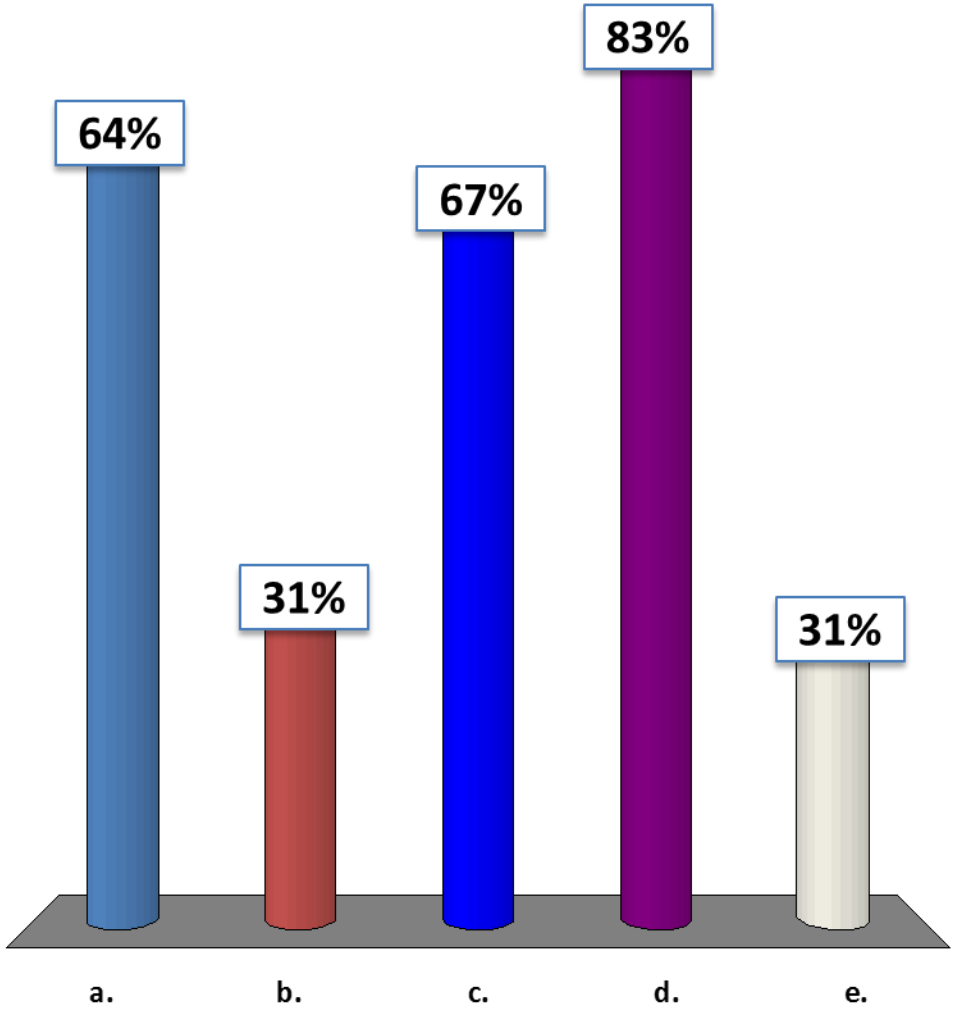
Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

Have you/your loved one ever had any of the following conditions?

Check all that apply

NOTE: Due to a technical error, the original response percentages were recorded incorrectly. The correct percentages have been listed below, and may not match the height of the bars in the graph.

a. Acute pain for which medical treatment was sought (*such as broken bones, dental work, post-surgery*)
b. Chronic pain (*such as neuropathic, cancer, posttraumatic*)
c. Other substance use disorder (*e.g., alcohol, amphetamines, cocaine, hallucinogens*)
d. Psychiatric or mental health conditions (*such as depression, anxiety, mood disorders*)
e. Other health conditions that I believe are relevant to today's discussion



Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

U.S. FOOD & DRUG ADMINISTRATION

Discussion Topic 1

Health Effects and Daily Impacts of Opioid Use Disorder

Sara Eggers, PhD

Office of Strategic Programs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

April 17, 2018

Topic 1 Discussion Questions

- Of all the ways that OUD negatively affects your health and well-being, which effects have the most significant impact on your daily life?
- How does OUD affect daily life on your best days? On your worst days?
- How has your OUD changed over time?
- What worries you most about your condition?

In general, what are the most bothersome health effects related to your/your loved one's opioid use disorder?

Please choose up to two answers.

NOTE: Due to a technical error, the original response percentages were recorded incorrectly. The correct percentages have been listed below, and may not match the height of the bars in the graph.

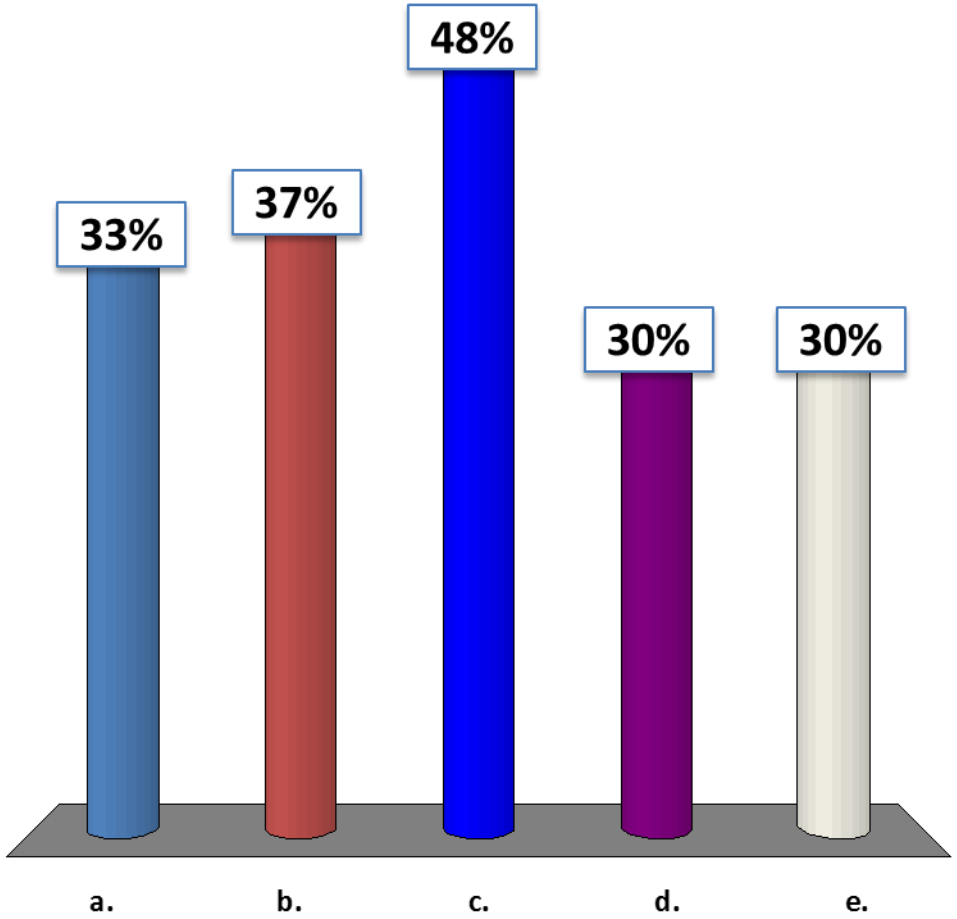
a. Health effects associated with use of opioids (*such as confusion, constipation, sleepiness*)

b. Symptoms associated with opioid withdrawal (*such as nausea, diarrhea*)

c. Symptoms associated with opioid "cravings"

d. Symptoms related to an underlying health condition (*such as unmanaged pain*)

e. Other health effects not mentioned



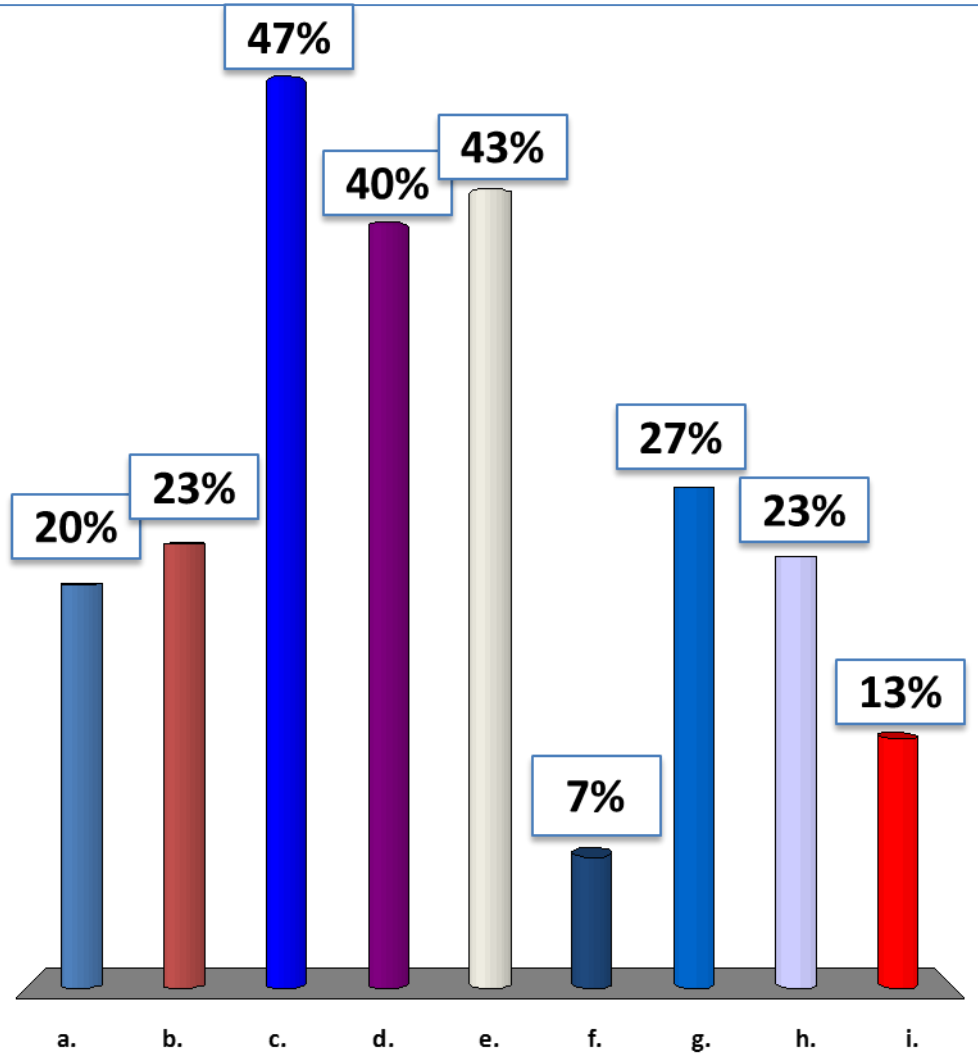
Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

Thinking specifically of reducing use or abstaining from opioids, what have been the most bothersome symptoms?

Please choose up to three answers.

NOTE: Due to a technical error, the original response percentages were recorded incorrectly. The correct percentages have been listed below, and may not match the height of the bars in the graph.

a. Fatigue or lack of energy
b. Cognitive effects (*such as inability to concentrate, or "brain fog")*
c. Anxiety, irritability, or jitteriness
d. Depression, apathy, or boredom
e. Insomnia or sleep issues
f. Nausea, vomiting, or diarrhea
g. Flu-like symptoms, such as fever or body aches
h. Pain
i. Other symptoms not mentioned



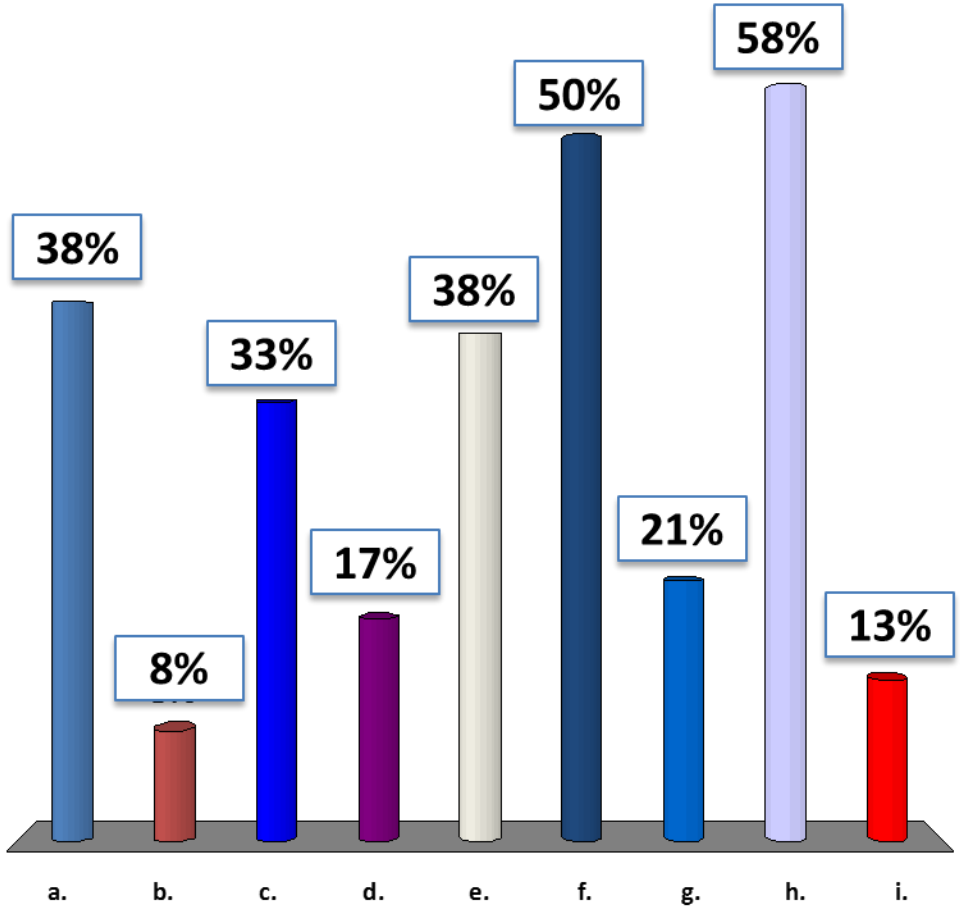
Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

What do you find to be the most significant impacts of your/your loved one's opioid use disorder on your/your loved one's daily life?

Please choose up to three answers.

NOTE: Due to a technical error, the original response percentages were recorded incorrectly. The correct percentages have been listed below, and may not match the height of the bars in the graph.

a. Ability to carry out important activities (such as go to work, school, hobbies)
b. Ability to care for myself or family
c. Having days when I am barely able to function at all
d. 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 relapse, overdose)
h. Emotional impacts (such as self-esteem, self-identify)
i. Other impacts not mentioned



Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

National Suicide Prevention Lifeline

1-800-273-8255

Send us your comments!

You can send us comments through the "public docket"

- The docket will be open until June 18, 2018
- Comments will be incorporated into our summary report
- Anyone is welcome to comment
- You can submit as anonymous

Visit:
https://www.regulations.gov/document?D=FDA-2018-N-0987-0001

Or Search "patient focused OUD" on www.regulations.gov

And **Click Comment Now!**

U.S. FOOD & DRUG ADMINISTRATION

BREAK

U.S. FOOD & DRUG ADMINISTRATION

Discussion Topic 2

Current Approaches to Treatment of Opioid Use Disorder

Sara Eggers, PhD

Office of Strategic Programs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

April 17, 2018

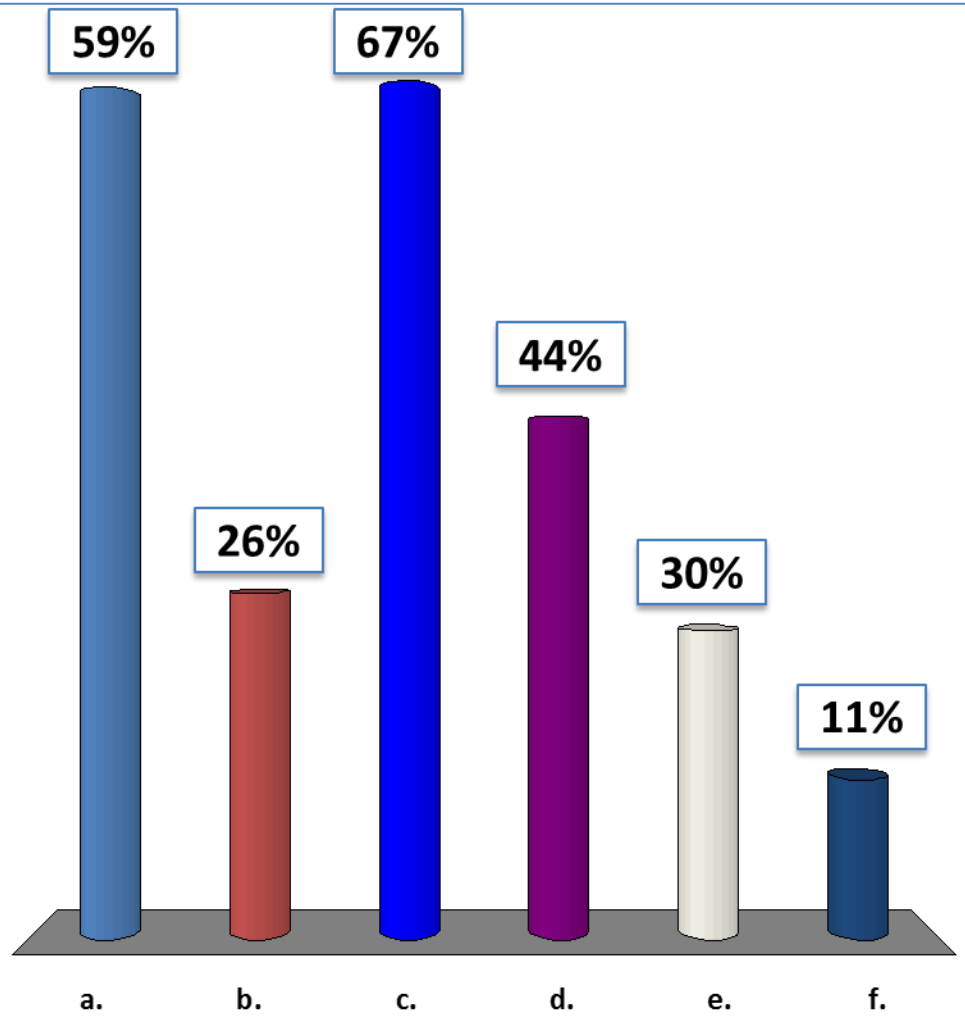
Topic 2 Discussion Questions

- Are you currently using, or have you used in the past, any prescription medical treatments to treat your OUD?
  - How well have these treatments worked for you? How well have they helped address the effects of OUD that are most bothersome to you?
  - What are the biggest problems you have faced in using these treatments?
- What other treatments or therapies do you currently use to address your OUD?
  - How well do these treatments or therapies help address the effects of OUD?
- What have you found to be most effective in helping you manage your OUD?
- What are the biggest factors that you take into account when making decisions about seeking out or using treatments for OUD?

Have you/your loved one ever used any of the following medications to manage your/your loved one's opioid use disorder? **Check all that apply.**

NOTE: Due to a technical error, the original response percentages were recorded incorrectly. The correct percentages have been listed below, and may not match the height of the bars in the graph.

a. Opioid Agonist (*such as methadone*)
b. Opioid Antagonist (*such as naltrexone*)
c. Opioid Partial Agonist (*such as buprenorphine, buprenorphine/ naloxone*)
d. Other prescription or over-the-counter medications
e. Other medications not mentioned
f. I've never used any medications



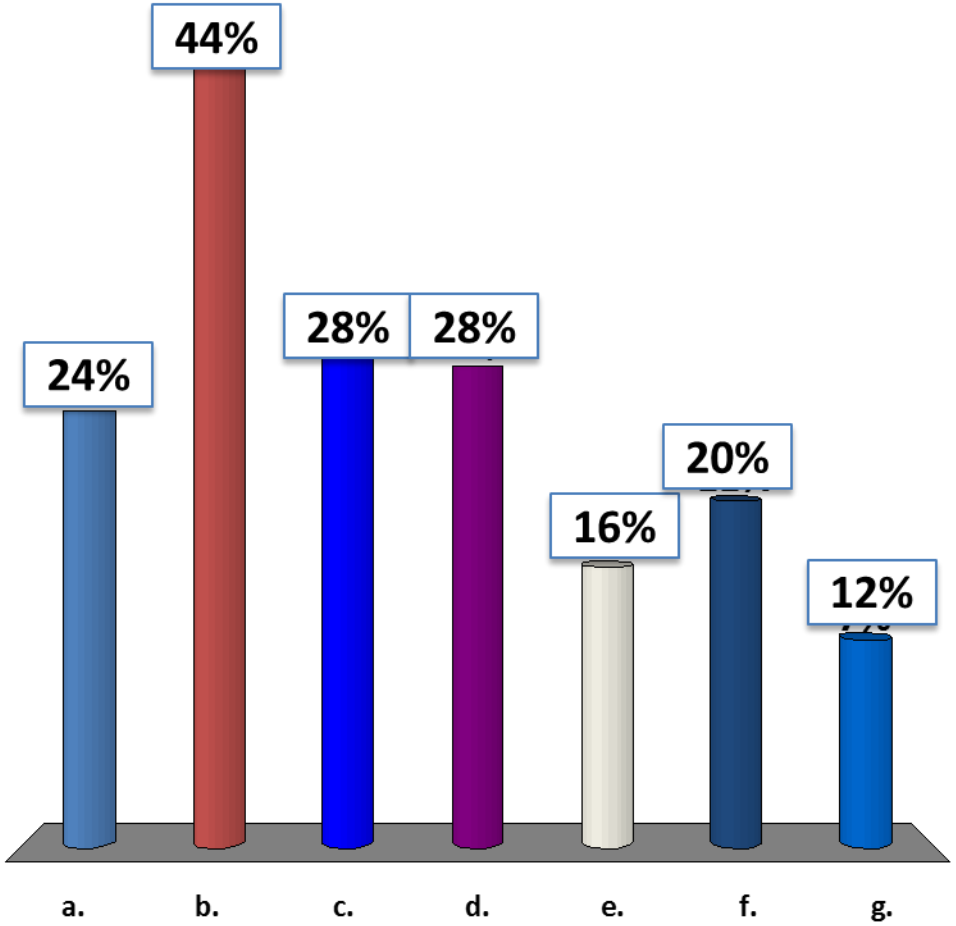
Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

When considering a new treatment for opioid use disorder, which of the following benefits would you consider to be most meaningful?

Please choose two answers.

NOTE: Due to a technical error, the original response percentages were recorded incorrectly. The correct percentages have been listed below, and may not match the height of the bars in the graph.

a. Help me control my use of opioids so that I can better function
b. Help me achieve complete abstinence of opioids
c. Reduce effects of opioid withdrawal
d. Reduce opioid "cravings"
e. Reduce how often I have to take the treatment
f. Ability to take my medication at home
g. Other benefits not mentioned



Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

Send us your comments!

You can send us comments through the "public docket"

- The docket will be open until June 18, 2018
- Comments will be incorporated into our summary report
- Anyone is welcome to comment
- You can submit as anonymous

Visit:
https://www.regulations.gov/document?D=FDA-2018-N-0987-0001

Or Search "patient focused OUD" on www.regulations.gov

And **Click Comment Now!**

U.S. FOOD & DRUG ADMINISTRATION

Open Public Comment

Shanon Woodward, PharmD, RPh
Office of Strategic Programs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

April 17, 2018

U.S. FOOD & DRUG ADMINISTRATION

Closing Remarks

Mitra Ahadpour, MD, DABAM
Deputy Director
Office of Translational Sciences
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

April 17, 2018