Duke
MARGOLIS CENTER for Health Policy

Patient-Focused Drug Development for Opioid Use Disorder

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U.S. FOOD & DRUG ADMINISTRATION

Patient-Focused Drug Development:
Opioid Use Disorder

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Duke-Margolis Meeting
Expanding Access to Effective Treatment for Opioid Use Disorder: Provider Perspective on Reducing Barriers to Evidence-Based Care

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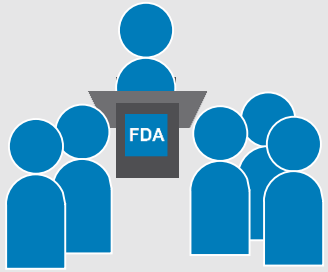
The views and opinions expressed in this presentation are those of the individual presenter and should not be attributed to or considered binding on the U.S. Food and Drug Administration (FDA).

Patient-focused drug development (PFDD) is a systematic approach to help ensure that **patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated** into drug development and evaluation.

FDA hosted a PFDD meeting to gain insight on Opioid Use Disorder (OUD)

April 17, 2018, 10 am – 4 pm

FDA's White Oak, MD campus



Meeting part of FDA's ongoing work aimed at reducing the impact of opioid abuse and addiction

Outreach supported by

- National Institute for Drug Abuse (NIDA)
- Patient, advocacy, and community organizations

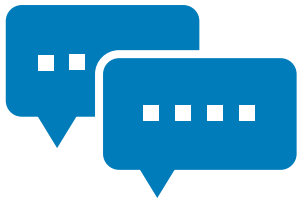
We heard from individuals and families across a **spectrum of experience**

> 100 individuals and family members attended the meeting in person

> 85 provided input through the interactive webcast

> 70 submitted comments through the public docket

Participants varied in age, history of opioid use, stage of recovery, and overarching perspectives on substance use and treatment



Discussion topics focused on experiences and perspectives:

- The effects of OUD on daily life
- Managing OUD, including medication-assisted treatment (MAT)

We are **now collating** this input

Each PFDD meeting results in *Voice of the Patient* summary report

Reports capture participants' input in their own words

The OUD PFDD meeting report is planned for release in Fall 2018

The following is a highlight of select input gathered at the meeting.

Results presented are preliminary.

Participants conveyed the **impacts of OUD**

"Your body just jerks. You feel like a cat on a hot tin roof."

"I could get through that first week of being sick… [but it's been] 5 months and still I will have nights of… skin crawls where you can't lay still."

"My brain disease doesn't even make me think, 'I need to take care of myself.'"

- They described complex journeys of use, misuse, addiction, and recovery
- They highlighted 'being a prisoner' to intense withdrawals ('drug sick'), irritability, skin crawls and spasms, irritability, and the obsession with getting their next hit
- They shared devastating impacts on their jobs, careers, school, relationships, well-being, and safety
- They spoke of lasting impacts, even in recovery: scars, insomnia, urges, stigma, and fear
- They had mixed perceptions about their risk of overdose

They offered insight on **“craving”**

- It is more than a physical craving for a substance
- It lasts well beyond the “drug sick”
- The feeling changes over time
  - In the beginning, it is an “occupying force . . . of fight or flight”
  - Over time, it resurfaces, even with the slightest trigger
- A parent described needing to “wrap our minds” this invisible facet of the illness

“My mind . . . will tell my body that I need drugs to manage the anxiety that I’m feeling . . . ”

“It’s the act of doing, it, preparing it, consuming it, the immediate relief afterward.”

“[I] used to use all night and I would go to the ATM—[and when I go to the ATM now] I would still feel the physical sickness about that longing and craving.”

Participants expressed their **treatment goals**

- They stressed needing an individualized, holistic approach
- There were varying perspectives on the desired outcomes
  - Some desire complete abstinence
  - Others focused on better controlling or managing their use
  - Common element: improve functioning, well-being, and safety
- They shared different views on the role of MAT
  - Some accept the need to stay on MAT for the long term
  - Some hope to "detox off MAT" once they have stabilized recovery
  - Some do not see a role for currently available MAT in their recovery

"You have a disease and no matter what you have to face it… and do what's best for you . . . "

"[The goal is] to be able to manage things yourself so that you function in the way you want to better."

"[T]o me [an opioids-based treatment is] somewhat like exchanging one opioid addiction for another."

They shared their **experience with MAT**

"The medication definitely saved my life."

"I have tried to taper off methadone before and I was always unsuccessful . . . the withdrawal symptoms were extremely high and my tolerance was very low."

"What I needed in the beginning didn't necessarily look like what I needed further down the road."

- Some highlighted the benefits
  - Reducing the "euphoric rush"
  - Being able to "arrest the cravings and compulsiveness"
  - Ability to regain their life and functioning
- Discussion also touched upon the downsides
  - Intolerable or bothersome side effects
  - Need to take treatment long term (e.g., methadone)
  - Not addressing the underlying health issue (e.g., anxiety, trauma, pain)
- Some participants offered insight into why they were successful on one treatment but not another

They described **challenges and barriers** to MAT

- Lack of access to MAT when they need it
  - Difficulty finding treatments facilities that provide MAT
  - Long wait times or medication not in stock
  - Prohibitive costs – medication, time from work, etc.
  - Strict requirements

"It took 8 weeks to get the appointment . . . [and then] I had to go out and score heroin in order to get into a methadone program."

- Unpleasant experiences, concerns about safety at treatment facility
- Stigma by family, healthcare providers, and community
- Intensity of withdrawal and craving
- Addressing co-morbid pain or mental health needs
- Their need to come to terms with illness

"Trying to come to terms with hearing things like I'm an addict and an abuser and the disrespect that goes with it."

They gave insight into how to **better help individuals** like themselves

- Raise awareness
- Integrate MAT into primary care, holistic approaches
- Make it easier to access and use MAT
- Develop MAT that do not involve opioids
- Reduce the stigma of OUD
- Don’t forget the pain, trauma, or mental health needs
- Create “situations of stability”

“[A]ll options . . . should be accessible . . . based on the patient's needs and experience with other treatments.”

“We are never going to get rid of this stigma until we can go out there and show the face of this.”

“We need to recognize these highly vulnerable states that people with opioid use disorders will encounter in their life, and they need to be given the proper outreach and support.”

This input **can help** FDA and others

- ✓ Identify specific areas of unmet need for individuals with OUD
- ✓ Support FDA's efforts to advise on medical product development programs
- ✓ Inform understanding of how to best assess the benefits of potential treatments
- ✓ Inform benefit-risk assessments for FDA's medical product regulatory decisions
- ✓ Facilitate wider appropriate use of FDA-approved medications

For more information:

https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm591290.htm

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