U.S. FOOD & DRUG ADMINISTRATION

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FDA Innovation Challenge:
Devices to Prevent and Treat Opioid Use Disorder

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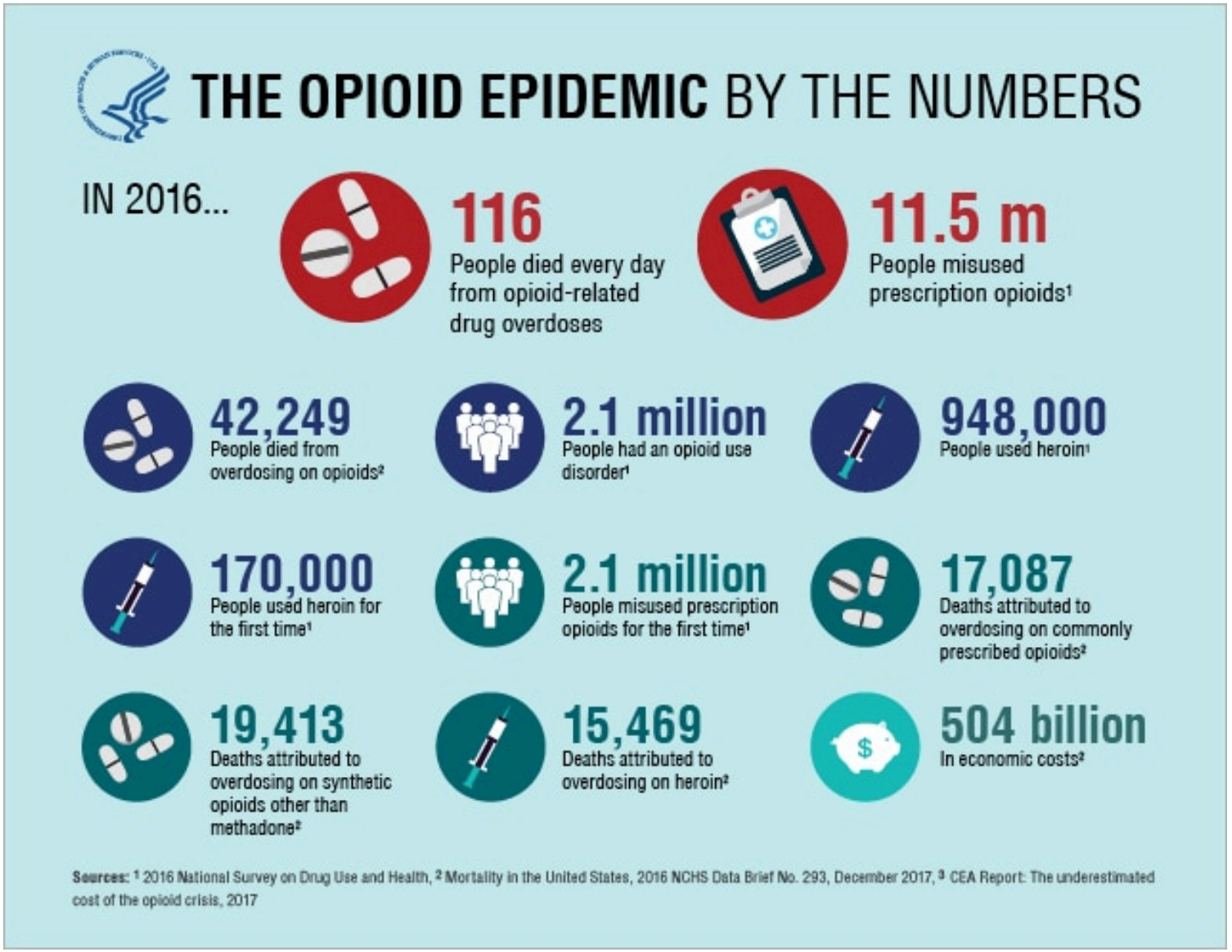
Agenda

- The Opioid Epidemic
- FDA's Efforts to Combat the Opioid Crisis
- Overview of the Innovation Challenge
- Tips for Potential Applicants
- Resources
- Questions


THE OPIOID EPIDEMIC BY THE NUMBERS
IN 2016...
116
People died every day from opioid-related drug overdoses
11.5 m
People misused prescription opioids[1]
42,249
People died from overdosing on opioids[2]
2.1 million
People had an opioid use disorder[1]
948,000
People used heroin[1]
170,000
People used heroin for the first time[1]
2.1 million
People misused prescription opioids for the first time[1]
17,087
Deaths attributed to overdosing on commonly prescribed opioids[2]
19,413
Deaths attributed to overdosing on synthetic opioids other than methadone[2]
15,469
Deaths attributed to overdosing on heroin[2]
504 billion
In economic costs[3]
Sources: [1] 2016 National Survey on Drug Use and Health, [2] Mortality in the United States, 2016 NCHS Data Brief No. 293, December 2017, [3] CEA Report: The underestimated cost of the opioid crisis, 2017

HHS 5-POINT STRATEGY TO COMBAT THE OPIOIDS CRISIS

1

Better addiction prevention, treatment, and recovery services

2

Better data

3

Better pain management

4

Better targeting of overdose reversing drugs

5

Better research

HHS.GOV/OPIOIDS

The Opioid Crisis: FDA's Priorities & Strategies

1. Decreasing Exposure & Prevent New Addiction

- Appropriate Dose/Duration Labeling
- Appropriate Packaging, Storage, and Disposal
- Health Care Provider Education

2. Supporting the Treatment of Those With Opioid Use Disorder

- Naloxone
- Medication Assisted Treatment (MAT)

3. Fostering the Development of Novel Pain Treatment Therapies

- Partnerships & Meetings
- Abuse Deterrent Formulations (ADFs)
- Pain Treatment Alternatives

4. Improving Enforcement & Assessing Benefit-Risk

- Improving Enforcement
- Assessing Benefit-Risk

FDA's Efforts to Combat The Opioid Crisis

- In the past few years, FDA has cleared, granted, or approved more than 200 devices related to the treatment or management of pain
- Includes 10 with new or novel technologies, such as brain and spinal cord stimulators to relieve pain and reduce the need for opioid drugs to patients suffering from either acute or chronic pain
- The FDA also recently granted a new indication to an electric stimulation device for use in helping to reduce the symptoms of opioid withdrawal

Overview of the Innovation Challenge

Challenge Goals:

- Innovative and creative approaches to the use of medical devices in combatting the U.S. opioid crisis
- Development of non-opioid treatments for acute and chronic pain
- Expedited development and review of innovative, safe and effective medical devices to help prevent and treat opioid use disorder

Overview of the Innovation Challenge

Eligibility

- Any medical device that prevents or treats opioid use disorder, including:
  - Diagnostic Devices
  - Therapeutic Devices
  - Digital Health Technologies (e.g., mobile medical apps)
  - Combination Products: primary mode of action is by the device
- Medical devices at any stage of development are eligible
- U.S.-based and foreign applicants are eligible to apply
- Per federal law, foreign firms will need a U.S. representative to market a device in the U.S.

Overview of the Innovation Challenge

Challenge Submissions Should Describe:

- Intended use
- Novelty of the medical device/concept
- Development plan for the medical device
- Development team
- Anticipated benefit of the device
- Impact on public health as compared to other available alternatives

Overview of the Innovation Challenge

Other Factors the FDA will Consider:

- Feasibility of device/concept
- Potential impact of FDA participation in development

Overview of the Innovation Challenge

Challenge Timeline

- Applications must be submitted electronically to FDA by September 30, 2018, through the dedicated mailbox: CDRH-Innovation-Opioid@fda.hhs.gov

- We intend to announce applications selected for the challenge in November 2018

Overview of the Innovation Challenge

What to Expect If Your Application is Selected:

- Development Phase
- Premarket Application
- Expedited Premarket Review

Tips for Potential Applicants

- You may submit multiple applications if you have more than one eligible device
- FDA will not review device applications prior to submission deadline or provide specific advice to challenge applicants. If your device/concept meets the challenge criteria, please submit an application.
- There is no official application form. The application format is outlined on the challenge website.

Resources

- Devices to Prevent and Treat Opioid Use Disorder Innovation Challenge Webpage (includes application format)

  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm609082.htm

- Device Advice: Comprehensive Regulatory Assistance

  https://www.fda.gov/medicaldevices/deviceregulationandguidance/

- Mobile Medical Applications Webpage

  https://www.fda.gov/medicaldevices/deviceregulationandguidance/

- Breakthrough Devices Webpage

  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm441467.htm

Questions?

About the Innovation Challenge:

CDRH-Innovation-Opioid@fda.hhs.gov

About Medical Device Regulation:

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Slide Presentation, Transcript and Webinar Recording will be available by August 2, http://www.fda.gov/training/cdrhlearn Under the Heading: Specialty Technical topics; Subheading: Neurological Device

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