

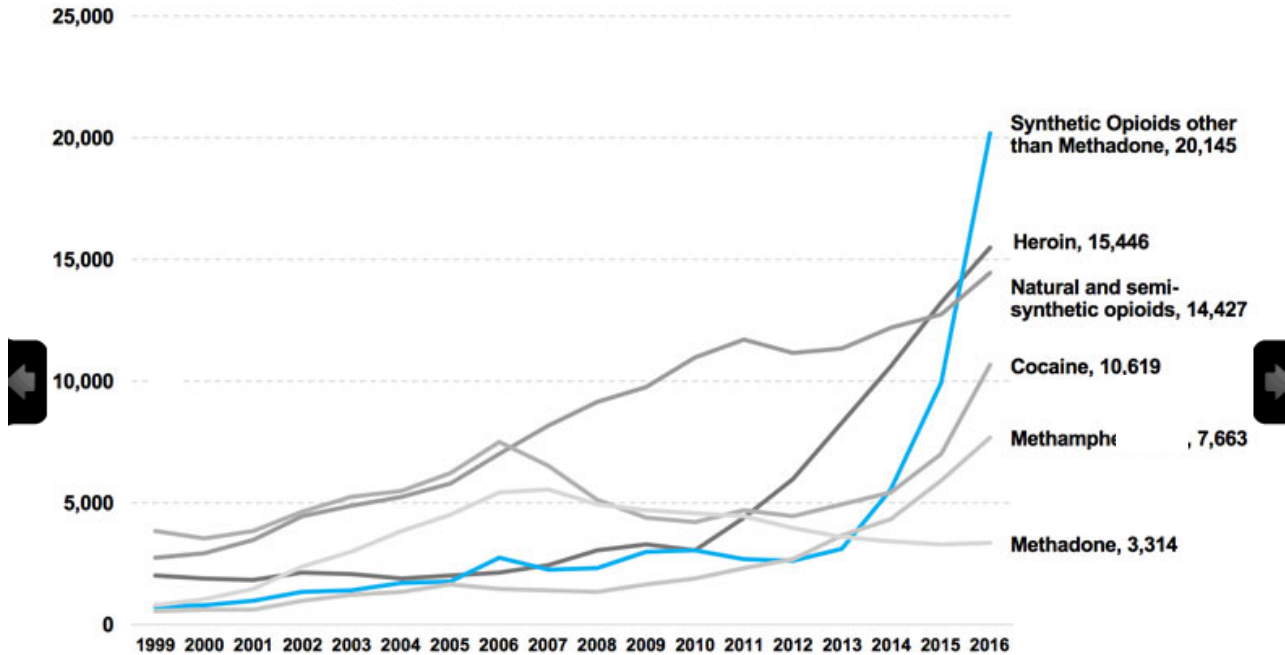
Charge to the Committee

National Academies of Science, Engineering, and Medicine
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Drug Overdose Deaths

Drugs Involved in U.S. Overdose Deaths, 2000 to 2016



Drugs Involved in U.S. Overdose Deaths* - Among the more than 64,000 drug overdose deaths estimated in 2016, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with over 20,000 overdose deaths. Source: CDC WONDER

FDA Response to this Crisis

"Unquestionably, our greatest immediate challenge is the problem of opioid abuse. This is a public health crisis of staggering human and economic proportion ... we have an important role to play in reducing the rate of new abuse and in giving healthcare providers the tools to reduce exposure to opioids to only clearly appropriate patients, so we can also help reduce the new cases of addiction."

- Scott Gottlieb, FDA Commissioner
Address to FDA staff, May 15, 2017

The Opioid Crisis: FDA's Priorities

1. Decreasing Exposure & Prevent New Addiction

2. Supporting the Treatment of Those With Opioid Use Disorder

3. Fostering the Development of Novel Pain Treatment Therapies

4. Improving Enforcement & Assessing Benefit-Risk

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

Treatment Guidelines

- Provide best available evidence for prescribers
- Support more appropriate prescribing of opioids while ensuring that patients with pain are adequately treated
- Develop new evidence where needed

Statement of Work: Framework Development

- Develop a framework for evaluating the evidence base underpinning clinical treatment guidelines for opioid prescribing for acute pain
 - Develop a threshold level of evidence needed to support such guidelines
- Consider standards established in the 2011 IOM Report *Clinical Practice Guidelines We Can Trust* and other established standards for clinical assessment

Statement of Work: Current State of Practice

- Inventory surgical and medical conditions associated with acute pain where opioids are used
 - Include available information on dose and duration of opioid use by indication
- Identify existing opioid prescribing guidelines for acute pain conditions and apply framework
- Identify and prioritize acute pain conditions where evidence-based practice guidelines for pain could help inform prescribing practices

Statement of Work: Research Agenda

- Develop a prioritized research agenda for
 - Work to develop new treatment-specific treatment guidelines
 - Work to support additional evidence to support existing guidelines
 - Agenda should include a minimum of 5 conditions for indications that are abuse-prone and/or commonly prescribed

Summary

- FDA goal is to improve the state of the science supporting clinical practice guidelines for acute pain
 - Creating a framework for evidence generation and assessment
 - Inventorying existing treatment of acute pain and available evidence on opioid use
 - Creating a research agenda for future work
- This framework can then be used to improve the prescribing of opioids while ensuring that patients with acute pain are adequately treated

Thank You





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