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

Synthetic Opioids other than Methadone, 20,145
Heroin, 15,446
Natural and semi-synthetic opioids, 14,427
Cocaine, 10,619
Methamphetamine, 7,663
Methadone, 3,314

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
"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