

# FDA Update: 2018

**Douglas C. Throckmorton MD**  
Deputy Director for Regulatory Programs  
CDER, FDA

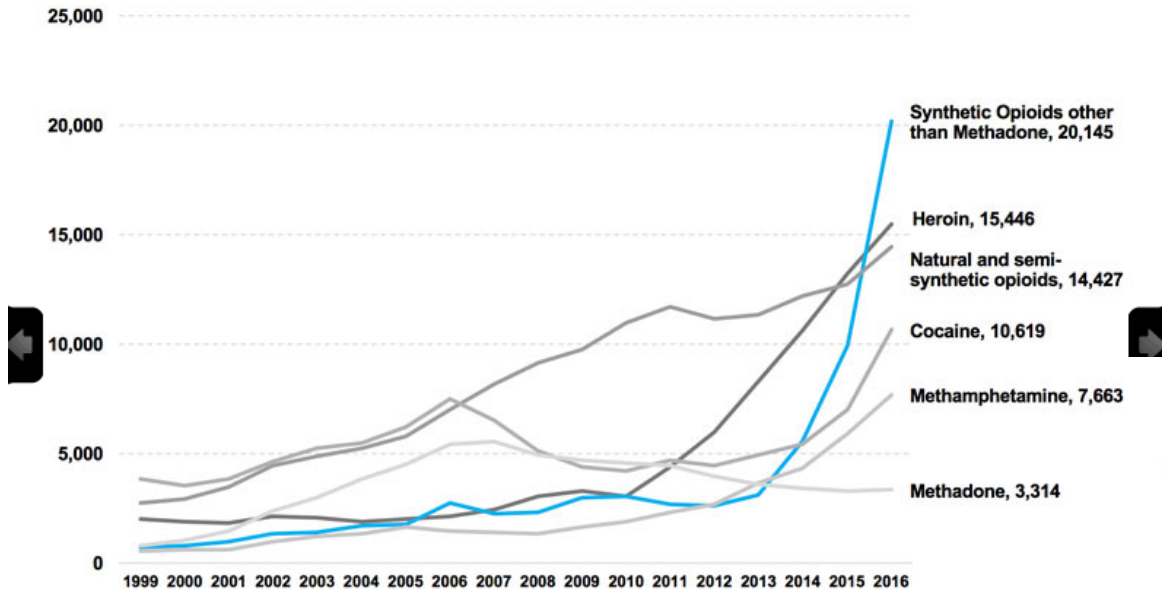
**American College of Surgeons**  
May 21, 2018

The opinions and information in this presentation are my own and do not necessarily reflect the views and policies of the FDA

# Drug Overdose Deaths



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



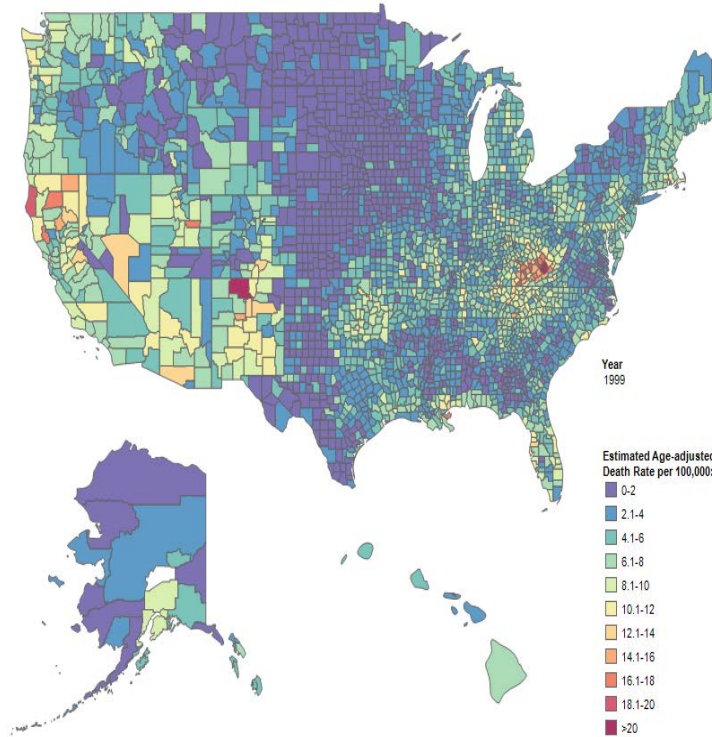
**Drugs Involved in U.S. Overdose Deaths\*** - Among the more than 64,000 drug overdose deaths estimated in 2016, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with over 20,000 overdose deaths. Source: CDC WONDER



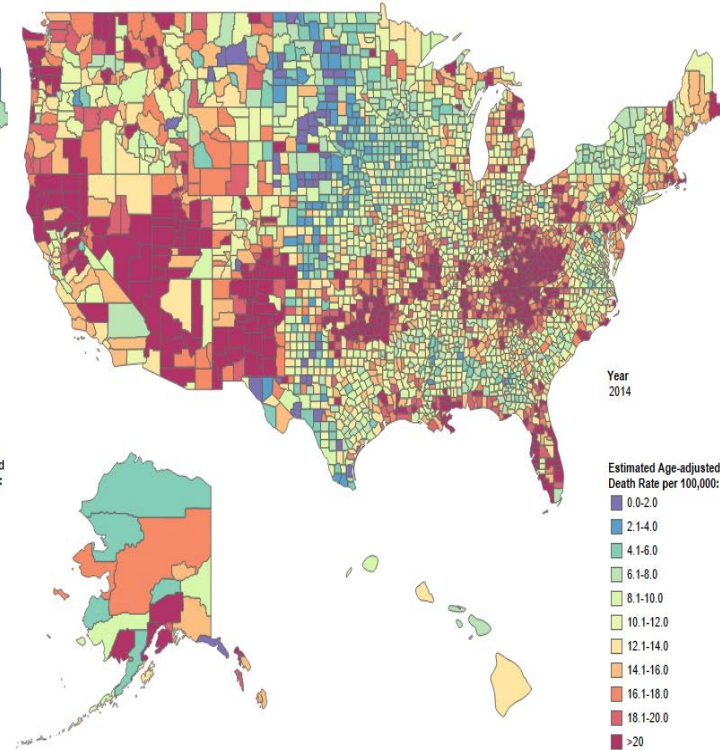
What does 53,000 people look like?

# Overdose Death Rates

## 1999



## 2014



# 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



# Available FDA Tools to Accomplish These Goals

- Improving the safe use of drugs through careful and appropriate **regulatory activities**
- Improving the safe use of drugs through careful and appropriate **policy development**
- Improving product development through **improved science**
- Improving the safe use of drugs through **communication, partnership and collaboration**

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# Responding to Challenges: Opioids

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# 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**

## 2. Supporting the Treatment of Those With Opioid Use Disorder



**Naloxone**



**Medication Assisted**

## 3. Fostering the Development of Novel Pain Treatment Therapies



**Partnerships & Meetings**



**Abuse Deterrent Formulations (ADFs)**



**Pain Treatment Alternatives**

## 4. Improving Enforcement & Assessing Benefit-Risk

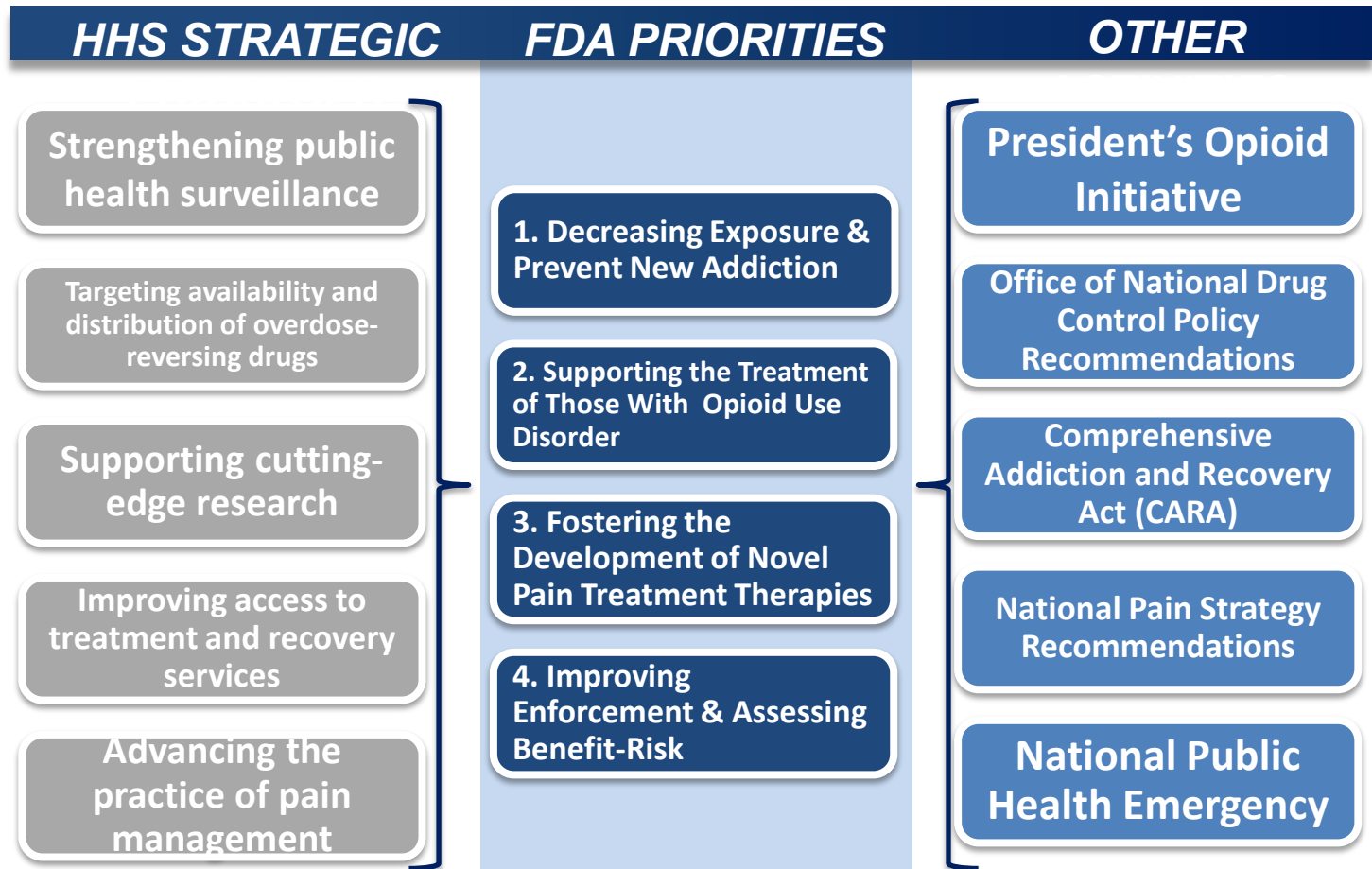


**Improving Enforcement**



**Assessing Benefit-Risk**

# FDA Priorities align to HHS Strategic Priorities and other National Activities



# Summary and Conclusions

- FDA working to address opioid epidemic as a part of the larger HHS response
  - One of the FDA's very highest priorities
- Going forward, FDA is committed to taking decisive actions, grounded in the available science and appropriate public input to address this critical challenge to the US health and welfare
- Collaboration with professional societies and other stakeholders is essential to successfully meeting this challenge
- Our focus is addressing opioid abuse while assuring appropriate access to effective pain treatment

# Thank You

