



FDA's Role in Confronting the Opioid Epidemic

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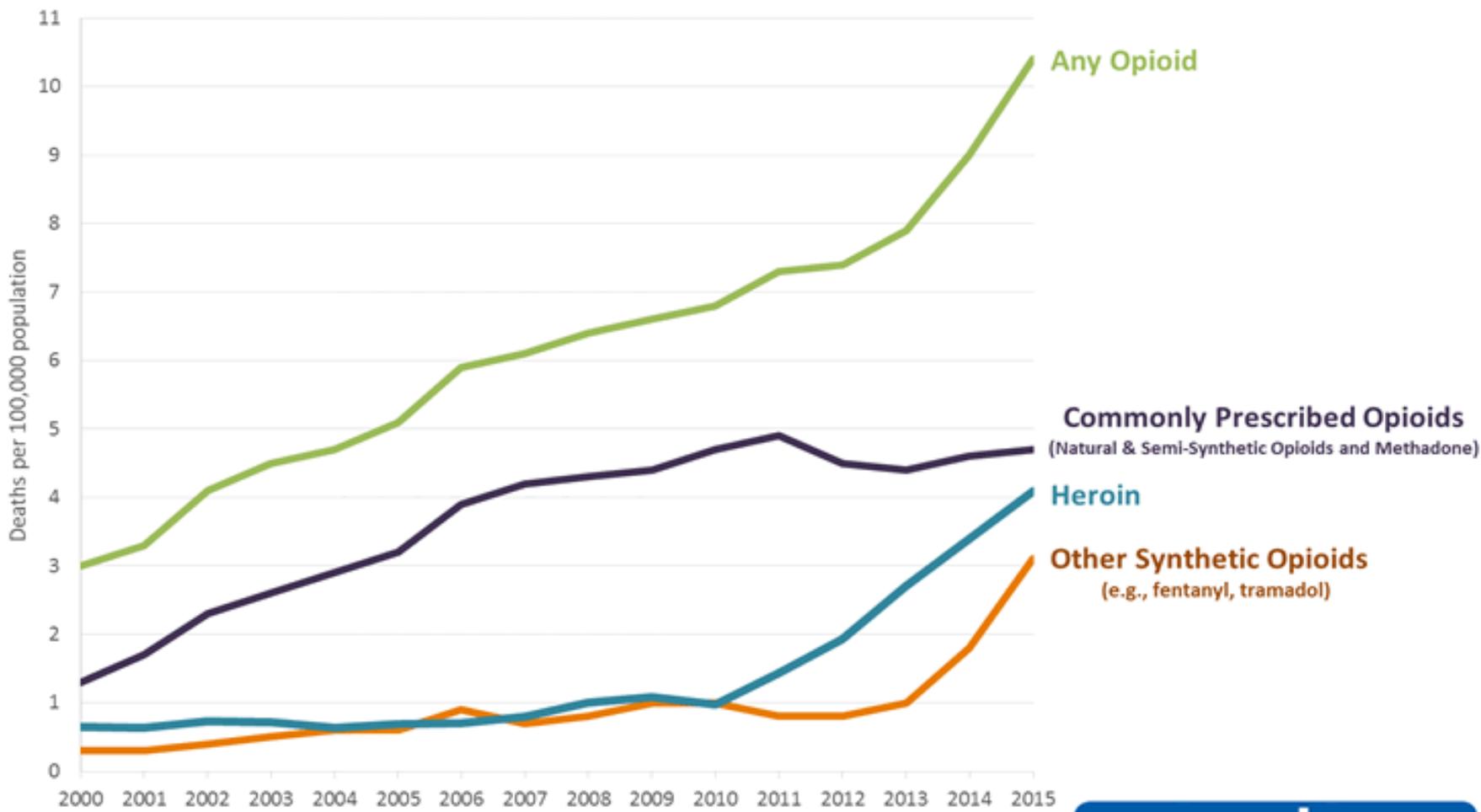
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Overall Messages

- The FDA work to improve the safe use of opioids is taking place within a larger policy framework aimed at addressing opioid abuse while assuring appropriate access to pain treatment
- Ongoing and planned activities reflect the commitment by FDA to use of all of our available tools to appropriately manage pain while also addressing the opioids crisis

Marked *Increases in Prescription Opioid and Heroin Overdose Deaths* in the USA 2000 to 2015

Overdose Deaths Involving Opioids, United States, 2000-2015

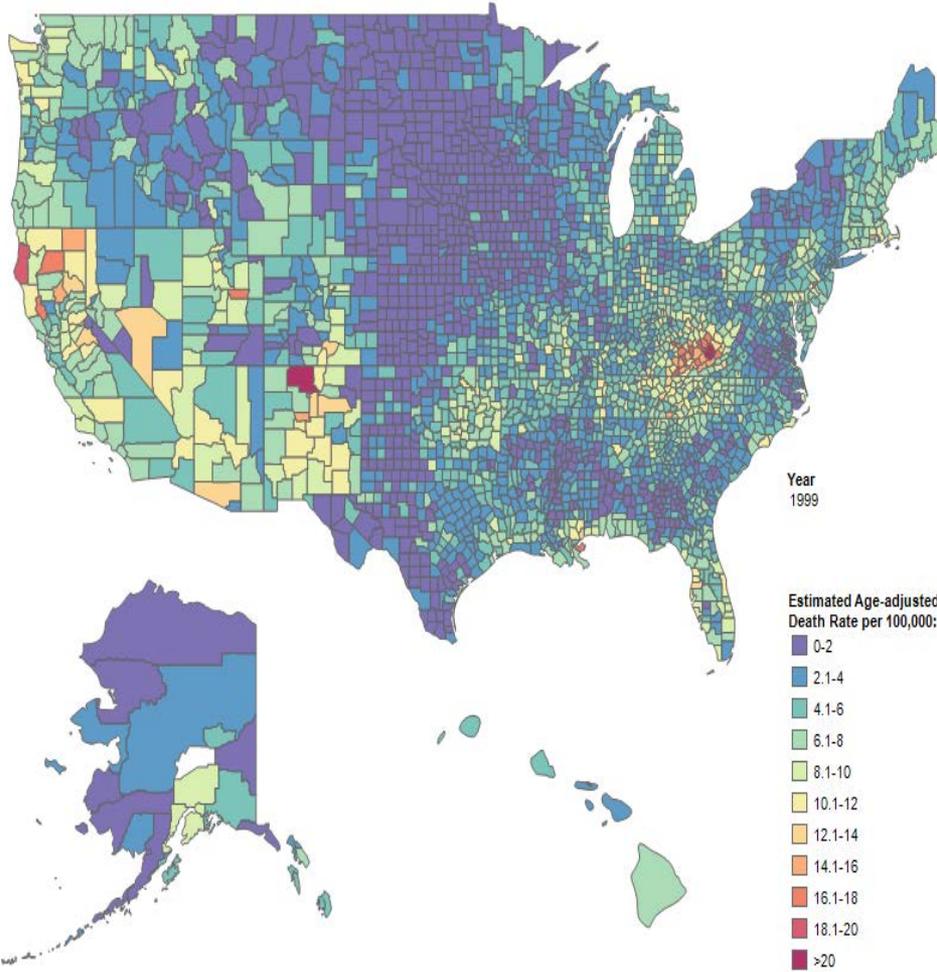


SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. <https://wonder.cdc.gov/>.

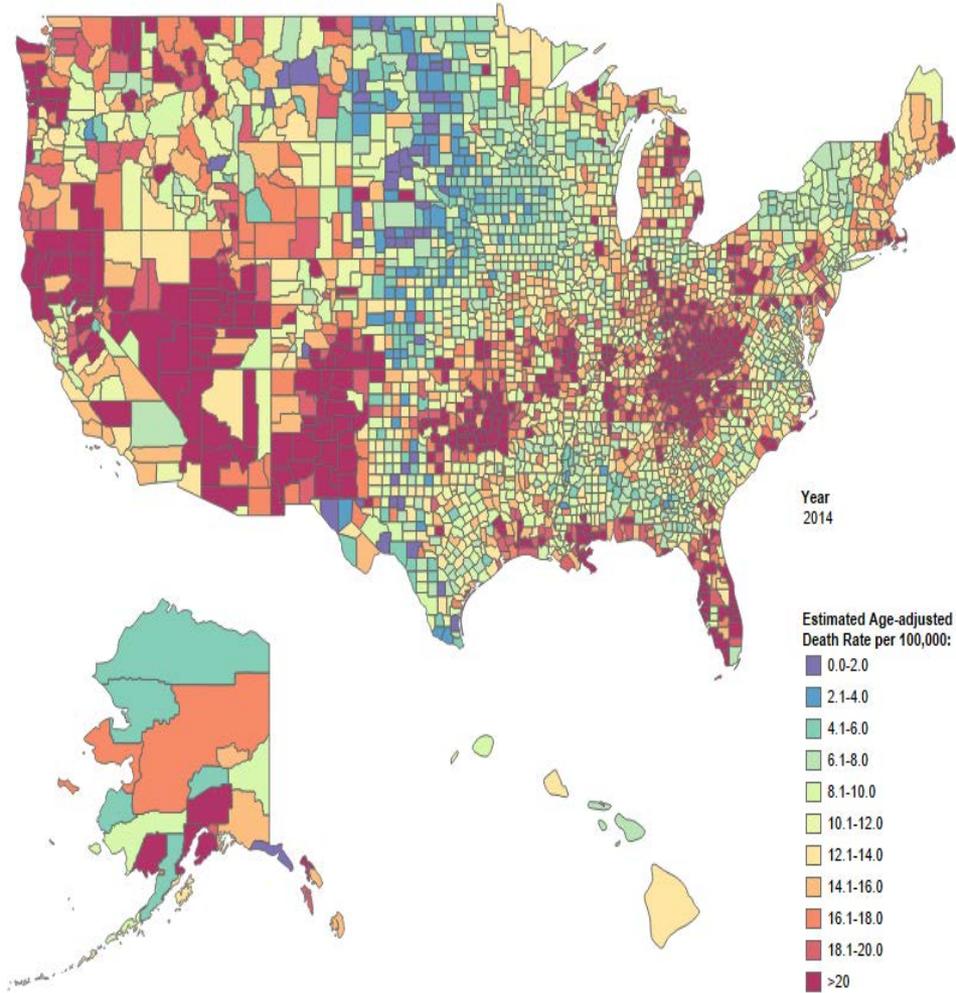


Overdose Death Rates

1999

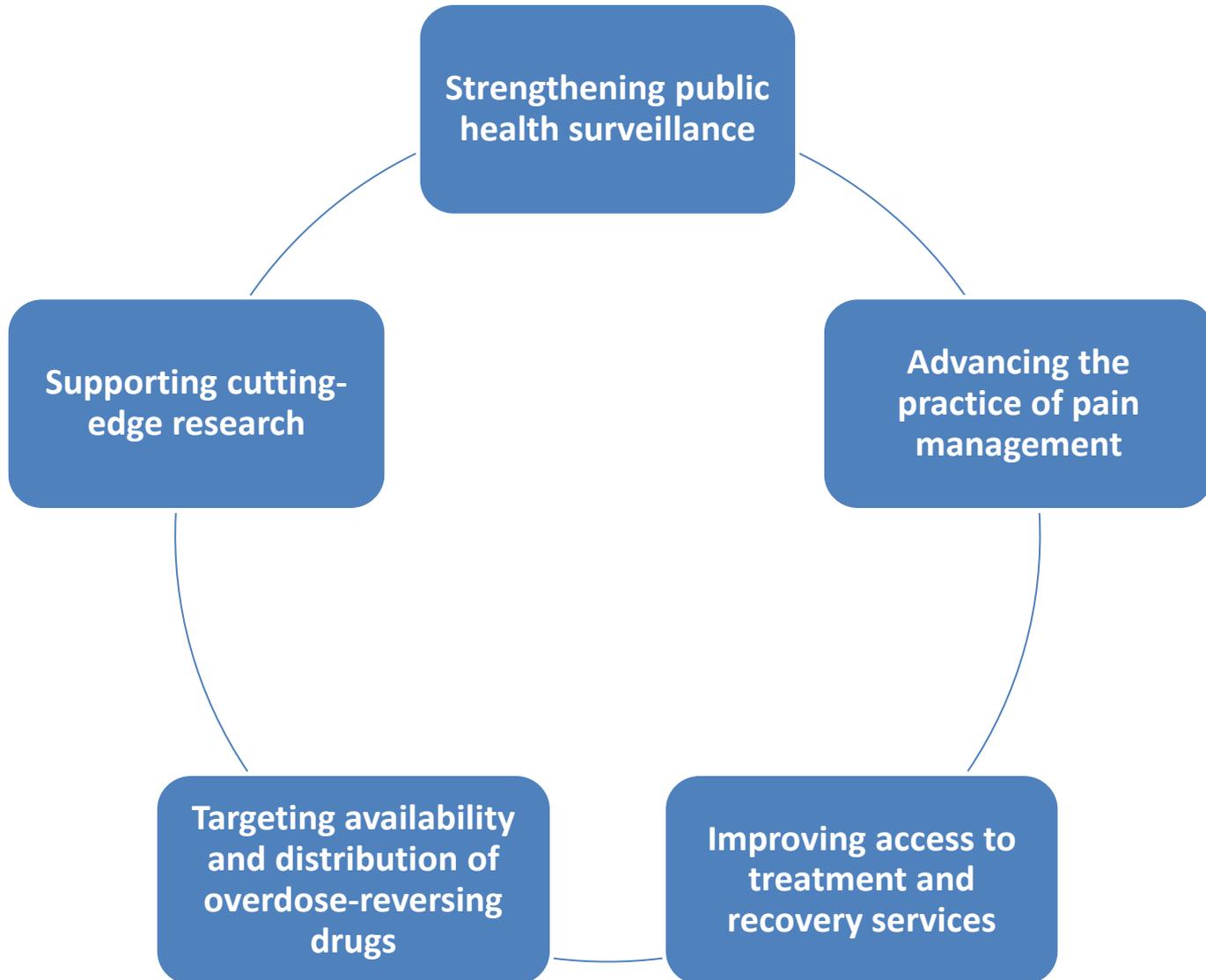


2014



HHS Response to Opioid Epidemic

HHS Opioid Strategy





Goals of HHS Opioid Strategy

- Empowering the public, patients and providers through education and awareness
- Preventing opioid abuse and overdose and related health consequences
- Improving function and quality of life for individuals living with pain
- Ensuring patients who need opioid addiction treatment have access to it
- Supporting people to achieve long-term recovery

FDA Role: Advancing the Practice of Pain Management

- **CDC**

- Prevention for States grants
- **CDC Opioid Prescribing Guideline implementation and associated training**

- **CMS**

- Reimbursement and coverage levers to increase access to full spectrum of pain treatment options

- **OASH**

- **National Pain Strategy implementation**

- **FDA**

- Incentivizing development of new pain treatments
- **REMS and associated education, safety labeling changes**

- **NIDA**

- Working with researchers to better understand pain pathways and develop new treatments
- Partnering with industry on early-phase development of treatments
- Leading the Interagency Pain Research Coordinating Committee

- **ASPE**

- **Research on coverage and evidence base for non-opioid treatments**





Examples of Other Federal Efforts to Address Opioid Epidemic

- **National Pain Strategy**
 - Focuses on key areas of pain and pain care, including professional education and training, public education and communication, service delivery and reimbursement
 - <http://iprcc.nih.gov/docs/DraftHHSNationalPainStrategy.pdf>
- **NIH Pain Consortium's Centers of Excellence in Pain Education Program.**
 - Developed and spearheaded by NIDA
 - https://painconsortium.nih.gov/nih_pain_programs/coepes.html
- **Surgeon General's Call to End the Opioid Crisis**
 - Includes a new prescriber education campaign, Turn the Tide
- **CDC Guidelines for Prescribing Opioids for Chronic Pain**
 - <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>

Presidential Commission

- Established by Executive Order on March 29, 2017.
- Mission: “to study the scope and effectiveness of the Federal response to drug addiction and the opioid crisis and to make recommendations to the President for improving that response.”
- Interim report release July 31, 2017*

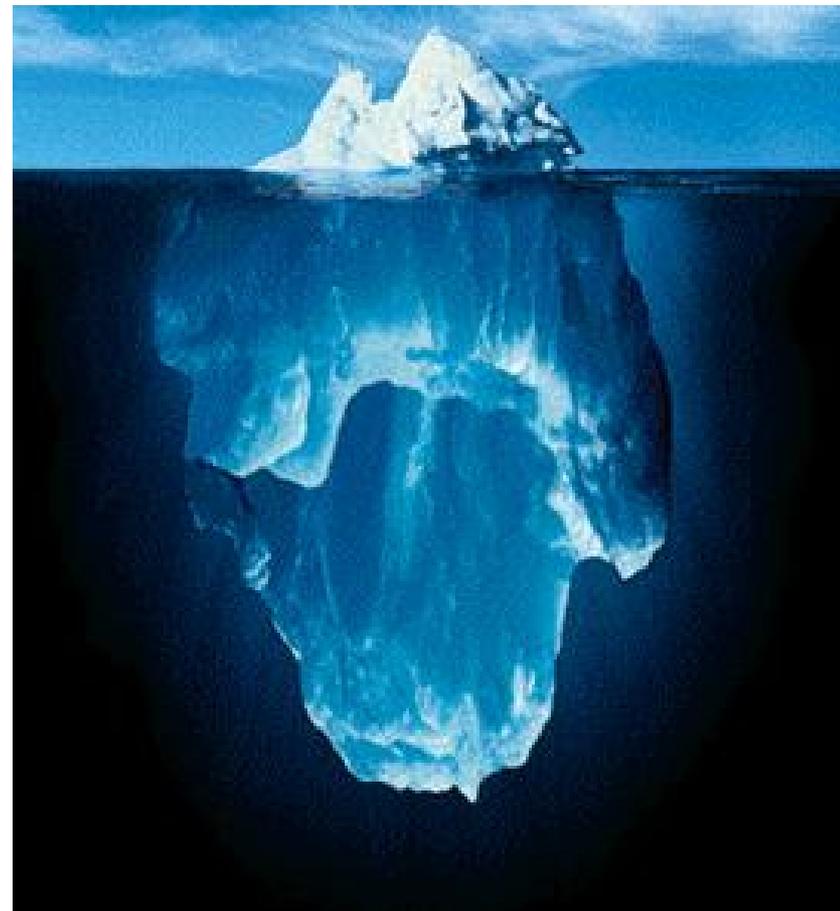
<https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf>

FDA Response to Opioid Epidemic



Solutions Must Come from Many Sources

- FDA is one of many Federal agencies addressing issues involving opioids
- Many Federal Agencies working together on issue
- Each state has programs to address opioids
- Guidelines and educational programs are available from specialty societies and State Medical Boards
- Healthcare institutions
- Advocacy groups
- Individual providers (n = 800,000+)
- Patients (n = millions)





FDA Action Plan (February 4, 2016)

- In response to the opioid abuse epidemic, FDA leadership called for a far-reaching action plan to reassess the agency's approach to opioid medications. The plan focused on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm>



FDA Opioids Action Plan

Goal: to reverse the epidemic while still providing patients with access to effective relief

Advisory Committees

IR Labeling

Post-market

REMS

Abuse Deterrent

Supporting Treatment

Risk-Benefit



FDA is using all of its Available Tools to Carry Out the Action Plan

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

Improving the Educational Tools for Healthcare Providers



- REMS program: requires drug companies making Extended-Release Long-Acting Opioids to fund continuing education programs on the use of these products
 - Content dictated by FDA Blueprint
- FDA held a public meeting regarding prescriber education on May 9 – 10, 2017
- FDA released a revised Blueprint with expanded topics to be included in the prescriber education program including education on pain management
- FDA has announced plans to expand the REMS:
 - to include the immediate-release (IR) opioids
 - to include pain management in the training , and
 - to expand training to include more members of the healthcare team

Intervening to Influence Prescribing of Opioids



- Professional Affairs and Stakeholder Engagement is supporting work targeting the prescribing of opioids by high-risk prescribers
 - Identifying high-risk prescribers (>90 MME/day or co-prescribing with a benzodiazepine) using PDMP data
 - Sending a letter from State Board to inform the prescriber that they “may have engaged in high-risk prescribing” and refers to educational resources (e.g., CDC Guideline)
 - Follow-up analysis of prescribing patterns 6 months after letters are sent
 - Assess the effect on number of high-risk prescriptions and high-risk patients



Supporting Abuse Deterrent Formulations (ADF) of opioids

- FDA has a goal of incentivizing the development of opioid medications with progressively better abuse-deterrent properties and support their widespread use
 - Abuse-deterrent is **not** *abuse proof*
- FDA requiring studies to understand the impact of ADFs in real-world settings
- In support of the goal, FDA has issued guidance for product development, including draft guidance on generic ADFs, reflecting importance of generic products in the US

Continuing our Work on Benefit-Risk Assessment of Opioids



- Prescription opioids have impacts on both the patients when used as prescribed and on society when used inappropriately
- FDA considers both impacts in our regulatory decisions and is seeking to formalize that assessment
 - Opana decision
- FDA sought NASEM input on issue last year and is working to determine next steps and improve our processes
 - “...to ensure drug approval and removal decisions are made within a benefit-risk framework that evaluates not only the outcomes of opioids when used as prescribed, but also the public health effects of the inappropriate use of these drugs”

What's Next for FDA?

"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

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
- FDA Opioid Action Plan provides framework for ongoing FDA response to the challenge of opioids abuse epidemic
- 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

Thank You



