



Ongoing Efforts to Address the Opioid Epidemic

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FDA Workshop: Training for
Opioids Prescribers

May 9-10, 2017

Outline

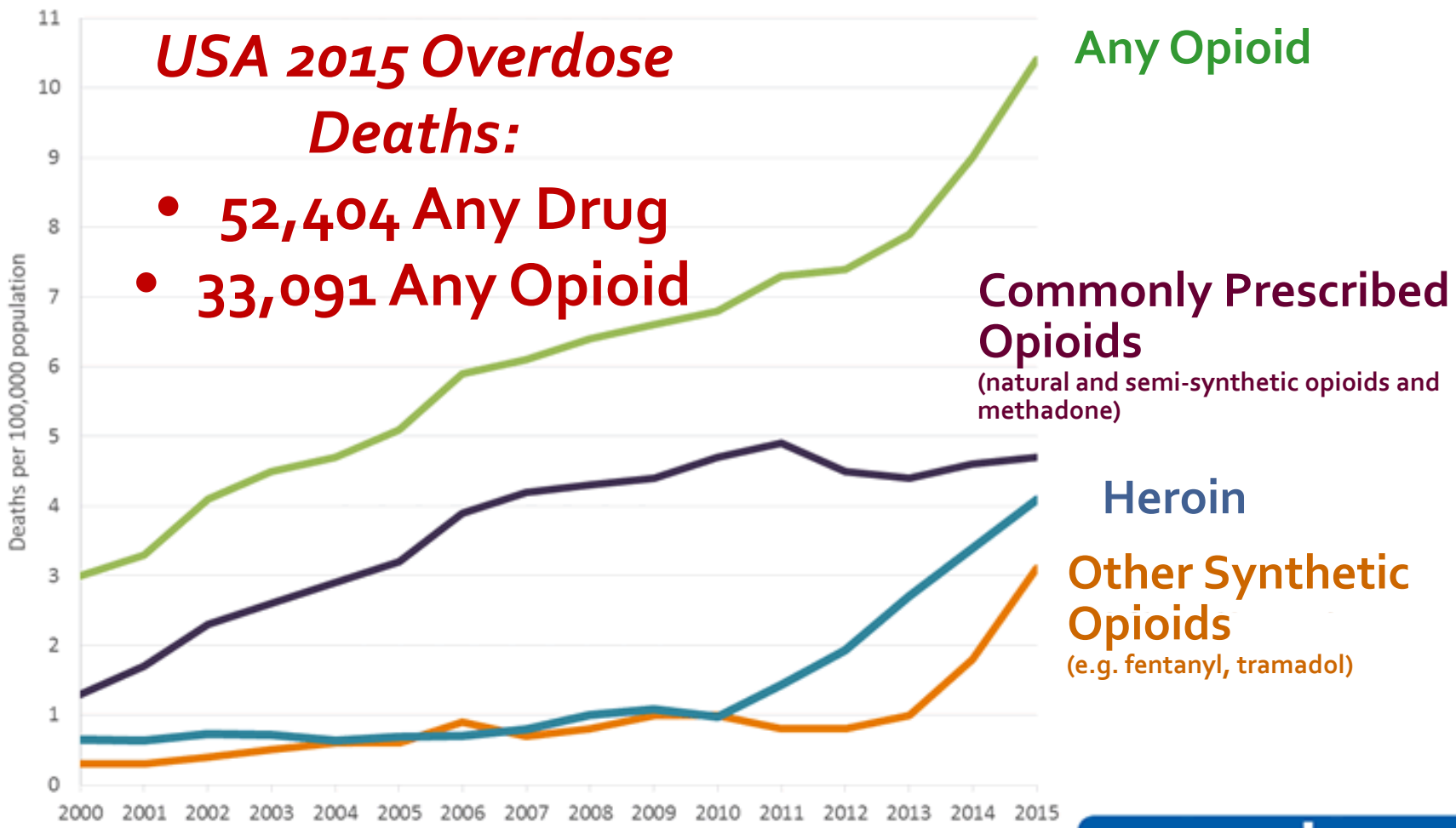
- Federal Context for FDA Efforts to Address Prescription Opioid Abuse
 - Other Federal Efforts
- FDA Action Plan
 - Focus on education
- Goals for the Workshop

Overall Message

- The broad Federal response to opioids epidemic includes important efforts related to education
- FDA is doing many things in this area under our Action Plan, including targeted work to support education of healthcare workers
- At this meeting, FDA needs your input on our efforts regarding education:
 - Role Federal educational efforts, especially FDA efforts, play within the larger set of activities in this area
 - Best approaches to use to provide education and training to healthcare providers

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

Overdose Deaths Involving Opioids, United States, 2000-2015



USA 2015 Overdose Deaths:

- 52,404 Any Drug
- 33,091 Any Opioid

Any Opioid

Commonly Prescribed Opioids
(natural and semi-synthetic opioids and methadone)

Heroin

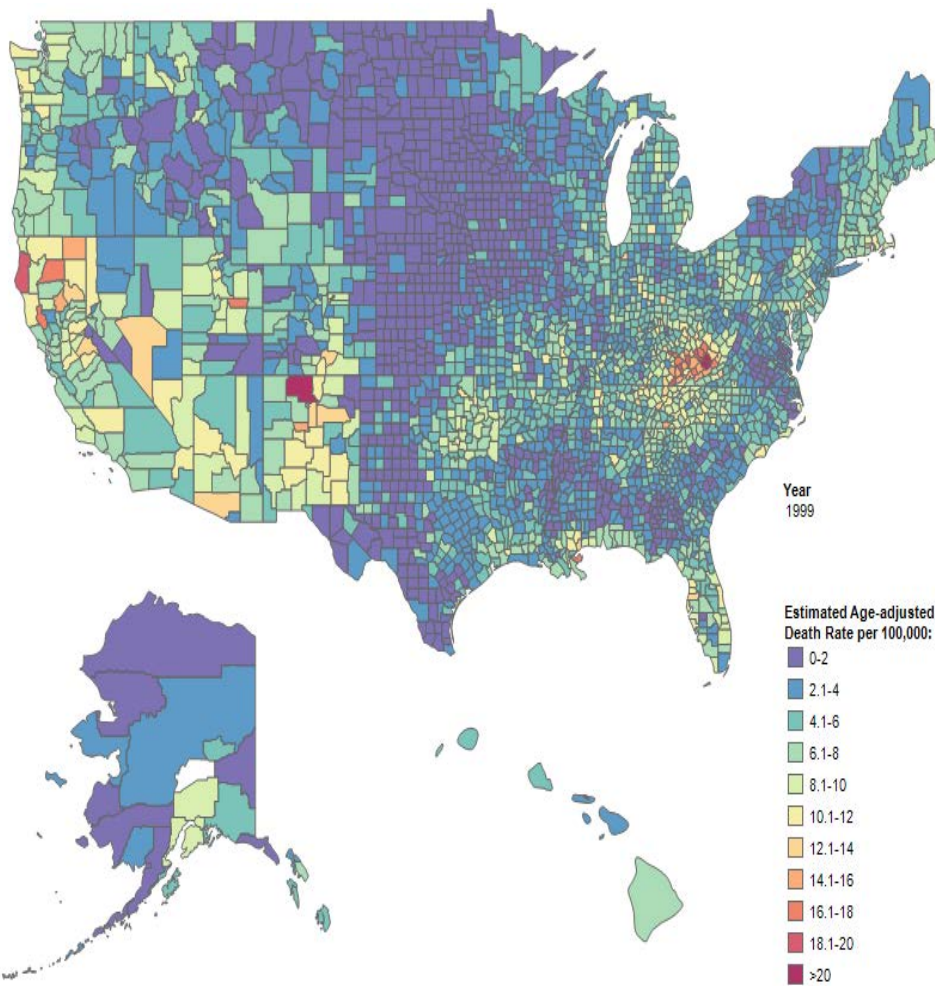
Other Synthetic Opioids
(e.g. fentanyl, tramadol)

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/>.

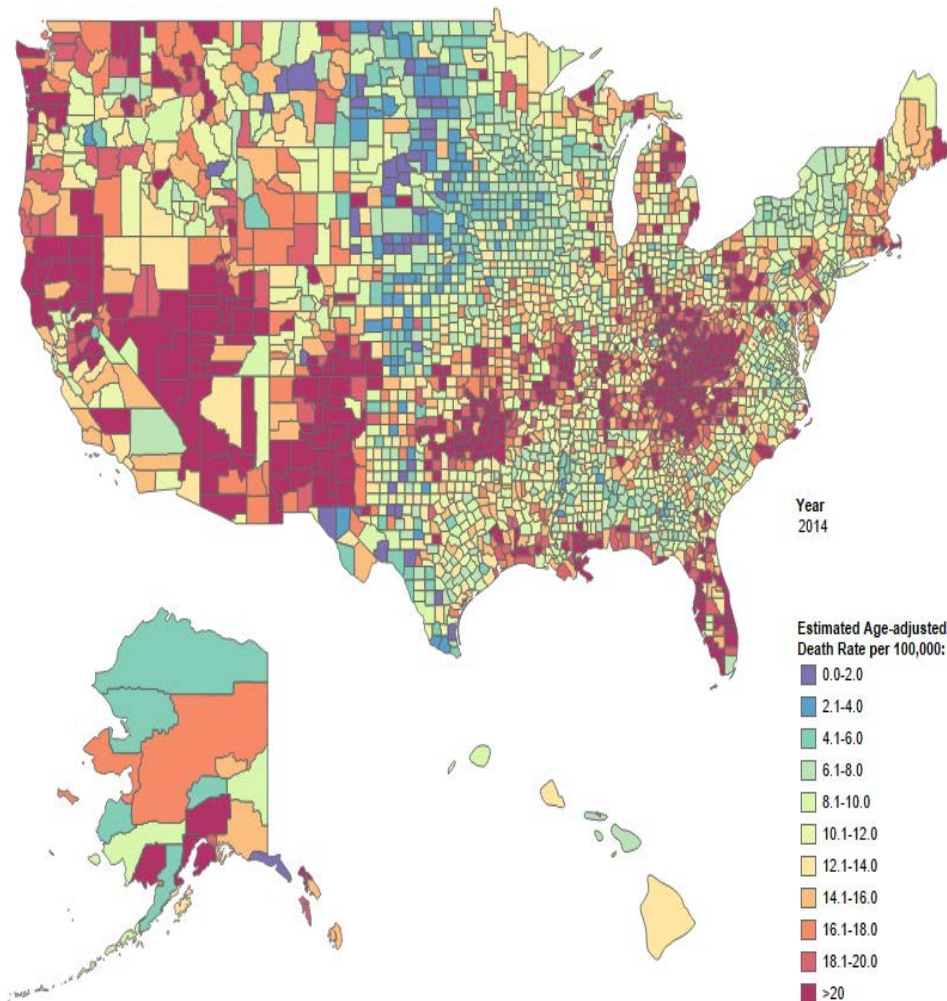


Overdose Death Rates

1999

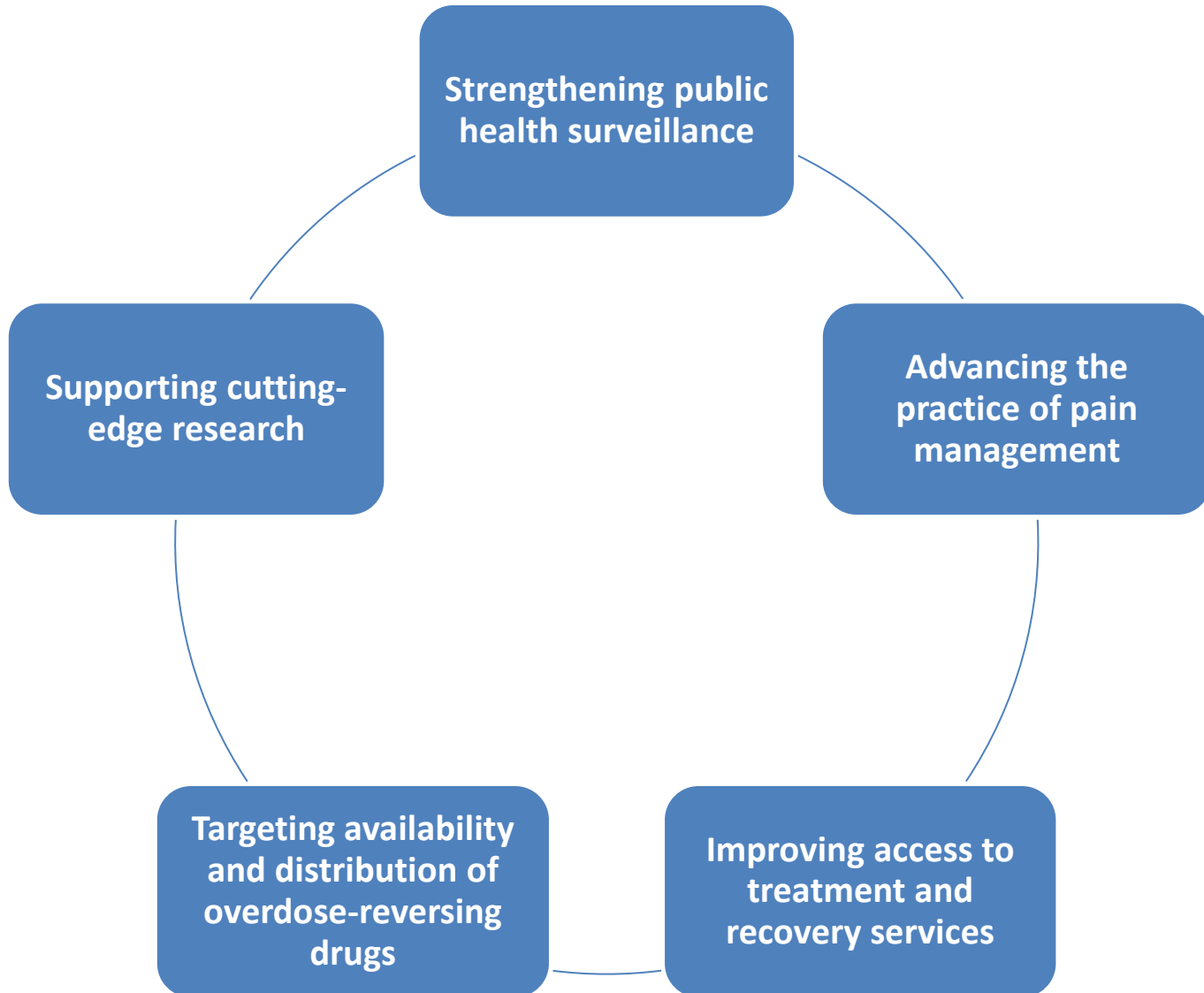


2014



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

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>

FDA Response to Opioid Epidemic



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.

[--http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm)



FDA Opioid Action Plan

- Expand the use of advisory committees
- Develop warnings and safety information for immediate-release (IR) opioid labeling
- Strengthen postmarket requirements to get needed data
- **Update Risk Evaluation and Mitigation Strategy (REMS) Program for Prescription Opioids**
- Expand access to abuse-deterrent formulations (ADFs) to discourage abuse
- Support better treatment for prescription opioid abuse and overdose
- Reassess the risk-benefit approval framework for opioid use

[--www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm](https://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm)

Tools Available to FDA 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**

Today's Meeting: Focus on FDA Efforts on Training and Education



- The relative role of Federal training/education efforts in the larger landscape of activities aimed at improving pain management, including the use of opioid analgesics
- The merits and challenges of utilizing Federal mechanisms to provide education on pain management and the safe use of opioid analgesics
 - This includes a discussion of the role, if any, of mandatory Federal education efforts
- The merits and challenges of utilizing partnerships between Federal agencies and other groups to provide education
- The aspects of the opioid epidemic that can be most impacted by education of prescribers and other health care providers and how outcomes from these programs can be measured.

Summary and Conclusions

- FDA working to address opioid epidemic as a part of the larger HHS response
 - One of the FDA's highest priorities
- FDA Opioid Action Plan provides framework for FDA response to the challenge of opioids abuse epidemic
- Since the Action Plan was announced, FDA has continued to make significant progress on the items identified in the plan, applying of all of our available tools to achieve our goals
- This meeting will provide us important help as we continue our efforts focused on the education of healthcare workers

Thank You



