

# **Search for Balance: FDA's Approach to the Opioids Crisis**

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# Topics for Today

- Scope and sources of opioid crisis of abuse and overdose
- Need for adequate pain treatment
  - Pain in America
  - Shortages of injectable opioids
- FDA response
- Selected FDA activities

# Take Homes



- The ‘Opioid Crisis’ is not one crisis, but multiple challenges to prescribers, patients and the healthcare system
- No single solution is going to suffice
- FDA is working in a prioritized way in multiple areas to confront opioid overdoses while working to ensure patients receive appropriate pain treatment

# **The Opioid Challenges:**

**Opioid Abuse and Misuse**

**Pain in America**

**Injectable Opioid Shortages**

# Misuse and Abuse of Prescription Opioid Analgesics Remains an Important Public Health Problem

- In 2017, prescription opioids were the largest category of pharmaceutical products misused and abused in US
  - 11.1 million people estimated to have past-year misuse/abuse
  - 1.7 million people estimated with DSM IV criteria for substance use disorder involving prescription opioid analgesics
- In comparison, 886,000 estimated to have past-year heroin use

**Source:** Substance Abuse and Mental Health Services Administration. (2018). Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health (HHS Publication No. SMA 18-5068, NSDUH Series H-53). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

# Consequences: Prescription Opioids and Overdose Death in the US



## Drugs Involved in U.S. Overdose Deaths, 1999 to 2017

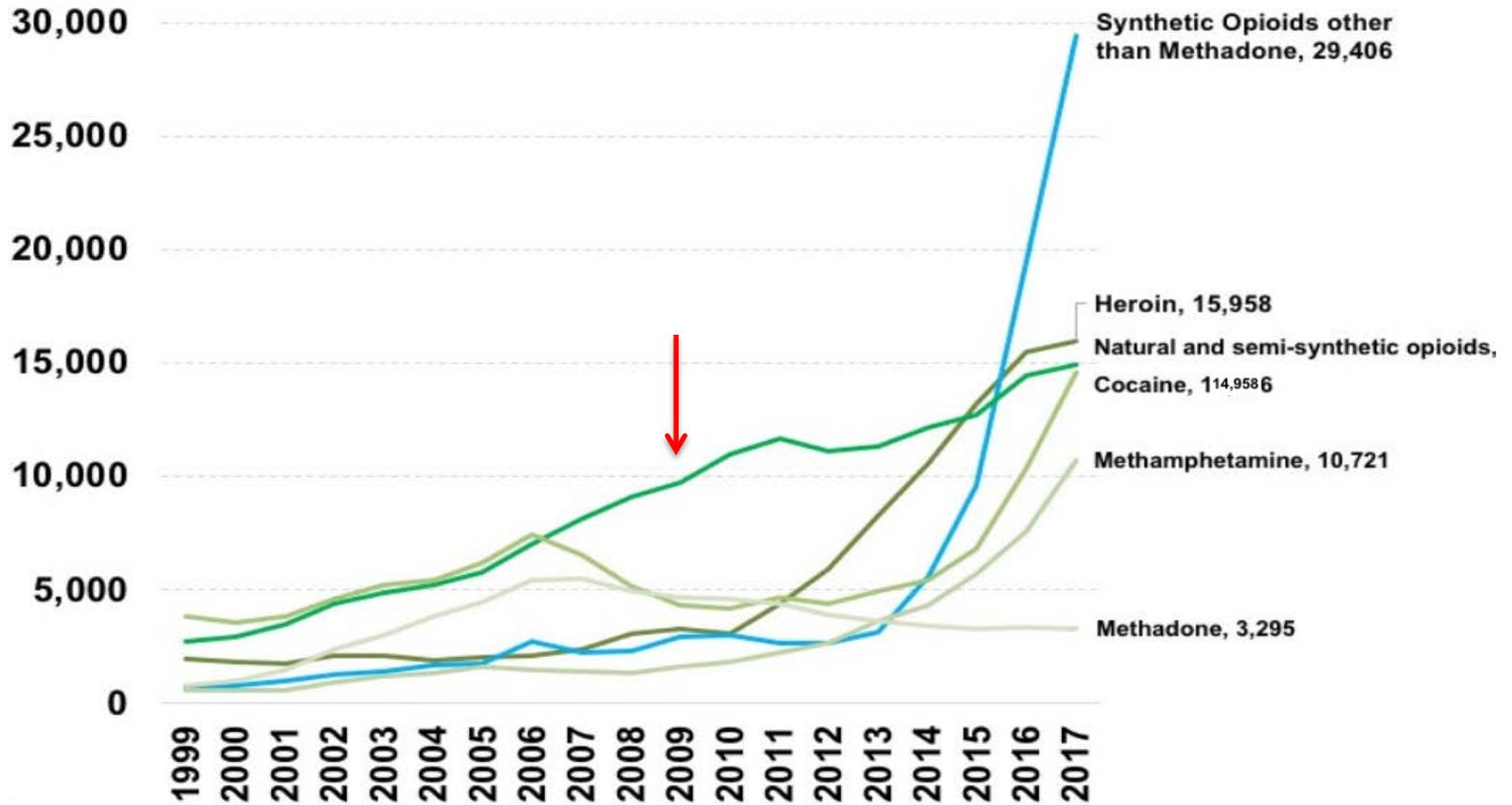


Figure Source: National Institute on Drug Abuse Data Source: CDC Wonder

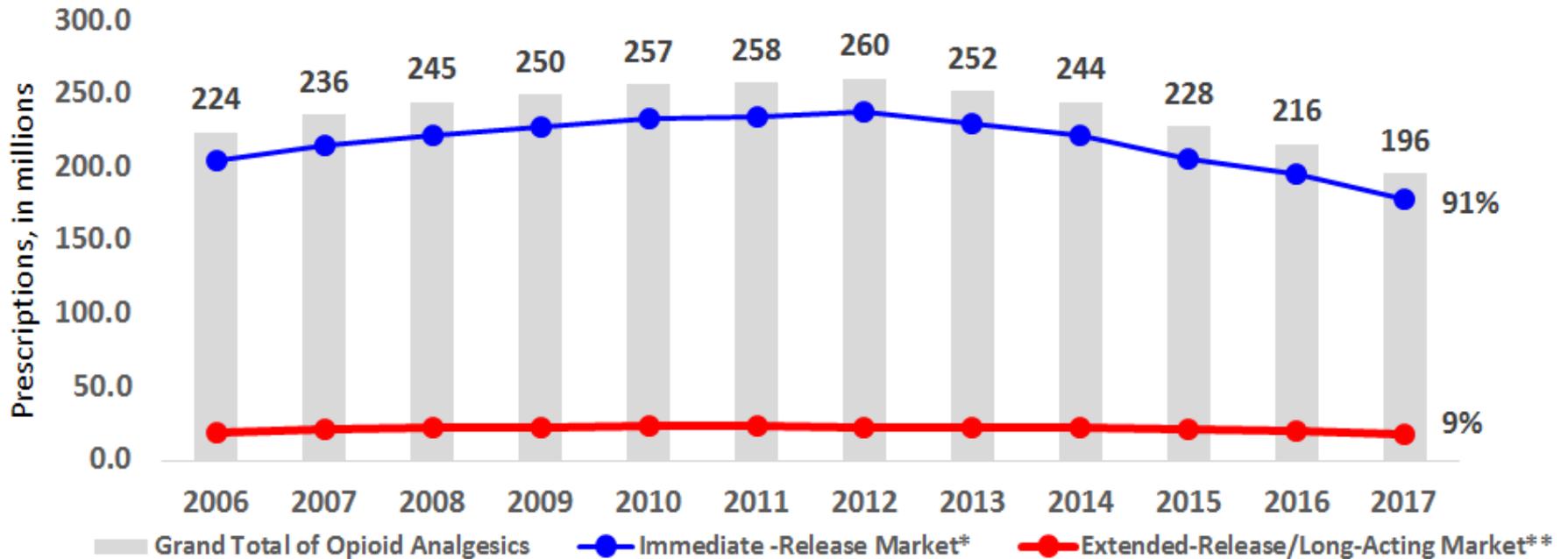
Available from: <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>

# Sources of the Opioid Crisis

- Prescribed opioids pose a risk beyond the patient who receives the prescription
- Among people who abuse prescription opioids, most get them
  - From a friend or relative for free (55%)
  - Prescribed by a physician (20%)
  - Bought from a friend or relative (11%)
- Among new heroin users, about **three out of four** report abusing prescription opioids before using heroin.

<https://www.cdc.gov/drugoverdose/data/prescribing.html>

# Crisis Ongoing Despite Falling # of Prescriptions for Opioid Analgesics



Source: IQVIA, National Prescription Audit (NPA) and static data 2006-2011. January 2006-December 2017.

Static data extracted March 2017 and 2012-2017 data extracted February 2018.

\*Immediate-Release formulations include oral solids, oral liquids, rectal, nasal, and transmucosal

\*\*Extended-Release/Long-Acting formulations include oral solids and transdermal patches

Note: Include opioid analgesics only, excluding injectable formulations as well as opioid-containing cough-cold products and opioid-containing medication-assisted treatment (MAT) products

# The FDA and Opioid Abuse/Misuse

"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 Challenges:

Opioid Abuse and Misuse

**Pain in America**

Injectable Opioid Shortages

# Equally Critical Social and Medical Issue: Pain in America

- From the Functioning and Disability Supplement of the 2012 National Health Interview Survey
  - 126.1 million adults reported some pain in the previous 3 months
  - 25.3 million adults (11.2%) suffering from daily (chronic) pain
  - 23.4 million (10.3%) reporting a lot of pain.
  - Based on the persistence and bothersomeness of their pain, 14.4 million adults (6.4%) were classified as having the highest level of pain, category 4, with an additional 25.4 million adults (11.3%) experiencing category 3 pain.

# Pain in America (cont)

- Treatment options for pain: pharmacologic, physical medicine, behavioral medicine, neuromodulation, interventional, and surgical
- Optimal patient outcomes often result from a comprehensive multidisciplinary approach where pharmacologic treatment is not the sole focus
- Patients experience ongoing barriers to adequate pain management
  - “many related to non-existent or insufficient insurance coverage and reimbursement for evidence- and consensus-based therapies”
    - American Academy of Pain Medicine, 2014*
- As a result, treatments have largely focused on prescription drugs, mainly opioids, and procedures, at least, in part, because of the reimbursement structure of our healthcare system

# 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

## 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

# FDA Priorities Align with Recently Passed SUPPORT Act

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
- Many new provisions affecting FDA including tools to:
  - more efficiently stop illegal, illicit, unapproved, counterfeit and potentially dangerous drugs from entering the U.S. through the IMFs
  - reduce exposure to opioids as a way to lower the rate of new addiction
  - require certain packaging, such as unit dose blister packs, for opioids and other drugs that pose a risk of abuse or overdose
  - require that opioids be dispensed with a mail-back pouch or other safe disposal option
- Implementation ongoing

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624268.htm>

# Example: Decreasing Exposure & Preventing New Addiction



## HOW?

## WHAT?



### Appropriate Packaging, Storage, and Disposal

- Explore how opioid analgesic drug products are **packaged, stored, and discarded**.
  - Examine use of packaging strategies, such as **unit-of-use packaging** to improve opioid analgesic safety.
- **Jun 1, 2017:** FDA/Duke Margolis **workshop and white paper** on packaging, storage, and disposal solutions.
  - **Dec 11-12, 2017: Public workshop** to gain input on **packaging strategies**. Public docket closed March 2018 with 44 comments.
  - **Jan 2018:** Requested **packaging in limited amounts** of over-the-counter anti-diarrheal medicine **loperamide** to **curb intentional misuse and abuse**.

# Opioid Analgesic Needs Vary by Condition/Procedure

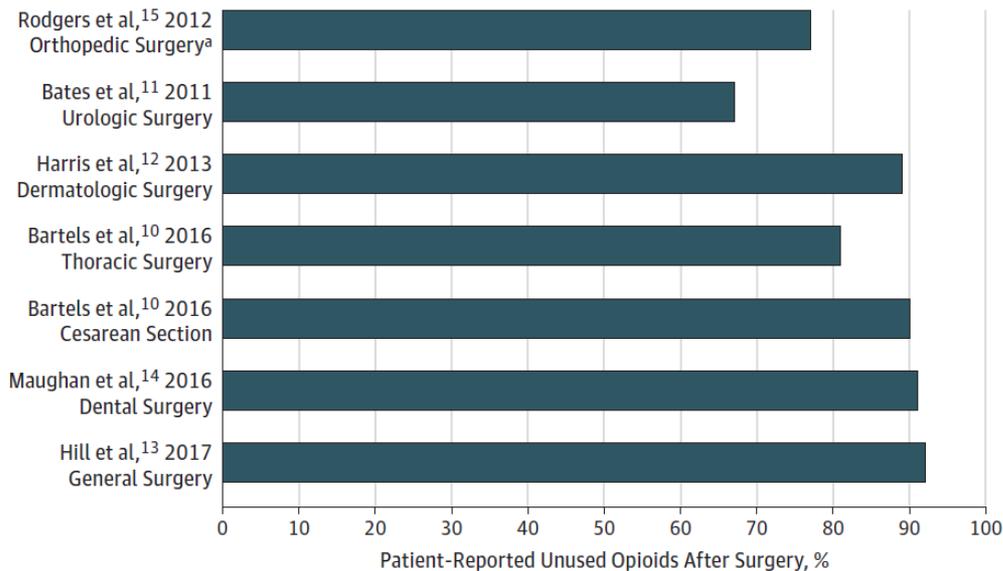
Procedure	Mean/ (range) tablets filled	Mean/Median tablets consumed	~Days Used	~Leftover tablets
Outpatient Shoulder Surgery	60 (n.d.)*	37 (n.d.)*	9-10	23
Cesarean Delivery	40 (5-80)*	20*	4-5	20
Tooth Extraction	28 (n.d.)	13	2-3	15
Upper Extremity Surgery	30 (n.d.)	14 (Bone); 9 (Soft Tissue)	2-3	15
Laparoscopic Cholecystectomy	30 (0-100)	10-12	2-3	20
Laparoscopic Appendectomy	30 (n.d.)*	12*	2-3	18
Partial Mastectomy with Node Biopsy	23 (0-60)	6	1-2	17
Laparoscopic Inguinal Hernia Repair	33 (15-70)	9	1-2	24
Open Inguinal Hernia Repair	30 (15-120)	9	1-2	21
Partial Mastectomy	21 (0-50)	3	1	18
Dermatologic Surgery	9 (3-20)	4	1	5

1. Hill, et al., *Ann Surg*, 2017  
 2. Bateman, et al., *Obstet Gyn*, 2017  
 3. Maughan, et al., *Drug Alc Dep*, 2016

4. Harris, et al., *JAMA Dermatol*. 2013  
 5. Bockman, et al. *J Pain*, 2017 (Abstract)  
 6. Kumar, et al. *AJSM*, 2017

# Target: Leftover Opioid Analgesics Reported in Post-surgical Populations

Figure. Prevalence of Unused Opioids Prescribed After Surgery

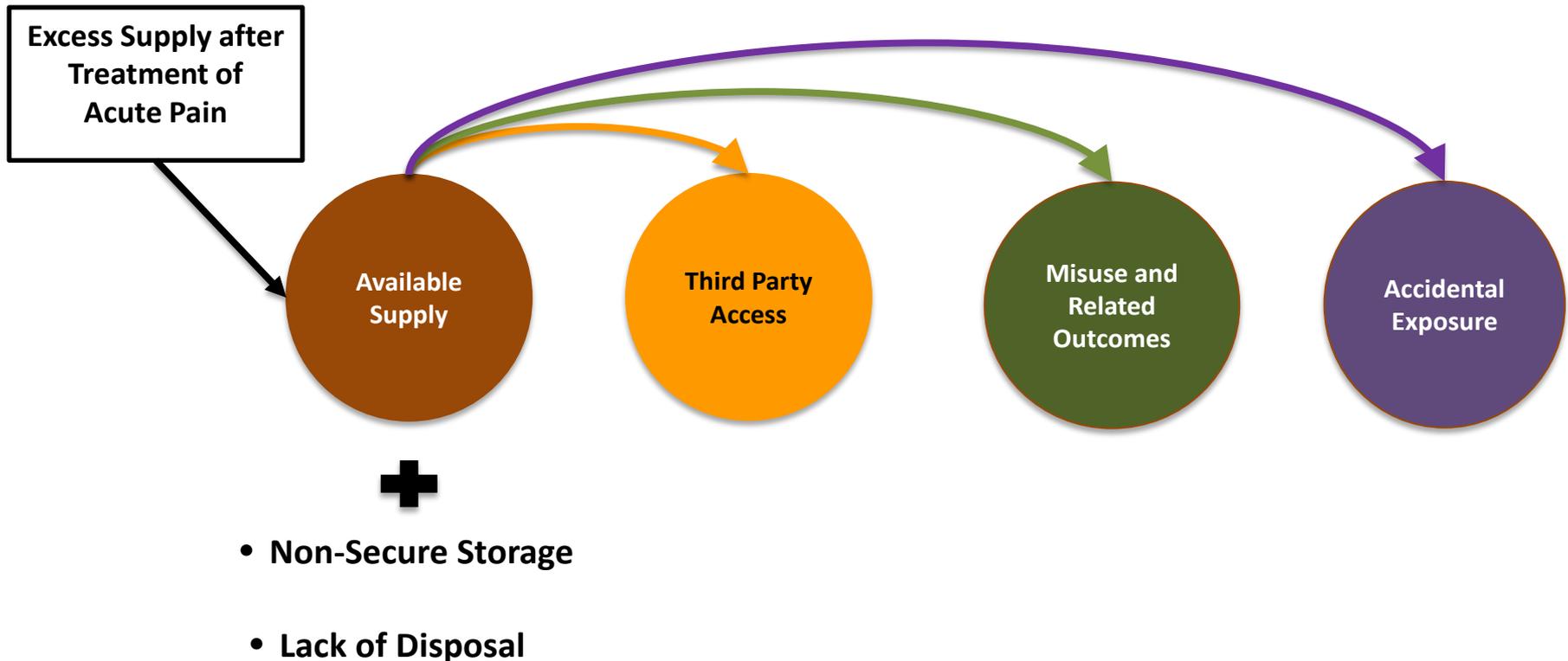


<sup>a</sup>percentage of patients reporting use of 15 tablets or fewer

- Across many surgical procedures,
  - >50% of patients reported excess supply of opioid analgesics after treatment of acute pain
  - Most patients kept excess supply and stored supply in unsecured locations

Figure Source: Bicket MC, Long JJ, Pronovost PJ, Alexander GC, Wu CL. Prescription Opioid Analgesics Common, ... After Surgery: A Systematic Review. JAMA Surg. 2017 Nov 1;152(11):1066-1071.

# Issue: Opioid Analgesics in the Home Can Feed Other Problems if Misused



## FDA Response: Potential Work on Packaging

- Exploring whether a defined, short-term supply of medication could be packaged in a manner that limits the number of pills dispensed (e.g., blister packs)
- Exploring packaging that could make it easier to track the number of doses that have been taken or reduce the risk for third-party access, such as teens ingesting pills they found in a medicine cabinet
- Work to improve storage and encourage prompt disposal to reduce the available supply of unused opioids

# FDA Response: Improved Data on Opioid Use

- Contract with National Academies of Science, Engineering and Medicine (NASEM)
- Work:
  - Provide best available evidence for prescribers
    - Develop framework for evaluating the evidence base on opioid use in specific therapeutic conditions
    - Inventory available evidence
    - Develop research agenda
  - Support development of new evidence where needed

# Other Packaging Work— OTC Loperamide Abuse

- Safe and effective for diarrhea when used as directed
  - Crohn’s Disease and Ulcerative Colitis
    - ~ 1.6 M people
  - Irritable Bowel Disease
    - ~ 35 M people
- Supra-therapeutic doses are abused and are linked to unusual and potentially fatal cardiac arrhythmia (Torsade de Pointes)
- FDA actions aim to prevent the abuse while preserving maximum access possible for patients

# FDA Actions on Loperamide to Date

- Safety communications highlighting risk of cardiac toxicity with loperamide abuse
  - <https://www.fda.gov/drugs/drugsafety/ucm594232.htm>
- Stakeholder engagement
  - Consumer Health Products Association (CHPA)
- Supplement request letters sent to NDA manufacturers requesting unit-dose packaging and package size limitations
  - F/U Discussions with individual retailers
- Ongoing discussions about the appropriate limits for online sales

# SAFE OPIOID DISPOSAL AND STORAGE

# Example: Decreasing Exposure & Preventing New Addiction



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## WHAT?



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# Opioids and Drug Disposal

- Part of Federal efforts to educate consumers about appropriate disposal of unused/unneeded drugs
- FDA's drug disposal webpage is consistently among the most viewed webpages on FDA's website
- FDA updated the disposal webpage on April 23, 2018
  - New infographic
  - New scientific research on environmental impact of drugs
- The website received 23,580 unique pageviews during week of April 23, 2018 leading up to DEA's National Rx Drug Take Back Day on April 28, 2018

# Drug Disposal (cont)

I need to get rid of this medication.

**Drug Disposal Options**  
Do you have medicine you want to get rid of?

**Do you have a drug take-back option readily available?**  
Check the [DEA website](#), as well as your local drugstore and police station for possible options.

**NO**

**YES**

Take your medicine to a drug take-back location.  
Do this promptly for [FDA flush list](#) drugs!

**Is it on the FDA flush list?**

**NO**  
Follow the [FDA instructions for disposing of medicine in the household trash](#).

**YES**  
**Immediately flush your medicine in the toilet.**  
Scratch out all personal info on the bottle and recycle/throw it away.

[www.fda.gov](http://www.fda.gov)

[www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal)

# Opioids and Drug Disposal: Drug Takeback Day

- Nationwide effort to get unneeded drugs out of homes
- April 2018-- **348** pounds of drugs returned at FDA main campus



# Remove *the* RISK

This opioid disposal education and outreach campaign, with digital toolkits available in English and Spanish, can be used when talking with others about safe opioid disposal.



Video Public Service Announcements (PSAs)



Social Media Posts



Radio PSAs



Fact Sheets



Print PSAs



Drop-in Content



Social Media Graphics



Website Badges

# Target Audience



- Women ages 35–64 who are caring for their children, grandchildren, and/or aging parents.
- According to the Department of Labor, women make 80% of health care decisions for their families
- An estimated 66% of caregivers are female and are likely to be the gatekeepers to opioids in the home, knowing where they are stored and how they should be dosed for various family members

# Video PSAs

**Keep Your Family Safe From Unused  
Opioid Pain Medicines**

**(0:30)**



**Medicamentos opioides no utilizados:  
Mantenga a su familia segura**

**(0:30)**



# EXPANDED NALOXONE AVAILABILITY AND USE

## 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

# Recent and Ongoing Activities Related to Naloxone

- Co-prescribing of Naloxone with RX Opioids
  - Results of recent public FDA Advisory Committee
- Over-the-Counter (OTC) Naloxone
  - Research to support labeling for OTC naloxone products to support product development

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



### HOW?

### WHAT?



Naloxone

- Exploring ways to **expand access** to naloxone and **facilitate the switch to OTC naloxone**

- **Jan 2019: Precedent setting:** Announced results of **FDA-led labeling study** to facilitate the **switch** from prescription to **OTC naloxone**.

# I. Naloxone Co-Prescribing with Rx Opioids



- Naloxone prescriptions rising (336.1K dispensed in 2017) but still inadequate
- FDA received Citizen Petition from maker of one of the naloxone products requesting FDA require co-prescribing of patients prescribed opioids
- FDA Advisory Committee held December 17-18 to get input from advisors and public

# Naloxone Advisory Committee (cont)



- In general:
  - Harm reduction advocacy groups very strong in their view that co-prescribing was not ‘enough’
  - Committee members split on value of required co-prescribing
    - Concerns expressed about cost to healthcare system and diversion of resources (both money and naloxone) away from underserved areas
    - Focus should be on educating prescribers/patients and supporting harm reduction efforts
- In addition, Committee members called on USG to take on broader actions to expand availability of naloxone (e.g., OTC naloxone)
- FDA considering next steps

## II. Over-The-Counter Naloxone

- Existing expanded access programs (such as pharmacy standing order programs) are a significant tool, but more is needed – not everyone can/wants to obtain the product through a healthcare professional
- Surgeon General's 2018 Advisory

# U.S. Surgeon General Advisory



“I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone. For patients currently taking high doses of opioids as prescribed for pain, individuals misusing prescription opioids, individuals using illicit opioids such as heroin or fentanyl, health care practitioners, family and friends of people who have an opioid use disorder, and community members who come into contact with people at risk for opioid overdose, **knowing how to use naloxone and keeping it within reach can save a life.**”

# Development Programs for Nonprescription Drugs

- Often rely on safety and efficacy established for the prescription product
- New studies may be required if proposing a new indication or a new patient population for the OTC market
- Need to “translate” key elements of the prescription label into consumer-friendly terms
- Consumer studies needed to evaluate the “OTC-ness” of product



## Drug Facts Label

<b>Drug Facts</b>	
<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Chlorpheniramine maleate 2 mg.....	Antihistamine
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat	
<b>Warnings</b>	
Ask a doctor before use if you have	
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis	
■ trouble urinating due to an enlarged prostate gland	
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives	
<b>When using this product</b>	
■ drowsiness may occur ■ avoid alcoholic drinks	
■ alcohol, sedatives, and tranquilizers may increase drowsiness	
■ be careful when driving a motor vehicle or operating machinery	
■ excitability may occur, especially in children	
If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

<b>Drug Facts (continued)</b>
<b>Other information</b> ■ store at 20-25° C (68-77° F) ■ protect from excessive moisture
<b>Inactive ingredients</b> D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

# FDA Support for OTC Naloxone

- With successful study results, Sponsors can adapt the model Drug Facts Label (DFL) to their naloxone product
  - Speeds development
- Sponsors would only need to add information specific to their particular device and assess through human factors
- Label comprehension was the key study to be conducted – self-selection and actual use are likely not needed

# Status of Research



- FDA-supported study completed December 2018
- Review by FDA scientists complete January 2019
  - FDA concluded that the results of this study are acceptable to support use of the tested naloxone DFL in the OTC setting
  - FDA announced results and findings for use by manufacturers seeking to develop OTC naloxone products
    - Data and drug facts boxes posted
      - <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629571.htm>

<b>Drug Facts</b>	
<b>Active ingredient (in each XX)</b> Naloxone hydrochloride X mg	<b>Purpose</b> Emergency treatment of opioid overdose
<b>Uses</b>	
<ul style="list-style-type: none"> <li>To "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin</li> <li>This medicine can save a life</li> </ul>	
<b>Directions</b>	
 <p><b>1) CHECK</b></p>	<p><b>Step 1: CHECK:</b></p> <ul style="list-style-type: none"> <li><b>CHECK</b> for a <u>suspected overdose</u>: the person will not wake up or is very sleepy or not breathing well <ul style="list-style-type: none"> <li>yell "Wake up!"</li> <li>shake the person gently</li> <li>if the person is not awake, go to Step 2</li> </ul> </li> </ul>
 <p><b>2) GIVE</b></p>	<p><b>Step 2: GIVE 1<sup>st</sup> dose</b></p> <ul style="list-style-type: none"> <li><b>GIVE</b> the 1<sup>st</sup> dose of this medicine</li> <li>place the injector on the LEG above the knee and press down</li> </ul>
 <p><b>3) CALL</b></p>	<p><b>Step 3: CALL</b></p> <ul style="list-style-type: none"> <li><b>CALL 911</b> immediately after giving the 1<sup>st</sup> dose</li> </ul>
 <p><b>4) WATCH/GIVE</b> 2-3 minutes</p>	<p><b>Step 4: WATCH &amp; GIVE</b></p> <ul style="list-style-type: none"> <li><b>WAIT</b> 2-3 minutes after the 1<sup>st</sup> dose to give the medicine time to work</li> <li>if the person <u>wakes up</u>: Go to Step 5</li> <li>if the person does <u>not wake up</u>: <ul style="list-style-type: none"> <li><b>CONTINUE TO GIVE</b> doses every 2-3 minutes until the person wakes up</li> <li>It is safe to keep giving doses</li> </ul> </li> </ul>
 <p><b>5) STAY</b></p>	<p><b>Step 5: STAY</b></p> <ul style="list-style-type: none"> <li><b>STAY</b> until ambulance arrives: even if the person wakes up</li> <li><b>GIVE</b> another dose if the person becomes very sleepy again</li> <li>You may need to give all the doses in the pack</li> </ul>
<b>Warnings</b>	
When using this product some people may experience symptoms when they wake up, such as shaking, sweating, nausea, or feeling angry. This is to be expected.	
<b>Other information</b> • store at room temperature • [advise insert tamper evident statement here]	
<b>Inactive Ingredients</b>	
<b>Questions?</b> (phone number, website)	

# Prototype Drug Facts Box for OTC Naloxone

# **The Opioid Challenges:**

**Opioid Abuse and Misuse**

**Pain in America**

**Injectable Opioid Shortages**

# Shortages of Injectable Opioids

## Opioid shortages leave US hospitals scrambling

By Pauline Bartolone, California Healthline  
Updated 5:45 AM ET, Mon March 19, 2018



More from CNN

- California te... charges after a...
- Utah teen ge... life for helpi... herself

HEALTH CARE

## In the midst of a massive opioid crisis, hospitals are experiencing an opioid shortage

By Aaron Schachter  
May 14, 2018 | 5:22 PM



HOME / CIVIC / HEALTHCARE OF TOMORROW

## Hospitals Face Prolonged Injected Opioid Shortage

The other opioid crisis: Hospitals are frequently running out of widely used injected painkillers, and some patients are feeling the pain.

June 27, 2016, at 8:54 a.m.



HEALTHCARE OF TOMORROW

The health care industry is evolving, thanks to changes, societal shifts and technological advances. Healthcare of Tomorrow from U.S. News & World Report examines the challenges facing health care, and how we must change to face the future. See more of our special reports.

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# Origins of the IV Opioids Shortage

- Critical need for use in post-op settings
- One large manufacturer reported shortages of multiple critical drugs including injectable hydromorphone and morphine due to manufacturing, distribution, third party supplier delays, as well as remediation efforts at one of their facilities, beginning in July of 2017
- Lack of alternative sources for needed products with sufficient capacity to meet added demand

# FDA Work to Address IV Opioids Shortage



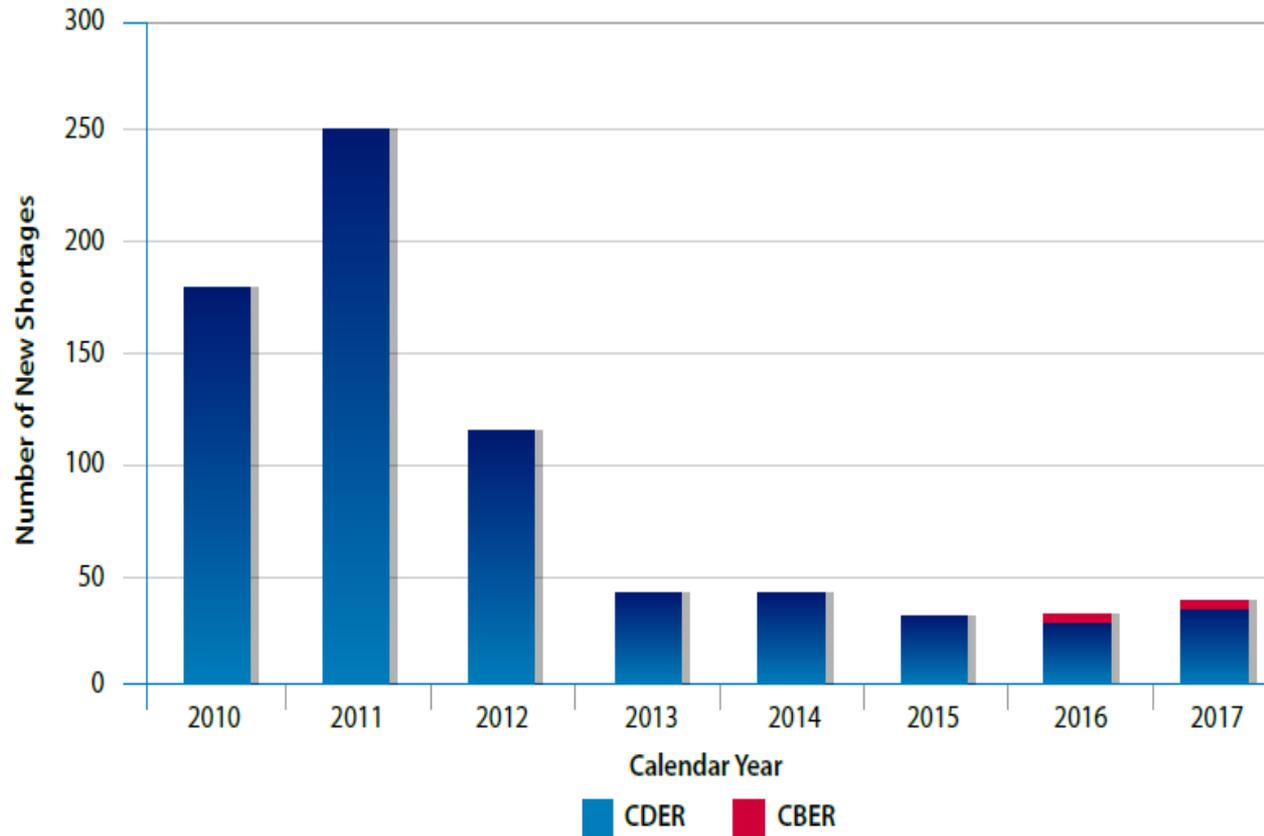
FDA working with manufacturers to bring additional products to market

- Expediting review of all related applications – new approvals from two other manufacturers for morphine and hydromorphone are now being launched
- Releasing Carpuject syringes with potential cracked needle hubs under regulatory discretion with instructions for healthcare professionals to inspect and withdraw contents with a filter needle before administering to patients
- Extending expiration dating for multiple opioid products listed on the FDA website based on data from the manufacturer
- Allowing temporary import of unapproved hydromorphone in coordination with DEA

# FDA Response to IV Opioids Shortage (cont)

- Coordinating with DEA on quota issues
  - FDA shares information with DEA through a Memorandum of Understanding
  - Providing a market assessment to DEA to assist them in their decision about whether to grant the quota

# Trends in New Drug Shortages 2010-2017



From FDA Drug Shortage Report to Congress, 2017  
<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM610662.pdf>

# What FDA Does to Address Drug Shortages



- Drug Shortage Staff focused on addressing drug shortages
- Facilitate temporary and long-term strategies to address shortages
- Coordinate timely and comprehensive risk/benefit decisions within FDA
  - Personnel across multiple FDA Offices involved in shortage response
- Distribute information (web posting, professional organizations):
  - <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>
- **Goal: Maintain availability while minimizing risk to patients**

# What FDA Cannot Do to Address Drug Shortages

- FDA cannot require:
  - A company to disclose details of why a shortage occurs
  - A company to make a drug
  - A company to make more of a drug
  - How much and to whom the drug is distributed

- Availability of drugs for patients is critical for healthcare
  - Interruptions of drug manufacturing due to any reason can lead to drug shortages with devastating impact on public health
- Sources of drug shortages include manufacturing challenges and natural disasters
  - FDA response tailored to address underlying cause(s)
  - Communications and information sharing are critical both to preventing and to mitigating shortages
- Recovery from shortages takes time. Prevention is critical to reducing the numbers of drug shortages

# Ongoing FDA Shortage Work



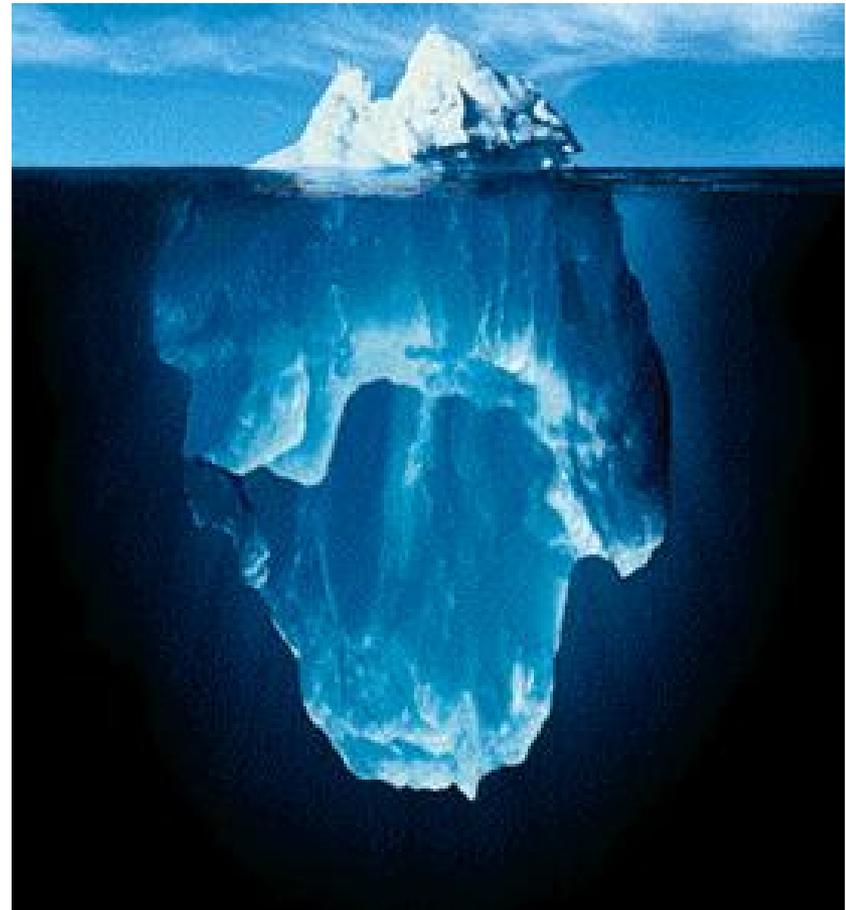
- FDA Drug Shortage Taskforce
  - Announced July 2018
  - Goal of improved understanding of the forces leading to drug shortages and identify potential solutions
- Stakeholder Listening Sessions
  - ✓ Pharmacies and Hospitals
  - ✓ Manufacturing Groups
  - ✓ Medical Groups
  - ✓ GPO's and Distributors
- Public meeting November 2018
- Taskforce Members
  - Food and Drug Administration (CDER, CBER, CDRH, ORA)
  - Center for Medicare and Medicaid Services
  - The Office of the Assistant Secretary of Preparedness and Response
  - The Department of Veterans Affairs
  - The Department of Defense
  - The Federal Trade Commission

# FDA Will Use All of its Available Tools to Accomplish These Goals

- 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**

# 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)



# Conclusions

- FDA's response to issues raised by opioids reflect unique challenges of how they are used, misused and abused
- Opioids are challenging on many fronts, and FDA is seeking to balance the appropriate need for them by patients with the crisis of opioid abuse and overdose
- Ongoing and planned FDA activities will utilize all of our existing tools to forcefully address the opioid crisis while continuing to support appropriate access to effective pain management

# Thank You

