

FDA Update: 2018

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Consumer Healthcare Products Association
Regulatory Scientific & Quality Conference
May 17, 2018

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

Outline

- Larger healthcare context:
 - Trends in medical products, including consumer products
 - Opioid crisis
- FDA response
 - Opioids
 - Drug Disposal
 - Loperamide
 - OTC User Fees
 - NSURE

Overall Message

- Regulation of consumer products by FDA is responding to trends in US healthcare as well as larger issues confronting public health
- Continued progress will require continued collaboration to support the timely development of safe, effective and innovative consumer products



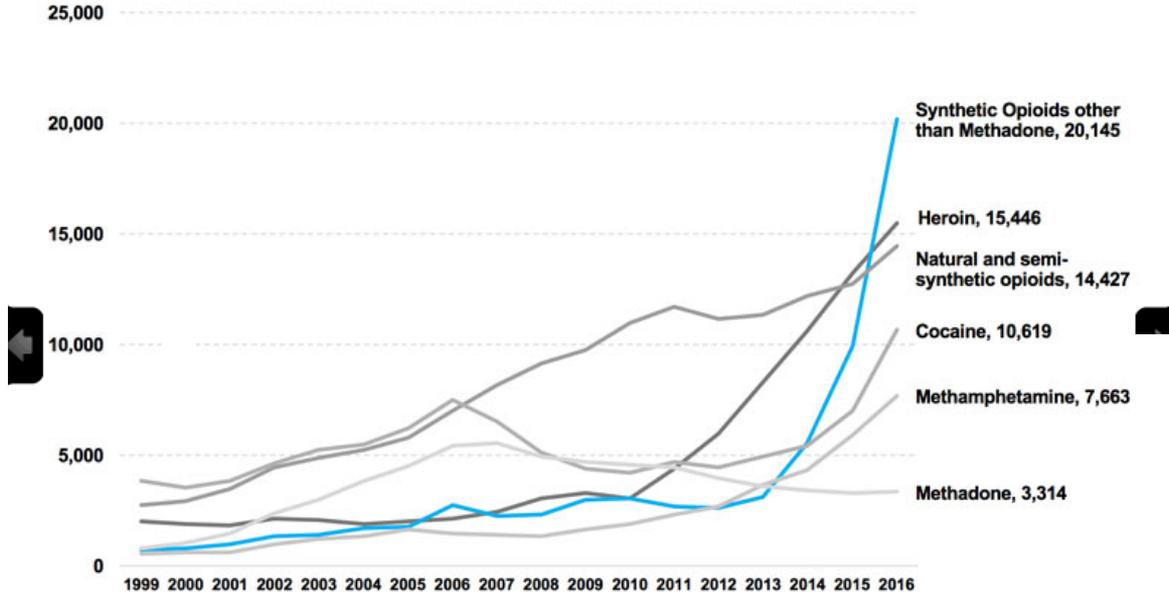
Trends Impacting Medical Product Regulation and Use

- Trend towards targeted therapies and therapies combined with devices/software
- Trend towards more patient involvement in their health
- Focus on the broader public health impact of products as a part of overall benefit-risk assessment
 - Prescription Opioid abuse and misuse

Increases in Drug Overdose Deaths



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

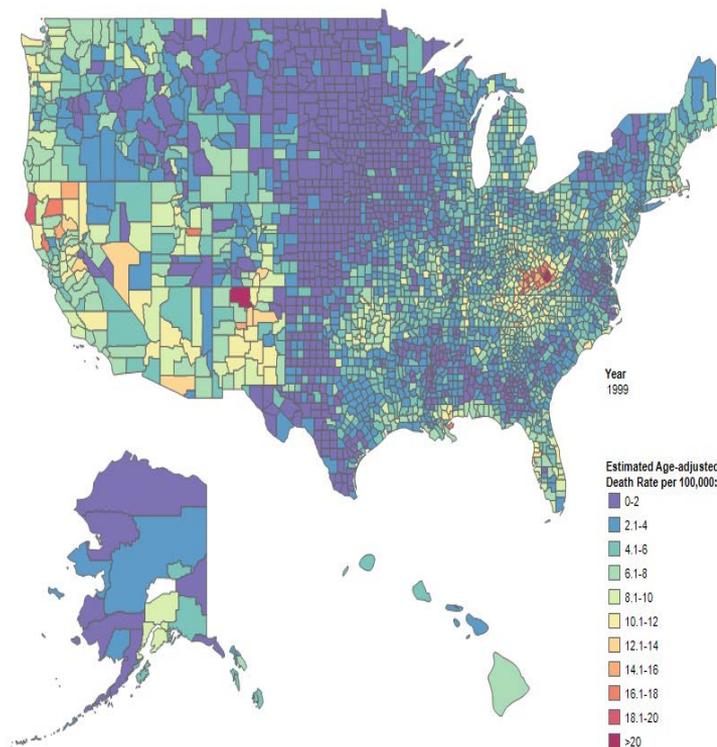


Drugs Involved in U.S. Overdose Deaths* - Among the more than 64,000 drug overdose deaths estimated in 2016, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with over 20,000 overdose deaths. Source: CDC WONDER

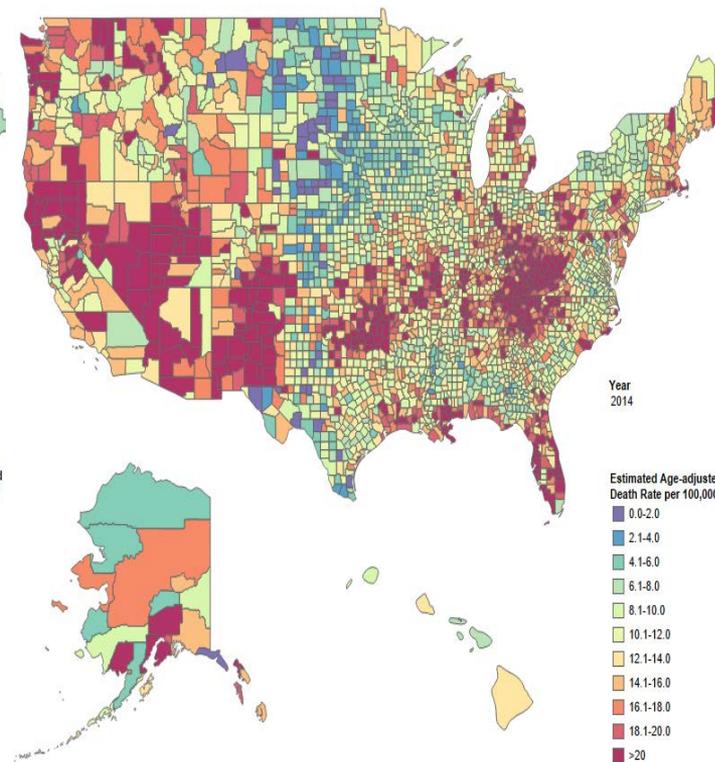
<https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>

Overdose Death Rates

1999



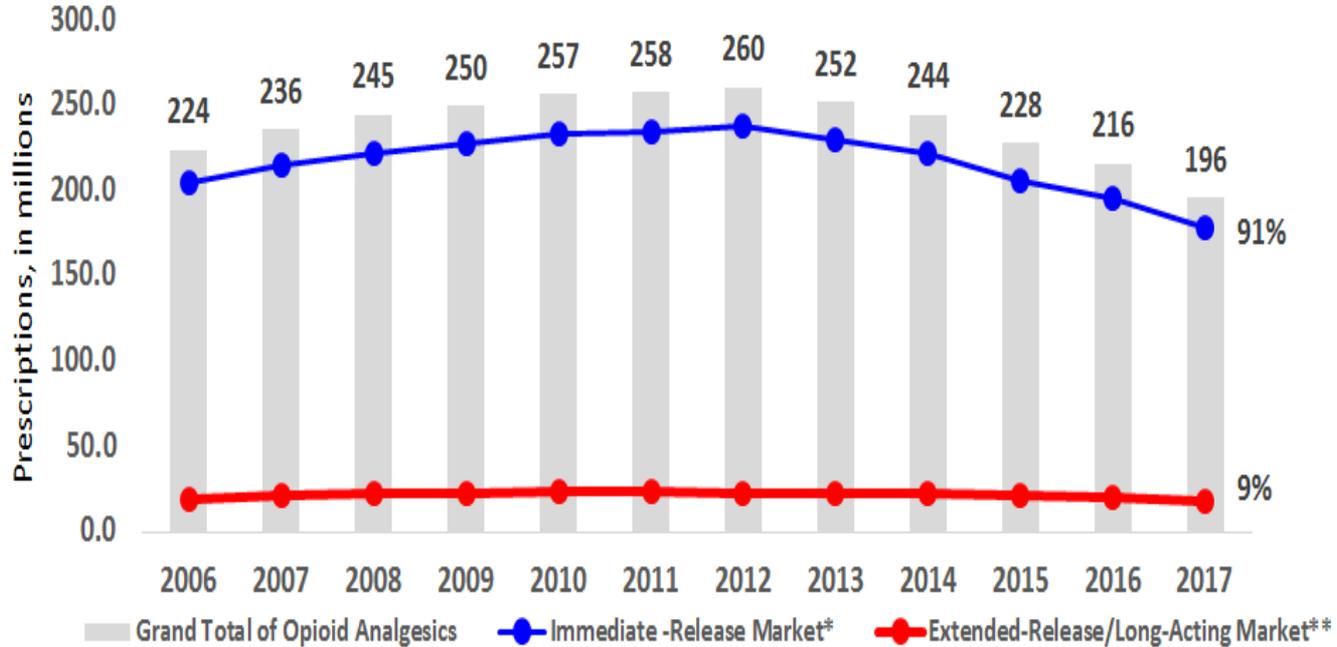
2014



Designed by L. Rossen, B. Bastian & Y. Chong. SOURCE: CDC/NCHS, National Vital Statistics System

*Science =
Solutions*

Nationally Estimated Number of Prescriptions Dispensed for Opioid Analgesics Products from U.S. Outpatient Retail Pharmacies



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

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

Responding to Challenges: The Opioids Crisis

FDA Will Use all of its Tools to Address the Opioid Crisis

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

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

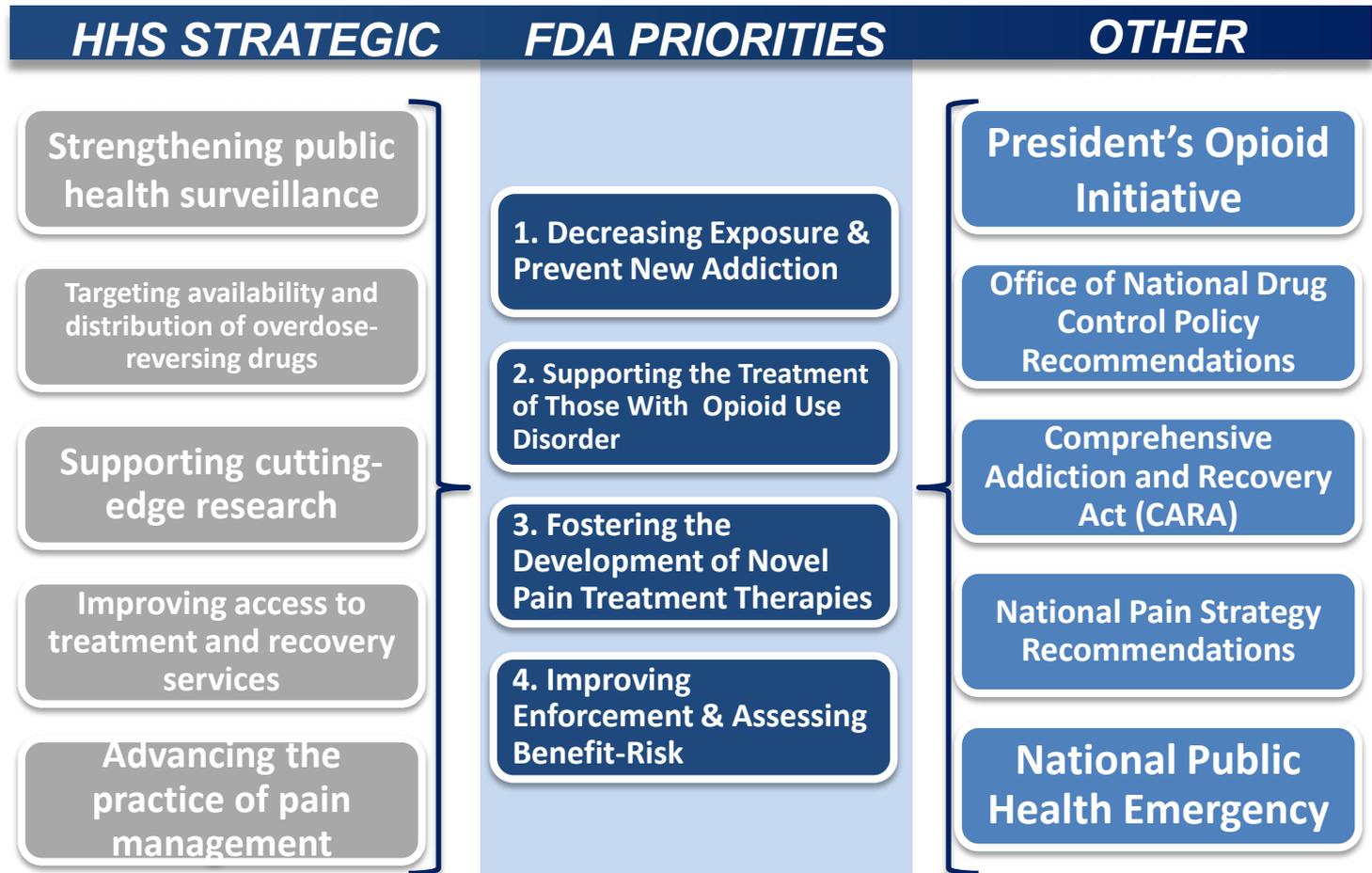


Improving Enforcement



Assessing Benefit-Risk

FDA Priorities align to HHS Strategic Priorities and other National Activities



FDA Work to Address Opioid Crisis



- FDA has taken numerous actions to address opioid use, misuse, and abuse and much work remains
- Actions include safety labeling changes; scientific workshops, public hearings, and advisory committee meetings; approval of abuse-deterrent formulations, medication-assisted treatments, and naloxone products; updating/expanding REMS; and requiring postmarket safety studies
- FDA's actions regarding opioid risks date back at least 15 years

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm>

Responding to Challenges: Opioids and Drug Disposal

- Part of Federal efforts to educate consumers about appropriate disposal of unused and 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 graphics
 - New scientific research
- 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

Responding to Challenges: Drug Disposal

I need to get rid of this medication.

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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

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.

YES

Take your medicine to a drug take-back location.

Do this promptly for [FDA flush list](#) drugs!

www.fda.gov

www.fda.gov/drugdisposal

Responding to Challenges: OTC Product Abuse--Loperamide

- Safe and effective for diarrhea when used as directed
- Populations affected:
 - Crohn’s Disease and Ulcerative Colitis
 - ~ 1.6 M people
 - Irritable Bowel Disease
 - ~ 35 M people
 - Traveler’s Diarrhea
- OTC version of loperamide has important role in access to treatment

Loperamide and Cardiac Toxicity



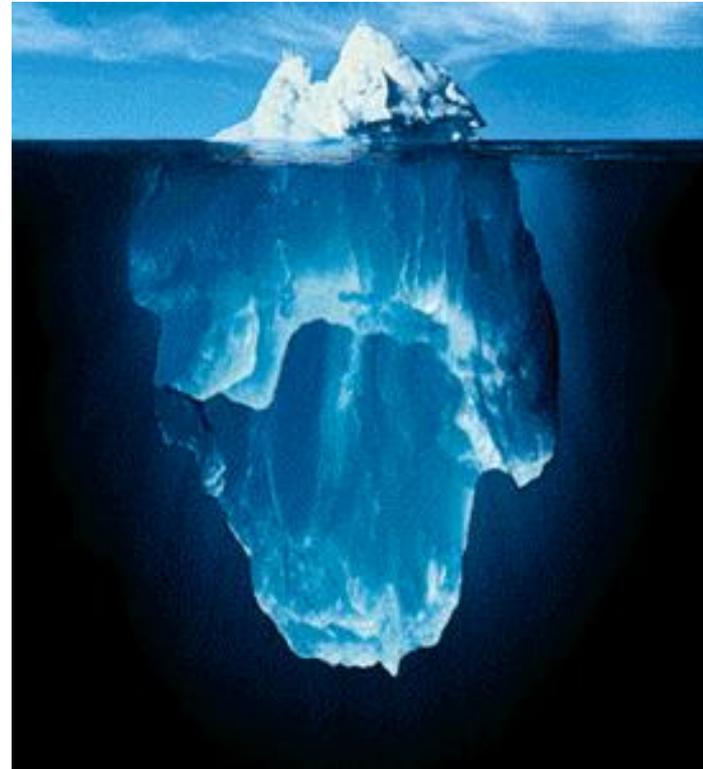
- Emerging signal for abuse of Loperamide
- Supra-therapeutic doses of Loperamide linked to unusual and potentially fatal cardiac arrhythmia (Torsade de pointes)
 - Strong pharmacologic basis for toxicity
 - Difficult to monitor for and detect
- Managing abuse and misuse critical to preserving access for patients

Patterns Similar to Earlier Dextromethorphan (DXT) Abuse

- DXT abused mixed with alcohol
- Calls for DEA scheduling and other federal activities that would limit OTC availability
- Voluntary industry actions were taken that helped address DXT abuse and preserve OTC status
 - Behind the Counter Status
 - Age verification

Addressing Loperamide Abuse: Solutions Must Come From Many Sources

- FDA has important role to play
 - To inform patient and providers
 - To work with industry on solutions
- States are involved as they see abuse and misuse
- Manufacturers and distributors have obligations too:
 - Seek ways to preventing abuse and misuse that also preserve maximum availability for patients
 - Own their role in the distribution of OTC products
- **Goal is to effectively prevent the abuse and misuse while preserving maximum access possible for patients**



FDA Actions 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

Responding to Challenges: Expanding Consumer Choice

**OTC Monograph Reform, User Fees and
NSURE**

Background:

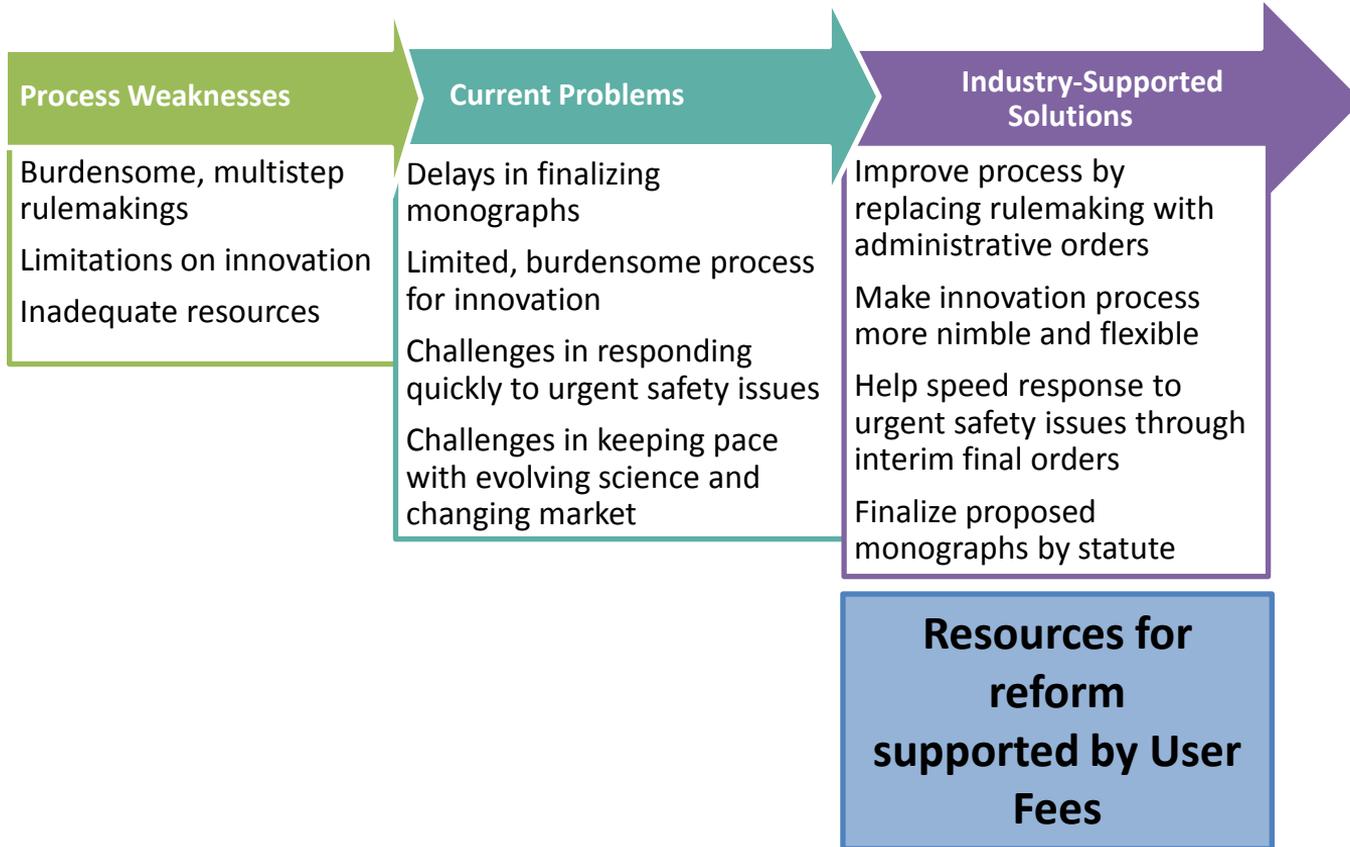
OTC Monograph System

- Established in 1972 to address hundreds of thousands of OTC products on the market
- Expert Advisory Panels to review safety and efficacy for classes of products
- Rule-making on conditions of use for products ('GRASE')
- Enables conforming product marketing without marketing application

Background: OTC Monograph System (cont)

- Process of product review is large and complex
 - 88 rulemakings in 26 broad therapeutic classes
 - 800 active ingredients, 1,400 therapeutic uses
 - Changes also require rulemaking
- Process isn't complete for all areas
 - Data inadequacies, resource challenges
- Products currently on the market so need to avoid actions that would disrupt availability unnecessarily

OTC Drug Reform Proposal (Under Consideration by Congress)



Nonprescription Drug Safe Use Regulatory

Expansion (NSURE) Initiative

- Goal to provide additional regulatory options for innovative OTC development programs
 - Expands which drug products can be considered nonprescription
 - Responsive to larger trends in healthcare towards patient autonomy and self-management
- Enabling Rx to OTC switches critical to OTC space
- FDA support unchanged for guidance and rulemaking

Conclusions



FDA Work on OTC Products: Responding to Challenges in Healthcare

- Using all of our regulatory tools to respond to trends in US healthcare as well as larger issues confronting public health
- Seeking partnerships wherever possible to accomplish our mission
- Seeking improvements in our process where possible to increase efficiency, transparency and effectiveness

FDA Work on OTC Products: Focus on Benefiting Patients

- Encouraging innovation; opening up new markets; expanding breadth and depth of OTC product lines
- Enhancing self-care to help reduce need for more costly forms of care
- Increasing efficiency, timeliness, and predictability
- Identifying and implementing effective responses to safety concerns to improve safe use of OTC medicines

Thank You

