

# Federal Efforts to Prevent Drug Shortages

## An FDA Perspective

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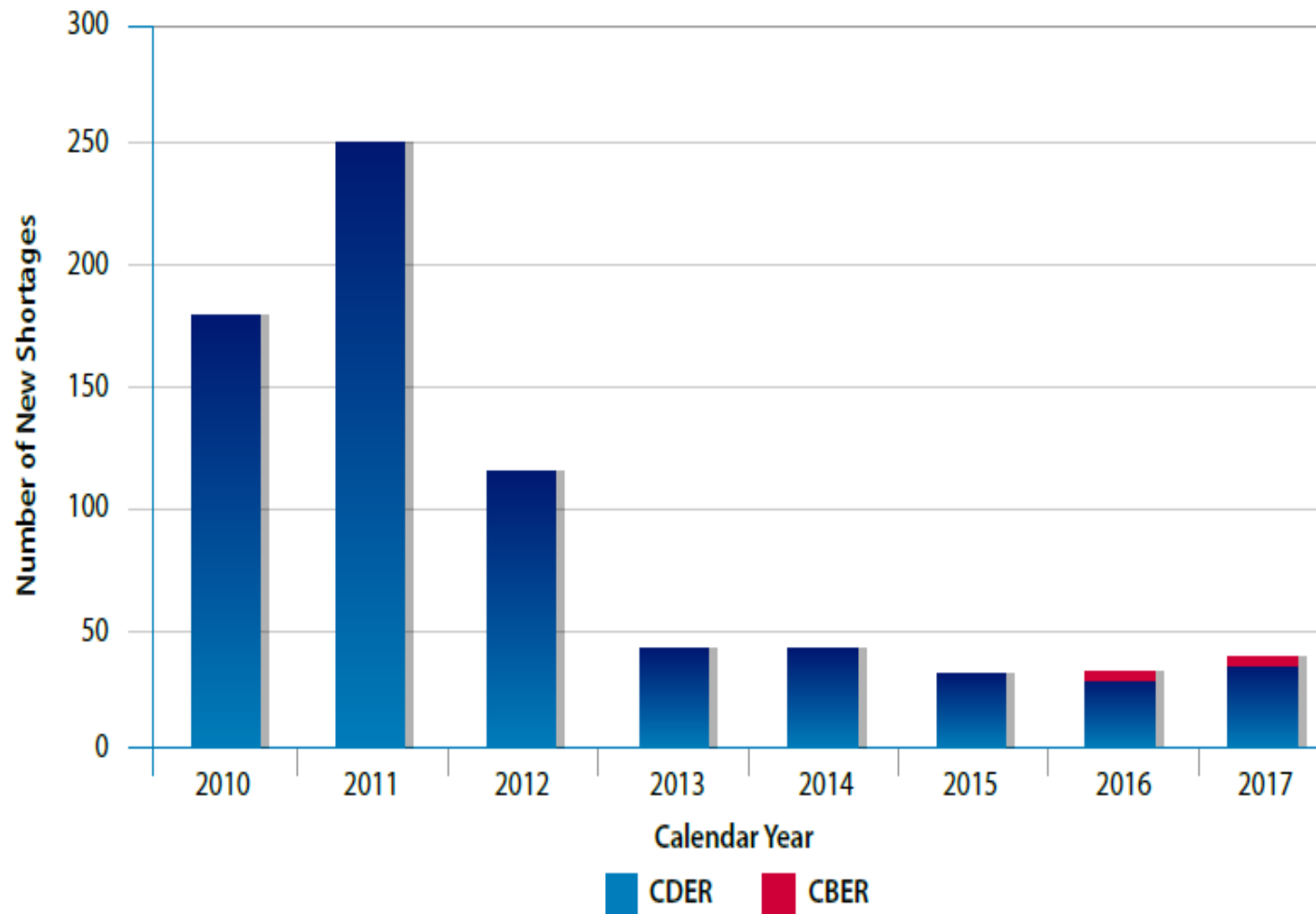
November 27, 2018

# Definitions of Medical Product Shortage

- **Drug Shortage (FDA):** *A drug shortage* means a period when the demand or projected demand for the drug within the United States exceeds the supply of the drug.
- **Drug Shortage (ASHP\*):** A drug product is in shortage:
  - once the shortage is verified with manufacturers
  - when supply issues affect how a pharmacy prepares or dispenses a drug product, or influence patient care requiring prescribers to use an alternative therapy

\*ASHP: American Society of Health-System Pharmacists

# Trends in New Drug Shortages 2010-2017

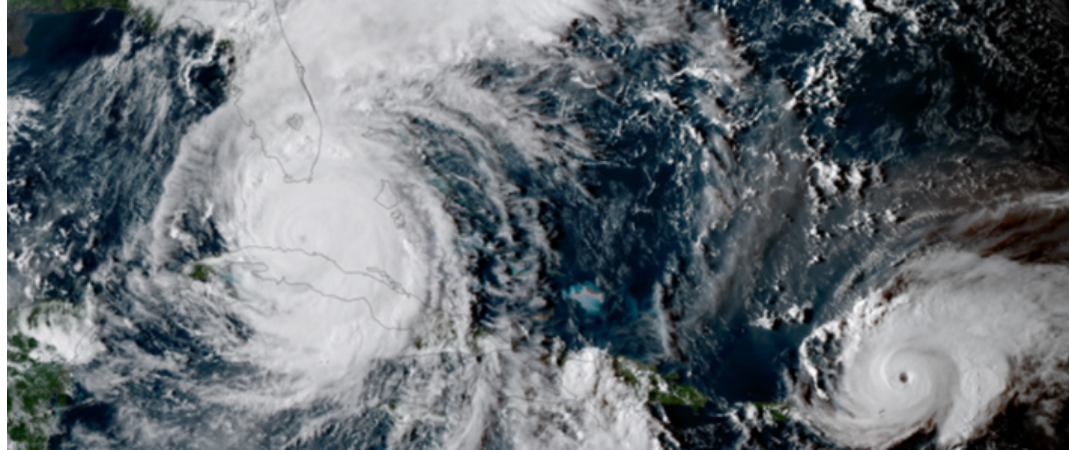


From FDA Drug Shortage Report to Congress, 2017  
<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM610662.pdf>

# Sources of Shortages: Manufacturing Challenges

- Consolidation in manufacturing of sterile injectables
  - In Fall of 2017, interruption of manufacturing by a single firm led to shortages of multiple critical drugs including injectable narcotics, “caines” and others drugs
- Shortages of critical sterile injectable drugs from increased demand or manufacturing problems
  - IV electrolyte salts, Magnesium Sulfate, Calcium Gluconate and Potassium Chloride

# Sources of Shortages: Natural Disasters



- Hurricane Maria affected multiple manufacturers in Puerto Rico
  - IV fluid shortages which began in 2014 were worsened due to Baxter facility impact in PR

# 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

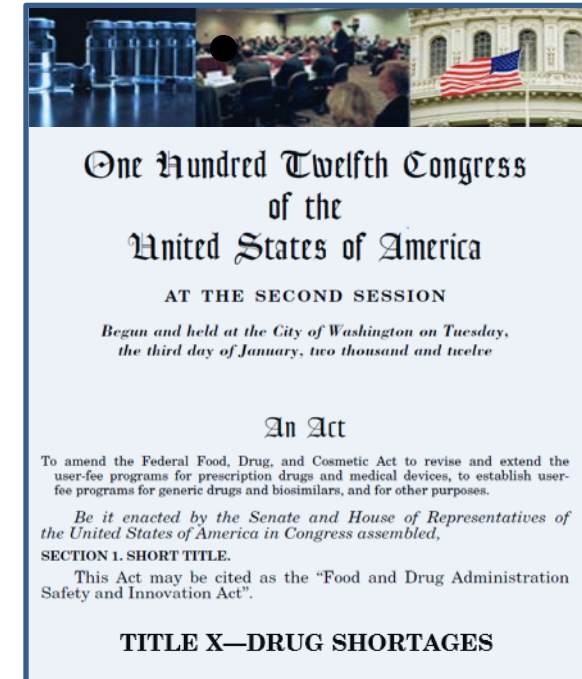
# Lessons Learned

- 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



# Communication is Critical

- **Requirements to Industry For Early Notification**
- Manufacturers are required to notify the FDA of a permanent discontinuance or interruption in manufacturing that is likely to lead to a meaningful disruption in the supply of a covered drug in the United States
- At least 6 months in advance of but in no case later than 5 business days after the interruption in manufacturing occurs
- Not limited to medically necessary products
- Regardless of market share, or number of companies marketing, or wholesaler volumes



# Today's Meeting

- Discussion goals:
  - Root Causes of drug shortages
    - Economics of drug shortages
      - Measurement of shortages and their public health impact
      - Economic drivers underlying drug shortages
    - Manufacturing and Distribution
      - Anticipating vulnerabilities, eliminating barriers to adequate drug supply
  - Potential tools to address drug shortages
    - Market-driven actions
    - Governmental actions
      - Incentives to encourage adequate drug supply and manufacturing redundancy and resiliency

# Thank You

