



# **Medical Product Shortages during Disasters: Opportunities to Predict, Prevent, and Respond**

## **An FDA Perspective**

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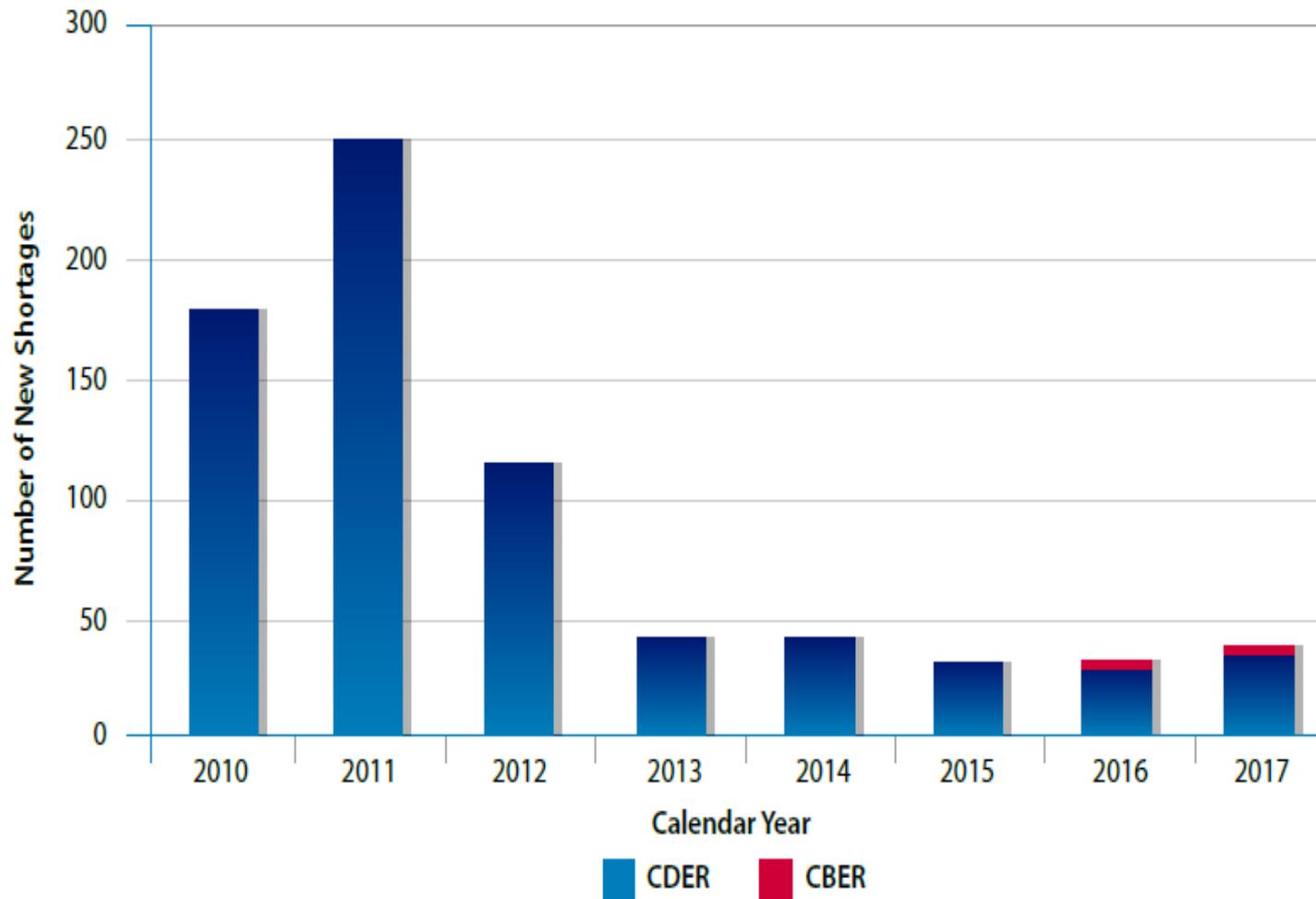
September 5, 2018

# 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

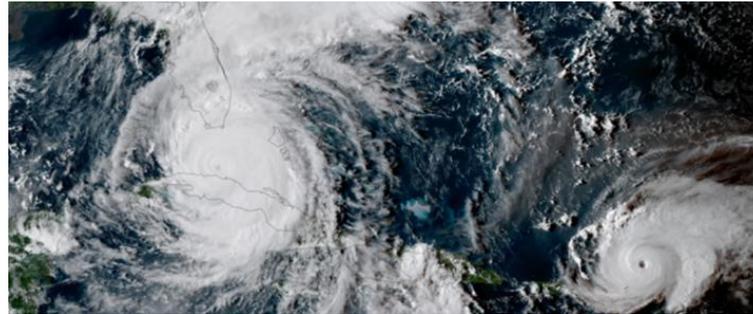
\*ASHP: American Society of Health-System Pharmacists

# Trends in Drug Shortages 2010-2017 (FDA)



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

# Shortages After Natural Disasters: Hurricanes



- Hurricane Maria affected multiple manufacturers in Puerto Rico
  - IV fluid shortages which began in 2014 were worsened due to Baxter facility impact in PR
- USG, including FDA worked closely with the firms to mitigate shortage impact
  - Temporary imports from B.Braun and Baxter from 6 different sites
  - New applications were approved for IV fluids from Laboratorios Grifols as well as Fresenius Kabi .
  - Expiration dating extended for multiple IV fluids still in distribution and new dating is posted on FDA website

# Shortages Due to Manufacturing Challenges

- Consolidation in manufacturing of sterile injectables has decreased capacity
- In Fall of 2017, interruption of manufacturing by a single firm led to shortages of multiple critical drugs including injectable narcotics, “caines” and others  
 FDA worked with manufacturers to mitigate the shortages
  - Expiration dating extended where possible
  - New application review expedited by FDA to speed new capacity to market
  - Temporary importation from other countries

# Other Drug Shortages

- Shortages of IV electrolyte salts Magnesium Sulfate, Calcium Gluconate and Potassium Chloride
- Epi-Pen Autoinjector Shortage
  - Shortage of one particular type of epinephrine autoinjector
    - Kaleo's Auvi-Q and Impax's epinephrine autoinjector are currently available.
  - FDA working with Mylan to resolve the shortage and posted Mylan's customer assistance number to help patients having difficulty obtaining EpiPens
  - Expiration dating was extended by FDA for certain lots of EpiPens based on data supplied by Mylan
  - Generic form of EpiPen was approved and planned to launch later this fall as well as another approved epinephrine autoinjector called Symjepi

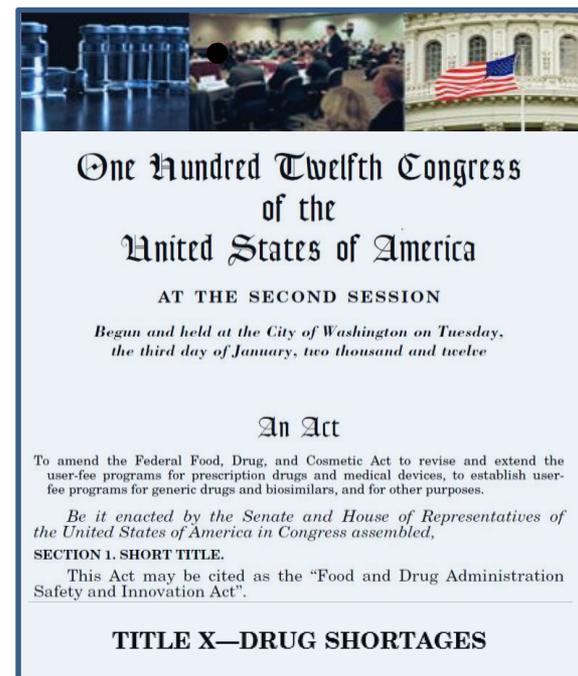
# Lessons Learned



- Drug manufacturing is a critical part of our healthcare infrastructure
- Interruptions of drug manufacturing of many kinds can lead to drug shortages
- 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 change in production that is reasonably likely to lead to a reduction 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



# What and When to Communicate?

At the time of any change in manufacturing that may lead to a reduction in supply of a product\*:

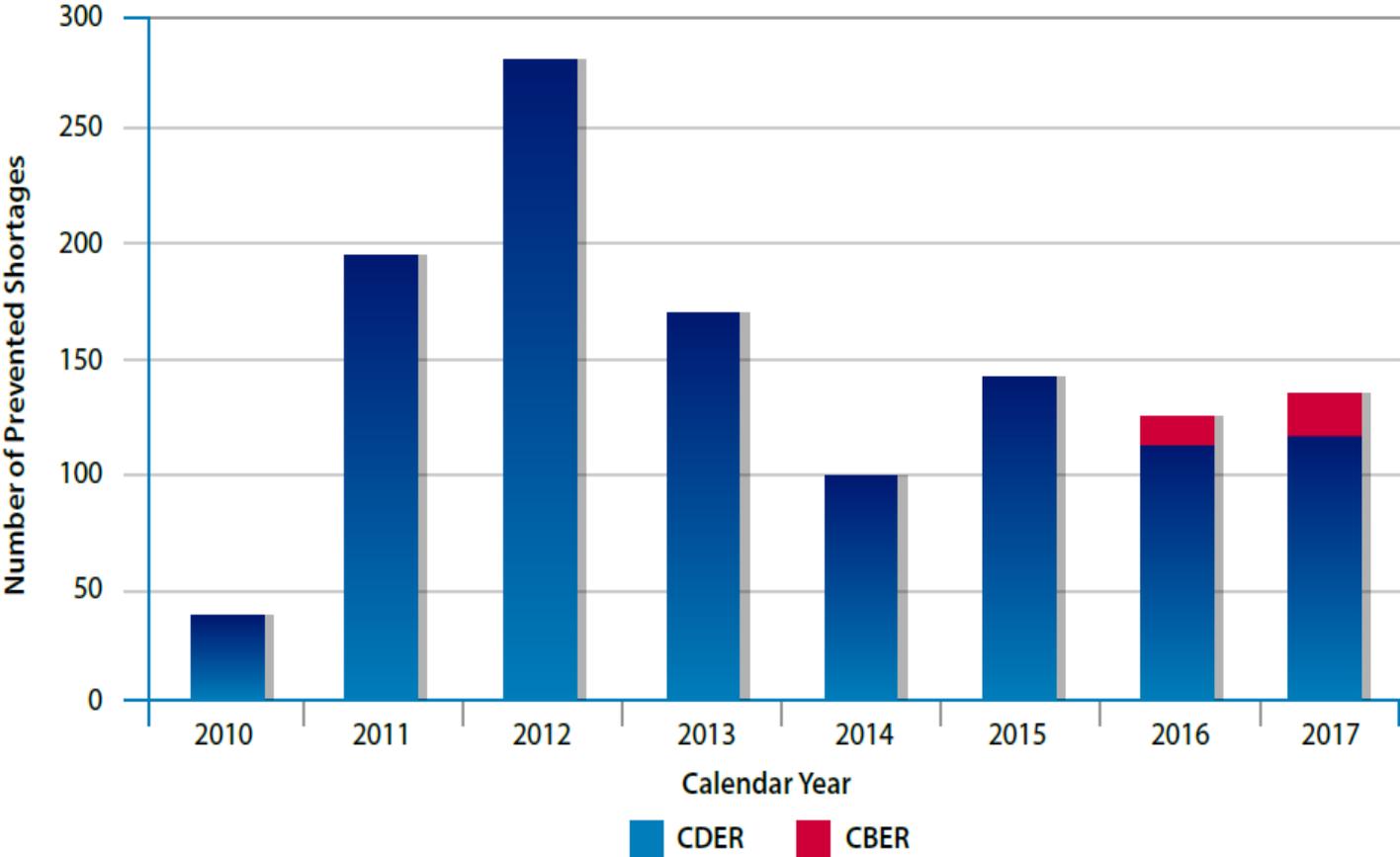
- Plans for upgrade or remediation
- **Manufacturing issues**
- Raw material batch failures
- Particulate issues
- Sterility issues



– *FDA wants manufacturers to notify FDA ahead of*, not as, or after, they are unable to fill orders or unable to meet expected demand

\*Note, product refers to a specific strength, dosage form, and route of administration

# Trends in Preventing Drug Shortages 2010-2017 (FDA)



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



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

# What FDA Cannot Do on Drug Shortages



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

# Ideas for What's Needed for Progress on Drug Shortages

- Resiliency and redundancy in the supply chain – companies that have backup plans for manufacturing, raw materials and components are less likely to experience shortages when something goes wrong.
- Better notifications - some firms still do not provide more than the minimum amount of information and provide it at the last possible minute
- More capacity, additional manufacturers making critical drugs

# Next Steps

- July, 2018, FDA Commissioner Gottlieb announced a new FDA Task Force has been implemented to identify more enduring solutions for shortages
- Public meeting and other stakeholder engagement are planned as a part of the new Task Force
- Additional FDA efforts include working to improve the notifications FDA receives from manufacturers regarding shortages

# Summary and Conclusions

- FDA has a critical role in the prevention and mitigation of medical product shortages
- FDA is one of many groups working together to successfully address this important public health issue
- Future success will build on the existing collaborations and on our shared responsibility to preventing drug shortages wherever possible and whatever their cause

# Thank You

