

Federal Efforts to Prevent Drug Shortages

An FDA Perspective

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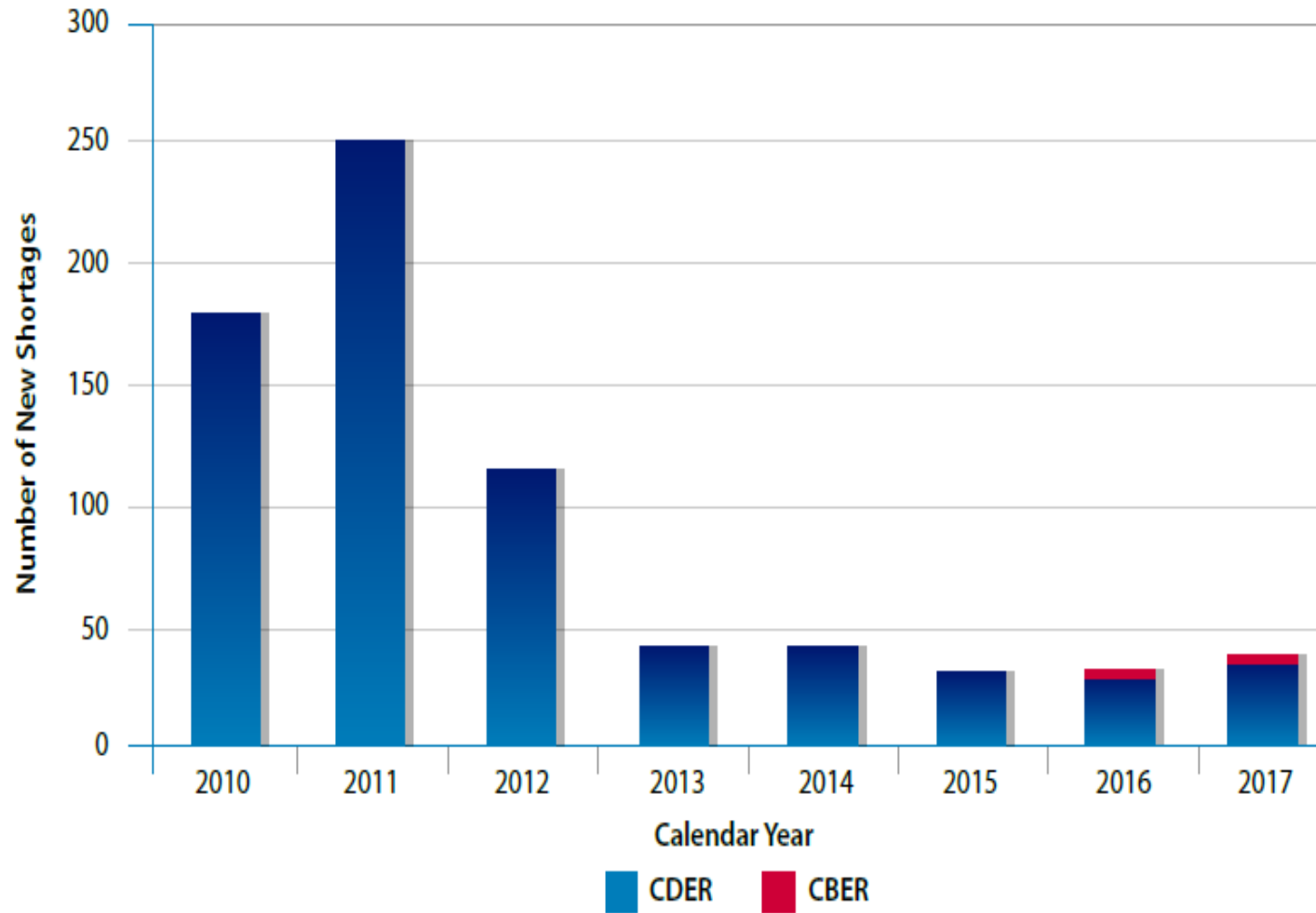
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Definitions of Medical Product Shortage

- **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

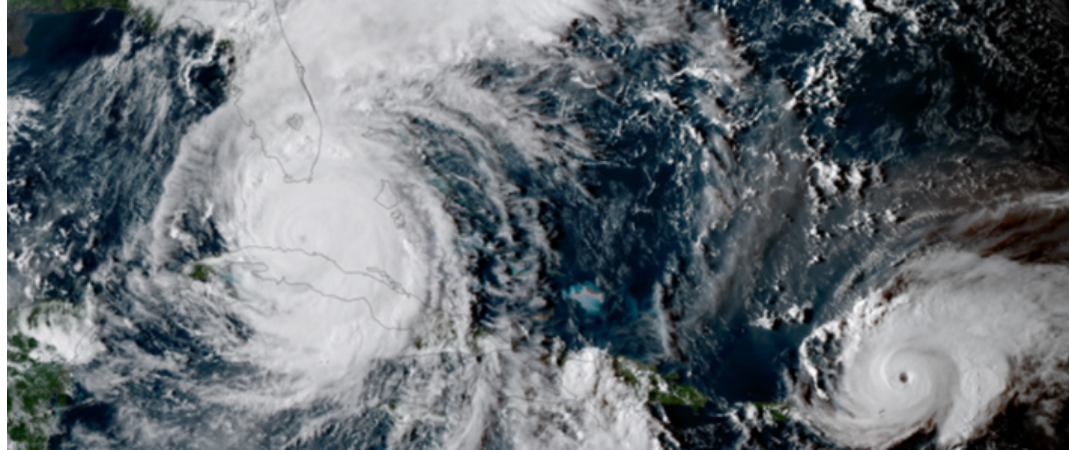


From FDA Drug Shortage Report to Congress, 2017
<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM610662.pdf>

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

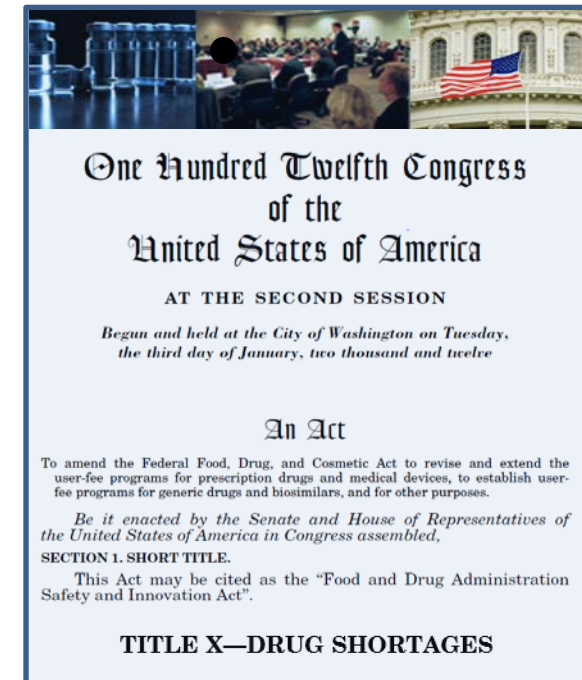
- FDA cannot require:
 - A company to disclose details of why a shortage occurs
 - A company to make a drug
 - A company to make more of a drug
 - How much and to whom the drug is distributed

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

