Drug Shortages: An Ongoing Crisis and Enduring Solutions

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Overview

- Drug Shortages -CDER Roles and Responsibilities
- Historical Shortage Landscape and Current Challenges
- Enduring Solutions

Drug Shortages - Roles and Responsibilities

Drug Shortage Staff: The program office that is designated by the CDER Director to oversee and facilitate the resolution of all drug shortage situations

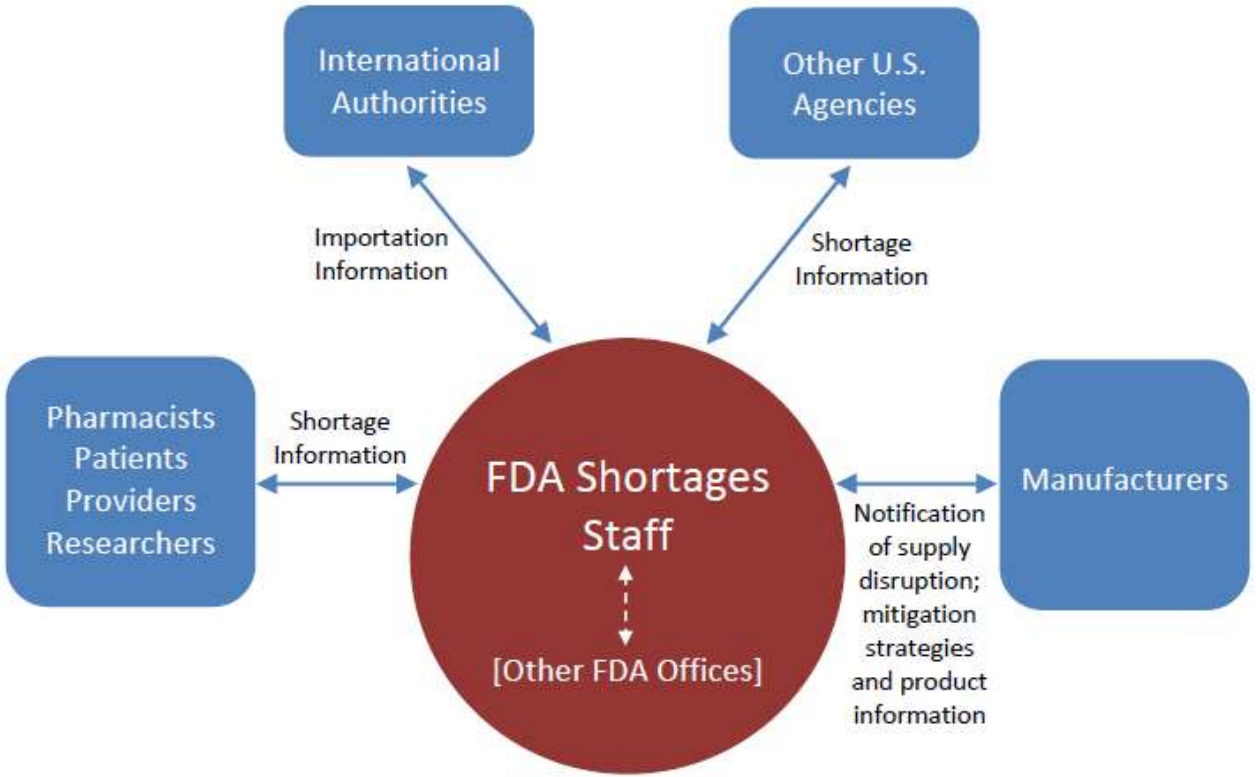
- **DSS serves to support CDER's mission of ensuring that safe and effective drugs are available to patients**

- Facilitate temporary and long-term strategies to address shortages
- Coordinate Center activities for timely and comprehensive risk/benefit decisions
- Distribute information (web posting, professional organizations)

- **Often working across suppliers, facilities, and issues – multiple moving parts, urgency**

- → Maintain availability while minimizing risk to patients

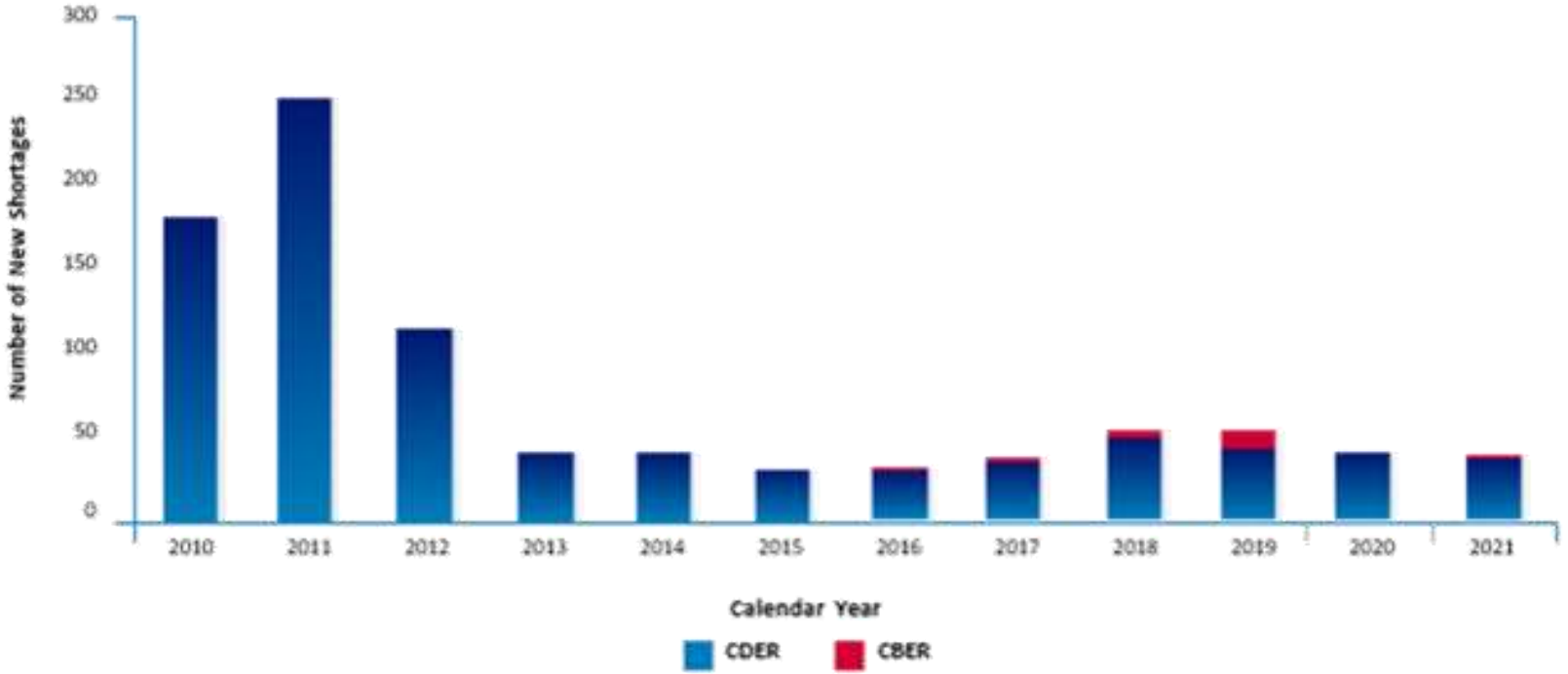
Drug Shortages - Roles and Responsibilities



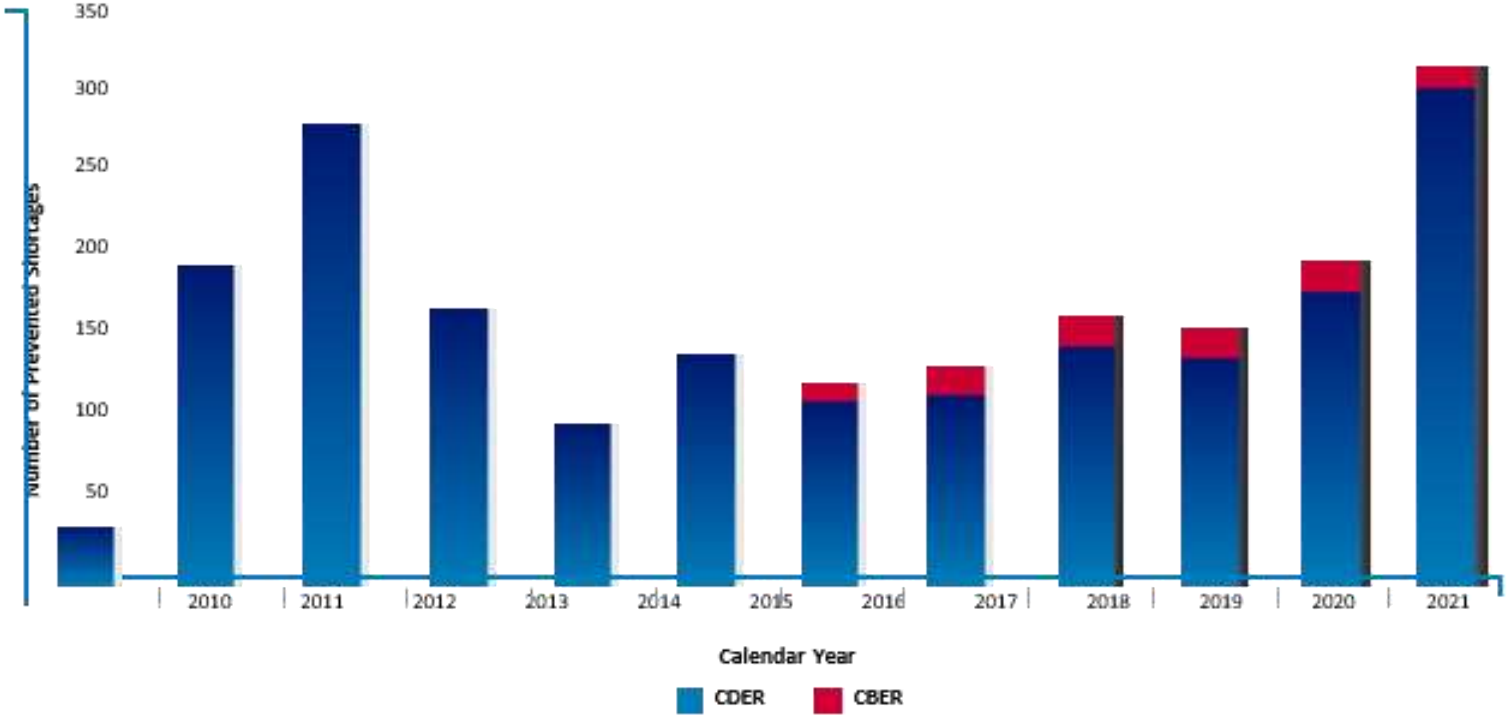
Drug Shortages - Roles and Responsibilities

- Requirements for Industry For Early Notifications under 506C of the FD&C Act (2012) (2020)
- All available regulatory tools are used to mitigate and prevent shortages
- Truly a collaborative Center effort - OPQ, OGD, Office of Compliance, OND, OSE, and OPSA

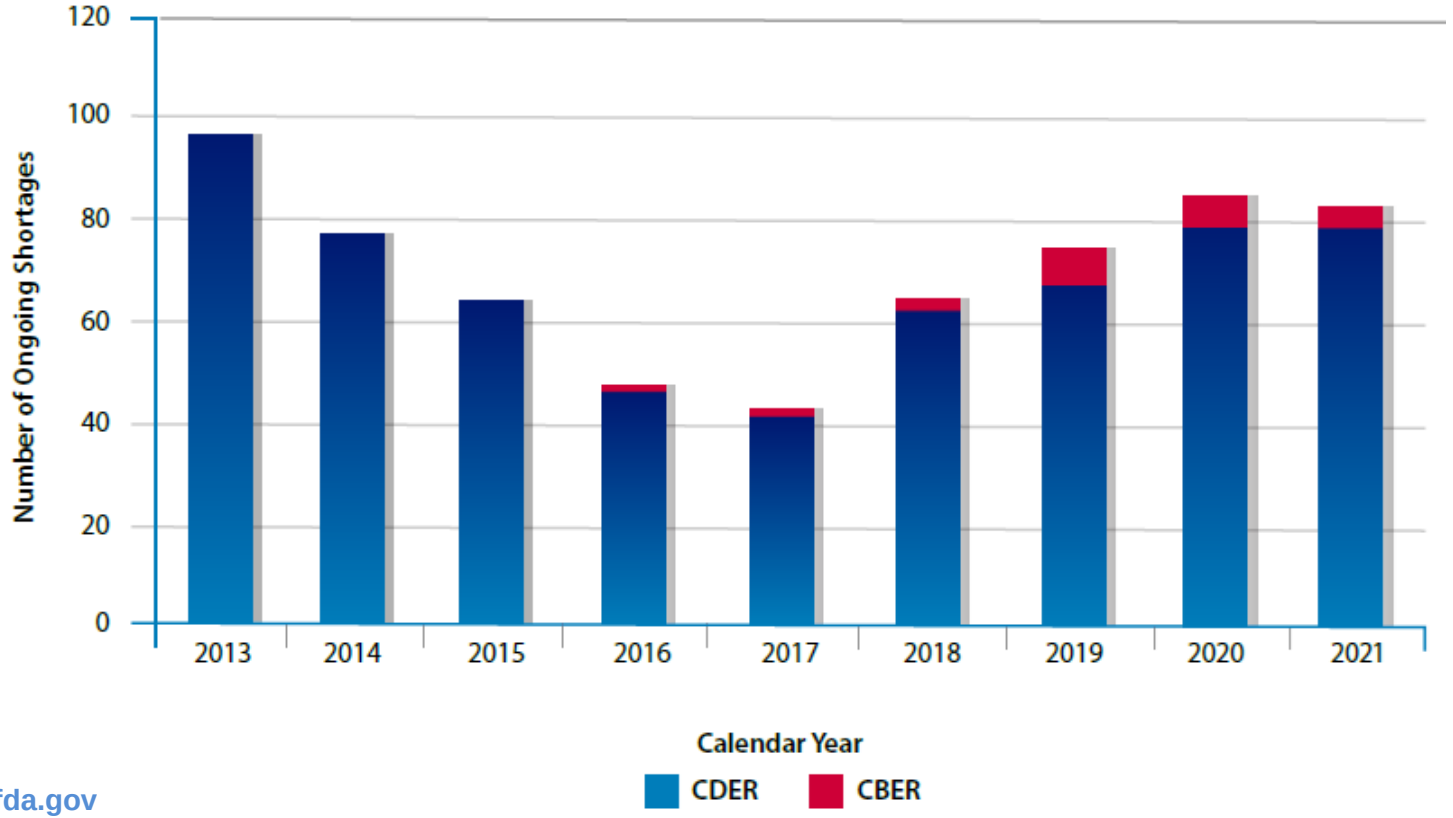
Historical Shortage Landscape – New Shortages



Historical Landscape - Prevented Shortages

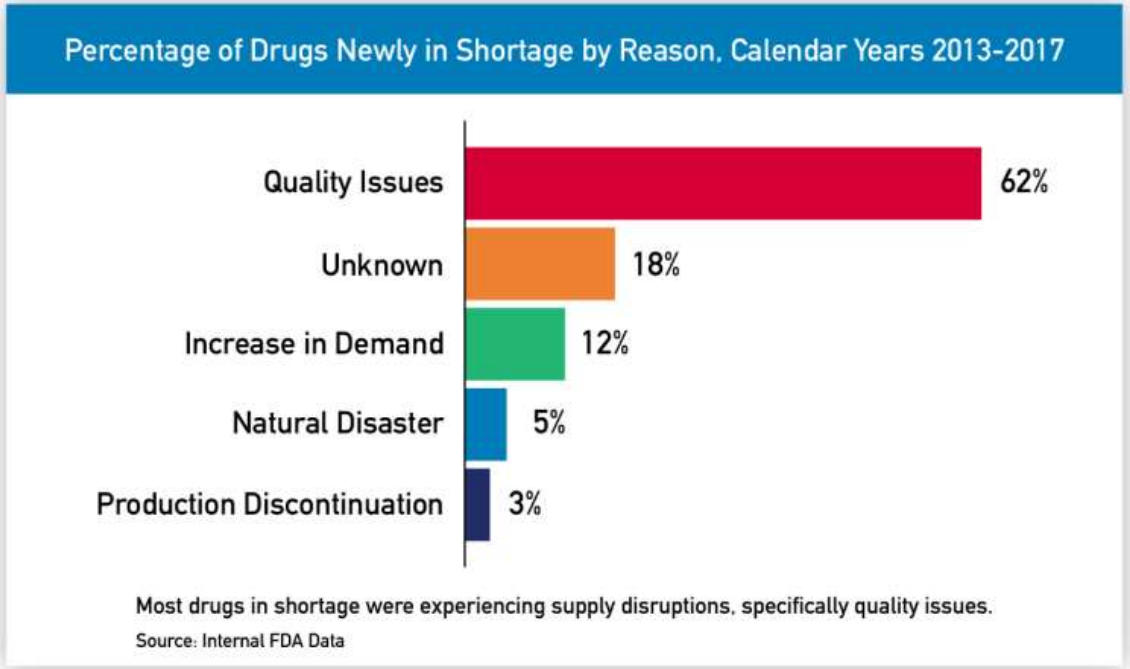


Historical Landscape - Ongoing Shortages



Historical Reasons for shortages

- 2019 FDA Task Force Report



Current challenges

- Increased demand – IV narcotics, IV fluids, etc
- Competition on manufacturing lines and in facilities due to limited capacity and vaccines/related products being made on the same lines
- Industry-wide short supply of manufacturing components (e.g. filters) and other commodities (glass, stoppers, bags)

Current challenges

- Quality-related causes remain significant
- In 2021:
  - 55% of shortages were attributed to manufacturing delays as well as quality-related issues
  - 32% of shortages were attributed to increased demand

Enduring solutions – 2019 Report

- Root Cause #2: The market does not recognize and reward mature quality management
- Recommendation: Create a Rating System to Incentivize Drug Manufacturers to Invest in Achieving Quality Management System Maturity

Enduring Solutions - What's still Needed?

- **Risk Management Planning**
  - **Recent CARES Act requires RMPs as well as notifications of API supply disruptions**
  - **FDA will be issuing guidance for industry on RMPS**
- **Communication is Key**
  - **Guidance to Industry issued April 2020 requesting notifications on increased demand in addition to supply disruptions**
  - **Ongoing Collaboration – Industry, Outside Stakeholders**


No one can do this alone
Ongoing collaboration with all stakeholders
Let's work together to mitigate and prevent shortages to improve the lives of patients

Thank you !

Resources

- FDA Report on Drug Shortages: Root Causes and Potential Solutions https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions
- FDA Shortages Additional News And information https://www.fda.gov/drugs/drug-shortages/drug-shortages-additional-news-and-information
- Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 506C (21 USC 356c) https://www.gpo.gov/fdsys/pkg/USCODE-2012-title21/pdf/USCODE-2012-title21-chap9-subchapV-partA-sec356c.pdf
- Federal Register Final Rule, 80 FR 38915 (July 8, 2015), Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products. https://www.gpo.gov/fdsys/pkg/FR-2015-07-08/pdf/2015-16659.pdf. See also 21 CFR 310.306, 314.81, and 600.82.
- CDER MAPP 4190.1 Rev. 2, Drug Shortage Management (11/1995; Rev. 1, 9/2006; Rev. 2, 9/2014): https://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm079936.pdf
- FDA Strategic Plan for Preventing and Mitigating Drug Shortages: https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf