



Drug Shortages: An Ongoing Crisis and Enduring Solutions

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Overview

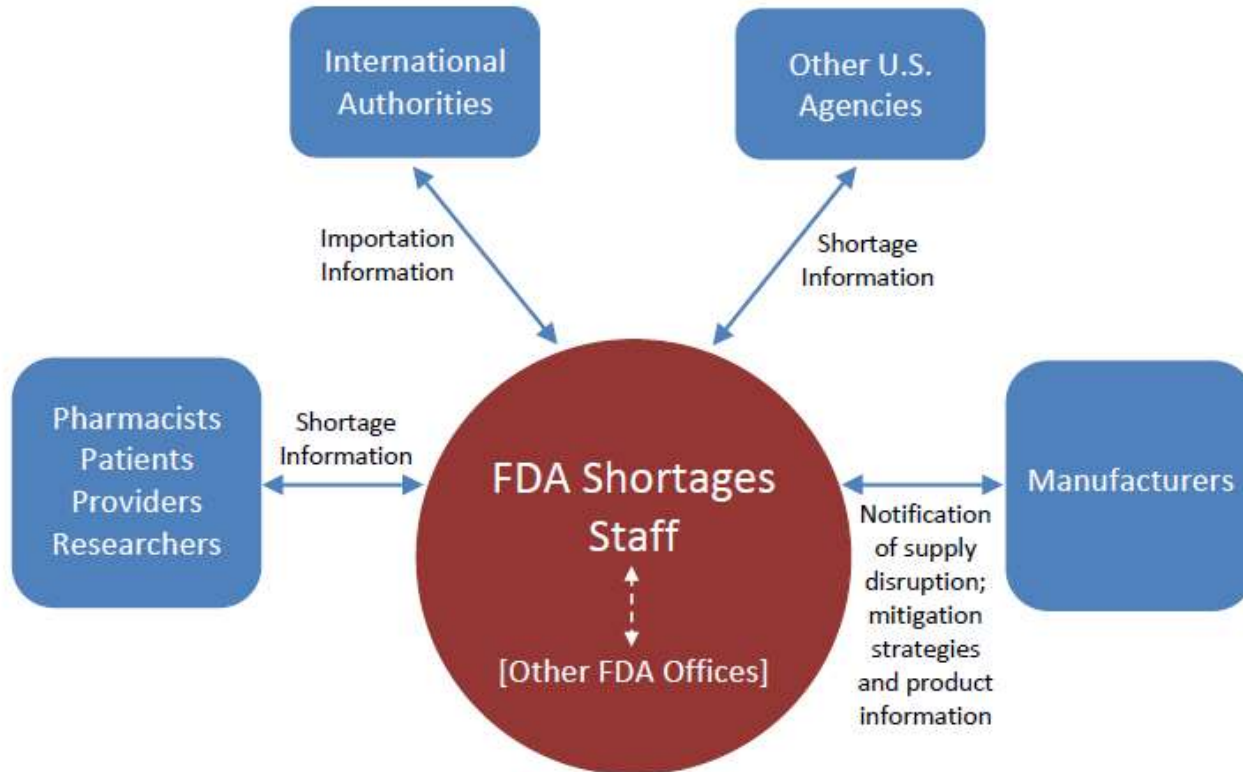
- Drug Shortages -CDER Roles and Responsibilities
- Historical Shortage Landscape and Current Challenges
- Enduring Solutions

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

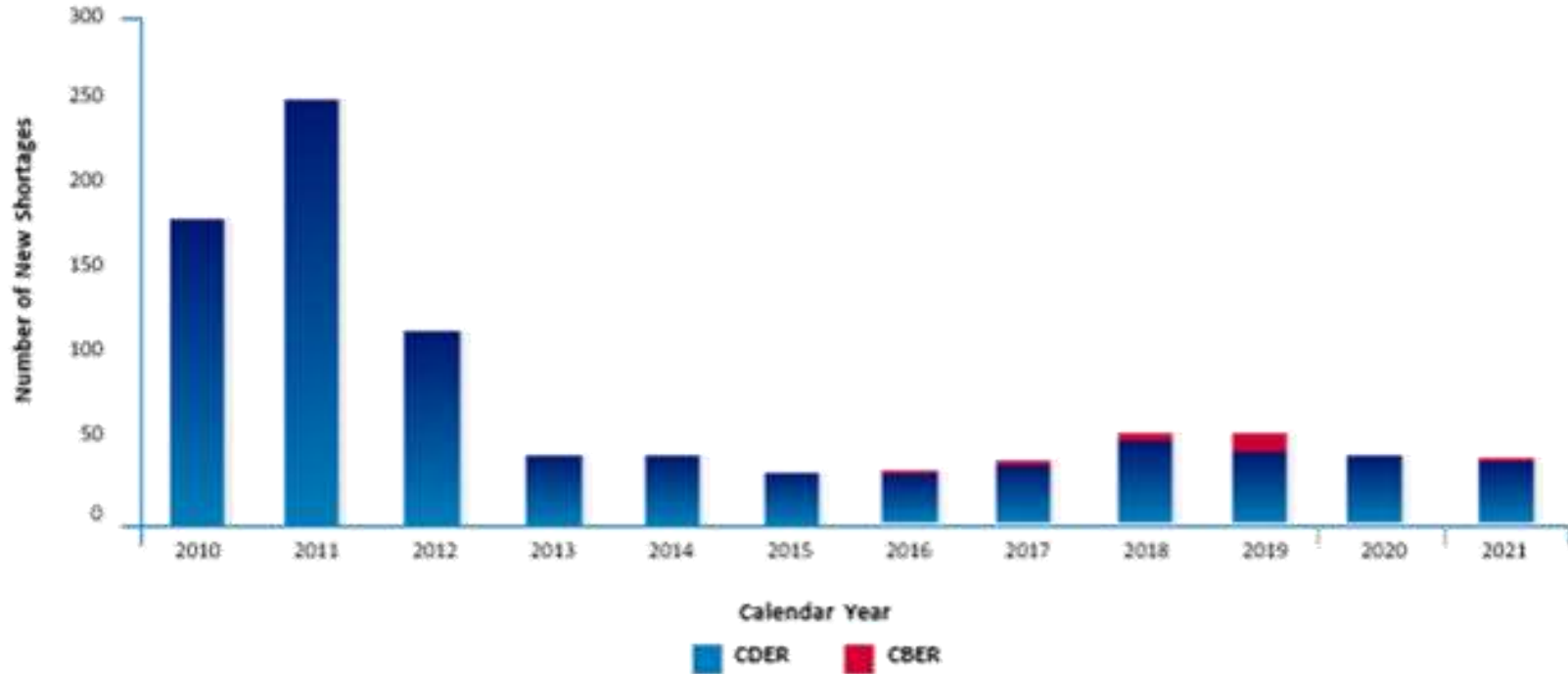


Drug Shortages - Roles and Responsibilities

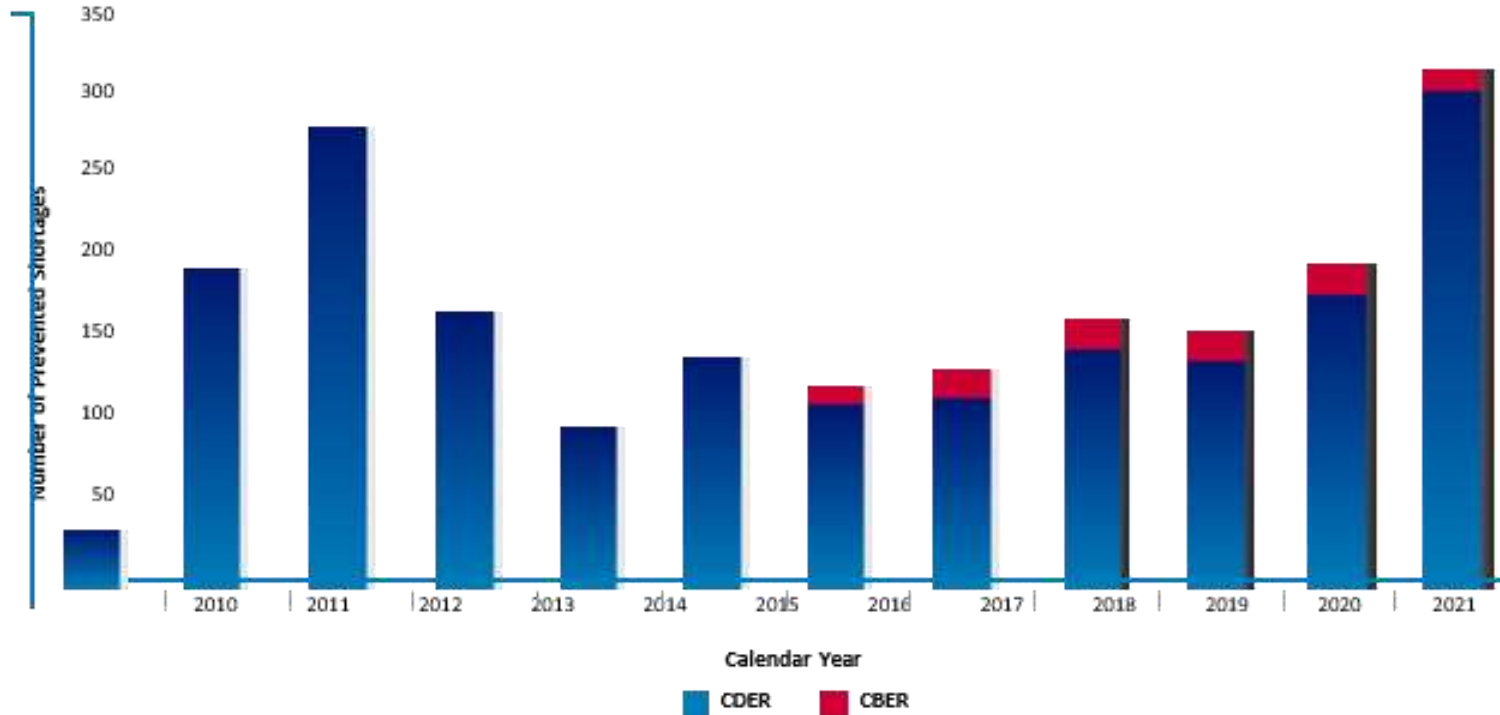


- Requirements for Industry For Early Notifications under 506C of the FD&C Act (2012) (2020)
- All available regulatory tools are used to mitigate and prevent shortages
- Truly a collaborative Center effort - OPQ, OGD, Office of Compliance, OND, OSE, and OPSA

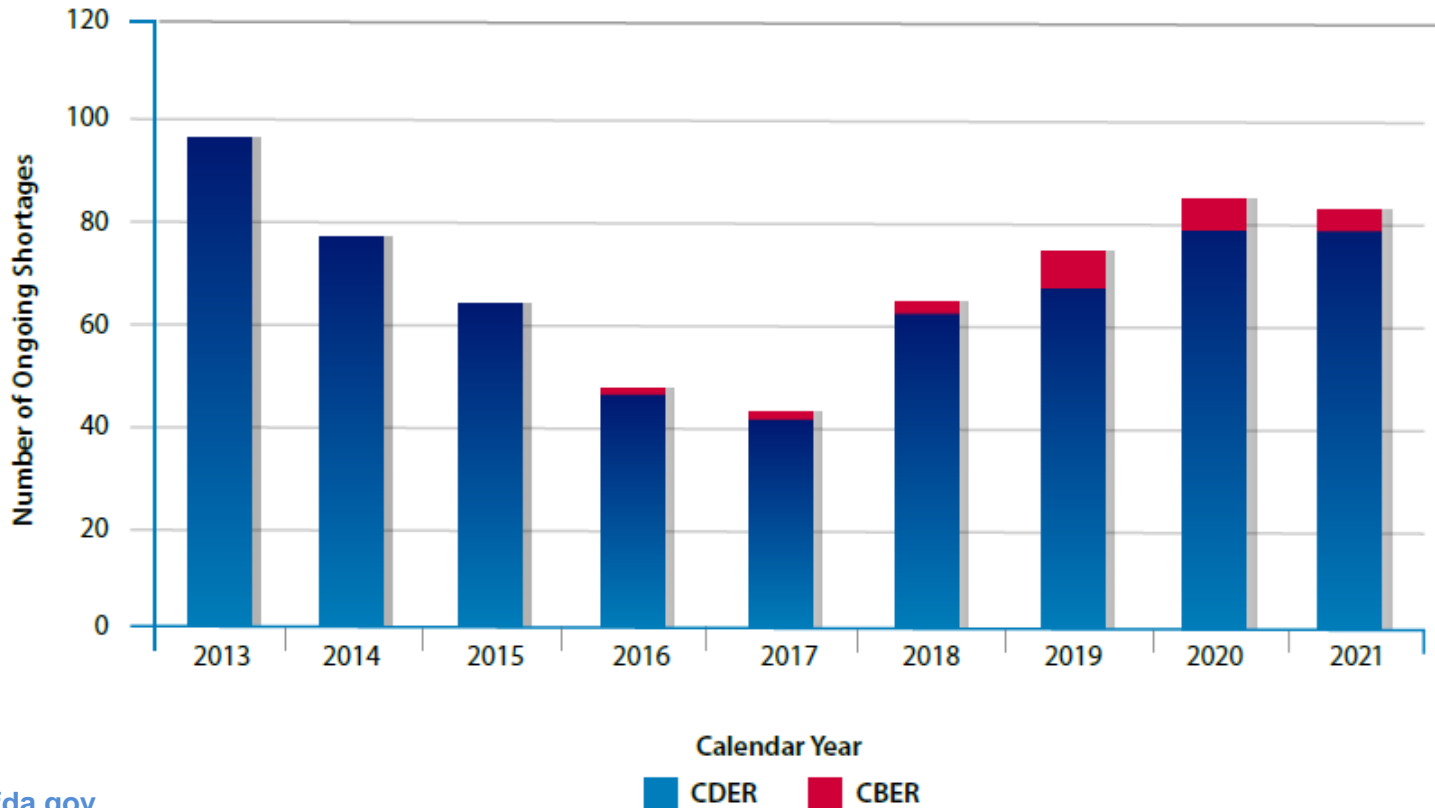
Historical Shortage Landscape – New Shortages



Historical Landscape - Prevented Shortages



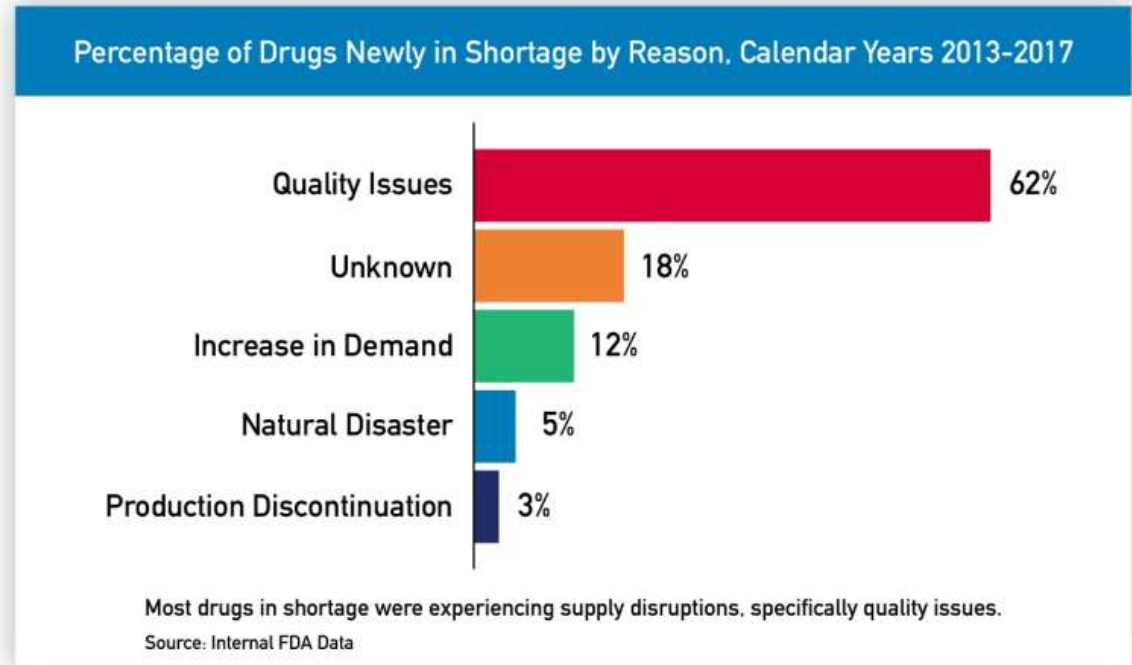
Historical Landscape - Ongoing Shortages



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**

A close-up photograph of a hand holding an orange plastic pill bottle. The bottle is tilted, and several white, oval-shaped pills are falling out. The background is blurred, focusing attention on the hand and the pills.

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>