

# Impact of Recalls and Drug Shortages

Emily Johnson, PharmD  
Elaine Nguyen, PharmD, MPH  
PGY-1 Pharmacy Residents  
Boise VA Medical Center

September 29, 2013

---

---

---

---

---

---

---

---

## Objectives

- Understand the similarities and differences between drug recalls and shortages
- Describe the impacts of drug recalls and shortages
- Recognize appropriate drug recalls and shortages resources

---

---

---

---

---

---

---

---

## Abbreviations

- FDA: Food and Drug Administration
- DSP: Drug Shortage Program
- GMP: Good Manufacturing Practices
- ASHP: American Society of Health-System Pharmacists

---

---

---

---

---

---

---

---

**Who has been impacted by a drug recall or shortage?**

---

---

---

---

---

---

---

---

**Background Information**

---

---

---

---

---

---

---

---

**Definitions<sup>1</sup>**

- Recall: Action taken to remove a product from the market
  - Class I: Serious adverse health consequences or death
  - Class II: Temporary or medically reversible adverse health consequences or remote probability of serious adverse health consequences
  - Class III: Not likely to cause adverse health consequences

---

---

---

---

---

---

---

---

## Definitions

- Drug Shortage: Situation in which the total supply of clinically interchangeable versions of an FDA-regulated drug is inadequate to meet user demand<sup>2</sup>
  - FDA (DSP) focus is on medically necessary products that significantly impact public health

Change in the drug supply that affects patient care<sup>3</sup>

---

---

---

---

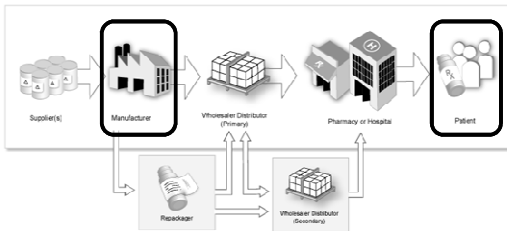
---

---

---

---

## Supply Chain<sup>4</sup>



---

---

---

---

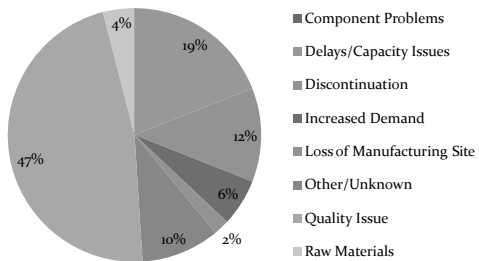
---

---

---

---

## 2011 Drug Shortage Causes for All Dosage Forms<sup>5</sup>



---

---

---

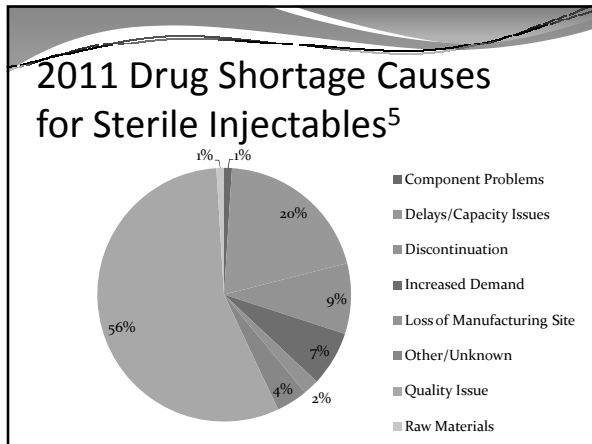
---

---

---

---

---



---

---

---

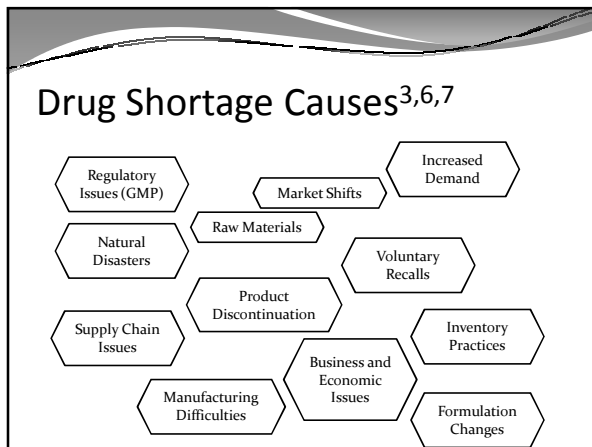
---

---

---

---

---



---

---

---

---

---

---

---

---

### The Role of the FDA<sup>5,6</sup>

- Work with manufacturers to prevent or lessen impact of shortages
- Identify alternative manufacturers and suppliers
- Expedite review processes
- Permit temporary importation
- Allow regulatory discretion

The FDA helped prevent 195 shortages in 2011

---

---

---

---

---

---

---

---

# The Impact of Drug Recalls and Shortages

---

---

---

---

---

---

---

---

## Impact – Multifactorial<sup>6</sup>

www.esu.edu      www.flickr.com  
www.pharmacytechniciantraining.org      cofdreams.com      writingmoose.wordpress.com

---

---

---

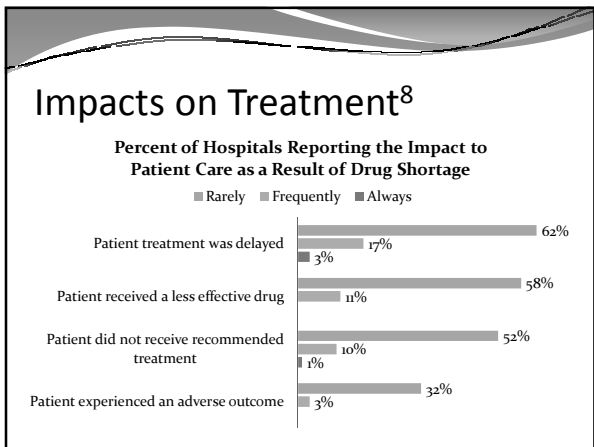
---

---

---

---

---



---

---

---

---

---

---

---

---

### Higher Hospital Expenses<sup>6</sup>

- Increased drug acquisition costs
  - \$200 million annually from more expensive therapeutic substitutes
- Increased personnel expenditures
  - \$216 million in additional labor
- Gray-markets are created upon knowledge of upcoming shortage
  - Drug marketed at 10 - 10,000 times the usual price

---

---

---

---

---

---

---

---

### Increased Labor Costs<sup>6,9</sup>

- Additional hours required per week to manage drug shortages:
  - Pharmacists - 9 hours
  - Technicians - 8 hours
- Significantly more time than that evidenced in 2004
- Communication with manufacturers and wholesalers, providing education to facility personnel, modifying policies/guidelines and updating medication administration systems

---

---

---

---

---

---

---

---

### Safety Risks<sup>6</sup>

- Compromised clinical outcomes
  - Rationing
  - Cancellation of procedures
  - Use of alternative treatments that have a worse safety profile or more prone to overdose
  - Alteration of chemotherapy regimens

---

---

---

---

---

---

---


---

### In the News...<sup>10</sup>

- “Drug shortages endanger cancer patients, study finds”

Lit: Szabo, USA TODAY 8:49 a.m. EDT June 3, 2013

*Most cancer specialists say their patients have been affected by shortages of critical cancer drugs, mostly caused by manufacturing problems at pharmaceutical plants.*



SHARE 181 127 5

Shortages of critical cancer drugs are threatening the care of patients who are already fighting for their lives, a new study shows.

About 63% of cancer specialists reported a drug shortage in the past six months, and 92% said patients' care has been affected, according to a survey of 245 doctors to be presented Monday in Chicago at the annual meeting of the American Society of Clinical Oncology.

(Photo: USA TODAY)

---

---

---

---

---

---

---

---

### Safety Risks Continued<sup>6</sup>

- Medication Errors
  - Physicians forced to prescribe unfamiliar agents
  - Lack of certainty with conversions
    - Potential under- or overdosing
  - Unfamiliarity within emergency situations
- Death

---

---

---

---

---

---

---

---

### Increased Risk in Quality Control<sup>6</sup>

- Different formulations in alternative medications
  - Various preservatives, antimicrobial retardants
- May be missing drug pedigrees
- Counterfeit drugs
- Risks with compounded sources

---

---

---

---

---

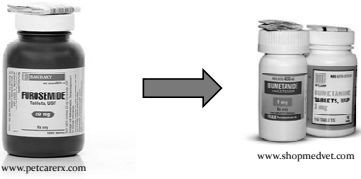
---

---

---

### What about other drugs?<sup>6</sup>

- One shortage can cause a decline in the supply of an alternative agent
  - Increased demand



The diagram illustrates a supply chain shift. On the left, a bottle of Furosemide is shown with the URL www.petcarerx.com below it. A grey arrow points to the right, where two smaller bottles of alternative agents are shown with the URL www.shopmedvet.com below them. The labels on the bottles include 'Furosemide', 'Furosemide', and 'Furosemide, USP'.

---

---

---

---

---

---

---

---

### Effect on Clinical Trials<sup>6</sup>

- Delay enrollment of patients
- Deviate from trial design
- Affect the strength or applicability of the study results

---

---

---

---

---

---

---

---

### **Are pharmacies ever blamed for the high price of medications?**

---

---

---

---

---

---

---

---



# Strategies to Manage Drug Recalls and Shortages

---

---

---

---

---

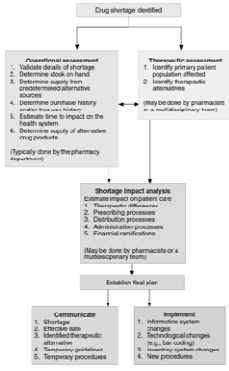
---

---

---

## Institutional Strategies<sup>6,7</sup>

- Identify and validate shortage, collecting details on the shortage
- Assessment
  - Inventory
  - Therapeutic alternatives



```

    graph TD
      A[Drug shortage identified] --> B[Pharmaceutical assessment]
      A --> C[Therapeutic assessment]
      B --> D[Shortage impact analysis]
      C --> D
      D --> E[Establish final plan]
      E --> F[Communicate]
      E --> G[Implement]
      B -.-> H["(May be done by pharmacists or a multidisciplinary team)"]
      C -.-> H
      D -.-> I["(May be done by pharmacists or a multidisciplinary team)"]
      F --> J["1. Shortage  
2. Effective date  
3. Identified therapeutic alternative  
4. Temporary procedures  
5. Temporary procedures"]
      G --> K["1. Alternative system changes  
2. Technological changes  
3. In- or low-cost  
4. New products"]
      B --- B1[1. Validate details of shortage  
2. Determine stock on hand  
3. Determine supply from direct/indirect/retroactive sources  
4. Determine purchase history and/or use history  
5. Estimate time to impact on the health system  
6. Determine supply of alternative ingredients  
Typically done by the pharmacy department]
      C --- C1[1. Identify primary patient population affected  
2. Identify therapeutic alternatives]
      D --- D1[1. Therapeutic alternatives  
2. Prescribing processes  
3. Distribution processes  
4. Administration processes  
5. Financial considerations]
      
```

---

---

---

---

---

---

---

---

## Institutional Strategies<sup>6,7</sup>

- Impact/threat prediction
- Develop and modify guidelines and policies
  - Patient prioritization
- Communicate!
  - Internal
  - External, as needed

---

---

---

---

---

---

---

---

**How does your practice site handle drug shortages?**

---

---

---

---

---

---

---

---

**Resources**

- Manufacturing company
- FDA  
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>
- ASHP  
<http://www.ashp.org/menu/DrugShortages.aspx>

---

---

---

---

---

---

---

---

**References**

1. U.S. Food and Drug Administration. Background and Definitions. U.S. Food and Drug Administration Website. <http://www.fda.gov/Safety/Recalls/ucm165546.htm>. Updated June 24, 2009. Accessed August 18, 2013.
2. Center for Drug Evaluation and Research. Drug Shortage Management. MAPP 6003.1. U.S. Food and Drug Administration Website. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM079936.pdf>. Updated February 3, 2012. Accessed August 18, 2013.
3. Taylor LS, Mark SM. Understanding Drug and Managing Shortages. American Society of Health-System Pharmacists Website. <http://www.ashp.org/DocLibrary/Policy/DrugShortages/DShort-abbott-drug.aspx>. Updated November 5, 2003. Accessed August 18, 2013.
4. U.S. Food and Drug Administration. Graphic - A Drug Supply Chain Example. U.S. Food and Administration Website. <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm277626.htm>. Updated November 2, 2011. Accessed August 18, 2013.
5. Dill S, Ahn M. Overview of U.S. Drug Shortages. U.S. Food and Drug Administration Website. <http://www.fda.gov/downloads/Drugs/UCM327108.pdf>. Updated November 6, 2012. Accessed August 18, 2013.

---

---

---

---

---

---

---

---

## References

6. American Hospital Association. AHA Survey on Drug Shortages. American Hospital Association Website. <http://www.aha.org/content/11/drugshortagesurvey.pdf>. Updated July 12, 2011. Accessed August 21, 2013.
7. Kaakeh R, Sweet B, Reilly C, et al. Impact of Drug Shortages on U.S. Health Systems. *Am J Health-Syst Pharm.* 2011;68:811-9.
8. Szabo, Liz. Drug Shortages Endanger Cancer Patients, Study Finds. USA Today Website. <http://www.usatoday.com/story/news/nation/2013/06/03/drug-shortages-cancer-patients/2382597/>. Published June 3, 2013. Accessed August 21, 2013.
9. Kaakeh R, Sweet B, Reilly C, et al. Impact of Drug Shortages on U.S. Health Systems. *Am J Health-Syst Pharm.* 2011;68:811-9.
10. Szabo, Liz. Drug Shortages Endanger Cancer Patients, Study Finds. USA Today Website. <http://www.usatoday.com/story/news/nation/2013/06/03/drug-shortages-cancer-patients/2382597/>. Published June 3, 2013. Accessed August 21, 2013.

---

---

---

---

---

---

---

---