Impact of Recalls and Drug Shortages

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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

1. Recall: Action taken to remove a product from the market
2. Class I: Serious adverse health consequences or death
3. Class II: Temporary or medically reversible adverse health consequences or remote probability of serious adverse health consequences
4. 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. FDA (DSP) focus is on medically necessary products that significantly impact public health.

Change in the drug supply that affects patient care.

Supply Chain

2011 Drug Shortage Causes for All Dosage Forms

- Component Problems 47%
- Delays/Capacity Issues 19%
- Discontinuation 6%
- Increased Demand 11%
- Loss of Manufacturing Site 10%
- Other/Unknown 2%
- Quality Issue 4%
- Raw Materials 4%
2011 Drug Shortage Causes for Sterile Injectables

- Component Problems
- Delays/Capacity Issues
- Discontinuation
- Increased Demand
- Loss of Manufacturing Site
- Other/Unknown
- Quality Issue
- Raw Materials

Drug Shortage Causes

- Regulatory Issues (GMP)
- Market Shifts
- Increased Demand
- Raw Materials
- Voluntary Recalls
- Product Discontinuation
- Inventory Practices
- Business and Economic Issues
- Formulation Changes
- Manufacturing Difficulties

The Role of the FDA

- 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

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

Impacts on Treatment

Percent of Hospitals Reporting the Impact to Patient Care as a Result of Drug Shortage

- Rarely
- Frequently
- Always

<table>
<thead>
<tr>
<th>Impact</th>
<th>Rarely</th>
<th>Frequently</th>
<th>Always</th>
</tr>
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<tbody>
<tr>
<td>Patient treatment was delayed</td>
<td>5%</td>
<td>5%</td>
<td>64%</td>
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<tr>
<td>Patient received a less effective drug</td>
<td>47%</td>
<td>38%</td>
<td>17%</td>
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<tr>
<td>Patient did not receive recommended treatment</td>
<td>42%</td>
<td>58%</td>
<td>1%</td>
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<tr>
<td>Patient experienced an adverse outcome</td>
<td>34%</td>
<td>37%</td>
<td>2%</td>
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Higher Hospital Expenses\textsuperscript{6}

- 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\textsuperscript{6,9}

- 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\textsuperscript{6}

- 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...  

- "Drug shortages endanger cancer patients, study finds"  

Safety Risks Continued

- 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

- Different formulations in alternative medications  
- Various preservatives, antimicrobial retardants  
- May be missing drug pedigrees  
- Counterfeit drugs  
- Risks with compounded sources
What about other drugs?6
- One shortage can cause a decline in the supply of an alternative agent
- Increased demand

Effect on Clinical Trials6
- 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**

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

References

References