SHORT ON DRUGS. 
SHORT ON TIME.

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PRESENTER DISCLOSURE INFORMATION

• No relevant financial relationship exists
OBJECTIVES

• Upon completion of this educational activity, you will be able to:
  • Summarize the past and present state of drug shortages
  • Identify various implications of drug shortages
  • Discuss potential short- and long-term solutions to the drug shortage crisis

OVERVIEW AND HISTORY OF DRUG SHORTAGES
AUDIENCE DISCUSSION
WITH REGARD TO RESUSCITATION:
WHAT ARE SHORTAGES THAT YOU HAVE NOTICED?
WHAT IS A DRUG SHORTAGE?

"Products used to prevent or treat a serious or life-threatening disease or medical condition for which there is no other available source with sufficient supply of that product or alternative drug available"

"A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent"

THE FDA CANNOT REQUIRE A COMPANY TO...

- Make a drug, even if it is medically necessary
- Make more of a drug
- Change how much and to whom a drug is distributed
A LITTLE BIT OF HISTORY...

• **Drug shortages are not a new problem!**
  • 1957:
    • Shortage of vaccines during influenza pandemic
  • **Natural disasters:**
    • 1998: Hurricane George
    • 2005: Hurricane Katrina and Hurricane Rita
    • 2017: Hurricane Maria

• **2001–2011:**
  • 1,190 drugs were in short supply, with an average duration of 286 days

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REASONS FOR THE LATEST SHORTAGES

- **Discontinuation**: 10%
- Manufacturing: 29%
- Supply/Demand: 8%
- Natural Disaster: 3%
- Raw Material: 1%
- Unknown: 49%

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**COMMON DRUG CLASSES IN SHORT SUPPLY**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>2018</th>
<th>2017</th>
<th>2016</th>
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<tr>
<td>Antibiotics</td>
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<td>Chemistry</td>
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**FREQUENTLY ASKED QUESTIONS**

Can we know earlier?

Can we try _________?

Can we make it ourselves?
DRUG SHORTAGE IMPLICATIONS AND SOLUTIONS

AUDIENCE DISCUSSION
WHAT ARE INSTITUTIONS DOING IN THE EVERYDAY MANAGEMENT OF DRUG SHORTAGES?
OPERATIONS IMPLICATIONS AND STRATEGY: AN EXAMPLE

- Implications:
  - Rationing
  - Cancellation of procedures
  - Alternative treatments with worse safety profiles
  - Medications more prone to error
  - Use of costly medications

Photo credit: https://tinyurl.com/y2tw2xjt

OPERATIONS CONSIDERATIONS

- Strategy
- Impact
- Changes
- Education and Communication

EXAMPLE: UK HEALTHCARE DRUG SHORTAGE TASK FORCE

Pharmacy Leadership
Chief Medical Officer
MD Service Lines
Nursing Leadership
Pharmacy IT
Pharmacy Clinical Services

Identify Shortage
Agenda for Bi-Weekly Meeting
Present Supply Outlook, Resolution, Our Supply, Alternatives
Send Communication to Physicians, Nurses, and Pharmacists

FREQUENTLY ASKED QUESTIONS

Can we know earlier?

Can we try ________?

Can we make it ourselves?
GOALS OF THE FDA STRATEGIC PLAN

Figure 4. Addressing Drug Shortages: Mitigation Activities and Long-Term Prevention

| Goal #1 | STRENGTHEN MITIGATION RESPONSE. Improve and streamline FDA’s current mitigation activities once the Agency is notified of a supply disruption or shortage. |
| Goal #2 | DEVELOP LONG-TERM PREVENTION STRATEGIES. Develop prevention strategies to address the underlying causes of production disruptions to prevent drug shortages. |

Strategic plan for preventing and mitigating drug shortages. FDA. 2013;1-40.

POTENTIAL LONG-TERM ANSWERS

- **Policies that increase competition**
- **FDA having resources to reduce backlog of generic drug applications**
- **Prohibiting “pay for delay” tactics for brand-drug manufacturers that prohibit generic market entry**

- **Transparency and redundancy requirements**
- **Incentives for high-quality generic injectables**
- **Strengthened contract clauses for supply interruptions**

- **New not-for-profit generic drug company**

ASHP. Drug Shortages Summit. 2014. Apr. 15, 2018
SAFETY IMPLICATIONS: AN EXAMPLE

Photo credit: http://tinyurl.com/y4zt2pob

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HOW DO ETHICS PLAY A ROLE IN SHORTAGES?

CASE EXAMPLE

• After increased utilization over the last several months, you are down to your last dose of epinephrine in the hospital

• Two patients are coding next door to each other in the emergency department, both in asystole. Who receives the dose of epinephrine?

Photo credit: http://tinyurl.com/y56uk7ol

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AUDIENCE DISCUSSION

WHAT CAN YOU DO AS A PROVIDER?

FDA DRUG SHORTAGES WEBSITE

SUMMARY

• Drug shortages continue to be a problem in the United States, and providers should remain vigilant

• A wide variety of implications, ranging from operational to safety, occur as a result of drug shortages

• A number of short- and long-term solutions have been implemented and/or suggested with no perfect solution at this time

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  • Emergency Medicine Clinical Pharmacy Specialist
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MULTIPLE STAKEHOLDERS IN COMMUNICATION

Strategic plan for preventing and mitigating drug shortages.
FDA. 2013;1-40.