



SHORT ON DRUGS. SHORT ON TIME.

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8 March 2019

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PRESENTER DISCLOSURE INFORMATION

- No relevant financial relationship exists

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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

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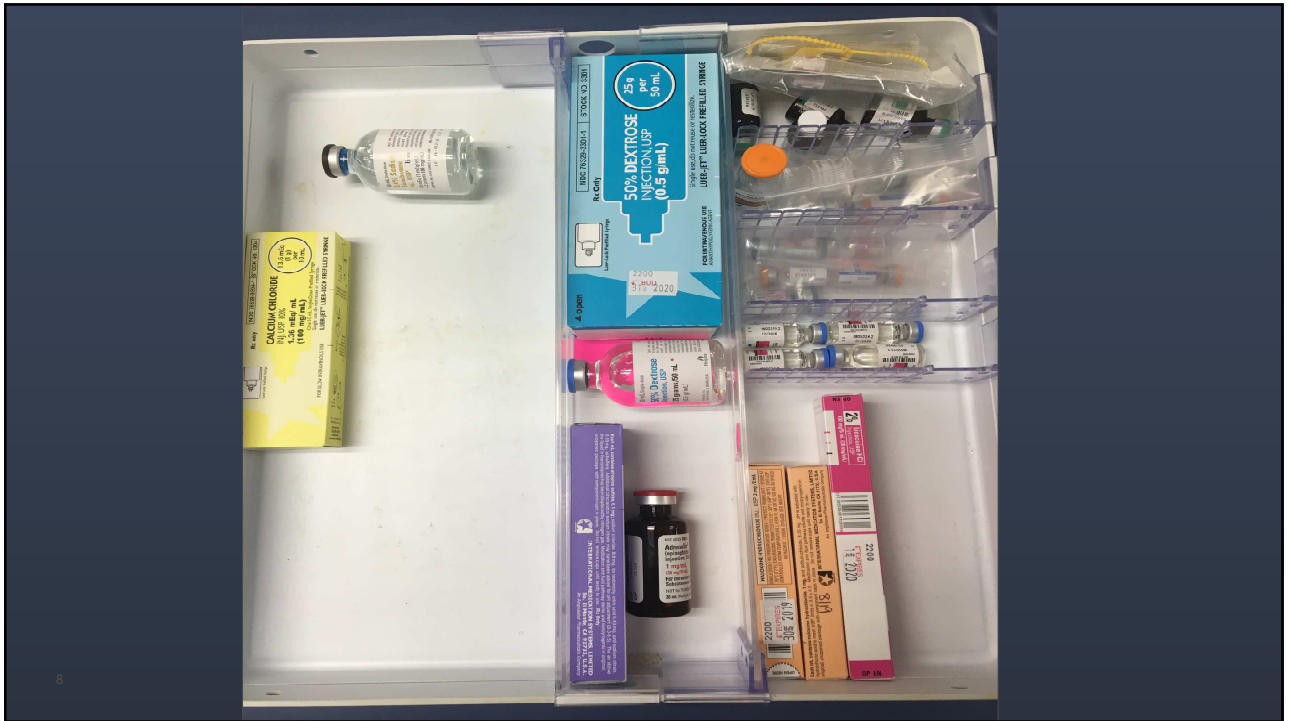
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WHAT IS A DRUG SHORTAGE?

“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”

P&T. 2011;36(11):740-57.
Mayo Clin Proc. 2014;89(3):361-73.

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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

FDA. Drug Shortages. 2018. Apr. 15, 2018.

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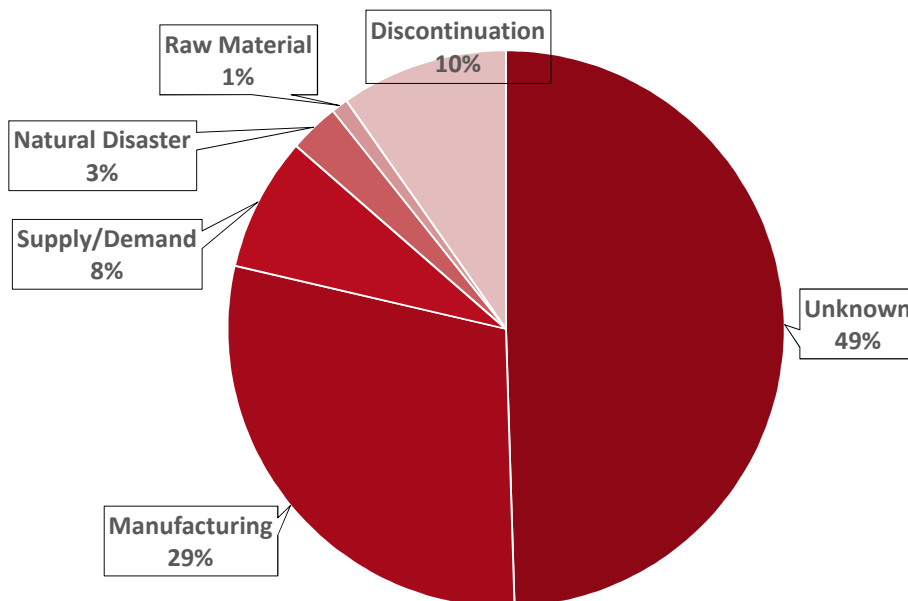
A LITTLE BIT OF HISTORY...

- **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

Clin Pharmacol Ther. 2013;93:145-7.
Clin Pharmacol Ther. 2013;93:245-51.
Seattle Times. Lessons to be learned from 1957 pandemic. 2009. Apr. 15, 2018.

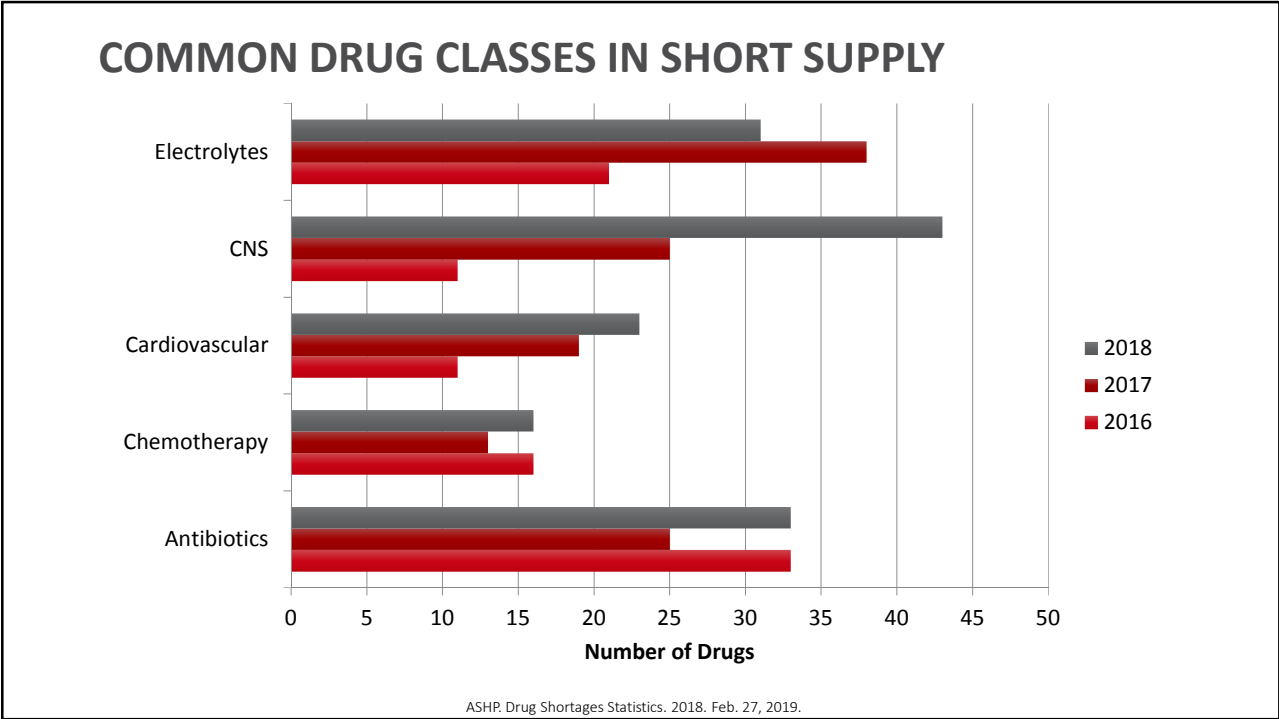
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REASONS FOR THE LATEST SHORTAGES



ASHP. Drug Shortages Statistics. 2018. Feb. 27, 2019.

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OPERATIONS IMPLICATIONS AND STRATEGY: AN EXAMPLE

- **Implications:**

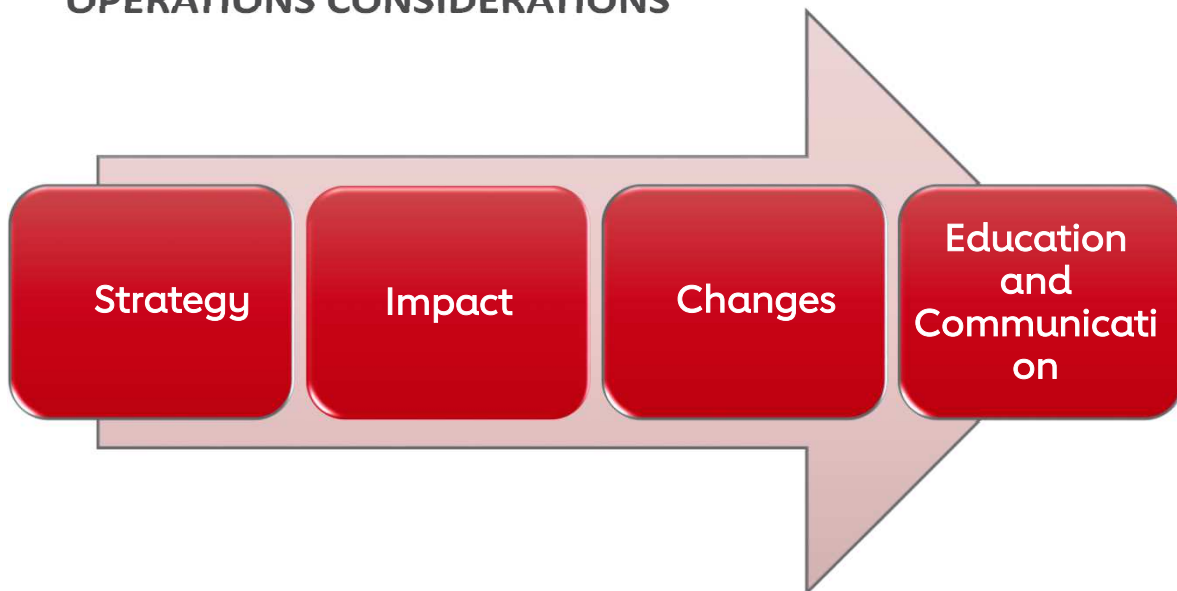
- Rationing
- Cancellation of procedures
- Alternative treatments with worse safety profiles
- Medications more prone to error
- Use of costly medications



P&T. 2011;36(11):740-57.
MMWR. 2013;62:398-400.
ISMP. 2010. Apr. 15, 2018.
Photo credit: <https://tinyurl.com/y2tw2xit>

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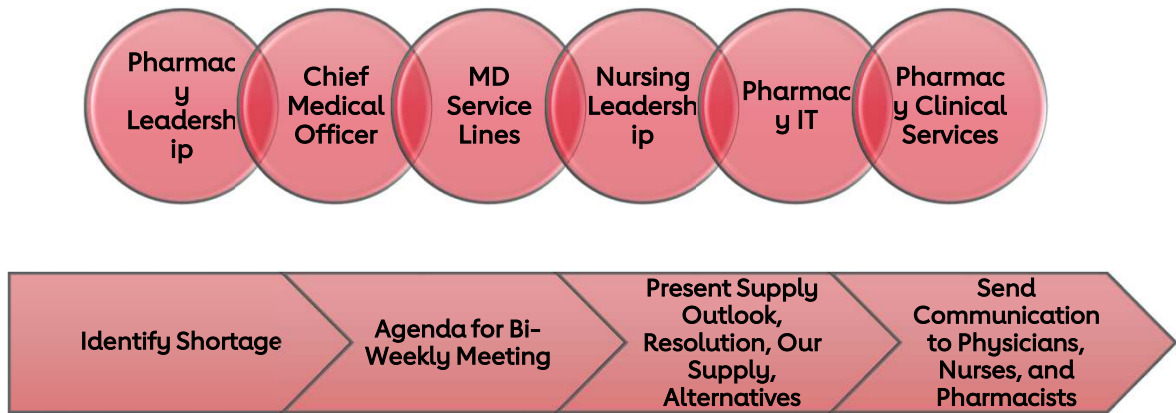
OPERATIONS CONSIDERATIONS



P&T. 2011;36(11):740-57.
Am J Health-Syst Pharm. 2009;66:1399-406.
Pharmacy Purchasing and Products. 2018. Apr. 15, 2018.

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EXAMPLE: UK HEALTHCARE DRUG SHORTAGE TASK FORCE



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FREQUENTLY ASKED QUESTIONS

Can we know earlier?

Can we try _____?

Can we make it ourselves?

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TEMPORARY STRATEGIES

Communication	<ul style="list-style-type: none"> • Emails • Database • Websites • Task Forces
In-House	<ul style="list-style-type: none"> • Compounding our own • Restrictions • IV push • Adjusting concentrations
Ordering	<ul style="list-style-type: none"> • Obtaining allocations • Active backorders • Direct manufacturer accounts • Outsourcing
Other	<ul style="list-style-type: none"> • Sharing with others or stockpiling • Frozen product • Gray or foreign markets • Non-formulary products • IV to PO • Syringe

N Engl J Med. 2018;1-3.
 Pharmacy Purchasing and Products. 2018. Apr. 15, 2018.
 FDA. Extension of shelf life provided by Baxter Healthcare Corporation to assist with IV solution shortages. 2018. Apr. 15, 2018.
 ASHP. Small-volume parenteral solutions shortages: suggestions for management and conservation. 2017.

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The screenshot shows the UK HealthCare P&T Committee website. The main navigation includes: Home, P & T Committee, Anticoagulation Subcommittee, Subcommittees (Antimicrobial, Compounding, Formulary, Med Use Safety & Informatics, Oncology, Pediatrics, Perioperative, Radiology & Contrast Agents), Recent (Protocol and Guideline Coversheet, P & T Committee Documents), P&T Committee, About Us, Pharmacy & Therapeutics Committee, Formulary Drug List, P & T Request, Education Material, Formulary Item Discussions, and Contact Us.

Agenda Packets and Minutes:
 P&T Committee minutes and agenda packets are posted in the P & T committee link to the left.
 P&T subcommittees each have their own site (see left column for specific committee/ subcommittee documents)

P&T News
 UK HealthCare
 3/27/2018

Drug Shortages - Discussed
 List to the right of this page

What went LIVE since last P&T

Formulary Additions: Inotuzumab - added Kayexalate powder - added	Guidelines: Inhaled Epoprostenol - order set revision Adult Sepsis Empiric guideline -
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Meeting Info
 Meetings are generally held on the 4th Tuesday of each month from 7:30 - 8:30am in the Charles T. Wethington Bldg (Corner of Rose & So. Limestone) CTW Room 317
 900 So. Limestone St.
 Lexington, KY 40383-0200

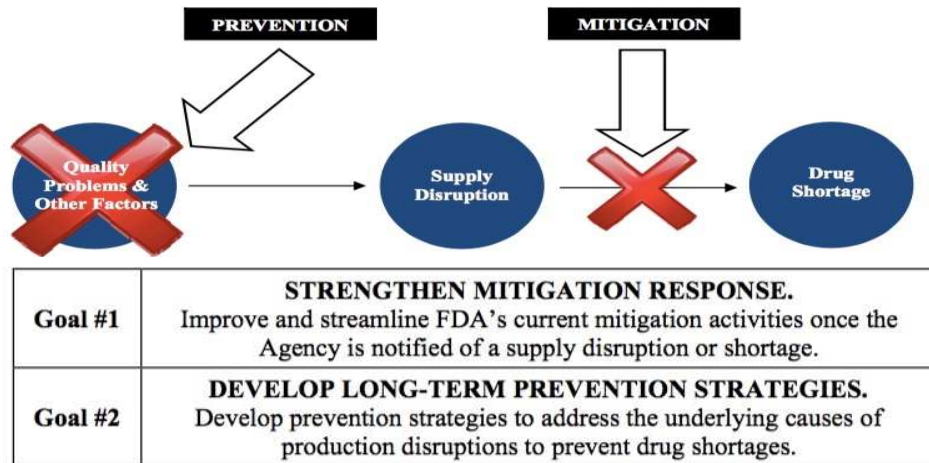
Drug Shortage Guidance Document
 Updated 4/13/2018

Resolved shortage/Consistent stock	Monitoring shortage/inconsistent stock	Critical shortage/out of stock
Acetylcysteine Inh.	Atropine Inj.	Cefotaxime
Atenolol Tablets	Bumetanide Inj.	Erythromycin Lactobionate Inj.
Buprenorphine Inj.	Bupivacaine w/ Epi	
Calcium Chloride Inj.	Calcium Gluconate Inj.	
Hydroxyzine Inj.	Dextrose Inj.	
Mannitol 25% Inj.	Diazepam Inj.	
Metronidazole Inj.	Diltiazem Inj.	
Pantoprazole Inj.	Dobutamine Premix and Inj.	

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GOALS OF THE FDA STRATEGIC PLAN

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



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

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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

Clin Pharmacol Ther. 2013;93(2):145-6.
N Engl J Med. Saline shortages—many causes, no simple solution. 2018. Apr. 15, 2018.
ASPE Issue Brief. 2011. 1-20.
ASHP Drug Shortages Summit. 2014. Apr. 15, 2018

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SAFETY IMPLICATIONS: AN EXAMPLE

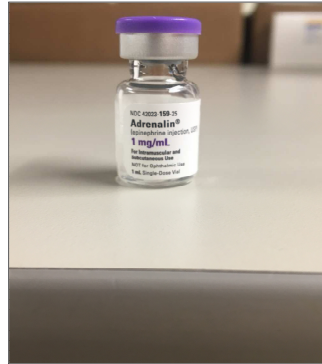


Photo credit: <http://tinyurl.com/y4zt2pob>

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HOW DO ETHICS PLAY A ROLE IN SHORTAGES?

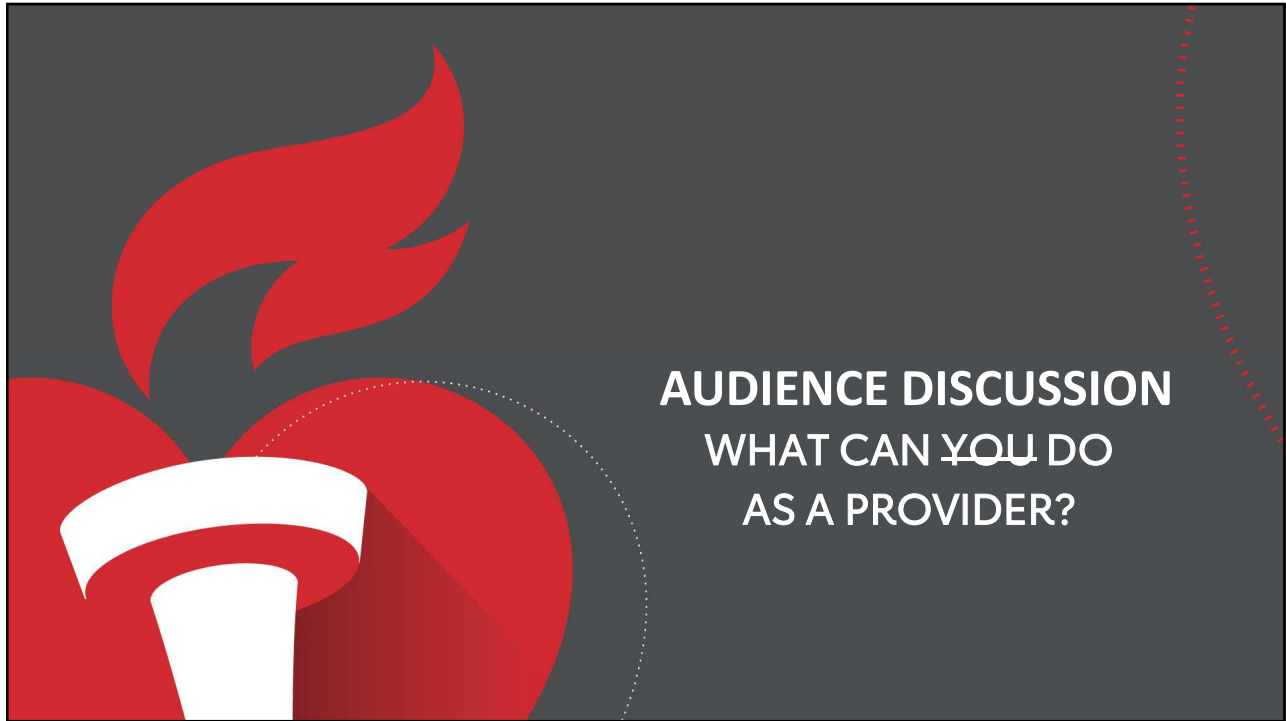
CASE EXAMPLE

- 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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FDA DRUG SHORTAGES WEBSITE

Resources for You

- Drug Shortages Infographic
- Drug Shortage Manual of Policies and Procedures (MAPPP) (PDF - 1.1MB)
- American Society of Health-System Pharmacists: Drug Shortages
- ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems
- FDA Drug Shortages RSS Feed (XML - 34KB)

Information for You

- Consumers: FDA Works to Lessen Drug Shortage Impact
- Drug Shortages: Additional News and Information

Reports to Congress

- Fourth Annual Report on Drug Shortages for Calendar Year 2016 (PDF - 4.7MB)
- Third Annual Report on Drug Shortages for Calendar Year 2015 (PDF - 268KB)
- Second Annual Report on Drug Shortages for Calendar Year 2014 (FDA Archive)
- First Annual Report on Drug Shortages for Calendar Year 2013 (FDA Archive)

News Item: FDA Commissioner Scott Gottlieb, M.D., updates on some ongoing shortages related to IV fluids

2017-2018 Influenza Season: Availability of Antiviral Medications (PDF - 39KB) (Updated 3/23/18)

FDA notifies health care professionals that Becton-Dickinson replaced problematic rubber stoppers in its syringes

FDA works to help relieve the IV fluid shortages in wake of Hurricane Maria
 [11/14/2017] The U.S. Food and Drug Administration is actively

FDA. Drug Shortages. 2018. April 15, 2018.

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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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SPECIAL THANKS

- **Laura Means Ebbitt, PharmD, BCCCP**
 - Surgery Clinical Pharmacy Specialist
- **Jonathan Labuhn, PharmD, MBA, BCPS**
 - Director, Pharmacy Supply Chain and 340B Compliance
- **Regan Baum, PharmD**
 - Emergency Medicine Clinical Pharmacy Specialist

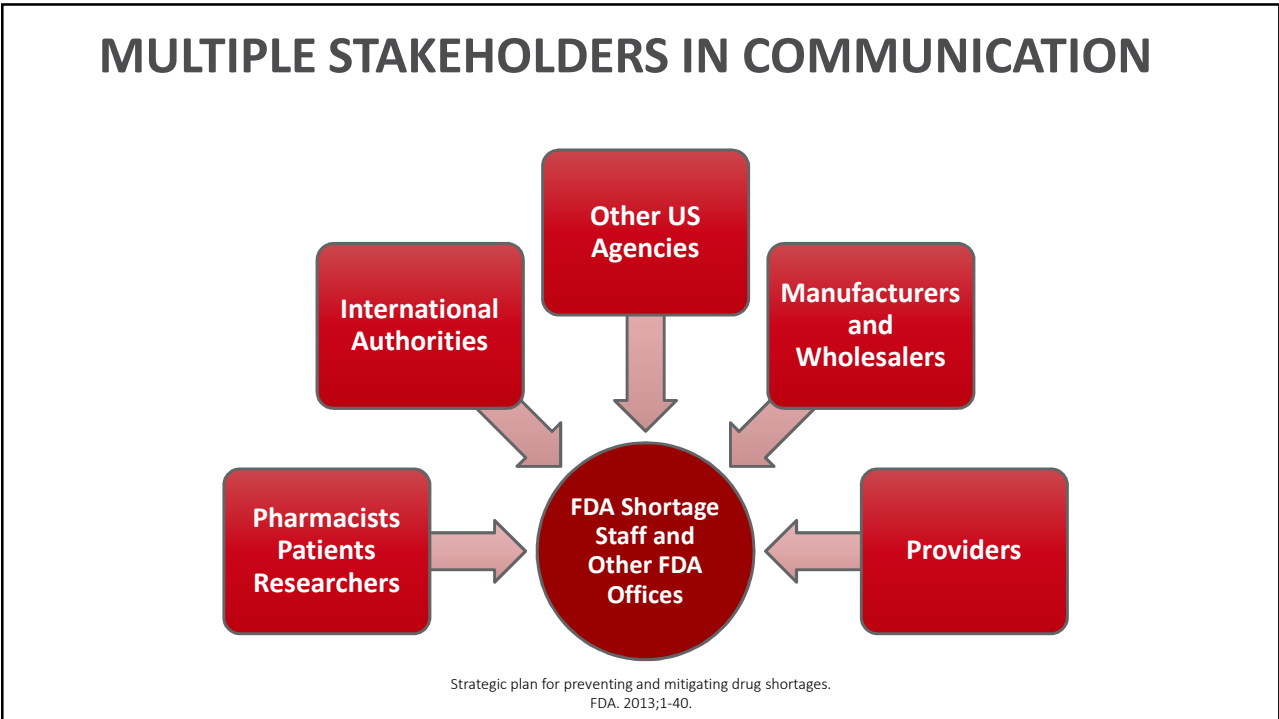
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