

# January 9, 2018

Chloe Bryson-Cahn MD  
Robert Cybulski, PhD  
Marisa D'Angeli, MD  
Zahra Escobar, PharmD  
Rupali Jain, PharmD  
John Lynch, MD, MPH  
Natalia Martinez-Paz, MA, MPA  
Paul Pottinger, MD  
Erica Stohs MD, MPH  
Ted Wright, MD

## Agenda

- Paul Pottinger: Antibiotic Shortages
- Rob Cybulski: Bug O' The Month
- Case Discussions
- Open Discussion



# *Antibiotic Shortages*

Paul Pottinger, MD, FIDSA  
Associate Professor  
UW Medical Center &  
The University of Washington School of Medicine

January 9, 2018

*This presentation is intended for educational use only, and does not in any way constitute medical consultation or advice related to any specific patient.*



## Disclosures

- No financial conflicts of interest
- Everything we discuss is QI, thus protected from legal discovery under WA State Code



Paul Pottinger MD



## Question...

Have you dealt with a shortage of antibiotic supply at your hospital in the last 3 months?

- A. Yep
- B. Nope
- C. Not sure...

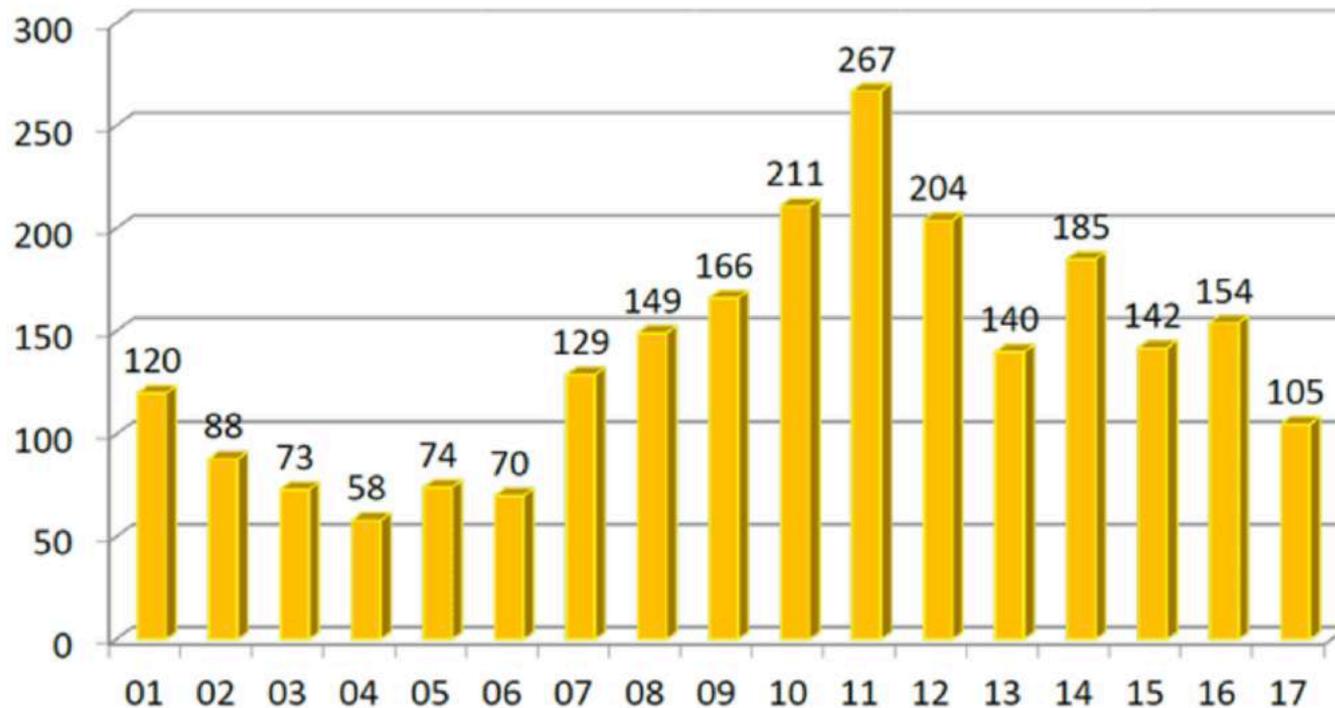


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# Scope of the Problem

National Drug Shortages: Annual New Shortages by Year

January 2001 to September 30, 2017



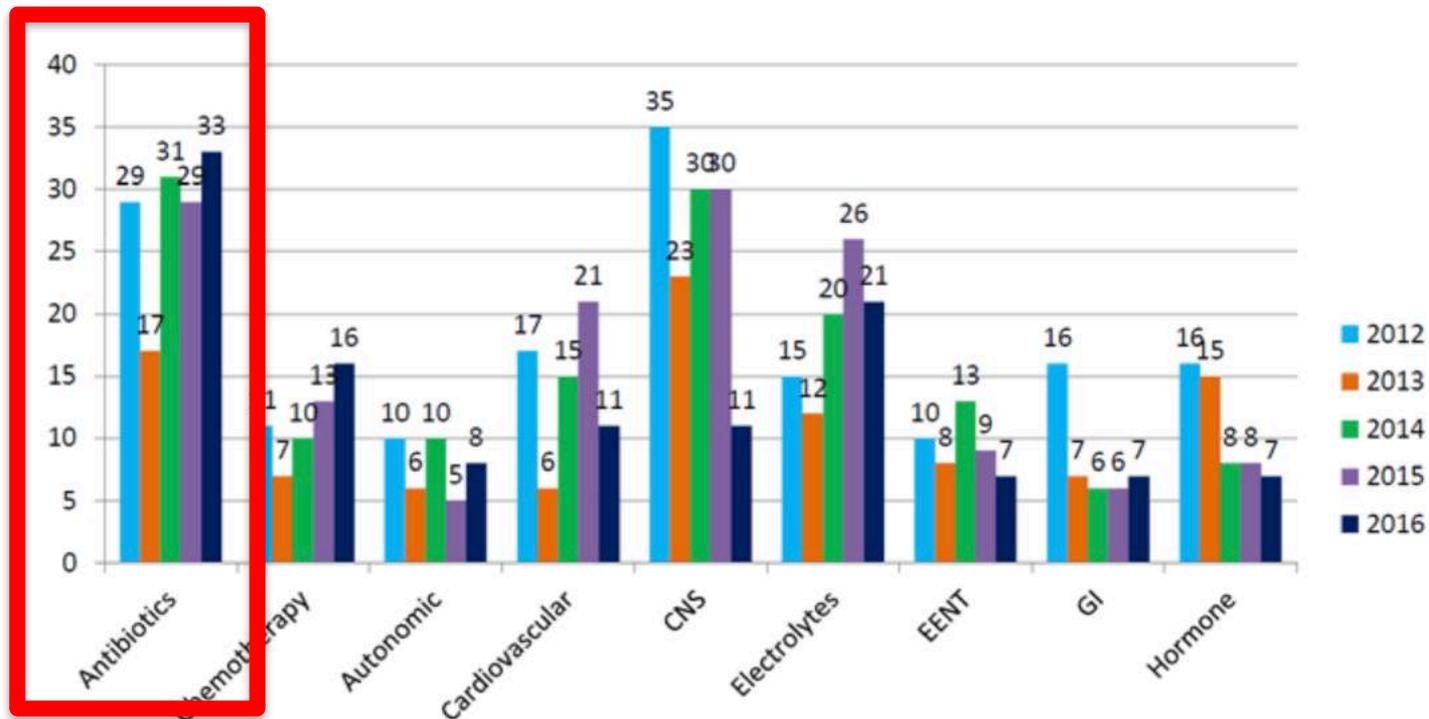
University of Utah Drug Information Service

Contact: [Erin.Fox@hsc.utah.edu](mailto:Erin.Fox@hsc.utah.edu), [@foxerinr](https://twitter.com/foxerinr) for more information.

# Abx in Particular

National Drug Shortages: Common Drug Classes in Short Supply

New Shortages Reported: 2011-2016



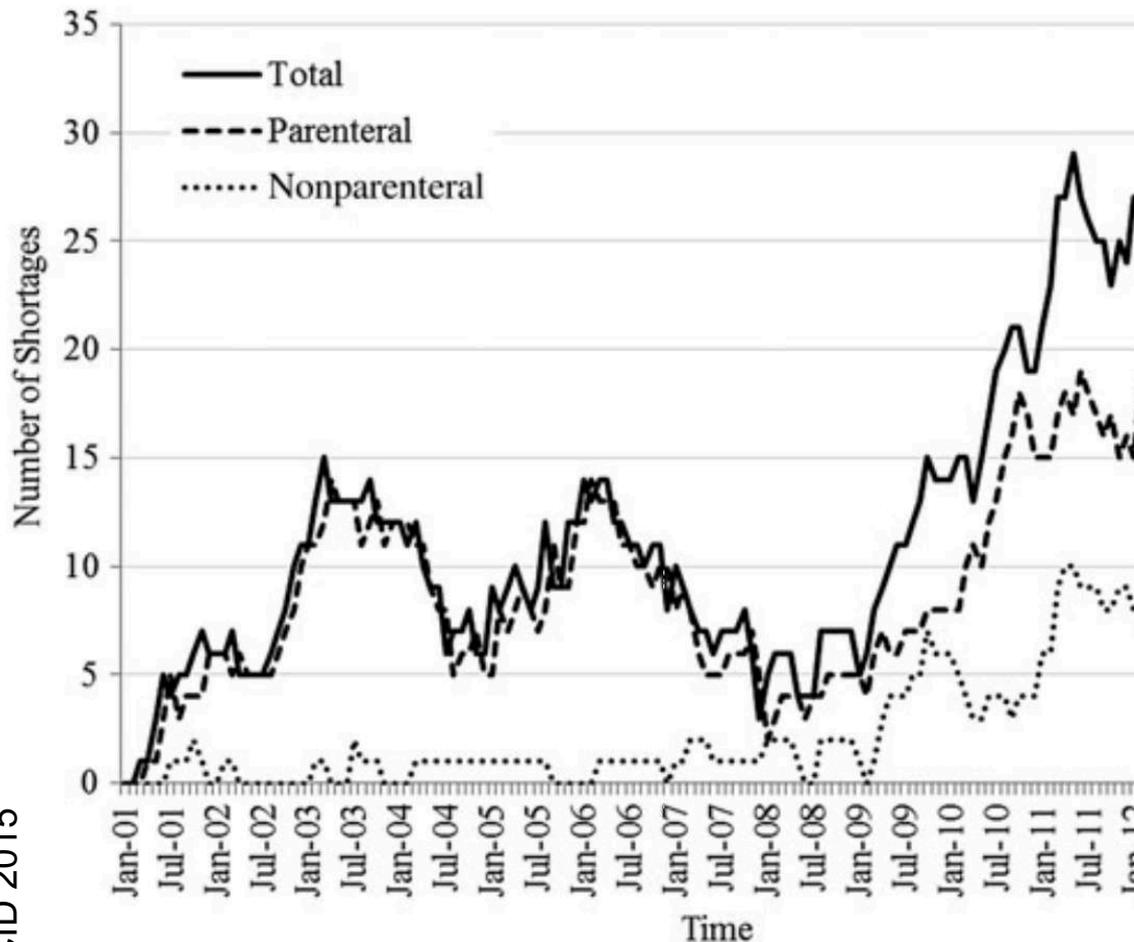
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Contact: [Erin.Fox@hsc.utah.edu](mailto:Erin.Fox@hsc.utah.edu), [@foxeirin](https://twitter.com/foxeirin) for more information.

# IV, PO, many classes

**Table 1. Drugs With Multiple Shortages: Both Active and Resolved, 2001–2013**

Drug Name	No. of Shortages	Total Days
Cefotetan	5	2141
Aztreonam	4	1990
Piperacillin-tazobactam	5	<b>1858</b>
Kanamycin injection	3	1682
Cefotaxime injection	3	<b>1542</b>
Doxycycline injection	3	1515
Erythromycin lactobionate	2	1245
Gentamicin injection, pediatric strength	2	1173
Meropenem	7	<b>1114</b>
Ampicillin-sulbactam	3	<b>1052</b>
Minocycline injection	2	944
Piperacillin sodium	2	942
Cefepime injection	3	801
Nafcillin	4	763
Azithromycin injection	4	<b>599</b>
Gentamicin injection	2	<b>574</b>
Cephalexin suspension	2	<b>535</b>
Imipenem-cilastatin	2	502
Ciprofloxacin 500 mg tablets	3	<b>442</b>
Ceftizoxime	2	405
Clindamycin injection	2	<b>394</b>
Vancomycin	3	<b>373</b>
Cefpodoxime	2	<b>344</b>
Colistimethate	2	255
Paromomycin (Humatin)	3	192
Cefuroxime injection	2	<b>185</b>
Sulfamethoxazole-trimethoprim injection	3	<b>165</b>
Methenamine	2	133
Dalfopristin/quinupristin (Synercid)	2	125
Ticarcillin-clavulanate	3	<b>123</b>
Ceftazidime	2	<b>69</b>
Spectinomycin	2	0

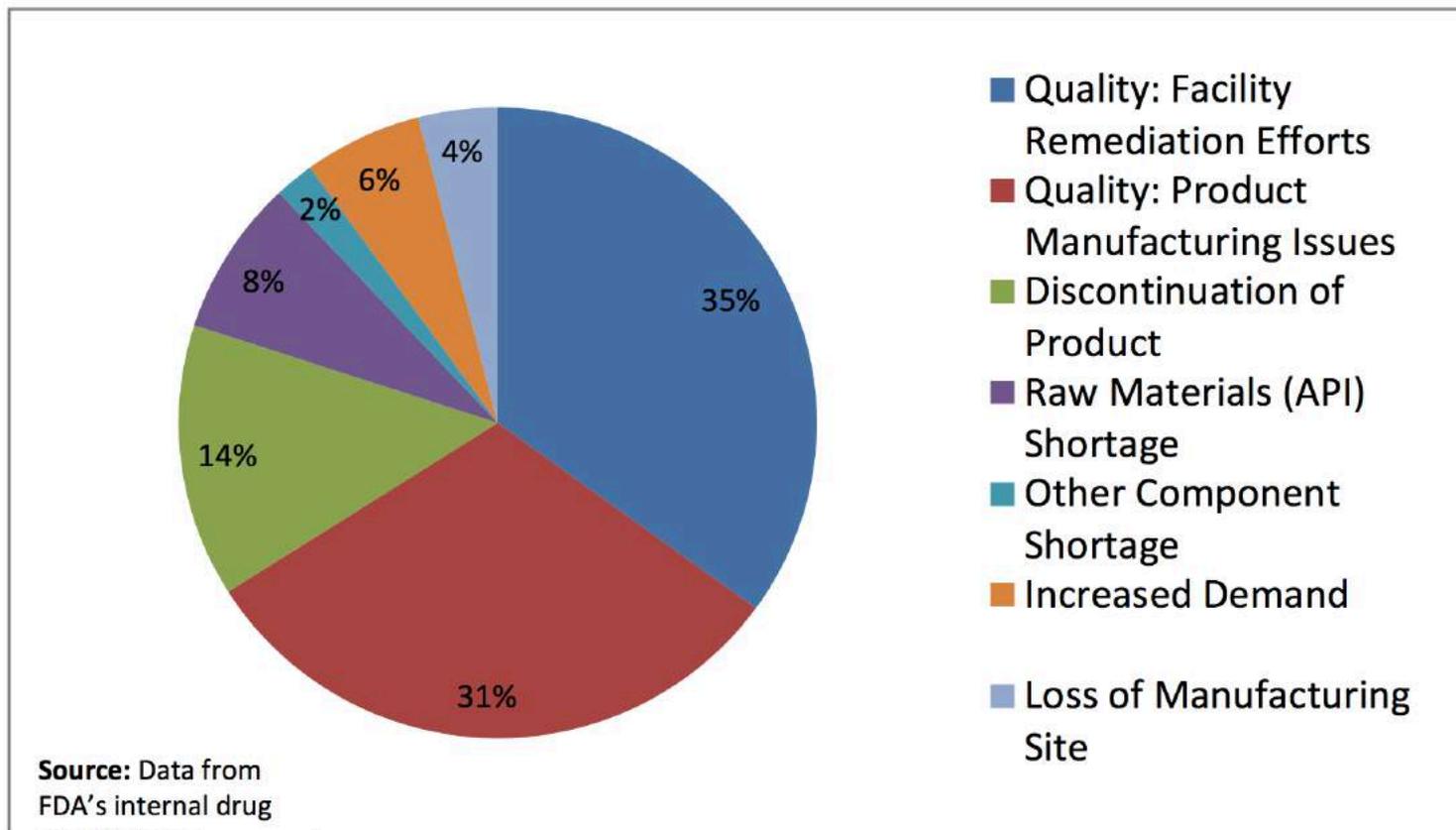


**Figure 1.** Trends in drug shortages, 2001–2013.

Includes both active and resolved shortages. Values in boldface indicate that the drug is currently experiencing a shortage.

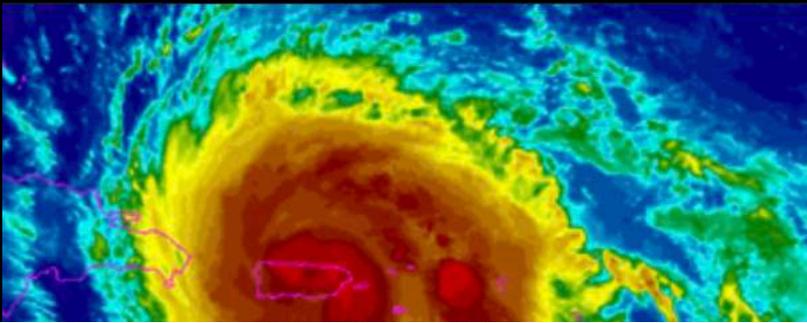
# Why?

**Figure 2. Drug Shortages by Primary Reason for Disruption in Supply in 2012**



**Source:** Data from FDA's internal drug and biologics shortages databases.

FDA 2013



# The Washington Post

*Democracy Dies in Darkness*

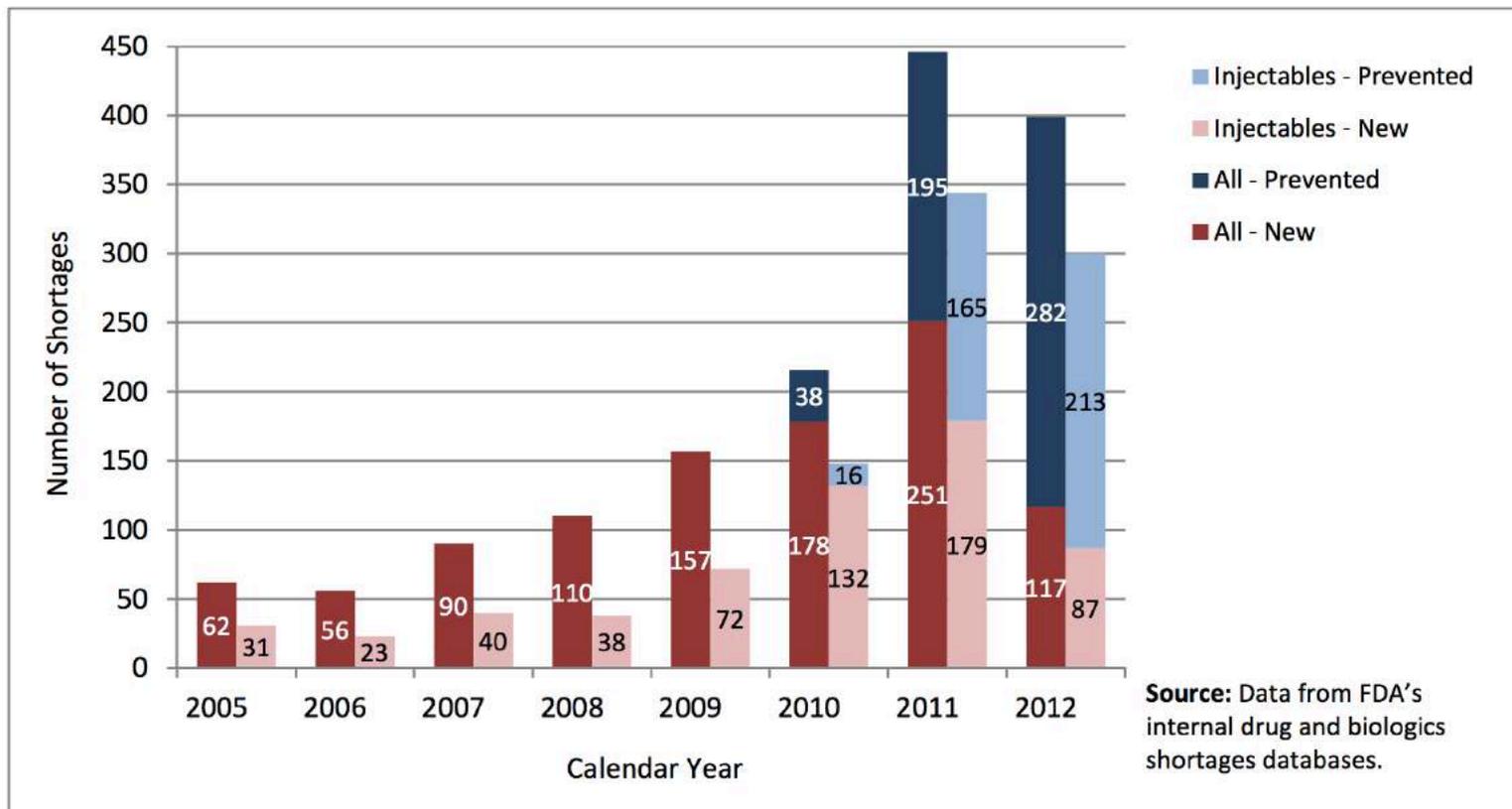
To Your Health

## Hospitals scramble to avert saline shortage in wake of Puerto Rico disaster



# FDA: Tracking & Responding

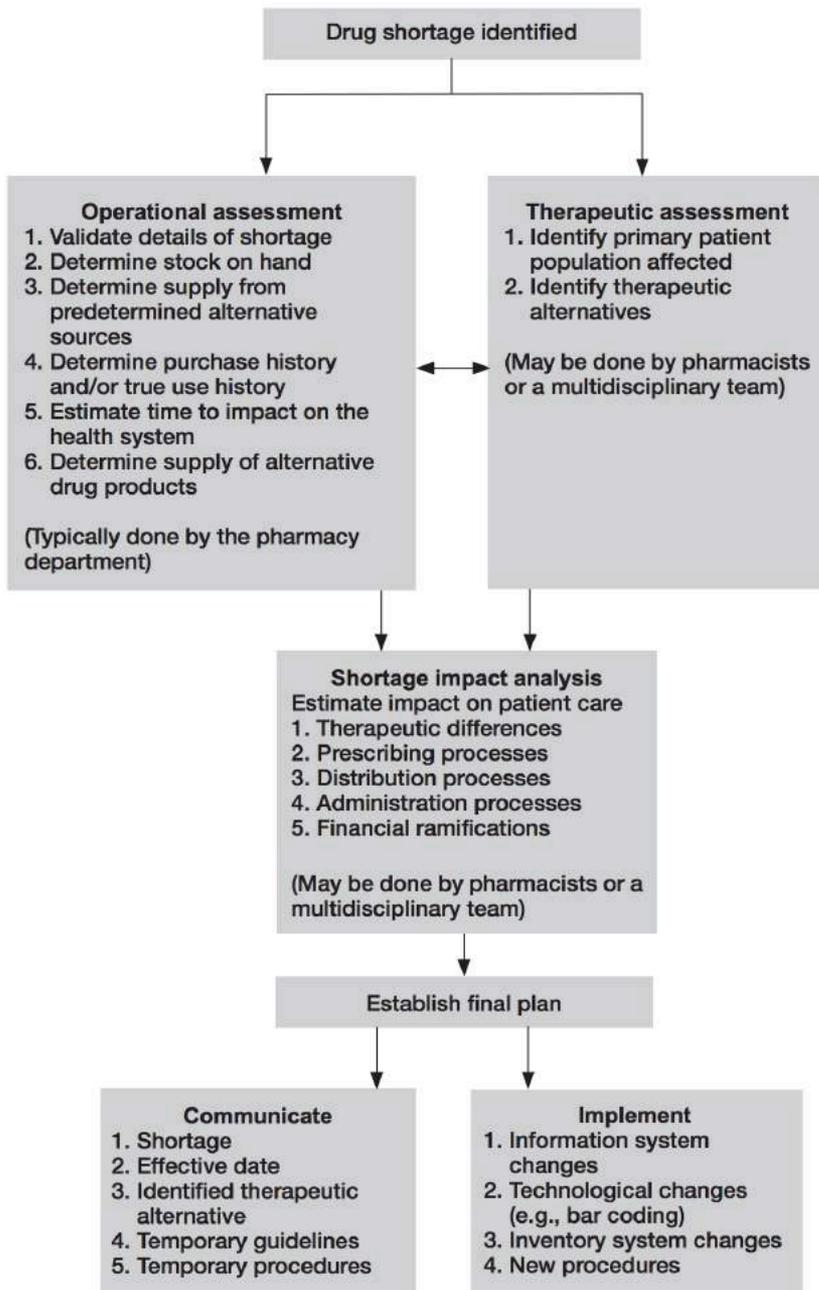
**Figure 1. Number of New and Prevented Shortages by Dosage Form, 2005-2012**



# Response: FDA

- **October 31, 2011, Executive Order 13588 – Reducing Prescription Drug Shortages**<sup>10</sup>: acknowledged the need for a “multifaceted approach” to address the many different factors that contribute to drug shortages, and, among other things, directed FDA to “[u]se all appropriate administrative tools” to require drug manufacturers to provide advance notice of manufacturing discontinuances that could lead to shortages.<sup>11</sup>
- **December 19, 2011, Interim Final Rule (IFR)**<sup>12</sup>: published in response to the Executive Order, the IFR amended FDA’s regulations related to early notification to improve the likelihood of FDA receiving advance notification of a potential drug shortage.<sup>13</sup>
- **July 9, 2012, FDASIA**: broadens the scope of the early notification provisions by requiring all manufacturers of certain medically important prescription drugs<sup>14</sup> (approved or unapproved) to notify FDA of a permanent discontinuance or (temporary) interruption in manufacturing. FDASIA also allows FDA to require, by regulation, early notification of discontinuances or interruptions in the manufacturing of biologics, and requires FDA to send a noncompliance letter to firms that fail to notify the Agency in accordance with FDASIA.<sup>15</sup>

**Figure 1.** Process for decision-making in the management of drug product shortages.



# What to Do?



# Take Action

- Weekly meeting or phone call with purchasing... give them a list of your “big ticket” items, ask them to make inquiries regularly.
- Internal stock may or may not reflect availability in near future.

# Take Action

- Public notifications: Email, in-person
- PO alternative? IV to PO should already be part of your ASP.
- Different formulation? Frozen vs lyophilized.
- There may be flexibility for Beyond Use Date (BUD)... d/w hospital exec team & risk mgmt.

# Take Action

- Special Pain: Diluent shortage!
- Repackage 1L NS into smaller volumes...  
huge regulatory & logistic challenges.
- Use other diluent if possible...

# Take Action

- Process and Protocol?
  - ✓ Frontline pharmacist authorized to auto-sub on the fly?
  - ✓ Need P&T blessing for long term changes?
  - ✓ When to ask for help? (Hint: TASP a great resource!)

# Resources

[www.fda.gov/Drugs/DrugSafety/DrugShortages/](http://www.fda.gov/Drugs/DrugSafety/DrugShortages/)

U.S. Department of Health and Human Services

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## Drugs

Home > Drugs > Drug Safety and Availability > Drug Shortages

### Drug Shortages

Drug Shortages: Additional News and Information

Frequently Asked Questions about Drug Shortages

### Resources for You

- Drug Shortages Infographic
- Drug Shortage Manual of Policies and Procedures (MaPP) (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

## Drug Shortages

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**Statement by FDA Commissioner Scott Gottlieb, M.D., update on recovery efforts in Puerto Rico, and continued efforts to mitigate IV saline and amino acid drug shortages**

**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 working with drug manufacturers to address critical shortages of IV fluids aggravated by Hurricane Maria's impact on Puerto Rican drug manufacturing facilities. ([Read full CDER statement](#))

### Information for You

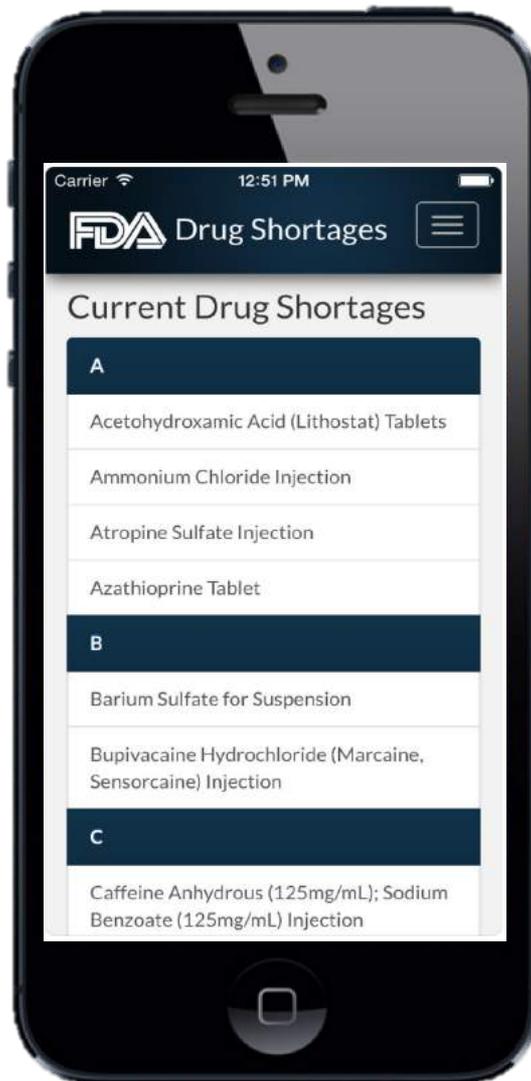
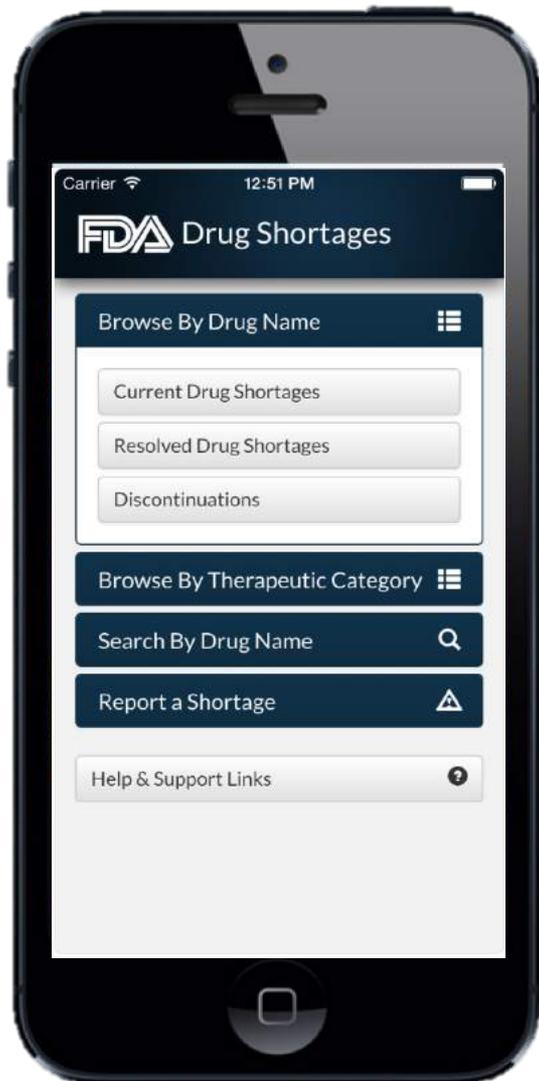
- Consumers: FDA Works to Lessen Drug Shortage Impact
- Drug Shortages: Additional News and Information

### 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 (PDF - 137KB)

# Resources

## App Store: “FDA Drug Shortages”



# Other Resources



- [ASHP Shortage Website](#)
- [ASHP Shortage Guidelines](#)
- [ASHP Small Volume Parenteral Info Sheet](#)
- [Antibacterial Shortages: CID 2015](#)

# Conclusions

## Antibiotic Shortages

- ✓ Happens frequently
- ✓ May impact patient care... and your budget
- ✓ No solution anticipated any time soon
- ✓ Be prepared!
- ✓ “Long Emergency...” Stamina may be required
- ✓ We are all in this together....

A stylized illustration of a man with short brown hair, a nose, and a slight smile, wearing a dark blue shirt. He is positioned on the left side of the slide, with a large speech bubble extending from his mouth towards the right.

Paul Pottinger MD