



# Purchasing & Forecasting: How it works

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# What is a drug shortage?



**Definition:** A period of time when the demand or projected demand for a *medically necessary* drug in the United States exceeds its supply. (national shortage)

**Audience:** Public

**Resolves:** One or more manufacturers are in production and able to meet full market demand.



**Definition:** 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.

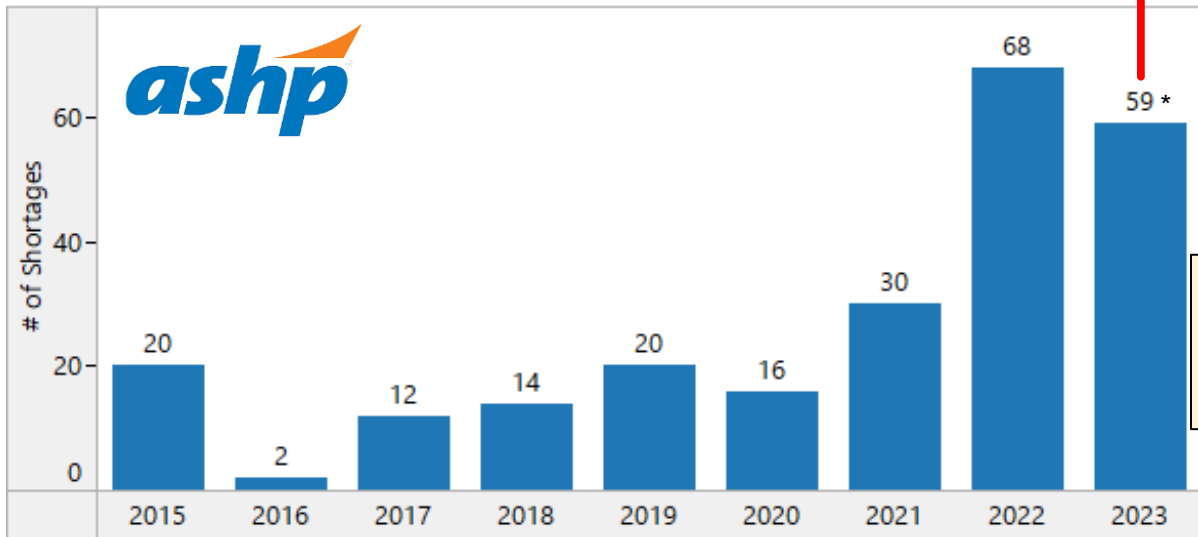
**Audience:** Healthcare Practitioners

**Resolves:** All manufacturers of the drug restore all formulations and dosage sizes to full availability.



# ASHP Current Drug Shortages

## Drugs Currently In Shortage | Date Created ASHP Drug Shortage List

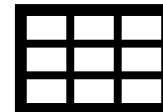


Total Current Shortages: **241**

- 2022/2023: **127** (52.7%)
- ≤ 2021: **114** (47.3%)

+ **NEW** drug shortages  
+ **EXISTING** drug shortages  
+ Staying on top of **updates**

Manually  
Tracked



\* Current as of: 06/28/2023 @ 3:30PM ET



# ASHP Drug Shortages: Last Updated

≤7-days	≤ 30-days	≤ 90-days	≤ 180-days	≤ 365-days	> 365-days
20%	41%	34%	3%	1%	0%

Generic Name	
Mycophenolate Sodium Delayed-Release ..	924
Pyridoxine Hydrochloride Injection	322
Menotropins - Follicle Stimulating Hormo..	240
Lindane 1% Shampoo	147
Neomycin Sulfate Tablets	111
Duloxetine Delayed Release Sprinkle Caps..	111
Testosterone Transdermal System	107
Flurazepam Capsules	104
Cefixime Capsules	100
Amphotericin B Lipid Complex	99

## Update Statistics:

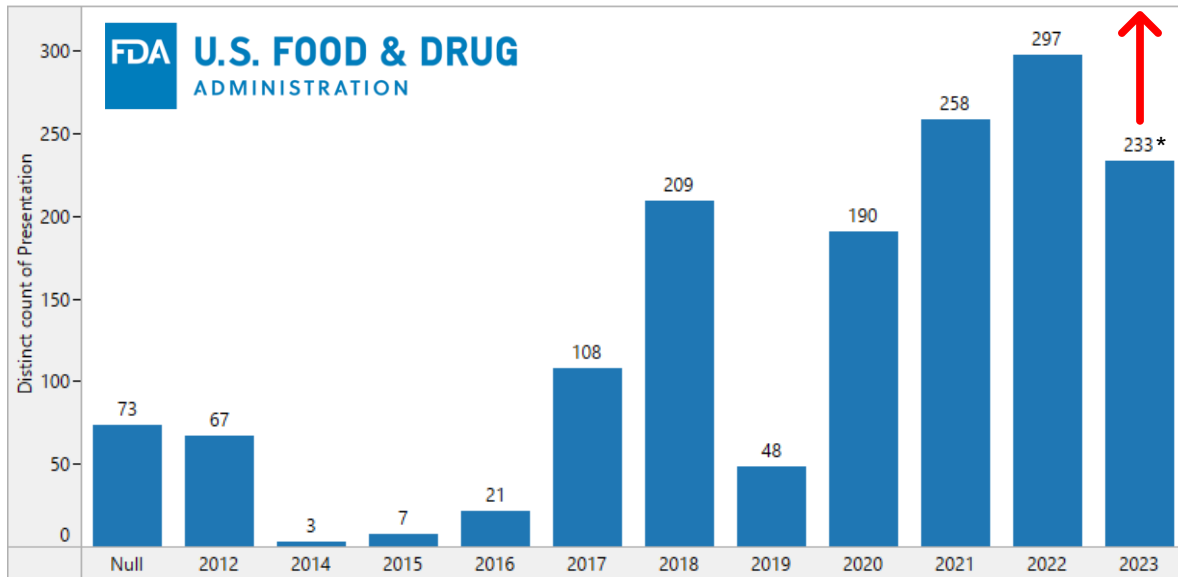
- Max: 924 days
- Average: 33.85 days
- **Median: 21 days**
- SD: 66.98 days
- Kurtosis: 132.14
- Skewness: 10.36

**Some drugs updated frequently, whereas others sit with no or very infrequent updates**



# FDA Current Drug Shortages

Drugs Currently In Shortage (NDC) | Initial Date  
FDA Drug Shortage List

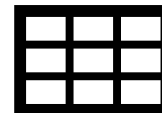


Total Current Shortages: **1519**

- 2022/2023: **530** (34.9%)
- ≤ 2021: **989** (65.1%)

+ **NEW** drug shortages  
+ **EXISTING** drug shortages  
+ Staying on top of **updates**

Manually  
Tracked



\* Current as of: 06/28/2023 @ 3:30PM ET



# FDA Drug Shortages: Last Updated

≤7-days	≤ 30-days	≤ 90-days	≤ 180-days	≤ 365-days	> 365-days
42%	22%	17%	10%	5%	4%

Presentation (NDC)	≡	
Guanfacine Tablets 2 mg, 100 Count (NDC 42806-..		855
Guanfacine Tablets 1 mg, 100 Count (NDC 42806-..		855
Chloroprocaine HCl Injection, USP 5mL ampules 5..		772
Azacitidine for Injection, 100 mg per vial (NDC 69..		750
Azacitidine for Injection, 100 mg per vial (NDC 16..		748
Rifampin Injection, 600 mg/10 mL, Lyophilized po..		736
Sincalide (Kinevac) Lyophilized Powder for Injectio..		712
Azacitidine for Injection, 100 mg single-dose vial i..		635
Azacitidine for Injection, 100 mg single-dose vial i..		635
Azacitidine for Injection, 100 mg single-dose vial i..		635

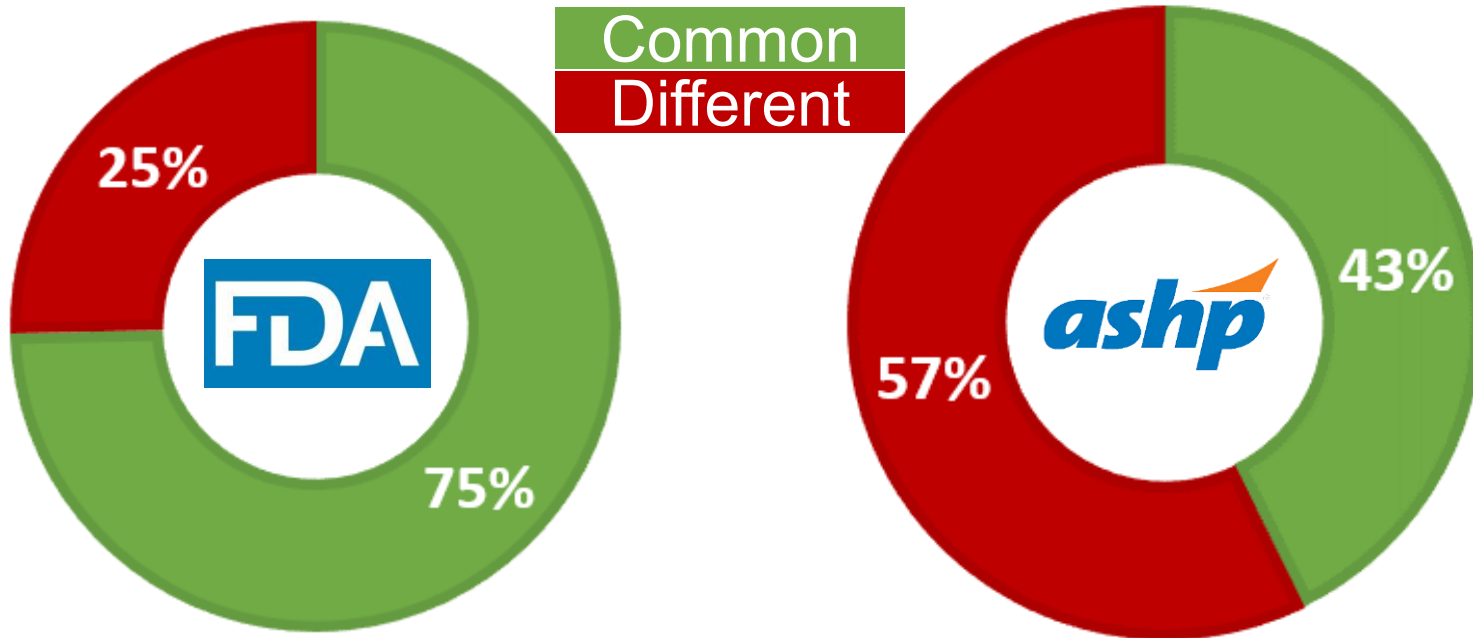
## Update Statistics:

- Max: 2.3 years
- Average: 59.6 days
- **Median: 16 days**
- SD: 119.5 days
- Kurtosis: 12.16
- Skewness: 3.33

Some drugs updated frequently, whereas others sit with no or very infrequent updates



## List Similarities and Differences



Both lists are **important**,  
serve different purposes



How to utilize both  
simultaneously?



# Drug Shortage Indications for Organizations

## CURRENT INDICATORS

- ASHP Drug Shortage list
- FDA Drug Shortage list
- Purchasing allocations
- Wholesaler availability
- Shipping delays
- Online forums
- Word-of-mouth
- Peer hospitals

## CURRENT OUTCOMES

- Manually tracked
- Time & resource intensive
- Lacks actionable insights
- **Reactive**
- Frustration





# Leveraging GPO Purchasing Data

**80%**

U.S. HOSPITALS USE PREMIER'S TECHNOLOGY AND/OR SUPPLY CHAIN SOLUTIONS



MORE THAN  
**97M**

TRANSACTIONS IN 2022



PURCHASE DATA FROM

**254** and **31,290**

HEALTH SYSTEMS

DISTINCT FACILITIES



**1,460**

SUPPLIERS WITH OVER

**3,400**

CONTRACTS, COVERING

**590+**

CATEGORIES



**27** DATA SOURCES\*

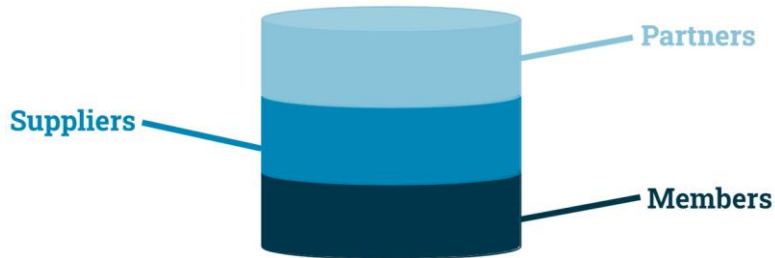


# Collaborative, Intelligent, Extensive

**GOAL:** Confront drug shortages using an **early detection system** that identifies drugs with **increased vulnerability** for *potential* supply disruption.

## CognitiveRx®

*Using artificial intelligence and machine learning, CognitiveRx® leverages market insights and actionable data to help providers reduce waste and time, proactively manage drug shortages, and optimize value.*



7 collaborative teams

12 data resources

90 million data points

>40 parameters evaluated

9,400 drugs scored for shortage risk

99.6% eligible drugs scored



# Identify drugs at risk for Shortage EARLIER

## CognitiveRx® capabilities:

- Pinpoint market signals for **early** shortage detection & management
- Offers **time & transparency**
- Plan and communicate medication strategies in advance with all caregivers to respond before impacting patient care

## PREDICT, ALERT, ACT WITH CognitiveRx®

Identifies drug shortages **early** with

**75%**

Average accuracy using the drug shortage alert model\*

\*An early detection rate (EDR) of 75% is from April 22 – April 23.

Since April 2022, the model detected

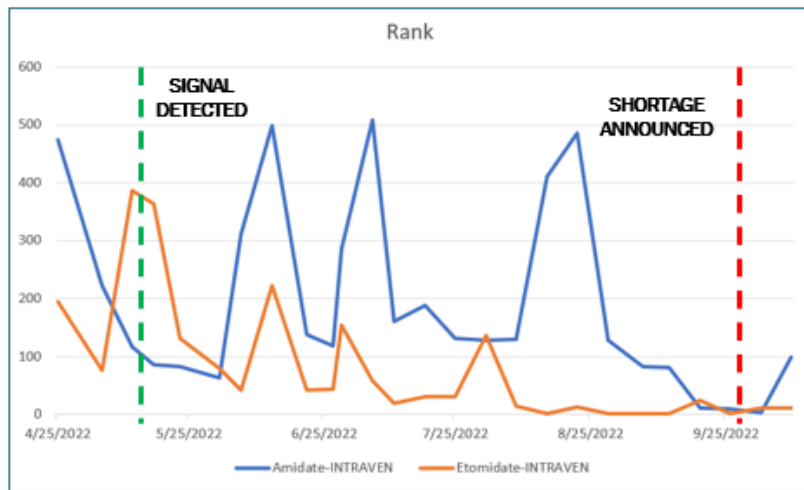
**189**

Drugs at risk for shortage with average of 128 days before an official announcement.



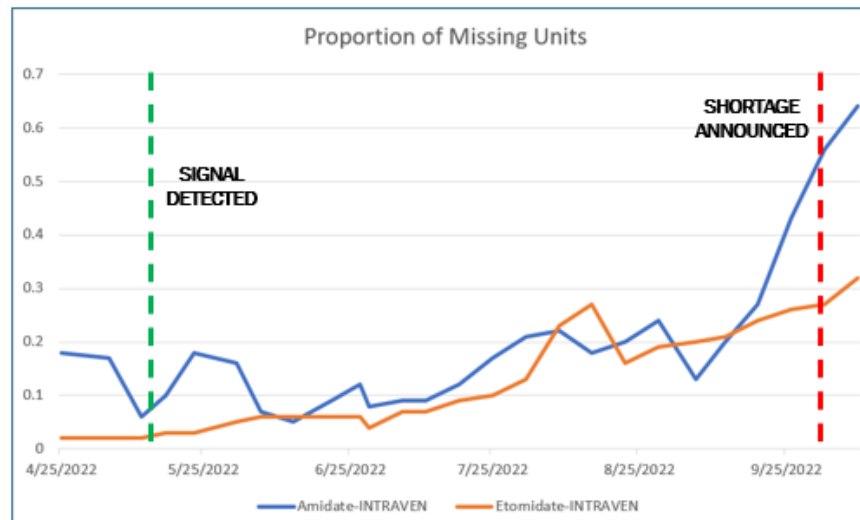
# Drug Shortage Alert - Success

Etomidate is a short-acting intravenous anesthetic used for rapid intubation.



Etomidate (generic) ranking: **#195 -> #1**  
Amidate (brand) ranking: **#474 -> #4**

**May 23, 2022: Model Signal Detection**  
**October 5, 2022: Official Shortage Announcement (ASHP/FDA)**



## Drug Shortage Alerts

- Reports
- Buy Ins ▾
- Margin
- Signals / Shortages ▴
  - National Shortages
  - My Shortages
  - Drug Shortage Alerts

- Products ▾
- Accounts
- Suppliers
- Preferences
- Support

### Phenytoin Sodium

Rank	<b>1</b>	Premier First Alert	ASHP Shortage Date	FDS Shortage Date	# of Weeks in Top 200	Reappearances in Top 200
Route	<b>Intraven</b>	<b>04/05/22</b>	<b>05/01/22</b>	<b>06/03/22</b>	<b>13 weeks</b>	<b>5</b>
Rank	<b>ASHP / FDA</b>	58 day lead time				

- Rank Over Time
- Potentially Impacted NDCs
- Generic Names
- Additional Impacted Routes
- Recommended Substitutions

#### Rank Over Time





## **Applying to 503B Outsourcing Facilities**

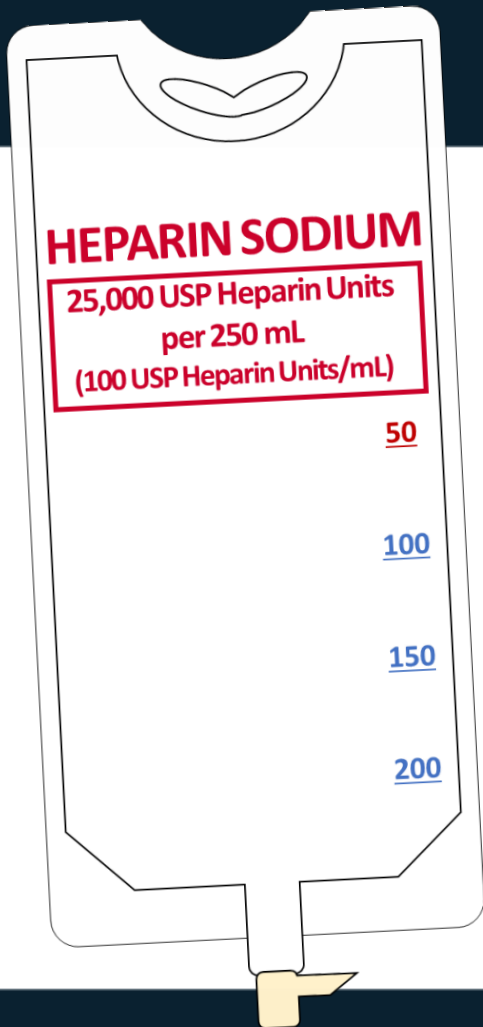


## Why do organizations outsource to 503Bs?




1. **Low Frequency** of use for certain CSPs (*difficult to maintain staff competency*)
2. **High Frequency** of use for certain CSPs (*limited staff resources available*)
3. Resolve operational inefficiencies
4. Financial and cost control
5. Conventionally manufactured products are not available, including drugs in shortage

To the **MAXIMUM EXTENT POSSIBLE**, commercially-prepared, premixed parenteral products and unit dose syringes are used *versus* manually compounded sterile products.



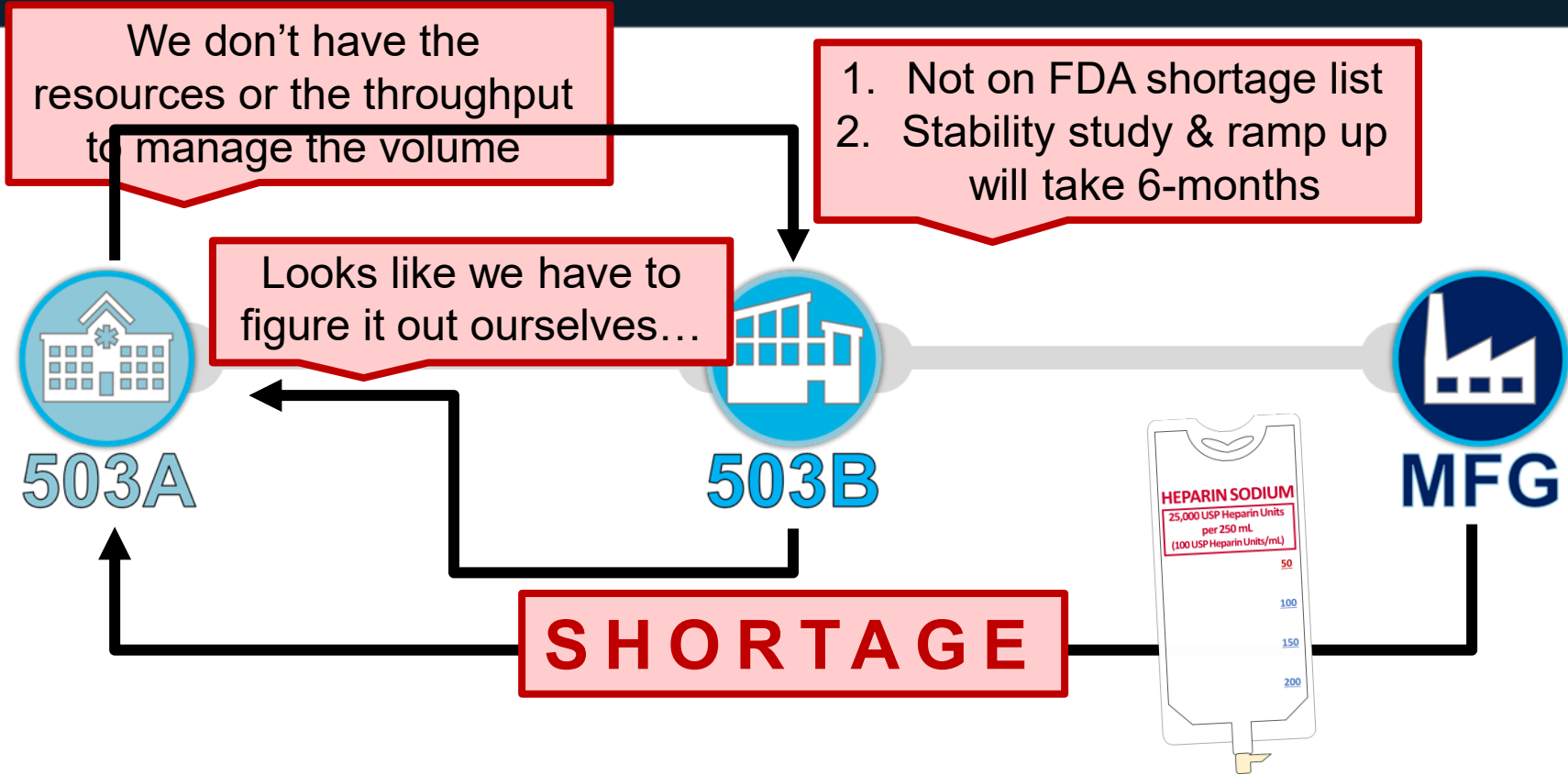
## Heparin Example

- ISMP high-alert medication
- Narrow-therapeutic index
- Rate-based dosing (need for accurate concentration)
- High volume of usage throughout hospitals & health-systems
- Commercially-available from manufacturer 





# Gaps and Challenges



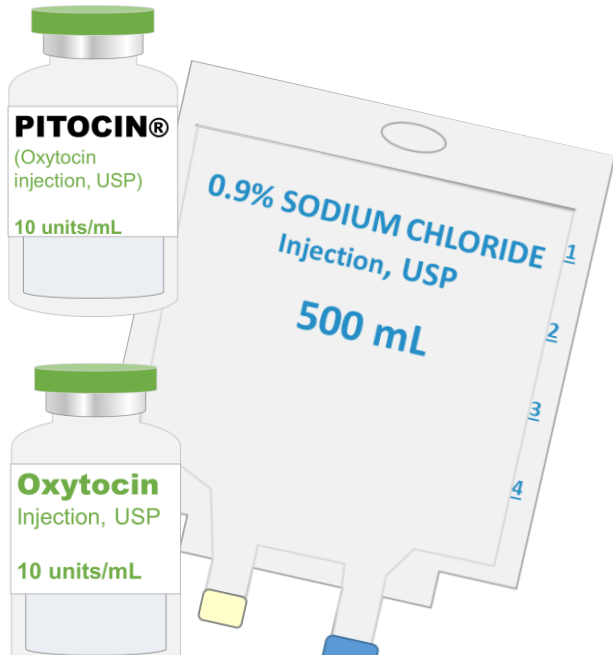


## 503B's and Drug Shortages

- **33%** of 503Bs do not produce any drug shortage products
- **25%** of 503Bs have 20% or more of their production volume for shortage drugs
- Overall trends in 503B drug shortage production:
  - 2019 (Jan-Jun): **7.6%**
  - 2019 (Jul-Dec): **8.8%**
  - 2020 (Jan-Jun): **17.3%**
  - 2020 (Jul-Dec): **15.8%**



# Example: Oxytocin Injection



**30 units/500 mL NS (0.06 units/mL)**  
*requires compounding*

	Date Disruption Signaled in Model	ASHP Shortage Date	FDA Shortage Date
Oxytocin	05-17-2022	09-13-2022 (+119 days)	09-23-2022 (+129 days)
Pitocin	06-01-2022	09-13-2022 (+104 days)	09-23-2022 (+114 days)

- Disruption signals detected **~116 days in advance** of notice
- Risk score demonstrated proper sensitivity to critical supply chain data points
- Ranking revealed deteriorating conditions prior to shortage
- Obvious trends in missing units further supported market destabilization
- Generics often found to show first signs of potential disruption over branded product



# FDA Product Report: 'who makes what'

- 503B's are required to report a list of drugs they compounded during the previous **six-month** period **twice per year**
  - By end of **June** (includes: December – May)
  - By end of **December** (includes: June – November)

**Outsourcing Facility Product Report search**

Search the Outsourcing Facility Product Report database

2023-1

Active Ingredients or establishment

Enter at least three characters

Search Clear

Finished Products ⓘ  Unfinished Products ⓘ  Compounded Products ⓘ

**NDC Compounded products search**

Search the NDC database for Compounded drug products

Select Type

Enter at least three characters

Search Clear

**Outsourcing Facility Product Report**

**National Drug Code Directory**



# FDA Product Report: 'who makes what'

The following data elements are reported to the FDA :

## Published publicly in report

- Active ingredient(s)
- Strength of each active ingredient in final product
- Dosage form
- Package description
- NDC of final product

## NOT published in public report

- Source NDC for each active ingredient
- Route of administration
- # of units produced
- Image of each product label

Active Ingredients	Active Ingredients Info	Dosage	Estab. Name	Package Description	NDC Package Code	Report Year
Lidocaine	.01 mg/1 mL	injection, solution	OLYMPIA PHARMACY(017674368)	30 MI in 1 Vial, Multi-Dose (73198-098-30)	73198-098-30	2023-1

Important data missing:  
**method** (sterile-to-sterile vs. API-to-sterile), **diluent**, **container type**, **RFID**, etc.



# FDA Product Report Analysis (2023-1)

- **Facilities:** 56 of 74 (~75%)\*
- **Total products:** 1,626
- **Total NDC's:** 1,301 (80%)
- **Sterile vs. Nonsterile:** 95% vs. 5%
- **Essentially Copies? Yes**

## Dosage Forms

Bag	34.81%
Syringe	27.55%
Vial	20.42%
Pellet	7.07%
Dropper Bottle	3.87%
Container	3.44%
Capsule	1.23%
Cartridge	1.05%
Troche	0.31%
Suppository	0.18%
Spray Bottle	0.06%

## Top 20 # Products

Fentanyl Citrate	103
Phenylephrine Hydrochloride	85
Testosterone	83
Hydromorphone Hydrochloride	70
Vancomycin Hydrochloride	52
Ketamine Hydrochloride	50
Estradiol	47
Oxytocin	43
Lidocaine Hydrochloride	41
Morphine Sulfate	39
Succinylcholine Chloride	37
Norepinephrine Bitartrate	37
Ephedrine Sulfate	30
Phentolamine Mesylate; Alprost..	29
Midazolam Hydrochloride	28
Rocuronium Bromide	25
Fentanyl Citrate; Bupivacaine H..	24
Epinephrine	22
Methylcobalamin	18
Ropivacaine Hydrochloride	16

## Example of Potential Essentially Copies

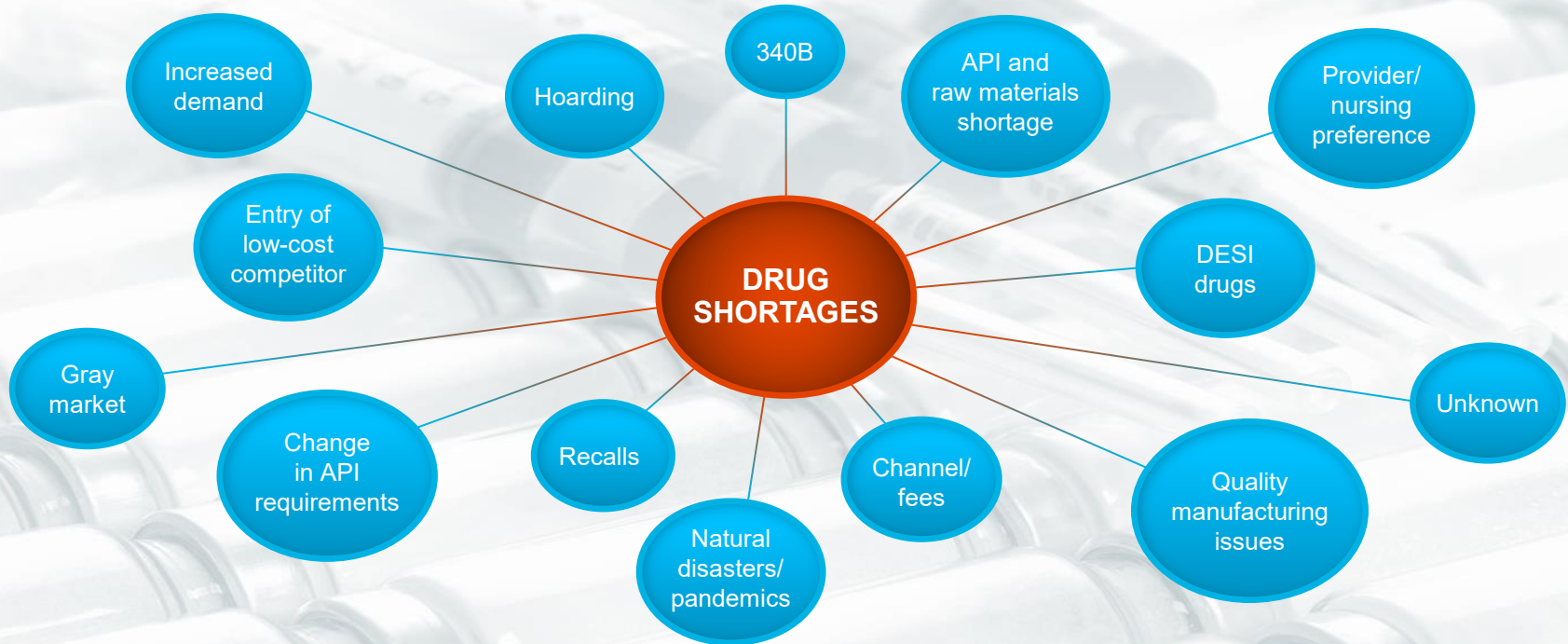
Product	# Products	# 503B Suppliers	Commercially Available?
Norepinephrine 4 mg/250 mL (16 mcg/mL) bag	17	11	Yes (x 3)
Norepinephrine 8 mg/250 mL (32 mcg/mL) bag	17	10	Yes (x 3)
Norepinephrine 16 mg/250 mL (64 mcg/mL) bag	12	7	Yes (x 2)



## **Volume Commitment Programs**



# Contributing Factors to Drug Shortages



**There is no single cause of drug shortages. Multiple contributing factors result in drug shortages.**





## Unpredictable Demand

Premier Survey to 56 generic drug manufacturers:

- **Top challenge:** unpredictable demand and volume
- **Top opportunity:** participating in supplier's committed programs

“...redundancies and raw material safety stock are key, but equally important is a steady demand signal from the market.”



# Premier's Pharmacy Drug Shortage Strategies

*Pervasive Challenges, Proven Solutions*

## Rapid Commit<sup>®</sup>

- Assists in short term market disruptions.
- Commitment is made per opportunity.
- Serviced through FFF or directly from supplier.

## ProvideGx<sup>®</sup>

- Addresses cyclical and chronic shortages.
- Long-term commitment leads to product sustainability.
- Secures product exclusively through FFF.
- 9 Key Suppliers covering 35 Key Molecules

## PremierProRx<sup>®</sup>

- Private label securing product through national wholesale channel for Premier members.
- Aids in preventing or resolving shortages for over 145 different molecules.
- Automatically substituted.



# Why ProvideGx<sup>®</sup>?

## Premier takes a *responsible and proactive* approach in managing the supply chain:

Work directly with *members* in determining realistic forecast commitments

Work directly with *suppliers* to understand member needs

Suppliers prioritize production and delivery to a secure *distribution* channel to meet known demand forecast, getting the right product to the right places at the right time.

These actions create **stability** leading to **sustainability** of products for the long term.





# ProvideGx<sup>®</sup>: A Model of Shared Commitment

BY WORKING TOGETHER, HEALTH CARE WITHOUT DRUG SHORTAGES IS POSSIBLE

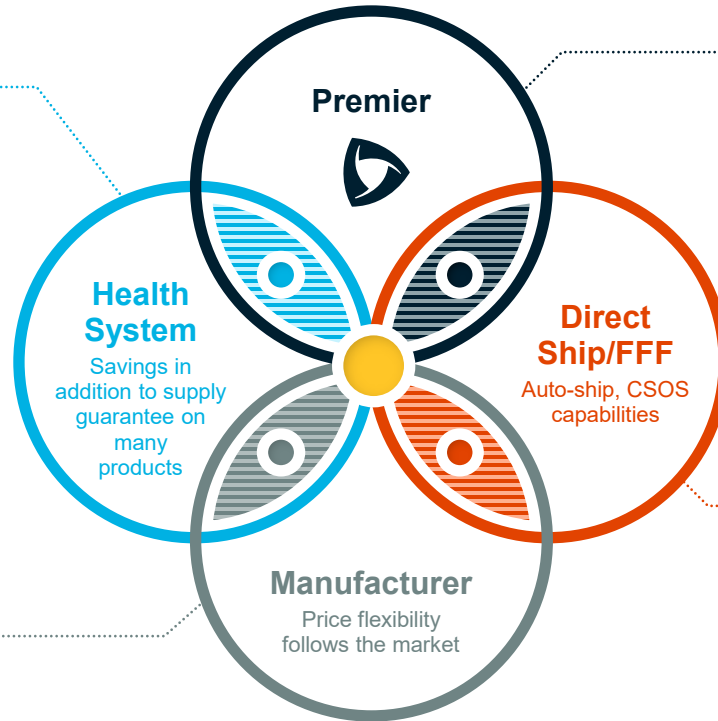


## Member's Commitment

- Letter of Commitment signed
- Forecast
- Take or pay

## Supplier Commitment

- Guarantee supply
- Safety Stock



## Premier's Commitment

- Contracting expertise
- Member/Supplier partnership
  - Advocacy



## Distributor Commitment

- Guarantee delivery
- Safety Stock



= Finding an end to drug shortages



# Success Stories

## Delivering across 9 suppliers, 35 molecules

### Emergency syringes:

During the pandemic, initial increases of 150% were satisfied.

### Bupivacaine with epinephrine:

Utilizing PGx along with PPRx distributing through FFF provided surety in supply for a market exclusive.

### Heparin bags:

National wholesale channel depleted during Q1 2022 while PGx was not.

### Diprivan® (propofol) injectable emulsion:

Long term supplier partnership to stabilize supply, vital for COVID-19 patient care.

Committed to retaining a significant strategic safety stock for Premier members.

Redundant global API sources and manufacturing locations enables ProvideGx® to deliver supply without interruption during surge demand.

“Having manufacturers come to the table in response to a steady demand signal and consistent forecast has resulted in a seamless receipt of vital medications that used to be a top-of-mind supply and safety concern.” ~ Premier PGx Member



**Thank you!**

**Kevin N. Hansen, PharmD, MS, BCSCP**

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