

Update on Drug Shortages

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FINANCIAL DISCLOSURE

- This presentation represents my own opinions.
- University of Utah Drug Information Service has a contract with Vizient (a GPO) to provide drug shortage information. No funds are paid to Erin Fox.
- Erin Fox is an unpaid volunteer member of the CivicaRx Advisory Board.
- Erin receives no financial remuneration from any ineligible company related to this presentation.

OBJECTIVES

- Describe current drug shortage trends in the United States.
- Assess the impact of drug shortages for patients and providers.
- Discuss policy options to create a more resilient medication supply chain in the United States.

SHORTAGES AND UNIVERSITY OF UTAH

- US drug shortage information since 2001 – www.ashp.org/shortages
- Investigate voluntary reports
- Confirm with drug companies
- Share information with US FDA
- Alternatives and safety recommendations



Current Drug Shortages

[VIEW RELATED LINKS](#) ↓

Drug Shortages and Management

WHAT IS A DRUG SHORTAGE?

- “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.”

AJHP American Journal of
Health-System Pharmacy™

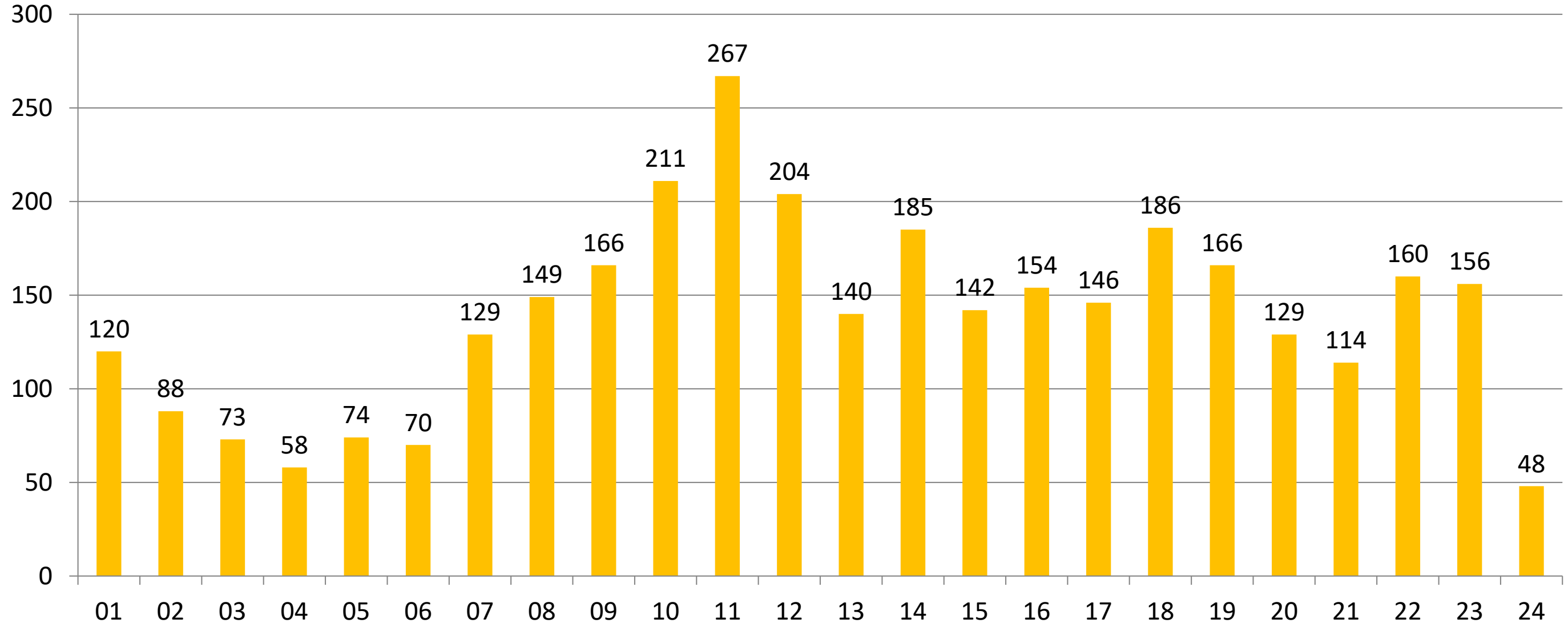
**ASHP guidelines on managing drug product
shortages**

<https://doi.org/10.2146/ajhp180441>

MOST COMMON SITUATION SOME PRODUCT IS AVAILABLE BUT...

- It's a different strength
- It's in different packaging
- It's a different size
- It's from a different manufacturer
- It's not enough!

NATIONAL DRUG SHORTAGES - NEW SHORTAGES BY YEAR JANUARY 2001 THROUGH MARCH 2024

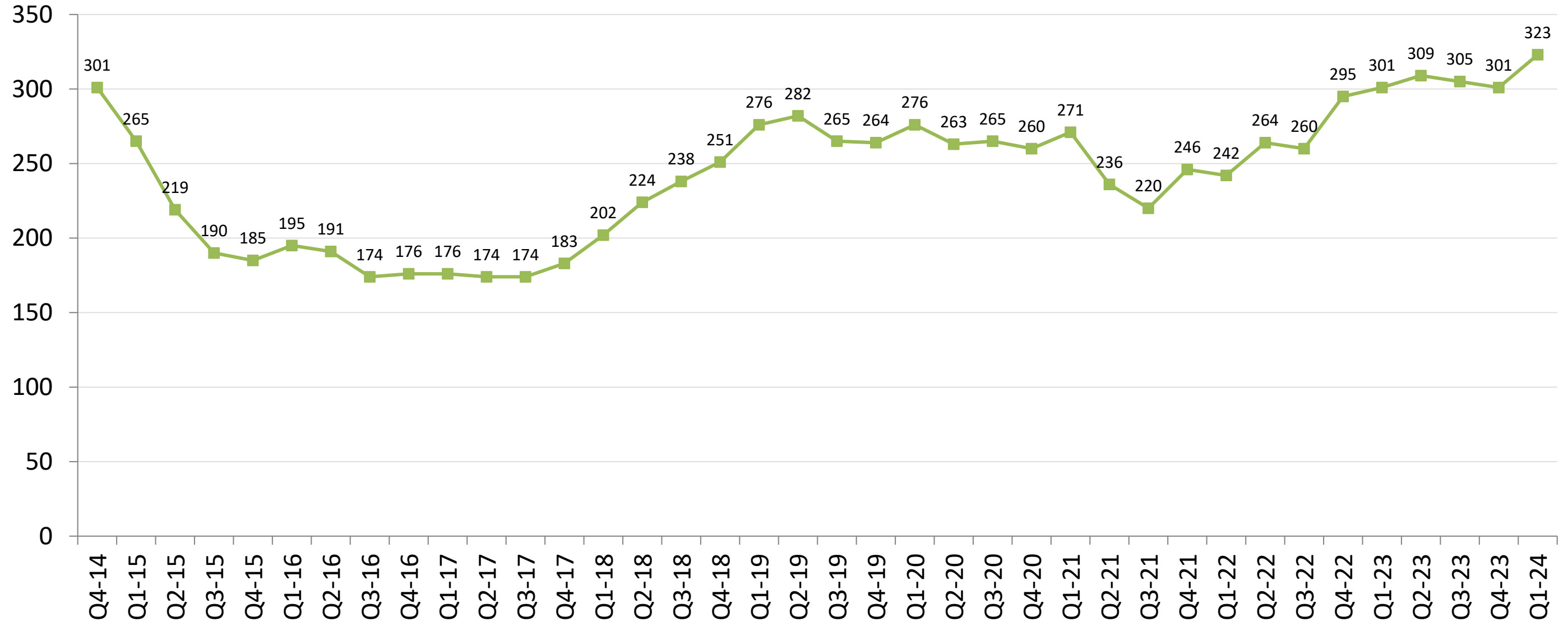


Note: Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

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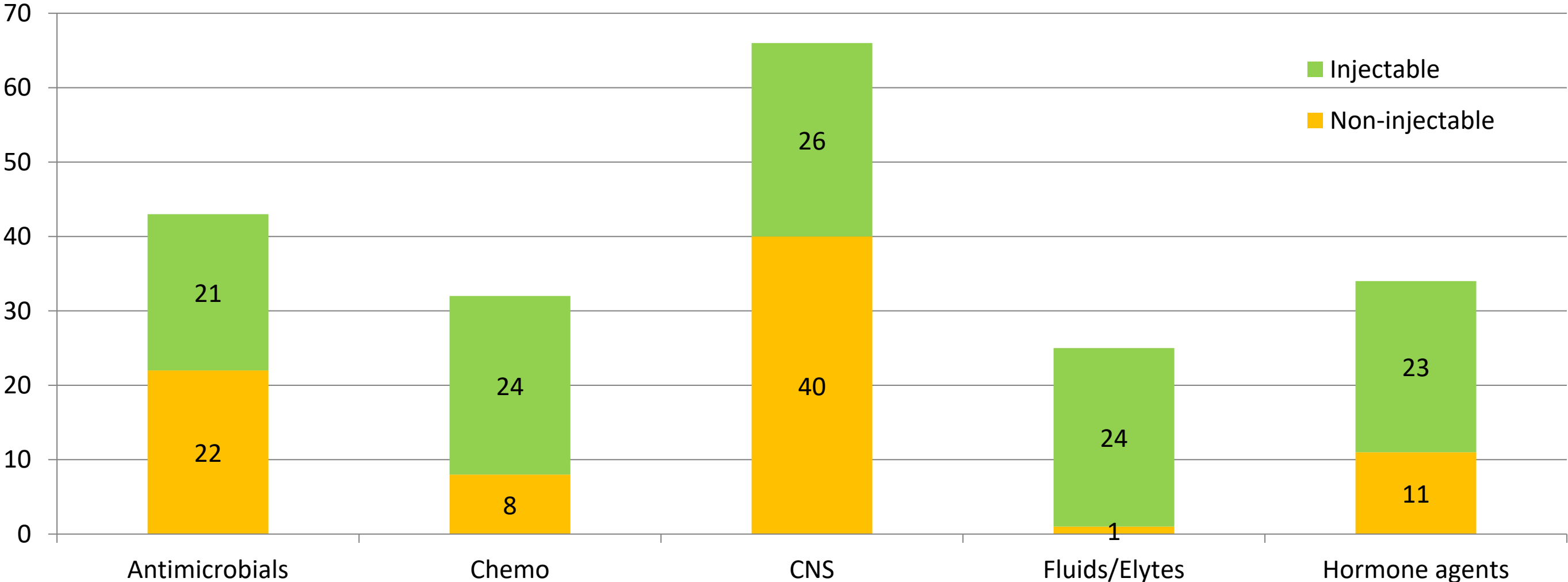
NATIONAL DRUG SHORTAGES – ACTIVE SHORTAGES BY QUARTER – 10 YEAR TREND



Note: Each point represents the number of active shortages at the end of each quarter. University of Utah Drug Information Service
Erin.Fox@hsc.utah.edu, @foxerinr

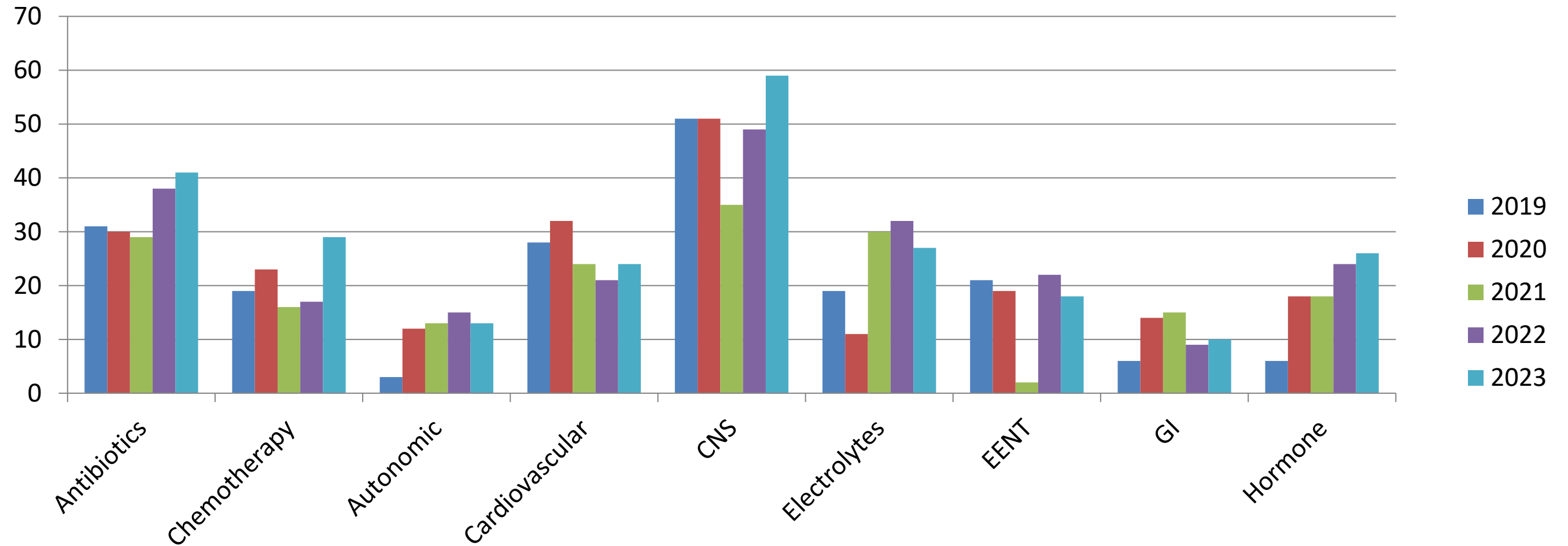
NATIONAL DRUG SHORTAGES – TOP 5 DRUG CLASSES

Active Shortages March 31, 2024

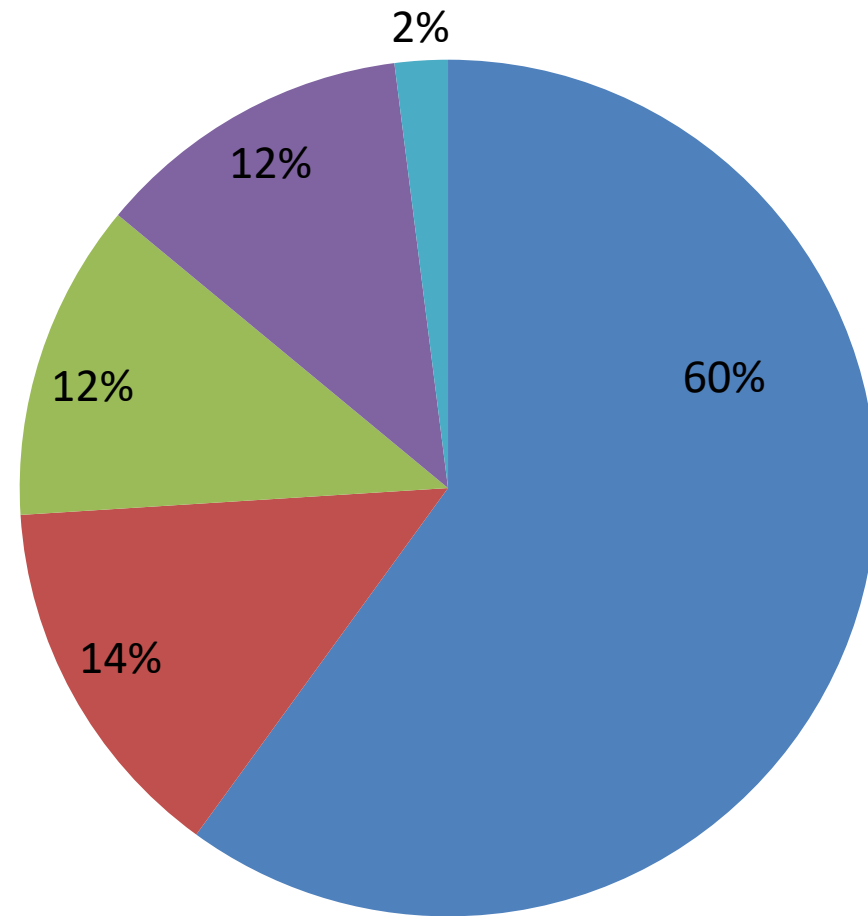


University of Utah Drug Information Service Erin.Fox@hsc.utah.edu, @foxeinr
Green = injectable, yellow = non-injectable

COMMON DRUG CLASSES IN SHORT SUPPLY – 5 YEAR TREND



2023



- Unknown / Would not provide
- Supply/Demand
- Manufacturing
- Business decision
- Raw material issue

WHY?

- Most shortages are generic, injectable
 - Inexpensive
 - Market does not recognize or reward quality
 - Regulatory hurdles to entry

Clinical Pharmacology
& Therapeutics

Review | Full Access

The Drug Shortage Era: A Scoping Review of the Literature 2001–2019

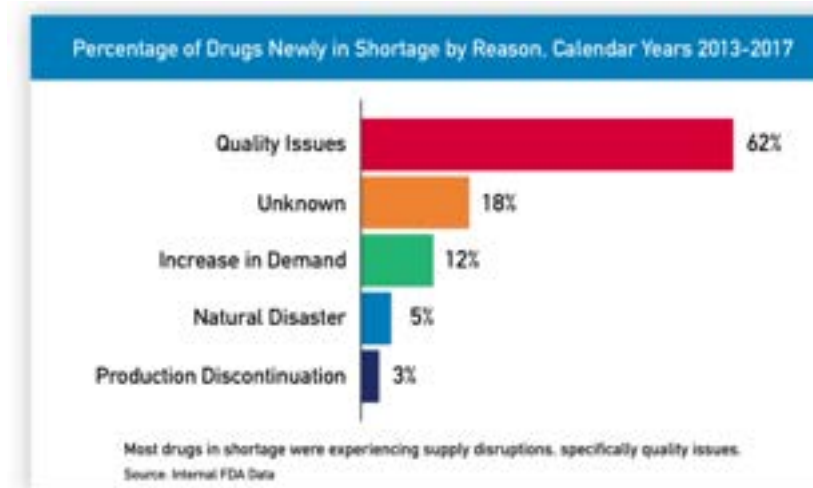
Emily L. Tucker, Yizhou Cao, Erin R. Fox, Burgunda V. Sweet

<https://doi.org/10.1002/cpt.1934>

- Most shortages are due to quality issues

Report | Drug Shortages: Root Causes and Potential Solutions

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<https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions>

WHAT ABOUT DEMAND SPIKES?

- 2020 COVID – ventilator medications
- 2023 shortages due to demand spikes
 - Semaglutide (aka TikTok shortage)
 - Children’s liquid formulations (acetaminophen, amoxicillin, ibuprofen, oseltamivir)
 - Adderall and ADHD meds
- Drug companies don’t have to report demand spikes to FDA
- Difficult to mitigate once shortage is ongoing
- Companies may not view as a shortage when producing to amount contracted

WHAT ABOUT DEA QUOTA?

- DEA changed their quota process from granting annual amounts to quarterly amounts
 - Goal? Help with ADHD medications that have been short.
 - Change made in November for a January implementation
- Unintended consequence...
 - Creating shortages of injectable products
 - Injectable manufacturers provided feedback about the potential harm this change would cause to their manufacturing process

Patient and Provider Impact

WHAT HAPPENS DURING A SHORTAGE?

- Pharmacy treats as emergency
 - How much do we have?
 - How long will it last?
 - Can we make it last longer?
 - What else can
- Pharmacists + Physicians work together
 - Identify alternatives
 - Prioritize patients or ration care
 - we buy?
- Risks
 - Medication errors
 - Delayed care
 - Patient harm

STRATEGY

- Customize – what type of shortage?
 - Some drug available
 - Ration vs. use until gone
 - No drug available, use alternatives
 - No drug available, no alternatives
 - Postpone therapy vs. no therapy
- Must customize for acuity / impact
 - (IV fluids vs. chemotherapy vs. vaccine)

IMPLEMENT A PLAN TO MITIGATE HARM

- Challenges
 - Automation requires the use of the **same** product **all** of the time
 - Electronic health record changes (time)
 - Clinically equivalent products are not always seen by technology or insurers as equal
 - Staffing
 - Extraordinary waste of time
 - >\$300M/year on labor alone

INCREASED LABOR

- Can lose entire supply with a single recall
- Laborious electronic health record changes
 - Switching to IV push required review and changes to 700 plans
- Vizient survey data
 - \$360 million annually
 - 8.6 M hours



Photo credit: Erin Fox

<https://www.modernhealthcare.com/finance/drug-shortages-drain-least-359m-health-systems>



Notes from the Field: Zinc Deficiency Dermatitis in Cholestatic Extremely Premature Infants After a Nationwide Shortage of Injectable Zinc – Washington, DC, December 2012

- Key supplier received a warning letter for poor quality
- Severe shortage results in patient harm



RATIONING

Vincristine- 2019

- Teva (3% market share) discontinued July 2019
- Pfizer (97% market) quality control issue – needed to investigate
- No “safety stock,” no back up plan, just a halt with poor communication

The New York Times

Faced With a Drug Shortfall, Doctors Scramble to Treat Children With Cancer

A critical chemotherapy medication is in short supply, and physicians say there is no appropriate substitute.




By Roni Caryn Rabin

Oct. 14, 2019

nature reviews
clinical oncology

Comment | Published: 12 December 2019

Oncology drug shortages in the USA – business as usual

Erin R. Fox  & Yoram Unguru 

CONTAMINATED DRUG VS. HIGH BLOOD PRESSURE?

FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)

Get updates on the recalls



Search ARB Recalls List

FDA's Assessment of Currently Marketed ARBs

- 48 FDA updates (7/13/18 – 12/16/19)
- 24 suppliers (many repackagers – delayed recalls)
- 1161 recalled lots
- Shortages

Cardiovascular Drugs and Therapy (2020) 34:579–584
<https://doi.org/10.1007/s10557-020-06976-0>

EDITORIAL

Reflections of the Angiotensin Receptor Blocker Recall by the FDA and Repercussions on Healthcare

Michael Gillette¹ • Addison Taylor¹ • Djenita Butulija¹ • Himabindu Kadiyala¹ • Hani Jneid¹

Published online: 21 April 2020

TAINTED DRUGS

When Medicine Makes Patients Sicker

The Food and Drug Administration is supposed to inspect all factories, foreign and domestic, that produce drugs for the U.S. market. But a KHN review of thousands of FDA documents — inspection records, recalls, warning letters and lawsuits — reveals how drugs that are poorly manufactured or contaminated can reach consumers.

FDA advises health care professionals and patients not to use any liquid drug products manufactured by PharmaTech and distributed by Rugby Laboratories and possibly other companies

CDC lab testing detects product contamination, links products to patient infections

[8/8/2017] FDA is advising health care professionals and patients not to use any liquid product manufactured by

FDA announces Leader Brand, Major Pharmaceuticals, and Rugby Laboratories recall of all liquid products manufactured by PharmaTech due to *B. cepacia* contamination risk

Update **[8/10/2017]** FDA is announcing a voluntary recall of all liquid products manufactured by PharmaTech, and distributed by Leader Brand, Major Pharmaceuticals, and Rugby Laboratories, due to possible *Burkholderia cepacia*

FDA advises health care professionals and patients of Centurion Labs' voluntary recall of Ninjacof and Ninjacof A due to potential contamination with *B. cepacia*

Update **[8/25/2017]** FDA is advising patients to immediately stop using recalled lots of Ninjacof (Lot# 200N1601)

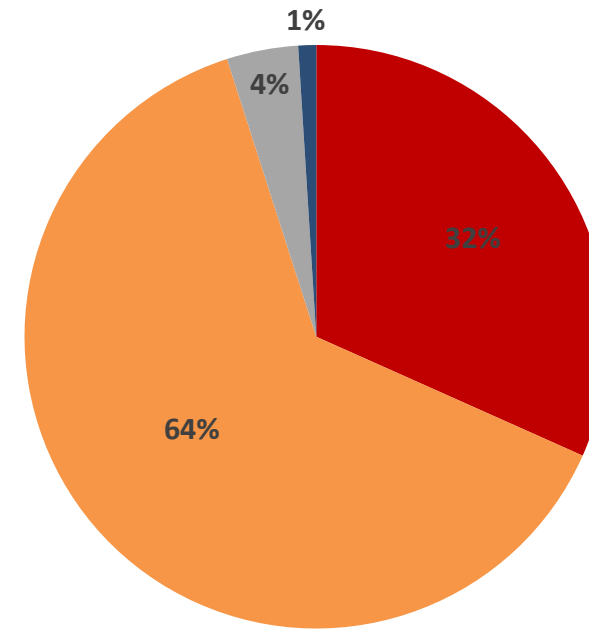
FDA advises health care professionals and patients of Mid Valley Pharmaceutical voluntary recall of Doctor Manzanilla Cough & Cold and Doctor Manzanilla Allergy & Decongestant Relief Syrup due to potential contamination with *B. cepacia*

Update **[9/1/2017]** FDA is advising patients to immediately stop using recalled lots of Doctor Manzanilla Cough & Cold (#22221701) and Doctor Manzanilla Allergy & Decongestant Relief Syrup (#22221701). See the [company's](#)

ASHP SHORTAGE SURVEY – JUNE 23 – JULY 14, 2023

Shortage Impact

- **Critical** = rationing, delaying, or canceling treatments (32%)
- **Moderate** = operational changes, but impacting patient care (63%)
- **Minimal** = operational changes, no effect to patient care (4%)



1,123 participants

- 93% pharmacists
- 88% hospitals
- 41% \geq 500 beds

<https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf>

MANAGEMENT STRATEGIES – PATIENT CARE

- Change medication to an alternative (97%)
- Implement rationing criteria (85%)
- Different dosage form (84%)
- Change order sets or protocols (75%)
- Delay or cancel treatments or procedures (42%)

<https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf>

OPERATIONAL STRATEGIES – INSIDE PHARMACY

- Purchase different concentrations or sizes (91%)
- Centralize inventory (83%)
- Change products in trays / carts (70%)
- Increase internal compounding (66%)
- Increase 503B compounding purchases (59%)

<https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf>

Fixing the Problem

CARES ACT

116TH CONGRESS
2D SESSION

S. 3548

To provide emergency assistance and health care response for individuals, families, and businesses affected by the 2020 coronavirus pandemic.

- ✓ Shortage reasons, expected duration, allow public reporting
- ✓ Sources of APIs, use of Contract Manufacturers
- ✓ Establish contingency plans during a disruption
- ✓ Incentives to produce drugs in shortage or at risk of shortage
- ✓ **HHS / DHS conduct a risk assessment of national security threats related to manufacturing, distribution of critical drugs, APIs, associated medical devices**

The Vox logo is displayed in a white, serif font on a dark blue rectangular background.

Why does the US keep running out of medicine?



America's frequent drug shortages put patients' health — and their lives at risk.

By Dylan Scott | @dylanlscott | Dec 5, 2022, 7:00am EST

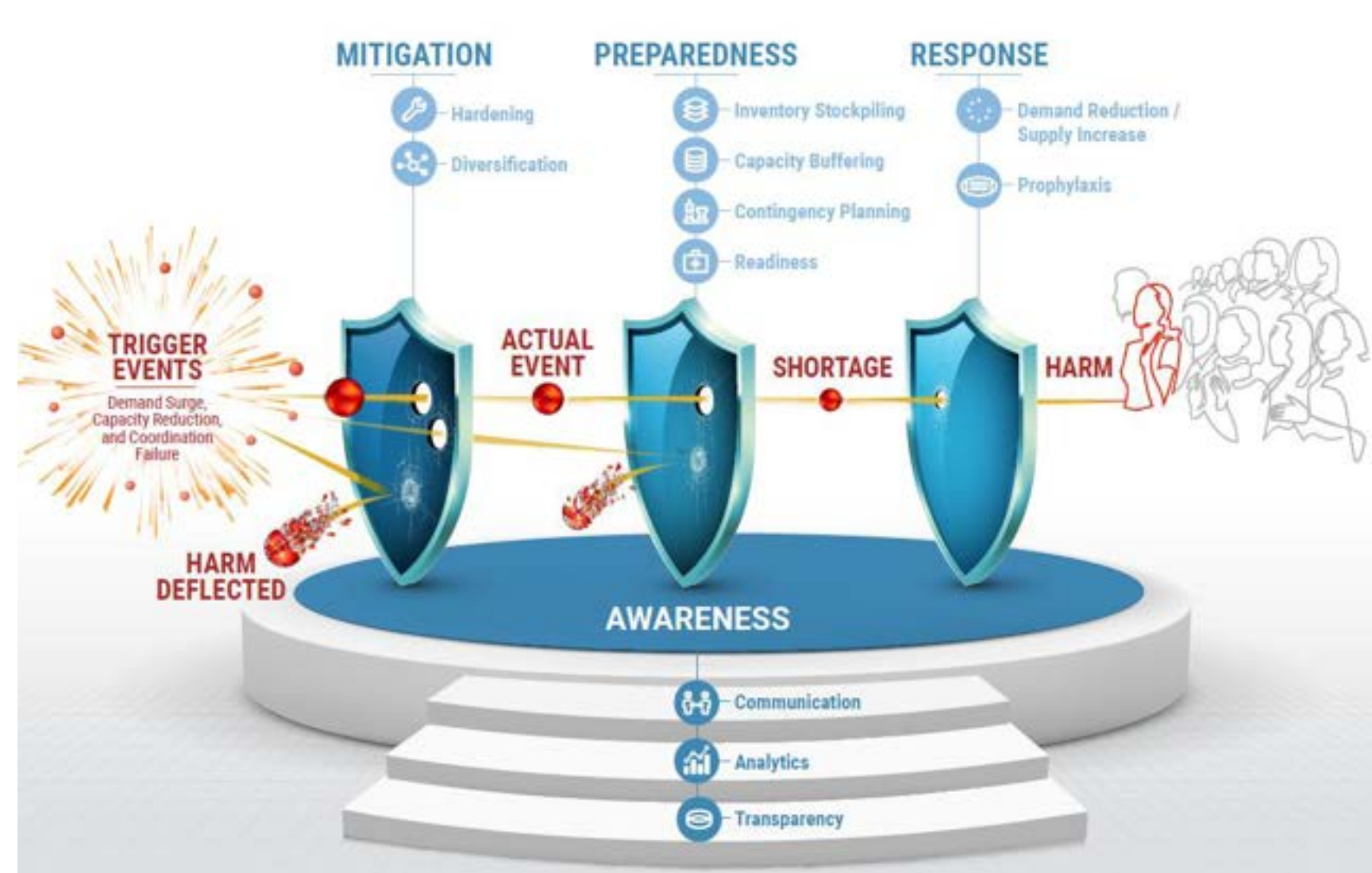
Transparency

- Government – to prioritize products or supply chains that need support
- FDA – to see demand spikes and implement prevention / mitigation measures
- Purchasers – to select vendors with high reliability and quality at low risk of shortages
- Providers – to make changes to patient care when needed

Challenge? Most information is business confidential

<https://www.vox.com/policy-and-politics/23484040/rsv-flu-amoxicillin-tamiflu-abuterol-drug-shortages>

NASEM MITIGATION FRAMEWORK



<https://www.nationalacademies.org/our-work/security-of-americas-medical-product-supply-chain>

Building Resilience Into US Prescription Drug Supply Chains

[Minje Park](#), [Rena M. Conti](#), [Marta E. Wosińska](#), [Ergun Ozlem](#), [Wallace J. Hopp](#), [Erin R. Fox](#)

JANUARY 30, 2023

10.1377/forefront.20230126.864137



<https://www.healthaffairs.org/content/forefront/building-resilience-into-us-prescription-drug-supply-chains>.

US PRESCRIPTION DRUG SUPPLY CHAINS

1. It's complicated

- More than 20K approved prescription drugs
- More than 13K facilities registered to make active ingredients or final dosage forms

2. Root causes are interconnected

- On shoring doesn't = better supply, most critical shortages are from US-based facilities

3. Societal benefits for improving resilience > private (fiduciary responsibility to shareholders)

- Drug companies lose some low cost sales
- Patient and providers lose critical or life-saving treatments

POLICY PROPOSAL – BROOKINGS INSTITUTE



- Quality ratings
- Incentives to purchase based on quality
- Domestic stockpile

<https://www.hamiltonproject.org/publication/policy-proposal/federal-policies-to-address-persistent-generic-drug-shortages/>

WHITE HOUSE / HHS PROPOSAL



OFFICE OF THE ASSISTANT SECRETARY
FOR PLANNING AND EVALUATION

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Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States

CURRENT STATE

- US buyers assume all products available on the market are equal.
- No data available beyond FDA approval to note quality or reliability.
- Suppliers do not reveal companies producing, site of manufacture, API source to single health systems.
- Name on product may not be manufacturer (CMO)
- Price is only differentiation point – higher quality is not visible or rewarded.

CALL TO ACTION - RELIABILITY

- Government – move forward with rating system identifying reliable suppliers
- Purchasers – select vendors with high reliability and quality at lower risk of shortages
- Suppliers – invest in quality and reliability
- Payers – reward use of high-quality products
- **Challenge? Who bears the cost**

CALL TO ACTION - TRANSPARENCY

- Government – prioritize support for most vulnerable products and supply chains
- Coordinating body – see demand spikes and implement prevention / mitigation measures
- Providers – exercise stewardship over supplies make changes to patient care when needed
- Distributors – ensure equitable product distribution
- **Challenge? Most information is business confidential**

SUMMARY

- The number of ongoing and active shortages is the highest – 323 – since we began tracking data in 2001. Unresolved shortages have been hovering above 300 for more than a year.
- Basic and life-saving products are in short supply including oxytocin, Rho(D) immune globulin, standard of care chemotherapy, pain and sedation medications, and ADHD medications.
- Workload required to manage shortages, including work to change pharmacy automation and electronic health records, adds to the challenges of pharmacy staff shortages.

SELECTED LINKS

- **Senate Committee on Homeland Security & Governmental Affairs (hearing and report)**
 - <https://www.hsgac.senate.gov/hearings/drug-shortage-health-and-national-security-risks-underlying-causes-and-needed-reforms/>
 - <https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf>
- **Federal Policies to Address Persistent Generic Drug Shortages**
 - <https://www.hamiltonproject.org/publication/policy-proposal/federal-policies-to-address-persistent-generic-drug-shortages/>
- **Building Resilience Into US Prescription Drug Supply Chains**
 - <https://www.healthaffairs.org/content/forefront/building-resilience-into-us-prescription-drug-supply-chains>
- **National Academies of Science, Engineering, and Medicine to examine the security of America's medical product supply chain**
 - <https://www.nationalacademies.org/our-work/security-of-americas-medical-product-supply-chain>
- **Improving the Quality and Resilience of the United States Healthcare Supply Chain**
 - <https://www.ashp.org/-/media/assets/news-and-media/docs/Healthcare-Supply-Chain-Recommendations>
- **National Strategy for a Resilient Public Health Supply Chain**
 - <https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf>
- **Essential Prescription Drugs Supply Chain and Manufacturing Resilience Assessment**
 - https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

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