



STRATEGIES TO MITIGATE MEDICATION ERRORS WITH THE UNPRECEDENTED RISE IN DRUG SHORTAGES

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SHORTAGES AND UNIVERSITY OF UTAH

WWW.ASHP.ORG/SHORTAGES



- US drug shortage information since 2001 Investigate voluntary reports
- Confirm with drug companies
- Share information with US FDA
- Alternatives and safety recommendations

Current Drug Shortages

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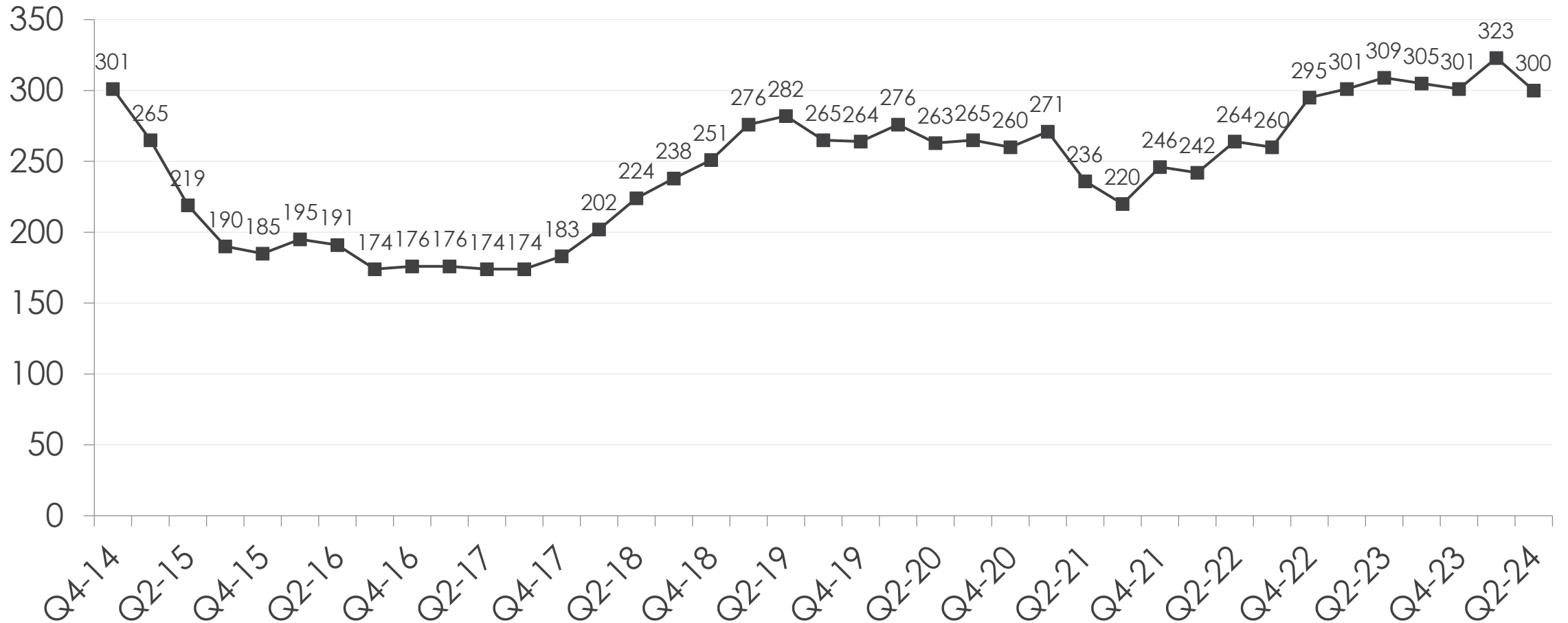
Drug Shortages and Management

“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.”

ASHP Guidelines on Managing Drug Product Shortages. <https://doi.org/10.2146/ajhp180441>

ACTIVE SHORTAGES BY QUARTER

10 YEAR TREND



Note: Each point represents the number of active shortages at the end of each quarter.
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ANESTHESIA MEDICATIONS

45 PRODUCTS ON U OF U HEALTH TRAYS

- 98% of medications in shortage between 2001 – 2024
- Average shortage duration 623 days
- 33 active shortages as of June 30, 2024
- 44 products experienced 191 shortages

Longstanding Shortage Issues

- Not 100% out, but some strength or formulation has not been available since the start date

Medication	Shortage Start Date
Vecuronium	September 16, 2008
Atropine injection	March 4, 2009
Ketorolac injection	November 11, 2009
Morphine injection	June 24, 2010
Dexamethasone	March 17, 2011
Lidocaine vials	September 7, 2011

University of Utah Drug Information Service

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!

WHY?

Most shortages are generic, injectable

- Inexpensive
- Market does not recognize or reward quality
- Regulatory hurdles to entry

Clinical Pharmacology
& Therapeutics

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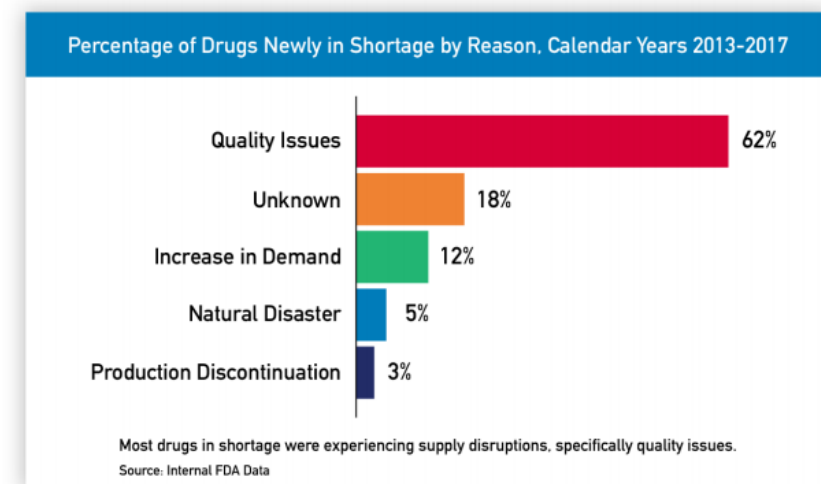
The Drug Shortage Era: A Scoping Review of the Literature 2001–2019

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

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>

CONGRESSIONAL HEARINGS / LEGISLATION



Full Committee Hearing

**Drug Shortage Health and National Security Risks:
Underlying Causes and Needed Reforms**

SHORT SUPPLY

*The Health and National Security
Risks of Drug Shortages*

HSGAC Majority Staff Report
March 2023



**Oversight And Investigations Subcommittee Hearing:
“Examining The Root Causes Of Drug Shortages: Challenges In
Pharmaceutical Drug Supply Chains”**

🕒 May 11, 2023, 8:30am MDT **PAST** 📍 2123 Rayburn House Office Building

UNITED STATES SENATE
COMMITTEE ON FINANCE

**Drug Shortages: Examining Supply Challenges, Impacts, and Policy
Solutions from a Federal Health Program Perspective**

Date: Tuesday, December 5, 2023



**Hearing on Examining Chronic Drug Shortages in the
United States**

🕒 FEBRUARY 6, 2024 — HEARING

POLICY PROPOSAL – BROOKINGS INSTITUTE



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

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

<https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/>

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**

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.



THANK YOU

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