ReVAMPing the Pharmaceutical Supply Chain

Implementing Policy to Prevent Drug Shortages

June 12, 2024



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Meeting Reminders

- Please be mindful of Duke-Margolis office space and consult front desk staff for directions.
- Though time for audience questions is limited, Zoom Q&A submissions are welcome.
- This meeting will be recorded and posted on the Duke-Margolis website.



Welcome & Introduction

Mark McClellan

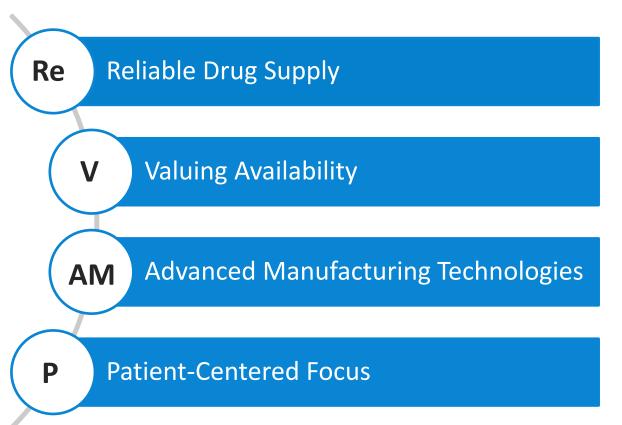
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Duke-Margolis ReVAMP Drug Supply Chain Consortium

The four tenets of the ReVAMP Consortium







Impact of Drug Shortages is Severe and Far-Reaching

Drug shortages are associated with:

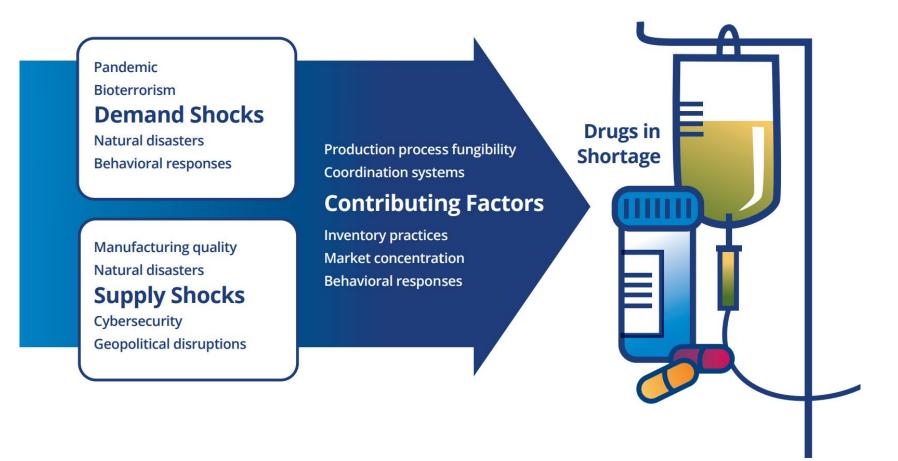
- Increased mortality rates A previous shortage of one critical care medicine was estimated to cause hundreds of excess deaths
- Rationing of treatment for cancer patients
- Medication errors
- Additional health care costs

Over **320 drugs** on the ASHP Drug Shortage List as of May 2024

1. https://www.ashp.org/drug-shortages/current-shortages/drug-shortageslist?page=CurrentShortages&loginreturnUrl=SSOCheckOnly 2. JAMA. 2017;317(14):1433-1442. doi:10.1001/jama.2017.2841



Frequent Disruptions Highlight the Need for a More Reliable Drug Supply Chain



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Manufacturing Quality Issues Drive Shortages

Over 60% of shortages are caused by quality issues

Over 65% of drugs that go into shortage have generic versions on the market

Median time since first approval for products that go into shortage is 35 years

Over half of new drug shortages in 2023 were sterile injectables, Over half of sterile injectables in shortage cost less than \$5

Key Takeaways:

- Drug shortages are largely driven by quality issues related to manufacturing of older, complex generic products such as sterile injectables.
- A lack of supply chain reliability causes significant patient impact when manufacturing quality issues and other disruptions occur.
- Health care purchasing priorities and payment models need to be addressed to resolve chronic shortages.

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- 1. FDA Drug Shortages Task Force Report, "Drug Shortages: Root Causes and Potential Solutions" (Published 2019, updated 2020)
- 2. USP Annual Drug Shortages Report: Economic factors underpin 2023 shortages, https://www.usp.org/news/us-drug-shortages-reach-decade-high-and-last-longer

Four Consortium Workstreams



- **1. Supporting a Coordinated and Sustained Federal Effort.** What federal efforts to promote supply chain reliability are ongoing, and how can they be supported, sustained, or expanded? What gaps currently exist and how can they be addressed?
- **2. Proposing Measurement and Tracking Mechanisms**. How can we assess supply chain reliability and quality and introduce more transparency to supply chains?
- **3. Exploring Policy and Practical Approaches to Improve Drug Supply Chain Reliability**. How can we leverage information on supply chains to encourage reliability and quality?
- **4. Increasing Adoption of Advanced Manufacturing Technologies.** What barriers persist that prevent greater adoption of advanced manufacturing technologies? What does success look like for advanced manufacturing? How can we get there?

Advancing Federal Coordination

Workstream 1: We proposed the establishment of a cross-cutting and coordinated federal effort to prevent drug shortages. We also provided a potential framework for how this effort can work collaboratively to develop supply chain reliability measurement and tracking mechanisms, enable well-targeted incentives that increase supply chain reliability, and take other steps.



Scan QR code to read the full paper summary.





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Workstream 2: We propose the establishment of a drug supply chain reliability program aimed at assessing the relative reliability of the manufacturers of various essential generic drugs. We also recommend the advancement of FDA's Quality Management Maturity program, focusing initially on a subset of essential, multisource generic drugs.

Supply Chain Reliability and Quality

Management Maturity Programs



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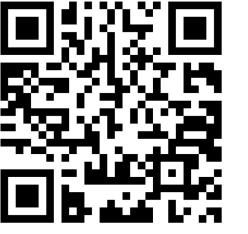


Duke December 12, 3023 Addressing Drug Shortages Through Quality Manag MARGOLIS CENTER Maturity and Supply Chain Reliab ties in the long term, and - Reduce administrative cost and burd nes effective if it permains a voluntary program rather than a mandatory program wheel backness SPAR afters del constituent to or Supply Chain Ballahilly mate but clinically related movels ed by an independent third party. As described below, establishment-level that plags into this product-level DSCR program. A DSCR program should lie set up now as a pilot program with overs and other federal agencies, to be ther a drug is safe and effective Head to Responded increations, such as increasing Carrier for h ives, price supports, Federal grants and loans, and other rty leadership of the DSCR Program car purchasers, pavers, manufacturers, and phers and decrease ad-A and others, to many cases, the involvement of independent th iny transparency and data sharing in sensitive area Eauthorize and accessigate dedicated Randow for CMM.

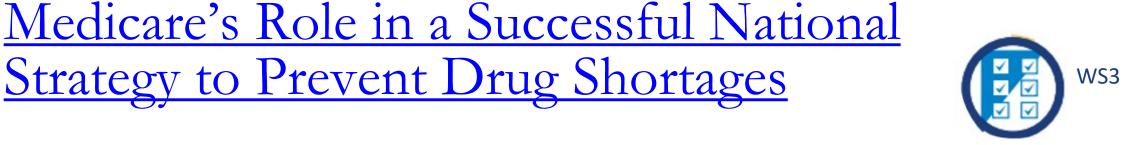
https://healthpolicy.duke.edu/publications/addressing-drug-shortages-through-quality-management-maturity-and-supply-chain

Duke | MARGOLIS INSTITUTE for Health Policy Workstream 3: We propose the establishment of a Medicare incentive payment program to cover costs to providers of shifting to more reliable drug contracting and purchasing practices, including committed contracting models and identifying and purchasing from more reliable suppliers.

Strategy to Prevent Drug Shortages



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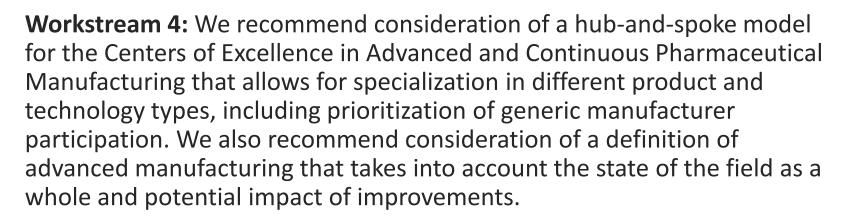


HealthAffairs	COVID-19	Topics	Journals	Forefront	Podcasts
Demand-Side Reforms To Prevent Drug					
Shortages: Medicare's Role In A					
Successful National Strategy					
Stephen Colvill, Thomas Roades, Gerrit Hamre, Marianne Hamilton Lopez, Mark B. McClellan					
JANUARY 26, 2024	10.1377/forefront.20240124.887798				

https://www.healthaffairs.org/content/forefront/demand-side-reforms-prevent-drug-shortages-medicares-role-successful-national-strategy



<u>Considerations for FDA's New Advanced</u> <u>Pharmaceutical Manufacturing Programs</u>





WS4



Scan QR code to read the full paper summary.

https://healthpolicy.duke.edu/publications/considerations-fdas-new-advanced-pharmaceuticalmanufacturing-programs



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API Innovation Center

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Eli Lilly

Genentech/Roche

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Healthcare Supply Chain Association (HSCA)

International Society for Pharmaceutical Engineering (ISPE)
Lachman Consultant Services, Inc.
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McKesson
National Institute for Pharmaceutical Technology and Education (NIPTE)
Novartis
US Pharmacopeia (USP)



Consortium Observers

ASPE | Office of the Assistant Secretary for Planning and Evaluation

ASPR | Administration for Strategic Preparedness and Response

DEA | Drug Enforcement Administration

FDA | Center for Biologics Evaluation and Research (CBER)

FDA | Center for Drug Evaluation and Research (CDER)

FDA | Office of Counterterrorism and Emerging Threats (OCET)



Opening Remarks

Christen Linke Young

Domestic Policy Council

