



ReVAMPing the Pharmaceutical Supply Chain

Implementing Policy to Prevent Drug Shortages

June 12, 2024

Duke | MARGOLIS INSTITUTE *for*
Health Policy

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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.

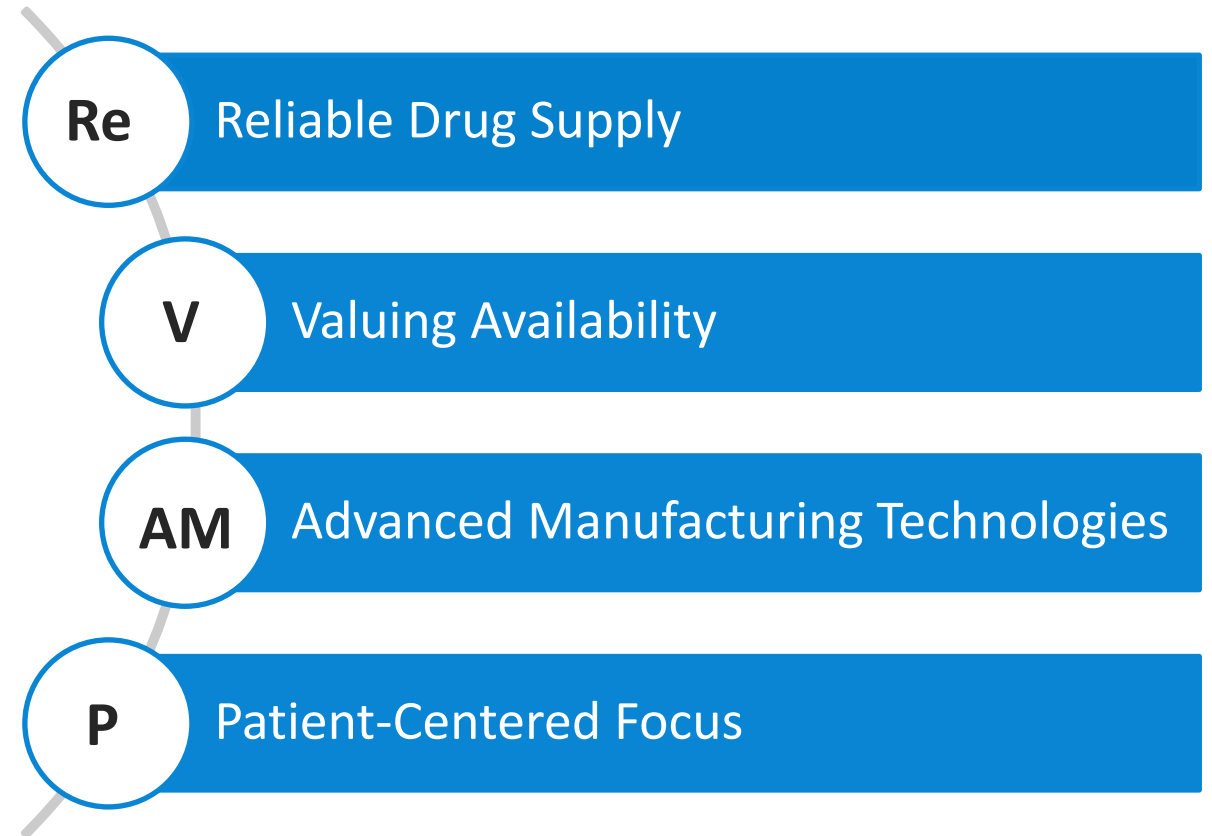
Welcome & Introduction

Mark McClellan

Duke-Margolis Institute for Health Policy

Duke-Margolis ReVAMP Drug Supply Chain Consortium

The four tenets of the
ReVAMP Consortium



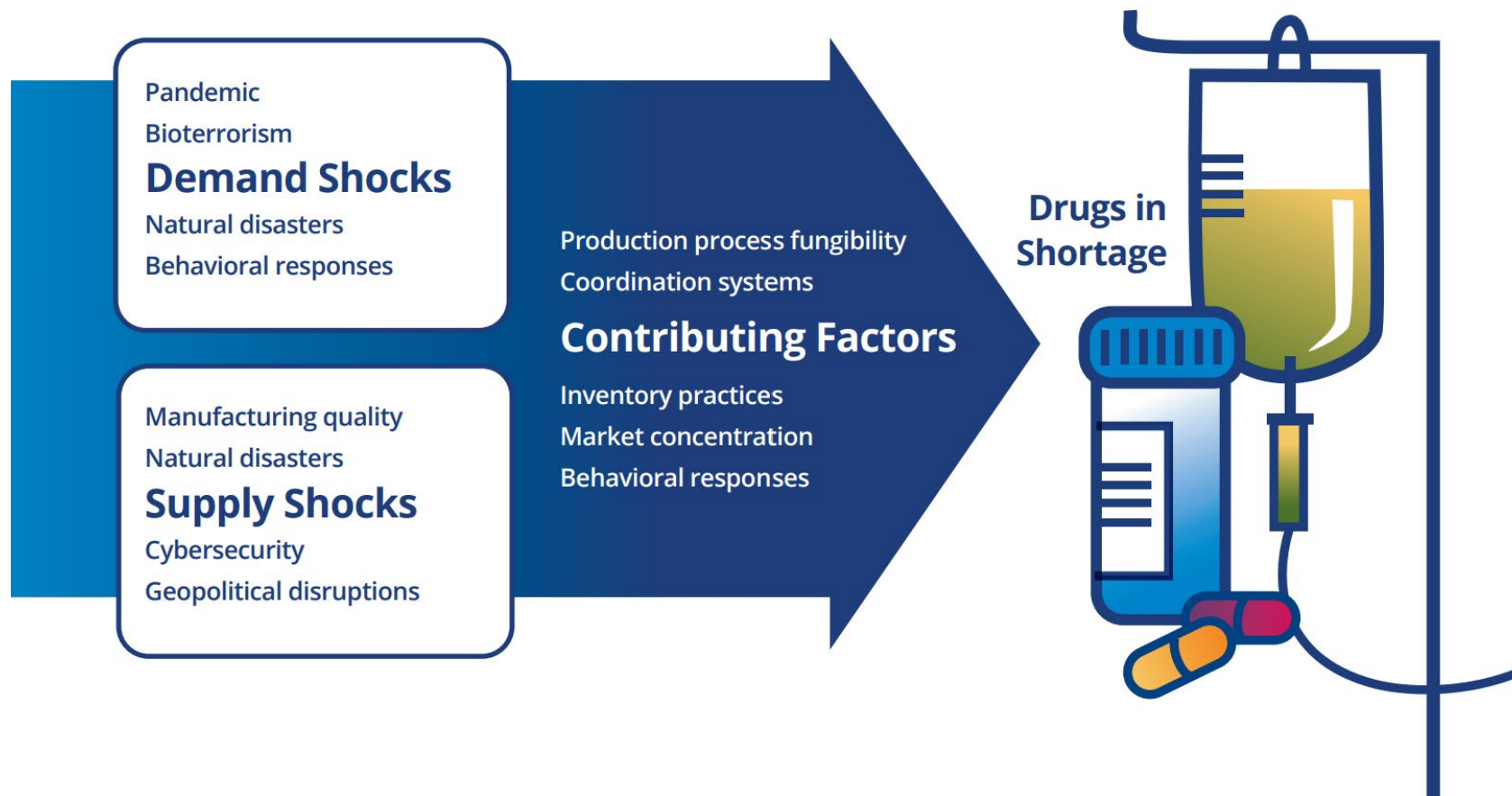
Impact of Drug Shortages is Severe and Far-Reaching

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

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



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.

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

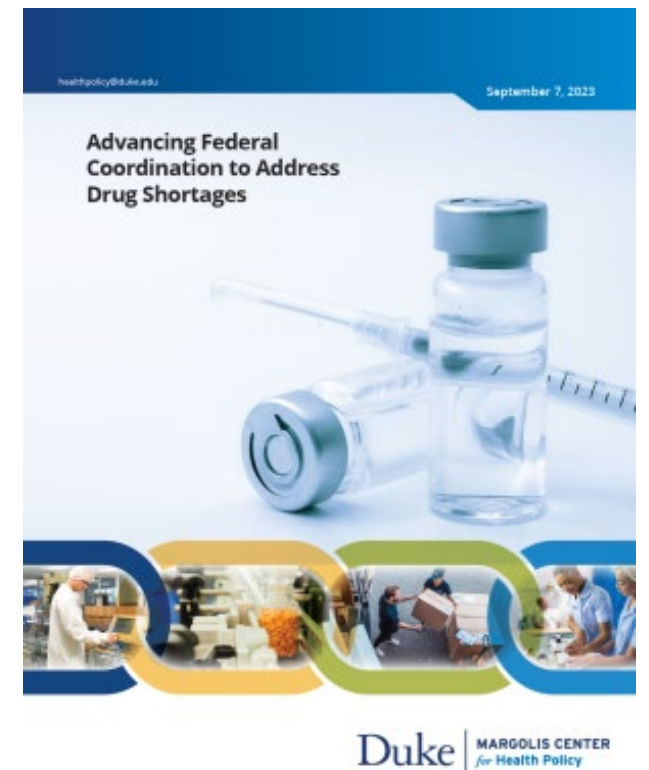


WS1

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.



Supply Chain Reliability and Quality Management Maturity Programs

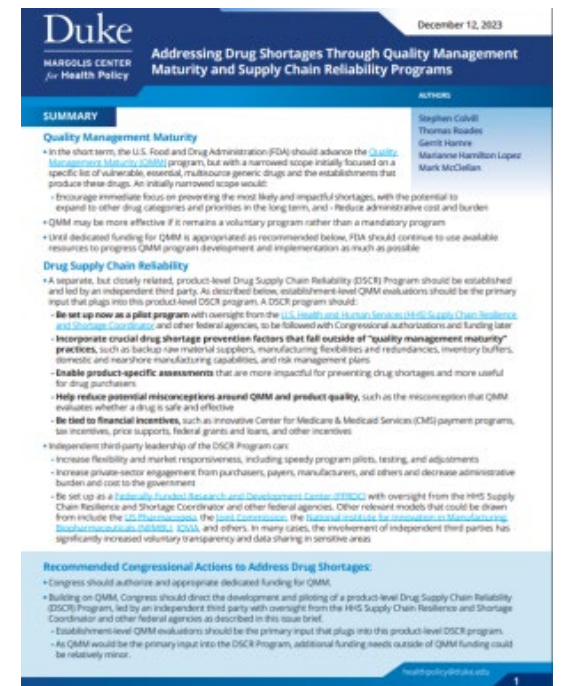


WS2

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.



Scan QR code to read the full paper summary.



Medicare's Role in a Successful National Strategy to Prevent Drug Shortages



WS3

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.



Scan QR code to read the full paper summary.



Considerations for FDA's New Advanced Pharmaceutical Manufacturing Programs



WS4

Workstream 4: We recommend consideration of a hub-and-spoke model for the Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing that allows for specialization in different product and technology types, including prioritization of generic manufacturer participation. We also recommend consideration of a definition of advanced manufacturing that takes into account the state of the field as a whole and potential impact of improvements.



Scan QR code to read
the full paper summary.



Consortium Members

AARP

API Innovation Center

Children's Hospital Association

Cencora

Eli Lilly

Genentech/Roche

Healthcare Distribution Alliance (HDA)

Healthcare Supply Chain Association (HSCA)

International Society for Pharmaceutical Engineering (ISPE)

Lachman Consultant Services, Inc.

Mayo Clinic

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