Assessing the Domestic Production of Pharmaceutical Products (DP3) for the Military Health System

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- **Conflicts of Interest:** No conflicts of interest to disclose

Agenda

- Domestic Production of Pharmaceutical Product (DP3)
  - Background
  - Project Lines of Effort
  - Current Status

Background

- The general public is impacted by the quality, safety, and availability of pharmaceutical products
- Production of most of America's generic drugs, especially the active pharmaceutical ingredients, has moved to China & India
- Concern over the quality & safety of our drug supply is growing
  - ~ 3 recalls/day in the U.S.

https://www.health.harvard.edu/blog/drug-recalls-are-common-202303292907

https://www.pharmaceuticalonline.com/doc/how-to-ensure-end-to-end-visibility-in-pharmaceutical-supply-chains-0001

Background

- Department of Defense (DoD) Instruction 4140.01 (03/06/2014)
  - Tasked the DoD with identifying, monitoring, and assessing the security and potential disruptions within and outside of the DoD supply chain to mitigate risk
    - DoW, like U.S., heavily reliant on foreign manufacturers
      - There is a need to assess quality & safety of drugs made by these manufacturers

https://www.cidrap.umn.edu/inspector-general-spotlights-dod-pharma-supply-chain-gaps

"The worst that could happen is we could have military personnel at risk from either infectious diseases or for either chemical warfare or other things and not have the supplies to have them prepared to properly do battle,"

-Stephen W. Schondelmeyer, PharmD, PhD

Congressional Appropriation

- $5M in Congressional research, development, testing & evaluation (RDT&E) FY24 funds for a “Program increase - identifying domestic ingredients for domestic production of critical pharmaceuticals identified by DLA [Defense Logistics Agency].”*
- Purpose of the appropriation:

  “[Conduct] research identifying domestic critical ingredients necessary for the domestic production of Critical Pharmaceuticals identified by the Defense Logistics Agency (DLA) in the anticipated report required under House Report 117–118 and solutions to mitigate pharmaceutical supply chain shortages.”
- Notification to USU PI: 7 May 2024

*Page 109b, Department of Defense Appropriations Act, 2024.

DP3 PROJECT LINES OF EFFORT

Project Overview

- Assessing the Domestic Production of Pharmaceutical Products for the Military Health System (DP3) is a multi-line of effort study conducted between October 2024 – September 2026.
- Results from this study are anticipated to inform policy making regarding sourcing & distribution of high-quality essential drug products for both the MHS & the Nation.

LOE 1
Quality & Supply Chain Resilience Assessment

LOE 2
Make-Buy-Invest Primers & Implementation Plan

LOE 3
Risk Assessment of Supply Chain for Controlled Substances & Evaluation of Essential Medicines List

LOE 4
Map of DOW Pharmaceutical Supply Chain Efforts

LOE 5
End to End Mapping of the Pharmaceutical Supply Chain

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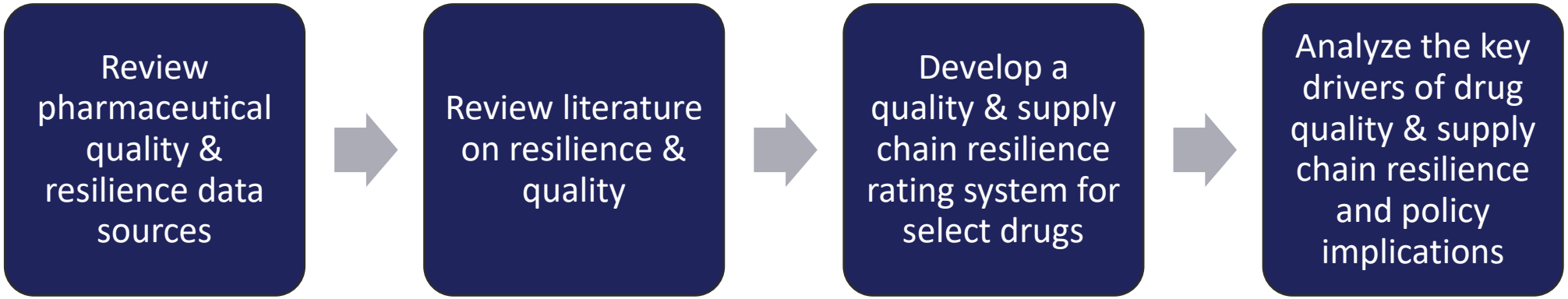
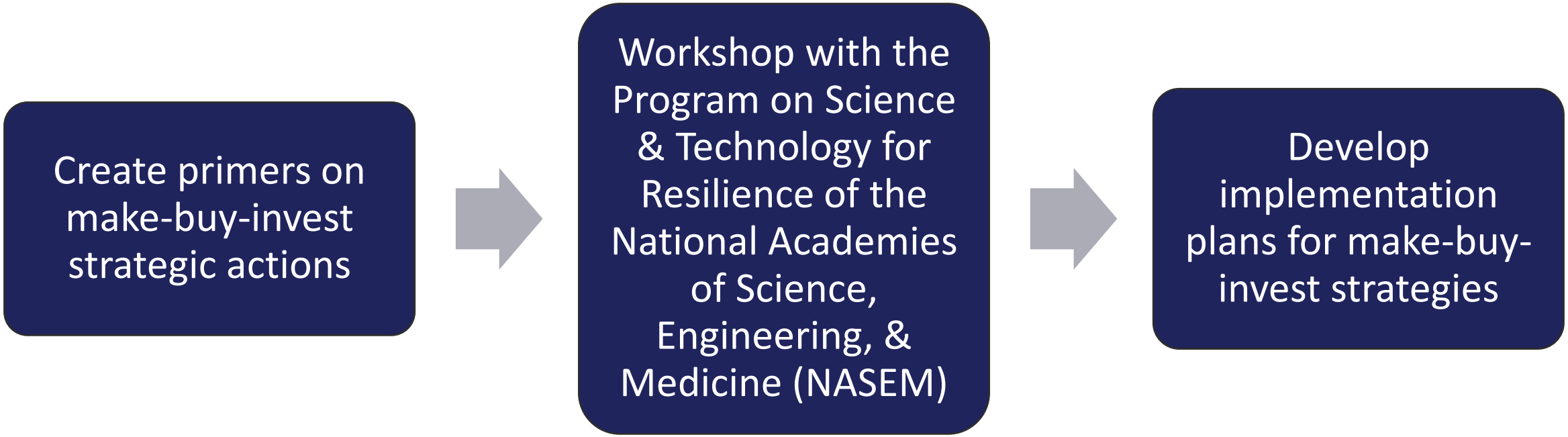
LOE 1: Quality & Supply Chain Resilience Assessment

- A comprehensive assessment of the US drug supply chain resilience & drug quality.
- Review of findings in the context of existing literature are expected to inform both military & civilian health systems.



LOE 2: Develop Make-Buy-Invest Strategy to Strengthen the US Supply Chain

- Synthesize key characteristics of drug production strategies as well as challenges & opportunities associated with the implementation of make-buy-invest strategic actions.



LOE 3: Risk Assessment for Schedule II Controlled Substance (CSII) Drug Supply Chains

Project will assess:

1. Vulnerability of CSII drug supply chains to different shocks
2. Ability of supply chains to absorb those shocks
3. The impact of Drug Enforcement Agency (DEA) regulations in supply chain resiliency

Source: Wosińska, Mattingly, Conti (2023)

Expected outputs

- Role of the DEA in CSII drug supply chain reliability
- Lessons learned from mapping upstream supply chains
- Recommendations for improving MHS CII supply chain reliability

LOE 3: Reassessing & refining essential medicine lists

Considering extensive vulnerabilities, we refine and substantiate other factors for prioritization

Criticality:
Without which drugs will individual patients suffer?

Reach:
What is the population and health system impact?

Vulnerability:
Risk for shocks of certain size, ability of supply chains to absorb

- How should we stratify critical drugs further? (e.g., needed within x amount of time)
- What is the footprint of various drugs in MHS? How does it vary by beneficiary type?
- What are the common nodes in MHS clinical care?
- What are the single or near single points of dependency in MHS clinical care?

LOE 4: Mapping of DoW Pharmaceutical Supply Efforts

- Develop a robust environmental scan & mapping of the DoW efforts to assess the domestic production of critical pharmaceutical products addressing resilience of the pharmaceutical supply chain quality, safety, & international dependence.

Example image taken from: White, H., Albers, B., Gaarder, M., Kornør, H., Littell, J., Marshall, Z., ... & Welch, V. (2020). Guidance for producing a Campbell evidence & gap map. *Campbell Systematic Reviews*, 16(4), e1125.

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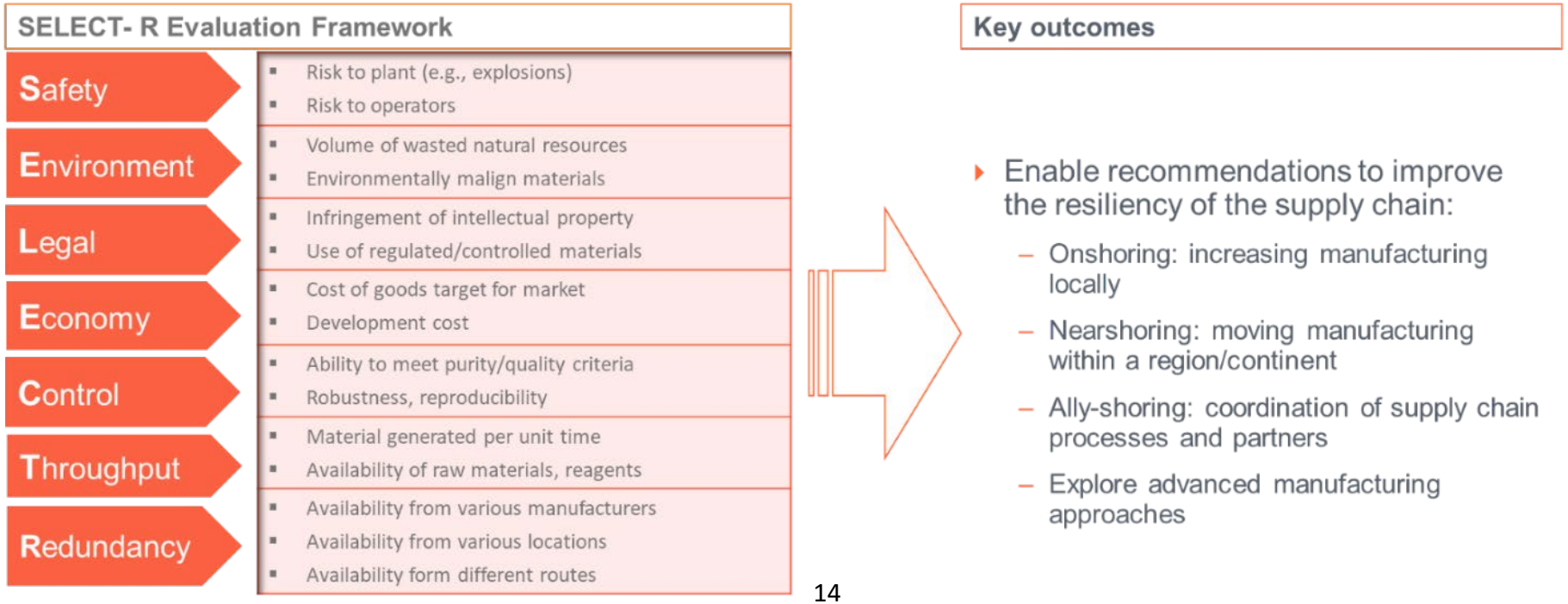
LOE 5: End to End Supply Chain Mapping & Risk Analysis

- Conduct end-to-end supply chain mapping, risk analysis, & recommendations for 25 APIs used for DoW Essential Medicines, identify KSMs, APIs, & FDF dependencies, highlight vulnerabilities through geographic-technoeconomic analysis using the SELECT-R framework, & provide actionable recommendations for building a resilient, reliable, & secure U.S. supply chain.



DP3 Lines of Effort: Status Report

- **Cross Project LOE's:**

Briefed the staff members of the Domestic Policy Council, Economic Policy Council, Office of Pandemic Preparedness and Response and other Cabinet level agencies on 17 October 2024.
Supported the White House in America First Trade Policy - Section 232 Investigation for Pharmaceuticals, Pharmaceutical Ingredients, and Derivative in April 2025.

Currently awaiting FDA data to go upstream in supply chain—project report to Congress in March 2026 in jeopardy due to issues with access to data.

- **LOE 1: Quality & Supply Chain Resilience Assessment**

Hired post-docs, linked key data from facilities to drugs. Created preliminary quality metrics. One manuscript drafted; one in planning phase

- **LOE 2: Develop Make-Buy-Invest Strategy to Strengthen the US Supply Chain**

Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center launched September 2025
Two manuscripts published, two are accepted. Publications available upon request.

- **LOE 3: Risk Assessment for Schedule II Controlled Substance (CSII) Drug Supply Chains & Reassessing and refining essential medicine lists**

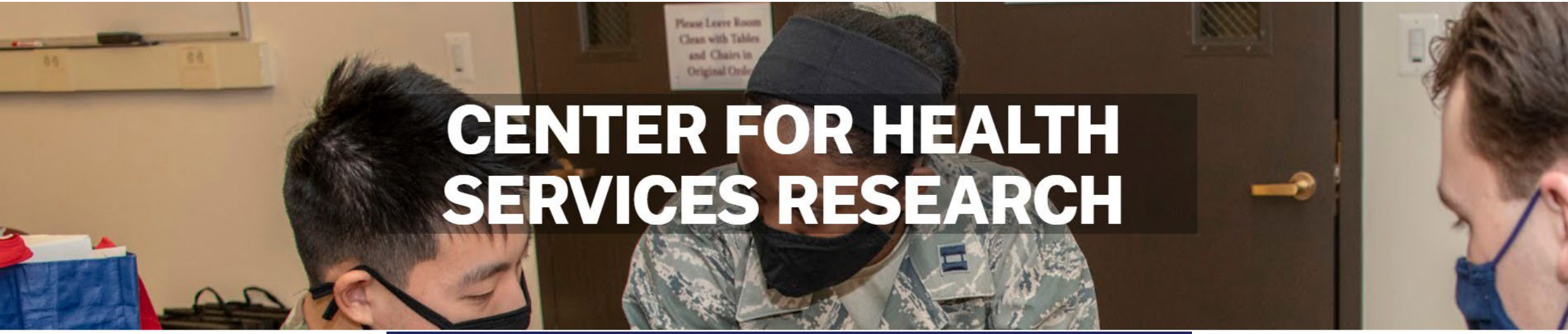
Institutional Review Board proposal approved September 2025. Three manuscripts in preparation.

- **LOE 4: Map of DoD Pharmaceutical Programs**

Institutional Review Board proposal submitted October 2025.

- **LOE 5: End to End Supply Chain Mapping & Risk Analysis**

Project initiated on 8 September 2025. Data collection for all supply chain segments is completed, & one full API report will be completed for USU/DOW review in November 2025.



Questions

For additional comments or feedback, please contact us:

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