



Improving Resiliency in the U.S. Pharmaceutical Supply Chain Through Make-Buy-Invest Strategic Actions

A Workshop

AGENDA

Day 1: October 22, 2025 | 9:00 AM – 5:30 PM ET

Day 2: October 23, 2025 | 8:30 AM – 3:30 PM ET

SPONSOR

Sponsored by Johns Hopkins University, with funding provided by the Uniformed Services University Center for Health Services Research via a grant from the U.S. Defense Health Agency, Department of War Grant #HU00012520014.

OBJECTIVES

The overall aim of this workshop is to leverage discussions and insights to support the creation of a decision framework that policymakers and stakeholders can apply across pharmaceutical drug categories and markets to determine the optimal strategic path of Make, Buy, or Invest to strengthen the U.S. prescription drug supply and safeguard national security and health.

1. **Level-set by clearly defining the systemic challenges** facing the U.S. pharmaceutical supply chain and their implications for national security and health. Review past policy proposals and industry responses and identify key barriers to implementation.
2. **Examine the critical factors** that should inform Make, Buy, or Invest strategies for different pharmaceutical markets from a national security perspective.
3. **Discuss the mechanisms** that can effectively incentivize and support strategic actions from a national security perspective.
4. **Understand how different systemic enablers** can support implementation, and **explore implementation pathways and cost trade-offs** for Make, Buy, or Invest strategies.
5. **Identify the public and private actors** who must engage in or act on Make, Buy, or Invest strategies, and highlight where leadership, coordination, and accountability are most critical.

MAKE: Refers to the domestic manufacturing capacity of pharmaceutical products, as well as key starting materials (KSMs) and active pharmaceutical ingredients (APIs). The MAKE action supports broader efforts to re-shore or expand U.S.-based supply chains, shifting manufacturing from foreign to domestic sources for the U.S. market.

BUY: Refers to the procurement of pharmaceutical products, as well as KSMs and APIs, from global or domestic suppliers with strong quality management systems and advanced or mature manufacturing capabilities that reduce the risk of disruption. The BUY action aims to minimize cost while ensuring consistent product availability, provided that associated supply chain risks are deemed acceptable.

INVEST: Refers to U.S. government's provision of financial or strategic support to expand, modernize, or secure pharmaceutical manufacturing capacity, either within the United States or through partnerships with allied nations.

DAY 1
WEDNESDAY, OCTOBER 22, 2025

Light breakfast provided at 8:30 a.m. ET

Workshop Opening and Keynote Address

9:00 AM Welcome and Opening Remarks from the Workshop Co-Chairs (10 min)

Nicolette Louissaint, *Workshop Co-Chair*
Chief Policy Officer
Healthcare Distribution Alliance (HDA)

Douglas C. Throckmorton, *Workshop Co-Chair*
Former Deputy Director of Regulatory Programs
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

9:10 AM Welcome and Opening Remarks from Johns Hopkins University Deans (5 min)

Alex Triantis
Dean
Johns Hopkins Carey Business School

Joshua Sharfstein
Vice Dean for Public Health Practice and Community Engagement
Distinguished Professor of the Practice
Johns Hopkins Bloomberg School of Public Health

9:15 AM FDA Keynote Presentation (30 min)

Martin Makary
United States Commissioner of Food and Drugs

9:45 AM Opening Presentations from the Workshop Sponsors (45 min)

John Gray
Dean's Distinguished Professor of Operations and Business Analytics
The Ohio State University

Mariana Socal
Associate Professor
Johns Hopkins Bloomberg School of Public Health

Tinglong Dai
Bernard T. Ferrari Professor of Business
Johns Hopkins University Carey Business School
Co-Chair, HBHI Workgroup on AI and Healthcare
VP – Marketing, Comms & Outreach, INFORMS

10:30 AM Break (30 min)

SESSION 1 Understanding the Problem from a National Security Perspective – The First Step Towards Make, Buy, Invest

Two separate panels will open the workshop by establishing a shared understanding of the challenges facing the U.S. pharmaceutical supply chain. Presentations/discussions will:

- *Establish a national security lens that will guide the rest of the workshop—grounded in defense readiness, disaster response, and critical care continuity.*
- *Examine past solutions have failed to scale or gain traction especially when applied in the context of national security.*
- *Ground the discussion in the human and strategic stakes: how these supply chain decisions directly impact patient care, disaster response, and mission-readiness.*

11:00 AM Supply Chain Vulnerabilities Through a National Security Lens (60 min)

- *The panel will examine pharmaceutical supply chains through a national security framework, and shift from a purely economic or public health perspective to one that includes geopolitical risks, strategic dependencies, and preparedness for disruptions (natural or man-made).*

MODERATOR

Nicolette Louissaint, Workshop Co-Chair
Chief Policy Officer
Healthcare Distribution Alliance (HDA)

PANELISTS

Natalie de Graaf
Vice President & General Manager of Data, AI, and ML Solutions
Health and National Security, API Innovation Center

Timothy Manning
Research Professor
Center for Global Health Science and Security
Georgetown University

Scott Biggs
Director of Supplier Services
IQVIA

12:00 PM Catered Lunch (60 min)

1:00 PM Disconnect Between Proposed Solutions and Action (60 min)

- *Examine why existing proposals have failed to scale or gain traction especially when applied in the context of national security.*
- *Identify persistent implementation barriers: misaligned incentives, procurement fragmentation, regulatory friction, and lack of return on resilience.*
- *Explore whether current market dynamics reward cost minimization over reliability, and whether stakeholders are willing to invest in resilience.*
- *Surface lessons from past initiatives that may inform future Make-Buy-Invest approaches.*

MODERATOR

Erin Fox, Planning Committee Member
Associate Chief Pharmacy Officer, Shared Services
University of Utah Health

PANELISTS

Diane Hustead

Chair, International Society for Pharmaceutical Engineering (ISPE) Drug Shortage Initiative Team
Executive Director, Regulatory Affairs, Merck

Marta E. Wosińska

Senior Fellow, Center on Health Policy
The Brookings Institution

SESSION 2 Make, Buy, Invest Decision Framework – Where to Intervene, and Why

In the closing two panels of Day 1, the workshop will shift toward introducing the Make-Buy-Invest strategic framework as a structured, flexible way for decisionmakers to assess market conditions and determine the most effective intervention. Presentations/discussions will:

- *Explore the criteria that could guide Make, Buy, or Invest decisions under routine and national security conditions, including: geopolitical exposure; disaster responsiveness and national security risk; clinical criticality; manufacturing complexity; market fragility; visibility into supply concentration and upstream inputs (e.g., KSMs and APIs); known regulatory and environmental constraints that may limit onshoring or domestic scale-up.*

2:00 PM Make, Buy, or Invest Criteria – Baseline Conditions (60 min)

- *Examine how manufacturers, investors, and policymakers evaluate Make/Buy/Invest decisions under normal, business-as-usual conditions—guided by market logic, regulatory feasibility, and commercial sustainability.*
- *Explore the impact of manufacturing issues on market resilience, including limited manufacturing base, geographic clustering and manufacturing complexity.*
- *Explore the impact of regulatory compliance on market resilience, including FDA requirements and environmental permitting on market resilience.*
- *Introduce how these dimensions shape commercial viability, manufacturing choices, and long-term sustainability.*
- *Consider whether manufacturing processes for APIs can be adapted to reduce environmental or human health impacts (e.g., substitution of toxic solvents, process efficiency). Evaluate how these considerations influence make/buy/invest decisions and the viability of domestic production.*

MODERATOR

Celeste Frankenfeld Lamm, Planning Committee Member

Senior Director, Quality and Regulatory CMC Policy, Merck
Co-Chair, Product Quality Lifecycle Implementation, International Society for Pharmaceutical Engineering (ISPE)
Member, DIA Annual Meeting Planning Committee

PANELISTS

Christine Baeder

President
Apotex USA

Rachel Haddock

Vice President, Medicine Development and Industrialization
GSK

Michael Ganio

Senior Director, Pharmacy Practice and Quality
American Society of Health-System Pharmacists (ASHP)

Stephen Colvill

Assistant Research Director
Duke-Margolis Institute for Health Policy

3:00 PM **Break (30 min)**

3:30 PM **Make, Buy, or Invest Criteria – National Security Perspective (90 min)**

- *Reframe Make, Buy, or Invest decisions when national security, emergency response, or geopolitical risk are at stake, and where cost-efficiency may conflict with strategic readiness.*
- *Explore how national security changes the rules—supply chain visibility, supplier allegiance, response time, risk tolerance.*
- *Continue defining the criteria that should guide Make, Buy, or Invest decisions, focusing on national security risk and emergency preparedness.*
- *Evaluate products based on their relevance to emergency response and national readiness.*
- *Discuss risks associated with reliance on non-allied suppliers or adversarial countries.*
- *Examine how limited visibility and traceability across the supply chain hinder strategic readiness.*
- *Introduce approaches to assess geopolitical exposure and sourcing fragility in the Make-Buy-Invest decision process.*

MODERATOR

Thomas Bollyky, Planning Committee Member

Bloomberg Chair in Global Health; Senior Fellow for International Economics and Law
Council on Foreign Relations (CFR)

PANELISTS

Melanie Hart

Senior Director, Global China Hub
Atlantic Council

Prashant Yadav

Senior Fellow for Global Health
Council on Foreign Relations

Timothy Manning

Research Professor
Center for Global Health Science and Security
Georgetown University

DAY 1 Closing

5:00 PM Day 1 Closing Remarks from the Workshop Co-Chairs (30 min)

Nicolette Louissaint, *Workshop Co-Chair*

Chief Policy Officer

Healthcare Distribution Alliance (HDA)

Douglas C. Throckmorton, *Workshop Co-Chair*

Former Deputy Director of Regulatory Programs

Center for Drug Evaluation and Research (CDER)

U.S. Food and Drug Administration (FDA)

5:30 PM Adjourn Day 1

*****Evening Reception Sponsored by Johns Hopkins University*****

DAY 2
THURSDAY, OCTOBER 23, 2025

Light breakfast provided at 8:00 a.m. ET

Day 2 Opening Session

8:30 AM Welcome Day 2 Remarks and Day 1 Recap from the Workshop Co-Chairs (15 min)

Nicolette Louissaint, *Workshop Co-Chair*
Chief Policy Officer
Healthcare Distribution Alliance (HDA)

Douglas C. Throckmorton, *Workshop Co-Chair*
Former Deputy Director of Regulatory Programs
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

8:45 PM Welcome Day 2 Remarks and Day 1 Recap from the Workshop Sponsors (15 min)

Mariana Socal
Associate Professor
Johns Hopkins Bloomberg School of Public Health

Tinglong Dai
Bernard T. Ferrari Professor of Business
Johns Hopkins University Carey Business School
Co-Chair, HBHI Workgroup on AI and Healthcare
VP – Marketing, Comms & Outreach, INFORMS

SESSION 3 From Strategy to Implementation – Incentives, Enablers, and Actors

In this final session, the workshop will transition from “what should be done” to “how it can get done”—mapping the mechanisms and incentives, system enablers, and actors needed to implement Make-Buy-Invest strategies effectively. Presentations/discussions will:

- *Establish a baseline understanding of existing levers and incentives and how they have historically supported supply chain resilience and examine new or adapted levers and incentives for national security readiness.*
- *Discuss specific implementation considerations from a national security perspective, including but not limited by economics/cost-effectiveness, labor and workforce readiness, and value chain transparency.*
- *Focus on the ecosystem of actors—federal agencies, state-level entities, payers, manufacturers, and procurement bodies—and clarify where leadership, coordination, and investment are most needed.*

9:00 AM Mechanism, Incentives, and System Enablers – Baseline Conditions (60 min)

- *Establish a baseline understanding of existing mechanisms, incentives, and system enablers, including strategic procurement, stockpiling authority, and public-private partnerships, and how they have historically supported pharmaceutical manufacturing and resilience.*
- *Examine traditional tools like subsidies, advance contracts, and cost-sharing.*
- *Frame this session as a foundation-setting panel: What has worked in “normal” contexts, and where do current mechanisms fall short in meeting national security demands?*

MODERATOR

Alexander Oshmyansky, *Planning Committee Member*
Co-Founder and CEO
Mark Cuban Cost Plus Drug Company, PBC
Nonresident Senior Fellow
USC Schaeffer Center for Health Policy and Economics

PANELISTS

Stephen Bozer
Senior Vice President, Human Health
Flavine

Craig Burton
Senior Vice President, Government Affairs and Policy
Fresenius Kabi USA

Fauzea Hussain
Vice President of Public Policy
McKesson

10:00 AM **Break (30 min)**

10:30 AM **Mechanism, Incentives, and System Enablers – National Security Perspective (90 min)**

- *Examine new or adapted mechanisms, incentives, and system enablers for national security readiness; what fills the gap when markets fail.*
- *Consider forward-looking approaches to sustain production of drugs critical to security when commercial ROI is weak or absent.*

MODERATOR

Chandresh Harjivan, *Planning Committee Member*
Chief Strategy Officer, Senior Advisor
Medical Countermeasures Coalition
Rios Management Consulting

PANELISTS

Daniel Singer
Former Director for Countering Biological Threats
National Security Council

Monica Gorman
Managing Director
Crowell Global Advisors

Robert Kadlec
Former Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services (HHS)

12:00 PM **Catered Lunch (60 min)**

Workshop Closing

1:00 PM Leadership Roundtable (90 min)

- *Highlight additional implementation considerations.*
- *Clarify where leadership, coordination, and investment are most needed—and what success looks like across different stakeholder perspectives.*

MODERATORS

Nicolette Louissaint, *Workshop Co-Chair*
Chief Policy Officer
Healthcare Distribution Alliance (HDA)

Douglas C. Throckmorton, *Workshop Co-Chair*
Former Deputy Director of Regulatory Programs
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

PANELISTS

Anita Patel, *Planning Committee Member*
Vice President, Pharmacy Services Development
Walgreens

Hilary Marston
Principal
Canal Row Advisors

COL Matthew Clark
Commander, Supreme Headquarters Allied Powers Europe (SHAPE) Healthcare Facility
Former Medical Portfolio Lead at Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)

2:30 PM Workshop Closing Remarks from the Workshop Sponsors (30 min)

Mariana Socal
Associate Professor
Johns Hopkins Bloomberg School of Public Health

Tinglong Dai
Bernard T. Ferrari Professor of Business
Johns Hopkins University Carey Business School
Co-Chair, HBHI Workgroup on AI and Healthcare
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3:00 PM Workshop Closing Remarks from the Workshop Co-Chairs (30 min)

Nicolette Louissaint, *Workshop Co-Chair*

Chief Policy Officer

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Former Deputy Director of Regulatory Programs

Center for Drug Evaluation and Research (CDER)

U.S. Food and Drug Administration (FDA)

3:30 PM End Workshop

****WORKSHOP ENDS****