NATIONAL ACADEMIES Sciences Engineering Medicine

A WORKSHOP

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

October 22 – 23, 2025

Washington, DC

MEETING MATERIALS

CONTENTS

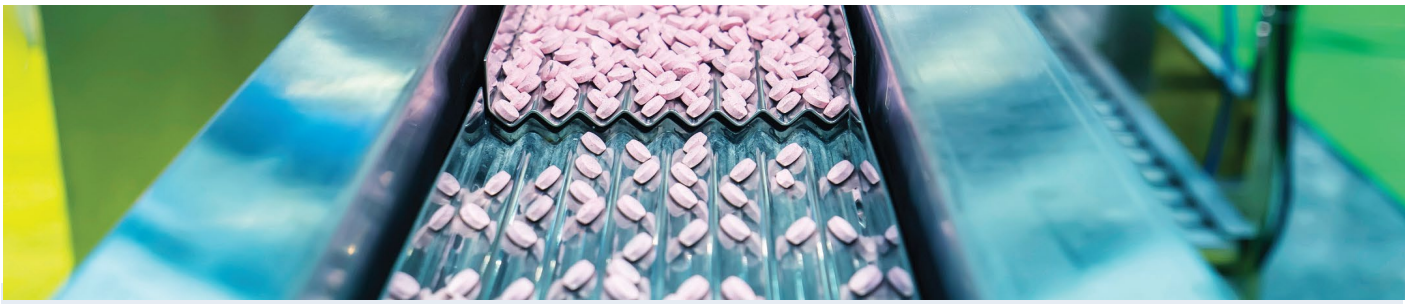
- Agenda, 1
- Workshop Fact Sheet, 11
- Planning Committee Roster, 12
- Biosketches, 13
- Meeting Resources, 29

JOHNS HOPKINS UNIVERSITY

CHSR Uniformed Services University

DEPARTMENT OF WAR · UNITED STATES OF AMERICA

NATIONAL ACADEMIES Sciences Engineering Medicine



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
VP – Marketing, Comms & Outreach, INFORMS

3:00 PM **Workshop 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)

3:30 PM **End Workshop**

****WORKSHOP ENDS****

NATIONAL ACADEMIES Sciences Engineering Medicine

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

A Workshop

A planning committee of the National Academies of Sciences, Engineering, and Medicine will convene a two-day hybrid public workshop to explore “make, buy, and invest” strategic actions to strengthen the resiliency of the U.S. pharmaceutical supply chain. “Make” strategies involve shifting pharmaceutical production to domestic manufacturers, “buy” strategies involve rewarding global manufacturers with good manufacturing practices, and “invest” strategies involve shifting pharmaceutical production from countries with higher supply chain risks to countries and regions with stronger reliability and established partnerships.

The workshop will explore the:

- identification of key drugs and markets that could benefit the most from strategic actions;
- consideration of potential opportunities and barriers; and
- essential steps for implementation of strategic actions (including core needs and associated costs).

The workshop discussions will advance understanding of the challenges and opportunities associated with make-buy-invest strategies to develop solutions to drug shortages and enhance the resilience of the US pharmaceutical supply chain against shocks and stressors from major events (i.e., health emergencies, natural disasters, conflicts) and other key global strategic concerns. A Proceedings of a Workshop—in Brief will be prepared by a designated rapporteur.

WEBPAGE
Please visit the project webpage for additional information.

SPONSOR
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.

PLANNING COMMITTEE

Nicolette Louissaint, Ph.D., M.B.A (CO-CHAIR)
Chief Policy Officer
Healthcare Distribution Alliance (HDA)

Douglas Throckmorton, M.D. (CO-CHAIR)
Former Deputy Director of Regulatory Programs
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Thomas J. Bollyky, J.D.
Bloomberg Chair in Global Health; Senior Fellow for International Economics and Law
Council on Foreign Relations (CFR)

Erin R. Fox, Pharm.D., M.H.A
Associate Chief Pharmacy Officer, Shared Services
University of Utah Health

Celeste Frankenfeld Lamm, Ph.D.
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

Chandresh Harjivan, Pharm.D., M.P.H.
Chief Strategy Officer, Senior Advisor
Medical Countermeasures Coalition
Rios Management Consulting

Alexander Oshmyansky, M.D., Ph.D. (D.Phil.)
CEO / Co-founder
Mark Cuban Cost Plus Drug Company, PBC
Nonresident Senior Fellow
USC Schaeffer Center for Health Policy and Economics

Anita Patel, Pharm.D., M.Sc.
Vice President, Pharmacy Services Development
Walgreens

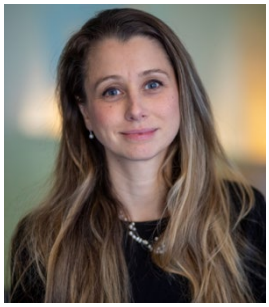
STAFF AND CONTACT INFORMATION

Lisa Brown, Senior Program Officer, lbrown@nas.edu
Lina Stankute-Alexander, Program Officer, lsalexander@nas.edu
Rayane Silva-Curran, Senior Program Assistant, rsilvcurran@nas.edu

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

A Workshop

JOHNS HOPKINS SPEAKERS BIOSKETCHES

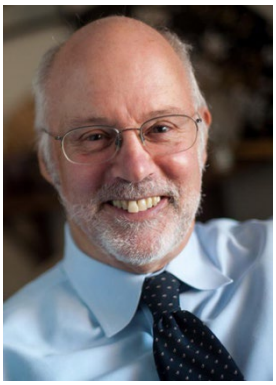


MARIANA P. SOCAL, M.D., PH.D., is the Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. Mariana Socal is an Associate Professor in the Department of Health Policy and Management, Johns Hopkins School of Public Health. Prof. Socal's research focuses on improving pharmaceutical access and affordability. Specific topics include the global pharmaceutical supply chain, gene therapies, generics and biosimilar markets, and ways to control spending without restricting access to prescription drugs. Prof. Socal has testified before the U.S. Congress on the drug pricing provisions established in the Inflation Reduction Act. Prof. Socal has also testified at the Food and Drug Administration on biopharmaceutical regulation, including insulins. Prof. Socal collaborates with state-level initiatives to increase access to prescription drugs, including the California Generic Drugs Initiative (CalRx). Prof. Socal has served as a member of the World Health Organization's Technical Advisory Group on Pricing Policies for Medicines since 2023. Prof. Socal is a physician trained in adult Neurology. She holds a Master's in Public Policy from Princeton University and a Ph.D. in Public Health/Health Systems from Johns Hopkins University. Prof. Socal teaches courses on U.S. Pharmaceutical Policy and the U.S. Healthcare System.

TINGLONG DAI, PH.D., is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. Tinglong Dai is also the Bernard T. Ferrari Professor at the Johns Hopkins Carey Business School, specializing in Operations Management and Business Analytics. He holds a joint faculty appointment at the Johns Hopkins School of Nursing. He is a member of the Johns Hopkins University Council and serves on the leadership team of the Hopkins Business of Health Initiative. He also co-leads the University's Bloomberg Distinguished Professorship Cluster on Global Advances in Medical Artificial Intelligence. As a co-chair of the Johns Hopkins Workgroup on AI and Healthcare, his current work focuses on integrating AI into clinical workflows and improving productivity, access, and equity in healthcare delivery. He joined Carey in 2013 after receiving a PhD in Operations Management/Robotics from Carnegie Mellon University.

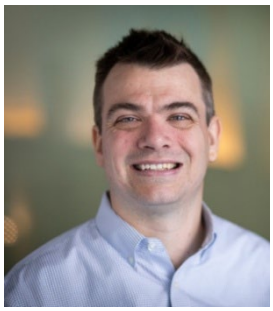
JOSHUA SHARFSTEIN, M.D., is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. Joshua Sharfstein is the Vice Dean for Public Health Practice and Community Engagement at the Bloomberg School of Public Health. Sharfstein is also professor of the practice in the Department of Health Policy and Management. Sharfstein was appointed by Governor Martin O'Malley as Secretary of the Maryland Department of Health and Mental Hygiene in January 2011. As Secretary of DHMH, Sharfstein led efforts to modernize Maryland's all-payer system for hospital payment. In March 2009, President Obama appointed Sharfstein to serve as the Principal Deputy

Commissioner of the U.S. Food and Drug Administration, the agency's second highest-ranking position. From December 2005 through March 2009, Sharfstein served as the Commissioner of Health for the City of Baltimore, Maryland. He began working on health and social policy matters as an advisor to longtime California Congressman Henry A. Waxman. Sharfstein also serves as a member of the editorial board at the Journal of the American Medical Association (JAMA). Sharfstein received his MD from Harvard Medical School.



GERARD ANDERSON, PH.D., is a professor of health policy and management and professor of international health at the Johns Hopkins University Bloomberg School Public Health, professor of medicine at the Johns Hopkins University School of Medicine, director of the Johns Hopkins Center for Hospital Finance and Management. His work encompasess studies of chronic conditions, comparative insurance systems in developing countries, medical education, health care payment reform, and technology diffusion.He has directed reviews of health systems for the World Bank and USAID in multiple countries. He has authored two books on health care payment policy, published over 250 peer reviewed articles, testified in Congress over 40 times as an individual witness, and serves on multiple editorial committees. Prior to his arrival at Johns Hopkins, Dr. Anderson held various positions in the Office of the Secretary, U.S. Department of Health and Human Services, where he helped to develop Medicare prospective payment legislation.is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. He directs the JHDAAI and is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center.

JOHNS HOPKINS PRESCRIPTION DRUG SUPPLY CHAIN RESOURCE CENTER PROJECT TEAM BIOSKETCHES

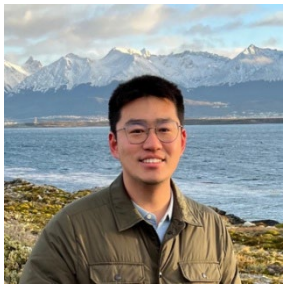


JEROMIE BALLREICH, PH.D., is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. JDr.Ballreich is an Associate Research Professor and Director of the Master's in Health Economics and Outcomes Research Program at the Johns Hopkins Bloomberg School of Public Health. Dr. Ballreich is a health economist specializing in three main areas: pharmaceutical economics and policy; economic evaluations alongside clinical studies; and high-cost/high-needs patient populations with a focus on trauma. In the pharmaceutical economics and policy space, Dr. Ballreich has been involved in a number of major U.S. policy discussions with key stakeholders including Congress, the U.S. Food and Drug Administration, Centers for Medicare and Medicaid services, and industry. He has conducted several economic evaluations ranging from cancer medications to pediatric audiology screening. His work on high-cost/high needs patients builds up on his health economics training and personal perspective as a quadriplegic. His peer-reviewed work has been published in New England Journal of Medicine, JAMA, American Journal of Managed Care, and other academic journals. He has been an invited workshop participant and presenter at the National Academy of Medicine, International Society of Pharmacoeconmics and Outcomes Research annual meeting, and other professional societies.He is a health economist with a research focus on US pharmaceutical policy and economic evaluation. His work is currently split the Johns Hopkins Drug Access and Affordability Initiative (JHDAAI) and the directorship of the Masters in Health Economics and Outcomes Research program at Johns Hopkins Bloomberg School of Public Health.

JEREMY GREENE, M.D., is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. Jeremy Greene is a Professor of the History of Medicine at the Johns Hopkins University School of Medicine. His area of clinical expertise includes internal medicine. Greene serves as the Elizabeth Treide and A. McGehee Harvey Chair in the History of Medicine. Greene's research interests include the history of therapeutics, especially pharmaceuticals. He also practices internal medicine at the East Baltimore Medical Center with admitting privileges to the Johns Hopkins University Hospital. Greene earned his MD and PhD from Harvard University. He completed his residency at Brigham & Women's Hospital. He serves on the Johns Hopkins University Press Faculty Editorial Board. Greene's research explores the ways in which medical technologies come to influence our understanding of what it means to be sick or healthy, normal or abnormal, on personal, regional, and global scales. Greene is the founding director of the Center for Medical Humanities and Social Medicine at Johns Hopkins University, Core Faculty in the JHDAAI, Associate Faculty at the Berman Institute of Bioethics, a co-Investigator in the Opioid Industry Documents Archive, the Black Beyond Data Project, and the Sawyer Seminar in Precision and Uncertainty in a World of Data. He holds joint appointments in the Department of History of Science and Technology and the Department of Anthropology at the Krieger School of Arts and Sciences.

MAQBOOL DADA, PH.D., is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. Maqbool Dada joined the Johns Hopkins Carey Business School in 2009. He is a Professor in Operations Management & Business Analytics. He has a joint appointment in Department of Anesthesia and Critical Care Medicine, School of Medicine and is on the Core Faculty of the Armstrong Institute for Patient Safety and Quality. He has expertise in the areas of operations management, health care operations, supply chain management and pricing models.

MOHAMMAD ALI ALAMDAR YAZDI, PH.D., is a Co-Principal Investigator for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. Mohammad Ali Alamdar Yazdi is an Associate Professor of Practice at the Johns Hopkins Carey Business School. He holds a Ph.D. and an MEng in Industrial and Systems Engineering, as well as an MS in Computer Science, all from Auburn University. Since joining Johns Hopkins in 2018, he has taught seven different courses and led numerous workshops in Data Science and Business Analytics. He designed and developed the Data Visualization course, which has become one of the school's most popular courses. His research interests include data visualization, machine learning and AI in healthcare, human-computer interaction, and transportation applications.



YUNXIANG SUN, M.S.P.H., is a Senior Biostatistician for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center where he contributes to the Pharmaceutical Supply Chain Data Dashboard project. His research focuses on drug shortages, global pharmaceutical trade, and supply chain vulnerabilities, with an interest in the intersection of trade policy and drug availability, as well as international health systems. Yunxiang holds a Master of Science in Public Health (MSPH) in International Health from Johns Hopkins and earned his bachelor's degree in Preventive Medicine and medical training in China. Yunxiang has experience working in Brazil, Canada, China and other locations, providing him with a global perspective on data systems, health policy, and cultural contexts.

JOY ONYEKACHI ACHA, M.P.H., MBA, is a Research Program Coordinator at the Johns Hopkins Bloomberg School of Public Health, where she manages the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. She manages internal workflows, nternal workflows, leads cross-departmental collaborations, and drives creative communication efforts, overseeing website development, strategy, and content through a pharmaceutical perspective. Joy's is a pharmacist. Her expertise bridges pharmacy, public health, and business strategy, focusing on clinical pharmacy operations, US pharmaceutical supply chain policy research, and social protection research to improve health outcomes. She is a Delta Omega Honorary Award recipient for Excellence in Public Health Practice and holds dual master's degrees in Public Health and Business Administration from Johns Hopkins University.

RIYA MODI serves as a Graduate Research Assistant for the Johns Hopkins Prescription Drug Supply Chain Data Dashboard and Resource Center. She is a master's student in Biomedical Engineering at Johns Hopkins University with a strong passion for data science, machine learning, and healthcare innovation. Her work focuses on combining deep learning with biomedical data to solve real-world problems, including medical imaging, and structured data analysis for public health.

DEPARTMENT OF WAR, UNIFORMED SERVICES UNIVERSITY TEAM BIOSKETCH

TRACEY PÉREZ KOEHLMOOS, PH.D., M.H.A., joined the faculty of the Uniformed Services University in July 2015 in order to lead the development of a robust health services administration and policy research and graduate programs in support of the US Military Health System. She is the Director of the Center for Health Services Research and the Director of Doctoral Programs in Public Health, with core teaching and graduate student advising responsibilities at USUHS and the National Defense University. Previously she served as the Special Assistant to the Assistant Commandant of the Marine Corps. With more than 200 publications and multimedia products, Dr. Koehlmoos is a health systems and policy scientist who specializes in leading complex tasks, program development and capacity building across the spectrum of health systems building blocks. Prior to transitioning to domestic and defense healthcare, she lived and worked in Saudi Arabia, Pakistan, Nepal, Bangladesh and Indonesia. She cut her teeth in public health leading the Health & Family Planning Systems Programme at ICDDR,B in Dhaka Bangladesh. Her research areas of interest include health equity, value-based care, women's health, systematic review, and health and National Security. She has served as the National Secretary of the Gold Star Wives of America and is the Deputy Chair of the Cochrane Library Oversight Committee. A former Army Air Defense Artillery officer.

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

A Workshop

PLANNING COMMITTEE BIOSKETCHES

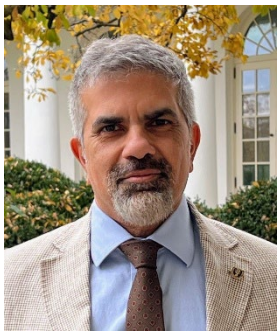
NICOLETTE LOUISSAINT, PH.D. M.B.A., *(WORKSHOP CO-CHAIR),* serves as the Chief Policy Officer for the Healthcare Distribution Alliance. In this role, she leads the organization's work to build policies and strategic approaches to build supply chain resilience and reinforce the role of healthcare distributors in the healthcare ecosystem. She previously served as the executive director and president of Healthcare Ready, a 501(c)(3) organization that focuses on strengthening the United States' healthcare supply chain preparedness and response before, during and after natural disasters and disease pandemics. Prior to this, Nicolette served as the Senior Advisor to the US State Department's Special Coordinator for Ebola and as a Foreign Affairs Officer at the US Department of State in the Bureau of Economic and Business Affairs. She served on the Federal Emergency Management Agency's (FEMA) National Advisory Council, as chair of the Equity Working Group. She serves on the Board of Directors for Project HOPE and the YMCA of Central Maryland. Nicolette earned Bachelors of Science degrees in Chemical Engineering and Biological Sciences from Carnegie Mellon University, a PhD in Pharmacology and Molecular Sciences from Johns Hopkins University School of Medicine, and an MBA from the University of Baltimore.

DOUGLAS THROCKMORTON, M.D. *(WORKSHOP CO-CHAIR),* is the former deputy director for regulatory programs where he shared the responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks. Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital. He is a board-certified physician.

THOMAS BOLLYKY, J.D., is the inaugural Bloomberg Chair in Global Health at the Council on Foreign Relations where he directs the global health program. Prior to coming to CFR, Bollyky served in a variety of positions in the U.S. government, most recently at the Office of the U.S. Trade Representative (USTR). He led the negotiations on medical technology regulation in the U.S.-Republic of Korea Free Trade Agreement and represented USTR in the negotiations with China on the safety of food and drug imports. Bollyky has testified five times before the U.S. Congress and foreign parliaments, served as a consultant to the Gates Foundation and the Coalition of Epidemic Preparedness Innovations, and been a member of several expert committees at the National Academies of Science, Engineering, and Medicine. His book "Plagues and the Paradox of Progress" was listed as one of the top ten selling health and medicine books in 2018 and has been translated into Chinese and Japanese. Bollyky received his BA in biology and history at Columbia University and his JD at Stanford Law School. In 2013, the World Economic Forum named Bollyky as one of its global leaders under forty.

ERIN R. FOX, PHARM.D., M.H.A., BCPS, FASHP, is Associate Chief Pharmacy Officer of Shared Services at University of Utah Health and is responsible for drug information and drug policy, pharmacy informatics, purchasing, billing, 340B, and antimicrobial stewardship. She and her drug information team have provided drug shortage information for the ASHP Drug Shortage Resource Center since 2001. Erin serves as a media resource and advocate for changes to improve the ongoing drug shortage situation. She has published over 40 peer-reviewed articles related to drug shortages, including the ASHP guidelines on managing drug shortages. Erin is recognized as an expert in drug shortages and has received the ISMP Cheers Award and the ASHP Award of Excellence for efforts related to drug shortages. She served as a member of the National Academies of Sciences, Engineering, and Medicine Committee on Security of America's Medical Product Supply Chain. Erin testified for the Senate Homeland Security and Government Affairs Committee hearing on drug shortages in March 2023. Erin received her Pharm.D. and M.H.A. from the University of Utah, is Board Certified in Pharmacotherapy, and is a Fellow of the American Society of Health System Pharmacists.

CELESTE FRANKENFELD LAMM, PH.D., Senior Director, leads the Chemistry, Manufacturing, and Controls (CMC) Policy team at Merck, with broad responsibility across Quality, Regulatory, and Technical CMC functions. Additionally, she is co-chair of the International Society for Pharmaceutical Engineering (ISPE) Product Quality Life Cycle Implementation (PQLI) committee, sits on ISPE's Regulatory Steering Council, and represents ISPE on the Duke-Margolis ReVAMP Drug Supply Chain Consortium. Her career in the pharmaceutical industry has equipped her with a deep understanding of manufacturing, regulatory submissions, and supply chain dynamics. An important component of her current role is to engage with diverse stakeholders, including regulators, patient advocacy groups, industry associations, and supply chain partners to share challenges and gain insights to facilitate collaborative solutions that enhance resiliency of the pharmaceutical supply chain. In addition to ISPE, she is a member of the DIA Annual Meeting Planning Committee, and the IFPAC Scientific Board, and frequently serves as an invited speaker at industry conferences and workshops where she shares her expertise on advanced manufacturing, quality systems and regulatory strategies that can improve supply chain resilience. She holds a Ph.D. in Pharmaceutical Chemistry from the University of Kansas.



CHANDRESH HARJIVAN, PHARM.D., M.P.H., served as the Special Assistant to the President for Domestic Preparedness and Response to Pandemics and Biological Threats at the White House. There, he established the Bio5 global supply chain alliance to enhance coordination across major markets, and pioneered AI frameworks to mitigate supply chain risks. Previously, he was President and Chief Operating Officer at SaponiQx, a next-generation vaccine adjuvant company which provided a supply chain innovation to produce adjuvants through cell culture replacing. Prior he led the Federal Health Practice at Boston Consulting Group supporting Operation Warp Speed in managing supply chain constraints. Earlier, he founded PwC's Global Public Health Practice, where he led many supply chain projects, including a DHS assessment of supply chains against biological threats, supply chain distribution for HIV/Malaria and TB drugs in Africa, and vaccine supply chain procurement with the Pan American Health Organization. Dr. Harjivan is a leading expert in biopharmaceutical supply chain strategy, with over two decades of experience advising governments, industry leaders, and global institutions on strengthening supply chain resilience for essential medicines and medical countermeasures. He earned a Doctor of Pharmacy from the University of Maryland, an MPH from Johns Hopkins University, and an MBA from Oxford University, and was a scholar at Harvard University's Department of Economics.

ALEXANDER OSHMYANSKY, M.D., PH.D. (D.PHIL), is the Co-founder and CEO of the Mark Cuban Cost Plus Drug Company. The Mark Cuban Cost Plus Drug Company is one of the leading organizations in the US addressing issues of systemic inequities in the pharmaceutical industry, dysfunctional and predatory dynamics in pharmaceutical supply chains, and the root causes of drug shortages. In this role, Alex oversaw the construction and startup of a now FDA approved sterile pharmaceutical manufacturing facility, a pharmaceutical wholesale marketplace, and a mail-order pharmacy platform serving over two million patients. Alex also holds a position as a nonresident senior fellow at the USC Schaeffer Center for Health Policy and Economics. He was previously a Senior Fellow at UCLA in the mathematics of intelligences program and a consulting assistant professor of pediatric radiology at Stanford University. Alex has been recognized by Time Magazine as one of the 100 most influential people in Health (2024) and Dow Jones Marketwatch as one of the 50 most influential people in the markets. Alex hold an M.D. from the Duke University School of Medicine. He earned a Ph.D. (D.Phil) from Oxford University in mathematics as a Marshall Scholar. Alex also earned a BA in Biochemistry from the University of Colorado at Boulder, graduating at the age of 18. He completed a surgical internship at Brigham and Women's Hospital / Harvard Medical School as well as a residency in diagnostic radiology and fellowship in pediatric radiology at the Johns Hopkins Hospital.

ANITA PATEL, PHARM.D., M.SC., leads the development of Walgreens clinical pharmacy services. She is responsible for the advancement of existing clinical programs such as immunizations and medication adherence across 9000 community sites; expansion into new therapeutic areas including health screenings, care gap closures for diabetes and hypertension; and innovation for clinical service delivery to improve access to quality care across communities. Dr. Patel also oversees the Walgreens COVID-19 strategy and execution, including vaccines, testing, data, and analytics. She has over 20 years of experience in the public health and healthcare industry helping to accelerate Walgreens into its pharmacy of the future strategy.

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

A Workshop

KEYNOTE SPEAKER BIOSKETCH

MARTIN MAKARY, M.D., M.P.H., was confirmed on March 25, 2025 by a bipartisan vote of the U.S. Senate as the 27th Commissioner of Food and Drugs. Prior to joining the FDA, Dr. Makary worked at Johns Hopkins University School of Medicine, where he was a surgical oncologist and chief of Islet Transplant Surgery. After six years on the faculty at JHU, Dr. Makary was named an endowed chair in gastrointestinal surgery, and subsequently promoted to full professor with tenure. He also served as a professor at the Johns Hopkins Carey Business School and founded the Johns Hopkins Center for Surgical Trials and Outcomes Research. Dr. Makary is a widely published writer, having authored more than 300 peer-reviewed articles in medical journals. He is the author of three New York Times bestselling books on health care, including: "Unaccountable – What Hospitals Tell You and How Transparency Can Revolutionize Health Care;" "The Price We Pay," which examined health care costs; and which was named 2020 Business Book of the Year by the Association of Business Journalists; and "Blind Spots -- When Medicine Gets It Wrong, and What It Means for Our Health," which presents the latest scientific research on the microbiome, food and other health topics. Dr. Makary has led cross-disciplinary research on a range of subjects, including cancer care, obesity, frailty and psychologic reserve in older patients, adverse event monitoring, the Orphan Drug Act, antimicrobial resistance, and Alzheimer's. Of particular note, he is the co-developer of the Surgery Checklist used in many operating rooms around the world today. Dr. Makary was the first to perform several novel surgical operations, including the first-in-the-world series of laparoscopic pancreas islet transplant operations. For his pioneering work, Dr. Makary was awarded the Nobility in Science Award from the National Pancreas Foundation. For the last 22 years, he has had an active clinical practice. During the COVID pandemic, he and his Johns Hopkins colleagues conducted landmark antibody studies on natural immunity published in JAMA. Most recently, his research has focused on vulnerable populations in health care. Dr. Makary has led national quality collaboratives, served on several editorial boards, and was the first editor-in-chief of MedPage Today. He has served in a leadership position at the World Health Organization Patient Safety Program, and in 2018 was elected to the National Academy of Medicine. Dr. Makary graduated from Bucknell University and earned an M.P.H. from the Harvard T.H. Chan School of Public Health. He received his M.D. from Thomas Jefferson University and did his surgical residency at Georgetown University, completing sub-specialty surgery training at Johns Hopkins University.

SPEAKER BIOSKETCHES

CHRISTINE BAEDER, M.B.A., joined Apotex in December 2023, serving as the President of Apotex Corp. She has responsibilities for all areas of business in support of the US market. In addition, she oversees the global portfolio function and coordinates the strategy on product selection. She was drawn to Apotex based on the organization's commitment to patient access and a North American Manufacturing presence. Christine previously served as the SVP, Chief Operating Officer for US Generics and Global Biosimilars at Teva Pharmaceuticals. Christine served in the US Generic leadership team for Teva for 15 years, where she held multiple positions across the commercial organization including most recently the addition of biosimilar. She held full P& L accountability for the US Generic market since 2018. Prior to joining Teva, Christine also supported Teva brand portfolio with supply chain and launch support. Christine served on Sandoz US generic team where she developed a deep expertise in the importance of cross functional alignment between commercial and operations. Christine has served on the board as on Association for Accessible Medicines (AAM); where she was served in both chair and vice-chair roles. She has a BS degree in Biology from Wright State University in Dayton, OH and an MBA from Fuqua School at Duke, Durham, NC.

SCOTT BIGGS serves as a Director in the Supplier Services Group at IQVIA, a leading global provider of advanced analytics, technology solutions, and clinical research services tailored for the life sciences and healthcare sectors. IQVIA's mission is to enhance patient outcomes by fostering healthcare innovations through its data, technology, and expertise. By integrating big data, advanced analytics, and industry knowledge, IQVIA assists clients in making informed decisions and speeding up the development of groundbreaking treatments. He initiated his career in the pharmacy field at Rite Aid, where he undertook various roles with escalating responsibilities. Prior to joining IQVIA in 2011, he was employed by other pharmaceutical information firms like Verispan and SDI. Scott holds a BS degree in Accounting from Penn State University and has nearly three decades of experience working with pharmacy data. In his capacity at IQVIA, Scott collaborates with retailers, software vendors, and various data suppliers, helping them gain insights into their market performance through business reviews and market analysis. Scott resides in Ludington, MI, with his wife and three children. He enjoys woodworking, honing his shooting skills, and volunteering. He actively contributes to his community through service on county boards, involvement with his church, and with the Mason County Sheriff's Office. Additionally, Scott and his wife are dedicated advocates for organizations aimed at combating human trafficking. Scott is also an Army Veteran who served in the U.S. Army Reserves and Pennsylvania Army National Guard.

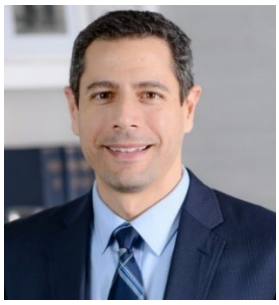
STEPHEN BOZER, M.B.A., joined Flavine North America in 2018 as the Senior Vice President of Human Health where he is leading the Sales & Marketing team in the U.S. office. He is an analytical chemist by training and has held senior positions in Quality Control and Marketing & Sales during his career. Stephen has over 25 years of pharmaceutical experience working for several companies, including Teva API, Berlex Laboratories (now Bayer) and Key International. Stephen has a Bachelor of Science degree in Biology from Binghamton University (SUNY) and an M.B.A. in Pharmaceutical Management from Fairleigh Dickinson University.

CRAIG BURTON, M.D., is the Senior Vice President of US Government Affairs for Fresenius Kabi USA. With more than 20 years of Federal health policy experience, Craig has served in key roles at the center of a range of pressing health care debates. He led policy development for the Association for Accessible Medicines and was Executive Director of the Biosimilars Council for 8 years. Prior to that, Craig helped clients anticipate and plan for the impact of change stemming from legislative, regulatory, or other market dynamics. Craig also established and directed the health policy and government relations efforts for two biopharmaceutical companies. Craig served as Deputy Assistant Secretary for Legislation in the U.S. Department of Health and Human Services. In this role, he advised the Secretary, senior Department leaders and White House officials on legislative strategy to achieve key priorities. Craig also served in the Senate, where he was Health Policy Advisor to Senate Majority Leader Bill Frist, M.D., and as professional staff on the U.S. Senate Committee on Health, Education, Labor and Pensions.

COLONEL MATTHEW CLARK, PH.D., PMP, currently commands the SHAPE and Brussels Healthcare Facilities, supporting NATO and partner nations. He has led the successful development, delivery, and operational implementation of 13 FDA-approved drugs, vaccines, and diagnostics in support of joint force readiness and whole-of-government preparedness for high-consequence emerging infectious diseases and weapons of mass destruction. His leadership has advanced international biodefense and medical resilience initiatives, framing medicine as a cornerstone of deterrence by resilience for the U.S., EU, and NATO. Previously, COL Clark served as the Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical and as Senior Policy Advisor and Director of COVID-19 International Response Operations at the White House, following his role as Lead Program Manager for the vaccine team in Operation Warp Speed. At the White House, he coordinated U.S. government and global partners—including Gavi, WHO, UNICEF, PAHO, and the African Union—to deliver over 534 million vaccine doses to 115 countries in just 10.5 months, while overseeing operations that mobilized doses he worked with 34 independent regulatory agencies worldwide. COL Clark's prior assignments include Director of the Office of Medical Systems under the Assistant Secretary of the Army (Acquisition, Logistics, and Technology); Joint Product Manager for Chemical Defense Pharmaceuticals; Director of the Eisenhower Leader Development Program at West Point and Columbia University; and Military Legislative Assistant in the U.S. House of Representatives. His career spans operational medicine, acquisition, and policy, including authoring urgent need statements that fielded the first armored ambulances in Iraq and integrating counter-IED technologies for the Army. He has advised EU and NATO leaders in biodefense and has served as an invited subject matter expert for Foreign Policy Magazine and Chatham House. He also has over 40 publications.

STEPHEN COLVILL, MBA, leads the ReVAMP Drug Supply Chain Consortium at the Duke-Margolis Institute for Health Policy, along with policy work on other supply chain and biomedical innovation topics. Stephen is a board member for the End Drug Shortages Alliance and a volunteer advisory board member for Angels for Change, and he frequently speaks at national forums on pharmaceutical supply chains, drug shortages, pharmaceutical regulation, and biomedical innovation. Stephen previously served in the White House Domestic Policy Council as Senior Policy Advisor for Medical Supply Chains. He also co-founded RISCS, a nonprofit drug supply chain rating and certification organization with a mission to prevent drug shortages and held various roles at Pfizer and Hospira in business analytics, supply chain, manufacturing, finance, marketing, and commercial portfolio management. Stephen received his MBA from Duke University.

NATALIE DE GRAAF, M.P.H., is the vice president & general manager of data, AI, and ML solutions for health & national security at the API Innovation Center where she oversees APIIC's portfolio harnessing data analytics and predictive modeling to solve complex challenges for industry, government and academia. Natalie brings a wealth of experience advancing U.S. national security priorities in biodefense, public health policy and data security. She has extensive experience advising senior government leaders, coordinating national and international initiatives to address biological threats and fostering global partnerships. Prior to joining the API Innovation Center, Natalie worked across government agencies such as the White House National Security Council, Department of Defense and Department of Health & Human Services including developing and implementing the U.S. National Strategy for a Resilient Public Health Supply Chain.



MICHAEL GANIO, PHARM.D., is Senior Director, Pharmacy Practice and Quality at the American Society of Health-System Pharmacists, where his responsibilities span the practice of pharmacy and include drug shortages, sterile and non-sterile drug compounding practices, hazardous drug safety, and other practice-related topics. Dr. Ganio earned his PharmD from the Rutgers University Ernest Mario School of Pharmacy and his master's degree in health-system pharmacy administration from The Ohio State University College of Pharmacy. He completed a PGY1 pharmacy practice residency at The Ohio State University Wexner Medical Center. Dr. Ganio is a Board-Certified Sterile Compounding Pharmacist (BCSCP), Board-Certified Pharmacotherapy Specialist (BCPS), and was inducted as a fellow of ASHP in 2017. Dr. Ganio has over 20 years of hospital and health-system experience. His previous job roles have included clinical pharmacy practice, pharmacy informatics and technology, and outpatient oncology pharmacy operations. He has extensive knowledge of drug shortage management, pharmacy informatics and automation, medication billing and reimbursement, sterile compounding, and outpatient infusion and ambulatory-care practice models. Dr. Ganio has been invited to participate in several national and international conferences as an expert on drug shortages, including with the Executive Office of the President and as an expert witness testifying before Congress.

MONICA GORMAN, M.PHIL., PH.D., is a former senior White House official who advises major industry clients on global trade, tariffs, supply chain resilience, and industrial policy. She is currently a Managing Director at Crowell Global Advisors, the global policy consulting firm affiliated with Crowell & Moring LLP. From 2022-25, she was Special Assistant to the President for Manufacturing & Industrial Policy, where she spearheaded the creation of the White House Council on Supply Chain Resilience, chaired the nation's Supply Chain Disruptions Task Force, and led a White House task force on pharmaceutical supply chains. Monica also served as Deputy Assistant Secretary of Commerce for Manufacturing from 2021-22. Monica is a seasoned corporate executive with nearly two decades of business experience. Prior to government service, she was Vice President of Responsible Leadership & Global Compliance at New Balance and led the company's trade and environmental, social, and corporate governance divisions. Before New Balance, she led American Eagle Outfitters' global trade, corporate responsibility, and product safety departments. As Director of Social Responsibility at Gap Inc., Monica was the architect of Gap's ground-breaking 2003 report that generated a record number of positive media impressions. PR News named her Communicator of the Year in 2008. Monica also served as executive producer of New Balance's short film, "Made Responsibly: Vietnam," which was nominated for an Emmy® award in 2020. Monica previously served on the Boards of Directors for the Fair Labor

Association, the US Footwear Manufacturers Association, and the USDA Cotton Board. She is a 2020 Presidential Leadership Scholar and past Term Member of the Council on Foreign Relations. Monica earned her A.B. summa cum laude from Dartmouth and her M.Phil. and Ph.D. from the University of Oxford. She is a sought-after public speaker and a frequent contributor to national and international media.

JOHN GRAY, PH.D., MBA, is Dean's Distinguished Professor of operations and business analytics. He joined Fisher after receiving his Ph.D. from the Kenan-Flagler Business School at the University of North Carolina-Chapel Hill. Prior to pursuing his Ph.D., he worked for eight years in operations management at Procter & Gamble, receiving an MBA from Wake Forest University's evening program during that time. He holds two undergraduate degrees from Dartmouth College and its Thayer School of Engineering. From August 2022-February 2024, he served as a part-time consultant for the Office of Science and Technology Policy (OSTP) in the Executive Office of the President (EOP) of the United States. He advised the EOP on issues related to pharmaceutical supply chain resilience. His work has been funded by outside entities on numerous occasions. He is currently the PI on a subaward grant from the Department of Defense, charged with examining global pharmaceutical supply chains. He was co-PI of a $1.7 million two-year contract with the FDA from October 2019-September 2021, and part of a major FDA subaward two years before that. In early 2010s, he was co-PI on an NSF grant. Dr. Gray teaches/has taught an elective he created called Strategic Global Sourcing (at the Ph.D., Executive, MBA, MSCM, and undergraduate levels) and Data Analysis (at the Ph.D., Executive, and MBA levels); he has won a college teaching award for each class. A student project from his elective led to a co-authored case (Scotts Miracle-Gro: The Spreader Sourcing Decision) that has been widely adopted, earning the title of an "Ivey Classic". He serves as academic co-director of the Master of Supply Chain Management program at Fisher. He also serves as academic director for Fisher's Ph.D. programs. Dr. Gray's research has been published in top multi-disciplinary management journals, including Decision Sciences, Management Science and Organization Science; and top operations and supply chain journals, including the Journal of Operations Management, the Journal of Supply Chain Management, and Production and Operations Management. His research has received several awards, the Jack Meredith Best Paper award from the Journal of Operations Management and the Emerald Citations of Excellence award which recognizes the most impactful articles across a wide range of journals. IN 2023, he was given the distinguished scholar award from the OSCM Division of the Academy of Management. He has also served as a Department Editor at the Journal of Operations Management and a Senior Editor at the Production and Operations Management journal. He is currently editing a special issue at the Journal of Operations Management on the operations and supply chains of pharmaceutical products. Finally, he recently became President of the Industry Studies Association; for which we served as conference chair for its 2023 conference in Columbus.

RACHEL HADDOCK, M.S., is an experienced biopharmaceutical leader with over two decades spanning manufacturing, development, and strategic operations. Currently serving as Vice President of Medicine Development & Industrialization, Large Molecule at GSK, Rachel is accountable for the overall project delivery of large molecule assets from the development of product for pivotal trials, through to the implementation of all significant Chemistry, Manufacturing and Controls (CMC) lifecycle plans and market registrations. Her prior roles include VP and Site Leader at both Rockville and Upper Merion Biopharm sites, where she oversaw large-scale manufacturing operations, implemented quality and EHS improvement programs, and delivered multimillion-dollar facility expansions. As VP and Technical Head of Biopharm & Steriles, she led global MSAT functions and partnered with R&D to accelerate platform development and technology roadmaps. Rachel also served

as VP of GMP Operations for Cell & Gene Therapy, where she championed manufacturing improvements for cutting-edge therapies and participated in NASEM Forum on Regenerative Medicine. Her career began at Merck, where she held roles in quality, technical operations, and manufacturing for vaccines drug substance and drug product.

MELANIE HART, PH.D., is the senior director of the Atlantic Council's Global China Hub. She leads the Hub's efforts to analyze Beijing's actions and their global impacts using rigorous analysis and innovative data to generate actionable policy solutions, enabling the United States and its allies to respond effectively to common policy challenges on China. In this role, she leverages the Hub's network of China policy experts around the world as well as the Atlantic Council's work on China across its sixteen programs and centers. Prior to joining the Council, Hart worked at the US Department of State, where she served as senior advisor for China in the Office of the Undersecretary for Economic Growth, Energy, and the Environment. In that role, Hart was instrumental in crafting strategies to reduce nation-state vulnerabilities to Chinese pressure. She developed the Department of State's playbook for responding to Chinese economic coercion and led an internal unit that provided coercion-response support to multiple nations. Hart developed the State Department's semiconductor strategy for the CHIPS and Science Act's International Technology Security and Innovation Fund. She also served as policy lead for the US-Taiwan Economic Prosperity Partnership Dialogue and worked with multiple US allies and partners to address common China policy challenges. Before joining the State Department, Hart served as senior fellow and director for China policy at the Center for American Progress, where her work helped shape domestic and global approaches to China on issues such as 5G policy, economic competition, energy and climate policy, and global governance. She also served as a senior advisor at the Scowcroft Group, where she helped US firms understand China's industrial policies. Hart has a PhD in political science from the University of California, San Diego and a BA from Texas A&M University.

FAUZEA HUSSAIN, M.P.H., is the Vice President of Public Policy at McKesson, where she champions innovative public policy strategies that drive the company's mission to improve health outcomes. With a keen focus on patient-first solutions, Fauzea collaborates across the enterprise to address the diverse needs of distributors, wholesalers, community providers, health systems, pharmacies, manufacturers, technology vendors, and consumers. During the COVID-19 pandemic, she elevated McKesson's role as a trusted public health partner for the Federal government, states, and underserved communities. A seasoned policy expert with over 25 years of experience, Fauzea has a proven track record in assessing the impact of state and federal policies on patient access, provider reimbursement, and the life sciences industry. Before joining McKesson, she led Avalere's Reimbursement and Market Access team, where she developed groundbreaking market access strategies for drugs, biologics, devices, and technologies. Fauzea's career began as the Assistant Director of Reimbursement Policy for the American Academy of Physician Assistants, where she honed her expertise in payment issues. A dedicated patient advocate, she serves on the board of the Cancer Support Community, a leading patient advocacy organization.

DIANE HUSTEAD, M.S., is honored to chair the ISPE Drug Shortage Initiative Team, a longstanding ISPE effort to improve drug shortage prevention. Her leadership for this team of industry volunteers is based on her pharmaceutical professional roles over the past 30 years, primarily at Merck, and draws on her deep cross functional expertise in US Regulatory Affairs, Global Labeling, Global CMC, Regulatory Operations, and Manufacturing Quality Auditing. Her current responsibilities encompass drug shortage reporting and mitigation strategy, and she has developed business continuity plans for large scale disruptive events. Diane is known for pragmatic, action-oriented leadership and looks forward to all engagement or collaboration opportunities that move the needle on global supply resiliency.

ROBERT KADLEC, M.D., is the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services (HHS). The ASPR serves as the Secretary's principal advisor on matters related to public health emergencies, including bioterrorism. The office leads the nation in preventing, responding to and recovering from the adverse health effects of manmade and naturally occurring disasters and public health emergencies. As such, the office coordinates interagency activities between HHS, other federal agencies, and state and local officials responsible for emergency preparedness and the protection of the civilian population from public health emergencies.

Dr. Kadlec spent more than 20 years as a career officer and physician in the United States Air Force before retiring as a Colonel. Over the course of his career, he has held senior positions in the White House, the U.S. Senate, and the Department of Defense. Most recently, he served as the Deputy Staff Director to the Senate Select Committee on Intelligence. Dr. Kadlec previously served as staff director for Senator Richard Burr's subcommittee on bioterrorism and public health in the 109th Congress. In that capacity, he was instrumental in drafting the Pandemic and All-Hazard Preparedness Bill which was signed into law to improve the nation's public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural. Dr. Kadlec also served at the White House from 2002 to 2005 as director for biodefense on the Homeland Security Council, where he was responsible for conducting the biodefense end-to-end assessment, which culminated in drafting the National Biodefense Policy for the 21st Century. He served as Special Assistant to President George W. Bush for Biodefense Policy from 2007 to 2009. Earlier in his career, he served as the Special Advisor for Counterproliferation Policy at the Office of the Secretary of Defense, where he assisted DOD efforts to counter chemical, biological, radiological, and nuclear (CBRN) threats in the wake of 9/11 and contributed to the FBI investigation of the anthrax letter attacks. He began his career as a flight surgeon for the 16th Special Operations Wing and subsequently served as a surgeon for the 24th Special Tactics Squadron and as Special Assistant to J-2 for Chemical and Biological Warfare at the Joint Special Operations Command. He was named U.S. Air Force Flight Surgeon of the Year in 1986. Dr. Kadlec holds a bachelor's degree from the United States Air Force Academy, a doctorate of medicine and a master's degree in tropical medicine and hygiene from the Uniformed Services University of the Health Sciences, as well as a master's degree in national security studies from Georgetown University.

TIMOTHY MANNING has worked on both the front lines and in the seniormost levels of crisis and emergency management, homeland security, and resilience for nearly thirty years, most recently as the White House COVID-19 Supply Coordinator, helping lead the U.S. Government's response to the pandemic. Tim is a former Deputy Administrator at the Federal Emergency Management Agency, Governor's disaster and homeland security advisor, firefighter-EMT (serving in both urban and rural departments and the wildland interface), rescue mountaineer, and geologist. He has recently served as Director of Washington D.C. operations for the Pacific Disaster Center, on the faculty of the Disaster and Emergency Management studies program at Georgetown University and the Center for Homeland Defense and Security at the Naval Postgraduate School, a Senior Fellow at the Atlantic Council, and President of Berglind-Manning l.c., an international resilience, security, and strategic policy consulting firm. Tim was appointed by President Joseph Biden in January 2021 to oversee the U.S. Government's efforts to support the global industrial base and resolve supply chain challenges and logistics for the essential tools needed to respond to the pandemic, having previously served the entirety of the Obama administration as the Deputy Administrator of the Federal Emergency Management Agency for Protection and National Preparedness, after being confirmed by the U.S. Senate in the spring of 2009. While at the White House, Tim worked with major global manufacturers, NGOs, and partner governments worldwide to further efforts to produce vaccine, therapeutics, medical devices, testing and diagnostics, and PPE and other supply chain challenges. And led the effort, in the space of two weeks, to create COVIDtests.gov, a multibillion-dollar operation of multiple U.S. Government agencies offering home test delivery with next or second-day fulfillment. Over his nearly three-decade career, Tim helped coordinate the response to countless emergencies and disasters throughout the United States and worked with partners around the globe, representing the United States as head of delegation in over 30 bilateral and multilateral engagements, including eight annual ministerial APEC forums, NATO senior Committee plenaries, and the U.N. World Disaster Forum in Sendai, Japan. Prior to joining federal service, Mr. Manning served as the Cabinet Secretary of the New Mexico Department of Homeland Security and Emergency Management and Homeland Security Advisor to Governor Bill Richardson; he originally joined the New Mexico State government civil service following a decade as a consulting geologist, serving in a number of roles including Chief of the Emergency Operations Bureau and Deputy Secretary of Public Safety for Emergency Services. He has served on a wide range of policy boards and committees across the homeland security and emergency management spectrum. Mr. Manning earned a Master of Letters with distinction in Terrorism and Political Violence from the University of St. Andrews, a Bachelor of Science in Geology from Eastern Illinois University, and a graduate of the Center for Homeland Defense and Security Executive Leaders Program at the Naval Postgraduate School.

HILARY MARSTON, M.D., M.P.H., served for more than a decade as a leader and strategic advisor on national public health policy and is a recognized expert in the clinical and regulatory aspects of medical product and vaccine development. She brings this expertise to her work with biotechnology and drug companies and investors at Canal Row, and prior to this, at Marston Health, LLC, which she founded after her tenure in FDA leadership. Dr. Marston was FDA's inaugural Chief Medical Officer, serving as the primary clinical advisor to the Commissioner and leading the office that oversees clinical matters involving multiple FDA product development centers, including financial incentives (e.g., for rare disease product development), targeted grantmaking, and research participant protection policy. She also led the Agency's response to health crises, including epidemics and medical product shortages.

Dr. Marston previously served as Senior Advisor for Global COVID-19 Response on the White House COVID-19 Response Team, as Director for Medical Biopreparedness and Response at the U.S. National Security Council, and as Policy Advisor for Pandemic Preparedness at the National Institute of Allergy

and Infectious Diseases. She also worked at McKinsey & Company and the Bill & Melinda Gates Foundation. Dr. Marston trained in Internal Medicine and Global Health Equity at Brigham & Women's Hospital. She completed her M.P.H. at the Harvard School of Public Health.

DANIEL SINGER, M.D., M.P.H., FACP
Former Director for Countering Biological Threats
National Security Council

PRASHANT YADAV, MBA, is a senior fellow at the Council on Foreign Relations (CFR). He is a globally recognized expert in pharmaceutical supply chains. Yadav's writing has appeared in major print media outlets, including the Financial Times, The Economist, Nature, the New York Times, the Wall Street Journal, and Foreign Affairs. He has frequently appeared as a supply chain expert on NPR, BBC, CNN, CBS, and CNBC. His research has received best paper awards from prominent scientific bodies. Yadav has held faculty positions at INSEAD, the MIT-Zaragoza Logistics Program, and the University of Michigan. He has also served as a lecturer at Harvard Medical School. Previously, Yadav was the strategy leader for supply chains at the Bill & Melinda Gates Foundation and vice president of healthcare research at the University of Michigan's William Davidson Institute. He currently serves on the boards of various global organizations and social enterprises. Yadav has provided expert testimony on multiple occasions before the U.S. Congress and other international legislative bodies on medicine supply chain issues. He has also been a member of multiple National Academy of Medicine Expert Committees and has chaired two expert committees.

MARTA E. WOSIŃSKA, PH.D., is an economist and a Brookings senior fellow in the Center on Health Policy. Her experience spans prominent academic institutions and government, including seven years with the FDA. For over a decade, she has been a leading expert on the economics of drug shortages. She served on the National Academies committee on Security of America's Medical Product Supply Chain and on Challenges in Supply Market Competition and Regulation of Infant Formula.

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

A Workshop

THE NATIONAL ACADEMIES PUBLICATIONS

Proceedings of a Workshop-in Brief

National Academies of Sciences, Engineering, and Medicine. 2024. *Supply Chain Disruptions: Impacts on Vulnerable Communities: Proceedings of a Workshop—in Brief*. Washington, DC: The National Academies Press. https://doi.org/10.17226/27390.

National Academies of Sciences, Engineering, and Medicine. 2022. *Addressing Supply Chain and Manufacturing Challenges and Opportunities: Proceedings of a Workshop Series–in Brief*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26593.

National Academies of Sciences, Engineering, and Medicine. 2022. *Climate-Resilient Supply Chains: Proceedings of a Workshop–in Brief*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26461.

National Academies of Sciences, Engineering, and Medicine. 2022. *Innovations in Pharmaceutical Manufacturing on the Horizon: Proceedings of a Workshop–in Brief*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26539.

National Academies of Sciences, Engineering, and Medicine. 2021. *Sustainable and Resilient Supply Chains Using Emerging Technologies: Policy Options: Proceedings of a Workshop–in Brief*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26193.

THE NATIONAL ACADEMIES PUBLICATIONS

Consensus Study Reports

National Academies of Sciences, Engineering, and Medicine. 2022. *Building Resilience into the Nation's Medical Product Supply Chains*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26420.

National Academies of Sciences, Engineering, and Medicine. 2021. *Innovations in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory Issues, and Recommendations*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26009.

National Academies of Sciences, Engineering, and Medicine. 2020. *Strengthening Post-Hurricane Supply Chain Resilience: Observations from Hurricanes Harvey, Irma, and Maria*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25490.

JOHNS HOPKINS PUBLICATIONS

Johns Hopkins Prescription Drug Supply Chain Resource Center
Explore our latest publications, reports, and data resources on the U.S. pharmaceutical supply chain.
https://supplychain.jhu.edu/publications-reports/

Johns Hopkins Prescription Drug Supply Chain Data Dashboard
https://supplychain.jhu.edu/supply-chain-dashboard/

JOHNS HOPKINS UNIVERSITY | EST. 1876 | JH150 | AMERICA'S FIRST RESEARCH UNIVERSITY

PRESCRIPTION DRUG SUPPLY CHAIN DATA DASHBOARD AND RESOURCE CENTER

A trusted hub for real-time data driving transparency and resilience in the U.S. pharmaceutical supply chain.

Drug Information

Access detailed product data

Drug Shortage Tracker

Track current and historical shortages

Global Manufacturing Map

Visualize where drugs are made

Regulatory Inspection Insights

Analyze FDA inspection outcomes

Potential Use Cases:

1. **Researchers:** Analyze geographic dependencies in pharmaceutical production.
2. **Policymakers:** Identify vulnerable supply-chain nodes.
3. **Healthcare Providers:** Plan procurement strategies for critical drugs.
4. **Patients:** Understand where their medicines are made.

supplychain.jhu.edu

NOTES

NOTES