

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

Committee

Nicolette A. Louissaint

Co-Chair

Nicolette Louissaint, Ph.D., MBA, 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 also is a registered lobbyist for HDA. 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

Co-Chair

Douglas Throckmorton, M.D., 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 J. Bollyky

Member

Thomas J. 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 Fox

Member

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

Member

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

Member

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

Member

Alex 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

Member

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.