ReVAMPing the Pharmaceutical Supply Chain: Implementing Policy to Prevent Drug Shortages

Meeting Summary

Hybrid Public Meeting | June 12, 2024 | 1:00 pm – 5:00 pm ET

The Duke-Margolis Institute for Health Policy hosted a public event on June 12, 2024 to discuss strategies for addressing drug shortage issues within the pharmaceutical supply chain. Discussions at the event addressed opportunities for coordinated policy action, measuring supply chain reliability, realigning incentives for reliability, and enabling reliability through advanced manufacturing technologies. Panelists included representatives from the U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), the Assistant Secretary for Planning and Evaluation (ASPE), the Administration for Strategic Preparedness and Response (ASPR), branded and generic manufacturers, health care providers, group purchasing organizations (GPOs), wholesalers, and more.

Opening Remarks

- Christine Linke Young of the White House Domestic Policy Council opened the event by describing misaligned incentives within the drug supply chain that mean supply chain reliability is not adequately rewarded. Legislative solutions, she suggested, must holistically evaluate and reward manufacturers and providers for taking appropriate and necessary steps to promote supply chain reliability.

Panel 1: Opportunities for Coordinated Policy Action

- Panelists noted that many federal agencies, especially within the Department of Health and Human Services (HHS), have begun working together in a more coordinated fashion to avoid redundancies and ensure that proactive, preventive steps are taken to address shortages.
    - ASPE has taken on a leadership role in coordinating these stakeholders and creating a strategic plan for addressing shortages.
    - FDA has worked to speed the process of bringing new manufacturing capacity online and extend the shelf life of existing product in case of shortages, issued guidance on risk management plans, developed a framework for quality management maturity, and supported advanced manufacturing.
    - ASPR has made significant direct investments in domestic manufacturing of essential medicines, especially advanced manufacturing, through its Industrial Base Management and Supply Chain Office.
    - CMS has proposed payments to small hospitals for maintaining a buffer stock of certain essential generic drugs at risk of shortage, reduced inflation rebates for certain drugs in shortage or at risk of shortage, and has partnered with ASPE to consider potential future policy actions.
- Panelists discussed the importance of coordination in addressing drug shortages. Each agency has strengths and limitations and cannot tackle the problem alone, but each can be more impactful in concert.

- Panelists identified key challenges in promoting reliability and resiliency in the drug supply chain, including a lack of adequate incentives for reliability, offshoring and resultant geographic concentration abroad, and recurring manufacturing quality issues.

Panel 2: Measuring Supply Chain Reliability

- Panelists noted distinct tools and programs used for measuring reliability, including the USP Medicine Supply map, the International Society for Pharmaceutical Engineering's Advancing Pharmaceutical Quality program, and individual manufacturers' internal efforts to identify opportunities for continual improvement.
- Panelists broadly agreed that the entirety of the pharmaceutical industry shares the objective of a reliable supply chain, which should include robust quality management practices but also other aspects that are typically outside of the "quality" realm, such as supply chain network planning, manufacturing capacity, and buffer inventory considerations. Furthering this aim could involve cross-industry collaborations or information exchange and public-private partnerships.
- In discussing elements of recent Congressional proposals, panelists emphasized the importance of committed contracting, enabling sustainable pricing for generics, a detailed plan for public-private partnerships, incentivizing resilience, and embracing advanced manufacturing.

Panel 3: Realigning Incentives for Reliability

- Panelists discussed the recent white paper published by HHS and draft legislation recently released by the Senate Finance Committee and were generally supportive of the demand-side approach laid out in these proposals but noted several outstanding concerns and open questions. Panelists expressed uncertainty about whether payments to providers would adequately impact manufacturer behavior. Panelists were also wary that an approach focused on committed contracting may overlook or exclude other factors that contribute to shortages.
- Further, panelists identified the issue of provider burden associated with new programs aimed at encouraging different purchasing practices, given already stretched labor capacity and the uncertainty of returns on demand side incentives.
- In creating policy solutions related to incentive structures, panelists suggested being mindful of where in the supply chain incentives should be placed for maximum efficacy.
- Panelists urged strategic thinking around the aims and implementation of buffer stocks as a mitigation measure for drug shortages, mentioning the need to consider equity and efficiency in inventory management and distribution, as well as the predicted duration of shortages.
- Finally, speakers noted that domestic manufacturing is not a guaranteed solution to many of the issues that have driven recent chronic drug shortages. Though they agreed geographic concentration in certain regions outside the U.S. is a concern, they also cautioned that geographic concentration in the U.S. could come with its own risks, and that U.S. sites are not immune to quality issues that have caused supply disruptions historically.

Panel 4: Enabling Reliability through Advanced Manufacturing Technologies

- Panelists pointed to the low return on investment in the generic manufacturing space as a major hinderance in the adoption of advanced manufacturing technologies, creating a risk-averse attitude for some in industry.

- Panelists discussed a distinction between “advanced” and “modernized” manufacturing technologies – the former referencing more innovative technologies such as continuous manufacturing, and the latter consisting of various technology upgrades that may not be cutting-edge, but would represent improvements in some sectors.
- Advanced manufacturing technologies may enable a transition to domestic manufacturing by offering flexibility and adaptability in production. Participants mentioned, however, that key starting materials are often not available in the US, requiring consistent global collaboration or a more concerted effort to diversify the upstream supply chain.
- In addressing the recent Senate Finance Draft Legislation, panelists suggested that the use of grants or other financial incentives directly to the manufacturers would be more impactful than demand-side support in encouraging the adoption of advanced manufacturing technologies. They emphasized that there is not one singular answer to address this complex, multi-factorial issue.

The Duke-Margolis Institute and the Duke-Margolis ReVAMP Supply Chain Consortium thank the participants in this meeting for their contributions. We look forward to continuing conversations with experts in government, industry, academia, and beyond to further the shared goal of ensuring patients have the medications they need.

Acknowledgements

The Duke-Margolis ReVAMP Drug Supply Chain Consortium consists of a group of experts in supply chain, manufacturing, regulatory science, national security, and drug shortages from academia, private industry, governmental agencies, and additional relevant stakeholder groups. The Consortium’s mission is to generate effective policy solutions that promote a reliable drug supply chain with advanced manufacturing capabilities and, ultimately, to improve patient outcomes by reducing the frequency and severity of drug shortages. This meeting summary may not represent the opinions of every Consortium member. This publication is not intended to limit the ability of Consortium members to provide their own comments on behalf of their independent organizations.

The Duke-Margolis project team for this meeting included Thomas Roades, Stephen Colvill, Gerrit Hamre, Marianne Hamilton Lopez, Grace Hoover, Cameron Joyce, and Katherine Hamilton.