

A call to action to mitigate and prevent drug shortages



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Drug Shortages: A Call to Action

Today, the undersigned organizations issue a Call to Action to mitigate and prevent drug shortages in the United States. **The time for change is now.** For far too long shortages have occurred with many classes of drugs and the impact on patients has been significant: treatment delays, the use of less effective treatments, or missed doses of therapies, often with life-threatening results. Policymakers, regulators, industry, payors, health systems and other stakeholders must act to identify and respond to the risks and vulnerabilities in the medicines supply chain – with a goal to ensure patients have access to the therapies they need.

Patient access to needed drugs can mean the difference between life and death. Shortages of critical drugs continue to plague our health care system and threaten patient access to lifesaving and life-sustaining therapies. At the end of 2022, there were 295 active and ongoing drug shortages in the United States, the highest number since 2014.¹ The impact upon patients has been significant, causing treatment delays or the use of less effective treatments, often with unfavorable outcomes.

Shortages are systemic and have long-lasting impacts on patients, health systems, and future innovation.

Drug shortages are regularly forcing health care providers into difficult ethical decisions, deciding which patients receive medications and which do not. Unfortunately, giving lower doses, fewer doses, or no drug at all to stretch a short supply among many patients is the only option when there are no other reasonable second- or third-line drug alternatives to a drug in shortage. In addition to delayed treatment, drug shortages also slow clinical trials of new treatments when those trials rely on the drugs in short supply as the standard of care, sometimes leading to institutions shutting down the trials altogether.

Solutions must also be systemic. The generic sterile injectable drug supply in particular has experienced shortages for over a decade.² With current competition for these drugs almost wholly dependent on price, the market neither recognizes nor rewards reliability and quality in drug production and delivery. Without the market rewarding drugs differentially based on their supply chain resilience, reliability, and quality, it is likely that shortages will continue even if resources are provided as one-time investments in manufacturing. While drug-specific prevention and mitigation activities are critical, systemic changes are needed to ensure patient

¹ ASHP. Drug Shortages Statistics. 2022; <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly>. Accessed July 2023.

² Federal Policies to Address Persistent Generic Drug Shortages. https://www.brookings.edu/wp-content/uploads/2023/06/20230621_ES_THP_GSI_Report_Final.pdf. Accessed October 2023.

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access to necessary medical treatments. Actions should address both short-term and long-term needs and include risk mitigation strategies, public and private investment and partnerships, payment reform to reward reliability and manufacturing quality, coordination and accountability, and policy reforms. Major areas include:

1. Coordinate Supply Chain Resilience and Reliability Efforts:

Medicines supply chain resilience and reliability activities should be coordinated among federal agencies and non-governmental stakeholders. Coordination efforts should include the organization of multi-disciplinary efforts, defining measurable outcome metrics for implementation efforts, and strategic planning activities to maximize the utility of new programs and increase the impact of existing initiatives. Additionally, necessary authorities and sufficient funding should be allocated to lead these cross-cutting efforts to improve drug supply chain resilience and reliability.

2. Increase Supply Chain Visibility:

A critical need exists to invest in early warning capabilities that signal threats to and vulnerabilities within the pharmaceutical supply chain. Recent and ongoing shortages in oncology drugs have made clear that while data signals exist that can help predict upstream pharmaceutical supply chain risk, the data are not integrated in a way that can generate actionable insights to prevent or mitigate drug shortages. U.S. Government entities and private sector stakeholders responsible for getting medical products to patients—including manufacturers, wholesalers, and hospitals—need actionable insights that can assist in anticipating and predicting supply chain vulnerabilities and their causes before they result in a drug shortage. A need prevails to integrate already existing data—such as unit volume, supply chain structure, facility quality management maturity, company financial health, epidemiology, and other demand drivers—to prevent drug shortages or mitigate their impact. Additionally, and importantly, an early warning system can help prevent protective purchasing in response to market signals such as FDA Form 483 publication. Such visibility needs to be available to all relevant medicine supply chain stakeholders. Furthermore, while visibility can help proactively inform stakeholders and allow for rapid implementation of mitigation strategies, such visibility does not address the root causes of shortages.

3. Establish a Vulnerable Medicines List:

A need exists to establish a vulnerable medicines list in the United States, as a complement to or a component of already established essential medicines lists, which factors in supply chain vulnerabilities. A

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vulnerable drugs list would be continually updated to reflect conditions that may increase the likelihood that a particular medicine could go into shortage. This list would ensure that finite resources and investments are focused on where they are most needed to improve medicines supply chain resiliency. Creation and utilization of vulnerable medicines lists will help prioritize medicines and properly target policy and economic interventions and finite resources with the aim to improve medicines supply chain resiliency. Supply chain vulnerabilities considered should include the quantity of suppliers and the quality of their manufacturing processes and inputs, geographic concentration of manufacturers and active pharmaceutical ingredient, excipient, and key starting material suppliers, political and geopolitical risks, climate change and vulnerabilities, manufacturing complexity, price, and other factors. This list can be used to target drugs for policy interventions that may include:

- Alternative payment and pricing models: guaranteed volume and price contracts, exclusive contracts, exclusion from Maximum Allowable Cost (MAC) lists, waiving Medicaid rebates, bonuses, or other preferential payments to providers;
- Targeted subsidies and tax incentives for broader geographic diversification of manufacturing to reduce risk including more domestic production, supply chain redundancies, and new market entrants;
- Other financial and regulatory incentives to encourage new market entry of manufacturers of the medicines.
- Advanced manufacturing technology investments;
- Development of reserves and incentives; and
- Transparency requirements, including of the product's upstream supply chain.

4. Align the Market to Incentivize a Quality and Adequate Supply Chain:

Policymakers and public and private drug purchasers should establish and utilize payment and purchasing models that value and incentivize supply chain quality, resilience, and reserves for drugs vulnerable to shortages. This will require developing or adopting objective metrics of quality, resilience, and reserves to drive these incentives.

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5. Bolster Manufacturing Capacity:

Policymakers should consider a range of reforms to foster more security in the manufacturing base for U.S. drug products to reduce the risk of disruptions and shortages. Some possible reforms include economic or other incentive measures that will encourage multiple suppliers for key drugs, geographic diversification of manufacturing facilities, and manufacturing location and component supply redundancies. Additionally, the development of tools and standards can help reduce technical barriers and facilitate wider adoption of advanced manufacturing technologies (AMTs) that have the potential to improve manufacturing efficiency, reduce production costs, reduce environmental footprints, and support supply chain resilience.

6. Research to Better Understand Market Interactions

To better understand the root causes of persistent drug shortages, non-biased and nonpartisan research into the complex market dynamics associated with generic medicines is necessary. Targeted pilots or demonstration projects can test interventions on a limited scope before scaling more broadly.

A fundamental shift in the market for lower-priced drugs is needed to align supply and demand forces to create a predictable, sustainable, and high-quality supply chain that can reliably provide critical drugs to patients. Policymakers and public and private drug purchasers must value quality and resilience through sustainable prices of drugs that demonstrate these characteristics. While the programs and policies to achieve this are being developed and implemented, there will continue to be a need in the near term for better tools to understand supply chain vulnerabilities and shortage risks, and ways to proactively intervene in a coordinated manner. Only by addressing both the short-term and long-term aspects of this issue will we be able to minimize impacts of the ongoing drug shortage crisis.

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