

VIA ELECTRONIC SUBMISSION

June 6, 2024

Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Wyden, Ranking Member Crapo, and members of the Committee,

The Drug Shortage Task Force on Preventing and Mitigating Drug Shortages (Task Force)¹ in the United States appreciates the opportunity to comment on the Senate Finance Committee's legislative draft to address shortages of critical medicines entitled: "Drug Shortage Prevention and Mitigation Act."

The Task Force is a 19 organization, multi-stakeholder collaborative of patient, provider, and public health organizations advocating for comprehensive reforms to prevent and mitigate drug shortages in the United States. We aim to raise awareness of the issue of drug shortages and the evidence about what's driving them, gather insights to inform recommended solutions, and advocate for reforms in a collaborative and productive manner. For far too long drug shortages, regardless of class, have significantly impacted patients across the United States. Shortages have led to treatment delays, the use of less effective treatments, or missed doses of therapies, often with life-threatening results. Limited patient access to needed drugs can mean the difference between life and death.

We write today to commend the Committee's work to address drug shortages with the discussion draft legislation which focuses on leveraging the Medicare and Medicaid programs to address the economic challenges faced by manufacturers of generic sterile injectables (GSIs). Shortages are systemic and have long-lasting impacts on patients, health systems, and future innovation. 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.

Immediate action is needed to reduce the impact on patients. Actions to mitigate and prevent shortages 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.

We are pleased that this timely discussion draft provides a first step for meaningful policy action to mitigate and prevent drug shortages and ultimately provide patients with uninterrupted access to critical medicines. The impact of shortages upon patients has been significant; [a recent HHS report](#) indicates that an average drug shortage impacts at least a half a million American consumers. Those impacted were ages 65 to 85 (32 percent), 55 to 64 (24 percent) and 45 to 54 (17 percent). These groups accounted for more than two-thirds of those impacted.

¹ Solving drug shortages: A call to action. 2024; <https://www.usp.org/supply-chain/drug-shortages>

Importantly, drug shortages cause treatment delays or the use of less effective treatments which often leads to harmful and costly outcomes for patients and the healthcare system.

The Drug Shortage Task Force has articulated a set of principles to guide our work that are designed to provide a holistic and coordinated response to this critical issue. These principles are reflected in a Call to Action, which urges Congress to enact comprehensive reform to prevent shortages and ensure patients with consistent and uninterrupted access to quality medicines and include:²

1. 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.

The Task Force is pleased to see that a fundamental element in the Committee's approach is focused on measuring resilience and reliability of the supply chain and includes payment reforms as well as acknowledgment of the need for ways to differentiate supplier and manufacturers.

2. Establish a vulnerable medicines list: As a complement to or a component of already established essential medicines lists, a vulnerable drugs list, which factors in supply chain vulnerabilities, should be established and 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. 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.

The Task force is pleased to see this bill focuses on generic injectables, which is the most shortage vulnerable class of medicines and accounts for the majority of shortages each year. We recommend that the committee consider including the establishment of a vulnerable medicines list to aid in the identification of drugs at risk of shortage and eligible for the newly proposed program.

3. 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.

² A call to action to mitigate and prevent drug shortages. 2024;
<https://www.usp.org/sites/default/files/usp/document/supply-chain/call-to-action-on-drug-shortages.pdf>

The Task Force supports the inclusion of mechanisms to incentivize greater adoption of AMT by manufacturers.

4. 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.

The Task Force is pleased to see efforts to collaborate among U.S. Federal Agencies included in the discussion draft. We encourage continued coordination among Agencies as well as with relevant supply chain stakeholders.

The Task Force thanks the Committee for its attention to addressing drug shortages and improving patient care. We are committed to working on bipartisan solutions to this urgent public health issue and look forward to working with this Committee and Congress to seek solutions to drug shortages that will ensure patients have access to the therapies they need. In the meantime, if you have any questions or would like additional follow up, please contact Amy Sonderman (Amy@usp.org) and Pam Traxel (Pam.Traxel@cancer.org), Co-Leads for the Drug Shortage Task Force.

Sincerely,

The Drug Shortage Task Force on Preventing and Mitigating Drug Shortages (Undersigned Organizations)

**Alliance for Aging Research
Alliance for Patient Access
American Cancer Society Cancer Action Network
Angels for Change
American Medical Association
American Pharmacists Association
Arthritis Foundation
American Society of Health-System Pharmacists
Association for Clinical Oncology
Cancer Support Community
Consumer Action
Friends of Cancer Research
Hemophilia Federation of America
Howard University College of Pharmacy
Susan G. Komen
National Consumers League
National Psoriasis Foundation
National Rural Health Association
United States Pharmacopeia**