

VIA ELECTRONIC SUBMISSION

July 26, 2024

The Honorable Chuck Schumer
Majority Leader, US Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Johnson
Speaker of the House
568 Cannon House office Building
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader, US Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Hakeem Jefferies
Minority Leader, House of Representatives
2433 Rayburn House Office Building
Washington, DC 20515

Dear Leaders Schumer, McConnell, Johnson and Jeffries,

The Task Force on Preventing and Mitigating Drug Shortages (Task Force)¹ writes today to urge you to prioritize the issue of preventing and mitigating drug shortages in the United States. For far too long, drug shortages have impacted millions of Americans and resulted in serious negative consequences for patients, health systems, and hospitals. Recent reports underscore the severity of the situation:^{2,3,4}

- The number of drugs in shortage is at an all-time high.
- Shortages are lasting longer – averaging over three years compared to around two years in 2020.
- A wide range of therapeutic classes are impacted by drug shortages.

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 Americans. While there will be periodic improvement in the availability of particular drugs, overall, drug shortages continue to compromise patient care in significant ways: treatment delays, the use of less effective treatments, or missed doses of therapies, all of which can lead to harmful and costly outcomes for patients and the healthcare system. Limited patient access to needed drugs can mean the difference between life and death. More must be done to prevent and address drug shortages – now.

The Task Force is a 20 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. **Task Force members encounter drug shortages first-hand every day.** We are comprised of patient groups who advocate for millions of Americans who are

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

² USP Annual Drug Shortage Report: Economic factors underpin 2023 shortages. 2024;

[https://go.usp.org/l/323321/2024-05-](https://go.usp.org/l/323321/2024-05-31/92zsjg/323321/1717187146zqOpt4vW/GEA_GC_056R_MSM_Report_2024_05_FINAL.pdf?_gl=1*1h1d8o*_gcl_a)

[31/92zsjg/323321/1717187146zqOpt4vW/GEA_GC_056R_MSM_Report_2024_05_FINAL.pdf?_gl=1*1h1d8o*_gcl_a](https://go.usp.org/l/323321/1717187146zqOpt4vW/GEA_GC_056R_MSM_Report_2024_05_FINAL.pdf?_gl=1*1h1d8o*_gcl_a)
[u*NjMzNTA5NzEuMTcxNjkwNjA0Ng..*_ga*MzlxNDMzMTkyLjE2NDA3MDk1NTA.*_ga_DTGQ04CR27*MTcxNzUyMTQ4Ni41NDMuMC4xNzE3NTIxNDg2LjAuMC4w](https://go.usp.org/l/323321/1717187146zqOpt4vW/GEA_GC_056R_MSM_Report_2024_05_FINAL.pdf?_gl=1*1h1d8o*_gcl_a)

³ Severity and Impact of Current Drug Shortages. ASHP. 2024; <https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf>

⁴ Big Questions on Drug Shortages: Why do Drug Shortages Happen? Generics Access Project. 2024; <https://genericsproject.org/wp-content/uploads/2024/06/GAP-BigQ-DrugShortages-June2024.pdf>

unable to access life-saving medicines, including cancer and arthritis drugs. We also include provider and healthcare professional groups, representing over 400,000 pharmacists and physicians across the country who are on the front lines of this issue. The Task Force aims to raise awareness of the severe impacts of shortages as well as the evidence about what's driving them, gather insights to inform recommended solutions, and advocate for reforms in a collaborative and productive manner.

While we are pleased to see the development of various legislative drafts and white papers seeking to address the issue of drug shortages, we urge leadership and timely, coordinated action now. These 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, and coordination and accountability.

The Task Force has articulated a Call to Action, which urges Congress to enact comprehensive reforms to prevent shortages and ensure patients have consistent and uninterrupted access to quality medicines:⁵

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 maintenance of reserves for drugs vulnerable to shortages. This will require developing or adopting objective metrics to assess quality, resilience, and reserves.
2. **Increase supply chain visibility:** A critical need exists to invest in early warning capabilities that can signal threats to and vulnerabilities within the pharmaceutical supply chain. 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.
3. **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.
4. **Bolster manufacturing capacity:** Policymakers should consider a range of reforms to foster more resilience in the manufacturing base for U.S. drug products to reduce the risk of disruptions and shortages.
5. **Coordinate supply chain resilience and reliability efforts:** Medicines supply chain resilience and reliability activities should be coordinated among federal agencies and non-governmental stakeholders.

⁵ 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>

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.

The Task Force thanks you for your attention to addressing drug shortages and improving patient care in the United States. We are committed to working on bipartisan solutions to this urgent public health issue and look forward to working with you to seek solutions to drug shortages that will ensure patients have access to the life-saving therapies they need. If you have any questions or would like additional follow up, please contact Amy Sonderman (Amy@usp.org) and Nishith Pandya (nishith.pandya@cancer.org) Co-Leads for the Task Force.

Sincerely,

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

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

cc:

Congresswoman Cathy McMorris-Rodgers, Chair, House Energy and Commerce Committee
Congressman Frank Pallone, Ranking Member, Energy and Commerce
Senator Bernie Sanders, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Bill Cassidy, Ranking Member, Health, Education, Labor and Pensions Committee
Congressman Jason Smith, Chair, House Ways and Means Committee
Congressman Richard Neal, Ranking Member, House Ways and Means Committee
Senator Ron Wyden, Chair, Senate Committee on Finance
Senator Mike Crapo, Ranking Member, Senate Committee on Finance