

February 20, 2024

The Honorable Joseph R. Biden
President of the United States
1600 Pennsylvania Avenue NW
Washington, DC 20500

Delivery via electronic mail

RE: Issue Brief: Supply Chain Resilience

Dear President Biden:

We write to commend you and your administration for your work to address drug shortages and to propose that you underscore the urgency of strengthening pharmaceutical supply chain resilience in your upcoming State of the Union address to Congress, given the ongoing urgency of this issue to the American people and our nation's public health. Drug shortages are not a partisan issue, and your address to Congress is an important opportunity to highlight the collaboration between Congress and your Administration to tackle the issue together.

By way of background, the United States Pharmacopeia (USP) in collaboration with the American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN), co-hosted [a summit](#) in September 2023 to explore the challenges of drug shortages, discuss mitigation strategies to prevent future shortages, and improve access to vulnerable medicines. Congruent with your administration's focus on pharmaceutical supply chain resiliency and commitment to address drug shortages, key themes that emerged from the summit are that the root causes of drug shortages are consistent across many categories of drugs; the underlying causes of shortages can only be corrected with policy reforms and economic incentives; and, most importantly, that sustainable solutions to this problem depend on coordinated action across U.S. government and non-governmental organizations.

In response to these learnings, this taskforce of organizations developed and proposed a set of principles - informed by the summit and conversations with key stakeholders - 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. We are committed to working with both sides of the aisle on bipartisan solutions to this urgent public health issue.

Mr. President, we believe your State of the Union address provides a timely and important opportunity for you to highlight the strides made in mitigating and preventing drug shortages and providing 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, and that more than two thirds of those impacted were consumers ages 65 to 85 (32 percent), 55 to 64 (24 percent) and 45 to 54 (17 percent). 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.

Your recent announcement of nearly 30 new actions to strengthen supply chains critical to America's economic and national security and to mitigate drug shortages is significant, and we stand ready to support these efforts. While FDA and other agencies have been in the forefront of mitigating shortages when they happen, our multi-stakeholder coalition believes that more can be accomplished to prevent them from occurring in the first place. For example, cross-governmental supply chain data-sharing capabilities can help better address vulnerabilities and points of failure for critical drugs. Payment system reforms can improve the sustainability of producing the medicines which are consistently vulnerable to shortages. It is important for Congress to hear from you that your Administration stands ready to work with Congress on policy reforms to complement your Administration's actions so that we build on the progress we have made toward a more resilience, sustainable supply chain that reliably provides critical drugs to American patients.

For far too long, drug shortages have posed a significant threat to our nation's patients and public health. The time for action is now and your continued leadership is needed on this issue. Together we can make a significant impact in finding sustainable solutions to this pressing issue for our nation's patients.

Please contact our taskforce lead Amy Sonderman (amy@usp.org) for any questions or further information.

Regards,

Taskforce Members

CC:

Jeff Zients, Chief of Staff to the President

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Steve Benjamin, Assistant to the President, Senior Advisor to the President and Director of Public Engagement

Xavier Becerra, Secretary, U.S. Department of Health and Human Services

Alliance for Aging Research

American Cancer Society Cancer Action Network

American Pharmacists Association (APhA)

American Society of Clinical Oncology (ASCO)

Angels for Change

Arthritis Foundation

Cancer Support Community (CSC)

Friends of Cancer Research

Generics Access Project/ Alliance for Patient Access

National Consumers League (NCL)

National Psoriasis Foundation

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