

United States Senate

WASHINGTON, DC 20510

January 3, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Ave.
Washington, DC 20201

The Honorable Robert Califf, MD, MACC
Commissioner of Food and Drugs
U.S. Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Secretary Becerra and Commissioner Califf:

We write to express our strong concern regarding the continued shortage of a significant number of critical acute and maintenance drugs vital to patients. Patients, their loved ones across the country, and providers have shared how these shortages have upended lives and had an adverse impact on patient care.

The Food and Drug Administration (FDA) notes¹ common and necessary drugs including amoxicillin and other antibiotics, anesthetics like Lidocaine, and anticoagulants used to prevent blood clots, heart attack and stroke (such as Heparin) are increasingly in short supply. Likewise, millions of Americans have been adversely affected by the shortage of drugs consumers routinely rely upon, such as Adderall, used to treat attention-deficit/hyperactivity disorder (ADHD) and narcolepsy. Additionally, short supplies of pediatric formulations of commonly-used drugs such as ibuprofen, acetaminophen, and amoxicillin, have resulted in parents and providers unable to treat sick children, and drug stores restricting sales in certain regions. The University of Minnesota notes that nationally between 23 and 46 percent of critical acute drugs are in shortage as of the date of this letter,² and it is estimated that many of these shortages will remain unresolved into 2023. Additionally, items used to make, store, or deliver drugs are contributing to problems accessing needed medication.

Last February, President Biden released an Executive Order on America's Supply Chains.³ In response, the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness Response (ASPR) and the FDA released policy recommendations to help boost domestic production, especially for medications that are in shortage.⁴ ASPR and FDA highlighted the need to ensure timely access to pharmaceuticals for Americans.

We urge HHS and the FDA to convene the Drug Shortage Task Force and work with stakeholders on identifying factors and potential solutions to mitigating the factors causing these shortages. Further, we request information on specific factors that have led to ongoing and increased shortages of acute critical drugs and important treatments, what actions FDA and HHS

¹ <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

² <https://www.cidrap.umn.edu/resilient-drug-supply/resilient-drug-supply-critical-acute-drugs>

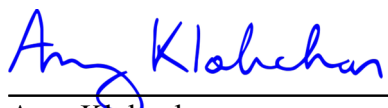
³ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/24/executive-order-on-americas-supply-chains/>

⁴ <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>

have taken to address these shortages, and an update on ongoing FDA initiatives to prevent and mitigate drug shortages in general, and what factors prevent more successful mitigation of such shortages.

We look forward to working with the Department and its agencies in continuing to address medical shortages as the supply chain and health care landscape evolve.

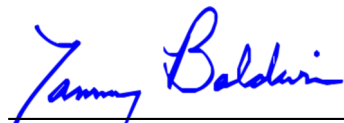
Sincerely,



Amy Klobuchar
United States Senator



Tina Smith
United States Senator



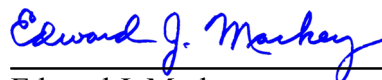
Tammy Baldwin
United States Senator



Tim Kaine
United States Senator



Sherrod Brown
United States Senator



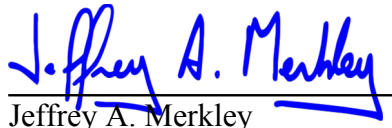
Edward J. Markey
United States Senator



Elizabeth Warren
United States Senator



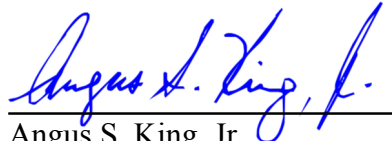
Chris Van Hollen
United States Senator



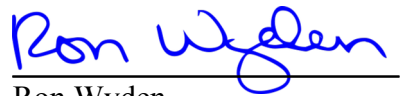
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