



May 21, 2024

The Honorable Bernie Sanders
Chair
HELP Committee
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bill Cassidy, MD
Ranking Member
HELP Committee
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

RE: Addressing the Drug Shortage Crisis

Dear Chair Sanders, Ranking Member Cassidy, Chair McMorris Rodgers, and Ranking Member Pallone:

On behalf of the Generics Access Project (GAP) and the undersigned organizations, we are writing to encourage Congress' focus on mitigating the ongoing drug shortage crisis by addressing the systemic issues that contribute to the continuation of this issue.

GAP is a coalition of patient advocacy organizations across disease states who advocate for policies that promote generic competition and efficient approval of generic medicines. Generic medicines are a critical cost-lowering mechanism for patients and the healthcare system. Ensuring that patients have timely access to these affordable medicines is crucial.

The ongoing drug shortage crisis continues to inhibit patient access, causing delays in treatment, forcing patients and clinicians to turn to often less effective treatment options, and leading to patients missing or altering doses to make up for the lack of access. A survey from the American Cancer Society Cancer Action Network showed that one-in-ten patients currently receiving cancer treatment have been affected by the recent drug shortages.¹ This is not unique to oncology. A survey conducted by the American Society of Health-System Pharmacists showed that 99.7% of respondents had experienced shortages of intravenous solutions, emergency syringes, as well as other critical drugs and medical supplies.² Patients across disease states have been impacted by these shortages, especially those in which generic medicines are used.

¹ [survey_drug_shortages_biomarkers_1.pdf \(fightcancer.org\)](#)

² [ASHP-Sterile-Injectable-Drug-Shortages-March2022.pdf](#)

Generic medications are an important resource in expanding access, as more affordable, effective treatment options for patients and the providers who treat them. These medicines make up about 91% of all prescriptions but only about 18% of the prescription spending. However, generic drugs are at an increased risk of shortage in large part due to market forces such as low prices and margins, short-term procurement contracts, and the ability of purchasing organizations to change suppliers. Lower priced generics have a higher likelihood of being in shortage. In the FDA's 2019 report "Drug Shortages: Root Causes and Potential Solutions," the first of the root causes discussed is the lack of incentives in place for manufacturers to produce less profitable drugs.

As the drug shortage crisis continues, it is clear that Congress needs to take a systemic and multi-faceted approach in establishing policy solutions. Solutions should address both short and long-term needs to help mitigate the current and active risks as well as progressive solutions to the ongoing systemic issues.

Manufacturing

Establishing models that incentivize the quality and resilience of the supply chain can lead to more sustainable practices and potentially prevent drug shortages before they occur. In the short-term, bolstering manufacturing practices through economic and policy incentives to ensure the increased capacity to meet the necessary demand of these medications can also help to lessen the potential for drug shortages.

Market Structure

Generic competition for oral generics, combined with the purchasing power of a handful of large generic purchasing organizations, have led to price deflations for certain oral generics. Policies should be considered to support stability in the generic marketplace, ensuring manufacturers do not opt out of making certain generics based on a lack of profitability.

Supply Chain

Increasing transparency within the supply chain can help stakeholders better anticipate and predict the vulnerabilities that could later lead to drug shortages. Shedding more light on these vulnerabilities allows stakeholders to adjust to help mitigate risks and avoid shortages. Strong supply chain tracking and disruption prediction should be enhanced throughout the entire process to allow for adjustments to be made earlier. Further, ensuring that the FDA's reporting requirements for generic manufacturers are useful in identifying and mitigating future shortages is critical; FDA should prioritize having the right information rather than more information.

Awareness

Addressing the drug shortage crisis begins with continuing to bring awareness to the root causes. The systemic nature of these ongoing shortages means that a solution cannot be found without understanding all the contributing factors and ensuring that there is a multifaceted approach to solving them.

GAP would also like to make you aware of resources being created by a drug shortages task force convened by U.S. Pharmacopeia (USP) and the American Cancer Society Cancer Action Network (ACS CAN). The task force, consisting of leading patient advocacy and health

professional organizations, has created a drug shortages [call to action](#) that contains specific recommendations that are aligned with the solutions outlined above.

It is imperative that Congress take meaningful action to address the drug shortage crisis. Access to these medications can often mean the difference between life and death, and patients cannot be left to continue waiting for solutions to be implemented.

Should you have any questions, please contact Gavin Clingham at gavin@allianceforpatientaccess.org.

Sincerely,

American College of Allergy, Asthma & Immunology
Allergy & Asthma Network
Alliance for Gout Awareness
Alliance for Patient Access
Arthritis Foundation
Asthma and Allergy Foundation of America
Biomarker Collaborative
Caregiver Action Network
Chronic Migraine Awareness
Coalition for Headache and Migraine Patients (CHAMP)
Coalition of Hematology and Oncology Practices
Clusterbusters, Inc.
Derma Care Access Network
DiabetesSisters
Endocrine Nurses Society
Exon 20 Group
Epilepsy Alliance America
Epilepsy Alliance Louisiana
Epilepsy Information Service of Wake Forest School of Medicine
Epilepsy Services Foundation, Inc.
Epilepsy Services of New Jersey
Epilepsy Support Network of Orange County
Foundation for Sarcoidosis Research
Future Leaders in Sight
Gout Support Group of America
Global Colon Cancer Association
GO2 for Lung Cancer
Headache & Migraine Policy Forum
HealthyWomen
International Cancer Advocacy Network (ICAN)
Lupus and Allied Diseases Association, Inc.
MET Crusaders
Migraine at School

Miles for Migraine
Movement Disorders Policy Coalition
National Alliance for Eye and Vision Research
National Headache Foundation
Patients Rising
PD-L1 Amplifieds
South Carolina Advocates for Epilepsy
Spondylitis Association of America
Support Fibromyalgia Network
TED Community Organization
U.S. Pain Foundation
U.S. Pharmacopeia
Vision Health Advocacy Coalition