

March 3, 2020

The Honorable Scott Peters
United States House of Representatives
Washington, DC 20515

The Honorable Brett Guthrie
United States House of Representatives
Washington, DC 20515

The Honorable Eliot Engel
United States House of Representatives
Washington, DC 20515

The Honorable Richard Hudson
United States House of Representatives
Washington, DC 20515

The Honorable Anna Eshoo
United States House of Representatives
Washington, DC 20515

The Honorable Michael McCaul
United States House of Representatives
Washington, DC 20515

The Honorable Kurt Schrader
United States House of Representatives
Washington, DC 20515

The Honorable Gus Bilirakis
United States House of Representatives
Washington, DC 20515

Re: The Preventing Drug Shortages Act

Dear Representatives Peters, Engel, Eshoo, Schrader, Guthrie, Hudson, McCaul, and Bilirakis,

The undersigned organizations are writing in support of *The Preventing Drug Shortages Act*. Drug shortages have been on the rise for several years, with an estimated 210 drugs currently at risk or not readily available for U.S. hospitals, according to the national database maintained by the American Society of Health System Pharmacists (ASHP).¹ The Food and Drug Administration (FDA) also states that drug shortages have grown more persistent since 2014 with many shortages lasting multiple years.²

Furthermore, as the United States takes steps in response to the outbreak of COVID-19, concerns with the integrity of the drug supply chain and the potential impact on downstream drug shortages have surfaced.

Drug shortages impact every single segment of the healthcare ecosystem and are a major driver of skyrocketing costs, contributing to half a billion dollars in increased healthcare expenditures annually.^{3,4}

Drug shortages also result in increased potential for adverse events and increased costs to the healthcare system, such as increased hospital days, due to the unavailability of a critical medication.

¹ Available at: <https://www.ashp.org/Drug-Shortages>

² FDA Public Hearing Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. Available at: <https://healthpolicy.duke.edu/events/drug-shortage-task-force>

³ "Changes in Drug Pricing After Drug Shortages in the United States" (*Annals of Internal Medicine*, September 2018). <http://annals.org/aim/article-abstract/2702478/changes-drug-pricing-after-drug-shortages-united-states>

⁴ "Impact of drug shortages on U.S. health systems" (*American Journal of Health-System Pharmacy*, October 2011). <https://www.ncbi.nlm.nih.gov/pubmed/21930639>

Shortages persist for a variety of complex reasons, and no one-size-fits-all strategy will fix the problem. Sustainable solutions to address drug shortages must decrease barriers to entry, namely the time and cost to enter the marketplace, while maintaining the quality and safety of the product.

Congress has made major strides in helping to address drug shortages in the past by enacting the Food and Drug Administration Safety and Innovation Act (FDASIA) Title X reporting requirements, the track and trace requirements of the Drug Quality and Safety Act, the Competitive Generics Therapy pathway under the FDA Reauthorization Act of 2017 (FDARA), and others. These bipartisan Congressional actions have made a significant contribution to the effort to reduce the impact of drug shortages, but more needs to be done to help eliminate drug shortages once and for all.

The Preventing Drug Shortages Act builds upon the prior work of Congress to provide additional authority to the FDA to help mitigate drug shortages to ensure a stable supply of medications critical for patient care. Specifically, the Preventing Drug Shortages Act:

- Strengthens FDASIA Title X reporting requirements to include full disclosure of the problems resulting in the shortage, information concerning the extent of the shortage, its expected durations, and other information the Secretary may require;
- Extends FDASIA Title X reporting requirements to active pharmaceutical ingredient (API) manufacturers;
- Studies FDA's efforts to improve intra-agency and inter-agency coordination to account for the downstream impact of cGMP violations, facility shutdowns, etc on shortages; and
- Requires manufacturers to implement risk management plans.

We applaud your bipartisan commitment to addressing drug shortages and decreasing healthcare costs while improving patient outcomes. Thank you for championing this very important issue and please use our organizations as a resource as you continue to lead this initiative forward.

Sincerely,

America's Essential Hospitals (AEH)
American Academy of Ophthalmology (AAO)
American Hospital Association (AHA)
American Society for Parenteral and Enteral Nutrition (ASPEN)
American Society of Anesthesiologists (ASA)
American Society of Consultant Pharmacists (ASCP)
American Society of Health-System Pharmacists (ASHP)
Association for Clinical Oncology (ASCO)
Association of American Medical Colleges (AAMC)
Children's Hospital Association (CHA)
Federation of American Hospitals (FAH)
Healthcare Supply Chain Association (HSCA)
Premier healthcare alliance