October 28, 2019

The Honorable Susan Collins
United States Senate
Washington, DC 20002

The Honorable Tina Smith
United States Senate
Washington, DC 20002

Re: The Mitigating Emergency Drug Shortages (MEDS) Act

Dear Senator Collins and Senator Smith,

The undersigned organizations are writing in support of *The Mitigating Emergency Drug Shortages (MEDS) 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]

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 consequently increased costs to the healthcare system such as increased hospital days, due to the unavailability of a critical medication. For example, a 2014 shortage of norepinephrine was significantly associated with increased mortality amongst patients with septic shock.[5] The FDA estimates that the norepinephrine shortage resulted in $13.7 billion of projected losses to the U.S. healthcare system.[6]

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

[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
[5] Vail, Emily, Gershengorn, Hayley, Hua, May, Walkey, Allan, Rubenfeld, Gordon & Wunsch, Hannah. (2017). Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. JAMA. 317.DOI: 10.1001/jama.2017.2841.
[6] 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

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 MEDS Act builds upon the prior work of Congress to provide additional authority to the FDA to help mitigate drug shortages and develop market-based incentives to help ensure a stable supply of medications critical for patient care. Specifically, the MEDS Act:

- Creates a priority pathway for the review of drug shortage applications;
- Requires the Secretary to develop a report to Congress with recommendations to incentivize manufacturers to enter the market for shortages as well as incentives to encourage the domestic manufacturing of finish dose formulations and active pharmaceutical ingredients (API);
- 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 API manufacturers;
- Requires manufacturers to report redundancy and contingency plans to ensure ongoing supply;
- Requires the Secretary to develop a report to Congress with recommendations on consumer notification of shortages;
- 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;
- Expands the FDA drug shortage list to include regional shortages as well as shortages based on strength and dosage form; and
- Examines the risk to national security as a result of shortages.

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 Society for Parenteral and Enteral Nutrition (ASPEN)
Federation of American Hospitals (FAH)
Premier healthcare alliance