

February 27, 2020

The Honorable Lamar Alexander
United States Senate
Washington, DC 20002

The Honorable Patty Murray
United States Senate
Washington, DC 20002

Re: S.2723 - The Mitigating Emergency Drug Shortages (MEDS) Act

Dear Chairman Alexander and Ranking Member Murray,

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. While no drug shortages have been reported thus far in direct correlation with COVID-19, past situations such as H1N1, Ebola, and Hurricane Maria have highlighted vulnerabilities in the drug supply chain that require congressional action to ensure a stable supply of critical medications is available for patient care. Furthermore, the World Health Organization (WHO) and the Food and Drug Administration (FDA) have stated the COVID-19 outbreak will likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products in the United States.

Therefore, the undersigned organizations are writing in support of *S.2723 - The Mitigating Emergency Drug Shortages (MEDS) Act* which is a holistic and sustainable approach to eliminating drugs shortages and addressing vulnerabilities in the drug supply chain. We urge the Senate Committee on Health, Education, Labor, and Pensions (HELP) to advance this critical piece of legislation expeditiously.

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 following scenarios exemplify the need for enactment of the MEDS Act:

- A major concern with the COVID-19 outbreak in China is the overreliance on a single nation for a significant portion of the United States' drug supply. The MEDS Act helps address this overreliance by requiring the Secretary of Health and Human Services (HHS) to develop a report to Congress with recommendations to incentivize the domestic manufacturing of finished dose formulations and active pharmaceutical ingredients (API). The MEDS Act also examines the risk to national security.
- A lesson learned from Hurricane Maria is the lack of transparency regarding where critical drugs are manufactured, the source of API, and redundancy plans. To overcome these lessons learned, the MEDS Act requires manufacturers to report to the FDA the exact location of manufacturing for these critical drugs, the exact source of all raw materials, and redundancy and contingency plans to ensure a stable supply. In the case of COVID-19, this type of information would be critical to understand exactly what is being manufactured in China, exactly what proportion of API and raw materials are manufactured in China, and what a

manufacturers' contingency plans are should manufacturing in China no longer be feasible. This is all critical information to understand the true risk to the supply chain and potential drug shortages due to pandemics such as COVID-19.

- Another major unknown currently is the downstream impact of any potential API shortages as a large portion of the world's API is manufactured in China. Currently, API manufacturers do not have to report supply disruptions to the FDA. The MEDS Act would expand FDASIA Title X reporting requirements to API manufacturers and require reporting of potential supply disruptions to the FDA, creating an early warning system that would allow the FDA upstream visibility to appropriately assess risk and rapidly work to identify alternative sources of supply.

Recognizing the importance of these critical drugs for patient care, we urge the Senate HELP Committee to markup the MEDS Act expeditiously so that the United States can strengthen its drug supply chain. In addition, 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
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
Association of American Medical Colleges (AAMC)
Children's Hospital Association (CHA)
Federation of American Hospitals (FAH)
Greater New York Hospital Association (GNYHA)
Healthcare Supply Chain Association (HSCA)
Premier healthcare alliance