

October 28, 2019

The Honorable Susan Collins
United States Senate
Dirksen Building, #413
Washington, D.C. 20510

The Honorable Tina Smith
United States Senate
Hart Senate Office Building, #720
Washington, D.C. 20510

Re: The Mitigating Emergency Drug Shortages (MEDS) Act

Dear Senator Collins and Senator Smith,

The undersigned organizations write in support of the “Mitigating Emergency Drug Shortages (MEDS) Act.” Our organizations, which have worked collaboratively to identify policy solutions to prevent drug shortages since 2010, believe that MEDS Act is a significant step in addressing the risk drug shortages present to patients, physicians and hospitals.

Serious shortages of critical drugs have become the norm for our nation’s healthcare system. Over the last several years, natural disasters, most notably Hurricane Maria, quality problems, manufacturer consolidation and other issues have disrupted pharmaceutical manufacturing in Puerto Rico and have left U.S. healthcare system on the brink of a significant public health crisis multiple times. Our healthcare system continues to grapple with numerous shortages stemming from quality and capacity issues that were exacerbated, rather than caused, by the storm.

There were well over 200 shortages in 2018 and that number has continued to grow in 2019.¹ Healthcare providers, including hospitals, health systems, and clinics, struggle to obtain medications, some of which are essential to maintain basic levels of patient care, such as sodium bicarbonate and IV immunoglobulin. Hospital pharmacists regularly report that they must spend considerable time identifying alternative sources of medication, which not only jeopardizes patient care, but also requires significant staff time, resulting in both financial and personnel challenges. In some cases, drug shortages have held healthcare hostage, forcing delay or cancellation of procedures until medication supply becomes available.

Last year, shortages of critical IV medications, running the gamut from life-supporting products like saline and amino acids to injectable opioids required for surgery, placed unsustainable burdens on clinicians who had to scramble to obtain these products. In some cases, there was no alternative therapy available and patients suffered.

The MEDS Act provides increased FDA authority, enhanced manufacturing reporting requirements, and new market-based incentives that will help mitigate the risks drug shortages pose to both our patients and the healthcare system generally. We were particularly pleased that the bill addresses our shared policy goals:

¹ See American Society of Health-System Pharmacists, “National Drug Shortages: Active Drug Shortages by Quarter”, available at <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>.

- Strengthening requirements to disclose the root causes and expected duration of shortages;
- Extending reporting requirements to active pharmaceutical ingredients (API) manufacturers;
- Requiring manufacturers have contingency plans to ensure ongoing supply;
- Developing recommendations to incentivize manufacturers to enter the market for drugs in shortage; and
- Examining the national security risks of shortages.

Our organizations applaud you for introducing this important legislation, and we look forward to working with you to move the bill forward. Please do not hesitate to use our organizations as a resource as you continue leading the effort to mitigate and prevent drug shortages.

Sincerely,

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