

VIA ELECTRONIC SUBMISSION

July 21, 2023

The Honorable Gary Peters
United States Senate
724 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Braun
United States Senate
404 Russell Senate Office Building
Washington, DC 20510

The Honorable James Lankford
United States Senate
316 Hart Senate Office Building
Washington, DC 20510

Subject: Mapping America's Pharmaceutical Supply Act (the MAPS Act)

Dear Senators Peters, Lankford and Braun:

The United States Pharmacopeia (USP) is pleased to offer its support for the "*Mapping America's Pharmaceutical Supply Act*" (S. 2364), or the MAPS Act. We applaud your leadership in advancing this initiative to help build a more resilient pharmaceutical supply chain.

In facilitating the mapping of the medicines supply chain, the MAPS act will enable the development of actionable insights on the pharmaceutical supply chain by identifying critical vulnerabilities. Moreover, a robust mapping can provide a greater understanding of where active pharmaceutical ingredients (APIs) and key starting materials (KSMs) are produced, can help target responses to help mitigate drug shortages, and inform policy reforms and U.S. government investments to enhance resilience.

USP is an independent, scientific, global non-profit organization governed by more than 500 organizations, including scientific, healthcare practitioner, consumer, and industry organizations, as well as dozens of government agencies, who together comprise the USP Convention.¹ Nearly 1000 experts from the scientific and healthcare community volunteer on USP's Expert Committees to establish nearly 5000 public quality standards for medicines, which are published in the *United States Pharmacopeia – National Formulary*. These scientific quality standards support a core pillar of USP's work which is to strengthen the global supply chain to help ensure the supply of quality medicines relied upon by patients in the US and around the world.

Identifying and addressing vulnerabilities in the upstream pharmaceutical supply chain is an essential component to foster a more resilient supply chain and to mitigate drug shortages, which have been increasing for both acute and chronic care medicines. According to our research, in many cases, upstream challenges, along with increasingly low prices for essential medicines, are frequently correlated with drug shortages. Unfortunately, insights into vulnerabilities of the upstream supply chain for medicines are especially limited, and these limitations include a lack of an in-depth understanding of the locations and volumes of the production of raw chemicals, KSMs, and APIs. Ultimately, this 'insights gap' undermines the ability of the US Government and other stakeholders to pinpoint responses that would create more resiliency and potentially avoid drug shortages.

¹ USP's governing bodies, in addition to the Council of the Convention, include its Board of Trustees and Council of Experts.

While these insight gaps are sobering, it is nonetheless encouraging that data signals exist that can be harnessed to help identify upstream risk and could contribute to an early warning system that could help provide predictive analysis of potential supply chain impacts from disruptions. An informed early warning capacity would provide data and insights to guide policy reforms to strengthen the resilience of the supply chain, and would help prepare the nation for public health emergencies. Data-informed insights will also help ensure that the US Government's investments in supply chain resilience are appropriately focused to address specific problems and provide confidence that taxpayer dollars are invested where they can be most effective.

The MAPS Act is a significant step to building a more resilient medicines supply chain. USP looks forward to working with you to advocate for passage of this critical legislation. If you have any questions or would like additional follow up, please do not hesitate to reach out to Joseph M. Hill, Director, U.S. Government Affairs at Joe.Hill@USP.org or 202-239-4137.

Sincerely,



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