

VIA ELECTRONIC SUBMISSION

July 10, 2023

The Honorable Bernie Sanders
Chair
Senate Health, Education, Labor and
Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member
Senate Health, Education, Labor and
Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bob Casey
Senate Health, Education, Labor and
Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mitt Romney
Senate Health, Education, Labor and
Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Subject: Bipartisan Discussion Draft of Pandemic and All-Hazards Preparedness Act (PAHPA)
Reauthorization

Dear Chairman Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney:

The United States Pharmacopeia (USP) is pleased to provide feedback on the bipartisan discussion draft to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). We greatly appreciate the opportunity to provide our initial input on provisions of particular interest in the bipartisan draft, and we look forward to working with the Committee and other stakeholders to reauthorize PAHPA.

USP is an independent, scientific, global non-profit organization founded in 1820 when eleven physicians took action to protect patients from poor quality medicines. Convening in the old U.S. Senate Chamber, they published a national, uniform set of guidelines for medicines called the U.S. Pharmacopeia. A core pillar of USP's work is to help strengthen the global supply chain so that the medicines that people rely on for their health are available when needed and meet quality standards as expected and required. USP is 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

USP supports the additions of capacity planning and identifying supply chain vulnerabilities in Section 201 of the discussion draft. This provision would amend the Public Health Service Act as it pertains to the Administration for Strategic Preparedness and Response and would incorporate medical product and supply capacity planning, including the identification of supply chain vulnerabilities, into the duties of the Assistant Secretary. Identifying vulnerabilities in the pharmaceutical supply chain is essential to enhance our national security, including medical and public health preparedness and response, and to ensure patients have access to the critical and routine medicines they need. Improved visibility into and analysis of the vulnerabilities of the upstream medicines supply chain – where raw chemical key starting materials (KSM), active pharmaceutical ingredients (APIs), and finished dosage forms are produced, refined, and

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

packaged – can help target potential policy reforms and inform U.S. government investments to enhance resilience.

Neither a single government agency nor any industry entities, however, have a complete view of upstream supply. This lack of clarity can lead to a poor understanding of the risks impacting the U.S. medicines supply chain. Data signals exist that can help predict upstream pharmaceutical supply chain risk, serving as an early warning system that can help provide predictive analysis of potential supply chain disruptions. This type of early warning capacity could provide data and insights that are needed to guide policy reforms to strengthen the resilience of the supply chain and prepare the nation for public health emergencies.

We would encourage the Committee to give consideration to expressly including additional investment and support in the PAHPA reauthorization – which can be provided through grants, contracts or cooperative agreements – to conduct ongoing surveillance of the pharmaceutical supply chain, provide alerts, and conduct research to fill the gaps in the mapping of the pharmaceutical supply chain. Such early warning capabilities would enable the U.S. Government and private sector pharmaceutical supply chain stakeholders to move to a more proactive and informed approach to preventing many more shortages and mitigating the impact of those that do occur. Early warning capabilities would also help the U.S. Government increase the return on its investments in strengthening the nation’s medicine supply by targeting investments and resources to the specific vulnerabilities of specific medicines.

USP appreciates the opportunity to engage with the Senate HELP Committee to reauthorize PAHPA, and to provide comments on certain provisions included in the discussion draft, to better prepare for and respond to, the next public health crisis. We look forward to working with you to ensure passage of this critical reauthorization. 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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