

## VIA ELECTRONIC SUBMISSION

August 22, 2023

The Honorable Cathy McMorris-Rodgers  
Chair, House Committee on Energy and  
Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone  
Ranking Member, House Committee on  
Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

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

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

Dear Senators Sanders and Cassidy and Representatives McMorris-Rodgers and Pallone,

The global medicines supply chain is complex, vulnerable, and often opaque. A single disruption can have serious negative consequences for patients, yet the limited information and insights available regarding the upstream supply chain for medicines means that these disruptions can be hard to predict. Increased visibility into the upstream supply chain will provide the opportunity to improve drug supply chain resiliency and more effectively address drug shortages and their patient care and national security implications. The United States Pharmacopeia (USP) supports efforts to make the drug supply chain more resilient and to encourage innovation in improving supply chain visibility as your respective Committees work on these critical issues and consider legislative vehicles for advancing such provisions.

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.<sup>1</sup> 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.

USP applauds your consideration of the need to address supply chain resilience as it impacts public health preparedness and drug shortages. 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. 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 location and volumes of the production of raw chemicals, key starting materials, and active pharmaceutical ingredients. Ultimately, this "insights gap" undermines the ability of the U.S. Government and other stakeholders to pinpoint responses that would create more resiliency and potentially avoid drug shortages. Therefore, a critical piece of any such effort to address drug shortages should include identification of upstream pharmaceutical supply chain vulnerabilities and ongoing capacity planning. Proactive identification methods and rapid

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

response approaches are essential to enhance our national security and ensure patients have access to the therapies they need.

We have been pleased to see these concepts embodied or referenced in multiple pieces of legislation. The House and Senate versions of the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization bills contain provisions to study and report on supply chain visibility and to require identification of upstream pharmaceutical supply chain vulnerabilities. As another example, S. 2364, the “Mapping America’s Pharmaceutical Supply (MAPS) Act,” directly addresses this concept. In addition, the Senate Fiscal Year 2024 Labor, HHS, Education and Related Agencies Appropriations report highlights the need to identify upstream supply chain vulnerabilities. These are examples of bipartisan, bicameral support for identifying supply chain vulnerabilities, and USP urges Congress to include this critical concept in either the final PAHPA reauthorization legislation or in any other legislative vehicle as the opportunity arises.

As the Chairs and Ranking Members of the Senate HELP Committee and House Energy and Commerce Committee, we thank you for your leadership on public health issues on behalf of patients. USP supports efforts to improve the resiliency of our pharmaceutical supply chain and welcomes the opportunity to continue to work with you toward this end. If you have any questions or would like additional follow up, please do not hesitate to contact Joseph M. Hill, Director, U.S. Government Affairs at [Joe.Hill@USP.org](mailto:Joe.Hill@USP.org) or 202-361-4163.

Sincerely,



Anthony Lakavage, J.D.  
Senior Vice President, Global External Affairs  
Secretary, USP Convention and Board of Trustees  
[APL@usp.org](mailto:APL@usp.org)  
(301) 816-8334

