VIA ELECTRONIC SUBMISSION

October 4, 2024

The Honorable Brad Wenstrup
U.S. House of Representatives
2335 Rayburn House Office Building
Washington, DC 20515

The Honorable August Pfluger
U.S. House of Representatives
1124 Longworth House Office Building
Washington, DC 20515

The Honorable Blake Moore
U.S. House of Representatives
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Washington, DC 20515

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Dear Representatives Wenstrup, Moore, and Pfluger,

The United States Pharmacopeia (USP) appreciates the opportunity to provide comments to your request for information (RFI) regarding policy solutions to secure and enhance domestic medical supply chains. USP is an independent, scientific, global non-profit organization founded in 1820 and dedicated to building trust in medicines through rigorous science-based public quality standards. We are guided by approximately 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention. USP's public standards and related programs are created by our expert committees and have helped to protect and improve the health of billions of people around the world. As a global leader in medicine quality, we share your desire to build a more resilient medicines supply chain and ensure that patients have access to the quality medicines that are essential for both critical and routine care.

A core pillar of our 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 the quality standards as expected. There are many components to the regulatory framework to safeguard medicine quality, and public quality standards and adherence to them are foundational for manufacturers, including new manufacturers producing medicines in diversified supply chains. USP standards provide publicly available guidance for quality testing, including validated test methods and the quality specifications for specific drug products and their ingredients. These standards articulate the quality expectations for a specific medicine, including its identity, strength, purity, and performance. They also provide broadly applicable information to industry on accepted processes, tests and methods to support product development and manufacturing. Adherence to public quality standards can help ensure that medicines are reliable and produced consistently and according to regulatory expectations for quality. USP public standards help manufacturers establish the key quality attributes of their products and how to test for them, thus facilitating the market entry of additional products from multiple manufacturers.

While the globalization of manufacturing and distribution of pharmaceutical products has facilitated access to lower cost therapies, it has also increased the risk of supply disruptions caused by disasters, trade wars, domestic or geopolitical conflict, or public health emergencies. **As a result, USP urges policy makers to consider:**

- **economic or other incentives to encourage additional suppliers to enter the market and promote geographic diversification;**[1]
- **economic incentives that encourage increased domestic manufacturing of active pharmaceutical ingredients (APIs) and finished dose products that are most vulnerable to a supply disruption;**
- **market based incentives to encourage utilization of excess domestic capacity; and**
- **financial incentives to provide pharmaceutical manufacturers with funding to utilize advanced manufacturing technologies.**

Below, we provide comments on several specific inquiries raised in the RFI, particularly as they pertain to policy solutions to secure and enhance domestic medical supply chains.

Supply chain insights will help bolster resilience

2. **Lessons learned, challenges, and opportunities with respect to efforts to diversify supply chains, address potential global vulnerabilities, and onshore key operations.**

3. **Feedback on the scope and priority level of medical products and services in need of onshoring, friendshoring, or increased diversification (ex. PPE, generics, devices, ingredients, pre-clinical or clinical services, etc.).**

The lack of clarity into the global pharmaceutical supply chain contributes to a limited understanding of the potential risks or supply disruptions that may occur. The first step in securing our pharmaceutical supply chain is the identification of upstream risks or vulnerabilities that when mitigated can help stave off a supply disruption, detect the most vulnerable medicines or APIs, and ensure proper deployment of economic or other resources targeted to those products identified as most vulnerable to a disruption.

Recognizing the urgent public health need for upstream supply chain insights, USP invested in the development and continuous improvement of a data intelligence platform known as the Medicine Supply Map. The Medicine Supply Map utilizes multiple data points to calculate a vulnerability score and identify finished dose products and API that are at the highest risk for a supply disruption. The vulnerability score is based upon risk factors generated by over 250 million aggregated datapoints to evaluate indicators of supply risk, including but not limited to geographic concentration of manufacturing, manufacturing complexity, price, and number and location of API suppliers. These data are crucial to identifying those products most at risk of a disruption and determining how to best target public resources to bolster the supply chains of products that are at the highest risk of a supply disruption. A recent *Annual Drug Shortage Report*[2] published by USP leverages data derived from the Medicines Supply Map and shows that multifaceted and interrelated factors have led to an increase in the number and duration of drug

[1] USP White Paper: Building geographic diversity in the medicine supply chain. 2023; https://www.usp.org/sites/default/files/usp/document/public-policy/USPWP_GeoDiversification_2023.pdf

[2] USP Annual Drug Shortage Report: Economic factors underpin 2023 shortages. 2024; https://go.usp.org/l/323321/2024-05-31/92zsjg/323321/1717187146zgOpt4vW/GEA_GC_056R_MSM_Report_2024_05_FINAL.pdf

shortages caused by supply chain vulnerabilities. **In order to increase supply chain insights in an effort to bolster resilience, USP recommends**:[3]

- **The establishment and funding of an Early Warning System and Research Coordinating Center** to conduct ongoing surveillance of the pharmaceutical supply chain, provide alerts, and conduct research to fill the gaps in the mapping of the U.S. pharmaceutical supply chain. Such early warning capabilities would enable the U.S. Government and private sector pharmaceutical supply chain stakeholders to adopt a more proactive and informed approach to preventing shortages and mitigating the impact of those that do occur.

- **The establishment of a vulnerable medicines list in the United States** as either a complement to or component of an essential medicines list, specifically addressing supply chain vulnerabilities. Such supply chain vulnerabilities should include sole or limited number of suppliers, geographic concentration of manufacturers and API, excipient, and KSM suppliers, political and geopolitical risks, climate change susceptibilities, manufacturing complexity, price, and other factors. Creation and utilization of a vulnerable medicines list will help prioritize medicines and properly target policy interventions and finite resources to improve medicines supply chain resiliency and preserve patient access to necessary medicines.

- **Efforts to coordinate supply chain resilience and reliability activities through public/private partnerships** as part of a jointly coordinated effort between the public and private sector. Coordination efforts should include the organization of multi-disciplinary efforts, defining measurable outcome metrics for implementation efforts, and strategic planning activities to maximize the utility of new programs and increase the impact of existing initiatives. Additionally, necessary authorities and sufficient funding should be allocated to lead these cross-cutting efforts to improve drug supply chain resilience and reliability.

Support for advanced manufacturing technologies requires investment

8. Current programs that can be utilized to assist in catalyzing new innovative technologies for advanced manufacturing.

Advanced manufacturing technologies (AMTs), such as pharmaceutical continuous manufacturing, additive (3D printing) manufacturing, direct perfusion, and decentralized manufacturing have shown potential to reduce production costs and environmental footprints, enhance product quality, and reduce the risk of supply chain disruptions through faster production of pharmaceutical products. For many years, USP has been supportive of efforts that enable innovative approaches and increased adoption and implementation of AMTs and has invested in specific laboratory capacity for the development of public quality standards that can be utilized to accelerate adoption of this technology. Standards for AMTs may provide greater regulatory predictability by providing manufacturers with guidance on ensuring product quality through advanced technologies for drug manufacturing.

[3] USP Global Policy Position: Identifying and addressing vulnerabilities in the upstream medicines supply chain to build resilience and reduce drug shortages. 2023; https://www.usp.org/supply-chain/build-resilience-and-reducedrug-shortages

USP supports policies that enable increased adoption and implementation of AMTs.[4]

We are pleased that the Consolidated Appropriations Act, 2023 included a provision directing the Department of Health and Human Services (HHS) to create national centers of excellence in advanced and continuous pharmaceutical manufacturing. Grants provided to the centers of excellence will support technology development, stakeholder collaboration, best practices, and implementation of the technology. However, **USP urges Congress to ensure that the Centers of Excellence in Advanced and Continuous Manufacturing are adequately funded and support additional appropriations to build and expand the work of the Centers**.

In addition to the Centers of Excellence, USP supports near and long-term incentives and public investments that enable greater adoption of AMT. These consist of financial incentives to support manufacturer investment in AMT, and direct or indirect market-based subsidies to support new manufacturing technologies.

9. What types of public-private partnerships could be most effective in accelerating the onshoring of pharmaceutical manufacturing?

AMTs represent a paradigm shift in pharmaceutical production with unique technical and practical considerations. To bridge knowledge gaps related to technical or scientific obstacles or regulatory uncertainties, stakeholders should leverage partnerships, learning opportunities, and development of resources that are essential for the adoption of this technology. **USP supports the establishment or expansion of consortia and coordination of efforts through public-private partnerships among government bodies, academia, industry, and other allied stakeholders.** These types of collaborations allow parties to share resources and information needed to address current obstacles and proactively address future challenges and may help stakeholders bring to market more quality products made with novel technologies and processes for the benefit of patients. **For example, the Continuous Manufacturing Knowledge Center (CMKC), an online, open access collaborative forum established by USP and the National Institute for Pharmaceutical Technology and Education (NIPTE), provides a space for discussion, information sharing, and learning.** The CMKC aggregates information organized by USP and NIPTE including research publications, industry practices, presentations at technical forums, and non-peer-reviewed materials, as well as facilitates discussion among stakeholders.

[4] USP Global Policy Position: Recognizing Challenges and Opportunities to Support Adoption of Advanced Manufacturing Technologies for Medical Products. 2023; https://www.usp.org/sites/default/files/usp/document/public-policy/USP%20AMT_PositionPaper_2024.pdf

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USP is committed to working with you to foster a more resilient pharmaceutical supply chain and ensure the quality of the medicine supply for American patients. If you have any questions or would like additional follow-up, please contact Joe Hill at Joe.Hill@usp.org.

Sincerely,

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