VIA ELECTRONIC SUBMISSION

January 30, 2024

The Honorable Doris Matsui
House of Representatives
2311 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, M.D.
House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Subject: Mapping America's Pharmaceutical Supply Act (the MAPS Act. H.R. 6992)

Dear Representatives Matsui and Bucshon:

The United States Pharmacopeia (USP) is pleased to support the "Mapping America's Pharmaceutical Supply Act" (H.R. 6992), or the MAPS Act. We applaud your leadership in helping 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.

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 U.S. and around the world.

Identifying, characterizing, and quantifying risks and vulnerabilities throughout the medicines supply chain—from raw materials and active pharmaceutical ingredients (APIs) to distribution and administration of drug products to patients—is an essential component to foster a more resilient supply chain and to mitigate drug shortages. Information platforms that provide actionable data-based insights into medicines supply chain vulnerabilities exist. For example, USP has invested in the development and continuous improvement of a data intelligence platform, the *Medicine Supply Map*[2], to:

1. Help identify, characterize and quantify vulnerabilities in the upstream pharmaceutical supply chain;
2. Deliver insights that can guide risk mitigation strategies and investments; and
3. Help inform policy changes that advance supply chain resilience.

The current version of the *Medicine Supply Map* provides visibility and insights on active pharmaceutical ingredients and finished dose forms for more than 90 percent of generic

[1] USP's governing bodies, in addition to the Council of the Convention, include its Board of Trustees and Council of Experts.
[2] The *Medicine Supply Map* uses multiple sources of information to identify the worldwide sites of pharmaceutical ingredient and finished dose medicine manufacturing. More than 40 datasets from USP, FDA, the Centers for Medicare & Medicaid Services, European Medicines Agency, World Health Organization and private sector sources are utilized by the *Medicine Supply Map* platform. These data are enriched with information about risk drivers such as price and ingredients and covers 92 percent of FDA-approved generic prescription drugs. Notably, the *Medicine Supply Map* includes over 250 million aggregated datapoints to evaluate indicators of drug shortage risk, including geographic concentration, manufacturing complexity, price, and quality. The model is also informed by insights on the use of USP quality standards in over 80 percent of FDA-registered finished dose and active pharmaceutical ingredient (API) manufacturing facilities.

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medicines approved in the United States. There are, however, information gaps on a broad range of vulnerabilities including key starting materials, APIs, and critical excipients. These gaps limit the ability of the U.S. Government and other stakeholders to most effectively target responses that would create more resiliency and potentially avoid drug shortages.

The MAPS Act would substantially address that information gap through support of efforts, including through public-private partnerships, to map the entire United States supply chain. These efforts can help create an early warning system that could provide predictive analysis of potential supply chain impacts from disruptions. Such early warning capabilities would help enable the U.S. Government to move to a more proactive and informed approach to preventing 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 particular vulnerabilities of specific medicines.

The MAPS Act is a significant step to building a more resilient medicines supply chain. We look forward to working with you to ensure 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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