May 31, 2022

The Honorable Maria Cantwell
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Roger Wicker
555 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Eddie Bernice Johnson
2306 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Lucas
2405 Rayburn House Office Building
Washington, DC 20515

Dear Senators Cantwell and Wicker, and Representatives Johnson and Lucas,

On behalf of the United States Pharmacopeia (USP), I am writing to applaud your leadership on the America COMPETES Act. The COVID-19 pandemic has highlighted risks and vulnerabilities in our pandemic preparedness response infrastructure and medicines supply chain, which need to be addressed to respond more effectively to the ongoing pandemic and to prepare better for the next one. USP supports the multifaceted approach taken in both the Senate- and House-passed versions of the COMPETES Act, and, in particular, the focus of both bills on supply chain resiliency. Additionally, USP supports efforts to promote innovative new manufacturing technologies such as continuous pharmaceutical manufacturing.

USP is an independent, scientific, global non-profit organization founded in 1820 and dedicated to building trust where it matters most: in the world's medicines, dietary supplements, and foods through rigorous science and public quality standards.[1] A core pillar of USP's mission is to help strengthen the global supply chain so that the medicines 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 communities, as well as dozens of government agencies, who together comprise the USP Convention.[2] The USP Convention elected the 12 members of the USP Board of Trustees, which oversees our work.[3]

As the Conference Committee addresses the differences between the two bills, USP respectfully requests that the final version include:

- The continuous manufacturing centers of excellence language in the House passed version.
- The supply chain resiliency program with the $45 billion in funding authorized in the House passed version.

[1] USP standards are developed by Expert Bodies comprised of more than 750 scientific experts. These experts collaborate to develop USP standards through an open, transparent process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology.

[2] USP's governing bodies in addition to the Council of the Convention include its Board of Trustees and Council of Experts.

[3] The 2020-2025 USP Board of Trustees, https://www.usp.org/about/board-of-trustees.

USP Headquarters
12601 Twinbrook Parkway | Rockville, MD 20852, USA
+1-301-881-0666 | usp.org

National Centers of Excellence in Continuous Pharmaceutical Manufacturing

As the conference committee addresses the differences between the House and Senate versions of the bill, we urge you to ensure that the continuous pharmaceutical manufacturing centers of excellence language in the House bill be included in the final version of the legislation. This language has bipartisan support, and has previously passed the House as a stand alone bill.

Pharmaceutical continuous manufacturing (PCM) is one of the most promising advanced manufacturing technologies (AMT) advancements because it enables continuous use of a production line that can yield significantly more product output. This type of AMT has the potential to improve manufacturing efficiency, reduce production costs, and significantly reduce environmental footprints. In contrast, in traditional batch manufacturing, the raw materials that are eventually transformed into the final product (e.g., a tablet) are processed in different machines at different times and potentially in different locations. This process naturally requires many starts and stops in manufacturing.

Despite its benefits, PCM is currently limited to nine FDA-approved medicines. There are significant challenges that stand in the way of broader adoption of PCM. For example, PCM technology requires upfront investment in new infrastructure, research, and development, while existing market dynamics make realizing a positive return on investment uncertain, especially for low-margin generic medicines. Additionally, limited experience with PCM across regulators, and limited guidance for industry, leads to uncertainty among manufacturers seeking regulatory approval for products manufactured with PCM technology. Finally, manufacturers may not have access to staff trained with the technical knowledge of the processes, capabilities, and constraints of PCM to enable them to develop new process analytical technologies and statistical tools while also hiring or retraining their workforce.

USP believes that the National Centers of Excellence in Continuous Pharmaceutical Manufacturing can help address the barriers to more widespread adoption. The Centers of Excellence could serve as effective collaboration platforms that provide an intersection between academia, regulators, industry, and standards organizations such as USP to share knowledge and provide workforce training. One way to build upon the Centers of Excellence is to promote greater partnerships with non-profit organizations that specialize in quality standard development, testing and analytical verification, and workforce training. For these reasons, we urge the conference committee to include the House language in the final bill.

Supply Chain Resiliency Program

While USP supports the creation of the supply chain resiliency program within the Department of Commerce in both versions of the COMPETES Act, we urge the conference committee to include language calling for coordination among federal agencies such as the Department of Health and Human Services (HHS) and the Biomedical Advanced Research and Development Authority (BARDA) and others as it relates to the pharmaceutical supply chain. USP believes that the supply chain resiliency program should not be duplicative of current efforts to enhance the resiliency of the pharmaceutical supply chain. Additionally, USP supports the $45 billion through FY27 authorized in the House bill to provide grants, loans and loan

guarantees to support the resilience, diversity, security, and strength of supply chains.

The global supply chain for medicines has numerous vulnerabilities that can be challenged by acute disruptions, for example, from natural disasters, public health emergencies, and quality-related disruptions in manufacturing. When such disruptions occur, the quality, safety, and adequate supply of medicines, particularly those used for critical treatments, become a national security issue, and can have unintended and dire consequences for public health infrastructure and the health of the American public. Unfortunately, the COVID-19 pandemic brought these impacts into sharp focus.

Consistent with the focus on this legislation, USP also urges Congress to prioritize the identification of upstream supply chain risks, which can enable regulator and industry action to reduce medicine supply disruptions while also providing evidence to inform public investment and policy reforms that build more resilience. Neither a single government agency nor any industry entity has 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.[4] A recent report by the National Forum to Secure America's Supply Chain for Essential Medicines calls for the creation a map of the supply chain for essential medicines that includes information such as fungibility of finished dosage form and raw material production; types of production equipment used; production capacity constraints; inventory levels, distribution timelines,and backorder metrics[5]. As a member of the forum, USP supports such capabilities, and we have recently developed a prototype of an upstream supply chain insights informatics tool.

USP has invested millions since early 2020 to develop and continuously improve upon an informatics tool, the ***Medicine Supply Map***, to help identify, characterize, and quantify vulnerabilities in the upstream pharmaceutical supply chain, deliver insights that can guide risk mitigation strategies and investments, and help inform policy changes that advance supply chain resilience.[6] The *Medicine Supply Map*, the first ever of its kind, uses multiple sources of information[7] to identify the worldwide sites of raw ingredient and medicine manufacturing. These data are enriched with information about risk drivers[8] such as price and ingredients and cover 92 percent of FDA-approved generic prescription drugs. The model is also informed by insights on the use of USP quality standards in nearly 22,000 finished drug product, active pharmaceutical ingredient (API), and excipient manufacturing sites in 150 countries.

To help build a more sustainable supply chain, USP recommends that Congress support efforts to identify and assess the resiliency of drugs and medical products, such as the *Medicine Supply Map*. USP also is pleased to have been in numerous discussions with federal agencies about formally utilizing these tools which have

[4] USP. 2021. *Are My Medicines at Risk of a Shortage?* Available at: https://qualitymatters.usp.org/are-my-medicines-risk-shortage
[5] May 2022, Essential Medicines Supply Chain and Manufacturing Reslience Assessment; National Forum to Secure America's Supply Chain for Essential Medicines.
[6] USP. 2022. Medicine Supply Map. Available at: https://www.usp.org/supply-chain/medicine-supply-map
[7] Over 20 datasets from USP, FDA, the Centers for Medicare & Medicaid Services, European Medicines Agency, World Health Organization, and private sector sources are included in the Medicine Supply Map
[8] Currently, the Medicine Supply Map includes over 250 million aggregated datapoints on risk indicators including manufacturing location, chemical information, price, dosage form, and quality.

been developed by USP without any external resources as a part of fulfilling our public health mission. Modest federal support to expand this work and formally utilize it to inform decision making with insights on vulnerabilities in the upstream supply chain would make an important and unique contribution to targeting US government investments where they can be most effective in fortifying the supply chain.

USP thanks you for your leadership this important legislation. We are committed to working with you on the advancement of this bill. Should you need additional information or wish to further discuss ways in which we can work together, 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,

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

CC.
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Congresswoman Zoe Lofgren
Congresswoman Suzanne Bonamici
Congressman Ami Bera
Congresswoman Haley Stevens
Congressman Jamaal Bowman
Congressman Bill Foster
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