

VIA ELECTRONIC SUBMISSION

September 29, 2020

Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

**Re: Summary for Inclusion in the Report
Investigation No. 332-580; COVID-19 Related Goods: The U.S. Industry,
Market, Trade, and Supply Chain Challenges**

The global pharmaceutical supply chain is currently affected by challenges and constraints, such as a general lack of resiliency and transparency. There is a lack of geographic diversity in the supply chain as a result of concentrated manufacturing and sourcing in few countries and disparate regulatory environments. A geographically concentrated pharmaceutical supply chain can result in drug shortages, especially when disruptions occur, such as natural disasters, trade wars, and pandemics. In order to minimize or prevent the occurrence of drug shortages due to disruptions, the United States Pharmacopeia (USP) encourages diversifying the supply chain and building redundancies into the system. To support supply chain resiliency, incentives for industry may be needed, such as federal government contracts or grants to encourage multiple suppliers of certain drug products in disperse locations.

The greater adoption of advanced manufacturing technologies by the pharmaceutical industry can also support resilience in the supply chain. Continuous manufacturing has the potential to foster greater quality control and increased cost-efficiency of active pharmaceutical ingredient (API) and finished product production. USP is currently engaging with a broad group of stakeholders, including academic research centers and manufacturers, to identify and articulate appropriate quality standards and practices to help make advanced manufacturing more accessible and achievable for industry uptake.

The complexity of the global medicine supply chain, which includes numerous players, such as ingredient suppliers, manufacturers, packagers, labelers, distributors, and contractors, is exacerbated by the generalized lack of transparency among these players regarding their roles. Thus, information about the origin, production volume, and distribution chain for drug products is not readily accessible to the public. The ability to identify potential safety problems with a drug product and respond quickly and efficiently may also be affected.

USP supports more transparency from the pharmaceutical industry to support a more resilient supply chain to help ensure the continued availability of safe, quality medicines. Practitioners and patients would also benefit with more publicly available supply chain information, especially in the event of a safety or quality related problem linked to a drug ingredient, such as the API.

Finally, the quality of drugs and their ingredients within the global supply chain is essential for public health. When quality is not prioritized, patients may be adversely affected, e.g., poor quality medicines may not have their intended therapeutic effect, and lapses in quality can result in drug shortages. Ensuring that drug products and their ingredients and packaging across the global supply chain meet pharmacopeial standards can help ensure continued access to quality medicines.