

December 16, 2019

The Honorable Diana DeGette  
U.S. House of Representatives  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Fred Upton  
U.S. House of Representatives  
2183 Rayburn House Office Building  
Washington, DC 20515

Dear Representative DeGette and Representative Upton,

On behalf of the United States Pharmacopeia (USP), I am writing to applaud your leadership in initiating “Cures 2.0” to modernize coverage and access to life-saving cures in the United States and across the globe.

USP is an independent, non-profit organization founded in 1820 to help ensure the quality and consistency of medicines relied upon by Americans. USP’s science-based quality standards are recognized in U.S. law as official standards for medicines, dietary supplements, and food ingredients. USP’s public standards and related programs have protected and improved the health of billions of people around the world. In addition, and as described in more detail below, we are working to build trust in tomorrow’s medical breakthroughs in order to benefit as many people as possible.

We thank you for the opportunity to submit comments on this initiative.

The United States has long been regarded as the global leader in ensuring safe and effective medicines. Inherent in this concept is the assurance of quality – that is, that a medicine is what it purports to be in terms of its identity, strength, purity, and performance. As medicines and other therapies evolve, we believe it is critical to continue to assure the quality of these products in order to realize their full life-saving potential. Although there are many components to the regulatory framework to safeguard medicine quality, publicly available quality standards and adherence to them are foundational.

### **Digital Therapeutics**

As noted in the Cures 2.0 Request for Information (RFI), digital health technologies hold great promise to modernize health care and to bring new therapeutic options to patients. Increasingly, therapies are combined or enhanced with some digital component. Also, the emergence of digital therapeutics creates opportunities to strengthen current clinical interventions and disease management options for patients with diabetes, asthma, heart disease, substance abuse, pain, sleep disturbances, and other conditions.

USP, in collaboration with the Digital Therapeutics Alliance, is exploring ways to safeguard product quality and integrity for digital therapeutics, with input from relevant stakeholders. By considering appropriate ways to address product quality in this emerging therapeutic modality, USP is building insights and expertise to develop standards or guidelines, following our trusted, science-based, rigorous public processes, should the need be identified.

As you examine digital health technologies, we encourage you to consider approaches – like product quality and data interoperability standards – that will help ensure the quality and consistency that will be required for patients and healthcare practitioners to have trust in these technologies. Stakeholders have identified this as

an area of need, and we fundamentally believe that the assurance of quality builds trust and confidence among patients and clinicians in these technologies and related products.

### **Advanced Manufacturing Technologies**

The term “advanced manufacturing” refers to medical product manufacturing technologies that can improve drug quality, address drug shortages, and speed time-to-market. These new approaches have many benefits, including the potential to closely monitor and ensure medicine quality. Quality standards are an integral part of this process. USP is currently engaging with a broad range of stakeholders, including, academic research centers, manufacturers, and regulators, to identify and articulate appropriate standards and practices that will make advanced manufacturing technologies, including continuous manufacturing, more accessible and achievable for generic industry uptake.

USP supports H.R. 4866, the “National Centers of Excellence in Continuous Manufacturing Act of 2019.” This bill would create National Centers of Excellence for continuous manufacturing, which would include institutions of higher learning that provide research, data, and leadership in continuous manufacturing. We believe the goals of H.R. 4866 align well with the goals of Cures 2.0 to modernize access to life-saving medicines and cures. We would encourage you to consider including H.R. 4866 in Cures 2.0. In addition, we would encourage you to consider expanding the designated Centers of Excellence to include other public or non-profit qualified organizations in addition to institutions of higher learning. These organizations could provide meaningful research and insights into continuous manufacturing.

### **Global Supply Chain**

As medicines and therapies evolve across an increasingly globalized supply chain, it is critical to ensure that regulatory systems across geographies are built and maintained. Over the last decade, medicine manufacturing in the U.S. has become increasingly dependent on foreign sources for both finished drug products and their main ingredients, known as active pharmaceutical ingredients (APIs). According to the U.S. Food and Drug Administration (FDA), over 70 percent of all API manufacturers for the U.S. market are outside the United States, and numerous sources have identified a variety of concerns about the quality of APIs in medicines.

As you may be aware, USP develops monographs for finished drug products, APIs, and excipients (inactive ingredients). Monographs are written documents that describe medicine quality requirements for the identity, strength, purity, and performance characteristics of medicines. Given the globalized supply chain, adherence to public quality standards is an essential tool to safeguard quality when they are used by manufacturers and regulators to test and monitor excipients, APIs, and finished products at any point along the supply chain. We would welcome the opportunity to explore ways that USP can provide information and expertise to help advance our shared goal of helping to assure American patients of the quality of their medicines, regardless of where they are sourced.

We commend the Energy & Commerce Committee for its sustained attention to this issue. We would encourage you as part of Cures 2.0 to prioritize access to quality medicines to help ensure patient safety and to explore potential policy solutions to further strengthen the regulatory system governing medicine ingredients and finished medicines to achieve these outcomes.



## Conclusion

We are committed to working with you as you consider these and other proposals. If you have any questions, please feel free to contact Joseph Hill, U.S. Government Affairs Director at (202) 239-4137 or [joe.hill@usp.org](mailto:joe.hill@usp.org).

Sincerely,



Anthony Lakavage, J.D.  
Secretary, USP Convention and Board of Trustees  
Senior Vice President, Global External Affairs, USP

