July 18, 2017

USP Comments to FDA Public Meeting: "*The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access*"

Good afternoon, I am Robert Femia, Senior Vice President of Chemical Medicines, at USP. Drs. Gottlieb, Woodcock, and esteemed panelists from FDA and FTC, on behalf of USP, I would like to thank the Agency for the opportunity to comment on this important topic of facilitating increased competition in the market for prescription drugs through the approval of generic medicines.

For more than three decades, generic medicines have significantly increased patient access to quality treatment, while lowering healthcare costs in the United States. We believe that generic medicines continue to hold similar promise for the future and applaud FDA's effort to modernize and enhance the abbreviated new drug application (ANDA) process created by the Hatch-Waxman amendments and help ensure the intended balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to originator drugs.

USP is an independent, scientific, nonprofit organization dedicated to protecting and improving public health. We collaborate with FDA, clinicians, other practitioners, manufacturers, and other stakeholders to develop public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP shares FDA's goal of advancing and promoting patient safety across medicines, and we support efforts to broaden access to safe and effective generic medicines. Better access to generic medicines will facilitate the availability of life-saving therapies, while helping to ensure costs to patients and the health care system remain affordable and sustainable, and upholding FDA's standard for evidence-based, science-based regulation.

USP offers the following comments for the agency's consideration and welcomes opportunities to work with the agency, industry, and other stakeholders to enhance patient access to quality medicines. My comments are focused on three main topics:

1. **USP's public standards help facilitate the entry of products from multiple manufacturers.**

USP's public standards provide common benchmarks, which help define the target for quality medicines for industry, also contributing to practitioner and patient confidence in the integrity of these products. In particular, generic drug manufacturers use USP standards to establish the key quality attributes of their products. In this way, USP's public standards facilitate the entry of products from multiple manufacturers, because manufacturers can use USP's public standards in their applications to set forth the quality, purity, and strength of their product or substance – thereby minimizing the necessity to establish these themselves—and advancing the availability of lower cost, beneficial medicines for patients.

Public standards help both industry and regulators navigate the complicated analytical environment for products. Consider for example, the category of products frequently referred to as nonbiologic complex drugs. Applications for generic versions of these drugs have presented challenges to industry and the agency. USP can contribute and has been contributing in a positive way to the development generic versions of these drugs. In certain cases, USP has been able to bring together scientific experts from the manufacturers and the agency to work collaboratively. Through such efforts, common analytical solutions have been identified and agreed upon by manufacturers, and these have led to public

standards development that define critical product quality attributes. It is our understanding that these public standards in turn have been useful to FDA in its approval of certain nonbiologic complex drugs.

Moreover, USP's standard-setting process is iterative to account for changes in innovation. USP's product specific standards are flexible to evolve with public health needs and advances in quality expectations. USP's standards are reflective of the approved medicine in the marketplace and evolve as the quality specifications for the product evolve. One example is USP's monograph for the drug *enoxaparin sodium*. It has been revised several times to accommodate subsequent US market entries for this product.

The resolution of these complex scientific issues is challenging and requires participation by all impacted stakeholders. Early, sustained, and active engagement by relevant stakeholders in the standards setting process is imperative for the efficient and successful development of a public standard. USP welcomes the opportunity to work with the agency and industry to explore mechanisms to facilitate this work.

2. **USP's standards-setting process supports the overall efficiency of the generic drug approval process.**

USP's processes are built to adapt and respond to stakeholders' needs. For example, working closely with the agency and industry, USP created the USP Pending Monograph process to allow for the development of monographs or monograph revisions for drugs awaiting approval by FDA. This new process helps prevent delays in certain drug approvals by reconciling the timing of FDA generic approvals with USP monograph updates.

3. **USP stands ready to collaborate even more effectively with FDA and industry to expand access to affordable quality generic medicines.**

In addition to this very important public meeting, FDA recently announced other policy initiatives designed to enhance patient access to generic medicines. In order to bring generic medicines to the patients who need them, USP is committed to collaborating effectively with FDA and stakeholders, bringing to the table our scientific standard-setting process and the great responsibility imparted by our statutory recognition for quality standards.

Again, thank you for the opportunity to share our comments.

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