Ronald Piervincenzi, CEO

U.S. Pharmacopeial Convention

By Ronald Piervincenzi

Today's public health challenges demand fast, innovative solutions. From the nation's opioid crisis to the need for better access to affordable, quality drugs, to biologics and biosimilars, to dietary supplements quality, these issues require partnerships and collaborations among numerous stakeholders, as well as new ways of thinking to achieve effective solutions.

USP is committed to doing both. As USP nears its 200th anniversary, we continue to evolve in the ways that we engage with our partners throughout government, academia and industry, and in the ways we approach the scientific standards of medicines quality so that we can help improve health around the world.

Opioid crisis

With nearly 100 Americans dying every day from an opioid overdose, according to the Centers for Disease Control and Prevention (CDC), this public health emergency demands collaborative approaches among experts and leaders in government, industry and health care.

As it has done with other public health crises, USP is pursuing quality standards that can help and protect patients, caregivers, first responders and other health practitioners. We've engaged stakeholders each step of the way, holding a roundtable last October that brought together leading experts and critical decision makers in the opioid crisis to provide critical feedback on quality standards USP is considering, including:

- Recommendations for effectively and safely storing and disposing of opioid prescriptions in order to help prevent misuse, including how this information should be communicated.
- Clear information on prescription labels to ensure patients understand that a prescribed drug is an opioid and can be addictive.
- Easy-to-follow instructions for using naloxone, so that first responders and others (including family, friends and others who may not be trained health care providers) can quickly understand when and how to administer this life-saving antidote.
- Effective tools and mechanisms to support health care providers in counseling patients about appropriate use of prescription opioids and how to avoid misuse.

Additionally, these discussions and early feedback by the participants in the roundtable will inform the work of USP's Healthcare Quality and Safety Expert Committee, whose members have been developing and evaluating these concepts. We will release a report based on the roundtable, and it is anticipated that some of these concepts will ultimately generate standards enabling implementation as quickly as possible.

> *'USP is exploring changes in biologics naming policy to align with the FDA.'*

Affordable medicines

Patients in the U.S. and throughout the world need access to affordable, quality medicines. Developed in partnership with hundreds of expert volunteers who contribute their time and expertise, USP's standards help support a robust and dependable generic medicines market that contributes to lower drug costs. This work aligns with recent efforts from the Food and Drug Administration to streamline and enhance the approval process for generic drug development.

USP provided comments to FDA's proposed approaches to increase the availability of generic drugs, which include expediting review of generic drug applications in therapeutic areas with few generic drugs and exploring innovative analytical tools to facilitate regulatory reviews, among other targeted, practical approaches. In its comments, USP applauded these efforts and noted that we are evaluating these approaches to consider how we as a standard-setting body can best contribute to support and advance these efforts.

Public quality standards help increase patient access to affordable, quality generic medicines and are a critical part of USP's work with our volunteers, partners and collaborators throughout government, academia and industry. These standards help manufacturers demonstrate the quality, purity and strength of generic medicines, so their products can advance to market and increase the availability of these lower-cost medicines.

Partnerships and collaborations are critical to how these public standards are developed. Using an open and collaborative process bringing together patients, practitioners, regulators, academics and industry, this diverse group of experts help create public standards with a strong scientific foundation in support of quality medicines.

Biologics and biosimilars

Early USP standards for biologic drugs covered a range of products that evolved over time to include more complex molecules, including extracts, peptides, proteins, vaccines, blood, cell and tissue-based products. The quality of these components is paramount in developing new, safe and effective biologic therapies. USP is evaluating types of raw materials critical to manufacturing biologics and exploring development of analytical procedures and associated reference materials to test their quality.

USP is also introducing performance standards, which support analytical testing for biologics throughout the product life cycle. In the current landscape, USP's performance standards would help ensure and demonstrate methods performance and may be applicable to product families (e.g., insulins) or classes (e.g., monoclonal antibodies — mAbs), rather than individual products. Developed in collaboration with health practitioners, industry and government agencies, we expect these standards to be included in USP-NF general chapters.

Additionally, in response to the FDA's recent guidance on biologics and biosimilars naming requirements, USP is exploring changes in its biologics naming policy to align with the FDA. The proposed changes, which will be open for public comment in January 2018, include flexible approaches to recently approved drugs.

Dietary supplements quality

Millions of people use dietary supplements in the U.S. and worldwide, and the quality of many of these products and their ingredients is critically important to consumers and health care providers, as well as manufacturers. USP's dietary supplements standards and verification programs for ingredients and products are one mechanism that can contribute to improving the quality of dietary supplements.

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With the goal of improving the quality of dietary supplements in mind, in early 2017 USP formed the Dietary Supplements Quality Collaborative (DSQC), a coalition of stakeholders that believe that consumers and providers should be able to expect the dietary supplements that they purchase and recommend are quality products and safe for use as directed. The coalition and its members are committed to identifying and sharing effective practices and responsible actions to promote safe, quality products.

Twenty-five members representing nonprofits, academia, industry and others are working to improve the quality of dietary supplements ingredients and products, making relevant information transparent and accessible. DSQC's actions and recommendations are based on available evidence, with the goal of improving public health related to dietary supplement safety and quality.

Together with our many collaborators and volunteers, USP is exploring innovative and practical approaches to the many public health challenges we face today. As we draw closer to marking USP's 200th anniversary in 2020, our work helping to protect the public through quality standards is as relevant and urgent as it was when USP was created so many years ago.