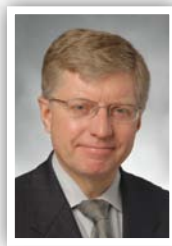




U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>



## A Message from USP Chief Executive Officer Roger L. Williams

We created this resource kit to explain the role that quality standards play in helping to ensure the quality of the medicines we are prescribed, the dietary supplements we consume, and the foods we eat.

While quality standards are not something most people consider on a daily basis, they are an essential, behind-the-scenes element in maintaining our well-being. Across all industries, standards are imperative for protecting citizens and preserving order. How would we be affected if there were no safety standards for cars, or building codes for houses? The same is true for items that we put in our bodies every day—whether these items are intended to treat or prevent disease, to supplement our health, or to sustain us nutritionally. The importance of quality standards is most clearly illustrated when they are not followed. We have seen such examples across industries in recent months and years, including the pharmaceutical and food industries, sometimes with tragic consequences.

For nearly 200 years, USP has worked as an independent, nonprofit, scientific organization to create quality standards for prescription and over-the-counter medicines. In the United States, these standards are recognized by law and enforced by the Food and Drug Administration (FDA). Medicines approved by FDA to be marketed in the United States (including those that are manufactured in other countries) are required to adhere to existing USP standards. These standards help ensure that medicines are of high quality, are pure, are of the appropriate and expected strength, and are consistent from one pill, bottle, shelf, and pharmacy to the next. It is these standards that allow doctors, pharmacists, and other healthcare providers to trust in the medications they are prescribing and, in turn, provide us with the confidence to fill a prescription without questioning what we are getting. USP standards help ensure that all manufacturers of a given medicine (or ingredient) meet the same fundamental requirements—even defining what a drug or ingredient is, at the most basic level. These standards play a key role in helping ensure the integrity of the drug supply in this country. USP standards are also used worldwide in more than 130 countries.

As medicines and their ingredients are produced all over the world, the existence of—and adherence to—quality standards is even more critical. The globalization of the pharmaceutical industry has provided greater access to medications worldwide, but it has also brought new challenges and risks. While the U.S. drug supply remains the safest in the world, it is important to guard against quality problems brought on by deficiencies in manufacturing processes (the traditional role of a USP standard) that are unintentional, as well as by the regrettable lure of economically motivated adulteration—in which unscrupulous parties seek profits by intentionally replacing higher-cost drug ingredients with lower-cost ones. This was seen in the tragic episode involving the blood thinner heparin, which resulted in patient deaths in this country and abroad. Because of these emerging threats, a vital USP activity at present is updating standards to guard against intentional adulteration of medicines and ingredients that are at risk—an endeavor on which USP is working closely with FDA.

In addition to medicines, USP sets standards for dietary supplements and food ingredients. While these standards are voluntary standards in contrast to our drug standards, they are a tool for manufacturers to help ensure quality—with you and all consumers as the ultimate beneficiaries.

I encourage you to explore the materials in the kit. We have proudly worked to advance public health for almost two centuries, and are continuing to evolve to meet the needs of patients and consumers today and in the future.

Sincerely,

Roger L. Williams, M.D.  
Chief Executive Officer

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