

Did you know...

Facts about how quality standards from USP help protect people every day

- ▶ Even though it's not perfect, the U.S. drug supply is the safest in the world because of interrelated regulatory requirements that make up the safety net overseen by the U.S. Food and Drug Administration (FDA). One key strand in that safety net: All drugs sold in the U.S.—prescription and over-the-counter, no matter where in the world they are made—must meet USP quality standards that exist for that product.
 - ▶ If you buy medications over the Internet, you're exposed to an increased threat of counterfeit or substandard drugs. In 2010, counterfeit and substandard drugs were estimated to be a \$75 billion market worldwide—up more than 90% since 2005 (Center for Medicine in the Public Interest). USP standards help protect against fakes by providing requirements and sophisticated tests for identity, quality, purity, potency, and consistency.
 - ▶ When the widely-used blood thinner heparin was adulterated with a cheaper ingredient that caused adverse reactions and deaths in many patients, USP worked quickly with FDA and manufacturers to develop new tests to identify the counterfeit drugs. This happened in 2008–2009, and there have been no further reported deaths from adulterated heparin.
 - ▶ Glycerin is a solvent and sweetener used in many drugs and consumer goods, such as cough syrups, toothpaste, and mouthwash. To better protect consumers from serious and potentially fatal health hazards, USP revised its standard for glycerin with a new test to help prevent glycerin diluted with diethylene glycol from entering the U.S. drug supply. Diethylene glycol is a poisonous, cheaper chemical used in industrial solvents and antifreeze. Over the past century, accidental or intentional adulteration of drugs with diethylene glycol has killed hundreds of people in many countries, including the United States.
- ▶ Patients and physicians who depend on careful measurements of the metabolism of three drugs for the treatment of epilepsy and bipolar disorders, as well as respiratory diseases, now have access to greater certainty about the measurement of medication levels in the bloodstream, thanks to new USP reference standards.
 - ▶ Parents who feed their babies infant formulas will benefit from new USP standards now being finalized that help ensure the quality and purity of key ingredients.
 - ▶ To help train new generations of pharmacists in the importance of quality standards to patient health, USP is providing U.S. schools of pharmacy with free, unlimited access to its electronic portfolio of standards for the quality of medicines and food ingredients.
 - ▶ One-third of antimalarial medicines sampled in Madagascar, Senegal, and Uganda were found to be substandard in a large-scale USP–World Health Organization study. Use of substandard medicines may contribute to the growth of drug-resistant strains of *Plasmodium falciparum*, the most virulent form of malaria. USP's work was supported by the U.S. Agency for International Development (USAID).
 - ▶ In a major crackdown in 2010, the Cambodian government forced nearly 65% of the more than 1,000 illegal pharmacies operating in the country to close within a five-month period. The shops were targeted because they were among the primary sources of substandard and counterfeit medicines in Cambodia. Part of the evidence was gathered and analyzed by USP's Promoting the Quality of Medicines program, which is funded by USAID.
 - ▶ To help regulators around the world track substandard and counterfeit drugs used to treat HIV/AIDS, malaria, and tuberculosis, USP created a free, Internet-based Medicines Quality Database, a searchable repository of data about such drugs found in developing countries. As of August 2010, almost 9,000 individual records of tested medicines were entered into the database.

- ▶ More and more foods and beverages have been sweetened with plant-based stevia (Rebaudioside A), after the zero-calorie sweetener was granted Generally Recognized as Safe status by the FDA in late 2008. In 2009, USP released new standards that manufacturers can use to help ensure the quality and purity of the stevia ingredients they put in their products.
- ▶ Health-conscious consumers have grown more interested in alternative sources of Omega 3 fatty acids, as fish oil may be more likely to contain heavy metals and leave a fishy aftertaste. USP has proposed quality standards for Krill oil, a natural marine source that is sustainable as well as rich in Omega 3s and antioxidants.
- ▶ Medication misuse results in over one million adverse drug events every year. Poor health literacy contributes, leading to non-adherence and medication errors and posing significant health risks to patients. With patient safety foremost in mind, USP has proposed changes in its standards to bring consistency to labeling on prescription medication packaging and to promote universal standards for labels.
- ▶ In addition to FDA, USP also sets standards for labeling and naming drugs that help protect patients from harmful medication administration errors. For example, Injectable drugs that carry serious health risks if misadministered will be subject to new standards that they must carry clear warning labels—and nothing else—on the top of the vial to help ensure that a nurse or doctor sees the warning just before injections.
- ▶ When you take a medicine or supplement, you won't get the therapeutic benefit unless the pill or capsule dissolves properly in your body. A medication or supplement that meets USP standards is able to pass tests that ensure it dissolves so your body can absorb it.

- ▶ All HIV/AIDS drugs provided to developing countries with U.S. government funding—more than \$32 billion since 2004—are required to meet USP's standards for quality.
- ▶ The USP Verified Mark (shown right) found on some dietary supplements means that the product has passed USP's rigorous quality reviews.
 - The USP Verified Mark signifies supplements that have been made according to the FDA's Good Manufacturing Practices, using sanitary and well-controlled procedures. They will break down and release into the body within a specified amount of time; contain the ingredients listed on the label, in the declared potency and amounts; and do not contain harmful levels of specified contaminants such as heavy metals, microbes, and pesticides.
- ▶ More than 200 million labels/packages of dietary supplements have carried the USP Verified Mark. Among those recommending USP Verified supplements: *Consumer Reports*, Dr. Mehmet Oz ("The Dr. Oz Show"), and Dr. Jennifer Ashton (CBS News). (Visit www.usp.org/USPVerified/dietarySupplements to see a list of verified supplements and where to get them.)
- ▶ Manufacturers, regulators, and patients in more than 130 countries rely on thousands of USP's quality standards.
- ▶ Scientists, healthcare experts, regulators, practitioners, and manufacturers around the world help USP to set its quality standards without regard to political or geographic boundaries—all in the interest of protecting public health.

