

## Board of Directors

**Marv D. Shepherd, Ph.D.**  
**President**  
Director, Center for  
Pharmacoeconomic  
Studies, College of  
Pharmacy, University  
of Texas-Austin  
Austin, Texas

**Bryan A. Liang, M.D.,  
Ph.D., J.D.**  
**Vice President**  
Executive Director,  
Institute of Health Law  
Studies, California  
Western School of Law;  
Director, San Diego  
Center for Patient Safety,  
University of California  
San Diego School of  
Medicine  
San Diego, Calif.

**Thomas T. Kubic**  
**Treasurer**  
President and C.E.O.,  
Pharmaceutical Security  
Institute  
Vienna, Va.

**James N. Class, Ph.D.**  
**Former Executive  
Director**  
Director, Global Public  
Policy, Merck  
Washington, D.C.

**Scott A. LaGanga**  
**Executive Director**  
Deputy Vice President,  
Pharmaceutical Research  
and Manufacturers of  
America (PhRMA)  
Washington, D.C.

8100 Boone Blvd., Ste. 220  
Vienna, VA 22182  
USA

Phone: +1-703-679-SAFE  
Fax: +1-703-848-0164  
info@safemedicines.org  
www.safemedicines.org

## Counterfeit vs. Substandard Drugs

### What Are Counterfeit Drugs?

Counterfeit drugs are fake medicines intentionally made by unknown manufacturers who hide their identity. These drugs do not meet established standards of quality. Counterfeit drugs deceive consumers by closely resembling the looks of a genuine drug. They are made without approval of the regulator, such as the U.S. Food and Drug Administration (FDA). Counterfeiters create fake versions of branded, generic and over-the-counter drugs. Counterfeit medicines have been found to be made:

- Missing key ingredients
- Too strong or too weak
- With the wrong active ingredient
- With dangerous contaminants
- In unsanitary or unsterile conditions
- Using unsafe methods
- With improper labels

**Here's an example** — Two persons were arrested in March 2011 for manufacturing counterfeit drugs. The counterfeiters advertised brand-name drugs, but instead, they made fakes in a basement without any medicine in the drugs. Then, they attached false labels and sold them as the real thing.

### What Are Substandard Drugs?

In contrast, substandard drugs are produced by a known manufacturer, but they do not meet the quality standards of the drug regulator. In the United States, these high standards are set by the United States Pharmacopeia and the National Formulary. There is no intent to fool or defraud the consumer. Substandard medications are a result of manufacturer that do not follow approved Good Manufacturing Practices, which is regulated by the FDA. Simply stated, these drugs fall below the established standard – hence the term “substandard” drugs.

**Here's another example** — In May 2011, a large pharmaceutical company voluntarily removed from the market one of its drugs used to prevent blood clots. They found the incorrect amount of medicine was used in one particular production run. It was a mistake, which when found, they immediately corrected.

### Why It's Important To Understand How Substandard And Counterfeit Drugs Are Different?

Both counterfeit drugs and substandard drugs can be harmful, but it is important to understand that they are different. When substandard medicines are found, the company that made them is known. Consequently, the authorities can work with the company to remove the substandard medicine and correct the problem. With counterfeit drugs, the company that manufactured them is unknown. Consumers have no assurance of what is actually in these products. Authorities are also unaware of how many illegal copies there are in the marketplace and where they are located.

**Remember** — Counterfeit drugs are always dangerous!

### About the Partnership for Safe Medicines

The Partnership for Safe Medicines (PSM) is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. To learn more about PSM, visit [www.safemedicines.org](http://www.safemedicines.org).