

### *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 & Unsafe Drugs in the United States*

### **What Are Counterfeit Drugs?**

Counterfeit drugs include any fake medicine that is not approved by U.S. Food and Drug Administration (FDA) and do not meet the established standards of quality set forth by the United States Pharmacopeia and the National Formulary, but hide this fact. They are not limited to brand-name prescription drugs as counterfeiters also create fake versions of generic and over-the-counter drugs. Counterfeits can be any, or all, of the following things:

- Too strong or too weak
- Missing key ingredients
- Made with incorrect active ingredients
- Made with dangerous ingredients
- Contaminated with foreign, even toxic, materials
- Made in unsanitary or unsterile conditions
- Created using unsafe methods
- Improperly labeled, stored or handled

### **Why Are Counterfeit Drugs Dangerous to U.S. Citizens?**

Anytime consumers venture outside of the U.S.' currently closed system, there is a very real risk to their health and welfare. This may include mediums such as rogue online pharmacies, which do not require a prescription and are not accredited by the National Association of Board of Pharmacy's VIPPS (Verified Internet Pharmacy Practice Site) program nor regulated by the FDA.

Although most of the counterfeit drugs found in the United States are found outside the normal supply chain, adulterated, fraudulently obtained, expired and counterfeit drugs remain an issue here and around the world. In fact, the Pharmaceutical Security Institute reports the following 2010 figures on pharmaceutical crime incidents worldwide:

- **1,735** counterfeit drug incidents
- **201** pharmaceutical crime incidents in North America alone
- **2.5 percent** increase in pharmaceutical crime incidents
- **112** countries impacted by pharmaceutical crime
- **593** unique products involved in pharmaceutical crime incidents
- **1,148** arrests related to pharmaceutical crime

The United States has already seen numerous counterfeit and unsafe drug incidents. Below are just a few cases that have impacted Americans in 2011 alone:

***April 15, 2011***

#### **U.S. Doctor Sold Fake Cancer Drugs to Patients: Gets 1 Year in Jail**

Kurt Walter Donsbach, 75, of San Diego, Calif. was sentenced to a year in county jail and probation of ten years after pleading guilty in December 2010 to 13 felony charges, including unlawfully selling fake drugs to cancer patients, practicing medicine without a license and attempted grand theft. Donsbach, of Bonita, Calif., identified himself as a chiropractor and naturopathic doctor online and in literature, frequently appearing on radio programs offering patients "natural" remedies to serious health conditions like rheumatoid arthritis and late stage cancer but instead sold them counterfeit medications made of dangerous and illegal ingredients. Donsbach gave false hope to the terminally ill, claiming terminal cancer patients would be alive in five years, while giving them supposedly natural supplements which in fact contained nimesulide, a non-steroidal anti-inflammatory drug not approved for treatment.

**March 25, 2011**

**New Jersey Residents Arrested for Fake Drug Manufacturing in Basement**

Brian Parker, 27, and Michelle Pfeiffer, 24, of Brielle and Toms River, N.J., were charged with conspiracy to misbrand drugs, impeding the lawful functioning of the FDA, fraud related to the misbranding of drugs and failure to register a drug manufacturing facility. The indictment alleges that, although Parker advertised brand name prescription drugs, he instead provided fakes that he manufactured in the basement of his home. Parker and Pfeiffer allegedly accepted orders via email and then manufactured the drugs in their residence by converting bulk active and inactive ingredients into capsules or tablets, creating false labels for the misbranded drugs, and then shipping them throughout the United States.

**February 7, 2011**

**Missouri Man Convicted of Selling Thousands of Fake Pills**

St. Louis, Mo. resident Mark Hughes was sentenced to four years in prison by U.S. District Court after being convicted of selling thousands of counterfeit erectile dysfunction pills. Hughes last shipment of 1,000 pills was intercepted by U.S. Customs and Border Protection in 2009 and delivered by investigators. After a search of Hughes' residence was conducted, he admitted buying approximately 11,000 pills and selling them without a prescription.

**January 14, 2011**

**Hacked Military and Government Computers Push Rogue Online Pharmacies**

A U.S. web hosting provider admitted that hackers invaded dozens of web pages of government, educational and financial websites through a software flaw to promote online rogue pharmacies. Hostmonster.com, a Utah-based website host provider, exploited a bug in a website administration tool used by a majority of hosting providers, as well as Hostmonster.com, to ultimately redirect visitors from institutional websites to online stores selling prescription drugs without prescription requirements. This significantly increased the risks to these patients both for unsupervised use of prescription drugs as well as for receiving counterfeit drugs.

**January 9, 2011**

**7,000 Pills Vanished in Florida Pharmacy Theft**

A Northeast Florida pharmacist was charged with the theft of 7,000 prescription painkiller pills from a Rite Aid drug store that are still missing. John Pearson, of Fleming Island, Fla., is accused of the felony crime of theft by taking, unlawful distribution of controlled substances and possession of hydrocodone, which is a Scheduled III controlled narcotic, according to Blackshear police Lt. Chris Wright. Pearson is charged with allegedly stealing 110 bottles of hydrocodone over two years of employment, beginning in October 2009. Police have not recovered any of the stolen pills, and cannot say if the pills were sold or consumed.

**Can You Tell Which One Is the Fake Drug in Each of These Pairs? \***



**About the Partnership for Safe Medicines**

Comprised of more than 65 non-profit organizations, 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 or to access the news articles mentioned above, visit [www.safemedicines.org](http://www.safemedicines.org).