THE PARTNERSHIP FOR

SAFEMEDICINES

INTERCHANGE 2014

THE KNIGHT CONFERENCE CENTER | NEWSEUM

WASHINGTON, D.C. | SEPTEMBER 18, 2014

www.safemedicines.org

#fakedrugs | #PSM2014

The Partnership for Safe Medicines
extends its sincerest gratitude and appreciation to all of the
2014 Interchange Sponsors
for their generous contributions and continued support.

SILVER

ALLERGAN

Genentech
A Member of the Roche Group

MERCK
Be well

BRONZE

ABREOS BIOSCIENCES

Celgene

Johnson & Johnson

Lilly

MEDIA SPONSORS

FFF enterprises
Helping Healthcare Care

RxTRACE

FiercePharma

ABOUT THE PARTNERSHIP FOR SAFE MEDICINES

Criminals make billions of dollars creating and selling counterfeit drugs around the world, and those products make their way into the United States. They duplicate the exact packaging, look and taste of the real thing. They can be difficult to detect, but detecting them is important. Counterfeit drugs can be a death sentence for the patients who end up taking them. Fake drugs deny patients treatment that can alleviate suffering and save lives, promote drug resistant strains of disease and may cause dangerous or deadly reactions to undeclared drug ingredients.

Comprised of over 70 not-for-profit organizations, the Partnership for Safe Medicines (PSM) is a public health group committed to the safety of prescription drugs and protecting consumers from counterfeit, substandard or otherwise unsafe medicines.

PSM follows a set of principles to support quality assurance programs and establish a drug distribution system that is without compromise. It is our hope that through these guidelines we can reduce the number of counterfeit drugs that defraud patients and deny them therapies that can alleviate suffering and save lives.

Our principles include:

- Unifying the fight against counterfeit drugs
- Securing and protecting the pharmaceutical supply chain
- Regulation of online sellers

Our members are dedicated to protecting the safety of American consumers by curbing the manufacture and sale of dangerous counterfeit drugs. Our goal is for all consumers to be aware that counterfeit medicines do exist, they are not safe and together we can take action to avoid them.

PSM works with patient advocacy groups and consumer groups to raise awareness of counterfeit drugs within the United States and to teach patients and medical professionals how to buy medication safely and affordably without risking patients' lives by dealing with dangerous, unlicensed counterfeit medication sellers.

Learn more about the dangers of counterfeit drugs at *safemedicines.org* or contact us at *info@safemedicines.org*.

GENERAL INFORMATION

VENUE

Newseum Freedom Forum
Knight Conference Center
555 Pennsylvania Avenue, N.W.
Washington, D.C. 20001
(888) 639-7386

CONFERENCE REGISTRATION AND INFORMATION

The Interchange Conference registration and information desk will be located on the 7th Floor of the Knight Conference Center. The desk will open at 7:30 a.m. and close at 5:00 p.m. Name badges and a portfolio of conference materials will be held at the registration desk for each registered attendee. Only registrants wearing PSM's Interchange name badges will be admitted to conference sessions.

EVENTS

Registration and all panels will be held on the 7th floor. Luncheon will be held on the 8th floor.

NO SMOKING POLICY

The Knight Conference Center is a tobacco-free facility. Smoking is strictly prohibited.

USE OF CELLULAR TELEPHONES

The Partnership for Safe Medicines asks that all cellular and wireless telephones be turned off during all conference sessions and social events.

PSM Interchange 2014 hashtag:
#fakedrugs
#PSM2014

Conference wifi information:
Network name: Newseum Guest
User name: newseumguest *(no password necessary)*

BOARD OF DIRECTORS AND LEADERSHIP

President

Marvin D. Shepherd, Ph.D.
Director, Center for Pharmacoeconomic Studies, University of Texas, Austin
Chairman of the Pharmacy Administration Division at the University of Texas at Austin's College of Pharmacy

Dr. Marv Shepherd is the Director of the Center for Pharmacoeconomic Studies and Chairman of the Pharmacy Administration Division at the University of Texas at Austin's College of Pharmacy. He also serves as the President of the Partnership for Safe Medicines.

Among his many research interests, Dr. Shepherd examines the policies related to drug importation and re-importation—especially from Mexico—the use of drug anti-counterfeiting strategies, and techniques for monitoring prescription drug diversion. His research and expertise on drug importation and drug counterfeiting has been featured on *CNN News*, *NPR Radio: First Edition*, *Newsweek*, *Wall Street Journal*, *Money Magazine*, *Time Magazine*, *Prevention Magazine*, *US News and World Report*, *New York Times*, *USA Today*, *Washington Post*, plus many other national newspapers, magazines, and television and radio news broadcasts. He earned a Bachelor of Science in biology from Michigan Technological University, Bachelor of Science in pharmacy from Ferris State University, a Master of Science from the University of Rhode Island, and a PhD from Purdue University.

Vice President

Bryan A. Liang, Ph.D., M.D., J.D.
Professor of Anesthesiology
Director, San Diego Center for Patient Safety, University of California, San Diego School of Medicine

Professor Bryan A. Liang is Professor of Anesthesiology and Director, San Diego Center for Patient Safety, University of California, San Diego School of Medicine as well as Vice President, Partnership for Safe Medicines. Professor Liang's research, policy, and advocacy focus is global health policy. He has published and spoken widely on the topic of global health, online governance concerns, and safety of the global medicines supply, with more than 400 publications and presentations in domestic and international public and private forums. He received his Bachelor of Science from MIT; PhD in Health Policy from the University of Chicago; MD from Columbia University College of Physicians & Surgeons; and JD from Harvard Law School.

Treasurer

Thomas T. Kubic
President and CEO,
Pharmaceutical Security Institute

Thomas T. Kubic is the President and CEO of the Pharmaceutical Security Institute (PSI), a non-profit association dedicated to protecting the public health by ensuring the distribution of pharmaceuticals that are safe and effective. Mr. Kubic currently serves on the World Health Organization's IMPACT Enforcement Working Group, the Interpol Intellectual Property Crime Action Group, and in an advisory capacity to the Permanent Forum Against International Pharmaceutical Counterfeiting. He is the Treasurer for the Partnership for Safe Medicines. Additionally, he has provided testimony before senior government officials around the world concerning the international nature of counterfeiting and its devastating impact.

Composed of the security directors from 26 pharmaceutical manufacturers with business operations in more than 160 countries, PSI shares information on the counterfeiting of pharmaceuticals and initiates enforcement actions through the appropriate authorities. Under Mr. Kubic's leadership, PSI was completely reorganized to emphasize information sharing and private-public sector cooperation. Major advances included the development of the PSI Anti-Counterfeiting Strategy and a unique, internationally recognized counterfeit medicines reporting system, the Counterfeit Incident System.

Prior to joining PSI, Mr. Kubic acquired substantial national and international investigative experience during his 30-year career as a federal law enforcement executive for the U.S. Federal Bureau of Investigation (FBI). As an FBI Deputy Assistant Director, his innovative programs in both the Laboratory Division and Criminal Investigative Division were recognized throughout the law enforcement community.

Executive Director

Scott A. LaGanga
Senior Vice President, Public Affairs - Advocacy,
Pharmaceutical Research and Manufacturers of America

Scott serves as Executive Director of the Partnership for Safe Medicines (PSM), a public-private partnership of more than 70 organizations dedicated to combating counterfeit and unsafe medicines around the globe. In this capacity, Scott has led the development of the annual PSM Interchange forum, which brings together public and private-sector leaders, including frequent participation by Food and Drug Administration Commissioner Margaret Hamburg. In late 2010, he successfully launched PSM's first international partnership, PSM India, as well as PSM China in late 2012.

In addition, Scott A. LaGanga serves as Vice President of Public Affairs and Alliance Development at the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's leading innovative biopharmaceutical research and biotechnology companies. In this role, he leads a team responsible for third-party stakeholder relations and coalition

development, which includes frequent outreach to patient groups, health care providers, business leaders, organized labor, venture capitalists and academic institutions. Additionally, Scott is a member of PhRMA's executive team and helps manage global public policy issues on behalf of the organization.

Prior to joining PhRMA, Scott was Executive Director and co-founder of the Property Rights Alliance, a Washington, D.C.-based advocacy organization dedicated to the protection of physical and intellectual property rights, both domestically and worldwide.

Scott completed a Master of Business Administration at George Washington University in 2009, with concentrations in international business and management. As a Henry J. Raimondo Fellow at the Eagleton Institute of Politics, Scott received a Master's degree in public affairs and politics from the Edward J. Bloustein School of Planning and Public Policy at Rutgers University. He holds a Bachelor of Arts degree in political science from the University of Maryland, College Park.

Board Member

James Dahl

Assistant Director, Office of Criminal Investigations, U.S. Food and Drug Administration (retired)

Jim Dahl is an independent product security consultant with significant experience in the public and private sectors. He is considered a subject matter expert in pharmaceutical crime and malicious product tampering. Jim is a retired federal law enforcement agent with 30 years experience having spent his last nine years in government as the Assistant Director of the FDA's Office of Criminal Investigations (OCI). Jim also served five years as the Global Product Security Director at Eisai Company Ltd., a research based pharmaceutical manufacturer with operations throughout the world. His experience includes managing his own independent consulting company and as Senior Managing Director for Crisis Management at an international security consulting firm. Jim currently serves as a member of the Board of Directors for the Partnership for Safe Medicines (PSM).

Ex-Officio Board Member

James N. Class, Ph.D.

Executive Director, Mid Europe Commercial Operations, Merk & Co., Inc.

Dr. James N. Class is Executive Director, Mid Europe Commercial Operations, Merk & Co., Inc. Prior to 2007, Dr. Class worked at PhRMA and as a liaison between anti-counterfeiting groups. He was the Executive Director for the United States' division of the Partnership for Safe Medicines.

In 2005, Dr. Class worked to coordinate establishing the first direct-to-consumer e-mail alert service on counterfeit drugs, which has since been integrated into the U.S. Food and Drug Administration's (FDA) Counterfeit Alert Network. In addition, he founded a news update on counterfeit drugs, which is sent out to the FDA, the Drug Enforcement Administration, U.S. Federal Bureau of Investigation, the International Criminal Police Organization (Interpol), local law enforcement agencies, industry and other communities. Currently, Dr. Class participates in the Interpol Intellectual Property Crime Action Group and the World Health Organization's IMPACT Enforcement Working Group.

Dr. Class is an alumnus of Georgetown University where he received his PhD with honors in 2004.

PROGRAM-AT-A-GLANCE

7:30 a.m. – 5:00 p.m.	Registration Open
7:30 a.m. – 8:30 a.m.	Continental Breakfast and Sponsor Table Browsing
8:30 a.m. – 8:40 a.m.	Welcome and Opening Remarks
8:40 a.m. – 9:10 a.m.	Research Presentations
9:10 a.m. – 10:25 a.m.	General Session (Panel I)
10:25 a.m. – 10:40 a.m.	Refreshment Break and Sponsor Table Browsing
10:40 a.m. – 11:55 a.m.	General Session (Panel II)
11:55 a.m. – 12:55 p.m.	Luncheon
12:55 p.m. – 1:05 p.m.	Pre-Panel Presentations
1:05 p.m. – 2:20 p.m.	General Session (Panel III)
2:20 p.m. – 2:50 p.m.	General Session (Panel IV)
2:50 p.m. – 3:05 p.m.	Refreshment Break and Sponsor Table Browsing
3:05 p.m. – 3:35 p.m.	General Session | Keynote Speaker
3:35 p.m. – 4:15 p.m.	General Session | Keynote Speaker
4:15 p.m. – 4:17 p.m.	Closing Remarks
4:17 p.m. – 5:15 p.m.	Networking Reception

PROGRAM

7th Floor

7:30 a.m. – 5:00 p.m. REGISTRATION OPEN

7:30 a.m. – 8:30 a.m. CONTINENTAL BREAKFAST AND SPONSOR TABLE BROWSING

8:30 a.m. – 8:40 a.m. WELCOME AND OPENING REMARKS

Scott LaGanga, Executive Director, Partnership for Safe Medicines; Senior Vice President, Public Affairs - Advocacy, Pharmaceutical Research and Manufacturers of America

8:40 a.m. – 9:10 a.m. RESEARCH PRESENTATIONS

New USP Guidelines for Drug Chain Distribution
Presented by
Marv Shepherd, PhD, Director, The Center for Pharmacoeconomic Studies, College of Pharmacy, The University of Texas, Austin (*PSM Board Member*); Chairman of the Pharmacy Administration Division at the University of Texas at Austin's College of Pharmacy

After Counterfeit Avastin—What have we learned and what can be done?
Presented by
Tim K. Mackey, MAS, PhD, Assistant Professor, UCSD School of Medicine, Department of Anesthesiology; Director, Global Health Policy Institute; Associate Director, MAS Program in Health Policy and Law

9:10 a.m. – 10:25 a.m. GENERAL SESSION (PANEL I)

Drug Counterfeiters Target Americans
Counterfeiters exploit weak global enforcement regimes to target unsuspecting Americans. To protect yourself and your family, learn what the global counterfeit drug situation is from policy and law enforcement experts.

Moderator:
Thomas T. Kubic, President & CEO, Pharmaceutical Security Institute (*PSM Board Member*)

Panelists:
Gillian Buckley, Program Officer, Institute of Medicine
Jim Dahl, Assistant Director, Office of Criminal Investigations, Food and Drug Administration (retired) (*PSM Board Member*)
Samantha Gompel, IPM Communications Manager, World Customs Organization
Philip Walsky, Acting Director, Office of Criminal Investigations, Food and Drug Administration

10:25 a.m. – 10:40 a.m. REFRESHMENT BREAK AND SPONSOR TABLE BROWSING

10:40 a.m. – 11:55 a.m. GENERAL SESSION (PANEL II)

Patient Safety and Criminal Prosecutions in the U.S.
Learn about recent cases involving counterfeit, misbranded, unapproved, and adulterated drugs and devices, the doctors who purchased them, and the sellers who market and distribute them. Federal prosecutors will discuss cases and explain the risks to American patients caused by these criminals.

Moderator:
Linda I. Marks, Senior Litigation Counsel, Consumer Protection Branch, U.S. Department of Justice

Panelists:
Lindsay A. Kelly, Assistant U.S. Attorney Criminal Division, Cybercrime Unit, Eastern District of Virginia, U.S. Department of Justice
Jaime A. Peña, Assistant U.S. Attorney/Senior Litigation Chief, Criminal Division, Colorado District, U.S. Department of Justice

8th Floor

11:55 a.m. – 12:55 p.m. NETWORKING LUNCHEON

7th Floor

12:55 p.m. – 1:05 p.m. PRE-PANEL PRESENTATION

Speakers:
Bejon Misra, Partnership for Safe Medicines India
Madame LiHong Gu, Partnership for Safe Medicines China

1:05 p.m. – 2:20 p.m. GENERAL SESSION (PANEL III)

The Impacts of Fake Online Pharmacies on Patient Safety
Law enforcement, American pharmacists and patient safety advocates will discuss recently discovered threats to patient safety from online pharmacies.

Moderator:
Special Agent **Daniel Burke**, Senior Operations Manager for Cybercrime Investigations Unit, Office of Criminal Investigations, U.S. Food and Drug Administration

Panelists:
Libby Baney, Executive Director, Alliance for Safe Online Pharmacies
Todd Brown, Executive Director, Massachusetts Independent Pharmacists Association
Kenneth "Mac" McCall, III, President, Maine Pharmacy Association

2:20 p.m. – 2:50 p.m. GENERAL SESSION (PANEL IV)

How the Black Market Impacts Patients
Public health experts discuss the impact on patients from counterfeit, non-FDA approved drugs in the U.S. and the world.

Moderator:
Jim Dahl, Board Member, Partnership for Safe Medicines; Assistant Director, Office of Criminal Investigations, U.S. Food and Drug Administration (retired)

Panelists:
Gaurvika Nayyar, Program Manager for Asia, U.S. Pharmacopeia's Promoting the Quality of Medicines Program
Kimberly New, National Association of Drug Diversion Investigators
Eric J. Sampson, Senior Science Advisor, CDC Foundation

2:50 p.m. – 3:05 p.m. REFRESHMENT BREAK AND SPONSOR TABLE BROWSING

3:05 p.m. – 3:35 p.m. GENERAL SESSION

KEYNOTE SPEAKER
Jim Hood
Attorney General, State of Mississippi

Introduced by **Thomas T. Kubic**, Board Member, President & CEO Pharmaceutical Security Institute

3:35 p.m. – 4:15 p.m. GENERAL SESSION

KEYNOTE SPEAKER
Howard Sklamberg, *JD*
Deputy Commissioner for Global Regulator Operations and Policy, Food and Drug Administration

Introduced by **Scott LaGanga**, Executive Director, Partnership for Safe Medicines; Vice President, Public Affairs - Advocacy, Pharmaceutical Research and Manufacturers of America

4:15 p.m. – 4:17 p.m. CLOSING REMARKS

Marv Shepherd, PhD, Director, The Center for Pharmacoeconomic Studies, College of Pharmacy, The University of Texas, Austin; Pharmacy Administration Division at the University of Texas at Austin's College of Pharmacy

4:17 p.m. – 5:15 p.m. NETWORKING RECEPTION

SPEAKERS

Libby Baney, J.D.

Libby is the founding Executive Director of the Alliance for Safe Online Pharmacies (ASOP), a nonprofit organization based in Washington, D.C. She leads ASOP operations, shapes public policy, and advocates for patient safety. Ms. Baney is a lawyer by training and health advocate by nature. Her work spans multiple continents and touches nearly all fifty U.S. states.

Before joining ASOP as Executive Director, Ms. Baney worked at an international law firm. In this role, she advised a large coalition in support of the recently-passed U.S. Drug Quality and Security Act and led policy efforts on a variety of other health issues.

Currently Ms. Baney also runs a consulting firm, FWD Strategies International, through which she advises pharmaceutical, pharmacy, Internet security and technology companies, trade associations and governments.

Todd Brown

Todd Brown is currently the Vice Chair in the Department of Pharmacy Practice at Northeastern University school of pharmacy. He has held a number of other academic positions in his 24 years as a faculty member. His research interests include the documentation and evaluation (both clinical and economic) of services offered by community pharmacies. Todd Brown is also currently the Executive Director of the Massachusetts Independent Pharmacists Association. This organization represents independent community pharmacy owners and the staff that are located in Massachusetts. Mr. Brown has served in this role for 17 years. He is also a past President of this association. Todd Brown has been a Registered Pharmacist in Massachusetts for 30 years. During this time he has practiced in community, long-term care as well as institutional environments. He has a Bachelor of Science in Pharmacy as well as a Master of Health Professions with a concentration in health policy from the Bouvé College at Northeastern University.

Gillian Buckley, Ph.D.

Gillian Buckley is a Program Officer in the Institute of Medicine Board on Global Health. She was study director and editor for the reports: *Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad*, *Countering the Problem of Falsified and Substandard Drugs*, and *Investing in Health Systems: Sustaining Gains, Transforming Lives*. She has a PhD in human nutrition and an MPH in international health, both from Johns Hopkins University. Her dissertation looked at the effects of prenatal vitamin A supplementation on the cognitive and motor development of Nepali children. She served as a Peace Corps volunteer in Nepal from 2000–2002.

Special Agent Daniel Burke

Dan Burke started his federal law enforcement career with the IRS-Criminal Investigation Division in 1995. In 1997, he transferred to the U.S. Customs Service where he primarily investigated on-line child pornography, drug and financial investigations. In 2002, he was promoted to Supervisory Special Agent for U.S. Customs, which is now known as ICE's-Homeland Security Investigations, where he managed a Financial Investigations Task Force. In 2005, Dan joined FDA's Office of Criminal Investigations.

Since joining OCI, Dan has completed a number of successful online pharmacy investigations spanning the globe. In 2012, Dan was promoted to Senior Operations Manager of OCI's Cybercrimes Investigation Unit (CcIU) and is also overseeing the development of OCI's international expansion and liaison efforts. Dan has attained a variety of certifications in the field of computer

forensics and cybercrime and holds a Master's degree in criminal justice administration from the University of Colorado-Denver where he currently teaches criminal justice classes as part of their adjunct faculty.

Samantha Gompel

Samantha Gompel works for the IPR and Health & Safety Program within the Enforcement and Compliance Directorate at the World Customs Organization (WCO). Capturing the attention of Customs officers and industries worldwide and ensuring their vigilance with regards to counterfeit products is at the heart of the WCO IPR and Health and Safety Program. With the protection of consumer health and safety as a key priority, the WCO is extremely active in delivering extensive capacity building actions, developing various enforcement tools and coordinating efforts of its Members and related international organizations. Ms. Gompel has been participating in and coordinating the WCO IPR operational and promotional activities for the past two years. Her previous experience includes 5 years working for a well-established European publication, following a previous 5 years spent in the private sector.

Madame LiHong Gu

Madame LiHong Gu, is with Partnership for Safe Medicines China. Founded in 2012, PSM China is a coalition of organizations that aims to strengthen drug safety by educating consumers about counterfeit medicines and by stopping the flow of counterfeit medicines before they reach patients.

Attorney General Jim Hood

Jim Hood has served as Attorney General of Mississippi since 2004. Prior to being elected as Attorney General, he served as a law clerk at the Mississippi Supreme Court and as a Special Assistant Attorney General. In 1995, he was elected the district attorney for seven counties in North Mississippi. During his eight years as district attorney, he tried more than 100 jury trials. He has personally prosecuted several historical cases, including the 2005 trial for the leader of the 1964 murder of three civil rights workers in a case which was previously depicted in the movie "Mississippi Burning."

As the father of three, Attorney General Hood has been a passionate champion for protecting Mississippi's children from the dangers brought by technology, particularly the Internet and cellular telephones. Mississippi's Cyber Crime Fusion Center and state-wide Internet Crimes Against Children task force have helped rescue child victims of predators, prevented children from being abused and exploited, and deterred cyber bullying.

Attorney General Hood has led Mississippi initiatives to prevent workplace and school violence, established a dedicated domestic violence unit, and statewide restraining order registry. AG Hood has developed several other unique units in his office, including the Deadbeat Parent Child Support Prosecution Unit, the Vulnerable Adults Unit, the Victims Compensation Unit, the Insurance Fraud Unit, and the Intellectual Property Theft Task Force.

AG Hood has also forged new strategies and programs to help and educate consumers. The Consumer Protection Division leads statewide efforts to investigate and prosecute consumer frauds and scams, identity theft, home repair fraud, price gouging, and dangerous counterfeit products. AG Hood consistently works to strengthen laws to protect consumers from these crimes.

He serves on the Board of Directors for the Jason Foundation, which is dedicated to preventing teen suicide, the National Association of Model State Drug Laws, and as a Non-Regional Director for the National White Collar

Crime Center (NW3C). In addition, Attorney General Hood serves as President-Elect for the National Association of Attorneys General (NAAG), as Co-Chairman for the Intellectual Property Theft Committee, and is a member of several NAAG Committees.

Attorney General Hood is a native of Chickasaw County in North Mississippi—a place he calls "God's Country." He is an avid outdoorsman and hunter. He and his wife, Debbie, have three children: Rebecca, Matthew and Annabelle Leigh.

Lindsay A. Kelly

Lindsay Kelly has been an Assistant United States Attorney in the Cybercrime Unit at the U.S. Attorney's Office for the Eastern District of Virginia since 2010. Ms. Kelly is the lead prosecutor in the government's case against Gallant Pharmaceuticals International, Inc., an unlicensed distributor of non-FDA-approved drugs, which resulted in 10 guilty pleas and 2 convictions following a jury trial. Since joining the U.S. Attorney's Office, Ms. Kelly has received an ICE Director's Award, CBP Commissioner's Award, and GSA Inspector General's Award. Prior to serving as an AUSA, Ms. Kelly clerked on the U.S. Court of Appeals for the Federal Circuit and spent four years in private practice in Washington, D.C.

Timothy K. Mackey

Timothy K. Mackey is an Assistant Professor, University of California, San Diego–Department of Anesthesiology. He has a global perspective and appreciation of diverse social and cultural backgrounds after living in a number of foreign countries in both developed and developing nations. He earned his Bachelor's degree in Political Science-International Relations at the University of California San Diego, received a Master's in Advanced Studies Degree in the Joint Program in Health Law, University of California San Diego-California Western School of Law, and earned his PhD in Global Health in the Joint Doctoral Program in Global Health at University of California San Diego School of Medicine and San Diego State University Graduate School of Public Health. He has a diverse background including working and consulting for the public and private sector including completing an internship at the World Health Organization, volunteer work in governance of a non-profit organization and over 7 years of experience in legal and compliance positions in the medical device industry. He has extensively published in the scientific literature on the subject of counterfeit medicines and illicit online pharmacies.

Linda I. Marks

Linda I. Marks is a Senior Litigation Counsel at the Consumer Protection Branch ("CPB," formerly the Office of Consumer Litigation), U.S. Department of Justice, where she handles Internet pharmacy, counterfeit pharmaceutical, FDA fraud, and complex odometer tampering and securities fraud cases. Ms. Marks has tried Internet pharmacy cases involving both controlled substances and non-controlled prescription drugs, and heads CPB's counterfeit drug team. She started her government career in 1980 as an attorney with the Office of General Counsel for the National Oceanic & Atmospheric Administration, where she handled fisheries, marine mammal, endangered species, and national marine sanctuary enforcement cases. She spent five years as an Assistant United States Attorney in Washington, D.C., where she prosecuted local crime and federal fraud cases. Ms. Marks has been with CPB since 1994.

Kenneth "Mac" McCall, III

Kenneth "Mac" McCall, III, BSPharm, PharmD, is an Associate Professor and founding faculty member of the Department of Pharmacy Practice at the University of New England College of Pharmacy. He earned his BS Pharmacy and Doctor of Pharmacy degrees from the University of Oklahoma Health Sciences Center and completed a primary care residency with the Department of Veterans Affairs. Prior to moving to Maine with his wife and son, he was an Associate Professor of Pharmacy Practice at Texas Tech University Health Sciences Center for eleven years. He currently is serving as President of the Maine Pharmacy Association (MPA). In 2013, Maine became the first state to enact a prescription drug importation ordinance. This new state law tears a hole in the comprehensive, closed system that Congress created for the safe distribution of prescription drugs in the United States. MPA is currently engaged in a lawsuit in federal court challenging the legality of Maine's pharmaceutical importation law.

Bejon Misra

Bejon Misra is the founding board member of the Partnership for Safe Medicines (PSM) India; Managing Director and trustee of the Consumer Online Foundation; founder and trustee of Healthy You Foundation; and the Chairman of Cell for Consumer Education & Advocacy based in New Delhi, India. He has worked in the consumer movement since 1983 when he started at an organization based in Jamshedpur, India.

Mr. Misra has been active within Consumers International (CI) since 1999 and is on the board of several consumer organizations based in India. In addition, he serves as a signatory and founding governing council member of the Consumer Coordination Council, a leading national coalition of more than 70 consumer organizations throughout India. He has also published several studies on consumers' perspective on Quality of Service (QoS) of products and services, particularly within the healthcare delivery system.

Mr. Misra is a member of the Food Safety & Standards Authority of India and has served on the boards of the Bureau of Energy Efficiency, the Quality Council of India and the National Accreditation Board for Accreditation of Certification Bodies. He is also member of the Consumer Complaint Council (CCC) within the Advertising Standards Council of India and was nominated as an Expert on Consumer Protection Policies in several government working groups and committees of various Ministries of Government of India.

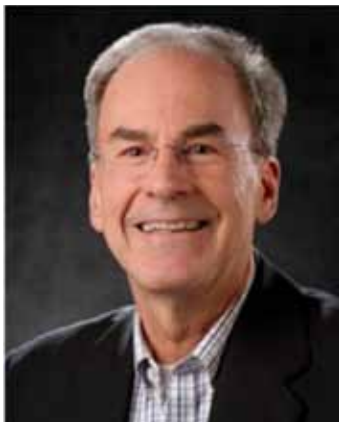
An alumnus of the Loyola School Jamshedpur, Mr. Misra also received a degree in business management and marketing from Banaras Hindu University in Varanasi, India.

Gaurvika Nayyar

Gaurvika Nayyar is the Program Manager for Asia at United States Pharmacopeia's Promoting the Quality of Medicines Program. Prior to joining USP, she has worked on access, commercial strategy, and quality of medicines programs for emerging markets at Janssen Pharmaceuticals, the Bill and Melinda Gates Foundation and Deloitte Consulting. Ms. Nayyar's research at the National Institutes of Health to better understand the extent of poor quality antimalarials in South East Asia & Sub-Saharan Africa has been widely covered by BBC, NYT, Reuters, CNN & others. She is also the director of the Global Network for Access to Medicines at Johns Hopkins, and is a fellow at the Center for Drug Safety and Effectiveness. Ms. Nayyar received her Master of Public Health and Master of Business Administration from Johns Hopkins University, and completed her undergraduate studies at Cornell University.

Kimberly New, J.D.

Kimberly New serves as a consultant and educator on controlled substance security and regulatory compliance to healthcare facilities across the country. She has extensive experience assisting facilities with starting and refining their drug diversion programs, with a goal of protecting patients from the harm that is frequently associated with diversion. Ms. New has a BS in Nursing from Wichita State University, and a JD from Washburn University School of Law. She is the President of the Tennessee Chapter of the National Association of Drug Diversion Investigators (NADDI), and a healthcare facility liaison to the NADDI Executive Board. Ms. New is a frequent author and national speaker on the subject of health facility diversion, and has been featured in the *Wall Street Journal* and *USA Today*. She has served as a guest blog author for the CDC Safe Healthcare blog and DHHS aids.gov.



Eric J. Sampson, Ph.D.

Between 1985 and 2010, Dr. Eric J. Sampson served as the Director, Division of Laboratory Sciences, CDC. As Director, Dr. Sampson led a staff of more than 400 scientists (100+ PhDs, 6 MDs) and was involved in a number of precedent-setting studies and investigations in which his group provided key data and information for resolving epidemics and for formulating public health polices. Major areas of applied research within his Division focused on: tobacco and smoking addiction, chronic diseases, environmental health, nutrition, newborn screening and genetics, and responding to chemical/radiologic terrorism.

From 2010 to 2013, Dr. Sampson served as a Senior Advisor to the Director, CDC on science and policy topics between CDC and FDA. He retired in 2013 and, since April 2014, has been serving as the Senior Science Advisor to the CDC Foundation, Atlanta, GA. Over the course of his career, Dr. Sampson authored or coauthored more than 120 publications and has been the recipient of numerous awards.

Howard Sklamberg, J.D.

Mr. Sklamberg is FDA's Deputy Commissioner for Global Regulatory Operations and Policy, the Directorate comprising the Office of Regulatory Affairs and the Office of International Programs. Mr. Sklamberg provides executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities.

Prior to being named Deputy Commissioner in January 2014, Mr. Sklamberg served for one year as Director of the Office of Compliance at FDA's Center for Drug Evaluation and Research (CDER). He led the Office in its efforts to protect the American public from unsafe and ineffective drug products. Mr. Sklamberg played key leadership roles in global drug supply chain security, pharmacy compounding oversight, pharmaceutical quality, and expanded cooperation with international regulatory partners.

Mr. Sklamberg also served as FDA's Deputy Associate Commissioner for Regulatory Affairs in the Office of Regulatory Affairs (ORA) from July 2011 until he joined CDER in January 2013. Prior to that, he was Director of ORA's Office of Enforcement. Mr. Sklamberg's work in ORA led to the development and use of the Food Safety Modernization Act's new enforcement tools.

Before coming to FDA, Mr. Sklamberg was a federal prosecutor serving as Deputy Chief of the Fraud and Public Corruption Section in the United States Attorney's Office for the District of Columbia, as an Assistant U.S. Attorney in that office, and as a trial attorney in the Justice Department's Public Integrity Section. He specialized in

the prosecution of white-collar crime. He is an adjunct professor at American University's Washington College of Law, where he teaches courses on congressional investigations and white-collar crime.

Mr. Sklamberg graduated from Harvard Law School, received a Bachelor's degree in economics and political science from Yale University, and earned a Master's degree from the Fletcher School of Law and Diplomacy.

Special Agent Philip J. Walsky

Special Agent Philip J. Walsky became the Acting Director of FDA's Office of Criminal Investigations (OCI) on March 10, 2014. He was named to the position by Howard Sklamberg, FDA deputy commissioner for global regulatory operations and policy; and Melinda K. Plaisier, FDA associate commissioner for regulatory affairs. Prior to his appointment, Agent Walsky served for two years as OCI's Special Agent in Charge, administrative operations division, at OCI headquarters. Mr. Walsky had worked before that in OCI's New York Field Office, as a field agent and later as the Assistant Special Agent in Charge. While there, Agent Walsky was one of the first responders following the 9/11 tragedy in 2001.

Before joining OCI, Mr. Walsky worked for three years with the U.S. Secret Service and for five years with the U.S. Marshals Service. Mr. Walsky began his career in law enforcement in a local police department in New Jersey. He has taught criminal justice at various universities in New Jersey and New York City. Mr. Walsky resides with his wife and two children in suburban Maryland.

SPONSORS

SILVER

Allergan

Allergan is a multi-specialty health care company focused on discovering, developing and commercializing innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential — to see more clearly, move more freely, express themselves more fully. From our beginnings as an eye care company to our focus today in several medical specialties including ophthalmology, neurosciences, medical aesthetics, medical dermatology, and urologics, Allergan is proud to celebrate more than 60 years of medical advances and proud to support the patients and physicians who rely on our products and the employees and communities where we live and work. To find out more about Allergan, visit *www.allergan.com*.

SILVER

Genentech

Considered the founder of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for more than 35 years, using human genetic information to discover, develop, manufacture and commercialize medicines for patients with serious or life-threatening medical conditions. Today, Genentech is among the world's leading biotech companies, with multiple products on the market and a promising development pipeline.

SILVER

Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Merck has created a cross-functional team with representatives from Global Security, Quality, Legal, Public Affairs and Human Health to execute a comprehensive anti-counterfeiting strategy aimed at protecting our patients. The team assures expeditious and efficient responses related to the increasing threat of counterfeiting. Merck also works closely with law enforcement (local police and federal agencies) and regulatory agencies (FDA and local regulatory agencies) to identify, stop and prosecute counterfeiters.

BRONZE

Abreos Biosciences

Abreos Biosciences develops TRxUST™ test sticks for rapid authentication of high value biologics. Our lateral flow based technology is cost efficient, lab-free, and easy to use, and delivers quality assurance and immediate authentication in field, forensic, or point of care settings. Our products create value by improving patient safety, ensuring brand integrity, and increasing confidence among end users and reimbursers while combating the growing scourge of counterfeit biological therapeutics.

BRONZE

Celgene

Celgene is a global biopharmaceutical company committed to improving the lives of patients worldwide. At Celgene, we seek to deliver truly innovative and life changing treatments for our patients. *www.Celgene.com*

BRONZE

Johnson & Johnson

Caring for the world, one person at a time inspires and unites the people of Johnson & Johnson. We embrace research and science—bringing innovative ideas, products and services to advance the health and well-being of people. Our approximately 128,300 employees at more than 275 Johnson & Johnson operating companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

BRONZE

Lilly

At Lilly, we make medicines that help people live longer, healthier, more active lives. Founded in 1876, we are the 10th largest pharmaceutical company in the world. Lilly has a long history of medical innovation, most notably in the treatment of infectious diseases, diabetes, and depression. Today, our portfolio also includes oncology and bio-medicines. And our emerging markets business unit works to deliver medicines to address unmet needs around the world. For additional information about our corporate history and significant medical breakthroughs, visit the "About" section of *www.lilly.com*.

MEDIA

FFF Enterprises

FFF Enterprises is the nation's largest and most trusted distributor of plasma products, vaccines and biopharmaceuticals. Now in its 27th year, FFF sets the standard with its commitment to Guaranteed Channel Integrity™ which ensures products are purchased only from the manufacturer and shipped to healthcare providers for uncompromised patient safety. FFF's proprietary systems, Verified Electronic Pedigree™ and Lot-Track™, provide verification of this secure channel. FFF's revolutionary vaccination programs, MyFluVaccine and VaxAmerica, add a new level of safety and convenience to healthcare providers and consumers. FFF's specialty pharmacy, NuFACTOR provides home infusion services and critical-care products to patients with chronic conditions.

MEDIA

FiercePharma

Every business day, FiercePharma updates pharmaceutical executives on company news & earnings, FDA regulations, drug safety, generic drug companies, and more. Beyond the news of the day, our editors produce in-depth features on industry leaders and market trends. As a member of our community, you will receive an exclusive invitation to each of our webinars and gain full access to our entire whitepaper and eBook library. Advance your career by attending our networking parties and taking full advantage of our job board. Visit our website and start receiving our free FiercePharma email newsletter! *www.FiercePharma.com*

MEDIA

RxTrace

RxTrace is a comprehensive exploration of the intersection between the pharmaceutical supply chain, track and trace technology, standards and regulatory compliance found at *www.RxTrace.com*. RxTrace is a website that publishes the insights and ideas of **Dirk Rodgers**, the Owner and Sole Contributor. New essays are published most Monday or Tuesday mornings.

We proudly support the

2014 Partnership for Safe Medicines Interchange:

September 18, 2014 ◆ Washington, D.C.

THE PARTNERSHIP FOR SAFEMEDICINES.org

ASOP | ALLIANCE FOR SAFE ONLINE PHARMACIES

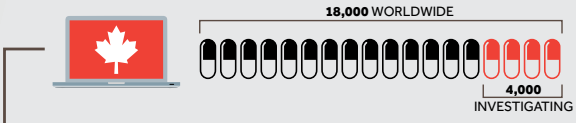
IS IT SAFE FOR AMERICANS TO ORDER LIFE-SAVING MEDICINE FROM ONLINE PHARMACIES OVERSEAS?

No. Like the Unites States, other countries are plagued by illegal Internet "pharmacies," endangering patients globally. More must be done.

The **G8** Report & Counterfeit Drug Incidents in Member Countries[1]:

CANADA

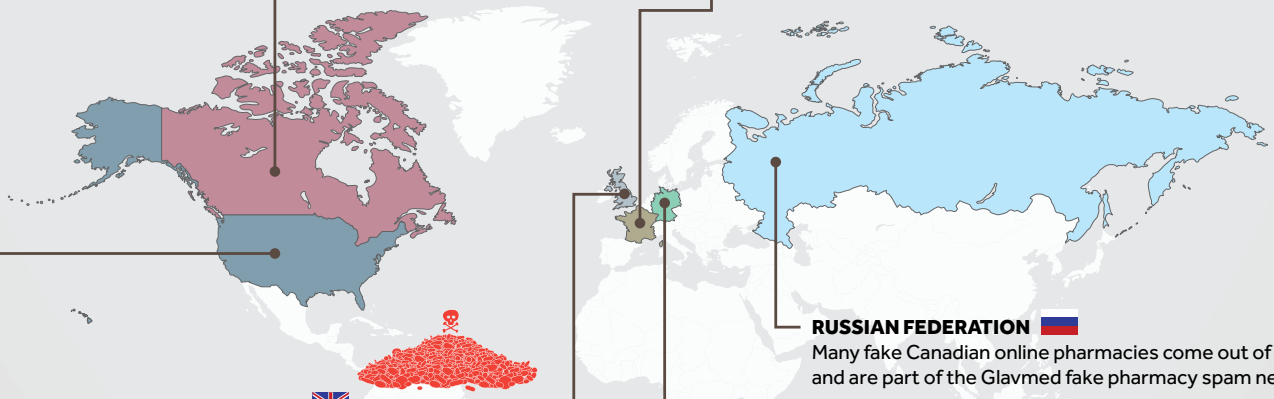
Thousands of websites around the world claim to be Canadian pharmacies, but they aren't Canadian nor are they pharmacies. Last year a global crackdown identified **4,000** of them under investigation by Canadian law enforcement.[2]



FRANCE

1.2 MILLION

In 2012, counterfeiters got so brazen that they tried to smuggle **1.2 million** fake aspirin into France in a shipment of tea.[3]



UNITED KINGDOM

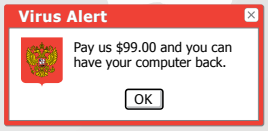
In 2012 the UK's version of the FDA, the MHRA, discovered **70,000** fake pills in UK pharmacies, with another **30,000** unaccounted for and possibly sold online.

The UK is one of many countries people think of as "safe," but its counterfeit problem is significant.[6]

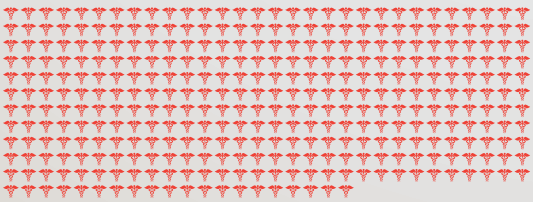
RUSSIAN FEDERATION

Many fake Canadian online pharmacies come out of Russia and are part of the Glavmed fake pharmacy spam network.

Russian investigators have found that **over 400 members** of this fake pharmacy network have a second job: fake antivirus ads that install on your computer and tell you there are threats you need to pay them to clean up.[5]



UNITED STATES



These drugs are all finding their way into the United States. **Over 350 US doctors** received warnings in 2012 about doing business with counterfeit drug suppliers specializing in fake cancer drugs, Botox, and osteoporosis medication.[7]

GERMANY

Pharmacists in Germany have illegally purchased ingredients to make their own cancer drugs found in at least **100 German pharmacies** in 2010. It is not known how much was shipped out of the country.[4]

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 or join visit our website at ***www.safemdicines.org***.

The Alliance for Safe Online Pharmacies (ASOP) is a nonprofit organization dedicated to protecting patient safety globally and ensuring patient access to safe and legitimate online pharmacies in accordance with applicable laws. To learn more, visit our website: ***www.safeonlinerx.com***.

Sources: http://www.safemedicines.org/counterfeit-drug-incidents-in-g8-countries.html

LEARN HOW TO DECODE A FAKE PHARMACY WEBSITE

WHAT THEY REALLY MEAN

What they really mean: These drugs were made in a dirty lab in the third world, but we put a maple leaf on the package to make you feel better.

What they really mean: We offer drugs that haven't been through the US FDA's safety trials. Don't be surprised if you start growing flippers or develop cardiac problems.

What they really mean: We have a special certification, but it's not by the FDA, or the board of pharmacy of the state you live in. It's some guys who like cashing our checks and know how to use the Photoshop 'Chrome' and 'Lens Flare' filters for this cool seal

What they really mean: Since a Canadian pharmacist is not allowed to fill an American doctor's prescription, we can't tell you who our pharmacist is or she'd lose her license. Just trust us that she won't mix up your prescription.

What they really mean: Real doctors don't examine you via instant message and then write you a prescription for a serious life-saving medication.

DON'T GET VICTIMIZED BY CRIMINALS OR DANGEROUS COUNTERFEIT DRUGS.

To learn how to save money safely without endangering your health with these fake online pharmacies, talk to your pharmacist, nurse, or physician about saving money through generics, smart shopping, and patient assistance programs or visit The Partnership for Safe Medicine at **www.safemedicines.org**

THE PARTNERSHIP FOR SAFEMEDICINES.org

Available as a poster. Ask PSM!

PARTNER with PSM

for a customized resource

designed just for your audience!

We can work with you to research, design, and layout a patient safety resource specifically targeted to members of your audience for you to approve. For patient organizations we can cover the cost of printing.

Examples of previous co-branded resources:

5 steps to SAVING MONEY and STAYING SAFE from COUNTERFEIT DRUGS

❶ Find out about assistance programs.

Many drug companies offer qualifying patients access to low cost or free medications. Check with your provider about supports available to you. You can also find these patient-assistance programs online at ***www.needymeds.com*** and ***www.pparx.com***.

❷ Discuss the price and alternatives to medication with your doctor or pharmacist.

When you are prescribed medication, ask what the price is. If you will have problems affording it, talk to your doctor or pharmacist about an alternative or generic medication that might cost less.

❸ Keep a record of the medication you're taking.

Be an informed patient. Understand the medications you're taking and why. Record the name and lot number of the product you are given, or take a photo with your camera phone. If there is a question later about the medication or a concern that you got the right one, you will have a record.

❹ Comparison shop for medication.

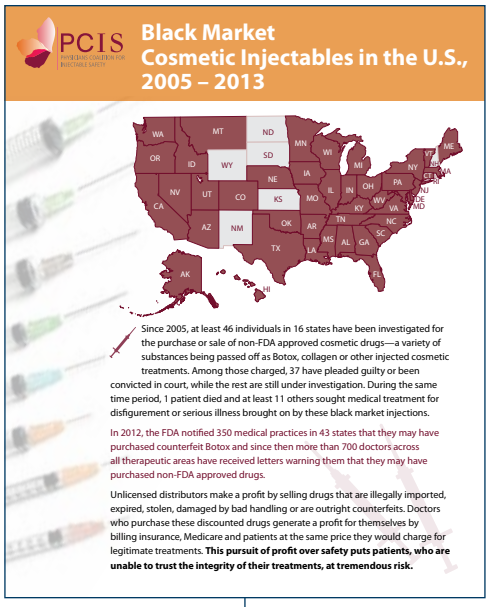
You can comparison shop around town for medication using websites and mobile apps such as ***WeRX.com***, ***LowestMeds.com***, and ***GoodRX.com***. Remember to make sure your pharmacist knows all the medications and supplements you're taking.

❺ Comparison shop online.

You can also look online at US-licensed pharmacies to find competitive prices on medication. Safe online pharmacies are licensed with the VIPPS logo. You can find a list of licensed online pharmacies at ***http://safedr.ug/vipps-rx***. Make sure your local pharmacist knows all the medications you're taking to watch for drug interactions.

NeedyMeds www.needymeds.org

The Partnership for SAFEMEDICINES www.safemedicines.org



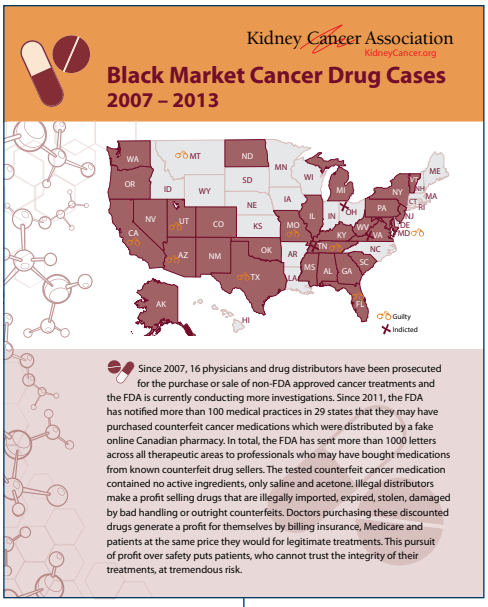
PCIS Physicians Coalition for Injectable Safety

Black Market Cosmetic Injectables in the U.S., 2005 – 2013

Since 2005, at least 46 individuals in 16 states have been investigated for the purchase or sale of non-FDA approved cosmetic drugs—a variety of substances being passed off as Botox, collagen or other injected cosmetic treatments. Among those charged, 37 have pleaded guilty or been convicted in court, while the rest are still under investigation. During the same time period, 1 patient died and at least 11 others sought medical treatment for disfigurement or serious illness brought on by these black market injections.

In 2012, the FDA notified 350 medical practices in 43 states that they may have purchased counterfeit Botox and since then more than 700 doctors across all therapeutic areas have received letters warning them that they may have purchased non-FDA approved drugs.

Unlicensed distributors make a profit by selling drugs that are illegally imported, expired, stolen, damaged by bad handling or are outright counterfeits. Doctors who purchase these discounted drugs generate a profit for themselves by billing insurance, Medicare and patients at the same price they would charge for legitimate treatments. **This pursuit of profit over safety puts patients, who are unable to trust the integrity of their treatments, at tremendous risk.**



Kidney Cancer Association KidneyCancer.org

Black Market Cancer Drug Cases 2007 – 2013

Guilty

Indicted

Since 2007, 16 physicians and drug distributors have been prosecuted for the purchase or sale of non-FDA approved cancer treatments and the FDA is currently conducting more investigations. Since 2011, the FDA has notified more than 100 medical practices in 29 states that they may have purchased counterfeit cancer medications which were distributed by a fake online Canadian pharmacy. In total, the FDA has sent more than 1000 letters across all therapeutic areas to professionals who may have bought medications from known counterfeit drug sellers. The tested counterfeit cancer medication contained no active ingredients, only saline and acetone. Illegal distributors make a profit selling drugs that are illegally imported, expired, stolen, damaged by bad handling or outright counterfeits. Doctors purchasing these discounted drugs generate a profit for themselves by billing insurance, Medicare and patients at the same price they would for legitimate treatments. This pursuit of profit over safety puts patients, who cannot trust the integrity of their treatments, at tremendous risk.

NeedyMeds *(dedicated to helping people locate assistance programs to help them afford their medications)*: We worked with NeedyMeds to create patient education materials to help patients with financial challenges learn about the safe ways to save money without using fake online pharmacies.

Physicians Coalition for Injectable Safety *(the largest group of cosmetic physicians dedicated to injectable safety)*: We produced materials to help educate cosmetic physicians about prior indictments around black market cosmetic injections, and how to avoid black marketers.

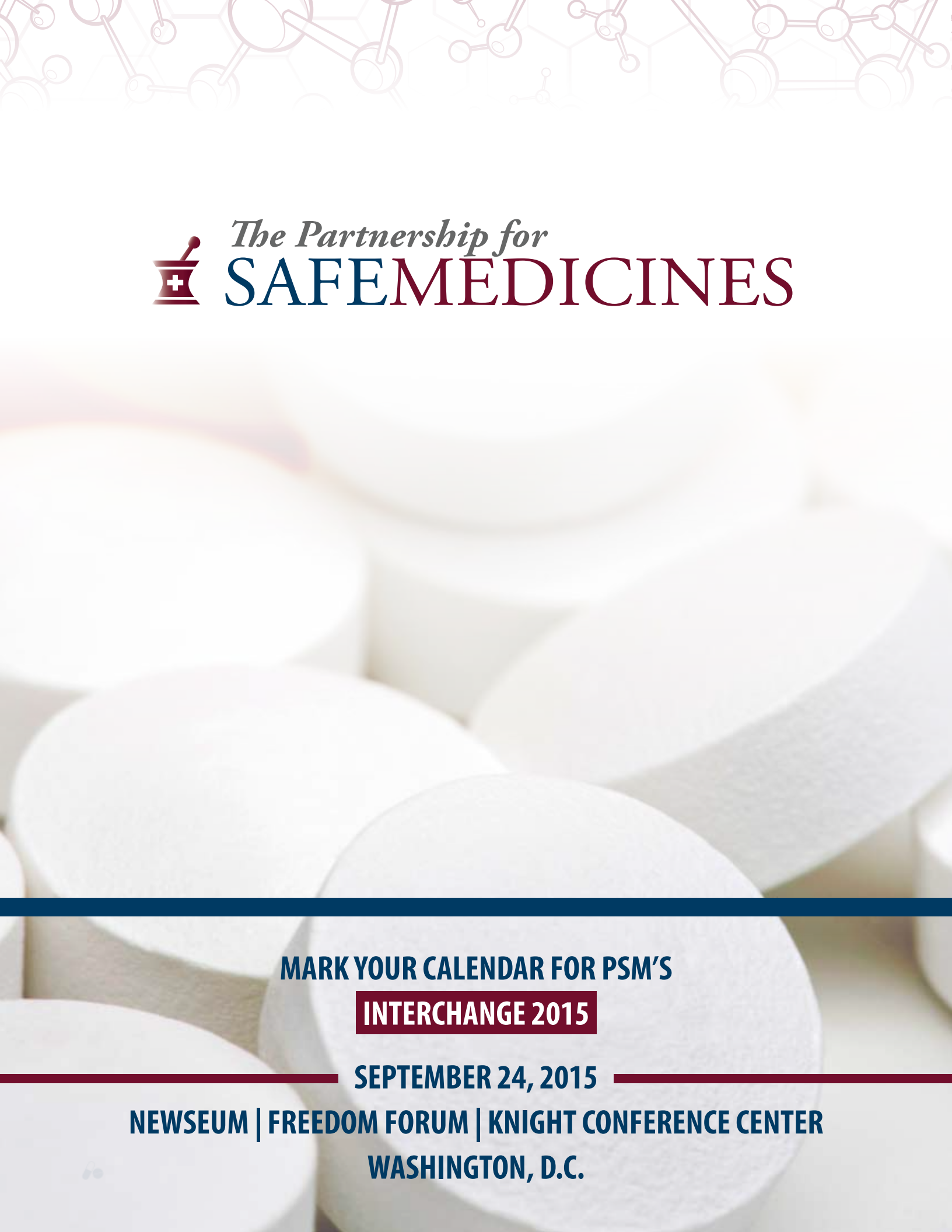
Kidney Cancer Association *(patient group)*: Educated patients and physicians about recent indictments of criminals for buying and distributing black market cancer drugs to American patients, many of which were tested as fake.

For further information, contact Sarah Imber: *phone* 1-323-577-9776; *email* editors@safemedicines.org.

The Partnership for SAFEMEDICINES

MEMBERSHIP

Academy of Managed Care Pharmacy
Alaska Pharmacists Association
The ALS Association
American Association for Homecare
American College Health Association
American Pharmacists Association
American Society of Health System Pharmacists
Arizona Pharmacy Alliance (AzPA)
Association of Nurses in AIDS Care
BioForward
Biotechnology Industry Organization
California Healthcare Institute
California Pharmacists Association
California Society of Health-System Pharmacists (CSHP)
Colorado Bioscience Association
Community Access National Network
The Council for Affordable Health Insurance
European Federation of Pharmaceutical Industries and Associations (EFPIA)
Generic Pharmaceutical Association
Global Medicines Program
Healthcare Distribution Management Association
HealthCare Institute of New Jersey
Healthcare Leadership Council
The Hispanic Institute
Illinois Pharmacists Association
Institute for Safe Medication Practices
International Anti-Counterfeiting Coalition
International Federation of Pharmaceutical Manufacturers and Associations
Kidney Cancer Association
The Latino Coalition
The Life Raft Group
Maine Pharmacists Association
Maine Society of Health-system Pharmacists
Maryland Pharmacists Association
Men's Health Network
Missouri Pharmacy Association
National Alliance for Hispanic Health
National Alliance On Mental Illness
National Association for Uniformed Services
National Association of Boards of Pharmacy
National Association of Chain Drug Stores
National Association of Drug Diversion Investigators
National Association of Manufacturers
National Alliance of State Pharmacy Associations
National Biopharmaceutical Security Council
National Community Pharmacists Association
National Grange of the Patrons of Husbandry
National Latina Health Network
NeedyMeds
Nevada Board of Pharmacy
New York State Council of Health-system Pharmacists (NYSCHP)
North Carolina Association of Pharmacists
Oklahoma Pharmacists Association
Parenteral Drug Association
PDMA Alliance
Pennsylvania Pharmacists Association
Pennsylvania Society of Health-system Pharmacists
Pharmaceutical Industry Labor Management Association (PILMA)
Pharmaceutical Security Institute
Pharmacists Planning Services, Inc.
PhRMA
RetireSafe
San Diego Center for Patient Safety
Spina Bifida Association of America
Texas Pharmacy Association
Texas Society of Health-system Pharmacists
United States Chamber of Commerce
University of New England College of Pharmacy
University of Texas Pharmacy School
Vietnam Veterans of America
Virginia Pharmacists Association
Vermont Pharmacists Association
West Virginia Rx
WomenHeart



The Partnership for SAFEMEDICINES

MARK YOUR CALENDAR FOR PSM'S

INTERCHANGE 2015

SEPTEMBER 24, 2015

NEWSEUM | FREEDOM FORUM | KNIGHT CONFERENCE CENTER

WASHINGTON, D.C.