

**Official Partnership for Safe Medicines (PSM) Remarks for the Intellectual Property Enforcement Coordinator (IPEC) for Public Comments Regarding the Joint Strategic Plan**

The Partnership for Safe Medicines (PSM)

**March 24, 2010**

---

The Partnership for Safe Medicines (PSM) is a public health organization, comprised of individuals and groups that have policies, procedures or programs to protect consumers from counterfeit and substandard medicines. In addition to publishing blog posts, expert articles, counterfeit drug incidents alerts and peer-reviewed articles, PSM participates in policymaking discussions. From our board of experts to our global engagement, the PSM believes that we are one of the most experienced authorities on the threats posed to public health and safety from counterfeit and substandard medicines.

A major aspect of our commitment to combating counterfeit drugs is consumer awareness, both through the numerous educational materials we produce, as well as through online vehicles. Yet PSM understands that only through extensive collaboration among all stakeholders, and aggressive support by the U.S. government's efforts—including the office of the Intellectual Property Enforcement Coordinator (IPEC)—will any of our efforts succeed. And as we all know, counterfeit medicines are not limited to brand-name prescription drugs. Counterfeiters also create fake versions of generic and over-the-counter (OTC) drugs. It is for this reason that we welcome the request for comment and are eager to assist the Coordinator's office in the future.

**Severity of Counterfeit Medicines Threat to Public Health**

Not only do counterfeit medicines defraud consumers, they deny patients the therapies that can alleviate suffering and save lives—and in too many cases, counterfeit drugs cause great harm and fatalities. They can cause allergic reactions, heavy metal poisoning, as well as promote drug resistant strains of diseases. Fake drugs may consist of anything from chalk, powdered concrete and boric acid (or worse), and are sold as if they were real medicines. Medicine counterfeiting is clearly a crime against patients, and because counterfeiters are very good at making their product look like the real thing, it is easy to confuse these harmful products with the real thing.

One of the PSM's member organizations is the Pharmaceutical Security Institute (PSI), which is a not-for-profit comprised of 24 pharmaceutical manufacturers from many nations, all dedicated to sharing information on the counterfeiting of pharmaceuticals and initiating enforcement actions through the appropriate authorities. In 2009, PSI continued to see increased growth in the number of counterfeiting incidents from around the globe, from 1,216 in 2006 to 1,585 in 2008. Additionally, PSI identified a significant expansion in the number of countries connected to counterfeiting incidents from 100 in 2006 to 115 in 2008.

Furthermore, there is a significant increase in counterfeit drugs in certain regions of the world. Of the nearly 1,600 incidents from 2008, more than half were witnessed in Asia (835), 402 in Latin America and 347 in Europe.

The issues associated with counterfeit drugs have presented significant challenges to communities worldwide. It has been estimated that as many as 300,000 Chinese per year die after taking substandard or fake medications.<sup>1</sup> In

---

<sup>1</sup> See Steve Boggan, "Headache pills made of rat poison and Viagra made of chalk: We reveal the chilling truth about internet drugs," April 27, 2009, MailOnline, <http://www.dailymail.co.uk/health/article-1173735/After-deacons-daughter-killed-medicine-bought-online--chilling-truth-internet-black-market-prescription-drugs.html> (last visited March 16, 2010).

Niger, between 60,000 to 80,000 children were treated with an inactive vaccine which may have led to 2,500 fatal infections that would have otherwise been prevented by the proper vaccine.<sup>2</sup>

As U.S. Federal Drug Administration (FDA) Commissioner Margaret Hamburg stated in connection with a 2009 FDA effort to curb illegal online sales of medical products:

Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, or unapproved products, or contain an inconsistent amount of the active ingredient. Taking these drugs can pose a danger to consumers.<sup>3</sup>

In addition, counterfeit medicines are intrinsically connected to the regular debate on Capitol Hill regarding prescription drug importation into the U.S. The Intellectual Property Enforcement Coordinator should be keenly aware of the challenges created by this policy and the effects on your position. Listed below are some of the key challenges faced by this proposal:

**1. Lack of Regulation for Products Trans-Shipped Through "Safe" Countries such as Canada and the U.K.** Drug importation advocates believe that drugs purchased from countries such as Canada and the UK are safe because of their strict health regulations. Unfortunately, this is simply not true. For example, Health Canada clearly states that drugs not earmarked for Canadians are not subject to the Canadian government's safety regulations. Hence, drug exporters can bypass Canada's safety regulations and mail fake or low-quality drugs made in high-risk countries such as China and India to the U.S. without Health Canada's oversight.

Likewise, the UK indicates that it lacks the power to stop suspected counterfeits on its shores destined for the U.S. because the goods are only transiting through the country. Indeed, recent conflicting E.U. rulings have created a situation where U.K. customs neither stop nor inspect goods as they transit through, allowing counterfeit medicines to move through the U.K. and into the U.S. undetected.

**2. Inability for Importation to Satisfy U.S. Demand, Foreign Provider and Citizen Resistance.** There are simply not enough legitimate drugs in foreign supply chains to satisfy U.S. demand. For example, if just half of elderly Americans shifted their purchases to Canadian sources, it would exhaust the entire Canadian drug supply in a few months. Hence, both Canadian providers and citizens oppose U.S. importation. In addition, this reality could have considerable impact for our political and economic relationships with smaller countries like New Zealand, Czech Republic, Romania and others, whose supply could be devastated by parallel traders exporting most of their supply to the U.S.

**3. Inaccurate Safety Perceptions for Risky Foreign Purchases.** A drug importation policy will give Americans an inaccurate—indeed, dangerous—perception that buying drugs from any Canadian pharmacy is safe because their government allows drug imports. This is particularly true for patients buying drugs through those high-risk Internet drug sellers.

**4. U.S. Policy in Hands of Foreign Governments.** Congressional importation proposals would place our drug policy in the hands of foreign governments. Price, quality, oversight (or lack thereof), and other critical issues would be defined by other governments without concern for U.S. patient protection and with unclear potential for safety regulation or enforcement. It would also reduce security of the supply chain to the weakest global link. The U.S. would effectively rely on the Asian, Baltic and Balkan region countries to serve as our "border patrol" against counterfeit drugs. However, these countries do not have sufficient knowledge or capacity to do so and will prioritize the needs of their own citizens with the scarce regulatory resources they have.

---

<sup>2</sup> Martijn ten Ham, "Health Risks of Counterfeit Pharmaceuticals," *Drug Safety* 2003; 26 (14): 991-997 and Roger Bate, "The Deadly World of Fake Drugs," Sept./Oct. 2008, *Foreign Policy*.

<sup>3</sup> <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm> (Nov. 19, 2009 FDA News Release).

### **The Internet's Role**

PSM has gone to extensive lengths in its patient education efforts to inform users of both the benefits and challenges to the online world in regard to counterfeit medicines. In fact, PSM recently provided recommendations to the FDA for their request for comment on social media and the Internet.

### **PSM Monitoring and Outreach**

As previously mentioned, PSM relies on the Internet to help bolster awareness about the dangers of counterfeit medical products and communicate breaches in the secure supply chain. Part of that includes publishing alerts derived from FDA updates, along with other counterfeit drug news, all of which are distributed by our Web site editors via:

- **The SafeMeds Alert System.** A free email service that sends official alerts from the FDA and other government agencies to anyone or any organization around the world, whenever specific drug incidents are detected.
- **The PSM Twitter feed.** A dedicated platform for general announcements and targeted messaging to affected followers based on keyword relevancy and tags (i.e. #diabetes and #asthma).
- **Topical message boards and forums.** Reposting FDA alerts to relevant patients or communities provide context on critical breaches in drug safety.
- **The PSM blog and e-newsletter.** Weekly blog posts and regular e-newsletters to members, consumers and policymakers convey pertinent news and information regarding drug safety.

Our approach to social media is as it should be: to be as transparent and fact-based as possible, as we believe that the Internet and social media, when used appropriately, are essential tools for the public health community for which best practices should be encouraged.

However, not all organizations in the public health realm operate in that same way. For example, popular e-health site WebMD has continually marked PSM alerts as SPAM, removing our messages from relevant health message boards where thousands of patients have turned for disease prevention and health care advice.

### **Search Engines**

As PSM expert board members have themselves attested, search engines pose one of the largest counterfeit drug threats to Americans today. In fact, recent reports released by LegitScript, an online pharmacy verification service, and KnujOn, an Internet compliance company, found that 80 to 90 percent of search engine-sponsored advertisements of online pharmacies violate federal and state laws, including selling substandard or counterfeit drugs to unsuspecting consumers.

Here are some key facts from our research, at a glance:

- The business of selling prescription pharmaceuticals online generated an estimated \$15-20 billion in 2004 alone.
- A detailed study of online drug retailers found that 85 percent of Web sites offering drugs for sale required no prescription from the patient's physician. To make matters worse, of the 15 percent of Web sites that

required a prescription, only half asked that the prescription be faxed—introducing tremendous opportunities for fraud and circumvention of legitimate and critical physician supervision.

- The uninsured and underinsured represent a significant at-risk group purchasing medications from these sites, as these patients do not have access to or cannot afford to see a physician who might prescribe drugs for treatment.
- SPAM email and other electronic solicitations also play a part in online drug sales, enticing individuals who may not have originally intended to buy medications online.

In early February, we were encouraged at changes to the advertising policy at Google, which would require online pharmacies in the U.S. to be accredited by the National Association of Boards of Pharmacy's Verified Internet Pharmacy Practice Sites (VIPPS) program. The changes cut out third-party verifiers, leaving VIPPS as Google's lone online pharmacy accreditation program for drug advertisers in the U.S.

While this is a significant step in the right direction, it's important that other search engines follow suit in order to prevent companies from profiting off of advertisers that peddle illicit drugs to unwitting buyers.

### **Social Media and Networking**

There's no doubt that social media and networking pose complex issues for the FDA and other regulatory bodies such as the Federal Communications Commission (FCC). Specifically, PSM has identified the following challenges with social media and pharmaceutical products:

- **Lack of advertiser oversight and gate-keeping.** For example, Facebook vaguely instructs its advertisers against posting ads for "uncertified pharmaceutical products."
- **Lack of cooperation from trusted medical sites.** As mentioned, PSM has historically had problems with its outreach efforts with trusted medical site WebMD—preventing legitimate organizations from communicating with affected groups.
- **Policing advertiser content versus user-generated content.** While advertiser content can be easily monitored, policing user-generated content about pharmaceuticals can be a gray area for administrators.

---

### **Recommendations to Protect Public Health**

In addition to better coordination of law enforcement, the FDA needs funding and authority to develop programs and systems that tighten the drug supply chain. In order to stop counterfeit drugs and other unsafe products from pouring out of foreign manufacturing facilities and into the U.S., the FDA needs to establish more foreign field offices and staff them with inspectors and criminal investigators armed with the same authority as their State-side colleagues. This includes the authority to enter and inspect foreign manufacturing facilities without previous notice.

Furthermore, the FDA necessitates onshore agency support and authority. The U.S. currently has 300 custom ports of entry, but the FDA only has 200 port inspectors and a mere 17 inspectors to cover all international mail centers. We must hire more inspectors here and grant the FDA and other agencies the authority to destroy unapproved and counterfeit drugs entering the U.S. rather than returning them to the criminals who sent them here—which is our current policy. IPEC should have a key role in the coordination of this policy.

Lastly, PSM has identified a number of ways in which the Coordinator, in conjunction with other U.S. government agencies and departments, can limit the challenges posed to public health by counterfeit medicines. In addition to the ideas highlighted above, we believe further support from the IPEC should be given to the FDA and the Drug Enforcement Agency (DEA) around the activity of online drug sellers and the products they distribute. There are certainly legitimate online entities engaged in this activity, but the size and scale of Internet sales necessitates greater coordination to assist patients with the ability to decipher the good from the bad.

Additional recommendations include:

### **1. Regulation of Internet drug sellers, including online pharmacies.**

While the FDA has stepped up efforts to educate the public about the dangers of online pharmacies, a recent survey conducted on imports by the FDA found that consumers continue to purchase drugs online for purposes of self-medication and because of cost considerations. As remarked by PSM Vice President Dr. Bryan A. Liang and Tim Mackey in their 2009 paper on search engine safety, these education efforts have not reached many of those who purchase drugs online.

As other experts, including PSM board members, have said, steps must be taken to limit the sale and distribution of drugs via online pharmacies.

“Unless the online pharmacy is licensed through a national Internet pharmacy licensing program such as VIPPS, selling drugs via the Internet should be illegal,” said Dr. Liang in September 2009. “We need new legislation that prohibits financial transactions for drug sales of unlicensed online pharmacies and creates substantive criminal penalties for any party, including Web sites and search engines, who engage in the illegal sale of contraband or counterfeit drugs.” Dr. Liang added that this should include the use of tools to intercept illicit sales transactions, including those that have been used successfully in combating online gambling.

Indeed, online pharmacies should be subject to the same rigorous oversight and standards that govern their offline counterparts. This means, at a minimum, licensure in each state that these Internet drug sellers conduct business; keeping a licensed pharmacist on staff; and a requirement for prescriptions and other standard professional oversight. Importantly, the reality of Internet transactions should be recognized.

Laws, specifically the Ryan Haight Online Consumer Protection Act, although a good start, is limited in its approach since it applies only to controlled substances—which are only a fraction of those drugs involved in online drug pushing—and focuses only on domestic Internet sites, whereas much of the illicit trade originates outside U.S. borders, and purportedly “requires” Internet sellers to require prescriptions, which have in the past been found to be fraudulently sold to Web site purchasers.

Since 1999, VIPPS has helped the public distinguish between legitimate and illegitimate online drug vendors. Currently, 15 pharmacy sites representing more than 12,000 pharmacies carry the VIPPS seal.

A national verification system based on VIPPS’ rigorous criteria would be a step in the right direction—safeguarding patient care and preventing unscrupulous vendors from peddling harmful products.

### **2. Search engine-specific regulations for advertising programs that discourage them to take advertising dollars from unlicensed and unapproved sources—and incentives for search engines to be more proactive about shutting down unauthorized or counterfeit drug sellers.**

This could include banning pharmaceutical-related keywords; a greater enforcement of advertisers bidding on trademarked pharmaceutical terms; or enhanced algorithms (or more staffers) checking landing URLs of paid advertisements to ensure legitimacy and compliance with a VIPPS-like verification program. This could also be

accomplished by requiring any drug-related searches to raise a banner to the FDA Web site, indicating the illegality of online purchases except through a VIPPS or similarly accredited, legitimate online pharmacy.

### **3. Verified social media accounts for authorized sellers and pharmaceutical companies.**

One way Twitter solved the problem of imitation celebrity accounts was to create a verification program, which allowed other users to see whether they were getting information and updates from the authentic source. The same could be done with pharmaceutical companies and authorized drug sellers—making it easy for social media and networking platforms to weed out and delete imitation accounts. Again, a clear statement of the background rule of illegality of online drug selling except through verified sites would be important to ensure that the message is being heard.

### **4. Software programs that block drug SPAM from infiltrating personal computers.**

Software makers should expand their suite of technologies to include programs that block pharmaceutical SPAM, which could come via unauthorized pop-ups, banners or sponsored links. The software could be easily installed on computers and B-to-B partnerships could be created to encourage computer makers to include complimentary software with new purchases. Importantly, software programs should recognize botnet and other mechanisms that are used to expand pharmaceutical SPAM distribution.

### **5. FDA monitoring of social media.**

The FDA should utilize various social media tools to monitor the conversation about pharmaceuticals online, which may pinpoint users who are using the platform for the solicitation of illicit pharmaceutical products. Importantly, this should include assessing conversations that target those who wish to purchase high-risk drugs online without a prescription and that target vulnerable groups such as children, young adults and seniors. Moreover, social media platforms like Twitter can enable the FDA—much as it has PSM—to reach people who may be affected by a particular recall, as well as treating physicians in specialties that see patients who are affected.

### **6. FDA SMS alerts.**

The FDA should consider text-based warnings for cell phones and other hand-held devices. This is an untapped means of preparedness and response, as well as for communicating drug recalls and counterfeit alerts, and could be utilized for rapid communication to affected patient groups, medical providers, hospitals and medical centers. Advancements in SMS-based alerts have been implemented and utilized in sub-Saharan Africa by PSM international partner organization mPedigree, which could serve as a model to the FDA.

### **7. Dedicate additional FDA agents to Internet investigations, including foreign assignments to source countries.**

Criminals selling counterfeit or unapproved drugs over the Internet remain outside the reach of FDA regulators and criminal investigators. By exploiting the anonymity of the Web and the many complex jurisdictional issues of international criminal law, these individuals remain outside the reach of domestic law enforcement agencies.

The FDA should dedicate additional criminal investigators to these cases and place them in key countries known to be sources of counterfeit and unsafe medicines. Comprehensive investigations aimed at dismantling these organizations should begin at the source country, continue through the international distribution routes they employ and conclude with detailed inquiries of the Internet operators.

Tom Kubic, president and CEO of the PSI, and former deputy assistant director for the Federal Bureau of Investigation (FBI), noted that the FBI greatly expanded its placement of agents abroad to address international organized crime during the 1990s. Today, in order to improve coordination and increase communication amongst international law enforcement agencies, the FDA should consider doing so as well.

#### **Related Resources:**

[“Partnership for Safe Medicines Applauds Google’s Updated U.S. Pharmaceutical Advertising Policy,”](#) Partnership for Safe Medicines.

[“Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales,”](#) Bryan A. Liang and Tim Mackey, April 2009.

[SafeMeds Tools](#), Partnership for Safe Medicines.

[Twitter Verified Accounts](#), Twitter.

[Verified Internet Pharmacy Practice Sites \(VIPPS\) Facts](#), Partnership for Safe Medicines.

[Verified Internet Pharmacy Practice Sites \(VIPPS\) Web Site](#).

#### **Complex Challenges Require Collaboration**

Collaboration and coordination by the IPEC is not only wanted, but certainly needed. The challenges to public health from counterfeit medicines that defraud consumers, deny patients therapies that can alleviate suffering, cause great harm and even fatalities—are too many to count. This is the exact reason your office’s efforts and focus is welcomed by this public health organization.

While the Internet and social media have undoubtedly changed the way the pharmaceutical industry markets and interacts with American consumers, it has also created new threats by way of unlicensed online pharmacies, SPAM and sellers of counterfeit or substandard drugs.

PSM appreciates the IPEC’s acknowledgement of these complex challenges and encourages your office to work with other relevant agencies and Congress to address the communication deficiencies among agencies; the lack of resources and staff for in-country pharmaceutical monitoring; the necessary regulation of online pharmacies and drug sellers; and the large profits generated by search engines that sell advertising space to these unlicensed sellers. We also encourage the creation of verified social media accounts for pharmaceutical organizations and advocacy groups, as well as the establishment of software that blocks drug SPAM from personal computers.

Such efforts will help combat the counterfeit drug issue here at home, with resonating impacts to our larger global community.

## Experts Available to You

PSM has four volunteer experts on its board. We encourage you to make full use of their vast knowledge and expertise. Our board members' names, titles and contact information are listed for your convenience.

We thank you for the opportunity to comment and for your consideration of our proposals. We encourage you to contact us regarding any further details or questions.

### **Marvin D. Shepherd, Ph.D**

Director, Center for Pharmacoeconomic Studies  
College of Pharmacy, University of Texas-Austin  
[Contact information for Dr. Shepherd.](#)

### **Bryan A. Liang, Ph.D, M.D., J.D.**

Executive Director, Institute of Health Law Studies, California Western School of Law  
Co-Director, San Diego Center for Patient Safety, University of California San Diego School of Medicine  
[Contact information for Dr. Liang.](#)

### **Thomas T. Kubic**

President and CEO, Pharmaceutical Security Institute  
[Contact information for Mr. Kubic.](#)

### **James N. Class, Ph.D**

Assistant Vice President, Pharmaceutical Research and Manufacturers of America  
[Contact information for Dr. Class.](#)

## **Partnership for Safe Medicines**

8100 Boone Blvd. Suite 220  
Vienna, VA 22182  
Twitter: @SafeMedicines

## **Additional PSM Resources on the Web**

In addition to our experts, many of our resources are available for free on the Web. We encourage you to take advantage of our:

- **Safe Medicines Blog:**<sup>4</sup> Weekly blog commentary by our expert board members on current counterfeit drugs topics.
- **Articles in Outside Publications:**<sup>5</sup> A collection of articles about the counterfeit drug problem published in outside journals as well as by our expert board members.
- **Press Releases:**<sup>6</sup> Significant updates and developments within the counterfeit drug world and the PSM.
- **Social Bookmarks For Counterfeit Drug News Stories:**<sup>7</sup> A living collection of select counterfeit drug news from around the world.
- **Counterfeit Drug Incident Encyclopedia:**<sup>8</sup> Summaries of key counterfeit drug incidents from around the world.

---

<sup>4</sup> <http://www.safemedicines.org/blog/>

<sup>5</sup> <http://www.safemedicines.org/articles/>

<sup>6</sup> <http://www.safemedicines.org/news-press-releases/>

<sup>7</sup> <http://delicious.com/Safemedicines>



- **Peer-reviewed Articles:**<sup>9</sup> An archive of research and peer-reviewed articles about counterfeit drugs appearing in academic literature.

PSM has also developed educational materials for patients, healthcare workers and policymakers, including PSM's Principles for Drug Safety, PSM's S.A.F.E.D.R.U.G. Checklist, and the L.E.A.D.E.R.'s Guide for Pharmacists, which provide a framework of the recommendations to protect public health from the safety challenges faced by these products.

These three resources are available online, as well as included below for easy reference.

### 1. *PSM Principles for Drug Safety*<sup>10</sup>

The Partnership for Safe Medicines has developed the following principles to support quality assurance programs and establish a drug distribution system that is without compromise.

#### **Protect Our Supply Chain**

- We believe there is strong need for strict, rigorous regulatory oversight of imported pharmaceuticals, including the regulation of the storage throughout the distribution system of imported pharmaceuticals.
- We support a dramatic and sustained increase in funding for the FDA in order to increase inspections of foreign facilities that manufacture drug products or components of drug products sold in the United States. Additionally, the FDA should be empowered to inspect distribution facilities.
- We endorse establishing permanent FDA field offices in China, India and other key exporting countries staffed with both inspectors and criminal investigators.
- We advocate the development and implementation of a standardized drug pedigree program at a national level.

#### **Regulate Online Drug Sellers**

- We value the rigorous oversight and standards that govern traditional pharmacies in the United States and believe all online drug sellers should be held to the same standards.
- We endorse the full [Verified Internet Pharmacy Practice Site \(VIPPS\)](#) accreditation program created by the [National Association of Boards of Pharmacy](#).
- We believe all Internet drug sellers, regardless of which state or country they are based in, must comply with the pharmaceutical licensing and survey requirements for every state they sell pharmaceuticals.
- We advocate that no one should be able to purchase prescription drugs, including controlled substances, over the Internet without a valid prescription and physician oversight.

#### **Unify in the Fight Against Counterfeit Drugs**

- We believe the United States needs to be a leader in the global fight against counterfeit drugs.
- We recognize that counterfeit drugs, tainted medicines, and rogue online drug sellers are a global problem that requires an international solution.

---

<sup>8</sup> <http://www.safemedicines.org/counterfeit-drug-incident-encyclopedia.html>

<sup>9</sup> <http://www.safemedicines.org/peer-reviewed-articles/>

<sup>10</sup> [http://www.safemedicines.org/doctrine\\_principles.html](http://www.safemedicines.org/doctrine_principles.html)

- We advocate for international cooperation between government agencies around the world in order to prosecute the unscrupulous counterfeiters who do not hesitate to use foreign, even toxic, materials in their products.
- We support increasing criminal penalties against the perpetrators of counterfeit medicines to reflect the gravity of their offenses.
- We endorse granting the FDA authority to destroy unapproved drugs entering the United States rather than returning them to the criminals who sent them here.

## 2. PSM S.A.F.E.D.R.U.G. Checklist<sup>11</sup>

This eight-step checklist will help patients judge whether their medications are safe and provides tips on what to do if you think a drug has been compromised.

**Sample:** Request a sample from your physician when you are first prescribed a medication to help you establish a “baseline” of a product’s characteristics, including its appearance, taste, texture, reactions and packaging. If using the Internet to purchase drugs, make sure the Web site is a [VIPPS](#) fully certified site. Please note that manufacturer samples are usually only available for brand name medications and not generic products. Generics may differ in shape or color but still be a safe and effective product. For specific questions on identification of medications, talk to your pharmacist.

**Appearance:** Compare the prescription medicine you receive with what it is supposed to look like by taking pictures of the original manufacturer's drug and all associated packaging with the drug you are taking. You can also find pictures in the [Physicians Desk Reference](#). When comparing packaging, look for differences in paper, printing, color, and fonts (i.e. is it the same size, raised print, embossed, etc.).

**Feel:** Take note of the prescription drug’s taste and any associated feelings once you take it. Is there anything unusual in your body’s reaction compared to previous experiences, such as a stomach ache or headache? Keep a diary of how you feel when you take your medications so you can compare.

**Evaluate:** Reflect on how your body has reacted over the course of the treatment. Do you feel that you are benefiting from the medication? Is your condition improving, stabilizing, or are you reverting back to ill health? Always ask your doctor or pharmacist what you should expect to feel when you take your medicine and when you should expect to begin feeling relief or improvement. Remember: counterfeit drugs can contain not enough, too much or no active ingredient.

**Doctor:** If your drugs do not seem to have the same taste or if you feel different than usual, immediately write down your symptoms and contact your doctor and pharmacist.

**Report:** If you have any concerns about the quality of your drugs, or have confirmed there is a difference in packaging, labeling, or pills, immediately contact the pharmacy where you purchased them. You may also want to contact the FDA and the manufacturer of the medication to report your concerns. The FDA can be contacted by calling toll-free 1-800-FDA-1088 (800-332-1088), or on the Web at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Unavailable:** If you confirm that your medicine is counterfeit, immediately remove it from your medicine cabinet. Mark it with a red pen and put tape around the top of the drug container so that it will be unavailable to you or others in your family. Until you can send the suspect medication to the appropriate local law enforcement officials, or dispose of it safely, it is important that you and any family members do not confuse this medication with any legitimate prescription drugs you may be taking. Contact the FDA for more information.

**Gather:** Gather all the information you can find on how, where and when you obtained the counterfeit medication and how long you have been taking it. Was it from the Internet, from a mail order, or from a local pharmacy? When did you purchase the medication? Do you still have the packaging? How long have you been taking the

<sup>11</sup> <http://www.safemedicines.org/safedrugs.html>

counterfeit drugs? If the medication must be taken routinely, you should also contact your physician or pharmacist to arrange for a checkup and a new supply so that you can resume taking your medication.

3. **L.E.A.D.E.R.'s. Guide for Pharmacists (Available in the following languages: English, en español, Tagalog, Vietnamese and 中文版).**<sup>12</sup>

Pharmacists know counterfeit drugs cheat consumers, deny patients the therapies that can alleviate suffering and save lives, as well as can actively harm patients' health. This is why it is important for all pharmacists to be aware of the dangers of counterfeit drugs, as well as be able to recognize and help prevent counterfeit drugs from reaching patients.

The Partnership for Safe Medicines encourages pharmacists to take an active role in helping to protect the supply chain and protect their customers from counterfeit drugs. Here are six steps for becoming a L.E.A.D.E.R. in the fight to protect patient safety.

**Learn** about contraband and counterfeit drugs. Discover the extent of counterfeit drugs and why they are an illicit public health threat with information from the SafeMeds Email Alert System, SafeMeds Weekly Update, and SafeMeds News Archive.

**Educate** customers. Help your customers safeguard their health, avoid counterfeit drugs, save money, and buy drugs safely online with consumer educational materials from the Partnership for Safe Medicines.

**Avoid** unsafe medicines and vendors. Learn the simple steps of S.A.F.E. Sourcing to get authentic drugs from legitimate sources with professional educational materials from the Partnership for Safe Medicines

**Decline** suspicious offers. Learn how to evaluate unsolicited sales offers and recognize the warning signs of a suspicious offer with professional educational materials from the Partnership for Safe Medicines.

**Evaluate** your medicines. Learn how to detect potential counterfeit drugs by evaluating the products, packaging, and labeling of the drug products you stock with professional educational materials from the Partnership for Safe Medicines.

**Report** counterfeit drugs and suspicious vendors. Help stop counterfeit drugs by reporting suspected counterfeit medicines and suspicious vendors to the proper authorities.

---

<sup>12</sup> <http://www.safemedicines.org/leaders-guide-for-pharmacists.html>