

## **Official Remarks on the Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools**

The Partnership for Safe Medicines

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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 or contraband medicines. In addition to publishing blog posts, expert articles, counterfeit drug incidents alerts and peer-reviewed articles, PSM participates in policymaking discussions and employs a comprehensive social media effort. From our board of experts to our daily work on the Web, the Partnership believes that we are one of the most experienced authorities on the online advertising and social media issues that were addressed during the U.S. Food and Drug Administration's (FDA) recent hearing.

A large part of our commitment to combating counterfeit drugs is consumer awareness, and the Internet plays a significant role in fulfilling that obligation. From blog posts to e-newsletters to tweets about breaking news and FDA alerts, we rely on the Internet to inform and educate. However, it is also through this work that we discovered the need for more oversight in the biopharmaceutical space.

### **PSM Monitoring and Outreach**

As previously mentioned, PSM relies on the Internet to help bolster awareness about the dangers of counterfeit products and communicate breaches in the secure supply chain. Part of that includes publishing alerts derived from FDA updates, along with other counterfeit news, 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 to 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 to 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.

Thus, it seems logical that any parameters the FDA sets around social media should also seek to protect legitimate Web communications in addition to protecting Web users from counterfeit and substandard drugs advertised and sold online.

### **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). The changes will 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. 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.

### **Solutions**

PSM has identified a number of ways in which the FDA, perhaps in conjunction with other regulatory bodies, can shutter advertisers and peddlers of counterfeit drugs.

#### **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 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. Bryan A. 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 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 US 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 website, 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 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 of the Pharmaceutical Security Institute 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**

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 FDA's acknowledgement of these complex challenges and encourages the FDA to work with other relevant agencies and Congress to address the regulation of online pharmacies and drug sellers; the large profits generated by search engines that sell advertising space to these unlicensed sellers; and encourage the

creation of verified social media accounts for pharmaceutical organizations and advocacy groups, as well as the creation 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 detail or questions.

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