

Comments of B&D Consulting
on the FDA's Request for Comments
on the Promotion of Food and Drug Administration-Regulated Medical Products
Using the Internet and Social Media Tools
Docket No. FDA-2009-N-0441

Introduction

B&D Consulting submits these comments on behalf of the Alliance for Safe Online Pharmacies ("ASOP"). ASOP is an informal coalition of stakeholders who seek to protect patient safety by ensuring patient access to safe and legitimate online pharmacies that sell medicines in accordance with U.S. laws.

Comments

As the FDA seeks public input on the important issues involving communication about medical products over the Internet, it is highly relevant to consider the many Internet websites currently advertising and selling medicines to U.S. patients via the Internet. Illegal online drug sellers often advertise to patients that no prescription is required and utilize online questionnaires, or other means, to prescribe and dispense medications in violation of State and Federal laws. In contrast, many State-licensed retail pharmacies operate and maintain websites for the convenience of their patients, through which their patients may obtain legitimate, doctor-prescribed medicines. Some of these pharmacies are certified by the National Association of Boards of Pharmacy's VIPPS program (see <http://www.nabp.net/>). However, there are many illegal online drug sellers that do not adhere to State or Federal laws, do not obtain VIPPS certification, do not comply with FDA requirements, and are therefore offering illegal and potentially unsafe medicines to U.S. patients.

Whenever a consumer enters a medicine's name into an Internet search engine, links to many websites appear in the search results (both sponsored¹ and organic). These search results yield links to illegal online drug sellers that offer medicines in violation of State and Federal laws, as well as to legitimate State-licensed pharmacy websites. Any patient or caregiver looking on the Internet for information about a medicine will no doubt encounter those illegal online drug sellers. In fact, links to certain illegal online drug sellers were included in screenshots attached by the FDA in its letters to manufacturers objecting to the manufacturers' sponsored links. Links to illegal online drug sellers have also been found in social networks and online communities.

We know that the risks posed to patients by illegal online drug sellers are real, and the FDA's action to warn the public about fake H1N1 treatments in the fall of 2009² reminds us all that patient safety must be protected. In that warning to the public, the FDA found that "products represented online as Tamiflu (oseltamivir)" either contained no active ingredient or contained various levels of active ingredient, but were not approved for sale in the United States. Any effort to regulate online communications about medicines should take into account online communications regarding unapproved and potentially dangerous medicines by illegal online drug sellers.

Patients seek accurate, timely and meaningful information regarding the medical products they purchase either online or in a traditional bricks-and-mortar pharmacy. Patient access to pharmaceuticals through

¹ We applaud Google's recent update to its Pharmacy Policy in the U.S. (announced February 9, 2010) to remove illegal online drug sellers from its sponsored links and only allow VIPPS-certified online pharmacies to advertise in the U.S. market. We encourage other Internet search engines to do the same.

² <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186861.htm>

the Internet has been, and continues to be, regulated through “a patchwork of federal and state laws in an array of areas” ranging from safety and efficacy to the possession and dispensing of legend drugs and controlled substances.³ Increasing patient communication with drug manufacturers and legitimate health care providers via the Internet and social media may help patients make informed decisions regarding their choices to access appropriate treatments from appropriate, safe sources, and avoid illegal online drug sellers.

One method to enhance patient access to accurate, timely and meaningful medical information on the Internet is for the FDA to facilitate the use of an FDA icon that would link a patient to FDA-approved labeling for the particular medical product. These links could be required to be used by any FDA-regulated entity in its own communication and promotional activities, but may also be used voluntarily, according to certain FDA standards and guidelines, by entities not currently regulated by the FDA. Legitimacy for non-regulated entities that are approved to use such an FDA icon would be enhanced, and patient safety would be improved by providing a quick and easy pathway to FDA-approved labeling. Risk of unauthorized use of such an icon could be reduced by technical measures and by increased penalties for counterfeiting that icon.

We note that there are thousands of websites, including illegal online drug sellers and affiliated websites, which actively and dangerously encourage and facilitate the purchase of drugs that are not FDA-approved. We suggest that websites operated by established organizations, including websites operated by entities regulated by the FDA (such as manufacturers and distributors of pharmaceutical products), can provide an important counterbalance to these illicit websites by disseminating accurate and thorough information about regulated medical products, and emphasizing the importance of drug safety in accordance with FDA requirements. Accordingly, as the FDA develops guidance to the industries it regulates regarding the Internet and social media communication and promotion, we encourage the FDA to ensure that illegal online drug sellers competing for the attention of patients are not inadvertently given higher prominence.

Conclusion

With the growing demand for accurate Internet-based information regarding medical conditions and the medicines that treat them, and for safe access to these medicines via the online marketplace, ASOP applauds the FDA's efforts to provide clear guidance to the regulated community regarding the use of social media promotional activities. ASOP also sees the need to educate consumers on how to safely use the Internet to obtain prescribed medications, and about the dangers of dealing with illegal online drug sellers. Additionally, ASOP encourages the FDA to continue taking concrete steps towards holding those accountable who provide access to or facilitate illegal and potentially counterfeit medicines via those same online channels. ASOP is happy to assist and contribute to such efforts.

³ CRS Report RL32191, *Prescription Drug Importation and Internet Sales: A Legal Overview*, by Jody Feder (p. 33) (March 31, 2005).