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LETTER TO THE EDITOR

Separating online piracy from counterfeit medicines: The need for policy reform and a call to action

Abstract

The recent public backlash against proposed federal anti-piracy legislation provides important lessons regarding promoting public policy for public health and patient safety online. Anti-piracy legislation contained many novel regulatory strategies that may have had an impact on combating counterfeit medicines sold by online pharmacies, but was derailed due to non-health related considerations and concerns about intellectual property rights protection. Instead, effective policy to regulate online pharmacies needs to focus on health and patient safety issues separate from intellectual property considerations to combat this online crime.

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Introduction

On January 18, 2012, the online encyclopedia, Wikipedia, shut down in protest of anti-piracy legislation based on claims that it would promote censorship and impinge on free speech over the Internet [1]. Wikipedia's blackout was also supported by other large technology stakeholders, with both Wikipedia and Google urging users to contact elected representatives and express opposition over two anti-piracy bills then pending in the U.S. House of Representatives and the Senate. Ironically, 2 days after these protests ensued, Senator Reid announced via the social media platform Twitter—a tool for mobilization of online protest against the legislation—that a vote on the bills would be delayed indefinitely [1]. The demise of these bills may represent a victory for advocates of an open and unfettered Internet, but it may also have adverse consequences on opportunities for improving patient safety online.

Anti-piracy legislation

Much of the public debate surrounding the U.S. House's Stop Online Piracy Act ("SOPA") and the Senate's Protect IP Act ("PIPA") focuses on copyright infringement and access to shared and pirated multimedia (videos, music, etc.). As drafted, SOPA expanded law enforcement powers against online piracy, including foreign websites that are designed or operated with the intent to infringe on copyrighted

materials. Enhanced enforcement mechanisms included the ability to require Internet service providers ("ISPs"), search engines, Internet advertising services, and payment processors to bar access to or authorization of payment transactions for infringing sites within 5 day of an issued court order. Although primarily targeted at multimedia content, the anti-piracy bills could have also had an impact on drug and patient safety given potential applicability to "rogue" websites that sell counterfeit medicines.

Debate regarding online pharmacies

Both the pharmaceutical industry and consumer-advocacy groups have argued over the appropriateness of SOPA in promoting safe online access to medications. Lessons can be learned from this dialogue and should be applied to current public health threats of rogue online pharmacies. Indeed, previous studies have shown an increase in prescription drug purchases online, including controlled substances as well as sourcing by drug dealers through the Internet [2,3]. As has been reported by public health regulators and entities such as the National Association of Boards of Pharmacy ("NABP"), the World Health Organization and the U.S. Food and Drug Administration ("FDA"), as well as numerous media outlets, purchasing drugs online is a known public health threat and can be extremely dangerous, including potential patient injury or even death [4,5]. Indeed, according to the NABP, of 8000 websites reviewed, only 4% were in compliance with

applicable U.S. domestic laws, meaning that the vast majority of remaining unregulated sites may place patients at risk by selling them counterfeit, unapproved, or otherwise adulterated medicines [6]. Ironically, sites like “Wikipharmacy” (<http://wiki-pharmacy.org/>), taking advantage of the “Wiki brand”, not only offer consumers drugs without a prescription, but are also listed as “not recommended” by the NABP, meaning they have already been identified as posing potential safety risks.

Importantly, mechanisms in SOPA employed several novel strategies that could be used to ensure online drug safety if implemented correctly. This included primarily targeting foreign websites, which are often risky sources for counterfeit drugs, and requiring Internet service companies who facilitate and profit from illicit online drug e-commerce, such as Google (indexes websites, sells advertising, and provides search), payment processors (which transact purchases of drugs from rogue websites) and ISPs (which host websites), to more proactively prevent such activity from occurring. This approach is in contrast to penalizing efforts such as Google’s \$500 million settlement with the U.S. Department of Justice regarding allegations that it profited from online Adwords and illegal sales of pharmaceuticals [7].

However, SOPA and PIPA fail from a public policy standpoint due to weaknesses that have plagued the global fight against counterfeit medicines: primarily competing interests between commercial intellectual property rights and medication access [8]. Instead of attempting to regulate online health-based concerns using copyright and trademark-infringement legislation, Internet health issues should be treated differently and distinctly from regulation of commercial consumer goods.

Reform

Targeted legislation that *specifically* addresses the dangers posed by rogue online pharmacies separate from other forms of intellectual property infringement should be pursued. Instead of an IP focus, health accreditation strategies should be utilized. Specifically, we believe that legislation mandating online pharmacy accreditation by NAPB’s verified internet pharmacy practice sites program (“VIPPS”) can be an important step towards achieving online patient safety. The VIPPS program is the only accreditation recommended by the FDA, and has robust systems of quality and credential assessments. Hence, VIPPS-accredited online pharmacies may represent a viable and convenient route for drug distribution to patients [6].

This effort should also be coupled with existing U.S. laws such as the Ryan Haight online pharmacy consumer protections act, named after an 18-year-old boy who died from an overdose of drugs purchased online [2,4]. This law mandates prescriptions for online purchases, but is limited in scope to controlled substances [4]. In addition, the proposed counterfeit drug penalty enhancement Act which aims to increase criminal penalties for counterfeit medicine manufacture and sale, and the recently introduced online pharmacy safety act which would create a registry of legitimate online pharmacies maintained by FDA, should also be included in policy discussions [9].

The reasons for immediate and swift action should be clear, as the repercussions for consumers accessing a pirated movie or music greatly differs in potential risk and injury from those of buying counterfeit medicines often accessed by vulnerable patient populations (i.e., the elderly, teens, and the uninsured/underinsured) [8]. Further, unregulated online direct-to-consumer marketing via the web, email spam, mobile platforms, and social media has globalized this dangerous trade increasing access and demand via fraudulent marketing [10,11]. A change in policy is clearly needed, and it should begin with policies that focus on patient safety, not commercial intellectual property protections.

The dangers of rogue online pharmacies that sell everything from essential vaccines and medications, FDA shortage drugs, and life-style drugs are real and present [5-13]. Instead of a Wikipedia blackout, websites such as Wikipharmacy and countless other rogue online pharmacies should be recognized as the public health threat they represent and be excluded in discussions about anti-piracy or commercial free speech. We should not forget the legal maxim *salus populi supra lex*—public health is the highest law [14]. That principle should guide any efforts addressing health and the Internet and needed regulation.

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