



nabp

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Internet Drug Outlet Identification Program

Progress Report for State and Federal
Regulators: July 2015

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: July 2015

I. INTRODUCTION

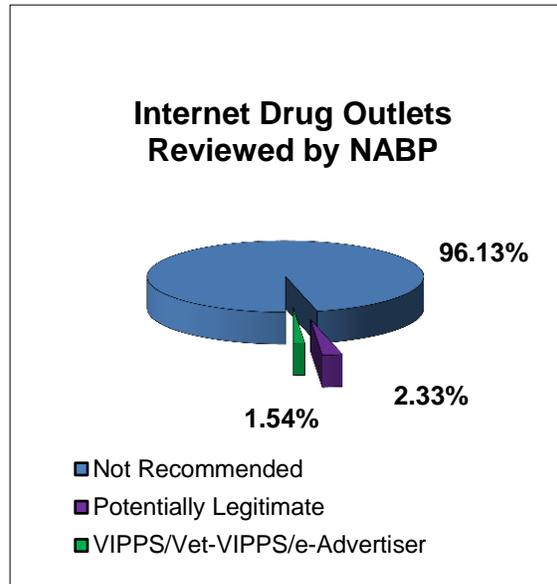
The call for accountability is a common refrain in today's Internet community. The Internet Corporation for Assigned Names and Numbers (ICANN), the organization that oversees the operation of the Internet domain name system, has come under pressure in recent months to be more accountable to the global multi-stakeholder community it claims to represent, which would include Internet users and consumers, for illegal activities taking place online. Accountability is critical where consumer safety is concerned, such as in the practice of pharmacy, whether practiced in a brick-and-mortar store or online. When there is no accountability, fraud is more likely to occur, and, with it, public harm, not the least of which includes adverse events associated with the illegal online sale of prescription drugs. When adverse events resulting from fraud do occur, patients who are harmed have no recourse.

As a public health advocate and now as the registry operator for the .pharmacy Top-Level Domain (TLD), the National Association of Boards of Pharmacy® (NABP®) holds online drug sellers accountable to the laws and standards that govern the practice by identifying those found to be out of compliance with United States laws as Not Recommended. This objective to increase accountability was among the tenets on which NABP launched its Internet Drug Outlet Identification Program in 2008 and remains at the core of its .pharmacy initiative. Today, more than 11,000 website reviews later, NABP still finds that 96% of the sites evaluated operate out of compliance with pharmacy laws and patient safety standards. Many public health agencies and patient safety advocates worldwide share NABP's concern over websites selling medicine illegally online and placing patient health at risk. Laws and practice standards governing the practice of pharmacy are in place in all developed countries. Yet the perpetrators and enablers of crimes online often are not held accountable for their actions in large part due to the lack of enforcement by registrars and by ICANN. These organizations have a duty to respond

appropriately when criminal activity is discovered online and to keep the public free of the harms these activities cause.

II. RESULTS

A. Findings of Site Reviews to Date: As of June 30, 2015, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 11,015 Internet drug outlets selling prescription medications. Of these, 10,588 (96.13%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. These sites are listed as Not Recommended in the “Buying Medicine Online” section



under Consumers on the NABP website, as well as on NABP’s AWA_Rx_E[®] Prescription Drug Safety website, www.AWARERX.ORG. Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. In fact, for each of the past seven years that NABP has been reviewing rogue Internet drug outlets, this was by far the most common reason sites were listed as Not Recommended. These findings include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. For most, dispensing without a valid prescription was one of several other concerning activities observed. Many also offer foreign and unapproved drugs. Both of these factors pose a public health risk that undermines the regulations put in place in the US and other developed countries to set standards for the practice of pharmacy, standards for medication safety and efficacy, and regulations for safeguarding the medication supply chain from counterfeit drugs. Most sites selling drugs illegally online do not post any address, and nearly half have their domain names registered anonymously. The 10,588 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.¹

¹ It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found to be noncompliant at the time of review but may since have been deactivated. It should also be noted that the numbers reported here do not represent the entire universe of websites selling prescription drugs illegally, but, rather, a representative sampling of the online environment over the last seven years.

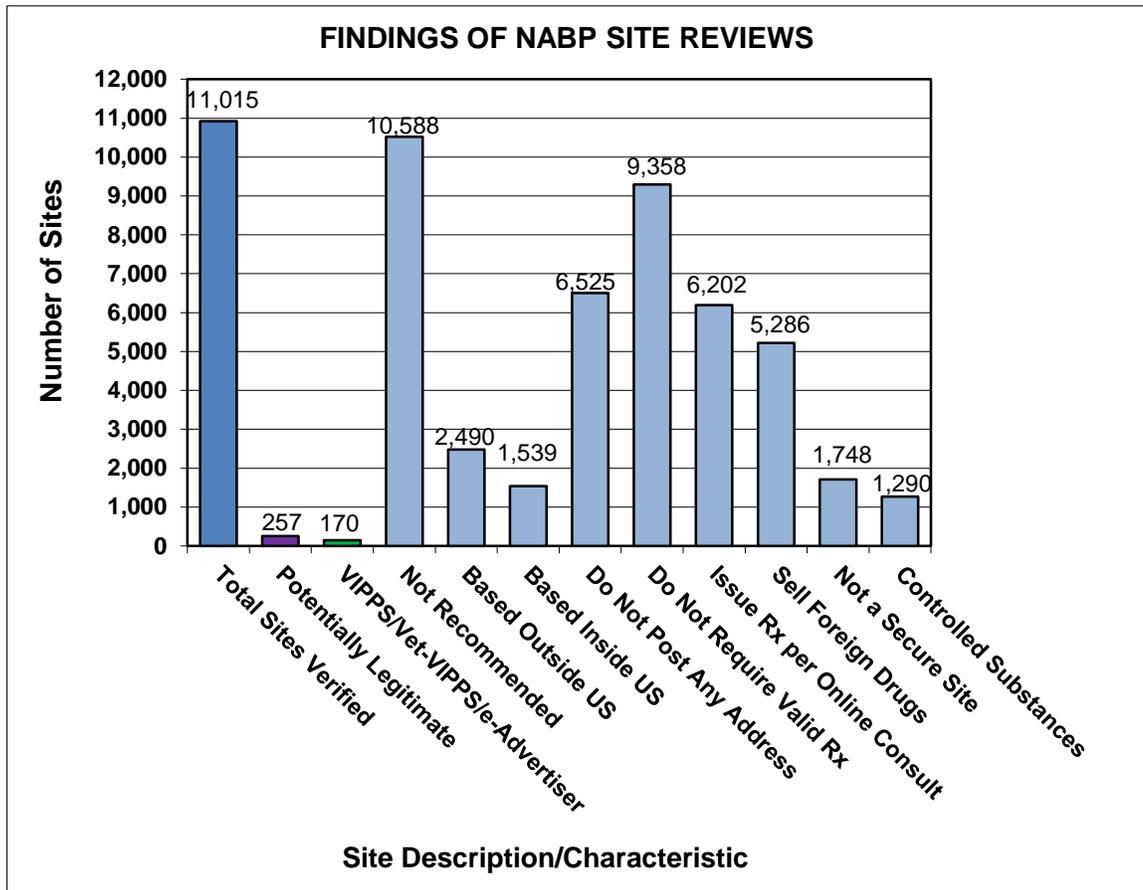
Of the total 11,015 sites reviewed, 257 (2.33%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites and their domain name registration information. One hundred seventy (1.54%) of the 11,015 reviewed sites have been accredited through NABP's Verified Internet Pharmacy Practice Sites[®] (VIPPS[®]) or Veterinary-Verified Internet Pharmacy Practice Sites[®] (Vet-VIPPS[®]) programs, or approved through the NABP e-Advertiser Approval^{CM} Program.

Not Recommended Sites

Physical Location:	2,490 (22.6%) outside US
	1,539 (14%) inside US
	6,525 (59.2%) no location posted on website
Prescription Requirements:	9,358 (85%) do not require valid prescription
	6,202 (56.3%) issue prescriptions per online consultations or questionnaires only
Medications:	5,286 (48%) offer foreign or non-FDA-approved medications
	1,290 (11.7%) dispense controlled substances
Encryption:	1,748 (15.9%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	4,436 (40.3%) outside US
	5,683 (51.6%) inside US
	461 (4.2%) have unknown server locations
Affiliations:	9,594 (87.1%) appear to have affiliations with rogue networks of Internet drug outlets

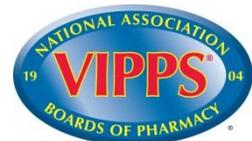
Sites listed as Not Recommended, in total, as of June 30, 2015

The standards against which NABP evaluates Internet drug outlets are provided in the appendix of this report.



Findings of NABP website reviews, in total, as of June 30, 2015

- B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that US patients use Internet pharmacies accredited through the VIPPS and Vet-VIPPS programs when buying medication online. These sites have undergone and successfully completed the thorough NABP accreditation process, which includes a review of all policies and procedures regarding the practice of pharmacy and dispensing of medicine over the Internet, as well as an on-site inspection of facilities used by the site to receive, review, and dispense medicine. Currently, 63 VIPPS and Vet-VIPPS pharmacy sites are listed as Recommended Internet Pharmacies. Several more applications are in progress.



- C. NABP e-Advertiser Approval Program: Sites that have received e-Advertiser Approval status do not fill new prescription drug orders via the Internet, and thus are ineligible for VIPPS, but accept refill requests from their existing customers, provide drug information or pharmacy information, or offer other prescription drug-related services. Sites that have received e-Advertiser Approval status have been found to be safe, reliable, and lawful. These sites are listed on the NABP website as Approved e-Advertisers. Currently, 107 entities are listed on the NABP website as Approved e-Advertisers, and several more applications are in progress.



III. ACCOUNTABILITY UNDER SCRUTINY

- A. Illegal Online Drug Sellers Dodge Culpability: While laws exist to govern the practice of pharmacy, enforcement of such law on the Internet tends to be lacking. Often, no one is held accountable for illegal activities perpetrated online. Where accountability is lacking and profits stand to be made, fraudsters rush in as if to fill the void. NABP Executive Director/Secretary Carmen A. Catizone, MS, RPh, DPh, and Libby Baney, JD, executive director of the Alliance for Safe Online Pharmacies, comment on this lack of accountability in a recent guest blog on the US Pharmacopeial Convention *Quality Matters* website. “Illegal Internet drug sellers often operate overseas, from countries such as Russia, China, India, Mauritius, and Turkey, and mask their identities to prevent detection by law enforcement. Many illegal drug sellers generate tens of millions of dollars annually – often avoiding prosecution by exploiting the global anonymity the Internet provides.”

One of the major concerns about rogue Internet drug outlets is their propensity to sell counterfeit drugs. The National Crime Prevention Council (NCPC) discusses the economic incentives for counterfeiters. “The most common counterfeit drugs in the US are those manufactured to mimic drugs prescribed for the treatment of chronic diseases such as erectile dysfunction (ED) drugs, high cholesterol, hypertension, antibiotics, cancer and HIV/AIDS. These drugs are expensive. That may cause people to search for cheaper sources of drugs and make them prey to unlicensed pharmacies – usually online – that may knowingly or unknowingly provide counterfeit drugs,” NCPC states in an article, “Fake Drugs Are Bad Medicine.” “The counterfeit drugs that are sold may be cheaper and more easily available than from legitimate sources, but they still reflect a high profit margin that makes the counterfeit drug trade especially lucrative.”

Similar problems are observed overseas when patients seek to obtain medicine outside of their country’s regulated supply chain. The French group International Institute of Research

Against Counterfeit Medicines states, “In France, patients are protected by a very secure distribution channel for medicines. However Internet and travel can be risky.” The group finds that the prevalence of fake medicines in Europe has increased dramatically with the rise in use of the Internet. This anonymous conduit allows criminals to circumvent traditional distribution channels and directly reach patients online.

In addition to the risk of obtaining counterfeit drugs from illegal online drug sellers, the increased likelihood of misuse also threatens public health. Again, problems stem from the lack of accountability of online drug sellers. In a July 5, 2015 article appearing in *The Times of India*, CH Paramathma, state secretary of Telangana Pharmacists’ Association in India pointed out that “it is easy for pharmacy stores to verify the authenticity of a prescription, as it contains details like the registration number of the medical practitioner and name of the hospital, but there is no such checking by online pharmacy stores.”

For these reasons, the Indian Pharmacist Association opposes the online sale of medicines and has written a letter to the Drugs Controller General of India urging that this practice be prohibited in India, as reported on June 16, 2015 by *EP News Bureau-Mumbai*. Concerns focus on the increased likelihood of regulatory violations, including the sale of counterfeit drugs, as well as medication misuse and abuse.

- B. Stakeholders Weigh In on ICANN’s Role: Some say ICANN should take some accountability for this online threat to consumer safety. In recent months, stakeholders representing multiple interests have expressed concerns about ICANN’s trustworthiness, accountability, and the execution and transparency of its current duties and initiatives. Several concerned stakeholders provided testimony to this effect during a May 13, 2015 US House Judiciary Committee hearing. Among them are trademark holders who assert their intellectual property rights are being infringed upon, and public health and safety advocates who observe the use of online domains to perpetrate fraud and other deceptive and illegal activities. NABP and Internet pharmacy monitoring company LegitScript, LLC, for example, have repeatedly urged ICANN to hold its accredited registrars accountable for operating within their contractual obligation, particularly relating to the use of online domains for criminal activities, such as the illegal sale of prescription drugs.

The current (2013) Registrar Accreditation Agreement (RAA) requires ICANN-accredited domain name registrars to take some accountability for eliminating blatantly abusive uses of registered domain names. Under the 2013 RAA, registrars must respond to complaints that domain names they sponsor are being used for copyright or trademark infringement or other

illegal activities. Specifically, the RAA requires domain name registrars to conduct a “reasonable and prompt investigation” and “respond appropriately” to complaints that domain names are being used for illegal activity. If a registrar fails to meet this contractual obligation, ICANN is authorized to penalize or revoke the accreditation of the registrar.

While many registrars voluntarily take appropriate actions in such circumstances, witnesses at the judiciary hearing, including LegitScript President John Horton, testified that some registrars are not responding to such complaints, and to date ICANN is not taking action to clarify and enforce these RAA provisions. This trend is evidenced by the fact that a handful of registrars carrying only a small percentage of all domain name registration activity on the Internet, by contrast, sponsor a significantly higher percentage of rogue online drug sellers. When registrars dodge their duty to ensure that they do not sponsor websites being used for illegal activities, ICANN is obliged to hold registrars accountable to their agreements or to discontinue their contracts. In some instances, however, ICANN, too, has chosen to dismiss cases involving illegal activities.

Lending urgency to the matter of ICANN’s accountability is the proposed September 2015 transition of the Internet Assigned Numbers Authority (IANA) functions contract from the National Telecommunications and Information Administration to ICANN and, theoretically, by extension, to the global multi-stakeholder community. Witnesses called on ICANN to implement strong accountability and transparency mechanisms prior to the IANA transition, and to enforce compliance of existing rules concerning intellectual property rights and public safety.

C. .Pharmacy TLD Based on Accountability:



The public health threat posed by rogue Internet drug outlets was the impetus for NABP’s development and launch of the .pharmacy TLD. Today, NABP operates an Internet domain that is built on a foundation of accountability. While anyone can register a .com or most any other domain name, use of the .pharmacy TLD is restricted to website operators that meet program standards for safe and legal practice. The .pharmacy initiative aims to provide consumers around the world a means for easily identifying safe and legal online pharmacies and related resources. NABP grants use of the .pharmacy domain only to legitimate website operators that adhere to pharmacy laws in the jurisdictions in which they are based and in which their patients and customers reside, so that consumers can easily find safe online pharmacies and related resources. Having completed a series of limited registration periods,

the .pharmacy TLD opened for General Availability on June 3, 2015. In General Availability, all entities providing pharmacy-related products, services, or information that meet .pharmacy eligibility standards are eligible to apply for and, if approved, register .pharmacy domain names. As of June 30, 2015, NABP has granted approval (in the form of electronic tokens) for 327 domain names, and 103 .pharmacy domain names have been registered, with more than 200 registrations pending. Additional information about the .Pharmacy TLD Program, as well as information about buying medicine safely online is available at www.safe.pharmacy.

IV. DISCUSSION

The accountability of licensed pharmacies is evident in the laws and regulations of the jurisdictions that license them. These laws are no less applicable to transactions conducted online. The Association remains committed to upholding the integrity of the practice of pharmacy – in any practice setting – and ensuring that patients worldwide have access to safe and effective prescription drugs. For further information, please contact Melissa Madigan, policy and communications director, via email at mmadigan@nabp.net.

V. APPENDIX

Internet Drug Outlet Identification Program Standards

1. **Pharmacy licensure.** The pharmacy must be licensed or registered in good standing to operate a pharmacy or engage in the practice of pharmacy in all required jurisdictions.
2. **DEA registration.** The pharmacy, if dispensing controlled substances, must be registered with the US Drug Enforcement Administration (DEA).
3. **Prior discipline.** The pharmacy and its pharmacist-in-charge must not have been subject to significant recent and/or repeated disciplinary sanctions.
4. **Pharmacy location.** The pharmacy must be domiciled in the United States.
5. **Validity of prescription.** The pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a person authorized to prescribe under state law and, as applicable, federal law. The pharmacy must not distribute or offer to distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a preexisting patient-prescriber relationship that has included a face-to-face physical examination, except as explicitly permitted under state telemedicine laws or regulations.

Definition. A valid prescription is one issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established: a) The patient has a legitimate medical complaint; b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner, or through a telemedicine practice approved by the appropriate practitioner board; and c) A logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

6. **Legal compliance.** The pharmacy must comply with all provisions of federal and state law, including but not limited to the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act (including the provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, upon the effective date). The pharmacy must *not* dispense or offer to dispense medications that have not been approved by the US Food and Drug Administration.
7. **Privacy.** If the pharmacy website transmits information that would be considered Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164), the information must be transmitted in accordance with HIPAA requirements, including the use of Secure-Socket Layer or equivalent technology for the transmission of PHI, and the pharmacy must display its privacy policy that accords with the requirements of the HIPAA Privacy Rule.
8. **Patient services.** The pharmacy must provide on the website an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the website an accurate, readily accessible and responsive phone number or secure mechanism via the website, allowing patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of a possible adverse event involving their medication.
9. **Website transparency.** The pharmacy must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.

10. **Domain name registration.** The domain name registration information of the pharmacy must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy. Absent extenuating circumstances, pharmacy websites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated Websites.** The pharmacy, website, pharmacy staff, domain name registrants, and any person or entity that exercises control over, or participates in, the pharmacy business must not be affiliated with or control any other website that violates these standards.