



National Association of Boards of Pharmacy

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Internet Drug Outlet Identification Program

Progress Report for State and Federal
Regulators: April 2015

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: April 2015

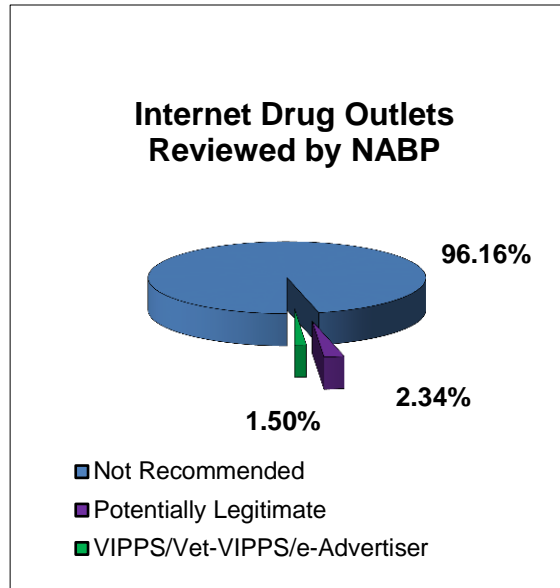
I. INTRODUCTION

Anyone can register a .com domain name. There are no eligibility requirements, no screening process, and no restrictions on how the website may be used. The same is true of most open registries. It is quick, easy, and inexpensive to launch and operate a website. This fact alone should give consumers pause to consider the source before they buy something as critical as medication from an unknown source over the Internet. The fact that the National Association of Boards of Pharmacy[®] (NABP[®]) has found 96% of nearly 11,000 websites selling prescription medicine online to be out of compliance with pharmacy laws and patient safety standards is further cause for concern. Many public health agencies and patient safety advocates worldwide echo this concern.

Still, public health advocates find that one of the primary challenges in protecting consumers from illegal online drug sellers is the lack of awareness of the potential health and safety risks posed by fake online pharmacies. This public health threat was the impetus for NABP's development and launch of the .pharmacy Top-Level Domain (TLD). 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. Alongside this initiative, NABP has made consumer education one of its primary objectives in 2015. Sharing patient safety information through television, radio, online advertising, and social media, NABP's multi-channel public outreach campaign, discussed further in Section III of this report, is well under way.

II. RESULTS

A. Findings of Site Reviews to Date: As of March 31, 2015, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,965 Internet drug outlets selling prescription medications. Of these, 10,544 (96.16%) 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



AWAR_xE[®] 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 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 United States 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 register their domain names anonymously. The 10,544 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.¹

Of the total 10,965 sites reviewed, 257 (2.34%) 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 sixty-four (1.50%) of the 10,965 reviewed sites have been

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.

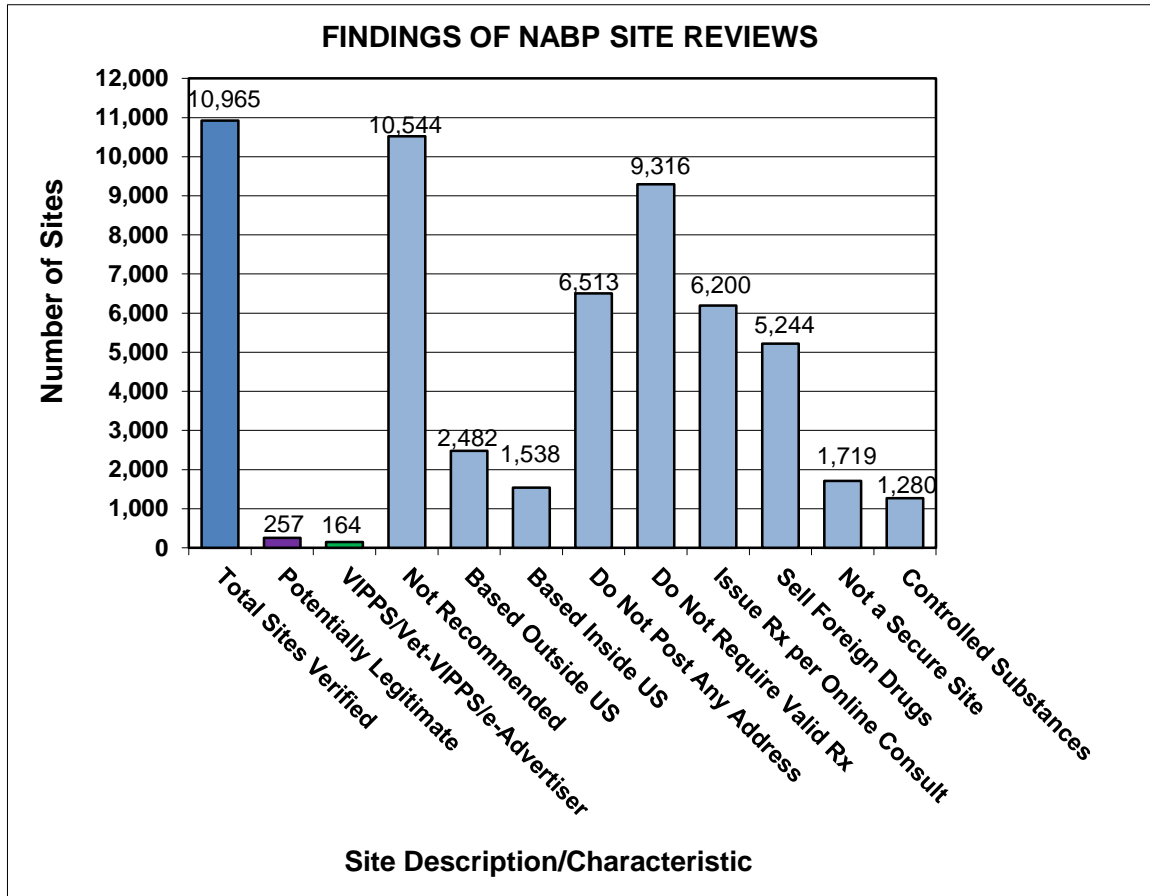
accredited through NABP's Verified Internet Pharmacy Practice Sites[®] (VIPPS[®]) or Veterinary-Verified Internet Pharmacy Practice Sites[®] (Vet-VIPPS[®]) programs, or approved through the NABP e-Advertiser Approval^{CM} Program.

Not Recommended Sites

Physical Location:	2,482 (23.5%) outside US
	1,538 (14.6%) inside US
	6,513 (61.8%) no location posted on website
Prescription Requirements:	9,316 (88.4%) do not require valid prescription
	6,200 (58.8%) issue prescriptions per online consultations or questionnaires only
Medications:	5,244 (49.7%) offer foreign or non-FDA-approved medications
	1,280 (12.1%) dispense controlled substances
Encryption:	1,719 (16.3%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	4,405 (41.8%) outside US
	5,675 (53.8%) inside US
	461 (4.4%) have unknown server locations
Affiliations:	9,576 (90.8%) appear to have affiliations with rogue networks of Internet drug outlets

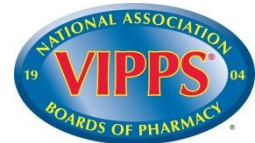
Sites listed as Not Recommended, in total, as of March 31, 2015

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 March 31, 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, 64 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 were granted 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 were granted 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, 100 entities are listed on the NABP website as Approved e-Advertisers, and several more applications are in progress.



III. CONSUMER EDUCATION CAMPAIGN

- A. Public Service Announcements: In light of the public health risks associated with illegal online drug sellers, NABP has made consumer education a priority in 2015 and is reaching out through multiple channels, including television, radio, online advertising, and social media. NABP has produced and distributed public service announcements (PSAs) throughout the country to encourage the safe purchase and use of medications. The video, “A Trustworthy Source,” portrays the importance of obtaining medications from a legitimate pharmacy operating within the laws and safety standards established to protect patient health.

A video player interface showing a still from a video titled "A Trustworthy Source - 60 seconds". The still depicts a man in a blue long-sleeved shirt sitting at a wooden dining table with a young boy. They are both looking at something on the table, possibly a toy or a book. In the background, a woman in a yellow top is standing in a kitchen area. The video player has a play button in the center and a close button in the top right corner.

As part of its consumer education campaign, NABP has posted an informational video on the .pharmacy website at www.safe.pharmacy/buying-safely. The video, “A Trustworthy Source,” portrays the importance of obtaining medications from a legitimate pharmacy operating within the laws and safety standards established to protect patient health.

Results of the consumer education campaign via television have been excellent. In March 2015, the PSAs aired 2,344 times, which translates to 11.39 million audience impressions. Results for radio have also been good. As of March 31, the PSAs aired 1,259 times, which translates to 9.55 million audience impressions. A Spanish version of the radio PSA was also recorded and will soon be running. NABP also reached out to bloggers with its public health message, and embarked on a search-intent and behavioral marketing campaign. In such a campaign, a consumer's online activity prompts .pharmacy banner ads to appear while they are using the Internet. As a result, the banner ads were seen 3.73 million times, and the ads were clicked on 13,374 times, exceeding the benchmark click-through rate by four times. In addition, planning for a satellite/Internet media tour began in March. This will take place in June and will feature NABP Executive Director/Secretary Carmen A. Catizone, MS, RPh, DPh, as well as an individual who has a personal story about a family member who was harmed by receiving counterfeit drugs by ordering them from a seemingly legitimate online drug outlet.

The AWA_Rx_E Prescription Drug Safety Program is another avenue through which NABP provides authoritative resources about medication safety, prescription drug abuse, medication disposal, and safely buying medications on the Internet. This program provides consumers with medication safety information through the website, WWW.AWARERX.ORG, informational materials, PSAs, and social media. AWA_Rx_E has a YouTube page, www.youtube.com/user/AWARxE, where the above-referenced video can be viewed, and also has a Facebook page, www.facebook.com/AWARxE, and a Twitter profile.

- B. .Pharmacy Top-Level Domain: To help raise public awareness of the dangers posed by rogue Internet drug outlets, and to provide an online domain where consumers can be sure the websites they find there are legitimate, NABP continues to publicize the launch of its .pharmacy TLD through multiple channels, including internationally distributed news releases. The .pharmacy TLD website, www.safe.pharmacy, has become a hub of information not only for potential registrants but also for consumers. A recent addition to the site is the “Buying Safely” section for consumers, presented in both English and Spanish. Also new to the .pharmacy website is the “Find a .pharmacy Website” page, www.safe.pharmacy/buying-safely/find-a-pharmacy-website, which lists all .pharmacy domain name registrants. An online form to report abuse is available on the .pharmacy website, www.safe.pharmacy/buying-safely/report-abuse. Alternatively, such reports can be emailed to NABP at abuse@safe.pharmacy.



NABP launched the .pharmacy TLD 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. The .pharmacy TLD is in the midst of its final limited registration period and will open for General Availability on June 3, 2015. In General Availability, all entities providing pharmacy-related products, services, or information that meet .pharmacy eligibility standards will be able to apply for and, if approved, register .pharmacy domain names. As of March 31, 2015, NABP has granted approval (in the form of electronic tokens) for 294 domain names, and 78 .pharmacy domain names are currently registered.

Additional information about the .Pharmacy TLD Program, as well as information about buying medicine safely online is available at www.safe.pharmacy.

IV. DISCUSSION

NABP continues to reach out to consumers and regulators worldwide to raise awareness of the risks associated with rogue Internet drug outlets and the value of the .pharmacy domain as a public health initiative. NABP supports the efforts of regulators, enforcement authorities, and patient advocates to contain the global public health threat these rogue sites pose. 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.