



nabp

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Internet Drug Outlet Identification Program

Progress Report for State and Federal
Regulators: April 2016

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: April 2016

I. INTRODUCTION

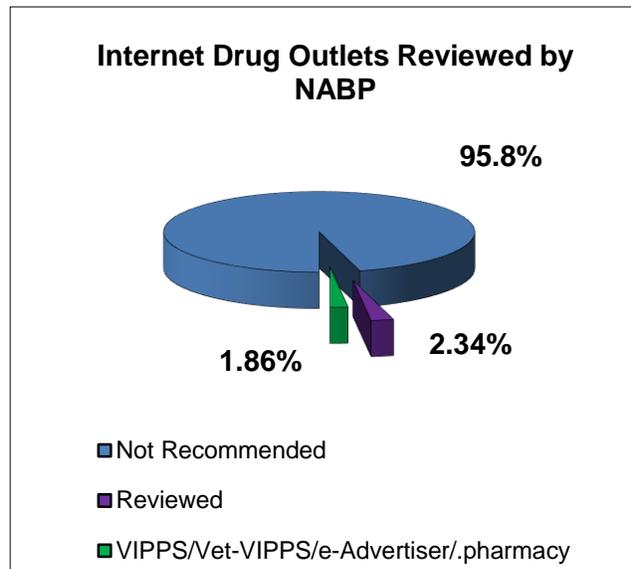
Antifreeze, house paint, and floor wax are among the contents patients may find in the medications they buy from unapproved and unknown sources over the Internet. For health care regulators and some patient safety advocates, this may come as no surprise. Consumers, however, may be dangerously unaware. The National Association of Boards of Pharmacy® (NABP®) is launching a new public service announcement (PSA) this spring to raise consumer awareness of the dangers of counterfeit and substandard medications frequently bought and sold online. The PSA also highlights NABP's .Pharmacy Top-Level Domain (TLD) Program, encouraging consumers to look to the right of the dot for Internet pharmacies and resources with website addresses ending in the .pharmacy suffix. These websites have been evaluated and approved by NABP as lawful organizations meeting high standards for legitimacy, safety, and reliability. An update on the .Pharmacy TLD Program and a peek behind the scenes of this PSA are provided later in this report.

Through research conducted over the past eight years, NABP finds that an alarming number of websites selling prescription medications online operate illegally, importing medications from outside of safeguarded supply chains, frequently without a prescription, medical oversight, or recourse for patients who experience adverse effects. NABP has reviewed over 11,000 websites selling prescription medications online to United States consumers and has found approximately 96% of them to be operating illegally, placing patients' health at risk. Specific findings are provided in the Results section below.

II. RESULTS

A. Findings of Site Reviews to Date: As of March 31, 2016, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 11,154 Internet drug outlets selling

prescription medications. Of these, 10,685 (95.8%) 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.awar_xe.pharmacy*. Of the



websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. 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 10,685 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.¹

Two hundred sixty-one (2.3%) of the 11,154 sites selling prescription medications to US patients were designated as reviewed. These sites lack any egregious violations that would cause them to be ranked as Not Recommended but have not satisfied the requirements of NABP’s Verified Internet Pharmacy Practice Sites® (VIPPS®), Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®), e-Advertiser Approval^{CM} Program, or .Pharmacy TLD Program. Two hundred eight (1.9%) of the 11,154 sites selling prescription medications

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 eight years.

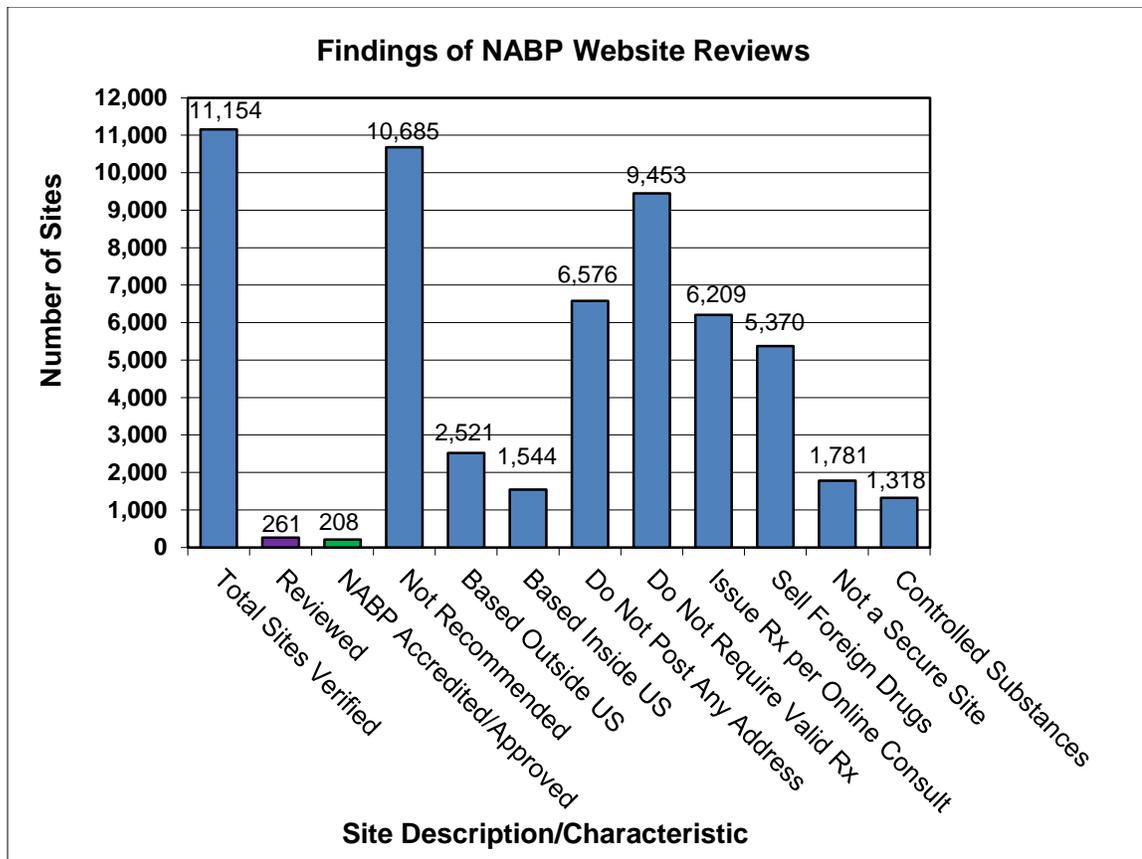
to US patients were accredited through VIPPS or Vet-VIPPS programs or were approved through the e-Advertiser Approval or .Pharmacy TLD programs.

Not Recommended Sites

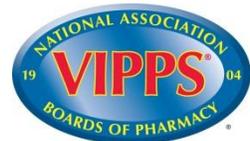
Physical Location:	<ul style="list-style-type: none">• 2,521 (23.6%) outside US• 1,544 (14.5%) inside US• 6,576 (61.5%) no location posted on website
Prescription Requirements:	<ul style="list-style-type: none">• 9,453 (88.5%) do not require valid prescription• 6,209 (58.1%) issue prescriptions per online consultations or questionnaires only
Medications:	<ul style="list-style-type: none">• 5,370 (50.3%) offer foreign or non-FDA-approved medications• 1,318 (12.3%) dispense controlled substances
Encryption:	<ul style="list-style-type: none">• 1,781 (16.7%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul style="list-style-type: none">• 4,490 (42%) outside US• 5,724 (53.6%) inside US• 461 (4.3%) have unknown server locations
Affiliations:	<ul style="list-style-type: none">• 9,605 (89.9%) appear to have affiliations with rogue networks of Internet drug outlets

Sites listed as Not Recommended, in total, as of March 31, 2016

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



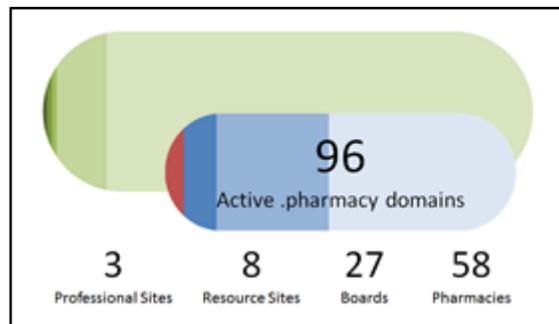
B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that patients use Internet pharmacies that have been granted VIPPS or Vet-VIPPS accreditation, Approved e-Advertiser status, or a .pharmacy domain name. These sites have been evaluated and found to be in compliance with pharmacy laws and meet high standards for pharmacy practice and patient safety. Currently, 66 pharmacies are listed on the NABP website as VIPPS and Vet-VIPPS accredited, and 133 entities are listed as Approved e-Advertisers. Ninety-six .pharmacy domain names are currently listed on the .Pharmacy TLD Program website, www.safe.pharmacy. Several more applications for these programs are in progress.



C. Pharmacy TLD Program: The public health threat posed by rogue Internet drug outlets was the impetus for NABP’s development and launch of the .pharmacy TLD. Now in its second year of operation, NABP has, as of March 31, 2016, granted approval for 373 domain names, and 235 .pharmacy domain names have been registered. Of these, 185 were registered to pharmacies (163 to human pharmacies and 22 to veterinary pharmacies), 3 were registered to professional sites, 35 were registered to boards of pharmacy or regulatory agencies, 8 were registered to resource sites, and 4 were registered to manufacturers. The 43 pharmacies that registered 185 domain names represent approximately 12,000 brick-and-mortar stores.



Of the 235 .pharmacy domain names registered, 96 are in use, while the remaining registered domain names are parked. Of those that are in use, 58 are registered to pharmacies, 27 are registered to boards of pharmacy or regulatory agencies, 8 are registered to resource sites, and 3 are registered to professional sites. Of the domain names in use, 7 are being used as the registrant’s primary domain name, 83 are redirecting to another domain name, and 6 are masking another domain name with the .pharmacy name



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. The .pharmacy TLD is available to pharmacies and other entities offering prescription drugs or prescription drug-related products, services, or information via the Internet, subject to their completion of the registrant application and approval process to establish compliance with all applicable laws and .Pharmacy TLD Program standards. The core standards that must be met to be eligible to register a .pharmacy domain name are included in Appendix B of this report.

III. NABP RAISES CONSUMER AWARENESS OF COUNTERFEIT MEDICATIONS



“Which one of these would you like to consume on a daily basis?” NABP’s public service announcement educates consumers as to the contents of some counterfeit and substandard medications purchased online.

- A. New PSA Ready for Release: NABP staff traveled to New York in March to work with a producer for a full day of lights, camera, and action, culminating in a PSA in the style of a person-on-the-street survey. The PSA aims to raise consumer awareness of the dangers of counterfeit and substandard medications, often obtained online. The PSA opens with a shot of four clear bowls containing neon green antifreeze, blue house paint, and greenish goopy floor wax. The fourth bowl is empty, representing fake and substandard medicines containing too little or none of the active pharmaceutical ingredients.

“Which one of these would you like to consume on a daily basis,” the interviewer asks, receiving responses of disgust and disbelief. The PSA informs consumers that 96% of all websites selling prescription medication operate illegally, and some websites selling cheap medicine use these toxic household items as filler ingredients to make a profit. The PSA advises consumers that some medication counterfeiters will coat pills in house paint to mimic authentic medications. The interviewer goes on to cite the World Health Organization estimate that between 100,000 and 1 million people die each year from counterfeit medications.

The PSA highlights the difficulty for patients to know what they are taking when the source of the medication is unknown or illegal. The PSA further presents that 20 new illegal pharmacies appear on the web each day, and “62% of medications purchased online are fake or substandard.” The PSA informs consumers of steps they can take to make sure the Internet pharmacy they use is legitimate, including looking for websites with web addresses ending in the .pharmacy suffix. “One of the safest ways to buy medication online is through a site with

the .pharmacy domain,” the interviewer states. “Sites that end in .pharmacy are secure and trustworthy so you and your loved ones can be sure the medications you buy online are safe.”

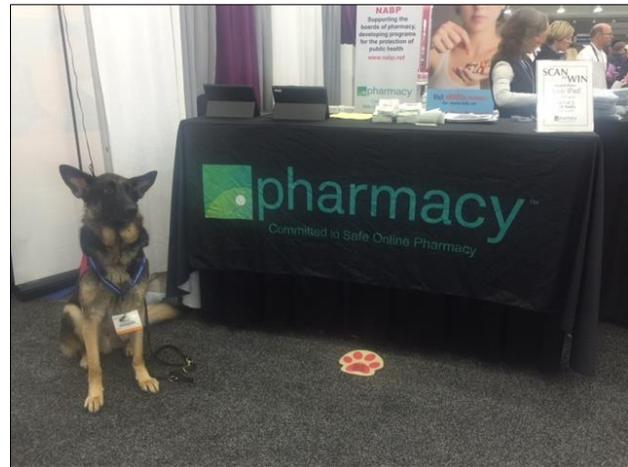
Upon its release in early May, the PSA is available in 60-, 30-, and 15-second versions that will be distributed to television stations in top markets around the country. Versions were also created for radio based on consumers’ reactions in the TV PSA. These recordings will be distributed to radio stations in top markets around the country. The PSA will also be available on the *www.safe.pharmacy* website and on the .pharmacy YouTube channel, https://www.youtube.com/channel/UCU-ZhIyPs5A0BejWjE-Ck_g.

B. Additional Public Outreach Efforts:

NABP also will reach out to consumers online via digital banner ads. These ads will be displayed to Internet users searching online for key words likely to prompt results for rogue Internet drug outlets. Once they arrive at the website they have clicked on in the search results, they will see the .pharmacy digital banner to inform them about the risk of buying harmful medications and help them to find safe .pharmacy websites. There will be two banners: one focusing on .pharmacy in general and the other playing off of the 2016 PSA. This digital banner ad campaign will start in May 2016 and will run for six months.

NABP also will display ads in public areas including inside buses, cabs, and trains, on train platforms, in bus stop shelters, and in shopping malls. The goal is to reach captive audiences (people riding public transportation or waiting for public transportation), as well as auto traffic (driving by bus stops) and foot traffic (including “mall walkers”). The text and images in the ad will be based off of the 2016 PSA, showing the toxins that could be in counterfeit medications purchased online. This tactic is expected to begin in May.

NABP’s 2014 PSA, “A Trustworthy Source,” continues to be aired via radio in English and Spanish and on television across the country. During first quarter 2016, the English version of the radio PSA received over 8 million audience impressions, and the Spanish version



NABP presented information about .pharmacy at the APhA annual meeting in March 2016. NABP also supported the APhA2016 Community Service Project, Paws for Veterans.

received over 9 million impressions. The TV PSA aired nearly 6,000 times and received over \$26 million audience impressions.

In addition, NABP has been reaching out to introduce health care organizations and professional associations to the .Pharmacy TLD Program. In March, for example, NABP shared information about .pharmacy at an exhibition booth at the American Pharmacists Association (APhA) 2016 Annual Meeting and supported APhA's community project, Paws for Veterans. NABP also has participated or plans to participate in events of organizations including Access to Safe Medicines, the Canadian Pharmacists Association, and the American Society of Health-System Pharmacists.

IV. DISCUSSION

As long as consumers continue to utilize websites selling prescription drugs illegally, such operations will continue to thrive. Unfortunately, many consumers, and even health care professionals, remain unaware of the dangers associated with obtaining unapproved medications from sources outside of regulated supply chains. Along with regulators and patient safety advocates, NABP is pushing forward with programs and outreach activities to educate the public on these concerns and to provide them with resources to purchase medications safely and find reliable pharmacy-related services and information online.

NABP continues to support the state boards of pharmacy in their mission to protect the public health. The Association applauds the multinational organizations dedicated to this same goal. NABP 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 medications. For further information, please contact Melissa Madigan, policy and communications director, via email at mmadigan@nabp.net.

V. APPENDICES

Appendix A

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.

Appendix B

.Pharmacy TLD Program Standards

1. **Licensure.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must possess all necessary licenses, registrations, or permits to practice in all required jurisdictions. This includes not only the jurisdiction where the entity is located, but also any jurisdiction where its patients or customers reside. All such licenses, registrations, or permits must be in good standing.
2. **Prior discipline.** An applicant, as well as any community members to which the applicant site links or with which it is affiliated, must not have been subject to significant recent and/or repeated disciplinary sanctions.
3. **Location.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must be domiciled in the US or in a country with a .pharmacy National Standard Setting Committee, or in a country that has established an understanding with NABP that will allow non-US .pharmacy applicant evaluations to be performed by NABP.
4. **Validity of prescription.** A pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined by the applicable jurisdictions. A valid prescription is one issued pursuant to a legitimate patient-prescriber relationship, as defined by the applicable jurisdictions.
5. **Legal compliance.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must comply with all provisions of jurisdictional law, including laws addressing regulatory agency approval of prescription medication.
6. **Privacy.** If the applicant website, or any site to which the applicant site links or with which it is affiliated, maintains or transmits patient health information, the information must be maintained or transmitted in accordance with jurisdictional patient information privacy and security laws, including those addressing notice to patients regarding privacy and security of such information.
7. **Patient services.** An applicant pharmacy, medical or veterinary practice, medical or veterinary practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must provide on the website an accurate street address of the dispensing pharmacy, medical practice, medical practitioner, or corporate headquarters. The applicant pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, 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 or medical practitioner regarding complaints or concerns or in the event of a possible adverse event involving their medication.
8. **Website transparency.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the practice, its staff, prescription drugs, or financial transactions.
9. **Domain name registration.** The domain name registration information of the applicant website, or of any community member it promotes, must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy, medical or veterinary practice, or medical or veterinary practitioner. Applicant websites utilizing anonymous domain name registration services will not be eligible for approval.

10. **Affiliated websites.** The applicant website, any community member it promotes, its staff, domain name registrants, and any person or entity that exercises control over, or participates in the applicant business, must not be affiliated with or control any other website that violates these standards. All .pharmacy registrants must meet these core standards. Registration within the .pharmacy TLD is open to eligible entities in any country, subject to verification of compliance with .pharmacy standards. Additional jurisdiction-specific standards may apply to registrants based in or serving customers in other jurisdictions.