

# nabp

# **National Association of Boards of Pharmacy**

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# **Internet Drug Outlet Identification Program**

Progress Report for State and Federal Regulators: January 2016

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#### I. INTRODUCTION

Misuse of prescription medications is a serious public health concern. Opioid overdose deaths, including prescription pain relievers and heroin, rose 14% to reach record levels in 2014, the Centers for Disease Control and Prevention (CDC) reported in December 2015. Commonly prescribed prescription opioid pain relievers such as oxycodone and hydrocodone are involved in more overdose deaths than any other opioid type, says CDC. Other reports have shown high abuse rates among college students using medications prescribed for attention-deficit hyperactivity disorder (ADHD) non-medically. Many other prescription medications, from muscle relaxants, to stimulants, to tranquilizers, remain common drugs of abuse. Many sources, including CDC, point to high prescribing rates as implicit in the prescription drug abuse epidemic. Little research has been done linking non-medical use of prescription drugs with illegal online drug sellers, ie, websites purporting to be legitimate pharmacies that dispense unapproved, substandard, and sometimes counterfeit medications without a prescription or medical oversight. One recent study, however, found that illegal online drug sellers commonly use the social media platform Twitter to spread information and share links to rogue sites selling drugs of abuse. This study is discussed further in Section III of this report. Meanwhile, the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) continues to identify websites selling prescription medications illegally – many of them selling drugs of abuse without a prescription.

# II. RESULTS

A. <u>Findings of Not Recommended Sites to Date</u>: As of December 31, 2015, NABP has identified 10,668 Internet drug outlets selling prescription medications 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<sub>x</sub>E® Prescription Drug Safety website,

www.AWARErx.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, including controlled substances, based solely on an online questionnaire, as well as those requiring no prescription at all. 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 have their domain names registered anonymously. The 10,668 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.

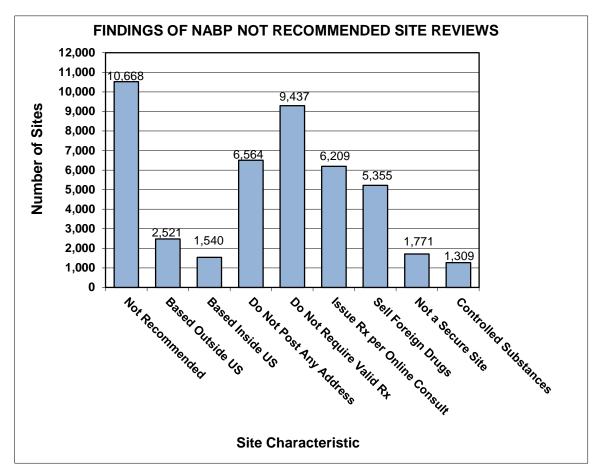
#### **Not Recommended Sites**

Physical Location:	<ul> <li>2,521 (23.6%) outside US</li> <li>1,540 (14.4%) inside US</li> <li>6,564 (61.5%) no location posted on website</li> </ul>
Prescription Requirements:	<ul> <li>9,437 (88.5%) do not require valid prescription</li> <li>6,209 (58.2%) issue prescriptions per online consultations or questionnaires only</li> </ul>
Medications:	<ul> <li>5,355 (50.2%) offer foreign or non-FDA-approved medications</li> <li>1,309 (12.3%) dispense controlled substances</li> </ul>
Encryption:	• 1,771 (16.6%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul> <li>4,486 (42.1%) outside US</li> <li>5,711 (53.5%) inside US</li> <li>461 (4.3%) have unknown server locations</li> </ul>
Affiliations:	• 9,605 (90%) appear to have affiliations with rogue networks of Internet drug outlets

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

<sup>&</sup>lt;sup>1</sup> 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.

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



Findings of NABP Not Recommended site reviews, in total, as of December 31, 2015

B. Year-by-Year Overview: Of the rogue Internet drug outlets NABP identified in 2015, 98% do not require a valid prescription. In fact, that percentage hovered between 98% and 99% in the three preceding years, as well. Openly offering controlled substances online has become less common since 2008, when 41% of the sites identified as being out of compliance with pharmacy laws and practice standards sold controlled substances. By the close of 2014, that percentage dipped by more than half to 18.5%, but rose again in 2015 to 27.2%. It bears repeating that virtually all of the sites NABP found to be selling controlled substances in 2015 were doing so without a valid prescription. While dispensing any prescription drug without a prescription can be dangerous, it is especially so with controlled substances, which are subject to abuse.

For most rogue sites, dispensing without a valid prescription was one of several other concerning activities observed. The number of sites identified as Not Recommended that

were found to be dispensing foreign or non-Food and Drug Administration (FDA)-approved drugs ranged from 37.2% in 2009 to 88.2% in 2014 and 88.4% in 2015. On average, about a third of the Not Recommended sites have posted their location as being in a foreign country. Since 2009, however, most sites selling drugs illegally online do not post any address. These sites tend to be the ones most likely to dispense counterfeit drugs. More than half (55.8%) of the websites listed in 2015 as Not Recommended for one of the reasons above had their domain names registered anonymously. The table below provides the number of sites added to the Not Recommended list in each year from 2008 through 2015.

Characteristic	2008	2009	2010	2011	2012	2013	2014	2015
Sites Added to Not								
Recommended List	1024	3899	2060	1345	1491	362	195	147
Sites Located in	504	748	680	216	126	53	61	47
Foreign Country	(49.2%)	(19.2%)	(33%)	(16.1%)	(8.5%)	(14.6%)	(31.3%)	(32%)
	89	1084	41	251	41	8	12	5
Sites Located in US	(8.7%)	(27.8%)	(2%)	(18.7%)	(2.7%)	(2.2%)	(6.2%)	(3.4%)
Sites That Do Not	431	2067	1339	878	1324	301	122	95
Post an Address	(42.1%)	(53.0%)	(65%)	(65.3%)	(88.8%)	(83.2%)	(62.6%)	(64.6%)
Sites That Dispense								
Controlled	420	322	164	75	108	106	36	40
Substances	(41.0%)	(8.3%)	(8.0%)	(5.6%)	(7.2%)	(29.2%)	(18.5%)	(27.2%)
Sites That Do Not	971	3001	1887	1268	1478	355	193	144
Require Valid Rx	(94.8%)	(76.9%)	(91.6%)	(94.3%)	(99.1%)	(98.1%)	(99.0%)	(98.0%)
Sites That Issue Rx	565	2285	180	1002	561	219	35	15
Per Online Consult	(55.2%)	(58.6%)	(8.7%)	(74.5%)	(37.6%)	(60.5%)	(17.9%)	(10.2%)
Sites That Are Not	282	640	180	348	123	53	59	60
Secured	(27.5%)	(16.4%)	(8.7%)	(25.9%)	(8.3%)	(14.6%)	(30.3%)	(40.8%)
Sites That Offer								
Foreign or Non-FDA-	616	1450	1033	637	1005	188	172	130
Approved Drugs	(60.2%)	(37.2%)	(50.2%)	(47.4%)	(67.4%)	(51.9%)	(88.2%)	(88.4%)
Sites with Domain								
Names Not Current	247	1736	408	695	624	259	89	82
and Public	(24.1%)	(44.5%)	(19.8%)	(51.7%)	(41.9%)	(71.5%)	(45.6%)	(55.8%)
Sites That Do Not								
Provide Address of	554	3073	2034	1339	818	351	195	136
Pharmacy	(54.1%)	(78.8%)	(98.7%)	(99.6%)	(54.9%)	(97.0%)	(100%)	(92.5%)

C. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that US patients use Internet pharmacies accredited through the Verified Internet Pharmacy Practice Sites® (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

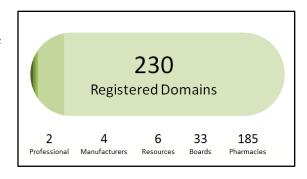




policies and procedures regarding the practice of pharmacy and dispensing of medicine over the Internet, as well as an on-site inspection of facilities used by the website to receive, review, and dispense medicine. Currently, 67 VIPPS and Vet-VIPPS pharmacy sites are listed as Recommended Internet Pharmacies. Several more applications are in progress.

- D. NABP e-Advertiser Approval Program: Sites that have been 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 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, 118 entities are listed on the NABP website as Approved e-Advertisers, and several more applications are in progress.
- E. Pharmacy TLD Program: An extension of NABP's long-standing accreditation programs, pharmacy is a restricted online community for legitimate entities, where the "safety seal" is built into the website address. The public health threat posed by rogue Internet drug outlets was the impetus for NABP's development and launch of the pharmacy Top-Level Domain (TLD). 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.

As of December 31, 2015, NABP has granted approval (in the form of electronic tokens) for 351 domain names, and 230 .pharmacy domain names have been registered, including such high-profile pharmacies as CVS, Express Scripts, PetMed Express, Target, and Rite Aid. Of



the 230 .pharmacy domain names registered, 185 are registered to pharmacies, 2 are registered to professional sites, 33 are registered to boards of pharmacy and regulatory agencies, 4 are registered to manufacturers, and 6 are registered to resource sites. Additional information about the .Pharmacy TLD Program, as well as a listing of active .pharmacy websites, is available at *www.safe.pharmacy*.

#### III. PRESCRIPTION DRUG ABUSE PROMOTED ONLINE

While programs like VIPPS and .pharmacy make finding legitimate online pharmacies easier, rogue Internet drug outlets continue to find ways to be discovered. The *Journal of Medical Internet Research* recently published a study showing that Twitter is frequently used to circulate information about drugs of abuse along with links to

"The study found over 45,000 tweets that promoted drug abuse even though we only looked at a two week period."

Co-author Timothy Mackey

online drug sellers that offer them without a prescription. The paper, "Establishing a Link Between Prescription Drug Abuse and Illicit Online Pharmacies: Analysis of Twitter Data," was co-authored by Timothy Mackey, MAS, PhD, director of the Global Health Policy Institute (GHPi) at University of California San Diego, Takeo Katsuki, PhD, and Raphael Cuomo, MPH, with support from the Alliance for Safe Online Pharmacies (ASOP Global). "This study is the first to establish an empirical link between Twitter content and illicit online pharmacies who promote the illegal sale of drugs that have significant abuse potential," Dr Mackey explained in a joint GHPi-ASOP news release. "Our results are concerning, as the study found over 45,000 tweets that promoted drug abuse even though we only looked at a two week period of Tweets."

More than three-quarters (76%) of the over 2 million Tweets analyzed that discussed drug abuse were found to contain links to a rogue marketing website that advertised the sale of the controlled substance Valium<sup>®</sup>, a commonly abused tranquilizer. This website "had a hyperlink prominently displayed on its landing page that sent users to an illegal online pharmacy that offered the sale of several other controlled substances without a prescription, a direct violation of Federal law under the Ryan Haight Act," Dr Mackey states. Young adults are the biggest abusers of prescription opioid pain relievers, ADHD stimulants, and anti-anxiety drugs, according to the US Department of Health and Human Services (HHS) and National Institute on Drug Abuse. While little research has been done tying this activity to illegal online drug sellers, this study shows a definite link – especially pertinent given that Twitter is currently used by a third of all teens and young adults.

### IV. DISCUSSION

Studies have indicated that a significant percentage of the youth population has used prescription medication non-medically and have identified a high correlation between using prescription opioids non-medically and using heroin. These substances have caused an inordinate number of deaths in recent years. While little research has linked the non-medical use of prescription drugs with illegal online drug sellers, the recent research discussed above suggests there is, indeed, a link between prescription drug abuse and the popular social media platform Twitter. While

programs like VIPPS and .pharmacy help patients to find legitimate online pharmacies, NABP plans to continue educating the public on the dangers of illegal online drug sellers and looks to regulators, enforcement authorities, and concerned stakeholders to help to curtail this activity, which can no longer be ignored. 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 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 CRF 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.