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Internet Drug Outlet Identification Program

Progress Report for State and Federal
Regulators: July 2016

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: July 2016

I. INTRODUCTION

Nearly 19,000 people died in the United States in 2014 due to an overdose of prescription pain relievers, outpacing the 10,500-plus heroin overdose deaths recorded the same year, according to data from the Centers for Disease Control and Prevention and the National Center for Health Statistics. Several states have implemented responsible prescribing policies and guidelines to help reduce the incidence of opioid overdose and diversion. While many prescription pain pills are, at least initially, obtained from legitimate sources with a doctor's prescription, opioids are also acquired illegally on the street and online. In fact, the *New York Times* reported on May 20, 2016, that opioid prescribing has declined for the first time in two decades but that overall opioid overdose deaths have increased. This finding suggests that some people using prescription opioids non-medically may be obtaining them from sources other than or in addition to their doctors. Intensifying the danger, prescription opioids obtained from illegal sources may be counterfeit or may contain powerful substances other than what the user expects, leading to unintentional overdose. As overdoses and fatalities related to the abuse of prescription opioids continue to rise, regulators and enforcement agencies have issued warnings about deadly counterfeit prescription opioids on the street. What is often overlooked, however, is that they are also readily available over the internet without a prescription from rogue internet drug outlets.

A recent study conducted by Fisher College Criminal Justice students in Boston, MA, found that opioids are readily available for purchase from multiple websites that appear to be operating illegally on the internet. This finding is consistent with research conducted by the National Association of Boards of Pharmacy® (NABP®). In the past eight years, NABP has identified over 1,300 illegally operating websites that sell controlled substances, or 12.6% of the 10,823 websites identified by NABP to be operating illegally. A more targeted Google search in April and May of 2016 found another 25 websites illegally hawking prescription opioids. Specific findings of

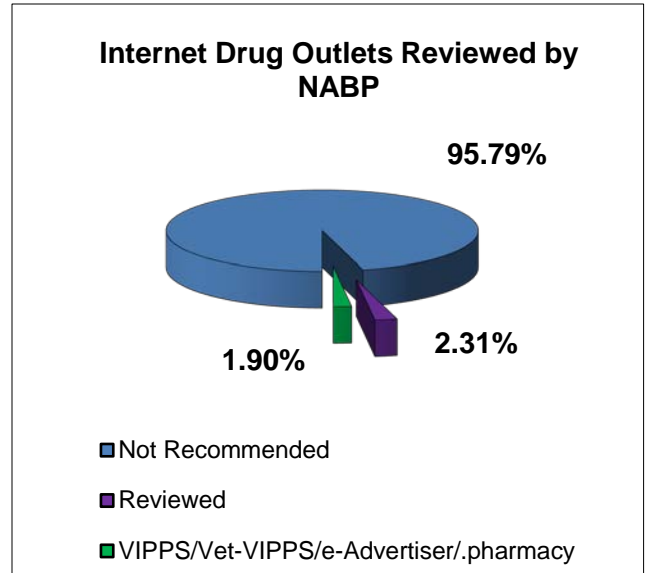
NABP’s and Fisher College’s research are provided in sections II and III of this report. Of the total number of websites reviewed by NABP, nearly 96% were found to be operating illegally and unsafely, contributing to a host of public health ills, including the opioid overdose epidemic.

II. RESULTS

A. Findings of Site Reviews to Date:

As of June 30, 2016, NABP has reviewed 11,299 internet drug outlets selling prescription medications. Of these, 10,823 (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.awarerox.pharmacy. Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs, sometimes including opioids, 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. Many also offer foreign and unapproved drugs that may contain the wrong dosage amount or even the wrong medicine. In any case, but especially in the case of opioids, these uncertainties can lead to unintentional overdose. There is also widespread concern that illegal online drug sellers are frequently the source for counterfeit medications. Illegal online drug sellers 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.



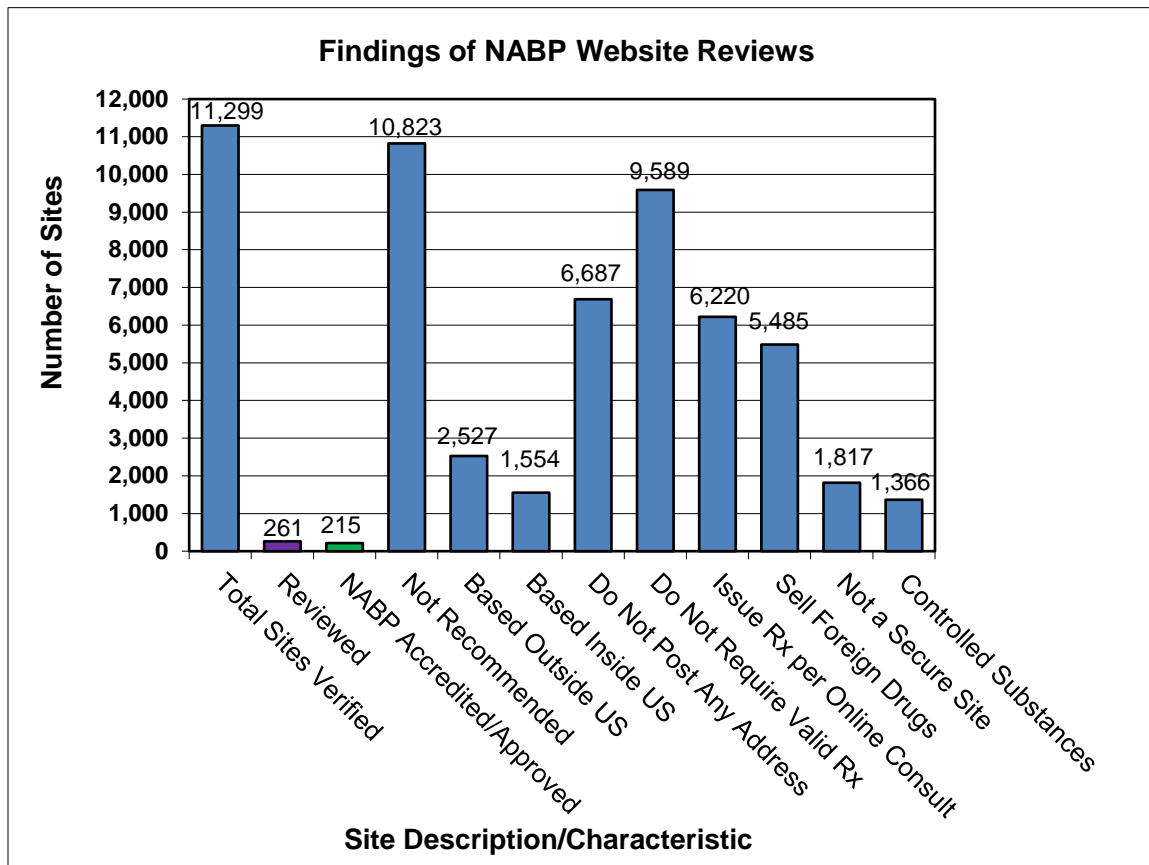
The 10,823 internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.¹

Not Recommended Sites

Physical Location:	<ul style="list-style-type: none">• 2,527 (23.3%) outside US• 1,554 (14.4%) inside US• 6,687 (61.8%) no location posted on website
Prescription Requirements:	<ul style="list-style-type: none">• 9,589 (88.6%) do not require valid prescription• 6,220 (57.5%) issue prescriptions per online consultations or questionnaires only
Medications:	<ul style="list-style-type: none">• 5,485 (50.7%) offer foreign or non-FDA-approved medications• 1,366 (12.6%) dispense controlled substances
Encryption:	<ul style="list-style-type: none">• 1,817 (16.8%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul style="list-style-type: none">• 4,583 (42.3%) outside US• 5,765 (53.3%) inside US• 461 (4.3%) have unknown server locations
Affiliations:	<ul style="list-style-type: none">• 9,628 (89%) appear to have affiliations with rogue networks of internet drug outlets

Sites listed as Not Recommended, in total, as of June 30, 2016

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.



Sites listed as Not Recommended, in total, as of June 30, 2016

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

Two hundred sixty-one (2.3%) of the 11,299 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 Top-Level Domain (TLD) Program. Two hundred fifteen (1.9%) of the 11,299 sites selling prescription medications to US patients were accredited through VIPPS or Vet-VIPPS programs or were approved through the e-Advertiser Approval or .Pharmacy TLD programs.

B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that patients use internet pharmacies that have been reviewed and approved by NABP. These sites include entities 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, 69 pharmacies are listed on the NABP website as VIPPS and Vet-VIPPS accredited, and 135 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.

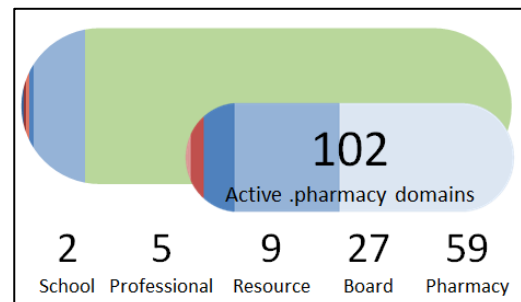
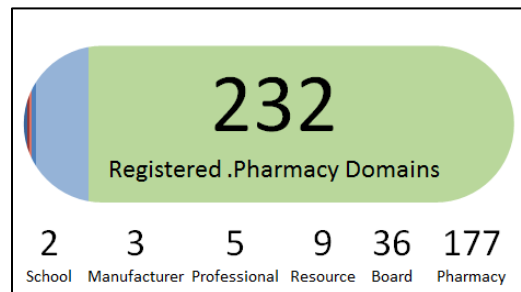


C. .Pharmacy TLD Program: .Pharmacy is the evolution of NABP's ongoing efforts to create a safe online environment for



consumers. NABP has, as of June 30, 2016, granted approval for 388 domain names, and 232 .pharmacy domain names have been registered. Of these, 177 were registered to pharmacies, 5 were registered to professional sites, 36 were registered to boards of pharmacy or regulatory agencies, 9 were registered to resource sites, 3 were registered to manufacturers, and 2 were registered to schools or colleges of pharmacy. The 40 pharmacies that registered 177 domain names represent approximately 12,220 brick-and-mortar stores.

Of the 232 .pharmacy domain names registered, 102 are in use, while the remaining registered domain names are parked. Of those that are in use, 59 are registered to pharmacies, 27 are registered to boards of pharmacy or regulatory agencies, 9 are registered to resource sites, 5 are registered to professional sites, and 2 are registered to schools or colleges of pharmacy. Of the domain names in use, 7 are being used as the registrant's primary domain name, 88 are redirecting to another domain name, and 7 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.

III. PRESCRIPTION OPIOIDS SOLD ON THE STREETS AND ONLINE

Many states have implemented responsible policies to address the opioid overdose epidemic, focusing primarily on prescribing practices and addiction recovery. Receiving less attention are the prescription opioids obtained from illicit sources. Though to a lesser extent than prescribed drugs, these illegally obtained prescription drugs, sometimes counterfeit or tainted, contribute to overdose deaths. Some regulators have issued warnings on the availability of illegally manufactured pain medicines on the streets and the danger they pose to users. These warnings, however, rarely note that prescription opioids are also available over the internet without a prescription from rogue internet drug outlets. Research conducted by NABP and others suggests that diverted and counterfeit opioids may find their way to consumers by way of the internet.

- A. Government Agencies Warn of Counterfeit Opioids: The Drug Investigation Division of the Tennessee Bureau of Investigation issued a warning on July 7, 2016, about the prevalence of fake Percocet® pills being sold on the streets. The counterfeit pills have been found to contain potentially lethal ingredients. Numerous overdoses across Middle Tennessee are being attributed to this batch of drugs. In a related case, the US Attorney's Office of the Southern District of California reported in an April 14, 2016 news release that hundreds of counterfeit oxycodone pills seized during an attempted smuggling across the border from Mexico earlier this year turned out to be the much more potent drug fentanyl. Authorities in Southern California attribute dozens of overdoses and at least 11 deaths to the counterfeit pills. In a statement at a US House of Representatives committee hearing, "America's Heroin and Opioid Abuse Epidemic," on March 22, 2016, Drug Enforcement Administration Deputy Assistant Administrator Louis J. Milione said the nation's opioid overdose epidemic is spurred by nonmedical abuse of prescription opioids, along with heroin and illicit fentanyl use. The statement also describes black-market sales for opioid prescription drugs and their contribution to the opioid epidemic. Like heroin, counterfeit prescription opioids purchased on the street vary in purity and dosage amounts, are often laced with other substances such as fentanyl, and can cause unintentional overdose.

B. **Study Finds Opioids Readily Available Online:** A research project by the Fisher College Criminal Justice Division in Boston, MA, found various types of opioids easy to locate and obtain illegally through multiple online platforms. The researchers investigated the availability of opioids on the internet as an extension of the Commonwealth of Massachusetts’ policy to address the increase of opioid abuse, addiction, and harm within the state. The state’s policy focuses mainly on overprescribing, theft, and treatment for addicts. “What may be missed in these efforts,” according to the study, “is Internet opioid traffic which completely falls outside of the traditional physician-pharmacist-patient supply chain of potentially dangerous and addictive drugs.” The study, *Online Opioids: Report Concerning Ease of Access, Highlighting Potential Solutions Using Existing Laws and Technology*, suggests that successful policy efforts to limit the availability of opioids through traditional channels may actually increase use of the internet as a source for the drugs.

‘What may be missed in these efforts is Internet opioid traffic which completely falls outside of the traditional physician-pharmacist-patient supply chain of potentially dangerous and addictive drugs.’

The researchers sought to determine the availability of opioids (Demerol[®], Dilaudid[®], Duragesic[®], Exalgo[®], Kadian[®], Lorcet[®], Lortab[®], Percocet[®], Roxicet[®], Vicodin[®], and Zohydro[®]) online using popular search engines (Google, Bing, and Yahoo!), shopping websites (eBay, Craigslist, Yahoo! Shopping, Overstock.com, Etsy, Oodle, eCRATER, Bonanza, Sell.com, Blujay, and Alibaba), and social media websites (YouTube and Twitter). The study, published on May 12, 2016, found that opioids were easiest to find – and readily available – using search engines. The shopping websites did not sell opioids themselves but had links to external websites that did. Regardless of the search engine, shopping website, or social media website used, researchers found that the final destination was a dedicated website selling opioids illegally. In searching for opioids online, student researchers found that the final destination shops offered nearly all opioids and/or substituted branded names for generics or vice versa.

The study also found that most websites directly engaged in opioid traffic operate at least to some degree in the US and appear to be in violation of existing law. Overall, the researchers collected and reviewed 252 websites, finding 164 had some or all of their technical infrastructure in the US. The Ryan Haight Online Pharmacy Consumer Protection Act

requires internet pharmacies to clearly disclose their location, their license, the names of professionals affiliated with the pharmacy, and other regulatory compliance documentation. The researchers indicate that the opioid websites reviewed in this study did not display location or license and/or offered opioids without prescription. The study points out that the law also permits the attorney general in one state to enforce against an illegal internet drug seller in another state, noting, “there is no legal excuse for flagrantly violating opioid websites anywhere in the US.”

- C. NABP Identifies Rogue Websites Selling Opioids: The findings of the Fisher College study are consistent with what NABP research has shown – that the internet remains a viable source for obtaining controlled substances illegally. While prescription opioids may not be the most commonly available drugs advertised by rogue internet drug outlets, they are certainly among them. Overall, 12.6% of all of the websites NABP has identified as Not Recommended were found to offer controlled substances. A more targeted search during the current quarter for websites selling prescription opioids, however, found nearly three times that percentage. From April 1 to June 30, 2016, NABP identified 138 sites operating out of compliance with pharmacy laws. Of those 138 sites, 136 (99%) do not require a valid prescription, 115 (83%) offer foreign or non-Food and Drug Administration-approved drugs, 36 (26%) do not have secure sites, and 48 (35%) dispense controlled substances. Twenty-five (18%) of the 138 noncompliant sites offer some or all of the same prescription opioids targeted in the Fisher College study.

IV. DISCUSSION

NABP applauds the work that states have done to address the opioid overdose epidemic to date. Many of the states’ programs and policies aimed at reducing this problem appropriately target prescribing practices and doctor shopping. Research shows, however, that it may also be important to consider illegal online drug sellers as contributors to the problem.

NABP continues to work with regulators and stakeholders to help shut down rogue internet drug outlets and eliminate the risks they pose to public health. The Association has been accrediting legitimate internet pharmacies since 1999, and the .pharmacy domain name now makes it easy to identify verified websites simply by looking to the right of the dot in a web address. Granted, making it easier to identify legitimate websites will do little to discourage opioid addicts from seeking drugs through illicit sources. Education, however, might. Raising awareness of the dangers of rogue internet drug outlets and the risk of overdose from counterfeit and tainted substances may cause consumers to think twice before buying medicine from unknown and

unapproved sources online. With continued urging from this community, internet service providers may also take a more active role in protecting consumers from illegal online drug sellers.

NABP continues to support the state boards of pharmacy in their mission to protect the public health. 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 medications. 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.