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Internet Drug Outlet Identification Program

Progress Report for State and Federal
Regulators: October 2016

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: October 2016

I. INTRODUCTION

Pharmacists are the backbone of patient care when it comes to using medication safely. Yet many websites selling prescription medication illegally and purporting to be pharmacies lack this vital component. In recognition of American Pharmacists Month, it is fitting to recognize the important role that pharmacists play in patient care. Because they interact directly with patients, they are also well positioned to educate patients on medication safety, and that includes avoiding illegal online drug sellers. For a pharmacy, having an online presence should not mean sacrificing patient care. Those pharmacies that have .pharmacy domain names, for example, must meet pharmacy practice standards, which include making it possible for patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of an adverse event involving their medication. Illegal online drug sellers, if they provide any contact details at all, sometimes provide the phone number for a call center where customer service representatives can assist in taking orders and credit card details but offer no pharmacy-related expertise. A lack of adequate patient care is one of many concerns relating to illegal online drug sellers. To date, the National Association of Boards of Pharmacy[®] (NABP[®]) has reviewed over 11,000 websites selling prescription medications to patients in the United States and has found approximately 96% of them to be operating illegally. Details of these findings are provided in the Results section below. Further discussion of the important role of the pharmacist in patient care and education is included in section III of this report.

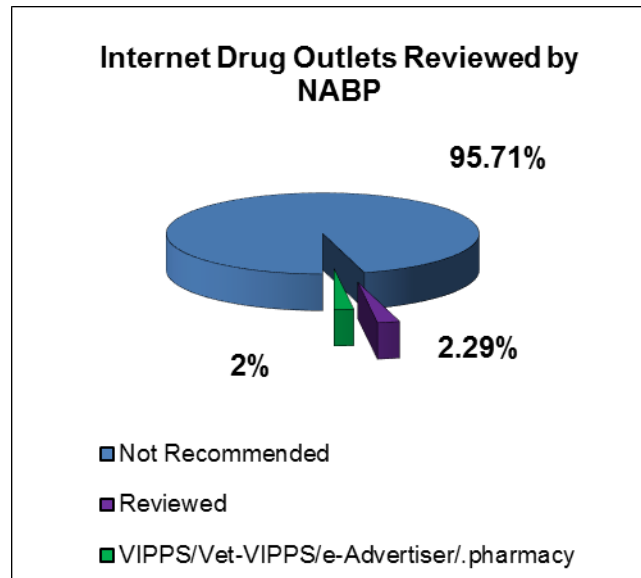
II. RESULTS

A. Findings of Site Reviews to Date:

As of September 30, 2016, NABP has reviewed 11,415 internet drug outlets selling prescription medications. Of these, 10,925 (95.71%) 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 Initiatives/.Pharmacy Verified Domain on the NABP website, www.nabp.pharmacy, as well as on NABP’s AWARE^xE[®] Prescription Drug Safety website, www.AWAREx.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. Many also offer foreign and unapproved drugs that may contain the wrong dosage amount or even the wrong medicine. 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, let alone contact information for the dispensing pharmacy or a way to reach a pharmacist, and nearly half have their domain names registered anonymously.



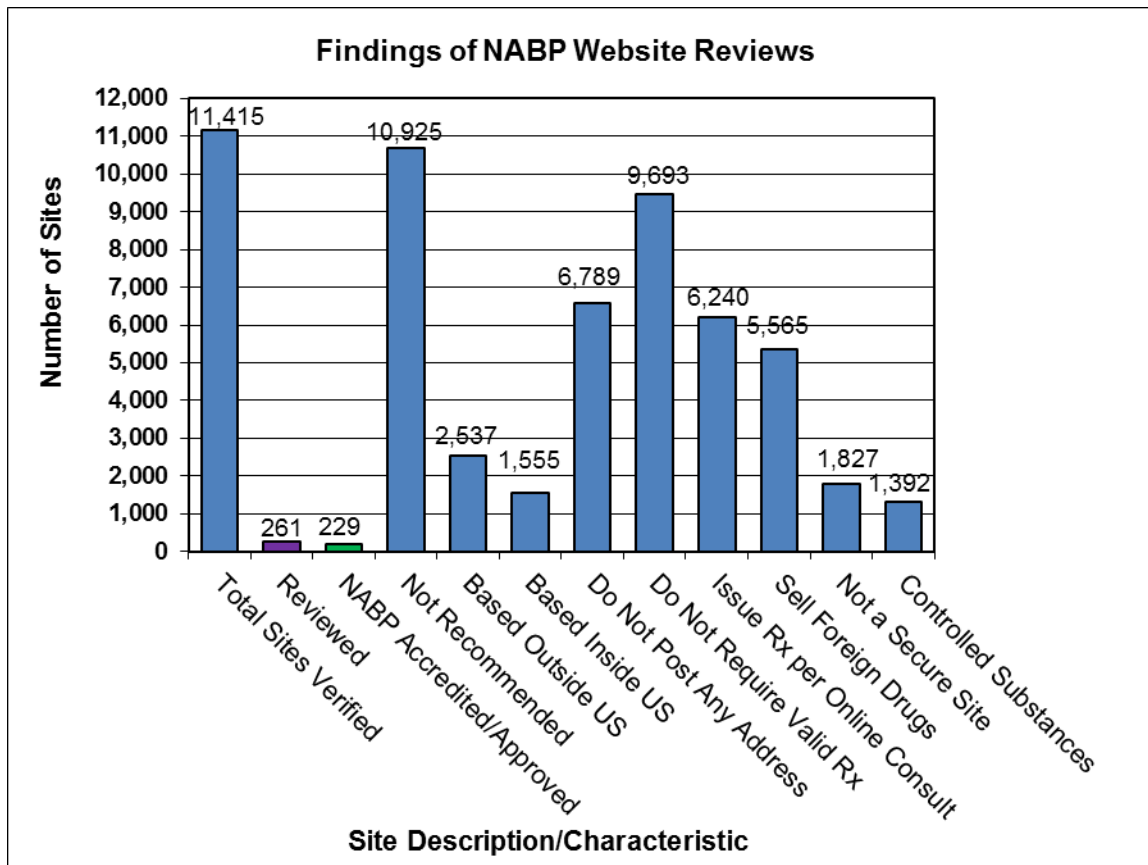
The 10,925 internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.¹

Not Recommended Sites

Physical Location:	<ul style="list-style-type: none"> • 2,537 (23.2%) outside US • 1,555 (14.2%) inside US • 6,789 (62.1%) no location posted on website
Prescription Requirements:	<ul style="list-style-type: none"> • 9,693 (88.7%) do not require valid prescription • 6,240 (57.1%) issue prescriptions per online consultations or questionnaires only
Medications:	<ul style="list-style-type: none"> • 5,565 (50.9%) offer foreign or non-FDA-approved medications • 1,392 (12.7%) dispense controlled substances
Encryption:	<ul style="list-style-type: none"> • 1,827 (16.7%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul style="list-style-type: none"> • 4,650 (42.6%) outside US • 5,800 (53.1%) inside US • 463 (4.2%) have unknown server locations
Affiliations:	<ul style="list-style-type: none"> • 9,652 (88.3%) appear to have affiliations with rogue networks of internet drug outlets

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

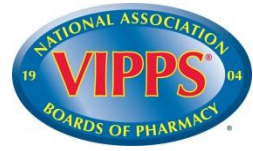
¹ It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found 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.



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

Two hundred sixty-one (2.29%) of the 11,415 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 twenty-nine (2%) of the 11,415 sites selling prescription medications or offering resources to US patients were accredited through VIPPS or Vet-VIPPS programs or were approved through the e-Advertiser Approval or .Pharmacy TLD programs.

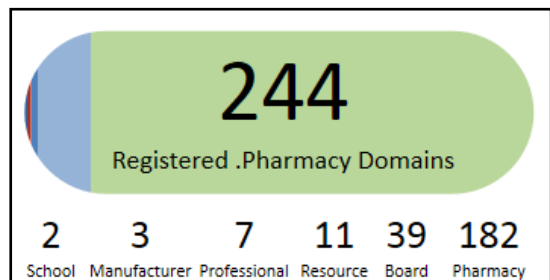
B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that patients use internet pharmacies that have been reviewed and approved by NABP. These sites include entities granted VIPPS or Vet-VIPPS accreditation, Approved e-Advertiser status, or a .pharmacy 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, 73 pharmacies are listed on the NABP website as VIPPS and Vet-VIPPS accredited, and 147 entities are listed as Approved e-Advertisers. Seventy .pharmacy registered entities are currently listed on the .Pharmacy TLD Program website, *www.safe.pharmacy*. NABP is no longer accepting applications for the Vet-VIPPS and e-Advertiser Approval programs, as these programs are being streamlined into the .Pharmacy TLD Program. Several .pharmacy applications are in progress.



C. .Pharmacy TLD Program: .Pharmacy is the evolution of NABP’s ongoing efforts to create a safe online environment for consumers. Online pharmacy practice is not going away. Unfortunately, neither is online fraud. Increasing reliance on technology in health care makes it more vital than ever to have a simple tool for legitimate entities to readily identify themselves, and for consumers to recognize them, as having been vetted and approved by a trustworthy organization. NABP’s .pharmacy TLD is such a tool. With .pharmacy, unlike other programs that use seals and logos that can easily be faked, the “seal of approval” is built into the web address. .Pharmacy is a verified TLD, meaning that applicants are evaluated for compliance with registry standards prior to being allowed to use a .pharmacy domain name.



NABP has, as of September 30, 2016, granted approval for 406 domain names, and 244 .pharmacy domain names have been registered. Of these, 182 were registered to pharmacies, 7 were



registered to professional sites, 39 were registered to boards of pharmacy or regulatory agencies, 11 were registered to resource sites, 3 were registered to manufacturers, and 2 were registered to schools or colleges of pharmacy.

Of the 244 .pharmacy domain names registered, 115 are in use while the remaining registered domain names are parked. Of those that are in use, 64 are registered to pharmacies, 32 are registered to boards of pharmacy or regulatory agencies, 10 are registered to resource sites, 7 are registered to professional sites, and 2 are registered to schools or colleges of pharmacy. Of the domain names in use, 9 are being used as the registrant's primary domain name, 99 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. PHARMACISTS' CRITICAL ROLE IN PATIENT CARE

Pharmacists have a critical role to play in patient care – a point central to American Pharmacists Month. Occurring annually in October, the event spotlights pharmacists as medication experts and integral members of their patients' health care team. In its observation of American Pharmacists Month, the American Pharmacists Association (APhA) spotlights pharmacists' contributions toward improving medication use and advancing patient care in all practice settings. The goal of American Pharmacists Month, says APhA, is "to educate the public, policy makers and other health care professionals about the role pharmacists play in the reduction of overall health care costs and the safe and effective management of medications. Pharmacists have a significant role in assessing patients' medication management in patients and referring them to physicians."

The International Pharmaceutical Federation (FIP) recognizes the critical role of pharmacists in patient care on World Pharmacists Day each year on September 25. The theme of the 2016 World Pharmacists Day was "Pharmacists: Caring for You." As FIP President Dr Carmen Peña explains on the FIP website, "The role of pharmacists has

evolved from that of a provider of medicines to that of a provider of care. Pharmacists have a vital role in the outcome of pharmacological therapies and ultimately strive to improve patients' quality of life." The American Society of Health-System Pharmacists (ASHP) set aside October 16-22, 2016 as National Pharmacy Week to recognize pharmacists and technicians. During this time, ASHP encourages pharmacists to celebrate their achievements in ensuring safe and effective medication use.

NABP, too, recognizes pharmacists' expertise and supports their increased role in patient care. The NABP Task Force of Pharmacist Prescriptive Authority convened in September 2015 to discuss existing regulations that allow pharmacists to manage patients' drug therapy and agreed on expanding the role of pharmacists in health care delivery systems. The task force recommended NABP support pharmacists having limited ability to initiate, modify, and terminate drug therapy under certain circumstances including, but not limited to, collaborative practice agreements and state protocols. Members discussed today's changing health care delivery landscape and indicated that pharmacists, who are the most accessible health care team member, may be the key to reaching patients with health care services that they may not otherwise receive or have difficulty accessing.

As providers directly involved in patient care, pharmacists are optimally positioned to educate patients. APhA encourages patients to "Know Your Pharmacist, Know Your Medicine." That is good advice, especially when patients are seeking to obtain medication and pharmacy-related information over the internet. Having an internet presence need not be a barrier to the pharmacist's role in patient care. Legitimate internet pharmacies, such as those with a web address ending in the .pharmacy TLD, use their websites as an extension of patient service. Patients have easy access to the pharmacist through the website and over the phone.

One of the 10 core safety standards that all pharmacies must meet in order to qualify for a .pharmacy domain name concerns patient care. The standard reads:

***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.

These program standards, along with additional information about the .pharmacy TLD, are available on the .pharmacy website at www.safe.pharmacy.

As practitioners on the front line of patient care, pharmacists are also well positioned to educate patients on the dangers of rogue internet drug outlets, including the risk of obtaining counterfeit medicine. The Alliance for Safe Online Pharmacies is preparing to launch a campaign encouraging health care providers to recognize this risk and educate their patients to make safe choices when buying medication. People trust their pharmacist. Consumer studies conducted by the Center for Safe Internet Pharmacies show that people are more likely to trust safety advice when it comes from a health care provider than just about any other source, including friends and family. This trust factor makes it especially important to health care providers, including pharmacists, to be aware of medication-related hazards, such as buying medicine from unknown and unapproved foreign sources, and to share this information with their patients.

IV. DISCUSSION

NABP continues to recognize and support the important role of pharmacists in patient care. The lack of availability of a pharmacist to counsel patients is one of the problems of illegal online drug sellers. Legitimate pharmacies with an online presence use their website as an extension of their services and have a pharmacist at the ready to counsel patients when needed. Technology is taking on a growing role in health care, but the pharmacist's direct interaction with patients remains an important part of the practice. 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.pharmacy.

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.