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# Internet Drug Outlet Identification Program

Progress Report for State and  
Federal Regulators: April 2013

**TABLE OF CONTENTS**

I. INTRODUCTION ..... 3

II. RESULTS ..... 4

    A. Findings of Site Reviews ..... 4

    B. Recommended Internet Pharmacies ..... 6

    C. Accreditation and Approval Programs ..... 6

III. INTERNATIONAL SCOPE AND DEVELOPMENTH OF .PHARMACY gTLD ..... 7

    A. Internet-Fueled Threat of Counterfeit Medicine Warrants Global Action ..... 7

    B. International Coalition of Stakeholders Backs .PHARMACY gTLD Initiative ..... 8

IV. DISCUSSION ..... 9

V. APPENDIX: Internet Drug Outlet Identification Program Standards ..... 11



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## **INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: April 2013**

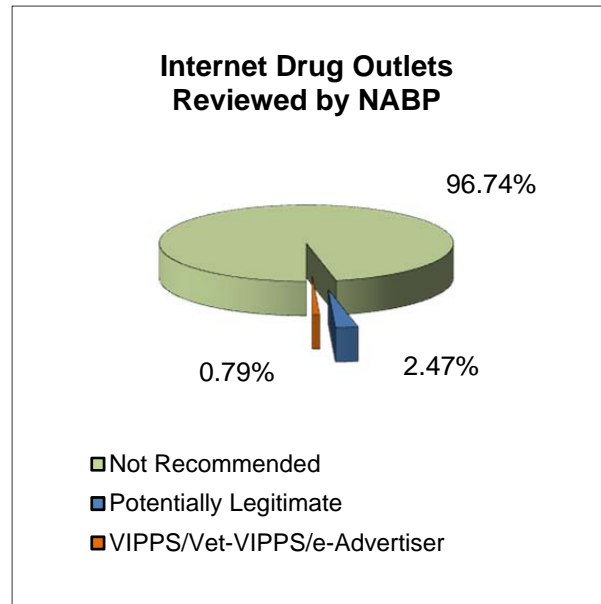
### **I. INTRODUCTION**

Illegal online drug sellers have played a significant role in the global spread of counterfeit and substandard medicine. They pose a public health problem that is indifferent to the jurisdictional boundaries of any one nation, and that must be addressed in cooperation with partners around the world. Recognizing the international scope of this problem, National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) and its member boards are working with regulatory authorities, industry leaders, and stakeholder groups worldwide to protect patient health. These efforts are exemplified in NABP's application to the Internet Corporation for Assigned Names and Numbers (ICANN) to own and operate the .PHARMACY generic Top-Level Domain (gTLD). Domain names in the .PHARMACY gTLD will be available to legitimate online pharmacies and prescription drug-related organizations worldwide. NABP and its partners have made significant progress in recent months to develop best practices for the use of .PHARMACY domain names and to clarify the intent and scope of this initiative.

While the .PHARMACY initiative moves forward on a global scale, NABP's Internet Drug Outlet Identification Program maintains its primary focus on Web sites selling prescription medicine to patients in the United States. NABP continues to find the vast majority of drug sites (97% of those reviewed) to be operating in contravention with US federal and state pharmacy laws. These sites, identified on the NABP Web site as Not Recommended, are characterized in Section II of this report. These findings and the concerns they raise, however, are not unique to the US. The global scope of the problem, and how the .PHARMACY initiative seeks to address this challenge, is discussed in Section III.

## II. RESULTS

A. Findings of Site Reviews: In all, as of March 29, 2013, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,421 Internet drug outlets selling prescription medications. Of these, 10,082 (96.74%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards, and are listed as Not Recommended in the “Buying Medicine Online” section, under Consumers, on the NABP Web



site, as well as on NABP’s consumer protection Web site, [WWW.AWARERX.ORG](http://WWW.AWARERX.ORG). This Web site is part of the AWA<sub>R</sub>x<sub>E</sub>® Consumer Protection Program, provided by NABP and the state boards of pharmacy to help educate the public about the risks of Internet drug outlets, and includes news, tips, and links to relevant NABP resources. It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of Web sites 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. Thanks to the successes of multistakeholder efforts to shut down rogue sites, many of these sites may now be defunct. It should also be noted that the numbers reported here do not represent the entire universe of Web sites selling prescription drugs illegally, but, rather, a representative sampling of the online environment over the last five years. The 10,082 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

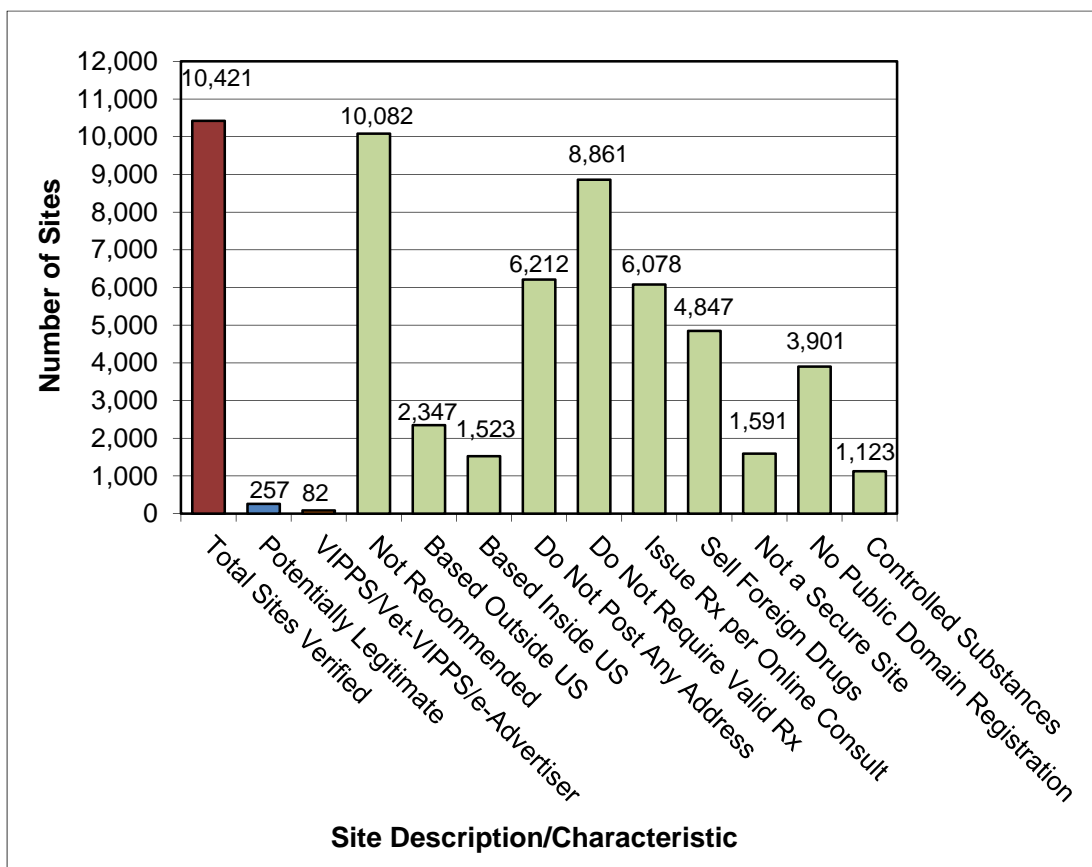
- 2,347 (23.3%) have a physical address located outside of the US
- 1,523 (15.1%) have a physical address located inside of the US
- 6,212 (61.6%) do not post any address
- 8,861 (87.9%) do not require a valid prescription
- 6,078 (60.3%) issue prescriptions per online consultation or questionnaire only
- 4,847 (48.1%) offer foreign or non-Food and Drug Administration (FDA)-approved drugs

- 1,591 (15.8%) do not have secure sites, exposing customers to financial fraud and identity theft
- 4,065 (40.3%) have server locations in foreign countries
- 1,123 (11.1%) dispense controlled substances (of these, 1,094 (97.42%) do not require a valid prescription)
- 3,901 (38.7%) do not have a public domain name registration (WHOIS information is registered using a privacy or proxy service)<sup>1</sup>

Of the total 10,421 sites reviewed, 257 (2.47%) 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. Eighty-two (0.79%) of the 10,421 reviewed sites have been accredited through NABP's Verified Internet Pharmacy Practice Sites<sup>CM</sup> (VIPPS<sup>®</sup>) or Veterinary-Verified Internet Pharmacy Practice Sites<sup>CM</sup> (Vet-VIPPS<sup>®</sup>) programs, or approved through the NABP e-Advertiser Approval<sup>CM</sup> Program. The standards against which NABP evaluates Internet drug outlets are provided in the appendix of this report.

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<sup>1</sup> It is noteworthy that the percentage of sites identified as Not Recommended that are registered privately or by proxy (38.7%) is considerably higher than that of domain names overall. This comparison is based on an ICANN study in 2009 that sampled 2,400 domain names and found 429 (18%) of them to be registered using a WHOIS privacy or proxy service. Domain name registration (ie, WHOIS information) is an issue of contention among Internet policy stakeholders. Some have suggested that privacy/proxy services are being abused to obscure the identity of perpetrators that use the domains for illegal activities. Enforcement authorities have encouraged requirements for accurate registrant and contact information in WHOIS records to enable the identification and prosecution of bad actors. NABP considers accurate domain name registration to be an important indicator of accountability and approval standards require accurately registered domain names. Further studies are ongoing in the Internet community to support or refute this correlation.



Findings of NABP Web site reviews, in total, as of March 29, 2013

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, 52 VIPPS and Vet-VIPPS pharmacy sites, representing more than 12,000 pharmacies, are listed as Recommended Internet Pharmacies. Several more applications are in progress.



C. Accreditation and Approval Programs: In addition to identifying rogue sites, the Internet Drug Outlet Identification program staff continues to assist in screening applicant Web sites for the VIPPS, Vet-VIPPS, and



e-Advertiser Approval programs. Sites that have received 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 Web site as Approved e-Advertisers. The standards that NABP uses to screen e-Advertiser Approval Program applicants are posted in the e-Advertiser Approval Program section, under Accreditation, on the NABP Web site. As of March 29, 2012, there were 30 entities listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.

### **III. INTERNATIONAL SCOPE AND DEVELOPMENT OF .PHARMACY gTLD**

- A. Internet-Fueled Threat of Counterfeit Medicine Warrants Global Action: While the illegal distribution of prescription drugs over the Internet poses many dangers, the threat that most worries public health agencies is the spread of substandard and counterfeit medicine. In its February 2013 report, *Countering the Problem of Falsified and Substandard Drugs*, the Institute of Medicine (IOM) notes that illegal online drug sellers contribute significantly to the spread of counterfeit and substandard medications worldwide, owing to the poor quality of the products they sell and the lack of official oversight of their operations. “All drugs sold outside the legitimate chains are suspect,” the IOM report states. “This includes medicines sold in unregulated markets and most drugs sold on the Internet.”

On its Web site, INTERPOL highlights the role of the Internet in perpetuating this problem, stating, “The increasing prevalence of counterfeit and illicit goods has been compounded by the rise in Internet trade, where they can be bought easily, cheaply and without a prescription.” INTERPOL announced on March 12, 2013, that, with the support of the pharmaceutical industry, it is expanding the scope of its Medical Product Counterfeiting and Pharmaceutical Crime Unit to combat the global health threat of counterfeit and fake medicines. A representative of INTERPOL participated in a recent meeting of the .PHARMACY gTLD Advisory Committee at NABP Headquarters.

Partnership for Safe Medicines applauds INTERPOL’s enhanced law enforcement effort in a March 12, 2013 news release, stating, “Counterfeit medicines threaten the lives of millions of people around the world, and finding ways to address such a complex, far-reaching issue requires ever-increasing global cooperation.”

The situation is similar the United Kingdom, where the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) describes on its Web site an "explosion" in recent years of Web sites selling medicine online, most of which do not meet regulatory standards established in the region to protect patient health. In a March 27, 2013 news release announcing the sentencing of perpetrators in a counterfeit medicines case, MHRA stresses its commitment to "pursuing those involved in the illicit supply of medicines and taking action to ensure the public is protected." MHRA warns consumers that buying medicines from unauthorized sources significantly increases the risk of getting substandard or fake medicines.

- B. International Coalition of Stakeholders Backs .PHARMACY gTLD Initiative: Mindful of the international spread of unapproved, substandard, and counterfeit medicine, and the contributing role that illegal online drug sellers play, NABP is taking steps to establish an online space exclusively for legitimate Internet pharmacies and other trustworthy prescription drug-related organizations. NABP has applied for the .PHARMACY gTLD as a community-based application on behalf of international pharmacy coalitions and national pharmacy associations, representing legitimate online pharmacies and prescription drug-related organizations worldwide.

ICANN's new gTLD program is expected to vastly alter the Internet landscape with the addition of hundreds of new gTLDs. Not surprisingly, it has led to some confusion and misinformation in relation to new gTLDs, including .PHARMACY. Contrary to misinformation that has appeared recently in some public forums, the .PHARMACY gTLD will *not* be limited to US pharmacies. It will be available to legitimate online pharmacies and prescription drug-related organizations worldwide. It has been suggested that .PHARMACY would give an unfair advantage to US pharmacies, would work against the interests of the public health, and impede online access to safe and affordable medicine. To clarify, NABP confirms that its intent for .PHARMACY is to ensure that only legitimate Internet pharmacies and related entities – those that adhere to pharmacy laws in the countries where they are based, as well as in the countries where they sell medicine – would be permitted to register in .PHARMACY. This includes legitimate online pharmacies and related entities that are located in countries other than the US. It is the position of NABP, and of the global coalition of stakeholders that has encouraged and supported this initiative, that requiring .PHARMACY registrants to comply with international standards does serve the public interest.

In February 2013, NABP convened its first meeting of the .PHARMACY gTLD Advisory Committee, composed of industry experts representing multiple countries and disciplines.



The meeting provided a history and overview of ICANN's new gTLD program, NABP's impetus and objectives in taking on this initiative, as well as input and perspectives from stakeholders including LegitScript, EAASM, and International Pharmaceutical Federation (FIP). Other industry experts working with NABP on the .PHARMACY initiative are the Canadian National Association of Pharmacy Regulatory Authorities, the US Alliance for Safe Online Pharmacies, Eli Lilly and Company, Merck and Company Inc, INTERPOL, and several of NABP's member boards of pharmacy.

Discussion at the February meeting focused on establishing a system of governance for the .PHARMACY gTLD that will ensure that it represents the global pharmacy community in the best interest of patient safety. Committee members are also considering a plan to identify and define a universal, common set of standards that would be consistently required of all domain name registrants in the .PHARMACY gTLD. These common standards would be supplemented by national specifications that would be required of registrants in those jurisdictions and may address variant policies relating to patient privacy, controlled substances, prescription requirements, and practitioner license requirements. The committee also discussed the scope of the .PHARMACY gTLD described in the application; domain names in the .PHARMACY gTLD will be available not only to legitimate pharmacies but also to approved schools and colleges of pharmacy, prescription drug manufacturers, patient advocacy groups, and other entities providing pharmacy or prescription drug-related services or information, in the interest of patient safety and the global pharmacy community.

Advisory committee members will hold follow-up discussions in the coming months to define domain name registration criteria, authorized usage policy, and compliance strategy for the .PHARMACY gTLD, as well as partnership opportunities for public outreach and consumer education to build public awareness of, and confidence in .PHARMACY. The advisory committee will reconvene via teleconference and/or Webinar in third quarter 2013 to further discuss the governance, standards, and outreach of the .PHARMACY gTLD.

#### **IV. DISCUSSION**

Rogue Internet drug outlets fuel the spread of counterfeit and substandard medicine, along with the public health problems they cause on a global scale. By working in concert with regulatory authorities, law enforcement, industry experts, and patient safety advocates across national borders, NABP seeks to help establish a safe online space where the health care community and patients alike can be sure the medicine they buy online is authentic and safe. The .PHARMACY gTLD, as proposed, will be available to legitimate pharmacies and other prescription drug-related

organizations worldwide that adhere to all applicable pharmacy laws in the countries where they are based and where they do business. Recognizing that international collaboration is needed to protect patient health, NABP and its partners are committed to upholding the integrity of the practice of pharmacy, curtailing the online trade of illicit and counterfeit medications, and ensuring that patients have access to safe and effective prescription drugs. Ultimately, this initiative will assure the health care community and patients worldwide that all pharmacy sites ending in the .PHARMACY gTLD are safe and legitimate. More information about NABP's application for the .PHARMACY gTLD is available on the NABP Web site at [www.nabp.net/programs/pharmacy/pharmacy-and-nabp](http://www.nabp.net/programs/pharmacy/pharmacy-and-nabp). For further information on this initiative or the Internet Drug Outlet Identification Program, please contact Melissa Madigan, policy and communications director, via e-mail at [mmadigan@nabp.net](mailto: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 Web site 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 Web site an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the Web site an accurate, readily accessible and responsive phone number or secure mechanism via the Web site, 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. **Web site transparency.** The pharmacy must not engage in practices or extend offers on its Web site 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 Web sites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated Web sites.** The pharmacy, Web site, 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 Web site that violates these standards.