



nabp

National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014

Tel: 847/391-4406 • Fax: 847/391-4502

Web Site: www.nabp.net

Internet Drug Outlet Identification Program

**Progress Report for State and
Federal Regulators:
July 2012**

TABLE OF CONTENTS

I. INTRODUCTION 3

II. RESULTS 4

 A. Findings of Site Reviews 4

 B. Recommended Internet Pharmacies 5

 C. Accreditation and Approval Applicant Screenings 5

III. PHARMACY REGULATION ON A GLOBAL SCALE..... 6

 A. Stakeholders Find Strength in Collaboration 6

 B. Proposed .Pharmacy gTLD Offers Consumer Safety ‘Net’ 9

IV. DISCUSSION 10

V. APPENDIX: Internet Drug Outlet Identification Program Criteria..... 12



National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

nabp

INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: July 2012

I. INTRODUCTION

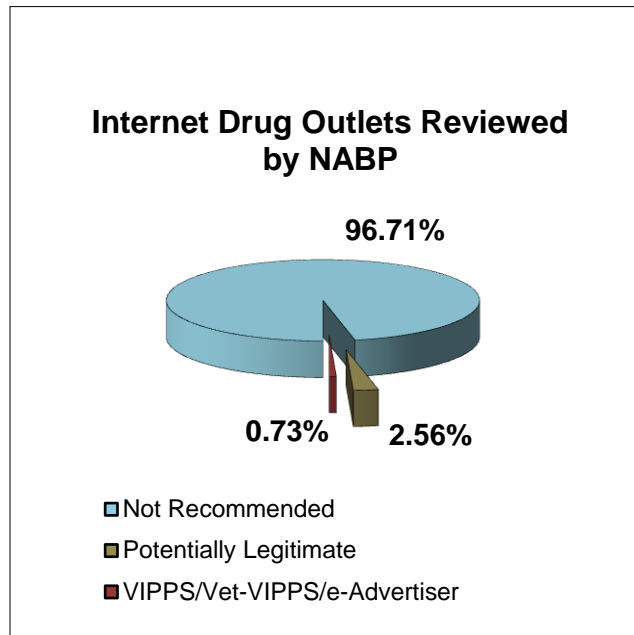
Unfortunately but undeniably, prescription medication counterfeiting has taken hold in the global marketplace, threatening public health worldwide. The illicit trade is perpetuated through a labyrinth of international transactions by multiple parties at various points along the medication supply chain, often ending with the rogue Internet drug outlets that sell the fake drugs to unwary consumers. As a result of this tangled supply chain, accountability for the safety and efficacy of medicines purchased from unknown Web sites is, in many cases, virtually nil. When counterfeit medicines emerge, as they have repeatedly in the last year, it is difficult to trace their origin, the point in the supply chain at which they were introduced, who perpetuated the illegal transaction, and which parties knew about it and enabled it in any way. Because Internet commerce transcends geographical and jurisdictional borders, protecting the public health requires the coordinated efforts of multiple, international public and private entities to diminish the threat that counterfeiters and rogue sellers pose.

This theme emerged at multiple points during the National Association of Boards of Pharmacy[®] (NABP[®]) 108th Annual Meeting, held in May 2012, in Philadelphia, PA. NABP leadership discussed the need to become more active in pharmacy regulation on a global scale and described current initiatives to adapt to these changes. Also during the Annual Meeting, NABP convened a panel of experts from various public and private sectors to discuss ways in which partnerships can stop illegal online drug sellers. The collaborative strategies discussed during the meeting are described further in Section III of this report.

As NABP continues to review and monitor Web sites selling prescription drugs, its findings remain fairly consistent – and consistently troubling – with 97% of the more than 10,000 Web sites reviewed operating out of compliance with pharmacy laws and practice standards established in the US, and many other developed countries, to protect public health. Specific findings are presented in Section II below.

II. RESULTS

A. Findings of Site Reviews: As of June 29, 2012, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,065 Internet drug outlets selling prescription medications. Of these, 9,734 (96.71%) 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. Sites listed as Not Recommended include those that were found to be noncompliant at the time of review but may since have been deactivated.

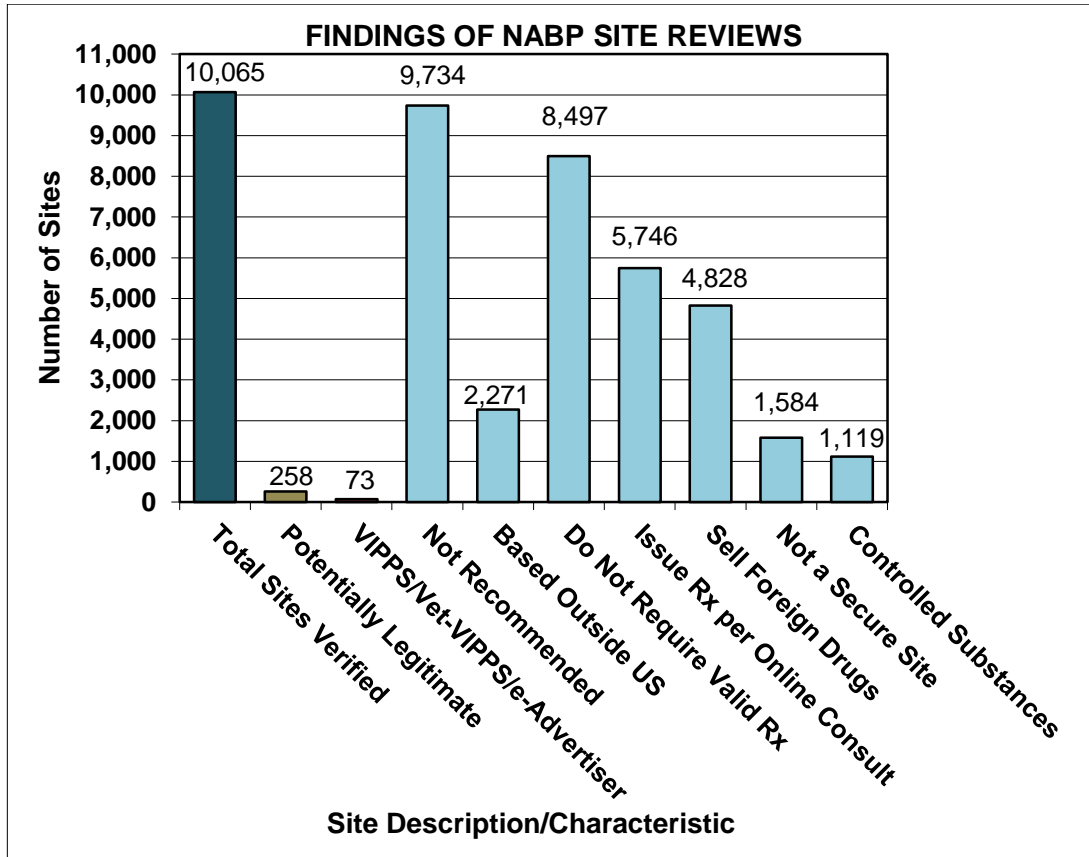


The 9,734 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 2,271 have a physical address located outside of the US (though most rogue sites do not post any address)
- 8,497 do not require a valid prescription
- 5,746 issue prescriptions per online consultation or questionnaire only
- 4,828 offer foreign or non-Food and Drug Administration (FDA-) approved drugs
- 1,584 do not have secure sites
- 3,614 have server locations in foreign countries
- 9,261 appear to be affiliated with a network
- 1,119 dispense controlled substances

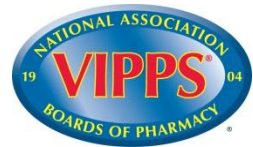
Of the total 10,065 sites reviewed, 258 (2.56%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites. Seventy-three (0.73%) of the 10,065 reviewed sites have been accredited through NABP’s Verified Internet Pharmacy Practice Sites^{CM} (VIPPS[®]) or Veterinary-Verified Internet Pharmacy Practice Sites^{CM} (Vet-VIPPS[®]) programs, or approved through the NABP e-Advertiser Approval^{CM} Program. The

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



Findings of NABP Site Reviews as of June 29, 2012

B. Recommended Internet Pharmacies: NABP, along with FDA and other patient safety advocates, continues to recommend that 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, 50 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 Applicant Screenings: 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 screens e-Advertiser Approval Program applicants against are posted in the e-Advertiser Approval Program section, under Accreditation, on the NABP Web site. These standards are essentially the same as those used to assess Internet drug outlets, only modified to accommodate a broader range of drug-related practices. As of June 29, 2012, 23 entities were listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.

III. PHARMACY REGULATION ON A GLOBAL SCALE

- A. Stakeholders Find Strength in Collaboration: In response to the global health problems counterfeiters and illegal online drug sellers pose, pharmacy stakeholders in the US and around the world are finding strength in collaboration. During the NABP President’s Address at the 108th Annual Meeting in May 2012 in Philadelphia, PA, outgoing President Malcolm J. Broussard, RPh, now NABP chairperson, discussed the need for NABP and its member boards of pharmacy to become more active in pharmacy regulation on a global scale. He stressed that, while there has been some reluctance for countries to agree to one set of standards, NABP will continue fostering opportunities for collaboration beyond our national borders. Mr Broussard has been an active participant in the Fédération Internationale Pharmaceutique (FIP), particularly in discussions of pharmacy regulatory and legislative changes across the world. “I think NABP is in an excellent position to take a leadership role in this discussion,” Mr Broussard said. “As an organization comprised of 64 jurisdictions, we have much experience compromising and collaborating to come up with uniform frameworks for regulatory systems that allow enough flexibility for states to retain their independence and autonomy.” To further this objective, NABP will be reaching out to international organizations to share ideas and best practices. “The goal of this outreach,” Mr Broussard

‘The goal of this outreach is to begin a dialogue with other nations that wish to accomplish the common goal of ensuring appropriate medication use and safe access to medicines.’

said, “is to begin a dialogue with other nations that wish to accomplish the common goal of ensuring appropriate medication use and safe access to medicines.”

In the Remarks of the Incoming President, Michael A. Burleson, RPh, pledged to carry on Mr Broussard’s leadership in supporting NABP’s existing programs and services. He also expressed the need to raise awareness about counterfeit medicine and rogue online sellers as Internet commerce becomes increasingly commonplace, giving special emphasis to recent endeavors including international pharmacy initiatives and the AWA_Rx_E[®] consumer protection program. President Burleson said, “Focusing on the topics of safe drug disposal, online pharmacies, and counterfeit drug dangers, AWA_Rx_E[®] educates consumers on prescription drug safety.”

Also during the Annual Meeting, a panel of experts representing facets of the public and private sectors led a continuing pharmacy education session, “Advancing Online Drug Safety: How Public-Private Partnerships Thwart Illicit Online Drug Sales.” Introduced by NABP Executive Committee member and session moderator James T. DeVita, RPh, the panel addressed drug safety as a global health problem requiring public-private cooperation.

With the increase in Internet use in the past decade, online drug sales have climbed, outpacing jurisdictional regulations, and creating a prime marketplace for counterfeiters and rogue online sellers and a global health concern, explained panelist Timothy Ken Mackey, MAS, a PhD student and an expert in global health, and health law studies. “Unregulated Internet pharmacies sell counterfeit drug products and represent a significant threat to global public health with tragic consequences for consumers,” Mr Mackey said. He discussed the easy accessibility of prescription drugs online, enforcement challenges, and the prevalence of counterfeit medicines sourced from various countries using questionable manufacturing practices. Sophisticated manufacturing and packaging make counterfeit drugs almost impossible to differentiate from their authentic counterparts, though their contents may be vastly different. Rogue online drug sellers do not act alone, Mr Mackey noted. Complicating matters, they work in concert with many private-sector entities – both legitimate and rogue – including manufacturers around the world, facilitators who act as middlemen to introduce product into the supply chain, and service providers (eg, domain name registrars, search engines, payment processors, and shippers) that, knowingly or unknowingly, enable illicit commerce. Thus, a solution, he said, must involve public-private partnerships, which offer a “comprehensive solution involving cooperation and sharing of information to engage in active surveillance, enforcement, and prevention.”

The multiple actors engaged in prescription drug commerce, be they legitimate or illicit, create the “bridge” connecting medicine and cybercrime, said panel speaker John Horton, JD, president and founder of LegitScript. This bridge provides a pathway for criminal organizations to introduce counterfeit, substandard, and otherwise illegally dispensed prescription drugs into the global medication supply chain and into the hands of patients. A workable solution must effectively sever that bridge, and it will take the cooperation of multiple entities to do it, he said. Taking down rogue Web sites is not enough; illegal online sellers easily put up new ones with domain name registrars (DNRs) willing to look the other way. Enforcement at all levels is also needed. “Fixing this problem cannot rely on government alone. It must involve private companies willing to take voluntary action,” Mr Horton said. He discussed the need to undertake collaborative efforts, such as those of the Center for Safe Internet Pharmacies (CSIP), and to encourage private sector actors to adopt voluntary compliance with NABP-recognized standards. Legitscript is working with CSIP, a recently established nonprofit group composed of several Internet commerce service providers, to create an information sharing portal database, through which service providers at various points in the drug supply and commerce chain can monitor and shut out illegal actors. The group also plans to undertake a consumer education campaign in the near future. CSIP will announce its official launch on July 23, 2012, at the White House.

Mr Horton pointed out that, while the current patchwork of laws and regulations has minimal impact on illegal online drug sellers, the Internet commerce community has its own rules of engagement. DNRs, for instance, have an obligation to comply with the rules of their agreement with its accrediting body, the Internet Corporation for Assigned Names and Numbers (ICANN). That agreement includes prohibiting their registrants from using domains to conduct illegal activities. Many DNRs voluntarily comply with this rule as a matter of good business practice. Others, however, apparently remain unconvinced.

The risks that prescription drug counterfeiters and rogue online sellers pose to public health have led FDA to undertake initiatives to understand and mitigate these problems, explained panelist S. Leigh Verbois, PhD, Acting Deputy Director of the Division of Supply Chain Integrity in FDA’s recently formed Office of Drug Security, Integrity, and Recalls (ODSIR), within the FDA Center for Drug Evaluation and Research. ODSIR works to ensure the quality, integrity, and security of human drugs for US consumers and addresses challenges of globalization and an increasingly complex drug supply chain through risk- and science-based policy development, surveillance, and enforcement. Its goal is to minimize consumer

exposure to unsafe, ineffective, and poor quality drug, such as unapproved or counterfeit drugs.

Ms Verbois' team examines the drug supply chain, from manufacture to end user, to identify vulnerabilities in the supply chain, including where counterfeits enter, how they are distributed, and what may motivate consumers to buy medicine online from unknown and unapproved foreign sources. One such trouble spot Ms Verbois described as "bait and switch," wherein American consumers are misled into buying drugs from alleged "Canadian" Web sites, thinking them to be of high quality due to Canadian regulations, when, in fact, the drugs are sourced from a number of other countries including Costa Rica, Israel, India, and Vanuatu. Counterfeiters may also take advantage of consumers in times of crisis, such as during the H1N1 influenza public health emergency in 2009, when rogue online drug sites were selling counterfeit Tamiflu[®] with no active ingredient or with undeclared active pharmaceutical ingredients. More recently, rogue online drug sellers have been quick to identify high-demand drugs that are in short supply to swindle unwary consumers with knock-offs and fakes.

To address these public health and supply chain threats, Verbois, like Mackey and Horton, stressed the need for communication and collaboration between public and private sector entities, and for pharmacists and other health care providers to counsel and educate patients. She also stressed the importance of health professionals reporting and staying abreast of recent incidents involving suspected counterfeit and substandard drugs through FDA's MedWatch program and Counterfeit Alert Network. She said it is important for federal agencies such as FDA to collaborate with public partners in the US and internationally, like the US Intellectual Property Enforcement Coordinator, Federal Bureau of Investigations, Drug Enforcement Administration, INTERPOL, and G8, as well as with private partners such as CSIP, Rx-360, World Health Organization, and NABP, to help make headway on policies and practices regarding Internet pharmacy. Ms Verbois and FDA are working to better understand what is happening in the supply chain globally, to identify weaknesses, and to assess gaps in oversight, accountability, and enforcement – "to help protect the US drug supply," she said, "in addition to helping drug supply chains world-wide move forward."

- B. Proposed .Pharmacy gTLD Offers Consumer Safety 'Net': Another way that NABP is working toward making pharmacy regulation more global is through its application to ICANN to become the official registry operator of the new generic Top-Level Domain (gTLD) .pharmacy, Mr Broussard explained during his Annual Meeting address. Supported by a global coalition of stakeholders, "we are pursuing this domain registry to ensure that

only those legitimate online pharmacies that abide by the pharmacy laws and practice standards of the regions in which they are doing business may utilize the new .pharmacy domain,” he said. If approved as the registry operator, NABP will work with the global coalition to develop guidelines for vetting each Internet pharmacy or related entity applying for a .pharmacy domain name, best practices for the .pharmacy gTLD, and a consumer education campaign through AWA_Rx_E designed to raise awareness and build trust in the .pharmacy domain. Mr Broussard also announced that FIP has formally endorsed NABP’s .pharmacy initiative and is in discussion with NABP to partner for the purpose of operationalizing .pharmacy on a global level.

IV. DISCUSSION

With the spread of counterfeit and substandard prescription drugs becoming a global health concern, protecting the integrity of the medication supply chain is a priority. Regulators and stakeholders are examining risks at multiple points along the supply chain, and recognizing that no single nation or entity can bring about needed changes on its own. Recent successes in dismantling illegal prescription drug operations demonstrate the effectiveness of collaboration between multiple public and private sector actors. But these successes have only begun to address the problem, and further collaborative efforts are needed to identify and eliminate weaknesses in the supply chain and educate consumers. Regulators, law enforcement, private sector companies, and nonprofit organizations must work together, across jurisdictional borders, and derive new methods and partnerships to protect the public health. NABP continues to encourage these efforts and to work with the state boards of pharmacy, federal regulators, and other public and private stakeholders to educate the public about counterfeit drugs and other potential dangers of buying medication from unknown and unapproved sources over the Internet. The Association remains committed to upholding the integrity of the practice of pharmacy – in any practice setting – and ensuring that patients have access to safe and effective prescription drugs.

Through communication and cooperation, NABP strives to advance the efforts of regulators and other entities to curtail the online trade of illicit and counterfeit medications. As always, NABP welcomes feedback on these reports, and on its Internet program, to determine how we can better serve your needs and better protect patients from these threats. In addition, we ask that you share with NABP any knowledge or concerns you might have pertaining to illegally or unprofessionally operating Internet drug outlets, so that we may support your efforts, assist in your research, or pass the information along as appropriate. As we have seen, the combined efforts of multiple

parties are a powerful force in bringing about positive change and protecting the public health, and we anticipate further improvement in the future.

For further information, please contact Melissa Madigan, policy and communications director, via e-mail at mmadigan@nabp.net.

V. APPENDIX

Internet Drug Outlet Identification Program Criteria

Patient Safety and Pharmacy Practice 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.