

## National Association of Boards of Pharmacy

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# **Internet Drug Outlet Identification Program**

Progress Report for State and Federal Regulators: October 2013

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### INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: October 2013

#### I. INTRODUCTION

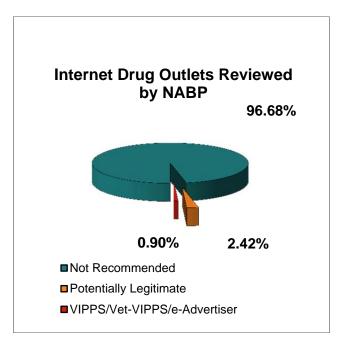
Whether referred to as fake, fraudulent, spurious, falsified, or counterfeit, unapproved drugs that defy established safeguards endanger patient health. There is little debate among national authorities that counterfeit or falsified medications pose a serious public health threat. Hindering resolution of this global scourge, however, is the continuing international debate over terminology and what constitutes a "counterfeit" drug. The lack of a consensus definition makes it difficult to gather definitive global statistics on the problem. Some national regulatory authorities and stakeholder groups emphasize trademark protections and intellectual property infringements as the crux of the counterfeiting problem and the path to a solution. They maintain that knockoff products fraudulently using trademarked brand names are almost always substandard, or worse. Because they do not meet established good manufacturing standards or criteria for drug safety and efficacy, these knockoff products come with a much higher risk to patients than those products manufactured and distributed in accordance with approved channels. Other national and international authorities reject the intellectual property (IP) issue as a matter of concern only to multinational drug companies and narrow their focus strictly to matters of safety. Some, particularly developing countries that do not recognize the intellectual property laws of other countries, argue that proponents of IP enforcement improperly lump generic drugs in with counterfeits. Either way, when discussing prescription medications not approved by national authorities, or circumventing approved distribution channels, the patient safety issue is inherent.

In its ongoing review of illegal online sales of prescription drugs to United States patients, National Association of Boards of Pharmacy® (NABP®) has found that most of the rogue online drug sellers reviewed in the last three months offer foreign or non-Food and Drug Administration (FDA)-approved medications, many fraudulently bearing trademarked brand names. Whether these are "counterfeit" is a matter of some debate. In nearly every case, however, their trademark violations are only one of many concerns; almost all of these sites also engage in other illegal

activities that further endanger patients. These findings, discussed further in the Results section of this report, illustrate the difficulty in completely separating IP-infringing medications from those that are falsified, fraudulent, or fake; one is often intrinsic to the other, and both pose significant risks to patient safety.

#### II. RESULTS

A. Findings of Site Reviews: As of September 30, 2013, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,642 Internet drug outlets selling prescription medications. Of these, 10,288 (96.68%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. They are also 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*. The 10,288 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized in the table below.<sup>1</sup>

Of the total 10,642 sites reviewed, 258 (2.42%) 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. Ninety-six (0.90%) of the 10,642 reviewed sites have been accredited through NABP's Verified Internet Pharmacy Practice Sites<sup>CM</sup> (VIPPS®) or Veterinary-Verified Internet Pharmacy Practice Sites<sup>CM</sup> (Vet-VIPPS®) programs, or approved through the NABP e-Advertiser Approval<sup>CM</sup> Program.

<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 Web sites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with

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.

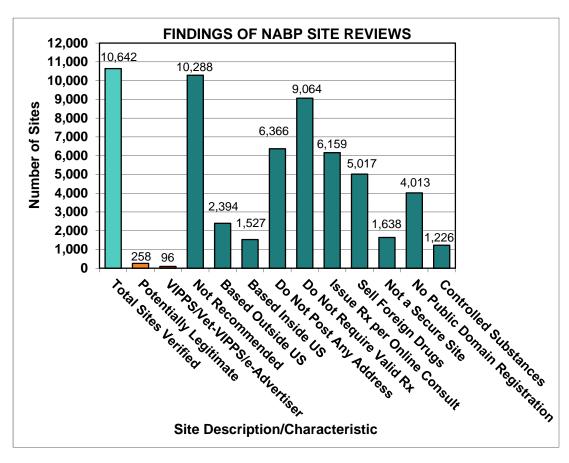
Physical Location:	2,394 (23.3%) outside US 1,527 (14.8%) inside US 6,366 (61.9%) no location posted on Web site
Prescription Requirements:	9,064 (88.1%) do not require valid prescription 6,159 (59.9%) issue prescriptions per online consultations or questionnaires only
Medications:	5,017 (48.8%) offer foreign or non-FDA approved medications 1,226 (11.9%) dispense controlled substances
Encryption:	1,638 (15.9%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	4,225 (41.1%) outside US 5,603 (54.5%) inside US 460 (4.5%) have unknown server locations
Domain Name Registration:	4,013 (39.0%) do not have a public domain name registration (WHOIS information is registered using a privacy or proxy service)
Affiliations:	9,450 (91.9%) appear to have affiliations with rogue networks of Internet drug outlets

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

A of this report.

Pharmacy Safe?

In Appendix B is a new info-graphic developed as a public education tool through the  $AWAR_XE^{\oplus}$  consumer protection program, provided by NABP.  $AWAR_XE$  joins forces with patient safety advocates in reaching out to educate consumers on the dangers of rogue Internet drug outlets, substandard and counterfeit drug products, and the importance of proper medication storage and disposal. More information is available on the  $AWAR_XE$  Web site, WWW.AWARERX.ORG.



Findings of NABP Web site reviews, in total, as of September 30, 2013

B. Trends Among Internet Drug Outlets Selling Foreign or non-FDA-Approved Medications:

From July through September 2013, NABP identified 109 additional Internet drug outlets that are operating out of compliance with pharmacy laws and practice standards and added them to the Not Recommended list. Of these 109 rogue Internet drug outlets, 84 (77.06%) offer foreign or non-FDA-approved medications. US federal law prohibits the importation of prescription drugs into the US from foreign countries by anyone other than the manufacturer. In the US, FDA approves a drug on the basis of scientific data proving it to be safe and effective. The manufacturing facilities and procedures for approved products are also carefully regulated by FDA to ensure product integrity. When foreign pharmacies ship prescription medications to the US, the medications are not subject to the safety requirements set by FDA to protect consumers and, therefore, US citizens cannot be certain the drugs meet the standards they expect, and the risk of receiving counterfeit medications is significantly greater.

Most frequently, Internet drug outlets offering non-FDA-approved medications offer "generic" versions of name brand erectile dysfunction medications. At this point in time, no FDA-approved generics exist for Pfizer's Viagra<sup>®</sup>, Eli Lilly and Company's Cialis<sup>®</sup>, or Bayer HealthCare Pharmaceuticals' Levitra<sup>®</sup>. However, the World Wide Web is plagued with Web sites offering to ship "Generic Viagra," "Cialis Soft Tabs," and "Levitra Jelly," to name a few, to US citizens. These products have not been subject to the safety and efficacy standards that their branded counterparts must successfully pass, and they are not sanctioned in any way by the companies whose names they use. Of the 84 sites selling foreign or non-FDA approved medications, 71 (84.52%) are selling drugs promoted fraudulently under approved brand names. Examples of these drugs include, but are not limited to, "Generic Cialis" (7), "Cialis Soft Tabs" (9), "Viagra Soft" (39), "Generic Viagra" (32), and "Generic Levitra" (1). Not only are these unapproved "generics" violating trademark laws, but they raise numerous patient safety concerns. Often, these illegal knockoffs will contain inaccurate amounts of the active ingredients, no active ingredients, or harmful fillers. The above is not an all-inclusive list of the non-FDA-approved medications offered on the 84 sample sites but reflects the most frequently promoted medications on these Web sites.

Also concerning is the fact that 82 (97.62%) of the 84 sites offering foreign or non-FDA-approved prescription medications are not requiring a valid prescription for the purchase of these drugs. This could lead to dangerous interactions with other medications patients may be taking, as well as other harmful side effects. Sixteen (19.05%) of the 84 sites are issuing prescription medications based solely on the results of an online questionnaire or consultation, which does not constitute a valid prescription. Twenty-two (26.19%) of the 84 sites posted physical locations outside of the US. Only four (4.76%) posted physical locations inside the US, while the remaining 58 (69.05%) did not post any physical address. Seventeen (20.24%) of the 84 sites do not use Secure-Socket Layer or equivalent technology for the transmission of protected health information (PHI). Therefore, patients' identifiable information, health records, as well as credit card information, are all susceptible to interception by unwanted third parties, subjecting customers to identity theft. Twenty-eight (33.33%) of the 84 sites are illegally selling controlled substances, allowing easy access to medications that should be carefully prescribed and monitored by an attending physician.

C. <u>Sites Using Privacy or Proxy Domain Name Registration Services Raise Red Flags</u>: As if neglecting to post an address on the Web site does not sufficiently obscure their identity, many illegal online drug sellers also register their Web site domain names anonymously. Recent studies have identified a correlation between Web sites utilizing privacy or proxy

domain name registration services (services that mask the identity of domain name registrants) and illegal activity on the Web. A September 2013 study conducted at the University of Cambridge shows that, in contrast to "legal pharmacies," which have a "low" rate of usage of privacy or proxy services (8.8%), "unlicensed pharmacies" have an "extremely high" rate of usage of privacy or proxy services (54.8%).

Of the 109 Internet drug outlets NABP discovered to be operating out of compliance with pharmacy laws and practice standards from July through September 2013, 45 (41.28%) of them utilize a privacy/proxy domain registration service, more than double that of domains in general. Of these sites, 42 (93.33%) do not require a valid prescription. Thirty-seven (82.22%) do not post a physical address, 33 (73.33%) offer foreign or non-FDA-approved medications, eight (17.78%) offer controlled substances without a valid prescription, and eight (17.78%) are not encrypted, exposing customers to financial fraud and identity theft. These findings further support the correlation between anonymous domain registration and illegal activity shown in the 2013 Cambridge study.

- D. 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, 59 VIPPS and Vet-VIPPS pharmacy sites are listed as Recommended Internet Pharmacies. Several more applications are in progress.
- E. 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. Currently, 37 entities are listed on

the NABP Web site as Approved e-Advertisers, and several more applications are in progress.

#### III. COUNTERFEIT MEDICINE: IP OR SAFETY ISSUE

While a precise, universal definition of a counterfeit medicine remains elusive, the fact that fake medicines pose a public health threat is recognized globally. The problem is cited as a concern by public health regulators in the US, United Kingdom, European Union, and regions of Asia and Africa, as well as by international groups including the World Health Organization (WHO), United Nations Office on Drugs and Crime (UNODC), International Pharmaceutical Federation (FIP), Group of 8, World Customs Organization, and Interpol. The problem is taken up as a charge by public and private organizations, regulatory agencies, and industry stakeholders, such as Partnership for Safe Medicines, Alliance for Safe Online Pharmacies, Center for Safe Internet Pharmacies, and European Alliance for Access to Safe Medicines. While it is, in many circles, also an economic concern, to such organizations as US Intellectual Property Enforcement Coordinator, Asia-Pacific Economic Cooperation, and World Intellectual Property Organization, overwhelmingly, even where economic interests are concerned, the problem of prescription drug counterfeiting is inherently, inextricably tied to public health.

A. The Name Game: WHO cites the lack of a universal definition of a counterfeit medicine as a barrier to fully understanding and combating the problem on a global scale. The debate has continued for more than two decades – since WHO convened the first international meeting on counterfeiting medicines in 1992, and participants agreed to a definition. WHO defined a counterfeit medicine as one that is "deliberately and fraudulently mislabelled [sic] with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging." Acceptance of this definition, however, was not universal. Countries including Brazil, India, and Thailand disagreed with this definition of the term "counterfeit." Critics suggested that its underlying intent was to target generics and protect IP rights of brand-name drug manufacturers, even in countries that do not recognize IP rights, and that it hindered patients' access to necessary drugs in the developing world.

WHO is currently engaged in negotiations with member states as to its future role in tackling the issue of what is currently referred to as spurious/falsely labelled/falsified/counterfeit" (SFFC) medical products. In a May 2012 fact sheet, WHO describes these products in terms very similar to its earlier definition of counterfeits – as medicines that are "deliberately and fraudulently

mislabeled with respect to identity and/or source," and can result in "treatment failure or even death," as well as "erosion of public confidence in health systems." They may include "products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging." SFFC medicines are found worldwide and "range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case," WHO says, "the source of a SFFC medicine is unknown and its content unreliable. SFFC medicines are always illegal. ... Eliminating them is a considerable public health challenge."

In many developed countries, notably the US, counterfeits are intrinsically linked with IP rights, but still strongly linked to patient safety. US law defines a counterfeit drug as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufacture, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

By contrast, UNODC makes a point to separate IP violations from other forms of medication fraud. UNODC uses the term *counterfeit* in reference to "falsely-branded or unlicensed products, where the crime involved is intellectual property theft." It calls the act of deceiving buyers as to the content of what they are buying *fraud*. This includes misbranding but is broader, and – most importantly – encompasses products that do not contain what they purport to contain. Whether they also violate IP rights, which many do, is beside the point. For example, in an April 2013 report, *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment,* UNODC points out the "large share" of "bogus" anti-malarial and other essential medicines sold in Southeast Asia and Africa. "In some cases," the report states, "there is deliberate brand counterfeiting, but in many others, the drugs are generic. For the consumer, the results are the same."

European health care regulators prefer the term *falsified* and are careful to distinguish falsified medicines from counterfeit medicines. The Falsified Medicines Directive, new legislation that took effect in Europe in January 2013, addresses fraudulent products that endanger patient health. It aims to prevent the entry of falsified medicines into the legal supply chain at all phases of distribution, including the Internet. According to the European Commission, "Falsified medicines are not to be confused with counterfeit medicines. The latter term refers to medicines that do not

comply with EU law on intellectual and industrial property rights, such as registered trademarks or patent rights. The Directive on 'falsified medicines' does not deal with this aspect." Rather, the Directive defines falsified medicines as:

Any medicinal product with a false representation of:

- a) its identity, including its packaging, and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
- b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
- c) its history, including the records and documents relating to the distribution channels used.

Most importantly, they are not approved by European public health regulators for sale in the EU. "Since they have not passed through the necessary evaluation of quality, safety and efficacy as required by the EU authorisation procedure," the Commission states, "they can be a major health threat." The European Commission notes on the trade policy page of its Web site, "Counterfeit products can also risk consumer safety and health."

The EU, along with several other countries, addresses IP violations through other designated channels. In 2012, the European Union, along with Mexico, signed on to the multinational Anti-Counterfeiting Trade Agreement (ACTA). Developed by the US and Japan in 2006, ACTA aims to establish international standards for IP rights enforcement pertaining to counterfeit goods, generic medicines, and copyright infringement on the Internet. As of February 2013, it had been signed by 31 states as well as the EU. Critics of ACTA have argued that, by focusing on IP violations, it treats all generic medications as counterfeits and deprives developing countries of cheaper versions of expensive drugs.

B. <u>Supply Chain Controls Deemed Essential</u>: Regardless of the terminology used to describe them, drug products that circumvent supply chain safeguards place patients at risk. On this point, it appears, nations more readily agree. Poor quality controls in developing countries, unregulated trade zones, and rogue wholesalers contribute to the problem. As reflected in the European legislation and as stated by FIP and other national and international groups, the key to reducing the availability of counterfeit and falsified medicines is maintaining the integrity of the quality controls at all stages in the manufacturing and distribution channel.

In its white paper, Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply, released in October 2013, NABP points to the roles of unscrupulous wholesalers in distributing counterfeit drugs and unapproved foreign-sourced drugs that have endangered patients across the country. The paper highlights the need for wholesale distribution

regulation to address problems yet unsolved by the Prescription Drug Marketing Act of 1987 and the current patchwork of state regulations, in spite of which "questionable entities have managed to identify the gaps in the distribution and regulatory structure in order to swindle their way in to the drug distribution system." Due to emerging trends in the current drug market, drug products may pass through several steps in the distribution process before reaching their final destination, "leaving them vulnerable to counterfeiting or unregulated conditions." This multiple changing of hands is common in the online trafficking of prescription drugs, such that even well-intentioned sellers offering foreign unapproved drugs, themselves, may have little idea where the drugs originated, what exactly they contain, or, assuming they were safe and effective to begin with, whether they were stored appropriately during the journey to maintain their safety and efficacy. In light of these concerns, NABP continues to assess and strengthen its Verified Accredited Wholesale Distributor® (VAWD®) program, currently recognized in 21 states, to help to ensure supply chain integrity.

#### IV. DISCUSSION

Regardless of the nuances ascribed to the term, counterfeiting undermines the long established controls of medication quality, safety, and efficacy by defying the safeguards designed to protect public health, that are provided by established and licensed medication supply channels, from manufacturer, to wholesaler, to pharmacy, to patient. NABP encourages and continues 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, including 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.

NABP prepares and releases these status reports quarterly to provide the boards of pharmacy, other state and federal regulators, and interested stakeholders with updates of Web site review findings and outreach efforts, as well as other events and trends related to Internet pharmacy practice. Through communication and cooperation, we hope to advance the efforts of regulators and other entities to curtail the online trade of illicit, falsified, and counterfeit medications. When aligned, the combined efforts of multiple parties are a powerful force in bringing about positive change and protecting the public health. For further information, please contact Melissa Madigan, policy and communications director, via e-mail at mmadigan@nabp.net.

#### V. APPENDICES

#### Appendix A

#### 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 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 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.

#### APPENDIX B

AWAR<sub>x</sub>E Consumer Protection Program Info-graphic

