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nabp

Internet Drug Outlet Identification Program

Progress Report for State and
Federal Regulators: July 2013

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: July 2013

I. INTRODUCTION

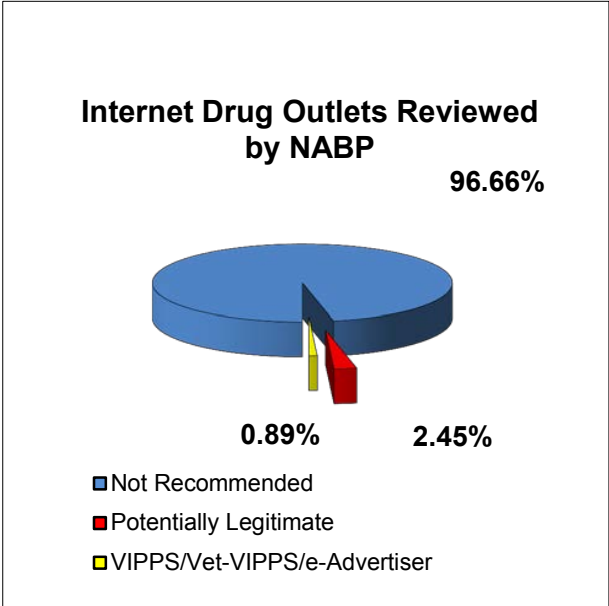
Illegal online drug sellers are masters of deception. They go to great lengths to make consumers believe they are legitimate, safe, and trustworthy. They create that façade, using images of smiling health care workers in white lab coats, stolen trademarks, fake licenses, sympathetic appeals to consumer concerns, and misleading information on the legality of their operations. This is all with the intent to sell medication that is anything but trustworthy. Through its review of more than 10,000 Web sites selling prescription drugs, National Association of Boards of Pharmacy® (NABP®) has found, under such façades, the majority of online drug sites are operating illegally, often selling counterfeit and substandard medicine from questionable sources. The deceptive practices of illegal online drug sellers, combined with the prevalence of consumers buying prescription medicine online, underscore the need for consumer outreach. NABP, along with national and international groups including INTERPOL, the United States Government Accountability Office (GAO), US Food and Drug Administration (FDA), Center for Safe Internet Pharmacies (CSIP), and Alliance for Safe Online Pharmacies (ASOP), stresses patient education as a crucial factor in the public health equation. And, like the collaborative approach that met with such success in recent international enforcement actions, raising public awareness about the dangers of buying medicine from online drug dealers will also require the coordinated efforts of many.

NABP has been involved in protecting US patients from rogue Internet drug outlets for over a decade through the VIPPS® (Verified Internet Pharmacy Practice Sites^{CM}) and Vet-VIPPS® accreditation programs, Internet Drug Outlet Identification, NABP e-Advertiser Approval^{CM}, and AWARE[®] Consumer Protection programs. Today, NABP is partnering with international public and private entities to develop the .PHARMACY generic Top-Level Domain (gTLD). Supported by regulatory authorities and industry leaders dedicated to educating patients around the globe, the .PHARMACY gTLD initiative will provide a trustworthy online space for consumers

worldwide to find legitimate, law-abiding Internet pharmacies. The success of this and other endeavors to protect patient health depends largely on raising public awareness. NABP looks forward to building upon its international partnerships in the months ahead to spread the word about .PHARMACY and ensure that once-unsuspecting buyers are empowered to choose safely when buying medicine online.

II. RESULTS

A. Findings of Site Reviews: Through its review of thousands of Web sites selling prescription medicine online, NABP has seen numerous examples of activities that are not only illegal but also deceptive, or, at the very least, opaque. During the last quarter alone, NABP discovered a number of Web sites falsely claiming to be VIPPS-accredited, sites selling counterfeit versions of brand-name drugs, and sites claiming to be Canadian that also dispense



prescription drugs without any prescription and sell counterfeit versions of brand-name drugs. In all, as of June 28, 2013, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,533 Internet drug outlets selling prescription medications. Of these, 10,181 (96.66%) 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*.

- Nearly 90% of the Web sites identified as Not Recommended sell prescription drugs without a valid prescription, which is not only illegal but also unsafe. Included in this group are the 60% of Not Recommended sites that dispense prescription drugs based solely on the customer’s responses to an online questionnaire. While many drug sites claim that a legitimately licensed doctor will review the patient’s medical information, legal investigations have revealed that, in many cases, there is no such

review. And of the 12% of Not Recommended sites that sell controlled substances, nearly all do so without a valid prescription.

- Nearly half of the sites listed as Not Recommended sell prescription drugs that are not FDA-approved, and many of these are counterfeit versions of approved brand-name drugs. Nearly all of these sell fake knock-offs of well-known brand-name drugs to treat erectile dysfunction. They take a trademarked name and tack on descriptors like “Professional,” “Soft,” “Sublingual,” “Super Active,” and “Super Dulox-Force,” as though such products had been developed, tested, and approved alongside the authentic

Characteristics of the 10,181 Internet Drug Outlets Listed as Not Recommended ¹		
Characteristic	Actual Number	Percentage of Total
Physical address outside the US	2,372	23.30%
Physical address inside the US	1,524	15.00%
No physical address posted	6,285	61.70%
Valid prescription not required	8,961	88.00%
Prescriptions issued per online questionnaire	6,129	60.20%
Foreign or unapproved drugs offered	4,935	48.50%
Customer information not encrypted	1,614	15.90%
Server located in foreign country	4,144	40.70%
Controlled substances offered	1,181	11.60%
Domain name registered anonymously	3,968	39.00%

drug. While these counterfeit drugs may (or may not) contain some quantity of the authentic drug’s active ingredient, because they are not subject to the testing and safety requirements as the approved drug, there is no way of knowing whether they contain the right amount of the active ingredient, or what other substances or impurities they may contain.

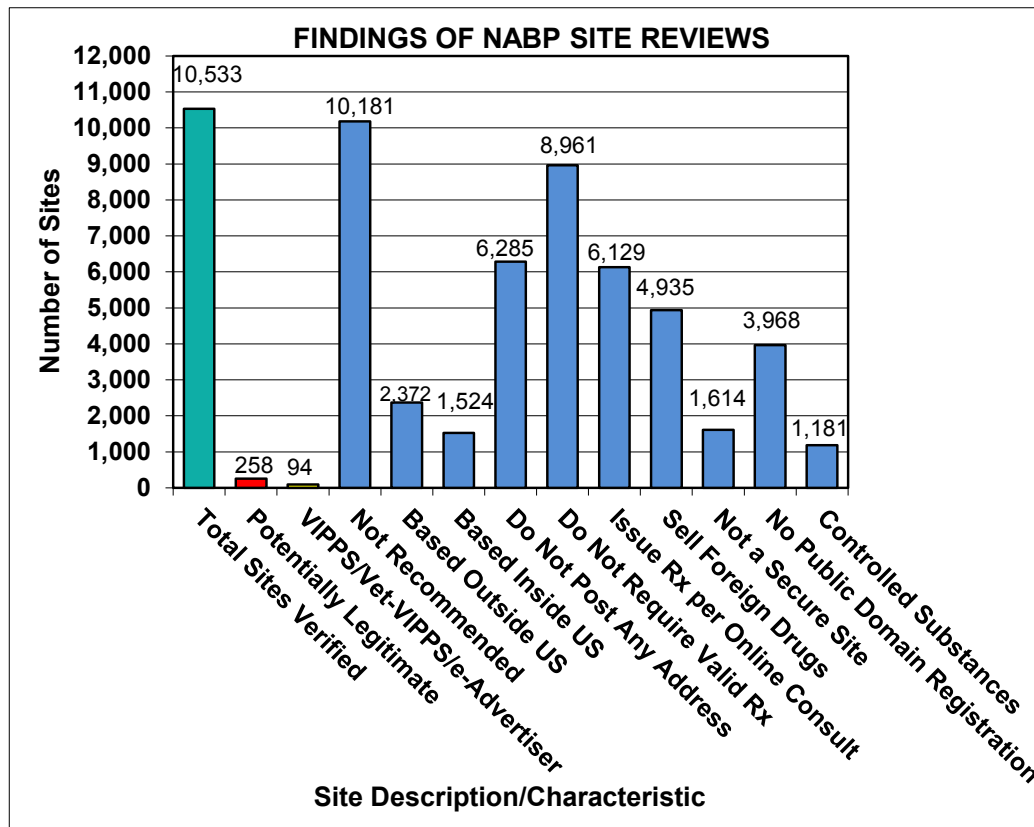
- More than 60% of the Web sites identified as Not Recommended fail to post a street address for the dispensing pharmacy or corporate headquarters as required for

¹ 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.

legitimately operating Internet pharmacies. Most of these provide no means for patients to contact a pharmacist with questions about their medication. Frequently, deceived patients report that they have not received the medicines they ordered, or that the site operators refuse to remove credit card charges. Many also complain that they are unable to contact anyone at the organization; phone lines are disconnected, no one answers, or no phone number is provided.

- Additionally, nearly 40% of them register their domain names anonymously, thus alleviating themselves of any accountability to their customers.
- Some 16% of the sites listed as Not Recommended do not protect customers' personal information with SSL (Secure Socket Layer) encryption, leaving their medical and financial information vulnerable to anyone who might want to use it for their own gain. Furthermore, evidence indicates that illegitimate prescribing outlets frequently sell their customer lists to other illegitimate online drug outlets and operators of Internet scam and pornography sites.

Of the total 10,533 sites reviewed, 258 (2.45%) 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-four (0.89%) of the 10,533 reviewed sites have been accredited through NABP's VIPPS or Vet-VIPPS programs, or approved through the e-Advertiser Approval Program. The standards against which NABP evaluates Internet drug outlets are provided in the appendix of this report.



Findings of NABP Web site reviews, in total, as of June 28, 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, 59 VIPPS and Vet-VIPPS pharmacy sites 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. Currently, 37 entities are listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.

III. DECEPTIVE TACTICS UNDERSCORE NEED FOR CONSUMER EDUCATION

Because most Web sites selling prescription drugs are not what they appear to be, patient education is an important part of the public health mission. As the GAO stresses in its July 2013 report on Internet pharmacies, widespread patient education, in conjunction with regulation and enforcement, is imperative to protecting public health. “Many rogue Internet pharmacies use sophisticated marketing methods to appear professional and legitimate, making it challenging for even well-informed consumers and health care professionals to differentiate between legal and illegal Internet pharmacies,” GAO states in the report. FDA and other national public health agencies tasked with monitoring the supply chain and ensuring the safety and efficacy of prescription drugs in their respective countries are unable to provide these assurances when patients buy drugs through channels outside the regulated supply chain, frequently via the Internet. Many Internet drug outlets operate without a license or in conflict with laws and regulations created to ensure patient safety. Furthermore, some of the medicines being sold on these Web sites may be too strong, too weak, fake, expired, stolen, diluted, or impure.

‘Many rogue Internet pharmacies use sophisticated marketing methods to appear professional and legitimate, making it challenging for even well-informed consumers and health care professionals to differentiate between legal and illegal Internet pharmacies.’

*US Government
Accountability Office*

A. International Collaboration Uncovers Fakes: Many illegal drug selling operations span multiple countries, creating a global problem calling for a collaborative, international response. In recent years, regulatory and enforcement strategies involving the collaborative efforts of multiple public and private entities around the world have met with much success – most recently, Operation Pangea VI, a global enforcement and awareness campaign targeting Web sites selling prescription medicine illegally online. Law enforcement, customs, and

regulatory authorities from 99 countries executed Operation Pangea VI, part of the sixth annual International Internet Week of Action culminating on June 25, 2013. Through their combined efforts, enforcement agencies, regulators, and stakeholders around the world shut down thousands of fake online pharmacies complicit in deceiving patients and endangering global public health.

FDA reports in a recent news release that many of the Web sites that were shut down during Operation Pangea IV “appeared to be operating as a part of an organized criminal network that falsely purported its websites to be ‘Canadian Pharmacies.’” FDA notes that the Web sites displayed fake licenses and certifications, advertised brand name drugs, and claimed that drug products were FDA-approved. Investigations during the course of Operation Pangea VI revealed that the products were not from Canada, were not brand name products, and were not FDA-approved.

- B. Risky Consumer Buying Habits Call for Greater Awareness: Consumer behavior studies show that many patients do entrust their health and safety to online drug sellers dealing in medicine from unknown sources. Based on a consumer survey completed in 2012, FDA finds that many Internet users continue to buy prescription medicine online, and that nearly half of those Internet users who purchased medicine online did so from unknown drug sellers (not associated with a local pharmacy or health insurance plan) based on the online ratings and comments of other Internet users. “Consumers should be cautious, as fraudulent sellers offering counterfeit, expired or otherwise unsafe drugs can manipulate posted ratings and comments to influence customers,” FDA advises on its BeSafeRx consumer Web page. Additionally, FDA finds that, while most (70%) of survey respondents felt it was riskier to buy from an online pharmacy outside the US, 15% of respondents said they would consider it. FDA says in its Survey Highlights that its findings “warrant interventions to raise awareness and educate consumers about the risks of buying medicines from online pharmacies” and underscore “the importance of health care provider and stakeholder outreach.”

US consumers tend to be particularly trusting of online drug sellers purporting to be Canadian pharmacies, many of which sell drugs that are neither approved by Health Canada nor legal to sell in Canada or the US. “Despite FDA warnings to consumers that the agency could not ensure the safety of drugs not approved for sale in the United States that are purchased from other countries,” there is a “perception among U.S. consumers that they can readily save money and obtain safe prescription drugs by purchasing them from Canada,” GAO reports.

“Many rogue Internet pharmacies seek to take advantage of this perception by purporting to be located in Canada, or sell drugs manufactured or approved for sale in Canada, when they are actually located elsewhere or selling drugs sourced from other countries.” In the last quarter alone, NABP discovered a cluster of so-called Canadian “pharmacy” sites that also offer counterfeit versions of brand-name drugs and offer to dispense prescription drugs without any prescription.

International police agency INTERPOL described the current environment in a recent news release announcing the success of Operation Pangea VI. “Transnational criminal networks are taking advantage of the Internet to deceive consumers into buying fake and often dangerous medicines with a wanton disregard for the health risks this poses to the unsuspecting buyers,” INTERPOL Secretary General Ronald K. Noble states in the news release. With this in mind, part of the mission of Operation Pangea VI was to increase awareness of the serious health risks connected to purchasing medicines online. “Ultimately,” said Aline Plançon, Assistant Director of INTERPOL’s Medical Products Counterfeiting and Pharmaceutical Crime Sub-directorate, “we hope that by increasing public awareness of the risks associated with illegal online pharmacies, people will take greater care the next time they turn to the Internet to purchase medicines.”

- C. .PHARMACY gTLD Strives to Make Internet Safer for Patients: Raising public awareness and providing consumers with a trustworthy online space where they can find legitimate pharmacies is precisely the purpose of the .PHARMACY gTLD initiative. NABP and its international partners recently reached a milestone in this ongoing initiative to make the Internet safer and more transparent for pharmacy patients. As NABP outgoing chairperson Malcolm J. Broussard, RPh, announced at the Association’s 109th Annual Meeting in May 2013, NABP has successfully passed the initial evaluation of its bid for the .PHARMACY gTLD. Through this program, “we want to provide a safe and trustworthy space for people around the world to find legitimate Internet pharmacies,” Mr Broussard said. The .PHARMACY gTLD is being developed in collaboration with international public and private entities, in response to the public health threat posed by rogue Internet drug outlets that target consumers not only in the US but around the world. “Among many other industry experts, participants included representatives from the International Pharmaceutical Federation, the National Association of Pharmacy Regulatory Authorities from Canada, INTERPOL, and the European Alliance for Access to Safe Medicines,” Mr Broussard said. “I am very gratified by the strong alliance we have formed with these organizations, and with the many other important stakeholders.”

In a continuing pharmacy education session at the NABP 109th Annual Meeting, LegitScript President John Horton, JD – who is among the important stakeholders to which Mr Broussard referred – illustrated the striking similarities between authentic and fraudulent Web sites, and noted that the .PHARMACY gTLD will provide an easy way for Internet users to ensure the legitimacy of Internet pharmacies. Mr Horton's company, LegitScript, is a founding member of ASOP; the company also serves as a technical and policy resource for CSIP. Both ASOP and CSIP include consumer education among their primary objectives.

- D. Coordinated Efforts Amplify Patient Safety Message: The success of the .PHARMACY gTLD and other endeavors to protect patient health depends largely on raising public awareness. As NABP and its international partners move forward with the development of the .PHARMACY gTLD, public outreach will move to the forefront of the group's focus. One avenue of public outreach will be the AWA_Rx_E Consumer Protection Program. As an example of its outreach potential, this spring the AWA_Rx_E program reached over a million race fans by showing public service announcements (PSAs) addressing prescription drug abuse and counterfeit drugs on the JumboTron at the Indianapolis 500. The AWA_Rx_E spots ran more than 300 times over the course of three days. These PSAs and other educational materials are available at *WWW.AWARERX.ORG*, as well as on Facebook, and in the biweekly *AWA_Rx_E Prescription Drug Safety News Newsletter*. Launched in June 2012, the AWA_Rx_E newsletter now has more than 14,000 subscribers.

IV. DISCUSSION

Illegal online drug sellers are largely responsible for distributing counterfeit and substandard medicine, and supplying potentially dangerous and addictive substances to anyone with a credit card and an inclination to self-medicate. NABP applauds the valuable contributions that organizations across the globe have made to educate patients on medication safety issues and is proud to have joined forces with many of them to further this goal. NABP also commends the regulators, enforcement agencies, and stakeholders around the world whose combined efforts shut down thousands of fake online pharmacies through Operation Pangea VI. This campaign, executed through the unified effort of public and private entities from 99 countries, illustrates the positive impact that international, interdisciplinary collaboration can have against a complex and wide-ranging problem. This collaborative approach is central to the .PHARMACY gTLD initiative and the global coalition of stakeholders that support it. NABP looks forward to building upon its partnerships with national and international stakeholders to spread the word about .PHARMACY and empowering consumers to choose safely when buying medicine online.

For further information on the Internet Drug Outlet Identification Program, please contact Melissa Madigan, policy and communications director, via e-mail at mmadigan@nabp.net. More information about the .PHARMACY gTLD initiative is available under the Programs section on the NABP Web site, www.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.