Internet Drug Outlet Identification Program

Progress Report for State and Federal Regulators:
July 2011
# 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 ........................................................ 6  

III. PRESCRIPTION DRUG ABUSE RISES; INTERNET CRIME KEEPS PACE ............... 6  
   A. Rogue Internet Drug Outlets Persist in Offering Controlled Substances ....................... 7  
   B. Study Links Prescription Drug Abuse to High-Speed Internet Access .......................... 8  
   C. Illegal Sellers Extend Reach Through Social Media ...................................................... 8  

IV. COLLABORATIVE EFFORTS KEY TO RAISING AWARENESS ............................... 9  
   A. NABP Joins Stakeholders in Educational Initiatives ..................................................... 9  
      1. NABP 107th Annual Meeting ............................................................................. 9  
      2. PSM Congressional Briefing ............................................................................. 9  
      3. ‘White List’ of Legitimate Online Pharmacies .................................................... 9  
   B. AWARxE Consumer Protection Program Provides Educational Resources ............... 10  

V. DISCUSSION ................................................................................................................. .. 10  

VI. APPENDICES ................................................................................................................ .. 12  
   APPENDIX A: Internet Drug Outlet Identification Program Criteria ............................. 13
INTERNET DRUG OUTLET IDENTIFICATION PROGRAM
PROGRESS REPORT: July 2011

I. INTRODUCTION

In the aftermath of her daughter’s death, Sandra Lambden condemned rogue Internet drug outlets like the one that sold her daughter the drug that killed her. London paramedic Lorna Lambden took amitriptyline she had purchased from a foreign Web site, without a prescription or medical oversight, to help her sleep, the London Metro reported on May, 21, 2011. She was found dead 48 hours later. Toxicology tests showed a fatal level of the drug in her blood. The article quotes her mother: “It’s terrible that these drugs are so freely available online and people can buy them without seeing any warnings about the harm they can do.” Though her story takes place across the Atlantic, it is chillingly reminiscent of those told by Dan Pearson and Francine Haight, who lost their sons, Justin and Ryan, to accidental overdoses of prescription painkillers bought online without a valid prescription a decade ago. In the years that followed, their deaths brought national attention to the public health risks associated with rogue Internet drug outlets, and helped to bring about Minnesota’s adoption of Justin’s Law, clarifying the definition of a valid prescription, and federal adoption of the Ryan Haight Online Pharmacy Consumer Protection Act, prohibiting the dispensing of controlled substances over the Internet without a valid prescription. The crisis, however, is far from over.

Prescription drug abuse continues to soar. State and federal regulators now look to prescription drug monitoring systems, data sharing, prescription drug take-back programs, and prescriber education, all of which are necessary and good, but they do not address the continuing underground role of illegal online drug sellers. Meanwhile, the Internet marketplace has evolved somewhat in response to new laws, but it remains a pervasive contributor to the rampant misuse and abuse of prescription drugs. The role of the Internet in this national epidemic, and efforts to raise awareness about illegal online drug sellers, are explored further in sections III and IV of this report.
At NABP Headquarters, staff continues to review Web sites selling prescription medications and has identified more than 8,000 – 96% of the total number of sites reviewed – as being out of compliance with pharmacy laws and practice standards established in the United States to protect the public health. As per usual, the vast majority of these sites can be traced to rogue affiliate networks obtaining prescription drugs from questionable sources, and dispensing them indiscriminately to patients without a valid prescription or medical oversight.

II. RESULTS

A. Findings of Site Reviews: As of July 1, 2011, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 8,353 Internet drug outlets selling prescription medications. Of these, 8,034 (96.18%) 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 8,034 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 2,100 have a physical address located outside of the US
- 6,812 do not require a valid prescription
- 5,089 issue prescriptions per online consultation or questionnaire only
- 3,687 offer foreign or non-Food and Drug Administration (FDA)-approved drugs
- 1,424 do not have secure sites
- 2,878 have server locations in foreign countries
- 7,781 appear to be affiliated with a network
- 962 dispense controlled substances
Of the total 8,353 sites reviewed, 260 (3.11%) appear to be potentially legitimate, i.e., meet program criteria that could be verified solely by looking at the sites. Fifty-nine (0.71%) of the 8,353 reviewed sites have been accredited through NABP’s Verified Internet Pharmacy Practice Sites™ (VIPPS®) or Veterinary-Verified Internet Pharmacy Practice Sites™ (Vet-VIPPS®) programs, or approved through the NABP e-Advertiser Approval™ Program.

Findings of NABP Site Reviews as of July 1, 2011

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

B. Recommended Internet Pharmacies: NABP 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, 41
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 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,
pharmacy information, or are medical practitioners’ Web sites or other
prescription drug-related services. Sites that have received e-Advertiser Approval 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 July 1, 18 entities were listed on the NABP Web site as Approved e-
Advertisers, and several more applications are in progress.

III. PRESCRIPTION DRUG ABUSE RISES; INTERNET CRIME KEEPS PACE

The April 2011 White House report, “Epidemic: Responding to America’s Prescription Drug
Abuse Crisis,” calls prescription drug abuse the nation’s fastest growing drug problem. Citing
prescription medication as the second most-abused category of drugs after marijuana, the report
notes that opiate overdoses, once almost always due to heroin use, now increasing result from the
abuse of prescription painkillers. Studies by the Substance Abuse and Mental Health Services
Administration (SAMHSA) and other public and private health groups corroborate this trend.
SAMHSA points out in its December 2010 Drug Abuse Warning Network report that emergency
department visits involving misuse or abuse of pharmaceuticals nearly doubled, increasing 98.4%
– from 627,291 to 1.2 million – in the five years from 2004 to 2009, and that the greatest
increases involved prescription painkillers. Conversely, the report notes, there was no such
increase in emergency department visits involving illicit drugs – which, unlike prescription
medicine, are not readily available online. While neither of these reports attribute more than a
small fraction of the problem to the Internet, other health care experts and medication safety advocates underscore the connection between increased use of the Internet, the proliferation of Internet drug outlets, and the concomitant rise in prescription drug misuse and abuse. They stress that this link cannot be ignored in devising effective solutions.

The current down-playing of the Internet’s role in prescription drug abuse is in sharp contrast to the mood a few years ago, prior to adoption of the Ryan Haight Act in October 2008. In 2007, the US Drug Enforcement Administration (DEA) called the Internet a major contributor to prescription drug abuse. The agency pointed out that the diversion of controlled substance painkillers was at an all-time high, and that rogue Internet drug outlets were dispensing inordinate amounts of controlled substance painkillers (95% of prescriptions dispensed) compared to legitimate brick-and-mortar pharmacies (11% of prescriptions dispensed). Seconding this correlation, an article in the March 2007 *Houston Journal of Health Law and Policy* asserts that, “In the War on Prescription Drug Abuse, E-Pharmacies Are Making Doctor Shopping Irrelevant.”

The authors point out the ease with which consumers can buy medication online, making the Internet a “prime marketplace” for diversion and a frequent source of the most commonly abused prescription drugs. Implementation of the Ryan Haight Act in April 2009 gave DEA additional power to crack down on the dispensing of controlled substances online without a valid prescription. And, while the law has inhibited the collusion of US doctors and pharmacies in illegal online drug sales, the idea that it has eliminated the problem, as has been suggested in recent media reports, may be overly optimistic.

A. **Rogue Internet Drug Outlets Persist in Offering Controlled Substances:** As NABP and others have shown in recent years, Web sites selling prescription drugs without a prescription or medical oversight are easy to find. A simple Internet browser search for “no prescription Vicodin,” for example, brings up a vast array of Web sites advertising controlled substance medications without a prescription. While some of these sites on their surface may not appear to be selling controlled substances, the right combination of clicks, or a follow-up phone call, enables consumers to purchase any number of controlled substances. A recent report by the online pharmacy verification service LegitScript documents 1,000 rogue Internet drug outlets – a fraction of those that exist – that overtly promote the illicit sale of controlled substances without a valid prescription, in violation of the Ryan Haight Act. While many of these sites have foreign ties, LegitScript notes that more than half and as many as three-fourths of these illicit drug sites are using US-based servers or domain name registrars. “In all of this,” the LegitScript report states, “it’s important to remember that the sole purpose of these websites
is to profit financially at the expense of Internet users’ addiction, health and – occasionally, as in Ryan Haight’s case – death.”

B. **Study Links Prescription Drug Abuse to High-Speed Internet Access:** A study published in May 2011 *Journal of Health Affairs* provides further evidence of the contributing role of the Internet in prescription drug abuse. The study identifies a link between the rise in prescription drug abuse and the increased availability of high-speed Internet access between the years 2000 and 2007. The authors, from Massachusetts General Hospital and the University of Southern California, find that, for every 10% increase in high-speed Internet use at the state level, there is a corresponding 1% increase in admissions to treatment centers for addiction to prescription drugs. For illicit drugs, however, they observe no such correlation. Based on these findings, the authors surmise that the rise in prescription drug abuse can be explained by increased access to rogue Internet drug outlets.

On July 12, 2011, in response to this study, New York Senator Charles Schumer called for a crackdown on illegal online drug sellers that dispense medicine without a valid prescription. Schumer urges the US Justice Department and DEA to immediately begin shutting down these sites, and asks major credit card companies and wire transfer services to block payments to illegal Internet drug outlets. “The war on illegally obtained prescription drugs requires that we use every possible tool at our disposal to stem the tide of this growing epidemic,” said Schumer. “By cracking down on these websites and cutting off their funding source at their choke point, we can put a serious dent into the proliferation of this scourge. It has to stop and we cannot leave any stone unturned in this effort.”

C. **Illegal Sellers Extend Reach Through Social Media:** Bryan Liang, MD, PhD, JD, vice president of the Partnership for Safe Medicines (PSM), discusses the public health threats posed by illegal online drug sellers, counterfeit medicine, and importation in an article posted June 22, 2011 on the *Dr. Oz Show* Web site. The article, “Protecting Our Drug Supply: Internet Pharmacies, Fake Drugs and the Debate over Imported Medicine,” seeks to raise awareness of the slippery, evolving nature of Internet crime. As restrictions in one area grow tighter, new technological trends create new opportunities to reach consumers. “While Ryan’s story brought attention to the very serious public health threat posed by phony online

`'By cracking down on these websites and cutting off their funding source at their choke point, we can put a serious dent into the proliferation of this scourge.'"`
pharmacies, many Americans do not realize that the problem is even worse today,” Laing states. “These illegal online drug sellers have now infiltrated the social media space as well. As my work has noted, they have adapted quickly to any opportunity to make illicit sales.”

IV. COLLABORATIVE EFFORTS KEY TO RAISING AWARENESS

A. NABP Joins Stakeholders in Educational Initiatives: Alongside other entities focused on protecting public health and safety, NABP has shared its research findings and raised awareness of the public health threat posed by illegal online drug sellers and the need for collaborative action during several recent gatherings of health care professionals, regulators, and policy makers.

1. NABP 107th Annual Meeting: At the NABP 107th Annual Meeting, which took place in May 2011 in San Antonio, TX, NABP and the Alliance for Safe Online Pharmacies discussed the problem of rogue Internet drug outlets during a continuing education session. During the session, “Rogue Internet Pharmacies – Can Collaboration Break the Link,” both groups stressed the need for a multidisciplinary approach to this problem. The presenters called on regulators, pharmacists, and other stakeholders to recognize the prevalence of, and factors contributing to, prescription drug misuse and abuse – as well as ongoing policy efforts that seek to choke off the life lines of rogue Internet drug outlets – and to educate their own patients, licensees, and constituents on these important issues.

2. PSM Congressional Briefing: On June 23, 2011, NABP participated in a Congressional briefing coordinated by PSM and Delaware Senator Chris Coons to discuss the problem of rogue Internet drug outlets. Topics included the risks of drug products distributed by such sites, and the deceptive practices they employ to appear legitimate. Participants, including representatives of PSM and FDA, also discussed developing strategies for combating rogue Internet drug outlets and the challenges faced by regulators.

3. ‘White List’ of Legitimate Online Pharmacies: To provide guidance for regulators, Internet commerce providers, and consumers, NABP supports the creation of a “White List” of legitimate Internet pharmacies. As proposed in the March 2011 Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and to Congress, the White List would allow Internet commerce providers and others to know which pharmacies are operating in compliance with federal law and can therefore lawfully use their services.
B. **AWAR\textsubscript{X}E Consumer Protection Program Provides Educational Resources**: NABP encourages regulators, health care professionals, and others to educate patients within their practices and jurisdictions and offers resources to facilitate such efforts. NABP provides the AWAR\textsubscript{X}E™ consumer protection program, for instance, as a resource not only for consumers, but also to help the boards of pharmacy, their licensees, and other stakeholders educate patients on medication safety. The Web site, WWW.AWARERX.ORG, provides information about rogue Internet drug outlets, prescription drug counterfeiting, proper medication use, storage and disposal, and other medication safety issues. Additionally, presenting under the banner of the AWAR\textsubscript{X}E program, NABP staff has spoken one-on-one with hundreds of consumers during trade shows and other consumer expositions, including two recent Active Senior Expos in the Chicago metropolitan area, about the dangers of rogue Internet drug outlets and other medication safety tips. Boards of pharmacy addressing the problem of prescription drug abuse in their state may recommend to their licensees and registrants that they use the AWAR\textsubscript{X}E Web site as a resource for educating their patients about this problem. As AWARERX.ORG resources are further developed, NABP will provide the boards and other pharmacy organizations with updates on using AWAR\textsubscript{X}E tools.

V. **DISCUSSION**

While regulators and other stakeholders have made significant progress in recent years to address rogue Internet drug outlets and the public health threats they pose, the job is not yet done. NABP encourages and continues to work with the state boards of pharmacy, federal regulators, and patient advocates to educate the public on the 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 and ensuring that patients have access to safe and effective prescription drugs, whether purchased from an Internet pharmacy or a brick-and-mortar store.

NABP prepares and releases these status reports quarterly to provide the boards of pharmacy, other state and federal regulatory agencies, 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 and counterfeit medications, in the interest of protecting the public health. 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.
VI. APPENDICES
APPENDIX A

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 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

Internet Drug Outlets Evaluated and Listed as Not Recommended
March 5, 2011-July 1, 2011
(See spreadsheet attached to main e-mail message)