



nabp

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Internet Drug Outlet Identification Program

Progress Report for State and
Federal Regulators:

January 2010

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: JANUARY 2010

I. INTRODUCTION

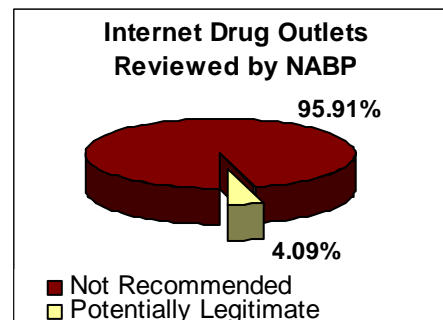
Prescription drug abuse is at an all-time high, and the black market is thriving on the anonymity and lawlessness of the Internet. The addictive nature of prescription painkillers, combined with the perception that prescription drugs are safer than street drugs, creates an eager market, while high profits and an unrestrained electronic marketplace provide a ready supply. Painkillers account for 75% of prescription drug abuse, and hydrocodone is the most commonly diverted and abused pharmaceutical in the United States, according to Drug Enforcement Administration (DEA). The increase in prescription drug abuse over the past decade is attributed largely to ease of access, due, to a great extent, to the Internet and the prevalence of rogue Web sites selling prescription drugs illegally. Supporting this correlation is the fact that rogue Internet drug outlets dispense a significantly higher volume of controlled substances than do legitimate brick-and-mortar pharmacies.

The misuse of pharmaceuticals was the focus of a Prescription Drug Abuse Summit, held December 8-9, 2009, in Bismarck and Fargo, ND, to raise awareness among health care professionals. During his welcome address, North Dakota Attorney General Wayne Stenehjem revealed a number of illuminating statistics. For instance, citing data from the National Drug Intelligence Center, Stenehjem noted that, while a single 80 mg tablet of OxyContin[®] retails for approximately \$6 at the local pharmacy, the same pill sells on the street for about \$80. A bottle of 30 would be worth \$2,400. At that markup, the motivation for this black-market industry becomes clear. At the summit, NABP shed light on the illegal distribution of prescription medications through rogue Internet drug outlets. Presenting information gathered through its Internet Drug Outlet Identification program, NABP revealed that most Web sites selling prescription drugs operate illegally, reviewed the criteria for legitimately operating Internet pharmacies, and illustrated how rogue Internet drug outlets contribute to the problem of prescription drug abuse. The latter subject is addressed further in Section III of this report.

NABP continues to uncover and review large numbers of rogue Internet drug outlets. In a recent news release, discussed further in Section IV.A. of this report, NABP announced that it has exposed more than 5,000 Internet drug outlets operating out of compliance with pharmacy laws and practice standards. Of the 5,226 sites found to be operating in conflict with pharmacy laws and practice standards as of January 6, 2010, approximately 81% do not require a valid prescription, and approximately 43% offer unapproved foreign medications, placing US patients at risk. Approximately 52% (2,693 sites) do not provide a physical address. An estimated 91% of the 5,226 sites are part of large networks that host similarly operating rogue Internet drug outlets. Bearing in mind these factors, as well as the correlation between the prevalence of rogue Internet drug outlets and the rise in prescription drug abuse, NABP continues to stress the importance of educating the public on these risks and continues working to provide patients with the knowledge and information needed to make informed decisions when purchasing prescription medications over the Internet.

II. RESULTS

A. Findings of Site Reviews: As of January 6, 2010, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 5,449 Internet drug outlets selling prescription medications. Of these 5,449 sites, 5,226 (95.91%) appear 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 on the NABP Web site.

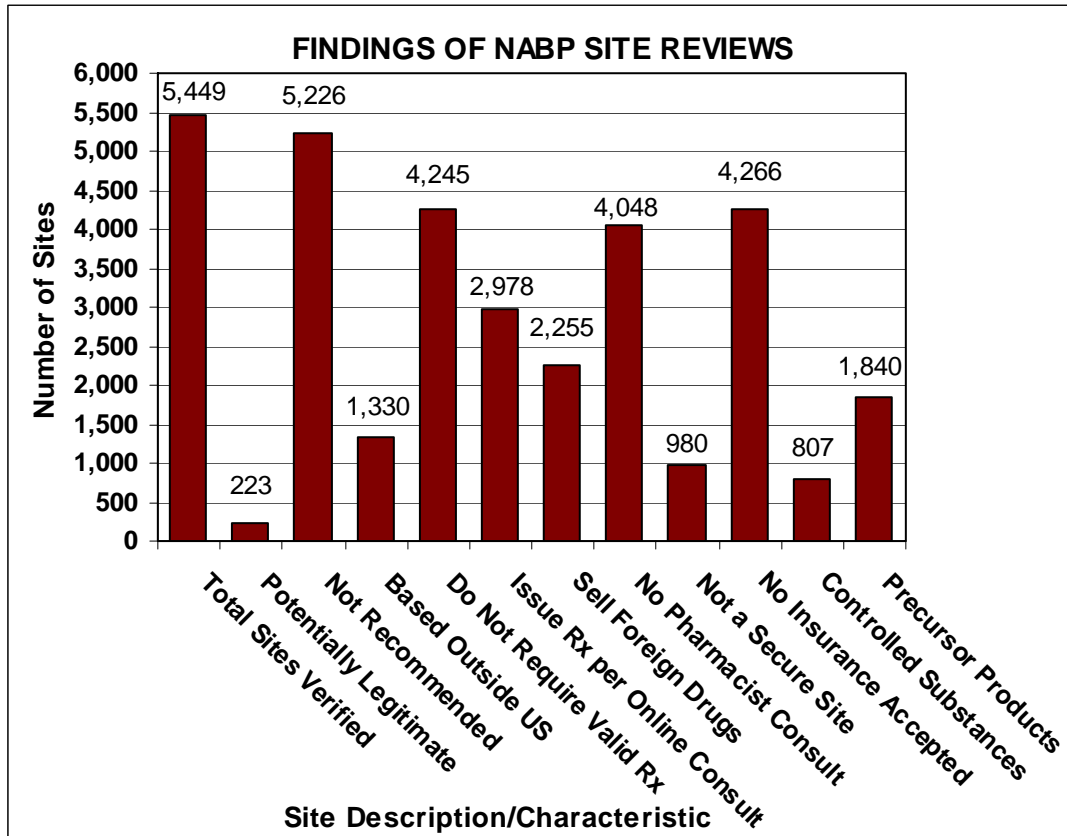


The 5,226 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 1,330 have a physical address located outside of the United States
- 2,693 sites do not provide any physical address
- 4,245 do not require a valid prescription
- 2,978 issue prescriptions per online consultation only
- 2,255 offer foreign or non-Food and Drug Administration-approved drugs
- 4,048 do not offer medical consult with a pharmacist
- 980 do not have secure sites
- 4,266 do not accept insurance
- 1,675 have server locations in foreign countries

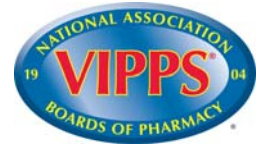
- 4,745 appear to be affiliated with a network
- 807 dispense controlled substances
- 1,840 sell precursor products

Of the total 5,449 sites reviewed, 223 (4.09%) appear to be potentially legitimate, ie, appear to meet program criteria that could be verified solely by looking at the sites.



The criteria against which NABP evaluates Internet drug outlets are provided in Appendix A of this report. Complete findings on those sites added to the Not Recommended list on the NABP Web site during November-December are included in Appendix B of this report. These data are sorted according to the physical locations of the Web site operations: US or Foreign, and, within those categories, by state and by country, respectively. Findings on sites listed as Not Recommended during April 2008 through October 2009 and appended to previous progress reports are available upon request.

B. Recommended Internet Pharmacies: NABP continues to recommend that patients use Internet pharmacies accredited through the NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) and Veterinary-Verified Internet Pharmacy Practice Sites™ (Vet-VIPPS™) programs when buying medication online. These sites have undergone and successfully completed the rigorous NABP accreditation process, which includes a thorough 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, 18 VIPPS pharmacy sites and one Vet-VIPPS pharmacy site, representing more than 12,000 pharmacies, are listed as Recommended Internet Pharmacies.



C. Patient Inquiries: Since the launch of our Internet program in May 2008, NABP has received through our Customer Service department and Web-based Report-a-Site feature 257 inquiries and reports from patients in regard to Internet drug outlets. Including documented inquiries predating the Internet Drug Outlet Identification program, NABP has received a total of 517 customer inquiries regarding Internet drug outlets. These correspondences include reports of injury (29) and financial fraud (137), inquiries as to whether a particular Internet drug outlet is safe to use, and reports of sites that appear to be operating suspiciously. Still others inquire about the requirements of operating an Internet pharmacy. In the latter cases, we directed these individuals to the appropriate state boards of pharmacy, as well as to our own program criteria posted in the Internet Pharmacies section of the NABP Web site. We believe these numbers represent only a fraction of the number of patients who have been negatively affected by rogue Internet drug outlets and who may seek guidance from NABP as word of our Internet program and patient resources spreads.

III. PRESCRIPTION DRUG ABUSE: THE CONTRIBUTING ROLE OF ROGUE INTERNET DRUG OUTLETS

To help educate health care professionals – and, through them, their patients – on the dangers of rogue Internet drug outlets, NABP participated in the Prescription Drug Abuse Summit hosted December 8-9, 2009, by the North Dakota Office of Attorney General. NABP’s presentation addressed the common misconception that prescription medications purchased from any Internet drug outlet are safe. The perception that prescription drugs are safer than street drugs contributes to the popularity of their abuse. Many patients fail to realize, however, that when purchasing

medications from unknown sources online, the quality and safety of those medications is also unknown. The presentation took attendees behind the electronic curtain of an online transaction, stressing that virtually anyone with a computer and a bank account can establish a Web presence and start selling drugs through an affiliate network. The operators of most Web sites selling prescription medications have no knowledge of or concern for patient safety, as evidenced by the fact that most of them do not require a valid, if any, prescription. And, as noted in our current research findings, many accept an online questionnaire in place of a prescription. NABP's presentation clarified several additional key points for health care providers: to be valid, a prescription must be based on a bona fide patient-practitioner relationship that has included a physical examination; most Web sites selling prescription drugs do not verify patient identity, medical history, or age, allowing minors to buy dangerous drugs; and many sites sell foreign or unapproved drugs, circumventing the closed and tightly regulated US supply chain, exacerbating the risk to those who purchase from these sites.

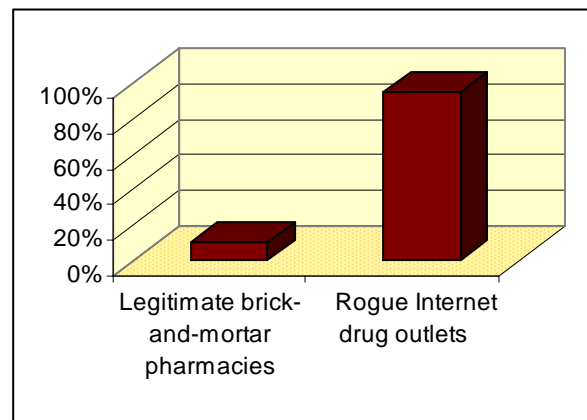


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This editorial cartoon, included in NABP's presentation at the Prescription Drug Abuse Summit, illustrates the common misconception that prescription medications purchased from any Internet drug outlet are safe.

A. Sales of Controlled Substances Soar Online: DEA links the dramatic increase in prescription drug abuse in recent years to ease of access and has named the Internet as one of the biggest culprits. Hydrocodone is the most commonly diverted and abused pharmaceutical in the US, and Internet drug outlets sell an inordinate volume of hydrocodone, among other controlled substance painkillers.

DEA tracked 34 known or suspected rogue Internet drug outlets and found that these sites dispensed 98.6 million dosage units of hydrocodone combination products in 2006, according to the 2007 Congressional testimony of Joseph T. Rannazzisi, deputy assistant administrator of the DEA Office of Diversion Control. Controlled substances account for approximately 11% of prescriptions



Controlled substances account for approximately 11% of prescriptions dispensed at legitimate brick-and-mortar pharmacies in the US, v 95% for the 34 rogue Internet drug outlets tracked by DEA in 2006.

dispensed by legitimate brick-and-mortar pharmacies. By contrast, controlled substances accounted for 95% of prescriptions dispensed by these rogue sites. These massive volumes of controlled substances obtained without a valid prescription feed the diversion and abuse of these drugs by making them widely available.

- B. Internet Provides Multiple Access Points: NABP research confirms that controlled substances are readily available online without a prescription. Among the myriad Web sites masquerading as legitimate pharmacies, many blogs residing on otherwise legitimate blog hosting servers or social network sites (eg, Twitter, Facebook, YouTube) promote rogue Internet drug outlets. Even more often, the operators of rogue sites hack into legitimate domain name servers to covertly redirect legitimate domains to illicit sites. In both cases, the illicit page's location on a subdomain of the host site not only gives it a veneer of credibility but also makes the perpetrators more difficult to track.
- C. Knowledge Is Key: Knowledge is key to protecting the public from high-tech drug dealers, and NABP encourages health care providers to educate their patients on these issues. Meanwhile, NABP continues to research Web sites selling prescription drugs and report its findings to you, the state boards of pharmacy, federal regulators, law enforcement, and patient advocates. NABP engages in and continues to seek partnership opportunities with other entities to educate health care professionals and the public on the dangers of buying prescription drugs online, thereby empowering patients to make informed decisions. The presentations given at the summit are available on the Web site of the North Dakota Office of Attorney General at www.ag.state.nd.us.

IV COMMUNICATION AND OUTREACH EFFORTS

In our ongoing efforts to bring these shadowy Internet operations into the light, NABP is undertaking a number of initiatives to inform regulators and health care professionals of our findings and to educate patients on the risks inherent in buying prescription drugs online.

- A. NABP News Release Reports 5,000 Internet Drug Outlets Listed as Not Recommended: On December 28, 2009, NABP issued a news release titled "5,000 Web Sites Selling Prescription Drugs Outside Of Pharmacy Laws and Practice Standards." The release discusses the bitter-sweet milestone reached by NABP in our ongoing review of Web sites selling prescription medications. NABP now lists more than 5,000 Internet drug outlets as Not Recommended. These sites – 96% of the total number of sites reviewed – have been found to be out of compliance with pharmacy laws and practice standards established in the US to protect the public health. The full news release is available in the News section of the NABP Web site

(www.nabp.net) and has been picked up by more than 50 other news sources, including *Reuters*, *DailyFinance*, and *HealthNewsDigest.com*.

- B. NABP in the News: NABP frequently serves as an information resource for the professional and consumer media on issues regarding protection of the public health. Two recent examples are as follows:
1. Prescription Drug Abuse: While people who are abusing prescription drugs often get them free from a friend or relative who obtained the drugs legitimately to treat a condition, or by convincing their doctor to write prescriptions they do not need, many abusers buy them, often without a prescription, from Internet drug outlets, NABP notes in a December 29, 2009 HealthDay News article, "[In U.S., Prescription Drug Abuse Is Growing](#)."
"We've seen the Internet move from an entrepreneurial, Amazon.com-type of marketplace to a primary area for drug abuse," the article states, quoting NABP Executive Director/Secretary Carmen Catizone. "It's easier to obtain prescription drugs online than it is to buy crack or heroin on the street."
 2. Online Prescribing Legislation: A January 5, 2010 *USA Today* article, "[In Utah, a Push to Expand Online Prescriptions Nationwide](#)," discusses Utah Senator Curt Bramble's plan to sponsor a bill that would allow sites similar to www.kwikmed.com to prescribe medications online. "Online prescriptions, absent a physical examination of a patient, do not meet the standard of care and in some states are illegal," the article states, quoting Mr Catizone. "For all of the sites, KwikMed included, if there's not a physical examination, that prescription is invalid." The article was picked up by other online news sources, as well.
- C. Pharmahelper: NABP recently introduced its newest supporter in protecting the public health from rogue Internet drug outlets, Pharmahelper.com. Pharmahelper is a prescription drug price comparison service recently redesigned in accordance with NABP standards as a reliable and trustworthy resource for patients seeking to purchase medications safely online. NABP worked with Pharmahelper Founder John Lattuca to approve content for the redesigned Web site and will continue to monitor the site to ensure that it lists only those Internet pharmacies that meet NABP criteria for legitimate practice.
- D. States' Attorneys General: At the request of some state boards of pharmacy, NABP is expanding the distribution of its Internet Drug Outlet Identification Program status reports to include the states' attorneys general, beginning with the current report. As always, our objective in sharing this information is to assist the states in their efforts to crack down on the illegal distribution of prescription drugs over the Internet, to protect the public health from

illegally operating Web sites, and to hold Internet drug outlets accountable to the same standards required of all legitimate pharmacies.

E. Link to Internet Pharmacies Section of NABP Web Site: Several state boards of pharmacy and other health professional and patient advocacy organizations display on their Web sites a link to the Internet Pharmacies section of the NABP Web site to help educate the public about the dangers of buying drugs online. The link is as follows: www.nabp.net/ip.asp. Please feel free to post it on your Web site as you see fit. For descriptive copy to accompany the link, or any technical assistance in posting it, please contact NABP directly. Additionally, NABP will be working with other state and national pharmacy professional groups to post this link and to communicate this public health threat to their members and, ultimately, to the patients.

V. DISCUSSION

As rogue Internet drug outlets continue to undermine the pharmacy laws and practice standards established to protect patient health, NABP maintains its commitment to inform regulators and educate the public on the dangerous and illicit practices of such sites. NABP staff will continue to evaluate Internet drug outlets and list sites that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards as Not Recommended on the NABP Web site. The Association also will continue to provide the boards of pharmacy, other state and federal regulatory agencies, and interested stakeholders with bimonthly updates of our findings. If pertinent information is discovered in the interim, we will distribute additional reports as needed. Through communication and cooperation, we hope to advance the efforts of regulators and other entities seeking to curtail the abuses perpetrated by these online drug dealers. In turn, we encourage those entities and other health care professionals to educate patients within their practices and jurisdictions.

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 to the public, as well as to the state and federal regulators and interested stakeholders. By working in concert, we can make considerable progress toward curbing the illegal trade of prescription drugs and protecting the public health from rogue Internet drug outlets.

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 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.

APPENDIX A (CONT.)

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 November-December 2009

(See spreadsheet attached to main e-mail message)