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Internet Drug Outlet Identification Program

Progress Report for State and
Federal Regulators:
August 2010

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**INTERNET DRUG OUTLET IDENTIFICATION PROGRAM
PROGRESS REPORT: AUGUST 2010**

I. INTRODUCTION

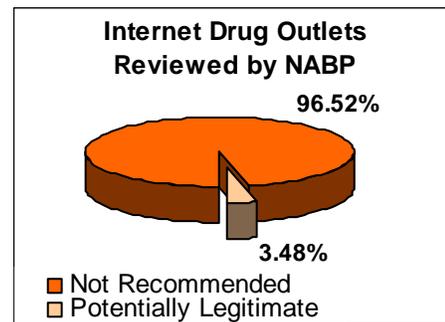
While the Internet remains a potentially dangerous place to purchase prescription medications, the National Association of Boards of Pharmacy® (NABP®) continues to move forward with state and federal regulators and other stakeholders to diminish the threat that rogue Web sites pose to patient health. Gradually but perceptibly, awareness is growing that many Internet drug outlets presenting themselves as lawful pharmacies are nothing more than a façade for the illicit sale of unapproved, substandard, and counterfeit drugs. But, like the snake oil salesmen of old, their guise wears thin, as legitimate practices gain ground. Word is spreading that the same laws that apply to brick and mortar pharmacies also apply online. And, while rogue Internet drug outlets continue to flaunt their wares in organic (key word-based) search results, social media venues, blog hosting services, and spam, it is encouraging that some avenues for rogue sites to reach unwitting customers are narrowing.

Since the major search engines began earlier this year to require NABP accreditation or approval for Internet pharmacy and prescription drug-related entities to advertise online, NABP is receiving an influx of new applications for Verified Internet Pharmacy Practice Sites^{CM} (VIPPS®) and Veterinary-Verified Internet Pharmacy Practice Sites^{CM} (Vet-VIPPS^{CM}) accreditation and for NABP e-Advertiser Approval. (The latter program is discussed further in section III of this report.) Accredited and approved practices play an important role in providing consumers with safe options for Internet pharmacies and other online drug-related services. Consumers utilizing Google, Microsoft, or Yahoo! to search sponsored links (ie, paid advertisements) for Internet pharmacies or other prescription drug-related services can now do so with increased confidence, knowing that these sponsored search results will provide e-Advertiser Approved and/or VIPPS/Vet-VIPPS accredited facilities that offer safe services to their customers.

Meanwhile, however, NABP continues to uncover and review large numbers of rogue Internet drug outlets. Of the 6,854 sites found to be operating in conflict with pharmacy laws and practice standards as of August 13, 2010, approximately 84% do not require a valid prescription, and approximately 45% offer unapproved foreign medications, placing United States patients at risk. Approximately 55% (3,776 sites) do not provide any physical address. The World Health Organization estimates that medicines purchased over the Internet from outlets that conceal their actual physical address are counterfeit in over 50% of cases. An estimated 94% of the 6,854 sites are part of large networks that host similarly operating rogue Internet drug outlets. NABP continues to stress the importance of educating the public on these risks and 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 August 13, 2010, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 7,101 Internet drug outlets selling prescription medications. Of these 7,101 sites, 6,854 (96.52%) 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 in the “Buying Medicine Online” section, under Consumers, on the NABP Web site.

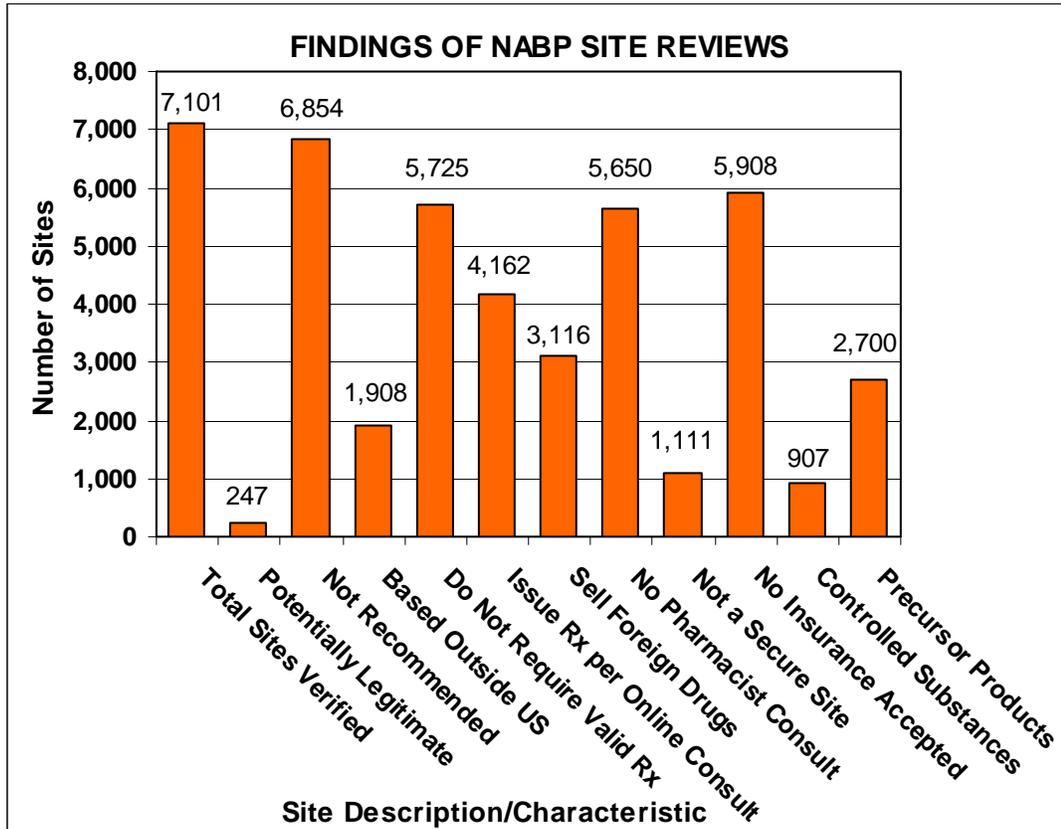


The 6,854 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 1,908 have a physical address located outside of the US
- 3,776 sites do not provide any physical address
- 5,725 do not require a valid prescription
- 4,162 issue prescriptions per online consultation or questionnaire only
- 3,116 offer foreign or non-Food and Drug Administration (FDA)-approved drugs
- 5,650 do not offer medical consult with a pharmacist
- 1,111 do not have secure sites
- 5,908 do not accept insurance
- 2,374 have server locations in foreign countries
- 6,430 appear to be affiliated with a network

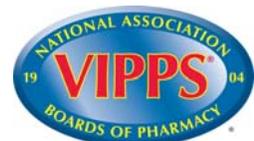
- 907 dispense controlled substances
- 2,700 sell precursor products

Of the total 7,101 sites reviewed, 247 (3.48%) 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 the “Buying Medicine Online” section of the NABP Web site.

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, 27 VIPPS and Vet-VIPPS pharmacy sites, representing more than 12,000 pharmacies, are listed as Recommended Internet Pharmacies.

III. NABP e-ADVERTISER APPROVAL PROGRAM



The findings generated by the Internet Drug Outlet Identification Program over the last two-and-a-half years illustrate the critical need for a uniform review and accreditation process for Web sites offering prescription drugs. Expanding our efforts to identify and support those pharmacy Web sites providing safe, reliable, and lawful pharmacy services, NABP has allocated Internet Drug Outlet Identification program staff time to screening applicant Web sites for the VIPPS, Vet-VIPPS, and e-Advertiser Approval programs. As a result, consumers are provided with a wider selection of approved and accredited Internet practices. As of August 13, 2010, staff has screened 44 applicants for all three programs.

- A. Standards: Prescription drug related entities applying for NABP e-Advertiser Approval must meet minimum standards for legitimate Internet practice, as defined in the program standards posted in the e-Advertiser Approval Program section, under Accreditation, on the NABP Web site and included as Appendix A of this report. 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. Applicants for VIPPS and Vet-VIPPS accreditation, ie, those pharmacies offering a full range of pharmacy services over the Internet, require a more intensive review and investigation to ensure they meet the highest standards for safe and reliable patient care. Applicants eligible for e-Advertiser Approval, on the other hand, do not accept or dispense new prescription drug orders over the Internet. These entities, along with any drug information, pharmacy information, or medical practitioner’s Web site, must meet basic standards and undergo a review to verify their legitimacy and to obtain the NABP e-Advertiser Approval seal. Currently, three entities are listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.
- B. News Release: On July 28, 2010, NABP issued a news release, “NABP Grants First ‘Approved e-Advertiser’ Status to Pharmahelper.com, QC Supply, and Kerr Drug.” The release discusses the e-Advertiser Approval of Pharmahelper.com, QC Supply, and Kerr Drug, which allows the organizations to advertise their pharmacy-related services on Google, Microsoft, and Yahoo! As stated in the release, “these entities offer reliable and trustworthy resources for patients seeking to purchase medications safely online.” The release is available for viewing in the Newsroom section of the NABP Web site (www.nabp.net/news).

IV. COMMUNICATION AND OUTREACH EFFORTS

- A. Public Events: Consumer outreach is a very important aspect of the NABP Internet Drug Outlet Identification Program. As a part of our efforts to inform the public on the dangers of purchasing prescription medications online, NABP is participating in the 15th Annual Senior Lifestyle Expo, August 24-25 in Oakbrook Terrace, IL. We hope to reach out to the thousands of expected attendees and provide them with information that will allow them to make educated decisions when buying their medications via the Internet. On August 10, 2010, NABP issued a news release, “AWAR_xE Alerts Seniors to Rogue Web Sites Selling Counterfeit and Substandard Medicine,” to 22 local media contacts to publicly announce NABP’s participation in the expo. As noted in the release, “By being aware of the dangers of buying medicine over the Internet, consumers can protect themselves and their families from the risks posed by rogue Web sites.” The release is available for viewing in the Newsroom section of the NABP Web site (www.nabp.net/news).
- B. ICANN, ISPs, and Registrars: NABP is working with LegitScript, the Internet pharmacy verification, investigation, and monitoring service that holds Internet pharmacies accountable to NABP-recognized standards, to encourage Internet commerce providers to require the Internet pharmacy domain holders they support to adhere to US pharmacy laws. The International Corporation for Assigned Names and Numbers (ICANN) is the overseer of domain name registrars and Internet service providers (ISPs) and has certain standards that these entities are expected to follow. Likewise, registrars – both domestic and foreign – have policies giving them the authority to shut down Web sites being used for illicit purposes. Some, when made aware of their illicit activities, have taken action against these domain holders. Others, however, continue to declare their impotence to intervene. NABP will continue working with LegitScript, stakeholder groups such as the Alliance for Safe Online Pharmacies, and ICANN to encourage Internet commerce providers to meet basic standards for lawful practices.
- C. Link to 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 Buying Medicine Online 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/programs/consumer-protection/buying-medicine-online. (The previously provided link, www.nabp.net/ip.asp, is still functional and redirects to this page.) 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.

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. 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

NABP e-Advertiser Approval Program Standards

Pharmacies conducting limited pharmacy services over the Internet and other businesses or persons conducting drug-related services over the Internet must meet the following standards to earn NABP e-Advertiser Approval status. 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.

1. **Licensure.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must be licensed or registered in good standing to practice in all required jurisdictions.
2. **DEA registration.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, if dispensing controlled substances, must be registered with the United States Drug Enforcement Administration (DEA).
3. **Prior discipline.** The pharmacy, pharmacist-in-charge, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must not have been subject to significant recent and/or repeated disciplinary sanctions.
4. **Location.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must be domiciled in the US.
5. **Validity of prescription.** A pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a medical practitioner authorized to prescribe under state law and, as applicable, federal law. A medical practitioner authorized to prescribe must not prescribe, distribute, or offer to prescribe or distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a pre-existing 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, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, 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). The pharmacy, medical practice, or medical practitioner must not prescribe, dispense, or offer to prescribe or dispense medications that have not been approved by the US Food and Drug Administration (FDA).
7. **Privacy.** If the applicant Web site, or any site to which the applicant site links or with which it is affiliated, transmits information that would be considered Protected Health Information (PHI) under the 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, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must provide on the Web site an accurate US street address of the dispensing pharmacy, medical practice, medical practitioner, or corporate headquarters. The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, 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 or medical practitioner regarding complaints or concerns or in the event of a possible adverse event involving their medication.
9. **Web site transparency.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, 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 practice, its staff, prescription drugs, or financial transactions.
10. **Domain name registration.** The domain name registration information of the applicant Web site, or of any pharmacy, medical practice, or medical practitioner it promotes, must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy, medical practice, or medical practitioner. Absent extenuating circumstances, applicant Web sites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated Web sites.** The applicant Web site, any pharmacy, medical practice, or medical practitioner it promotes, its staff, domain name registrants, and any person or entity that exercises control over, or participates in the applicant business, must not be affiliated with or control any other Web site that violates these standards.