



# **National Association of Boards of Pharmacy**

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# **Internet Drug Outlet Identification Program**

Progress Report for State and Federal Regulators:
June 2010

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## INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: JUNE 2010

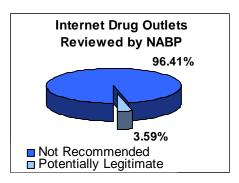
#### I. INTRODUCTION

Against a backdrop of some 96% of Internet drug outlets selling prescription drugs unlawfully, the National Association of Boards of Pharmacy® (NABP®) is pleased to report a few steps forward in making the Internet a safer place for patients to buy prescription medications. As of June 7, 2010, drug sellers seeking to advertise in the United States through any of the three major search engines must be accredited through the Verified Internet Pharmacy Practice Sites CM (VIPPS CM) program. Under the new policies implemented this spring, Internet pharmacies that are not accredited by VIPPS are no longer permitted to display advertisements in sponsored search results appearing on Google, Microsoft, or Yahoo! Additionally, stakeholder groups like the Alliance for Safe Online Pharmacies (ASOP) and some government agencies continue to pave in-roads toward to the development of policy changes to further protect patients from illegal drug sellers and ensure patient access to safe, Food and Drug Administration (FDA)-approved medications – not only at the hospital or corner drug store, but also over the Internet. These improvements in the situational landscape are discussed further in section III, Strategic Developments, of this report.

Meanwhile, NABP continues to uncover and review large numbers of rogue Internet drug outlets. Of the 6,237 sites found to be operating in conflict with pharmacy laws and practice standards as of May 25, 2010, approximately 83% do not require a valid prescription, and approximately 46% offer unapproved foreign medications, placing US patients at risk. Approximately 53% (3,314 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 93% of the 6,237 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 May 25, 2010, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 6,469 Internet drug outlets selling prescription medications. Of these 6,469 sites, 6,237 (96.41%) appear to be operating out of compliance with state and federal laws and/or NABP patient safety and

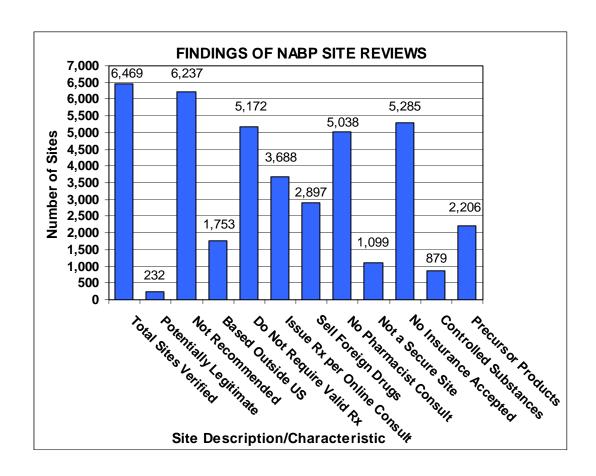


pharmacy practice standards, and are listed as Not Recommended on the NABP Web site.

The 6,237 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 1,753 have a physical address located outside of the US
- 3,314 sites do not provide any physical address
- 5,172 do not require a valid prescription
- 3,688 issue prescriptions per online consultation or questionnaire only
- 2,897 offer foreign or non-FDA-approved drugs
- 5,038 do not offer medical consult with a pharmacist
- 1,099 do not have secure sites
- 5,285 do not accept insurance
- 2,186 have server locations in foreign countries
- 5,821 appear to be affiliated with a network
- 879 dispense controlled substances
- 2,206 sell precursor products

Of the total 6,469 sites reviewed, 232 (3.59%) 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 March-May 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 February 2010 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 VIPPS and Veterinary-Verified Internet Pharmacy Practice Sites<sup>CM</sup> (Vet-VIPPS<sup>CM</sup>) 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, 21 VIPPS pharmacy sites and four Vet-

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

#### III. STRATEGIC DEVELOPMENTS

A. Search Engines Improve Advertising Program Standards: Beginning with Google on March 1, 2010, followed by Microsoft and Yahoo! on June 7, 2010, the three major search engines limit participation in their online advertising programs to Internet pharmacies that are accredited through VIPPS, or, for veterinary pharmacies, Vet-VIPPS. Those that are not VIPPS-accredited are no longer permitted to display advertisements in the search engines' sponsored links (ie, those links that advertisers pay to display above and to the right of "natural" key-word based search results). Rather, they are directed to NABP, with whom they may apply for accreditation involving a thorough review and investigation of their Web sites, policies and procedures, facilities, and affiliations.

NABP issued a news release on June 7, commending Microsoft for its policy change and another on June 9, welcoming Yahoo! to the pool of search engines requiring VIPPS accreditation for Internet pharmacy advertisers. In the first, NABP Chairperson Gary A. Schnabel, RN, RPh, comments favorably on the "forward momentum in the protection of the public health." He states, "NABP is pleased to work with companies to help weed out rogue Internet drug outlets that place patient safety at risk for the purpose of profit. We applaud Microsoft for barring these sites and for prioritizing consumer safety above advertising dollars." In the second news release, NABP President William T. Winsley, MS, RPh, congratulates Yahoo! on its "conscientious decision to hold pharmacy advertisers accountable to the laws established in the US to protect patient health." He states, "On behalf of the state boards of pharmacy, NABP is pleased to see Yahoo! taking steps to protect the public health against rogue Internet drug outlets." (The NABP news release commending Google's policy change was published on February 11, 2010.)

B. NABP Launches e-Advertiser Approval Program: Because the VIPPS accreditation program is structured to address licensed pharmacies engaged in the practice of pharmacy and a full range of defined business activities online, NABP has developed a complementary program, the NABP e-Advertiser Approval Program, that identifies legitimate Internet advertisers that offer only limited pharmacy services or other prescription drug-related services online. The review process and fees for the program are dependent upon the level of pharmacy and drug-related services the advertisers offer. The application, along

with the new program applicant eligibility descriptions and fee schedule, are posted under Accreditation on the NABP Web site.

C. ASOP Identifies 'Choke Points' as Key to Strategic Efforts: The search engines' decisions to require VIPPS accreditation for Internet pharmacy advertisers represents, to NABP and other stakeholders, a step in the right direction. ASOP, for example, is working to bring



about policy changes requiring Internet search engines, domain name registrars, and other "gatekeepers" to stop enabling rogue Internet drug outlets. Established earlier this year by a group of corporate and nonprofit stakeholders, the group's objective is to ensure that patients have access – whether online or offline – to safe, FDA-approved medicine through licensed US pharmacies. With the support of NABP and other stakeholders, ASOP is educating government policymakers about the role Internet commerce stakeholders (eg, Internet service providers, search engines, domain name registrars), financial transaction entities, and other entities could play in protecting patient safety by promoting legitimate online pharmacies. The group calls these enablers gatekeepers, or choke points, and identifies search engines and domain name registrars as primary among them. ASOP aspires to see choke-point stakeholders and government actors cooperate to ensure that search results, domain names, promotional ads, and payment mechanisms are only available to legitimate online pharmacies that sell FDA-approved medicines to US patients in compliance with federal and state law.

Engaging with key government agencies, ASOP seeks to choke off these routes to illegal drug sales to protect US patients from substandard, unapproved, and counterfeit drugs. Already this year, ASOP has met with the Drug Enforcement Agency, US Intellectual Property Enforcement Coordinator, and FDA to discuss the problem of illegal online drug sellers, possible legislative solutions, and other strategies to protect consumers from these rogue entities and ensure the availability of legitimate, FDA-approved medications online.

While the search engines' now restrict advertising, or "sponsored links," to those Internet pharmacies that are VIPPS accredited, they still enable consumers to access illegal drug sellers through "natural," key-word search results. ASOP, along with NABP and other groups interested in protecting the public health, would like to see the search engines apply these standards to natural search results as well. Contributing to the problem, many domain name registrars indiscriminately sell domain names (ie, Web site addresses) to drug sellers who use them to deceptively attract consumers to the sellers' unlawfully operating sites. While some registrars have demonstrated their willingness to shut down Web sites that are clearly being used to facilitate illegal practices (largely due to the efforts of ASOP member LegitScript),

ASOP also hopes to see regulatory influence emerge to persuade all domain name registrars to block domains for rogue Internet drug outlets.

ASOP's founding members include the American Pharmacists Association, Eli Lilly & Company, the National Association of Chain Drug Stores, and LegitScript. NABP is one of four observer groups that support the ASOP mission, participate in meetings, and offer information, but are not voting members of the decision making process. Other observer groups include National Health Council and Partnership for Safe Medicines.

#### IV. COMMUNICATION AND OUTREACH EFFORTS

- A. NABP Reaches Out to Seniors: NABP continues to undertake a number of initiatives to inform regulators and health care professionals of our findings on rogue Internet drug outlets and to educate patients on the risks inherent in buying medicine online. In a recent effort to reach out directly to consumers, NABP participated in the "Fifty-Plus Health and Wealth Expo" on May 23, 2010, at the Hotel Pennsylvania in New York, NY. Under the banner of NABP's consumer protection program, AWAR<sub>x</sub>E, NABP spoke one-on-one with hundreds of consumers about safely obtaining their prescription drugs and also gave a presentation to a group of attendees, providing them with essential information on buying medicine online.
- B. Redesigned Web Site Features Enhanced Patient Information: In April 2010, NABP launched a newly designed user friendly Web site that includes a section targeted for consumers. The goal of the sweeping redesign was to improve the navigation to provide a new look and a more streamlined user experience. As part of the change in navigation Members, Pharmacists, Students, Accreditation, Government Affairs, and Consumers have designated pages where they can find information tailored to fit their particular need. The revised "Buying Medicine Online" pages are contained within the Consumers section.

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 new link is as follows: <a href="https://www.nabp.net/programs/consumer-protection/buying-medicine-online">www.nabp.net/programs/consumer-protection/buying-medicine-online</a>. (The old link, <a href="https://www.nabp.net/ip.asp">www.nabp.net/ip.asp</a>, 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

#### 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. <u>**DEA registration.**</u> 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.
  - <u>Definition.</u> 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. <u>Legal compliance.</u> 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. <u>Privacy.</u> 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. <u>Web site transparency.</u> 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. <u>Affiliated Web sites.</u> 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-May 2010

(See spreadsheet attached to main e-mail message)