



National Association of Boards of Pharmacy

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Internet Drug Outlet Identification Program

Progress Report for State and
Federal Regulators:
January 2012

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**INTERNET DRUG OUTLET IDENTIFICATION PROGRAM
PROGRESS REPORT: January 2012**

I. INTRODUCTION

Throughout 2011, reports of rogue Internet drug outlets, prescription drug counterfeiting, e-mail and Internet scams, and prescription drug abuse permeated the news. Meanwhile, public health regulators and enforcement agencies worldwide continued to take action to shut down illegal online drug sites and increase penalties for counterfeiters. Multiple groups also have undertaken efforts to educate health care professionals and consumers, and to establish policies to better protect patient health. A sampling of the year's counterfeit drug news, regulatory and enforcement efforts, and educational initiatives is provided in section III of this report.

Through its own research in 2011, the National Association of Boards of Pharmacy® (NABP®) identified an additional 1,322 Web sites operating out of compliance with United States federal and state pharmacy laws and practice standards, and posted these sites to the Not Recommended list on the NABP Web site. In all, NABP has found more than 8,400 Web sites – 96% of the total number of sites reviewed – to be out of compliance with pharmacy laws and practice standards established in the US to protect the public health. The deception and defrauding of pharmacy patients by rogue online drug sellers and counterfeiters, however, is by no means limited to the US, and NABP encourages efforts at home and abroad to recognize and address this global problem. NABP is taking steps to expose these dangers, to assist regulatory and enforcement agents in eliminating these unlawful practices, and to create new opportunities for the state boards to learn more about global pharmacy issues and the potential for collaboration among international pharmacy regulators.

II. RESULTS

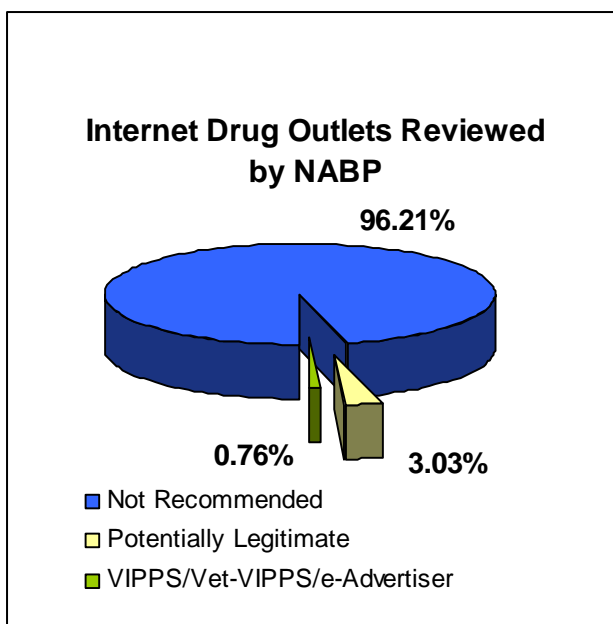
A. Findings of Site Reviews: As of December 31, 2011, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 8,789 Internet drug outlets selling prescription medications. Of these, 8,456 (96.21%) were found to be operating out of

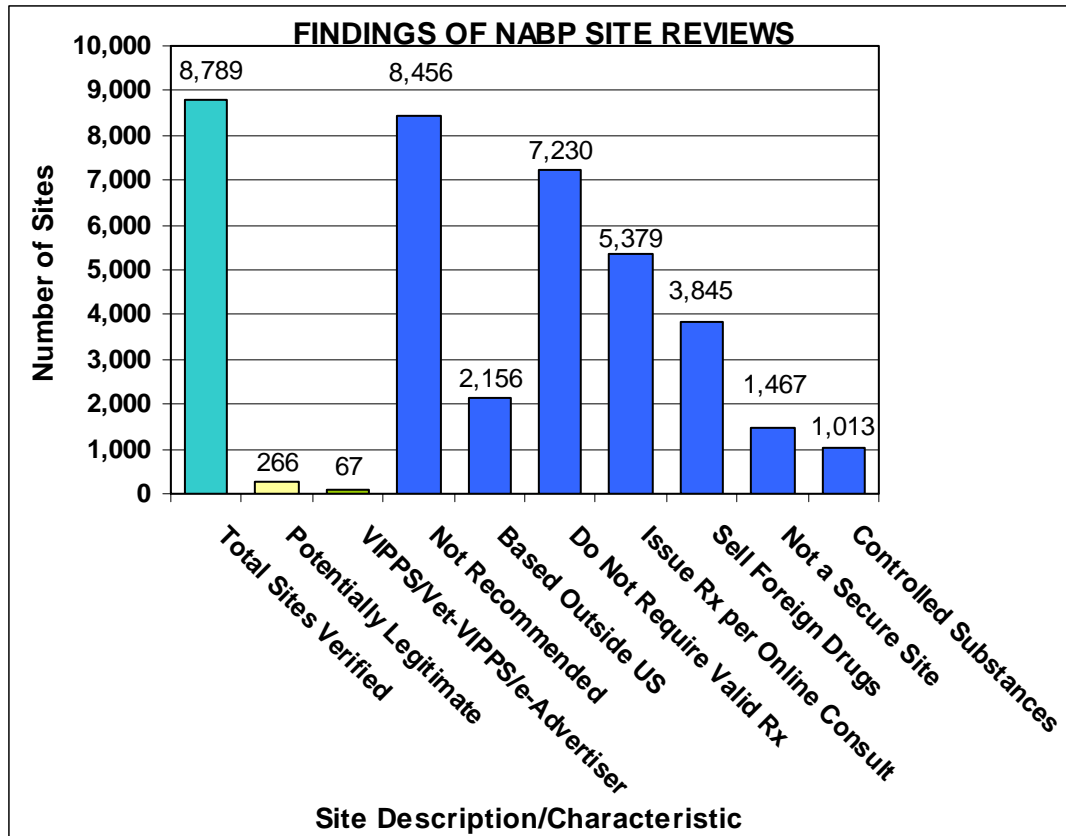
compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards, and are listed as Not Recommended in the “Buying Medicine Online” section, under Consumers, on the NABP Web site. Sites listed as Not Recommended include those that were found to be noncompliant at the time of review but may since have been deactivated.

The 8,456 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 2,156 have a physical address located outside of the US
- 7,230 do not require a valid prescription
- 5,379 issue prescriptions per online consultation or questionnaire only
- 3,845 offer foreign or non-Food and Drug Administration (FDA)-approved drugs
- 1,467 do not have secure sites
- 3,004 have server locations in foreign countries
- 8,265 appear to be affiliated with a network
- 1,013 dispense controlled substances

Of the total 8,789 sites reviewed, 266 (3.03%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites. Sixty-seven (0.76%) of the 8,789 reviewed sites have been accredited through NABP’s Verified Internet Pharmacy Practice Sites^{CM} (VIPPS[®]) or Veterinary-Verified Internet Pharmacy Practice Sites^{CM} (Vet-VIPPS[®]) programs, or approved through the NABP e-Advertiser Approval^{CM} Program. The criteria against which NABP evaluates Internet drug outlets are provided in the appendix of this report.





Findings of NABP Site Reviews as of December 31, 2011

- B. Year-to-Year Comparison: As a result of site reviews completed during the year 2011, the Not Recommended list has grown 19% from the 7,134 sites posted by the end of 2010. NABP posted 1,322 additional sites to its Not Recommended list in 2011 – a 31% decrease from the 1,926 sites added to the list in 2010, but still clearly reflective of an ongoing problem. The decrease is attributable to NABP’s reallocation of certain resources to identify legitimate Internet pharmacies, rather than to a reduction in the activities of illegal online drug sellers. The percentage of sites reviewed that were designated as Not Recommended as of year-end 2011 (96%) is consistent with findings as of year-end 2010.
- C. Recommended Internet Pharmacies: NABP, along with FDA and other patient safety advocates, 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, 46 VIPPS and Vet-VIPPS pharmacy sites, representing more than 12,000 pharmacies, are listed as Recommended Internet Pharmacies. Several more applications are in progress.

- D. 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 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. 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 December 31, 2011, 22 entities were listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.



III. 2011 YEAR IN REVIEW

- A. Medication Counterfeiting: Reports of prescription drug counterfeiting were common throughout the year in consumer and professional media, as well as in news releases and government-issued reports. Drugs to treat erectile dysfunction were among the most commonly sold online. Print, broadcast, and Web-based media publicized the risks to patients, and many encouraged consumers to look for legitimately licensed, law-abiding Internet pharmacies displaying the VIPPS Seal, while policymakers vowed to step up their efforts to curtail the problems. The list below provides a sampling of these events:
- March 4: Several US federal agencies express their commitment to curb prescription drug counterfeiting at home and abroad in the “Counterfeit Pharmaceutical Inter-agency Working Group Report to the Vice President of the United States and to Congress.” The report proposes the creation of a “White List” of legitimate Internet pharmacies.

- March 13: Government officials and other security experts share information on the growing threat of counterfeit pharmaceuticals in a CBS *60 Minutes* segment.
- May 1: *Healthday* posts article, “Dangers Lurk in Impotence Drugs Sold on Web,” highlighting the risks to men with hypertension or heart disease.
- May 23: *Fox News (Tampa Bay Times)* article, “Feds Targeting Fake Drugs,” cites the Internet as a vulnerability in the drug supply chain.
- May 24: *CBS Los Angeles* article, “Fake Erectile Dysfunction Drugs Could Pose Health Threat,” notes nearly 80 such products being shipped from India and China.
- June 21: Health Canada issues advisory, “Counterfeit Cialis Seized in the Greater Toronto Area.”
- June 22: *Dr. Oz Show* Web site posts article, “Protecting Our Drug Supply: Internet Pharmacies, Fake Drugs and the Debate over Imported Medicine,” discussing the public health threats posed by illegal online drug sellers, counterfeit medicine, and importation.
- August 5: An article in the *Journal of Sexual Medicine* notes that most counterfeit erectile dysfunction drugs enter the US drug market via fraudulent Web sites that are easily accessible online.
- August 10: US Customs and Border Protection issues news release stating that officers in Cincinnati, OH, seized a package from India manifested as containing “Harmless Generic Medicine” that was found to contain more than 8,000 counterfeit tadalafil tablets.
- August 24: *Drug Store News* article, “Counterfeit Threat Intensifies,” states that global drug counterfeiting is growing at 12% to 16% a year.
- October: 7: *USA Today* article, “The Dangerous World of Counterfeit Prescription Drugs,” describes fake medicine as “a growing trend, widely recognized as a public health risk and a serious concern to public health officials, private companies, and consumers.”
- October 27: *Consumer Reports* article, “Save Money by Ordering Drugs from Canada? Not so Fast,” quotes NABP and cites NABP report.
- November 1: Actavis issues news release, “Counterfeit Phentermine Found in US,” noting that the company does not distribute phentermine to online sellers.

- November 11: *ABC 2 News* article, “Warning: Prescription Drugs Bought Online May Have Deadly Ingredients,” reports that federal agents seized about 1,200 shipments of fake erectile dysfunction drugs.
- November 15: The journal *Vaccine* posts study, “Vaccine Shortages and Suspect Online Pharmacy Sellers,” highlighting the prevalence of illicit vaccine sales over the Internet.
- November 28: National Intellectual Property Rights Center releases “Intellectual Property Rights Violations: A Report on Threats to United States Interests at Home and Abroad,” pointing to the Internet as enabling the sale of counterfeit products, including pharmaceuticals, that threaten public health and safety.

B. Computer Crimes and Cyber-Scams: Throughout the year, cyber-criminals continued inventing and implementing schemes to deceive and defraud patients and to promote rogue drug sites.

- January 7: FDA warns of scam victimizing consumers who purchased drugs via Internet or phone.
- March 15: KnujOn Internet Security Report exposes current scam trends involving rogue Internet drug outlets and other illicit operators. Several million Web sites, mostly at universities and non-profit organizations, are covertly infected with malware that redirects victims to a handful of illicit drug sites, KnujOn reports.
- August 11: Carnegie Mellon University report spotlights the manipulation of online search results and other modes of cyber-deception that redirect consumers to illegal Internet drug sites.
- October 18: *Securing Pharma* posts findings of study, “Twitter on Drugs: Pharmaceutical Spam in Tweets,” exposing the role of social media in promoting rogue Internet drug outlets.
- December 31: Commtouch.com’s 2012 “Internet Threats Trend Report” cites pharmacy as the most common spam topic, at 31.2% of all spam messages in 4Q2011 (about 2% more than the previous quarter).

C. Prescription Drug Abuse: Prescription drug abuse was recognized as a national epidemic in 2011, likely fueled by easy access via the Internet. 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.

- White House report *Epidemic: Responding to America’s Prescription Drug Abuse Crisis*, issued in April, calls prescription drug abuse the nation’s fastest growing drug problem. The report notes that opiate overdoses, once almost always due to heroin use, now increasing result from the abuse of prescription painkillers.
- A study, “Growing Internet Use May Help Explain The Rise In Prescription Drug Abuse In The United States,” published in the May *Journal of Health Affairs* finds that, over a seven-year period, states with the greatest expansion in high-speed Internet access also had the largest increase in admissions for treatment of prescription drug abuse. The report stresses that the link between these phenomena cannot be ignored in devising effective solutions.

D. Regulatory Policy and Enforcement Efforts: Meanwhile, public health regulators and enforcement agencies worldwide continued to take action against counterfeiters and illegal online drug sellers worldwide in 2011.

1. Domestic Enforcement Actions: In the US, a representative of NABP provided expert testimony in multiple trials involving rogue Internet drug outlets, and reports of successful enforcement efforts appeared frequently in the media. A few examples follow:

- January 21: US Department of Justice (DOJ) announces the guilty plea of a Belgian citizen to charges filed in US District Court in Kansas alleging he operated an Internet pharmacy that sold \$1.4 million worth of misbranded and counterfeit drugs as well as controlled substances.
- February 16: An indictment names 11 defendants, all citizens of the Dominican Republic, charged with crimes related to extorting money from US citizens who had purchased drugs from rogue Internet sites.
- May 16: New Jersey State’s Attorney news release announces that a New Jersey couple pleaded guilty to selling counterfeit prescription drugs manufactured in India to US patients.
- June 3: DOJ announces the sentencing of a Chinese national to federal prison for trafficking counterfeit pharmaceutical weight loss drug, Alli®.

- August 24: DOJ announces Google’s forfeiture of \$500 million generated by online advertising and prescription drug sales by Canadian Internet drug outlets.
 - December 15: *Times Daily* reports “Three sentenced in online pharmacy scheme,” describing the illicit sale of controlled substances over the Internet.
2. Call for Stronger Measures: Still, many patient safety advocates, regulators, and lawmakers stress that current enforcement efforts are not enough, and seek to establish policies to better protect the public health.
- June 8: LegitScript report, “Drug Dealers on the Internet: Is the DEA enforcing the Ryan Haight Act?” spotlights Web sites selling controlled substances without a prescription and calls on the Drug Enforcement Administration (DEA) to move forward with full implementation of the Ryan Haight Online Pharmacy Consumer Protection Act.
 - July 12: In response to the May *Journal of Health Affairs* study, Senator Charles Schumer urges the DOJ to immediately begin shutting down illegal online drug sellers, and asks financial service providers to block payments to these sites.
3. US Legislative Activity: Lawmakers floated several new bills aimed to protect consumers from illegal online drug sellers in 2011. A balance between free commerce and public protection that would be acceptable to all parties, however, proved elusive, as proponents and critics battled the issues.
- Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property (Protect IP) Act of 2011, introduced on May 12, targets Web sites “dedicated to infringing activities,” such as the sale of counterfeit drugs. The Senate Judiciary Committee approved the bill, but critics subsequently blocked it, saying it would stifle free speech and innovation. A revised version of the bill, the Enforcing and Protecting American Rights Against Sites Intent on Theft and Exploitation Act, was scheduled to go before the Senate on January 24, 2012. While supporting the protection of intellectual property rights, Present Barack Obama has said he will veto any bill that threatens an open and innovative Internet.

- The Stop Online Piracy Act was introduced on October 26, and examined during a House Judiciary Committee hearing on December 16. President Obama has rejected the bill because its scope is too broad and could infringe on the rights of legitimate users.
 - Counterfeit Drug Penalty Enhancement Act of 2011, introduced in the House and Senate on November 17, would increase the maximum penalties, including fines, for trafficking counterfeit drugs. On December 8, the Senate Judiciary Committee approved the bill. The House bill has been referred to the Subcommittee on Crime, Terrorism, and Homeland Security. Further action is pending.
 - The Online Pharmacy Safety Act of 2011, introduced on December 16, would require the US Department of Health and Human Services to create a consumer-accessible registry of legitimate, law-abiding Internet pharmacy Web sites to provide consumers with a resource to help them make informed decisions when buying medication online. Further action is pending.
4. International Initiatives: Pointing to the complex, global nature of the problem, many regulators stress the need for international policies to effectively crack down on prescription drug counterfeiting and illicit trafficking.
- The *Journal of Pharmaceutical Sciences* posts commentary, “The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks,” on June 22, stating that enforcement efforts “have not stemmed supplies from illegal online sellers or kept up with their creativity in illegally selling their products.” It proposes “a global policy framework utilizing public-private partnership models with centralized surveillance reporting that would enable cooperation and coordination to combat this global health crisis.”
 - FDA issues a special report, *Pathway to Global Product Safety and Quality*, in June, stating, “[o]ver the next decade, FDA will transform itself from a domestic agency operating in a globalized world to a truly global agency fully prepared for a regulatory environment in which product safety and quality know no borders.”
 - The Stimson Center, a nonprofit group addressing issues of national and international security, in February issued a report, *Counterfeit Drugs and National Security*, calling for “a layered strategy . . . involving a wider array

of inter-agency actors from within the government, enhanced cooperation between governments internationally, and improved partnerships with legitimate private pharmaceutical and supply chain industry actors.”

- The European Alliance for Access to Safe Medicine held a conference on May 4 in London to discuss the Falsified Medicines Directive, a recent law in the European Union that targets prescription drug counterfeiters. Titled “Counter-Punching the Counterfeiter,” the conference brought together interested parties from throughout the supply chain.
- The World Health Professions Alliance convened the “Prague Call to Action” workshop on November 21 to address the problem of falsified medical products worldwide.
- In an example of successful international cooperation, regulatory agencies from 81 countries, including the US FDA, participated in the 2011 International Internet Week of Action September 20-27. Dubbed Operation Pangea IV, the maneuver was a cooperative effort to curb online sales and distribution of counterfeit and illegal medical products.

5. Enforcement Abroad: In other parts of the world in 2011, regulatory and enforcement authorities continued to take action against pharmaceutical counterfeiters and illegal online drug sellers:

- In the United Kingdom, new rules to prevent counterfeit medicines from entering the legal supply chain were approved on June 8 by the European Council of Ministers. The amended law covers Internet sales and introduces new safety and traceability measures, as well as sanctions against counterfeiters, and goes into effect on January 2, 2013.
- *BBC News* reported on September 29 that the UK’s Medicines and Healthcare Products Regulation Agency seized more than a million doses of fake and unlicensed medicines worth more than \$4 million US dollars during a recent crackdown. The article, “Fake Medicine Trade: UK Crackdown on Drug Importers,” states, “More people are diagnosing their medical problems and buying medicines online - boosting the growing trade in fake and illegitimate drugs supplied without a prescription.”

- In China, a change to the criminal law that went in to effect on May 1 removes the three-year maximum jail sentence for those found guilty of producing and selling counterfeit medicines. The amendment broadens the scope of the law and sets no new upper limit for jail terms.
- An *MSN News* article on November 30, “96 Chinese Held in Fake Medicine Racket,” describes the seizure of \$7.7 million in fake medicines in “one of the biggest operations in Shanghai against [the] sale and manufacture of fake medicines.”
- On December 29, a *China Daily* article, “China busts counterfeit drug racket,” describes the raid of more than 1,800 “dens” that made or sold counterfeit drugs in cases that involved 3.35 billion yuan (\$530 million).
- In India, *The Hindu* reports on September 29 that the Narcotics Control Bureau apprehended an illegal online drug network that had been used for the last six years to ship psychotropic drugs from India to customers in the US, Europe, and Canada.

E. Consumer Education: NABP and multiple other groups have reached out in 2011 to educate consumers on the dangers of rogue Internet drug outlets, substandard and counterfeit drug products, and the importance of proper medication storage and disposal.

- Under the banner of the AWA_R_xE™ consumer protection program, NABP staff spoke one-on-one with hundreds of consumers throughout the year during trade shows and other consumer expositions in the Chicago metropolitan area, about the dangers of rogue Internet drug outlets and other medication safety tips.
- On March 25, NABP relaunched the AWA_R_xE.ORG Web site, the primary communication vehicle of the AWA_R_xE program, to more effectively reach consumers seeking information on prescription drug abuse and medication safety. And in August, NABP launched its first advertising campaign, “Does a Drug Dealer Lurk in Your Medicine Cabinet?” under the AWA_R_xE program.
- The Advertising Council hosted a roundtable discussion on June 23 in Washington DC to discuss with multiple stakeholder groups a possible educational initiative to raise consumer awareness of illegal online drug sellers.

- On September 29, NABP and Pfizer announced a collaborative effort to draw attention to the risks associated with counterfeit drugs and to help patients learn to identify safe Internet pharmacies.
- NABP submitted comments on November 18 in favor of FDA's proposal to conduct an online survey of consumer attitudes and behaviors relating to buying prescription medication online. FDA published a notice of its proposal and request for comments in the October 19 *Federal Register* (76 FR 209, Docket No. FDA-2011-N-0494). The data collected through this process is intended to support communications to educate consumers on how to safely purchase medicine online.
- Across the "pond," the Irish Medicines Board issued a news release on May 4 warning consumers of the dangers of buying prescription medicines over the Internet, stressing that no Internet pharmacy Web site has been authorized to operate in Ireland.

F. Professional Outreach: Several groups in the US and abroad also reached out in 2011 to educate health care professionals and regulators about the problems of medication counterfeiting and illicit prescription drug trafficking.

- NABP issued quarterly Internet Drug Outlet Identification Program Progress Reports to keep the boards of pharmacy and other regulators, enforcement authorities, and stakeholders up to date on NABP research findings and other current issues relating to Internet pharmacy. The January 2011 report, for instance, highlights advances made in protecting public health from rogue Internet drug outlets. In July, NABP reports that 85% of fake online drug outlets do not require a valid prescription and explores the connection between these rogue sites and prescription drug abuse.
- The Pew Health Group Charitable Trusts hosted a roundtable discussion on March 15 in Washington DC to address the safety of the US drug supply. The meeting was part of a large discussion about the issues and solutions raised in a draft white paper entitled "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs."
- NABP held a continuing education session, "Rogue Internet Pharmacies – Can Collaboration Break the Link?" on May 24 during the NABP 107th Annual Meeting. The Alliance for Safe Online Pharmacies and NABP jointly presented information on rogue Internet drug outlets, their contributing role in prescription drug abuse, and the need for collaborative efforts to tackle these problems and advance patient safety.

- NABP participated with the Partnership for Safe Medicines (PSM) and FDA in a Congressional briefing on June 23, 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 rogue sites, deceptive practices they employ to appear legitimate, strategies for combating these sites, and the challenges faced by regulators.
- PSM sent letters on June 8 urging 10 major online advertising networks to refuse advertisements promoting rogue Internet drug outlets.
- The second annual PSM Interchange took place on October 27 in Washington DC, providing local and international perspectives on the issues involving counterfeit medicine and the risks to patient safety.
- The US Chamber of Commerce hosted a Rogue Sites Event on December 13 to help raise awareness among members of Congress and their staff about the growing epidemic of rogue Internet sites

IV. DISCUSSION

Throughout 2011, as in previous years, the illicit prescription drug trade has expanded, bleeding across jurisdictional borders, forcing regulators to step up their efforts and derive new methods and partnerships to protect the public health. While the events of 2011 have demonstrated the persistence of prescription drug counterfeiters and illegal online drug sellers, they have also shown intensified efforts by regulators, enforcement authorities, and patient advocates worldwide to understand and contain the risks these rogue sites pose. NABP continues to encourage these efforts and to work with the state boards of pharmacy, federal regulators, and other public and private stakeholders to educate the public about counterfeit drugs and other 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 – in any practice setting – and ensuring that patients have access to safe and effective prescription drugs.

Through communication and cooperation, NABP strives to advance the efforts of regulators and other entities to curtail the online trade of illicit and counterfeit medications. 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.

V. APPENDIX

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.
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.