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Internet Drug Outlet Identification Program

Updated Progress Report for
State and Federal Regulators:
April 2012 – Re-Issued May 14,
2012

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM UPDATED PROGRESS REPORT: April 2012 – Re-Issued May 14, 2012

I. INTRODUCTION

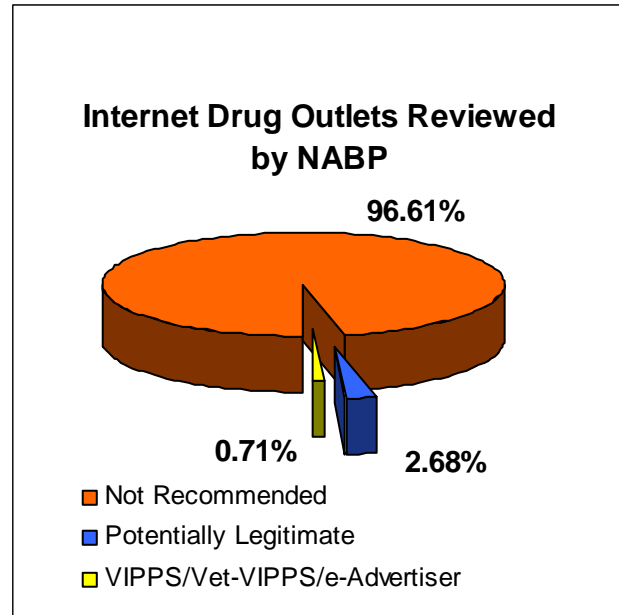
Criminals, like legitimate enterprises, adapt to the rhythms of supply and demand. Unfortunately, when the legitimate suppliers fall short of fulfilling consumer demand, crooks rush in to fill the void. This age-old pattern has come to light amidst the current prescription drug shortages. The ongoing shortage of certain medications has created a lucrative niche market for counterfeiters and so-called gray-market distributors. The National Association of Boards of Pharmacy[®] (NABP[®]) has assisted in the investigations of operations that turn a blind eye to pharmacy laws and patient safety in the interest of their own financial gain. Additionally, NABP has identified illegal online drug sellers that exploit consumers' worries about prescription drug shortages to sell substandard, unapproved knock-offs of brand-name drugs that are available in plentiful supply through normal legal channels. Such rogue sites are among the more than 9,000 Web sites NABP has found to be operating out of compliance with pharmacy laws and practice standards established in the United States to protect the public health. These rogue sites – composing the vast majority (96%) of the total number of sites NABP staff has reviewed – are posted to the Not Recommended list on the NABP Web site to serve as a resource for health care professionals and patients alike. Among these rogue sites are several that offer medications listed on the Food and Drug Administration (FDA) list of drugs in short supply.

Regulators, enforcement agencies, and patient safety advocates worldwide are honing in on this criminal activity that freely spans the globe in a tangled web of international affiliations and back-door deals. In response, NABP, with the support of a global coalition of pharmacy stakeholders, is taking on an unprecedented, but necessary, initiative to hold online drug sellers accountable to the pharmacy laws and patient safety standards established by responsible jurisdictions worldwide to protect the public health. NABP is applying to the International Corporation for Assigned Names and Numbers (ICANN) to obtain and operate a .pharmacy top-

level domain. The plan will create a safe and secure space on the Internet for legitimate Web site operators. These exploits and efforts will be discussed further in sections III and IV of this report.

II. RESULTS

A. Findings of Site Reviews: As of March 30, 2012, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 9,677 Internet drug outlets selling prescription medications. During the period from January 1, 2012 through March 30, 2012, staff identified nearly 900 additional Internet drug outlets operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards.

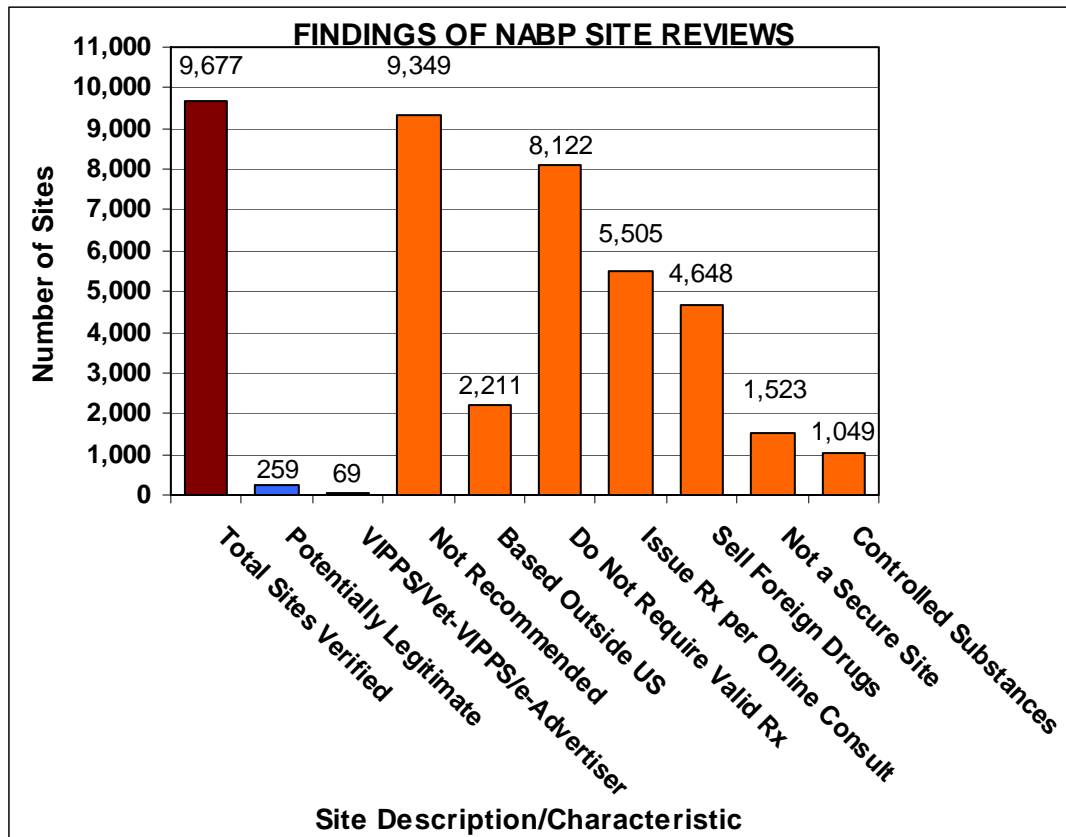


These findings bring the total number of sites operating out of compliance with laws and standards to 9,349, or 96.61% of the 9,677 Internet drug outlets reviewed and verified. These illegitimate Internet drug outlets are listed as Not Recommended in the “Buying Medicine Online” section, under Consumers, 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 9,349 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

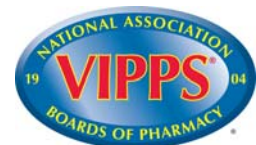
- 2,211 have a physical address located outside of the US (though most rogue sites do not post any address)
- 8,122 do not require a valid prescription
- 5,505 issue prescriptions per online consultation or questionnaire only
- 4,648 offer foreign or non-FDA-approved drugs
- 1,523 do not have secure sites
- 3,363 have server locations in foreign countries
- 9,062 appear to be affiliated with a network
- 1,049 dispense controlled substances

Of the total 9,677 sites reviewed, 259 (2.68%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites. Sixty-nine (0.71%) of the 9,677 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 March 30, 2012

- B. 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, 48 VIPPS and Vet-VIPPS pharmacy sites, representing more than



12,000 pharmacies, are listed as Recommended Internet Pharmacies. Several more applications are in progress.

- C. Accreditation and Approval Applicant Screenings: In addition to identifying rogue sites, the Internet Drug Outlet Identification program staff continues to assist in screening applicant Web sites for the VIPPS, Vet-VIPPS, and e-Advertiser Approval programs. Sites that have received e-Advertiser Approval 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 March 30, 2012, 21 entities were listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.



III. DRUG SHORTAGES CREATE NICHE FOR SWINDLERS

- A. Gray-Market Risks: The number of drugs in short supply more than tripled from 61 in 2005 to more than 200 by the end of 2010, and the University of Utah Drug Information Service reported a record high of 180 drug shortages from January 1 to July 31, 2011. Sterile injectables accounted for the majority of the drug shortages in 2010-2011. The most critical shortages involve cancer, antibiotic, nutrition, and electrolyte-imbalance medicines, according to FDA. For many community pharmacies, health-system pharmacies, and patients, the lack of availability of needed – and often life-saving – medications through official, authorized supply channels means resorting to unconventional and more dangerous means of obtaining the medications, sometimes turning to unknown sellers online. The unfulfilled demand for these medications has created a lucrative niche market for counterfeiters and so-called gray-market distributors.

The primary problem with gray-market drug sellers is that health care facilities and patients have no assurance that the substances they receive are what they are purported to be. Many of the replacement drugs purchased online are unregulated, meaning there are no safeguards in

place to ensure their identity, safety, or efficacy, where and under what conditions they were made, or how they were handled.

As a February 2012 issue of *Journal of Medical Internet Research* correctly reports, “FDA shortage drugs are widely marketed over the Internet. Suspect online drug sellers and intermediaries dominate these sales offers.” The report, “Online Availability and Safety of Drugs in Shortage: A Descriptive Study of Internet Vendor Characteristics,” warns that “patients, providers, and policymakers should be extremely cautious in procuring shortage drugs through Internet sourcing.” The authors found 291 offers online for 68 of the FDA shortage-listed drugs, mostly by rogue Internet drug outlets selling direct to consumers without a prescription. In fact, two-thirds of the online drug sellers discovered in this study are represented on the NABP list of Not Recommended sites. These illegal online drug sellers pose serious risks to patient health. The risk is especially high with vaccines, which represent half the products on the FDA Biologics Product Shortages list because, as noted in the November 2011 issue of *Vaccine*, these products require specialized quality control, storage, and transportation to maintain their safety and efficacy, posing a higher-than-average patient risk when mishandled.

B. Counterfeit Medications and Unapproved Foreign Drugs: In recent months, gray-market activity has proved not only costly and suspicious, but dangerous, with multiple appearances of counterfeit drugs finding their way into the legitimate medication supply. The unfortunate reality for an unknown number of cancer and other patients in the US and abroad is that their health care providers administered to them unknown substances, thought to be life-saving medication, obtained through untrustworthy sources.

‘This is exactly why it’s illegal to sell unapproved drugs from overseas in the U.S.’

In a May 7, 2012 weekly update, Partnership for Safe Medicines (PSM) brings to light the dangers of prescription drug counterfeiting in recognition of World Malaria Day. The PSM update cites a blog post by Tom Kubic, president and CEO of the Pharmaceutical Security Institute, titled “Malaria And Me: How Americans Are Part Of The World Of Global Medicine Counterfeiting,” which highlights the potential dangers of unbridled international distribution. “A key benefit of globalization is that lifesaving medications can be readily transferred from anywhere in the world to countries like Ghana, Kenya, and South Africa. Unfortunately, globalization has also brought criminal organizations that take advantage of the need for these medications,” says Kubic, who is also on the PSM Board. “Criminals cheat patients out of lifesaving medications. They counterfeit everything from anti-fungals and

antibiotics to chemotherapy and antivirals. A medication with no healing power is worthless. Whether the victim is a child with malaria in Lagos, or a child with cancer in Los Angeles, neither will be cured, and both may be killed by the counterfeiter's malice.

Earlier this year, multiple vials of counterfeit Avastin[®] were purchased by 19 medical clinics in the US, FDA reported on February 14, 2012. The fake Avastin was sold to doctors in the US by Montana Healthcare Solutions, and was shipped by a company in the United Kingdom with the same owner, *CBS News* reported on March 22, 2012. *CBS* states that the proprietor, Tom Haughton, also reportedly owns several pharmaceutical-related businesses in Barbados.

NABP was consulted during the *CBS* investigation and provided comment in a March 22 *CBS News* segment, available online at www.cbsnews.com/8301-505263_162-57402214/fake-avastin-shipper-tied-to-canadadrugs.com.¹ *CBS* linked the fake Avastin shipper, Tom Haughton, to Canadadrugs.com, which, *CBS* reports, utilizes Haughton as a key supplier.²

CanadaDrugs.com denies any involvement in the counterfeit Avastin. Haughton states he did not know the Avastin was counterfeit.

In the *CBS* report, NABP Executive Director/Secretary Carmen Catizone, MS, RPh, DPh, explains that of the shipments NABP has seen, "No drugs that are being shipped via the Internet to U.S. consumers from these websites we've identified actually come from Canada or have actually been approved by Health Canada." For years, FDA, NABP, and other entities interested in protecting the public health have warned that, outside the closed and tightly regulated domestic drug supply chain, the safeguards put in place to ensure the identity, efficacy, and safety of prescription medications no longer apply. As *CBS News* reports, regulators and law enforcement officials say "this is exactly why it's illegal to sell unapproved drugs from overseas in the U.S."

Still more recently, another injectable cancer medication, originating from a foreign source and purchased by US medical practices, has been determined to be counterfeit. FDA alerted health care professionals on April 3, 2012, that laboratory tests confirmed a counterfeit version of Roche's Altuzan[®] 400 mg/16 ml (bevacizumab), which is not approved by FDA

¹ NABP identified some 3,000 Web site domain names registered to Tom Haughton, many resolving to Canadadrugs.com. NABP has identified CanadaDrugs.com as Not Recommended because NABP believes that it offers unapproved medications from numerous foreign sources to US patients without a valid prescription. See, eg, www.canadadrugs.com/search.php?keyword=sildenafil and the "Your Guarantee" section of CanadaDrugs.com.

² As referenced in the aforementioned March 22, 2012 *CBS News* article, CanadaDrugs.com offers US consumers numerous non-FDA approved medications sourced from India, Turkey, Australia, and the United Kingdom. For example, US consumers visiting the CanadaDrugs.com Web site are offered tadalafil, the generic version of the erectile dysfunction drug Cialis[®], and ezetimibe, the generic version of the cholesterol lowering drug Zetia[®], both sourced from Global Drug Supply Ltd in Barbados. Tom Haughton is the owner of Global Drug Supply and is a supplier of CanadaDrugs.com, as reported in a March 7, 2012 *Wall Street Journal* article entitled "Drug Distributor Is Tied to Imports of Fake Avastin." Neither tadalafil nor ezetimibe is FDA approved.

for use in the US, contains no active ingredient. Medical practices obtained the counterfeit Altuzan and other unapproved products through foreign sources, in particular from Richards Pharma, also known as Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc, FDA reports, adding that many, if not all, of the products sold and distributed through this distributor are not FDA approved.

In the hopes of avoiding further influx of such unapproved drugs, PSM has composed, and NABP has signed on to a letter to Congress opposing potential amendments to the Prescription Drug User Fee Act that would allow drug importation, undermining US drug safety protocols in the process. The letter states, “Drug importation advocates believe that drugs purchased from countries such as Canada and the United Kingdom are safe because of their strict health regulations. Unfortunately, this is simply not true. There is no regulation for products trans-shipped through ‘safe’ countries such as Canada and the United Kingdom and thus, Americans would be put at great risk.” In reference to the appearances of counterfeit cancer medications in US health care facilities, the letter states, “Such incidents demonstrate conclusively that if trained doctors cannot reliably source their medications, we will endanger all Americans by encouraging them to break the closed, secure drug supply chain.”

On its home page, www.safemedicines.org, PSM provides a tool that patients can use to see if doctors in their state purchased counterfeit cancer medications. The PSM Web site also posts a link to a YouTube video describing prescription drug counterfeiting and encouraging patients to use VIPPS-accredited Internet pharmacies when purchasing medication online.

- C. Fake Pharmacy Schemes: Three US Congressional committees are investigating schemes in which individuals obtained pharmacy licenses only to use them as a means for purchasing short-supply cancer drugs that they then sold to gray-market wholesalers for a profit. The House Committee on Oversight and Government Reform stated in a March 21, 2012 news release that it had obtained documents indicating that, rather than dispensing the medication to patients, these pharmacies instead transferred them to wholesaler companies owned by the same individuals. The wholesalers then sold the drugs back into the gray market, sometimes in violation of state law and at exorbitant markups. “It appears that some of these individuals essentially established ‘fake pharmacies’ to obtain drugs that are in critically short supply and are desperately needed to treat patients with cancer and others diseases,” Committee Chairman Elijah Cummings states in the news release. These findings are part of a broader ongoing investigation launched October 5, 2011. NABP provided information that assisted in this investigation.

NABP has found that rogue Internet drug outlets also exploit consumers' concern over prescription drug shortages to spread misinformation and sell counterfeit and substandard drugs, such as erectile dysfunction

**'Prescription Drug Shortage?
Get Your Viagra Prescription
Online.'**

(ED) medications – many of them knockoffs of legitimate brands – that are not in short supply. One such site, SuperPforce.com, distorts the situation to deceive consumers with the headline, “Prescription Drug Shortage? Get Your Viagra Prescription Online.” The site sells a variety of unapproved fake versions of common ED medications, all without a prescription. It states, in mock concern, “Pharmacists everywhere are unable to fill prescriptions due to a lack of inventory. . . leaving some folks to fill their Viagra prescription online.”

- D. Registrars' Role in Illicit Drug Sites: In the last several years, NABP has reached out to several domain name registrars and other Internet service providers, encouraging them to stop enabling illegal online drug sellers. Some of these outreach efforts have been met with a helpful willingness to protect consumers from rogue Internet drug outlets. Others, however, approach this trend as a business opportunity. NABP sent a letter on March 13, 2012, urging ICANN to take action against Internet.bs, a domain name registrar that has been found to be responsible for 44% of the Web sites that NABP has designated as Not Recommended due to their noncompliance with pharmacy practice laws. NABP took this step after learning of an investigation by LegitScript that found that Internet.bs sponsors one-third of the world's active rogue Internet drug outlets, even though it is the registrar for only about 0.2% of the world's domain names overall.

The LegitScript report, available at www.legitscript.com, details an undercover investigation of Internet.bs in which the company agreed to help researchers, who were posing as an international cybercrime network, sell fake cancer medications and controlled substances without a prescription. Undercover researchers told Internet.bs that they planned to create thousands of Web sites that would sell controlled substance medications without requiring a prescription, as well as unapproved formulations of various cancer medications to be falsely marketed as genuine “branded” pharmaceuticals. The report includes screenshots of e-mail messages in which Internet.bs welcomed the business, saying that it is “one of the safest [registrars] for pharma domains,” and offered to help the registrants avoid being shut down by drug safety regulators. The undercover researchers ultimately were able to register hundreds of Web sites with names such as oxycodonenoprescription.com and genuine-anti-cancer-drugs.com, and post fake online pharmacy content, LegitScript reports.

Subsequently, Internet.bs agreed to prohibit any domain names that are listed on NABP's Not Recommended list – unless they are sanctioned by any one of three other organizations whose standards NABP does not recognize because they are out of compliance with US federal and state pharmacy laws.

IV. OUTREACH . . . EDUCATION . . . ACTION!

- A. .Pharmacy gTLD Initiative: NABP announced to its member boards of pharmacy in late February 2012 that the Association will stand with the global pharmacy community in applying to ICANN to obtain and operate the .pharmacy top-level domain. ICANN has opened a new round of assigning generic top-level domains (gTLDs; ie, the text to the right of the “dot” in an Internet address, such as .com, .net, .gov). This process will allow for industries, corporations, and locations to secure a customized, secured gateway for their organization or community, and will likely result in the creation of many new gTLDs, such as .hotel, .London, and .bank. This action by ICANN comes at a time when NABP, the boards of pharmacy, and other stakeholders are focused on efforts to ensure a safe and secure location on the Internet for legitimate pharmacies to operate and for patients to acquire medications. To that end, NABP is taking on this unprecedented, but necessary, initiative to hold online drug sellers accountable to the pharmacy laws and patient safety standards established by responsible jurisdictions worldwide to protect the public health.

Under this plan, use of the .pharmacy domain will be restricted to legitimate Web site operators the world over that adhere to the pharmacy laws specific to the jurisdictions in which the pharmacy is domiciled and to which it sells prescription drugs. As such, it will provide a powerful tool to educate consumers, distinguish legitimate Internet pharmacies from the throngs of illicit drug sellers, and reinforce the value of purchasing medications only from trustworthy online sources. In recent months, NABP has been networking with pharmacy stakeholders internationally to generate public support for this effort, and to demonstrate to ICANN that the global community is behind this initiative. The application window closed on April 12, 2012, and ICANN will post the list of applicants and applied-for gTLDs on April 30. Initial results are expected to be released on November 12.

- B. NABP Task Force on Internet Pharmacy Practice: To address patient risks associated with illegal online drug sellers, NABP convened a Task Force on Internet Pharmacy Practice on March 6-7, 2012, whose charge was to review existing Internet pharmacy practices, review current state laws and regulations, VIPPS standards, and the *Model State Pharmacy Act and Model Rules of the National Associations of Boards of Pharmacy* language, and to examine

future opportunities and challenges in an emerging global environment. Task force members also discussed current federal legislative efforts, as well as the need for increased education and awareness. For instance, NABP has publicly stated its support of the Online Pharmacy Safety Act of 2011, which 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. The task force recommendations will be presented at the NABP 108th Annual Meeting set for May 19-22, 2012, in Philadelphia, PA, and subsequently will be available on the NABP Web site. The Annual Meeting also will include a special session to address the critical issue of drug shortages and its implications for patients, pharmacists, and boards of pharmacy.

- C. AWAR_xE Consumer Protection Program: The AWAR_xE[®] consumer protection program, provided by NABP, joins forces with patient safety advocates in reaching out 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. This spring, AWAR_xE has worked with Drug Enforcement Administration (DEA) to promote its fourth National Prescription Drug Take-Back Day. This event, set for April 28, 2012, allows consumers a convenient way to safely dispose of unneeded medications, including prescription pain pills and other controlled substance medications, which can only be accepted for disposal when law enforcement is present. Thousands of DEA-coordinated collection sites will be available across the country. During the previous three DEA National Prescription Drug Take-Back Days, consumers disposed of 995,185 pounds (498.5 tons) of unwanted medication, reducing the risk of diversion and misuse. More information and a link to the DEA Take-Back Day collection site locator is available on the AWAR_xE Web site, WWW.AWARERX.ORG.



Additionally, AWAR_xE public service announcements (PSAs) are being delivered via Internet, social media, and radio. The PSAs, in addition to the “Does a Drug Dealer Lurk in Your Medicine Cabinet?” ad, which appeared in the April 2012 issue of the AARP Bulletin (circulation 22 million), encourage consumers to participate in the DEA National Prescription Drug Take-Back Day, and to learn about other steps they can take to protect their loved ones from prescription drug misuse and abuse. AWAR_xE video and radio PSAs stress that most Americans who abuse prescription drugs – including 12 and 13-year-olds – get them from friends and family for free, some taking them right out of the medicine

cabinet. AWARe radio PSAs were distributed to radio stations targeted to complement video PSAs that were provided to television stations in 16 geographical markets. In addition, Internet Web sites and bloggers that focus on health care, parenting, and other issues relevant to AWARe were provided with Web site banners and content for use in encouraging their readers to visit the AWARe Web site. Each Internet blog post, Web site banner, or Web site article brings AWARe just a click away to readers.

V. DISCUSSION

The problems of prescription drug shortages, gray-market wholesalers, and illegal online drug sellers are intertwined. Patients and health care providers must be educated about which medications are in short supply, and how to distinguish legitimate sources from conniving frauds. Likewise, regulators, law enforcement, and patient safety advocates must work together, across jurisdictional borders, and derive new methods and partnerships to protect the public health. 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.

VI. 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.