Internet Drug Outlet Identification Program

Progress Report for State and Federal Regulators: March 2017

Prepared By

The National Association of Boards of Pharmacy

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Introduction

"Antibiotic resistance (AR), when bacteria don't respond to the drugs designed to kill them, threatens to return us to the time when simple infections were often fatal," says the Centers for Disease Control and Prevention (CDC)[1]. According to CDC, at least 2 million people become infected with antibiotic-resistant bacteria each year in the United States, and at least 23,000 people die each year as a direct result of these infections.[2] Because the use of antibiotics is the leading cause of antibiotic resistance, antibiotics must be used judiciously, correctly, and only when needed. Every year in the US, however, 47 million unnecessary antibiotic prescriptions are written in doctors' offices, emergency rooms, and clinics.[3] Recognizing the potential severity of the problem, Congress appropriated $160 million to CDC in 2016 to fight antibiotic resistance. CDC allocated the funds to implement the Antibiotic Resistance Solutions Initiative, which is intended to improve national infrastructure to detect, respond to, and contain resistant infections in health care settings and communities. One of the goals of this initiative is to cut inappropriate prescribing practices in doctors' offices and hospitals.

A factor contributing to the overuse of antibiotics that is often overlooked, however, is the ready availability of prescription antibiotics without a valid prescription over the internet. Research performed by the National Association of Boards of Pharmacy® (NABP®) found that nearly two-thirds of online search results for antibiotics lead to websites selling the medicine without a valid prescription, contributing to the likelihood of improper use. Solutions geared

[1] CDC. Providing critical support to combat antibiotic-resistant bacteria. https://www.cdc.gov/drugresistance/solutions-initiative. Updated January 10, 2017. Accessed January 18, 2017.

[2] CDC. Antibiotic resistance threats in the US. https://www.cdc.gov/features/antibioticresistancethreats. Updated September 16, 2013. Accessed January 18, 2017.

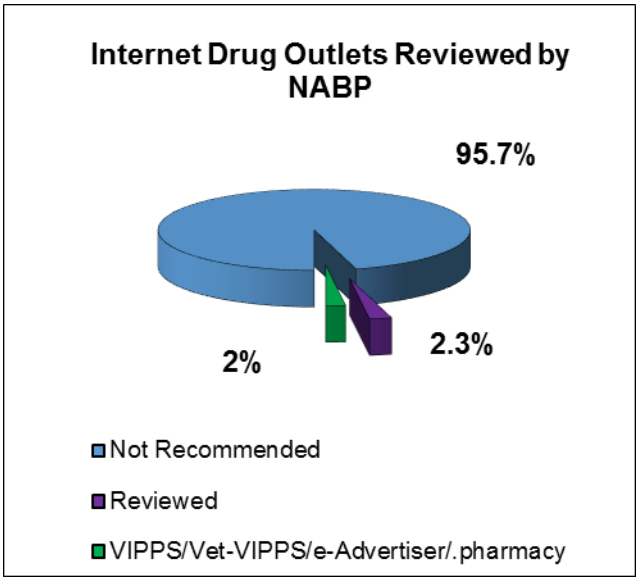
[3] CDC. Antibiotics aren't always the answer. https://www.cdc.gov/features/getsmart/. Updated November 14, 2016. Accessed January 18, 2017.

toward addressing the problem of antibiotic resistance therefore should also account for the rogue internet drug outlets that sell antibiotics and other medicines illegally.

In addition to research on internet search results for antibiotics, which is described on pages 9 to 11 of this report, NABP continues to review websites selling prescription drugs and identify those that do and do not comply with pharmacy laws and practice standards. After reviewing over 11,000 websites selling prescription medicine, NABP has identified approximately 96% of them as Not Recommended. These findings are presented below.

Results

A. Findings of Site Reviews to Date: As of December 31, 2016, NABP has reviewed 11,486 internet drug outlets selling prescription medications. Of these, 10,990 (95.7%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. These sites are listed as Not Recommended in the Initiatives section of the NABP website, *www.nabp.pharmacy,* under .Pharmacy Verified Domain. Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. These findings include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. Many also offer foreign and unapproved drugs that may be substandard or counterfeit. The 10,990 internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.[4]

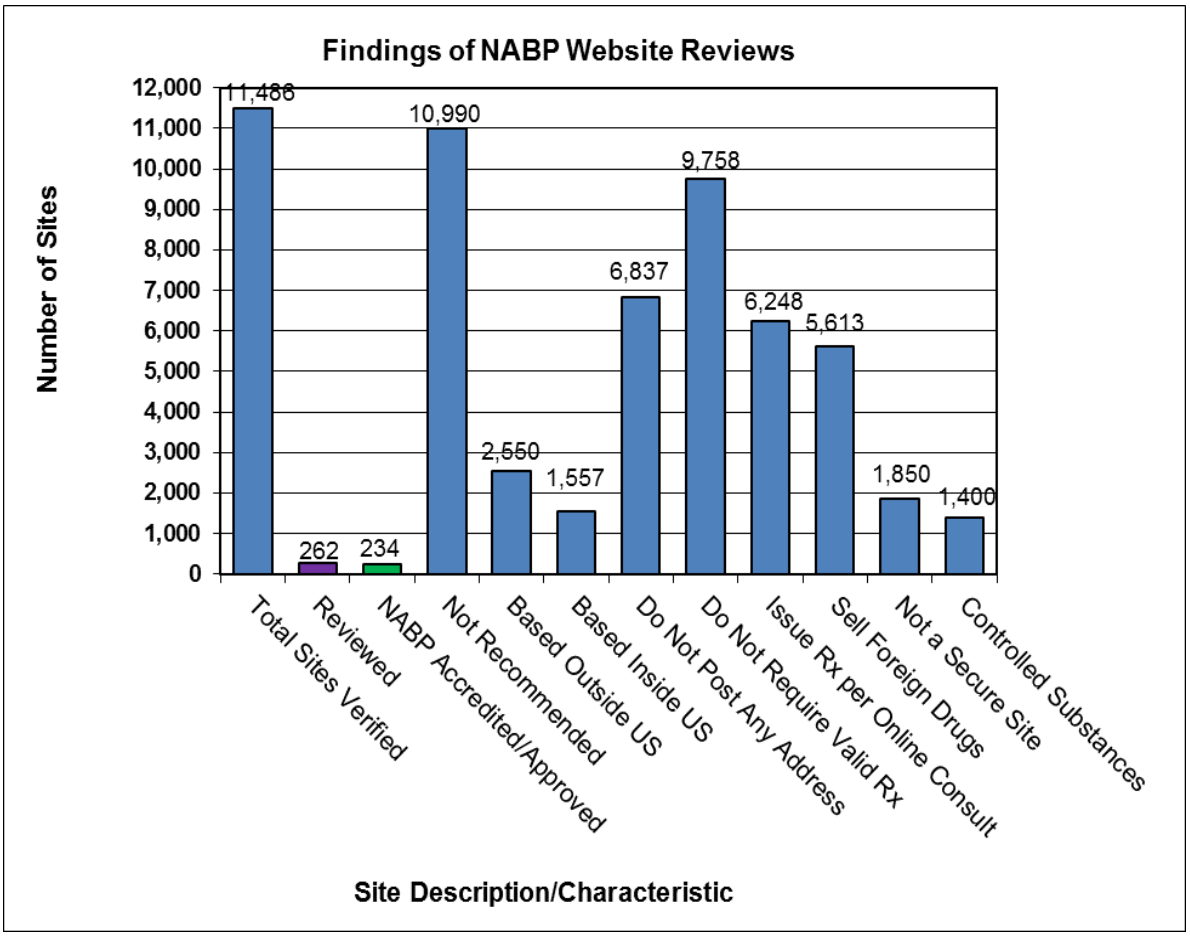


[4] It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found to be noncompliant at the time of review but may since have been deactivated. It should also be noted that the numbers reported here do not represent the entire universe of websites selling prescription drugs illegally, but rather, a representative sampling of the online environment over the last eight years.

Not Recommended Sites

Physical Location:	• 2,550 (23.2%) outside US • 1,557 (14.2%) inside US • 6,837 (62.2%) no location posted on website
Prescription Requirements:	• 9,758 (88.8%) do not require valid prescription • 6,248 (56.9%) issue prescriptions per online consultations or questionnaires only
Medications:	• 5,613 (51.1%) offer foreign or non-Food and Drug Administration-approved medications • 1,400 (12.7%) dispense controlled substances
Encryption:	• 1,850 (16.8%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	• 4,692 (42.7%) outside US • 5,822 (53%) inside US • 464 (4.2%) have unknown server locations
Affiliations:	• 9,660 (87.9%) appear to have affiliations with rogue networks of internet drug outlets

Sites listed as Not Recommended, in total, as of December 31, 2016



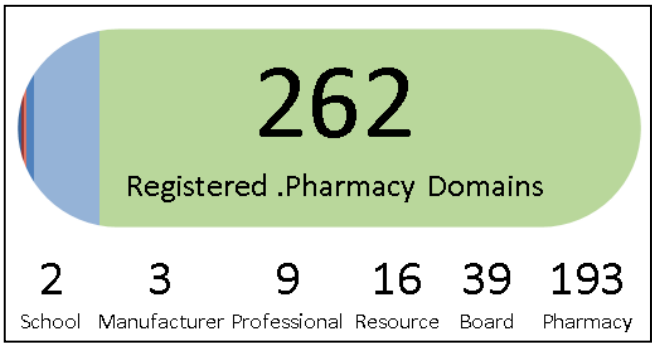
The standards against which NABP evaluates internet drug outlets are provided in the Appendix of this report.

Two hundred sixty-two (2.3%) of the 11,486 sites selling prescription medications to US patients were designated as reviewed. These sites lack any egregious violations that would cause them to be ranked as Not Recommended but have not satisfied the requirements of NABP's Verified Internet Pharmacy Practice Sites® (VIPPS®), Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®), e-Advertiser Approval℠ Program, or .Pharmacy Top-Level Domain (TLD) Program. Two hundred thirty-four (2%) of the 11,486 sites selling prescription medications or offering resources to US patients were accredited through VIPPS or Vet-VIPPS programs or were approved through the e-Advertiser Approval or .Pharmacy TLD programs.

B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that patients use internet pharmacies that have been reviewed and approved by NABP. These sites include entities granted VIPPS or Vet-VIPPS accreditation, Approved e-Advertiser status, or a .pharmacy domain name. These sites have been evaluated and found to be in compliance with pharmacy laws and meet high standards for pharmacy practice and patient safety. As of December 31, 2016, 75 pharmacies are listed on the NABP website as VIPPS and Vet-VIPPS accredited and 140 entities are listed as Approved e-Advertisers; 87 .pharmacy registered entities were listed on the .Pharmacy TLD Program website, *www.safe.pharmacy.* NABP is no longer accepting applications for the Vet-VIPPS and e-Advertiser Approval programs, as these programs are being streamlined into the .Pharmacy TLD Program. Several .pharmacy applications are in progress.

C. .Pharmacy TLD Program: Increasing reliance on technology in health care makes it more vital than ever to have a simple tool for legitimate entities to readily identify themselves, and for consumers to recognize them, as having been vetted and approved by a trustworthy organization. NABP's .pharmacy TLD is such a tool. With .pharmacy, unlike other programs that use seals and logos that can easily be faked, the "seal of approval" is built into the web address/URL. .Pharmacy is a verified TLD, meaning that applicants are evaluated for compliance with registry standards prior to being allowed to use a .pharmacy domain name.

NABP has, as of December 31, 2016, granted approval for 430 domain names, and 262 .pharmacy domain names have been registered. Of these, 193 were



registered to pharmacies, 9 were registered to professional sites, 39 were registered to boards of pharmacy or regulatory agencies, 16 were registered to resource sites, 3 were registered to manufacturers, and 2 were registered to schools or colleges of pharmacy.

Of the 262 .pharmacy domain names registered, 130 are in use while the remaining registered domain names are parked. Of those that are in use, 72 are registered to pharmacies, 32 are registered to boards of pharmacy or regulatory agencies, 15 are registered to resource sites, 9 are registered to professional sites, and 2 are registered to schools or colleges of pharmacy. Of the domain names in use, 17 are being used as the registrant's primary domain name, 105 are redirecting to another domain name, and 8 are masking another domain name with the .pharmacy name.

The .pharmacy initiative aims to provide consumers around the world a means for easily identifying safe and legal online pharmacies and related resources. NABP grants use of the .pharmacy domain only to legitimate website operators that adhere to pharmacy laws in the jurisdictions in which they are based and in which their patients and customers reside.

The Role of Illegal Online Drug Sellers in Antibiotic Resistance

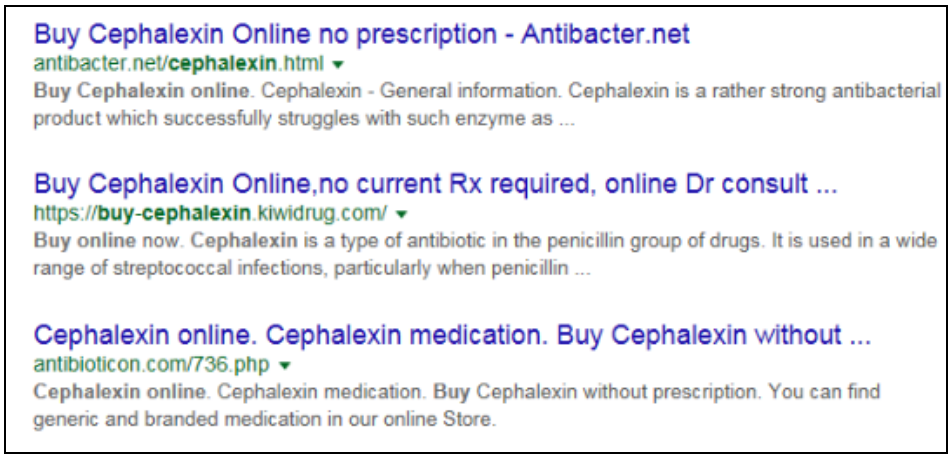
A. Rogue Sites Perpetuate Misuse: As discussed in the section above, illegal online drug sellers pose a number of public health risks. Research conducted by NABP suggests that they also contribute to the improper use of antibiotics by selling them without a prescription. According to the *National Action Plan for Combating Antibiotic-Resistant Bacteria, March 2015,* "Misuse and over-use of antibiotics in healthcare and food production continue to hasten the development of bacterial drug resistance, leading to loss of efficacy of existing antibiotics." The plan was developed in response to Executive Order 13676: Combating Antibiotic-Resistant Bacteria, issued by President Barack Obama on September 18, 2014, and outlines steps for implementing a national strategy to address the problem. Solutions discussed include cutting inappropriate prescribing of antibiotics in doctors' offices and hospitals, but this approach does not

Of the 150 search results, 98 (65%) provided access to a website where antibiotics could be purchased without a valid prescription.

address the problem of consumers obtaining antibiotics without any prescription. The fact that the medicines obtained from illegal online drug sellers may be substandard or counterfeit further compounds the problem. These factors suggest that solving the problem of overusing antibiotics should involve attempts to crack down on websites selling prescription medicine illegally and to educate consumers on the dangers of buying medicine from unknown and unapproved sources online, as well as on the large-scale dangers of using antibiotics inappropriately.

B. Two-Thirds of Top Search Results Lead to Sites Selling Antibiotics Without a Prescription:

To determine the extent to which prescription antibiotics are available online without a valid prescription, NABP performed online searches for five of the most commonly used antibiotics.



Nine of the top 10 Google search results for "buy Cephalexin online" led to websites selling antibiotics without a prescription.

The antibiotics searched for were azithromycin, amoxicillin, cephalexin, trimethoprim and sulfamethoxazole (commonly known as Bactrim®), and ciprofloxacin. The search terms used were "buy Azithromycin online," "buy Amoxicillin online," "buy Cephalexin online," "buy Trimethoprim & Sulfamethoxazole online," and "buy Ciprofloxacin online." The term "without a prescription" was intentionally left out of the search terms to provide an unbiased view of how a typical search might return results for sites that are operating illegally. The search engines used were Google, Bing, and Yahoo! The top 10 results (not including paid advertisements) for each of the five searches were recorded. The websites to which the search results linked were reviewed to determine whether antibiotics could be purchased through the website without a valid prescription.

Of the 50 search results returned using Google, 34 (68%) provided access to a website where antibiotics could be purchased without a valid prescription. Of the 50 search results returned using Bing, 31 (62%) provided access to such sites. And, of the 50 search results returned using Yahoo!, 33 (66%) provided access to such sites. Combined, 98 (65%) of the 150 search results returned using all three search engines led to websites where antibiotics could be purchased without a prescription. (Search results obtained per antibiotic are shown in the table below.)

It should be noted that paid advertisements for pharmacies and prescription medicine are virtually free of illegal online drug sellers. Google, Bing, and Yahoo! all require advertisers using pharmacy or prescription drug terms to be verified by NABP. Organic search results, on the other hand, are not screened and are heavily populated with search results for rogue internet drug outlets posing as legitimate pharmacies.

	Number of top 10 search results leading to websites selling antibiotics without a valid prescription			**Total search results leading to no-Rx sites**
Antibiotic searched	**Google**	**Bing**	**Yahoo!**	
Azithromycin	4	5	5	14
Amoxicillin	6	6	5	17
Cephalexin	9	6	7	22
Trimethoprim & Sulfamethoxazole	7	5	7	19
Ciprofloxacin	8	9	9	26
Total (%)	34 (68%)	31 (62%)	33 (66%)	98 (65%)

C. UK Study Raises Similar Concerns About Online Drug Sellers and Antibiotic Resistance: A similar study was performed by researchers at Imperial College London and recently published in the *Journal of Antimicrobial Chemotherapy*. The study looked at 20 online pharmacies available to consumers in the United Kingdom. The sites were discovered using Google and Yahoo! and the search term "buy antibiotics online." Researchers found that 80% of the online pharmacies surveyed let customers choose the antibiotic, dosage, and duration of treatment, according to a February 17, 2017 study summary[5] posted on the Imperial College website. In addition, researchers found that 45% of the websites did not require a prescription from the patient.

"These findings are a real concern, and raise several important issues regarding antibiotic resistance and patient safety with online pharmacies," says Dr Sara Boyd, study coauthor and National Institute for Health Research academic clinical fellow in Infectious Diseases and Microbiology at Imperial College. Like NABP's research, the study provides a small snapshot of how online drug sellers operate. "Our study paves the way for larger, more thorough research into this worrying new trend so that we can ensure patient safety and promote the responsible use of antibiotics in all areas of healthcare provision."

Discussion

Given that misuse and overuse of antibiotics fuel antibiotic resistance, it is necessary to ensure judicious prescribing practices. Actions being taken by the federal government and CDC are commendable and will go a long way toward reversing the disturbing trend of antibiotic resistance. At the same time, illegal online drug sellers dispensing antibiotics without a prescription cannot be ignored. Consumer education is key to using antibiotics appropriately and only when needed and to recognizing the dangers of buying medicine from rogue internet drug outlets. These rogue sites pose a variety of public health risks. Contributing to the inappropriate use of antibiotics is yet another reason to work toward making the internet a safer place for consumers. NABP remains committed to upholding the integrity of the practice

[5] Brogan C. Online pharmacies not requiring prescriptions could fuel antibiotic resistance. Imperial College London Web site. http://www3.imperial.ac.uk/newsandeventspggrp/imperialcollege/newssummary/news_15-2-2017-14-34-3. Published February 17, 2017. Accessed March 1, 2017.

of pharmacy – in any practice setting – and ensuring that patients worldwide have access to safe and effective prescription medications. For further information, please contact Melissa Madigan, policy and communications director, via email at mmadigan@nabp.pharmacy.

Appendix

Internet Drug Outlet Identification Program 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 website 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 website an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the website an accurate, readily accessible and responsive phone number or secure mechanism via the website, 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. **Website transparency.** The pharmacy must not engage in practices or extend offers on its website 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 websites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated websites.** The pharmacy, website, 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 website that violates these standards.