

Internet Drug Outlet Identification Program *Progress Report for State and Federal Regulators: August 2017*

Prepared By

The National Association of Boards of Pharmacy



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Internet Drug Outlet Identification Program Progress Report: August 2017

Introduction

Many online drug sellers display the Canadian maple leaf as a symbol of the safety and reliability of medications approved for sale in Canada. The drugs they sell to customers outside of Canada, however, are often something altogether different. Since the subject of importing prescription medicine from Canada has made a reappearance in the halls of Congress in recent months, many health care regulators and patient safety advocates have voiced their opposition to importation, stating that such policy would open the floodgates for unapproved and counterfeit medications of unknown origins to enter the United States medication supply chain.



The National Association of Boards of Pharmacy® (NABP®) expressed this concern in a [letter](#) to Congress earlier this year. “In NABP’s nearly 20 years of experience in verifying internet pharmacies, US consumers buying medications from Canadian online pharmacies rarely, if ever, receive the Health Canada-approved products afforded to Canadian customers,” NABP wrote. “Instead, these Canadian pharmacy websites sell US patients medicines manufactured in places where buyers would not even drink the water, eg, India, Turkey, or Southeast Asia.” According to the US Food and Drug Administration (FDA) article, “[Imported Drugs Raise Safety Concerns](#),” “Drugs coming to the United States from Canada may be coming from some other country and simply passing through Canada. The drugs could also be counterfeit, contaminated, or subpotent, among other things.”

To substantiate these concerns, NABP recently reviewed more than 100 websites with “Canada” or “Canadian” in their name or URL, or posting a Canadian address on their websites to see how many of them dispensed prescription medicine from outside of Canada. These sites are among the nearly 11,700 websites selling prescription medications that NABP has reviewed since 2008. In all, NABP has found nearly 96% of these sites to be operating illegally, out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice

standards. These findings are described in the Results section below. In many instances, these sites are foreign drug sellers masquerading as Canadian online pharmacies but actually dispensing medications that are approved by neither FDA nor Health Canada. In fact, nearly three-quarters (74%) of the so-called Canadian sites NABP reviewed from July 1, 2016, through June 30, 2017, state on their websites that they source their drugs from countries outside of Canada. These findings are described on pages 9 and 10 of this report. Such products are not approved by Health Canada and would be illegal to sell in that country. Yet, online drug sellers routinely dispense these products to patients in the US, in contravention of US federal law and endangering patient health.

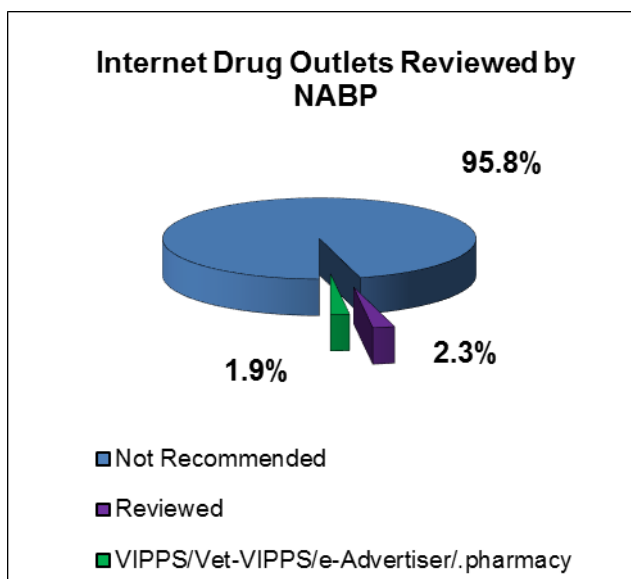
Results

A. Findings of Site Reviews to Date:

As of June 30, 2017, NABP has reviewed 11,688 internet drug outlets selling prescription medications to US patients. Of these, 11,142 (95.8%) 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. 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 11,142 internet drug outlets



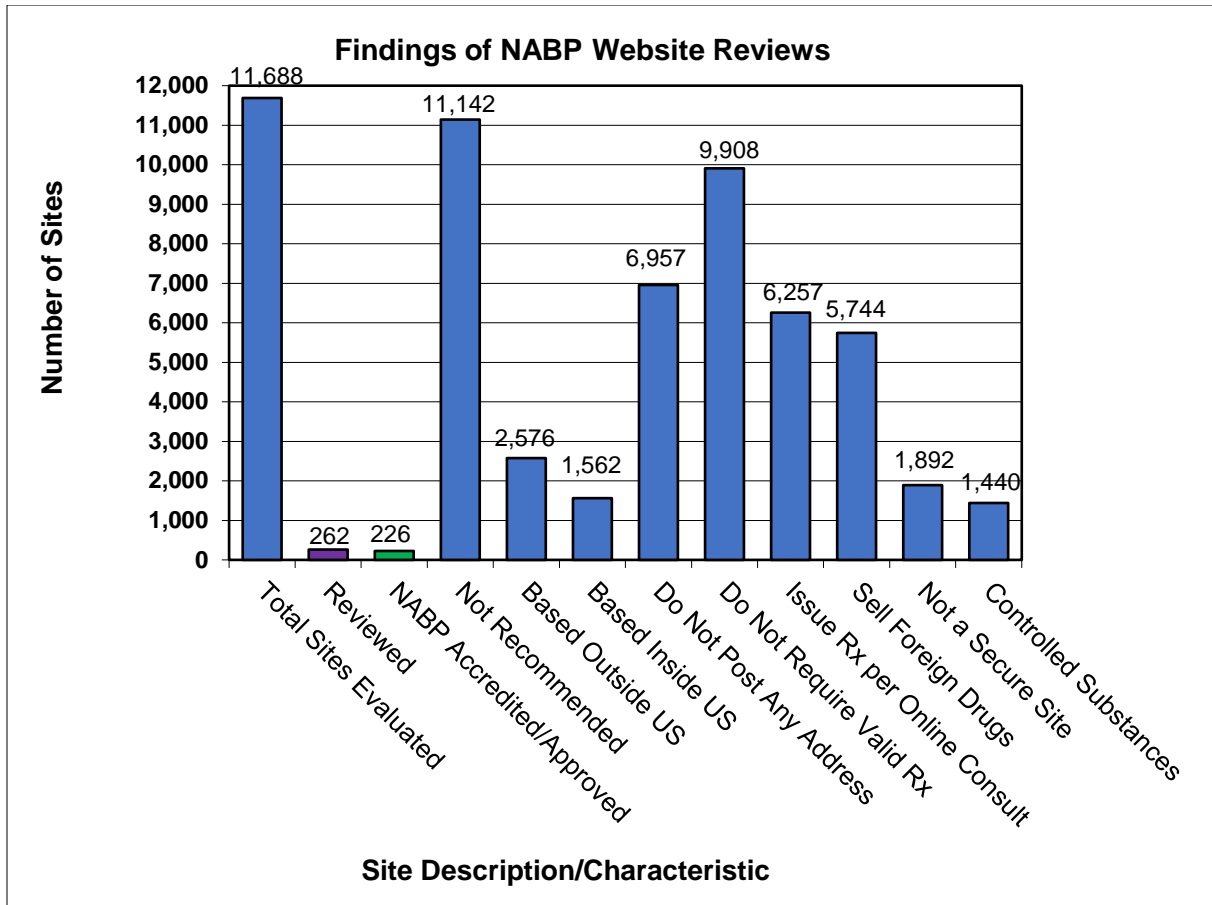
currently listed as Not Recommended on the NABP website are characterized in the table below.¹

Not Recommended Sites

Physical Location:	<ul style="list-style-type: none"> • 2,576 (23.1%) outside US • 1,562 (14%) inside US • 6,957 (62.4%) no location posted on website
Prescription Requirements:	<ul style="list-style-type: none"> • 9,908 (88.9%) do not require valid prescription • 6,257 (56.2%) issue prescriptions per online consultations or questionnaires only
Medications:	<ul style="list-style-type: none"> • 5,744 (51.6%) offer foreign or non-FDA-approved medications • 1,440 (12.9%) dispense controlled substances
Encryption:	<ul style="list-style-type: none"> • 1,892 (17%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul style="list-style-type: none"> • 4,762 (42.7%) outside US • 5,903 (53%) inside US • 464 (4.2%) have unknown server locations
Affiliations:	<ul style="list-style-type: none"> • 9,681 (86.9%) appear to have affiliations with rogue networks of internet drug outlets

The table above, as well as the bar graph on page 6 of this report, shows the characteristics of drug sites listed as Not Recommended on the NABP website as of June 30, 2017. More than half sell foreign or non-FDA-approved medications to US patients, and 85.5% are either based outside of the US or, as in most cases, do not post any physical address on the website.

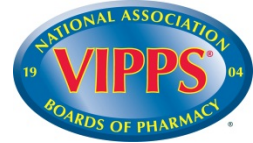
¹ It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found 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 nine years.



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 11,688 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^{CM} Program, or .Pharmacy Verified Websites Program. Two hundred twenty-six (1.9%) of the 11,688 sites selling prescription medications or offering resources to US patients were accredited through the VIPPS or Vet-VIPPS programs or were approved through the e-Advertiser Approval or .Pharmacy 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 June 30, 2017, 80 pharmacies were listed on the NABP website as VIPPS or Vet-VIPPS accredited, and 111 entities were listed as Approved e-Advertisers. While the VIPPS program will continue to operate, NABP is no longer accepting applications for the Vet-VIPPS and e-Advertiser Approval programs, as these programs are being streamlined into the .Pharmacy Program. Several applications for VIPPS accreditation are in progress. Including all types of .pharmacy-registered entities – pharmacy, board of pharmacy and regulatory agency, resource and referral, association and consumer advocacy, professional, pharmaceutical manufacturer, and school and college of pharmacy – 132 .pharmacy registered entities are listed on the [Buying Safely](#) page of the .Pharmacy Program website, www.safe.pharmacy. Over 100 .pharmacy applications are in progress.



C. .Pharmacy Program: NABP believes strongly that its .Pharmacy Program is the future of safe pharmacy and pharmacy-related services provided online, offering a superior means of displaying approval to consumers and other entities. It is no longer enough to have a seal of approval that can be copied and pasted and displayed fraudulently to dupe patients into thinking they are visiting a safe website. The .pharmacy domain name identifies legitimately operating pharmacies and pharmacy-related entities for consumers, advertisers, and search engine companies by incorporating the “seal of approval” into the domain name. With .pharmacy, patients know they are visiting a safe website.



NABP has, as of July 19, 2017, granted approval for 576 domain names, and 353 .pharmacy domain names have been registered (up from 310 at the close of first quarter 2017). Of these, 261 were registered to pharmacies, 12 were registered to professional sites, 41 were

registered to boards of pharmacy or regulatory agencies, 18 were registered to associations and consumer advocacy sites, 16 were registered to resource and referral sites, 3 were registered to manufacturers, and 2 were registered to schools or colleges of pharmacy.

Of the 353 .pharmacy domain names registered, 192 are in use, while the remaining registered domain names are parked. Of those that are in use, 124 are registered to pharmacies, 31 are registered to boards of pharmacy or regulatory agencies, 16 are registered to associations and consumer advocacy sites, 14 are registered to resource and referral sites, 5 are registered to professional sites, and 2 are registered to schools or colleges of pharmacy. Of the domain names in use, 25 are being used as the registrant's primary web address, 156 are redirecting to another domain name, and 11 are masking another domain name with the .pharmacy name.

.Pharmacy is a verified Top-Level Domain, meaning that applicants are evaluated for compliance with registry standards prior to being allowed to use a .pharmacy domain name. 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. As such, pharmacies licensed in Canada and dispensing medicine only to patients residing in Canada are eligible for a .pharmacy domain name, provided they meet all other program standards.

So-Called Canadian Internet Pharmacies Selling Not-So-Canadian Drugs

The regulations in Canada that ensure medication safety and efficacy – such as those prohibiting the importation of unapproved foreign medications into the country – do not protect US patients buying medicine from so-called Canadian online pharmacies. These drug sellers generally source the medications they sell to the US from all over the world – often from third-world countries where regulations and oversight are not as stringent or effective as they are in the US and Canada. Sourcing medications from outside of a tightly regulated supply chain also

Nearly three-quarters (80, or 74%) of the 108 so-called Canadian online pharmacies that NABP reviewed state on their websites that they source the medications they sell from outside of Canada.

greatly increases the chances of counterfeit medicines finding their way to consumers.

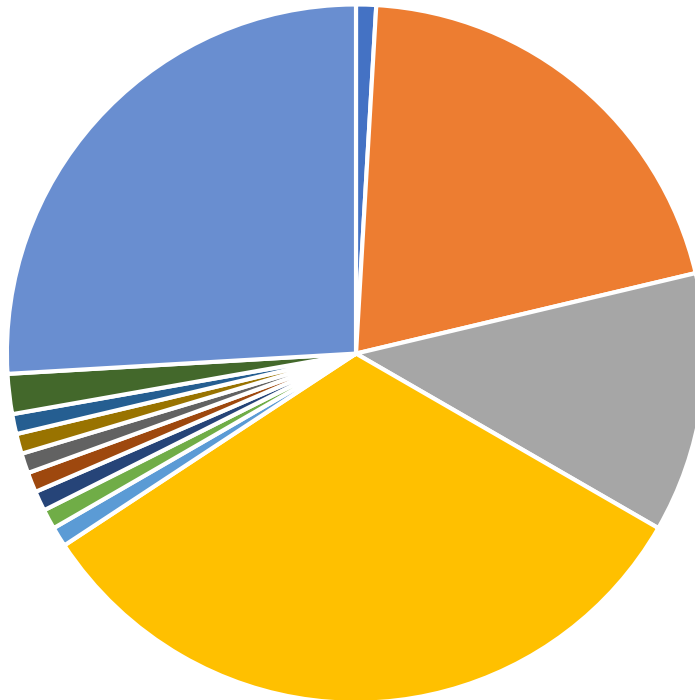
The pie chart on page 10 of this report shows the results of a year-long study NABP performed and is based on information provided on over 100 websites. All sites reviewed in this study use “Canada” or “Canadian” in their web business name or URL, or post an address in Canada, and offer to sell medications to customers in the US.

A. NABP Study Findings: From July 1, 2016, to June 30, 2017, NABP identified 108 websites using “Canada” or “Canadian” in their web business name or URL, or posting an address in Canada, all of which were offering to sell medications to customers in the US. Nearly three-quarters of them (80, or 74%) stated on the website that they sourced their medications from outside of Canada. These medications are not approved by Health Canada, nor are they legal to sell in Canada. The remaining 28 sites did not indicate the locations from which they source the medications they sell.

Half (54) of the 108 so-called Canadian pharmacies that NABP reviewed source the medications they sell from India, or from a combination of various countries including India, Hong Kong, and Singapore. The likelihood of receiving substandard or counterfeit medicine from these countries is considerable. According to the 2017 Special 301 [Report](#) issued by the Office of the US Trade Representative (USTR), “studies have suggested that up to 20% of drugs sold in the Indian market are counterfeit and could represent a serious threat to patient health and safety.” USTR also reports, “Ninety percent of all counterfeit pharmaceuticals seized at the US border in Fiscal Year 2016 were shipped from or transshipped through four economies: China, Hong Kong, India, and Singapore.”

While India was the most common source for medications sold online from so-called Canadian pharmacies, 20% (22) of the 108 source the medications from unspecified foreign locations, and 26% (28) do not say where they get the medications they sell. Only 14% (15) post a physical address for the pharmacy. None of the 108 sites require a valid prescription, and 27% (29) dispense controlled substances.

From Where Do So-Called Canadian Internet Pharmacies Source Their Drugs?



- Mauritius, New Zealand, Singapore, Turkey, UK, and India
- Unspecified international locations
- US and India
- India
- US, UK, Hong Kong, India, etc
- Turkey
- New Zealand
- India, Singapore, Hong Kong, Germany, and Great Britain
- Canada, India, Mauritius, New Zealand, Singapore, Turkey, UK, and US
- Singapore, UK, New Zealand, Turkey, Mauritius, India, Australia, and US
- Hong Kong, India, and Pakistan
- Canada, UK, Australia, and New Zealand
- Does not say

- 74% (80) of the 108 so-called Canadian pharmacy sites NABP reviewed source the medications they sell from outside of Canada.
- Half (54) of them source the drugs they sell from India, or India and some combination of other countries.
- 20% (22) source them from unspecified foreign locations.
- 26% (28) do not say where they get the drugs they sell.
- Only 14% (15) post a physical address for the pharmacy.
- None of them require a valid prescription.
- 27% (29) dispense controlled substances.

B. Proposed Importation Legislation Raises Concerns

These findings underscore the concerns that NABP and others have raised about proposed legislation that would allow US consumers to import prescription medications from Canada. “NABP and many other patient safety advocates have found that the dangers of drugs dispensed outside of FDA’s or Health Canada’s drug approval process are significant,” NABP wrote to Congress. “Outside these closed and tightly regulated drug supply chains, the safeguards put in place to ensure the identity, efficacy, and safety of prescription medications no longer apply.” FDA cites quality assurance concerns among the potential health risks with imported drugs: “Medications that have not been approved for sale in the United States may not have been manufactured under quality assurance procedures designed to produce a safe and effective product.”

Among those raising such concerns is Leona Aglukkaq, who served as Canada’s minister of health from 2008 until 2013. Under proposed plans to allow importation, “Canada would simply serve as an intermediate transshipment point for unapproved drugs heading to the United States,” Aglukkaq said in an opinion [column](#) appearing in the May 12, 2017 *Washington Post*. “Canadian authorities do not inspect every shipment of products headed for the U.S. marketplace to ensure that packages don’t contain adulterated, counterfeit or illegal drugs. Canada does not have the resources to undertake such comprehensive searches, and the Canadian and U.S. governments are not currently set up to facilitate such a program.”

The Alliance for Safe Online Pharmacies (ASOP Global) dedicates a [section](#) of its website to educating the public about Canadian internet pharmacies selling to US residents. “In short,” ASOP Global states in its [FAQs](#), “the drugs U.S. residents get from a site that claims to be a Canadian online pharmacy are *not* Health Canada-approved and are not the same quality drugs that a Canadian resident would receive either from the same Canadian online or brick and mortar pharmacy.”

Discussion

Buying prescription medications from a Canadian online pharmacy seems like a great deal, until consumers realize that what they are getting is not what they bargained for. Given that online

drug sellers presenting themselves as Canadian pharmacies rarely, if ever, sell Health Canada-approved medicine to US consumers, and until such time as a safe and tightly regulated international supply chain can be established, importing medication from Canada presents a considerable public health threat. Any US policy that would allow US patients to buy medications from so-called Canadian online pharmacies is considered by many to be irresponsible. Such action would put patients in this country at risk of harm from counterfeit or adulterated medicines.

In keeping with its mission to assist its member boards and jurisdictions in protecting the public health, NABP remains committed to upholding the integrity of the practice of pharmacy – in any practice setting or location – 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 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 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.