

#### **FAQS ON CANADIAN INTERNET PHARMACIES SELLING TO U.S. RESIDENTS**

### 1. What Do U.S. Residents Get When They Search for a "Canadian Online Pharmacy"?

U.S. residents will find hundreds of websites that initially, but incorrectly, appear to sell them drugs supplied by licensed pharmacies located in Canada. But in fact:

- 1. The Canadian pharmacy owns and operates, or receives a commission from the owner and operators of, the online pharmacy website. It may display a genuine Canadian pharmacy license, leading U.S. residents to *believe* that the Canadian pharmacy is the source of the medicines.
- 2. But often, the drugs are actually sourced from shippers (often not licensed as a pharmacy anywhere) outside of Canada, typically in India, Turkey, Southeast Asia or elsewhere. These foreign sources simply put the Canadian pharmacy's brand on the label to make U.S. consumers believe they are from Canada.
- **3.** Or, the drugs are shipped from such places as India, Turkey, or Southeast Asia to a midway point where a licensed pharmacy in the UK or a similar country perceived as "safe" by U.S. residents will slap a label on the drugs.
- **4.** None of this is legal, and the online pharmacy websites lack legally required licenses and drug safety regulatory approvals.
- **5.** In short, 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 & mortar pharmacy.

Additionally, there are many more websites that claim to have some nexus to Canada – slap a maple leaf on a website – to dupe U.S. consumers. These sites have no real connection to Canada at all – do not work with a pharmacy or pharmacist licensed by a Canadian province and do not have physical presence in Canada. Like the other "Canadian online pharmacy" websites described above, these sites also do not source drugs that are approved by Health Canada.

# 2. Are There ANY Legitimate Canadian Online Pharmacies that Supply Medicines to Canadians?

Yes. There are legitimate Canadian online pharmacies. Indeed, LegitScript has approved a few that are solely targeting Canadian residents and that are operating legally under Canadian laws. (Of note, these pharmacies do not ship to U.S. residents in response to internet-based orders.) But from the perspective of a U.S. resident there are no legitimate Canadian online pharmacies. That's not just because of the laws prohibiting Americans from buying Health Canada-approved medicines; it's because we have never seen a case where the website is shipping all or even most drugs from the Canadian pharmacy. Sometimes some of the drugs are, but never all of them.

This is the risk to U.S. residents: while the website might be safe if you're in Canada, it does not consistently sell Americans the same safe, Health Canada approved medicines.

# 3. Why Can't Congress Just Make It Legal for U.S. Residents to Buy From *Only* Websites Supplying from *Actual* Canadian Pharmacies?

It's fundamentally a problem of jurisdiction. When a pharmacy is physically located in the United States, there is a built-in disincentive against supplying sub-standard drugs to U.S. residents: the risk of civil or criminal enforcement action. For pharmacies in the U.S., if they violate safety rules, the FDA, DEA, or a State Board of Pharmacy can exercise regulatory, even prosecutorial, authority over the pharmacy operators.

When a pharmacy is based in Canada, the U.S. government cannot effectively exercise cross- border jurisdiction to ensure that the drugs shipped into the U.S. really come from the actual Canadian pharmacy.

Put bluntly, if a U.S. pharmacy knowingly swaps out FDA-approved medicine for toxic counterfeits and someone dies, the FDA can execute a search warrant, arrest the offender and protect the public health. If a Canadian (or UK, or Indian, etc.) foreign national does the same, the FDA has no power to execute search warrants or arrest individuals in other countries absent extraordinary circumstances. Simply put, the FDA and other regulatory boards, including Canadian ones, are rendered impotent to protect the public health as they cannot ensure the medicines supplied from online sellers are actually legitimate.

# 4. Can the U.S. Increase FDA/DOJ Enforcement Authority and Penalties for Illegal Actors?

Adding more resources, authorities, and penalties won't change the fact that international criminals can evade U.S. law enforcement simply by operating off-shore in jurisdictions that don't prioritize internet pharmacy crime and/or don't cooperate with U.S. on law enforcement matters generally. While the U.S. Government can and does take action against illegal online pharmacy operators *in the U.S.*, our government's power stops at our borders. In some cases, foreign jurisdictions cooperate with the U.S. on enforcement actions but many internet pharmacy criminals remain at large internationally.

Take, for example, the *Canadadrugs.com* case of 2015. In this case, the U.S. DOJ charged fourteen companies and individuals associated with *canadadrugs.com* with smuggling \$78 million worth of mislabeled, unapproved and counterfeit cancer drugs into the U.S. to sell to doctors. Of the fourteen defendants, only one was U.S.-based. He appeared in court, entered into a deferred prosecution agreement, and the charges were dropped. <u>U.S. officials sought assistance</u> through extradition treaties to detain the other thirteen defendants in their various foreign locations. The defendants remain at-large.

## 5. What Are the Risks to U.S. Residents Who Buy From a "Canadian" Online Pharmacy?

- Patients who buy medications online from unapproved foreign sources online do not know where the drugs are coming from or if they are safe or effective.
- Medicines sold online come from places where there isn't even safe drinking water.
- A "bait and switch" is used by some licensed Canadian online pharmacies, substituting ineffective non-Canadian drugs when the buyer is a U.S. resident.
- Medicines sold on these sites may have changed hands many times along the way, creating multiple
  opportunities for falsified and substandard drugs to enter the supply chain and be shipped to the
  patients.
- There is no way for a consumer to know the conditions under which the medicines were manufactured, stored, and transported, creating opportunities for the product to become degraded, ineffective or unsafe.

- The products may contain either too much, too little or no active pharmaceutical ingredients, or have the wrong dosage. Medical devices may be faulty or even hazardous.
- The drugs may come from manufacturers in third-world countries that are not approved for use by Health Canada or U.S. FDA for use in Canada or the United States.
- Canadian law currently prohibits the transshipment of drugs from any country—including those in
  the third world—into Canada and then into the United States. However, a proposed new law (S. 38)
  would allow for transshipment of health products through Canada for the sole purpose of export,
  which further exacerbates concerns about the safety and reliability of these medicines and would
  exempt these transshipped products from FDA requirements.
- All of these uncertainties put patients at risk of harm or death.

# 6. What Do Regulators Think About the Risks?

- U.S. FDA, Dr. Robert Califf recently stated: "FDA evaluation of non-FDA-approved imported drugs revealed that while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of such drugs were actually from different countries.
- Canadian health officials have stated that they cannot guarantee products sold to U.S. citizens from Canadian are safe and effective.

#### 7. What Has Law Enforcement Done?

- CanadaDrugs, approved by both CIPA and PharmacyChecker, and its partners and affiliates were
  involved in selling counterfeit cancer medicine to U.S. patients via the company's wholesaler
  business, as detailed in the indictment available HERE.
- In the case of Andrew Strempler and Mediplan Health Consulting/RxNorth a Canadian online pharmacy owner was <u>indicted in U.S. Federal court</u> for selling counterfeitdrugs to U.S. citizens.

#### 8. How Can So Many "Canadian" Online Pharmacies Be Fake?

The anonymous nature of the internet makes it easy for criminals to falsely claim to be:

- Located in Canada and affiliated with a licensed Canadian pharmacy, but actually supplying drugs from a foreign jurisdiction outside of Canada;
- A licensed pharmacy with licensed doctors and pharmacists on staff, but actually operating without professional licenses, as required by law;
- A licensed pharmacy legally operating in the patients' jurisdiction, but actually failing to have the required regulatory approvals, as required by law;
- Approved but actually using fake certification organizations and/or using forged seals of approval.
   (Unfortunately, the pharmacy licensing boards do not have the resources or the legal pathways to prosecute or require the illegal Canadian online pharmacy sites to be removed from the internet.
   Many of the Canadian online pharmacy websites are blocked within Canada and cannot be viewed by the authorities in Canada, or "geo-target" content, displaying only legitimate content when accessed from a Canadian IP address.)

#### 9. What about PharmacyChecker-Approved Canadian Sites?

While some U.S. pharmacy websites approved by PharmacyChecker may be safe and legal, patients should consider the following information:

- PharmacyChecker approved an online pharmacy run by Titilayo Akintomide Akinyoyenu (aka Tommy Akin). Tommy is <u>now under indictment</u> for allegedly filling prescriptions for customers solely on the basis of an online questionnaire, without requiring a prior in-person doctor's visit.
- In 2015, PharmacyChecker's Director of Pharmacy Policy and International Verifications Ram Kamath was one of eight people indicted in <u>a U.S. Department of Justice case</u> for allegedly participating in a conspiracy to distribute \$78 million worth of non-FDA-approved and counterfeit cancer medications into U.S. doctors' offices. The charges against Kamath were eventually dropped.
- According to LegitScript, the following are additional illicit online pharmacies that had been certified by PharmacyChecker:
  - o RxNorth.com, owner and president indicted and convicted for selling counterfeit drugs;
  - shopeastwest.com, promoted on PharmacyChecker's own website, and selling prescription drugs without a prescription from India; the principal was recently convicted of illegal online medicine sales and was sentenced in 2016; and
  - o *TotalCareMart.com*, a supposedly Canadian online pharmacy certified by PharmacyChecker that the Canadian government ordered to be shut down (see here),
  - CanadaDrugs, individuals affiliated with this website are currently under indictment for counterfeit drug sales (see <a href="here">here</a>);
  - o *pharmnet.com*, advertising controlled substances that were sold without a prescription from India:
  - o *livewellrx.com*, which sold to an undercover "13-year-old" muscle relaxants without a valid prescription;
  - o *pillsbargain.com*, which did not require a valid prescription fortramadol;
  - o tenpharmastores.com, linked to websites offering Vicodin without a prescription;
  - o top10pharma.com, selling drugs without a valid prescription.

# 10. How Can Patients Find More Affordable Medicines from Safe Sources?

Access to affordable medications is a priority for patients worldwide, but it should not come at the cost of safety. There are resources available to help patients get access to safe and reliable pharmacies without buying from unapproved foreign sources:

- <u>www.NeedyMeds.org</u> steers people to assistance programs to help them afford their medications and other healthcare costs.
- The AWARXE prescription drug safety website, <u>www.awarerx.pharmacy/acquire-safely</u>, and the ASOP Global website, <u>www.BuySafeRx.Pharmacy</u>, also provide information on discount medication programs.
- The National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada lists all the
  provincial pharmacy licensing bodies at the website <a href="www.napra.ca">www.napra.ca</a>. By clicking on the specific
  province, the patient can confirm the pharmacy is licensed and meets all practice standards.