



Drug Importation, Online Pharmacies, Savings

Myths vs. Facts

1. *Myth: Importation is not safe and international online pharmacies are all dangerous.*

FACT: Importation is safe when consumers buy and import medication from licensed pharmacies. Peer-reviewed, empirical studies demonstrate that when Americans import lower cost medication for personal use, purchased from a properly credentialed international online pharmacy and based on a valid U.S. prescription, they receive lower cost, lawfully manufactured, safe and effective medications.¹

The myth is often perpetrated by taking legitimate concerns about counterfeit drugs sold online and in poorer countries and conflating them with safe international online pharmacies and personal drug importation. The role of the pharmaceutical industry in funding misleading campaigns is well documented.² Through such industry-funded programs, all non-U.S. online pharmacies, including properly credentialed international online pharmacies, are branded as “rogue,” “not recommended,” “not approved,” or “fake.”³

2. *Myth: Americans will not really save money with importation.*

FACTS:

- Approximately 19 million Americans say they have imported a prescription medication for personal use because the medications were more affordable.⁴ CDC figures show that about four million Americans, annually, import medication for personal use because of cost.⁵
- Savings of 90% are common on brand name medications when purchased internationally as compared to in the U.S.⁶
- Thousands of consumers across the U.S. have provided public testimonials about saving money using international online pharmacies and how it’s their only option.⁷

3. *Myth: Lots of people are getting hurt from importation and online pharmacies*

FACT: The FDA has never reported a serious adverse incident or death resulting from a medication ordered online and imported for personal use from a pharmacy that required a valid prescription.

In the U.S., between 2001-2011, three people have died and six were sickened, either by ordering *controlled* drugs online *without* a prescription due to overdose, or buying, without prescription, tainted or the wrong medication from rogue sites: and mostly from *domestic* sources.⁸ These problems can be avoided with credentialed international online pharmacies.

The most serious drug safety tragedies in America have related to medication purchased *in the U.S.*, not from buying medication online for personal use. In 2008, 81 people died from ingesting tainted heparin, manufactured by an American drug company which used adulterated pharmaceutical ingredient from China.⁹ In 2012, 64 Americans died and many hundreds more were sickened by tainted steroids manufactured by American compounding pharmacies.¹⁰

4. *Myth: Since the FDA states that it cannot verify the quality or safety of imported medication, importing medication is dangerous.*

FACT: Just because the FDA states that it cannot verify the quality or safety of imported medication doesn't mean medication sold in foreign countries is not safe. The FDA's stated function is to regulate medications sold in the U.S., while it is the function of drug regulatory authorities in other countries to do the same in those countries.¹¹

5. *Myth: Imported medications are not "FDA-approved" and are therefore unsafe.*

FACT: Opponents of importation argue that medicines sold outside the U.S. are not FDA-approved. However, "FDA-approved" is not the only designation of medication safety worldwide.¹² In many cases, imported drugs often *are* FDA-approved medications but with different labeling, or foreign versions of FDA-approved drugs (including ones made and marketed by well-known companies, such as Pfizer, Eli Lilly and Merck).

Pharmaceutical importation is already legal and considered safe, but only for the pharmaceutical industry: 80 percent of active pharmaceutical ingredients used to make all prescription drugs sold domestically are imported; and 40% of finished medications sold in U.S. pharmacies are imported.¹³

6. *Myth: There is no way for a consumer to know whether an online pharmacy is rogue or an actual pharmacy.*

FACT: There are existing reliable resources which inform consumers about the credentials of international online pharmacies. The leading resource is PharmacyChecker.com, a New York company founded in 2002 by Tod Cooperman, M.D., that verifies the credentials of international online pharmacies and compares prescription drug prices. Consumers can access its information for free.

Independent research has shown that medication purchased from PharmacyChecker.com-verified pharmacies is genuine and as safe as medication purchased from U.S. pharmacies.¹⁴

The PharmacyChecker Verification Program allows eligible online pharmacies¹⁵ meeting strict program standards and policies to become members. The Program is run by a licensed pharmacist, who was Director of Pharmacy Quality Assurance for the Massachusetts Board of Pharmacy.¹⁶ The Program's practice and safety standards are publicly available and include the following:

Pharmacy / Pharmacist licensure - all transactions processed through the online pharmacy must be directly confirmed, dispensed and shipped by a licensed pharmacy that is also a verified member of the Verification Program. Medication orders must only be dispensed by a pharmacist licensed in the dispensing pharmacy's jurisdiction.

Valid prescription requirement – the online pharmacy must require a valid prescription and its website must clearly display this requirement.

Controlled substances – in accordance with the Ryan Haight Act, the online pharmacy (unless dispensing from within the U.S.) may not market or sell controlled substances into the U.S., as defined by the U.S. Drug Enforcement Agency (DEA).

Country transparency – the online pharmacy must disclose to consumers the specific country or, if applicable, the list of potential countries, from which a drug will be dispensed.

Location/Customer service – the online pharmacy must clearly publish a telephone number and mailing address that allows consumers to reach the pharmacy staff for customer service.

Pharmacist consultations – the online pharmacy must conspicuously publish the fact that a pharmacist consultation with a licensed pharmacist is available for patients who have questions about their medication orders.

Information security – the online pharmacy must employ Secure-Socket Layer or equivalent technology to ensure protection of health and financial information of consumers.

Marketing claims – the online pharmacy must only make claims that are truthful and not misleading to the consumer, e.g. claims about generic medications may not refer to generic medications as “exactly the same as” or “identical to” their brand name counter parts.

Verified online pharmacies are authorized to publish the PharmacyChecker Seal¹⁷ which links to its pharmacy profile, hosted on www.PharmacyChecker.com. By clicking on the seal, consumers can obtain additional information about the online pharmacy.

7. *Myth: Allowing personal importation would require the FDA to approve the safety of all imported medication – and at great taxpayer expense.*

FACT: As noted above, personal drug importation into the U.S. is already being done safely, without FDA oversight. In several countries, it’s expressly legal for consumers to personally import medication, without government oversight. An example is Australia (<https://www.tga.gov.au/personal-importation-scheme>) where an individual may import a 3-month supply of a drug which need not be approved for sale in Australia. Australia provides general information to consumers regarding how medication may be legally imported as well as warnings.

For further questions contact Jodi Dart at jodi@prescriptionjustice.org.

¹ Bate, R., Jin, G. & Mathur, A. (2013). In Whom We Trust: The Role of Certification Agencies in Online Drug Markets. *The B.E. Journal of Economic Analysis & Policy*, 14(1), pp. 111-150. Retrieved 1 Feb. 2017, from doi:10.1515/bejeap-2013-0085. See <https://www.degruyter.com/view/j/bejeap.2014.14.issue-1/bejeap-2013-0085/bejeap-2013-0085.xml> [Last accessed 2/1/2017].

² See Malcolm, Jeremy, “How Big Pharma’s Shadow Regulation Censor the Internet,” October 6, 2016, Electronic Frontier Foundation. See <https://www.eff.org/deeplinks/2016/09/how-big-pharmas-shadow-regulation-censors-internet> [Last accessed 12/11/2016]. See Roger Bate, “The Risks and Benefits of the Online Pharmacy Market,” Safe Medicines Coalition: <http://safemedicinescoalition.org/resources/The-risks-and-benefits-of-the-Online-Pharmacy-Market.pdf>; See Gabriel Levitt, “Online Pharmacies, Personal Drug Importation and Public Health: Ill-Considered Enforcement Prevents Access to Safe and Affordable Medication” February 2015. See <https://www.pharmacychecker.com/online-pharmacies-personal-drug-importation-public-health.pdf> [Last accessed 12/11/16].

³ Ibid.

⁴ Bluth, Rachel, “Faced With Unaffordable Drug Prices, Tens of Millions Buy Medicine Outside the U.S.,” December 20th, 2016, Kaiser Health News, see <http://khn.org/news/faced-with-unaffordable-drug-prices-tens-of-millions-buy-medicine-outside-u-s/> [Last accessed 1/29/2017].

⁵ Cohen RA, Villarroel MA. Strategies used by adults to reduce their prescription drug costs: United States, 2013. NCHS data brief, no 184. Hyattsville, MD: National Center for Health Statistics. 2015. See <http://www.cdc.gov/nchs/data/databriefs/db184.htm> [Last accessed 12/11/2016].

⁶ PharmacyChecker.com Price Comparisons: <https://www.pharmacychecker.com/news/medications-dropped-from-pbms-2017-cost-less-outside-u.s.asp>.

⁷ See <http://www.rxrights.org/testimonials/>; https://www.change.org/p/kathleen-sebelius-please-don-t-stop-americans-from-getting-medicine-at-lower-cost-outside-the-u-s/c?source_location=petition_show.

⁸ Levitt, Gabriel, “Online Pharmacies, Personal Drug Importation and Public Health: Ill-Considered Enforcement Prevents Access to Safe and Affordable Medication” February 2015. See <https://www.pharmacychecker.com/online-pharmacies-personal-drug-importation-public-health.pdf> [Last accessed 12/11/16]. Page 17.

⁹ Greenemeier, Larry, “Heparin Scare: Deaths from Tainted Blood-Thinner Spur Race for Safe Replacement,” *Scientific American*, November 4, 2008; see <https://www.scientificamerican.com/article/heparin-scare-deaths/> [Last accessed 2/1/2017].

¹⁰ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/hai/outbreaks/meningitis.html>.

¹¹ Noel T. (Tom) Curb, R.Ph. Oral Presentation Prescription Drug Importation Public Meeting (Docket No. 2004N-0115) Public Hearing, Task Force on Drug Importation, April 14, 2004; Natcher Auditorium, Building 45, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892. See <http://www.fda.gov/ohrms/dockets/dockets/04n0115/04n-0115-ts00007-curb.pdf> [Last accessed 2/1/2017].

¹² Ibid.

¹³ Sklamberg, Howard and Michael Taylor, “In India, With Our Sleeves Rolled Up,” March 18, 2015, *FDA Blog*. See <http://blogs.fda.gov/fdavoices/index.php/tag/finished-drugs/> [Last accessed 12/11/2016].

¹⁴ <https://www.degruyter.com/view/j/bejeap.2014.14.issue-1/bejeap-2013-0085/bejeap-2013-0085.xml>

¹⁵ Online pharmacies are websites offering prescription processing and dispensing services. In addition to requiring that online pharmacies demonstrate compliance with program standards, PharmacyChecker verifies that the online pharmacy is only referring prescription orders to licensed dispensing pharmacies who are also Members of the Verification Program. See https://www.pharmacychecker.com/verification_program_guide_and_standards_1_3.pdf.

¹⁶ See Kelly Ann Barnes LinkedIn page: <https://www.linkedin.com/in/kelly-ann-barnes-id-rph-b65a3956> [Last accessed 2/1/2017].

¹⁷ See a sample PharmacyChecker Seal: <https://www.pharmacychecker.com/sealprogram/choose.asp>.