

PharmacyChecker.com Public Comments to the Department of Health and Human Services Request for Comments on How to Lower Drug Prices and Out-of-Pocket Costs

Agencies: Department of Health and Human Services and the U.S. Food and Drug Administration

Document Number: 2018-10435

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Date: July 13th, 2018

Introduction

Launched in 2003, PharmacyChecker.com evaluates online pharmacies; provides online pharmacy drug price comparisons and local U.S. pharmacy price comparisons in conjunction with a discount card; and advocates for expanding access, online and off, to safe and affordable imported medicines. We are a stakeholder in the online business community seeking an open Internet environment that promotes innovation and new business models that serve the public health.

PharmacyChecker.com is a proud American company based in New York. We appreciate the opportunity to submit recommendations on how to immediately safeguard and expand access to lower-cost medicines in order to help U.S. citizens and all people living in the U.S. reduce their out-of-pocket prescription drug costs.

The key point made herein is that Americans already lower their out-of-pocket costs by purchasing medicines internationally, ones that are imported from pharmacies to fill their prescriptions. The practice is technically restricted under federal law, but no one is prosecuted for doing so. Wrongly, this practice has recently been curtailed and threatened by overzealous enforcement actions by the FDA.

Tens of millions of Americans don't fill prescriptions due to cost, making it clear that safe international purchases of affordable medicines are a lifeline. The FDA, however, never focuses on or recognizes the very real and provable public health benefits of safe personal drug importation, instead choosing to highlight the problems of rogue online pharmacies and the dangers of importing unsafe or counterfeit medicines. It's possible to do both: guide patients who choose to import to the safest international options and also warn against rogue sites and take enforcement actions against them.

Despite the de facto decriminalization of personal drug importation for individual patients, the FDA provides a blanket warning on its website and media relations against the practice by informing Americans that importation is inherently dangerous. The FDA sometimes prevents lawfully-manufactured medicines, imported from licensed pharmacies, from reaching the patients who ordered them by holding the medicines at international mail facilities, sending them back to the pharmacy or destroying them. The FDA also appears to be ramping up a crackdown against safe personal drug importation that started during the Obama administration. Current efforts are often under the guise of

stopping illegal opioid sales both online and through importation. The Secretary should end these efforts.

PharmacyChecker.com does not sell or facilitate the sale of medication. Medications are not purchased on our site, and we have no role in the processing of prescription orders. We verify pharmacy credentials and publish information about online pharmacies and drug prices. That information is globally accessible on the Internet.

Online pharmacies verified in the PharmacyChecker Verification Program meet critical licensure, medicine quality, prescription, transparency, and security requirements that safeguard the health of their customers. Our focus is on the verification of international online pharmacies, websites that process orders for prescription medicines, which are filled internationally by mail order.

Our company's key managers founded a non-profit organization called Prescription Justice, which advocates for legislative regulatory reforms including those which would 1) end the ban on Medicare negotiating drug prices; 2) ban reverse payment schemes, also known as "pay-for-delay," between pharmaceutical companies that delay entry of lower-cost generics; 3) legalize the wholesale and personal importation of lower-cost medicines; and 4) immediately expressly permit individuals to import prescription medicines for their own use, such as those ordered online from properly-credentialed international online pharmacies. Although we fully support policies to lower medicine prices here, which would make personal drug importation far less necessary, these comments are dedicated to Prescription Justice's fourth policy recommendation.

Recommendations

- Under Section 804 (j) of the Food, Drug and Cosmetic Act, the Secretary of Health and Human Services should expressly permit medicine imports for personal use to empower patients seeking affordable medication.
- Per the above, implement the Australian model of making personal drug importation legal with caveats to prohibit personal use imports of controlled drugs, especially prescription narcotics.
- The FDA should end its blanket warning against ordering medicines online, imported for personal use from pharmacies in Canada and other countries, and instead provide guidance on best practices for those who choose to import.
- The FDA should stop seizing personal imports of non-controlled medicines arriving from pharmacies that the FDA knows are licensed and require valid prescriptions.
- The FDA should take no enforcement actions against international online pharmacies that it has reason to believe are the safest international options available to Americans and instead focus on those that represent the gravest threats, particularly ones that sell prescription narcotics.

Public Health Benefits of Personal Drug Importation and Online Pharmacies

High drug prices prevent patients from taking medicines they need to get better, stay healthy, or, in some cases, live.¹ Since the beginning of this millennium, Americans have successfully used the Internet to buy lower-cost medicines, ones imported for personal use from licensed pharmacies in Canada and other countries, while the FDA and pharmaceutical companies have pushed back.² According to one survey by the Kaiser Family Foundation, about eight percent of Americans (almost 20 million people), say that they have imported medicines due to cost.³

The same medicines sold domestically are often 80% less in other countries.⁴ In Canada specifically, commonly-prescribed, brand-name medicines cost about 70% less than in the U.S.⁵ About 45 million Americans did not fill a prescription in 2016 due to cost.⁶ Lower prices at pharmacies outside the U.S. can help millions receive treatments that are otherwise out of reach: a clear benefit to public health.

FDA Consumer Education and Enforcement Discretion

The U.S. Food and Drug Administration is known for using its enforcement discretion to allow personal imports of medicines in some cases.⁷ Most notable is the fact that no one has ever been prosecuted for illegally importing a non-controlled medicine for personal use.⁸

Despite this, the FDA provides a blanket warning to consumers against all international purchases of lower-cost medicines over the Internet.⁹ In doing so, the FDA wrongfully ignores the public health benefits of personal drug importation and potentially scares people away from medicine they can afford.¹⁰ This is entirely unnecessary and unfair to uninsured and under-insured Americans.

As recently reported by the non-profit media organization, Tarbell, cooperation between the FDA and the pharmaceutical industry that began during the Obama administration has led to measures imposed on Internet companies that curtail access to safe, international online pharmacies.¹¹

Recently, under the Trump administration, the FDA Office of Criminal Investigations has raided offices in Florida that help Americans safely navigate the Internet to purchase lower-cost medicines. The agency has even increased seizures of medicines ordered by people with valid prescriptions.¹²

Accessing legitimate, lower-cost medicines for personal import means immediate relief from high drug costs for those that have no other choice. At a maximum, the FDA should be transparent about this lifeline of affordable medicines and help Americans find the safest international options. At a minimum, the FDA should stop 1) seizing medicines they know are coming from licensed pharmacies by refusing the import; or 2) using the opioid crisis as a pretense to crackdown on Internet sales of non-controlled medicines dispensed by licensed pharmacies that require valid prescriptions.

The Secretary of Health and Human Services Has the Authority to Expressly Permit Personal Drug Importation

The wholesale importation of medicines that are not FDA-approved is against the law, but there are clear statutory allowances to expressly permit personal drug importation.

Short of legalization, Section 804 (j) of the Food, Drug and Cosmetic Act, empowers the Secretary of Health and Human Services to *permit* personal drug importation by setting policies for enforcement discretion by the FDA.¹³ A [report published by Prescription Justice](#) shows exactly how and why this can be done in [Appendix A](#):

Section 804 (J) allows for the creation of regulations to achieve the public health benefit of personal drug importation and allows the access to extend beyond Canada. Short of *legalization*, the Secretary is empowered to create guidelines for *enforcement discretion* to expressly permit importation by individuals “by regulation or on a case-by-case basis.” The law states that the Secretary can “exercise discretion to **permit** individuals to make such importations in circumstances in which...the importation is clearly for personal use...and the prescription drug or device imported does not appear to present

an unreasonable risk to the individual.” Lawfully-manufactured medications from Canada and many other countries do not present an unreasonable risk to individuals who import them.¹⁴

The Secretary should exercise this authority by instructing the FDA to end its blanket warning against safe personal drug importation; identifying the safest international online pharmacy options; ceasing seizure of imports of non-controlled medicines for personal use known to be purchased by licensed pharmacies that require valid prescriptions; and ending enforcement threats against the safest international online pharmacies.

The PharmacyChecker Verification Program

Online pharmacies, including those based outside the U.S., that meet the requisite pharmacy standards of practice can apply to the PharmacyChecker Verification Program (the “Program”). The pharmacy standards and policies are public:

https://www.pharmacychecker.com/pdf/membership_standards_and_guide_rev_4.16.18.pdf.

Applicants must meet the following standards of practice to be eligible for the Program.

1. *Valid prescription requirement*- The online pharmacy must require a valid prescription and its website must clearly display this requirement.
2. *Controlled Substances Restricted* - Controlled substances, as defined by the U.S. Drug Enforcement Agency (DEA), may only be marketed, sold, processed and/or dispensed by pharmacies that are properly registered with the DEA. The online pharmacy must meet all the requirements of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008.
3. *Information Security* - The online pharmacy’s website must employ Secure-Socket Layer or equivalent technology to ensure protection of health and financial information of consumers.
4. *Country Transparency* - The online pharmacy’s website must disclose to consumers the specific country or, if applicable, the list of potential countries from which a drug will be dispensed.
5. *Customer Service for consumers* - The online pharmacy’s website must clearly publish a telephone number that allows consumers to reach the pharmacy staff for customer service.
6. *Pharmacist Consultations* - The online pharmacy’s website must conspicuously publish that pharmacist consultation with a licensed pharmacist is available for patients who have questions about their medications.
7. *Pharmacy / Pharmacist Licensure* - All transactions processed through the online pharmacy’s website must be directly confirmed, dispensed and shipped by a licensed pharmacy that is also verified by PharmacyChecker. Medication orders must only be dispensed by a pharmacist licensed in the pharmacy’s jurisdiction.
8. *Marketing Claims* - The online pharmacy’s website must only make claims that are truthful and/or not misleading to the consumer, e.g. claims about generic medications may not refer to generic medications as “the same as” or “identical to” their brand-name counterparts.

Verified pharmacies must adhere to laws in the countries where they operate in addition to PharmacyChecker standards. Verified online pharmacies are authorized to publish the PharmacyChecker Seal, which links to its pharmacy profile hosted on www.PharmacyChecker.com. By clicking on the seal, people can verify the approved status of the online pharmacy.

PharmacyChecker staff monitor compliance utilizing various audit techniques, such as mystery shopping, remote monitoring of websites, as well as inspections performed by PharmacyChecker staff.

Pharmacies found to be out-of-compliance are subject to penalties up to and including termination from the Program. As a private verification firm, that is the extent to which we can sanction a pharmacy.

The PharmacyChecker Verification Program is managed by Shivam Patel, PharmD, a licensed pharmacist in Massachusetts. His predecessor and former mentor, Kelly Ann Barnes, JD, Rph, was Vice President of Pharmacy Verification and Information from 2016-2018, during which time our company further developed and enhanced its pharmacy standards and policies. Ms. Barnes came to PharmacyChecker from the Massachusetts Board of Registration in Pharmacy where she held the title of Director of Pharmacy Quality Assurance.

Online Drug Price Comparisons

Many online pharmacies in the Program list their pharmacy and drug prices on www.PharmacyChecker.com. This information is freely available to the public. Patients can compare prices on medicines and find safe international online pharmacies that enable them to import safe and effective medicines they can afford.

Recently, PharmacyChecker conducted an analysis of medicines identified in a report published by the Senate Homeland Security and Governmental Affairs Committee as the most commonly prescribed medicines through Medicare Part D in 2015. In the U.S., those products increased in price by 12% annually between 2012-2017. PharmacyChecker's analysis showed that the lowest prices available internationally were 80% less than average U.S. pharmacy prices.¹⁵

Peer-Reviewed Research of PharmacyChecker-Verified Online Pharmacies

Peer-reviewed research has proven that patients who order from PharmacyChecker-verified international online pharmacies import and receive lawfully-manufactured, safe and effective medicines at much lower prices than available in the U.S.¹⁶ The research was led by Roger Bate, who is affiliated with the American Enterprise Institute, a think tank and policy organization with which FDA Commissioner Scott Gottlieb, MD, was also affiliated before his appointment to the FDA.

From 2008 to 2016, 822 online medication orders were tested: 275 medications from 22 international online pharmacies verified by PharmacyChecker.com (12 of which are also verified by the Canadian International Pharmacy Association); 127 medications from eight U.S.-only online pharmacies verified by the National Association of Boards of Pharmacy and/or LegitScript.com; and the rest from websites with no verification. Brand-name medicines were tested using a Raman Spectrometer and by authenticating the products with pharmaceutical companies. Generic medicines were tested using the Global Pharma Health Fund (GPHF) e.V. Minilab®.¹⁷

Verified U.S. pharmacies sold zero counterfeits but one (out of 127) order of generic Cipro was slightly substandard.

Verified international pharmacies sold zero counterfeits but one (out of 275) order of generic Cipro was slightly substandard.¹⁸

It's important to note that the one substandard medicine was available for sale at brick and mortar pharmacies in the U.S., not just at online pharmacies.¹⁹

In contrast, online pharmacies with *no verification* sold eight counterfeits and 16 substandard drugs (out of 332 tested).

Overall, the peer-reviewed research found that the PharmacyChecker-verified pharmacies sold medicines of equal quality to the U.S. pharmacies and required valid prescriptions.

Encouraging patients to access to these verified international online pharmacies and steering them away from rogue websites help people obtain prescribed medicines at affordable prices and protect them from falsified and substandard products.

The Australian Model of Patient Empowerment and Freedom

In Australia, people are expressly permitted to import small quantities of prescription medicines for family members or their own use – not for resale. Imports must be limited to a three-month supply per order, and, for certain medicines, a prescription is needed by the individual importer.²⁰ Medicines containing a controlled substance, such as prescription narcotics, are not permitted for import.²¹

The Australian model, under the authority of the Therapeutic Goods Administration, respects the integrity and intelligence of its citizens to make their own healthcare decisions. The TGA clearly communicates this policy on its website, with warnings about ordering medicines over the Internet.²² Under the authority of the Secretary, the FDA should implement a similar protocol to permit personal importation. The FDA's website and patient communications should end the blanket warning against purchasing medicines over the Internet from sites that offer lower prices than available in the U.S.

Conclusions

Personal importation of lower-cost medicines helps millions of Americans each year lower their out-of-pocket costs. The Secretary should grant the FDA the authority to guide patients to the safest international online pharmacy options, while continuing to crack down on rogue pharmacy sites and illegal online opioid sales and imports

The work of PharmacyChecker is a useful model for providing people with the information they need to find the lowest prices from licensed international pharmacies and to avoid rogue sites.

Pretending safe personal drug importation does not exist simply exacerbates the problems of high out-of-pocket costs, cost-related non-adherence, and diminishing faith in government agencies with ties to the pharmaceutical industry.

¹ "CVS/Caremark Survey Says Cost is Biggest Barrier to Prescription Adherence," *CVS/Caremark Insights*, September 27th, 2012, see <http://info.cvscaremark.com/cvs-insights/cvs-caremark-survey-says-cost-biggest-barrier-prescription-adherence> [Last accessed 9/17/2014]; or See <http://www.prnewswire.com/news-releases/cvs-caremark-survey-pharmacists-say-cost-is-biggest-barrier-to-medication-adherence-171516471.html> [Last accessed 9/17/2014]. According to data cited by the U.S. Food and Drug Administration (FDA), 125,000 deaths are caused by prescription non-adherence (failure to take prescribed medication as directed) each year: See U.S. Food and Drug Administration website: See <http://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm485545.htm> [Last accessed 12/16/2016].

² Levitt, Gabriel, "Scare Tactics Over Foreign Drugs," March 24th, 2014, *New York Times*. See <http://www.nytimes.com/2014/03/25/opinion/scare-tactics-over-foreign-drugs.html> [Last accessed 12/11/16].

³ Kaiser Health Tracking Poll: September 2016. By Ashley Kirzinger, Bryan Wu, and Mollyann Brodie

The Henry J. Kaiser Family Foundation. <http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/>.

⁴ <https://www.pharmacychecker.com/news/american-seniors-save-80-percent-medication.asp>

⁵ <https://www.pharmacychecker.com/news/70-percent-of-brand-name-drugs-are-imported-cost-87-percent-less-in-canada.asp>.

⁶ R. Osborn, D. Squires, M. M. Doty, D. O. Sarnak, and E. C. Schneider, "In New Survey of 11 Countries, U.S. Adults Still Struggle with Access to and Affordability of Health Care," Health Affairs Web First, Nov. 16, 2016. [Last accessed 1/20/2017]; and U.S. The survey shows that 18% of the adult population did not fill a prescription in 2016 because of cost. Census Bureau data: <https://www.census.gov/quickfacts/table/PST045216/00Based>: 18% of the adult population in 2016 is 45 million persons.

⁷ Elliott A. Foote, "Prescription Drug Importation: An Expanded FDA Personal Use Exemption and Qualified Regulators for Foreign-Produced Pharmaceuticals," 27 Loy. *Consumer L. Rev.* 369 (2015). See <http://lawcommons.luc.edu/lclr/vol27/iss3/2> [Last accessed 12/11/2016]

⁸ "Supreme Court Decision Removes Barrier to Importing US Patented Drug Products at Lower Cost," in National Academy for State Health Policy Blog: see <https://nashp.org/supreme-court-decision-removes-barrier-to-importing-us-patented-drug-products-at-lower-cost/> [Last accessed 7/19/2018].

⁹ Vedantam, Shankar. (2012). FDA's Stance On Online Pharmacies May Go Too Far, Study Says. [online] Npr.org. Available at: <https://www.npr.org/sections/health-shots/2012/04/06/150151885/fdas-stance-on-online-pharmacies-may-go-too-far-study-says> [Accessed 10 Jul. 2018].

¹⁰ 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].

¹¹ McAuliff, Michael, "Keeping International Pharmacies Under a Cloud: The drug industry worked with the Obama administration to sow safety fears about cheaper medications from foreign sources," May 2, 2018, *Tarbell.com*. See <https://www.tarbell.org/2018/05/keeping-international-pharmacies-under-a-cloud/> [Last accessed 7/10/2018].

¹² McAuliff, Michael, "FDA Boss Confirms Opioid Crackdown is Aimed at Cheaper Medicines Too," July 3, 2018, *Tarbell.com*. See <https://www.tarbell.org/2018/07/fda-boss-confirms-opioid-crackdown-is-aimed-at-cheaper-prescriptions-too/> [Last accessed 7/10/2018].

¹³ Section 804 of the Food, Drug and Cosmetic Act, 21 U.S. Code § 384 - Importation of prescription drugs. See <https://www.law.cornell.edu/uscode/text/21/384> [Last accessed 12/11/2016].

¹⁴ Prescription Justice Paper, "How the Trump Administration Can Rapidly Lower Drug Costs for Americans," January 2017. See http://prescriptionjustice.org/PJ_recommendations_for_Trump_on_drug_prices.pdf [Last accessed 7/12/2018].

¹⁵ <https://www.pharmacychecker.com/news/american-seniors-save-80-percent-medication.asp>.

¹⁶ Bate, Roger, Ginger Zhe Jin, and Aparna Mather, "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets," *The B.E. Journal of Economic Analysis & Policy*. Volume 14, Issue 1, Pages 111–150, ISSN (Online) 1935-1682, ISSN (Print) 2194-6108, DOI: [10.1515/bejeap-2013-0085](https://doi.org/10.1515/bejeap-2013-0085),

¹⁷ Bate, Roger, "Web pharmacies: A field study of ciprofloxacin and atorvastatin," 2016, See http://safemedicinescoalition.org/resources/New-Internet-Study_cipro_atorvastatin.pdf [Last accessed 7/10/2018].

¹⁸ Bate, Roger, "Catch 22: Credentialed online pharmacies are so safe that peer review literature is no longer interested in results showing it," July 18, 2017, AEI Ideas Blog, see <http://www.aei.org/publication/catch-22-credentialed-online-pharmacies-are-so-safe-that-peer-review-literature-is-no-longer-interested-in-results-showing-it/> [Last accessed 7/10/2018].

¹⁹ Bate, Roger, "Web pharmacies: A field study of ciprofloxacin and atorvastatin," 2016, See http://safemedicinescoalition.org/resources/New-Internet-Study_cipro_atorvastatin.pdf [Last accessed 7/10/2018].

²⁰ Australian Government, Department of Health, Therapeutic Goods Administration Personal Import Policy. See <https://www.tga.gov.au/personal-importation-scheme> [Last accessed 12/11/2016].

²¹ Ibid.

²² Ibid.

Appendix A



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Taking on the Crisis of High Drug Prices in America®

How the Trump Administration Can Rapidly Lower Drug Costs for Americans

Executive actions that can ease the drug affordability crisis
using online pharmacies and personal drug importation

January 2017

The new administration can rapidly lower drug costs for Americans at no cost to the government and without legislative reform. Prescription Justice developed a framework and recommendations designed to provide immediate relief from high drug prices by expressly permitting consumers to import lower cost medication for personal use from safe international online pharmacies. In many cases, prescription drugs can be purchased from safe non-U.S. pharmacies for 10% of their cost in the United States.¹

Despite federal restrictions, tens of millions of Americans have purchased medication from other countries, including over the Internet, to find lower cost medication from Canada and other countries. For many of them, safe international online pharmacies are a lifeline for affordable medication, but there are also rogue pharmacy websites, which are a threat to consumers. Executive actions can help Americans reach the latter but avoid the former.

At a time when Americans are looking for decisive action to bring down their healthcare costs, giving them a choice in how to manage their prescription drug purchases will put more money into their pockets and reduce the number of patients, currently about 45 million, who go without needed medications due to cost.

Principles and Policies for Executive Action

- Consumers should have access to the widest possible choices online to access safe and affordable medication.
- Drug safety is inextricably linked to the issue of price because an unaffordable medication is neither safe nor effective. Therefore, the safest online sources for affordable medication save American consumers from forgoing prescribed medication.
- Government should promote a competitive online marketplace for safe pharmaceuticals, one that respects and empowers consumers and the public health necessity of access to lower prices.
- Laws, regulations, and enforcement actions that impede online access to lower-priced, personally imported medication are inimical to good public health and economic fairness.

- Federal policies that affect online access to medication should be consumer-focused, patient-centered, evidence-based, and created within the context of a health crisis caused by high drug prices in America.
- Federal enforcement efforts to curtail the online sale of counterfeit and substandard medication should give priority to the dangerous, illegally operating online pharmacies and recognize the public benefit of the safest international online pharmacies.
- Federal agencies should not knowingly curtail access to safe international online pharmacies and should use the utmost discretion to avoid doing so through their enforcement efforts to combat rogue sites and counterfeit drugs.

Background/Rationale

The Drug Affordability Crisis

Prescription drug costs comprise an increasing percentage of federal, state, and municipal budgets each year, but the crisis hits home hardest where out-of-pocket drug costs are too high. Every day, thousands of Americans are faced with having to pay for expensive medications and the realization they cannot. The Commonwealth Fund estimates that 45 million Americans did not fill a prescription in 2016 due to cost.² A survey by the Harvard School of Public Health indicates that over 50 percent of people who don't take prescribed medication due to cost are getting sicker.³ That's potentially 22.5 million Americans whose health suffers because of high drug prices, in addition to the countless millions who can manage to pay unreasonable prices but would benefit from lower ones.

According to the National Consumers League and the Food and Drug Administration (FDA), 125,000 deaths are caused by prescription non-adherence (failure to take prescribed medication as directed) each year.⁴ Not all are the result of cost factors but a survey of CVS pharmacists, in which 62 percent of 2,400 retail pharmacists reported cost as the number one reason patients aren't taking their medications,⁵ makes it clear that high drug prices significantly contribute to people dying.

There's a public consensus that the price of prescription medication in the United States is unreasonable.⁶ The nearly 30 million uninsured Americans and tens of millions of underinsured Americans, ones who don't have adequate coverage for prescriptions, are facing stark choices because of drug prices.⁷ Over 10 million households have had to choose between food and medication.⁸

Americans with cancer are two and half times more likely to declare bankruptcy; and those that do declare bankruptcy are 80 percent more likely to die from their illness.⁹ New medications exist to treat Hepatitis C, an infection of the liver which lead to 19,659 deaths in 2014, but they are so expensive that private and government insurance programs usually do not cover them except for patients who become very ill. For the uninsured, these medications, priced at close to \$100,000 for a three-month treatment are entirely out of reach. While Cancer and Hepatitis C medications are far more expensive than treatments for most conditions, Americans with common conditions, such as asthma, depression, diabetes, and heart disease, are too often ending up in the hospital because they can't afford their prescriptions.¹⁰

Importation and Online Pharmacies: A Lifeline of Affordable Medication

During his campaign, Mr. Trump supported allowing Americans to import lower cost medications.¹¹ Thirty-three members of Congress have recommended executive action to immediately assist Americans by exploring new rules affecting prescription drug importation that are already permitted under U.S. law.¹² Current law gives the Secretary of Health and Human Services the authority to revise regulations on enforcement discretion to permit safe personal drug importation. As part of that

action, it's critical to understand that safe personal drug importation through properly verified online pharmacies is already a lifeline of affordable medication.¹³ Actions to expand this lifeline will benefit the public's health.

Patented drugs, on average, cost less than half in member countries of the Organization for Economic Cooperation and Development (OECD) than in the U.S.¹⁴ The world's top selling 20 medications are three times more expensive in the U.S. than in the U.K.¹⁵ It is common for brand name drugs to be as much as 90 percent lower from pharmacies outside the U.S. purchased online.¹⁶ Here are some examples:

**Brand Drug Price Comparison
U.S. vs. Canada and other International Prices**

Drug	U.S. Price¹	Canadian Price² / (Savings)	International Price³ / (Savings)
Advair Diskus Asthma and COPD	\$978	\$341 (65%)	\$99 (90%)
Zetia⁴ High Cholesterol	\$836	\$227 (73%)	\$156 (81%)
Januvia Type-2 Diabetes	\$1,061	\$351 (67%)	\$91 (91%)
Daraprim Toxoplasmosis	\$4,604	N/A	\$97 (98%)
Epipen Autoinjector Severe allergic reactions	\$631	\$225 (64%)	\$172 (73%)

(Prices based on a 90-day supply of the medication collected in September 2016)

1 Based on the Lowest Price in New York found on GoodRx.com.

2 Prices at Canadian pharmacies available online at Pharmacies verified by PharmacyChecker.com.

3 Lowest international prices found on PharmacyChecker.com drug price comparisons.

4 Marketed as Ezetrol in Canada and other countries internationally.

Despite federal restrictions, each year about four million Americans personally import medication due to cost.¹⁷ For some, it's their only option.¹⁸ Many of them do so by placing orders with online pharmacies that process prescription orders, which are then shipped from pharmacies outside the U.S.¹⁹ When done safely, this is a boon to public health as it enables Americans to afford medications filled by licensed pharmacies that require valid prescriptions written by U.S. prescribers.²⁰

Legitimate public health concerns about rogue online pharmacies and counterfeit drugs are being misused by the pharmaceutical industry to encourage legislative, regulatory, and private sector actions that curtail access to licensed pharmacies providing safe and affordable medication.²¹ With proper guidance, American consumers can be protected from dangerous websites and medicines without being deprived of online access to safe and affordable medication.²²

Federal Law, Regulation, and Practice

In policy debates about *legalizing* drug importation, the reality of international trade in pharmaceuticals becomes obscured. Drug importation is already legal and imported pharmaceuticals comprise a large share of domestically dispensed medications. According to the FDA, 80 percent of

active pharmaceutical ingredients and 40 percent of finished FDA-approved drugs, the ones sold in U.S. pharmacies, were made in other countries.²³ The relevant questions are: which drugs can be imported, who can and cannot do the importing, and who *should* be able to?

Individuals are not technically banned from importing a prescription drug for their own use, unless it's a drug manufactured domestically. However, in contrast to commercial importation, there are three reasons why it is, under most circumstances, unlawful to import medication for personal use:

1. *Reimportation*, meaning medications made domestically, exported, and then imported back, is expressly banned except by the manufacturer.
2. Imported medications manufactured in FDA-registered establishments, ones which would be identical in their composition to those sold in a U.S. pharmacy, are packaged and labeled differently for foreign markets and pharmacies and, therefore, considered *misbranded*.
3. Lawfully-manufactured imported medications that are foreign versions of FDA-approved drugs (and therefore *not* "FDA-approved") are not necessarily made in accordance with FDA manufacturing standards and, therefore, are designated by FDA as *unapproved*. For example, Daraprim, made by GlaxoSmithKline in Germany and sold in the UK, is considered an *unapproved* drug by the FDA. The FDA-approved Daraprim, licensed to Turing Pharmaceutical, is made by a contract manufacturer in North Carolina.

Though usually technically illegal, and always discouraged by the FDA, personal importation appears to be generally permitted.

- The FDA's published guidance allows its personnel to use discretion to allow personal imports of medications that have yet to be approved for sale in the U.S.
- Medications intended for personal use almost always reach the patient.
- Since individuals are not prosecuted for importing small quantities of medications for their own use, the practice is *de facto* decriminalized.
- Since many personally imported medications are the exact same drugs sold in local pharmacies (meaning ones produced under FDA's exact safety protocols), importers (consumers) could potentially overcome misbranding designations if they properly challenge the FDA for refusing their imports.

The FDA is permitted to destroy personally imported medication, even those that are lawfully manufactured and made in FDA-registered facilities.²⁴ Section 708 of the Food and Drug Administration Safety and Modernization Act of 2012 amended the Food, Drug and Cosmetic Act (FDCA) to permit the FDA to destroy imported medication valued at \$2,500 or less, but only after creating regulations providing the importer with due process to defend the import.²⁵ The final rule was adopted in August 2015. To date, the new law has not been used to widely stop the safe importation of medication for personal use. Consumers, however, are fearful of that potential.²⁶ Several members of Congress have publicized concerns about this provision of law as detrimental to patients seeking lower cost medications.²⁷

Flexibilities in the law allow for more consumer choice

Section 804 of the Food, Drug, and Cosmetic Act allows for new regulations to expand and encourage the importation of lower cost medications, including and specifically for personal use. Section 804 of the FDCA makes it legal to import medication from Canada, both commercial and personal quantities.²⁸ That express legality is relegated only to importation from Canada and *only* if the Secretary of Health and Human Services certifies the safety of such importation poses "no additional risk to the public's health and safety."²⁹ However, it is unrealistic to provide such certification because

it is virtually impossible to meet the bar of “no additional risk” to the public’s health: any regulatory change that expands access to even one new medication carries *some* additional risk, even if the added risk is far outweighed by the benefits.

Lawful drug importation already occurs (even without activating Section 804 provisions) from Canada but only through distribution channels controlled by pharmaceutical companies, which means the same drugs sold in Canada are priced much higher in the U.S. Section 804 changes the rules of distribution to benefit consumers who would have lawful access to the lower prices charged in Canada, and other countries as explained below.

Section 804 (J) allows for the creation of regulations to achieve the public health benefit of personal drug importation and allows the access to extend beyond Canada. Short of *legalization*, the Secretary is empowered to create guidelines for *enforcement discretion* to expressly permit importation by individuals “by regulation or on a case-by-case basis.” The law states that the Secretary can “exercise discretion to **permit** individuals to make such importations in circumstances in which...the importation is clearly for personal use...and the prescription drug or device imported does not appear to present an unreasonable risk to the individual.” Lawfully-manufactured medications from Canada and many other countries do not present an unreasonable risk to individuals who import them.³⁰

Examples of Federal Actions that Curtail Online Access to Safe Personal Drug Importation

Unfortunately, Federal actions both past and present are impairing the ability of Americans to buy lower cost medication from other countries, contrary to what is technically permissible under law and what is fair to cash-strapped Americans, 30 million of whom lack health insurance. Such actions do not protect but hurt consumers and should not continue.

Most notably, the White House Office of the Intellectual Property Enforcement Coordinator caused the formation of the Center for Safe Internet Pharmacies (CSIP) in 2010, through which gatekeepers to Internet commerce are asked to voluntarily refuse service to safe international online pharmacies that sell lawfully manufactured medication pursuant to a prescription.³¹ CSIP members include search engines, credit card companies, domain registrars and private mail carriers. Their efforts are misleadingly publicized as targeting only rogue online pharmacies that sell counterfeit drugs, fill orders from unlicensed sources, or don’t require a prescription. However, they ensnare the safest international online pharmacy options as well.³²

Search engines, for example, are effectively prevented under the threat of prosecution from allowing Canadian pharmacies to advertise to Americans – even though such advertising is not *prima facie* illegal.³³ A well-publicized non-prosecution agreement between the U.S. and Google did not establish that it was illegal for Google to allow ads for licensed pharmacies in Canada.³⁴ It did show that Google flouted its own internal rules on blocking ads that enabled rogue online pharmacies to advertise the sale of controlled drugs without a prescription, which was then used as justification to force Google to agree to stop ads from safe international online pharmacies.³⁵

In Bing’s search results, a click on online pharmacies that the FDA has identified as “fake” results in a warning that reads: “The FDA has issued a Warning Letter related to this site, and it may offer drugs that are unsafe.” The FDA’s list of websites that have received warnings are referred to as “fake online pharmacies” – a group that includes some real online pharmacies that meet the highest standards of international online pharmacy practice. For example, one of the companies on the FDA’s list is a licensed brick and mortar pharmacy in Canada. This policy may lead consumers to forgo a safe international online pharmacy due to the pop-up warning but then end up choosing a rogue site as they continue to search for affordable medication. Under Bing’s policy, consumers can be scared away

from lower cost medication, which is bad for their health and savings, and more likely to choose a rogue site and end up with a counterfeit drug.³⁶

Through membership in CSIP, credit card companies VISA and MasterCard have adopted policies prohibiting the use of credit cards by consumers on websites in which a person buys a medication that is imported for personal use into the U.S. Americans, therefore, must often pay by check.³⁷

The strategic conceptualization and plan to pressure the Internet ecosystem of businesses to curtail access to all international online pharmacies was articulated in the 2010 public comments of an organization started by Eli Lilly, the National Association of Chain Drugstores and LegitScript, called Alliance for Safe Online Pharmacies (Alliance).³⁸ The Alliance and LegitScript are ex-officio members of CSIP. Their combined efforts with the federal government are viewed as censorship by respected Internet free speech organizations and publications.^{39, 40}

The FDA's public education campaigns wrongly provide a blanket warning against buying a medication online from outside the U.S.⁴¹ Due to the real online dangers that exist, the agency's warnings about the threats posed by dangerous online pharmacies are helpful but some of its assertions contradict the facts about buying medication online, and inadvertently prevent Americans from finding affordable and safe medication. FDA's communications with Congress have also conflated illegally imported but lawfully-manufactured medications with counterfeit drugs, equating the two as equally dangerous.⁴²

These actions by the federal government and private companies are overreaching, unnecessary and unfair to consumers. Executive actions designed to allow consumers the ability to access safe international pharmacies while warning them of the risks of rogue sites are sensible and achievable. A blanket policy that wraps all online pharmacies together is simply undermining public health, as well as trust in government, and works as a disservice to Americans looking for affordable medication.

Recommendations for Executive Action

- Pursuant to Section 804 (J) of the Food, Drug and Cosmetic Act (FDCA), enact regulations that would permit individuals who have a valid prescription to import non-controlled prescription medication for their own use, not to exceed a three-month supply. A fitting model for regulations is offered by Australia's law on personal drug importation, a country in which personal imports are expressly legal.⁴³ The key elements of Australia's law (as would apply to U.S. application) reflect commonsense respect for consumer choice:
 - Imported medications are for personal use or an immediate family member;
 - If the medication requires a prescription in the U.S., the importer must have a prescription from a U.S. provider;
 - Imported medications for personal use may not include controlled substances, as defined under U.S. law (such as Vicodin, Adderall, or valium); and
 - The total quantity of the imported medications within a 12-month period does not exceed 15 months' supply (at the maximum dose recommended by the manufacturer).

- Revise FDA's website's consumer information to:
 - Warn consumers about rogue online pharmacies, but *no longer provide a blanket warning against purchasing medication internationally.*

- Use a definition of “rogue online pharmacies” or “fake online pharmacies” that reflects a rational, consumer-focused, patient-centered, and evidence-based analysis of online pharmacies, one that focuses strictly on public health considerations, rather than technical restrictions on personal drug importation and intellectual property law.
 - Accurately communicate the benefits and risks of ordering from international online pharmacies.
- Redirect federal enforcement initiatives that target the “chokepoints” of the Internet ecosystem (e.g., registrars, registries, mail carriers, payment processors, credit card companies, search engines) so that they do not curtail online access to medication from safe online pharmacies and, instead, focus exclusively on rogue online pharmacies.
 - Refrain from enforcement actions against the safest international online pharmacies. For example, the FDA has cited the existence of about 34,000 rogue active Internet pharmacies.⁴⁴ There are 55 international online pharmacies vetted by credentialing and price comparison company PharmacyChecker.com.⁴⁵ Those international online pharmacies are known to meet stringent safety criteria among websites selling to consumers in the U.S. for personal import and should remain as safe options for Americans who need them.⁴⁶ There are tens of thousands of rogue and dangerous medication-selling websites to investigate and take legal action against to protect consumers.
 - Develop clear guidelines for FDA enforcement discretion to minimize refusals and destructions of lawfully manufactured, genuine medication imports held at international mail facilities. Failing to do so will mean patients will not receive appropriate medications they have ordered.

Conclusion

These recommendations for executive action on personal drug importation and online pharmacies will not solve the crisis of high drug prices in America but will give more Americans immediate and necessary relief from staggering drug costs.

The past 15 years in which Americans have purchased lower cost medication online for personal import has served as a live pilot project. During that time, the FDA has never reported a death or serious adverse reaction by an American who ordered medication from an international online pharmacy that required a valid prescription. But the practice is still discouraged and made more difficult by federal regulators.

These recommendations are meant to buttress, not undermine the role of the FDA. Prescription Justice respects the FDA’s critical role in safeguarding our nation’s drug supply, but we urge the agency and other relevant federal and state agencies to use the widest possible discretion so that their actions against unsafe and counterfeit drugs and rogue online pharmacies do not impede access to safe personal drug importation from *safe* international online pharmacies. At a minimum, the FDA needs to provide the facts in an objective manner about buying medication online.

Until we pass sensible legislation to make personal importation of lower cost medication expressly legal, and, more importantly, bring down drug prices in the U.S., expressly permitting safe importation is good for public health and for American consumers who are struggling to purchase or simply cannot afford their prescribed medication.

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About Prescription Justice

Prescription Justice is a not-for-profit organization dedicated to providing relief and protection from the soaring costs of prescription medication for American patients. Forty-five million Americans did not fill a prescription in 2016 due to cost. Millions must choose between food and medicine in the world's richest country. Forgoing prescribed medication leads to sickness and death, and even greater healthcare costs due to hospitalizations. Americans need justice when it comes to drug prices.

Through education, outreach and coalition building, Prescription Justice advocates for regulatory and legislative reforms and commonsense policies to lower domestic drug prices and expand access to lower cost medication from pharmacies in other countries. Prescription Justice brings together doctors, lawyers, public health advocates, and companies dedicated to helping people afford medication. Prescription Justice received initial funding by PharmacyChecker.com.

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