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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

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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.<sup>1</sup>

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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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,<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> Over 10 million households have had to choose between food and medication.<sup>8</sup>

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.<sup>9</sup> 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.<sup>10</sup>

### Importation and Online Pharmacies: A Lifeline of Affordable Medication

During his campaign, Mr. Trump supported allowing Americans to import lower cost medications.<sup>11</sup> 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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> The world's top selling 20 medications are three times more expensive in the U.S. than in the U.K.<sup>15</sup> It is common for brand name drugs to be as much as 90 percent lower from pharmacies outside the U.S. purchased online.<sup>16</sup> Here are some examples:

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

<b>Drug</b>	<b>U.S. Price<sup>1</sup></b>	<b>Canadian Price<sup>2</sup> / (Savings)</b>	<b>International Price<sup>3</sup> / (Savings)</b>
<b>Advair Diskus</b> Asthma and COPD	\$978	\$341 (65%)	\$99 (90%)
<b>Zetia<sup>4</sup></b> High Cholesterol	\$836	\$227 (73%)	\$156 (81%)
<b>Januvia</b> Type-2 Diabetes	\$1,061	\$351 (67%)	\$91 (91%)
<b>Daraprim</b> Toxoplasmosis	\$4,604	N/A	\$97 (98%)
<b>Epipen Autoinjector</b> 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 price 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.<sup>17</sup> For some, it's their only option.<sup>18</sup> 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.<sup>19</sup> 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.<sup>20</sup>

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.<sup>21</sup> With proper guidance, American consumers can be protected from dangerous websites and medicines without being deprived of online access to safe and affordable medication.<sup>22</sup>

## 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.<sup>23</sup> 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.<sup>24</sup> 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.<sup>25</sup> 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.<sup>26</sup> Several members of Congress have publicized concerns about this provision of law as detrimental to patients seeking lower cost medications.<sup>27</sup>

## **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.<sup>28</sup> 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.”<sup>29</sup> 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.<sup>30</sup>

### *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.<sup>31</sup> 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.<sup>32</sup>

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.<sup>33</sup> 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.<sup>34</sup> 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.<sup>35</sup>

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.<sup>36</sup>

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.<sup>37</sup>

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).<sup>38</sup> 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.<sup>39, 40</sup>

The FDA's public education campaigns wrongly provide a blanket warning against buying a medication online from outside the U.S.<sup>41</sup> 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.<sup>42</sup>

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.<sup>43</sup> 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.<sup>44</sup> There are 55 international online pharmacies vetted by credentialing and price comparison company PharmacyChecker.com.<sup>45</sup> 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.<sup>46</sup> 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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<sup>1</sup> PharmacyChecker Price Data, Press Release, October 8<sup>th</sup>, 2015. See <https://www.pharmacychecker.com/news/fda-destroy-lower-cost-imported-medication.asp> [Last accessed 12/11/2016].

<sup>2</sup> 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. Census Bureau data: <https://www.census.gov/quickfacts/table/PST045216/00Based>: 18% of the adult population in 2016.

<sup>3</sup> Harvard School of Public Health/USA Today/Kaiser Family Foundation, Health Care Costs Survey (conducted April 25 –June 9, 2005). The survey finds that 20% of respondents, adult Americans, report not filling a prescription due to cost; 54% of those respondents said their condition got worse as a result.

<sup>4</sup> U.S. Food and Drug Administration website: See <http://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm485545.htm> [Last accessed 12/16/2016].

<sup>5</sup> "CVS/Caremark Survey Says Cost is Biggest Barrier to Prescription Adherence," *CVS/Caremark Insights*, September 27<sup>th</sup>, 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]

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<sup>11</sup> Nather, David, "Trump's Healthcare Plan Takes (another) Page from the Democrats," March 2, 2016, Stat News. See <https://www.statnews.com/2016/03/02/trump-health-care-plan/> [Last accessed 12/11/2016].

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<sup>41</sup> Vedantam, Shankar, "FDA's Stance On Online Pharmacies May Go Too Far, Study Says," April 6, 2012, NPR Shots. See <http://www.npr.org/sections/health-shots/2012/04/06/150151885/fdas-stance-on-online-pharmacies-may-go-too-far-study-says> [Last accessed 12/11/16].

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<sup>44</sup> Administrative Destruction of Certain Drugs Refused Admission to the United States. 21 CFR Part 1. 79 Federal Register 25758. See <https://www.regulations.gov/document?D=FDA-2014-N-0504-0001> [Last accessed 12/11/2016].

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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 common sense 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](http://PharmacyChecker.com).

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