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PRESCRIPTION DRUG IMPORTATION: AN  
EXPANDED FDA PERSONAL USE  
EXEMPTION AND QUALIFIED REGULATORS  
FOR FOREIGN-PRODUCED  
PHARMACEUTICALS

*Elliott A. Foote*

ABSTRACT

*High-priced prescription drugs have been a problem for U.S. consumers. The United States market economy coupled with patent protection for these products creates an incentive for pharmaceutical companies to charge as much as possible. Unable to afford these drugs, many people are reaching out to neighboring countries and abroad to seek lower-cost options. It has also created a market for online mail-order pharmaceuticals. Despite the need for these drugs, the Food and Drug Administration (“FDA”) continues to make importation illegal.*

*In formulating its policy, the FDA cites to safety and innovation concerns. Claimed uncertainty about the source of foreign prescription drugs has led to ineffective federal policy in this area. To date, none of the major amendments to the Food, Drug, and Cosmetic Act have successfully provided a framework for securing foreign importation. Without proper federal guidance, various states,*

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including Maine, have implemented legislation to facilitate the importation of prescription drugs from other developed countries like Canada and England.

*This Article proposes two potential solutions to implement policy on the federal level. With an eye towards Maine's new law and its successes, there is potential for an expanded, codified personal use exemption. Moreover, using "qualifying" countries, or those with an adequate level of manufacturing oversight for prescription drugs, may provide an alternative safeguard for allowing importation.*

## I. INTRODUCTION

U.S. citizens travel to other countries to obtain medical treatment and prescription drugs because of high local prices. Prescription drug costs in America are much higher than in other surrounding countries. Yet, importing these medications remains illegal. "Medical tourism" is the umbrella term used to describe going abroad to receive medical services or treatment. Tourism can include major surgical procedures, prescription drugs, or other medical treatments like dentistry.<sup>1</sup> This practice has become a lucrative trade for the countries facilitating cheap healthcare and medications.<sup>2</sup>

The people who are harmed most by criminalizing this conduct, however, are those who have terminal illnesses and serious conditions but remain unable to afford costly treatments. In desperation, some people resort to traveling across the border to nearby countries like Canada and Mexico<sup>3</sup> to buy prescription drugs.

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<sup>1</sup> See I. GLENN COHEN, PATIENTS WITH PASSPORTS: MEDICAL TOURISM, LAW, AND ETHICS (2015); see also JILL R. HODGES & ANNE MARIE KIMBALL, RISKS AND CHALLENGES IN MEDICAL TOURISM: UNDERSTANDING THE GLOBAL MARKET FOR HEALTH SERVICES (2012) (discussing the American incentive for crossing the border to obtain healthcare).

<sup>2</sup> *Mexico Second in Medical Tourism, Government Reports*, MEX. GULF REP. (Feb. 9, 2104), <http://www.mexicogulfreporter.com/2014/02/mexico-second-in-medical-tourism.html> (noting medical tourism as a three billion dollar business for Mexico in 2013).

<sup>3</sup> Lorne Matalon, *Desperate Patients Smuggle Prescription Drugs from Mexico*, MARKETPLACE HEALTHCARE (Jan 20, 2014), <http://www.marketplace.org/topics/health-care/desperate-patients-smuggle-prescription-drugs-mexico>; see also Michele L. Creech, *Make a Run for the Border: Why the United States Government is Looking to International Market of Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 643 (2001); Helkei Tinsley,

More recently, large numbers of people and entities locally buy bulk foreign drugs online and have them shipped to the United States to meet their medical needs. Needless to say, both options have received harsh treatment by the United States government. Recognizing the government's policy toward importation, others have pushed for price-caps on drugs, but to no avail.<sup>4</sup>

With the proper policy push, however, America could be on the verge of a drug importation breakthrough. A new law on prescription drug importation in Maine may hold at least one of the keys to lower the high prices of prescription drugs throughout the United States—evidence of successful implementation and safety. The problem of high-priced prescription drugs is longstanding,<sup>5</sup> and remains a concern due to a number of policy barriers preventing both efficient importation and price competition.

In response, the U.S. government has attempted to incrementally adjust its stance to combat this increasingly difficult area of regulation, but has yet to implement a satisfactory framework. Such a framework, however, is possible with a close look at proposed legislation before Congress as well as the newly passed importation law in Maine. Moreover, Maine's program suggests American citizens desire better importation policy while also hinting at the potential for success on the national level.

This Article will discuss the issues surrounding the importation of prescription drugs into the United States and will propose solutions that build on existing policy through economic efficiency arguments and diverting regulatory efforts. Part I provides the background for the problem of high-price prescription drugs and the influence of illegality on consumer behavior. Part II will explain the modern state of prescription importation laws, the newly passed importation law in Maine, and the Food and Drug Administration's concerns with importation. Part III proposes the use of an expanded, codified personal use exemption and an established regulation

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*Prescription Without Borders: America Looks to Canada for Answers to Solve the Prescription Drug Pricing Predicament in the U.S., But is Importation Really the Solution?*, 25 *HAMLIN J. PUB. L. & POL'Y* 437, 438 (2004).

<sup>4</sup> See Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceutical*, 16 *CONN. J. INT'L L.* 149 (2000).

<sup>5</sup> See *Gadler v. United States*, 425 F. Supp. 244 (D. Minn. 1977).

program for foreign manufacturers to register with the FDA along with a permitted substance listing.

## II. THE ISSUES OF PRESCRIPTION DRUG IMPORTATION

Facilitating access to useful prescription drugs in the United States faces two major problems. First, consumers of prescription drugs face prohibitively high prices in the United States, which often encourage them not to purchase necessary medications. The United States' free market economy, patent protection, and the lack of an effective price board (e.g., an independent agency regulating pharmaceutical prices) entrenches these high prices. The problem becomes even more complicated when reviewing the heavily entrenched pharmaceutical industry interest in legislation and attempts to keep this industry highly profitable. Second, seeking out prescription drugs at lower prices from countries like Canada and Mexico is technically illegal and uncertain, and thus has a deterrent effect for risk-averse individuals.<sup>6</sup>

### A. High-Price Prescription Drugs

As mentioned in the introduction to this Article, consumers in the United States tend to pay significantly more for prescription drugs than people in other countries. A simple comparison to United States price norms to Canada is illustrative of this issue—though other countries maintain comparably better-priced pharmaceuticals as well.<sup>7</sup> In 2004, the median prescription drug prices in Canada were as much as 78.6% lower than those in the United States.<sup>8</sup> In 2006, Brian Beirne

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<sup>6</sup> See *Maine Enacts Law Enabling Prescription Drug Importation*, CHAIN DRUG REV. (June 28, 2013), <http://www.chaindrugreview.com/newsbreaks-archives/2013-06-24/maine-enacts-law-enabling-prescription-drug-importation> (“Americans have accessed medication internationally for over the past decade, but federal prohibitions on personal drug importation, while not enforced against individuals, have deterred millions.” (internal quotation marks omitted)).

<sup>7</sup> See Patricia M. Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Counties*, HEALTH AFFAIRS (Oct. 29, 2003), available at <http://content.healthaffairs.org/content/early/2003/10/29/hlthaff.w3.521.full.pdf+html>.

<sup>8</sup> Logan Beirne & Michael Tucker, *Reimportation of Canadian Prescription Drugs into the United States: Regulatory, Economic, and Policy Implications*, 10

and Michael Tucker conducted a comparative study through several 100-count medication prices and found over \$1,000 in aggregate difference between the ten selected prescriptions.<sup>9</sup> Per the 2013 Annual Report of the Patented Medicine Prices Review Board—Canada’s prescription drug price board—the average price ratio shows consumers in the United States paying over double for patented-drug products compared to Canadian consumers, a trend that will likely increase in the coming years.<sup>10</sup> Even generic drugs, an oft-cited solution to high-priced prescription drugs, have shown price hikes by as much as 17.7% in the past year.<sup>11</sup>

With such high prices, many consumers either cannot afford their medication or make the conscious decision to “go without.” A Consumer Reports survey returned that “28% of chronically ill adults taking regular medications for their conditions reported skipping doses or not filling their prescriptions because they could not afford to pay for it,” which is a 1% increase from the year before.<sup>12</sup> This is particularly interesting given the inelastic demand for medical treatment in general. That prescription drug prices are so high as to deter filling prescriptions for chronic illnesses speaks volumes.

Why, then, does the United States struggle with prescription drug costs? The obvious answer can be found in its economic system.

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MICH. ST. U. J. MED. & L. 491, 493–94 (2006) (citing Patent Medicine Prices Review Board Annual Report 24 (2004)).

<sup>9</sup> *Id.* at 520 exh. 1.

<sup>10</sup> See PATENT MEDICINE PRICE REVIEW BOARD ANNUAL REPORT 24 fig. 9 & 25 (2013), [http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2013/2013-Annual-Report\\_2013-09-15\\_EN.pdf](http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2013/2013-Annual-Report_2013-09-15_EN.pdf) (noting a 107% average price differential and that even accounting for cost of living, the United States and Germany still have larger consumption costs).

<sup>11</sup> See, e.g., Ellen Jean Hirst, *Generic Drug Prices Skyrocket in the Past Year* (Nov. 21, 2014), <http://www.chicagotribune.com/business/ct-rising-generic-drug-prices-1102-biz-201411>

21-story.html; see also Susan Barry, *Cost of Generic Drugs Soaring Due to Increased Demand From Obamacare* (Feb. 1, 2014), <http://www.breitbart.com/Big-Government/2014/01/31/Why-Are-Costs-For-Generic-Medications-Soaring>.

<sup>12</sup> Shari Roan, *Americans Struggle to Pay for Prescription Drugs*, TAKEPART (Sept. 12, 2012), [http://www.takepart.com/article/2012/09/11/americans-struggling-pay-prescription-drugs\\_\(noting\\_survey\\_through\\_landline/cellphone\\_“randomized\\_nationally\\_represented\\_sample\\_of\\_4,432\\_adult\\_ages\\_19\\_and\\_older\\_living\\_in\\_the\\_continental\\_US”\)](http://www.takepart.com/article/2012/09/11/americans-struggling-pay-prescription-drugs_(noting_survey_through_landline/cellphone_“randomized_nationally_represented_sample_of_4,432_adult_ages_19_and_older_living_in_the_continental_US”)).

Unlike the rest of the world that uses price boards to control drug prices, the United States allows pharmaceutical companies to set the market price.<sup>13</sup> A few major players dominate the market through patent control and market share, which creates a sort of oligopoly between the pharmaceutical companies.<sup>14</sup> This also creates a strong incentive to price gouge consumers for high profit. To demonstrate the incentive, the sale of prescription drugs constitutes a \$300 billion industry worldwide with profit margins as high as 30%.<sup>15</sup> In the United States alone, prescription drug sales yield \$329.2 billion in gross revenue.<sup>16</sup> And due to the political clout of the pharmaceutical lobby,<sup>17</sup> the federal government has shown little, if any, desire to adopt prescription price controls.<sup>18</sup> Efforts to cap prices have been characterized as a “slowing innovation” and “rewarding special

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<sup>13</sup> Beirne & Tucker, *supra* note 8, at 494 (noting “patent protection often limits substitute products creat[ing] highly inelastic demand not seen with other products.”).

<sup>14</sup> *Top Pharma Companies by Global Sales*, PMLIVE (last visited Nov. 27, 2014), [http://www.pmlive.com/top\\_pharma\\_list/global\\_revenues](http://www.pmlive.com/top_pharma_list/global_revenues).

<sup>15</sup> *Pharmaceutical Industry*, WORLD HEALTH ORG. (last visited Nov. 27, 2014), <http://www.who.int/trade/glossary/story073/en/>

<sup>16</sup> *Spending on Medicines*, IMSHEALTH (Apr. 15, 2014) [http://www.imshealth.com/DeployedFiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/US\\_Use\\_of\\_Meds\\_2013/2013\\_Medicine\\_Spending.pdf](http://www.imshealth.com/DeployedFiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/US_Use_of_Meds_2013/2013_Medicine_Spending.pdf) (charting medication spending, including \$329.2 billion the in US).

<sup>17</sup> Martin L. Hirsch, *Side Effects of Corporate Greed: Pharmaceutical Companies Need a Dose of Corporate Social Responsibility*, 9 MINN. J. L. SCI. & TECH. 607, 631 (2008) (citing Julian Borger, *Industry that Stalks the U.S. Corridor of Power*, GUARDIAN, Feb. 13, 2001) (noting that “[t]he pharmaceutical lobby is recognized as the most powerful lobby in Washington); see also Beirne & Tucker, *supra* note 8, at 493 (noting the pharmaceutical industry spent “\$675 million on lobbying and employ[ed] more than three thousand lobbyists between July 1998 and July 2005”).

<sup>18</sup> Julie Appleby, *Got Insurance? You Still May Pay a Steep Price for Prescriptions*, ST. LOUIS POST-DISPATCH (Oct. 13, 2014, 10:48 AM), [http://www.stltoday.com/news/special-reports/mohealth/got-insurance-you-still-may-pay-a-steep-price-for/article\\_5fd08e32-725f-535e-a7a1-5776f403f91a.html](http://www.stltoday.com/news/special-reports/mohealth/got-insurance-you-still-may-pay-a-steep-price-for/article_5fd08e32-725f-535e-a7a1-5776f403f91a.html) (noting presence of state legislative response and “debate over how to slow the rapid rise of spending on prescription drugs,” but also that “more direct government influence on prices drug makers can charge . . . is still seen as a political nonstarter”).

interests.”<sup>19</sup> As a result, consumers in the United States continue to pay more than other countries, while nearby Mexico and Canada enjoy attractive pricing for the same medications.<sup>20</sup>

### B. Illegality

From these price concerns, some people are turning to places like Canada and Mexico to fill their prescriptions or ordering drugs online through Internet pharmacies. Efficient behavior dictates that people will often seek out substitute goods in different markets if the price is significantly lower, so long as quality remains comparable.<sup>21</sup> However, both activities—going across the border to bring drugs back and ordering them online from other countries—are illegal.<sup>22</sup> Thus, as it stands, people must choose between paying exorbitant prices, risking prosecution from illegal importation, or going without their medication. Wrongful importation can result in criminal charges against the importer, depending on the amount imported, usually a federal misdemeanor resulting in a potential year in jail and/or fine of \$1,000 per violation.<sup>23</sup> Larger or subsequent violations are punished with anywhere from 3–10 years in jail, or \$10,000 to \$250,000 in fines, or both.<sup>24</sup> The seizures, charges, and fines are even larger for bulk importation from Internet pharmacies and other outlets.

Recently the FDA has even begun taking online pharmacies to task, shutting them down and seizing their assets to make an example

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<sup>19</sup> Phil Kerpen, *Price Controls for Prescription Drugs Would Reward Special Interests and Slow Innovation*, DAILY CALLER (Oct. 27, 2014, 4:30 PM), <http://dailycaller.com/2014/10/27/price-controls-for-prescription-drugs-would-reward-special-interests-and-slow-innovation/>.

<sup>20</sup> Danzon & Furukawa, *supra* note 7.

<sup>21</sup> Valentino Piana, *Substitute Goods*, ECON. WEB INST. (2005), <http://www.economicwebinstitute.org/glossary/substitute.htm>

<sup>22</sup> 21 U.S.C. § 331(t) (prohibiting “importation of a drug in violation of section 381(d)(1), regarding importation of un-approved foreign drugs”); *see also* § 381 (addressing importation and reimportation of prescription drugs).

<sup>23</sup> 21 U.S.C. § 333(a)(1); *see also* Edward Lamb, *When is it OK to Import a Prescription Drug into the U.S. for Personal Use?*, ABOUT.COM, <http://pharmacy.about.com/od/Technology/f/When-Is-It-Ok-To-Import-A-Prescription-Drug-Into-The-U-S-For-Personal-Use.htm> (last visited Nov. 27, 2014).

<sup>24</sup> 21 U.S.C. § 333(a)–(b) (2012).

against this type of conduct.<sup>25</sup> The FDA has shut down several pharmacy operations for illegal importation in violation of its approval authority, including more well-known cases such as *Rx Depot* and “Canada Care Drugs, Inc.”<sup>26</sup> It has also made efforts to shut down other businesses that facilitate the importation of these prescription drugs. For example, three years ago, Google was forced to forfeit \$500 million in online advertising revenue for “assisting” Canadian and other foreign online pharmacies to sell prescription drugs.<sup>27</sup> Despite attempts by the FDA to shut down these operations, however, numerous foreign pharmacies websites exist and function for United States citizens to buy prescription drugs online.<sup>28</sup>

The problem with the FDA’s punitive function is it deters at least some people from seeking low-priced prescription drugs. Though the FDA may disagree—for reasons, including safety and innovation, discussed below—there is no real reason to continue preventing this type of drug importation for cheaper prescription drugs and efficient access. The basic push of this Article, then, is the need to develop some method to allow the efficient transfer of these foreign-manufactured drugs into the United States to allow a lower-cost alternative to high-priced prescription-drug options. To explain the necessity for this change, it is first necessary to walk through the

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<sup>25</sup> See Press Release, FDA, Permanent Court Order Halts Illegal Importation of Prescription Drugs (March 31, 2006), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108627>

.htm (recounting investigation and injunction of Canada Care Drugs Inc. operations).

<sup>26</sup> *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003) (upholding injunction); Press Release, FDA, Permanent Court Order Halts Illegal Importation of Prescription Drugs (Mar. 31, 2006), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108627.htm>.

<sup>27</sup> Press Release, Department of Justice, Google Forfeits \$500 Million Generated By Online Ads & Prescription Drug Sales by Canadian Online Pharmacies (Aug. 24, 2011), <http://www.justice.gov/opa/pr/google-forfeits-500-million-generated-online-ads-prescription-drug-sales-canadian-online> (explaining that it is illegal to aid or facilitate importation and marketing of illegal prescription drugs to U.S. citizens).

<sup>28</sup> See, e.g., Canadian Generic Pharmaceutical Association, CGPA, <http://www.canadiangenerics.ca/en/index.asp> (last visited Nov. 2, 2104).

current state of prescription drug law and its inadequacies at addressing these issues of access, price, and importation.

### III. CURRENT IMPORTATION LAW

This Part will address the current state of the law surrounding prescription drug importation in two major parts. First, it will discuss issues under the Federal Food, Drug, and Cosmetic Act (FFDCA), including major amendments and importation exceptions. Second, it will evaluate the concerns—safety and innovation—raised by the FDA in maintaining the prohibition on prescription drug importation. Third, it will discuss the various attempts at state regulation of prescription drug importation. Fourth, this Part will address Maine’s new prescription drug importation legislation as a laboratory for federal policy. These issues will be discussed in turn.

#### *A. Federal Food, Drug, and Cosmetic Act*

The FDA regulates all aspects of prescription drugs in the United States, including manufacturing, production, and transport. Its original authority comes from the Federal Food, Drug, and Cosmetic Act of 1938, which also allows it to regulate the import and export of prescription drugs.<sup>29</sup> Under the Act, the FDA has the authority to establish procedures for the monitoring and approval of new drugs.<sup>30</sup> Its power extends to enforcement against violations of these regulated areas under the FFDCA as well.<sup>31</sup> As discussed above, the FDA also leads investigations to seize wrongfully imported and counterfeit drugs.<sup>32</sup> The United States Customs and Border Protection (CBP), with FDA guidance, helps to enforce prescription drug mandates

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<sup>29</sup> 21 U.S.C. § 381(d) (2012).

<sup>30</sup> 21 C.F.R. pt. 314 (2014).

<sup>31</sup> See 21 C.F.R. § 1.4 (2001).

<sup>32</sup> *Imported Drugs Raise Safety Concerns*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm> (referencing a 2002 FDA investigation where agents uncovered “more than 25,000 counterfeit Viagra pills . . . [supplied] from China and India”) (last updated Aug. 24, 2011).

against importation.<sup>33</sup> This includes a ban on “the importation of prescription drugs that were purchased outside the United States.”<sup>34</sup>

All drugs imported into the United States require FDA approval.<sup>35</sup> The FDA has this authority through the power to regulate drugs issued into “interstate commerce,” which also includes foreign importation.<sup>36</sup> Additionally, drugs imported into the United States must conform to labeling and manufacturing requirements set by the FDA, which also happens to be among the strictest standards set by a regulating agency worldwide.<sup>37</sup> Once inside the United States, approved prescription drugs are processed through a “closed” distribution system.<sup>38</sup> As such, the only people able to receive the imports are U.S.-licensed pharmacists and wholesalers.

### 1. Personal Use Exemption

Due to difficulties regulating individual importation, in 1954 the FDA issued a personal use exemption for individual people to import up to a ninety-day supply under certain conditions.<sup>39</sup> The statute provides the FDA power to “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.”<sup>40</sup> The personal use exemption, however, is a discretionary guidance on the FDA’s choice to allow importation rather than a legally binding exception that importers may rely upon.<sup>41</sup>

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<sup>33</sup> *Prohibited and Restricted Items*, U.S. CUSTOMS & BORDER PROT., <http://www.cbp.gov/travel/international-visitors/kbyg/prohibited-and-restricted-items> (last visited Nov. 2, 2014).

<sup>34</sup> *Id.*

<sup>35</sup> *Imported Drugs Raise Safety Concerns*, *supra* note 32.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* (explaining FDA requirements and foreign-registered manufacturer inspections).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*; see also *Prohibited and Restricted Items*, *supra* note 33.

<sup>40</sup> 21 U.S.C. § 384(j)(1)(B) (2003).

<sup>41</sup> See *Imported Drugs Raise Safety Concerns*, *supra* note 32; Peter S. Reichertz & Melinda S. Friend, *Hiding Behind Agency Discretion: The Food and Drug Administration’s Personal Use Drug Importation Policy*, 9 CORNELL J. L. & PUB. POL’Y 493 (2000).

There is no right to import prescription drugs for personal use. Thus, people looking to import prescription drugs for personal use lack certainty and guidance.

In 1988, the FDA used the personal use exemption to save regulatory resources and allow importation of new AIDS drugs against an epidemic. It modified the personal use exemption for the benefit of drugs where no equivalent was available, or approved for use, in the United States.<sup>42</sup> The personal use exemption currently includes the following factors for use in the FDA's discretionary ruling whether to enforce:

- if the intended use is for a serious condition without effective domestic treatment available;
- if the product is considered to represent an unreasonable risk;
- if the individual seeking to import affirms in writing that it is for personal or patient use and provides the name and address of the U.S.-licensed doctor responsible for the treatment;
- if there is evidence that the drug is for continuation of a treatment begun in a foreign country;
- if the product is for personal use and is a three-month supply or less and not for resale, since larger amounts suggest commercial use; and
- if there is a known commercialization or promotion to U.S. residents by those involved in distribution of the product.<sup>43</sup>

While this exemption would seem to provide a reasonable allowance for personal importation of necessary treatment, in reality it is a narrow application with difficult-to-satisfy criteria. Specifically, it is difficult to imagine a serious condition in modern times where the

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<sup>42</sup> See *Benten v. Kessler*, 799 F. Supp. 281, 282 (E.D.N.Y. 1992) (criticizing the personal use exemption as an "ill-considered promulgation" in a case involving an FDA import alert banning importation of RU486, an experimental abortion drug); see also *Imported Drugs Raise Safety Concerns*, *supra* note 32.

<sup>43</sup> Marvin A. Blumberg, *Information on Importation of Drugs*, U.S. FOOD & DRUG ADMIN, <http://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (last updated June 30, 2010); See also *Imported Drugs Raise Safety Concerns*, *supra* note 32.

United States has no comparable “effective domestic treatment.”<sup>44</sup> Moreover, drugs purchased in a foreign country, even by the same name as a United States counterpart, are likely not FDA-approved and would not meet the importation standards under its regulation.<sup>45</sup>

The personal use exemption has largely been ineffective at either providing relief for importation or helping to regulate the flow of unapproved, and thus illegal, prescription drugs. Not only has the personal use exemption failed to provide a safe haven in legitimate cases, it has not discouraged attempts at technically illegal importation by people willing to risk violation and has not helped to decrease prices, nor increase access.<sup>46</sup> On the other hand, it has discouraged many people who need medication from seeking it out at the risk of committing a crime.<sup>47</sup>

## 2. Reimportation

Another commonly posited solution to high-price prescription drugs in the United States is the practice of so-called drug “reimportation.” Drug reimportation is when American drug manufacturers export their products to foreign countries, adjust them to price norms in those countries, and designate them for sale there.<sup>48</sup> Once the product is abroad, price boards of nearly all other developed countries<sup>49</sup> dictate a lower price for the exported drug. At this point,

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<sup>44</sup> As a matter of history, the personal use exemption was most widely used to justify importation of early experimental Cancer medication and some abortion drugs. See, e.g., *Benten*, 799 F. Supp. at 281; see also *Gadler*, 425 F. Supp. at 244.

<sup>45</sup> See 21 U.S.C. § 331 (2013) (prohibiting interstate shipment of unapproved new drugs).

<sup>46</sup> *Importation of Drugs into the United States: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 107th Cong. (2001) (statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, Food and Drug Administration), available at <http://www.fda.gov/NewsEvents/Testimony/ucm115214.htm> (discussing personal importation and oversight issues in mail and over the border).

<sup>47</sup> See *Maine Enacts Law Enabling Prescription Drug Importation*, *supra* note 6.

<sup>48</sup> See *Imported Drugs Raise Safety Concerns*, *supra* note 32; see also Monali J. Bhosle & Rajesh Balkrishnan, *Drug Reimportation Practices in the United States*, 3(1) THERAPEUTICS & CLINICAL RISK MGMT. 41, 41–42 (2007).

<sup>49</sup> Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 352 (2010).

individual consumers may solicit particular prescriptions from foreign pharmacies at a lower price and have them shipped back into the United States at a minimal cost that generates a net savings.<sup>50</sup> This idea also presents a price discrimination issue, whereby some consumers willing to pay for higher-price drugs will buy them domestically, while others less willing will choose to go abroad for their medications.<sup>51</sup> Further, perhaps the idea of needing to export products to a foreign market where the price is regulated and then shipping it back domestically to gain savings demonstrates the absurdity of the current price system as it exists.

On the flip side, the manufacturer, in theory, could reimport them into the United States and pass along the savings to consumers locally with reduced prices.<sup>52</sup> Such is the theory of the FDA to the extent that it accepts the idea of reimportation, but this has yet to become an accepted practice.<sup>53</sup> There is also very little incentive for manufacturers to engage in reimportation themselves, as imports back into the country must still abide by the FDA's costly regulations.<sup>54</sup> On the other hand, pharmaceutical companies still benefit from having this extended market to tap into these consumers who are less willing to pay high prices domestically.

Further complicating this problem, it is difficult to track the origin of these "reimported" drugs,<sup>55</sup> which has resulted in the FDA not implementing any reimportation policy to date.<sup>56</sup> Given regulatory resource concerns, the FDA has trouble ensuring that the prescriptions coming back through the mail were, in fact, manufactured in the United States. If not manufactured domestically, it is unlikely that the drugs will meet the FDA's requirements, and are thus unacceptable

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<sup>50</sup> Bhosle & Balkrishnan, *supra* note 48, at 41–42.

<sup>51</sup> See Beirne & Tucker, *supra* note 8, at 501 (discussing European prescription drug model and prohibited price discrimination between countries).

<sup>52</sup> Bhosle & Balkrishnan, *supra* note 48.

<sup>53</sup> See *Imported Drugs Raise Safety Concerns*, *supra* note 32; see also Beirne & Tucker, *supra* note 8, at 493 (noting that PMAA "does not explicitly prohibit importation from other countries that adhere to safety requirements"). The issue becomes that meeting such requirements is extremely complicated, and thus prohibitive. Without making it officially illegal, it makes the reimportation de facto illegal.

<sup>54</sup> See *Imported Drugs Raise Safety Concerns*, *supra* note 32.

<sup>55</sup> Bhosle & Balkrishnan, *supra* note 48, at 41–42.

<sup>56</sup> See Carmona, *infra* note 65 and accompanying text.

for importation or sale in the United States. Even where the manufacturing regulation appears to be on par with the United States', the FDA denies access.<sup>57</sup> Furthermore, the burden of meeting importation standards rests with the importer and is often impossible to meet, even for the original manufacturers.<sup>58</sup>

Nonetheless, it would seem that such an option, helping to cut cost, would still be sufficient. Per FDA policy, however, prescription drug reimportation is still viewed with suspicion.<sup>59</sup> The FFDCA also includes several labeling and approval provisions that make it extremely difficult to reimport.<sup>60</sup> Some scholars, on the contrary, have argued that reimportation is a valid option to encourage cost competition and eventually encourage government-mandated price caps on prescription drugs.<sup>61</sup> To date, however, the FDA has yet to implement a reimportation policy, despite several FFDCA amendments aimed at integrating access and subsidizing prescription drug prices, which will be discussed in the following section.

### 3. Recent Amendments

There have been a number of FFDCA amendments in response to this issue of high prices and prescription drug access, but none have been sufficient at addressing the problem as it stands today, either through inadequate alternative solutions or failed implementation. This subsection will discuss the three most pertinent amendments in turn: (1) the Medicine Equity and Drug Safety Act of 2000; (2) the Medicare Prescription Drug, Improvement and Modernization Act of 2003; and (3) the Food and Drug Administration Safety and Innovation Act of 2012.

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<sup>57</sup> See *Imported Drugs Raise Safety Concerns*, *supra* note 32.

<sup>58</sup> *Id.* Additionally, the FDA has recently proposed counterfeit-resistant technology and other special requirements to make it more difficult to import prescription drugs. Beirne & Tucker, *supra* note 8, at 505.

<sup>59</sup> See *Imported Drugs Raise Safety Concerns*, *supra* note 32; Beirne & Tucker, *supra* note 8, at 505 (explaining safety risks of reimportation).

<sup>60</sup> Beirne & Tucker, *supra* note 8, at 500.

<sup>61</sup> *Id.* at 519. *But see* Devin Taylor, *Importing a Headache for Which There's No Medicine: Why Drug Reimportation Should and Will Fail*, 15 J.L. & POL'Y 1421, 1468 (2007) (advocating that drug reimportation is too dangerous).

In 2000, Senator Jim Jeffords proposed the Medicine Equity and Drug Safety Act (MEDS) in Congress.<sup>62</sup> The Act had the objective of achieving reimportation success but was never passed in Congress due to alleged safety concerns by the Secretary of Health.<sup>63</sup> The bill recognized that “the cost of prescription drugs for Americans continue to rise at an alarming rate” and that “many life-saving drugs are available in countries other than the United States at substantially lower prices.”<sup>64</sup> As such, it provided authority for the Secretary of Health to create and implement regulatory frameworks regarding both importation and reimportation of prescription drugs from foreign countries, including Canada.<sup>65</sup>

As a renewed effort to address the issues of importation and popular pressure against high prescription prices, in 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA).<sup>66</sup> This amendment implemented Part D Medicare benefits and also permitted the limited importation of certain drugs from Canada, closely mirroring the factors of the personal use exemption.<sup>67</sup> While this amendment provided authority to allow importation, once again the Secretary of Health and Human Services never used the discretion to initiate this program.<sup>68</sup> Thus, it subsidized some useful prescriptions through its Part D benefit, but the MMA amendment was largely ineffective in addressing importation concerns and never really provided legal support for

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<sup>62</sup> Medicine Equity and Drug Safety Act of 2000, S. 2520, 106th Cong. (2000), available at <https://www.govtrack.us/congress/bills/106/s2520#overview>.

<sup>63</sup> *Id.*; see also *Prescription Drug Re-Importation Question and Answer Sheet*, AARP, [http://assets.aarp.org/www.aarp.org/\\_articles/international/ReimportationQA.pdf](http://assets.aarp.org/www.aarp.org/_articles/international/ReimportationQA.pdf).

<sup>64</sup> S. 2520 § 2 (referred to the Committee on Health, Education, Labor, and Pensions).

<sup>65</sup> *Id.* § 3.

<sup>66</sup> *Report of the HHS Task Force on Drug Importation: Hearing Before the Committee on Health, Education, Labor, and Pensions, U.S. Senate* (2005) [hereinafter *Report HHS Task Force*], available at <http://www.hhs.gov/asl/testify/t050216b.html> (statement of Richard H. Carmona, Surgeon General of the U.S. Public Health Service).

<sup>67</sup> Daniel L. Pollock, *Blame Canada (And the Rest of the World): The Twenty-Year War on Imported Prescription Drugs*, 30 SETON HALL LEGIS. J. 331, 349–51 (2006); see Beirne & Tucker, *supra* note 8, at 500 (explaining MMA inclusion of Canadian imports and similarities to the personal use exemption).

<sup>68</sup> *Report HHS Task Force*, *supra* note 66.

importation. Rather, the FDA continued to take a “strong stance” against importation of prescription drugs for safety reasons, which later led to other creative state alternatives to federal law.<sup>69</sup>

The most recent amendment to the FDCA, passed on July 9, 2012, as the Food and Drug Administration Safety and Innovation Act (FDASIA), was likewise inadequate at addressing the issue of drug importation,<sup>70</sup> although the amendment acknowledges that a significant portion of finished drugs and active ingredients come from overseas sources.<sup>71</sup> As a part of its content, the amendment expands the FDA’s authority to protect and monitor the drug supply chain of approved prescription drug materials and manufacturer reimportations.<sup>72</sup> While providing for safer supply chains for U.S.-produced pharmaceuticals, the amendment does little, if anything, to address importation or price controls.<sup>73</sup>

### B. FDA’s Concerns

The Agency puts forward two major concerns when discussing its decision to continue prohibiting importation: (1) the inability to ensure the safety of imported substances, and (2) that cheaper imported drugs would undercut the incentive for pharmaceutical companies to invest in research and development. The following subsections will discuss these issues in turn.

#### 1. Safety

FDA importation policy mentions safety as a major concern for prescription drug importation. The safety concern is that the FDA

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<sup>69</sup> Jennifer Micheletto, *The Illinois Prescription Drug Plan: Will it Last? An Analysis of the Current State of Health Care, Congressional Efforts to Lower Prescription Drug Costs, and Illinois’ Response to High Prices*, 9 DEPAUL J. HEALTH CARE L. 1261, 1261 (2006).

<sup>70</sup> *Food and Drug Administration Safety and Innovation Act (FDASIA)*, FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FDASIA/> (last updated October 28, 2014).

<sup>71</sup> *Id.* (noting 40% of all finished drugs and 80% of the raw ingredients come from abroad).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

cannot know where certain drugs originate and is unable, given its resources, to verify the content of all imports.<sup>74</sup> While this problem certainly exists, especially for developing countries and indeterminate sources, it is significantly overstated as a barrier for effective importation. For unapproved as well as approved drugs, the FDA typically cites safety standards and dangerous counterfeiting as the reasons for denying access to importation.<sup>75</sup> Safety concerns receive disproportionate media coverage, but are not as significant as the FDA suggests, especially for countries with comparable manufacturing and transport regulatory schemes.

The FDA's concern for drug safety consists of at least six factors listed on its website and in importation literature: (a) Quality Assurance Concerns, (b) Counterfeit Potential, (c) Presence of Untested Substances, (d) Risks of Unsupervised Use, (e) Labeling and Language Issues, and (f) Lack of Information.<sup>76</sup> Interestingly enough, all of these standards basically say the same thing, namely that drugs are not "safe."

In determining how to best handle this issue of safety, the FDA has implemented a "risk-based" approach to importation.<sup>77</sup> Under this approach, the FDA chooses when to exercise its prosecutorial discretion depending on how much of a risk is posed by a given importation, which is often denoted by "import alerts" for

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<sup>74</sup> *FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries*, FOOD & DRUG ADMIN. (Dec. 16, 2005), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108534.htm> (alleging "Canadian" drugs typically originate in other countries).

<sup>75</sup> *See Imported Drugs Raise Safety Concerns*, *supra* note 32 (citing retired Regulatory Affairs officer, Joseph McCallion, stating, "If you buy drugs that come from outside the U.S., the FDA doesn't know what you're getting, which means safety can't be assured" (internal quotation marks omitted)).

<sup>76</sup> *Looks Can Be Deceiving*, FOOD & DRUG ADMIN. (Apr. 3, 2012), available at <http://www.fda.gov/Drugs/ResourcesForYou/ucm078900.htm>.

<sup>77</sup> *Import, Counterfeit, and Unapproved Drugs: Hearing before the Subcomm. on Oversight and Investigations H. Comm. on Energy and Commerce* (2003) (statement of William K. Hubbard, Associate Commissioner for Policy and Planning), available at <http://www.fda.gov/NewsEvents>

/Testimony/ucm161030.htm (noting the FDA has responded to the influx of importations by "employing a risk-based enforcement strategy to deploy our existing enforcement resources in the face of multiple priorities").

particularly dangerous shipments.<sup>78</sup> It is for this reason that the FDA's enforcement objectives have largely targeted the businesses that facilitate the importation rather than the individuals seeking the medication.<sup>79</sup> Thus, for practical purposes, importation only becomes subject to an enforcement action once it becomes "commercial" in nature, or large enough to register profit as a business.<sup>80</sup> To reflect this reality, recently the FDA proposed regulation allowing authority to seize and destroy improperly imported prescription drugs valued at less than \$2,500, with the purpose of "increasing the integrity of the drug supply chain."<sup>81</sup>

This approach has received heavy criticism because of its apparent support for industry profit margins rather than securing safety for consumers, or effective deterrence.<sup>82</sup> The same critics have also noted that the FDA often fails to test the drugs it seizes in busting up these operations—suggesting less than a true concern for safety by the FDA.<sup>83</sup> It is also worth noting that enforcement that takes this approach removes one of the best consumer safeguards to consumer purchasing—the vendor. Entities, like online pharmacies and wholesalers, are often in a better position to negotiate precautions and safeguards for consumers.<sup>84</sup>

Instead, the enforcement policy encourages behavior such that individuals, navigating the vast sea of prescription drugs online, are the ones bearing the safety risk, although perhaps not the legal one, of the imported drug because the FDA refuses to recognize legitimate sellers in this arena.<sup>85</sup> Prosecuting vendors functions to discourage legitimate companies from selling to U.S. consumers, while leaving

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<sup>78</sup> *Id.*

<sup>79</sup> JODY FEDER, CONG. RESEARCH SERV., RL 32191, PRESCRIPTION DRUG IMPORTATION AND INTERNET SALES: A LEGAL OVERVIEW, CRS 12-13 (2004).

<sup>80</sup> *See id.*

<sup>81</sup> *See* Administrative Destruction of Certain Drugs Refused Admission to the United States, 79 Fed. Reg. 25758 (Proposed May 6, 2014) (to be codified at 21 C.F.R. pt. 1), *available at* <https://www.federalregister.gov/articles/2014/05/06/2014-10304/administrative-destruction-of-certain-drugs-refused-admission-to-the-united-states>; *see also* 21 U.S.C. § 381(b) (explaining disposition of refused articles).

<sup>82</sup> *See id.*

<sup>83</sup> FEDER, *supra* note 79.

<sup>84</sup> Bruce Watson, *Need Cheap Medication? Move to Maine*, DAILYFINANCE (Oct. 13, 2013), <http://www.dailyfinance.com/on/cheap-medication-maine-canadian-prescription-drugs/>.

<sup>85</sup> *See id.*

the illegitimate vendors who will risk the sale regardless. Yet, despite FDA warnings about safety and uncertainty for imported drugs, some consumers are still purchasing these products from abroad.<sup>86</sup> Even still, as a practical matter, the FDA policy turns a blind eye to the reality of most personal use importations,<sup>87</sup> which begs the question: if knowing prohibition does not work and the FDA is concerned about safety, then why not regulate actively, instead of maintaining this umbrella prohibition?

To continue discouraging the leap to a more liberal importation standard, the FDA periodically releases a story about the safety concerns and unpredictability of imported drugs.<sup>88</sup> Likewise, it also attempts to debunk the “myth” that Canadian prescription drugs are somehow cheaper.<sup>89</sup> While, at the same time, pharmaceutical companies continue to import their raw materials from foreign countries and even manufacture abroad.<sup>90</sup> In one instance, the FDA

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<sup>86</sup> *FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet: Practice Puts Consumer at Risk and May be More Expensive than Domestic Purchasing*, FOOD & DRUG ADMIN. (July 2, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108946.htm>; see also *FDA Test of Prescription Drugs from Bogus Canadian Website Show All Products are Fake and Substandard*, FOOD & DRUG ADMIN. (July 13, 2004), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108320.htm> (explaining continued importation by United States citizens despite FDA warnings about safety).

<sup>87</sup> Neil Osterweil, *The Letter (and Spirit) of Drug Import Law*, WEBMD, <http://www.webmd.com/healthy-aging/features/letter-and-spirit-of-drug-import-laws> (last visited Nov. 2, 2014).

<sup>88</sup> Aaron Carroll, *How Safe are your prescription drugs*, CNN OPINION (Feb. 24, 2014), <http://www.cnn.com/2014/02/25/opinion/carroll-drugs-imported-safety/>; see also *FDA Test Results of Prescription Drugs from Bogus Canadian Website Show All Products are Fake and Substandard*, FOOD & DRUG ADMIN. (July 13, 2004), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108320.htm> (identifying Canadian drugs as fakes).

<sup>89</sup> See Linda Bren, *Study: U.S. Generics Cost Less than Canadian Drugs*, FOOD & DRUG ADMIN. (July, 2004), <http://www.fda.gov/Drugs/ResourcesForYou/ucm134441.htm>.

<sup>90</sup> See e.g., Jennifer L. Halser, *Canadian Pharmacies: A Prescription for a Public Health Disaster*, 54 DEPAUL L. REV. 543 (2005); *Regulatory Information, Food and Drug Administration Safety and Innovation Act*, FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FDASIA/> (last updated Aug. 28, 2014) (noting “40 percent of finished drugs being

issued a press release detailing a 2003 drug seizure. It found that 88% of packaged drugs in the inspected shipment did not meet FDA standards.<sup>91</sup> In another instance, the FDA seized packets in 2005 and found that 88% of the drugs, alleged from Canada, were produced in 27 other countries.<sup>92</sup> The National Association of Boards of Pharmacy (NABP), a professional association of pharmacists, has also been implicated in these attacks through sponsoring studies about the safety of Canadian online pharmacies.<sup>93</sup>

Studies show, however, that the risks of counterfeiting and safety are probably much higher in developing countries than others with regulation similar to the United States. It is estimated that about 30% of all drugs in developing countries are counterfeit,<sup>94</sup> while only an estimated 1% of all drugs face this problem when exported from a developed country.<sup>95</sup> Thus, importing from a developing, rather than developed, country has a significantly higher risk of being counterfeit.

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imported, and nearly 80 percent of active ingredients coming from overseas sources.”).

<sup>91</sup> Gilbert Ross, *Why Drug ‘Reimportation’ Won’t Die*, WALL ST. J. (Jan. 7, 2010), <http://online.wsj.com/articles/SB10001424052748704842604574642184130409874>

<sup>92</sup> See *FDA Operation Reveals Many Drugs Promoted as “Canadian” Products Really Originate From Other Countries*, *supra* note 74.

<sup>93</sup> *Save Money by Ordering Drugs from Canada? Not so Fast*, CONSUMER REP. NEWS (Oct. 27, 2011 06:08 AM), <http://www.consumerreports.org/cro/news/2011/10/save-money-by-ordering-drugs-from-canada-not-so-fast/index.htm> (attacking Canadian prescription drugs). The study reviewed 8,300 online pharmacies and found that around 3 % were actually “legitimate” operations. *Id.* Furthermore, 85% did not require a valid prescription from the customers, 44% offered foreign drugs or FDA-unapproved drugs, and 25% had physical addresses outside of the United States. *Id.*

<sup>94</sup> Judy Stone, *Counterfeit Drugs: A Deadly Problem*, SCI. AM. BLOG (Aug. 20, 2012), <http://blogs.scientificamerican.com/molecules-to-medicine/2012/08/20/counterfeit-drugs-a-deadly-problem/>; see also Priya Shetty, *Counterfeit Drugs: Facts & Figures*, SCIDEV.NET (Mar. 30, 2011), <http://www.scidev.net/global/health/feature/counterfeit-drugs-facts-figures-1.html>.

<sup>95</sup> *Medicines: Spurious/Falsely-Labelled/Falsified/Counterfeit (SFFC) Medicines*, WORLD HEALTH ORG. (May 2012), <http://www.who.int/mediacentre/factsheets/fs275/en/> (noting that “incidences of SFFC medicines is extremely low” in Australia, Canada, Japan, New Zealand, the United States, and the European Union); see also *Counterfeit Medicines*, WORLD HEALTH ORG. (Nov. 14, 2006), [http://www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/).

At 1% counterfeiting for developed countries, however, the risk seems fairly minimal in reality.

The FDA argues that these safety concerns expand to all foreign countries, but evidence suggests that there is no such concern. In fact, some argue that safety concerns regarding countries like Canada are “unwarranted” and that safety standards in these countries are “very similar” to those required in the United States.<sup>96</sup> For example, manufacturers in Canada must also comply with the “Good Manufacturing Practices” promulgated by the FDA,<sup>97</sup> the quintessential quality standard requirement imposed on drug manufacturers.<sup>98</sup> Several agencies, including the North American Pharmacy Accreditation Commission and Health Canada’s Therapeutic Product Directorate, regulate compliance and quality assurance.<sup>99</sup> The process for approval also includes licensing of individuals engaged in the production and oversight of prescription drug manufacturing.<sup>100</sup> Research also suggests that in Canada the “incident reporting of internal process errors [is] more rigorous [...] than in the US,” which suggests a stronger feedback loop to minimize faulty drugs making it to the consuming public.<sup>101</sup>

Similar to Canada, many European countries, among others, also utilize similar approval and quality assurance processes for prescription drugs.<sup>102</sup> While some aspects of the process might differ,

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<sup>96</sup> Beirne & Tucker, *supra* note 8, at 503–04 (“United States and Canada have comparable requirements at virtually every step in the process. Both nations require that quality control units test both the raw materials prior to production and the finished product.”); *see also* Petra Brhlikova, Ian Harper & Allyson Pollock, *Good Manufacturing Practice in the Pharmaceutical Industry*, CTR. FOR INT’L PUB. HEALTH POLICY (July 2–3, 2007), [http://www.csas.ed.ac.uk/\\_data/assets/pdf\\_file/0011/38828/GMPinPharmaIndustry.pdf](http://www.csas.ed.ac.uk/_data/assets/pdf_file/0011/38828/GMPinPharmaIndustry.pdf).

<sup>97</sup> *Id.* at 504.

<sup>98</sup> *Facts About Current Good Manufacturing Practices (cGMPs)*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm> (last updated Oct. 23, 2014).

<sup>99</sup> Beirne & Tucker, *supra* note 8, at 504.

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *See Medicines*, MED. PRODUCTS AGENCY (Feb. 5, 2006), <http://www.lakemedelsverket.se/english/overview/About-MPA/Activities/Medicines/> (outlining Sweden’s regulatory

studies suggest that the European Union still achieves comparable safety levels while avoiding the delays of the FDA's process.<sup>103</sup> The FDA has even recognized the utility of sharing approval methods and process discussions with European and Scandinavian countries like Sweden.<sup>104</sup>

## 2. Innovation

The other argument that the FDA uses to justify prohibiting importation is a concern for stifled innovation. Some scholars argue that importation would be the first step in effective price controls for pharmaceuticals,<sup>105</sup> while others feel that it would kill the incentive for investments in developing new, cutting-edge prescription drugs.<sup>106</sup> The basic argument is that allowing "backdoor price controls"—through cheap imported drugs—will have this same effect.<sup>107</sup> Allowing importation will kill demand in the high-price market for pharmaceuticals, drastically cutting profits, which in turn will be siphoned from R&D operations.

Despite this concern, it seems that there will always be consumers willing to pay high prices for brand-name goods.<sup>108</sup> Moreover, the federal government is often responsible for funding the majority of the most important pharmaceutical research for public

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agency process for approving new medicines and quality control measures used to maintain safety); see also *Pharmaceutical Administration and Regulations in Japan*, JAPAN PHARM. MFG. ASS'N 24 (2010), <http://apps.who.int/medicinedocs/documents/s18577en/s18577en.pdf> (requiring adherence to the Good Manufacturing Practice for quality control of Japanese manufactured prescription drugs).

<sup>103</sup> See Ines M. Vilas-Boas & C. Patrick Tharp, *The Drug Approval Process in the U.S., Europe, and Japan*, 3 J. MANAGED CARE PHARMACY 459 (1997), <http://amcp.org/WorkArea/DownloadAsset.aspx?id=5884>.

<sup>104</sup> FDA – Swedish National Board of Health, FOOD & DRUG ADMIN. (Mar. 5, 2009), <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm107628.htm>.

<sup>105</sup> See *Beirne & Tucker*, *supra* note 8, at 493.

<sup>106</sup> Ross, *supra* note 91.

<sup>107</sup> *Id.*; see also Kerpen, *supra* note 19.

<sup>108</sup> This issue links into the inelastic demand for prescription drugs and the demand for luxury goods in the United States in times of higher income.

health.<sup>109</sup> Studies have found that between 1965 and 1992, as much as 66% of the funding for important drugs was publicly-provided.<sup>110</sup> Thus private R&D is not the only, and certainly not the most significant, source of funding to develop important pharmaceuticals. All things being equal, maintaining public funding is perhaps more important than concerns about private incentives to develop. Moreover, pharmaceutical companies also receive such high profits—at around 30%<sup>111</sup>—that cutting some profits will likely not significantly affect R&D.<sup>112</sup>

### C. State Importation Legislation

In the early 2000s, given the lack of viable alternatives for cheap medicine, states began to implement their own laws to allow for the importation of prescription drug from certain countries including Canada.<sup>113</sup> State intervention programs existed on a spectrum: some involved as little as informing consumers about the option for Canadian or foreign prescription drugs,<sup>114</sup> while others implemented contractual plans with foreign pharmacies and wholesalers to facilitate the purchase of prescription drugs.<sup>115</sup> In particular, the Illinois “I-SaveRx” plan established “benefit-manager” relationships to purchase pharmaceuticals through countries like Canada, Ireland, and the United Kingdom.<sup>116</sup> This more involved type of state intervention still only utilized personal use importation rather than facilitating state importation of FDA-restricted prescription drugs.<sup>117</sup>

Not surprisingly, the FDA and pharmaceutical syndicates responded negatively to both types of programs regardless of the

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<sup>109</sup> Beirne & Tucker, *supra* note 8, at 514.

<sup>110</sup> *Id.* at 514.

<sup>111</sup> *Pharmaceutical Industry*, *supra* note 15.

<sup>112</sup> *See* Beirne & Tucker, *supra* note 8, at 515.

<sup>113</sup> Micheletto, *supra* note 69, at 1261; Lynn Sweet, *Illinois Defying Feds, Importing Rx Drugs; But FDA is Threatening to Take State To Court*, CHI. SUN-TIMES, Aug. 17, 2004, at 8.

<sup>114</sup> Micheletto, *supra* note 69, at 1277–78 (discussing Minnesota plan to inform consumers about “state-approved Canadian pharmacies” but not being “directly involved in importing prescription drugs” (internal quotation marks omitted)).

<sup>115</sup> *Id.* at 1279.

<sup>116</sup> *Id.* (citing Anna Wilde Mathews, *Illinois to Set Up a Program to Promote Drug Importation*, WALL ST. J., Aug. 17, 2004, at D4).

<sup>117</sup> *Id.* at 1279–80.

degree of state involvement.<sup>118</sup> It is difficult to ignore the benefit derived by these state programs in passing on savings to its citizens.<sup>119</sup> Despite the relative savings provided by these programs, the states that explored this type of legislation largely abandoned them in 2006 when the prescription-drug benefit was added to Medicare via the MMA amendment implementation,<sup>120</sup> as well as other programs expressly denied by the FDA.<sup>121</sup> Others states, deterred by fears of violating federal law and risking infringement on FDA jurisdiction,<sup>122</sup> never implemented their own program, but nonetheless recognized the problem of high-price prescription drugs. Yet, even today, states continue attempting to contravene FDA policy and formulate importation programs,<sup>123</sup> which shows the continued interest for import policy reform.

#### D. Maine's New Legislation

The most recent state program to emerge is Maine's "Act to Facilitate the Personal Importation of Prescription Drugs from

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<sup>118</sup> *Id.* at 1278–80.

<sup>119</sup> See, e.g., Serena Lipski, *Excessive Pricing and Pharmaceuticals: Why the Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. TOL. L. REV. 913, 916–17 (2008); Micheletto, *supra* note 69, at 1261 (noting that Illinois state important law had "hopes of saving its citizens a significant sum of money").

<sup>120</sup> See Kristin E. Schleiter, *Court Support for FDA Regulation of Drug Importation*, 11 AMER. MED. ASSOC. J. OF ETHICS 521 (2009); see also Jennifer Levitz & Timothy W. Martin, *Maine to Allow Prescription-Drug Imports*, WALL ST. J. (last updated Oct. 11, 2013), <http://online.wsj.com/articles/SB10001424052702303442004579123613325473946>; Medicine Equity and Drug Safety Act of 2000, *supra* note 66.

<sup>121</sup> Vermont v. Leavitt, 405 F. Supp. 2d 466 (D. Vt. 2005); see also Schleiter, *supra* note 120.

<sup>122</sup> Ark. Att'y Gen. Op. No. 2001-035 (Mar. 15, 2001); Tenn. Att'y Gen. Op. No. 06-019 (Jan. 27, 2006); Tenn. Att'y Gen. Op. No. 05-083 (May 16, 2005) (deferring to FDA regulation and federal preemption); Tex. Att'y Gen. Op. No. GA-0384 (Dec. 21, 2005).

<sup>123</sup> Jackie Farwell, *British Pharmacy Chain Launches Online Drugstore for Maine Consumers*, BANGOR DAILY NEWS (Nov. 27, 2014), <http://bangordailynews.com/2014/10/07/health/british-pharmacy-chain-launches-online-drugstore-for-maine-consumers/>.

International Mail Order Prescription Pharmacies.”<sup>124</sup> Under the law, Maine residents may import prescription drugs from licensed pharmacies in Australia, Canada, New Zealand, and the United Kingdom.<sup>125</sup> The Maine Pharmacy Association, along with representatives of the pharmaceutical industry, recently filed suit challenging the law on various grounds.<sup>126</sup> While the claims by pharmaceutical interests were dropped for lack of standing, the suit remains ongoing.<sup>127</sup>

In discussing the Maine law, those in opposition use the same safety rhetoric used against the federal level policy.<sup>128</sup> And as some suggest, perhaps it is more of a “turf” issue surrounding pharmaceutical profits rather than safety.<sup>129</sup> Moreover, the benefits recognized by the program are quantifiable. Maine has consistently pushed the envelope in this arena since the first state programs back in the early 2000s.<sup>130</sup> Between the years of 2004–2012, Maine residents experienced \$3.2 million aggregate savings on prescription drugs.<sup>131</sup> Given that states have historically acted as the laboratories for federal policy,<sup>132</sup> Maine’s success is a useful indicator for further individual

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<sup>124</sup> S.P. 60, L.D. 171 126th Leg., 1st Reg. Sess. (Me. 2013), <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0060&item=2&snm=126>.

<sup>125</sup> See *Maine Enacts Law Enabling Prescription Drug Importation*, *supra* note 6.

<sup>126</sup> Complaint, *Maine Pharmacy Ass’n v. Mills*, No. 1:13-cv-00347-NT (D. Me. 2013), <http://freepdfhosting.com/7c2bcf9ba9.pdf>; Kurt R. Karst, *Mainers and FDC Act Preemption “In,” and PhRMA and Foreign Commerce Clause “Out” in Dispute Over Drug Importation Law*, FDA L. BLOG (May 20, 2014), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2014/05/page/2/](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/05/page/2/).

<sup>127</sup> Ed Silverman, *In Maine, the British are Coming...to Sell Prescription Medicines Online*, WALL ST. J. (Oct. 8, 2014), <http://blogs.wsj.com/pharmalot/2014/10/08/in-maine-the-british-are-coming-to-sell-prescription-medicines-online/>.

<sup>128</sup> Dave Sterrett, *Maine Drug Reimportation law May Benefit Consumers if Safety Can Be Assured*, CITIZENVOX (Oct. 24, 2014), <http://www.citizenvox.org/2013/10/24/maine-drug-reimportation-law-may-benefit-consumers/>.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.*

<sup>132</sup> *New State Ice Co. v. Liebmann*, 285 U.S. 262, 386–87 (1932) (“To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is

state policy reform. Not to mention, a fifty-state system of prescription drug import regulation would prove an administrative nightmare. A single regulator concerned with safety is important, but the FDA needs to relax its limits.

#### IV. NORMATIVE SOLUTION

A solution to the limited access and high price of prescription drugs is complicated, but attainable. Potential solutions to this issue could include everything from skipping FDA-approval rounds for desired importations, implementing price control boards, or closing patent loopholes to open up generic markets faster. None of these solutions, however, have garnered sufficient popular or governmental support to be a realistic possibility. A uniform federal policy allowing importation, on the other hand, would provide for efficient regulation and unprecedented access to already available prescription drugs. Rather than directly controlling prices through a board, allowing competition through imports could indirectly drive down price by putting pressure on U.S. pharmaceutical companies. With lower prices and increased access, there could be an efficient allocation of prescription drugs to U.S. citizens needing treatment.<sup>133</sup>

At this time, the FDA is too cautious and makes it too difficult for people to get the medicines they want or need. FDA deterrence effectively functions as a large transaction cost to importing drugs and discourages an efficient market and maximum benefit to consumers. As mentioned in Part II.B, the FDA's concern for safety is likely overstated and can largely be ameliorated by limiting accepted drug importation to other developed countries with a similar regulatory standard as the United States.<sup>134</sup> Moreover, the government allowing

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one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country. . . . If we would guide by the light of reason, we must let our minds be bold.”).

<sup>133</sup> With a lowered price and increased demand, might this create a shortage? While this is possible, especially for countries like Canada where the United States could bleed the supply, it would likely adjust in time. If more markets open their supply, potential shortage could be negated.

<sup>134</sup> See Part II.B, *supra* note 95–103.

importation of cheaper drugs would not significantly harm incentives for pharmaceutical innovation.<sup>135</sup>

As such, the solution to pricing and access can be solved, on a federal level, in one of two ways that this Article proposes: (1) an expanded, codified personal use exemption, and (2) permitted importation of prescription drugs from similarly regulated foreign countries. Both of these proposals could include provisions writing out patent infringement in cases where the drug would otherwise be properly sold abroad.<sup>136</sup> Moreover, legislation could list certain essential, non-addictive pharmaceuticals—like heartburn treatment, blood thinners, or cholesterol medicine—that may be deemed not to pose a “significant health risk.” This may also exclude highly scheduled controlled substances and other narcotics that are often subject to abuse.

Recent bills have been submitted to Congress in continued attempts to resolve this importation issue. While none have received majority support for enactment, the bills include some interesting proposals that deserve a closer look.<sup>137</sup> The Pharmaceutical Market Access and Drug Safety Act of 2011 (PMADSA) proposes the designation of qualifying countries and drugs to be allowed for importation.<sup>138</sup> It also, like my proposals, would limit patent infringement where drugs would have been properly sold abroad and would establish a regulatory framework for Internet vendors.<sup>139</sup> Likewise, the Personal Drug Importation Fairness Act of 2013 (PDIFA) proposes an extension of the personal use exemption based

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<sup>135</sup> See Part II.B.2, *supra* note 106–111.

<sup>136</sup> See Pharmaceutical Market Access and Drug Safety Act of 2011, S. 319, 112th Cong. (2011), <https://www.govtrack.us/congress/bills/112/s319#summary/libraryofcongress> (denoting exception for when “resale in the United States of prescription drugs that were properly sold abroad” as not constituting patent infringement). Recognizing the patent implications of an import proposal, and while this issue is pressing, it is outside of the scope of this article. For a discussion of state regulators and patent infringement issues, see Lipski, *supra* note 119.

<sup>137</sup> S. 319; see also Personal Drug Importation Fairness Act of 2013, H.R. 3715, 113th Cong. (2013), available at <https://www.congress.gov/bill/113th-congress/house-bill/3715> (listing proposed factors to permit importation of foreign prescription drugs, including the “same active-ingredients” as an FDA approved counterpart and coming from a “qualified country”).

<sup>138</sup> S. 319.

<sup>139</sup> S. 319.

on similar active ingredients, strength, direct shipping, and origin from a “qualified” country.<sup>140</sup> With these suggestions in mind, it is possible to see successful importation policy in action.

#### *A. Expanded Personal Use Exemption*

An expanded personal use exemption would remedy the uncertainty inherent in the current model.<sup>141</sup> As it currently stands, personal use importers cannot be sure that their conduct will go unpunished, and the FDA discretionary standards do not establish a realistic chance for use of the exemption. Much like Maine’s legislation, a reliable importation right under federal law would provide an effective means to import drugs for personal use and would lead to savings for United States consumers.<sup>142</sup> Similar to the PDIFA, it would also be important to allow the exemption to function in more instances. This could include an exemption past having “no domestic alternatives” as under the current framework, as well as a codification that would provide importer reliance.<sup>143</sup> To the extent that an individual bearing their own cost for importation safety is problematic, there may also be potential for the legislation to include some method for the registration of international sellers and pharmacists as well.<sup>144</sup>

#### *B. Foreign Regulatory Quality*

Another potential effective method for providing cheaper prices and higher access to prescription drugs would be to permit drugs from foreign countries with regulatory methods similar to the United States. As described in Part II.B.1, the FDA is incorrect in its assumption that it is the only agency capable of ensuring safety for consumers. Rather countries with a similar quality control for drug manufacturing and oversight (e.g., a sufficiently acceptable regulatory body overseeing operations) should be included for potential

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<sup>140</sup> H.R. 3715.

<sup>141</sup> Reichertz & Friend, *supra* note 41, at 493.

<sup>142</sup> Sterrett, *supra* note 128.

<sup>143</sup> See *supra* note 44 and accompanying text.

<sup>144</sup> S.P. 60, L.D. 171 126th Leg., 1st Reg. Sess. (Me. 2013).

importation of these goods.<sup>145</sup> How far the geographical limitations should extend (e.g., which countries meet the level of being “qualified”)<sup>146</sup> is unclear. What is clear, though, is the need for an expansion of this rule to allow for efficient pricing and access to useful medications. Moreover, Maine’s success with a similar expansion to Canadian and European pharmacies suggests a reliable policy that would be conceivable without risking major safety concerns. Such a policy may also include a list of acceptable pharmaceuticals or qualifying substances through matching active ingredients.<sup>147</sup>

Two questions arise, however, with regard to this type of solution: (1) would this be a personal use or bulk importation basis? (2) might it include foreign importation or, alternatively, only domestic reimportation? On the first issue of importation amount, the legislation in Maine, on the one hand, only permits such importation from certain countries for “personal use.”<sup>148</sup> I would argue, however, that suitable regulatory oversight and funneling of these medications through the proper channels in cooperating countries should negate concerns for importing larger amounts of these medications from foreign countries. Similarly, with regard to importing foreign drugs versus reimporting domestically produced drugs, proper foreign oversight could potentially disavow the need to limit policy to merely a reimportation of domestically manufactured prescription drugs.<sup>149</sup>

## V. CONCLUSION

In conclusion, this Article proposes two potential, nonexclusive solutions to progress prescription drug importation policy in the United States and bridge the regulation gap that currently exists today. These solutions could set up an efficient, cost-effective

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<sup>145</sup> *Id.*; see also H.R. 3715.

<sup>146</sup> See e.g., H.R. 3715 (designating “qualified” countries generally without providing specific guidelines for designation). *But see supra* note 95 (denoting countries with “extremely low” instances of counterfeit or misleading medication at 1%). Perhaps these same countries could serve as a baseline for opening importation.

<sup>147</sup> H.R. 3715 (listing use of the “same active ingredient” as one factor in permissible drug importation).

<sup>148</sup> S.P. 60.

<sup>149</sup> See *infra* note 94 and accompanying text.

market for prescription drugs, while simultaneously solving the problem of access to medications due to price. It seems important, if not necessary, in our increasingly globalized world to expand this commercial interchange between countries. Even larger—yet immeasurable—potential benefits past monetary savings may later manifest as well, such as increased access to effective medication affecting overall healthcare or commercial interchange bringing up prescription drug quality standards in more countries worldwide.