

12-9-2013

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### Recommended Citation

Peral, Eloy A. "FDA Regulation on the Importation of Prescription Drugs: Opportunities and Barriers to Legal Importation." *Health Law & Policy Brief* 3, no. 1 (2009): 48-55.

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# FDA REGULATION OF THE IMPORTATION OF PRESCRIPTION DRUGS: OPPORTUNITIES AND BARRIERS TO LEGAL IMPORTATION

Eloy A. Peral\*

## I. Introduction

In Beebe Plains, Vermont, there is a street, appropriately named Canusa Avenue, that runs right along the United States-Canada border. Houses on the northern side of the street are in Canada while houses on the southern side are in Vermont. If a resident of the northern side of Canusa Avenue needs medication to control high cholesterol, he or she can purchase a 90-day supply of 20 milligram Lipitor for \$170. On the southern side of the street, Vermont residents will have to dig much deeper if they need to purchase the same drug. The same 90-day supply of Lipitor costs about \$330 in the United States.<sup>1</sup>

This is not what one would expect to find in the globalized economy. However, today's global economic system has seen the acceleration of cross-border economic, cultural, and political interactions. These forces have led to a convergence in the price of many goods and services. Due to a host of factors, but especially due to the safety considerations unique to pharmaceutical drugs and the monumental costs needed to protect the public health against unhealthy and ineffective drugs, drugs sold in the United States escape the equalizing effects of the global economy. It is estimated that Americans pay between 35% and 55% more for brand name prescription drugs than people around the world.<sup>2</sup> At a time when health care costs are consuming an increasingly unacceptable share of U.S. Gross Domestic Product (GDP), public pressure has mounted for the use of international market forces in order to lower the price of American prescription drugs. As the government agency tasked with regulating prescription drugs, the U.S. Food and Drug Administration's (FDA) role of ensuring safety and effectiveness is threatened by legitimate demands that health- and life-sustaining drugs become more affordable. The debate on whether to ease the restrictions on the importation and re-importation of drugs reflects a struggle to gain access to cheaper

drugs despite the dangers that a relaxation of the FDA's control over drugs will have on public health. Although the importation and re-importation of drugs remains illegal under almost every scenario, otherwise law-abiding Americans are choosing to ignore the law and potential risks associated with consuming drugs that have not received FDA approval. The prospect of alleviating the high cost of health care by purchasing cheaper drugs has even led states to enthusiastically flout federal laws barring importation of unapproved (and thus illegal) drugs.<sup>3</sup>

Due to the explosion of illegal transactions involving the purchase of cheaper drugs in Canada by Americans who seek to transport them into the United States, much of the debate focuses on *re-importation* from Canada and other industrialized nations. Drug re-importation in the United States "involves [Americans] buying American-made prescription drugs from countries to which U.S. pharmaceutical companies export their products, either by traveling there to buy drugs or purchasing them through the mail."<sup>4</sup> Enforcing restrictions on the importation of drugs manufactured in less developed countries, that lack oversight and inspections by an FDA-equivalent government agency, fail to spark the same outcry as the ban on re-importation of drugs from industrialized countries, such as Canada. The FDA frequently cites concerns about the labeling, shipping, and handling of drugs imported from Canada as a policy justification for maintaining the ban on re-importation.<sup>5</sup> The proposition that the Canadian drug supply is less safe has seen effective rebuttals, with some analyses even concluding that it is safer than drugs in the United States.<sup>6</sup> A more convincing reason for prohibiting the re-importation of drugs is that the public health suffers when pharmaceutical companies are discouraged from researching and developing new drugs due to the reduced profitability that would follow re-importation.

This article first provides a summary of the two most accepted explanations for the stark price differential between drugs sold in the United States and those sold in the rest of the industrialized world, specifically in Canada. Second, this article sketches an overview of how the FDA regulates domestic drugs and imported drugs that are FDA approved. Third, this article discusses the law applicable to imported drugs the

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FDA did not approve, and to re-imported drugs that the FDA subjected to its approval process. Finally, this article concludes by briefly analyzing the political variables that may affect the future of drug importation and re-importation.

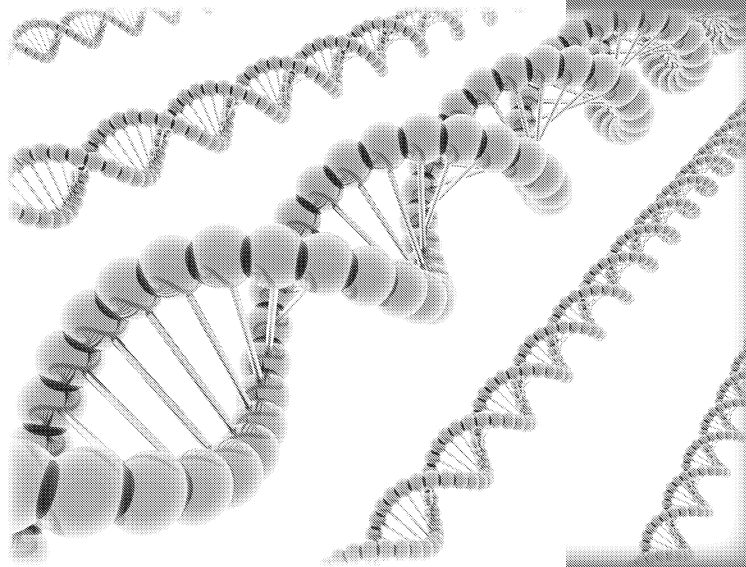
There are numerous theories advanced to explain why drug prices in the United States and Canada diverge so significantly, even among American-manufactured drugs whose only substantive difference lies in where they are sold. Although no simple explanation exists, the two most common explanations are government drug price controls and price discrimination.

Unlike the market-driven pharmaceutical industry in the United States, Canada's Patented Medicine Prices Review Board (PMPRB) enforces price controls on patented medicines.<sup>7</sup> The PMPRB is an independent arm of the Canadian Government that has the power to "investigate and regulate excessive pricing of patented pharmaceutical drugs," including levying fines if prices exceed the allowable amount.<sup>8</sup> The maximum amount a pharmaceutical company may charge for patented drugs is based on the average price of the drug in seven other developed countries.<sup>9</sup> PMPRB regulations permit patented drug price increases only on a yearly basis, and only if the increase is proportional to an increase in the Consumer Price Index (CPI).<sup>10</sup> The PMPRB estimates that Americans pay 67% more for patented drugs than Canadians do.<sup>11</sup>

Price discrimination may also contribute to the drug price differences and may even supersede price controls as the primary cause.<sup>12</sup> Price discrimination occurs when a company charges different prices in different markets for the same product.<sup>13</sup> Price discrimination is possible when markets are segmented based on certain factors, such as the disposable income and tastes of consumers.<sup>14</sup> A common example of this phenomenon at work occurs when movie theaters charge a lower price for a movie ticket to seniors and students due to their lower average income relative to the general population. Aidan Hollis, a Canadian economist and proponent of price discrimination as the major factor driving price differences, asserts that pharmaceutical companies set a lower price in the Canadian market than they do in the United States, because of Canadians' lower income compared to that of Americans'.<sup>15</sup>

## II. The FDA's Regulatory Framework

The FDA's role as a modern regulatory agency is the result of the Federal Food, Drug, and Cosmetics Act of 1938 (FDCA).<sup>16</sup> Congress amended the FDCA more than one hundred times. Some of the amendments



may be described as "technical and remedial," but the most prominent have significantly altered the way the FDA regulates and have expanded the depth and breadth of the FDA's regulatory authority.<sup>17</sup> A notable example is the Medical Device Amendment, which "transformed its approach to regulation of [medical devices] and substantially enlarged the array of regulatory tools available to it."<sup>18</sup> The FDA's regulatory authority, as originally established by the FDCA, is generally categorized into two concepts: (1) "adulteration," which pertains to the content of a product; and (2) "misbranding," which pertains to the labeling of a product.<sup>19</sup> The majority of enforcement power in the FDCA originates from the adulteration and misbranding provisions. Through amendments to the FDCA, the FDA adjusted the definitions of adulteration and misbranding in order to broaden the scope of the FDA's regulatory role. The statutorily prescribed enforcement remedies available to the FDA include criminal prosecution (in coordination with the Department of Justice) of individuals and firms who commit prohibited acts, injunction against such acts, seizure of adulterated or misbranded goods, and pursuit of civil penalties for some violations.<sup>20</sup> Yet informal remedies "comprise the primary routine enforcement tools of the agency."<sup>21</sup> These tools include recalls, publicity, and warning letters.<sup>22</sup>

### A. Overview of FDA Regulations Applicable to Imported and Domestic Drugs

For the FDA to permit the importation of a foreign-manufactured drug, it must comply with the same requirements applicable to domestic drugs in interstate commerce.<sup>23</sup> The FDA's regulation of drugs is appropriately referred to as a "closed" system in which the agency regulates the manufacturing, marketing, and labeling of every drug legally sold in the United

A more convincing reason for prohibiting the re-importation of drugs is that the public health suffers when pharmaceutical companies are discouraged from researching and developing new drugs due to the reduced profitability that would follow re-importation.

States. Imported and domestic drugs must satisfy five requirements, among others, under the FDCA before they can be legally introduced into interstate commerce.<sup>24</sup> First, a drug is *adulterated*, and thus is prohibited from entering interstate commerce, if it is not produced in accordance with good manufacturing practice (GMP).<sup>25</sup> Even if a drug is not “pharmacologically deficient,” it is adulterated if it does not comply with GMP.<sup>26</sup> Second, a drug must not be *misbranded*, “which, among other things, means that the labeling must bear the name and address of the manufacturer, packer, or distributor, and [must] not be false or misleading, and that the drug must be manufactured in an establishment registered with the FDA under FDCA § 510.”<sup>27</sup> “Any drug, even a foreign version of an FDA approved drug, will be an unapproved drug unless it meets all U.S. packaging, labeling, and dosage requirements.”<sup>28</sup> Third, a drug subject to FDCA § 503(b)(1) will be exempt from FDCA § 502(f)(1), when it is “in the possession of a person . . . regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs,”<sup>29</sup> labeling requirements (e.g., re Rx Only), and includes a package insert in the precise language and format approved by FDA.<sup>30</sup> Fourth, “[a]ny imported drug must be dispensed only upon a valid prescription by a licensed prescriber, and distributed with a pedigree<sup>31</sup> except in the case of a manufacturer or ADR.”<sup>32</sup> Lastly, and the most onerous of all the requirements, the FDA must approve the drug itself.<sup>33</sup>

#### *i. The FDA Drug Approval Process*

As of 2002 it takes an average of 8.5 years and costs about \$500 million to comply with the rigorous FDA drug review process and subsequently bring a drug to the consumer.<sup>34</sup> The financial costs and regulatory risks involved in this review process may help explain the broad gap between the price of drugs sold in the United States and those sold in other countries. The drug development process usually begins in laboratories, where scientists test the effects of chemical compounds involved in the disease whose treatment they seek.<sup>35</sup> The chemicals are then tested in two or more species of animals in order to determine whether they can be safely used in humans.<sup>36</sup> This initial laboratory testing of chemicals is referred to as *preclinical research*.

If the FDA finds the approach promising and an institutional review board of scientists, ethicists, and health-care specialists approves the sponsor’s study protocol, the drug enters a progression of tests in humans. Each new trial phase is predicated on a successful outcome of the previous one: *Phase I studies* test the product

for its adverse effects on a small number of healthy volunteers. *Phase II studies* probe the drug’s effectiveness in patients who have the disease or condition the product is intended to treat. *Phase III studies* seek to determine the drug’s safety, effectiveness and dosage. In these trials, hundreds or thousands of patients are randomly assigned to be treated either with the tested drug or a control substance, most frequently a placebo.<sup>37</sup>

The data gathered from these studies and other information about the drug such as, “what the ingredients of the drug are, the results of the animal studies, the way in which the drug behaves in the body, and how it is manufactured, processed and packaged,” are then included in a New Drug Application (NDA).<sup>38</sup> An NDA is a formal proposal to the FDA to approve a new pharmaceutical for sale and marketing in the United States.<sup>39</sup> Applications for generic drugs, “a copy that is the same as a brand-name drug in dosage, safety, strength, the way it is taken, quality, performance and intended use,”<sup>40</sup> come in the form of an Abbreviated NDA (ANDA). These applications are “‘abbreviated’ because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).”<sup>41</sup>

#### *ii. Importing FDA Approved Drugs*

The FDCA places an additional burden on drug importers by prohibiting the importation of food and drugs that “appear” to be adulterated or misbranded.<sup>42</sup> If FDA field staff at a port of entry determine that an FDA-regulated product “appears” to be adulterated or misbranded, the FDA does not admit the product and issues an Import Alert (Alert). If an Alert is issued, identifying a manufacturer, shipper, grower, importer, or a geographic area, “future shipments of that product will not be allowed to enter the United States, unless the importer demonstrates that the product is in compliance with the FDCA.”<sup>43</sup> Thus, Alerts transfer the burden of showing compliance to the importer.<sup>44</sup> Furthermore, Alerts identify products that may be detained based on information *other than the results of physical examination of a sample*.<sup>45</sup> The FDA, through its reference manual for FDA personnel, has interpreted “or otherwise” in the enabling statute<sup>46</sup> to mean “. . . a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative.”<sup>47</sup> “Appearance” is not defined by FDA regulations.<sup>48</sup> By law, the Secretary of the

Department of Health and Human Services (HHS) holds discretion over the admissibility of FDA-regulated products offered for import and therefore a decision to refuse admission is not reviewable under the Administrative Procedure Act (APA).<sup>49</sup> FDA regulations do provide for an informal hearing to contest refusal of admission,<sup>50</sup> but testimony offered by the owner or consignee of the product is not mandatory or limiting upon the Secretary.<sup>51</sup>

### III. Importation of Unapproved and Reimported Drugs

As noted earlier, foreign versions of FDA approved drugs and re-imported drugs are considered unapproved, and thus are prohibited from being introduced into interstate commerce.<sup>52</sup> Despite the narrow and clearly defined legal avenues by which Americans may legally obtain pharmaceutical drugs unapproved by the FDA, in 2003 “nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately \$700 million entered the United States from Canada.”<sup>53</sup> Yet, notwithstanding vigorous legislative efforts to permit the re-importation of drugs for commercial use, it remains nonexistent and illegal, despite the discretion held by the HHS Secretary to waive the restriction.<sup>54</sup> The current enforcement environment is less restrictive as to the personal importation of unapproved drugs, perhaps because of the widely publicized toll prohibitively expensive drugs place on many Americans.<sup>55</sup>

#### A. Personal Importation of Unapproved Drugs

There are two ways that currently make it possible for an individual to import unapproved drugs into the United States for personal use: (1) the FDA’s enforcement guidelines for U.S. Custom and Border Protection (CBP) officers that arguably creates a de facto exemption for individuals who import or reimport unapproved drugs for personal use;<sup>56</sup> and (2) Section 535 of the 2007 Homeland Security Appropriations Act which prohibits CBP from preventing personal reimportation of drugs from Canada.<sup>57</sup> Primarily due to its greater resources, the CBP is tasked with enforcing the drug laws and policies of the FDA and the Drug Enforcement Agency (DEA).<sup>58</sup> These avenues place formal and informal limitations on the amount of unapproved drugs that an individual can import.

The Controlled Substances Act (CSA) also contains specific provisions which allow individuals to travel internationally with limited quantities of their prescription medications “if: (1) the substance is found

in one of the approved ‘schedules,’ (2) the substance is in its original container, (3) a declaration is made to the United States Customs Service, and (4) use of such substance is permitted by federal and state laws.”<sup>59</sup> The CSA limits the amount of the controlled substance that can be imported to 50 dosage units of the controlled substance unless the individual possesses a valid prescription issued by a practitioner in accordance with federal and state law.<sup>60</sup> The general purpose of these provisions is to allow patients to only travel with medication that may be medically necessary for their health.

#### i. FDA’s Personal Importation Policy

The FDCA provides no legal exception for the importation or re-importation of unapproved drugs, regardless of whether the importer is an individual or a business. Notwithstanding the limited exception to personal re-importation from Canada located in the 2007 Department of Homeland Security Appropriations Act, personal importation or re-importation of unapproved drugs, remain illegal. In order to “best protect consumers with a reasonable expenditure of resources,” and perhaps as a recognition of the potential public backlash for punishing offenders susceptible to sympathy, the FDA maintains in its Regulatory Procedure Manual a personal import policy.<sup>61</sup> The guidelines permit FDA personnel to “use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.”<sup>62</sup> Elaborating this guidance, the manual states that:

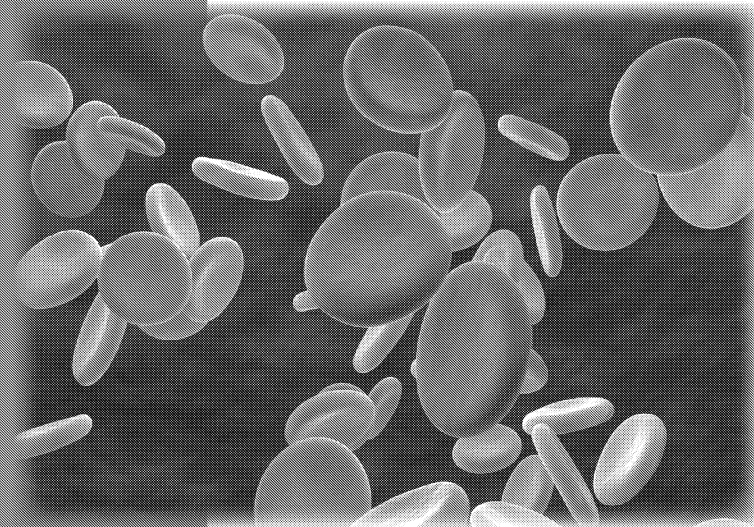
In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations: (1) when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; and (2) when a) the intended use is unapproved and *for a serious condition for which effective treatment may not be available domestically* either through commercial or clinical means; b) there is *no known commercialization or promotion* to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an *unreasonable risk*; and d) the individual seeking to import the product affirms in writing that it is *for the patient’s own use* (generally not more than 3-month supply) and provides the name and address of the doctor licensed in the U.S.

“The current enforcement environment is less restrictive as to the personal importation of unapproved drugs, perhaps because of the widely publicized toll prohibitively expensive drugs place on many Americans.”

responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.<sup>63</sup>

The guidance does not cover “commercial and promotional shipments” and lists factors such as “the type of product, accompanying literature, size, value, and/or destination of the shipment,” that may be used to distinguish between personal shipments and “commercial and promotional shipments.”<sup>64</sup>

Although the FDA’s enforcement guidelines have been said to create a de facto exemption for individual, non-commercial importation, the guidance states that it “should *not* be interpreted as a license to individuals to bring in such shipments.”<sup>65</sup> Despite its clear language, the policy contained in the guidance has been “widely misunderstood and mischaracterized as somehow allowing individuals to bring in any medicines, regardless of the otherwise-applicable import requirements.”<sup>66</sup>



#### *ii. 2007 Homeland Security Appropriations Act*

Section 535 of the 2007 Homeland Security Appropriations Act prohibits the CBP from preventing individuals “not in the business of importing a prescription drug (within the meaning of section 801(g) of the Federal Food, Drug, and Cosmetic) from importing a prescription drug *from Canada that complies with the Federal Food, Drug, and Cosmetic Act . . .*”<sup>67</sup> This section essentially permits the re-importation of drugs from Canada that would otherwise comply with FDA standards. This law does provide for important limitations for those who seek to act on this prohibition against enforcement because the section is only applicable to “individuals transporting *on their person* a personal-use of the prescription drug, *not to exceed a 90-day supply . . .*”<sup>68</sup> These

qualifications substantially limit individuals who may exploit this exception to the ban on re-importation. Only individuals who live near the American-Canadian border can benefit from this exception due to the prohibitive cost of traveling from further distances.

#### **B. Commercial Re-Importation**

There are no legal or enforcement exceptions permitting the importation of foreign-manufacturer drugs for commercial purposes. There are two conditional exceptions to the prohibition on re-importation: (1) the HHS Secretary has the authority to authorize re-importation if the “drug is required for emergency medical care;”<sup>69</sup> and (2) importation may be allowed under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).<sup>70</sup>

The Prescription Drug Marketing Act (PDMA) of 1988<sup>71</sup> amended the importation provision of the FDCA to prohibit the re-importation of a drug unless the drug is imported by the manufacturer of the drug.<sup>72</sup> The PDMA was a result of a series of hearings held in the mid-1980s by the House Committee on Energy And Commerce “aimed at illuminating flaws in the U.S. drug distribution system.”<sup>73</sup> A House oversight report encapsulated the impetus behind the passage of the PDMA:

The realities of the wholesale marketplace have combined to create a system in which a large amount of attractively priced pharmaceuticals are constantly available, some of which are not safe or effective. The physical movement, conditions of storage, and, in some cases, even the origins of much of this merchandise is unknown to the first, second, or third level buyer, who in effect plays a form of Russian roulette. This situation cannot be allowed to continue.<sup>74</sup>

In addition to amending the FDCA to prohibit re-importation by anyone other than the manufacturer of the drug, the PDMA also established minimum federal requirements for the wholesale distribution of drugs, including requiring pedigree papers for certain transactions.<sup>75</sup>

#### *i. The Re-Importation Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA)*

The MMA superseded the Medical Equity Drug Safety Act, which had similar import provisions to the MMA. The MMA, which became effective January 1, 2006, was an ambitious and comprehensive response to the high cost of drugs. Although it is

arguably incomplete and severely skewed toward the interests of drug manufactures,<sup>76</sup> it did lead to notable outcomes. The most notable outcome of the MMA was that it added Part D, the Medicare Prescription Drug Benefit, to Title XVIII of the Social Security Act. The program disperses the risk of drug cost by including private insurance plans that contract with the Federal government.<sup>77</sup> The drug coverage is provided through Medicare Advantage prescription drug plans chosen by Medicare beneficiaries.

Indeed, Medicare Part D, as it is commonly referred to, is the most substantial expansion of Medicare ever. Due to its extension of Medicare benefits to prescription drugs, research suggests that the MMA may have led to a decline in importation of drugs from Canada.<sup>78</sup> It has been alleged that the U.S. Government has strengthened enforcement against personal re-importation in order to encourage enrollment in Medicare Part D.<sup>79</sup>

The MMA provides that “The [HHS] Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.”<sup>80</sup> The MMA then provides requirements that importers and imported drugs must comply with. The MMA also contains a provision allowing the HHS Secretary to authorize waivers for individual importation: “The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.”<sup>81</sup> However, these provisions are ineffective until the “Secretary certifies to the Congress that the implementation of this section will – (A) pose no additional risk to the public’s health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer.”<sup>82</sup> To date, all HHS Secretaries since the MMA and its predecessor, the Medical Equity Drug Safety Act became effective have declined to issue certification.<sup>83</sup>

## ii. The States Respond

The re-import provisions of the MMA provides states with an uncertain legal window, but a potent political instrument to move forward with state-sponsored drug programs that would give residents access to cheaper re-imported drugs. The MMA prompted states to petition the HHS to grant waivers to permit individuals to re-import drugs from Canada and to issue a certification permitting the commercial re-importation of drugs from Canada. As mentioned before, no

waivers or certifications have been issued under MMA and its predecessor. All state efforts to have the MMA legitimize their state re-importation efforts through litigation have also failed. Despite this, states have continued to operate re-importation programs with the aid of Canadian pharmacies.<sup>84</sup>

In 2005, the Vermont Agency of Administration submitted a citizen petition to the FDA requesting that the FDA allow the Vermont State Employee Medical Benefit Plan (VTSEMBP) to “establish a program for the orderly individual importation of prescription medications.”<sup>85</sup> In the petition, the State of Vermont explained that it wanted:

Authority to contract with providers to create a system under which its members have the option of forwarding a prescription to a Canadian firm where the prescription would be reviewed by a physician familiar with the member’s medical history and re-written as a Canadian prescription, which would be forwarded to a licensed Canadian pharmacy to be filled and sent by mail to the member in the United States.<sup>86</sup>

The FDA denied this petition. In *Vermont v. Leavitt*,<sup>87</sup> Vermont alleged that the FDA’s refusal of a Vermont’s citizen’s petition was “arbitrary and capricious” in violation of the Administrative Procedure Act (APA).<sup>88</sup> Vermont utilized some creative, yet very unconvincing applications of statutory interpretation to argue that the MMA authorized their program<sup>89</sup> and challenged the constitutionality of the Act by unsuccessfully invoking the non-delegation doctrine.<sup>90</sup> The Defendants claimed that they were required to deny the petition because it proposed a drug importation program that violated federal law.<sup>91</sup> In granting the Defendant’s motion to dismiss, the Court held that the MMA could not be construed to authorize Vermont’s importation program and that the program would violate 21 U.S.C. section 331(t) by “causing” its members to import drugs in violation of 21 U.S.C. section 381(d)(1).<sup>92</sup>

A year later in *Montgomery County, Md. v. Levitt*, Montgomery County, Md. (County) requested a waiver to allow the residents of the County and its government to import drugs from Canada.<sup>93</sup> The County applied the same arguments used by Vermont, which yielded the same results.<sup>94</sup>

Undeterred, states have persisted in their efforts to facilitate the purchase of cheaper foreign drugs. The most ambitious state leader was former Illinois Governor Milord R. Blagojevich, who created the web site I-Save RX, which also serves residents of Wisconsin, Kansas, Missouri, and Vermont.<sup>95</sup> I-Save

RX uses a Canadian Pharmacy Benefit Management (PBM), which sources the drugs from Canada, Ireland, the United Kingdom, New Zealand, and Australia. “Under the program, US prescriptions and medical histories are forwarded to physicians in the supplying countries, apparently rewritten to comply with local laws, and dispensed by local, licensed pharmacists who then ship the medicine to the United States.”<sup>96</sup> The program only applies to refills and excludes most drugs that require special handling.<sup>97</sup> Former Governor Blagojevich maintains that, on average, the drugs from these countries are 25–50% less expensive than in the United States and identical to the FDA-approved counterpart in every respect other than price.<sup>98</sup>

Despite the purported savings the program offers, its aggregate impact has been minimal. Pharmaceutical companies have sought to obstruct foreign pharmacies selling to Americans by tightening oversight over their wholesale distribution<sup>99</sup> and the FDA has targeted shipments into the United States by I-Save RX.<sup>100</sup> Moreover, with 27 million eligible residents to the program, fewer than 20,000 orders were placed in its first two years of operation. Perhaps its most important (and intended) function is as a “political symbol.”<sup>101</sup>

## V. Conclusion

Despite the re-importation-friendly political environment that has likely emerged from the presidential and congressional elections, the possibility of a relaxation of restrictions on drug importation and re-importation is uncertain. As a U.S. Senator, President Barack Obama voted in favor of legislation that would permit drug re-importation.<sup>102</sup> The Senate and House of Representatives are currently in the hands of Democrats, who have been generally more receptive to re-importation than Republicans. Further, the recent credit crisis engulfing the global economy, if it precipitates a sustained economic decline, may pressure Congress to take actions to lower the cost of healthcare by passing re-importation legislation. Legislation enabling re-importation is already awaiting action in Congress.<sup>103</sup>

Yet recent events remind us of the added health risks associated with the manufacturing of drugs and other FDA regulated products that are not under the constant regulatory watch of the FDA. The deaths caused by Heparin manufactured in a Chinese facility<sup>104</sup> and the warning letters<sup>105</sup> and import alert<sup>106</sup> issued by the FDA to the largest foreign supplier of generic drugs to the United States, Ranbaxy Laboratories Ltd., for deviations from GMP in two of their facilities in India,<sup>107</sup> eroded the public’s support for re-importation. Advisors for President Obama express that the Heparin incident will make it more challenging to pass reimportation legislation.<sup>108</sup> Lastly, the influence of the pharmaceutical industry can never be underestimated. With billions of dollars at stake, American pharmaceutical companies will continue their vigorous lobbying efforts. It is thus uncertain whether the “invisible hand” will provide Americans with cheaper drugs anytime soon.

1 *Vermont State v. Leavitt*, 405 F. Supp. 2d 466, 469 (D. Vt. 2005) (explaining facts of case).

2 See Melicia Seay, *Drug Importation*, Health Policy Tracking Service (Thomson West) ¶ 3 (July 10, 2006), available at <http://www.netscan.com/EG-NSCNFS-B02/HPTFILES%5C%ISSUEBRIEFS%5CDrug1460.pdf>.

3 See *infra* Part IV(B)(ii).

4 Colleen Newvine, *Conference explores pros and cons of drug reimportation*, University of Michigan News Service, Nov. 3 2003, available at [http://www.umich.edu/~urecord/0304/Nov03\\_03/07.shtml](http://www.umich.edu/~urecord/0304/Nov03_03/07.shtml).

5 See *infra* Part IV(B).

6 See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 288 (2005).

7 See Devin Taylor, Note, *Importing a Headache for Which There’s No Medicine: Why Drug Re-importation Should and Will Fail*, 15 J.L. & POL’Y 1421, 1434 (2007).

8 See *id.* at 1434-35.

9 Jared Martin, Note, *United States Prescription Drug Crisis: Reimportation of Canadian Prescription Drugs Is Not the Answer*, 27 J. LEGAL MED. 477, 478-79 (2006).

10 Taylor, *supra* note 7, at 1435.

11 Seay, *supra* note 2, at ¶ 3.

12 Martin, *supra* note 9, at 479.

13 Matthew Bishop, *Price Discrimination* adapted from *Essential Economics* (Profile Books), available at <http://www.economist.com/research/economics/searchActionTerms.cfm?query=price+discrimination>.

14 *Id.*

15 Martin, *supra* note 9, at 479.

16 21 U.S.C. §§ 301-399 (2008); Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, *Food and Drug Law: Cases and Materials* 13 (3rd ed. 2007).

17 See HUTT, MERRILL & LEWIS, *supra* note 16, at 14-15

18 *Id.* at 15.

19 See *id.* at 13.

20 See *id.* at 14

21 See *id.*

22 See *id.*

23 See Matthew B. Van Hook, *Securing the Global Supply Chain: Evolving Federal/State Law – Prescription Drug Distribution, Counterfeit, Pedigree Requirements, and the Internet*, in PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES 917-18 (Practicing Law Institute 2006).

24 See *id.* at 918.

25 21 U.S.C. § 351(a) (2008).

26 See *Leavitt*, 405 F. Supp. 2d at 473.

27 21 U.S.C. § 331 (2008); Van Hook, *supra* note 23, at 918.

28 *Leavitt*, 405 F. Supp. 2d at 473; see 21 U.S.C. §§ 331(a), (d) (2008).

29 21 C.F.R. § 201.100(a)(1)(i) (2009).

30 See Van Hook, *supra* note 23, at 919.

31 A pedigree is a “statement . . . identifying each prior sale, purchase, or trade of such drug (including the date of transaction and the names and addresses of all parties to the transaction), *id.* at 915 (citing 21 U.S.C. § 353(e)(1)(A) (2008)).

32 See *id.* at 919.

33 See *generally* Part II.A.i.

34 Food and Drug Administration, FDA and the Drug Development Process: How the Agency Ensures That Drugs are Safe and Effective (2002), available at <http://www.fda.gov/opacom/factsheets/justthefacts/17drgdev.pdf>.

35 See *id.*

36 See *id.*

37 See *id.*

38 See Food and Drug Administration Center for Drug Evaluation and Research, New Drug Application (NDA) Process, <http://www.fda.gov/cder/regulatory/applications/nda.htm> (last visited Feb. 9, 2009).

39 See *id.*

40 Food and Drug Administration Center for Drug Evaluation and Research, Generic Drugs: Questions and Answers, [http://www.fda.gov/cder/consumerinfo/generics\\_q&a.htm#whatare](http://www.fda.gov/cder/consumerinfo/generics_q&a.htm#whatare) (last visited Feb. 9, 2009) (explaining distinctions between generic and brand-name drugs).

41 Food and Drug Administration Center for Drug Evaluation and Research, Abbreviated New Drug Application (ANDA) Process for Generic Drugs, <http://www.fda.gov/cder/regulatory/applications/ANDA.htm> (last visited Feb. 9, 2009).

42 See 21 U.S.C. § 381(a) (2008).



- 43 Christine M. Humphrey, Note, *The Food and Drug Administration's Import Alerts Appear to be "Misbranded"*, 58 FOOD & DRUG L.J. 595, 597 (2003).
- 44 See *id.* at 597.
- 45 See *id.* at 597-98; see also 21 U.S.C. § 381(a) ("If it appears from the examination or otherwise...").
- 46 See 21 U.S.C. § 381(a).
- 47 See Food and Drug Administration, Office of Regulatory Affairs, Regulatory Procedures Manual, Ch. 9-6 "Detention without Physical Examination (DWPE)," available at [http://www.fda.gov/ora/compliance\\_ref/rpm/chapter9/ch9-6.html](http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-6.html).
- 48 See Humphrey *supra* note 43 at 595.
- 49 See *Sugarman v. Forbragd*, 405 F.2d 1189, 1190 (9th Cir. 1968) (involving an action to review FDA refusal to admit coffee beans offered for import).
- 50 21 C.F.R. § 1.94(a) (2008).
- 51 *Sugarman v. Forbragd*, 267 F. Supp. 817, 824 (N.D. Cal. 1967).
- 52 American-manufactured drugs that comply with FDA standards, but that cannot be imported because of the express ban on reimportation and foreign drugs manufactured abroad, will be referred to collectively as unapproved unless referred to individually.
- 53 DEP'T OF HEALTH & HUMAN SERVS., TASK FORCE ON DRUG IMPORTATION, REPORT ON PRESCRIPTION DRUG IMPORTATION ix (2004), available at <http://archive.hhs.gov/importtaskforce/Report1220.pdf>.
- 54 See *infra* Part IV(B).
- 55 See e.g., Katie Merx, *Canadian Drugs Beat Medicare, Many Say*, DETROIT FREE PRESS, Apr. 6, 2006, available at [http://www.redorbit.com/news/health/460473/canadian\\_drugs\\_beat\\_medicare\\_many\\_say\\_seniors\\_us\\_plan\\_not/index.html](http://www.redorbit.com/news/health/460473/canadian_drugs_beat_medicare_many_say_seniors_us_plan_not/index.html).
- 56 Food and Drug Administration, Office of Regulatory Affairs, Regulatory Procedures Manual, Ch. 9-2 "Coverage of Personal Importation," available at [http://www.fda.gov/ora/compliance\\_ref/rpm/chapter9/ch9-2.html](http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-2.html) [hereinafter *Manual*]; see Terry, *Prescriptions sans Frontières*, *supra* note 59, at 272 n. 129 (characterizing the enforcement guidelines found in the manual as a de facto exemption for personal importation from the general prohibition on drug importation and re-importation).
- 57 Department of Homeland Security Appropriations Act of 2007, Pub. L. No. 109-295 § 535 (2008).
- 58 Nicolas P. Terry, *Prescriptions Sans Frontières (or How I Stopped Worrying About Viagra on the Web but Grew Concerned About the Future of Healthcare Delivery)*, 4 YALE POL'Y L. & ETHICS 183, 203-4 (2004).
- 59 Terry, *Prescriptions sans Frontières*, *supra* note 56, at 205 (citing 21 U.S.C. § 956(a) (2008)). 21 U.S.C. § 956(a) (2008).
- 60 *Id.* § 956(a)(2); see Terry *supra* note 56 at 204.
- 61 *Manual*, *supra* note 56.
- 62 *Id.*
- 63 *Id.* (emphasis added).
- 64 *Id.*
- 65 *Id.* see Terry, *Prescriptions sans Frontières*, *supra* note 56, at 272 n. 129 (characterizing the enforcement guidelines found in the manual as a de facto exemption for personal importation from the general prohibition on drug importation and re-importation).
- 66 Van Hook, *supra* note 23, at 921.
- 67 Department of Homeland Security Appropriations Act of 2008, § 535 (emphasis added).
- 68 *Id.* (emphasis added).
- 69 21 U.S.C. § 381(d)(2).
- 70 Pub. L. No. 108-173, 117 Stat. 2066.
- 71 Pub. L. No. 100-293, 102 Stat. 95.
- 72 21 U.S.C. § 381(d)(1) ("Except as provided in paragraph (2) and section 384 of this title, no drug subject to section 353(b) of this title or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.")
- 73 Van Hook, *supra* note 23, at 914.
- 74 *Id.* (quoting) (*Dangerous Medicine: The Risk to American Consumers From Prescription Drug Diversion and Counterfeiting*, 99th Cong., 2nd Sess., p. 20 (Comm. Print 99-Z 1986) (Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Hon. John D. Dingell, Chairman)).
- 75 *Id.*
- 76 Martin, *supra* note 9, at 484.
- 77 *Id.* at 483
- 78 See Martin, *supra* note 9, at 484.
- 79 *Id.*
- 80 21 U.S.C. § 384(b) (2008).
- 81 *Id.* § 384(j)(2).
- 82 *Id.* § 384(1)(1).
- 83 *Montgomery County, Md. v. Leavitt*, 445 F. Supp. 2d 505, 510 (S. Div. Md. 2006).
- 84 *Id.*
- 85 *Vermont*, 405 F. Supp. 2d at 469-70.
- 86 *Id.* at 471.
- 87 *State v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005).
- 88 *Id.* at 470.
- 89 *Id.* at 474 ("Vermont relies on a highly implausible interpretation of the statute.").
- 90 *Id.* at 475.
- 91 *Id.* at 474.
- 92 See 21 U.S.C. § 331 ("The following acts and the causing thereof are prohibited:").
- 93 *Leavitt*, 445 F. Supp. 2d at 507.
- 94 See *id.* at 516.
- 95 Nicolas P. Terry, *Under-Regulated Health Care Phenomena in a Flat World: Medical Tourism and Outsourcing*, 29 W. New Eng. L. Rev. 421, 450 (2007) [hereinafter *Medical Tourism and Outsourcing*].
- 96 *Id.* at 450.
- 97 *Id.*
- 98 See Martin *supra* note 9, at 486.
- 99 See, e.g., Bernard Simon, *Pfizer Moves To Try To Stop Drugs from Canada*, N.Y. TIMES, Jan. 14, 2004, at W1, available at 2004 WLNR 5507399 (Westlaw); Fearing End to Canada Drugs, States Now Look to Europe, USA Today, Jan. 14, 2005, available at [http://www.usatoday.com/news/health/2005-01-14-drugs-europe\\_x.htm](http://www.usatoday.com/news/health/2005-01-14-drugs-europe_x.htm).
- 100 FDA: Seizes Shipments Imported Through I-Save Rx Program, Am. Health Line, Mar. 10, 2005, available at [http://www.lexisnexis.com/lawschool/research/default.aspx?ORIGINATION\\_CODE=00092&signoff=off](http://www.lexisnexis.com/lawschool/research/default.aspx?ORIGINATION_CODE=00092&signoff=off).
- 101 *Medical Tourism and Outsourcing*, *supra* note 102, at 451.
- 102 See generally Jeffrey Young, *Biotech industry not seeing much difference between McCain, Obama*, The Hill, Sept. 8, 2008 available at [http://thehill.com/business--lobby/biotech-industry-not-seeing-much-difference-between-mccain-obama-2008-09-08\\_2.html](http://thehill.com/business--lobby/biotech-industry-not-seeing-much-difference-between-mccain-obama-2008-09-08_2.html).
- 103 See Pharmaceutical Market Access and Drug Safety Act of 2007 S.242, 110th Cong. (2007); See Drug and Device Accountability Act of 2008 S.3409, 110th Cong (2008).
- 104 *McCain and Obama Rethink Drug Importation*, Legal Broadcast Network., Oct. 1, 2008. Available at <http://blog.legalbroadcastnetwork.com/the-lbn-blog/2008/10/1/mccain-and-obama-rethink-drug-importation.html>.
- 105 See 21 C.F.R. § 100.2 (2008) ("Informal enforcement actions include warning letters . . .").
- 106 See *supra* Part III.a.ii.
- 107 *FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India*, U.S. Food and Drug Administration, Sept. 16, 2008, available at <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01886.html>.
- 108 *McCain and Obama Rethink Drug Importation*, Legal Broadcast Network., Oct. 1, 2008. Available at <http://blog.legalbroadcastnetwork.com/the-lbn-blog/2008/10/1/mccain-and-obama-rethink-drug-importation.html>.