

2008

## Importing a Headache for Which There's No Medicine: Why Drug Reimportation Should & Will Fail

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### Recommended Citation

Devin Taylor, *Importing a Headache for Which There's No Medicine: Why Drug Reimportation Should & Will Fail*, 15 J. L. & Pol'y (2007).  
Available at: <https://brooklynworks.brooklaw.edu/jlp/vol15/iss3/14>

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## **IMPORTING A HEADACHE FOR WHICH THERE'S NO MEDICINE: WHY DRUG REIMPORTATION SHOULD AND WILL FAIL**

*Devin Taylor\**

### INTRODUCTION

On Canusa Avenue houses on one side of the street are in Canada while houses right across the street are in Beebe Plain, Vermont.<sup>1</sup> When the Canadian residents of Canusa Avenue need medication for high cholesterol they can purchase a ninety-day supply of twenty milligram Lipitor for one hundred seventy dollars.<sup>2</sup> On the other side of the street, the very same supply costs the Vermont residents approximately three hundred thirty dollars in the United States.<sup>3</sup>

This astonishing price difference is illustrative of the realities of the modern marketplace: United States citizens are paying between 35% and 55% more for brand name prescription drugs than people around the world.<sup>4</sup> Canada's Patented Medicines

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\* Brooklyn Law School Class of 2008; B.A. Wake Forest University, 2002. The author wishes to thank his parents Brian and Jackie Taylor and brother, Kyle Taylor for their love and support. He would also like to thank Doris Lane, Dr. Paul Orser and his friends for their encouragement and guidance over many years. Many thanks to the members of the Brooklyn Journal of Law and Policy, particularly Leon Yel, Heather Maly, Stephen Blank and Lee Jacobs.

<sup>1</sup> Vermont v. Leavitt, 405 F. Supp. 2d 466, 469 (D. Vt. 2005).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> Melicia Seay, *Drug Importation: Health Policy Tracking Service Issue*

Price Review Board (“PMPRB”) estimated that Americans pay 67% more for brand name drugs than Canadians.<sup>5</sup> Additionally, one estimate suggests that U.S. consumers would have saved \$59.7 billion had they purchased all their brand name prescription drugs at Canadian prices in 2004.<sup>6</sup> In perspective, that amount exceeds the combined gross national products of Kuwait, Iceland and Jamaica.<sup>7</sup>

The extreme price difference has created problems for Americans who often ration drugs instead of taking the prescribed dosage or choose between purchasing the drugs they need and other necessities.<sup>8</sup> Understandably, many Americans are upset about having to make these difficult choices, while Canadian neighbors can purchase the very same drugs at a fraction of the price.

This reality is especially frustrating considering many of these drugs were manufactured in the United States and produced by U.S. pharmaceutical companies.<sup>9</sup> Logically, this outrage has turned to ingenuity as many Americans are buying drugs from Canada to the dismay of the Food and Drug Administration (“FDA”).<sup>10</sup> In 2003 “nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately \$700 million entered the U.S. from Canada.”<sup>11</sup>

The federal government needs to address soaring drug prices in order to make prescription drugs affordable for the entire

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*Brief*, Health Policy Tracking Service (Thomson West), July 10, 2006 at 1, available at <http://www.netscan.com/EG-NSCNFS-B02/HPTSFILES%5CISSEBRIEFS%5CDrug1460.pdf>.

<sup>5</sup> *Id.*

<sup>6</sup> *Vermont*, 405 F. Supp. at 469.

<sup>7</sup> *Id.*

<sup>8</sup> See *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505, 507 (D. Md. 2006).

<sup>9</sup> Seay, *supra* note 4, at 2.

<sup>10</sup> *Id.*

<sup>11</sup> HHS Task Force on Drug Importation, Report on Prescription Drug Importation, ix (Dec. 2004), <http://www.hhs.gov/importtaskforce/Report1220.pdf>.

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citizenry. One potential course of action that has been the subject of debate is drug reimportation. Drug reimportation “involves people in this country 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>12</sup> However, drug reimportation from foreign countries is not the appropriate solution to escalating drug prices.

This note will explore and identify the reasons that meaningful drug reimportation legislation will not pass, as well as the reasons that a reimportation plan would be unsuccessful. Part I of this note will explore current federal statutes, including state response to the perceived failings of the federal government and litigation involving drug reimportation and the authority of the Secretary of Health and Human Services (“HHS”) under the Federal Food Drug and Cosmetics Act (“FDCA”). Part II deals with the reasons for the drastic price differences between the United States and Canada. Part III explores the FDA’s regulatory regime and examines the dangers of bringing drugs from foreign sources into the United States, as well as the steps the FDA has taken to enforce the law. Part IV discusses State experiences with drug reimportation and the shortcomings that have been identified. Part V investigates the strength of the pharmaceutical lobby, its resources and manpower as well as its ability to get results that favor drug companies. Finally, Part VI will explore the current state of the law and potential changes in the future.

## I. DRUG REIMPORTATION AND THE LAW

The federal government, through a series of statutes has created a system that makes it impossible for prescription drugs to be imported into the United States without the consent of the

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<sup>12</sup> Colleen Newvine, *Conference explores pros and cons of drug reimportation*, University of Michigan News Service (2003), [http://www.umich.edu/~urecord/0304/Nov03\\_03/07.shtml](http://www.umich.edu/~urecord/0304/Nov03_03/07.shtml).

HHS Secretary.<sup>13</sup> The past three HHS Secretaries have refused to allow drug reimportation<sup>14</sup> and courts have unequivocally upheld the ability of the HHS Secretary to deny importation.<sup>15</sup> In response to rising drug costs and the federal government's current unwillingness to act, some state governments have initiated importation programs for their citizens, creating tension with federal agencies.<sup>16</sup> Ultimately this tension has surfaced in litigation where courts have uniformly endorsed the authority of the federal government in this matter.<sup>17</sup>

*A. Federal Law*

The current law, under the FDCA, allows only drug manufacturers to import prescription drugs that were originally manufactured in the United States back into this country.<sup>18</sup> There are two exceptions to this rule:<sup>19</sup> (1) the HHS Secretary has the ability to authorize importation for emergency use;<sup>20</sup> and (2) importation may be allowed under the Medicare Modernization Act's ("MMA") importation provision.<sup>21</sup> The MMA has a provision authorizing the HHS Secretary to "promulgate regulations" allowing importation of prescription drugs into the United States from Canada.<sup>22</sup> Furthermore, the MMA states that the HHS 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

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<sup>13</sup> See discussion *infra* Part I.A.

<sup>14</sup> *Id.*

<sup>15</sup> See *infra* Part I.C.

<sup>16</sup> See *infra* Part I.B.

<sup>17</sup> See *infra* Part I.C.

<sup>18</sup> 21 U.S.C. § 381(d)(1) (2006).

<sup>19</sup> 21 U.S.C. § 381(d)(2); Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 804(b) (2003).

<sup>20</sup> 21 U.S.C. § 381(d)(2).

<sup>21</sup> Pub. L. No. 108-73, § 804(b).

<sup>22</sup> *Id.*

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the Secretary determines to be appropriate.”<sup>23</sup> For either of these exceptions, the Secretary must certify to Congress that implementation “will pose no additional risk to the public’s health and safety; and result in significant reduction in the cost of covered products to the American consumer.”<sup>24</sup>

The MMA replaced the Medicine Equity and Drug Safety Act of 2000<sup>25</sup> (“MEDS Act”), which likewise allowed the HHS Secretary “to pass regulations allowing commercial importation of prescription drugs.”<sup>26</sup> The MEDS Act also conditioned importation on a certification to Congress by the HHS Secretary. Neither former HHS Secretary Donna Shalala, under President Bill Clinton, nor former Secretary Tommy Thompson, under President George W. Bush, approved certification for any prescription drug.<sup>27</sup> Likewise, current HHS Secretary, Michael Leavitt, has refused to issue a certification under the MMA.<sup>28</sup>

Moreover, the FDCA establishes a “closed” system where “the FDA regulates the manufacture, marketing and labeling of drugs sold in the United States.”<sup>29</sup> Any drugs not manufactured according to the FDA’s current “good manufacturing practice” (“cGMP”) per the FDCA are not allowed into interstate commerce.<sup>30</sup> Unless a drug meets all U.S. packing, labeling and dosage requirements it will not be approved, even if it is a foreign version of an FDA approved drug.<sup>31</sup> Thus the FDCA is designed to keep pharmaceutical drugs within the closed system, monitored by the FDA.

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<sup>23</sup> Pub. L. No. 108-73, § 804(j)(2)(A).

<sup>24</sup> Pub. L. No. 108-73, § 804(l)(1).

<sup>25</sup> Medicine Equity and Drug Safety Act of 2000, Pub. L. No. 106-387 (2000).

<sup>26</sup> Vermont v. Leavitt, 405 F. Supp. 2d 466, 474 (D. Vt. 2005).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 473.

<sup>30</sup> 21 U.S.C. § 351(a) (2006).

<sup>31</sup> See 21 U.S.C. § 331(a),(d) (2006).

*B. State Response*

Due to the federal government's perceived inability to make progress in reducing the price of prescription drugs, many state governments have decided to enter the Canadian market.<sup>32</sup> Some have even created websites linking to Canadian pharmacies so that state residents can fill prescriptions at Canadian prices.<sup>33</sup> In February 2004, Minnesota became the first to create such a website, and by the end of the same year, eight other states had followed.<sup>34</sup> Eleven states<sup>35</sup> and the District of Columbia now have such websites.<sup>36</sup> Illinois Governor Rod Blagojevich has been, perhaps, the most aggressive participant in the drug reimportation debate. In 2004, Blagojevich and Wisconsin Governor Jim Doyle started the I-SaveRx program<sup>37</sup> which permits Illinois and Wisconsin residents access to less expensive prescription drugs from Canada, Ireland and the United Kingdom via a website and telephone number.<sup>38</sup> The program utilizes CanaRx, "a pharmacy benefits manager that operates a network of online pharmacies,"<sup>39</sup> to offer drug information from nearly sixty pharmacies in Canada, Ireland and the United Kingdom for approximately one hundred twenty commonly prescribed drugs.<sup>40</sup>

Prior to the unveiling of I-SaveRx, Blagojevich

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<sup>32</sup> Seay, *supra* note 4, at 5.

<sup>33</sup> *Id.*

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

<sup>35</sup> Minnesota, Wisconsin, New Hampshire, North Dakota, Rhode Island, Illinois, Washington, Missouri, Vermont, Nevada and Kansas offer access to imported drugs to their residents via the internet. Melicia Seay, *Drug Importation: Health Policy Tracking Service Issue Brief*, Health Policy Tracking Service (Thomson West), Jan. 8, 2007 at 6, available at <http://www.netscan.com/EG-NSCNFS-B02/HPTFILES%5CISISSUEBRIEFS%5CDrug1680.pdf>.

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

<sup>37</sup> <http://www.i-saverx.net/>

<sup>38</sup> Seay, *supra* note 4, at 5-6.

<sup>39</sup> *Id.* at 6.

<sup>40</sup> *Id.*

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commissioned a study on the potential cost savings associated with drug reimportation.<sup>41</sup> The results of the study indicated that the state could develop a system with “safety checks equal to or greater than Illinois’ current pharmaceutical system and achieve savings of up to \$90.7 million.”<sup>42</sup> In fact Blagojevich said “we suspected that the Canadian procedures for distributing, labeling and handling prescription drugs were safe, but we didn’t expect them in some cases to be even safer than the procedures we use here in the United States.”<sup>43</sup> Additionally Blagojevich charged, “it’s time the FDA stops protecting the big drug companies, it’s time they start helping people.”<sup>44</sup>

However, a major problem with these state initiatives is that they may be unreliable. For example, during the first two weeks of February 2005, only a few months after the launch of I-SaveRx, the FDA blocked over 25% of the shipments from Canadian pharmacies to U.S. consumers purchased thru the I-SaveRx program.<sup>45</sup> The FDA maintains that current law, under the FDCA, allows only drug manufacturers to import prescription drugs that were originally made in the United States.<sup>46</sup> According to the FDA, “the law was designed to facilitate a closed drug distribution system to ensure that the domestic drug supply is safe and effective.”<sup>47</sup> Although the FDA has not yet initiated a lawsuit against any of the states, the FDA has seized shipments from Canada intended for U.S. consumers.<sup>48</sup> Thus this conflict may create disincentives to

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<sup>41</sup> Press Release, Office of the Governor, Blagojevich releases much-anticipated report on feasibility and savings of prescription drug importation (Oct. 27, 2003) (on file with author), <http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=3&RecNum=2346>.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> Seay, *supra* note 4, at 6.

<sup>46</sup> *Id.* at 1.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 6 (citing that “during the first two weeks of February 2005, the FDA blocked more than 25 percent of prescription drug shipments purchased by U.S. residents from Canada through the I-SaveRx program.”).



utilize the programs.

Additionally, the state solution is inadequate because consumers in thirty-nine states do not have access to such programs.<sup>49</sup> Many state governors oppose programs such as I-SaveRx because they violate federal law, but others are distressed by the fact that initiating such programs could make the state liable for its failings.<sup>50</sup> After vetoing a series of bills approved by the California state legislature that would have created a web site linking California residents to Canadian pharmacies, California Governor Arnold Schwarzenegger<sup>51</sup> said: "Importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the state to civil, criminal and tort liability."<sup>52</sup> Therefore, while state action has been influential in bringing the concerns surrounding drug reimportation to the foreground, it has not yielded permanent solutions that can be enjoyed by the entire citizenry.

### C. Judicial Review

By including provisions for the possibility of drug reimportation, the MMA may have provided hope for those in favor of reimportation. However, in practice these provisions have achieved little since courts have given great deference to the findings of the HHS Secretary and have been unwilling to subject the Secretary's findings or the FDA's enforcement to

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<sup>49</sup> *Id.* at 7.

<sup>50</sup> Seay, *supra* note 4, at 8.

<sup>51</sup> In 2006, Governor Schwarzenegger changed his position, writing a letter asking Congress to relax federal barriers to buying drugs from foreign countries. Critics have speculated that Schwarzenegger's new position is political posturing and not his true feelings on the issue. Melicia Seay, *Drug Importation: Health Policy Tracking Service Issue Brief*, Health Policy Tracking Service (Thomson West), Oct. 2, 2006 at 14, available at <http://www.netscan.com/EG-NSCNFS-B02/HPTFILES%5CISUEBRIEFS%5CDrug1558.pdf>.

<sup>52</sup> *Id.* at 8.

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judicial review.<sup>53</sup> In *United States v. Rx Depot, Inc.*<sup>54</sup> the United States District Court of Oklahoma supported the FDA's finding that Rx Depot was illegally importing drugs from Canada. Meanwhile, in both *Vermont v. Leavitt*<sup>55</sup> and *Montgomery County v. Leavitt*,<sup>56</sup> courts upheld the discretion of the HHS Secretary in granting or denying states' waivers allowing drug importation.<sup>57</sup>

In *Rx Depot*, the United States District Court of Oklahoma issued an injunction against Rx Depot, Inc., an organization operating to assist U.S. citizens in purchasing drugs from Canada.<sup>58</sup> This organization had nearly 85 storefronts throughout the United States and served around 800 customers per day.<sup>59</sup> Customers were able to mail or fax their medical history, a prescription and other documents to one of the storefronts, and an employee would then send the information and the customer's credit card information to a Canadian pharmacy.<sup>60</sup> A Canadian doctor would then write a new prescription which would be filled in Canada and shipped to the U.S. customer.<sup>61</sup> The owners of Rx Depot would receive between a ten and twelve percent commission on each order.<sup>62</sup> The court affirmed the FDA's finding that this organization violated U.S. law each time it imported prescription drugs from Canada.<sup>63</sup> Moreover the court supported the FDA's use of

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<sup>53</sup> *Andrews v. United States Dep't of Health and Human Services*, 2005 U.S. Dist. LEXIS 5710, at 9 (D.D.C. 2005); *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 475 (D. Vt. 2005); *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505, 513 (D. Md. 2006).

<sup>54</sup> 290 F. Supp. 2d 1238, 1252 (N.D. Okla. 2003).

<sup>55</sup> *Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005).

<sup>56</sup> *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505 (D. Md. 2006).

<sup>57</sup> 405 F. Supp. 2d at 474; 445 F. Supp. 2d at 512.

<sup>58</sup> *Rx Depot*, 290 F. Supp. 2d 1238, 1240.

<sup>59</sup> *Id.* at 1240.

<sup>60</sup> *Id.* at 1240-41.

<sup>61</sup> *Id.* at 1241.

<sup>62</sup> *United States v. Rx Depot*, 290 F. Supp. 2d 1238, 1241 (N.D. Okla. 2003).

<sup>63</sup> *Id.* at 1245.

discretion in selectively enforcing illegal drug reimportation due to the Agency's limited resources.<sup>64</sup>

Additionally, courts have denied states the opportunity to legally import drugs into the U.S.<sup>65</sup> In *Vermont v. Leavitt*, the state of Vermont brought suit against HHS Secretary Michael Leavitt because Leavitt denied Vermont's petition to initiate a state run importation program in which prescriptions would be forwarded 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>66</sup> The impetus for the lawsuit was Vermont's concerns about the number of citizens already importing drugs from nearby Canada and the safety of individual citizens bringing home drugs from across the border.<sup>67</sup> The state believed that it would be better equipped to deal with the safety issues than individual citizens and complained that the state does not "have the opportunity to intervene to minimize the risks associated with prescription medications obtained outside the U.S."<sup>68</sup>

The *Vermont* court agreed with the court in *Rx Depot*<sup>69</sup> that this is an issue for Congress, saying "to the precise question at issue,"<sup>70</sup> the court "must give effect to the unambiguously expressed intent of Congress."<sup>71</sup> In interpreting the intent of Congress, the court did not equivocate, saying "[g]iven the legislative history, it is difficult to escape the conclusion that Congress expected the importation provisions of the MMA

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<sup>64</sup> *Id.* at 1249 (finding that this ruling was in response to RxDepot's claim that the FDA was being "unconstitutionally selective" in its enforcement of the FDCA).

<sup>65</sup> *Vermont v. Leavitt*, 405 F. Supp. 2d at 470.

<sup>66</sup> *Id.* at 471.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *United States v. Rx Depot*, 290 F. Supp. 2d 1238, 1245 (N.D. Okla. 2003).

<sup>70</sup> *Vermont v. Leavitt*, 405 F. Supp. 2d at 470.

<sup>71</sup> *Id.*

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would never be implemented.”<sup>72</sup> In finding against Vermont, the court concluded that Vermont’s proposed program was illegal and that based on the MEDS Act and the MMA it is clear that certification of drug reimportation depends solely on the discretion of the HHS Secretary.<sup>73</sup>

In 2006, in *Montgomery County v. Leavitt*, Montgomery County, Maryland sought a waiver from the FDA, under the MMA, allowing its residents to import drugs from Canada.<sup>74</sup> Unlike the claim from Vermont,<sup>75</sup> Montgomery County claimed it was entitled to a waiver simply because its residents were paying too much money for prescription drugs.<sup>76</sup> In a letter to HHS Secretary Mike Leavitt, County Executive Douglas Duncan claimed that residents of the county were forced to “‘choose between their health and putting food on the table’”<sup>77</sup> and that it is “fundamentally unfair that people living in Canada pay a fraction of what Americans pay for the same prescription.”<sup>78</sup>

The FDA denied the waiver application on the basis that it would be virtually impossible for a foreign wholesaler to meet all the requirements of the FDCA.<sup>79</sup> Moreover, the Agency felt that it would be deceptive and dangerous to allow the importation of drugs that American consumers believed to have originated in Canada, when actually many of these drugs “originate from other countries such as India and Costa Rica.”<sup>80</sup>

In addition, Montgomery County claimed that since the FDA had often failed to enforce provisions of the FDCA the result is a de facto waiver for drug reimportation.<sup>81</sup> Once again, the court disagreed and found that the FDA has “absolute

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<sup>72</sup> *Id.* at 478.

<sup>73</sup> *Id.* at 478-79.

<sup>74</sup> *Id.* at 507.

<sup>75</sup> *Vermont v. Leavitt*, 405 F. Supp. 2d at 470.

<sup>76</sup> *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505, 507 (D. Md. 2006).

<sup>77</sup> *Id.*

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

<sup>79</sup> *Id.* at 508.

<sup>80</sup> *See id.* at 507.

<sup>81</sup> *Id.* at 512.

discretion” whether or not to prosecute or enforce a particular provision.<sup>82</sup> Furthermore, the court affirmed the HHS Secretary’s sole discretion as to whether to grant waivers and stated that based on the language of the legislation there is no issue for judicial review.<sup>83</sup> The *Montgomery County* court, like the court in *Vermont v. Leavitt*, found that changes to drug reimportation must be made by Congress since the HHS Secretary’s actions were in accordance with all relevant legislation.<sup>84</sup> Significantly, these cases solidified the role of the FDA and the HHS Secretary as the gatekeepers to drug reimportation.

## II. WHY IS THERE A PRICE DIFFERENTIAL?

There are several reasons why brand name prescription drugs are more expensive in the United States, though experts disagree on which reasons wield the most influence.<sup>85</sup> Drug companies often cite “research and development” of new drugs as the most important reason for soaring drug prices.<sup>86</sup> In 2001, brand name drug companies spent over \$30 billion on research and development.<sup>87</sup> Although developing even one new drug takes an average of eleven years and costs over \$800 million, an independent study showed that 65% of the new drugs approved by the FDA from 1989 to 2000 “contained active ingredients already present in products available on the market,”<sup>88</sup> which indicates “that the industry has not introduced many new and innovative drugs to the market.”<sup>89</sup>

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<sup>82</sup> *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505, 512 (D. Md. 2006).

<sup>83</sup> *Id.* at 514.

<sup>84</sup> *Id.* at 516.

<sup>85</sup> Farin Khosravi, *Price Discrimination in the United States: Why Are Pharmaceuticals Cheaper in Canada and Are Americans Seizing Opportunities Across the Border?*, 9 L. & BUS. REV. AM. 427, 429 (2003).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

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Advertising poses another significant expense for pharmaceutical companies.<sup>90</sup> The average pharmaceutical manufacturer spends 27% of their total revenues on “marketing, advertising and administration.”<sup>91</sup> Most companies commit a greater number of employees to marketing than to research activities.<sup>92</sup> For example, the top nine brand name drug manufacturers employed on average 81% more people in their marketing departments than in research and development.<sup>93</sup> Moreover from 1995 to 2000, “research personnel in these nine companies declined by 2 percent, while marketing staff increased by 59 percent.”<sup>94</sup>

Executives in pharmaceutical companies are also often paid significantly more than their counterparts in other industries.<sup>95</sup> In 2001 the average annual income of the highest paid executive at the nine major pharmaceutical manufacturers was nearly \$21 million, not including unexercised stock options which averaged \$48 million in 2001 alone.<sup>96</sup>

Further, pharmaceutical manufacturers are required to give a 24% discount to the four largest federal customers<sup>97</sup> and drug manufacturers are similarly mandated to give discounts to Medicaid per the Omnibus Reconciliation Act of 1990 (“OBRA”).<sup>98</sup> These discounts shift the cost to other consumers via increased prices as the manufacturers look to recover lost profits from their discounted sales.<sup>99</sup>

American consumers face the additional obstacle created by price regulation policies of foreign countries, including Canada.<sup>100</sup> In order to control drug prices some countries will

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<sup>90</sup> Khosravi, *supra* note 85, at 431.

<sup>91</sup> *Id.* at 430.

<sup>92</sup> *Id.* at 430-31.

<sup>93</sup> *Id.* at 431.

<sup>94</sup> *Id.*

<sup>95</sup> Khosravi, *supra* note 85, at 431.

<sup>96</sup> *Id.*

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

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> Khosravi, *supra* note 85, at 432.

regulate the cost of drugs.<sup>101</sup> Often those countries will negotiate prices directly with the drug manufacturers that are significantly less expensive than what the American consumer is paying.<sup>102</sup> Particularly frustrating about this policy to many Americans is that they feel as though they are subsidizing the cost of prescription drugs of other countries.<sup>103</sup>

In fact, price controls are just one of the techniques the Canadian government has used to regulate the price of drugs within their borders.<sup>104</sup> In the 1960's Canada had some of the highest drug prices of any country.<sup>105</sup> In response to soaring prices the Canadian government created a regulatory scheme that allowed generic drugs into the marketplace prior to the expiration of the drug patent.<sup>106</sup> Amid criticism that this scheme did not allow drug companies to recover their costs for research and development, the Canadian legislature, in 1987, "passed Bill C-22, which gave the Canadian patent-holder an exclusive right to market the drug for the first seven years of the patent term."<sup>107</sup> Then in 1993, Canada implemented Bill C-91 which extended the patent term from seven to twenty years.<sup>108</sup>

Bill C-22 created the Patented Medicine Prices Review Board (PMPRB) "to enforce price controls on patented medicines."<sup>109</sup> The PMPRB is an independent arm of the government that has the ability to "investigate and regulate excessive pricing" of patented pharmaceutical drugs.<sup>110</sup> According to Bob Nakagawa, Assistant Deputy Minister, Pharmaceutical Services for the British Columbia Ministry of Health, the prices of all drugs must fit within a specific range

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

<sup>102</sup> *Id.*

<sup>103</sup> See discussion *supra* Part I.C.

<sup>104</sup> Khosravi, *supra* note 85, at 433.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> Khosravi, *supra* note 85, at 433.

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

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determined by the PMPRB.<sup>111</sup> Moreover, the PMRRB monitors drug prices and has the power to lower prices and levy fines to those charging excessive rates.<sup>112</sup> A drug in a “new class” cannot be sold at a price that exceeds the median price for the same drug in seven countries.<sup>113</sup> For drugs that fall into an existing class, a manufacturer cannot set the price higher than what is currently being charged in Canada.<sup>114</sup> Prices can be raised on a yearly basis, but only at a rate that is in proportion to the Consumer Price Index.<sup>115</sup>

### III. THE FDA’S ROLE IN PROVIDING SAFE DRUGS

The evolution of federal policy on the regulation of pharmaceutical drugs in the United States began in 1939 in response to numerous incidents of unsafe drugs infiltrating the country.<sup>116</sup> Congress responded by directing the FDA to create a regulatory scheme that would ensure that Americans were not receiving drugs that would cause harm.<sup>117</sup> Fifteen years later Congress expanded the scheme to ensure that the drugs were effective as well.<sup>118</sup> Today, the United States has what has been called the “gold standard” for allowing only drugs that are safe and effective within its borders.<sup>119</sup>

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<sup>111</sup> Bob Nakagawa, *Why Canadians Pay Less for Brand-Name Drugs and More for Generics*, AARP RX WATCHDOG REPORT, Jan.-Feb. 2007, at 3.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* The seven countries are: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. *Id.*

<sup>114</sup> *Id.*

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

<sup>116</sup> *Buyer Beware: The Danger of Purchasing Pharmaceuticals Over the Internet: Hearing Before the Permanent Subcomm. on Investigations of the S. Comm. On Governmental Affairs*, 108<sup>th</sup> Cong. 227 (2004) [hereinafter *Hearings*] (statement of John M. Taylor, III Associate FDA Comm’r for Regulatory Affairs), available at <http://www.fda.gov/ola/2004/importeddrugs0722.html>.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Statement of the U.S. Food and Drug Administration Before the Nevada State Board of Pharmacy*, (2006), available at <http://www.fda.gov/>



*A. Federal Regulatory System*

Under the current regulatory system the FDA and state officials oversee every step of drug manufacture and distribution so consumers can rely on “product potency, purity and quality.”<sup>120</sup> Furthermore, the FDA has several layers of protection to shield against drug quality or effectiveness being compromised.<sup>121</sup> First, per the FDCA the FDA “maintains high standards for prescription drug approval.”<sup>122</sup> In order for a drug to be approved the manufacturer must show that the product is “safe and effective” for its prescribed use.<sup>123</sup> The product’s labeling must contain proper directions for use, and the drug must be manufactured only at certain facilities that are registered and approved by the FDA.<sup>124</sup> After the drug has been approved the particular manufacturer is required to sustain compliance with cGMP’s “to ensure that the quality of the product is systematically evaluated throughout the manufacturing process.”<sup>125</sup> The facilities where drugs are manufactured are also subject to random inspection by the FDA.<sup>126</sup> After manufacture, the pharmacists or wholesalers responsible for drug distribution must be “licensed or authorized by the states in which they operate.”<sup>127</sup>

Perhaps most relevant to the drug reimportation debate is that there are few ways for drugs to enter the stream of

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[oc/opacom/hottopics/importdrugs/stmt042006.html](http://oc/opacom/hottopics/importdrugs/stmt042006.html).

<sup>120</sup> Letter from Tommy Thompson, Secretary Department of Health and Human Services, to Senator James Jeffords (July 9, 2001) (on file with author), *available at* <http://www.fda.gov/oc/po/thompson/medsact.html>.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> Letter from Tommy Thompson, Secretary Department of Health and Human Services, to Senator James Jeffords (July 9, 2001) (on file with author), *available at* <http://www.fda.gov/oc/po/thompson/medsact.html>.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

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commerce.<sup>128</sup> This measure protects against counterfeit or low quality drugs being placed into the distribution system.<sup>129</sup> These safeguards protect the United States' closed system of manufacture and distribution.<sup>130</sup>

Once a product leaves the closed system the FDA can no longer assure that the product is safe and effective for its intended use.<sup>131</sup> Joe McCallion, a consumer safety officer in the FDA's Office of Regulatory Affairs said; "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."<sup>132</sup> Advocates of drug reimportation propose to open this closed system. However, the substantial risks identified by the FDA combined with the fact that HHS Secretaries past and present have opposed opening the closed system suggest that significant legislation allowing drug importation is unlikely.

*B. Counterfeiting*

Although proponents of drug reimportation claim that safeguards in Canada will sustain the high level of security to which Americans have grown accustomed,<sup>133</sup> there is evidence to the contrary. One of the biggest risks of drug reimportation is the potential for infiltration of counterfeit drugs into the distribution system.<sup>134</sup> Due to the United States' closed system,

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<sup>128</sup> *Id.*

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

<sup>130</sup> Letter from Tommy Thompson, Secretary Department of Health and Human Services, to Senator James Jeffords (July 9, 2001) (on file with author), available at <http://www.fda.gov/oc/po/thompson/medsact.html>.

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

<sup>132</sup> Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER MAGAZINE, Sept.-Oct. 2002 at 2, available at [http://www.fda.gov/fdac/features/2002/502\\_import.html](http://www.fda.gov/fdac/features/2002/502_import.html).

<sup>133</sup> Press Release, Office of the Governor, Blagojevich releases much-anticipated report on feasibility and savings of prescription drug importation (Oct. 27, 2003) (on file with author), available at <http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=3&RecNum=2346>.

<sup>134</sup> See Donald G. McNeil Jr., *In the World of Life-Saving Drugs*, a

counterfeit drugs that have been an issue for other nations are not a significant problem in the United States.<sup>135</sup>

In 2001 the World Health Organization (“WHO”) estimated that between eight and ten percent of the world’s prescription drugs were counterfeit.<sup>136</sup> Even though counterfeiting has been a rare phenomenon in the United States, attempts at bringing counterfeit drugs into the country have been on the rise.<sup>137</sup> In order to combat the rise in counterfeiting the FDA has devoted more resources to preventing these products from entering the country.<sup>138</sup> During the late 1990’s the FDA performed five counterfeit drug investigations per year.<sup>139</sup> Since 2000 the FDA has increased the number of investigations to twenty per year.<sup>140</sup>

In response to increased counterfeiting, the FDA recommends stricter licensing requirements for distributors and implores those within the drug supply chain to refuse to do business with people of unknown backgrounds.<sup>141</sup> These recommendations are directly contrary to a drug reimportation policy that would allow more people into the distribution system, all of whom would be outside the capability and authority of the FDA to monitor.

### C. FDA Investigation and Enforcement

Many of the FDA’s concerns about implementing an importation program have been buttressed by FDA “blitz exams” and undercover investigations. During the course of

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*Growing Epidemic of Deadly Fakes*, N.Y. TIMES, Feb. 20, 2007, at F1.

<sup>135</sup> Meadows, *supra* note 132, at 2.

<sup>136</sup> Letter from Tommy Thompson, Secretary Department of Health and Human Services, to Senator James Jeffords (July 9, 2001) (on file with author), available at <http://www.fda.gov/oc/po/thompson/medsact.html>.

<sup>137</sup> *Protecting Consumers From Counterfeit Drugs*, FDA CONSUMER MAGAZINE, May-June 2004 at 1, available at [http://www.fda.gov/fdac/features/2004/304\\_drug.html](http://www.fda.gov/fdac/features/2004/304_drug.html).

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

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these investigations the FDA has gathered hard evidence that opening our borders to imported drugs heightens the risks for several potential problems including unapproved drugs and products that have been improperly packaged, labeled and stored.

In July and November of 2003 the FDA conducted “blitz exams” which consist of examining shipments of foreign drugs bound for the United States.<sup>142</sup> During a three day period at several different mail locations across the country, the FDA identified several problems.<sup>143</sup>

First, of 1,153 searched shipments, 88% contained unapproved drugs.<sup>144</sup> Furthermore, the FDA seized twenty-five controlled substances, as well as drugs removed from the United States markets due to safety concerns.<sup>145</sup> Finally, some drugs were not packaged properly.<sup>146</sup> For instance, drugs were found shipped in tissue paper and sandwich bags.<sup>147</sup>

These blitzes identified several of the concerns raised with opening up the U.S. distribution system to foreign countries, such as labeling and storage. Often drugs imported from foreign countries are not labeled in English.<sup>148</sup> This can cause significant problems for the consumer who will not likely understand the instructions on the label.<sup>149</sup>

Another problem is storage. Some drugs require specific storage conditions, like refrigeration, in order to work effectively.<sup>150</sup> There is also no way to know if a particular drug was stored properly before it arrives in the United States. In fact, in 2003 the FDA discovered that CanaRx, a website that ships drugs from a Canadian pharmacy into the U.S., was

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<sup>142</sup> *Hearings, supra* note 116.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Hearings, supra* note 116.

<sup>148</sup> *Id.* at 2.

<sup>149</sup> *See id.*

<sup>150</sup> *Id.* at 2.

shipping insulin, a drug needing refrigeration, in a “manner that did not satisfy the storage conditions specified in FDA approved labeling, and which could potentially compromise the safety and effectiveness of the insulin.”<sup>151</sup> Similarly, in *Rx Depot* the court noted that the drugs obtained from Canada through Rx Depot did not have the FDA required patient package inserts, nor were they in FDA approved “unit of use packaging.”<sup>152</sup> In the United States, this packaging is utilized to ensure “that certain drugs received by customers arrive in designated dosages with the approved patient package insert.”<sup>153</sup> These examples highlight the concern that if drugs leave the “closed system,” once they re-enter there will be no way for either the authorities or the consumers to know if they have been properly stored along the way,<sup>154</sup> which could compromise the drug’s effectiveness.<sup>155</sup>

Another significant issue concerns the possible interaction of imported drugs with other drugs a consumer may be ingesting. This is often referred to as “drugs with clinically significant drug-drug interactions.”<sup>156</sup> There have been instances where the FDA has gone undercover and discovered that the proprietors of these websites will sell and send a particular drug even if they are aware that an individual is taking medication that will combine with the new medication to have adverse effects on the patient.<sup>157</sup>

During the blitzes in 2003 the FDA found many “foreign

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<sup>151</sup> *Id.* at 14-15.

<sup>152</sup> *United States v. Rx Depot*, 290 F. Supp. 2d 1238, 1242 (N.D. Okla. 2003).

<sup>153</sup> *Id.*

<sup>154</sup> *Hearings*, *supra* note 116.

<sup>155</sup> *See id.* at 2.

<sup>156</sup> Press Release, Food and Drug Admin., Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (January 27, 2004) (on file with author), *available at* <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html>.

<sup>157</sup> Press Release, Food and Drug Admin., FDA Test Results of Prescription Drugs from Bogus Canadian Website Show All Products Are Fake and Substandard (July 13, 2004) (on file with author), <http://www.fda.gov/bbs/topics/news/2004/NEW01087.html>.

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versions” of FDA approved drugs.<sup>158</sup> “Foreign versions” of FDA approved drugs are similar to the drugs approved by the FDA but may deviate from the FDA approved version in “potency and purity.”<sup>159</sup> Moreover the FDA cannot assure the “safety and efficacy” of these drugs because the FDA has “not monitored the manufacturing and quality control processes of the facility in which the product was produced.”<sup>160</sup> These “foreign versions” are illegal in the United States because they are not approved by the FDA, but purport to be the same as an FDA approved version.<sup>161</sup>

There were at least six drugs found during the blitzes that require professional supervision.<sup>162</sup> For example, APO-Warfarin was discovered during a November 2003 blitz.<sup>163</sup> This is a “foreign version” of the blood thinner, warfarin.<sup>164</sup> According to the FDA, “the potency of warfarin may vary depending on how it is manufactured, and the drug must be carefully administered and monitored by a health professional in order to prevent serious bleeding problems.”<sup>165</sup> This seized drug is illustrative of several problems. First, since the drug was sent from another country there is no way to ensure that the drug is taken with a doctor’s supervision. If the drug had been prescribed by a physician in the United States, the physician could make certain that the patient was given only a safe amount, necessitating another trip to the doctor for more medication. Since this drug left the “closed system” there is also no way for the FDA to know the exact potency of each dose

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<sup>158</sup> FDA News: Recent FDA/US Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments, *supra* note 151.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> FDA News: Recent FDA/US Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments, *supra* note 151.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

since it varies depending on the manufacturer.<sup>166</sup>

In addition to blitzes, the FDA has conducted undercover investigations into the illegal importation of drugs from Canada, and has found significant threats to the public health.<sup>167</sup> In February and August 2004 the FDA made undercover purchases from Canada Care, a company engaged in the importation of drugs into the United States from Canada.<sup>168</sup> In this particular undercover investigation the FDA purchased both Sporanox and Neurontin.<sup>169</sup> Instead of receiving Neurontin, the undercover agent was sent two drugs that are unapproved by the FDA, APO-Gabapentin and Novo-Gabapentin.<sup>170</sup> Since the drugs received are not approved, the FDA cannot “assure the safety and efficacy” of these drugs.<sup>171</sup> Furthermore the FDA has no information on how the drugs are made, what information is included with the drug or possible side effects of the drug.<sup>172</sup> Thus, the drugs are “more likely to be contaminated, counterfeit, inherently ineffective, or contain different amounts of the active ingredients from similar drugs that have been reviewed and approved by the FDA.”<sup>173</sup>

The shipment of Sporanox did contain the FDA approved version of the drug, but the method of shipment caused the FDA

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<sup>166</sup> Press Release, Food and Drug Admin., Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (January 27, 2004) (on file with author), *available at* <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html>.

<sup>167</sup> Press Release, Food and Drug Admin., FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs (December 1, 2004) (on file with author), *available at* <http://www.fda.gov/bbs/topics/news/2004/NEW01142.html>.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> Press Release, Food and Drug Admin., FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs (December 1, 2004) (on file with author), *available at* <http://www.fda.gov/bbs/topics/news/2004/NEW01142.html>.

<sup>173</sup> *Id.*

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to consider it a “potentially serious health threat.”<sup>174</sup> Normally Sporanox is taken in one week “pulses.”<sup>175</sup> Patients then wait three weeks before continuing with another “pulse” treatment.<sup>176</sup> In between the “pulses” a patient is supposed to consult with his doctor to determine whether the treatment should continue or terminate.<sup>177</sup> Termination would be due to the patient experiencing side effects that could potentially damage his heart or liver.<sup>178</sup> The Canadian pharmacy sent the undercover agent three packages of Sporanox, potentially allowing the patient to consume two “pulses” without consulting a physician in between.<sup>179</sup> This could result in serious side effects, including fatality.<sup>180</sup> Accordingly, in *Rx Depot*, the court found that “[p]rescription drugs obtained through Rx Depot frequently are dispensed in greater quantities than are requested by the prescribing physician.”<sup>181</sup> Additionally, Rx Depot dispensed drugs in preset amounts regardless of the patient’s prescribed quantity, and “without directions to take the drug for only the number of days prescribed by the U.S. physician.”<sup>182</sup> The findings of this undercover investigation are particularly significant because legalizing drug reimportation could lead to the exact consequences the FDA fears. If citizens are allowed to legally import drugs from Canada, or other countries, the drugs they receive will be outside the FDA’s regulatory scheme and this could lead to dangerous consequences.

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<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> Press Release, Food and Drug Admin., FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs (December 1, 2004) (on file with author), *available at* <http://www.fda.gov/bbs/topics/news/2004/NEW01142.html>.

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *United States v. Rx Depot*, 290 F. Supp. 2d 1238, 1242 (N.D. Okla. 2003).

<sup>182</sup> *Id.*



## IV. STATE PROGRAMS

The clamoring for an importation program has come largely from state governors looking for ways to save money and satisfy citizens frustrated by high drug costs. As noted in Part II, several states, including Minnesota and Wisconsin, have established websites that will link citizens to websites selling drugs from Canada.<sup>183</sup> Unfortunately some of these programs have not worked as effectively as the state governments had hoped. In fact, in many instances, these programs have demonstrated the importance of sustaining the closed distribution system.<sup>184</sup>

Research by the state of Minnesota exposed several problems with how drugs are distributed and produced in Canada.<sup>185</sup> During a pre-announced visit to Canada, Minnesota officials noticed that many pharmacies used “unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions.”<sup>186</sup> Furthermore one of the pharmacies the officials visited had its pharmacists “review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high it would have been impossible to assure safety.”<sup>187</sup> The issue of proper labeling<sup>188</sup> was not a priority for at least one pharmacy who did not label any of its products, choosing instead to send the labels along unattached, even to those customers who were receiving more than one prescription.<sup>189</sup> Even more troubling, the Minnesota officials noted that many products that required refrigeration were being shipped unrefrigerated.<sup>190</sup>

Moreover, the state of Wisconsin had similar problems when

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<sup>183</sup> *Hearings, supra* note 116.

<sup>184</sup> *See id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

<sup>188</sup> *See supra* Part III.C.

<sup>189</sup> *Hearings, supra* note 116.

<sup>190</sup> *Id.*

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it reviewed reports presented by the three Canadian pharmacies it linked to via its website.<sup>191</sup> Wisconsin officials found that 361 of the 765, or 41%, of the prescriptions filled by the Canadian pharmacies violated the terms of the agreement made between the pharmacies and the state.<sup>192</sup> “Specifically, 127 of the dispensed drugs were products not approved by FDA or available in the U.S., while 189 of the drugs were products not authorized by the state program.”<sup>193</sup> Additionally, in six instances the pharmacies mistakenly sent drugs that required refrigeration in the mail.<sup>194</sup> The state of affairs became so drastic that the Wisconsin Department of Health and Family Services mailed letters to all three pharmacies demanding they stop these practices.<sup>195</sup> Even more revealing is this statement from the executive director of the Wisconsin Pharmacy Society: “no one in Wisconsin has any real idea what these Canadian businesses are doing.”<sup>196</sup>

These studies are significant because many proponents of drug reimportation maintain that Canadian safety measures are on par with the best in the world.<sup>197</sup> In addition to the findings of both Minnesota and Wisconsin, in August 2005 the FDA performed an investigation at airports in New York, Los Angeles and Miami “which found that nearly half of the imported drugs the FDA intercepted from four selected countries were shipped to fill orders that consumers believed they were placing with ‘Canadian pharmacies.’”<sup>198</sup> It turned out that 85%

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<sup>191</sup> *Id.*

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Hearings, supra* note 116.

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> Press Release, Office of the Governor, Blagojevich releases much-anticipated report on feasibility and savings of prescription drug importation (Oct. 27, 2003) (on file with author), <http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=3&RecNum=2346>.

<sup>198</sup> Press Release, U.S. Food and Drug Admin., FDA Warns Consumers Not to buy or Use Prescription Drugs from Various Canadian Websites that Apparently Sell Counterfeit Products (August 30, 2006) (on file with author),

of the drugs being promoted as “Canadian” actually came from 27 other countries around the world.<sup>199</sup> The findings of this investigation drive home the importance of sustaining a closed distribution system and indicate that many internet sites that claim to be “Canadian” are in fact selling drugs of unknown “origin, safety and efficacy.”<sup>200</sup>

When officials from New Hampshire Governor Craig Benson’s office traveled to the on site location of CanadaDrugs.com they found conditions that were later termed “significant safety issues.”<sup>201</sup> Moreover as part of the “terms of service” for this site “purchasers . . . agree that they ‘will not be liable for damages arising from personal injury or death’ from the use of drugs sold by the pharmacy.”<sup>202</sup> As a result a consumer would have no remedy *vis a vis* CanadaDrugs.com for “injuries arising from the use of drugs from this shipper.”<sup>203</sup> Presumably the lack of legal remedy would lead to the increase in insurance. This is significant because the biggest advantage drug reimportation is purported to have is the opportunity to save Americans money. The ability of importation to save Americans money is one of the two considerations the HHS Secretary is mandated to take into account when considering whether to implement drug importation per the MMA.<sup>204</sup> Therefore an increase in insurance costs could potentially mitigate any savings a comprehensive drug reimportation plan would bear.

## V. THE PHARMACEUTICAL LOBBY

The pharmaceutical industry has used its vast resources, including spending a significant amount of money on political

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available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01441.html>.

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*

<sup>201</sup> *Hearings, supra* note 116.

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 804(b) (2003).

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donations, to influence politicians and hire lobbyists to advocate on its behalf.<sup>205</sup> The pharmaceutical industry has achieved significant legislative victories, as seen in the Medicare Modernization Act of 2003 and patent extensions, and the industry is expected to fight importation with the same vigor.<sup>206</sup>

*A. Pharmaceutical Industry Resources*

The pharmaceutical lobby has been called an “elephant among chickens”<sup>207</sup> because of its influence and ability to achieve its desired results.<sup>208</sup> In fact, pharmaceutical manufacturers spend money on lobbying efforts and campaign contributions at a rate that exceeds almost any other industry.<sup>209</sup> In 2003 the pharmaceutical industry’s trade group, The Pharmaceutical Research and Manufacturers of America (“PhRMA”) spent \$8.5 million on lobbying.<sup>210</sup> Furthermore, several PhRMA members have their own lobbying budget in the millions of dollars.<sup>211</sup> For instance, in only the first six months of 2003 Eli Lilly and Co. spent \$2.9 million on lobbying services, Bristol-Myers Squibb spent \$2.6 million, Johnson & Johnson \$2.2 million, Hoffmann-LaRoche \$2 million and Pfizer \$1.8 million.<sup>212</sup> In sum, the pharmaceutical industry spent over \$29 million in the first half of 2003, when the drug reimportation debate was at its apex.<sup>213</sup> From 1998 to 2004 pharmaceutical and health care product companies spent more

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<sup>205</sup> See *infra* Part V.A.

<sup>206</sup> See *infra* Part V.C.

<sup>207</sup> Greg Gordon, *Drug Firms Flex their Political Muscle*, STAR TRIB. (Minn.), Aug. 27, 2000, at 1A.

<sup>208</sup> See *id.*

<sup>209</sup> Frederic J. Frommer, *Drug Lobby Wages War on Imports*, Associated Press, Oct. 13, 2003, available at <http://www.cbsnews.com/stories/2003/10/15/politics/main578173.shtml>.

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

than \$675 million on federal lobbying.<sup>214</sup> This figure exceeded the industry with the second most expenditures by almost \$80 million.<sup>215</sup> Moreover, these figures do not take into account the money spent on campaign contributions from these companies and their Political Action Committees (“PAC”).<sup>216</sup>

During the 2003-2004 election cycle, the pharmaceutical industries combined expenditures on campaign contributions and lobbying was \$818 million; second most of any industry.<sup>217</sup> In the 2003-2004 election cycle, Pfizer’s PAC contributed \$2,261,777 to various candidates and committees.<sup>218</sup> In the 2005-2006 cycle that number rose to \$3,241,156.<sup>219</sup> In addition, Eli Lilly’s PAC contributed \$1,678,376 in 2003-2004 and an additional \$1,565,336 in 2005-2006.<sup>220</sup> These numbers are particularly significant considering federal election law only allows a PAC to contribute \$5,000 dollars each election cycle to any particular candidate.<sup>221</sup>

The pharmaceutical industry provides politicians with additional benefits beyond just campaign donations. In addition to the \$161,000 that Senator Joe Lieberman received in campaign donations from 1993 up to his vice-presidential run in 2000, Lieberman also flew on Pfizer’s corporate jet and made a speech before PhRMA’s membership.<sup>222</sup> The pharmaceutical industry paid for events at both the Democratic and Republican conventions in 2000, including a “Mardi Gras-style gala” on the sets of Paramount studios in Los Angeles for the Democratic

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<sup>214</sup> Alison Lapp, *Drug Lobby Forks Out a Fortune; Pharmaceutical Industry Outspends All Others to Get Its Way in Washington*, THE HERALD-SUN, July 17, 2005, at B1.

<sup>215</sup> *Id.*

<sup>216</sup> *See id.*

<sup>217</sup> Lapp, *supra* note 214.

<sup>218</sup> Federal Election Commission, [http://herndon1.sdrdc.com/cgi-bin/ancomsrs/?\\_04+C00016683](http://herndon1.sdrdc.com/cgi-bin/ancomsrs/?_04+C00016683) (last visited Nov. 30, 2006).

<sup>219</sup> *Id.*

<sup>220</sup> *Id.*

<sup>221</sup> 2 U.S.C. § 441a (2002).

<sup>222</sup> Greg Gordon, *Drug Firms Flex their Political Muscle*, STAR TRIB. (Minn.), Aug. 27, 2000, at 1A.

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convention.<sup>223</sup> The industry also contributed \$625,000 to the Bush-Cheney inaugural committee.<sup>224</sup> Industry companies paid for tens of millions of dollars worth of television and radio ads on behalf of a non-profit group that was attacking President Clinton's proposal for a "government-run prescription drug program."<sup>225</sup>

*B. Industry Manpower*

Not only does the pharmaceutical industry have significant resources, but it uses those resources to wield a great deal of influence. In 2004 PhRMA hired former Congressman Billy Tauzin to become the president and CEO of its organization.<sup>226</sup> This hire was particularly controversial and drew the ire of Democrats and public advocacy groups, because Tauzin was being considered for the job while he was still chairman of the House Energy and Commerce Committee, which has "regulatory oversight of the pharmaceutical industry."<sup>227</sup> Furthermore, Tauzin and the committee he chaired played a critical role in constructing the Medicare Modernization Act of 2003<sup>228</sup> which has been lauded as a rousing success for the drug industry.<sup>229</sup>

In 2001 more than half of the pharmaceutical industry's 625 lobbyists were former members of Congress, former

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<sup>223</sup> *Id.*

<sup>224</sup> Leslie Wayne, *A Muscular Lobby Rolls Up Its Sleeves*, N.Y. TIMES, Nov. 4, 2001, at Money and Business, p. 1.

<sup>225</sup> Gordon, *supra* note 222, at 1A.

<sup>226</sup> *Tauzin Tapped To Become PhRMA's New Chief*, WASH. DRUG LETTER (FDA News, Falls Church, VA), Dec. 20, 2004, Vol. 36 No. 5 at 9.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> M. Asif Ismail, *Drug Lobby Second to None: How the Pharmaceutical Industry Gets its Way in Washington*, The Center for Public Integrity, available at <http://www.publicintegrity.org/rx/report.aspx?aid=723>; M. Asif Ismail, *FDA: A Shell of its Former Self*, The Center for Public Integrity, available at <http://www.publicintegrity.org/rx/report.aspx?aid=722>.

Congressional staff members and former government officials.<sup>230</sup> Former Secretary of Defense Donald Rumsfeld was once chief executive at the drug company G.D. Searle.<sup>231</sup> Not only are there hundreds of pharmaceutical lobbyists, but they are also broadly dispatched. The drug industry lobbied at least 1,600 bills from 1998-2004.<sup>232</sup>

### C. Industry Influence and Victories

As illustrated above the pharmaceutical industry spends a great deal of money with the intent of influencing politicians and political candidates. Of course, these companies would not consistently dole out millions of dollars if these tactics were ineffective. The pharmaceutical lobby began in earnest in the 1960's after the creation of Medicare and gained widespread attention for its efforts and influence in defeating President Clinton's health care plan in the 1990's.<sup>233</sup> Perhaps the effort that best demonstrates the pharmaceutical lobby's ability to wield influence is its lobbying of the Medicare Modernization Act (MMA) of 2003. That legislation, which went into effect in 2006, created a prescription drug benefit for seniors that was funded by taxpayer dollars.<sup>234</sup> The remarkable aspect of the bill is that despite the fact that it created a reliable market of 41 million customers<sup>235</sup> for the pharmaceutical industry, there was still a provision in the bill that prohibited the government from negotiating lower prices with pharmaceutical companies.<sup>236</sup>

This provision was not included in the MMA to prevent drug

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<sup>230</sup> Wayne, *supra* note 224.

<sup>231</sup> *Id.*

<sup>232</sup> M. Asif Ismail, *Drug Lobby Second to None: How the Pharmaceutical Industry Gets its Way in Washington*, The Center for Public Integrity, available at [http: www.publicintegrity.org/rx/report.aspx?aid=723](http://www.publicintegrity.org/rx/report.aspx?aid=723).

<sup>233</sup> See Wayne, *supra* note 224.

<sup>234</sup> Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 101 (2003).

<sup>235</sup> Ismail, *supra* note 232.

<sup>236</sup> Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 222 (2003).

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companies from losing money because drug companies actually stand to make a huge profit.<sup>237</sup> Analysts at Goldman Sachs predict that the MMA will result in a 9% increase in profits for drug companies.<sup>238</sup> This percentage represents \$13 billion per year.<sup>239</sup> Furthermore, a Boston University study on the impact of the MMA predicted that 61% of the Medicare money spent on prescription drugs will turn directly into profit for the drug companies.<sup>240</sup> In addition, the study predicts that drug companies will see increased profits of \$139 billion over an eight year period.<sup>241</sup> The positive impact the MMA will have on drug industry profits demonstrates the success of the industry's lobbying efforts. In fact, Helen Savage of the North Carolina state office of AARP said, "[t]he lack of effective cost containment or price controls for prescription drugs in the Medicare Modernization [of 2003] reflects the strength of the pharmaceutical lobby."<sup>242</sup>

Perhaps as significant as what the drug companies gained via the passage of the MMA is what they avoided. Despite polls that showed a majority of Americans supported drug reimportation, a provision allowing full scale importation was not included in the MMA.<sup>243</sup> Moreover, other provisions the drug industry strongly objected to were not in the bill, such as government price controls that have proven effective in Canada for reducing drug prices and increased access to the marketplace for generic drugs.<sup>244</sup> Both price controls and greater access to generics would likely have the effect of driving drug costs down, yet

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<sup>237</sup> Ceci Connolly, *Drugmakers Protect Their Turf: Medicare Bill Represents Success for Pharmaceutical Lobby*, WASH. POST, Nov. 21, 2003, at A4.

<sup>238</sup> *Id.*

<sup>239</sup> *Id.*

<sup>240</sup> Ismail, *supra* note 232.

<sup>241</sup> *Id.*

<sup>242</sup> Alison Lapp, *Drug Lobby Forks Out a Fortune; Pharmaceutical Industry Outspends All Others to Get Its Way in Washington*, THE HERALD-SUN, July 17, 2005, at B1.

<sup>243</sup> Connolly, *supra* at note 237.

<sup>244</sup> *Id.*



these provisions proved elusive.<sup>245</sup> Of the MMA one Republican close to the drug industry said, "In their [drug industry] view, by improving access for all seniors, we will ameliorate any pressure on the industry toward price controls or reimportation."<sup>246</sup>

The MMA illustrates the influence exerted by the drug industry in Washington, and such success is not an aberration. For instance at the end of 2001 Congress passed the Best Pharmaceuticals for Children Act that extended patents on certain drugs by six months.<sup>247</sup> The impetus for this measure was the fear of an anthrax attack and the government's desire to stockpile Cipro,<sup>248</sup> an antibiotic used to treat anthrax exposure.<sup>249</sup>

Just prior to passing the Best Pharmaceuticals for Children Act, Bayer, the manufacturer of Cipro, agreed to give the government a 46% discount on the first 100 million doses of Cipro sold, saving the government \$82 million.<sup>250</sup> Not coincidentally, the 2001 bill had provisions that were favorable to Bayer.<sup>251</sup> In fact, the bill permitted a six month extension on certain drug patents, including Cipro, in return for drug companies performing tests on these drugs to ensure their safety and efficacy in children.<sup>252</sup>

Some groups have argued that safe use for children should be part of the FDA approval process in the first place, before a drug can be obtained in the marketplace.<sup>253</sup> Additionally, the

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<sup>245</sup> *Id.*

<sup>246</sup> *Id.*

<sup>247</sup> S. 1789 § 7, 106th Cong. (2001) (enacted).

<sup>248</sup> See *Patently Offensive: Congress Set to Extend Monopoly Patents for Cipro and Other Drugs*, Public Citizen, [http://www.Citizen.org/print\\_article.cfm?ID=6435](http://www.Citizen.org/print_article.cfm?ID=6435).

<sup>249</sup> Wayne, *supra* note 224.

<sup>250</sup> *Cipro Saga Exposes how Drugmakers Protect Profits*, USA TODAY, Oct. 29, 2001.

<sup>251</sup> See Connolly, *supra* note 237.

<sup>252</sup> S. 1789 § 7, 107th Cong. (2001) (enacted).

<sup>253</sup> *Patently Offensive: Congress Set to Extend Monopoly Patents for Cipro and Other Drugs*, Public Citizen, <http://www.Citizen.org/>

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amount of money drug companies gain through patent extension greatly exceeds the amount of testing.<sup>254</sup> According to a study performed by the Tufts Center for the Study of Drug Development, pediatric testing costs an average of \$3.87 million per drug. Per this legislation the FDA requested testing on 188 drugs, putting the total cost of testing at \$727 million.<sup>255</sup> The patent extensions were expected to give patent holding companies an additional \$29.6 billion in additional sales, handing each company an additional \$592 million per year in added profits.<sup>256</sup> Thus, the amount in added sales is forty times the cost of testing,<sup>257</sup> a veritable windfall for the drug companies. Eli Lilly and Company was able to make an additional \$900 million in revenue on the anti-depressant, Prozac, because of the six month patent extension.<sup>258</sup> In addition, Bayer stood to gain an additional \$358 million thanks to the extension.<sup>259</sup> Thus, Bayer would recover all of their \$3.7 million in lobbying expenses from 1999-2001 in a mere two days.<sup>260</sup> Not surprisingly, the bill's sponsors, Senator Chris Dodd and Senator Mike DeWine, received the third and seventh highest contributions, respectively, from drug companies among senators from 1990-2000.<sup>261</sup>

The losers in this political exchange are U.S. consumers. The longer drug patents are extended, the longer cheaper, generic manufacturers are excluded from the marketplace.<sup>262</sup> This particular patent extension cost consumers \$14 billion over

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print\_article.cfm?ID=6435.

<sup>254</sup> *Id.*

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Id.*

<sup>258</sup> Maureen Groppe, *Departing Congress Treated Drug Companies Well*, GANNETT NEWS SERVICE, Nov. 28, 2002.

<sup>259</sup> *Patently Offensive: Congress Set to Extend Monopoly Patents for Cipro and Other Drugs*, Public Citizen (2001), [http://www.Citizen.org/print\\_article.cfm?ID=6435](http://www.Citizen.org/print_article.cfm?ID=6435).

<sup>260</sup> *Id.*

<sup>261</sup> *Id.*

<sup>262</sup> *See* Wayne *supra* note 224.

what generics would have cost.<sup>263</sup>

Protecting and extending patents is one of the primary goals of the pharmaceutical industry and it has been very effective in getting results. In 2003, the World Trade Organization was forced to appease the drug industry because the Bush administration, fiercely supporting the industry, would not sign an agreement that may have compromised drug industry profits, even in the face of desperate need for humanitarian aid.<sup>264</sup> In the face of AIDS, malaria and tuberculosis epidemics in Africa, the WTO tried to respond with worldwide agreement to get less expensive drugs to those in Africa who badly need them.<sup>265</sup> The United States government rejected the initial proposal, saying that the agreement should be limited to only a small number of countries and apply to only a few diseases.<sup>266</sup> The rationale for this position was that impoverished nations would somehow exploit multi-national drug companies, whose profits are among the largest in the world.<sup>267</sup> Every other country that was home to a major pharmaceutical company was willing to sign the agreement.<sup>268</sup> In fact, an Indian pharmaceutical company, Cipla, was willing to sell AIDS drugs to African countries for 4% of the price charged by multi-national companies.<sup>269</sup> The final agreement included the Bush administration's demands that "generic medicines could be imported to cure any life-threatening disease, so long as it was a public health emergency" and provisions that would ensure countries would not take advantage of the reduced costs for commercial profit

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<sup>263</sup> Wayne, *supra* note 224.

<sup>264</sup> Elizabeth Becker, *Cheaper Medicines for World's Poor; Trade Rules Altered on Patented Drugs*, INT'L HERALD TRIB., Sept. 2, 2003 at 1.

<sup>265</sup> *Id.*

<sup>266</sup> *Id.*

<sup>267</sup> *See Id.*

<sup>268</sup> Becker, *supra* note 264.

<sup>269</sup> Aravind Adiga, *Prescription For Profits; India's generic-drug makers are flooding international markets with cheap copycat pills, infuriating behemoth rivals from the U.S. and Europe*, TIME ASIA, Sept. 22, 2003, at 44.

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instead of meeting public health needs.<sup>270</sup>

Critics railed against the United States accusing the Bush administration of including too much “bureaucratic red tape” that would “doom” the effective implementation of the agreement.<sup>271</sup> Ellen Hoen of Doctors Without Borders said the “deal was designed to offer comfort to the U.S. and the Western pharmaceutical industry. Unfortunately, it offers little comfort for poor patients. Global patent rules will continue to drive up the price of medicines.”<sup>272</sup>

The drug industry’s relationship with the federal government has serious health implications besides those in Africa. For instance, in 1992 the Prescription User Fee Act streamlined the process of bringing life-saving drugs into the marketplace, with the condition that companies are required to perform follow up studies to prove that these drugs are safe.<sup>273</sup> Additionally in 1997, Congress passed the FDA Modernization Act, which lowered the standards for approving new drugs.<sup>274</sup> Some drugs were only required to be tested in one clinical trial “to show that the drug was reasonably safe and effective.”<sup>275</sup>

Both pieces of legislation were helpful to the drug industry but have proven problematic in practice. Marcia Angell, M.D., a former editor in chief of the *New England Journal of Medicine*, called the FDA Modernization Act, “a bundle of gifts to the pharmaceutical industry.”<sup>276</sup> Angell went on to say, “[a]mong other gifts was a dropping of standards for approving new drugs.”<sup>277</sup> The consequences of reduced standards have been severe. For instance, Merck’s painkiller Vioxx is estimated

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<sup>270</sup> Becker, *supra* note 264.

<sup>271</sup> *Id.*

<sup>272</sup> *Id.*

<sup>273</sup> M. Asif Ismail, *FDA: A Shell of its Former Self: The Food and Drug Administration lacks the power to regulate pharmaceuticals and keep you safe*, The Center for Public Integrity, <http://www.publicintegrity.org/rx/report.aspx?aid=722>.

<sup>274</sup> *Id.*

<sup>275</sup> *Id.*

<sup>276</sup> *Id.*

<sup>277</sup> *Id.*

to have caused 140,000 heart attacks and 55,000 deaths in the United States.<sup>278</sup> Additionally, many drug companies are not performing the follow up tests that are required by law and the FDA simply does not have the resources to ensure the tests take place.<sup>279</sup> A study performed by Congressman Ed Markey's office found that half of the post marketing studies that should have begun, have not started, despite the fact that companies have been selling the drugs for an average of twenty months.<sup>280</sup> In one instance the companies had been selling the drug for six years and nine months with no testing.<sup>281</sup>

The FDA does not have the resources to monitor drug companies at the rate with which they are able to get drugs approved.<sup>282</sup> For example, Pfizer's revenue went from \$11.3 billion in 1996 to \$52 billion in 2004.<sup>283</sup> On the other hand the FDA's budget was only \$1.7 billion in 2004.<sup>284</sup> Moreover, in 2005 the FDA employed 11,000 people, only a slight increase from the 8,200 that were employed by the agency twenty-five years ago.<sup>285</sup> Thus, the great disparity in resources only serves to exacerbate the effectiveness in getting drug companies the results they desire.

Furthermore, given the FDA's limited resources, it is difficult to understand how an expanded regulatory scheme, via drug reimportation would be viable. Even if proponents of drug reimportation are willing to sacrifice some degree of safety in return for a reduction in prices, without a significant and probably costly expansion of FDA resources, it seems likely that comprehensive drug reimportation would rely almost solely on the safety provisions of other countries. Although there are no reported instances of Americans being injured due to

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<sup>278</sup> Ismail, *supra* note 266.

<sup>279</sup> *Id.*

<sup>280</sup> *Id.*

<sup>281</sup> *Id.*

<sup>282</sup> *Id.*

<sup>283</sup> Ismail, *supra* note 266.

<sup>284</sup> *Id.*

<sup>285</sup> *Id.*

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consumption of Canadian pharmaceuticals, the idea of relying on another country to provide millions of American citizens with drugs is a daunting proposition.

It seems clear that the “worst case scenario” of drug reimportation would involve evil doers infiltrating a foreign drug source and importing drugs to America. In one of the stranger ploys by the pharmaceutical industry, PhRMA was reported to have attempted to commission a fiction novel designed to scare people away from drug reimportation.<sup>286</sup> PhRMA even admits to considering the idea, but says they ultimately decided against funding the project.<sup>287</sup> The novel was going to involve a terrorist organization that uses Canadian pharmaceutical websites to murder millions of American customers.<sup>288</sup> Kenin Spivak, who was to co-write the abandoned project said, “they wanted lots of people to die.”<sup>289</sup> Although playing on people’s worst fears to curry political favor in such a clandestine manner is abhorrent, the prospect of opening America’s borders to drugs of unknown sources just five years removed from terrorist attacks on U.S. soil and with counterfeiting on the rise<sup>290</sup> is unnerving. Even without PhRMA support, the novel is due out next year<sup>291</sup> and although it is a work of fiction, opening the “closed system” seems to at least make the premise a real life possibility.

## VI. LOOKING AHEAD

As the 2008 presidential election nears, solutions to high drug costs will likely receive greater public attention. In fact, legislation passed at the end of 2006 that allows Americans to carry a moderate amount of drugs into the United States from

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<sup>286</sup> Lloyd Grove, *Drug Business Prescribes A Novel Cure For its Ills*, N.Y. DAILY NEWS, Oct. 17, 2005, at 24.

<sup>287</sup> *Id.*

<sup>288</sup> *Id.*

<sup>289</sup> *Id.*

<sup>290</sup> *Protecting Consumers From Counterfeit Drugs*, FDA CONSUMER MAGAZINE, May-June 2004 at 1.

<sup>291</sup> Grove, *supra*, note 286.

Canada should raise the temperature of the debate.<sup>292</sup> In addition, the results of the 2006 mid-term elections have left some reimportation supporters optimistic that a comprehensive reimportation plan may be implemented.<sup>293</sup> However, these reimportation advocates may be disappointed, as there remains the possibility that legislators will instead focus their efforts on modifying the MMA as a means of reducing drug costs.<sup>294</sup> Even if modification of the MMA is unsuccessful there remain several alternatives that do not include the importation of drugs from foreign countries.<sup>295</sup>

#### A. 2007 Homeland Security Appropriations Bill

In the fall of 2006, Congress passed the 2007 Homeland Security appropriations bill which included a provision that would allow Americans to personally transport as much as a 90 day supply of FDA approved drugs from Canada.<sup>296</sup> This measure has been lauded as indicative that more meaningful drug reimportation is inevitable, prompting Congressman David Vitter to say, “[n]ow it is only a matter of time before we pass a comprehensive drug reimportation bill.”<sup>297</sup> Although it is true that this provision allows drugs to be legally imported from Canada, Congressman Vitter’s rhetoric is overly simplistic.

First, this legislation only allows an individual to personally

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<sup>292</sup> See 2007 Homeland Security appropriations bill, Pub. L. No. 109-295 § 535 (2006).

<sup>293</sup> See Press Release, Office of Senator David Vitter, U.S. Senator David Vitter Scores Major Victory for Drug Reimportation (Sept. 27, 2006) (on file with author), <http://vitter.senate.gov/?module=PressRoom/PressItem&ID=5ce075ed-62fd-4f7d-bf28-772b6529b780>.

<sup>294</sup> See *infra* Part VI.C.

<sup>295</sup> See *infra* Part VI.D.

<sup>296</sup> 2007 Homeland Security appropriations bill, Pub. L. No. 109-295 § 535 (2006).

<sup>297</sup> Press Release, Office of Senator David Vitter, U.S. Senator David Vitter Scores Major Victory for Drug Reimportation (Sept. 27, 2006) (on file with author), <http://vitter.senate.gov/?module=PressRoom/PressItem&ID=5ce075ed-62fd-4f7d-bf28-772b6529b780>.

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purchase their drugs in Canada.<sup>298</sup> The only citizens that will benefit in a meaningful way are those that live close enough to Canada to make traveling across the border more cost effective than simply buying drugs in the United States. Particularly ironic is that Congressman Vitter is a Representative of the State of Louisiana, a state so far from the Canadian border<sup>299</sup> that it is hard to imagine a trip to Canada for a 90 day supply of drugs being cost effective for any resident of that state.

Moreover, those most in need of prescription drugs, senior citizens, may not benefit from this legislation because the bill requires an individual to personally purchase the drugs in Canada.<sup>300</sup> It seems likely that many senior citizens will be physically unable to travel north to purchase drugs. Furthermore, there will inevitably be a group of people who find it inefficient to travel to Canada to buy drugs for only a 90 day supply. Although this legislation will certainly help some people gain access to cheaper drugs in Canada, the scope of this legislation is very narrow and can hardly be considered suggestive that full scale drug reimportation for the entire country is imminent.

Additionally, as previously discussed, the drug industry has demonstrated the ability to make small concessions in order to achieve its overall goals.<sup>301</sup> This kind of savvy was seen in their handling of the MMA, patent extensions and in dealing with the WTO.<sup>302</sup> Thus, there is good reason to be skeptical that pro-reimportation members of Congress will be successful in asserting their agenda. A more comprehensive reimportation program would inevitably be met with massive resistance by the drug industry and would involve overcoming all the hurdles already discussed.<sup>303</sup>

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<sup>298</sup> Pub. L. No. 109-295 § 535 (2006).

<sup>299</sup> Mapquest.com places the distance from New Orleans, LA to Beebe Plain, VT at 1,681.42 miles.

<sup>300</sup> Pub. L. No. 109-295 § 535 (2006).

<sup>301</sup> *See supra* Section V.C.

<sup>302</sup> *Id.*

<sup>303</sup> *See supra* Part V.



*B. 2006 Mid-Term Elections*

The 2006 mid-term elections gave Democrats a majority in the House and Senate<sup>304</sup> and have left many importation advocates feeling optimistic about the prospects for a comprehensive reimportation plan.<sup>305</sup> Democrats have tried to strengthen their position for implementing drug reimportation by adding reimportation advocates, Senators Sherrod Brown, Bernie Sanders and Barack Obama to the Senate Health Committee.<sup>306</sup> Although Democrats view reimportation more favorably than Republicans, Democrats hold only a slight majority in both houses of Congress and any comprehensive plan could be vetoed by President Bush, who has consistently been against reimportation because of the safety concerns expressed by the FDA and HHS Secretaries past and present.<sup>307</sup> Of more pressing concern to Democrats could be modification of the MMA.<sup>308</sup> Thus, it would be difficult for Congress to also initiate drug reimportation considering the heavy opposition that can be expected to both reimportation and price negotiations.

*C. Modification of the MMA*

In fact the prescription drug benefit included in the MMA, known as Part D,<sup>309</sup> may be ripe for modification and could

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<sup>304</sup> Charles Babington, *New Congress Unlikely to Rush Toughest Issues*, WASH. POST, Nov. 11, 2006, at A3.

<sup>305</sup> Maria Bartiromo, *Should Business Be Worried?*, BUSINESS WEEK, Nov. 20, 2006, at 1221; Josh Fischman, *Health's Ailment*, U.S. NEWS & WORLD REP., Nov. 20, 2006.

<sup>306</sup> *New Health Committee Members May Push Biogenerics, Reimportation*, INSIDE CMS (FDA News, Falls Church, VA), Nov. 16, 2006, Vol. 9 No. 23.

<sup>307</sup> See Seay, *supra* note 4.

<sup>308</sup> See Fischman, *supra* note 305.

<sup>309</sup> Kara Gavin, *Study: Senior Medicare drug costs vary widely among states*, University of Michigan News Service, [http://www.umich.edu/~urecord/0607/Jan22\\_07/18.shtml](http://www.umich.edu/~urecord/0607/Jan22_07/18.shtml). "Medicare Part D which took effect January 2006 . . . offers prescription drugs to seniors and people with certain disabilities." Dan McLean, *Seniors Share Concerns with Sanders*,

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potentially quiet clamoring for importation. The success of Part D and its ability to provide affordable drugs to those who might otherwise favor importation will be a critical issue in whether the importation debate gains steam or dissipates.<sup>310</sup> Even as currently constituted, Part D is saving the average beneficiary 55%.<sup>311</sup> One of the problems with the MMA is that the cost of drugs is distributed unevenly throughout the country.<sup>312</sup> A recent study at the University of Michigan found that “the plan reduces costs for some seniors more than others, depending on where they live.”<sup>313</sup> An individual in a given state, taking the same drugs, could be paying thousands more than someone in a sister state.<sup>314</sup> For instance the study found that depending on what medicines one might be taking and the individuals enrollment plan, a person in one state may pay 10 percent of their annual income “for prescription drug coverage and premiums and co-pays, while someone taking the same medicines in another state would spend 20 percent of their income.”<sup>315</sup> The study also concluded that cost of living had no impact on disparate drug prices.<sup>316</sup> In fact the researchers found that those in poorer parts of the country were generally paying more than others.<sup>317</sup> Matthew Davis, M.D. who led the study said “[t]his has implications for individuals’ ability to afford and keep taking their medicines, and for policy as the prescription drug benefit is

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BURLINGTON FREE PRESS, April 24, 2007.

<sup>310</sup> See Seay, *supra* note 4.

<sup>311</sup> Ceci Connolly, *Drug Benefit Disparities Cited*, WASH. POST, April 19, 2005.

<sup>312</sup> Kara Gavin, *Study: Senior Medicare drug costs vary widely among states*, University of Michigan News Service, [http://www.umich.edu/~urecord/0607/Jan22\\_07/18.shtml](http://www.umich.edu/~urecord/0607/Jan22_07/18.shtml).

<sup>313</sup> *Study Finds “Tremendous” Disparity In Medicare Prescription Drug Prices*, available at [http://www.consumeraffairs.com/news04/2007/01/medicare\\_rx\\_prices.html](http://www.consumeraffairs.com/news04/2007/01/medicare_rx_prices.html).

<sup>314</sup> *Id.*

<sup>315</sup> *Id.*

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*

evaluated and changes are considered.”<sup>318</sup> Davis went on to state, “[n]o one doubts that the Part D benefit has helped many seniors by giving drug coverage to those who previously had none, but the level of variation among the lowest-cost plans is far greater than many seniors and policymakers probably anticipated.”

The need for reform is clear considering drug manufacturers increased prices by 6.2% in 2006.<sup>319</sup> General inflation was 3.2%.<sup>320</sup> The increase comes on the heels of a six year period where brand name drugs increased by 54%, compared to a general inflation rate of 20%.<sup>321</sup> On the other hand the Medicare prescription drug benefit has been credited with increasing drug sales in the U.S. by 8.3% in 2006 by providing coverage to those were “previously uninsured or underinsured.”<sup>322</sup> Thus, the drug benefit has led to improvements and some cost savings, but there is room for more.

Reform has been on the minds of policy makers, as some in Congress are eager to pass legislation allowing Medicare to negotiate prices with drug companies.<sup>323</sup> Presently, commercial insurers negotiate drug prices with pharmaceutical manufacturers and “set their own drug lists, premiums and co-pays.”<sup>324</sup>

A bill<sup>325</sup> sponsored by Congressman John Dingell would change the current system and allow the HHS Secretary to

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<sup>318</sup> *Study Finds “Tremendous” Disparity In Medicare Prescription Drug Prices*, available at [http://www.consumeraffairs.com/news04/2007/01/medicare\\_rx\\_prices.html](http://www.consumeraffairs.com/news04/2007/01/medicare_rx_prices.html).

<sup>319</sup> *AARP Rx Watchdog Report* (AARP, Washington, DC), Mar. 2007.

<sup>320</sup> *Id.*

<sup>321</sup> *Id.*

<sup>322</sup> Theresa Agovino, *Prescription-drug sales up 8.3% in U.S. for 2006*, THE ARIZONA REPUBLIC, Mar. 10, 2007.

<sup>323</sup> Fischman, *supra* note 305.

<sup>324</sup> *Study Finds “Tremendous” Disparity In Medicare Prescription Drug Prices*, available at [http://www.consumeraffairs.com/news04/2007/01/medicare\\_rx\\_prices.html](http://www.consumeraffairs.com/news04/2007/01/medicare_rx_prices.html).

<sup>325</sup> Medicare Prescription Drug Price Negotiation Act of 2007, H.R. 4, 110th Cong. (2007). This bill has passed the House of Representatives and is in Senate Committee.

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negotiate lower drug prices with drug manufacturers.<sup>326</sup> While critics contend that the bill is toothless because it doesn't allow the Secretary the authority to limit the drugs covered by Medicare, a technique used by private insurers to get discounts, at least one proponent of the bill has argued that even if this is true at least the "secretive process of drug price setting will be exposed to public scrutiny."<sup>327</sup>

*D. Potential Solutions to Reducing Drug Prices*

Other legislative efforts could be geared toward allowing generic drugs easier entry into the marketplace. Drug companies have been able to exploit a loophole in the current law that allows them to exclude generics from competing with their brand name drugs.<sup>328</sup> Sources at the FDA have indicated that drug companies are misusing "citizen petitions"<sup>329</sup> to prevent generic competition for longer than Congress intended.<sup>330</sup> Merely filing a petition initiates a review of the generic version of the drug by the FDA.<sup>331</sup> The process often takes months, or even years to complete.<sup>332</sup> FDA Chief Counsel Sheldon Bradshaw said these petitions, "appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the agency to review arguments that could have been made months before."<sup>333</sup> One estimate indicates that a citizen petition, filed by the drug manufacturer Biovail

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<sup>326</sup> *Id.*

<sup>327</sup> John Rother, Medicare Negotiating Authority Could Help Turn the Tide on High Drug Prices, AARP RX WATCHDOG REPORT, (AARP, Washington, DC) Jan.-Feb. 2007, at 4.

<sup>328</sup> Marc Kaufman, *Petitions to FDA Sometimes Delay Generic Drugs*, WASH. POST, July 3, 2006, at A1.

<sup>329</sup> *Id.* (noting that, "[R]equests for agency action that any individual, group or company can file.").

<sup>330</sup> *Id.*

<sup>331</sup> *Id.*

<sup>332</sup> *Id.*

<sup>333</sup> *Id.*

Corp., delaying the introduction of a generic version of Wellbutrin to the marketplace is costing consumers \$37 million per month.<sup>334</sup>

In an effort to facilitate the expansion of generic drugs, Senators Lott and Stabenow introduced legislation in the 109<sup>th</sup> Congress that would have allowed consumers earlier access to generic drugs and closed the “citizen petition” loophole.<sup>335</sup> The legislation remained in Senate committee in the last Congress and has yet to be re-introduced in the 110th Congress. This issue has been the subject of reform efforts since the late 1990s<sup>336</sup> and thus it seems likely to once again be the subject of legislative debate.

A bill<sup>337</sup> currently before the Senate, sponsored by Senator Byron Dorgan and supported by members of both parties, would allow U.S. customers to order prescription drugs from nineteen countries around the world.<sup>338</sup> The pharmaceutical industry immediately voiced its objection to the bill, with Tauzin reminding members of Congress of the serious threat counterfeiting poses and citing the Medicare prescription drug benefit as a source of reduced drug prices.<sup>339</sup> Additionally, a 2004 study by the Congressional Budget Office indicates that importation from foreign countries would save U.S. consumers only one percent over a ten year period and that a program that allowed importation only from Canada “would produce a

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<sup>334</sup> Kaufman, *supra*, note 328.

<sup>335</sup> Lower Priced Drugs Act, S. 2300, 109<sup>th</sup> Cong. (2006).

<sup>336</sup> Kaufman, *supra*, note 328. (citing that, “This is not the first time that the generic industry has complained about citizen petitions that it believed were unfairly blocking generic applications. The Clinton administration responded to those complaints in 1999 with a proposal that would have changed the way the FDA received and handled citizen petitions. PhRMA strongly opposed the rule, and the Bush administration withdrew it in 2003.”).

<sup>337</sup> Pharmaceutical Market Access and Drug Safety Act of 2007, S.242, 100<sup>th</sup> Cong. (2007).

<sup>338</sup> *Id.*

<sup>339</sup> Matthew Perrone, *Drug Imports Battle Heats Up Again*, <http://www.forbes.com/feeds/ap/2007/03/07/ap3495523.html>.

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negligible reduction in drug spending.”<sup>340</sup>

A potential complication to drug importation is the Canadian government’s threat to ban the bulk export of prescription drugs.<sup>341</sup> In July, 2005 Canada’s health minister, Ujjal Dosanjh said “[w]e will enhance and systemize our drug-supply monitoring activity, and if necessary we will use export control to protect human health and our nation’s drug supply.” Later that same year Dosanjh told a Harvard Medical School audience, “[i]t is difficult for me to conceive of how a small country like Canada could meet the prescription drug needs of approximately 280 million Americans without putting our own supply at risk.”<sup>342</sup> He also stated that Canada “cannot be the drug store of the United States.”<sup>343</sup> Despite Dosanjh’s explanation, Senator Dorgan blamed another culprit saying, “[t]his demonstrates the strength and the reach of the pharmaceutical industry,” noting that drug companies have tried to limit the amount of drugs they supply to Canada to “discourage the sale of those drugs to U.S. consumers.”<sup>344</sup> In fact, seven pharmaceutical companies have reduced their supply of drugs to Canadian companies who sell to U.S. customers.<sup>345</sup> Thus far, Canadians have not felt the effects of this reduction in medications thanks to stockpiling by Canadian pharmacists, but this is only a short term solution.<sup>346</sup> If Canada does place greater restrictions on the export of drugs to the United States it would be damaging to the state plans

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<sup>340</sup> CONGRESSIONAL BUDGET OFFICE: ECONOMIC AND BUDGET ISSUE BRIEF, WOULD PRESCRIPTION DRUG IMPORTATION REDUCE U.S. DRUG SPENDING? (2004).

<sup>341</sup> Jeffrey Young, *Canada may limit drug exports to U.S.*, The Hill, July 29, 2005, available at <http://thehill.com/business—lobby/canada-may-limit-drug-exports-to-u.s.-2005-07-29.html>.

<sup>342</sup> Associated Press, *Canada: Country cannot be U.S. drug store*, USA Today, 2004, available at [http://www.usatoday.com/news/health/2004-11-10-canada-drugs\\_x.htm](http://www.usatoday.com/news/health/2004-11-10-canada-drugs_x.htm).

<sup>343</sup> *Id.*

<sup>344</sup> Young, *supra* note 341.

<sup>345</sup> See Seay, *supra* note 4.

<sup>346</sup> *Id.*

described earlier.<sup>347</sup> In fact, in response to the Canadian threat the state of Illinois began exploring opportunities to import pharmaceuticals from Belgium and France.<sup>348</sup> Additionally, Rhode Island Secretary of State Matt Brown said reduced access to the Canadian market “would totally undermine our program.”<sup>349</sup> Therefore, the reaction of the Canadian government to U.S. importation efforts will be an important factor in the success of state and federal importation programs.

One avenue of compromise that has received less attention is the possibility of passing legislation that would prevent drug companies from advertising on television and radio. Since drug companies spend 27% of their revenue<sup>350</sup> and approximately \$4 billion per year<sup>351</sup> on direct to consumer advertising (“DTCA”) any reduction in those numbers would likely lead to a decrease in pharmaceutical costs<sup>352</sup> to the U.S. consumer. Legislation of this kind is not unprecedented.<sup>353</sup> In the early 1970’s Congress passed legislation banning the advertisement of cigarettes on television or radio.<sup>354</sup> In order to satisfy first amendment safeguards protecting restrictions on commercial speech the government “must assert a substantial interest to be achieved by its restriction and employ a regulatory technique in proportion to that interest.”<sup>355</sup> There is a strong argument that television advertisements for pharmaceutical drugs are harmful and that the only way to protect patient safety is to ban such advertisements.

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<sup>347</sup> Young, *supra*, note 341.

<sup>348</sup> *Canadian Drug Halt Looms, Illinois, Montana Seek New Sources*, [http://www.bloomberg.com/apps/news?pid=10000087&sid=aBIpIC2fQi7I&refer=top\\_world\\_news](http://www.bloomberg.com/apps/news?pid=10000087&sid=aBIpIC2fQi7I&refer=top_world_news).

<sup>349</sup> *Id.*

<sup>350</sup> Khosravi, *supra* note 85, at 430.

<sup>351</sup> Robert Cohen, *J&J Exec says pharma will fight ad ban*, STAR LEDGER, Nov. 17, 2006.

<sup>352</sup> See Robert M. Crentor, *Take drug ads off the air*, USA TODAY, June 12, 2005.

<sup>353</sup> See 15 U.S.C.S. § 1335 (1971).

<sup>354</sup> *Id.*

<sup>355</sup> *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York*, 447 U.S. 557, 564 (1980).

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Direct to consumer advertising can result in the public desiring newer drugs that are not as effective as drugs that have been in the market much longer.<sup>356</sup> When combined with the FDA's less rigorous drug approval process and lack of follow up testing,<sup>357</sup> newly advertised drugs can have dangerous consequences. Perhaps the best example is the aforementioned heart attacks and deaths caused by Vioxx.<sup>358</sup> One study on direct to consumer advertising found that "more advertising leads to more requests for advertised medicines, and more prescriptions. If DTCA opens a conversation between patients and physicians, that conversation is highly likely to end with a prescription, often despite physician ambivalence about treatment choice."<sup>359</sup> Perhaps that is why the United States is one of only two countries that allows direct to consumer advertising.<sup>360</sup>

Moreover, as the tragic consequences of the Vioxx episode demonstrate, it is also likely that physicians will prescribe requested advertised drugs even if more effective treatments exist.<sup>361</sup> In 2005, there was legislative action to limit the amount of television and radio advertising of prescription drugs, but those proposals did not make it out of House committee.<sup>362</sup> Neither of the previous proposals goes as far as banning television and radio advertisements of prescription drugs, but it seems clear that an effort to do so would not only increase patient safety but would also create more affordable drugs for U.S. consumers.<sup>363</sup>

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<sup>356</sup> Barbara Mintzes, Morris L. Barer, Richard L. Kravitz, Ken Bassett, Joel Lexchin, Arminee Kazanjian, Robert G. Evans, Richard Pan & Stephen A. Marion, *How does direct-to-consumer advertising affect prescribing? A survey in primary care environments with and without legal DTCA*, 169 CANADIAN MEDICAL ASSOCIATION JOURNAL, 405, 406 (2003).

<sup>357</sup> See *supra* Section V.C.

<sup>358</sup> *Id.*

<sup>359</sup> Mintzes, *supra* note 356, at 406.

<sup>360</sup> *Id.*

<sup>361</sup> See Rita Rubin, *Newest drugs not always the best*, USA TODAY, Oct. 18, 2006, at 9D.

<sup>362</sup> H.R. 1420, 109th Cong. (2005); H.R. 3950, 109<sup>th</sup> Cong. (2005).

<sup>363</sup> See Robert M. Crentor, *Take drug ads off the air*, USA TODAY, June



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## CONCLUSION

There is no doubt that soaring prescription drug prices must be remedied. However, that remedy should not require jeopardizing the safety of prescription drugs or opening our borders to products of unknown sources. The findings of the FDA, HHS Secretaries past and present, some state governments and others indicates that there are legitimate risks in implementing a full scale drug reimportation plan. Although there is optimism that the current political and economic landscape will result in drug reimportation being passed, the reality is that drug companies have gained desirable results for decades. Alternatives to drug reimportation exist and they should be thoroughly explored before we expose ourselves to the risks reimportation entails.