

## Canadian Pharmacies: A Prescription for a Public Health Disaster

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# CANADIAN PHARMACIES: A PRESCRIPTION FOR A PUBLIC HEALTH DISASTER

*It began as a novelty: grannies riding buses to Canada in search of cheaper medicines. But today, that search has mushroomed into a cross-border war that pits desperate consumers and defiant state and local governments against the powerful pharmaceutical industry and the Bush administration.<sup>1</sup>*

## INTRODUCTION

Prescription drug costs in America have reached record prices.<sup>2</sup> Americans pay more for prescription drugs than citizens of any other country.<sup>3</sup> To make matters worse, the cost of prescription drugs is increasing faster than ever.<sup>4</sup> Since 1998, drug prices have increased at a rate that is more than double the rate of inflation.<sup>5</sup> These increasingly high prices are creating a nationwide epidemic of Americans who are unable to afford the medications they need.<sup>6</sup>

In response to the rising cost of prescription drugs, many Americans are turning to Canada for a solution.<sup>7</sup> Some people take bus trips into Canada to get their prescriptions filled.<sup>8</sup> More commonly, Americans just turn on their computers and order the medications online from Canadian pharmacies.<sup>9</sup> Canadian pharmacies supply Americans with prescription drugs from Canada by mail.<sup>10</sup> Any American can fax a prescription to Canada where a Canadian pharmacist reviews and rewrites the prescription, fills it, and ships it back.<sup>11</sup> These Canadian

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1. William M. Welch, *Seniors Seek Bargains; FDA Cracks Down*, USA TODAY, Oct. 7, 2003, at 1A.

2. See Public Health Association of New York City (PHANYC) Policy Statements, *Making Medicines Affordable: The Price Factor* (May 9, 2000), at <http://www.phanyc.org/affordable.html>.

3. Welch, *supra* note 1.

4. PHANYC Policy Statements, *supra* note 2.

5. Danielle Deaver & Kristi E. Swartz, *Hard To Swallow Ad Costs Help Put Drug Prices Out of Reach for Some*, WINSTON-SALEM J., Apr. 27, 2003, at A1.

6. Welch, *supra* note 1.

7. Although this Comment will focus on reimportation from Canada, Americans are also obtaining prescription drugs from other countries such as Mexico. See generally Donald E. deKieffer, *The Mexican Drug Connection: How Trade in Pharmaceuticals Has Wrecked the FDA*, 9 SW. J. L. & TRADE AM. 321 (2003).

8. Welch, *supra* note 1.

9. *Id.*

10. For an example of a Canadian pharmacy, see CanaRx Services, Inc. (CanaRx), at <http://www.CanaRx.com> (last visited Oct. 21, 2004).

11. See *infra* notes 128–140 and accompanying text.

pharmacies take orders over the internet and mail the drug orders to American consumers.<sup>12</sup>

The practice of importing drugs across the border from Canada is known as reimportation.<sup>13</sup> Many of these drugs are originally manufactured by American pharmaceutical companies and distributed to Canadian pharmacies.<sup>14</sup> The Federal Food, Drug, and Cosmetic Act (FFDCA) expressly prohibits reimportation.<sup>15</sup> Although currently illegal, reimporting prescription drugs across the border<sup>16</sup> is a rapidly growing enterprise. In 2000, the importation of prescription drugs from Canada constituted a business of just a few million dollars per year.<sup>17</sup> By contrast, in 2003, the amount of reimportation activity was predicted to be \$800 million.<sup>18</sup>

The numbers are shocking. Consumers can save between 32% and 57% on commonly purchased prescription drugs by purchasing them from an online Canadian pharmacy.<sup>19</sup> For example, a person can purchase Celebrex<sup>20</sup> from the Canadian pharmacy CanaRx Services, Inc. (CanaRx) for more than 50% less than at Walgreens. Specifically, CanaRx sells 100 mg pills in quantities of 300 for \$218.90,<sup>21</sup> where Walgreens.com sells the same quantity of Celebrex pills for \$564.95.<sup>22</sup>

Mark McClellan, former Commissioner of the Food and Drug Administration (FDA) has said, "we are enforcing the law,"<sup>23</sup> but to date, only one Canadian pharmacy, Rx Depot, Inc. (Rx Depot) has been

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12. See *infra* notes 128–140 and accompanying text.

13. Michael Dickson, *International Pharmaceutical Expenditure Differentials: Why?*, in SUPPLEMENT TO MANAGED CARE: REIMPORTATION OF PHARMACEUTICALS: ECONOMIC AND POLICY IMPLICATIONS 3 n.1 (March 2004), available at [http://www.managedcaremag.com/supplements/0403\\_reimport/MC\\_0403\\_reimport\\_suppl.pdf](http://www.managedcaremag.com/supplements/0403_reimport/MC_0403_reimport_suppl.pdf).

14. See Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 153 (2000) (explaining that "the vast majority of biotech today is located within the United States" and that "[t]he American pharmaceutical industry is the undisputed world leader in developing new and effective treatments").

15. 21 U.S.C. § 381(d)(1) (2000).

16. *Id.*

17. Welch, *supra* note 1.

18. *Id.*

19. Tim Jones, *Seniors Find Canada Is Refuge from Drug Prices: U.S. Costs Leave No Choice, They Say*, CHI. TRIB., Sept. 21, 2003, § 1, at 1 (including a chart comparing U.S. drug prices with the price for the same drug from a Canadian pharmacy).

20. Celebrex is a well-known prescription drug made by Searle and Pfizer and is prescribed for the treatment of arthritis and to reduce other forms of pain and swelling. See Celebrex Website, at <http://www.celebrex.com> (last visited Oct. 25, 2004).

21. CanaRx, Medications List, at [http://www.CanaRx.com/Store/Medications\\_List.htm](http://www.CanaRx.com/Store/Medications_List.htm) (last modified Oct. 12, 2004) (listing the company's drug prices in U.S. dollars for sale to Americans).

22. Walgreens Pharmacy Website, at <http://www.walgreens.com/library/finddrug/druginfol.jhtml?id=15101> (last visited Oct. 25, 2004) (listing Celebrex 100 mg capsules at \$112.99 for a container of 60 capsules).

23. Welch, *supra* note 1.

shut down.<sup>24</sup> The FDA has also sent warning letters to other Canadian pharmacies,<sup>25</sup> but at this time it is too early to tell what the fate of Canadian pharmacies will be. Regardless of federal regulations prohibiting reimportation, many state and local politicians are seeking to begin reimportation programs for their constituents and individual consumers are already reimporting their medications in record numbers.

At the center of the reimportation issue is one piece of federal legislation. The United States House of Representatives passed the Pharmaceutical Market Access Act of 2003, H.R. 2427 (H.R. 2427)<sup>26</sup> on July 25, 2003.<sup>27</sup> If enacted into law, this bill would legalize reimportation of prescription drugs from twenty-six countries and remove the requirement that the Secretary of the Department of Health and Human Services (HHS) certify the safety of imported drugs.<sup>28</sup> This bill is becoming an important health care issue with tensions rising among the pharmaceutical industry, the FDA, Canadians, state and federal governments, and Americans who cannot afford their medication.

This Comment will demonstrate why Congress should not pass H.R. 2427 to legalize reimportation of prescription drugs from Canada. Part II of this Comment provides the detailed background necessary to analyze the problem of reimporting prescription drugs including descriptions of the following: (1) the Canadian and American health care systems; (2) the way prescription drugs are priced and regulated in each country; (3) the way in which Canadian pharmacies operate; and (4) the current American law regarding reimportation.<sup>29</sup> Part III discusses the views of all groups interested in the reimportation issue and introduces H.R. 2427.<sup>30</sup> Part IV explores alternatives to importing prescription drugs from Canada.<sup>31</sup> Finally, Part V concludes that legalizing reimportation is not an adequate solution to the rising costs

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24. See *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003).

25. See *infra* notes 157–162 and accompanying text.

26. H.R. 2427, 108th Cong. (2003). The Senate counterpart to H.R. 2427 is S. 1781. See S. 1781, 108th Cong. (2003). H.R. 2427 is the primary bill regarding legalizing reimportation. However, another bill addressing reimportation was recently introduced in the senate. See *The Pharmaceutical Market Access and Drug Safety Act of 2004*, S. 2328, 108th Cong.

27. *House Approves Reimportation; Senate Stands Against It*, WASH. DRUG LETTER, Aug. 4, 2003, 2003 WL 10134747 (explaining that the House approved H.R. 2427 by a vote of 243–186).

28. See H.R. 2427.

29. See *infra* notes 33–212 and accompanying text.

30. See *infra* notes 213–319 and accompanying text.

31. See *infra* notes 320–389 and accompanying text.

of prescription drugs and suggests that the best solution is for the United States to adopt its own system of price controls.<sup>32</sup>

## II. BACKGROUND

The soaring costs of prescription drugs in the United States and the affordability of these same drugs in Canada are driving Americans to purchase prescription drugs from online Canadian pharmacies.<sup>33</sup> The problem surrounding the Canadian pharmacies controversy is complex, and for an effective analysis of the legal issues surrounding this controversy, it is necessary to understand the health care systems in the United States and Canada. Accordingly, this section will briefly compare those health care systems and examine the pricing and regulation of prescription drugs in both countries. The types of Canadian pharmacies and the way in which Canadian pharmacies conduct business will also be addressed. Finally, this section will explain the current law on reimporting prescription drugs and introduce the most recent case in this area of law, *United States v. Rx Depot, Inc.*<sup>34</sup>

### A. A Comparison of U.S. and Canadian Health Care Systems

Americans purchase prescription drugs from Canadian pharmacies because they are cheaper than drugs available in the United States.<sup>35</sup> A comparison of the United States health care system to the health care systems in other countries reveals that Americans pay more for health care than anyone else in the world, not just Canada.<sup>36</sup> Understanding the basic differences between the health care systems of the United States and Canada is essential to analyzing the soaring costs of prescription drugs and the reimportation problem.

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32. See *infra* Part V.

33. See Welch, *supra* note 1.

34. 290 F. Supp. 2d 1238 (N.D. Okla. 2003)

35. Welch, *supra* note 1. See also Andrew Harris, Comment, *Recent Congressional Responses to Demands for Affordable Pharmaceuticals*, 16 LOY. CONSUMER L. REV. 219, 227–29 (2004); Jane Bryant Quinn, *A Remedy for Pricey Drugs*, NEWSWEEK, Sept. 27, 2004, at 31, 31; Vicki Kemper, *Importing Drugs Seen as a Way to Lower Costs*, L.A. TIMES, Mar. 20, 2004, at 23A.

36. See, e.g., HANDBOOK OF INTERNATIONAL HEALTH CARE SYSTEMS 118 (Khi V. Thai et al. eds., 2002) [hereinafter HANDBOOK]; HEALTH CARE DELIVERY IN THE UNITED STATES 4 (Anthony R. Kovner & Steven Jonas, eds., 7th ed. 2002) [hereinafter HEALTH CARE DELIVERY]; Michele L. Creech, Comment, *Make a Run For the Border: Why the United States Government Is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 612 (2001).

## 1. *The U.S. Health Care System*

The U.S. health care system is essentially a free market system.<sup>37</sup> Health care in the United States is a mostly privatized regime where citizens pay for their own privately financed and privately delivered health care programs and services.<sup>38</sup> America's health care system is a complex and loosely structured system that has even been described as a "non-system."<sup>39</sup> The complexity of the United States's system stems from a number of factors, including the country's population, its geographic size, the variety of methods available for providing health care services, managed care influences, and the challenges of financing health care.<sup>40</sup> Most health care coverage in America is provided through voluntary employer programs for employees and their dependents.<sup>41</sup> Government programs are generally limited to the poor, aged, and disabled.<sup>42</sup> Although many Americans have the option of health care insurance through an employer program or a federally funded program, a significant number of Americans do not have access to any health insurance.<sup>43</sup>

Medicare and Medicaid are the two major federally funded programs in the American health care system.<sup>44</sup> These two programs are also important to the issue of drug reimportation because many senior citizens receive the benefits of Medicare or Medicaid.<sup>45</sup> Medicare is a

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37. Creech, *supra* note 36, at 596.

38. Nicole A. Rothstein, Comment, *Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada*, 53 FED. COMM. L.J. 343, 366 (2001).

39. HANDBOOK, *supra* note 36, at 135 (describing the U.S. health care system as a colander, a leaky vessel being plugged one hole at a time). However the system is characterized or criticized, the American health care system provides the most cutting-edge technology, has the highest paid doctors, and has the most expensive hospitals in the world. HEALTH CARE DELIVERY, *supra* note 36, at 4; *see also* HANDBOOK, *supra* note 36, at 118.

40. *See generally* HANDBOOK, *supra* note 36. The private-public system of reimbursement for health care services is particularly complicated. Physicians can be reimbursed by a fee for service arrangement, salary, or prepayment. *Id.* at 121. This system is further complicated by the plethora of players in the insurance system and bureaucracy at all levels. *See id.* at 118–22.

41. *Id.* at 125. In 1995, about 70% of U.S. citizens were covered by private health insurance, and 85% of these individuals were insured through work-related insurance plans. *Id.* at 119.

42. *Id.* at 125.

43. HANDBOOK, *supra* note 36, at 124. In 1993, there were 39.7 million Americans, 15.3% of the population, without health insurance. *Id.* In 1995, there were 40.3 million Americans, 17.4% of the population, without health insurance. *Id.* at 124.

44. HEALTH CARE DELIVERY, *supra* note 36, at 50 (stating that "[i]n 1997, Medicare and Medicaid accounted for 83.5% of public outlays for personal health care services").

45. *See generally* Centers for Medicare and Medicaid Services (CMS), Medicaid Home Page, at <http://cms.hhs.gov/medicaid> (last modified Sept. 16, 2004); CMS, Medicare Home Page, at <http://cms.hhs.gov/medicare> (last modified Sept. 16, 2004). Medicare is specifically directed at those aged sixty-five and older. CMS, Medicare Home Page, *supra*. Senior citizens with low-

health insurance program that originated in 1966 and provides medical care benefits for citizens age sixty-five and older, disabled persons and their dependents, or those suffering from chronic kidney disease.<sup>46</sup> Medicaid, on the other hand, is a program run by federal and state governments together and provides medical assistance for certain individuals and families with low incomes.<sup>47</sup> Although the federal government has established guidelines for eligibility, Medicaid eligibility requirements are determined by each state.<sup>48</sup> Thus, whether a person will be eligible for Medicaid depends on the requirements of the state where she lives.<sup>49</sup>

Unfortunately, the trend in American health care is to decrease access to services and raise the cost of treatment.<sup>50</sup> Americans spend more on health care than do the people of any other country.<sup>51</sup> Furthermore, in 1995, 9% of the total expenditures allocated to health care were devoted to pharmaceuticals.<sup>52</sup> Even if a person has health insurance, the insurance typically will cover less than 100% of the drug costs.<sup>53</sup> In 1992, governmental and private health insurers covered 96% of hospital services and 82% of physician services, but only covered 72% of the cost of pharmaceuticals.<sup>54</sup> Because many senior citizens require a significant number of prescription drugs, the rising cost of prescription drugs impacts them more than any other category of citizens in America.<sup>55</sup>

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incomes are eligible for Medicaid. CMS, Medicaid Home Page, *supra*. Therefore, these two programs are significant sources of health insurance coverage for senior citizens.

46. HEALTH CARE DELIVERY, *supra* note 36, at 47–49.

47. CMS, Medicaid Home Page, *supra* note 45.

48. CMS, Medicaid Site for State & Territorial Government Information, at <http://www.cms.hhs.gov/states/default.asp> (last modified Sept. 16, 2004). The federal guidelines provide Medicaid eligibility to the following: low-income families with children, Supplemental Security Income (SSI) recipients, infants born to Medicaid-eligible women, children under age nineteen, pregnant women whose family income is at or below 133% of the federal poverty level, recipients of adoption assistance and foster care subsidies, and specially protected groups that may keep Medicaid for a limited period of time, such as people who lose Medicaid coverage due to loss of SSI payments or increased wages. CMS, Medicaid Eligibility, at <http://cms.hhs.gov/medicaid/eligibility/criteria.asp> (last modified Sept. 16, 2004) (explaining Medicaid eligibility requirements). States have discretion to allow Medicaid coverage for “categorically needy” people who share the characteristics of the mandatory groups. *Id.*

49. CMS, Medicaid Site for State & Territorial Government Information, *supra* note 48.

50. HANDBOOK, *supra* note 36, at 137.

51. Stephen R. Latham, *Pharmaceutical Costs: An Overview and Analysis of Legal and Policy Responses by the States*, 24 J. LEGAL MED. 141, 141 (2003) (explaining that in 2001 Americans spent \$140.6 billion on outpatient prescription drugs).

52. HANDBOOK, *supra* note 36, at 121.

53. *Id.*

54. *Id.* at 121–22.

55. Welch, *supra* note 1.

## 2. *The Canadian Health Care System*

In contrast to the U.S. health care system, the Canadian health care system is publicly financed but privately delivered.<sup>56</sup> Canada's system, known as Medicare, provides universal coverage to all Canadian residents.<sup>57</sup> Canadian Medicare covers hospital and physician services that are medically necessary.<sup>58</sup> Each Canadian province provides a health care plan that must meet criteria set forth in the 1984 Canada Health Act.<sup>59</sup> The delivery of health care is carried out by the private sector, including not-for-profit hospitals and physicians that are solo practitioners.<sup>60</sup> Thus, the insurance system in Canada is socialized, but health care delivery remains privately administered.<sup>61</sup>

Whereas the U.S. system is primarily privately financed,<sup>62</sup> Canada's health care system is financed by five different sources: the federal government, provinces, local government, workers compensation boards, and private sources.<sup>63</sup> Although money comes from all of these five sources, the majority of Canada's health care dollars come from the federal government and the provinces, through individual and corporate taxes.<sup>64</sup> The federal government also pays provinces on a per capita rate.<sup>65</sup> This rate is tied to the growth of the economy, as measured by the country's gross domestic product.<sup>66</sup>

Americans have demonstrated interest in adopting a system similar to Canada's,<sup>67</sup> but the Canadian system is not flawless.<sup>68</sup> Beginning in the 1980s, Canada began to experience problems with budget cuts, hospital closings and staff reductions, and delays or waiting lists for health care services.<sup>69</sup> Since the 1980s, the increasing federal budget deficit decreased spending on health care.<sup>70</sup> This left the provinces to bear more of the health care costs, but the provinces were experienc-

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56. Rothstein, *supra* note 38, at 366.

57. JANE FULTON, CANADA'S HEALTH SYSTEM: BORDERING ON THE POSSIBLE 2 (1993). Canadian Medicare arose out of political tensions surrounding the need for publicly financed health care insurance and was eventually implemented in every Canadian province by 1971. *Id.*

58. HANDBOOK, *supra* note 36, at 81.

59. *Id.*

60. *Id.* at 82.

61. *Id.*

62. *See supra* notes 37-55 and accompanying text.

63. FULTON, *supra* note 57, at 27.

64. *See id.*; HANDBOOK, *supra* note 36, at 84.

65. HANDBOOK, *supra* note 36, at 80-81.

66. *Id.* at 84.

67. *Id.* at 88.

68. *Id.* at 87-92.

69. *Id.*

70. *Id.* at 89-90.



ing budget deficits of their own.<sup>71</sup> The lack of sufficient funding resulted in hospital closings and staff reductions.<sup>72</sup> These budget cuts, hospital closings, and staff reductions have led to waiting lists and delays in service.<sup>73</sup> For example, hospitals have set limits on the number of procedures they will perform each year due to budget constraints, and the patient waiting time has substantially increased.<sup>74</sup>

*B. A Comparison of Pricing and Regulation of Prescription Drugs in the United States and Canada*

A comparison of pharmaceutical regulation and pricing systems in the United States and Canada reveals some similarities as well as a number of differences.<sup>75</sup> While both countries protect public health and safety through federal regulations of food and drug products, pharmaceuticals are priced very differently in each country.<sup>76</sup> While pharmaceutical companies in the United States determine the price of prescription drugs, pharmaceutical prices in Canada are subject to federal price controls.<sup>77</sup>

*1. Pricing and Regulation of Prescription Drugs in the United States*

Pharmaceutical companies set the prices of prescription drugs in the United States.<sup>78</sup> These companies have broad discretion to price drugs at whatever levels the market will allow.<sup>79</sup> Factors that contribute to the cost of drugs in the United States include research and development (R&D) expenditures, access to the newest technology, patent protection, an increase in drug use, marketing expenses, and lobbying expenses.<sup>80</sup> In short, prescription drug prices in the United States are high to offset the huge expenditures that pharmaceutical companies spend on developing and marketing their products.<sup>81</sup>

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71. HANDBOOK, *supra* note 36, at 89-90.

72. *Id.* at 90-91 (with a large increase in the number of doctors migrating to the United States).

73. *Id.* at 91-92.

74. *Id.*

75. See Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L.J. 215, 220-58 (1999). Carter's article compares the U.S. and Canadian systems' regulation and pricing of prescription drugs. *Id.*

76. See Creech, *supra* note 36, at 596-625 (discussing regulation and pricing of prescription drugs in various countries).

77. *Id.*

78. *Id.* at 600-12 (discussing factors that affect the price of drugs in the United States).

79. *Id.* at 596.

80. *Id.* at 600-10.

81. *Id.* at 596-612.

While pharmaceutical companies boast profit margins averaging nearly four times that of the average Fortune 500 company,<sup>82</sup> this industry is distinct from other industries.<sup>83</sup> While pharmaceutical companies seem to be incredibly profitable, enjoying the benefits of sales at high prices, in reality these companies are not as profitable as they seem.<sup>84</sup> Empirical studies have revealed that “the pharmaceutical industry’s profitability is within 1% of its real cost of capital, clearly not an excessive level of profitability.”<sup>85</sup> Pharmaceutical companies spend a considerable amount on R&D, but not every drug developed can recoup the costs incurred to bring it to market.<sup>86</sup> In addition to R&D expenditures, marketing costs must also be factored into the ultimate cost of drugs.<sup>87</sup> Furthermore, there is a long lag time between the initial investment in developing a drug and the time when the company makes money on the drug.<sup>88</sup> The development of a drug also requires a high amount of sunk costs,<sup>89</sup> which these companies must eventually recover.<sup>90</sup>

Although drug manufacturers determine the price of prescription drugs based on what the market will allow, pricing is not based on supply and demand.<sup>91</sup> Since consumers are not free to choose which drugs to purchase, comparison shopping is not feasible, and insurance companies (who are the ultimate purchasers of drugs for their insureds) have nothing to do with determining which drugs are prescribed and at which prices they are available, the pharmaceutical industry is not subject to free market forces.<sup>92</sup> Moreover, the reality is

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82. Not all pharmaceutical companies are profitable. Stanton, *supra* note 14, at 153. In fact, only 14 of the 260 publicly traded biotech companies are profitable. *Id.*

83. *Id.* at 154–57.

84. *Id.*

85. *Id.* at 156.

86. “On average only 3 out of every 10 prescription drugs available to treat Americans generate revenues that meet or exceed average R&D costs.” PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AM. (PhRMA), WHY DO PRESCRIPTION DRUGS COST SO MUCH . . . AND OTHER QUESTIONS ABOUT YOUR MEDICINES 2 (June 2000), <http://www.phrma.org/publications/publications/brochure/questions/questions.pdf>.

87. See Harris, *supra* note 35, at 225–26 (discussing how the pharmaceutical industry is impacted when marketing budgets exceed research and development (R&D) budgets).

88. *Id.* (explaining that it takes ten to twelve years on average to develop a drug).

89. Sunk costs are those “incurred in preparing to bring a product to market, and are largely unrecoverable once spent.” Stanton, *supra* note 14, at 155. Sunk costs include R&D, efficacy studies, and time delays due to experimentation and approval processes. *Id.*

90. *Id.*

91. Michael B. Moore, Comment, “Open Wide” (*Your Pocketbook That Is!*) – A Call for the Establishment in the United States of a Prescription Drug Price Regulatory Agency, 1 Sw. J. L. & TRADE AM. 149, 154–55 (1994).

92. *Id.*

that certain drugs are priced much higher than the costs to bring them to market.<sup>93</sup>

In the United States, the FDA is the federal agency charged with regulating the safety and efficacy of prescription drugs.<sup>94</sup> It has become a “direct regulator of industry through issuance of substantive rule, screening of new products for safety and effectiveness prior to marketing, and adjudication of a broad range of formal and informal proceedings subject only to limited review by courts.”<sup>95</sup> The statute currently governing this area is the FFDCA, which is the statute that regulates food, over-the-counter drugs, prescription drugs, and cosmetics.<sup>96</sup>

U.S. Customs also works with the FDA in investigating violations of public health and safety laws.<sup>97</sup> Customs ensures that all imports and exports comply with U.S. laws and regulations.<sup>98</sup> Customs has the authority to intercept illegal importation, exportation, and trans-ship-

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93. See Latham, *supra* note 51, at 147 (arguing that it is not unfair that Americans pay more for prescription drugs than people in other countries). Latham explains that (1) liability for drug manufacturing in the United States is higher than in other countries due to the litigious nature of the country, (2) other countries have health systems that function as monopsony buyers of drugs, able to negotiate lower prices, (3) the United States has a large economy that is not as price-sensitive as countries with smaller economies overall, and (4) it is cheaper for pharmaceutical companies to grant concessions to small foreign buyers of pharmaceuticals than it is to grant concessions to U.S. buyers. *Id.*

94. The Mission Statement of the U.S. Food and Drug Administration (FDA) is:

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

FDA, FDA's Mission Statement, at <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Oct. 28, 2004).

95. FOOD AND DRUG LAW 1 (Richard M. Cooper ed., 1991).

96. 21 U.S.C. §§ 301–399 (2000).

97. See Press Release, U.S. Food and Drug Administration, FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments (Oct. 1, 2003), at [http://www.cbp.gov/xp/cgov/newsroom/press\\_releases/archives/cbp\\_press\\_releases/0102003/10012003.xml](http://www.cbp.gov/xp/cgov/newsroom/press_releases/archives/cbp_press_releases/0102003/10012003.xml). See also Ivette P. Gomez, Note, *Beyond the Neighborhood Drugstore: U.S. Regulation of Online Prescription Drug Sales by Foreign Businesses*, 28 RUTGERS COMPUTER & TECH. L.J. 431, 439 (2002) (explaining that the FDA has partnered with such agencies as Customs, the Department of Justice, the Federal Bureau of Investigation (FBI), and the Postal Inspection Service to oversee regulation of drug importation into the United States).

98. U.S. Customs & Border Protection, U.S. Customs Service – Over 200 Years of History, at <http://www.cbp.gov/xp/cgov/toolbox/about/history/history.xml> (last visited Oct. 25, 2004) (detailing over 200 years of history of the organization).

ment of products that may jeopardize public health and safety, including the types of drugs being imported from Canada.<sup>99</sup>

## 2. Pricing and Regulation of Prescription Drugs in Canada

Unlike the U.S. government, the Canadian government sets price controls to regulate the cost of prescription drugs.<sup>100</sup> Although the Canadian system of pricing pharmaceuticals differs greatly from that of the U.S. system, the Canadian government also has a federal agency that regulates the pharmaceutical industry.

In contrast to the United States, Canada has federal price controls.<sup>101</sup> Over the years, Canada has experimented with various methods of price controls.<sup>102</sup> In 1968, the prices Canadians were paying for prescription drugs were among the highest in the world.<sup>103</sup> As a result, the Canadian government enacted legislation that mandated licensing of patented drugs to manufacturers.<sup>104</sup> In 1987, in response to concerns that patentee's rights were being undermined by the mandatory patent licensing law, Canada amended its patent act to guarantee exclusivity to the patentee for the first seven years of the patent's term before mandatory licensing could be imposed.<sup>105</sup> Anticipating the North American Free Trade Agreement, which eliminated compulsory licensing and imposed a twenty-year patent term, Canada established the Patented Medicines Prices Review Board (PMPRB) in 1987 and expanded its powers in 1993.<sup>106</sup>

Under the current method of price regulation, the PMPRB regulates prices of all pharmaceuticals.<sup>107</sup> The PMPRB sets a maximum price for each drug based on the average price of the drug in seven other developed countries.<sup>108</sup> The price of any given drug may fluctu-

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99. See U.S. Immigration & Customs Enforcement: Smuggling/Public Safety Division Website, at <http://www.ice.gov/graphics/investigations/publicsafety/index.htm> (last visited Oct. 25, 2004).

100. Stanton, *supra* note 14, at 160.

101. *Id.* at 167. In fact, most of the industrialized world (including Germany, Japan, and France), imposes price controls on pharmaceuticals. *Id.* at 160–65.

102. *Id.* at 160.

103. *Id.*

104. *Id.*

105. Stanton, *supra* note 14, at 160.

106. *Id.*

107. Creech, *supra* note 36, at 615. The Patented Medicines Prices Review Board (PMPRB) is “a quasi-judicial body, protects consumers and contributes to health care by ensuring that the manufacturers’ prices of patented medicines are not excessive.” Health Canada Home Page, at <http://www.hc-sc.gc.ca/english/about/org.html#1a> (last modified Sept. 24, 2004) (describing the various responsibilities of groups within the Health Canada organization).

108. Creech, *supra* note 36, at 615. The seven other countries are: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. *Id.* at 615 n.121.

ate within the Canadian Consumer Pricing Index,<sup>109</sup> but may not exceed the price established by PMPRB.<sup>110</sup> In addition, the PMPRB also compares the price of new drugs to medicines already available in Canada and may ask manufacturers to lower prices, pay fines, or return excess revenues if the price of a particular drug becomes too high.<sup>111</sup> Most manufacturers voluntarily comply with the PMPRB's requests for price reductions, but the PMPRB does have the authority to enforce compliance through formal hearings.<sup>112</sup> Thus, the prices of prescription drugs in Canada are significantly lower than the prices of the same drugs in the United States.

Although extremely attractive, lower prescription drug prices do not come without consequences.<sup>113</sup> One significant problem that Canadians face is that the newest, cutting-edge drugs are not available in Canada until well after they are available in the United States.<sup>114</sup> To keep drug prices low, Canadian health officials delay approval and introduction of new and more expensive drugs.<sup>115</sup> Although U.S. politicians and media focus on stories of Americans seeking prescription drugs from Canada, Canadians have also been coming to the United States to buy prescription drugs.<sup>116</sup>

Similar to the United States's FDA, Canada has an administrative program to ensure the safety of prescription drugs. In response to concerns about inadequate clinical testing of drugs for human use, the Canadian Parliament enacted the Food and Drugs Act in 1951.<sup>117</sup> This statute required that information about new drugs be submitted

109. The Statistics Canada website explains in detail what the Canadian Consumer Price Index is:

The Consumer Price Index (CPI) is an indicator of changes in consumer prices experienced by Canadians. It is obtained by comparing through time, the cost of a fixed basket of commodities purchased by consumers. Since the basket contains commodities of unchanging or equivalent quantity and quality, the index reflects only pure price movements. . . .

The CPI is widely used as an indicator of the change in the general level of consumer prices or the rate of inflation.

Statistics Canada, Consumer Price Index, at <http://www.statcan.ca/english/sdds/2301.htm> (last visited Oct. 25, 2004).

110. Creech, *supra* note 36, at 615.

111. *Id.*

112. Stanton, *supra* note 14, at 161 (explaining that the PMPRB has withstood legal challenges to its authority and jurisdiction).

113. Sally C. Pipes, *Cheaper Doesn't Mean Better. Ask a Canadian*, WASH. POST, Sept. 21, 2003, at B-3.

114. *Id.*

115. *Id.*

116. *Id.*

117. Carter, *supra* note 75, at 219.

to the Food and Drugs Division of the Department of Health and Welfare, the predecessor of the Health Products and Food Branch (HPFB).<sup>118</sup> The Canadian Food and Drugs Act provides the framework for regulation of prescription drugs in Canada.

The Canadian equivalent to the FDA is Health Canada.<sup>119</sup> The organization within Health Canada that is responsible for the regulation of pharmaceuticals is the HPFB.<sup>120</sup> Similar to the Food and Drug Commissioner in the United States, Canada has a Minister of Health.<sup>121</sup> The PMPRB and HPFB, among others, report to the Canadian Parliament through the Minister of Health.<sup>122</sup> Also like the FDA, Health Canada regulates a broad array of health issues including pharmaceuticals, food, the environment, and agricultural health issues.<sup>123</sup> Structured as a branch of Health Canada, the HPFB is the organization "responsible for evaluating, regulating and monitoring drugs, biologics, and medical devices."<sup>124</sup> In addition to regulating food and health products, the HPFB oversees food and natural health products and promotes good nutrition among Canadian citizens.<sup>125</sup>

### C. How Canadian Pharmacies Work

Cyberspace has changed the way people shop.<sup>126</sup> Consumers armed with virtual shopping carts can purchase just about anything online, including books, clothing, and now—prescription drugs.<sup>127</sup> The typi-

118. *Id.*

119. See Health Canada Website, at <http://www.hc-sc.gc.ca/english/about/about.html> (last modified Mar. 3, 2003). The mission and vision of Health Canada is the following: "Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all Canada's people and to making this population among the healthiest in the world." *Id.*

120. Health Products and Food Branch, Welcome, at [http://www.hc-sc.gc.ca/hpfb-dgpsa/index\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/index_e.html) (last modified Oct. 26, 2004).

121. The Minister of Health at the time of writing is The Honourable Ujjal Dosanjh. See Health Canada, Health Minister, at <http://www.hc-sc.gc.ca/english/media/minister/index.html> (last modified Oct. 25, 2004) (providing the biography of the current Minister of Health).

122. Devidas Menon, *Pharmaceutical Cost Control in Canada: Does it Work?*, HEALTH AFFAIRS, May–June 2001, at 92, 93. See also Health Canada Home Page, Online Organizational Chart, at <http://www.hc-sc.gc.ca/english/about/org.html> (last modified Sept. 24, 2004) (providing the organizational chart of Health Canada).

123. See Health Canada Home Page, at <http://www.hc-sc.gc.ca/english/index.html> (last modified Oct. 27, 2004).

124. HEALTH PRODUCTS & FOOD BRANCH, YOUR HEALTH & SAFETY: OUR PRIORITY, [http://www.hc-sc.gc.ca/hpfb-dgpsa/your\\_health\\_e.pdf](http://www.hc-sc.gc.ca/hpfb-dgpsa/your_health_e.pdf) (last modified Dec. 31, 2002) (describing the role of the Health Products and Food Branch (HPFB)).

125. *Id.* See also HPFB, About Us, at [http://www.hc-sc.gc.ca/hpfb-dgpsa/aboutus\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/aboutus_e.html) (last modified Apr. 13, 2004).

126. *Cybermedicine: The Benefits and Risks of Purchasing Drugs over The Internet*, 5 J. TECH. L. & POL'Y 1, 1 (2000) (explaining the widespread growth of the internet and "e-commerce").

127. See *id.*

cal corner drugstore is no longer the only way for people to fill their prescriptions. A comparison of the Canadian pharmacies available to Americans reveals that there are two types of Canadian pharmacies: (1) American companies that function as a local storefront of a Canadian pharmacy;<sup>128</sup> and (2) Canadian pharmacies operating from Canada via websites.<sup>129</sup>

### 1. *American Storefront Canadian Pharmacies*

The first type of Canadian pharmacy is the American company that acts as a local storefront of a Canadian pharmacy, serving customers by facilitating the reimportation of prescription drugs from Canada.<sup>130</sup> For example, Canada Drug Service is a franchise based in Naples, Florida with storefronts across the country.<sup>131</sup> Each location serves its customers by helping customers place orders for prescription drugs from Canadian pharmacies.<sup>132</sup> Customers of storefronts bring their written prescription to the store and fill out a medical questionnaire.<sup>133</sup> Storefronts then fax the prescription to one of seven Canadian pharmacies in British Columbia where a Canadian physician signs the prescription; the prescription is filled and then mailed directly to the customer.<sup>134</sup>

### 2. *Website Pharmacies Operating From Canada*

The second type of Canadian pharmacy consists of pharmacies that are located in and operate from Canada, taking orders through a website or a toll free telephone number.<sup>135</sup> For example, to purchase from

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128. Julie Appleby, *Firm Fights for Canadian Drugs*, USA TODAY, Oct. 7, 2003, at 3B.

129. See *infra* note 135 and accompanying text.

130. Appleby, *supra* note 128 (discussing how Rx Depot, Inc. (Rx Depot) serves its customers and explaining the lawsuit pending against them). Local storefronts such as Rx Depot have also been dubbed "facilitators" by the National Association of Boards of Pharmacy (NABP). NABP, POSITION PAPER ON THE IMPORTATION OF FOREIGN PRESCRIPTION DRUGS 2 (Mar. 2003), <http://www.nabp.net/ftpfiles/NABP01/foreigndrug.pdf> [hereinafter NABP POSITION PAPER]. The NABP states that "[a]lthough these operations, which range from Internet sites to store fronts, do not stock or dispense drugs, it is the position of the NABP that they are conducting the practice of pharmacy and must be appropriately licensed by the state board of pharmacy." *Id.*

131. Appleby, *supra* note 128. See also Kelly A. Young, *Business Provides Link to Canadian Drug: Mount Pleasant Operation That Brokers Prescriptions Is Fourth to Open in State*, MILWAUKEE J. SENTINEL, Nov. 9, 2003, at 5Z (describing operations of Canada Drug Service in Wisconsin).

132. Appleby, *supra* note 128; Young, *supra* note 131.

133. Appleby, *supra* note 128.

134. *Id.*

135. An example of a Canadian pharmacy that falls into this category is Medsforless.com, which operates out of White Rock, British Columbia. See Medsforless.com, *How to Order*, at <http://www.medsforless.com/howtoorder.htm> (last visited Oct. 28, 2004) (explaining the process for ordering). See also CanadaPharmacy.com, *How to Order Prescription Drugs*, at <http://www>.

Universal Drugstore, Ltd. (Universal Drugstore) in Winnipeg, Manitoba, the patient mails or faxes her prescription directly to Universal Drugstore in Winnipeg.<sup>136</sup> Some Canadian pharmacies, such as Universal Drugstore, also have the patient complete a questionnaire and release form.<sup>137</sup> Then a Canadian pharmacist contacts the American customer to review the prescription.<sup>138</sup> The Canadian pharmacist approves the prescription,<sup>139</sup> and it is mailed directly to the customer.<sup>140</sup>

To help inform consumers about the reliability of all types of online pharmacies, the National Association of Boards of Pharmacy (NABP)<sup>141</sup> has created the Verified Internet Pharmacy Practice Sites (VIPPS) program.<sup>142</sup> VIPPS was established in the spring of 1999 in response to a NABP task force recommendation that the internet pharmacy industry impose self-regulation.<sup>143</sup> Online pharmacies are entitled to display the VIPPS seal if they are deemed compliant with NABP standards.<sup>144</sup> Specifically, NABP standards require that the online pharmacies meet the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.<sup>145</sup> Other VIPPS criteria include "patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists."<sup>146</sup> The VIPPS seal contains a hyperlink to a website displaying verified information regarding the pharmacy's

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canadapharmacy.com/cart/index.cfm?fuseaction=prescriptions (last visited Oct. 28, 2004) (explaining the procedure of getting an American prescription filled). CanadaPharmacy.com is a Canadian pharmacy operating out of Surrey, British Columbia. CanadaPharmacy.com, at <http://www.canadapharmacy.com/index.cfm?CFID=3560413&CFTOKEN=50488851t> (last visited Oct. 26, 2004).

136. Universal Drugstore, How to Order: Option A, at <http://www.universaldrugstore.com/optionA.asp> (last visited Oct. 26, 2004) [hereinafter How to Order: Option A].

137. *Id.*

138. *Id.*

139. Universal Drugstore, Customer Service, at <http://www.universaldrugstore.com/customer-service.asp> (last visited Oct. 26, 2004).

140. How to Order: Option A, *supra* note 136.

141. Established in 1904, NABP "assist[s] state licensing boards in developing, implementing, and enforcing uniform standards to protect the Public Health." NABP Home Page, VIPPS, at <http://www.nabp.net/vipps/intro.asp> (last modified Aug. 13, 2004). NABP membership consists of the pharmacy boards of all fifty states and "the District of Columbia, three U.S. territories, eight Canadian provinces, [and] two Australian states." *Id.*

142. *See id.* (explaining the Verified Internet Pharmacy Practice Sites (VIPPS) program); Gomez, *supra* note 97, at 431.

143. *See* John Michael Ward, *Online Pharmaceutical Regulation: An Avenue to a Safer World*, 24 J. LEGAL MED. 77 (2003). Part II of Ward's article provides a thorough discussion of the regulatory scheme of internet pharmacies.

144. *See id.* Part II.1.

145. NABP Home Page, VIPPS, *supra* note 141.

146. *Id.*



website and information about the pharmacy.<sup>147</sup> A survey of Canadian pharmacy websites reveals none that bear the VIPPS seal.<sup>148</sup>

#### *D. The Current Law on Reimportation of Prescription Drugs*

The reimportation of prescription drugs from Canada into the United States is illegal.<sup>149</sup> Reimportation is expressly prohibited by 21 U.S.C. § 381(d)(1).<sup>150</sup> Drugs brought into the United States through reimportation will likely fail to comply with numerous other laws.<sup>151</sup> Furthermore, Canadian pharmacies, which claim that a personal use exception allows reimporting prescription drugs, are misleading American consumers because there is no existing policy to that effect.<sup>152</sup>

##### *1. FFDCA, 21 U.S.C. § 381(d)(1)*

The FFDCA, Title 21 of the United States Code § 381(d)(1) states that “except as provided in paragraph (2) and section 384 of this title, no drug . . . which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.”<sup>153</sup> Even if a particular drug is FDA-approved for use in the United States, it is illegal to bring the drug back into the United States through a Canadian pharmacy.<sup>154</sup>

Although reimporting prescription drugs is clearly illegal, this statute has not been strictly enforced.<sup>155</sup> Due to the increasing attention given to this issue, the FDA has recently made public statements that

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147. See Ward, *supra* note 143, at Part II.

148. The NABP Website contains a list of VIPPS certified pharmacies; none of them are Canadian pharmacies. See NABP Website, VIPPS Database Search Results, at <http://www.nabp.net/vipps/consumer/listall.asp> (last visited Oct. 28, 2004).

149. See 21 U.S.C. § 381(d)(1) (2000).

150. *Id.*

151. See Letter from William K. Hubbard, Associate Commissioner for Policy Planning, FDA, to Robert P. Lombardi, The Kullman Firm (Feb. 12, 2003), <http://www.fda.gov/ora/import/kullman.pdf> [hereinafter Hubbard Letter] (describing various laws violated by the reimportation of prescription drugs).

152. For a more specific discussion of personal importation provisions, see *infra* notes 174–185 and accompanying text. See generally Peter S. Reichertz & Melinda S. Friend, *Hiding Behind Agency Discretion: The Food and Drug Administration's Personal Use Drug Importation Policy*, 9 CORNELL J.L. & PUB. POL'Y 493 (2000). See also 21 U.S.C. § 856(a) (2000).

153. 21 U.S.C. § 381(d)(1) (2000).

154. *Id.*

155. Welch, *supra* note 1 (stating that “[w]hile acknowledging they cannot stop the importation of cheaper drugs, the FDA and Justice Department have begun efforts to crack down on cross-border drug sales and an Oklahoma-based chain of storefront sellers” (referring to Rx Depot)).

they are enforcing this law.<sup>156</sup> The FDA has begun to issue warning letters to parties violating this act.<sup>157</sup> For example, on September 16, 2003, the FDA sent a warning letter to the Detroit-based Canadian pharmacy, CanaRx.<sup>158</sup> Employees of CanaRx, a United States-based company, fill the prescriptions in Canada, bring the drugs into the United States, and then mail the prescriptions to its U.S. customers.<sup>159</sup> In this letter, the FDA explained that the agency learned about CanaRx's drug reimportation activities and advised the company that these activities are illegal.<sup>160</sup> Specifically, the FDA highlighted its concerns about violations of the FFDCRA and other federal laws, CanaRx's misleading statements, and public health and safety.<sup>161</sup> Finally, the FDA gave CanaRx fifteen days to notify the agency as to what steps it would take to comply with the law.<sup>162</sup>

Violations of the FFDCRA can result in either civil or criminal liability.<sup>163</sup> Under 21 U.S.C. § 332, a court can enjoin violations of the FFDCRA.<sup>164</sup> Alternatively, a person may be held criminally liable

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156. *Id.* Welch quotes the FDA Commissioner as saying, "We are enforcing the law, FDA's job is to assure drug safety in the United States, and unapproved, imported drugs are illegal because FDA does not have the resources under current law to assure their safety." *Id.* (internal quotation marks omitted).

157. There are several recent instances where the FDA has issued a warning letter to a party who violated the law regarding drug reimportation. *See, e.g.*, Letter from David J. Horowitz, Director, Office of Compliance, Center for Drug Evaluation and Research, FDA, to Harry Lee Jones, Store Manager, Rx Depot, Inc. in Lowell, Arkansas (Mar. 21, 2003), [http://www.fda.gov/foi/warning\\_letters/g3888d.pdf](http://www.fda.gov/foi/warning_letters/g3888d.pdf); Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Gregory Gonot, Deputy Attorney General, State of California (Aug. 25, 2003), <http://www.fda.gov/opacom/gonot.pdf>.

158. *See generally* Letter from David J. Horowitz, Director, Office of Compliance, Center for Drug Evaluation and Research, FDA, to G. Anthony Howard, President, CanaRx Services, Inc. (Sept. 16, 2003), [http://www.fda.gov/foi/warning\\_letters/g4291d.pdf](http://www.fda.gov/foi/warning_letters/g4291d.pdf) [hereinafter FDA Warning Letter to CanaRx] (warning that the company's drug reimportation activities violate the FFDCRA).

159. *Id.* at 1. Specifically, the FDA letter alleged that CanaRx is an Internet and U.S. mail operation that sends U.S. prescriptions, credit card information, and paperwork . . . to a U.S. mail Post Office box in Detroit, MI. . . . [T]he prescription and forms are retrieved by fax or from your Detroit P.O. Box and transported into Canada by yourself or by one of your employees. A prescription is then obtained from a medical doctor in Canada, and Canadian drugs are dispensed by Eastown Pharmacy, located in the Canadian province of Ontario, to your firm for mailing directly to the U.S. consumer.

*Id.* *See also* CanaRx, Welcome, at <http://www.canarx.com/> (last visited Oct. 26, 2004).

160. FDA Warning Letter to CanaRx, *supra* note 158, at 1.

161. *See id.* at 1-4.

162. *Id.* at 4.

163. Hubbard Letter, *supra* note 151, at 1.

164. 21 U.S.C. § 332 provides:

Injunction proceedings

under 21 U.S.C. § 333.<sup>165</sup> The U.S. Department of Justice (DOJ) is the primary enforcement mechanism for federal laws.<sup>166</sup> When a violation of the FFDCFA occurs, the DOJ will bring the lawsuit.<sup>167</sup>

## 2. *Other Illegalities of Reimportation*

Although 21 U.S.C. § 381(d)(1) is the primary provision making reimportation illegal, this activity will likely violate other laws.<sup>168</sup> For example, certain drugs reimported from Canada might not be approved by the FDA for U.S. consumers, might not meet FDA mandated labeling requirements, or might not be dispensed with a valid prescription.<sup>169</sup> The FFDCFA requires that all drugs introduced into interstate commerce be FDA-approved.<sup>170</sup> All prescription (and over-the-counter) drugs must also meet FDA labeling requirements, as set forth in the FFDCFA.<sup>171</sup> Furthermore, the FFDCFA requires that all prescription drugs be dispensed with a valid prescription.<sup>172</sup> Additionally, all drugs must meet FDA standards as to location of manufacture, formulation, source and specification of active ingredients, processing methods, manufacturing controls, container or closure system, and appearance.<sup>173</sup>

## 3. *Personal Use*

Canadian pharmacies mislead American consumers regarding the legality of reimportation by claiming that a personal use exemption

(a) Jurisdiction of courts. The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of section 301 [21 USCS § 331], except paragraphs (h), (i), and (j).

(b) Violation of injunction. In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury.

21 U.S.C. § 332 (2000).

165. 21 U.S.C. § 333 details civil and criminal penalties available to punish a party who violates the Federal Food, Drug, and Cosmetic Act (FFDCFA). *Id.* § 333.

166. Rothstein, *supra* note 38, at 351.

167. *See id.*

168. Hubbard Letter, *supra* note 151, at 2–3.

169. *Id.*

170. 21 U.S.C. § 355 (2000). This section provides: “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.” *Id.*

171. *Id.* § 353(b)(2) (listing labeling requirements). *See also* 21 C.F.R. §§ 201.56, 201.57 & 201.100(d) (providing the labeling requirements for prescription drugs for human use).

172. 21 U.S.C. § 353(b)(1) (requiring prescription by a physician).

173. 21 C.F.R. § 314.50 (2004) (prescribing content and format required for an application to the FDA for approval to market a new drug).

exists.<sup>174</sup> There are generally two types of personal use exemptions regarding reimportation of drugs: (1) a personal import exemption for controlled substances;<sup>175</sup> and (2) a personal importation policy in the FDA's Regulatory Procedures Manual.<sup>176</sup> This discussion of personal importation policies will, however, demonstrate that there is no personal use exception that allows the reimportation of prescription drugs in the manner carried out by Canadian pharmacies.

First, 21 U.S.C. § 956(a), which amends the Controlled Substances Act, allows a U.S. resident to import up to fifty dosage units of a controlled medication without a prescription.<sup>177</sup> When crossing the border with such a substance, the substance must be declared to Customs, the individual must intend to use the substance personally, and the substance must not present unreasonable health risks.<sup>178</sup> This provision, however, applies to *illegal* drugs—not the prescription drugs sold by the Canadian pharmacies.<sup>179</sup>

Secondly, there is a personal use exemption that applies to *unapproved* drug products imported into the United States for personal use by individuals.<sup>180</sup> This exemption applies to pharmaceuticals that will become prescription drugs but have not yet obtained FDA approval.<sup>181</sup> This policy exists only in the FDA's Regulatory Procedures Manual and not in any statute or regulation.<sup>182</sup> The unapproved drug product exemption is implemented primarily by individual FDA personnel, exercising their discretion to allow the importation of small

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174. For example, Canadian Pharmacy Discounts disclaims on its website, “[n]ote that U.S. residents are limited legally to importing no more than a three months supply of prescription drugs from a Canadian Pharmacy for personal use. Anything beyond that is not considered personal use.” Canadian Pharmacy Discounts Website, at <http://www.canadian-pharmacy-discounts.com/> (last visited Oct. 26, 2004). This website serves as an informational site, linking consumers to the Canadian pharmacy DiscountMedsForLess.com. *Id.*

175. 21 U.S.C. § 956(a) (2000).

176. FDA, REGULATORY PROCEDURES MANUAL: CHAPTER 9, SUBCHAPTER: COVERAGE OF PERSONAL IMPORTATIONS, [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html) (last visited Oct. 26, 2004) [hereinafter FDA REGULATORY PROCEDURES MANUAL]. Chapter 9 of the Regulatory Procedures Manual is currently being revised by the FDA. FDA, Regulatory Procedures Manual Chapter Descriptions, at [http://www.fda.gov/ora/compliance\\_ref/rpm/default.htm](http://www.fda.gov/ora/compliance_ref/rpm/default.htm) (last visited Oct. 26, 2004).

177. 21 U.S.C. § 956(a) (2000). *See also* U.S. Customs & Border Protection, FDA Enforcement Policy Regarding the Personal Importation of Violative Drugs, at [http://www.cbp.gov/xp/cgov/travel/alerts/medication\\_drugs.xml](http://www.cbp.gov/xp/cgov/travel/alerts/medication_drugs.xml) (last visited Oct. 25, 2004) (stating that an individual may be allowed to import a “three month supply of an unapproved drug”).

178. U.S. Customs & Border Protection, *supra* note 177.

179. 21 U.S.C. § 956(a) applies to all controlled substances except for subchapter I controlled substances. 21 U.S.C. § 956(a) (2000). *See id.* § 812 (defining and listing controlled substances).

180. Reichertz & Friend, *supra* note 152, at 493–94.

181. *Id.* at 493–97.

182. *Id.* at 493–94. *See* FDA REGULATORY PROCEDURES MANUAL, *supra* note 176.

quantities of unapproved drugs on a case-by-case basis.<sup>183</sup> This particular personal use exemption was used in the past to allow “AIDS buyers clubs” to bring unapproved AIDS therapies from Canada into the United States.<sup>184</sup> Although the FDA acknowledges this policy, the FDA has explained:

this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being “commercialized” to U.S. citizens. (Foreign versions are often what Canadian pharmacies offer to sell to U.S. consumers.) Moreover, the policy simply describes the agency’s enforcement priorities. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States. Although we must concede that FDA has not often prosecuted those importing illegal drugs into the United States from Canada, FDA reserves the right to do so in the appropriate circumstance.<sup>185</sup>

### *E. The Rx Depot Case: Reimportation Law Applied*

While tensions rise over the controversial Canadian pharmacies, the FDA and DOJ have started to crack down on the reimportation of prescription drugs from Canadian pharmacies.<sup>186</sup> The first targets of the FDA were Rx Depot and Rx of Canada, LLC (Rx Canada).<sup>187</sup> On September 11, 2003, the DOJ filed a suit against Rx Depot and Rx Canada, seeking a preliminary injunction to enforce the FFDCA.<sup>188</sup> On November 6, 2003, Judge Claire Eagan in the United States District Court for the Northern District of Oklahoma issued a preliminary injunction, which effectively shut down the storefront-type Canadian pharmacy, Rx Depot.<sup>189</sup>

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183. Reichertz & Friend, *supra* note 152, at 494.

184. *Id.*

185. Hubbard Letter, *supra* note 151, at 4.

186. Welch, *supra* note 1.

187. *FDA Blitzes Reimporters In Three-Pronged Assault*, DRUG INDUSTRY DAILY, NOV. 10, 2003, § 220, LEXIS, News [hereinafter *FDA Blitzes Reimporters*]. It seems that the FDA’s next target is CanaRx, another Canadian pharmacy. *Id.* The FDA has issued a warning letter to CanaRx, stating that it is considering enforcement options against the company. *Id.*

188. *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003). The Arkansas State Board of Pharmacy and the FDA together initiated the action against Rx Depot. NABP POSITION PAPER, *supra* note 130, at 10. The Arkansas State Board of Pharmacy issued a “Cease and Desist Letter” to Rx Depot, while the FDA issued a warning letter to Rx Depot. *Id.* According to the NABP, at least six state boards of pharmacy have taken action against local business facilitating American consumers obtaining prescription drugs from Canada, including Pennsylvania, South Dakota, Washington, Montana, and Arkansas. *Id.*

189. *Rx Depot*, 290 F. Supp. 2d at 1250.

The defendants in the lawsuit were Rx Depot, Rx Canada, Carl Moore, and David Peoples.<sup>190</sup> Rx Depot was a Nevada corporation that conducted business in Tulsa, Oklahoma.<sup>191</sup> The president of Rx Depot was defendant Carl Moore<sup>192</sup> and the secretary of Rx Depot was David Peoples.<sup>193</sup> Rx Canada was a limited liability company owned by defendant Jo-Max Moore, Carl Moore's son.<sup>194</sup>

Rx Depot and Rx Canada were American storefronts that assisted individuals in obtaining prescription drugs from pharmacies in Canada.<sup>195</sup> Rx Depot and Rx Canada had several U.S. storefront locations that would submit a U.S. customer's prescription and forms (including a medical history form and the customer's check or credit card information) to a cooperating pharmacy in Canada.<sup>196</sup> A Canadian doctor then rewrote the prescription, and the prescription was filled and shipped directly to the American customer.<sup>197</sup> The defendant companies received about 10% to 12% commission on each sale they facilitated for the Canadian pharmacy, thus the defendants essentially acted as commissioned sales representatives for the cooperating pharmacies.<sup>198</sup>

After the FDA made two undercover purchases of prescription drugs through Rx Depot,<sup>199</sup> the FDA issued a warning letter to the company.<sup>200</sup> The letter from the FDA to Rx Depot informed defendants that they were violating 21 U.S.C. § 381(d)(1), which makes reimportation of prescription drugs illegal, and 21 U.S.C. § 355, which

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190. *Id.* at 1240.

191. *Id.*

192. "Moore started Rx Depot a year ago after his ex-wife was diagnosed with cancer and discovered that the medication she needed was cheaper in Canada." Appleby, *supra* note 128.

193. *Rx Depot*, 290 F. Supp. 2d at 1240.

194. *Id.*

195. *Id.*

196. *Id.* Prior to being shut down, Rx Depot had 85 stores in 26 states. Appleby, *supra* note 128.

197. *Rx Depot*, 290 F. Supp. 2d at 1241.

198. *Id.*

199. In its first undercover purchase, an FDA investigator prepared a prescription for 60 pills of the FDA-approved drug, Serzone, used to treat depression. *Id.* at 1242. The investigator ordered a 100-pill package rather than the 60 pills "prescribed." *Id.* The investigator received a package containing 99 pills (but marked that it contained 100) of a foreign-manufactured version of the drug, known as APO-Nefazodone, from Pharmacy North, Inc., in Manitoba, Canada. *Id.* at 1242-43. APO-Nefazodone is not FDA-approved, thus, importing it violated 21 U.S.C. § 355. *Rx Depot*, 290 F. Supp. 2d at 1243. The drug also failed to meet U.S. labeling requirements and had a less descriptive package insert than the FDA-approved insert for Serzone. *Id.* at 1243. The second undercover purchase was of the drug Sporanox, an FDA-approved prescription drug, manufactured in Puerto Rico for the treatment of fungal nail infections. *Id.* This second prescription was also received from Pharmacy North, Inc. *Id.*

200. *Id.* at 1244.

pertains to importing unapproved new drugs into the United States.<sup>201</sup> After correspondence between defendants and the FDA, the FDA brought suit.<sup>202</sup>

At trial, the defendants (Rx Depot) unsuccessfully raised a variety of arguments ranging from constitutional arguments to policy arguments.<sup>203</sup> Rx Depot argued that its business helped further the important cause of providing cheaper prescription drugs to Americans who could not afford prescription drugs at U.S. prices.<sup>204</sup> Additionally, Rx Depot offered a “geographical discrimination argument” that the government was applying the law unevenly because residents in border states had more access to cheaper drugs than residents inland.<sup>205</sup> Rx Depot further argued that the government’s enforcement activities violated the Privileges and Immunities Clause of the Fourteenth Amendment and the First Amendment.<sup>206</sup>

Judge Eagan rejected each of Rx Depot’s arguments, ruling that defendants violated 21 U.S.C. § 331(d), § 331(t), and § 381(d)(1), by reimporting prescription drugs from Canadian pharmacies.<sup>207</sup> She also granted a preliminary injunction against the defendants, requiring them to cease all of Rx Depot’s and Rx Canada’s activities, including selling, importing, advertising, or promoting the business through any media, including their websites.<sup>208</sup>

Judge Eagan reasoned that the preliminary injunction was proper because the test for granting a preliminary injunction was clearly met.<sup>209</sup> In her analysis, Judge Eagan explained that the “defendants openly and notoriously violate the law”<sup>210</sup> and that “the evidence conclusively demonstrates that the defendants’ violations will continue

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201. *Id.*

202. *Rx Depot*, 290 F. Supp. 2d at 1244. Defendant’s response to the FDA’s warning letter was that all drugs they reimported were manufactured in the United States and that the drugs obtained by its customers “are not FDA approved.” *Id.* at 1294 (internal quotation marks omitted). The FDA deemed this response inadequate and so notified Rx Depot through a subsequent letter. *Id.* Defendant Moore also testified that they “would continue their activities unless this Court enjoins them.” *Id.* In furtherance of their cause, defendants also opened up an additional 50 Rx Depot and Rx Canada stores after they received the warning letter. *Id.*

203. *Id.* at 1238.

204. *Rx Depot*, 290 F. Supp. 2d at 1248.

205. *Id.* at 1240.

206. *Id.* at 1248–49.

207. *Id.* at 1248–50.

208. *Id.* at 1250–52.

209. *Id.* at 1247–48. An injunction is proper where the moving party shows: “1) a substantial likelihood of success on the merits; 2) irreparable injury if the injunction is not granted; 3) that injury outweighs any harm the injunction will cause the opposing party; and 4) the injunction is not adverse to the public interest.” *Rx Depot*, 290 F. Supp. 2d at 1246.

210. *Id.* at 1247.

absent an injunction by this Court.”<sup>211</sup> The court also emphasized, “[n]ot only is Congress the best forum to address the high cost of prescription drugs for U.S. citizens, but also Congress is currently considering legislation which could allow prescription drug importation from Canada.”<sup>212</sup>

### III. ANALYSIS

Great tension exists between American consumers and state governments who want to allow the reimportation of prescription drugs and the FDA and pharmaceutical companies who want it to remain illegal.<sup>213</sup> This section will address the tensions surrounding the Canadian pharmacies controversy and will discuss each group’s concerns. Then, this section will review congressional action involving reimportation. Finally, this section will propose federal legislation that would resolve the Canadian pharmacies debate.

#### A. Tensions Rising over Canadian Pharmacies

Canadian pharmacies are drawing increasing national attention.<sup>214</sup> Everywhere one looks, there is an article about senior citizens boarding buses to Canada or a news story about people not able to afford prescription drugs.<sup>215</sup> The primary stakeholders include American consumers, the FDA and NABP, pharmaceutical companies, the U.S. government, state governments, and Canadians. This section will discuss each group’s stance on Canadian pharmacies and their concerns in making reimportation of prescription drugs legal.

##### 1. American Consumers’ Concerns Regarding Reimportation

American consumers have two main interests related to Canadian pharmacies: (1) saving money on prescription drugs;<sup>216</sup> and (2) the safety and effectiveness of the drugs they obtain from Canadian pharmacies.<sup>217</sup> The statistics, however, indicate that, as the “industry” of

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211. *Id.*

212. *Id.* at 1245.

213. *See* Welch, *supra* note 1.

214. Gilbert M. Gaul & Mary Pat Flaherty, *Canada Is a Discount Pharmacy for Americans: FDA Doing Little to Stop Cross-Border Trade in Drugs*, WASH. POST, Oct. 23, 2003, at A17.

215. *See, e.g.*, Deaver & Swartz, *supra* note 5; Jones, *supra* note 19; Welch, *supra* note 1.

216. *See* Jones, *supra* note 19 (discussing how senior citizens save up to 70% on their prescription drugs when they purchase them from Canada).

217. McClellan, the former FDA Commissioner, explained: “FDA’s job is to assure drug safety in the United States, and unapproved, imported drugs are illegal *because* FDA does not have the resources under current law to assure their safety.” Welch, *supra* note 1 (emphasis added) (internal quotation marks omitted).



reimporting prescription drugs grows, Americans are more concerned with saving money on prescription drugs than with the safety of them.<sup>218</sup> The estimated one million Americans who are obtaining prescription drugs from Canada are “buying under buyer-beware conditions,” according to Mark McClellan, the former FDA Commissioner.<sup>219</sup>

Evidence also suggests that while most Americans seem to favor allowing reimportation,<sup>220</sup> Americans are not informed enough to make an objective decision about the issue.<sup>221</sup> For example, a survey of American consumers shows that those who were in favor of legalizing reimportation often changed their minds when given more information about the practice.<sup>222</sup> Prior to receiving information (from FDA and consumer groups) on the consequences and dangers of reimportation, 67% of adults surveyed said they favored importing drugs from Canada.<sup>223</sup> Prior to receiving information about reimportation, 58% of those surveyed also said they would encourage a friend or close family member to purchase prescription drugs from Canada.<sup>224</sup> The consumers’ answers to survey questions after reviewing information from the FDA and consumer groups changed dramatically.<sup>225</sup> After receiving such information, 58% said they *opposed* drug importation,<sup>226</sup> and 64% would *discourage* family and close friends from reimporting.<sup>227</sup> Furthermore, 77% of those surveyed said that people should not reimport drugs from Canada if it is ille-

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218. See generally Carol Ukens, *Uh-Oh Canada! U.S. Regulators Target the New Gold Rush—prescription Drug Imports from Across the Border*, DRUG TOPICS, May 5, 2003, at 37, 37. In 2002, about five Canadian pharmacies sold primarily to Americans. *Id.* In 2003, there were 75. *Id.* The FDA Director of Pharmacy Affairs, Thomas McGinnis, expected that number to rise to 95 by July or August of 2003. *Id.* Furthermore, “[f]rom just a few million dollars in 2000, the importation of price-controlled drugs from Canada has grown to a projected \$800-million this year and shows no signs of letting up.” Welch, *supra* note 1.

219. Welch, *supra* note 1.

220. Survey results reveal that, generally, Americans strongly support reimportation. See *Public Opinion Strongly Behind Reimportation, Survey Says*, WASH. DRUG LETTER, Oct. 20, 2003, 2003 WL 10134921. A Harris Interactive Health-Care Poll released in October 2003 indicated that “more than three-quarters of consumers in the U.S. said it would be ‘unreasonable’ for drugmakers to try to stop Canadian pharmacies from selling drugs over the internet.” *Id.* Additionally, the number of survey participants who bought drugs from a Canadian or other foreign pharmacy rose from 5% to 7% between November 2002 and October 2003. *Id.*

221. Ukens, *supra* note 218, at 47.

222. *Id.* (providing the results of a survey of 1,005 adults conducted for the National Association of Chain Drug Stores Foundation in March 2003).

223. *Id.*

224. *Id.*

225. *Id.*

226. *Id.*

227. Ukens, *supra* note 218, at 47.

gal,<sup>228</sup> and 81% were more opposed to the practice after learning that reimportation is enabling “large-scale” counterfeit drug operations.”<sup>229</sup>

## 2. *The FDA’s and the NABP’s Concerns Regarding Reimportation*

The FDA and NABP<sup>230</sup> are opposed to legalizing the reimportation of prescription drugs from Canada.<sup>231</sup> The FDA cites public health concerns as its primary reason for opposing the reimportation of prescription drugs.<sup>232</sup> Specifically, the FDA argues that drugs obtained from Canadian pharmacies are of “unknown quality,” even though they appear to be or purport to be the same FDA-approved products available in the United States.<sup>233</sup> The FDA further argues that Canadian pharmacies may provide “expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or drugs unaccompanied by adequate directions for use.”<sup>234</sup> While recognizing that the increasing cost of prescription drugs is an important public health issue, the FDA urges Congress to remedy the problem by implementing a prescription drug benefit in Medicare.<sup>235</sup>

In furtherance of its views on reimportation and in the name of public health, the FDA has unleashed a three-prong attack on reimportation.<sup>236</sup> First, the FDA began the process of shutting down Rx Depot, a Canadian pharmacy with storefronts across the United States.<sup>237</sup> Second, the FDA has begun targeting another Canadian

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228. *Id.*

229. *Id.*

230. NABP is the professional association made up of the State Boards of Pharmacy for all states in the United States, as well as the Boards of Pharmacy of “the District of Columbia, Guam, Puerto Rico, the Virgin Islands, New Zealand, eight Canadian provinces, two Australian states, and South Africa.” NABP Website, at <http://www.nabp.net> (last visited Oct. 28, 2004).

231. NABP POSITION PAPER, *supra* note 130, at 12 (explaining that the NABP opposes the legalization of drug reimportation); Letter from Mark McClellan, Commissioner of Food and Drugs to The Honorable W.J. “Billy” Tauzin, Chairman, House Committee on Energy and Commerce 1 (July 18, 2003), <http://www.phrma.org/publications/quickfacts/2003-07-25.813.pdf> [hereinafter FDA Letter to House] (explaining that FDA opposes the legalization of drug reimportation). See also *Examining Prescription Drug Reimportation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 107th Cong. 32 (2002) (statement of William Hubbard) [hereinafter Prescription Drug Reimportation].

232. FDA Letter to House, *supra* note 231, at 1.

233. *Id.* at 2–3.

234. *Id.* at 2. Prescription drugs obtained from Canada also may not have adequate labeling or package inserts, and there is no way to know whether the drugs have been stored in proper conditions to avoid a loss of efficacy. *Id.*

235. *Id.* at 4.

236. FDA *Blitzes Reimporters*, *supra* note 187.

237. *Id.* See also *supra* notes 186–212 and accompanying text.

pharmacy, CanaRx.<sup>238</sup> Early in November 2003, the FDA issued a warning letter to CanaRx, saying that the agency was considering its enforcement options against the company because it is violating federal laws, similar to Rx Depot's violations.<sup>239</sup> Finally, the FDA Commissioner of Policy and Planning, William H. Hubbard, "blasted a widely circulated study" commissioned by Illinois Governor Rod Blagojevich regarding how much money the State of Illinois would save by reimporting prescription drugs.<sup>240</sup> Hubbard criticized the study as overestimating the savings that Illinois would receive, emphasized that large-scale reimportation would encourage drug counterfeiting, and explained that "there are far better ways to get savings in medical costs for Illinois residents."<sup>241</sup>

Like the FDA, the NABP also opposes reimporting prescription drugs from Canada.<sup>242</sup> The NABP has urged the FDA to enforce the current laws regarding the reimportation of drugs from foreign countries.<sup>243</sup> In a letter from the NABP to Tommy G. Thompson, former HHS Secretary, and Mark B. McClellan, former FDA Commissioner, the NABP explained:

While recognizing that access to affordable medications is an important concern for U.S. citizens, NABP believes that existing laws and regulations prohibiting this activity need to be obeyed and enforced to allow for the safe and regulated supply of drugs and medications. Allowing the practice of cross-border Internet trade of medicines to continue and expand opens up the U.S. population to those who would take full advantage of the lack of regulatory enforcement to increasingly prey on American patients.<sup>244</sup>

The NABP has also criticized the "blatant disregard for the law by those in positions of authority," such as politicians sponsoring bus trips to Canada and Mexico.<sup>245</sup> The NABP explains that when authority figures support illegal activities, it sends a confusing message to Americans and wrongfully de-emphasizes the public health risks at stake.<sup>246</sup> In addition to supporting the FDA's position on reimporta-

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238. *FDA Blitzes Reimporters*, *supra* note 187. CanaRx is the only drug reimporter in Springfield, Massachusetts, which is the only U.S. jurisdiction actively reimporting drugs for its residents. *Id.*

239. *Id.*

240. *Id.*

241. *Id.* (internal quotation marks omitted).

242. *See* NABP POSITION PAPER, *supra* note 130, at 1.

243. *Id.* at 9.

244. *Id.* (quoting Letter from Carmen A. Catizone, Executive Director/Secretary NABP to Tommy G. Thompson, Secretary, United States Department of Health and Human Services and Mark B. McClellan, Commissioner, FDA (Feb. 26, 2003) (on file at NABP)).

245. *Id.* at 12.

246. *See id.*

tion, the NABP emphasizes that what is particularly disturbing about Canadian pharmacies is that “patients may never know there is a problem” with the drugs they are obtaining from those pharmacies.<sup>247</sup> If patients discover a problem, they have little or no recourse because the actual dispenser of the drug may be unknown, there may be no legal authority having jurisdiction over the problem, and oftentimes patients waive their right to sue when dealing with Canadian pharmacies.<sup>248</sup>

### 3. *Pharmaceutical Companies’ and the Pharmaceutical Research and Manufacturers of America’s (PhRMA) Concerns Regarding Reimportation*

The pharmaceutical companies and Pharmaceutical Research and Manufacturers of America (PhRMA)<sup>249</sup> oppose the practice of Americans reimporting prescription drugs from Canada.<sup>250</sup> Pharmaceutical companies and PhRMA support a Medicare prescription drug benefit and pharmaceutical company programs rather than reimportation.<sup>251</sup> PhRMA’s website also contains a statement directed to individuals unable to afford their medicines: “[f]or patients who can’t afford medicines, we urge you to avoid the risks of unsafe imports.”<sup>252</sup> PhRMA then encourages the individuals to visit a website containing “information about pharmaceutical-company programs offering free and discounted medicines to” those who qualify.<sup>253</sup>

Some pharmaceutical companies have begun to take direct action to secure their current market and pricing schemes by means of restricting supply and raising prices of pharmaceuticals.<sup>254</sup> Five major drug companies have moved to restrict supplies of pharmaceuticals to Ca-

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247. *Id.* at 1.

248. See NABP POSITION PAPER, *supra* note 130, at 1.

249. PhRMA is the primary lobbying group representing America’s “leading research-based pharmaceutical and biotechnology companies, which are devoted” to developing beneficial medicines. PhRMA, *Who We Are*, at <http://www.phrma.org/howeare/> (last visited Jan. 26, 2005).

250. See PhRMA, *Imports Carry Risks*, at <http://www.phrma.org/publications/publications/20.08.2003.832.cfm> (last visited Oct. 28, 2004).

251. *Id.*

252. *Id.*

253. *Id.* The website consists of information linking users to member pharmaceutical companies that offer programs for those who are eligible to receive free or discounted medications. See *Helping Patients Website*, at <https://www.helpingpatients.org/Intro.php> (last visited Oct. 28, 2004).

254. *Eli Lilly Fights Drug Sales from Canada*, BIOTECH WEEK, Nov. 12, 2003, at 154, Westlaw, NEWSRX Database; Bernard Simon, *Curtailing Medicines from Canada*, N.Y. TIMES, Nov. 11, 2003, at W1.

nadian pharmacies.<sup>255</sup> As of October 21, 2003, Eli Lilly joined Pfizer Inc. (Pfizer), GlaxoSmithKline (GSK), AstraZeneca, and Wyeth in limiting sales of their drugs to the amount sufficient to supply the Canadian market only.<sup>256</sup> Using loopholes in the Canadian price control system, several pharmaceutical companies have also raised the prices 4% to 8% since the summer of 2003.<sup>257</sup> An executive at Shoppers Drug Mart, one of Canada's largest drugstore chains, said "there was little doubt that the recent price increases were an attempt by drug makers to narrow the gap between [drug prices in] Canada and the United States."<sup>258</sup> Because the movement to restrict supply and raise prices began in 2003, it may be too early to tell what effect the restricted supply of drugs and increased prices will have on the Canadian pharmacy industry.<sup>259</sup> One Canadian pharmacy has already devoted a portion of its website to fighting GSK's ban.<sup>260</sup>

The pharmaceutical industry and PhRMA cite "well-documented concerns about the safety of imported drugs" as the basis of their opposition to reimportation.<sup>261</sup> Despite this, it is extremely hard to believe that they are not also concerned about their own profits. PhRMA touts the Medicare prescription drug benefit, but adding a prescription drug benefit will not impact the pricing of pharmaceuticals.<sup>262</sup> Supporting the Medicare prescription drug benefit, which does not lower the prices of drugs, allows PhRMA to show concern

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255. *Eli Lilly Fights Drugs Sales from Canada*, *supra* note 254, at 154.

256. *Id.*

257. Simon, *supra* note 254.

258. *Id.*

259. "The effectiveness of efforts by the brand-name companies to choke off supplies to the online pharmacies is hard to judge. IMS Health, a market research group in Montreal, estimated the growth in wholesale shipments of prescription drugs to Canadian pharmacies slowed to 5 percent in the third quarter." *Id.* The owner of one online Canadian pharmacy has been quoted as saying "that the clampdown by the pharmaceutical groups has changed the amount of effort it takes to purchase supplies every day. What used to take 15 minutes now takes two or three hours." *Id.* (internal quotation marks omitted).

260. See Canadian Drugs CA Website, at <http://canadiandrugs.ca/> (last visited Oct. 28, 2004). The Canadian pharmacy Canadian Drugs CA is urging its customers to help ensure that they can continue to supply Canadian drugs to Americans. *Id.* The website encourages customers to voice their opposition to GlaxoSmithKline's (GSK) restriction on Canadian supply by voicing their concerns to U.S. Senators, the GSK company, and the Canadian Competition Bureau. *Id.*

261. PhRMA, The Issues, at <http://www.phrma.org/issues/reimportation/> (last visited Oct. 28, 2004) (explaining PhRMA's position against legalizing reimportation but favoring a Medicare prescription drug benefit).

262. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

about the problem of high costs of prescription drugs without reducing the companies' bottom lines.<sup>263</sup>

#### 4. U.S. Government's Concerns Regarding Reimportation

Currently, the reimportation issue is also a hot topic in Congress.<sup>264</sup> President George W. Bush's administration has issued a Statement of Administration Policy explaining that the administration strongly opposes H.R. 2427, the bill currently in Congress that would legalize reimportation from Canada.<sup>265</sup> Instead, President Bush and his supporters prefer a Medicare prescription drug benefit, such as the one recently enacted.<sup>266</sup> The President argues that the Medicare prescription drug benefit would reduce the hardship of prescription drug costs for senior citizens.<sup>267</sup> Of course, it should not be overlooked that Bush and the Republican Party have received "tens of millions of dollars in campaign contributions from the pharmaceutical industry."<sup>268</sup>

On the other hand, most Democrats support legalizing reimportation.<sup>269</sup> Democrats who criticize the pharmaceutical industry argue that pharmaceutical companies get tax breaks for R&D and spend "lavishly on advertising and lobbying."<sup>270</sup> They further argue there are no reported cases of illnesses from drugs imported from Canadian pharmacies.<sup>271</sup>

#### 5. State and City Governments' Concerns Regarding Reimportation

The FDA remains steadfast in its opposition to reimportation, refusing to approve any large-scale proposals to import prescription drugs from Canada.<sup>272</sup> As the FDA continues to oppose reimportation, several state and city governments are getting involved in the reimportation issue.<sup>273</sup> Local governments in Illinois, Wisconsin, Min-

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263. See generally *id.*; PhRMA, *The Issues*, *supra* note 261 (explaining PhRMA's position on the issue of reimportation).

264. Welch, *supra* note 1.

265. EXECUTIVE OFFICE OF THE PRESIDENT, STATEMENT OF ADMINISTRATION POLICY, H.R. 2427 – PHARMACEUTICAL MARKET ACCESS ACT OF 2003 (July 23, 2003), available at <http://www.phrma.org/publications/quickfacts/2003-07-25.814.pdf> [hereinafter STATEMENT OF ADMINISTRATION POLICY].

266. *Id.*

267. *Id.*

268. Welch, *supra* note 1.

269. See *id.*

270. *Id.*

271. *Id.*

272. Ceci Connolly, *Kennedy Endorses Drug Importation; Senator Criticizes FDA, Plans Bill for Limited Program*, WASH. POST, Dec. 19, 2003, at A16.

273. *First U.S. State Is Set to Buy Canadian Drugs; Cross-Border Sales of Drugs*, PHARMA MARKETLETTER, Dec. 15, 2003, 2003 WL 55674850 [hereinafter *First U.S. State*]; *Health Canada*

nesota, Massachusetts, New Hampshire, and New York have all taken steps toward facilitating reimportation.<sup>274</sup>

City and state governments' efforts toward legalizing reimportation fall into three distinct categories. First, local government efforts towards legalizing generally consist of plans to establish programs to provide city employees and retirees with drugs from Canadian pharmacies.<sup>275</sup> Secondly, Illinois Governor Rod Blagojevich is attempting to obtain federal approval to have an Illinois reimportation program designated as the nation's first reimportation pilot program.<sup>276</sup> Finally, officials in Wisconsin and Minnesota are initiating investigations into whether pharmaceutical companies are violating antitrust laws by restricting sales to Canadian companies that export prescription drugs to the United States.<sup>277</sup>

To date, several cities and one state have announced plans to purchase for their residents prescription drugs from Canada.<sup>278</sup> New Hampshire is the only state so far to unveil plans to obtain drugs from Canadian pharmacies for prisoners, Medicaid recipients, and retired state employees.<sup>279</sup> The largest U.S. city to reveal such a plan is Boston, which plans to offer drugs from Canadian pharmacies as an option for city employees and retirees.<sup>280</sup> Additionally, Springfield, Massachusetts was the first jurisdiction to actually begin importing prescription drugs from Canada for its employees.<sup>281</sup> Burlington, Ver-

*Concerned Reimportation Will Cause Shortages*, DRUG INDUSTRY DAILY, Oct. 31, 2003, § 214, LEXIS, News [hereinafter *Health Canada Concerned*].

274. *Health Canada Concerned*, *supra* note 273. Other states such as Iowa, Minnesota, and California have "expressed interest." *Id.*

275. One Washington Post staff writer noted that "the FDA's adamancy has served to embolden the growing number of elected officials across the country who say they are desperate for a way to reduce skyrocketing drug bills and score political points with consumers." Connolly, *supra* note 272.

276. Monica Davey, *Illinois to Seek U.S. Exemption to Buy Drugs from Canada*, N.Y. TIMES, Dec. 22, 2003, at A27.

277. Joe Manning, *Doyle Seeks Antitrust Probe of Drug Firms*, MILWAUKEE J. SENTINEL, Dec. 20, 2003, at 3D; *States Likely to Coordinate Canadian Distribution Probes*, DRUG INDUSTRY DAILY, Nov. 14, 2003, § 224, LEXIS, News [hereinafter *States Likely to Coordinate*] (discussing Minnesota).

278. *First U.S. State*, *supra* note 273.

279. *Id.* See also Sanjay Gupta, *Blame Canada: New Hampshire Will Defy the FDA and Buy Drugs on the Net*, TIME, Dec. 22, 2003, at 130, 130. Gupta, CNN Medical Correspondent, opines that the New Hampshire plan "sounds pretty safe to me." *Id.*

280. *First U.S. State*, *supra* note 273. The City of Boston spends \$61 million per year on prescription drugs and estimates that its plan to offer drugs from Canadian pharmacies will save the city \$1 million per year. *Id.*

281. *Health Canada Concerned*, *supra* note 273. Springfield, Massachusetts expects to reduce its \$18 million annual drug bill by half. Cyril T. Zaneski, *Canada's Internet Pharmacies Thriving on Business from U.S.; Low Costs of Prescriptions Attract Seniors, Criticism*, BALTIMORE SUN, Dec. 21, 2003, at 1A.

mont has also announced its intent to import prescription drugs for city employees.<sup>282</sup>

While other government officials seem to be ignoring the law, Illinois Governor Blagojevich insists that he will not break the law.<sup>283</sup> Blagojevich's efforts began with an online petition to the FDA in hopes of persuading the FDA to allow Illinois to import Canadian drugs.<sup>284</sup> On December 22, 2003, Governor Blagojevich and Congressman Rahm Emanuel (D) announced they were sending a formal request to former HHS Secretary Tommy Thompson proposing that federal authorities waive the prohibition on reimportation.<sup>285</sup> If approved, the proposal would allow Illinois to reimport prescription drugs for its state employees and retirees.<sup>286</sup> Blagojevich emphasized that he wanted to "work hand in hand with the federal government to safely and legally import prescription drugs from Canada."<sup>287</sup> Despite insisting he will not break the law, Governor Blagojevich was embarking on a path that will inevitably require him to do so. Ironically, on August 17, 2004, Governor Blagojevich announced his plan to provide Illinois residents with access to prescription drugs from Canada, from Ireland, and from the United Kingdom.<sup>288</sup> Then on October 5, 2004, Governor Blagojevich unveiled I-Save Rx, a program that allows Illinois, Wisconsin, and Missouri residents to obtain prescription drug refills from Canadian and British pharmacies.<sup>289</sup>

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282. Zaneski, *supra* note 281.

283. Davey, *supra* note 276, at A27.

284. See The Fight for Affordable Prescription Drugs, at <http://www.affordabledrugs.il.gov/petitionInfo.cfm> (last visited Oct. 28, 2004).

285. Press Release, Governor Rod R. Blagojevich, Blagojevich and Emanuel Ask HHS Secretary Thompson to Let Illinois Import Approved Canadian Prescription Drugs (Dec. 22, 2003), at <http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=32&RecNum=2549> [hereinafter Blagojevich and Emanuel Ask]; *Illinois Governor Pushes for Drug-Buying Program* (Dec. 22, 2003), at <http://www.cnn.com/2003/HEALTH/12/22/prescription.drugs.ap> [hereinafter *Illinois Governor*].

286. *Illinois Governor*, *supra* note 285. The proposal has three distinct limitations: (1) that only a preapproved list of drugs would be reimported; (2) all prescriptions would be first filled by an Illinois pharmacist and only refills could be obtained from Canadian pharmacies; and (3) participation in the program would be entirely voluntary. *Id.*

287. Blagojevich and Emanuel Ask, *supra* note 285.

288. Press Release, Governor Rod R. Blagojevich, Governor Blagojevich Announces Plan to Make Illinois First State in the Nation to Provide Consumers with Access to Prescription Drugs from Canada, Ireland and the UK (Aug. 17, 2004), <http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=32&RecNum=3295> (announcing his plan to provide Illinois residents with access to Canadian prescription drugs).

289. Courtney Flynn, *State Starts Drug Import Plan*, CHICAGO TRIB., Oct. 5, 2004, § 1, at 1. The program is called I-SaveRX. See I-SaveRX, at [www.isaverx.net](http://www.isaverx.net) (last visited Oct. 28, 2004).



Wisconsin and Minnesota<sup>290</sup> are launching a different type of attack on the issue of reimportation, investigating whether pharmaceutical companies are violating antitrust laws by restricting sales to Canadian pharmacies that export prescription drugs to American citizens.<sup>291</sup> On December 19, 2003, Wisconsin Governor Jim Doyle asked the United States Attorney General John Ashcroft to investigate whether prescription drug companies have violated antitrust laws.<sup>292</sup> In spring 2003, the Minnesota Attorney General, Mike Hatch, launched an investigation into GSK's Canadian distribution practices.<sup>293</sup> Hatch claims that GSK has "violated state antitrust law and perhaps conspired with other drugmakers to do so."<sup>294</sup> In response, GSK argues that it is immune from violating antitrust laws because it is assisting the FDA in furthering its goal of preventing illegal reimportation of prescription drugs.<sup>295</sup> At the time of writing, Hatch is still involved in the ongoing investigation of GSK's alleged "conspiracy" to prevent reimportation of prescription drugs from Canada.<sup>296</sup>

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290. Minnesota has also launched a website that provides contact information to Minnesota residents regarding state-approved Canadian pharmacies but does not have the capability of taking orders directly through the website. See Minnesota RxConnect, at <http://www.MinnesotaRxConnect.com> (last visited Oct. 28, 2004). Despite a warning letter from the FDA, Minnesota's website is still online to date. See Helkei Tinsley, *Current Public Law and Policy Issues: Prescriptions Without Borders: America Looks to Canada for Answers to Solve the Prescription Drug Pricing Predicament in the U.S., but Is Importation Really the Solution?*, 25 *HAMLIN J. PUB. L. & POL'Y* 437, 468-72 (2004) (explaining in further detail the Minnesota website); *Minnesota's Canadian Drug Website Draws FDA Warning*, USA TODAY, Feb. 24, 2004, [http://www.usatoday.com/tech/webguide/internetlife/2004-02-24-fda-minn-warning\\_x.htm](http://www.usatoday.com/tech/webguide/internetlife/2004-02-24-fda-minn-warning_x.htm) (explaining the FDA warning letter issued to Minnesota officials regarding the website).

291. See Manning, *supra* note 277; *States Likely to Coordinate*, *supra* note 277.

292. Manning, *supra* note 277.

293. *Minnesota AG Demands GSK's Documents on Canadian Drugs Sales*, DRUG INDUSTRY DAILY, Oct. 2, 2003, § 193, LEXIS, News.

294. *Id.*

295. Press Release, GSK, GSK's Position on the Minnesota AG's Motion to Compel Documents, [http://www.gsk.com/press\\_archive/press2003/press\\_11172003b.htm](http://www.gsk.com/press_archive/press2003/press_11172003b.htm) (last updated Nov. 17, 2003). GSK explains:

The FDA has specifically encouraged manufacturers' assistance in halting the illegal importation of drugs. State antitrust enforcement that conflicts with the FFDCA and the FDA's initiatives to halt imports of unapproved drugs from Canada is preempted under the Supremacy Clause. Because GSK Canada's restrictions are consistent with federal drug policy, and because illegal trade is not protected by the antitrust laws, the AG may not pursue an antitrust enforcement action against GSK for its efforts to stem illegal importation of its medicines. There simply cannot be a conspiracy in violation of the antitrust laws to restrain trade in illegal goods.

*Id.*

296. Press Release, Minnesota Attorney General, Hatch Applauds Landmark Decision That Prescription Drugs May Legally Be Imported from Canada (May 10, 2004), at [http://www.ag.state.mn.us/consumer/PR/PR\\_040510GlaxoSmithKline.htm](http://www.ag.state.mn.us/consumer/PR/PR_040510GlaxoSmithKline.htm). See also *Fresh Off 2003 Victories, Pharma Lobbying Faces New Challenges*, THE FOOD & DRUG LETTER, Dec. 19, 2003, No. 690, 2003 WL 10527048.

## 6. *Canadians' Concerns Regarding Reimportation*

Americans are not the only ones engaged in political debate over Canadian pharmacies. Canadians are also upset about American reimportation of Canadian drugs.<sup>297</sup> Canadians are concerned that legalizing reimportation will restrict Canadians' access to the newest drugs by destroying incentives to invest in R&D to make new and better drugs.<sup>298</sup> In response, the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA)<sup>299</sup> asked the Canadian government to enact laws prohibiting the export of Canadian drugs to the United States.<sup>300</sup> In a November 13, 2003 press release, NAPRA said that exports of prescription drugs are causing difficulties in protecting Canadian public safety, placing much of the blame on the failure of the United States to enforce federal law prohibiting reimportation.<sup>301</sup> To date, the Canadian government has not enacted such legislation.

The Canadian public is not the only concerned group; executives at Canadian internet pharmacies also have concerns regarding reimportation.<sup>302</sup> Canadian pharmacies that export prescription drugs to Americans "are watching with a mixture of delight and dread as more and more cities and states announce that they are considering reimportation programs."<sup>303</sup> Canadian pharmacies want to expand their businesses to increase profits but have concerns regarding their ability to handle a "massive influx of new customers."<sup>304</sup> Additionally, these businesses do not want to "taunt the pharmaceutical industry," which is already restricting the supply of drugs to Canadian pharmacies, and cause them to take even more drastic measures to reduce the supply of drugs.<sup>305</sup>

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297. Pipes, *supra* note 113.

298. *Id.* "While Americans are flocking to Canada to get inexpensive drugs, Canadians have for years been going in the opposite direction, desperately seeking new and necessary medicines that they can only obtain in the United States." *Id.*

299. See NAPRA Website, at [www.napra.org](http://www.napra.org) (last modified Oct. 28, 2004) (providing information about the organization).

300. *Canadian Pharmaceutical Agency Wants Ban on Exports to U.S.*, PHARMACEUTICAL & MED. DEVICE L. BULL., Dec. 12, 2003, at 5.

301. *Id.* See Press Release, Canadian National Association of Pharmacy Regulatory Authorities, Canadian Pharmacy Regulators Call for Government Action on Prescription Exports (Nov. 13, 2003), <http://www.bcpharmacists.org/pdf/NAPRApressrelease03.pdf>.

302. *Reimportation: Advocates to Push for Legislation in 2004*, AM. HEALTH LINE, Dec. 15, 2003, Westlaw, APN-HE Database [hereinafter *Reimportation*].

303. *Id.*

304. *Id.* (internal quotation marks omitted).

305. *Id.* (internal quotation marks omitted).

### B. Proposed Federal Legislation on Reimportation

Although state and local governments favoring reimportation seek to implement reimportation programs, proponents of reimportation are calling for the passage of federal legislation.<sup>306</sup> Such federal legislation would amend the FFDCA to allow U.S. citizens and states to purchase prescription drugs from Canada.<sup>307</sup> One bill currently in Congress, H.R. 2427,<sup>308</sup> would legalize reimportation by amending the FFDCA if passed.<sup>309</sup>

On July 25, 2003, the House of Representatives passed<sup>310</sup> H.R. 2427, the Pharmaceutical Market Access Act of 2003.<sup>311</sup> H.R. 2427 would legalize reimportation by requiring the Secretary of HHS to promulgate rules permitting “wholesalers” and “qualifying individuals” to reimport prescription drugs into the United States.<sup>312</sup> H.R. 2427 would amend the Medical Equity and Drug Safety Act of 2000 (MEDSA), a previous effort to legalize reimportation.<sup>313</sup> The law was passed by Congress but never enacted.<sup>314</sup> MEDSA provided the Secretary of HHS with the option to implement the law, but the Secretary declined to do so.<sup>315</sup> On the other hand, H.R. 2427 would require the

306. *Id.* For a comprehensive discussion of past federal legislative efforts, see Creech, *supra* note 36, at 622–39. The most notable past attempt at legalizing reimportation was the Medical Equity and Drug Safety Act of 2000 (MEDSA). *See id.* at 622–28. Congress passed this law, which is codified at 21 U.S.C. § 384, but the Secretary of HHS never implemented it due to various problems with the bill. *Id.* at 635. The four major problems with the bill were (1) the bill’s labeling requirements gave drug manufacturers too much control over reimportation; (2) the bill’s Sunset provision took away incentive for pharmacists and wholesalers to invest in the resources necessary for reimportation (the Sunset provision required that the Act was only effective for five years after implementation); (3) because the bill would have allowed manufacturers to interfere with the resale of prescription drugs, language trying to prevent such an inference was not strong enough; and (4) the Act was not sufficiently funded. *Id.* at 635–39.

307. *See* H.R. 2427, 108th Cong. (2003).

308. The Senate companion to H.R. 2427, S. 1781, is not currently on the Senate’s legislative calendar, which “identifies bills and resolutions awaiting Senate floor actions.” United States Senate, Senate Legislative Calendar, at [http://www.senate.gov/pagelayout/legislative/one\\_item\\_and\\_teasers/Senate\\_leg\\_calendar\\_page.htm](http://www.senate.gov/pagelayout/legislative/one_item_and_teasers/Senate_leg_calendar_page.htm) (last visited Oct. 28, 2004). Government aides who work for Representative Gil Gutknecht (the sponsor of the bill) and Representative Bernard Sanders (who assisted in drafting the bill) say “they expect a ‘big push’ to get a bill through Congress.” *Reimportation, supra* note 302.

309. *Id.*

310. Elizabeth White, *Pharmaceuticals Drug Importation Bill Clears House, As 87 Republicans Buck Party Leaders*, BNA’S HEALTH CARE DAILY REPORT, July 28, 2003, Westlaw, BNA\_HCD Database.

311. H.R. 2427.

312. *Id.*

313. 21 U.S.C. § 384.

314. Creech, *supra* note 36.

315. For a discussion of why the MEDSA was never enacted into law, see Creech, *supra* note 36.

Secretary to lift the ban on reimportation within 180 days of when it was passed.<sup>316</sup>

If enacted into law, H.R. 2427 would require that anyone reimporting a drug into the United States provide the Secretary of HHS with records containing: "the name and amount of the active ingredient, the date of shipment and quantity shipped, points of origin and destination, the prices paid and charged by the importer, and the manufacturer's lot or control number for the product."<sup>317</sup> H.R. 2427 would also require reimported drugs to be in counterfeit-resistant packaging<sup>318</sup> and to comply with the sections of the FFDCA relating to approval, misbranding, and adulteration of drugs.<sup>319</sup>

#### IV. IMPACT

Reducing the cost of prescription drugs without sacrificing investment on R&D and without reducing quality and safety is a difficult, if not impossible, task. Because of the complexity of the issue and the high tensions between groups involved, there is no easy answer. Although the problem of escalating prescription drug costs is complex, several proposals could lessen the impact of the high costs of prescription drugs. This section will review proposed initiatives including manufacturer discount programs, a Medicare prescription drug benefit, legalizing reimportation, and price controls in the United States.

##### A. *Manufacturer Discount Programs*

Several major pharmaceutical companies, either jointly or as a team, offer discount programs on pharmaceutical products for low-income seniors or other eligible customers. For example, the Together Rx program is a joint effort of major drug manufacturers that offers eligible senior citizens discounts of up to 20% to 40% on many of their products.<sup>320</sup> Together Rx was founded by Abbott Laboratories, AstraZeneca, Aventis, Bristol Myers Squibb, GSK, Janssen, Novartis, and Ortho-McNeil.<sup>321</sup> Together Rx allows a patient to carry just one

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316. H.R. 2427.

317. *H.R. 2427, The Pharmaceutical Market Access Act of 2003, as Passed by the U.S. House of Representatives on July 23, 2003* (Nov. 19, 2003), at <http://www.cbo.gov/showdoc.cfm?index=4852&sequence=0> (summarizing the requirements of H.R. 2427).

318. H.R. 2427.

319. *Id.* (referring to §§ 501, 502, and 505 of the FFDCA).

320. Together Rx, Frequently Asked Questions, at <http://www.togetherrx.com/faq.html> (last visited Oct. 28, 2004).

321. Together Rx, Founding Members, at <http://www.togetherrx.com/alliance.html> (last visited Oct. 28, 2004).

card to get discounts on prescription drugs from the member PhRMA manufacturers.<sup>322</sup>

Similarly, other companies such as Pfizer and Eli Lilly have their own individual programs. Pfizer offers the "Pfizer For Living Share Card," where eligible senior citizens can obtain certain Pfizer prescription drugs for a substantially reduced rate.<sup>323</sup> Eli Lilly offers a similar program called Lilly Answers.<sup>324</sup> In Eli Lilly's program, low-income senior citizens can purchase Eli Lilly's prescription drugs at a substantial discount.<sup>325</sup>

While these manufacturer discount programs are a good first-step toward reducing prescription drug prices, they are not a sufficient solution. These programs are only directed toward senior citizens. Although the high cost of drugs greatly affects senior citizens, *all* Americans, not just senior citizens, are suffering from the staggering prices of prescription drugs. For example, children and adults with chronic ailments who require daily medications are overlooked by the manufacturer discount programs. While these programs should be encouraged to continue until more permanent measures are effectuated, manufacturer discount programs are only a partial solution.

### B. *Addition of a Prescription Drug Benefit to Medicare*

Opponents of reimportation and advocates of the pharmaceutical industry called for the legislature to add a prescription drug benefit to Medicare rather than legalizing reimportation.<sup>326</sup> The Senate voted to pass the Prescription Drug and Medicare Improvement Act of 2003<sup>327</sup> on November 25, 2003,<sup>328</sup> and it was enacted into law on December 8, 2003.<sup>329</sup> This piece of legislation was the "first major expansion of the Medicare program since it was created thirty-eight years ago."<sup>330</sup> It provides prescription drug coverage for low-income senior citizens and disabled persons.<sup>331</sup> Until 2006, when the main benefit of the legislation goes into effect, drug discount cards will be available to senior

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322. Together Rx, Frequently Asked Questions, *supra* note 320.

323. See Pfizer For Living, Who Can Enroll?, at <http://www.pfizersharecard.com/nudoyouqual.asp?cardImageOver=2> (last visited Oct. 28, 2004).

324. Lilly Answers, at <http://www.lillyanswers.com> (last visited Oct. 28, 2004).

325. *See id.*

326. Jill Zuckman & Bruce Japsen, *Medicare Drug Bill Redraws Landscape*, CHI. TRIB., Nov. 26, 2003, § 1, at 1 (discussing the views of notable members of Congress).

327. Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066.

328. Zuckman & Japsen, *supra* note 326.

329. 117 Stat. at 2066.

330. Zuckman & Japsen, *supra* note 326.

331. §§ 101-102, 117 Stat. at 2071-81.

citizens from competing companies that “charge different annual fees and different prices for the same medications.”<sup>332</sup>

This bill has received mixed reviews. Republicans (including President Bush) view the bill very positively because the passage of the bill gives Republicans an edge on what is typically a Democratic issue.<sup>333</sup> Pharmaceutical companies support the bill because it does not affect their pricing systems or profits.<sup>334</sup> Senior citizens, the individuals the bill was supposed to help, are “confused” or “think it stinks.”<sup>335</sup>

The primary objection senior citizens have is that they find the bill complicated and difficult to understand.<sup>336</sup> In response, the Bush administration, American Association of Retired Persons, and HHS are undertaking efforts to explain the new law to senior citizens.<sup>337</sup> Other objections are that senior citizens and retirees who currently have prescription drug coverage through an employer’s insurance will be worse off on Medicare if that employer discontinues insurance, which is an unfortunate trend many retirees are experiencing.<sup>338</sup> Also, “[t]he legislation has been criticized for not offering seniors, particularly middle-income seniors, much of a prescription-drug benefit.”<sup>339</sup> Wisconsin Senator Herb Kohl (D) argued:

The bill fundamentally changes the nature of Medicare. . . . Instead of enhancing the current guaranteed benefit under Medicare with prescription drug coverage, the bill allocates billions to insurance companies to entice them to serve Medicare beneficiaries.

. . . .

And what will these insurance companies do with this extra money? They will design their plans to attract the healthiest, wealthiest seniors—and leave poorer, sicker seniors in traditional Medicare facing higher costs.<sup>340</sup>

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332. Edward Walsh & Bill Brubaker, *Drug Benefit's Impact Detailed; Many Will Face Big Out-of-Pocket Costs*, WASH. POST, Nov. 26, 2003, at A10.

333. See Bob Kemper, *Bush, GOP Revel in Medicare, Economy*, CHI. TRIB. Nov. 26, 2003, § 1, at 11.

334. See *Statement by Alan F. Holmer, President and CEO, Pharmaceutical Research and Manufacturers of America (PhRMA), On the Passage of the Medicare Prescription Drug Benefit*, PR NEWswire, Nov. 25, 2003, LEXIS, News.

335. Confusion Surrounds New Medicare Law (Dec. 22, 2003), at <http://www.cnn.com/2003/HEALTH/12/22/medicare.confusion.ap>.

336. *Id.*

337. *Id.*

338. Tammie Smith, *Medicare Overhaul 'Bad Deal'?; Advocates for Senior Citizens Are Prepared to Get to Work to Try to Improve the Plan*, RICH. TIMES DISPATCH, Nov. 26, 2003, at A-11, 2003 WL 8040168.

339. *Id.*

340. Patricia Simms, *Kohl, Feingold Say Medicare Legislation Is Seriously Flawed*, WISC. STATE J., Nov. 25, 2003, at A1 (internal quotation marks omitted).

Kohl further explained that the government will actually pay these insurance companies more than it would currently cost Medicare to provide the same coverage.<sup>341</sup> Likewise, some people worry that this bill might lead to an eventual privatization of Medicare.<sup>342</sup>

Although some have criticized the passage of a Medicare prescription drug benefit, many view it as a step in the right direction.<sup>343</sup> One advocate for senior citizens has said that this “gives all of us a chance to do some advocacy work on it, what it is and what we still need to have.”<sup>344</sup> Like the manufacturer discount programs, the addition of a Medicare prescription benefit is directed specifically toward senior citizens and will not benefit working-age Americans who do not qualify as low-income persons. While senior citizens are among the most affected groups, this measure also does not address the real problem—it does not lower the high cost of pharmaceuticals nor does it cure any of the reasons for these high costs.

### C. *Legalizing Reimportation Through H.R. 2427, The Pharmaceutical Market Access Act of 2003*

Legalizing reimportation is not an adequate solution to remedy the high costs of prescription drugs. If enacted into law, H.R. 2427 would legalize reimportation. The idea behind reimportation is to “get U.S. prices down to Canada’s prices.”<sup>345</sup> The primary argument against legalizing reimportation is that doing so would effectively cause America to adopt Canada’s system of price controls. Other reasons that legalizing reimportation is not an adequate solution include the expense of implementing a regulatory system to oversee reimportation and the difficulty of ensuring public safety. Finally, legalizing reimportation may not solve the problem for the long term.

#### 1. *Effectively Adopting Canada’s Price Controls*

Legalizing reimportation would have the practical effect of adopting Canada’s price controls. Two major problems arise when a country adopts another country’s price controls. First, Americans generally “do not support the idea of letting another country dictate what prices our manufacturers can charge.”<sup>346</sup> Secondly, adopting an-

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341. *Id.*

342. Smith, *supra* note 338.

343. *Id.*

344. *Id.*

345. JOHN CALFEE, FALSE SOLUTION: WHY DRUGS FROM CANADA WON’T CUT PRICES 10 (Nov. 2002), <http://www.phrma.org/publications/policy/admin/2003-07-10.771.pdf>.

346. *Id.*

other country's price controls does not make economic sense. America is home to most of the leading pharmaceutical manufacturers.<sup>347</sup> The primary reason is that the United States has the most conducive business environment for pharmaceutical companies, operating in a free market pricing system that rewards innovative pharmaceutical research solutions.<sup>348</sup> The United States may eventually decide to follow Canada and most of Europe and adopt price controls on pharmaceuticals. But why should the United States just blindly adopt Canadian price controls? If Americans in fact decide to implement price controls, America should develop its own system—one that preserves some of the incentives for pharmaceutical companies to develop new treatments and medicines.

## 2. *Expensive to Implement Effective Regulatory System*

In addition to not making economic sense, another reason not to legalize reimportation is that implementing a regulatory system to oversee reimportation will cost the United States an enormous amount of money.<sup>349</sup> The FDA predicts that the first year cost of implementing a regulatory program to ensure compliance with requirements of H.R. 2427 could be over \$50 million.<sup>350</sup> Furthermore, the cost of the anti-counterfeiting technology required by this bill "could raise the cost of prescription drugs by as much as \$2 billion in the first year."<sup>351</sup>

The Congressional Budget Office (CBO) reports that if Congress enacts H.R. 2427, it would "reduce total prescription drug expenditures by about 1% or \$40 billion over the 2004–2013 period."<sup>352</sup> However, the CBO report neglects to consider the cost of implementing a regulatory program and fails to consider the cost of this bill to the pharmaceutical industry.<sup>353</sup> Compliance with H.R. 2427 will cost

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347. See CALFEE, *supra* note 345, at 12. Interestingly, 45% of all new drug development in the entire world happens in the United States. Rhonda Kay McPherson, *Policy Considerations: Medicare and Prescription Drug Coverage*, 8 GEO. PUB. POL'Y REV. 25, 31 (2003).

348. *Id.*

349. FDA Letter to House, *supra* note 231, at 4.

350. *Id.* This cost estimate is based on a system where approximately 1000 samples would be taken. *Id.* The letter notes that this estimate "could increase based on the necessary sampling rate for the sampling that is allowed by [H.R. 2427]." *Id.*

351. *Id.*

352. H.R. 2427, *The Pharmaceutical Market Access Act of 2003*, *supra* note 317. The CBO report goes on to say the bill would also "reduce spending on health benefits for firms that provide health insurance. As a result, more of employees' and retirees' compensation would be in the form of taxable income, thus increasing tax revenues. CBO estimates that H.R. 2427 would increase federal revenues by \$1.5 billion over the 2004–2013 period." *Id.*

353. See generally *id.*



pharmaceutical companies a substantial amount of money. The pharmaceutical companies will in turn pass that cost onto consumers. Regulation of reimportation to ensure public safety will also cost the federal government, and ultimately taxpayers, a large sum of money.

### 3. *Public Health and Safety Problems*

Another cost of H.R. 2427 is the impact on public health and safety. Americans might pay more for their prescription drugs, but the U.S. government contends that they enjoy the safest and highest quality drug products in the world.<sup>354</sup> If enacted, H.R. 2427 would “create serious drug safety problems.”<sup>355</sup> HHS Secretary Tommy Thompson explained that legalizing reimportation could “increase the flow of counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions.”<sup>356</sup> He further explained, “in light of the anthrax attacks of last fall [2001] that’s a risk we simply cannot take.”<sup>357</sup> The FDA has no way to verify where reimported drugs were manufactured, where they have been, their previous storage conditions, or that they have not been tampered with or contaminated.<sup>358</sup>

In 2001, the FDA and U.S. Customs conducted a survey of imported drug products entering the United States through a Carson City, California mail facility.<sup>359</sup> From this survey, the FDA summarized the primary risks to Americans associated with importation of this type: “1) taking drugs of unknown origin or quality, and 2) taking prescription drugs without prescriber supervision.”<sup>360</sup> Perhaps the worst public health problems are yet to come. Legalizing reimportation will open the doors to potentially huge public safety problems.<sup>361</sup>

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354. According to the Executive Office of the President, “[t]he overall quality of drug products that consumers purchase from licensed pharmacies in the United States is the highest in the world and Americans can be confident that the drugs they use are safe and effective.” STATEMENT OF ADMINISTRATION POLICY, *supra* note 265.

355. *Id.*

356. Prescription Drug Reimportation, *supra* note 231.

357. *Id.*

358. NABP POSITION PAPER, *supra* note 130, at 2.

359. *Id.*

360. *Id.* at 3. The Carson City survey found that officials discovered that 8% of the packages contained drugs that were unidentifiable. *Id.* at 2. Several of the drugs found did not correspond to FDA-approved drugs. *Id.* One package contained a drug that was denied FDA approval because of cardiac risks and a lack of data showing its efficacy. *Id.* Several shipments contained drugs which were withdrawn from the market or controlled (illegal) substances. NABP POSITION PAPER, *supra* note 130, at 2. Finally, many of the drugs which passed through this survey were drugs intended to treat conditions properly diagnosed only by a physician and have serious side effects and interactions with other drugs and foods. *Id.*

361. *Id.* at 1-4.

If enacted, H.R. 2427 would greatly impede the FDA's authority and ability to ensure the safety of prescription drugs used by Americans.

#### 4. *Reimportation May Not Solve the Problem of High Drug Prices*

Legalizing reimportation might provide some immediate relief from the high costs of prescription drugs, but it is not clear that it will provide long-term relief. One scholar, John Calfee, predicts that legalizing reimportation will backfire.<sup>362</sup> Calfee predicts that U.S. prices will not drop to the current Canadian levels.<sup>363</sup> Instead, he forecasts that Canadian prices will increase to almost the current U.S. levels.<sup>364</sup> Calfee explains, "reimportation would fail to achieve its primary goal [of lowering pharmaceutical prices] but it would have the side effect of upsetting our Canadian neighbors, whose health care system is perpetually in fiscal crisis."<sup>365</sup>

The reason reimportation will not have the intended effect is that applying Canadian prices to the much larger U.S. market will set off a chain of events, unanticipated by supporters of H.R. 2427.<sup>366</sup> If the United States legalizes reimportation, drug manufacturers will face huge reductions in revenues because of drug purchases at Canada's lower prices.<sup>367</sup> It will follow that American drug manufacturers then may stop shipping drugs to Canada.<sup>368</sup> If the manufacturers stop shipping to Canada, they would lose their Canadian sales but retain American drug sales at the higher American price.<sup>369</sup> Canada would then find itself without U.S. drugs and would have no choice other than to raise their drug prices back to something close to the U.S. prices.<sup>370</sup> The result would be that "our prices would go down very little, but Canadian prices would go up a lot."<sup>371</sup> To make matters worse, America would have adopted a "very strange pharmaceutical pricing system," adopting Canada's price controls and linking the two countries' systems of pricing pharmaceutical products.<sup>372</sup>

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362. CALFEE, *supra* note 345, at 10.

363. *Id.*

364. *Id.*

365. *Id.*

366. *Id.* at 11.

367. *Id.*

368. CALFEE, *supra* note 345, at 2.

369. *Id.*

370. *Id.*

371. *Id.*

372. *Id.*

### D. Price Controls on Prescription Drugs

Government initiated price controls are the most sensible solution to the rising cost of prescription drugs. One survey indicates that 72% of Americans support direct governmental limitations on the costs of prescription drugs.<sup>373</sup> The current buzz surrounding reimportation is likely due to legislation currently under consideration and the advocacy of politicians. However, while reimportation is considered a solution to high drug costs, it is only fair to consider imposition of price controls in the industry. If one consequence of legalizing reimportation is that America would effectively adopt Canada's system of price controls, America should consider instituting its own system of price controls.

#### 1. Other Countries "Free-Riding" Off the Unregulated American System

The United States is "one of the only industrialized nations in the world where pricing in the pharmaceutical industry is unregulated."<sup>374</sup> Just because other countries have price controls does not mean the United States should blindly follow. The problem, however, is that the United States is "subsidizing European health care."<sup>375</sup> The pharmaceutical industry in this country is the "undisputed world leader in developing new and effective treatments."<sup>376</sup> Because almost all other industrialized nations have price controls to keep drug costs low, drugs cost more in America to compensate drug companies for profits not realized abroad. All of these other countries are essentially "free-riding" off the unregulated American system.

American citizens should not bear the burden of the development of new and innovative drug therapies for the world. "Since most industrialized nations have implemented drug price controls, instituting

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373. Stonybrook University, Health Pulse of America 2003 Survey, at [http://www.sunysb.edu/surveys/HPANov03\\_Pharma.htm](http://www.sunysb.edu/surveys/HPANov03_Pharma.htm). The Stonybrook survey also indicates that approximately two out of every three Americans support legislative action legalizing reimportation. *Id.* The author of this Comment believes that the survey is most useful to illustrate that Americans are supportive of any measures that will reduce the costs of prescription drugs, especially considering that Americans changed their minds when informed about the risks of reimportation. See Ukens, *supra* note 218, at 47.

374. Creech, *supra* note 36, at 595.

375. Martha Ann Holt, Note, *International Prescription Drug Cost Containment Strategies and Suggestions for Reform in the United States*, 26 B.C. INT'L & COMP. L. REV. 325, 326 (2003).

376. Stanton, *supra* note 14, at 153. Specifically, "between 1970 and 1992, American firms accounted for 42.8% of the world's breakthrough drugs, and American firms lead in all drug categories." *Id.* at 154. These numbers are striking, especially compared with Britain, which accounts for 14%, Germany, which accounts for 7%, and France, which accounts for 3% of the world's breakthrough drugs. *Id.*

similar controls in the U.S. may simply be leveling the playing field.”<sup>377</sup> Instituting modest price controls, starting slightly under current prices, will put pressure on pharmaceutical manufacturers to streamline their businesses. Furthermore, the imposition of price controls in the American pharmaceutical industry would force other countries to bear some of the R&D burden of new and better drugs.

## 2. *Why the United States Should Institute Price Controls in the Pharmaceutical Industry*

Although pharmaceutical companies are strongly opposed to price controls,<sup>378</sup> the U.S. government should implement price controls because it is the lesser of two evils. Critics argue that price controls will “severely reduce the money available for new drug R&D.”<sup>379</sup> Essentially, the argument is that “the immediate financial savings to consumers from limiting the price of existing pharmaceuticals will substantially reduce the industry’s incentive to innovate future advances, and its ability to fund research at current levels.”<sup>380</sup>

However, the same result would occur from legalizing reimportation. If H.R. 2427 is enacted into law, Americans will obtain increasing amounts of prescription drugs from Canada. Increased sales at lower Canadian prices and decreased sales at the higher American prices will have the effect of slashing profits for pharmaceutical companies. If it is inevitable that the industry suffers pressure against innovation, the federal government should choose the option giving it the most control over the pricing of drugs. The United States should adopt *its own* price controls, rather than adopting the price controls of another country. Although it is impossible to predict the future, the U.S. government could carefully evaluate economic factors to develop a system of price controls that will preserve incentives for pharmaceutical companies to develop new and better drugs. Furthermore, if the United States controls drug prices, the government will have the power to make adjustments that will help preserve the incentives for innovation.

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377. Moore, *supra* note 91, at 161.

378. *Id.* at 152–56.

379. *Id.* at 155.

380. Stanton, *supra* note 14, at 149–50. Stanton further points out that “America’s overwhelming lead in worldwide pharmaceutical innovation [is attributed] to the absence of price regulation here.” *Id.* at 168.

### 3. *Implementation of Price Controls in the United States*

The first step in implementing price controls in the American pharmaceutical industry will involve the creation of a government agency to regulate and oversee price controls.<sup>381</sup> Because so many other countries regulate drug prices, the United States can look to other countries' successes and failures in developing its own system.<sup>382</sup> Since so many Americans are looking to Canada's drugs for relief from high prices, perhaps the U.S. government should be looking at Canada's system of price controls and Canada's PMPRB.

The government agency created to implement and oversee price regulation in the pharmaceutical industry would ideally be "empowered to set reasonable drug prices, to disseminate drug information to the medical community, and to effect necessary remedial measures if the agency's guidelines are not followed."<sup>383</sup> Additionally, there are certain features that this agency must have in order to be effective.<sup>384</sup> It must have full access to pharmaceutical industry records, especially confidential records of drugmakers.<sup>385</sup> Furthermore, this agency must have broad power to enforce its regulations, including the power to punish drug manufacturers in a pecuniary manner, by levying fines or recovering excess profits.<sup>386</sup> An effective regulatory agency will also provide unbiased information to the public and to the medical community regarding prescription drugs as an alternative to the information provided by pharmaceutical companies themselves.<sup>387</sup> Most importantly, the agency should also have the power to limit drug prices and to limit price increases to rates equal to or only slightly above the rate of inflation.<sup>388</sup> The federal government must also allow the agency to use its power to demand lower prices by "blacklisting" drugs that it determines are priced too high, as long as comparable alternatives exist.<sup>389</sup>

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381. Pharmaceutical companies have proposed instituting "voluntary price controls" on themselves. Moore, *supra* note 91, at 166. However, "the fox should never be put in charge of the hen house." *Id.* It seems clear that the most practical way to implement price controls in the pharmaceutical industry in America would be through a government agency, rather than the pharmaceutical industry itself. *See id.* at 166-69.

382. *Id.*

383. *Id.* at 167.

384. *Id.*

385. Moore, *supra* note 91, at 167.

386. *Id.* at 168.

387. *Id.*

388. *Id.*

389. *Id.*

## V. CONCLUSION

Reimportation of prescription drugs should remain illegal. By legalizing reimportation, the United States will invite public health disasters and will be effectively adopting Canada's system of price controls. The better solution is for the United States to join the vast majority of industrialized nations and implement their own system of price controls. Americans must take steps to prevent other countries from "free-riding" off the U.S. system, which is currently free from federal price regulations. The U.S. government cannot continue to let other countries take advantage of the American system because Americans cannot afford their drugs.

Until a system of federal price regulation can be implemented, perhaps a more comprehensive Medicare prescription drug benefit and more manufacturer discount programs will help alleviate the problem for the short-term. However, American lawmakers should work towards a long-term solution. Although the U.S. government may be reluctant to implement federal price regulations, the government should take steps to improve the availability of prescription drugs to its own citizens. The federal government should take action to lower American prescription drug prices so that millions of Americans do not have to go without medications that will improve their health.

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