

**IN SEARCH OF A GOVERNMENT THAT  
WILL GOVERN: SENATE BILL 812 AND  
“REIMPORTING” PRESCRIPTION  
MEDICATION FROM CANADA**

*Abraham N. Saiger*

*America’s senior citizens pay more for prescription medication than those of any other nation, both because the United States places no price controls on prescription medication, and because the strong U.S. economy can withstand such differential pricing. As a result, many American seniors are turning to Canadian pharmacies to provide their medication. In this note, Abraham N. Saiger examines Senate Bill 812 (S. 812), the Greater Access to Affordable Pharmaceuticals Act, which would allow U.S. citizens to reimport low-cost prescription drugs from Canada. Mr. Saiger argues that S. 812 is unlikely to resolve the problems that it was designed to address because it is unsafe, economically unsound, and will not create adequate pressure to force the pharmaceutical industry to drive down prices. He ultimately concludes that S. 812 will never become law because no one will be willing to certify its safety. Mr. Saiger posits that S. 812 is not a valid solution to the problem of expensive prescription medication and recommends instead that reimportation proposals such as S. 812 be forgotten in lieu of privatizing the U.S. prescription health care system.*

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Abraham N. Saiger is an Associate Editor 2003–2004, Member 2002–2003, *The Elder Law Journal*; J.D. 2004, University of Illinois College of Law; B.A. 1998, History, Northwestern University.

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## I. Introduction

The United States of America is the wealthiest country in the world<sup>1</sup> thanks in no small part to today's senior citizens.<sup>2</sup> The wealth and power that generation has cultivated and grown has paid handsome dividends, but has taken its toll as well. The strong and secure U.S. market created by America's seniors made possible innovations in science and technology, especially in the field of medical research.<sup>3</sup> The tangible benefits of these innovations include life-enhancing and life-prolonging prescription medications.<sup>4</sup> Paradoxically, precisely because the U.S. market and economy is so strong, the senior population in America pays more for prescription medications than any other population on earth.<sup>5</sup> The result is that many of America's seniors are driven to Canadian pharmacies by a U.S. government that fails to address their medical needs, and continued to fail in the summer of 2002.

This note focuses on Senate Bill 812 (S. 812), or the Greater Access to Affordable Pharmaceuticals Act,<sup>6</sup> and Senate Amendment 4300, drafted by Senator Byron Dorgan (D-N.D.) (the Dorgan Amendment<sup>7</sup>), allowing for wholesale commercial reimportation of prescription medication from Canada. Part II of this note discusses the background of this issue, namely, internal and external conditions in the pharmaceutical medicine industry and how S. 812 purports to address them. Part III analyzes S. 812 and "reimportation" in the context of gray markets and price differentiation and price controls, and finds that S. 812 is unlikely to resolve the problems it is designed to address. Part IV recommends that reimportation proposals be taken off the table, and that Congress privatize the U.S. prescription health care system. Part V concludes that S. 812 will never become law, rather the U.S. Senate will continue to avoid making hard decisions

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1. CENT. INTEL. AGENCY, CIA WORLD FACT BOOK 2003, at <http://www.cia.gov/cia/publications/factbook/index.html>.

2. See Robert L. Bartley, *Trade Warriors: Baby-Boomers Toy with Matches*, WALL ST. J., Mar. 17, 1993, at A14.

3. See Jonathan Rauch, *Taking Stock*, ATLANTIC ONLINE, Jan.-Feb. 2003, at <http://www.theatlantic.com/issues/2003/01/rauch.htm>.

4. See Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 162 (2000).

5. See 146 CONG. REC. S7194 (daily ed. July 19, 2000) (statement of Sen. Jeffords).

6. S. 812, 107th Cong. (2002).

7. 148 CONG. REC. S6969 (daily ed. July 17, 2002).

until this crisis for the elderly and for the nation is unfixable, and the stakes of making a clear decision are too high. At that point, it will be too late to craft an operational plan, and Congress will be forced to take drastic and destructive measures that could have been avoided.

## II. Background

### A. The Current State of Affairs

The senior population in America pays more for prescription medications than any other population.<sup>8</sup> And, there is no denying that pharmaceutical prices are higher in the United States than in any other country.<sup>9</sup> Comparative studies show that for every dollar spent on pharmaceutical medication in the United States, the same drugs cost only sixty-five cents in Switzerland, sixty cents in Sweden, sixty-four cents in the United Kingdom, fifty-one cents in France, and forty-nine cents in Italy.<sup>10</sup> Senator Mark Pryor (D-Ark.) compared U.S. prices for the five most popular drugs for seniors—Lipitor (Pfizer), Celebrex (Pharmacia and Upjohn), Zocor (Merck), Prilosec (Astra/Merck), and Prevacid (TAP Pharmaceuticals)—to prices in other industrial nations, namely Canada, France, the United Kingdom, Italy, and Japan.<sup>11</sup> Senator Pryor found that uninsured seniors in the United States paid approximately 128% more for Prilosec, 131% more for Prevacid, 129% more for Celebrex, 101% more for Lipitor, and 72% more for Zocor.<sup>12</sup> While Senator Pryor's study focused on the most successful flagship drugs, Senator Dorgan conducted similar research and found that the average brand name drug in Canada is 38% cheaper than in the United States.<sup>13</sup>

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8. See 146 CONG. REC. S7194 (daily ed. July 19, 2000) (statement of Sen. James Jeffords).

9. See *id.*

10. See *Talk of the Nation: Obstacles to Reimporting Prescription Drugs from Abroad as a Way to Lower Pharmaceutical Drug Prices in the United States* (NPR radio broadcast, Jan. 2, 2001), 2001 WL 4189807 [hereinafter *Talk of the Nation*].

11. MARK PRYOR FOR U.S. SENATE, PRESCRIPTION DRUGS ARE MORE EXPENSIVE IN ARKANSAS THAN IN CANADA, EUROPE, AND JAPAN 4 (July 2002) [hereinafter PRYOR].

12. *Id.* at 8.

13. Press Release, Office of Sen. Dorgan (D-N.D.), U.S. Consumers Pay Substantially Higher Prices for Their Medications than Consumers in Canada and Other Countries (on file with The Elder Law Journal).

Pharmaceutical spending in the United States increased dramatically over the last ten years.<sup>14</sup> As a percentage of health care spending, prescription drug spending increased from 5.6% in 1993 to 7.9% in 1998.<sup>15</sup> The cost of drugs rose 19.1% in 1999,<sup>16</sup> and continued to rise in 2001—increasing nearly 19% to more than \$132 million.<sup>17</sup> Additionally, the number of prescriptions written every year is expected to double in the next ten years, possibly exceeding 4.5 billion prescriptions per year as early as 2004.<sup>18</sup> This simultaneous increase in drug prices and drug usage necessarily places a heavy burden on the U.S. health care system.

Ballooning drug prices are especially problematic for the elderly, whose ranks are growing, whose incomes are often fixed, and whose need for prescription drugs is higher than the general population.<sup>19</sup> According to the most recent estimates from the Congressional Budget Office (CBO), Medicare beneficiaries accounted for about 40% of the more than \$100 billion spent on prescription drugs in the United States.<sup>20</sup> Despite talk of reforming and modifying Health Maintenance Organizations (HMOs), socializing medicine, health care, or prescription benefits, or privatizing Social Security, Medicare and prescription benefits, little has been done.<sup>21</sup> The plight of Amer-

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14. See *Examining Prescription Drug Importation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs: Hearing Before the House Subcomm. on Health of the Comm. on Energy & Commerce*, 107th Cong. 65 (2002) (prepared statement of Elizabeth A. Wennar, President and CEO, United Health Alliance).

15. Gail Shearer, *Prescription Drugs for Medicare Beneficiaries: 10 Important Facts*, <http://www.consumersunion.org/health/drugdc400.htm> (Apr. 14, 2000).

16. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE AMOUNTS AND AVERAGE ANNUAL PERCENT CHANGE BY TYPE OF EXPENDITURE: SELECTED CALENDAR YEARS 1980–2011, at <http://www.cms.hhs.gov/statistics/nhe/projections-2001/ta.asp> (last modified July 17, 2002).

17. See Bruce B. Fallik, *Beyond Co-Pays*, *WORLDATWORK J.* Apr. 1, 2003, 2003 WL 19186227.

18. *Id.*

19. See Eric Schmidt, *Politics Stalls Congressional Action on Medicare Drug Benefits*, *N.Y. TIMES*, Feb. 27, 2000, at A35. This problem is especially acute among the uninsured elderly, who face a formidable two-tiered pricing system that seeks to capture profits from individuals that it lost in negotiations with insurance providers. See FED. TRADE COMM'N, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE*, at <http://www.ftc.gov/reports/pharmaceutical/drugexsum.htm> (last visited Feb. 23, 2004).

20. *Administration's FY 2003 Budget Proposal for Prescription Drugs: Hearing Before the S. Comm. on Fin.*, 107th Cong. 71 (2002) (statement of Dan L. Crippen, Director, Cong. Budget Office).

21. See Jennifer Rak, Note, *An Rx for Reform: A Medicare Prescription Drug Benefit*, 12 *HEALTH MATRIX* 449 (2002).

ica's growing senior population, however, has worsened<sup>22</sup> and will continue to deteriorate as the baby-boomer generation begins to retire and to put more and more pressure on the Medicare system.<sup>23</sup>

## B. Causes

There are several reasons why U.S. seniors pay more than anyone else for prescription medications, but patents and profits are at the core. Prescription medications are patented goods and are therefore entitled to various government protections.<sup>24</sup> These protections are intended to fuel confidence in inventors and encourage them to innovate and create new products,<sup>25</sup> as well as reward useful innovation with a brief monopoly window for exploitation by the inventor.<sup>26</sup> It is not clear, however, that patent protection has its intended effect in the area of prescription medication. In fact, the first half of S. 812 attempts to supplement and amend the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, which created patent protection for pharmaceutical medications.<sup>27</sup> A related area of concern for those who sell patented materials around the world is the desire to keep each market isolated from the others in order to maximize profits in each market.<sup>28</sup> This market segregation is especially critical in the pharmaceutical industry and has been the subject of litigation on numerous occasions.<sup>29</sup> Whether this type of market segregation is fundamental to the pharmaceutical industry's innovation is the subject of heated debate, as

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22. See *id.* (explaining many of the deficiencies with current Medigap policies, and detailing the program's failure to adequately meet seniors' needs in the way of prescription medication costs).

23. See *id.*

24. 35 U.S.C. § 154(a)(2) (2000).

25. See, e.g., *id.* § 102(a)–(f) (requiring that inventions be a novel item that applicant created).

26. See Am. Soc'y of Int'l Law, *General Agreement on Tariffs and Trade—Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, [Dec. 15, 1993], 33 I.L.M. 81, 93–96 [hereinafter TRIPS].

27. See *Hearing on Generic Pharmaceuticals: Hearing on S. 812 Before the S. Comm. on Commerce, Sci. & Transp.*, 107th Cong. (2002) [hereinafter *Hearing on Generic Pharmaceuticals*] (testimony of Dr. Greg Glover, Pharm. Research & Mfrs. of Am.), 2002 WL 735406.

28. A. Bryan Baer, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 126 (2001).

29. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statements of Sen. Byron Dorgan including a request for patent extension that was based on ability to crush up and sprinkle the drug on apple sauce).

many allege the pharmaceutical industry is not merely financing research and development but is reaping excessive profits by price gouging.<sup>30</sup>

#### 1. PATENTS

The United States grants a twenty-year monopoly to inventors of patented goods.<sup>31</sup> This regime is intended to reward and encourage the creation of new products, and this type of intellectual property protection is considered essential to the capitalist system.<sup>32</sup> The United States is 1 of the 144 members of the World Trade Organization (WTO), who have agreed to extend certain minimum protections to all patented goods.<sup>33</sup> The protections include preventing third parties from copying a drug's chemical formula and competing with the drug's original manufacturer.<sup>34</sup> United States patents are especially important in the pharmaceutical industry, where large research and development expenditures are made with the expectation that investors will have an exclusive opportunity to market their creations both in the United States and around the world (subject to international trade agreements such as WTO and the GATT Uruguay Round Agreement on Trade-Related Aspects of International Property Rights (TRIPS)).<sup>35</sup> Recognizing both the costs and benefits of patents, the Hatch-Waxman Act created a patent renewal program for pharmaceutical medications that sought to balance industry's interest in profits and society's interest in competition.<sup>36</sup> The first half of S. 812 specifically addresses patents and pharmaceutical medications, as many be-

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30. Bernie Sanders, Editorial, *Corporate Greed Keeps Drug Prices High*, WALL ST. J., Aug. 8, 2002, at A13.

31. 35 U.S.C. § 154(a)(2) (2000).

32. See, e.g., *id.* § 102(a)-(f).

33. Christopher R. Stambaugh, *State Price Control Laws Are the Wrong Prescription for the Problem of Unaffordable Drugs*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 897, 902-03 (2002).

34. *Id.*

35. See TRIPS, *supra* note 26, at 93-96; see also WORLD HEALTH ORG., WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUGS, [http://www.who.int/medicines/library/edm\\_general/who-wto-hosbjor/wto\\_background\\_e.doc](http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/wto_background_e.doc) (Apr. 2001).

36. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (testimony of Dr. Greg Glover); Stephanie E. Piatt, *Regaining the Balance of Hatch-Waxman in the FDA Generic Approval Process: An Equitable Remedy to the Thirty-Month Stay*, 59 N.Y.U. ANN. SURV. AM. L. 163, 167 (2003).

lieve there are large loopholes in the Hatch-Waxman Act that are being abused.<sup>37</sup>

Patents mean exclusivity.<sup>38</sup> Patent protection extends for twenty years from the time of the filing.<sup>39</sup> Though some drugs are not covered for the full twenty years (especially where years of testing are still required after the patent is granted but before marketing can begin),<sup>40</sup> any protected good is entitled to monopolistic protection. Basic economic and profit-seeking behavior dictates that when a patent expires, market competition will commence where products were financially successful. In the pharmaceutical industry this means that when a lucrative drug loses its patent protection, competition from generic-brand manufacturers will ensue, driving down the cost of that medicine.<sup>41</sup> Although the ensuing market competition should provide more drugs for less,<sup>42</sup> because patent holders can file for extensions,<sup>43</sup> and because producers of lucrative medications usually do,<sup>44</sup> it can be years before competition even takes shape, let alone drives down prices.<sup>45</sup>

Because monopolistic protection reaps higher profits, many pharmaceutical companies try to extend their patents for several years beyond their original termination dates.<sup>46</sup> Even supporters of the current patent regime do not deny the effect that patents have on the production and distribution of prescription medication.<sup>47</sup> In short, for American consumers to get the on-patent drug, they have to pay either the patent owner's price or the price of someone authorized by the patent owner.<sup>48</sup> This exclusive arrangement results in higher

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37. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statements of Sen. John Edwards).

38. 35 U.S.C. § 154(a)(2) (2000).

39. *Id.*

40. WORLD HEALTH ORG., *supra* note 35, at 6.

41. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (noting that through the 1980s and 1990s the market share of generic drugs, as a percentage of the total market for prescription drugs, increased by approximately thirty percent).

42. See *id.* (statement of Sen. Byron Dorgan).

43. 35 U.S.C. § 155 (2000).

44. *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. Byron Dorgan) (noting that of the thirty most lucrative prescription medications, over sixty-five percent are currently engaged in litigation with generic competitors over patent extensions).

45. See *id.* (statement of Sen. Charles Schumer).

46. *Id.* See generally Stambaugh, *supra* note 33, at 908.

47. See generally Stambaugh, *supra* note 33, at 908.

48. See *id.* at 903.

prices for on-patent drugs.<sup>49</sup> Although on-patent drug prices are higher in general,<sup>50</sup> it is important to note that the authorized wholesalers and retailers will sell the same medications for different prices, depending on what country they are operating in.<sup>51</sup> These different prices represent price discrimination and are at the heart of the reimportation proposals in S. 812.

## 2. GRAY MARKETS AND MARKET DIFFERENTIATION

American consumers pay more for pharmaceutical medication than consumers in any other country, even though many of those countries rely on the United States for their medical needs.<sup>52</sup> Because most countries have some form of socialized medicine, their governments play a much larger role in determining what medicines and procedures are available and how much they will cost.<sup>53</sup> These price-control policies do not necessarily result in lower costs across the board, but when applied to some of the premier pharmaceutical products being offered in the United States and abroad, the contrast is often striking.<sup>54</sup> Although the market would normally grant the price-controlled medications to the highest bidder regardless of where they live, these artificially low prices are protected by laws and trade restrictions that do not allow pharmaceutical medications to be purchased freely in the global market.<sup>55</sup> These drugs are not free to flow back and forth between their U.S. point of origin and their foreign destination because of patent protection and nonreimportation treaties.<sup>56</sup>

Significant price differences brought about by market differentiation can be surprising and frustrating to those who pay the higher price, but there is a reason for the “madness.” Market differentiation

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49. *Id.*; see also CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 2-3 (July 1998), <ftp://ftp.cbo.gov/6xx/doc655/pharm.pdf>.

50. See Stambaugh, *supra* note 33, at 903; CONG. BUDGET OFFICE, *supra* note 49.

51. See Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 191-92 (2003); Stambaugh, *supra* note 33, at 911, 913.

52. See Danzon & Towse, *supra* note 51.

53. See Michelle 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, 613 (2001).

54. See *id.*

55. See Stambaugh, *supra* note 33, at 903.

56. See *id.*



allows a seller to capture the full potential of each target market. Capturing the full potential means that each market contributes as much as it can to the seller's overall revenues.<sup>57</sup>

Economic principles dictate that a seller will only bring an additional unit of his product to market if he can charge a price that exceeds the costs of creating, processing, and marketing that last unit (marginal costs).<sup>58</sup> In the differentiated market scenario it is only necessary that each market covers marginal costs.<sup>59</sup> This means that a seller generating large profits in one market can afford to barely break even in other markets because the firm's overall losses will not exceed gains.<sup>60</sup> This economic scheme makes goods available to poorer markets that are price-sensitive and would otherwise be priced-out, but does so at the expense of wealthier price-insensitive markets, which can more easily absorb rate hikes.<sup>61</sup> Although this may appear to be a lopsided arrangement, so long as each market contributes more than marginal costs, everyone receives some benefit.<sup>62</sup> Undoubtedly, some consumers receive greater benefits than others, but ultimately this scheme optimizes overall social benefit and overall good.<sup>63</sup> This economic scheme is called "Ramsey Optimal Pricing."<sup>64</sup>

The U.S. market is the insensitive consumer that is charged the highest prices by the pharmaceutical industry.<sup>65</sup> Price controls around the world limit both the quantity of medications being exported from U.S. pharmaceutical companies and profits derived from those medications.<sup>66</sup> Because there are no government price controls in the United States, the pharmaceutical industry is free to charge U.S. consumers whatever it wants.<sup>67</sup> Prices are set high to make up for smaller returns on exports and to try and cover the industry's very large re-

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57. See Danzon & Towse, *supra* note 51.

58. See *id.*

59. See *id.*

60. See *id.*

61. *Id.* at 187.

62. See *id.*

63. *Id.*

64. *Id.* at 186–87.

65. See Creech, *supra* note 53, at 601–03 (describing various stages of research and development, as well as cost estimates across the industry); Danzon & Towse, *supra* note 51.

66. See Stanton, *supra* note 4, at 155.

67. See Sanders, *supra* note 30.

search and development “sunk costs.”<sup>68</sup> If the industry was not able to charge different prices in different markets, poorer markets would no longer have access to these goods, and the contribution those markets currently make would have to be absorbed by the wealthier markets—meaning even higher prices in the United States.<sup>69</sup> In the event that the wealthier markets insisted on lower prices as well (i.e., price controls), supply, quality, and investment would decrease in the industry.<sup>70</sup> Thus, if pharmaceutical medications remain available to everyone, and if everyone pays the same (necessarily low) amount for drugs, there will be a sharp decline in industry profits followed by reduced research and development and reduced access to many of the goods that the market currently seeks.<sup>71</sup> If markets cannot be differentiated, then one price will prevail.<sup>72</sup>

In order to maintain the “Ramsey Optimal Pricing” scheme, it is critical to restrict competition between domestic patented goods and identical patented goods imported from other markets.<sup>73</sup> When this type of competition occurs, a “gray market” develops.<sup>74</sup> In addition to the economic issues, there are several intellectual property objections to allowing gray markets to develop, including consumer confusion and maintaining the quality and source function of patents.<sup>75</sup> There are also unique liability concerns in a gray market because the various middlemen may mishandle the products and create problems that implicate the original manufacturer and its reputation, even though the manufacturer did not authorize those sales and may not be responsible for the defects that resulted.<sup>76</sup>

Although there may be sound economic, moral, and intellectual property explanations for maintaining these pricing schemes, the bot-

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68. Danzon & Towse, *supra* note 51; Creech, *supra* note 53, at 601 (citing estimates that up to seventy percent of drugs available to Americans generate less revenue than the average R & D cost per drug).

69. See Danzon & Towse, *supra* note 51.

70. See *id.*; Stambaugh, *supra* note 33, at 911, 913.

71. See Stanton, *supra* note 4, at 155.

72. Baer, *supra* note 28, at 127.

73. See *id.* at 125–27.

74. William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, 9 TUL. J. INT'L & COMP. L. 483, 490 (2001).

75. Hazbo Skoko, Theory and Practice of Parallel Imports 10–11 (unpublished manuscript), available at <http://athene.mit/csu.edu.au/~hskoko/parallel%20imports/pimptheory.pdf>.

76. See *id.*

tom line is that many Americans cannot afford the steep prices.<sup>77</sup> Pharmaceutical companies sell their products all over the world, but because of price controls and differentiated pricing schemes, the highest prices and the highest profits are found in the United States.<sup>78</sup> Is it fair that an elderly person in the United States must subsidize the health care available to the world? This question has two very different answers, both of which depend on the scope of the question. At the microlevel it does not seem fair that every American is subjected to higher price for drugs simply because many Americans can afford them. Poor and middle-class seniors in the United States do not have the means to access these drugs, no matter how wealthy the nation is relative to other nations.<sup>79</sup> However, when the scope of the fairness question is enhanced to the macrolevel, it appears that everyone consuming pharmaceutical medications may be doing his or her part in footing the bill.

### 3. PROFITS

*a. The Pharmaceutical Industry's Understanding of Profits and Prices* The pharmaceutical industry claims that the current prices of drugs reflect the natural course of market development and the only challenge is to figure out how best to provide drugs to those in need, without financially ruining this important industry.<sup>80</sup> The pharmaceutical industry would have government focus its efforts on creating a plan to pay the medical bill, not reduce it.<sup>81</sup> In making this argument, the pharmaceutical industry places a lot of emphasis on high research and development costs, risks of failure in developing drugs, and the many benefits the world derives from effective, state-of-the-art prescription medications.<sup>82</sup>

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77. NEWSHOUR WITH JIM LEHRER ET AL., NATIONAL SURVEY ON PRESCRIPTION DRUGS: HIGHLIGHTS AND CHARTPACK, chart 2e (2000), at <http://www.pbs.org/newshour/health/prescriptions/summaryandchartpack.pdf> [hereinafter NEWSHOUR WITH JIM LEHRER].

78. See 146 CONG. REC. S7194 (daily ed. July 19, 2000) (statement of Sen. Jeffords).

79. See NEWSHOUR WITH JIM LEHRER, *supra* note 77, at chart 2.

80. See PHARM. RESEARCH & MFRS. OF AM., PHARMACEUTICAL INDUSTRY PRIMER 2001: A CENTURY OF PROMISE (2001), at <http://www.phrma.org/publications/publications/primer01/>.

81. See *id.*

82. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. Byron Dorgan); PHARM. RESEARCH & MFRS. OF AM., *supra* note 80.

The pharmaceutical industry has certainly taken risks. Following passage of the 1984 Hatch-Waxman Act, and then the Prescription Drug Marketing Act of 1987 (PDMA),<sup>83</sup> the pharmaceutical industry experienced a significant infusion of capital, as investors became confident in the industry's ability to reap profits.<sup>84</sup> While these two congressional acts had a dramatic impact on the industry, they helped increase the stakes but not the odds of success.

Studies suggest that in the early 1990s less than one in ten approved pharmaceutical compounds proved profitable for drug manufacturers.<sup>85</sup> Additionally, pharmaceutical companies relied heavily on those rare successes to fund research and development.<sup>86</sup> A recent study estimates that the industry spends over \$800 million in discovery and development of each medication that successfully goes to market.<sup>87</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA) claims that as much as 30% of industry revenues are re-invested in research and development each year.<sup>88</sup> Thus, if prices, and therefore revenues, are artificially forced down—by price control, for example—the research and development that makes U.S. pharmaceutical manufacturers the world's leaders and innovators will suffer.<sup>89</sup>

Some scholars contest the notion that price differentiation and U.S. support for research and development worldwide increase pharmaceutical medication costs in the United States across-the-board.<sup>90</sup> Although several Senate studies suggest that other countries pay far less than U.S. customers for pharmaceutical medication,<sup>91</sup> the Senate's research has been criticized for focusing too heavily on very

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83. Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (currently codified at 21 U.S.C. § 381(d) (2000)).

84. See Davis, *supra* note 74, at 486.

85. See Allan Z. Litovsky, *The Law of Unintended Consequences: How Will the Affordable Prescription Drugs and Medical Inventions Act Affect American Health Care?*, HEALTH LAW, Aug. 2001, at 20, 21–22.

86. See *id.* at 22.

87. News Release, Tufts Ctr. for the Study of Drug Dev., Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at \$802 Million (Nov. 30, 2001), at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6>.

88. See Danzon & Towse, *supra* note 51.

89. See Stanton, *supra* note 4, at 155.

90. See Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & ECON. 203, 234 (1997) (arguing that products liability risk is a significant yet overlooked factor in the higher prices of pharmaceuticals in the United States).

91. Davis, *supra* note 74, at 501.

popular drugs with the highest rate of return.<sup>92</sup> These critics allege that in studying the price of pharmaceuticals, Congress focused on ten of the most popular drugs and compared the prices paid by retail consumers at pharmacies to the prices paid by federal customers to manufacturers.<sup>93</sup> These comparisons did not consider federal customers' discount (which is mandated by statute) or the manner in which these ten drugs interact with their generic equivalents and consumers' overall drug expenditures (weighted averages).<sup>94</sup> Thus, the validity and utility of these congressional studies are uncertain.

When discussing the prices of medications, there are other factors to consider as well. American companies face a unique "liability environment"<sup>95</sup> that contributes to higher U.S. prices because of market share liability and larger and more frequent punitive damages.<sup>96</sup> Another issue in the area of drug safety and responsibility is whether the cost of drugs is a result of overregulation by the Food and Drug Administration (FDA)—an activity that will most likely increase if medications are introduced from other countries.<sup>97</sup> Finally, the scope of the "pricing" conversation may not be broad enough. Americans may be getting more in return than they even realize. PhRMA and individual manufacturers are not the only beneficiaries of research and development successes or the potentially large profits driving the pharmaceutical industry.<sup>98</sup> Rather, state-of-the-art drugs may be saving the entire country money by reducing the number of operations and serious procedures that are necessary.<sup>99</sup> Thus, the health and preventative effects of innovations in the pharmaceutical industry may be keeping costs down in other areas of health care.

*b. Criticism of Pharmaceutical Prices, Profits, and Politics* Critics of the pharmaceutical industry allege that the industry should not be

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92. *Id.*

93. Patricia M. Danzon, Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies (Apr. 1999) (unpublished manuscript), <http://www.whartonhealthcare.org/pdfs/ContentDanzinarticle.pdf>.

94. *Id.* at 3.

95. See Manning, *supra* note 90, at 208.

96. *Id.* at 207–08.

97. Robert Batterson, *Canadian Drug Imports Won't Bring Down the Costs of Drugs; Would Likely Raise Prices*, TIP SHEET: BUS., LAW & ECON., Dec. 16, 2003, at <http://news-info.wustl.edu/tips/page/normal/591.html>.

98. See Stanton, *supra* note 4, at 162.

99. See *id.* at 152.

characterized as risk-taking and innovative, but as monopolistic and corrupt.<sup>100</sup> Critics accuse the pharmaceutical industry of price gouging and abusing patent protections—all with the blessing and funding of the U.S. government.<sup>101</sup> While other countries take steps to make sure their citizens have access to health care and medications, the U.S. pharmaceutical industry is free to charge extraordinary rates in order to maintain extraordinary profit margins—all at the expense of U.S. taxpayers.<sup>102</sup>

Throughout the 1990s, the pharmaceutical industry was more profitable than any other industry. While most other industries were earning 5% profits, the pharmaceutical industry was making 17%,<sup>103</sup> with the top ten pharmaceuticals bringing in profits as high as 30%.<sup>104</sup> These incredible margins were made possible by the monopoly grant called “price discrimination” given to the pharmaceutical industry by the U.S. government.<sup>105</sup> While other industrialized countries protect their citizens with various price control regimes,<sup>106</sup> the United States allows pharmaceutical companies to make as much as they want at the expense of U.S. consumers.<sup>107</sup> This regime is the equivalent of granting a monopoly right because U.S. consumers are denied access, by law, to cheaper drugs that are available to the rest of the world.<sup>108</sup> The result is that more and more elderly Americans choose not to refill their prescriptions due to price considerations.<sup>109</sup> Thus, critics argue, the industry’s greed is sowing pain and suffering among elderly Americans.<sup>110</sup>

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100. See Sanders, *supra* note 30.

101. See MINN. SENIOR FED’N METRO. REGION, PRESCRIPTION DRUG PRICES, at <http://www.mnseniors.org/issues/rxprices.html> (last visited Feb. 10, 2004).

102. See *id.*

103. Press Release, Office of Sen. Dorgan (D-N.D.), Frequently Asked Questions About the Prescription Drug Price Parity for Americans Act 3 (on file with *The Elder Law Journal*) [hereinafter Dorgan, Frequently Asked Questions].

104. Marcia Angell, *The Pharmaceutical Industry—To Whom Is It Accountable?*, 342 NEW ENG. J. MED. 1902, 1903 (2000).

105. See Rep. Bernie Sanders, *Reduce Drug Prices by Importing Medicines*, HILL, July 18, 2001, [http://bernie.house.gov/documents/opeds/2001-07-18-Rx\\_drugs\\_The-Hill.asp](http://bernie.house.gov/documents/opeds/2001-07-18-Rx_drugs_The-Hill.asp) [hereinafter Sanders, *Reduce Drug Prices*].

106. See PRYOR, *supra* note 11, at 5.

107. See Sanders, *Reduce Drug Prices*, *supra* note 105.

108. See *id.*

109. See generally NEWSHOUR WITH JIM LEHRER, *supra* note 77 (finding that sixteen percent of the elderly surveyed say they have not filled a prescription because of cost).

110. See Angell, *supra* note 104, at 1902.

Innovation is not at risk. Abnormally high profit margins are not a prerequisite to innovation in the pharmaceutical industry.<sup>111</sup> There is a tremendous market for this product and someone will perform the necessary tests and manufacturing to satisfy that market. If profits are reduced, perhaps less money will be spent on advertising and perhaps the drugs will not be as available to the entire world,<sup>112</sup> but the innovation will continue and perhaps fewer of the Americans in need will be neglected.<sup>113</sup> This is true because innovation is spurred not only by money, but also by the pursuit of science—which is funded in large part by the U.S. government<sup>114</sup> directly through research and indirectly through grants and education to scientists.<sup>115</sup> To suggest that the pharmaceutical industry is at risk of running out of money and incentives to continue to manufacture its product is naive.<sup>116</sup>

To the extent that research and development requires a significant amount of capital, those funds may not be coming from the pharmaceutical industry. The National Institutes of Health (NIH) plays a very large role in much of the initial research conducted on medications.<sup>117</sup> The NIH budget for 2002 was \$23.2 billion dollars,<sup>118</sup> and this budget is increasing rapidly.<sup>119</sup> Of the 2002 budget, 82% went

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111. *Talk of the Nation*, *supra* note 10 (statement of Rep. Sanders claiming that pharmaceutical manufacturers focus their time and energy on reaping profits not creating new drugs and suggesting that lower prices will not jeopardize availability of drugs).

112. *Id.* (statement of Rep. Sanders denouncing pharmaceutical manufacturers' marketing budgets which reach as high as forty percent and demanding that U.S. government focus on taking care of U.S. citizens).

113. See generally NEWSHOUR WITH JIM LEHRER, *supra* note 77, chart 9.

114. See OFFICE OF BUDGET/NIH, DISTRIBUTION OF NIH BUDGET, FY 2002, <http://grants1.nih.gov/grants/award/trends/distbud02.htm> (last updated Mar. 17, 2003) [hereinafter NIH BUDGET, FY 2002].

115. *Talk of the Nation*, *supra* note 10 (statement of Rep. Sanders alleging that “[t]axpayers fund more than 36 percent of all of the medical research and development through the NIH” and that “[s]even out of the top 21 most important drugs introduced between ‘65 and ‘92 were developed with these federal funds”); see NIH BUDGET FY 2002, *supra* note 114.

116. See Sue Rochman, *Drug Wars*, HIV PLUS, Oct.–Nov. 2000, at <http://www.aidsinfonyc.org/hivplus/issue11/features/wars.html>.

117. See OFFICE OF THE CHAIRMAN, CONNIE MACK, JOINT ECON. COMM., U.S. SENATE, BENEFITS OF MEDICAL RESEARCH AND THE ROLE OF THE NIH (May 17, 2000), at <http://rxpolicy.com/studies/nih-randd-jec.pdf>.

118. NIH BUDGET, FY 2002, *supra* note 114.

119. See *The National Institutes of Health: Investing in Research to Prevent and Cure Disease: Hearing Before the Subcomm. on Health of the House Comm. on Energy & Commerce*, 107th Cong. 2 (2002) [hereinafter *Rep. Brown Statements*] (statement of Rep. Sherrod Brown).

to research grants, training, and research and development (R & D) contracts.<sup>120</sup> Critics argue that Americans do not always benefit from this tax-funded research.<sup>121</sup> The NIH has contractual relationships with the private sector, whereby private companies are not only licensed patents on NIH-developed medical breakthroughs, but also receive a period of market exclusivity.<sup>122</sup> Famous examples include Tamoxifen and other cancer drugs—92% of which were originally researched and developed by the NIH,<sup>123</sup> as well as Prozac and others.<sup>124</sup> Critics argue that it is U.S. taxpayer dollars that actually assume the greatest risk, and that manufacturers only begin to invest heavily in research and development after a medical compound has cleared several of the early hurdles.<sup>125</sup> Congressman Bernie Sanders (I-Vt.) complained that “[c]urrently, taxpayers fund more than 36% of all medical R&D through the NIH, with much of that R&D given to the pharmaceutical industry.”<sup>126</sup> Thus, at the very least, these critics would like to see more candid discussion about how much the NIH is investing on behalf of private companies, how much the companies are investing, and whether the NIH should use its patent-busting power to reduce prices and enhance production of generic drugs.<sup>127</sup>

Some critics allege that research and development is secondary to advertising.<sup>128</sup> Although creating new drugs requires tremendous research and development, the pharmaceutical industry’s research and development budget may actually be much smaller than the industry’s advertising budget.<sup>129</sup> The United States allows for direct-to-

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120. NIH BUDGET, FY 2002, *supra* note 114.

121. See OFFICE OF REP. BERNARD SANDERS, PUBLIC DOLLARS FOR PRIVATE PROFIT 2, <http://bernie.house.gov/pc/issues/tamoxifen.pdf> (July 14, 2000) [hereinafter SANDERS, PUBLIC DOLLARS].

122. *Rep. Brown Statements*, *supra* note 119, at 3.

123. See SANDERS, PUBLIC DOLLARS, *supra* note 121, at 2.

124. See OFFICE OF THE CHAIRMAN, *supra* note 117.

125. See Brian Gamell, *Mokhiber and Weissman on Pharmaceutical Drug Price Gouging*, at <http://www.libertysearch.com/articles/2002/000053.html> (July 23, 2002). Some critics also claim that the industry derives many benefits from research funded by universities. *Id.* However, to the extent research is conducted through universities, those universities can demand royalties on any profits taken in. *Id.*

126. Bernie Sanders, *Prescription Drug Pricing Reform*, at <http://bernie.house.gov/prescriptions/index.asp> (last visited Feb. 23, 2004) [hereinafter Sanders, *Prescription Drug Pricing Reform*].

127. See *Rep. Brown Statements*, *supra* note 119, at 2–3.

128. See Stanton, *supra* note 4, at 149.

129. *Id.* at 155.



consumer advertising for prescription drugs.<sup>130</sup> The government allows the pharmaceutical industry to spend large amounts of money on advertising—\$13.9 billion on promotions alone in 1999<sup>131</sup>—and there has been a direct and steep correlation between advertising for a drug and the number of patient requests for the advertised drug.<sup>132</sup> While this has been a valuable tool for boosting profits in the U.S. market,<sup>133</sup> it is also a valuable tool in effectively maintaining product recognition and differentiation and in thwarting the benefits to consumers from competition between competing prescription medications and generic medications.<sup>134</sup>

PhRMA's commitment to the continued use of advertising to generate profits is reflected in its decision to hold out research and development as the area that will be hit hardest by any decrease in profits.<sup>135</sup> Critics allege that the pharmaceutical industry has plenty of profits that it can distribute and expend as it wishes, and that decreases in profits need not affect R & D.<sup>136</sup>

The pharmaceutical industry counters that any changes may threaten R & D directly or indirectly, and that specific attacks on advertising are entirely misplaced.<sup>137</sup> The basic argument is that a few pharmaceutical products have been wildly successful and have generated sufficient profits to justify massive investment in R & D in the hope that these fantastic profits might be repeated.<sup>138</sup> Laws that limit what developers can expect to earn dampen enthusiasm and discourage investment in R & D.<sup>139</sup> In this vein, anything that adds to profits

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130. See Shawna Lydon Woodward, *Will Price Control Legislation Satisfactorily Address the Issue of High Prescription Drug Prices?: Several States Are Waiting in the Balance for PhRMA v. Concannon*, 26 SEATTLE U.L. REV. 169, 176 (2002).

131. See *id.*

132. See *id.*

133. See Stanton, *supra* note 4, at 154.

134. See generally Angell, *supra* note 104.

135. See Davis, *supra* note 74, at 505.

136. See Merrill Matthews, Jr., *Prescription Drug Prices and Profits*, IDEAS (Inst. for Policy Innovation, Lewisville, Tex.), Jan. 9, 2003, [http://www.ipi.org/ipi%5CIPublications.nsf/0/92952DA95732C34F86256CAF000713D0/\\$File/II-AnsweringCritics-Profits-2.pdf?OpenElement](http://www.ipi.org/ipi%5CIPublications.nsf/0/92952DA95732C34F86256CAF000713D0/$File/II-AnsweringCritics-Profits-2.pdf?OpenElement).

137. See Merrill Matthews, Jr., *Prescription Drug Advertising: Problem or Solution?*, IDEAS (Inst. for Policy Innovation, Lewisville, Tex.), Jan. 9, 2003, [http://www.ipi.org/ipi%5CIPublications.nsf/0/9CFBAA5401D2735886256CAE007DD482/\\$File/II-AnsweringCritics-DTC.pdf?OpenElement](http://www.ipi.org/ipi%5CIPublications.nsf/0/9CFBAA5401D2735886256CAE007DD482/$File/II-AnsweringCritics-DTC.pdf?OpenElement).

138. Stambaugh, *supra* note 33, at 907.

139. See *id.*

encourages R & D, so a large marketing budget may play an important role in increasing profits.<sup>140</sup>

The other major complaint about the pharmaceutical industry is patent abuse. Critics blame loopholes in the Hatch-Waxman Act for allowing the pharmaceutical industry to engage in unfair competition by continuously filing for patent extensions on frivolous grounds.<sup>141</sup> Extensions that thwart competition by generics only work to extend price gouging and do not promote any social good.<sup>142</sup> Patents have limits for a reason—there is a bargain according to which the inventor shares his or her ideas with the public in exchange for the initial opportunity to take advantage of the idea.<sup>143</sup> Critics argue that by allowing pharmaceutical manufacturers to extend patents on trivial grounds by invoking the Hatch-Waxman Act's "three-year exclusivity for new uses"<sup>144</sup> clause (which was intended to promote the development of a generic market), the U.S. government is granting pharmaceutical industries an effective monopoly over U.S. health care.<sup>145</sup> If this is true, innovation has been thwarted and pharmaceutical industries are simply cashing in on old patents in order to continue to meet Wall Street's financial targets and expectations.<sup>146</sup>

The evidence suggests that patent abuse is a real problem. Approximately 67% of the top thirty drugs sold are currently in litigation to receive extended patent protection.<sup>147</sup> Presumably, in addition to these cases, similar weaker cases were initiated but never pushed to trial. Commenting on the law's pro-pharmaceutical manufacturers bias, U.S. Senator John Edwards (D-N.C.) said, "I can't think of another example where by filing a lawsuit, somebody gets two and a

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140. See Stanton, *supra* note 4, at 155.

141. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. Byron Dorgan).

142. See ARTHUR R. MILLER & MICHAEL H. DAVIS, *INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS, AND COPYRIGHT* 14 (3d ed. 2000).

143. See MARTIN J. ADELMAN ET AL., *CASES AND MATERIALS ON PATENT LAW* 1 (1998).

144. *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. John Edwards).

145. See NAT'L INST. FOR HEALTH CARE MGMT. FOUND., *CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION* 16–17 (May 2002), <http://www.nihcm.org/innovations.pdf>.

146. See *id.*

147. *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. Byron Dorgan).

half years of relief. No matter how much merit or meritless the lawsuit is.”<sup>148</sup>

### C. Striving for a Solution: Previous Legislation

The roots of the reimportation debate can be found in the 1987 Prescription Drug Marketing Act, which sought to exclude pharmaceutical medications from outside the United States because of counterfeiting and tampering concerns.<sup>149</sup> Congress revisited the issue of reimportation in the Medicine Equity and Drug Safety Act of 2000 (MEDS Act), but without success.<sup>150</sup> In 2002, the Senate returned with a bill very similar to the 2000 MEDS Act, but with a narrower scope and fewer loopholes.<sup>151</sup>

#### 1. PDMA (1988)

In the late 1980s, many American-made drugs were reimported into the United States, under the heading “goods returned.”<sup>152</sup> Congress believed that these reimported drugs were vulnerable to tampering and adulteration and represented a threat to the health of American consumers.<sup>153</sup> On April 22, 1988, the Prescription Drug Marketing Act of 1987 became law.<sup>154</sup> PDMA covered human prescription drugs and made reimportation from foreign countries illegal, except when reimported by the manufacturer or for emergency medical needs with permission of the Department of Health and Human

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148. *Id.* (statement of Sen. John Edwards).

149. *Reimportation Legislation: Will It Succeed in Lowering US Drug Prices and Safeguard Quality?*, RX POL’Y UPDATE (Ctr. on Drugs & Pub. Pol’y, Baltimore, Md.), Oct. 2001, <http://www.pharmacy.umaryland.edu/cdpp/pdf/Rx%20Policy%20October%202001.pdf>.

150. See Mark Kaufman, *Shalala Rejects GOP Drug Price Law: Plan Won’t Save Money, She Says*, WASH. POST, Dec. 27, 2000, at A1; Michael Kinsley, *No Free Lunch at the Pharmacy*, WASH. POST, Dec. 29, 2000, at A33; Robert Pear, *In a Turnaround, White House Kills Drug-Import Plan*, N.Y. TIMES, Dec. 27, 2000, at A1; Alissa J. Rubin, *Plan to Allow Lower-Cost Drug Imports Is Blocked*, L.A. TIMES, Dec. 27, 2000, at A1.

151. See BLANCHARD RANDALL IV & DONNA U. VOGT, REPORT FOR CONGRESS: IMPORTING PRESCRIPTION DRUGS 1–14 (Aug. 20, 2002), <http://rxpolicy.com/studies/crs31503.pdf>. [hereinafter RANDALL & VOGT, IMPORTING PRESCRIPTION DRUGS].

152. See Robert T. Angarola & Judith E. Beach, *The Prescription Drug Marketing Act: A Solution in Search of a Problem?*, 51 FOOD & DRUG L.J. 21, 27 (1996).

153. See *id.* at 28; Lars Noah, *NAFTA’s Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293, 1308 (1997).

154. Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (currently codified at 21 U.S.C. § 381(d) (2000)).

Services.<sup>155</sup> PDMA regulates “drug samples” and the manner in which they are distributed as well as the resale of drugs purchased by health care entities.<sup>156</sup> Also under PDMA, wholesale distribution of prescription drugs would be carefully licensed and documented and basic storage and handling standards imposed.<sup>157</sup>

PDMA never purported to be an airtight seal on reimported medications. The FDA has always allowed patented drugs to be reimported by the domestic manufacturer that exported them.<sup>158</sup> Additionally, individuals may import prescription medications for private use.<sup>159</sup> Although technically illegal under PDMA, the FDA has turned a blind eye to small-scale reimportation for personal use, defined as a ninety-day supply.<sup>160</sup> For many years, individuals were only able to import these drugs themselves by traveling across the Canadian or Mexican border, so the issue was a relatively minor one.<sup>161</sup> With the development of the Internet, facilitating private individual reimportation has turned into a major industry—one that the FDA is finding increasingly problematic.<sup>162</sup> Only recently has the FDA attempted to en-

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155. See 21 U.S.C. §§ 331, 333, 353, 381; see also Angarola & Beach, *supra* note 152, at 22.

156. Angarola & Beach, *supra* note 152, at 22.

157. *Id.*

158. See 21 U.S.C. § 381(d)(1) (explaining that drugs containing insulin have typically been reimported by the domestic manufacturer).

159. See Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER Sept. 1, 2002, at 18 (outlining basic guidelines for permitting individual reimportation of medicines, but explicitly noting that “saving money on prescription drugs isn’t one of the circumstances” motivating the FDA policy).

160. See OFFICE OF REGULATORY AFFAIRS, U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, ch. 9, [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html) (last revised Sept. 2002). Resorting to personal importation was originally a major issue in the HIV-positive community because of difficulty getting drugs approved in the United States. See 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, 505 (2000). As prices of prescription medication have climbed in the last decade, elderly living in border states, or using the internet, have increasingly taken advantage of this loophole to reimportation. See *id.* at 504–05.

161. See Meadows, *supra* note 159.

162. Although there have not been many cases of counterfeiting or tampering in commercial sales of pharmaceutical medications, there have been some rather significant cases of counterfeiting on the Internet. See Reichertz & Friend, *supra* note 160, at 504–05. PhRMA, and other opponents of S. 812, point to some of these instances as harbingers of the danger reimportation may pose. See *id.* Counterfeit versions of Hoffman-LaRoche’s dideoxycytidine (ddC) were being imported for individual use before the FDA discovered the imports lacked any dideoxycytidine, and highlighted the dangers of importing drugs not approved by the FDA. See *id.*

force these laws,<sup>163</sup> and studies show that it is more difficult than anticipated.<sup>164</sup> The FDA has been criticized for failing to implement the personal use exception in a predictable manner with appropriate procedural safeguards.<sup>165</sup> If these concerns about FDA enforcement are well-founded, such shortcomings do not bode well for the FDA's ability to take on the even larger project of commercial reimportation for the entire nation.<sup>166</sup>

## 2. THE MEDS ACT (2000)

In 2000, Congress sought to undo some of the damage attributed to the PDMA.<sup>167</sup> Congress passed the Medicine Equity and Drug Safety Act of 2000,<sup>168</sup> which would allow retailers to reimport prescription medications from Australia, Canada, Israel, Japan, New Zealand, South Africa, and members of the European Union.<sup>169</sup> Although President Clinton signed the bill, it never became law.<sup>170</sup> The MEDS Act of 2000, like S. 812, required the Secretary of Health and Human Services (HHS) to ultimately declare that the new bill will result in significant savings for taxpayers, and will not pose a greater threat to the safety and security of the public than the existing regime.<sup>171</sup> The HHS Secretary at the time, Donna Shalala, could not certify that MEDS would lower prices or be absolutely safe.<sup>172</sup>

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163. See 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, 2003 WL 12037227.

164. See *id.* (recounting the dismal results of a five-week test in Carson City, Cal.).

165. See Reichertz & Friend, *supra* note 160, at 495; see also RANDALL & VOGT, IMPORTING PRESCRIPTION DRUGS, *supra* note 151, at 7 (describing Sen. Paul Wellstone's Personal Prescription Drug Import Fairness Act (S. 1229) which would make importation of a ninety-day supply legal across the board).

166. See generally William K. Hubbard, Guest Editorial, *Controversy Over Importation of Pharmaceuticals into the U.S.*, BIOMEDICAL MARKET NEWSL. (Biomedical Market Newsletter, Inc., Costa Mesa, Cal.), July 31, 2002, at 37, 2002 WL 18187271; Ukens, *supra* note 163.

167. "[T]he PDMA was not intended to affect parallel importation because it has, for a long time, been an important pro-consumer activity in America. The unfortunate reality, however, is that the PDMA has in effect become a barrier to parallel trade in prescription drugs in this country." Dorgan, *Frequently Asked Questions*, *supra* note 103, at 4.

168. 21 U.S.C. § 384 (2000); Davis, *supra* note 74, at 487.

169. 21 U.S.C. § 382(b)(1)(A)(i)–(ii).

170. See Creech, *supra* note 53, at 635.

171. 21 U.S.C. § 384(l)(1)–(2); S. 812, 107th Cong. § 804(o)(A)–(B) (2002).

172. Laurie McGinley, *Shalala Declines to Implement Law on Importing Drugs*, WALL ST. J., Dec. 27, 2000, at B2.

HHS Secretary Shalala stressed her concerns about the various loopholes that would allow pharmaceutical manufacturers to keep prices high.<sup>173</sup> Because the MEDS Act included a five-year sunset provision,<sup>174</sup> essentially making the entire program a brief experiment, Shalala argued that few companies would be confident enough to make the investments necessary for the program to work on a large enough scale to drive down prices.<sup>175</sup> Additionally, Shalala objected to the MEDS Act's failure to guarantee U.S. importers access to approved FDA labeling (a requirement for importation),<sup>176</sup> and its failure to ban drug makers from forcing U.S. distributors to charge higher prices or reduce supply.<sup>177</sup> This focus on the economic problems with the proposal, however, could not completely mask the fact that there were unanswered safety questions, and political pitfalls for any HHS director who certified the program as perfectly safe.<sup>178</sup> Tellingly, Shalala was not the only one to express concern about the legislation. The Congressional Research Service (CRS) also expressed its doubts about the viability of the program—challenging the ability to certify these products as safe.<sup>179</sup>

### 3. FROM THE MEDS ACT TO S. 812

The MEDS Act never became law and the crisis of high-priced medication played a prominent role in the 2000 U.S. elections.<sup>180</sup>

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173. See *id.* (“[T]he measure was so riddled with ‘serious flaws and loopholes’ that she couldn’t make such determinations.”).

174. 21 U.S.C. § 384(m).

175. See McGinley, *supra* note 172.

176. *Id.*

177. *Id.*

178. It was also alleged that pharmaceutical industry influence played a part in President Clinton’s decision to support Shalala. See Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 14 FLA. J. INT’L L. 217, 243 (2002); Kaufman, *supra* note 150; Kinsley, *supra* note 150; Pear, *supra* note 150; Rubin, *supra* note 150. Further supporting this argument is the report that Shalala believed a mere \$24 million devoted to security and safety would alleviate her concerns in those areas. Ivette P. Gomez, *Beyond the Neighborhood Drugstore: U.S. Regulation of Online Prescription Drug Sales by Foreign Business*, 28 RUTGERS COMPUTER & TECH. L.J. 431, 450–51 (2002).

179. DONNA U. VOGT & BLANCHARD RANDALL IV, REPORT FOR CONGRESS: THE PRESCRIPTION DRUG IMPORT PROVISIONS OF THE FY2001 AGRICULTURE APPROPRIATIONS ACT P.L. 106-387, at 5 (2001), <http://rxpolicy.com/studies/crs-106thimports-0101.pdf> (highlighting several concerns relevant to S. 812).

180. See *Election 2002 Election—Roundup: Both Parties Tout Rx Drug Plans to Win Senior Votes*, AM. HEALTH LINE, Sept. 3, 2002, [http://nationaljournal.com/cgi-bin/ifetch4?ENG+AMERICAN\\_HEALTHLINE+7-ahindex+1078515-Reverse](http://nationaljournal.com/cgi-bin/ifetch4?ENG+AMERICAN_HEALTHLINE+7-ahindex+1078515-Reverse)

Aware of the high voter turn out among the elderly, the growing problem of uninsured Americans, and the need for change in Social Security and Medicare and Medicaid, candidates for office in 2000 campaigned heavily on health care issues.<sup>181</sup>

In 2002, with elections again on the horizon, the Senate was determined to produce something to show improvements on the pharmaceutical medication front.<sup>182</sup> In late July 2002, the Senate rejected compromise legislation on a Medicare prescription drug benefit plan<sup>183</sup> and opted instead to revive the quick-fix approach of the MEDS Act. The sponsors of the critical amendments to S. 812 are U.S. Senators from states that are particularly affected by this issue due to large elderly populations and close proximity to Canada—namely North Dakota, Minnesota, Michigan, Vermont, and New Hampshire.<sup>184</sup> The Senators did not need to look far to find a potential solution to high drug costs.

American seniors have taken action to benefit from international pharmaceutical price differentials by traveling to Canada or Mexico to purchase identical medicines for lower prices.<sup>185</sup> While many individuals make these trips on their own, others go on group trips, sometimes in a highly publicized, politically charged manner.<sup>186</sup> Many seniors, however, are homebound and cannot travel abroad to get

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181. *See id.*

182. *See* 148 CONG. REC. S7875 (daily ed. Aug. 1, 2002) (statement of Sen. Hatch) (expressing concerns about rushed legislation, especially with regards to the Hatch-Waxman Act of 1984).

183. *See Opinionmakers—Rx Drug Benefit: AHL Rounds Up Reactions*, AM. HEALTH LINE, Aug. 5, 2002, [http://nationaljournal.com/cgi-bin/ifetch4?ENG+AMERICAN\\_HEALTHLINE+7-ahindex+1078677-RE-](http://nationaljournal.com/cgi-bin/ifetch4?ENG+AMERICAN_HEALTHLINE+7-ahindex+1078677-RE-)

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184. *See* Sarah Lueck, *Senators Push Drug-Reimportation Bill*, WALL ST. J., June 3, 2002, at A4. Because of their close proximity and their larger elder populations, this cross-border phenomenon is much more prevalent in states along the northern U.S. border. *Id.* Although all federal representatives feel pressure to improve America's health care systems, the congressmen of these northern states feel particularly acute pressure. *See id.* It is not surprising that these are the primary supporters of much of the health care initiatives that come through Congress.

185. *See, e.g.*, Associated Press, *Michigan Mayor Organizes Trips to Canada for Cheaper Prescribed Drugs*, CAN. PRESS, Nov. 7, 2002, 2002 WL 102279344.

186. *Id.*

medicines.<sup>187</sup> These seniors often take advantage of mail order services or online services to import medicines for their personal consumption.<sup>188</sup> S. 812 follows the lead of these seniors.

Just one week prior to passing S. 812, the Senate failed to pass a prescription drug benefit bill.<sup>189</sup> The United States House of Representatives approved a Medicare prescription drug benefit—H.R. 4954—in June 2002, but that bill did not include any amendments to drug patent law.<sup>190</sup> When S. 812 came to the floor of the Senate it was passed without considering amendments suggested by Republican senators.<sup>191</sup> Those amendments were never officially proposed because even the Republican leaders in the Senate wanted to pass legislation before the summer recess.<sup>192</sup> Against this backdrop, the Senate passed S. 812, but took care to make sure that they could not be held responsible for any unintended consequences of this hastily enacted bill by leaving ultimate approval to HHS.<sup>193</sup>

There were two major prongs to the MEDS Act: patent reform and reimportation.<sup>194</sup> Each of these prongs was modified by S. 812.<sup>195</sup> The patent reform prong seeks to limit the abuse of “30 month stays” available to patent owners.<sup>196</sup> Widespread criticism of loopholes in the 1984 Hatch-Waxman Act<sup>197</sup>—including filing patent infringement claims, reformulating drugs for the sole purpose of extending patents, and lobbying for longer windows of patent protection<sup>198</sup>—motivated the push to put limitations on patent extensions for pharmaceutical

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187. *Point, Click, Self-Medicare: A Review of Consumer Safeguards on Internet Pharmacy Sites: Hearing Before the House Comm. on House Gov't Reform*, 108th Cong. 44–66 (2003) (statement of William Hubbard, Assoc. Comm'r for Policy, Planning & Legis., Food and Drug Admin.).

188. MINN. SENIOR FED'N METRO. REGION, MNSF CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM, <http://207.3.79.232/canadainport/importprogram.html> (last visited Feb. 9, 2004).

189. *Drugs: Senate Approves Drug Patent Law Changes, Rejects Medicare Drug Benefit Amendment*, WASH. INSIDER, Aug. 1, 2002, at D9 [hereinafter *Senate Approves Drug Patent Law Changes*].

190. H.R. Res. 4954, 107th Cong. (2002) (enacted); *Senate Approves Drug Patent Law Changes*, *supra* note 189.

191. *Senate Approves Drug Patent Law Changes*, *supra* note 189.

192. *Id.*

193. S. 812, 107th Cong. § 804(o)(A)–(B) (2002).

194. See 21 U.S.C. § 384 (2000).

195. S. 812, 107th Cong. §§ 103–104.

196. See *id.* § 104.

197. The Hatch-Waxman Act of 1984 was passed in order to deal with patents on prescription drug medications and facilitate competition from generic competitors. See 148 CONG. REC. S7876 (daily ed. Aug. 1, 2002) (statement of Sen. Hatch).

198. Stanton, *supra* note 4, at 157, 159.



drug manufacturers.<sup>199</sup> The major change in the patent reform prong was the elimination of the five-year sunset provision.<sup>200</sup> The MEDS Act was originally going to be five experimental years for competitors of brand name drugs.<sup>201</sup> There were concerns, however, that such a limited window for competition would discourage the significant investment required to make a difference in the industry.<sup>202</sup> That language was removed from S. 812.<sup>203</sup>

The major change in the reimportation prong of the MEDS Act was to amend chapter VIII of the Federal Food, Drug, and Cosmetic Act to allow the FDA to authorize reimportation of prescription medications and to punish any manufacturer that sought to discriminate against reimporting parties.<sup>204</sup> Unlike the original MEDS Act, S. 812 included the Dorgan Amendment, which restricted reimportation to Canada.<sup>205</sup> From the outset, Senator Dorgan made clear that his intent was to put pressure on the pharmaceutical industry to reduce prices.<sup>206</sup> Although these two changes were significant, the MEDS Act's requirement that the HHS Director certify that reimportation would be safe and cost effective was left in place.<sup>207</sup>

Senate Bill 812 appears to be a simpler, more focused proposal than the MEDS Act. The Bill limits reimportation to drugs from Canada only.<sup>208</sup> By limiting reimportation to Canada, the Senate was hoping both to alleviate concerns about safety and ability to monitor the contents and quality of the pharmaceutical imports, and to receive the HHS Director's certification of approval.<sup>209</sup> Canada's prices are

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199. See *Branded and Generic Drug Groups Butt Heads over Patent Reform*, CHEMICAL MARKET REP., Aug. 12, 2002, at 5 [hereinafter *Branded*]. The Generic Pharmaceutical Association in particular is very vocal about closing loopholes and leveling the playing field in order to promote competition and create significant customer savings. *Id.*

200. Creech, *supra* note 53, at 636.

201. See 21 U.S.C. § 384(m) (2000).

202. See *Branded*, *supra* note 199.

203. Compare 21 U.S.C. § 384(m), with S. 812, 107th Cong. § 804(o)(A)–(B) (2002) (demonstrating omission of language in S. 812).

204. *Id.* § 804(i)(1)–(2).

205. *Id.*; 148 CONG. REC. S6960 (daily ed. July 17, 2002).

206. *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. Byron Dorgan).

207. S. 812, 107th Cong. § 804(o)(A)–(B) (2002).

208. *Importation*, PUB. POL'Y BRIEFS (Pfizer, New York, N.Y.), Oct. 10, 2002, at 2, <http://www.pfizer.com/download/importation.pdf>.

209. See AM. THORACIC SOC'Y, SENATE DEBATES PRESCRIPTION DRUG LEGISLATION, [www.thoracic.org/advocacy/reports/wr071902.pdf](http://www.thoracic.org/advocacy/reports/wr071902.pdf) (last visited Feb. 11, 2004).

cheaper than the United States' due to government regulations, price controls, and bulk buying.<sup>210</sup> Proponents of S. 812 claim that reimportation will promote free trade and finally grant Americans access to the global market of pharmaceutical medications.<sup>211</sup> On July 31, 2002, the Senate passed S. 812, with the Dorgan Amendment on reimportation attached, by a vote of 78–21.<sup>212</sup> Regardless of whether or not S. 812 ever becomes law, there are serious questions about whether this is a safe alternative, an example of free trade, or a viable policy at all.

### III. Analysis of Senate Bill 812

Many arguments are advanced in support of S. 812. Unfortunately, the bill is shortsighted and will not achieve its intended results. Senate Bill 812 is economically unsound and will not create enough pressure on the pharmaceutical industry to drive down prices. Rather, at best, this bill will simply have an adverse impact on the Canadian market. At worst, it will stymie innovation and make pharmaceutical medications prohibitively expensive around the world. Fortunately, neither outcome will come to fruition, as the Senate ensured S. 812 will never become law by passing the responsibility-buck to the HHS Director.

#### A. Supporters of S. 812: Americans Will Benefit When the Pharmaceutical Industry's Unhealthy Profits Are Reduced

Supporters argue that S. 812 will bring Americans into the global market and allow them access to prices that the rest of the world enjoys.<sup>213</sup> According to this argument, the only detrimental effect of this

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210. Canada had a compulsory licensing scheme in place, but needed to terminate the program because of NAFTA's restrictions on compulsory licensing. See Robert Weissman, *NAFTA Issues in the Context of Canadian Implementation of the Paragraph 6 Agreement*, Oct. 7, 2003, <http://www.cptech.org/ip/health/c/Canada/weisman10072003.html>. As a compromise, Canada's Patent Medicine Price Review Board was established as price controls on patented medicines accompanied the elimination of compulsory licensing. Edward Hore, *Intellectual Property: Patent and Copyright Law*, CAN. LAW., Feb. 1997, <http://www.edwardhore.com/CL9702.htm>; see also Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L.J. 215, 234 (1999).

211. See Baer, *supra* note 28, at 129–30.

212. S. 812, 107th Cong. (2002); Kim Coghill, *Democrats Want Canada's Borders Open for Drug Reimportation*, BIOWORLD TODAY, Mar. 6, 2003, 2003 WL 6612933.

213. See Sanders, *supra* note 30.

open market policy will be toward the unhealthy profits of the pharmaceutical industry.<sup>214</sup>

#### 1. PROFIT MARGINS

Supporters of S. 812 argue that pharmaceutical drug prices are only high because of greed in the pharmaceutical industry.<sup>215</sup> The pharmaceutical industry is a very large and profitable industry, with what critics call “obscene profit margins.”<sup>216</sup> Critics of the pharmaceutical industry allege that monopoly, not innovation, is the real issue.

#### 2. OPEN MARKETS AND FREE TRADE WILL LEAD TO REAL COMPETITION AND FORCE DOWN PRICES ACROSS THE BOARD

Supporters argue that it is time for the United States to open its borders and embrace the free market system it purports to champion.<sup>217</sup> The United States claims to favor free markets and capitalism, yet we force our citizens to buy drugs in the United States at prices set by the pharmaceutical industry, when Americans could easily buy elsewhere for less.<sup>218</sup> The pharmaceutical industry is taking advantage of materials from all over the world<sup>219</sup> and getting the benefits of treaties (minimal tariffs) and other aspects of globalization.<sup>220</sup> Proponents argue that S. 812 extends the benefits of free trade to American consumers of prescription drugs by making the global economy work for them.<sup>221</sup>

By allowing Americans access to the Canadian market for pharmaceutical medications, U.S. consumers will receive tremendous financial and health benefits, and the pharmaceutical industry will finally be subject to competitive pricing like every other industry.<sup>222</sup> Not only would Americans benefit from access to specific cheaper drugs, but American drug prices across the board would have to be

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214. *See id.*

215. *See id.*

216. *Id.*

217. *See* Dorgan, *Frequently Asked Questions*, *supra* note 103, at 1.

218. *See id.* at 3.

219. *See id.*

220. *See id.*

221. *See id.*

222. *See* Sanders, *Reduce Drug Prices*, *supra* note 105.

reduced in order to remain competitive.<sup>223</sup> This downward pressure on prices is exactly what the Senate hopes to achieve.<sup>224</sup>

### 3. STUDIES SHOW BENEFITS OF OPEN MARKETS

The savings from the resultant downward pressure on prices would be significant. A Congressional Budget Office (CBO) study suggests that American consumers could save \$60 billion over the next ten years,<sup>225</sup> and a study by Dr. Alan Sager suggests the savings could be as high as \$38 billion in the first year alone.<sup>226</sup>

These incredible savings would benefit everyone. A major source of tension between Democrats and Republicans in the U.S. Congress is the scope of any proposed expansion of prescription drug benefits under Medicare.<sup>227</sup> In general, Republicans favor targeted changes that would only affect those who are most in need.<sup>228</sup> Democrats tend to favor universal changes to the system.<sup>229</sup> A reimportation regime would offer competitive prices to all consumers using the free market as the vehicle for change, not the American taxpayer.<sup>230</sup> Thus, everyone would benefit to some extent and some pressure would be removed from all seniors.

Reimportation would not lower prices for everyone. In fact, open borders may have a detrimental effect on third-world countries. Reimportation would most likely cause some price increases outside of the United States as the international pharmaceutical market reacts to new levels of demand and new, relatively wealthy consumers. Some consumers outside the United States would likely be hurt by these price increases. However, suffering already exists in the United States, as many Americans cannot afford the drugs that are available to the rest of the world.<sup>231</sup> It is the duty of U.S. representatives to advocate for the Americans they represent—so foreign interests will

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223. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. Byron Dorgan).

224. See *id.*

225. *Senate Approves Drug Patent Law Changes*, *supra* note 189.

226. See Lueck, *supra* note 184.

227. See, e.g., Associated Press, *Democrats' Prescription Benefit Defeated*, CHI. TRIB., June 23, 2000, § 1, at 17.

228. See, e.g., *id.*

229. See, e.g., *id.*

230. See 148 CONG. REC. S6919 (daily ed. July 17, 2002) (statement of Sen. Dorgan discussing goals of reimportation).

231. See PRYOR, *supra* note 11, at 5; NEWSHOUR WITH JIM LEHRER, *supra* note 77, chart 3.

come second. It would be wise to note, however, that this natural focus on one's own population is a double-edged sword and may also affect how Canadians respond to S. 812. Although reimportation may not be anyone's ideal solution, supporters argue that it is a movement in the right direction and a major, pain-free step that can be taken to alleviate suffering in the short term.<sup>232</sup>

#### 4. SUCCESS MADE POSSIBLE BY CHANGES TO THE MEDS ACT

Supporters believe S. 812 will be successful due to two critical changes to the MEDS Act of 2000, namely, the removal of the five-year sunset provision and the narrowing of reimportation to Canada alone.

*a. Sunset Provision Removed* One of the significant changes from the MEDS Act is the removal of the five-year sunset provision, which loomed like a dark cloud over potential investors.<sup>233</sup> With this cloud removed, supporters anticipate tremendous investment in new providers of pharmaceutical medications, coupled with significant growth in the generics markets (due to changes in patent extensions and leveling of the playing field).<sup>234</sup> Under the MEDS Act, reimportation was to be a five-year experiment.<sup>235</sup> Critics, including HHS Secretary Shalala, considered this provision to be one of the fatal loopholes in the Act.<sup>236</sup> Responsible companies could not be expected to invest wholeheartedly in an experiment scheduled to end in five years. With the removal of this provision, importers and distributors can invest seriously and heavily in this potentially lucrative market. The growing volume of drugs being sold to the United States from Canada by way of Internet, mail services, and cross-border trips suggests there is already a ripe market for these imports,<sup>237</sup> and it will take no time to establish the infrastructure necessary to cultivate and accommodate that market.

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232. See, e.g., 148 CONG. REC. S6897 (daily ed. July 17, 2002) (statement of Sen. Wellstone discussing benefits of reimportation).

233. 21 U.S.C. § 384(m) (2000).

234. See Creech, *supra* note 53, at 636. Concerns about the limited time frame that were expressed during the MEDS Act would no longer be relevant to the reimportation debate. *Id.* at 636–37.

235. 21 U.S.C. § 384(m).

236. See McGinley, *supra* note 172.

237. See Ukens, *supra* note 163.

b. *Reimporting Only from Canada Reduces Safety Concerns* Limiting reimportation to Canada means that safety should not be an issue. Canada's drug approval and distribution system is very similar to the United States's FDA.<sup>238</sup> The close proximity and secure borders also suggests safety is less of a concern. Finally, the large quantity of cross-border pharmaceutical sales that already exist suggests that reimportation is already happening and without the horrific effects that PhRMA always cautions against.<sup>239</sup> To date, due in large part to special licensing by respected umbrella organizations like the National Association of Boards of Pharmacy, prescription medication traffic from Canada has not been a problem.<sup>240</sup>

Supporters of S. 812 claim that the bill creates no new security risks.<sup>241</sup> Continued strict regulation and documentation is a part of S. 812. Drugs will be subject to FDA safety inspections and FDA safety labeling.<sup>242</sup> Senator Dorgan points to:

[s]trict FDA oversight; [p]roof of FDA approval of imported medicines (must maintain paper "chain of custody"); [o]nly licensed pharmacists and wholesalers can import medicines for resale; [i]mporters will have to meet requirements for handling as strict as those already in place for manufacturers; [r]egistration of Canadian pharmacies and wholesalers with HHS; . . . [l]ab testing to ensure purity, potency, and safety of medications; and HHS Secretary can immediately suspend importation of prescription medicines that appear counterfeit or otherwise violate the law.<sup>243</sup>

The bill will also have penalties in place to discourage would-be violators. As in the MEDS Act, penalties for violations can reach up to \$250,000 and ten years in prison.<sup>244</sup>

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238. See Debbie Stabenow, *Medication Equity and Drugs Savings Act II (MEDS II)*, at <http://stabenow.senate.gov/infocus/medequity.htm> (last visited Feb. 11, 2004) (citing to Congressional Research Service finding that Canadian drug approval and distribution system is very similar to U.S. system). Stabenow also claims that senior members of FDA are confident in safety of drugs reimported from Canadian system. *Id.*

239. See Gomez, *supra* note 178, at 450–51.

240. See *id.* But see Anna Wilde Mathews & Scott Hensley, *FDA Targets an Upsurge in Fake Drugs*, WALL ST. J., Sept. 11, 2003, at B1 (noting recent upsurge in counterfeit prescription drugs).

241. See, e.g., Helen Dewar, *Senate Votes to Allow Drug Reimportation; U.S.-Made Pharmaceuticals Could be Shipped from Canada at Lower Cost*, WASH. POST, July 18, 2002, at A4.

242. See RANDALL & VOGT, IMPORTING PRESCRIPTION DRUGS, *supra* note 151, at 5–7.

243. Dorgan, *Frequently Asked Questions*, *supra* note 103, at 2.

244. RANDALL & VOGT, IMPORTING PRESCRIPTION DRUGS, *supra* note 151, at 6.

The FDA is up to the challenge. Not only is the FDA adequately policing and supervising the manufacturing and production processes of drugs, but it is already sufficiently staffed for handling the influx of new drugs at the border.<sup>245</sup> According to Senator Dorgan's office, by "mitigating the need for consumers to import their own prescription drugs via the Internet and mail-order, this bill would allow the FDA and Customs to focus their resources on other imports"<sup>246</sup> and use the FDA's resources more effectively.<sup>247</sup>

Advocates of S. 812 discount many of PhRMA's warnings about safety issues as scare tactics designed to prevent any real discussion of the reimportation strategy.<sup>248</sup> Although PhRMA may hypothesize that Canada will turn into the counterfeit-drug capitol of the world, for now, even PhRMA representatives acknowledge that "they are aware of no major counterfeiting problems involving drugs from Canada."<sup>249</sup> The conclusion: PhRMA is not concerned with safety, only profits. Although the pharmaceutical industry harps on the dangers of reimporting drugs that have not been under the watchful eye of the FDA, it simultaneously presses the FDA to expedite its drug-approval rates.<sup>250</sup> It is generally accepted that it takes a lot of time and money to develop a new drug. The FDA's approval process for new drugs is famous for both its stringency and slowness.<sup>251</sup> Supporters of S. 812 argue that the pharmaceutical industry's position undermines its safety arguments and exposes its hypocrisy.<sup>252</sup> The accusation has been made that, when there is money to be made from lower safety standards, PhRMA supports less safety.<sup>253</sup> It follows, then, that when lower safety standards will reduce profits, PhRMA supports more safety.

Some S. 812 supporters question whether there is anything to be afraid of at all.<sup>254</sup> *Managed Care Magazine* reported that "[i]n an im-

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245. See Dorgan, *Frequently Asked Questions*, *supra* note 103, at 2.

246. *Id.* at 3.

247. See *id.*

248. See Sanders, *Prescription Drug Pricing Reform*, *supra* note 126.

249. David Wenner, *Foreign Aid; Mail Orders from Canada Cut Drug Costs*, *HARRISBURG PATRIOT*, Oct. 16, 2002, at D1, 2002 WL 3013131.

250. See Jill Wechsler, *Industry Faces Challenges*, *PHARMACEUTICAL EXECUTIVE*, Jan. 1, 2002, at 24, 2002 WL 13373443.

251. Carter, *supra* note 210, at 234; see also *Testing Testing*, *THE ECONOMIST*, Feb. 1, 1997, at 81.

252. See Sanders, *supra* note 30.

253. See SANDERS, *PUBLIC DOLLARS*, *supra* note 121.

254. See Sanders, *Prescription Drug Pricing Reform*, *supra* note 126.

pressive display of star power and sheer political skill, PhRMA secured testimony from 11 former FDA commissioners who cautioned that reimportation would threaten public safety.”<sup>255</sup> This overwhelming opposition to reimportation is discounted by supporters of S. 812 and reimportation as pure politics.<sup>256</sup> Representative Bernie Sanders, among others, points out that seven of the eleven former FDA commissioners have “strong financial ties to the pharmaceutical and medical equipment industry.”<sup>257</sup> The fact that there have been relatively few instances of counterfeiting in the last decade lends weight to these arguments.<sup>258</sup>

The supporters of reimportation initiatives conclude that pharmaceutical special interests and lobbyist groups do not share interests with average consumers.<sup>259</sup> Rather, PhRMA and their constituency are primarily interested in maintaining their very high profit margins and will use a variety of scare tactics—including warnings about economic and criminal threats—to protect those profits.<sup>260</sup> While most of S. 812’s supporters would prefer a broader more comprehensive piece of legislation to address health care issues,<sup>261</sup> for now they view this as a reasonable short-term fix.

#### **B. Arguments Supporting S. 812 Are Flawed**

The supporters of S. 812 are wrong. Senate Bill 812 is neither safe, nor economically sound. Opponents of S. 812 correctly challenge the appropriateness of free markets and free trade discussion where unnatural government price caps have been imposed on certain parts of the market.<sup>262</sup> Additionally, opponents correctly note that by importing non-U.S. price caps with the reimported drugs, S. 812 will

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255. Michael D. Dalzell, *Prescription Drug Reimportation: Panacea or Problem?*, MANAGED CARE, Dec. 2000, at <http://www.managedcaremag.com/archives/0012/0012.reimport.html>.

256. See Sanders, *Prescription Drug Pricing Reform*, *supra* note 126.

257. *Id.*

258. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (testimony of Dr. Greg Glover).

259. See Sharona Hoffman, *Unmanaged Care: Towards Moral Fairness in Health Care Coverage*, 78 IND. L.J. 659, 710 (2003).

260. See Sanders, *Prescription Drug Pricing Reform*, *supra* note 126.

261. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statement of Sen. Byron Dorgan).

262. See Baer, *supra* note 28, at 129; Ghosh, *supra* note 178, at 243.



thwart innovation and undermine a risky and fragile industry that is currently providing a tremendous service to much of the world.<sup>263</sup>

#### 1. SAFETY RISK IS REAL

Although counterfeiting and tampering were always an issue for the FDA, after the terrorist attacks on September 11, 2001, and the anthrax letters mailed to congressmen and others shortly thereafter, security concerns are at an all-time high.<sup>264</sup> As Americans come to terms with the idea of a prolonged war against terrorism, and the reality of acts of terrorism and bioterrorism directed at civilian populations, safety will be a major focus of any new policies—especially public health policies.<sup>265</sup>

In a July 10, 2001, letter to Senator James Jeffords (I-Vt.) (one of the primary supporters of S. 812), HHS director Tommy Thompson explained, “Once an FDA-approved prescription drug is exported for sale in another country, it is no longer subject to U.S. requirements and it can no longer be monitored by U.S. regulators.”<sup>266</sup> Director Thompson’s concern for safety was also a concern in the previous administration under Director Shalala and of the MEDS Act,<sup>267</sup> and will play a more prominent role in S. 812. Significantly, the 107th Senate, which passed S. 812 by a vote of 78–21, passed the Cochran Amendment to S. 812 that deals with security by a vote of 99–0,<sup>268</sup> suggesting that nobody, not even the sponsors of the bill, is willing to stake his or her career on the potential economic benefits of S. 812 alone.

William K. Hubbard, Senior Associate Commissioner at the FDA, testified before the House Health Subcommittee on July 25, 2002, and addressed the issue of reimportation.<sup>269</sup> In his testimony, Hubbard commented on the gradual increases in counterfeit activity

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263. See Baer, *supra* note 28, at 128–29.

264. See Jon Cohen & Elliot Marshall, *Should the Government Make Vaccines?*, MIT’S TECH. REV., May 1, 2002, 2002 WL 3504600. See generally Mark B. McClellan, *Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products—Remarks of the Commissioner of Food and Drugs*, 58 FOOD & DRUG L.J. 191 (2003).

265. See Cohen & Marshall, *supra* note 264 (describing the need for vaccines); Lueck, *supra* note 184, at 2.

266. See Meadows, *supra* note 159, at 20.

267. *Id.*

268. AM. THORACIC SOC’Y, *supra* note 209.

269. William K. Hubbard, *Faking It*, DAILY DEAL, Aug. 20, 2002, 2002 WL 22400438; see also FDA Official Testifies About Dangers of Importing Drugs, *Regulatory Developments*, HEALTH CARE FRAUD & ABUSE NEWSL., July 2002, at 9.

in the pharmaceutical areas<sup>270</sup> and said, “The FDA remains strongly concerned about any possibility that counterfeit or otherwise unsafe drugs may find their way into the American drug supply.”<sup>271</sup> These risks include: quality assurance concerns, counterfeit potential, presence of untested substances, risks of unsupervised use, labeling and language issues, and lack of information (ingredients of the drugs that would help in treatment of side effects).<sup>272</sup>

Beyond the mere existence of counterfeit drugs in Canada, there are serious differences in the way U.S. and Canadian drug inspectors operate, and this has been cause for alarm.<sup>273</sup> The pharmaceutical industry and the FDA have a much more adversarial relationship than exists in most countries.<sup>274</sup> The Canadian drug regulators, the Health Protection Branch (HPB) of the government, routinely choose to rely on persuasion, education, and cooperation, rather than litigation to achieve their objectives.<sup>275</sup> This laxity has raised serious concerns in the United States about whether the FDA and the HPB really are enforcing comparable laws in a comparable manner.<sup>276</sup> The FDA is confident in its closed system but does not think the sample-testing method of inspection included in S. 812 is sufficient or secure.<sup>277</sup>

## 2. NEGATIVE EFFECTS OF LEGISLATION AND REGULATION ON INNOVATION AND AVAILABILITY

Senate Bill 812 threatens more than just the safety of pharmaceutical medications. The pharmaceutical industry has adjusted to earlier legislation and changing the rules now would be exceptionally costly.<sup>278</sup> In addition to changing their internal marketing schemes,

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270. Hubbard, *supra* note 269.

271. *Id.* Interestingly, this exact same testimony is cited by supporters of S. 812, who claim that Mr. Hubbard warned to S. 812 and said “he would have a ‘relatively high degree of confidence’ in drugs imported from Canada.” Press Release, Office of Sen. Dorgan, Prescription Drug Price Parity for Americans Act, Bill Summary (on file with *The Elder Law Journal*).

272. Meadows, *supra* note 159, at 18–20.

273. See Carter, *supra* note 210, at 234.

274. See *id.* at 234–35; see also Robert E. Curran, *Canadian Regulation of Food, Drugs, Cosmetics & Devices—An Overview*, 30 FOOD & COSM. L.J. 644, 648 (1975).

275. See Carter, *supra* note 210, at 224–28; see also Curran, *supra* note 273, at 648.

276. See Carter, *supra* note 210, at 233–34.

277. See Hubbard, *supra* note 166, at 37 (discussing new efforts by the FDA to try and better regulate medications reimported via the Internet); see also Mathews & Hensley, *supra* note 240.

278. See Angarola & Beach, *supra* note 152, at 52. “The PDMA has imposed a substantial burden on industry, and many companies have invested significant

any imposition of price controls, even if they are indirect, will have a tremendous impact on profits, disrupt pricing systems, and result in fewer quality products and less research and development.<sup>279</sup>

Although there is little public sympathy for loss of pharmaceutical industry profits, a strong argument can be made that the overall benefits of these profits are tremendous and widespread.<sup>280</sup> Access to state-of-the-art medications makes for a more efficient health care system with many alternatives to in-patient and surgery procedures.<sup>281</sup> By imposing Canadian price controls on the U.S. market, S. 812 will squash financial incentives that motivate this important industry to make innovative and life-saving products.<sup>282</sup> These disincentives to innovation will put additional stress on the industry, just as major patented money-making drugs are now coming off patent in larger numbers.<sup>283</sup>

Most economists strongly disfavor price controls,<sup>284</sup> and for good reason. Essentially, price controls reduce the amount of trade in the economy and create incentives to waste resources.<sup>285</sup> Although price controls may hold down the per-unit price of pharmaceutical medications, it appears that these controls tend to undermine competition and incentives for generics to enter new markets.<sup>286</sup> In France and Italy, where strict government-imposed price controls exist, the cost of over the counter medications is more than 200% higher than in the United States.<sup>287</sup>

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resources and modified their operating procedures to comply with the PDMA's terms." *Id.*

279. See Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311, 312 (2000).

280. See Katherine Hutt Scott, *Minnesota Senator Wants Tax on Drug Companies*, GANNETT NEWS SERV., July 18, 2002, 2002 WL 5259042.

281. See ROBERT M. GOLDBERG, INST. FOR POLICY INNOVATION, PHARMACEUTICAL PRICE CONTROLS: SAVING MONEY TODAY OR LIVES TOMORROW? 1 (1993), [http://www.ipi.org/ipi/IPIPublications.nsf/PublicationsLookupFullTextPDF/84F76FCFC5E22847862567EA0079022C/\\$File/pharm.pdf?OpenElement](http://www.ipi.org/ipi/IPIPublications.nsf/PublicationsLookupFullTextPDF/84F76FCFC5E22847862567EA0079022C/$File/pharm.pdf?OpenElement).

282. See Scott, *supra* note 280.

283. See Piatt, *supra* note 36, at 181–83 (discussing pressure on pharmaceutical industry resulting from major drugs coming off patent as well as attempts by insurers to increase their own profits by pushing for greater use of generic drugs).

284. See Fiona M. Scott Morton, *The Problems of Price Controls*, REGULATION, June 20, 2001, <http://www.cato.org/dailys/06-20-01.html>.

285. See *id.*; see also Stambaugh, *supra* note 33, at 901.

286. Stanton, *supra* note 4, at 166; see Patricia Danzon, *Drug Prices: Let the Competition Begin*, at <http://www2.mba-exchange.com/db/mba2.nsf/Wharton/Drug+Prices+Let+the+Competition+Begin?OpenDocument> (last visited Feb. 11, 2004).

287. Stanton, *supra* note 4, at 166.

Regulat[ion] of the most expensive drugs does not save health care dollars, but merely shifts them to non-regulated drugs that are used in ever-greater quantities. Rather than conserving health care resources, the technique of direct regulation tends to increase total drug expenditures even while limiting expenditures for the targeted drugs.<sup>288</sup>

Controls not only affect the patented products, but generics and undeveloped drugs, as well. Patricia Danzon, economics professor at the Wharton School of Business and pharmaceutical industry expert, notes, "Generic market shares of off-patent products are significantly higher in countries that permit (relatively) free pricing, such as the United States, the United Kingdom, and Germany, than in countries with strict price or reimbursement regulation, such as France, Italy, and Japan."<sup>289</sup> Innovation has suffered as well in these heavily regulated markets.<sup>290</sup> Generics perform better in free-pricing regimes because they are forced to compete on price,<sup>291</sup> and are not simply licensed out to comarketers, or otherwise manipulated by the regulating government or competing manufacturers.<sup>292</sup> Furthermore, where regimes use price controls, expected profits are lower across-the-board, and many generic manufacturers are discouraged from ever entering the market.<sup>293</sup> In some instances, price regulations have created incentives for local manufacturers to introduce therapeutic substitutes that are "chemically distinct compounds that have similar therapeutic effects for at least some patients."<sup>294</sup> In general, where these market-regulating practices exist, they have undermined innovation and competition in R & D.<sup>295</sup>

Today, the United States leads the pharmaceutical industry in innovation, which at least one researcher attributes to the absence of U.S. price regulation.<sup>296</sup> If faced with price controls and government regulation, the U.S. pharmaceutical industry might begin to resemble the ineffective markets of Europe or suffer the way the U.S. vaccine industry has since the government decided to regulate it.

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288. *Id.* at 166–67.

289. Danzon & Chao, *supra* note 279, at 312.

290. *See generally* Stanton, *supra* note 4, at 166.

291. Danzon & Chao, *supra* note 279, at 314.

292. *Id.*

293. *Id.* at 319.

294. Danzon & Chao, *supra* note 279, at 321–22.

295. *See id.*

296. Stanton, *supra* note 4, at 170.

The vaccine market is an example of the downside to price controls that consumers may experience if Canadian price controls are imposed on the U.S. pharmaceutical industry.<sup>297</sup> A severe vaccine shortage currently exists in the United States in large part because market factors do not offer sufficient incentives for manufacturers to produce vaccines unless there is a specific contract in place and money to pay for it.<sup>298</sup> As a result, many companies have exited the vaccine market, and now only four vaccine manufacturers exist in the entire United States.<sup>299</sup> Like pharmaceuticals, vaccines take a long time to bring through the pipeline, so changes in government regulations may have a tremendous impact.<sup>300</sup> Unlike pharmaceuticals, however, vaccines lack constant and growing demand.<sup>301</sup> Vaccines simply do not play the same role in people's day-to-day lives, so it is a less lucrative industry.<sup>302</sup> Whether the vaccine industry is a perfect analogy to pharmaceuticals is debatable, but many claim that it was price controls that undermined the vaccine industry.<sup>303</sup>

### 3. FREE TRADE AND FREE MARKET ARGUMENTS ARE MISAPPLIED

Those who argue that reimportation is a free trade issue are not entirely correct.

This free trade argument when applied to the pharmaceutical industry is flawed for two reasons: (1) Different nations have different patent regimes; and (2) Government regulations on pharmaceuticals often include price controls artificially reducing the price of drugs. Consequently, price differentials are not the result of market forces. Thus, free trade via parallel imports is not truly free in the traditional "laissez-faire" sense and would not improve world-wide welfare. To the contrary, allowing parallel imports could have drastic consequences on world-wide welfare.<sup>304</sup>

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297. See Cohen & Marshall, *supra* note 264.

298. See *id.*

299. See *id.*

300. See *id.*; see also *Vaccine Availability: Aventis Pasteur Official Tells Senate Committee that Vaccine Shortages Are Preventable*, VACCINE WKLY., July 17, 2002, at 16, 2002 WL 9342903.

301. See Peter A. Ubel & Ann Boulis, *When the Free Market Fails: Facing the Vaccine Shortage*, NEW LEADER, July 1, 2002, 2002 WL 14541965.

302. See *id.*

303. Cohen & Marshall, *supra* note 264; see also *Vaccine Availability: Aventis Pasteur Official Tells Senate Committee that Vaccine Shortages Are Preventable*, *supra* note 300.

304. Baer, *supra* note 28, at 129–30. Ending the ability to price discriminate would have a tremendous impact on those countries that cannot afford to pay for, or support development of, pharmaceutical medications. *Id.* at 128. Although the U.S. consumer may see a short-term benefit, many argue that the global ramifica-

Industries set their pricing schemes in order to maximize profits. For example, Canadians make less money than Americans so it makes sense that their goods, including pharmaceuticals, are cheaper.<sup>305</sup> Even in the United States, prices for pharmaceuticals may vary by region.<sup>306</sup> It is only because U.S. taxpayers pay higher prices for drugs than consumers in developing countries that drug manufacturers can supply African countries, for example, at all.<sup>307</sup> Without the U.S. cushion and with no chance of profits in poorer countries, no motivation exists to offer poor countries life-saving and life-enhancing medications.<sup>308</sup>

Alteration or termination of price differentiations may have a tremendous ripple effect and warrant more investigation. It is not clear that the same global marketplace of pharmaceutical medications will exist if price differentiation is undermined by reimportation policies (which is what happens when the U.S. market is no longer off-limits to reimported drugs). Realizing that today's marketplace is full of artificial constructs that have been adapted to over time is an important first step in a discussion about free trade, and one that undermines much of the oversimplified political rhetoric swirling around S. 812.

#### 4. TRIP WIRES WILL PREVENT S. 812 FROM EVER BECOMING LAW

Senate Bill 812 will never become law for several reasons. Namely, S. 812 has built-in trip wires that make it politically and economically impossible to enact. Under President Clinton, HHS Director Donna Shalala declined to certify the MEDS Act as safe or more economically beneficial than the existing regime.<sup>309</sup> Prior to September 11, 2001, HHS Director Tommy Thompson said, "Opening our

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tions would be disastrous. *See id.* at 128–32; *see also* Ghosh, *supra* note 178, at 243 (analyzing gray markets with a specific focus on how Canadian price controls and agency regulations could affect pricing and behavior by the pharmaceutical industry if reimportation of prescription medication is authorized by the U.S. government).

305. John E. Calfee, *Drug Reimportation from Canada: Not So Fast*, Oct. 2002, [http://www.cnehealth.org/pubs/calfee\\_canada.htm](http://www.cnehealth.org/pubs/calfee_canada.htm) (last visited Feb. 11, 2004).

306. *See* John R. Graham, *Executive Summary: Prescription Drug Prices in Canada and the United States—Part 3. Retail Price Distribution*, PUB. POL'Y SOURCES (Fraser Institute, Vancouver, British Columbia, Can.), at [http://oldfraser.lexi.net/publications/pps/50/section\\_01.html](http://oldfraser.lexi.net/publications/pps/50/section_01.html) (last visited Feb. 11, 2004).

307. Baer, *supra* note 28, at 128–29.

308. *Id.*

309. McGinley, *supra* note 172.

borders as required under this program would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions.”<sup>310</sup> These reservations were seconded by the Bush administration, which also opposes the legislation on safety grounds.<sup>311</sup> Concerns that existed in 2000 about criminals and terrorists tampering with medication are significantly more audible following the terrorist attacks on the United States on September 11, 2001.<sup>312</sup> No government official is going to stick his or her political neck out and certify this as a safe program, especially in the Bush administration, which favors the pharmaceutical industry<sup>313</sup> and is trying to take a tough line on international threats to U.S. citizens.<sup>314</sup>

5. **STRATEGIES TO THWART S. 812: THE PHARMACEUTICAL INDUSTRY WILL NOT RISK ITS BREAD AND BUTTER MARKET**

It is unclear how much money consumers should expect to save on annual drug expenditures under S. 812 and reimportation. Estimates for the average U.S. senior range from 0.5% (PhRMA study)<sup>315</sup> to 75% (foreignpharmacies.com).<sup>316</sup> What should be clear, however, is that the pharmaceutical industry will never let S. 812 take any meaningful share of its profits.<sup>317</sup>

The U.S. market is the bread and butter of the pharmaceutical industry’s profits and income. The pharmaceutical industry is able to remain profitable because, despite the deep discounts it offers to the rest of the world, the industry charges Americans more per unit of medication than anyone else.<sup>318</sup> The industry will never let the far-less-significant Canadian market of \$5.2 billion per year put its signifi-

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310. *Drug Reimportation Unfeasible for Safety Reasons, Thompson Claims*, CAL. HEALTH L. MONITOR, July 30, 2001, at 3.

311. *Senate Approves Drug Patent Law Changes*, *supra* note 189.

312. *E.g.*, Lueck, *supra* note 184.

313. Cassell Bryan-Low, *Drug-Firm Insiders Have Been Cashing In*, WALL ST. J., Dec. 13, 2000, at C24.

314. *See Senate Approves Drug Patent Law Changes*, *supra* note 189.

315. *Branded*, *supra* note 199.

316. Lueck, *supra* note 184.

317. *See* Editorial, *Sure, Cheap Canadian Drugs*, WALL ST. J., July 23, 2002, at A14 [hereinafter *Sure, Cheap Canadian Drugs*].

318. *See* Susan Wamer, *A New Bid to Lower U.S. Drug Prices*, PHILA. INQUIRER, Sept. 17, 2000, at E1.

cant U.S. profits of \$91.2 billion per year at risk.<sup>319</sup> A July 23, 2002, *Wall Street Journal* editorial pointed out that “if a flood of cheap pills looked to threaten [the pharmaceutical industry’s] core profit center in the U.S., they’d simply demand Canada get serious at the bargaining table.”<sup>320</sup> This has already happened in countries where the government refused to negotiate its price cap.<sup>321</sup> When France refused to pay Merck’s asking price for Maxalt (migraine treatment), Merck called off the talks and exported Maxalt to the French market “outside the state-run reimbursement system.”<sup>322</sup> Additionally, nothing is in place to stop manufacturers from selling fewer drugs to the Canadian government (i.e., just enough to meet Canada’s needs but no surplus that will ultimately benefit Canadian and U.S. middlemen engaging in reimportation (who also pull in profits) at the expense of the manufacturer who makes and sells the drugs).<sup>323</sup>

A strategy of “under providing” has been used before. Prior to enactment of the PDMA in 1988, pharmaceutical companies tried to limit reimportation by reducing sales outside the United States.<sup>324</sup> If the PDMA is effectively rolled back, will manufacturers attempt to limit sales to a foreign country in order to prevent the return of these drugs into the United States market?<sup>325</sup> This decision is made easier under S. 812, as the industry need only target Canada,<sup>326</sup> and not the multiple markets included under the MEDS Act.<sup>327</sup> Where there are multiple markets involved, the industry would have to think long and hard before reducing exports across the world; when the focus is on exports to one country, the decision is less difficult. Of the many countries approved for reimportation in the MEDS Act, Canada was only the sixth-largest reimporter of medications (reimported by the original manufacturer) and was virtually tied for that spot with France, Ireland, and Sweden.<sup>328</sup> From 1995–1999, however, Canada’s share had only increased by 7.1%, as opposed to France’s 16.5%, Ire-

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319. *Id.*

320. *Sure, Cheap Canadian Drugs, supra note 317.*

321. *See id.*

322. *Id.*

323. *See id.*

324. *See Reimportation Legislation: Will It Succeed in Lowering US Drug Prices and Safeguard Quality?, supra note 149.*

325. *See id.*

326. *See Sure, Cheap Canadian Drugs, supra note 317.*

327. 21 U.S.C. § 384 (2000).

328. *See Dalzell, supra note 255.*



land's 65.9%, and Sweden's 31.2%.<sup>329</sup> The CRS estimates that the United States exported \$2.2 billion in pharmaceutical products to Canada in 2000 and imported approximately \$853 million.<sup>330</sup> That \$853 million is about 6.5% of total reimported medications to the United States.<sup>331</sup> Canada simply does not represent a large enough market to force the pharmaceutical industry to make real adjustments other than reducing exports of popular medications to Canada to the bare minimum.<sup>332</sup> Indeed, these kinds of cutbacks have already begun.<sup>333</sup> On February 28, 2003, the *Wall Street Journal* announced that, "GlaxoSmithKline, the world's second largest pharmaceutical manufacturer . . . is cutting off supplies to Canadian pharmacies that deliver to American patients."<sup>334</sup> And the world's largest pharmaceutical manufacturer, Pfizer Inc., is now planning to implement similar policies.<sup>335</sup>

Supporters of S. 812 counter that the pharmaceutical industry's image is on the line and it has too much to lose by going against public pressure and reducing sales to Canada.<sup>336</sup> Public pressure and stigmatization, however, will not be enough. Individual consumers have no leverage with the pharmaceutical industry, which is why high pharmaceutical prices are tolerated in the first place.<sup>337</sup> Additionally, all of the compelling financial arguments for keeping prices higher—namely the risk to innovation and to research and development—remain equally potent even after passage of a reimportation bill. Furthermore, regardless of public opinion or industry maneuver-

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329. *See id.*

330. *See* Press Release, Office of Sen. Dorgan, Comparison of U.S. and Canadian Requirements for Approving and Distributing Prescription Drugs, Summary of Congressional Research Service Report (on file with The Elder Law Journal).

331. *See id.*; Dalzell, *supra* note 255 (dividing \$853 million by \$2.2 billion).

332. *See* Sure, *Cheap Canadian Drugs*, *supra* note 317.

333. *See* John R. Graham, *Americas: Canada's Mail-Order Drug Houses Plague Glaxo*, WALL ST. J., Feb. 28, 2003, at A9.

334. *Id.*

335. *See* Scott Hensley & Anna Wilde Mathews, *Pfizer Warning May Curb Drugs from Canada*, WALL ST. J., Aug. 7, 2003, at A2 (reporting on Pfizer's attempt to enforce stricter antireimportation contract terms against forty-six Canadian pharmacies by forcing them to buy Pfizer products directly from Pfizer and not wholesalers).

336. *See* U.S./Canada Pharma Reimportation, M2 PRESSWIRE, July 1, 2003, 2003 WL 56423376 (suggesting that reducing sales to Canada "is almost certain to prove detrimental for company image").

337. *See generally*, James Carroll, *Rising Prescription Drug Costs: What Is Involved and What Can Be Done*, ME. POL'Y REV., Spring 2003, at 70, <http://www.umaine.edu/mcsc/MPR/Vol12No1/Carroll/carroll.pdf>.

ing, it is not entirely clear that Canada could come to the rescue in the best of circumstances. Even if exports remain constant, Canada may not have the infrastructure necessary to make this plan work in the United States.<sup>338</sup>

The Senate's decision to act alone will also have a serious impact on Canadian industry and the experience of their pharmaceutical drug consumers.<sup>339</sup> In the event that reimportation helps U.S. consumers save money, the potential responses by U.S. and Canadian pharmaceutical industries indicate that these savings would be at the expense of Canadian consumers.<sup>340</sup> Not having coordinated this change in policy with the Canadian government, reimportation will be limited to whichever drugs the Canadians decide to buy, or more accurately, whichever drugs they decide to buy in excess.<sup>341</sup> How much Americans save will depend on Canadian prices, taxes, and their desire to make profits by selling valuable commodities in bulk back to the United States.

The more money American consumers save from reimportation, the more pressure the pharmaceutical industry will put on the Canadian government when they negotiate prices.<sup>342</sup> As tougher negotiations make pharmaceutical medications more expensive, the Canadian government may simply opt to pass those costs along to the reimporting industry and players. A government that already takes steps to insulate its population from high medical expenses might pass laws that limit the ability to sell back drugs, ration the amount of medicines distributed, tax exporters of drugs, or go so far as to change their entire distribution system in order to make sure that certain drugs go directly to individual consumers through government clinics or agencies and not through private retailers or distributors who might sell their inventory to American importers.<sup>343</sup> Thus, in keeping with the spirit of S. 812, we should expect that, as far as the Canadian government is concerned, Canadians come first. The fact that the Canadian government has already publicly declared that it is not responsible for

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338. See Calfee, *supra* note 305 (explaining that Canadian pharmaceutical market is less than one-tenth the size of the U.S. market).

339. See Ghosh, *supra* note 178, at 243; Calfee, *supra* note 305.

340. See Ghosh, *supra* note 178, at 243; Calfee, *supra* note 305.

341. Calfee, *supra* note 305.

342. See *Sure, Cheap Canadian Drugs*, *supra* note 317; Calfee, *supra* note 305.

343. See, e.g., Joel Baglole, *U.S. Drug Imports Worry Canadians*, WALL ST. J., Oct. 22, 2002, at A7.

the risks taken by those who reimport drugs<sup>344</sup> demonstrates that this is a program intended for Americans and that Canada has no intention of being a true partner in this venture.

#### 6. SAVINGS WILL NEVER TRICKLE DOWN TO U.S. CONSUMERS

Middlemen and distributors may absorb all of the “savings” that were supposed to go to consumers. Even if the pharmaceutical industry does not maneuver to secure its profits, others can be expected to take advantage of the opportunity to make money—thereby driving drug prices up before consumers ever get a chance to purchase them.<sup>345</sup> Interestingly, one might predict that the strongest supporters of S. 812 will gain the most if this redistribution of profits occurs.<sup>346</sup> Due to large senior populations, U.S. senators from the northern states are in the best position to reap the benefits of this bill.<sup>347</sup> Considering their close proximity to Canada, these same states could become the hubs of distribution to the rest of the United States. Thus, border states may benefit from reimportation because they will receive reimported drugs first and with few middlemen involved, and because they can serve as the launching points or middlemen for reimportation and distribution into the United States.<sup>348</sup> Senate Bill 812 appears to generate political and financial capital for its key supporters, many of whom were in hotly contested senate races in 2002.<sup>349</sup> To whatever extent S. 812 was intended to win constituents’ support for the next few elections, the bill offers little in the way of long-term thinking.<sup>350</sup>

Unfortunately for S. 812, achieving a successful balance of safety (easier to monitor and control reimportation from one country) and

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344. Kim Coghill, *Americans Wary of Prescription Drugs Coming in from Canada*, BIOWORLD TODAY, May 9, 2003, 2003 WL 6613223.

345. Davis, *supra* note 74, at 501–02.

346. See Lueck, *supra* note 184. Ms. Lueck mentions Senate races in Maine, Michigan, and Vermont in particular. *Id.* Another supporter of this bill, the late Senator Paul Wellstone, was also in a very close race in Minnesota. See Dalzell, *supra* note 255 (noting pressure for reimportation in Minnesota, North Dakota, Vermont, and Washington).

347. See Lueck, *supra* note 184.

348. See, e.g., MINN. SENIOR FED’N METRO. REGION, *supra* note 188 (offering similar internet services nationwide).

349. See Lueck, *supra* note 184; Dalzell, *supra* note 255.

350. See Dalzell, *supra* note 255; *Election 2002—Election Roundup: Both Parties Tout Rx Drug Plans to Win Senior Vote*, *supra* note 180 (pointing out the decisive lead Sen. Stabenow secured by taking an early stand on prescription medication in Michigan).

economics (add more countries for larger market share) may not be possible just yet.

#### IV. Recommendations

It is time for a long-term solution to our national health care crisis. As the senior population grows larger and larger this crisis will deepen until the damage is permanent. If we do not act with foresight and care, we may not like the options that are forced upon us down the road. To begin with, Congress should reject reimportation as a valid solution to expensive prescription medications. And, for the same reasons that Congress should reject reimportation, it should move forward with plans to privatize prescription health care benefits.

Many of S. 812's supporters are exasperated by the lack of progress in health care reform, and simply want to get something moving on the drug-price issue.<sup>351</sup> This frustration is understandable, but foolish action is worse than a soul-searching debate followed by difficult action. Even advocates of S. 812 admit that the bill is a less than deal band-aid solution. On the floor of the House of Representatives, Democrats complained that "the only reason the panel was considering reimportation was because the Republican leadership refused to consider any legislation to contain prescription drug prices."<sup>352</sup> Socializing medicine is expensive and takes time and taxes.<sup>353</sup> Privatizing medicine in the midst of an economic recession, when markets are performing poorly<sup>354</sup> and corporate executives even worse,<sup>355</sup> is not an easy sell. Which system would offer the best incentives, best quality, and most affordable and most accessible health care is all subject to debate. However, if there is a genuine belief that S. 812 is not a real solution to the problem at hand, it is foolish to open a Pandora's box like reimportation for short-term political gain.

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351. See *Drugs: House Panel Debates Drug Reimports, While FDA Official Cites Safety Concerns*, WASH. INSIDER, July 26, 2002, at D14.

352. See *id.*

353. See Tamara Lytle, *Bush Scrambles for Medicare Votes*, ORLANDO SENTINEL, Nov. 22, 2003, at A1.

354. See John M. Berry, *Recession Ended in November of 2001; But Panel Still Sees Economy Slumping*, WASH. POST, July 18, 2003, at E01.

355. See Holman W. Jenkins, Jr., *White Collar Crime Wave?*, WALL ST. J., June 19, 2002, at A19.

The strength of the American pharmaceutical industry lies in its cutting-edge innovation. Allowing abusive patent extensions only harms this innovation, so patent law reform should be encouraged. The patent reform law prong of S. 812 makes sense and should encourage competition and innovation. To suggest that competition from generic drug manufacturers will dissuade research and development is to reject the entire justification of our patent system, which grants a brief period of market exclusivity in exchange for sharing new products with the public.<sup>356</sup>

Unlike the patent reform law prong of S. 812, the reimportation prong, if successful, will hurt American pharmaceutical innovation by importing Canadian price controls.<sup>357</sup> As argued above, only private sector incentives will allow innovation in pharmaceutical industry to continue. Socializing prescription benefits will simply not provide sufficient returns for the industry to continue with their costly research and development. Although competition is good, and should be encouraged through tighter controls on patent extensions, reimportation is just a back-door manner of imposing price controls.<sup>358</sup> Price controls have had devastating effects around the world<sup>359</sup> and most likely would succeed only in hurting Canadians by reducing their access to medicine. However, because the Senate ensured the failure of S. 812 by requiring the HHS Director to certify that it will work perfectly, this is a moot point.

I propose that the first half of S. 812 be made law and that patent law reform be initiated. Healthy competition between generics and brand-name drugs should drive prices down. The next step is to allow for private market forces to dictate the prices for drugs in the context of an organized nationwide plan. One market-oriented approach involves pharmaceutical benefit management companies (PBMs) that negotiate with the manufacturers and wholesalers of pharmaceutical drugs.<sup>360</sup> The PBMs primarily rely on drug formularies, which are lists of drugs for which enrollees will be reimbursed.<sup>361</sup> The formulary

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356. See TRIPS, *supra* note 26.

357. See Scott, *supra* note 280.

358. See *Prescription Drug Benefit: Congressional Testimony on H.R. 4954 Before the Subcomm. on Health of the House Comm. on Energy & Commerce*, Apr. 8, 2003 (statement of David Herman, Executive Director of The Seniors Coalition), 2003 WL 11717136.

359. See Stanton, *supra* note 4, at 166–67.

360. Rak, *supra* note 21, at 487.

361. *Id.*

is a list of medications intended to serve all the needs of the enrollees, however, it is the cheapest drug that meets the particular need that will be included on the list.<sup>362</sup> This system forces manufacturers to compete so that they can offer the lowest prices and be the preferred drug on the list.<sup>363</sup> The PBMs then capture lower prices through rebates and discounts that they receive by purchasing in bulk.<sup>364</sup>

The PBM system gives the consumer the leverage needed to negotiate a competitive price for their pharmaceutical needs. This leverage, however, exists within a true market system, in which pharmaceutical innovation and creativity are allowed to flourish. Unlike extending Canadian price controls to the U.S. market, this privatization plan truly does take advantage of the market, and will benefit America's elderly, America's industry, and the world.

Alternatively, a socialized plan will require price caps on what the government is willing to spend and essentially imposes the price controls that are so dangerous to this industry.<sup>365</sup> The innovative success of the U.S. pharmaceutical industry is simply unmatched by any country that imposes price controls.<sup>366</sup> Additionally, with prices expected to increase in the industry, it is not feasible for the Medicare system to expand to cover all of these costs.<sup>367</sup> With growing numbers of seniors, Medicare expansion would require large tax increases—a policy Americans have so far been reluctant to accept.<sup>368</sup> Additionally, advocates of socialized plans usually seek to offer universal coverage,<sup>369</sup> which necessarily means providing coverage to millions who are not truly in need, at taxpayers expense.<sup>370</sup>

## V. Conclusion

Senate Bill 812 is an interesting bill that raises a variety of questions about the global pharmaceutical marketplace. Although the bill's focus on patent law reform is a step in the right direction, its fo-

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362. *See id.*

363. PBMs may also help employees and employers make better decisions about which drugs to take and how to balance and mix various prescriptions. *See Fallik, supra* note 17.

364. *See Stambaugh, supra* note 33, at 908–14.

365. *See id.* at 914.

366. *Id.*

367. *See Rak, supra* note 21, at 449.

368. *See id.* at 462.

369. *See id.* at 483.

370. *Id.*

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cus on reimportation is a mistake. It is unwise to promote reimportation as a potential answer to high-priced drugs when the issues involved are more complicated than simple access to lower-priced drugs. The reality, however, is that S. 812 will never become law because the Senate's desire for a quick fix solution to a complicated issue is matched only by its desire not to be held accountable for a quick fix solution to a complicated issue. The unanimous decision requiring the HHS Director to certify this program as safe displays the Senate's lack of backbone on this issue and ensures that S. 812 will never become law.