

# AMERICA'S NEW WAR ON DRUGS:

## SHOULD THE UNITED STATES LEGALIZE PRESCRIPTION DRUG REIMPORTATION?

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### I. INTRODUCTION: A NEW WAR ON DRUGS

Many Americans in the United States are in the midst of a war on drugs. However, the enemy in this war on drugs has changed since President Ronald Reagan started the social crusade in the 1980's. For millions of Americans, the pharmaceutical companies, and the high price of their prescription drugs, are the enemy. The weapon many Americans brandish? Increasingly, they fight the cost of prescription drugs through methods of reimportation.

Reimportation takes many forms. An estimated one million Americans cross the border into Canada each year to purchase a few months' supply of prescription drugs at prices not found in the United States.<sup>1</sup> Many others gain access to foreign pharmaceuticals through the Internet.<sup>2</sup> Some take advantage of a growing number of strip mall storefronts like Rx Depot, which sell imported Canadian drugs at Canadian prices across the United States.<sup>3</sup> All of these forms seek to combat the rising costs of pharmaceuticals by obtaining prescription drugs from markets outside the United States.

This Note first discusses the history of high prescription drug prices in the United States compared to foreign countries. It then analyzes the proposed plan to permit reimportation of prescription drugs from foreign markets such as Canada, addressing the economic strengths and weaknesses as well as the safety issues present in a reimportation plan. Finally, it concludes that recent congressional efforts to implement reimportation must address the safety concerns used to defeat such plans, work to restrict direct-to-consumer advertising, and spread the research and development burden

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1. Patricia Barry, *More Americans Go North for Drugs*, at [www.aarp.org/bulletin/yourmoney/Articles/a2003-06-25-moreamericans.html](http://www.aarp.org/bulletin/yourmoney/Articles/a2003-06-25-moreamericans.html) (last visited Apr. 2, 2005).

2. In fact, the Food and Drug Administration has acknowledged the popularity of this practice by offering a website with advice for buying prescription drugs online. See U.S. Food and Drug Admin., *Buying Medicines and Medical Products Online*, available at [www.fda.gov/oc/buyonline](http://www.fda.gov/oc/buyonline) (last visited Mar. 16, 2005).

3. Thomas M. Burton & Sarah L. Lueck, *FDA Sends Letter on Canada Drugs*, WALL ST. J., Mar. 24, 2003, at B5.

placed upon the United States to countries with the economic strength to handle a larger share of the burden.

## II. A HISTORY OF HIGH DRUG PRICES IN AMERICA

The problem of high pharmaceutical costs is nothing new, for it has troubled American consumers for years. In fact, in the late 1950's and early 1960's, Senator Estes Kefauver (D-Tenn.) pushed the debate over pharmaceuticals into the political sphere. His efforts led to congressional investigations into the high costs of prescription drugs.<sup>4</sup> These investigations began after senior citizens complained about high drug prices.<sup>5</sup> Shortly thereafter, members of Congress observed that drug prices abroad were significantly lower than prices in the United States.<sup>6</sup> Depending on the drug, prices abroad were often half the domestic cost of the same drug.<sup>7</sup> In Kefauver's eyes, this difference was "immoral."<sup>8</sup> Additionally, in the 1950's, the profits of drug companies "were considerably higher than those for any of the other industries."<sup>9</sup> Several drug companies had net profits of over 30%.<sup>10</sup> For Senator Kefauver, "[T]hose [profits] were excessive by any test you put them to—particularly in a field where every effort should be made to get prices down . . . ."<sup>11</sup> His reform attempts led to a bill that sought to lower prescription drug prices, increase competition by opening the market to small manufacturers, and protect drug buyers from the dangers involved with having a prescription filled.<sup>12</sup> However, by the time President Kennedy signed the Kefauver bill into law in 1962, the legislative process had narrowed its scope to only safety issues.<sup>13</sup> As a result, Senator Kefauver never achieved his goal of lowering drug prices, and the high price of prescription drugs remains a hot political issue today.

## III. THE AMERICAN MARKET TODAY

### A. *The Effect on the Consumer Today*

Prescription drug prices have not fallen over the years. In the 1950's, a few politicians noticed that many American citizens had to choose between prescription drugs and food.<sup>14</sup> For some, hunger often appeared more appealing than pain.<sup>15</sup> Americans, especially senior citizens, face a similar choice today.<sup>16</sup> The high cost of

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4. See generally RICHARD HARRIS, *THE REAL VOICE* (1964).

5. *Id.* at 6.

6. *Id.*

7. *Id.* at 73.

8. *Id.* at 214.

9. *Id.* at 17.

10. HARRIS, *supra* note 4, at 34.

11. *Id.*

12. *Id.* at 119.

13. *Id.* at 240.

14. *Id.* at 37.

15. *Id.*

16. See William M. Welch, *Once Just a Trickle, Canada's Rx Drugs Pouring Into USA*, USA TODAY, Oct. 7, 2003, at A01. The article notes the plight of one American senior forced to forego his medication so

drugs hits seniors hardest because they frequently have a greater need for drugs and must often cope with fixed economic resources and limited access to private prescription drug plans.<sup>17</sup> In 2003, for instance, the average Medicare recipient spent nearly \$1,000 out of pocket on prescription drugs.<sup>18</sup> Nearly 30% of all seniors' drug prescriptions go unfilled because seniors cannot afford the cost.<sup>19</sup> The problem shows no sign of abating in the future. Over the next ten years, the Congressional Budget Office estimates that Americans over the age of sixty-five will spend \$1.8 trillion on prescription drugs.<sup>20</sup>

The problem of the high cost of prescription drugs is not limited to senior citizens. According to Congressman Dan Burton, the chairman of the House of Representatives' Subcommittee on Human Rights and Wellness:

As many as 108 million Americans have one or more chronic health conditions such as diabetes, high blood pressure, asthma, and heart disease. Many require prescription drugs to manage these conditions. Seventy-five percent of Americans age 50 to 64 are on at least one prescription drug, and fourteen percent of women aged sixty-five are on five prescription drugs in any given week.<sup>21</sup>

In fact, Americans spent an estimated \$140.6 billion on outpatient prescription drugs in 2001.<sup>22</sup> Meanwhile, prescription prices rose at more than six times the rate of inflation.<sup>23</sup> This was an estimated 15.73% increase over 2000 spending,<sup>24</sup> a slightly *smaller* increase than in previous years.<sup>25</sup> A greater number of prescriptions written by physicians, the use of more expensive drugs, and an increase in the price of drugs generally account for these increases.<sup>26</sup> These upward trends show little sign of subsiding in the future.

his wife could afford to buy hers.

17. Jennifer Rak, Note, *An Rx for Reform: A Medicare Prescription Drug Benefit*, 12 HEALTH MATRIX 449, 456–62 (2002).

18. *International Prescription Drug Parity: Are Americans Being Protected or Gouged? Hearing Before the Human Rights and Wellness Subcomm. of the House Comm. on Government Reform*, 108th Cong. 116 (2003) (statement of Robert M. Hayes, President, Medicare Rights Center), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108\\_house\\_hearings&docid=f:87228.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_house_hearings&docid=f:87228.pdf) (last visited Mar. 28, 2005) [hereinafter Statement of Robert M. Hayes].

19. Congressman Gil Gutknecht, *Prescription Drugs*, at [www.gil.house.gov/Issues/PDrugs/pdrugsummary.htm](http://www.gil.house.gov/Issues/PDrugs/pdrugsummary.htm) (last visited Oct. 26, 2003) (on file with author) [hereinafter *Prescription Drugs*].

20. *Projections of Medicare and Prescription Drug Spending: Hearing Before the Senate Comm. on Finance*, 107th Cong. (2002) (statement of Dan L. Crippen, Director, Congressional Budget Office).

21. *International Prescription Drug Parity: Are Americans Being Protected or Gouged?: Hearing Before the Human Rights and Wellness Subcomm. of the House Comm. on Government Reform*, 108th Cong. 2 (2003) (opening statement of Rep. Dan Burton, Chairman, House Subcomm. on Human Rights and Wellness), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108\\_house\\_hearings&docid=f:87228.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_house_hearings&docid=f:87228.pdf) (last visited Mar. 28, 2005) [hereinafter Opening Statement of Dan Burton].

22. Stephen R. Latham, *Pharmaceutical Costs: An Overview and Analysis of Legal and Policy Responses by the States*, 24 J. LEGAL MED. 141, 141 (2003) (citations omitted).

23. Statement of Robert M. Hayes, *supra* note 18.

24. Latham, *supra* note 22, at 141 (citations omitted).

25. See Rak, *supra* note 17, at 453 ("During the year 2000, prescription drug spending increased by 17.3% to \$121.8 billion.") (citations omitted).

26. *Id.*

### B. *The Effect on the Pharmaceutical Companies in the United States Today*

If the profits of pharmaceutical companies in the 1950's shocked Senator Kefauver,<sup>27</sup> their profits today would cause him even greater dismay. As consumers receive more prescriptions and pay more for the drugs prescribed to them, the pharmaceutical companies continue to prosper with record profits.<sup>28</sup> In 2001, profits in the pharmaceutical industry were 18.5% of revenues.<sup>29</sup> Even in the economic downturn of the early 21st century, pharmaceutical companies continue to economically outperform all other industries, who had a return on revenue of only 2.2%.<sup>30</sup> In 2002, the top ten drug companies listed in the Fortune 500 had profits of \$35.9 billion.<sup>31</sup> By comparison, the other 490 companies on the Fortune 500 list had profits of only \$33.7 billion combined.<sup>32</sup> While economic prosperity is usually praised during difficult economic times, the drug companies continue to find themselves under attack. Representative Bernard Sanders (I-Vt.) noted, "Make no mistake about it, there is a direct connection between the drug companies [sic] massive profits and Americans being charged the highest prices for prescription drugs in the world."<sup>33</sup>

### C. *The Fleecing of America?*

Americans have complained about the high price of prescription drugs for years.<sup>34</sup> Compared to the prices in other countries around the world, it appears American drug purchasers have a reason to complain.<sup>35</sup> By some calculations, Americans are paying 69% more for the same drugs than their neighbors to the north in Canada are paying.<sup>36</sup> Prices in Europe can range from 30 to 300% less than the same drugs in the United States.<sup>37</sup> These statistics are usually based on the prices of well-known, commonly used prescription drugs like the cholesterol medication Zocor, the antidepressant

27. See *supra* Part II.

28. Latham, *supra* note 22, at 141–42.

29. *Id.* at 142.

30. Statement of Robert M. Hayes, *supra* note 18.

31. Public Citizen Congress Watch, *2002 Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries* 1 (June 2003), available at [www.citizen.org/documents/Pharma\\_Report.pdf](http://www.citizen.org/documents/Pharma_Report.pdf) (last visited Mar. 28, 2005).

32. See *id.*

33. Congressman Bernard Sanders, *New Figures Prove Pharmaceutical Industry Continues to Fleece Americans*, at <http://bernie.house.gov/prescriptions/profits.asp> (last visited Mar. 28, 2005).

34. See HARRIS, *supra* note 4, at 42. After Kefauver began his investigations into drug pricing in the late 1950's, he received several hundred letters of support a day. *Id.*

35. There is some dispute over the calculation of statistics used to compare the price of American drugs to prices in other countries. For instance, Patricia Danzon criticizes international price comparisons conducted by the General Accounting Office and others as "based on a small, unrepresentative sample of leading branded prescription drugs sold by the same originator in all countries." PATRICIA DANZON, *PHARMACEUTICAL PRICE REGULATION* 32 (1997) [hereinafter DANZON 1997]. She advocates comparing prices based on the weighted average price rather than the price per pack of drugs as well as including over-the-counter drugs and generics in price comparisons. See *id.* at 32–37. The result, she notes, is that "conclusions on the difference in drug prices across countries can differ dramatically . . ." *Id.* at 36.

36. David Gross, *Prescription Drug Prices in Canada* 7, available at [http://assets.aarp.org/rgcenter/health/ib62\\_can\\_rx.pdf](http://assets.aarp.org/rgcenter/health/ib62_can_rx.pdf) (last visited Apr. 3, 2005).

37. Press Release, Congressman Rahm Emanuel, Emanuel Seeks to Reduce Prescription Drug Costs through Market Reforms, Co-sponsors Bills to Foster Competition and Lower Prices (June 20, 2003), available at [http://www.house.gov/apps/list/press/il05\\_emanuel/pr\\_030620.html](http://www.house.gov/apps/list/press/il05_emanuel/pr_030620.html) (last visited Apr. 3, 2005).

Prozac, and the breast cancer drug Tamoxifen.<sup>38</sup> While the inclusion of over-the-counter and generic drugs in the comparison narrows the price gap between countries, it does not change the stark difference in price of popular American-made prescription drugs. This difference drives millions of Americans, faced with tight budgets, into the international market for prescription drugs.

#### IV. THE PLAN OF ATTACK TODAY

Though the practice of personal reimportation is still illegal in the United States,<sup>39</sup> it continues to thrive.<sup>40</sup> For the most part, the Food and Drug Administration ("FDA") "has exercised its enforcement discretion and allows individual patients to import small amounts of prescription drug, when the product is NOT commercially available" in the United States.<sup>41</sup> The exceptions to the importation ban permitted by the FDA are enumerated in the FDA's "Coverage of Personal Importations" document.<sup>42</sup> For example, some senior citizens, including those who board buses organized by their congressmen and other politicians, frequently import a 90 day supply of prescription drugs without much hassle from the American authorities at the border. However, with the increased security measures imposed following the 9/11 terrorist attacks, the FDA has reconsidered its leniency on drug importation. William Hubbard, Senior Associate Commissioner of the FDA, stated, "We [the FDA] believe that virtually all drugs imported to the United States from Canada by or for individual U.S. consumers violate U.S. law."<sup>43</sup> He further insisted that anyone who assists in the importation of prescription drugs from Canada faces "civil and criminal liability."<sup>44</sup> Of course, any

38. Gross, *supra* note 36, at 7.

39. See Prescription Drug Marketing Act of 1987 § 4, 21 U.S.C. § 353 (2000).

40. See *supra* Part I.

41. See *Testimony of the American Pharmacists Association on International Prescription Drug Parity Submitted to the Human Rights and Wellness Subcomm. of the House Comm. on Government Reform*, available at [http://www.nacds.org/user-assets/PDF\\_files/APhA\\_Importation\\_Hearing.doc](http://www.nacds.org/user-assets/PDF_files/APhA_Importation_Hearing.doc) [hereinafter *Testimony of the APhA*].

42. See Office of Regulatory Affairs, U.S. Food and Drug Admin., Regulatory Procedures Manual, Ch. 9: Subchapter Coverage of Personal Importations, available at [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html) (last visited Mar. 28, 2005). The FDA, in exercising its regulatory discretion, may permit a limited amount of prescription drug importation only:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or
2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

*Id.*

43. Opening Statement of Dan Burton, *supra* note 21, at 3.

44. *Id.*; see also *International Prescription Drug Parity: Are Americans Being Protected or Gouged?: Hearing Before the Human Rights and Wellness Subcomm. of the House Comm. on Government Reform*, 108th Cong. 90-93 (2003) (statement of Elizabeth A. Wennar, President and CEO, United Health Alliance), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108\\_house\\_hearings&docid=f:87228.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_house_hearings&docid=f:87228.pdf) (last visited Mar. 28, 2005) [hereinafter *Statement of Elizabeth A. Wennar*].

increased crackdown on the importation of prescription drugs would require additional funding and personnel. However, the FDA's threats to end the importation practice solicited a response from Capitol Hill.

In 2000, before the FDA threatened to end its discretionary policy toward prescription drug importation, Congress made an attempt to validate the practice. The Medicine Equity and Safety ("MEDS") Act, passed by Congress and signed into law by former President Bill Clinton, conditionally opened foreign drug markets to American buyers in what has been called a "reimportation" plan.<sup>45</sup> The MEDS Act permits the reimportation of American-made, FDA-approved drugs from foreign markets into the United States by pharmacists and drug wholesalers, who can sell the drugs at prices lower than those available in the United States.<sup>46</sup> However, though the FDA largely wrote the bill, they have not implemented the law.<sup>47</sup> Before implementation, the reimportation portion of the law requires the approval of the Health and Human Services ("HHS") Secretary.<sup>48</sup> The MEDS Act allows the Secretary to implement the plan only after he or she certifies that the imported drugs would be safe.<sup>49</sup> Neither Donna Shalala in the Clinton Administration nor Tommy Thompson in the first George W. Bush Administration granted such approval after the law's passage in 2000.<sup>50</sup>

Because of the continued burden on American prescription drug purchasers, the reimportation plan became a hot issue once again in 2003. The Pharmaceutical Marketing Access Act of 2003 ("the proposed 2003 Amendments"),<sup>51</sup> a bipartisan bill sponsored by Representatives Gil Gutknecht (R-Minn.) and Rahm Emanuel (D-Ill.), seeks to amend the MEDS Act of 2000.<sup>52</sup> The proposed 2003 Amendments, which state that an "unaffordable drug is neither safe nor effective," orders the HHS Secretary to implement a reimportation plan.<sup>53</sup> Additionally, the proposed 2003 Amendments permit "qualifying individuals" to participate in the reimportation plan.<sup>54</sup> This change effectively expands the reimportation plan to all individuals.<sup>55</sup> Finally, the proposed 2003 Amendments expand the security and safety measures by expanding the use of counterfeit-resistant technologies.<sup>56</sup>

45. See Medicine Equity and Safety Act § 1(a), 21 U.S.C. § 384 (2000).

46. A. Bryan Baer, Note, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 109–10 (2001).

47. *Prescription Drugs*, *supra* note 19.

48. 21 U.S.C. § 384(b).

49. *Id.* § 384(c).

50. David Espo, *House OKs Importation of Lower-Cost Drugs*, ASSOCIATED PRESS, July 25, 2003, available at [www.bernie.house.gov/documents/articles/20030725101028.asp](http://www.bernie.house.gov/documents/articles/20030725101028.asp) (last visited Mar. 28, 2005).

51. Pharmaceutical Marketing Access Act of 2003, H.R. 2427, 108th Cong. (2003).

52. See Ceci Connolly, *An Unlikely Pair Fights for Cheaper Medications*, WASH. POST, Sept. 1, 2003, at A03.

53. Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. § 2(3) (2003).

54. *Id.* § 4.

55. *Id.* The MEDS Act of 2000 limited reimportation plans to "pharmacists and wholesalers." 21 U.S.C. § 384 (2000). The 2003 Amendments adds "qualifying individuals" to the list of possible participants. H.R. 2427 § 4. The bill defines "qualifying individual" as "an individual who is not a pharmacist or a wholesaler." *Id.*

56. H.R. 2427 § 5.

The proposed 2003 Amendments passed in a vote on the House floor on July 25, 2003.<sup>57</sup> Within hours after the bill left the House, fifty-three senators signed a letter opposing it,<sup>58</sup> even though a similar bill passed the Senate in July 2002.<sup>59</sup> By the time President Bush signed the major Medicare overhaul bill in November 2003, the proposed 2003 Amendments were nowhere to be found.<sup>60</sup>

## V. THE ISSUES BEHIND DRUG REIMPORTATION PLANS

### A. Reimportation Economics: The American Way?

#### 1. The Politics Behind the Economics

Americans seek a solution to the high costs of their prescription drugs, and a reimportation plan would save Americans billions. According to Congressional Budget Office statistics obtained by Rep. Gutknecht, the Pharmaceutical Market Access Act of 2003 would save the federal government \$4.5 billion over ten years.<sup>61</sup> Alan Sager, a health care economist, estimates American consumers would save \$38.4 billion if they could purchase prescription drugs at Canadian prices.<sup>62</sup>

Of course, the reimportation plan has a political effect similar to that of a tax cut because plans that put cash into people's pockets are popular with Americans. Those consumers most affected by the reimportation plan are not just any Americans, though. Reimportation plans largely benefit senior citizens, and senior citizens vote in masses.<sup>63</sup> Unquestionably, the political proponents of reimportation are well aware of the potential political gain with voters.

No one, however, leaves empty-handed. Those opposing reimportation plans receive their own political gains. According to figures collected by the Center for Responsive Politics, pharmaceutical companies gave over \$20 million in political contributions in the 2002 election and \$19.4 million in the 2000 elections—nearly 80% of those donations went to Republicans.<sup>64</sup> Traditionally, the pharmaceutical companies have counted on the Republican Party to support their interests. Unsurprisingly, in the

57. See Bill Summary & Status H.R. 2427, at <http://thomas.loc.gov/cgi-bin/bdquery/z?d108:HR02427:@@R> (last visited Mar. 25, 2005). The bill passed on a vote of 243–186, with 155 Democrats, 87 Republicans, and 1 Independent in favor of the bill, and 45 Democrats and 141 Republicans opposed. See *Espo*, *supra* note 50.

58. Connolly, *supra* note 52, at A03.

59. See Greater Access to Affordable Pharmaceuticals Act of 2001, S. 812, 107th Cong. (2002).

60. See Ellen Beck, *Senate Sends Medicare Bill to President*, UNITED PRESS INT'L, November 25, 2003, available at <http://64.233.161.104/search?q=cache:g1wOHGhAlmUJ:www.upi.com/view.cfm%3FStoryId=20031125-062809-6471r> (last visited Mar. 25, 2005).

61. See Press Release, Congressman Gil Gutknecht, Gutknecht Confirms Rx Market Access Cost-Savings (Oct. 17, 2003), available at <http://www.gil.house.gov/Newsroom/Statements/StateOCT/101703pd.htm> (last visited Oct. 26, 2003) (on file with author).

62. *Id.*

63. See *supra* Part III.A.

64. See *Espo*, *supra* note 50; see also Center for Responsive Politics, *Pharmaceutical Manufacturing: Long-Term Contribution Trends*, available at [www.opensecrets.org/industries/indus.asp?Ind=H04](http://www.opensecrets.org/industries/indus.asp?Ind=H04) (last visited Mar. 25, 2005).

July 2003 House vote on the Pharmaceutical Market Access Act, Republicans led the opposition to the bill.<sup>65</sup> Such opposition on the issue may result in temporary criticism from a politician's constituency; however, the political contributions gathered from pharmaceuticals provide an appealing band-aid to voter discontent on the prescription drug price issue.

## 2. The Economics Behind the Politics

There is little question that American consumers pay more for their prescription drugs than those in almost every comparable country in the world.<sup>66</sup> Supporters of drug reimportation see its illegality as a bar to the influence of market forces on the pharmaceutical industry in America.<sup>67</sup> In the words of Representative Rahm Emanuel, a sponsor of the proposed 2003 Amendments, "The legislation we are debating today is about inserting competition and the free market into the pricing of medication."<sup>68</sup> House Majority Leader Tom DeLay fired back, "From a free-market perspective, I'm not interested in importing price controls."<sup>69</sup> While a reimportation plan promises to save American consumers millions of dollars, economists also warn about the plan's lasting negative effect on the pharmaceutical industry.

### a. *The Economic Effect on Profits*

While supporters of the proposed 2003 Amendments use free market language to promote their drug plan in the United States, the reality is that the market is not truly free. Prescription drugs are cheaper in Canada and other countries because those foreign governments have enacted price controls on the pharmaceutical markets.<sup>70</sup> Essentially, American reimportation plans propose to bring drugs into the United States at lower prices set under foreign country price controls. If the American government permits reimportation, the pharmaceutical companies have three choices: (1) maintain existing price differentials, (2) set a higher uniform price worldwide, or (3) market the drug exclusively in high price nations.<sup>71</sup>

The first option, to maintain existing price differentials, is the response supporters of the proposed 2003 Amendments appear to anticipate from the drug companies.<sup>72</sup>

65. See *Espo*, *supra* note 50.

66. See *supra* Part III.C.

67. See Michael B. Moore, Note, "Open Wide" (Your Pocketbook That Is!)—A Call for the Establishment in the United States of a Prescription Drug Price Regulatory Agency, 1 SW. J.L. & TRADE AM. 149, 169 (1994) ("[T]he pharmaceutical industry is, in fact, protected by the government from free market forces.").

68. Sheryl Gay Stolberg, *House Approves Bill Easing Imports of Less Expensive Drugs*, N.Y. TIMES, July 25, 2003, available at [http://mult-sclerosis.e-banshee.net/030819/Cheaper\\_medications\\_bill\\_clears\\_one\\_hurdle.html](http://mult-sclerosis.e-banshee.net/030819/Cheaper_medications_bill_clears_one_hurdle.html) (last visited Mar. 25, 2005).

69. *Id.* Because Canada and many other countries have government-imposed price controls on prescription drugs, DeLay argued that making drugs available at foreign market prices basically pushes foreign government-imposed price controls on the American market. See *id.*

70. See DANZON 1997, *supra* note 35, at 93; see also Baer, *supra* note 46, at 109–10.

71. Baer, *supra* note 46, at 127–28.

72. A survey of the websites and news articles covering the proposed 2003 Amendments uncovers little acknowledgment from the bill's supporters that a fully implemented reimportation system may result in the drug companies reforming their business practices. When GlaxoSmithKline, a major pharmaceutical



This option results in a shift of the demand of American buyers to the lower-priced imported drugs.<sup>73</sup> This causes an increased demand on the foreign market, which results in a rise in the drug's price in the foreign market.<sup>74</sup> With price controls in effect, the drug companies, if they have an interest in maintaining their current profit levels, will seek to renegotiate their prices in the price-controlled countries' markets (and thus, move closer to achieving the second option, uniform prices) or pull out of the lower price markets altogether (the third option).<sup>75</sup> The drug companies can effectively remove the market force effects between a free market (the United States) and a price-controlled market (the foreign countries exporting drugs into the United States) by pursuing the second or third options instead of maintaining price differentials.<sup>76</sup>

Most economists reject options which impose price controls of any kind. In a profession frequently divisive in its views, Robert Litan of the Brookings Institution notes, "Ninety-five percent of economists would say that price controls are always dumb or that there should be a very strong presumption against price controls."<sup>77</sup> As Patricia Danzon points out, "Theory suggests . . . that the competitive approach, applied at the level of the individual health plan, is more likely to preserve incentives for the efficient use of drugs and appropriate incentives for innovation than is the regulatory approach, applied at the level of government."<sup>78</sup>

For Danzon and others who oppose price controls, the long-term effects on innovation through research and development outweigh the short-term benefits of lowered public spending on prescription drugs.<sup>79</sup> Therefore, governments must carefully balance these considerations.<sup>80</sup> Danzon supports a system of Ramsey pricing where "prices . . . differ depending on how different countries value innovative drugs . . ."<sup>81</sup> Under this differential pricing system, consumers who highly value drugs pay more for those drugs, while those who value drugs at a lower level stay in the market, but pay a reduced price.<sup>82</sup> As a result, the drug companies earn higher revenues, which they presumably can use to develop innovative new drugs.<sup>83</sup>

Some economic analysis suggests that an American drug reimportation plan's importation of foreign price controls will not result in losses to the drug companies. Paul Pecorino developed a model in which a good sold in a foreign country is subject to

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manufacturer, cut off its prescription drug sales to Canada, some older Americans boycotted the company's nonprescription drugs, while a consortium of consumer groups ran a full-page ad in the *New York Times* "accus[ing] Glaxo of cutting off vital supplies." Barry, *supra* note 1. These acts of protest have done nothing to change Glaxo's decision.

73. See Baer, *supra* note 46, at 128.

74. *Id.*

75. See *id.*

76. See *id.*

77. Christopher R. Stambaugh, Note, *State Price Control Laws are the Wrong Prescription for the Problem of Unaffordable Drugs*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 897, 899 n.15 (2002) (citations omitted).

78. DANZON 1997, *supra* note 35, at 4.

79. See *id.* at 92.

80. *Id.*

81. *Id.* at 18.

82. See *id.* at 12.

83. *Id.*

a negotiated price that is determined in a Nash bargaining game.<sup>84</sup> In the home market, the monopolist (a pharmaceutical company with patent protection) is free to charge its profit maximizing price.<sup>85</sup> He found that “[a]llowing reimports back into the home country will cause the domestic monopolist to bargain harder in the Nash bargaining game. As a result, profits earned by the monopolist may not fall when reimports from the foreign country are allowed.”<sup>86</sup> Essentially, the pharmaceutical companies must grant fewer price concessions to foreign countries when a system of reimportation is in place in the United States. Of course, the drug companies must not bargain a foreign country out of the market by seeking a price which exceeds the demand in that country.<sup>87</sup> If the price does not exceed demand, drug companies can continue to maximize profits under a system of reimportation.<sup>88</sup>

*b. What Happens to Research and Development?*

As John E. Calfee, a resident scholar at the American Enterprise Institute, points out, “There is no substitute for the profit motive for inducing and guiding research.”<sup>89</sup> New drug development is an expensive and high risk activity. The research and development (R&D) for each new drug released in the United States costs an estimated average of \$500 million.<sup>90</sup> The ratio of R&D to current sales is roughly 18% for American drug companies, the highest of any industry.<sup>91</sup> The pharmaceutical industry requires the profit motive to continue to drive its search for new and useful drugs due to the high risk of failure in developing new pharmaceutical products, increased competition between drug companies in developing drugs, and the impending threat of generic competitors when drug patents expire.<sup>92</sup>

The evidence suggests that limiting the profit motive through the use of price controls (or the importation of a price control through reimportation) slows the drug companies’ investment in R&D.<sup>93</sup> Recent trends in drug innovation show that most countries with price control regulations in place have seen a decrease or a leveling off of R&D expenditures, and many have developed few or no new drugs.<sup>94</sup> By comparison, the United States has continued to increase its spending on R&D in a rapid

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84. See Paul Pecorino, *Should the US Allow Prescription Drug Reimports from Canada?*, 21 J. HEALTH ECON. 699, 700 (2002).

85. *Id.*

86. *Id.* (citations omitted).

87. *Id.* at 707–08 (citations omitted).

88. *Id.* at 707.

89. JOHN E. CALFEE, *PRICES, MARKETS, AND THE PHARMACEUTICAL REVOLUTION* 46 (2000) [hereinafter CALFEE 2000].

90. John E. Calfee, *Pharmaceutical Price Controls and Patient Welfare*, 134 ANNALS OF INTERNAL MED. 1060, 1061 (2001). The pharmaceutical industry insists the number is as high as \$800 million. See, e.g., Eli Lilly & Co., *Lilly Research Laboratories*, at <http://www.lilly.com/research> (last visited Mar. 28, 2005).

91. DANZON 1997, *supra* note 35, at 3.

92. CALFEE 2000, *supra* note 89, at 62–63.

93. See *id.* at 45–49; see also DANZON 1997, *supra* note 35, at 58–63.

94. DANZON 1997, *supra* note 35, at 60–64.

fashion.<sup>95</sup> American drug companies are responsible for the discovery of over 40% of the innovative drugs developed in the last 30 years.<sup>96</sup>

For many American citizens, it appears that the rest of the world's population became free riders in the pharmaceutical industry, putting little time or money into the R&D of new prescription drugs and still having access to the drugs at a decreased price set by their governments. In a sense, they are right.<sup>97</sup> According to Danzon, "These R&D costs are global joint costs that are essential to supply the drug but cannot rationally be attributed to any individual consumer or country."<sup>98</sup> Danzon suggests that under a theory of Ramsey pricing, "charging different prices to different consumers based on demand elasticity is the most efficient way of covering the joint costs."<sup>99</sup> As a result, the pharmaceutical companies recoup R&D costs from the wealthiest buyers (in this case, those in the United States) by selling prescription drugs to them at higher prices than they do to poorer buyers, who are able to buy prescription drugs closer to the marginal cost.<sup>100</sup>

The pharmaceutical industry cites high R&D costs as one reason for high drug prices in America.<sup>101</sup> For American pharmaceutical companies, R&D accounts for roughly 30% of total costs, not revenue.<sup>102</sup> By comparison, manufacturing and distribution account for 29%, administrative costs account for 12%, and marketing accounts for 24% of total costs.<sup>103</sup> However, the pharmaceutical industry does not fund R&D in its entirety. In 1993, the private pharmaceutical companies only funded slightly more than half of the total amount spent on health care R&D, with the federal government funding the remainder.<sup>104</sup> The government also provides large tax breaks to American pharmaceutical companies.<sup>105</sup> As a result, the industry remains extremely profitable. In 1992, profits for the top seven pharmaceutical companies were approximately \$15 billion;<sup>106</sup> by 2002, profits for the same seven companies had grown

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95. *Id.* at 59.

96. *Id.* at 2, 62.

97. See Baer, *supra* note 46, at 132 ("In essence, governments enacting price controls are free-riding on consumers in the United States and other free market countries who pay the tremendous fixed costs associated with research and development.").

98. DANZON 1997, *supra* note 35, at 3.

99. PATRICIA DANZON, PRICE COMPARISONS FOR PHARMACEUTICALS 41 (1999) [hereinafter DANZON 1999].

100. Latham, *supra* note 22, at 148.

101. See generally Pharmaceutical Research and Manufacturers of America, *Tough Questions, Straight Answers—Pharmaceutical Marketing & Promotion*, at <http://www.phrma.org/publications/policy/2004-11-10.1095.pdf> (last visited Mar. 28, 2005).

102. DANZON 1997, *supra* note 35, at 5.

103. *Id.*

104. Moore, *supra* note 67, at 156. See also *U.S. Netted Little From Cancer Drug*, GAO Reports, WASH. POST, June 7, 2003, at A03. Even though the government funds a significant portion of the pharmaceutical industry's research and development, it receives little in royalties for its successful discoveries. For example, the National Institute for Health spent \$484 million in research on Taxol, the best-selling cancer drug ever, including much of the early, riskiest research. It received only \$35 million in royalties from the drug, according to the General Accounting Office, while drugmaker Bristol-Myers Squibb earned \$9 billion from the drug. *Id.*

105. Moore, *supra* note 67, at 157.

106. See Jerry Stanton, Comment, *Lesson for the United States From Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 154 (2000).

to \$20.3 billion.<sup>107</sup> As noted above, pharmaceutical companies pocket 18.5% of these profits, the highest of any industry in the United States.<sup>108</sup>

*c. Where Does Marketing and Advertising Fit in?*

In 1997, the FDA relaxed its television advertisement rules for drugs marketed directly to consumers.<sup>109</sup> The United States is now the only large developed country that permits direct-to-consumer advertising.<sup>110</sup> In 1998, the total cost of pharmaceutical advertising was about \$6 billion.<sup>111</sup> Of that total, some \$1.5 billion was spent on direct-to-consumer advertising.<sup>112</sup> By 2001, that cost had grown to \$2.7 billion.<sup>113</sup> Some laud these expenditures, noting that consumers need information about new drugs and companies need to pursue a market share in a competitive field.<sup>114</sup> Others feel they merely contribute to the rising cost of prescription drugs by increasing demand for higher priced medications.<sup>115</sup> Either way, the drug companies' spending on prescription drug advertising does nothing to reduce the cost of drugs for consumers.

*B. Safety: The Real Issue?*

While economists argue against reimportation plans based on economic reasoning, the politicians and government officials opposing the Pharmaceutical Marketing Access Act of 2003 have almost uniformly played another card in their anti-reimportation campaign: fear. Playing to Americans' insecurities in this age of terrorism, the parties rejecting reimportation have made safety concerns and consumer dangers the central focus of their opposition.<sup>116</sup> In fact, the Bush Administration went so far as to label the proposed 2003 Amendments "dangerous legislation."<sup>117</sup>

Opponents of the bill charge that drug importation increases the likelihood of counterfeit drugs.<sup>118</sup> Representative John Dingell (D-Mich.) argued in the House debate that "[t]he country is going to be flooded with unsafe pharmaceutical counterfeits, over-age pharmaceuticals, pharmaceuticals that don't preserve and protect the safety of our citizens."<sup>119</sup> Representative Billy Tauzin (R-La.), who retired in 2005 to pursue a \$2 million job as President and CEO of the Pharmaceutical Research and

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107. See Congressman Bernard Sanders, *New Figures Prove Pharmaceutical Industry Continues to Fleece Americans*, at <http://bernie.house.gov/prescriptions/profits.asp> (last visited Mar. 28, 2005).

108. See Latham, *supra* note 22, at 142.

109. CALFEE 2000, *supra* note 89, at 24.

110. *Id.* at 29.

111. *Id.* at 26.

112. *Id.* at 28.

113. Greg Critser, *One Nation, Under Pills*, L.A. TIMES, Dec. 15, 2002, at M6.

114. See CALFEE 2000, *supra* note 89, at 25-31.

115. See Shawna Lydon Woodward, Note, *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).

116. See Espo, *supra* note 50.

117. *Id.*

118. *Id.*

119. *Id.*

Manufacturers of America ("PhRMA"),<sup>120</sup> reported that some drugs purchased from Canada were "bogus, counterfeit, old, rotten drugs"<sup>121</sup> manufactured in third world countries.<sup>122</sup> FDA Commissioner Mark McClellan said the legislation "creates a wide channel for large volumes of unapproved drugs and other products to enter the United States that are potentially injurious to public health and pose a threat to the security of our nation's drug supply."<sup>123</sup> PhRMA sponsored advertisements in Washington, D.C. newspapers showing two pills and stating, "One of these pills is a counterfeit. Can you guess which one?"<sup>124</sup> A spokesman for PhRMA chimed in, "We do believe there is a safety problem."<sup>125</sup>

The current laws banning prescription drug importation and reimportation, which were started, according to the American Pharmacists Association, after "several critical incidents resulted in patient harm,"<sup>126</sup> seek to keep prescription drugs within the United States's regulatory system.<sup>127</sup> Doing so, the bill's opponents say, ensures the American government can more highly assure the safety, effectiveness, and quality of prescription drugs, and American physicians can track the content and strength of their patients' prescription drugs.<sup>128</sup> Of course, if the system successfully keeps all prescription drugs within the United States's current regulatory system, it cuts off all drugs imported from abroad, including those currently permitted in limited quantities under the FDA regulations discussed above.

While opponents of the proposed 2003 Amendments used scare tactics to drown out support for the reimportation proposal, the bill's proponents fired back. During a 2002 Senate Hearing, witnesses opposing reimportation cited examples of counterfeit drugs seized in the mail as dangers of the plan.<sup>129</sup> However, none of the drugs referenced in their examples originated from Canada,<sup>130</sup> and no known deaths have ever resulted from the consumption of imported prescription drugs.<sup>131</sup> Though supporters of

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120. See Frank Ahrens, *Tauzin Quits Chairmanship, Will Retire from House*, WASH. POST, Feb. 4, 2004, at A09; Demetri Sevastopulo, *Democrats Attack Tauzin Over Drugs Lobbying Job*, FIN. TIMES, Feb. 6, 2004, at 2.

121. Nick Anderson, *House OKs Bill Allowing Lower-Cost Drug Imports*, L.A. TIMES, July 25, 2003, at 1.

122. See Espo, *supra* note 50.

123. *Id.*

124. See 146 CONG. REC. S7142 (daily ed. Mar. 29, 2005) (statement of Sen. Dorgan) (referring to the ads in the Washington Post); see also Scott Hensley, *Drug Makers Cry 'Danger' Over Imports*, WALL ST. J., Sept. 22, 2003, at B1 (noting that a PhRMA-hired public relations firm, after conducting focus groups, recommended that American pharmaceutical companies "question the safety and effectiveness of medicines procured elsewhere" in order to "shatter the impression that the cheaper medicines are the same as more-costly American drugs").

125. *House Votes to Allow Purchase of Prescription Drugs Abroad*, ASSOCIATED PRESS, July 25, 2003, available at [www.gil.house.gov/Issues/PDrugs/articlesNAT.htm](http://www.gil.house.gov/Issues/PDrugs/articlesNAT.htm) (last visited Oct. 26, 2003) (on file with author).

126. Testimony of the APhA, *supra* note 41.

127. *Id.*

128. *Id.*

129. Barry, *supra* note 1.

130. *Id.*; see also Paul Winston, *Pricing Disparity is One Bitter Pill*, BUS. INS., Nov. 3, 2003, at 6 (noting that the FDA's suggestion to the American public that Canadian drugs are less safe than those purchased in America is "not only fear mongering but also is insulting to Canadians").

131. Congressman Gil Gutknecht, *The Safety Provisions of H.R. 2427*, at [www.gil.house.gov/Issues/PDrugs/pdrugsafety.htm](http://www.gil.house.gov/Issues/PDrugs/pdrugsafety.htm) (last visited Oct. 26, 2003) [hereinafter *The Safety Provisions of H.R. 2427*]; see also Hensley, *supra* note 12424 (noting that "the documented risks [of counterfeiting] pale next to the rhetoric where imports are concerned").

the proposed 2003 Amendments noted this fine safety record, they included additional safety measures as precautions. For instance, the proposed 2003 Amendments require that any drugs imported into the United States originate from the European Union, Australia, Canada, Iceland, Israel, Japan, Lichtenstein, New Zealand, Norway, Switzerland, or South Africa.<sup>132</sup> Furthermore, the FDA must approve all imported drugs and the production facilities.<sup>133</sup>

If the plan restricted reimportation to Canada alone, reimportation could reduce the burden placed on the FDA even further.<sup>134</sup> The FDA's Hubbard confirmed that he is not aware of any incidents where a Canadian drug harmed an American.<sup>135</sup> Additionally, the Congressional Research Service confirmed that Canadian pharmaceutical regulations are as rigorous as those implemented by the FDA in the United States.<sup>136</sup> As one Canadian online pharmacist noted, "The drug companies would have you believe we're all renegades . . . . But we are licensed pharmacists and professionals, and patient safety is our paramount concern . . . ."<sup>137</sup> In response to the accusations from those opposed to drug reimportation, these licensed pharmacists in Canada took action, forming the Canadian International Pharmacy Association ("CIPA") to regulate the growing online pharmacy industry in Canada.<sup>138</sup> CIPA follows the regulations of the Health Protection Branch ("HPB"), a department of Health Canada, Canada's equivalent of the FDA.<sup>139</sup> "[A] high degree of collaboration between HPB and the FDA as well [as] the fact that a vast majority of prescription pharmaceuticals are manufactured in the United States and are bio-equivalent or identical in both countries" ensures that the prescription drugs imported from Canada pass safety standards similar to those in the United States.<sup>140</sup>

Finally, the proposed 2003 Amendments also require the use of the latest technology to eliminate any risk of counterfeiting.<sup>141</sup> If the Pharmaceutical Market Access Act of 2003 were to become law, it would require all drugs distributed in the United States to use the same counterfeit-proofing technology used in new American currency.<sup>142</sup> If the packaging of a pharmaceutical shipment does not contain this technology, then the bill requires the wholesaler to conduct tests to ensure the safety and authenticity of the shipment's drugs.<sup>143</sup> These safety measures adequately address the limited existing risks present in prescription drug reimportation.

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132. See Pharmaceutical Market Access Act of 2003, H.R. 2427 108th Cong. § 4 (2003); see also *The Safety Provisions of H.R. 2427*, *supra* note 131.

133. H.R. 2427 § 4.

134. See Testimony of Elizabeth A. Wennar, *supra* note 44, at 90–93.

135. See Opening Statement of Dan Burton, *supra* note 21, at 3.

136. Barry, *supra* note 1.

137. *Id.*

138. *Id.*

139. *International Prescription Drug Parity: Are Americans Being Protected or Gouged?: Hearing Before the Human Rights and Wellness Subcomm. of the House Comm. on Government Reform*, 108th Cong. 105 (Apr. 3, 2003) (prepared statement of Andy Troszok, Vice President, Standards, Canadian International Pharmacy Association).

140. *Id.*

141. See Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. § 5 (2003); see also *The Safety Provisions of H.R. 2427*, *supra* note 131.

142. See H.R. 2427 § 5.

143. See *id.*

## VI. THE NEXT STEP? PLEASING EVERYONE WITH THE PHARMACEUTICAL MARKET ACCESS ACT

Though supporters of the proposed 2003 Amendments failed in their quest to have a reimportation plan included in the \$400 billion Medicare package passed by Congress in late 2003, they have no reason to end their efforts now. Americans have sought a solution to the high costs of prescription drug prices for years.<sup>144</sup> While many in Congress have high hopes for the steps taken in 2003, criticism abounds from politicians and citizens alike.<sup>145</sup> With the right adjustments, a bill similar to the proposed 2003 Amendments may find political success in the future. Such a bill can serve as a band-aid for the current problems facing American prescription drug users until the United States government and the pharmaceutical companies work together to develop a more long-term approach. However, supporters of a reimportation plan must make a number of changes.

First, the bill's supporters must address, though perhaps only in a limited manner, the safety concerns used to defeat it in 2003. The evidence suggests that reimportation from countries like Canada and the United Kingdom is a safe alternative.<sup>146</sup> Proponents of reimportation must publish this evidence to voters so that the pharmaceutical industry and the politicians who benefit from the pharmaceutical industry's monetary donations cannot continue to use this argument as a scare tactic to kill the bill. After reaching voters with the evidence, reimportation supporters must encourage them to contact their congressional representatives about the issue. The web of propaganda spread by the pharmaceutical industry and its allies to curb past reimportation proposals must face the reality that these plans offer safe alternatives to the American drug market.

Second, the bill should include restrictions on direct-to-consumer advertising. While advertising unquestionably increases demand for pharmaceutical products,<sup>147</sup> the increased demand causes an increase in the price of prescription drugs. It also distorts the nature of the patient-physician relationship by encouraging patients to demand certain medications. If pharmaceutical reform truly seeks to provide prescription drugs at a reasonable price to all Americans, then reducing the more than \$2 billion spent annually on direct-to-consumer advertising is a good start. Admittedly, some advertising is necessary; however, the current frequency of prescription drug advertising results in an added cost for American consumers purchasing drugs. If advertising were restricted, perhaps through a return to pre-1997 standards on television advertising, prices would fall because of a decrease in demand. Additionally, the pharmaceutical companies would save hundreds of millions each year, which they could

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144. See *supra* Part II.

145. See, e.g., Ronald Brownstein, *The \$500 Billion Bender; Bush is Racking Up a Crushing Debt for Future Generations*, SAN JOSE MERCURY NEWS, Dec. 5, 2003, at OP2, available at <http://www.mercurynews.com/mld/mercurynews/news/opinion/740263.htm> (last visited Mar. 23, 2005); Pip Klein, *Medicare Reform Draws Praise and Criticism*, FAIRFIELD COUNTY BUS. J., Dec. 15, 2003, at 15, available at [http://www.fairfieldcountybusinessjournal.com/current\\_issue/121503ffoc01.html](http://www.fairfieldcountybusinessjournal.com/current_issue/121503ffoc01.html) (last visited Mar. 23, 2005); Sarah Lueck, *Drug-Benefit Bill Gets Treated*, WALL ST. J., Feb. 10, 2004, at A4.

146. See *supra* Part V.B.

147. Consider how many people have followed one commercial's command to ask their doctor if the "purple pill" is right for them. For a discussion on the absurdity of many drug advertisements, see Bruce Japsen, *Costly Dose of TV Drug Ads*, CHI. TRIB., Apr. 11, 2004, at § 5.

allocate as they deem necessary—to further reduce prices, to increase spending on research and development, or even to pocket as profits. Under current advertising standards, the industry appears willing to drive up demand for prescription drugs through the use of an excessive amount of direct-to-consumer advertising, passing these additional costs on to consumers.

Finally, the federal government must take steps to spread the burden placed upon the United States and its citizens to pay for and develop new prescription drugs. Specifically, the foreign countries who currently act as free riders in the prescription drug market should pay their fair share. A successful reimportation system should lower drug prices for American buyers currently paying exorbitant prices at the same time it provides an incentive for pharmaceutical companies to continue pursuing research and development. This could happen in a number of ways. The drug companies could agree to maintain R&D spending and lower profit levels, or the American government could impose a profit regulation system similar to the one in place in the United Kingdom, where government regulations apply to the rate of return on capital.<sup>148</sup> It might also happen through some sort of incentive-based package that motivates the American pharmaceuticals to renegotiate the sale price of prescription drugs to foreign countries instead of cutting R&D costs. The reimportation plan offered by the Pharmaceutical Market Access Act of 2003 creates one such incentive by ending the monopolistic hold on American consumers and forcing the pharmaceutical industry into a Nash bargaining game. Unfortunately, the drug companies can respond by cutting R&D costs rather than negotiating new drug prices. Future reimportation proposals should grant tax-based incentives for firms to retain R&D spending levels while cutting American prices and working with foreign countries to spread R&D costs in a more equitable manner.

Unquestionably, the population size and wealth of the United States fuel the demand for prescription drugs domestically. However, most of the countries operating under price controls have not considered the demand in their countries when setting drug prices. Canada, for instance, does not permit drug price increases to exceed the rate of increase of the consumer price index.<sup>149</sup> Lately, Canadian officials have expressed concerns about depleting their supply of drugs because of the increase in unauthorized personal reimportation to the United States and the resulting threats from the pharmaceutical companies to stop the sale of prescription drugs to Canada in order to curb this activity.<sup>150</sup> If the drug companies can cause a stir in the Canadian government by threatening to limit sales of prescription drugs to Canada, they undoubtedly can use their bargaining power to spread additional costs onto Canada and other foreign markets. Quite simply, the assumption that consumer demand in foreign countries with price controls sets the market prices in these countries appears false. Future legislation must compel the American pharmaceutical companies to renegotiate with price-controlled foreign countries in order to spread costs in a more equitable manner. While America prides itself on its technological innovations and economic

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148. See DANZON 1997, *supra* note 35, at 53–54.

149. See DANZON 1999, *supra* note 99, at 27–28.

150. See, e.g., Tamsin Carlisle, *What's Left for Canadians If Americans Buy Their Drugs?*, WALL ST. J., Nov. 4, 2003, at D3; Winston, *supra* note 130, at 6.



independence, it should not fund the costs of prescription drug research and development for countries with strong enough economies to contribute a greater share.

## VII. CONCLUSION: A TRUCE IN SIGHT?

Millions of Americans seek relief from the onslaught of rising prescription drug costs. While the Pharmaceutical Market Access Act of 2003 failed to become law, it raised important discussions about the current state of the pharmaceutical industry in America. With any luck, the Medicare package passed by Congress and signed by President George W. Bush in late 2003 will meet some of the need existing in the United States today. However, other attempts to lower prescription drug costs failed in the past fifty years, and the problem problems to persist. Legalized reimportation remains an untested fix for America. Many states have implemented or are considering the implementation of reimportation plans for state employees,<sup>151</sup> so reimportation already plays a visible role at the state level as a viable weapon in this new war on prescription drug costs. While most economists will despise any plan associated with price controls and the pharmaceutical companies will keep lobbying for the status quo in America, the American people will continue calling for an end to this price battle with the drug companies. With a few changes to existing proposals, a reimportation system might not offer the truce so many seek, but it can at least offer a cease fire until a more permanent plan is in place.

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151. See Carlisle, *supra* note 150, at D3. Eleven states already have implemented importation plans in some form. Congressman Gil Gutknecht, *Prescription Drugs Facts & Figures*, at <http://www.gil.house.gov/issues/pdrugs/factsfigures.htm> (last visited Apr. 3, 2005).

