

PRESCRIPTION DRUGS IN AMERICA: THE PAIN OF PRICING HAS AN UNPROMISING CURE

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The escalating cost of prescription drugs in the United States greatly burdens consumers and mystifies state and federal legislators. As an increasing elderly population struggles to pay for prescription drugs, law makers try to find a solution that balances the public interest with the profit-seeking interests of private drug manufacturers. Short-term solutions, such as illegal importation of drugs and replacement of name brands with generic drugs, temporarily alleviate some, but not all, of the rising costs to consumers. Moreover, some short-term solutions are putting the health and safety of consumers at risk.

This note examines federal and state attempts to resolve the prescription drug crisis in the United States. The author discusses reasons for high prices in the United States, the problems associated with short-term solutions, and alternative systems successfully used by other countries to control drug costs. The author recommends two long-term solutions that balance free-market principles with the health and welfare of American citizens. The author proposes that: (1) decreasing patent protection terms to make cheaper alternatives available more quickly; and (2) creating a federal committee to oversee drug manufacturers' pricing mechanisms in order to reduce and regulate arbitrarily high prices will decrease costs but still maintain market competition. Although these solutions are not perfect, they are the most realistic solutions currently available.

I. INTRODUCTION

Rising health care costs are on the minds of all. In particular, the escalating cost of prescription drugs affects everyone, regardless of age, race, ethnicity, and socioeconomic status. This problem is especially urgent given the fact that people over the age of sixty-five consume nearly three times as many prescription drugs as those in younger age groups,¹

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1. Yahoo! Finance, Pharmaceutical Industry Profile, http://biz.yahoo.com/ic/profile/majrrx_1486.html (last visited Feb. 16, 2005).

and healthier living habits and scientific advances are enabling people to live longer. In fact, by 2025, there will be an estimated 690 million Americans over the age of sixty-five.² Making the situation worse, approximately 45 million people in the United States do not have health insurance to help defray the cost of prescription drugs.³

The financial strain placed on senior citizens by the rising cost of prescription drugs has forced some to take extreme measures. For example, Ray and Gaylee Andrews, both seventy-four and on Medicare, spent nearly \$800 per month on prescription drugs.⁴ They claimed that buying their drugs from Canadian pharmacies via the Internet could save them as much as \$350 a month.⁵ However, because these purchases are illegal, the Andrews had to resort to getting jobs and selling their house, in which they had lived for thirty-two years.⁶

Not all senior citizens, however, obey the law. Several months ago, 450 packages of prescription drugs ordered from a Canadian website, purchased somewhere in Europe, shipped through Grand Bahama, and intended for senior citizens in Minnesota, Wisconsin, and Vermont, were seized in Miami.⁷ In fact, a Food and Drug Administration (FDA) Press Release stated that, in an examination of mail shipments at four mail facilities, 1,728 out of 1,982 packages contained unapproved prescription drugs.⁸

This note tries to find a long-term solution to the prescription drug cost problem. In Part II, this note will review legislation and policy that has led to the nation's current prescription drug crisis. In Part III, the note will analyze the problems caused by the position the United States has taken, various arguments advanced by those on both sides of the debate, several pieces of legislation that have been proposed to deal with the problem, solutions that various states and countries are using to deal with the issue, and finally the pros and cons of implementing these techniques nationally. In Part IV, the note will recommend: (1) decreasing the patent protection terms to make cheaper alternatives available sooner; and (2) appointing a committee to ensure that manufacturers do not abuse their ability to price drugs in a free market.

2. Yahoo! Finance, *supra* note 1.

3. *Card Will Offer Drug Discount to the Uninsured*, ARLINGTON STAR-TELEGRAM, Jan. 12, 2005, at 4A (statistics are from 2003, the last year for which statistics are available).

4. Valerie Jablow, *Consumers, States Challenge Federal Bank on Drug Imports*, 40 JUN. TRIAL 12, 12 (2004).

5. *Id.*

6. *Id.*

7. John Dorschner, *Drug Shipment Seized in Miami*, MIAMI HERALD, Sept. 15, 2004, at C1. Although the packages were seized in July, the Food and Drug Administration did not notify customers until around September. *Id.*

8. Press Release, Food and Drug Administration, Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (Jan. 27, 2004), available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html>.

II. BACKGROUND

Congress has passed a great deal of legislation dealing with prescription drugs. It first authorized the Federal Food, Drug and Cosmetic Act (FFDCA), which regulates the manufacturing and distribution of pharmaceuticals.⁹ Beginning in the late 1980s, Congress passed a series of bills to address increasing drug costs. Recently, states have also begun to regulate prescription drugs.

A. *Federal Food, Drug and Cosmetic Act*

The purpose of the FFDCA is to protect the public health and safety, or . . . more specifically . . . to secure the purity of drugs, and to protect the consumer from the hazards of adulteration, mislabeling, and misbranding, and, from products that are dangerous, deleterious, illicit and noxious, or have not been proven to be safe and effective for their alleged uses.¹⁰

A manufacturer trying to market a new drug must first complete a New Drug Application.¹¹ This requirement costs time and money because the manufacturer must include data from studies demonstrating the drug's safety and effectiveness.¹² New-drug approval requires, among other things, full reports of investigations regarding the extent of the safety and effectiveness of the drug; a full statement of the composition of the drug; a full description of the methods, facilities, and controls used at all levels of production; samples of the drug; and specimens of the labeling that may be used for the drug.¹³

B. *Other Congressional Attempts to Deal with Drug Costs*

Congress has also passed other laws to deal with the cost of prescription drugs. In 1987, Congress passed the Prescription Drug Marketing Act of 1987 (PDMA).¹⁴ The PDMA completely banned parallel im-

9. See 21 U.S.C. § 301 (2000); David S. Copeland & Stephen J. Elliott, *Defending Indirect Purchaser Class Actions*, in CLASS ACTION LITIGATION: PROSECUTION & DEFENSE STRATEGIES 442 (2004). The article includes the Memorandum Opinion and Order Denying Plaintiffs' Motion for Class Certification, Granting Pfizer's Unopposed Motion to Extend the Page Limitation, Granting Great Lake's Motion to Extend the Page Limitation, and Denying Pfizer's Unopposed Motion for Oral Argument.

10. 28 C.J.S. *Drugs and Narcotics* § 11 (1996).

11. 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug."); see also *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998) (stating the requirement).

12. *Mova Pharm. Corp.*, 140 F.3d at 1063.

13. 21 U.S.C. § 355(b)(1).

14. See Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988).

ports unless the manufacturer of the drug imported them on its own.¹⁵ Parallel trade occurs when one country's product is exported and resold to another country without the permission of the patent holder in the exporting country.¹⁶ However, an exception existed for consumers purchasing drugs for personal use.¹⁷ Hence, the PDMA was a failure from its inception because of the money-making potential for individuals illegally importing and reselling drugs and the lax government enforcement.¹⁸

Because the original legislation did little to fix the problem, a series of Acts followed to amend the FFDCA. Thirteen years after the PDMA, Congress passed the Medicine Equity and Drug Safety Act of 2000 (MEDSA).¹⁹ The MEDSA allowed pharmacists and wholesalers to reimport drugs that were made in the United States and approved by the FDA.²⁰ Although the Secretary of Health and Human Services (Secretary) had the power to promulgate regulations to implement the law,²¹ no steps were ever taken due to health and safety concerns and loopholes in the MEDSA.²²

The House again attempted to fix the problem with the Pharmaceutical Market Access Act (PMAA) in July 2003.²³ The purpose of the PMAA was to "allow importation of drugs only if the drugs and the facilities where they were manufactured [were] approved by the Food and Drug Administration," and "[t]o require that imported prescription drugs be packaged and shipped under counterfeit resistant technologies."²⁴ The Senate never passed the PMAA, and it is unlikely that it will, because of the passage of the Medicare Prescription Drug, Im-

15. *Id.* § 3(d)(1) (codified as amended at 21 U.S.C. § 381 (2000)); *see also* Andrew Harris, *Recent Congressional Responses to Demands for Affordable Pharmaceuticals*, 16 LOY. CONSUMER L. REV. 219, 229 (2004).

16. Lana Kraus, *Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry*, 37 VAND. J. TRANSNAT'L L. 527, 541 (2004).

17. *See* Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, § 5, 102 Stat. 95; *see also* Harris, *supra* note 15, at 229.

18. Donald E. deKieffer, *The Mexican Drug Connection: How Trade in Pharmaceuticals has Wrecked the FDA*, 9 SW. J.L. & TRADE AM. 321, 326-27 (2002-2003).

19. *See* Medicine Equity and Drug Safety Act of 2000, Pub. L. No. 106-387, 114 Stat. 1549.

20. *Id.* § 745(c)(a).

21. *Id.*

22. Harris, *supra* note 15, at 231. One reason given for all the loopholes was that the pharmaceutical industry gave \$9 million to the Republican Party to fight the implementation of MEDSA. Other concerns with the Act included labeling requirements that gave pharmaceutical companies too much control over reimportation, a five-year sunset provision that gave companies little reason to reimport, the ability of American companies to charge foreign companies high prices, and insufficient funding. Michele L. Creech, *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, 635-37 (2001). "[T]he pharmaceutical industry used its more than \$80 million in campaign contributions to persuade the GOP leadership to add loopholes that make the bill unworkable." *Id.* at 635 (citing Rep. Bernard Sanders, *Editorial: Medication Inflation*, WASH. POST, Jan. 6, 2001, at A19).

23. Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong.

24. *Id.* § 3.

provement, and Modernization Act (MMA), which President Bush signed into law on December 8, 2003.²⁵

The MMA does not allow the U.S. government to negotiate with “pharmaceutical companies for better Medicare drug prices, [but] it gives the [Secretary] the power to approve imports of cheaper drugs from Canada”²⁶ by pharmacists and wholesalers.²⁷ The Secretary can also make an exception for individuals to import drugs²⁸ if the Secretary finds that no safety or health risks exist.²⁹ In order to make this determination, the MMA states a series of requirements that importers must meet when bringing drugs back to the United States.³⁰ The Secretary must also certify that the program will cut costs for the American consumer.³¹ Furthermore, under the MMA, nearly twelve million low-income seniors will qualify to receive drug benefits at a lower premium or no premium at all.³² Those with a higher income, in exchange for a monthly premium around \$35, will get a benefit that will pay, on average, half their prescription drug costs.³³ However, since President Bush signed the MMA, the Secretary has yet to implement the MMA’s provisions through regulations.

Although Congress has considered legalizing unrestrained personal importation of prescription drugs, it has faced strong resistance from the White House and the pharmaceutical industry.³⁴ However, political parties and interest groups need to reach an agreement soon. If they do not, drug prices will continue to get higher and more unbearable for all individuals.

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

26. Jablow, *supra* note 4, at 12.

27. Medicare Prescription Drug, Improvement, and Modernization Act, § 1121, 117 Stat. 2066, 2464.

28. *Id.* at 2467–68.

29. *Id.* at 2468.

30. *Id.* at 2465.

31. *Id.* at 2468.

32. *Ensuring Access to Health Care*, 292 JAMA 2010, 2011 (2004); see also Nicholas P. Terry, *Prescriptions Sans Frontières (or How I Stopped Worrying About Viagra on the Web but Grew Concerned About the Future of Healthcare Delivery)*, 4 YALE J. HEALTH POL’Y L. & ETHICS 183, 214 (2004) (stating that the House has already passed a bill allowing reimportation once but it failed to garner the support of the Senate and the White House).

33. Fact Sheet: Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (The White House, Office of the Press Secretary), Dec. 8, 2003, <http://www.whitehouse.gov/news/releases/2003/12/20031208-3.html>.

34. CBS News, Import Drug Bill Clears House, July 25, 2003, <http://www.cbsnews.com/stories/2003/07/25/politics/main565066.shtml>.

C. States' Action

The FDA regulation scheme assumes that every person will follow its mandates.³⁵ However, the FDA does not take into account that those who import drugs in violation of the law have nothing to lose; rather, importers that provide cheaper drugs are considered heroes to recipients of the drugs.³⁶ Since the FDA can only regulate legitimate markets, the FDA is powerless to control illegally imported drugs.³⁷ Therefore, the FDA must be granted greater jurisdictional authority if it is to stay in the game.

The FDA is already disadvantaged because, although it oversees the drug industry, the practice of pharmacology and medicine is regulated by the states.³⁸ All states have enacted laws regulating these practices.³⁹ Laws regulating pharmacology and medicine are strict and firmly enforced to ensure the professions are properly and safely practiced.⁴⁰ For example, in most states, "prescribing drugs to a patient outside the state where the physician is licensed is illegal."⁴¹ However, no state laws directly regulate or prohibit the sale of prescription drugs over the Internet.⁴² This gap in state and federal law has created a regulatory void, further exacerbating the prescription drug crisis in the United States.

III. ANALYSIS

Despite the heavy regulation of prescription drugs, the United States has prospered in the industry. Global sales of pharmaceuticals top \$300 billion annually.⁴³ The United States contributes significantly to this figure, which is not surprising considering that it has the largest market share and houses five of the ten largest drug manufacturers.⁴⁴ In addition, prices are comparatively high in the United States.⁴⁵ The two lead-

35. deKieffer, *supra* note 18, at 327–28. Drug manufacturers, distributors, doctors, and pharmacists have a lot to lose if they violate the law; therefore, the FDA assumes they will follow the regulations. *Id.* at 328.

36. *Id.*

37. *Id.* at 328–29.

38. Kristin Yoo, *Self-Prescribing Medication: Regulating Prescription Drug Sales on the Internet*, 20 J. MARSHALL J. COMPUTER & INFO. L. 57, 59 (2001).

39. *Id.*; see also Linda C. Fentiman, *Internet Pharmacies and the Need for a New Federalism: Protecting Consumers While Increasing Access to Prescription Drugs*, 56 RUTGERS L. REV. 119, 145–46 (2003) (showing that states have used their police power to shape the practice of medicine through common law, statutory enactments, administrative processes, case law, and care standards).

40. Yoo, *supra* note 38, at 59.

41. *Id.* at 67.

42. *Id.*

43. Yahoo! Finance, *supra* note 1. This dollar amount includes prescription, both brand name and generic, as well as over-the-counter drugs.

44. *Id.* The five drug companies are Bristol-Myers Squibb, Johnson & Johnson, Merck & Co., Pfizer, and Abbott Laboratories.

45. Abraham N. Saiger, *In Search of a Government that Will Govern: Senate Bill 812 and "Reimporting" Prescription Medicine from Canada*, 12 ELDER L.J. 177, 178 (2004).

ing causes of these high drug prices are patents and profits.⁴⁶ Many states have taken the problem into their own hands and have tried to come up with a way to help their residents.⁴⁷ After all, other countries have successfully kept drug prices down.⁴⁸ This Part will analyze and evaluate federal, state, and foreign regulatory schemes to determine whether they can provide a long-term solution to the problem of inflated prescription drug prices.

A. Federal Regulation of Drugs

The FDA has the authority to regulate the prescription drug industry under the FFDCA.⁴⁹ The FDA monitors the amount of active ingredients and type of inactive ingredients drugs contain because both can affect how the products work.⁵⁰ The FDA also ensures that drug producers properly test, manufacture, and label their drugs.⁵¹

1. Importation

If the government allowed consumers to import drugs, the FDA would be unable to verify the exact composition of the drugs. Although strict requirements no doubt increase the cost of the prescription drugs, few would be willing to give up these stringent standards. Because minimal changes to prescription drug ingredients can mean the difference between life and death, the public welcomes that the industry is heavily regulated.⁵² Therefore, creating lax standards would not be a solution to the problem.

However, it should be noted that when the manufacturer's profit depends solely on a drug's effectiveness, self-policing still exists. No company would produce harmful or ineffective drugs; immense lawsuits would result. Furthermore, other countries that do not have such demanding standards have had successful prescription drug industries.⁵³ There is no reason the outcome in the United States should be any different.

46. *Id.* at 181 (stating that patents and profits are at the core of why U.S. residents pay more than anyone else for prescription drugs).

47. See *infra* text accompanying notes 114–25 and 162–74.

48. See Saiger, *supra* note 45, at 179.

49. 21 U.S.C. § 379d (2000).

50. *On Examining the Implications of Drug Importation: Before the S. Comm. on the Judiciary*, 108th Cong. 2–3 (2004) (statement of the American Pharmacists Association), available at <http://www.aphanet.org/AM/TemplateRedirect.cfm?template=/CM/ContentDisplay.cfm&ContentDisplay.cfm&ContentID=2392>.

51. 21 U.S.C. § 379d.

52. Joshua P. Davis & Steig Olson, *Efforts to Delay Competition From Generic Drugs: Litigation Along a Seismic Fault Between Antitrust and Intellectual Property Law*, 39 U.S.F. L. REV. 1, 1 (2004).

53. See *infra* Part III.D.

2. *Factors That Lead to High Prices*

Many factors contribute to high prices, including intense research and development, easy access to innovative drugs, long patent protection, steady increase in number of prescriptions, vigorous marketing and advertising, and heavy lobbying and campaign contributions.⁵⁴ Besides these factors, drug prices are set above cost so that drug manufacturers can reap a healthy profit.⁵⁵ Consequently, prices are often too high for many to handle.⁵⁶

a. Profits

Due to the free market system in the United States, drug manufacturers can price drugs at as high a price as the market will allow.⁵⁷ Unlike other countries across the world, prescription drugs have no price caps.⁵⁸ Furthermore, the price-setting mechanisms a company uses in determining prices are unregulated; the price is simply accepted by the FDA and by consumers.⁵⁹ Some consider this a monopoly because U.S. consumers pay more for prescription drugs than the rest of the world.⁶⁰ As a result, almost twenty-five percent of the seniors in the United States skip doses of their medicines because they cannot afford them.⁶¹

Contrary to the belief of many, lowering drug prices will not hurt innovation.⁶² Nearly two and a half times the amount that is expended on innovation is spent on marketing, advertising, and other administrative costs.⁶³ If anything, less can be spent in those areas, shifting funds toward innovation. Furthermore, profits of brand-name manufacturers are already suffering as consumers opt for cheaper generic drugs.⁶⁴ It would be beneficial for the brand-name manufacturers to lower prices on

54. See Creech, *supra* note 22, at 600–09.

55. Saiger, *supra* note 45, at 190.

56. See Todd A. Rosenfield, *The Counterfeit Drug Invasion: How Drug Reimportation Unjustifiably Poses a Threat to the Health of the U.S. Public*, 25 U. PA. J. INT'L ECON. L. 1047, 1054 (2004).

57. Creech, *supra* note 22, at 596.

58. *Id.* at 599.

59. *Id.*

60. Saiger, *supra* note 45, at 190.

61. See Rep. Bernie Sanders, Prescription Drugs, Reimportation, Prescription Drug Prices, <http://bernie.house.gov/prescriptions/> (last visited Mar. 16, 2005).

62. Rep. Bernie Sanders, The R & D Argument, <http://bernie.house.gov/Prescriptions/rd.asp> (last visited Sept. 20, 2005).

63. Marcia Angell, *The Truth About Drug Companies*, MOTHER JONES, Sept. 7, 2004, <http://www.motherjones.com/news/ga/2004/09/09-401.html> (last visited Sept. 20, 2005).

64. Melissa Ganz, *The Medicare Prescription Drug, Improvement & Modernization Act of 2003: Are We Playing the Lottery with Healthcare Reform?*, 2004 DUKE L. & TECH. REV. 11, 74–75, available at <http://www.law.duke.edu/journals/dltr/articles/PDF/2004OLTR00112005.pdf> (stating that since the patent on Claritin, a leading brand-name allergy medicine, expired, sales declined more than \$1.8 billion in the first six months).

their own initiative. However, because the incentive to keep prices high remains,⁶⁵ few, if any, manufacturers are likely to cut prices.

b. Research and Development

Higher living standards are increasing the demand for access to sophisticated drugs.⁶⁶ This demand leads to drug development,⁶⁷ which in turn keeps research and development costs climbing.⁶⁸ Research and development costs include initial investments, product liability costs, low variable costs (when compared to most non-biotech products), and uncertainties in return because of a dependence on consumers in the market.⁶⁹ Drugs are made at “a variable cost of pennies per pill,” but to recoup some of the research and development costs, the drugs must be sold at a higher price.⁷⁰ Otherwise, drug companies would lose money.⁷¹ However, as discussed above, making a profit does not require the huge differential between price and cost that drug companies create.⁷²

Although the drug market is saturated with drugs for almost any ailment, better drugs can always be made. Americans are not willing to bypass drugs that may provide for quicker recovery or require lower dosage. Research and development costs must be allowed to escalate at the current rate to ensure that the best drugs are brought to market; cutting costs here is not an option.

c. Patents

Patents are tremendously important to drug manufacturers because they ensure that generic versions of their drugs will not be introduced into the market for twenty years,⁷³ thereby allowing them to price their drugs at a high price.⁷⁴ Patent holders can also file for extensions to prolong the favorable profit margin.⁷⁵ Profits depend on patents because they allow the manufacturer to temporarily corner the market on a cer-

65. Helkei Tinsley, *Prescriptions Without Borders: America Looks to Canada for Answers to Solve the Prescription Drug Pricing Predicament in the U.S., but Is Importation Really the Solution?*, 25 *HAMLIN J. PUB. L. & POL'Y* 437, 449 (2004).

66. Yahoo! Finance, *supra* note 1.

67. *Id.*

68. Medscope.com, Trend of the Month-Rising R&D Costs, <http://www.medscope.com/viewarticle/416822> (last visited Sept. 20, 2005).

69. Kraus, *supra* note 16, at 530. Kraus notes that research and development costs can account for almost 30% of the total product output costs. *Id.* at 531.

70. Richard G. Frank, *Prescription-Drug Prices*, 351 *NEW ENG. J. MED.* 1375, 1375 (2004).

71. *Id.*

72. See *supra* text accompanying notes 62–63.

73. Saiger, *supra* note 45, at 183 (noting that the time period starts from the date of filing).

74. Kraus, *supra* note 16, at 531–32.

75. Saiger, *supra* note 45, at 183.

tain drug. Studies have shown that no-patent systems in other countries drive drug prices down considerably.⁷⁶

A possible solution, however, would be to limit the time a patent owner has a monopoly over the market.⁷⁷ This would bring generic drugs to market more quickly and provide consumers with a cheaper cost alternative to a brand-name drug. Studies show that the entrance of generics into the market lowers costs of the drugs.⁷⁸

However, because the pharmaceutical lobby is such a strong force in Washington, D.C., it would undoubtedly campaign heavily against patent protection reduction and, most likely, would defeat such a proposal. The argument has also been made that the long patent period “ensures that there is incentive to undertake the risky, time-consuming, and expensive process of developing a drug.”⁷⁹ However, prices can be set to recover costs even with reduced patent periods.

3. *Generic Drugs*

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendment, amended the FDCA to “make available more low cost generic drugs.”⁸⁰ Generic drugs are drugs that contain the same active ingredients as the brand names but not the inactive ingredients.⁸¹ The noticeable cost difference results from the fact that active ingredients in most prescription drugs consist of less than ten percent of the drug; the remainder consists of inactive ingredients such as coatings, binders, and capsules.⁸² Furthermore, generic drug producers do not have to go through the New Drug Application Process.⁸³ Under the Hatch-Waxman Amendment, those who wish to manufacture a generic version of a FDA approved drug only need to fill out an Abbreviated New Drug Application.⁸⁴ The application

76. Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 25 U. PA. J. INT'L ECON. L. 1079, 1125–26 (2004). Studies also show that drug industries have expanded in countries with a small or nonexistent patent program because imitation is simple. *Id.* at 1126.

77. Donald P. Harris, *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States*, 25 NW. J. INT'L L. & BUS. 99, 156 & n.242 (2004). Currently, a patent holder possesses a patent for twenty years from the date of filing. 35 U.S.C. § 154(a)(2) (2000). Prior to TRIPS, a patent was valid only for seventeen years from the date of issuance. 35 U.S.C. § 154 (1988).

78. Weissman, *supra* note 76, at 1124–25. “[G]eneric producers enter the market quoting prices much lower than those of their branded competitors, and these prices also decline as the number of generic competitors increases, potentially falling to roughly seventeen percent of the branded producer’s pre-entry price.” *Id.* at 1125. Once the research has been done by the drug manufacturer, almost anyone can enter the market because the formula for the drug is already available in the market.

79. Tinsley, *supra* note 65, at 442.

80. Copeland & Elliott, *supra* note 9, at 442.

81. *United States v. Generix Drug Corp.*, 460 U.S. 453, 454–55 (1983).

82. *See id.* at 454.

83. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

84. *Id.*

process takes into account the FDA's prior decision regarding the safety and effectiveness of the drug, thereby making new safety and effectiveness tests unnecessary.⁸⁵ Other factors that make generic drugs noticeably cheaper are the lower research and development costs and promotional costs associated with making and selling the original drug.⁸⁶

Although some have proposed generic drugs as the answer to the high-cost problem, noting that they are even cheaper than drugs purchased abroad, this may be a problematic solution because generic drugs are not available for all brand-name drugs.⁸⁷ For the Andrews, mentioned in Part I, no generics are available for many of the medications they take.⁸⁸ When Ms. Andrews did try a generic drug that was available for her needs, it caused complications and forced her back to the brand name.⁸⁹

In most cases, however, generic drugs are a reliable and cheaper alternative to brand-name drugs.⁹⁰ Because there is no need to carry out research and development, and patents cannot be issued for generic drugs, prices are driven down considerably.⁹¹ Furthermore, generic manufacturers are not concerned with the packaging or aesthetic appeal of a drug,⁹² which further decreases prices. Unfortunately, because of the long patents on brand-name drugs, generics take time to enter the market. Even after they are brought to market, many consumers avoid generic drugs: Americans believe that generic simply is not as good as brand name,⁹³ even though that is not the case with prescription drugs.

4. *Therapeutic Drugs*

In addition to generic drugs, a wide variety of therapeutic drugs are also now available as an alternative to brand-name prescription drugs. Therapeutic drugs treat the disease or condition in the same manner but have different active ingredients.⁹⁴ Nevertheless, these have not been able to lower drug costs for everyone.⁹⁵ In cases where they have, the result suggests that "increased investment in the development of new drugs

85. *Id.*

86. *Generix Drug Corp.*, 460 U.S. at 455 n.1 (stating that "[g]eneric drugs . . . are usually marketed at relatively low prices").

87. Jablow, *supra* note 4, at 16.

88. *Id.*

89. *Id.*

90. Committee on Antitrust & Trade Regulation, *Supplement to the 2003 Milton Handler Annual Antitrust Review Proceedings*, 2004 COLUM. BUS. L. REV. 379, 487.

91. *Generix Drug Corp.*, 460 U.S. at 455 n.1 (stating that "[g]eneric drugs . . . are usually marketed at relatively low prices").

92. *See id.*

93. David V. Mihalic, *Generic Versus Brand Name Prescription Drugs*, <http://cpmu.org/Generics.html#about> (last visited Oct. 22, 2005).

94. Rosenfield, *supra* note 56, at 1073-74.

95. *Id.* at 1074.

could be a better long-term solution.⁹⁶ Also, therapeutic drugs may result in having to take medication more frequently or for longer durations, and they may cause minor side effects.⁹⁷ The patient has to determine whether the saved costs are worth the extra inconvenience and minor discomforts.⁹⁸

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The FDA's stringent standards and the lack of supervision over drug pricing have led to higher prices.⁹⁹ Research and development costs¹⁰⁰ and patents¹⁰¹ have also added to the steep escalation in prices. However, by merely reducing the patent protection term, drug manufacturers can still reap profits for several years while the market more quickly provides generic alternatives to consumers.

B. State Regulation of Drugs

Since the field of drug regulation is not exclusively within the power of the federal government,¹⁰² states have established initiatives to help their residents cope with rising drugs prices. Because these programs are fairly new, whether they work or not remains to be seen.

1. Reimportation

A few states have experimented with importing or reimporting drugs.¹⁰³ Reimported drugs are drugs that are manufactured in the United States, exported to a foreign country, reimported back into the United States, and sold at lower prices.¹⁰⁴ According to the FFDCA, no drug, subject to exemptions from certain requirements and manufactured abroad, can be reimported into the United States except by the manufacturer of the drug¹⁰⁵ unless the imported drug is required for emergency medical care.¹⁰⁶ As far as prescription drug imports from Canada are

96. *Id.*

97. Samia A. Hurst et al., *Conserving Scarce Resources: Willingness of Health Insurance Enrollees to Choose Cheaper Options*, 32 J.L. MED. & ETHICS 496, 496 (2004).

98. *Id.*

99. Rosenfield, *supra* note 56, at 1050.

100. *See supra* text accompanying notes 66–72.

101. Rosenfield, *supra* note 56, at 1050.

102. 28 C.J.S. *Drugs and Narcotics* § 8 (1996). Although the FDA has voiced concern that the states are violating the federal ban on the importation of drugs, the federal government has been loathe to take any action. Tinsley, *supra* note 65, at 478.

103. *See* Gretchen Ruethling, *National Briefing Midwest: Missouri: Drug Import Program Stats*, N.Y. TIMES, Oct. 29, 2004, at A16.

104. Creech, *supra* note 22, at 627–28.

105. 21 U.S.C. § 381(d)(1) (2000). Section 353(b) exempts certain drugs from labeling and prescription requirements if approved by the Secretary of Health. *See* 21 U.S.C. § 353(b)(2)(2000).

106. 21 U.S.C. § 381(d)(2).

concerned, the Secretary can, by regulation, grant individuals waivers that allow them to import prescription drugs into the United States if the drugs meet certain requirements.¹⁰⁷

However, importing a drug for personal use is difficult because of the many guidelines that must be followed.¹⁰⁸ Almost all drugs imported to the United States for personal use will violate other requirements laid out in the FFDCA, such as requirements about labeling, dispensing, and obtaining FDA approval.¹⁰⁹ Furthermore, because there are only minimal limits on the Secretary's authority to regulate the importation of prescription drugs,¹¹⁰ the Secretary has broad power to refuse the importation.

Reimportation will also be met with strong resistance from the pharmaceutical companies.¹¹¹ In order to impede the reimportation process, companies may restrict the quantity of supplies shipped to countries participating in reimportation, contract with the foreign countries regarding the price at which the drugs can be sold back in the United States, and sell only prescription drugs that do not meet FDA packaging requirements in foreign countries.¹¹² However, even though reimporting is illegal unless all the strict requirements prescribed in the U.S. Code are met, illegal shipments worth \$1.4 billion entered the United States in 2003, nearly half of which shipments came from Canada.¹¹³

2. States' Action

a. Illinois, Wisconsin, Missouri, Kansas, and Vermont

Illinois, Wisconsin, Missouri, Kansas, and Vermont have all begun a program called I-SaveRx, a prescription drug program designed to let the residents of the five states import drugs at lower prices.¹¹⁴ The creators

107. 21 U.S.C. § 384(j)(3) (Supp. III 2003). In order to meet the requirements, the drug must be (1) imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a ninety-day supply; (2) accompanied by a copy of a valid prescription; (3) imported from Canada, from a seller registered with the Secretary; (4) a prescription drug approved by the Secretary; (5) in the form of a final finished dosage that was manufactured in an establishment registered under § 360 of this title; and (6) imported under such other conditions as the Secretary determines to be necessary to ensure public safety. 21 U.S.C.A. § 384(j)(3)(A)–(F).

108. Tinsley, *supra* note 65, at 458–59.

109. *Id.* at 459.

110. 21 U.S.C. § 384(k) (Supp. III 2003). Section 381(d)(1) states that the Secretary cannot allow for the import of anything consisting of insulin unless it is by the manufacturer of the drug. 21 U.S.C. § 381(d)(1).

111. Rosenfield, *supra* note 56, at 1065.

112. *Id.* at 1065–66. These are only the procedural handicaps that come with reimportation; other problems exist as well. See *infra* text accompanying notes 147–61.

113. *Drug Re-importation: Risks Worth the Rewards?*, MED. ETHICS ADVISOR, Feb. 1, 2005, available at 2005 WLNR 2186766.

114. I-Save Rx Safe and Affordable Prescription Drugs, Welcome to I-SaveRx, <http://www.i-saverx.net> (last visited Feb. 15, 2005); see also Healthy Kansas, I-Save Rx Program, <http://www.accesskansas.org/healthykansasrx/isaverx.shtml> (last visited Feb. 16, 2005) (stating that Kansas joined Illinois, Wisconsin, and Missouri in the I-Save Rx program so that Kansas residents have access to the

of the program state that customers “can compare prices for prescription drugs from Canada, Ireland, and the United Kingdom and purchase them at prices that are, on average, 25–50% less than what [they] would pay in the United States.”¹¹⁵ I-SaveRx claims to have strict quality control and safety checks.¹¹⁶ The pharmacies associated with the program have all been approved by each state’s regulatory agencies and follow the same standards and procedures as pharmacies in the respective state.¹¹⁷

Although the federal government bans the importation of drugs from foreign pharmacies, the FDA has not shut down I-SaveRx.¹¹⁸ However, William Hubbard, the FDA’s Associate Commissioner, said that “opening America’s door to prescription drugs from the United Kingdom leaves it propped open for sketchier drug imports from less-developed countries.”¹¹⁹ The states respond that the drugs imported are all FDA approved, meaning that they are produced at plants the agency already inspects.¹²⁰

The program works as follows: customers enroll in the program and obtain verification of the medications from their doctor; then I-SaveRx reviews the forms, conducts safety checks, and sends the prescription to a licensed physician for further review; and finally, I-SaveRx network pharmacists perform further checks, ensure compliance with local laws, and inspect and approve all pharmacies participating in the program.¹²¹ The program operates through a Canadian clearinghouse that links residents to foreign pharmacies and wholesalers that have been approved by each state’s health inspectors.¹²² Included in this program are more than one hundred of the most commonly used brand-name drugs,¹²³ but they can only be purchased as refills.¹²⁴ Excluded from the program are most generic drugs because they are usually cheaper in the United States, medications requiring refrigeration because they may spoil during transit, narcotics and controlled substances because of safety concerns and laws and regulations, and medication needed immediately because of the time required to get drugs from abroad.¹²⁵

same low price drugs from Canada, the United Kingdom, and Ireland); Vermont AHS, Welcome to I-SaveRx, <http://www.ahs.state.vt.us/Isaverxvt.cfm> (last visited Oct. 24, 2005) (stating that Governor Douglas signed the I-SaveRx bill into law on Feb. 17, 2005).

115. I-SaveRx Safe and Affordable Prescription Drugs, *supra* note 114.

116. I-SaveRx Safe and Affordable Prescription Drugs, About I-SaveRx, <http://www.i-saverx.net/about.htm> (last visited Feb. 15, 2005).

117. *Id.*

118. David Klepper, *Kansas Law Allows Promotion of I-Save Rx*, KANSAS CITY STAR, Apr. 5, 2005, at B1, available at 2005 WLNR 5260666.

119. *FDA Criticizes Illinois Drug Proposal*, BELLEVILLE NEWS DEMOCRAT, Aug. 25, 2004.

120. *Id.*

121. I-SaveRx Safe and Affordable Prescription Drugs, How I-SaveRx Works, http://www.i-saverx.net/how_works.htm (last visited Feb. 15, 2005).

122. I-SaveRx Safe and Affordable Prescription Drugs, About I-SaveRx, *supra* note 116.

123. I-SaveRx Safe and Affordable Prescription Drugs, Medication Questions, <http://www.i-saverx.net/faq/medications.htm> (last visited Feb. 15, 2005).

124. Vermont AHS, Welcome to I-SaveRx, *supra* note 114.

125. I-SaveRx Safe and Affordable Prescription Drugs, Medication Questions, *supra* note 123.

i. Internet Pharmacies

The Internet plays a big role in the I-SaveRx program. Although many legal pharmacies operate online and seek only to provide convenience to their patients who have valid prescriptions, many Internet pharmacies also seek to offer foreign or reimported drugs to customers who have no prescription¹²⁶ or insurance.¹²⁷ Despite the FDA's condemnation of these Internet sites and its consistent stance that these sites are illegal, many of the Internet pharmacies lead their customers to believe that their activities are perfectly legal.¹²⁸

To the dismay of many, the Canadian prime minister is considering preventing the Internet pharmacies from selling mail order prescription drugs to the United States¹²⁹. The reasons Canada gives for this proposed move include reduction of the Canadian drug supply and violation of medical ethics, which require the doctor to see a patient before signing the prescription.¹³⁰ Under the proposed changes, Canadian doctors would be able to sign the prescriptions being sent to the Internet pharmacies only if the patient goes to the doctor in person.¹³¹ However, the Internet pharmacies would still be prevented from selling to foreigners who are not physically present in Canada and from selling drugs which are in high demand in Canada.¹³²

Unless the proposed laws are enacted, states that disapprove of the Internet pharmacies will be able to do very little because of their inability to regulate foreign commerce.¹³³ However, one proposed solution has been to allow the FDA to regulate this activity.¹³⁴ Although the FDA does not currently have the power, Congress has the ability to enhance the FDA's power.¹³⁵ The FDA would then be given the authority to

126. Rosenfield, *supra* note 56, at 1057.

127. *Alcock Hopes to Save Net Jobs: Believes He'll Strike Deal to Rescue Web Pharmacies*, WINNIPEG FREE PRESS, Feb. 4, 2005, at a1, available at 2005 WLNR 1554086.

128. Rosenfield, *supra* note 56, at 1057-58.

129. See Jennifer L. Halser, *Canadian Pharmacies: A Prescription for a Public Health Disaster*, 54 DEPAUL L. REV. 543, 575 (2005) (stating that the Canadian National Association of Pharmacy Regulatory Authorities asked the Canadian government to enact laws that prohibit exporting drugs to the U.S. because of a fear regarding Canadian Public Safety).

130. Canada Considers Proposal Aimed at Shutting Down Internet Pharmacy Prescription Drug Trade, <http://cachestechologyreview.com/articles/05/01/ap/ap-2010605.asp?p=1> (last visited Sept. 20, 2005).

131. Canada Considers Proposal Aimed at Shutting Down Internet Pharmacy Prescription Drug Trade, *supra* note 130. Under current practice, the patient faxes a prescription from her American doctor to the Canadian doctor. The Canadian doctor then reviews her medical history, signs the prescription, and faxes it over to the Internet pharmacy who in turn ships it to the American purchaser. Under the proposed law this would not be possible because faxing the prescription would no longer be allowed.

132. Canada Considers Proposal Aimed at Shutting down Internet Pharmacy Prescription Drug Trade, *supra* note 130.

133. Ludmila Bussiki Silva Clifton, *Internet Drug Sales: Is It Time to Welcome "Big Brother" into Your Medicine Cabinet?*, 20 J. CONTEMP. HEALTH L. & POL'Y 541, 553 (2004).

134. *Id.* at 562.

135. *Id.* at 563.

“monitor the sale of prescription drugs online, regulate the importation of drugs from abroad, set up labeling standards for drugs that come from overseas, and ensure that all drugs that enter the country have been approved by the FDA for domestic use.”¹³⁶

There are three problems with this approach: cost, resources, and its near impracticability. With nearly three hundred to four hundred sites selling drugs,¹³⁷ the FDA alone would not be able to keep up with the flow of the drugs. Far too many shipments and mailings come into the United States for the FDA to ensure that each drug has met the approved standards. Even in regulating the rules it has set forth as of today, the FDA has acknowledged that it cannot at times fully enforce all of them.¹³⁸

Several actions taken by the FDA to deal with the Internet pharmacies have already proven to be ineffective. One example is the FDA’s issuance of cyber-letters, which are letters that warn the Internet pharmacies that they may be taking part in activities that violate U.S. laws dealing with prescription drugs.¹³⁹ However, the problem with the warning letters is just that—they only provide a warning. The FDA has no power to do anything about these Internet pharmacies, so the warning often goes unheeded.¹⁴⁰

Another proposed solution to deal with the Internet pharmacies is a federally run International Coalition on Online Pharmacies (Coalition).¹⁴¹ The members of the Coalition, who would be experts in laws regarding pharmacy sales, importation and exportation of controlled substances, customs service, and the Internet, would help customers identify properly licensed online pharmacies in order to protect the customer.¹⁴² The Coalition would require online pharmacies to give the name of the website operator, the address and telephone number of the main location, and the countries where the pharmacy and pharmacists are licensed to operate.¹⁴³ The Coalition would also require all the sites to register with it and would ensure customers are protected from illegitimate sites by not allowing those sites to sell drugs to customers in the United States.¹⁴⁴

The problem with this solution is the same as with allowing the FDA to regulate all Internet pharmacies: costs and resources. Training the individuals to become experts in the field would cost taxpayers large amounts of money. Furthermore, because there are many Internet phar-

136. *Id.*

137. *Id.* at 553.

138. deKieffer, *supra* note 18, at 325.

139. Yoo, *supra* note 38, at 75.

140. *Id.* at 75–76.

141. *Id.* at 84.

142. *Id.* at 86–87.

143. *Id.* at 87.

144. *Id.* at 87–88.

macies, it would be hard to ensure that every legitimate pharmacy has registered with the Coalition. Such regulation might also deter legitimate online pharmacies from functioning because of the additional regulatory burdens.¹⁴⁵ Finally, additional federal government regulation in an area typically left up to the states may be unpopular.¹⁴⁶

ii. Problems with Using Foreign Drugs

The FDA's website states that its main concern with importing drugs is safety; it cannot ensure that drugs bought abroad will be safe.¹⁴⁷ The American Pharmacists Association, which "represents more than 50,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession," states that its concerns with importing drugs are the integrity of the drug product itself and the impact of importation on the patient's care.¹⁴⁸ Various rules and regulations have been put into place by the United States to regulate drugs produced here, including evidence of safety and effectiveness and oversight of the production and distribution of prescription drugs.¹⁴⁹ By allowing importation of drugs, and thereby avoiding this regulatory system, the chances increase that counterfeit, mislabeled, mishandled, or subpotent drugs will wind up in the hands of ailing patients.¹⁵⁰ These are among the problems that will prevent importation from being a long-term solution to rising health care costs.

1. Counterfeit Drugs

Production of counterfeit drugs abroad is a major safety problem in the United States.¹⁵¹ A large number of counterfeit drugs are coming from Canada and Mexico, which is where many are turning for lower cost alternatives.¹⁵² Drugs have also been arriving into the United States from other places, such as the Bahamas and Pakistan, as well as "drugs

145. *Id.*

146. *Id.* Typically the state board of pharmacy makes up rules that it thinks are best for that state. *Id.* at 88. Given the general dislike for government intrusion, many would not be too fond of additional intrusion into this area.

147. U.S. FOOD AND DRUG ADMIN., IMPORTING PRESCRIPTION DRUGS, <http://www.fda.gov/importeddrugs> (last visited Feb. 15, 2005). In a Consumer Alert, the FDA warned that certain drugs have special safety restrictions on how they are given to the public; therefore, buying those drugs online bypasses important FDA regulation of manufacturing controls and FDA inspection of manufacturing facilities. U.S. FOOD AND DRUG ADMIN., IMPORTANT CONSUMER SAFETY ALERT, <http://www.fda.gov/oc/buyonline/consumeralert120902.html> (last visited Feb. 16, 2005).

148. *On Examining the Implications of Drug Importation, supra* note 50, at 4.

149. *Id.*

150. *Id.* at 2.

151. Natasha Wong, *Counterfeit Medicine: Is it Curing China?*, 5 ASIAN-PAC. L. & POL'Y J. 5, 182 (2004).

152. *Id.* at 183-84. Even though a large number of counterfeit drugs end up in Mexico, Canada might be the bigger problem because many feel it is safer to buy drugs from Canada than Mexico. *Id.*

shipped from Belize, but identified as Canadian, [and] counterfeits from India shipped in Tupperware.”¹⁵³

The counterfeit market thrives mainly because, as prescription drug prices continue to rise, consumers seek alternative means of obtaining essential medication.¹⁵⁴ However, over half of all counterfeit drugs can be harmful because they either contain no active ingredients, contain the wrong ingredients, or contain contaminants.¹⁵⁵ As counterfeiters become more sophisticated, it is hard to tell if the medicine is authentic. The counterfeiters make packaging that is unbelievably difficult to distinguish from that of the approved drug.¹⁵⁶ Even with the strict regulatory system in the United States, counterfeit drugs are still able to get through. Since the late 1990s, the number of counterfeit drug investigations has increased nearly four-fold.¹⁵⁷ Allowing imported drugs will only increase this statistic, which in turn increases the potential of harm to the American people.

2. Labeling and Shipping

Another problem is that improper labeling or shipping of drugs can cause them to be unsafe for consumers. Due to critical incidents in the past, the United States put into effect laws that would protect patients against contaminated or ineffective medications.¹⁵⁸ By importing drugs, the consumer has no way of knowing if the drugs were stored at the proper temperature in a suitable container, or if the drugs were properly handled during shipping. The FDA regulates these details; therefore, a consumer of American medications knows that they are safe to consume. The FDA has no way to give the same assurance to imported drugs.

3. Ineffective Drugs

Although many concerned about high prices of prescription drugs look to importation, they fail to consider that even higher costs will result if imported medication turns out to be ineffective. Because importing drugs is illegal, patients generally do not disclose to their doctor that they are obtaining their medication in such a manner.¹⁵⁹ Unless the patient provides this information, doctors will not be able to advise the patient on any adverse interactions that may result from combining various

153. William Hubbard, *Risks are too High*, USA TODAY, Aug. 23, 2004, at 10A.

154. Wong, *supra* note 151, at 172.

155. *Id.* at 160.

156. *Id.* at 162. In response to the ease with which the packaging could be duplicated, Pfizer Corporation created a hologram for all of its packaging, which is generally difficult to duplicate. *Id.* However, between November 1999 and May 2001, police seized 147,000 tablets that were wrapped in counterfeit packaging that included the hologram. *Id.*

157. *On Examining the Implications of Drug Importation*, *supra* note 50, at 4.

158. *Id.*

159. *Id.*

medications.¹⁶⁰ Importation may also lead to unnecessary prescriptions and unnecessary increases in dosages.¹⁶¹ In the long run, importation clearly is not worth the risks associated with the practice.

b. Maine

In the spring of 2000, in response to the federal government's inaction, Maine passed a law to attempt to bring its drug prices down and help its citizens who could not afford prescription drugs.¹⁶² Shortly after, a lawsuit was filed by nonresident drug manufacturers who claimed the program, known as Maine Rx, was preempted by federal laws.¹⁶³ However, the U.S. Supreme Court upheld the program,¹⁶⁴ and Maine continued its efforts by making some changes and renaming its program Maine Rx Plus.¹⁶⁵

The program works by providing participants, who become eligible based on household income or household prescription drug or health care costs, with a Maine Rx card, which entitles them to discounts at participating pharmacies.¹⁶⁶ The program claims initial discounts will be thirteen percent for brand-name drugs and larger for generic drugs.¹⁶⁷ The state is able to provide these discounts by negotiating the discounts with pharmacies and drug manufacturers.¹⁶⁸ The discounts are in the form of rebates that are paid directly to the state by manufacturers.¹⁶⁹ When participants pay the discounted prices at the pharmacies, the pharmacies are reimbursed the discounted amount by the state and given an administrative fee.¹⁷⁰ The state is reimbursed by the rebates it re-

160. *Id.*

161. *Id.* Because an interaction between drugs or an ineffective drug can prevent the desired result from being achieved, the doctor will believe that the drug is not the right one for the patient or that the dose was too low. This in turn will cause the doctor to prescribe other medication or increase the dose to one that is stronger than what the patient was previously taking. The end result is more money spent on purchasing medication and a longer recovery period. *Id.*

162. Maine Citizen Leadership Fund Rx Express, Maine Launches Maine Rx Plus, <http://www.rxmaine.com/rx/rx.htm> (last visited Feb. 15, 2005).

163. Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 650 (2003). The suit alleged the Maine Rx Program was unconstitutional because it was preempted by the federal Medicaid statute and that it violated the negative Commerce Clause. *Id.* The District Court agreed and entered a preliminary injunction preventing implementation of the program. See Pharm. Research & Mfrs. of Am. v. Comm'r, No. Civ. 00-157-B-H, 2000 WL 34290605, at *6-7 (D. Me. Oct. 26, 2000). However, the Court of Appeals reversed. See Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 85 (1st Cir. 2001).

164. *Walsh*, 538 U.S. at 670. In denying the injunction, the Supreme Court noted that the association had, among others reasons, failed to show any possibility of success on the merits. *Id.*

165. Maine Citizen Leadership Fund Rx Express, Maine Launches Maine Rx Plus, *supra* note 162.

166. Maine Rx Express, Maine Rx Program, <http://www.rxmaine.com/home/resources/billsummary.cfm> (last visited Feb. 15, 2005).

167. Maine Rx Express, *supra* note 166.

168. *Id.*

169. *Id.*

170. *Id.*

ceives from the drug companies.¹⁷¹ If a drug manufacturer refuses to participate in the program by providing a rebate, its products are placed on the Medicaid program's list of drugs that require preauthorization for payment.¹⁷² This is a powerful weapon because it often provokes consumers to shift to alternative drugs and generic equivalents.¹⁷³ However, Maine's program will likely not work on a national scale because of the government's apathy towards providing health care for all its people.¹⁷⁴

C. *Bills Pending in Congress*

Since the states have not successfully developed an effective plan, the federal government must do something. When asked what his plans were to help with the rising drugs costs, President Bush stated that until the MMA takes effect in 2006, more than 4.3 million Americans are saving up to 30% on brand-name medicines, and an even greater percentage on generic medicines, through Medicare-approved drug discount cards.¹⁷⁵ Furthermore, over 1.1 million low-income seniors would receive \$1200 through the end of 2005, which is to be used to help them purchase prescription drugs at reduced prices.¹⁷⁶ However, it is unlikely that the Secretary will implement the MMA plan; therefore, a long-term solution must be implemented.

Several bills currently before Congress would help decrease the cost of prescription drugs for consumers.¹⁷⁷ For example, the Pharmaceutical Market Access Act of 2005 (PMAA of 2005) allows importation of drugs if the drugs and the facilities in which they are manufactured are approved by the FDA.¹⁷⁸ Furthermore, in order to ensure the safety of drugs, it requires that all imported prescription drugs be packed and shipped in counterfeit resistant technology.¹⁷⁹ Other bills, such as the

171. *Id.*

172. *Id.*

173. *Id.*

174. Jason B. Saunders, *International Health Care: Will the United States Ever Adopt Health Care For All? A Comparison Between Proposed United States Approaches to Health Care and the Single-Source Financing Systems of Denmark and the Netherlands*, 18 SUFFOLK TRANSNAT'L L. REV. 711, 711 (1995) (stating that the "United States is one of the only industrialized nations that does not guarantee its citizenry basic health care").

175. George W. Bush, *Ensuring Access to Health Care*, 292 JAMA 2010, 2011 (2004) (stating George Bush's response to the question of how he would ensure that all U.S. citizens had access to the health care system).

176. *Id.*

177. These include Safe IMPORT Act of 2005, S. 184, 109th Cong. (2005); Medicare Enhancements for Needed Drugs Act of 2005, S. 239, 109th Cong. (2005); Pharmaceutical Market Access Act of 2005, S. 109, 109th Cong. (2005); Pharmaceutical Market Access Act of 2005, H.R. 328, 109th Cong. (2005); Prescription Drug Affordability Act of 2005, H.R. 563, 109th Cong. (2005); Medicare's Equitable Drugs for Seniors Act of 2005, H.R. 376, 109th Cong. (2005); Affordable Health Care Act, S. 16, 109th Cong. (2005).

178. Pharmaceutical Market Access Act of 2005, H.R. 328, 109th Cong. § 3(3) (2005).

179. *Id.* § 3(4).

Prescription Drug Affordability Act of 2005, deal mainly with Medicare beneficiaries and only focus on drug imports from Canada.¹⁸⁰

The general themes among all the bills are subsidies by the state, negotiated prices, or importation of drugs. The difficulties with importing were discussed above.¹⁸¹ Even without the difficulties, it is unlikely that President Bush would sign legislation supporting importation.¹⁸² Subsidies, on the other hand, will take large amounts of resources to keep up with the number of people who cannot afford prescription drugs. Such a plan would only make the budget deficit worse. Finally, some pieces of legislation call for the Secretary to negotiate prices with drug manufacturers. The legislation, however, does not provide how exactly the Secretary would go about doing so in order to lower prices.

D. Prescription Drug Programs in Other Countries

Prescription drugs enter the United States from various countries including Canada, Mexico, Costa Rica, India, New Zealand, Taiwan, and Thailand.¹⁸³ Since drugs from these other countries, as well as others, are attractive to many, the United States should closely analyze their safety regulations to decide if the drugs are safe enough for American consumers. The United States also may benefit from adopting other countries' regulation procedures.

Other countries seem to be able to keep their prices low enough to make drugs affordable for their residents.¹⁸⁴ The difference in prices of prescription drugs results from a combination of factors, including regulatory and legislative systems, currency, patent status, prescription requirements, and approaches to reimbursement.¹⁸⁵ Canada and several European countries have publicly funded health care systems and use an array of methods to control drug prices or manufacturers' profits and total drug expenditures.¹⁸⁶ Mainly, however, the lower drug prices result from the lack of a free market for prescription drugs in countries whose governments, unlike the United States, can impose price controls on the drugs sold within their borders.¹⁸⁷ The United States has not been able to drive down costs with its current enforcement methods and should consider looking to certain aspects of foreign regulation.

180. See generally Prescription Drug Affordability Act of 2005, H.R. 563, 109th Cong. (2005).

181. See discussion *supra* Part III.B.2.a.ii.

182. Ed Lamb, *Presidential Policies and Pharmacy: Where the Candidates Stand on Our Issues*, PHARMACY TODAY, Oct. 2004, at 2, available at <http://www.pharmacist.com/pd/pt/search=Pharmacy%20Today%20Ed%20Lamb> (stating that Bush supports laws making it illegal for individuals to buy prescription drugs from suppliers outside the United States).

183. *On Examining the Implications of Drug Importation*, *supra* note 50, at 4.

184. See, e.g., Kraus, *supra* note 16, at 536.

185. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 195 (2005).

186. *Id.* The European countries include France, Germany, Sweden, Switzerland, and the United Kingdom. *Id.*

187. Kraus, *supra* note 16, at 533.

1. *Canada*

In Canada, the prescription drug industry is overseen by Health Canada,¹⁸⁸ which is similar to the FDA. Health Canada's website states that "[d]rugs approved for use in Canada are safe. Canada's regulatory requirements for the approval of drugs are among the best and most rigorous in the world, and Canada has one of the best safety records."¹⁸⁹ The Department conducts regulatory reviews of drugs to make sure that they are safe and effective and meet certain standards of quality before they are approved for sale.¹⁹⁰ Health Canada continues to monitor the drugs once they are available in the market.¹⁹¹ Each province, through its College of Pharmacists, then regulates and inspects the pharmacies to ensure they are being run in a manner that is safe for consumers.¹⁹²

In 1987, under the Patent Act, the Patented Medicine Prices Review Board (PMPRB) was created

to protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive. . . . [and] to contribute to informed decisions and policy making by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.¹⁹³

Under the Patent Act, new drug prices are limited to prices of other drugs that are prescribed for the same disease as well as to prices at which the drug is sold in the six European countries and the United States.¹⁹⁴ For a given drug, the price is limited by the Canadian Consumer Price Index, but in no case may it exceed the price set by the PMPRB.¹⁹⁵

Because Canada's prescription drug industry is heavily regulated,¹⁹⁶ the safety of its drugs may be comparable to the United States. Canada's

188. Health Canada, Health Protection, http://www.hc-sc.gc.ca/index_e.html (last visited Oct. 26, 2005).

189. Health Canada, The Regulation of Prescription Drugs: Roles and Responsibilities, http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2004/2004_pharmbk1_e.html (last visited Oct. 27, 2005).

190. Health Canada, Drugs & Health Products: Drug Products, http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index_e.html (last visited Oct. 26, 2005).

191. Health Canada, Drugs & Health Products: Compliance and Enforcement, http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index_e.html (last visited Oct. 26, 2005).

192. See, e.g., COLLEGE OF PHARMACISTS OF BRITISH COLUMBIA, PHARMACY MATTERS 3, available at <http://www.bcpharmacists.org/resources/pdf/PhmcyMattersBrchur.pdf>; Alberta College of Pharmacists, Vision and Mandate, http://www.altapharm.org/about/vision_values.aspx (last visited Oct. 27, 2005); The Nova Scotia College of Pharmacists, NSCP Vision/Mission, <http://www.napra.org/docs/0/203/245/247/254.asp> (last visited Oct. 27, 2005).

193. Patented Medicine Prices Review Board, About the PMPRB, <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=175&mp=87> (last visited Oct. 24, 2005) (discussing the dual role of the PMPRB).

194. Benjamin A. Drabiak, *Reimportation of Prescription Drugs: Long-Lasting Relief or Short Term Analgesic?*, 4 WASH. U. GLOBAL STUD. L. REV. 135, 146 (2005).

195. Halser, *supra* note 129, at 553-54.

196. See Health Canada, The Regulation of Prescription Drugs, *supra* note 189 (stating that the "Department conducts regulatory reviews of drugs to ensure there is sufficient evidence of safety, efficacy and quality before they authorize their sale").

regulation may even be better than that of the United States because each individual government is responsible only for what is sold in its state or province.¹⁹⁷ Unlike the FDA, which has to monitor an entire country, the provincial governments are only responsible for drug plans in their respective province.¹⁹⁸ However, even though Canadian drug prices are lower than those in the United States and their regulatory system is sound, importing drugs from Canada will cause other countries to start shipping their drugs to the United States or finding other ways to penetrate the system.¹⁹⁹ This result will make it impossible to tell which drugs have passed the regulatory standards and which are counterfeit or unsafe.

On the other hand, the United States could benefit from the PMPRB concept. If the FDA had an agency to keep watch over how high prices were being set, there would be less abuse of the monopoly status by brand-name manufacturers. The agency would not tell the manufacturer how high to price its drugs due to the free-market system. Rather, it would make sure that the manufacturer did not abuse its ability to price drugs. This may lead to a decrease in prices because manufacturers would not be able to set their prices arbitrarily. Once prices are lowered, the United States would not need to import drugs. More people would also be able to afford the drugs that they needed, which would lead to better health, especially among the senior population. The United States has the ability and resources to create an agency comparable to the PMPBR.

2. *United Kingdom*

In the United Kingdom, the National Health Service (NHS), the universal health care provider for all U.K. citizens, reimburses all drug purchases, and nearly 85% of the drugs are given to citizens at no cost.²⁰⁰ “Rather than directly regulating prices, the Pharmaceutical Price Regulation Scheme (PPRS) regulates companies’ profits on sales to the NHS.”²⁰¹ The manufacturer of the drug is free to determine the price for the drug, as long as it is less than the overall rate of return on capital for all the products sold to the NHS.²⁰² Prices can be lowered at any time, but an increase in price must be approved before being implemented.²⁰³

197. *Id.*

198. Joel Lexchin, *Price Controls for Prescription Drugs: Canada Does It, So Can the United States*, 20 CONN. J. INT’L L. 243, 245–46 (2005) (describing plans in Ontario, Quebec, and British Columbia).

199. *On Examining the Implications of Drug Importation*, *supra* note 50, at 2.

200. Creech, *supra* note 22, at 619.

201. *Id.*

202. *Id.*

203. *Id.*

Furthermore, purchasers can pay either a flat per-prescription fee or a certain amount per year for an unlimited number of prescriptions.²⁰⁴

William Hubbard, the FDA's associate commissioner, said that the United Kingdom has a "sophisticated regulatory system."²⁰⁵ However, importing drugs from the United Kingdom would cause the same problems that importing drugs from Canada would cause.²⁰⁶ Adopting the United Kingdom's structure is also not feasible in the United States, where government-sponsored health care historically has been unpopular.²⁰⁷ Although drug manufacturers would still be making money by selling to the government, they would not take kindly to a ceiling on their profits. Furthermore, the government would not be able to afford such a policy with the high number of Americans that rely on prescription drugs. Giving individuals an unlimited supply of drugs for a set fee would not be something that the American government could handle.

3. *France*

Drug costs in France remain low because it has a national health care system and a national budget for the purchase of drugs.²⁰⁸ The manufacturers have some control in setting the price of the prescription drugs,²⁰⁹ but the government usually determines the price of a new drug based on various factors.²¹⁰ Because the government reimburses the purchaser of the prescription drug, the price cannot be set too high; the reimbursement is capped by a ceiling on the health insurance funds.²¹¹ If a manufacturer sets the price of a drug, the government must approve the price before the drug qualifies for reimbursement.²¹² Next, the government determines the reimbursement price for the consumers.²¹³ This is done by analyzing data provided by the manufacturer regarding costs, sales, and investments on the drugs.²¹⁴ After that price is settled, the con-

204. *Id.*

205. Diedra Henderson, *FDA Frets Illinois Drug Import Plan May Usher in Counterfeits*, Aug. 24, 2004, <http://www.sfgate.com/cgi-bin/article.cgi?file=news/archive/2004/08/24/national/252EDTO556.DTL&type=printable>.

206. See Henderson, *supra* note 205; see also *supra* text accompanying note 199 (discussing the possibility of other countries sending drugs to the United States if imports from Canada were allowed).

207. See, e.g., W. John Thomas, *The Clinton HealthCare Reform Plan: A Failed Dramatic Presentation*, 7 STAN. L. & POL'Y REV. 83, 84 (1996) (noting that the middle class is "unwilling to relinquish" control over their health insurance).

208. Rosenfield, *supra* note 56, at 1053.

209. *Id.*

210. Creech, *supra* note 22, at 616. These factors include comparing the new drug with existing products on the market, determining its therapeutic value, and evaluating the drug manufacturer's contribution to the economy. *Id.*

211. *Id.* at 616-17.

212. *Id.*; see also Rosenfield, *supra* note 56, at 1053.

213. Creech, *supra* note 22, at 617.

214. *Id.*

sumer only pays the amount that is not reimbursed.²¹⁵ In the future, further regulation will drive prices down even more.²¹⁶

France's structure poses some of the same problems for the United States as the United Kingdom's structure. The U.S. government would not want to reimburse purchasers of prescription drugs. Likewise, manufacturers would reject a government-imposed price ceiling. Although other countries' systems work well for them, they would not be adaptable to the capitalist mindset of the United States. Because the government is opposed to providing health care, and because manufacturers are so tied to their profits, the United States would not be able to adopt any plans of foreign countries. In addition, government and private interests are intertwined in that the profits of the drug manufacturers are protected because they contributed heavily to Bush's reelection campaign.²¹⁷ As long as the government and the pharmaceutical lobby are scratching each other's backs, government-subsidized prescription drug plans will not succeed.

E. Prescription Drug Discount Cards: A Private Sector Solution

Eleven leading pharmaceutical companies have launched a drug discount card program geared toward helping the public cope with drug costs.²¹⁸ The Together Rx Access Card will provide savings of 25–40% off the retail price of nearly 275 drugs.²¹⁹ The catch: the card is only available to legal residents who are uninsured, under the age of sixty-five, ineligible for Medicare, and have no other public or private drug coverage.²²⁰ If an individual meets all those requirements, she must also meet an income requirement: the applicant must make less than \$30,000 if single, or less than \$60,000 if a family of four.²²¹

The program has been called “the latest effort by drug makers to meet public demand for their products while dispelling public anger about the prices.”²²² Proponents of the card are hoping that the discount will bring the push for legalized importation of drugs from other countries to a halt.²²³ The reasoning appears to be that only those without insurance are being hurt by high prices; those who are eligible for the card will sign up for it and importation of drugs will no longer be necessary.

215. *Id.*

216. *Id.*

217. See CAMPAIGN MONEY WATCH, BUYING A LAW: BIG PHARMA'S BIG MONEY AND THE BUSH MEDICARE PLAN (2004), <http://www.campaignmoney.org/buyingalaw/#section05>.

218. *Card Will Offer Drug Discount to the Uninsured*, ARLINGTON STAR TELEGRAM, Jan. 12, 2005, at 1A.

219. *Id.*

220. *Id.*

221. *Id.*

222. *Id.* at 4A.

223. *Id.*

However, figures show that the Together Rx Card program, which is the complement to the Together Rx Access Card, has problems. Only about 1.5 million seniors have enrolled since 2002,²²⁴ which is considerably below the number of seniors who actually need help.²²⁵ Many people feel confused by the card programs because the discount only applies to certain drugs.²²⁶ Another possible reason for the lower than expected participation in the program could be general apathy towards going to a pharmacy and using a card every time the consumer needs to purchase prescription drugs. Consumers can obtain the same discount rate for most prescriptions, if not a higher one, by simply going to a Canadian Internet site and then having the drugs mailed to their front door.²²⁷ However, the discount will help many save large amounts of money for drugs purchased at American pharmacies.

IV. RESOLUTION—WHAT DO WE DO NOW?

The American Pharmacists Association properly states that the solution must

maintain a safe drug supply, respect the patient-pharmacist-physician relationship, require valid prescriptions, assure consumer recourse for harm, prevent efforts to circumvent U.S. health care professionals, include measures to limit counterfeit and contaminated drugs, and address the differences between FDA-approved medications and foreign products.²²⁸

Importing, although potentially reducing monetary costs, will not meet many of the other requirements that a proper solution requires. Counterfeit drugs and improper labels can result in making a condition worse or even result in death. The FDA has neither the resources nor the ability to monitor each shipment of drugs or regulate foreign manufacturers.²²⁹ The FDA simply cannot be expected to keep up with the vast international pharmaceutical industry. Even if the FDA were to approve drugs from certain countries or certain foreign companies, approval would open the door for others to try to get their drugs into the United States.

224. THE TOGETHER RX™ CARD AT A GLANCE, http://www.togetherrxaccess.com/en/pressroom/TRx_Access_At-A-Glance.pdf (last visited Mar. 8, 2006).

225. THE TOGETHER RX™ CARD AT A GLANCE, *supra* note 224 (noting that an estimated eight to eleven million Medicare Recipients are eligible for the Together Rx Card).

226. See Jenny L. Phipps, *Discount Drug Cards Pay Off for Some*, Sept. 23, 2003, <http://www.bankroute.com/brm/news/insurance/discount-plans1.asp>.

227. Clifton, *supra* note 133, at 544; see also U.S. GEN. ACCOUNTING OFFICE, PRESCRIPTION DRUGS: PRICES AVAILABLE THROUGH DISCOUNT CARDS AND FROM OTHER SOURCES 4–10 (2001), available at <http://www.gao.gov/new.items/d02280r.pdf>. The General Accounting Office found that prescription drug prices for certain medications were cheaper online than at the surveyed local pharmacies. *Id.*

228. *On Examining the Implications of Drug Importation*, *supra* note 50, at 4.

229. Lisa Schultz Bressman, *Judicial Review of Agency Inaction: An Arbitrariness Approach*, 79 N.Y.U. L. REV. 1657, 1697 (2004) (acknowledging the limits on resources and priorities of the FDA).

Another possible solution involves convincing drug manufacturers to agree to lower prices. However, due to the free market system in the United States, manufacturers will never agree to lower prices when they are free to set them as high as they wish. Even though price controls in other countries benefit consumers by creating lower prices, they discourage research and development and competition in the pharmaceutical industry.²³⁰ Manufacturing a drug in the United States generates high costs that companies undoubtedly want to recover.

Government subsidies or reimbursements, though they have worked in other countries, are not feasible in this country. Figures from 2004 show that the current annual national deficit is around \$665 billion dollars.²³¹ Considering that the United States has long opposed government-funded health care, it does not seem the government would even consider such a step, especially now with the deficit being so high.

There are two possible long-term solutions at this time. First, the federal government could decrease the number of years that a patent is available for the brand-name drugs. This will bring generic drugs, which are just as safe and effective as brand-name drugs and, in most instances, more affordable, to market faster. Because new illnesses and diseases are constantly surfacing, new drugs are constantly being created. Newer drugs, which provide quicker relief or require smaller dosages, are also being created to replace existing drugs. In order to let every consumer benefit from these drugs, the patent protection term should be decreased so the drugs are accessible. Although generics may not be available for all drugs, they are available for most. Many of the people who are burdened by the costs of drugs take more than one prescription. It is a safe assumption that generics are available for most of what they take. Congress should be free to determine a lower protection term after taking into account the needs of the industry and the consumer. Congress will not have to worry about the pharmaceutical lobby if it adequately protects the industry's needs.

The other solution is creating a FDA-run agency, similar to Canada's PMPRB, to oversee the pricing process of manufacturing companies. Manufacturers would still be free to set prices to recover costs and make a profit, but the agency would make sure that there is no abuse in determining the price. The agency would work by making manufacturers disclose the components that determine the price of various drugs. The disclosure requirement would ensure that prices are not set arbitrarily. This would differ from price controls because it would only regulate abuse of the free market privilege. Even though neither solution is com-

230. Kraus, *supra* note 16, at 533. Studies have found that between 1970 and 1992, American companies produced 42.8% of the newly discovered drugs, compared to 14% for the United Kingdom and 3% for France. *Id.*

231. L. Josh Bivens, *Debt and the Dollar: The United States Damages Future Living Standards by Borrowing Itself into a Deceptively Deep Hole* (Dec. 14, 2004), <http://www.epinet.org/content.cfm/Issuebrief203>.

pletely satisfactory, they are viable solutions for a country that encourages lobbying, continuing innovation, and carrying on business in a free market.

V. CONCLUSION

For the time being, individuals such as the Andrews will have to continue working multiple jobs and cutting down other costs so they can afford the drugs they desperately need. The U.S. government must take steps to help the country solve this problem. Although the ban on importation may be a wise idea, it is time the United States considers other solutions instead of worrying about closely policing illegal imports. If another solution is reached, imports will automatically stop: no consumer would put her life at risk if cheaper drugs are available in the United States. Moreover, inaction will only make the situation worse at a time when more people are attaining an age when drugs are their only hope to improve their health. The pain of affordable pricing seems to have no fully satisfactory cure, and the federal government and drug manufacturers are too rigid to institute any major changes.