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Comments

To the U.S. Government: Whether or not Reimportation is the Answer, Something MUST be Done to Help Americans Afford Their Necessary Prescription Drugs!

Anthony F. Andrisano Jr.*

Roland and Carolyn Watson, 74 and 72 respectively, combine to take thirty-two prescriptions for their numerous health disorders, which include diabetes, renal failure, congestive heart failure, and Parkinson's disease.¹ Although they have some coverage through a Kaiser Permanente health plan and the Department of Veterans Affairs, they still expend about \$8,000 a year in out-of-pocket drug prescription expenses.² Unfortunately, Roland and Carolyn are not alone. There are many American citizens, especially seniors, who are finding that they

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1. Abigail Trafford, *Second Opinion: The Great Pharmacy to the North*, THE WASHINGTON POST, Sept. 30, 2003, at HE01.

2. *Id.*

need to choose between taking essential medications and paying for the basic necessities of life.³ In fact, approximately twenty percent of Americans are unable to afford some or all of their prescription drugs.⁴ Moreover, these skyrocketing health costs are also posing serious challenges to many city, state, and federal budgets.⁵ Congress continually fails to address this critical issue and many Americans, like Roland and Carolyn Watson, are turning to foreign countries, such as Canada or Mexico, to fulfill their prescription needs.⁶

Turning to foreign markets allow Americans, on average, to purchase their necessary prescription drugs for forty percent less than in the American market.⁷ For example, Actos, which treats diabetes, sells in the United States for \$516.63. The same quantity of Actos sells in Canada for only \$268.52, amounting to a forty-eight percent difference.⁸ Similarly, a three-month supply of the anti-cholesterol drug Lipitor, the world's top-selling prescription drug, sells in the United States for \$208. Canada sells the same quantity of the drug for only \$132, amounting to a thirty-seven percent difference.⁹ These vast differences in prices on top

3. Jarret T. Barrios and Michael Festa, *A Free Market for Medicines*, BOSTON GLOBE, Sept. 21, 2003, available at http://www.boston.com/news/globe/editorial_opinion/oped/articles/2003/09/21/a_free_market_for_medicines?mode=PF (last visited Feb. 15, 2005). One elderly woman regularly signed over her Social Security check to the pharmacy to pay for a blood thinner. *Id.* The nurse that collected this story stated that the elderly woman's doctor "openly wondered how she found food to eat." *Id.*

4. *State Should Join Drug Price Revolt; Tens of Millions of Dollars Could Be Saved On Health Costs for Workers and Retirees*, SAN JOSE MERCURY NEWS, Sept. 21, 2003, available at <http://www.affordabledrugs.il.gov/article.cfm?RecNum=53> (last visited Feb. 15, 2005).

5. Wyn Snow, *FDA Strangling Consumer Health* (Nov. 6 2003), available at http://www.supplementquality.com/news/skyrocketing_drug_costs.html (last visited Feb. 15, 2005). While the high cost of prescription drugs may only be the "tip of the iceberg," (concerning city, state and federal budgets) "it is the most visible and easiest to attack." *Id.*

6. Trafford, *supra* note 1.

7. Joe Biesk, *Auditor: State could save millions by importing drugs*, LEXINGTON HERALD-LEADER, Sept. 28, 2004, available at <http://www.kentucky.com/mld/kentucky/news/local/9781516.htm> (last visited February 15, 2005). There are various other reports on the percentage Americans can receive from purchasing their prescription drugs from Canada with some sources asserting that prescription drugs reimported from Canada are up to seventy-seven percent cheaper. See Bloomberg News, *Drug firms sued over prices, Suit says Canadian medicines kept out*, Aug. 27, 2004, available at http://www.boston.com/business/markets/articles/2004/08/27/drug_firms_sued_over_prices/ (last visited Feb. 15, 2005).

8. Tim Jones, *Seniors find Canada is Refuge from Drug Prices; U.S. costs leave no choice, they say*. CHICAGO TRIBUNE, Sept. 21, 2003, at 1. These are only two of the many examples within this article—the price comparisons are based on prices taken on July 16, 2003 at Walgreen's in the United States and at the MediMart Pharmacy in Canada. *Id.*

9. *Drugs up to 80 percent cheaper in Canada*, PROVIDENCE JOURNAL-BULLETIN, Nov. 6, 2003, at A10. This is one example of the ten prescription drugs that were surveyed and found to be up to eighty percent cheaper in Canada—the prices from

of the current economic conditions¹⁰ encourage Americans, especially those struggling to make ends meet, to explore their options in pursuing their prescription drug needs from foreign markets.

These options, or reimportation¹¹ channels, have become extremely easy to utilize. At first, any American who wished to exploit the cheaper Canadian prices had to travel across the border, find a Canadian doctor willing to rewrite the prescription, and then take the prescription to a Canadian pharmacy.¹² Approximately ten million United States citizens *per year* utilize this reimportation channel and personally reimport their prescription drugs into the United States.¹³ While this channel genuinely helps those Americans who happen to live reasonably close to a foreign border, it does very little for those Americans living farther away.¹⁴

The Internet has proven to be another useful means of obtaining prescription drugs, because it allows individuals to simply go to an Internet website and order the necessary prescription drugs.¹⁵ In 2003,

Canada were taken from CanadaRx, a Toronto-based company, and the United States prices were taken from the Web sites of CVS Corporation and Walgreen Company. *Id.* The biggest price difference came from the antipsychotic drug Risperdal, which was eighty percent cheaper in Canada. *Id.*

10. The weakness of the Canadian dollar favors Americans. See Nicolas P. Terry, *Prescriptions sans Frontieres (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, 207 (2004).

11. John A. MacDonald, *Drug Battle Heats Up*, THE HARTFORD COURANT, Sept. 18, 2003. Experts use the term reimportation because most prescription drugs are manufactured in the United States, sent to other countries, where price controls are in effect, and then reimported by Americans looking for savings. *Id.*

12. *Id.* United States Senator Mark Dayton pays for seniors Americans to take bus trips to Canada. *Id.* The seniors would bring their prescriptions written by a U.S. physician, have a Canadian physician rewrite the prescription, and then submit it to a Canadian pharmacy. *Id.* See also Markian Hawryluk, *Drugs Without Borders: When Prescription Drugs Go over the Line*, AMNEWS.COM, (Oct. 22/29, 2001), available at <http://www.amednews.com/2001/gvsa1022> (last visited Feb. 15, 2005). This article demonstrates that many political candidates and seniors groups from northern states have organized bus trips to purchase Canadian prescription drugs. *Id.*

13. Terry, *supra* note 10, at 203 (citing Mary Pat Flaherty & Gilbert M. Gaul, *Millions of Americans Look Outside U.S. for Drugs*, THE WASHINGTON POST, Oct. 23, 2003, at A1). In order to save money, many individuals or organizations organized bus trips to Canada. Mike Hall, *What Drug Companies Aren't Telling YOU*, available at http://www.aflcio.org/aboutaflcio/magazine/0503_bigfix.cfm (last visited Feb. 15, 2005). For example, the Alliance for Retired Americans organized a bus trip to Canada, which entailed 375 seniors saving more than half a million dollars on their prescription drugs. *Id.*

14. For instance, a resident in the middle of Kansas would find it extremely hard to routinely travel across the Canadian or Mexican border simply to obtain prescription drugs. *But see* Hawryluk, *supra* note 13. In a survey taken at a Mexican border crossing, one doctor observed individuals from thirty-seven different states reimporting prescription drugs. *Id.*

15. For a more in-depth analysis of Internet pharmacies, see Linda C. Fentiman, *Internet Pharmacies and the Need for a New Federalism: Protecting Consumers While*

approximately eighteen percent of online United States households purchased prescription drugs online, a number that is expecting to rise to twenty-seven percent in 2004.¹⁶ Even with these rising statistics, many Americans, especially seniors, are still finding it very difficult to obtain affordable prescription drugs.¹⁷ Most Senior Americans are not particularly Internet savvy and, thus, are unable to take advantage of the ease the Internet provides.¹⁸

Furthermore, some Americans are deterred from using Internet suppliers because there has been evidence that some Internet drug suppliers pretend to be based in Canada when they are actually based in other countries that do not have the same safeguards as the United States or Canada.¹⁹ Many of these Internet suppliers obtain their prescription drugs illegally from wholesalers or by other undisclosed, unregulated sources that have been deemed counterfeit.²⁰ For instance, in Florida, nineteen people were indicted on charges of watering down or selling counterfeit drugs to fulfill prescriptions for consumers through Internet businesses.²¹ Moreover, the National Association of Boards of Pharmacies estimates that only 275 of the 400 U.S.-based online pharmacies in operation offer legitimate prescription drugs; the remainder having undetermined business practices.²²

An entrepreneur, Carl Moore, recognized these problems and attempted to rectify them by establishing storefront distributors across

Increasing Access to Prescription Drugs, 56 RUTGERS L. REV. 119, 126-132 (2003).

16. Terry, *supra* note 10 at 183 (citing Eric G. Brown with Bradford J. Homes et al., *Forrester's Top 10 Healthcare Predictions for 2004* (December 15, 2003), available at <http://www.forrester.com/ER/Research/Brief/0,1317,33444,00.html> (last visited February 15, 2005)).

17. Theresa Agovino, *Entrepreneur Fills an Order for Trouble*, ST. LOUIS POST-DISPATCH, Oct. 8, 2003.

18. *Id.* The owner of the original storefront distributor, Rx Depot, first operated a website offering the same service, but, because most of his customers were seniors and not particularly Internet savvy, few were utilizing the website. *Id.*

19. Terry Hillig, *Critics are wary of Illinois' Drugs-From-Canada*, ST. LOUIS POST-DISPATCH, Sept. 20, 2003. This article quotes Mike Patton, a spokesman for the Illinois Pharmacists Assoc., stating that "some suppliers of drugs on the Internet pretend to be based in Canada when they are actually [based] in other countries." *Id.*

20. Jack Nicolis, *Don't Allow Import of Canadian Drugs*, THE JOURNAL NEWS (New York) Nov. 17, 2003. A report by a United States research firm found that only thirty percent of Canadian Internet pharmacies selling prescription drugs to United States citizens were not affiliated with any licensed pharmacy. *Id.*

21. Steve Stanek, *Illinois Gov. Ignores Rx Warning*, HEALTH CARE NEWS, Nov. 2003, at 17. In addition to the Florida indictment, a counterfeit version of Pfizer's Lipitor was discovered in Nebraska after pharmacists and patients complained the medicine tasted unusually bitter and dissolved too quickly. *Id.*

22. Anna Wilde Matthews and Nick Wingfield, *Drugstore.com Battles Portals with Imported-Drug Ads*, WALL ST. J., Oct. 31, 2003. Additionally, only fifteen of the four-hundred U.S.-based online pharmacies are certified by state regulators. *Id.*

the United States.²³ These storefront distributors, known as Rx Depot or Rx Canada,²⁴ became the easiest and most popular channel for Americans to reimport prescription drugs from Canada. An American seeking less expensive prescription drug prices simply needed to go to one of the storefront distributors, hand over a prescription, pay a cheaper price, and wait for the prescription to arrive.²⁵ As this comment will further express, a recent District Court decision has eliminated the use of Storefront Distributors,²⁶ further hindering many Americans search for affordable prescription drugs.

The overall reimportation concern is very complex and involves many significant issues. This Comment intends to address many of these reimportation issues by breaking each issue into easily understood components.²⁷ Part I of this Comment will provide an overview of the reimportation debate, addressing the concerns expressed by those in favor of reimportation and by those who oppose it. Part II will address the actions the states have taken on this issue of reimportation. Part III will give an in-depth synopsis of the judicial action taken by the FDA through the Department of Justice. Finally, Part IV of this Comment concludes with a brief assessment of the 2003 Medicare Prescription Drug Improvement and Modernization Act²⁸ and provides a suggestion on how to deal with the issue of reimportation.

I. The Reimportation Debate

The United States is the only industrialized country where drug manufacturers set prices without government interference.²⁹ This “free market system”³⁰ allows a pharmaceutical company to determine and set

23. *Id.* Carl Moore is the founder of a chain of approximately eighty-five storefront distributors, known as Rx Depot or Rx of Canada. *Id.*

24. *Id.*

25. Gardiner Harris, *U.S. Moves to Halt Import of Drugs From Canada*, N.Y. TIMES, Sept. 10, 2003, at C2. Rx Depot has now accumulated eighty-five stores in twenty-six states.

26. See discussion *infra* Part III.

27. Canada is the country that most Americans and storefront distributors import prescription drugs from. Therefore, this Comment will direct its attention mainly to issues concerning the reimportation of drugs from Canada—although other countries will also be discussed.

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

29. Gardiner Harris, *Pfizer Moves to Stem Canadian Drug Imports*, N.Y. TIMES, Aug. 7, 2003, at C1, Col. 2. The pharmaceutical industry earns approximately half of its revenues and most of its profits in the United States because, unlike other industrialized nations, the United States government does not control drug prices. *Id.*

30. A free market system involves companies setting the price of their products according to what they think the market will bear. Helkei Tinsley, Comment, *Prescriptions without Borders: American looks to Canada for Answers to Solve the*

the price for its prescription drugs without having to provide any justification for its choice.³¹ This has resulted in a substantial increase in the price of prescription drugs in the United States.³² For instance, between 2002 and 2003, the price of Zocor and Pravachol³³ rose ten to eleven percent.³⁴ In fact, the price of prescription drugs in the United States has increased seven to eight times the standard rate of inflation in America.³⁵

Other countries, such as Canada, are not troubled with similar pricing problems because their governments' set price controls on prescription drugs by negotiating directly with pharmaceutical companies.³⁶ The pharmaceutical companies are forced to negotiate with these countries because, otherwise, they would be unable to sell in these foreign markets.³⁷ In the past, the pharmaceutical companies were able to tolerate these negotiated differences in profits because their profits in America were so substantial that it did not matter that the rest of the world was buying the drugs at a discount.³⁸ With more and more Americans buying their prescription drugs through cheaper reimportation channels, the pharmaceutical industry has changed its attitude, and is, again,³⁹ undertaking an extensive lobbying campaign⁴⁰ to help nullify

Prescription Drug Pricing Predicament in the U.S., But is Importation Really the Solution?, 25 *HAMLIN J. PUB. L. & POL'Y* 437, 440 (2004).

31. *Id.* at 440-441.

32. *Id.* at 442.

33. Both are cholesterol drugs.

34. Tinsley, *supra* note 30, at 442 (citing U.S. Representative Dan Burton (R-IN) Holds Hearing on Canadian Drug Importation before the House Comm. on Government Reform, Subcomm. on Human Rights and Wellness, 108th Cong. 10 (June 25, 2003) (testimony of U.S. Representative Gil Gutknecht (R-MN))). Further, Claritin, before going over-the-counter, rose twenty-one percent between 2002-2003. *Id.*

35. *Id.* (citing U.S. Senator John McCain (R-AZ) Holds Hearing on Cost of Prescription Drugs and Drug Importation. Before the Science and Transportation Comm., Subcomm. of S. Commerce, 108th Cong. 41 (2003) (testimony of Senator Snowe (R-ME))).

36. *Id.* at 447-48. Canada controls prescription drug prices by forcing pharmaceutical manufacturers to disclose confidential information concerning their drug pricing; based on this disclosure, the Canadian government determines an affordable wholesale price that would give a reasonable return on the patented drug. *Id.* (citing Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, *CONN. J. INT'L L.* 149, 160 (2002)).

37. Tinsley, *supra* note 30, at 448.

38. Nina Owcharenko, *Why Drug Importation is Bad Policy*, *HEALTH CARE NEWS*, Nov. 2003, at 9.

39. It is important to note that, after an expensive lobbying campaign in 1987, the pharmaceutical industry won a battle in Congress that banned the reimportation of prescription drugs into the United States. See Barrios and Festa, *supra* note 3. Since then, Congress has enacted the Medical Equity and Drug Safety Act (MEDSA), which gives the Secretary of Health and Human Services the power to allow the reimportation of prescription drugs as long as the Secretary demonstrates that these imports would pose

any efforts of legalizing reimportation.⁴¹

The United States Food and Drug Administration (FDA) has taken the side of the pharmaceutical industry by warning that reimportation of drugs presents a serious safety risk to the health of Americans.⁴² FDA Commissioner Mark McClellan actually has warned that importation “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.”⁴³ While the FDA understands that reimportation allows Americans to save money, it also realizes that “it has taken many years to build up the safety system we now have in place, and it is misguided to think it can be drastically changed quickly without negative consequences.”⁴⁴

Notwithstanding the FDA’s position, the House of Representatives passed the Gutknecht-Emerson bill⁴⁵ that would legalize imports of drugs from Canada and some other industrialized countries.⁴⁶ Although the Senate has opposed this exact bill,⁴⁷ it illustrates that there is

no additional health risks and that the imports would result in cost reductions in the United States. See Tinsley, *supra* note 30, at 453-54. Although this law was enacted in 2000, no Secretary (under the Clinton or the Bush Administration) has attempted to implement it. *Id.*

40. See Terry, *supra* note 10 at 210.

41. See discussion *infra* Part I.B.2.C.

42. It is important to note that the FDA has an “enforcement discretion policy” whereby the FDA can choose to not enforce the Federal Food, Drug and Cosmetic Act (FDCA) against individuals who travel to Canada or use the Internet to purchase prescription drugs from Canada for personal use. See, 21 U.S.C. § 956(a) (2004). See also Julie Appleby, *Firm fights for Canadian drugs; Justice Department lawsuit against U.S. Storefront—Rx Depot gains wide attention*, USA TODAY, Oct. 7, 2003, available at http://www.usatoday.com/money/industries/health/drugs/2003-10-06-rxdepot_x.htm (last visited Feb. 7, 2005). The FDA’s “personal use policy” gives United States residents the ability to reimport ninety-day supplies of drugs not available in the United States to treat serious conditions. *Id.* According to University of Texas Professor Marven Shepherd, twenty-five to forty percent of all U.S. residents who travel to Mexico bring back prescription pharmaceuticals. Hawryluk, *supra* note 12.

43. Grace-Marie Turner, *Why Drug Importation Endangers the Country’s Drug Supply*, HEALTH CARE NEWS, Nov. 2003, at 8. The FDA believes that allowing drug imports from Canada and other countries will open United States borders to unsafe, counterfeit, and contaminated drugs.

44. Marc Kaufman, *FDA’s Authority Tested Over Drug Imports; At Issue Is Whether Agency Will Lose Role in Assessing Safety of Medications*, THE WASHINGTON POST, Nov. 9, 2003, at A11. This is a quote from the FDA Commissioner Mark McClellan about how safety will be compromised if consumers continue to import drugs from foreign countries. *Id.*

45. Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. § 2(3). Unenacted bill passed by the House of Representatives on July 21, 2003 that legalizes the importation of prescription drugs from Canada and other industrialized nations. *Id.*

46. Scott Hensley, *Drug Makers Cry “Danger” Over Imports*, WALL ST. J., Sept. 22, 2003. This act was passed by a vote of 243-186. *Id.*

47. MacDonald, *supra* note 11.

overwhelming support for legalizing the reimportation of prescription drugs. The crux for this argument is that “an unaffordable drug is neither safe nor effective,” and “allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers.”⁴⁸

A. Arguments Against Importation

1. Safety

Opponents core argument against reimportation lies with the issue of safety. “In our experience, many drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality.”⁴⁹ The only way to ensure the safety of prescription drugs is to obtain the drugs within the United States; this helps to guarantee that the drugs were tracked and approved by the FDA.⁵⁰ Many pharmacies in other countries do not necessarily follow the same standards or have the same safeguards as those in the United States.⁵¹ Furthermore, many of the drugs obtained outside of the United States are counterfeit and some of the drugs sold overseas do not even have an active ingredient.⁵²

In support of this argument, FDA associate Commissioner, William Hubbard, has said that FDA inspectors and undercover investigators have found numerous instances in which medications alleged to have come from legitimate Canadian pharmacies were counterfeit, mislabeled or expired.⁵³ For instance, in Springfield, Massachusetts, the FDA staged an unusual sting operation in which agents bought insulin from CanaRx,

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

49. MacDonald, *supra* note 12. This is a quote from associate commissioner of the FDA, William K. Hubbard, which was taken from a seven-page letter addressed to the deputy attorney general of California showcasing the FDA’s opposition to importation. *Id.*

50. Leslie Boyd, *High medicine costs have some shopping across the border*, THE CITIZEN-TIMES (North Carolina), Sept. 19, 2003, available at <http://cgi.citizen-times.com/cgi-bin/story/wncbusiness/42089> (last visited February 7, 2005). Michael Overman, owner of Lord’s Pharmacy and a former member of the North Carolina Pharmacy Board, believes that the only way to ensure the safety of prescription drugs is to obtain them within the United States. *Id.*

51. *Id.*

52. *Id.* David Work, director of the North Carolina Pharmacy Board, is quoted as saying “there are a lot of counterfeit drugs outside the United States, and there are drugs being sold overseas that do not have an active ingredient.”

53. Ceci Connolly, *Iowa Plans to Procure Drugs From Canada; State Joins Growing Group Seeking Cheaper Medicines Outside the U.S.*, THE WASHINGTON POST, Sept. 24, 2003, at A02.

an Ontario-based supplier of imported drugs.⁵⁴ The insulin arrived at room temperature, which does not comply with the crucial requirement that insulin be kept refrigerated.⁵⁵

In May 2003, the FDA made an undercover purchase through Rx Depot, a storefront distributor, by downloading the necessary Rx Depot order forms and related paperwork from the Rx depot website.⁵⁶ The agent filled out the forms as though he was a patient, took the forms to Rx Depot storefront distributor and placed an order for a 100-pill package of the FDA-approved prescription drug Serzone.⁵⁷ Although the prescription the agent used only authorized sixty pills, the agent was able to order the 100-pill package offered on the Rx Depot website.⁵⁸ In late May 2003, the agent received a package from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada that contained ninety-nine pills of a foreign-manufactured version of Serzone known as APO-Nefazodone.⁵⁹ APO-Nefazodone is not generally recognized among qualified experts as being safe and effective and it does not have FDA approval of any new drug or abbreviated new drug.⁶⁰ In addition, the labeling provided by the Canadian pharmacy was far less descriptive in warning against the potential side effects than the FDA-approved packaging insert for Serzone.⁶¹

Additionally, a spot inspection conducted by FDA agents in the summer of 2003 “illustrated the real and serious health risks created by the importation of unapproved drugs.”⁶² The spot inspections occurred

54. MacDonald, *supra* note 11. The article illustrates the veracity of the FDA’s safety argument by providing an example of how reimportation can be dangerous. *Id.*

55. *Id.*

56. United States v. Rx Depot, 290 F.Supp.2d 1238, 1242-43 (N.D.Okla. 2003). This example was presented as evidence in the Northern District Court of Oklahoma by the Department of Justice to showcase the danger of allowing reimportation. *Id.* Also see discussion *infra* Part III.

57. Rx Depot, 290 F.Supp.2d at 1242-43.

58. *Id.*

59. *Id.* Even though the agent received only ninety-nine pills, the package was labeled as containing one hundred pills. *Id.*

60. *Id.* at 1243. APO-Nefazodone does not have FDA approval of any new drug or abbreviated new drug applications filed pursuant to 21 U.S.C. Sections 355 (b) or (j) and it does not have in effect a valid exemption from such approval requirements under 21 U.S.C. Section 355(i). *Id.*

61. *Id.* The Canadian instructions do not specify some of the liver failure symptoms listed on the Serzone insert. For example, it does not mention drugs that should be avoided when taking APO-Nefazodone and it does not convey the sense of urgency reflected in the Serzone insert. These substandard instructions could increase the risk of adverse events, including life-threatening liver failure.

62. Gardiner Harris, *F.D.A. Faults Quality of Imported Drugs*, N.Y. TIMES, Sept. 30, 2003, available at <http://www.aei-brookings.org/dailyreport/archives/008592.php>. This quote is taken from Mark B. McClellan, the commissioner of the FDA, after evaluating the results of a random spot inspection. *Id.*

over two three-day periods at mail processing centers in Miami, New York, San Francisco and Carson, California. The inspectors pulled out 1,153 packages that appeared from the outside to contain drugs and found that approximately 1,019 or eighty-eight percent of the packages contained unapproved drugs.⁶³

In light of these facts, opponents of reimportation argue that encouraging American consumers to purchase prescription drugs from foreign sources is counter to public policy, and that the public should know that reimportation is simply unsafe.⁶⁴ In addition, American consumers must realize that they may waive their legal rights, at least with respect to the United States court system, if they suffer an injury by a prescription drug purchased directly from Canada.⁶⁵

The crux of this argument is that the United States has a unique, closed system of drug distribution regulated by the FDA that protects Americans from counterfeit, mislabeled or otherwise adulterated drugs coming from unapproved foreign sources. Other countries, such as Canada or Mexico, do not necessarily have the same regulations or safeguards. In fact, many foreign countries do not purchase their prescription drugs solely from the United States; they acquire many of their drugs from the world market.⁶⁶ Even though many foreign countries have safe drug distribution systems in place,⁶⁷ safety concerns still arise when drugs move across borders because they are not under the monitoring and control of any regulatory agency.⁶⁸ This creates an opportunity for unscrupulous merchants to slip unapproved drugs into an otherwise safe distribution system,⁶⁹ which makes it virtually impossible

63. *Id.*

64. Nicolis *supra* note 20. Believing reimportation to be illegal because it is unsafe, this article addresses LePharmacy.com's announcement that it would be opening a storefront in Westchester County. *Id.*

65. Position Paper, *Importation of Foreign Prescription Drugs*, National Association of Boards of Pharmacy, March 2003, available at <http://www.nabp.net/ftpfiles/NABP01/foreigndrug.pdf> (last visited Feb. 7, 2005). If a problem with a prescription drug purchase from Canada actually occurs, there is little or no recourse because the actual dispenser or prescriber may be unknown. *Id.* Additionally, the National Board of Pharmacy has discovered that most, if not all, Canadian Internet pharmacies require United States, but not Canadian, patients to waive their right to sue if a medication error occurs. *Id.*

66. Nicolis *supra* note 20.

67. Bernard Simon, *Canada Rebuffs U.S. on Prescription Drugs*, N.Y. TIMES, Nov. 19, 2003, available at <http://www.globalaging.org/health/world/canadadrug2.htm> (last visited Feb. 7, 2005). The Canadian Government refused to clamp down on exports of prescription drugs to the United States because it asserts that "Canada's safety record is second to none internationally," and that the exports do not violate Canadian law. *Id.*

68. Kaufman, *supra* note 44, at A11. The FDA uses this point to dismiss any claim that Canadian drugs are safe because Canada has similar safety standards as those within the United States.

69. *Id.*

to control the flow of unapproved products into the United States. Opponents of reimportation rightfully argue that this clearly poses a serious threat to the health of Americans, because it allows the drug supply of the United States to be contaminated.

2. Intellectual property rights

Opponents of the reimportation of prescription drugs also argue that reimportation violates the United States Constitutional rights of pharmaceutical companies.⁷⁰ While cheaper drug prices sound like a good idea, they can wind up destroying the free-market motivation that produced the public good in the first place.⁷¹ Pharmaceutical companies in the United States sink millions of dollars into research, testing, development, and patents to produce some of the most sophisticated, effective, and safe medicines in the world.⁷² A recent study by the Tufts Center for the Study of Drug Development found that pharmaceutical manufacturers spend around \$897 million to develop a new drug.⁷³ If these drugs are sold for below market value, then who is going to pay for the pharmaceutical companies heavy investment in research, development, and production?⁷⁴ More precisely, who will pay the drug companies for their property rights from which the public benefits?

Article 1, Section 8 of the United States Constitution authorizes Congress “to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”⁷⁵ Furthermore, the Fifth Amendment states that “. . . [n]or shall private property be taken for public use, without just compensation.”⁷⁶ If Americans are able to reimport drugs from Canada for cheaper prices, then these aforementioned rights of pharmaceutical companies would be manifestly violated.⁷⁷ Additionally, the pharmaceutical companies will most likely

70. Nancie G. Marzulla, *The Property Rights Pill: Why It's Good Medicine*, Urban Spectrum, Oct. 2003, available at <http://www.defendersproprights.org/regulatory/030924.asp> (last visited Feb. 7, 2005). This article, written by the President of Defenders of Property Rights, addresses the constitutional protection of the pharmaceutical companies' intellectual property rights. *Id.*

71. *Id.*

72. *Id.*

73. Owcharenko, *supra* note 38, at 9. Only one out of every five drugs that reach human trials ultimately will be approved for marketing. *Id.* This crucial investment in research and development is supported by market-oriented countries (such as the United States), and is thwarted by governments in price-controlling countries (such as Canada). *Id.*

74. Compare discussion *infra* Part I.B.2.

75. U.S. Const. art. I, § 8.

76. U.S. Const. amend. V.

77. Marzulla, *supra* note 71.

suffer losses, which, in turn, will force the industry to be unable to utilize its resources in the research and development of new, innovative prescription drugs.

Furthermore, one of the reasons many pharmaceutical companies are located within the United States is because of the country's commitment to protecting intellectual property rights.⁷⁸ Both inventors and investors have always been confident that the laws and Constitution of the United States will protect their inventions and their investments.⁷⁹ Opponents of reimportation believe that by allowing reimportation, the United States will undoubtedly diminish confidence in the free-market motivation that has always existed by creating a chain of events that would weaken the intellectual property rights of pharmaceutical manufacturers.⁸⁰

This chain of events will first start with Canadian pharmacies reimporting prescription drugs to United States citizens, which logically will result in less prescription drug sales within the United States. In an attempt to prevent this from occurring, the pharmaceutical companies will limit, if not completely cut-off, its sales to Canadian pharmacies.⁸¹ The Canadian government would then have to negotiate with a generic manufacturer to produce or sell the drugs the country would need to satisfy the prescription needs of its citizens. These generic companies would most likely not obtain the approval of the pharmaceutical company that holds the patent, which would allow the generic company to make profits from a drug that it has spent very little, if any, money in researching or developing.⁸² This, in turn, would weaken United States intellectual property rights, because the United States patent holder would have incurred the expense of researching and developing the drug while a foreign generic company was able to reap the benefits. This weakened respect for intellectual property rights, a serious unintended consequence of allowing reimportation, would create repercussions that most likely would be felt worldwide.⁸³

78. *Id.*

79. *Id.*

80. Owcharenko, *supra* note 38, at 9. This article states that the allowing reimportation of prescription drugs will create the serious unintended consequence of weakening intellectual property rights, which would cause severe repercussions that would be felt worldwide. *Id.*

81. See Ceci Connolly, *Pfizer Cuts Supplies to Canadian Drugstores—Sales Are Halted to Reimporters of Bargain Drugs*, THE WASHINGTON POST, Feb. 19, 2004, at A10. Pfizer, the world's largest drug manufacturer, wrote a letter to Winnipeg-based Universal Drug Store and half a dozen other companies informing them that "effective immediately, your pharmacy is no longer approved to purchase Pfizer products from Pfizer Canada's authorized distributors." *Id.*

82. *Id.*

83. *Id.*

The pharmaceutical companies could assert various International agreements such as the WTO Agreement on Trade-Related Aspects of Intellectual Rights (TRIPS)⁸⁴ and the North American Free Trade Agreement (NAFTA),⁸⁵ which require governments to protect intellectual property rights because of the common recognition that strong property rights protection fosters an effective trade regime.⁸⁶ Those countries that are part of these trade agreements, however, are able to circumvent patent protections by declaring a national health emergency, which, basically, strips a patent from a particular pharmaceutical company and allows a generic manufacturer to steal the formula and produce a generic drug.⁸⁷ For example, the African government was able to circumvent patent protections and purchase generic prescription drugs, without violating TRIPS or NAFTA, by declaring a national health emergency due to the rise in AIDS cases within the country.⁸⁸

A similar situation would exist if United States pharmaceutical companies decided to boycott prescription drug sales to Canada. Canada most likely would be unable to provide its citizens with the proper prescription drugs, which, in turn, would give the Canadian government the right to declare a national health emergency and allow Canada to circumvent TRIPS's and NAFTA's patent protections by purchasing generic prescription drugs. This would allow foreign companies to sell these generic drugs and reap the benefits of the drug in violation of the patent held by the pharmaceutical company responsible for researching, developing, and producing the drug.

While this may not violate an international treaty, opponents of reimportation believe it discourages drug companies from developing new drugs and, thus, creates repercussions worldwide. Why would a pharmaceutical company spend exorbitant amounts of money on researching and developing new drugs when it can simply wait for another company to do so and then steal the formula to sell to foreign countries? Opponents of reimportation adamantly answer this question by saying "they won't." These companies will not expend money if the

84. Agreement of Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299, 326.

85. North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.-U.S., 107 Stat. 2057, 32 I.L.M. 605.

86. Marzulla, *supra* note 70.

87. *Id.* Although taken away, certain individual countries, at one time, were able to invalidate certain patents for particular reasons. See Luke W. Cleland, *Modern Bootlegging and the Prohibition on Fair Prices: Last Call for the "Repeal" of Pharmaceutical Price Gouging*, 15 ALB. L.J. SCI. & TECH. 183, 201 (2004).

88. Marzulla, *supra* note 70.

traditional intellectual property protections are not in place. This, in turn, would carry worldwide repercussions because the pharmaceutical industry would put less money in the research and development of new drugs—which hinders the advancement of medicine.

B. In Favor of Importation

1. It is About Profits, Not About Safety

Proponents of reimportation believe the issue of drug importation circles around the profits of pharmaceutical companies, not the safety of reimported drugs. Over the past few years the U.S. economy has struggled under a recession with unemployment reaching its highest level since 1995.⁸⁹ But one sector of the U.S. economy continues to prosper—the pharmaceutical industry.⁹⁰ In 2001, corporate profits sank for the average Fortune 500 Company, but the pharmaceutical industry (on the Fortune 500 list) watched as their profits soared by thirty-three percent.⁹¹ While working families are struggling to pay for necessary medicines and to deal with an increasingly bleak economic picture, the pharmaceutical industry has continued to prosper.⁹²

In addition to the pharmaceutical industry's prosperity, the top executives in this industry were not exactly struggling to make ends meet. In fact, the top five most highly paid industry executives pocketed more than \$183 million in compensation during the 2001 calendar year.⁹³ This does not even take into account stock options, which can add millions of dollars to an executive's income.⁹⁴

While the pharmaceutical industry and its "big-time executives" rake in vast sums of money, proponents of reimportation point out that working families and seniors struggle with the high cost of prescription drugs. In 2000, about twenty-nine percent of Americans failed to fill a prescription simply because they were unable to afford to.⁹⁵ This is largely attributable to the fact that the cost of prescription drugs in the United States has been increasing at a rate of about fourteen percent

89. Hall, *supra* note 13.

90. *Id.*

91. *Id.* The nine largest pharma companies raked in \$30.6 billion in 2001. *Id.* Over the past decade, drug companies' profits represented an 18.5 percent return on revenue as opposed to a median return of Fortune 500 companies of 3.3 percent. *Id.*

92. *Id.*

93. *Id.* Additionally, the average compensation for the top twenty-five pharmaceutical executives was \$6 million. *Id.*

94. *Id.* For example, in 2000, the chairman and CEO of Bristol-Myers Squibb held unexercised options valued at \$227.9 million. *Id.*

95. *Id.*

annually, sixteen percent from 2000-2001.⁹⁶ With the aforementioned prosperity of the drug industry and its executives, are these price increases really necessary?

Proponents of reimportation would answer this question in the negative, and then, in addition, point to the price of prescription drugs in foreign markets. On average, brand-name prescription drugs, when compared to U.S. prices, are fifty-three percent cheaper in Italy, fifty-five percent cheaper in France, sixty-four percent cheaper in Sweden, sixty-five percent cheaper in Germany and sixty-nine percent cheaper in the United Kingdom.⁹⁷ It is even more surprising when U.S. prices are compared to the prices of its close neighbor, Canada, which, on average, are sixty-two percent less than the U.S. for the exact same prescription drugs.⁹⁸ To that end, even though the pharmaceutical industry is thriving in the American market, American working families and seniors are burdened with outrageous drug prices while foreign markets are receiving the benefit of cheaper prescription drugs.⁹⁹ Now, when struggling Americans are trying to use the foreign market to attain affordable prescription drugs, the pharmaceutical industry says these drugs are unsafe.

This begs the question—is the drug industry opposing reimportation of prescription drugs because these drugs are actually unsafe or because it wants to ensure it can continue to make vast profits from the United

96. Barrios and Festa, *supra* note 3. Although prescription drug spending in the United States historically increases about fourteen percent annually, from 2000 to 2001, prescription drug spending grew sixteen percent. *Id.*

97. Hall, *supra* note 13.

98. *Id.* See also, Hawryluk, *supra* note 12. This article contains a chart comparing U.S. prices at Drugstore.com with prices obtained by MedicineAssist, an online service allowing seniors to order from pharmacies in Canada. *Id.* Moreover, Dr. Alan Sager of Boston University has estimated that purchasing U.S. prescription drugs at Canadian prices would result in a \$38.4 billion per year savings. Terry, *supra* note 10 at 207-08 (citing Hawryluk, *supra* note 12). A congressional estimate is even more optimistic; American consumers could save approximately \$635 billion per year. *Id.* (citing Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. § 2(5)).

99. To illustrate, both spouses of an elderly American couple have been suffering from high blood pressure and cholesterol. Connolly, *supra* note 53, at A02. Since the couple is unable to afford to purchase a full dose of necessary prescription drugs, the couple has been taking free samples of Lipitor, which they have received from their doctor, and splitting it in half. *Id.* Proponents of reimportation quickly point out that by utilizing foreign sources, this elderly couple would more likely be able to afford enough Lipitor to keep both of their high blood pressures under control. *Id.* Also see Jones *supra* note 9. Ray Park, an employee who worked as a train operator for LTV Steel for forty-one years, lost his health benefits when LTV Steel filed for bankruptcy in late 2000. *Id.* Mr. Park is a diabetic who has had open-heart surgery and pays approximately \$1,315 a month for drugs to control his diabetes, cholesterol, and high blood pressure. *Id.* By crossing the border to Canada, Mr. Park was able to obtain almost a year's worth of prescription drugs for only \$999. *Id.*

States, the one market where the government does not regulate the price of prescription drugs? Proponents of reimportation argue the latter, believing that foreign-market drugs pose no larger danger to Americans than domestically manufactured medications.¹⁰⁰ This argument carries a lot of weight considering Dr. Peter Rost, vice president of the drug company Pfizer, publicly criticized his own industry by announcing his belief that “patented drugs from Europe or Canada may even be safer than buying drugs in the United States.”¹⁰¹ For instance, Canada’s equivalent to the FDA, Health Canada, conducts similar regulatory reviews of drugs to ensure there is “sufficient evidence of safety, efficiency and quality before they authorize their sale in Canada.”¹⁰² Furthermore, the Canadian health ministry has assured the FDA that all imported drugs will be equally safe and effective whether they are for use by Canadians or for export.¹⁰³ With these assurances of safety, proponents of reimportation hold firmly to their position that the pharmaceutical industry is more concerned with profits and less concerned with safety.

Proponents of reimportation also realize that the pharmaceutical industry is not alone in its position; the FDA also believes that reimportation presents a serious safety risk to the health of Americans.¹⁰⁴ But, in almost every other sector of the American economy, Americans are allowed to benefit from the cost savings born of free market competition, safely.¹⁰⁵ Rather than banning only those prescription drugs that do not measure up to the FDA standards and making sure unapproved drugs do not enter into the United States, the FDA spends its time scaring Americans into compliance with a law that inhibits them

100. See The ChamplainChannel.com, *Industry Executive Calls for Drug Reimportation: Vermont Lawmakers Consider Proposal* (Jan. 14, 2005), at <http://www.thechamplainchannel.com/health/4082083/detail.html> (last visited Feb. 9, 2005) [hereinafter ChamplainChannel].

101. *Id.* Dr. Rost further stated, “Others are paid to oppose reimportation and one day I believe they too will be held responsible, just like the tobacco executives have been. So, why am I, a drug company executive, standing before you today to speak out? Like many others in my industry, I joined the pharmaceutical industry to save lives. . . .” *Id.*

102. Health Canada, *The Regulation of Prescription Drugs: Roles and Responsibilities* (May 2004) available at http://www.hc-sc.gc.ca/english/media/releases/2004/internet_pharmacybk1.htm (last visited Feb. 11, 2005). Once in the market, Health Canada monitors its use for ongoing safety and effectiveness, and continues to ensure that manufacturers comply with Canada’s Regulations. *Id.*

103. Marc Kaufman, *Canada to Guarantee Imported Medicine*, THE WASHINGTON POST, May 8, 2003, at A06.

104. Turner, *supra* note 43, at 8.

105. Barrios and Festa, *supra* note 3. Whether it is a kiwi from New Zealand or a Kia automobile from South Korea, federal law has always allowed Americans to participate in free market competition. *Id.*

from participating in the free market.¹⁰⁶ If the FDA is worried about unsafe drugs entering into the United States, it should set up a regulatory system that allows the FDA to review and license companies seeking to import prescription drugs from Canada.¹⁰⁷ This would ensure the FDA one hundred percent compliance with federal law, while still providing a route to safe purchases of cost-saving drugs.¹⁰⁸

Proponents of reimportation want American lawmakers to realize that safety should not be the only issue surrounding the importation of prescription drugs; they must concentrate on the profits of the pharmaceutical industry. Although the pharmaceutical industry has a right to use the American market to maximize its profits, it must realize that American working families and seniors also have a right, pursuant to free market competition, to pursue cheaper prescription drugs in foreign countries. The industry's safety argument is quashed, considering Health Canada has similar regulations. If the pharmaceutical industry chooses to sell drugs to foreign countries at cheaper prices, then it should suffer the consequences—not hide behind the fallacy issue of safety.

2. Research and Development Costs and the Costs of Advertising

The pharmaceutical industry and critics of reimportation argue that higher prices for prescription drugs are necessary for the research and development that has made the United States the global engine for pharmaceutical innovation.¹⁰⁹ Proponents of reimportation attack this argument on several grounds: First, the pharmaceutical industry is simply playing a research and development “Scare Card” because it actually does not spend as much on research and development as it claims; second, even assuming, *arguendo*, that the pharmaceutical industry is spending as much as it says it is on research and development, the burden should not be placed entirely on U.S. citizens; and finally, if research and development is so important, then why does the industry spend a considerable amount more on advertising?

106. *Id.* This is even assuming, *arguendo*, that prescription drugs from foreign markets are unsafe. The vice president of Pfizer, a senior executive of a major drug company, stated that he believed foreign-made drugs pose no larger danger to Americans than domestically manufactured medications; “however painful it is for me to say this, I think patented drugs from Europe or Canada may even be safer than buying drugs in the U.S.” ChamplainChannel, *supra* note 100.

107. *Id.* The authors of this article believe that this is the best solution to the debate on drug importation.

108. *Id.*

109. Kaufman, *supra* note 44, at A11.

a. The Pharmaceutical Industry's R&D "Scare Card"

The drug industry claims that, on average, the research and development costs for a new drug is approximately \$500 million.¹¹⁰ The industry argues that if anything is done to moderate prices or profits in the United States, then research and development will suffer and "it's going to harm millions of Americans who have life-threatening conditions."¹¹¹ In other words, the high prescription drug prices allow for continued research and development funding, and any decrease in pricing would eventually result in decreasing research and development, which would finally harm the end consumer.¹¹²

Proponents of reimportation understand this argument, but believe the \$500 million cost for researching and developing a new drug is heavily inflated.¹¹³ Proponents argue that the actual costs of research and development are inflated because they fail to account for public contributions, tax credits, and other sources of contributions that actually decrease the final cost to the pharmaceutical companies.¹¹⁴ In support, proponents of reimportation simply point to Pharmaceutical Research and Manufacturers of America's own assertions: during the 1990's, drug companies spent \$139.8 billion on research and development; during this same period, the FDA approved 857 new drugs; after simple division, this suggests that only \$163 million was spent on research and development of a single new drug in the 1990's.¹¹⁵ Moreover, this

110. Public Citizen, *Rx R&D Myths: The Case Against the Drug Industry's R&D 'Scare Card,'* at <http://www.citizen.org/publications/release.cfm?ID=7065> (last visited Feb. 12, 2005) [hereinafter Public Citizen]. A 2003 study conducted by the Tufts Center for the Study of Drug Development concluded that it costs \$897 million to develop a new prescription drug. Tinsley, *supra* note 30, at 443 (citing The Tufts Center for the Study of Drug Development, *News Release: Total Cost to Develop a New Prescription Drug, Including Cost Of Post-Approval Research, is \$897 million,* at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29> (last visited Mar. 6, 2004)). These studies, however, have been heavily criticized for being inflated. *Id.* at 444.

111. Public Citizen, *supra* note 110. Pharmaceutical Research and Manufacturers of America's (PhRMA) president made this statement in defending the high price of prescription drugs in the U.S. *Id.*

112. Tinsley, *supra* note 30, at 446 (citing Michele L. Creech, Comment, *Make a Run for the Border: Why the United States Gov'n't is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 600 (2001)).

113. Public Citizen, *supra* note 110. It is important to note that Public Citizen only used domestic expenditures in its analysis, assuming that foreign expenditures of U.S.-owned firms will be directed primarily to non-U.S. introductions. *Id.*

114. Tinsley, *supra* note 30, at 444 (citing Public Citizen, *supra* note 113). In addition, federal funding makes up nearly half of the total amount spent on health care research and development. *Id.* at 446 (citing Michael B. Moore, "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, 156 (Fall 1994)).

115. Public Citizen, *supra* note 110.

number could be significantly lower if further analysis is undertaken. For instance, the \$139.8 billion total spent on research and development is a pre-tax figure; in fact, research and development expenses are tax deductible and every dollar spent on research and development has a net cost of only \$0.66.¹¹⁶

To that end, the proponents of reimportation believe the pharmaceutical industry is playing a “Scare Card” with the issue of research and development costs. In actuality, the generous estimation of \$163 million to research and develop a new drug is a significant number, but it is no where near the \$500 million cost claimed by the drug industry. Instead of claiming the total amount it costs to introduce a new drug, the pharmaceutical industry should simply reveal *its* actual cash outlay for the new drug—it should not include public contributions, tax benefits and any other contributions that inflate *its* actual cost for research and development.

b. Only the U.S. is Burdened

Even assuming, *arguendo*, that research and development costs are equal to \$500 million per new drug, why are Americans the only ones bearing the burden of paying for research and development of new innovations—when the entire world is reaping the benefits?

It is most likely because the United States is the only industrialized nation that does not have government set price controls on prescription drugs.¹¹⁷ FDA Commissioner Mark McClellan has argued that countries regulating drug prices do not pay their fair share of the research and development costs—they depend on the United States to pick up the slack.¹¹⁸ In Canada, the Patented Medicine Prices Review Board (PMPRB)¹¹⁹ dictates the maximum price for a new prescription drug entering the Canadian market by ensuring the prices of Canadian pharmaceuticals are no higher than a product’s mean price in seven industrialized nations.¹²⁰ In setting a drug’s price, the PMPRB can

116. *Id.*

117. Harris, *supra* note 25. Approximately half of the pharmaceutical industry’s profits come from the United States. *Id.*

118. Tamsin Carlisle, *Pfizer Pressures Canadian Sellers of Drugs to U.S.*, WALL ST. J., Jan. 14, 2004. The large pharmaceutical companies and the FDA believe that the rest of the world needs to contribute in the research and development of new prescription drugs. *Id.*

119. Patented Medicine Prices Review Board, *Home Page*, available at <http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1> (last visited Feb. 15, 2005).

120. Mary E. Wiktorowicz, *Emergent Patterns In The Regulation Of Pharmaceuticals: Institutions And Interests In The United States, Canada, Britain, And France*, 28 J. HEALTH POL. POL’Y & L. 615, 627 (2003). In setting and limiting prices, the PMPRB considers the drug’s Canadian price, the price in other markets, the price of

consider manufacturing and marketing costs, but it cannot take the cost of research and development into its calculations.¹²¹ Similarly, each European nation has instituted its own price control system, many of which coincide with each other.¹²² These price control systems have prevented innovative pharmaceutical firms from reaping infinite profits anywhere but in the United States.¹²³

This has also forced many of the traditional European firms, such as GlaxoSmithKline and Novartis, to move many of their most essential operations to the United States where more money can be spent on research and development.¹²⁴ While this relocation has given American manufacturers the ability to account for seven of the top ten worldwide best-selling medicines, it also reflects a large and growing disparity in research and development expenditures.¹²⁵ In 2000, United States manufacturing firms outspent European firms on research and development by approximately \$6.1 billion.¹²⁶ This is a remarkable turnaround considering that ten years ago, before such stringent government price controls were in effect,¹²⁷ European pharmaceutical firms outspent American firms on research and development by approximately \$2.7 billion.

This large, disproportionate research and development expenditure is causing unrest in the United States.¹²⁸ “The United States is now

similar medicines within Canada, Canada’s Consumer Price Index, and the cost of making and marketing the drug. See Farin Khosravi, Comment, *Price Discrimination In The United States: Why Are Pharmaceuticals Cheaper In Canada And Are Americans Seizing The Opportunities Across The Border?*, 9 SPG L. & BUS. REV. AM. 427, 433 (2003). If the PMPRB determines that the price of a drug is too high, it can induce the manufacturer to voluntarily reduce the price; hold a public hearing and either order the maker to reduce the price or take away its market exclusivity; or require the patent owner to reduce the price of another drug or remit money to the government. *Id.*

121. Todd A. Rosenfield, Comment, *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, 1053 (2004).

122. *Id.* For example, the Netherlands takes into account the average price of prescription drugs in Belgium, France, Germany, and the United Kingdom in setting its price. *Id.* Another example is Portugal, which demands the lowest price set in France, Italy, or Spain. Greece wants the lowest price in all of Europe, period. *Id.*

123. *Id.* This is one of the reasons why the world pharmaceutical industry, which twenty years ago was primarily based in Europe, has largely relocated to the United States.

124. *Id.*

125. *Id.* American manufactures also account for fifteen of the top twenty best-selling medicines.

126. *Id.*

127. *Id.* The European Commission is sufficiently alarmed by these trends and is proposing measures to relax price controls in order to rejuvenate its pharmaceutical industry.

128. Elizabeth Becker, *Overseas drug prices targeted by industry U.S. officials pressure Australia on controls*, THE SAN DIEGO UNION-TRIBUNE, Nov. 27, 2003. This

covering most of the costs of developing a new drug to the point where it can be used by the population of the world,"¹²⁹ according to FDA commissioner Mark McClellan. "It is clear to me [Mr. McClellan] that we cannot carry the lion's share of this burden for much longer."¹³⁰ The benefits of United States drug innovations are global, and the cost for researching and developing these drugs should be global as well.¹³¹

By the United States allowing reimportation or even dropping its drug cost to the average of the rest of the world, it may be able to compel each foreign country to take on their respective share of the cost of researching and developing new prescription drugs.¹³² Proponents of reimportation believe this drop in sales would prompt the pharmaceutical industry to negotiate higher price regulation with foreign countries, which, in turn, will spread out the cost of research and development.¹³³

c. Advertising/Lobbying Expenses are Too High

The pharmaceutical industry has adamantly stressed its position that higher prescription drug prices are necessary to fund research and development of new innovative drugs. The question, however, is how much of the costs are actually being allocated to research and development, as opposed to advertising, marketing, lobbying, and public relations?

The answer to this question can be ascertained by evaluating how drug manufacturers spend their revenues. Take a look at the cost breakdown of Lipitor, one of the most popular and highly prescribed drugs for high cholesterol.¹³⁴ Twenty-four percent of the cost of Lipitor is pure (net) profit, twenty-six percent covers "other expenses,"¹³⁵ thirty-

article explains how the United States is asking other countries, such as Australia, to agree to pay higher prices for new drug innovations. *Id.*

129. *Id.* Mark McClellan made this statement in denouncement of other countries who are allowing the United States to bear the burden of developing new drug innovations. *Id.*

130. *Id.*

131. *Id.* This idea comes from a speech made in September by FDA commissioner Mark McClellan. *Id.*

132. Julie Appleby, *More cities, states opt for Canadian drugs; FDA might be forced to challenge each program*, USA TODAY, Dec. 23, 2003, available at http://www.usatoday.com/money/industries/health/drugs/2003-12-23-canadadrugs_x.htm (last visited Feb. 7, 2005).

133. *Id.* Tony Howard, the chief executive at CanaRx, stated that "If the United States were to drop costs to the average of the world, and then the pharmaceutical industry said it needed more money for research and development, then it could add a dollar to every prescription filled throughout the world." *Id.* Compare discussion *supra* Part I.B.2.

134. Hall, *supra* note 13.

135. Such as manufacturing, executive pay, worker costs, etc.

five percent covers advertising and marketing and only fifteen percent covers the cost of research and development.¹³⁶ These percentages alone showcase that pharmaceutical companies, on average, spend more to advertise their drugs than they do to research and develop their drugs. This begs the question—why do the pharmaceutical companies blame the high cost of prescription drug prices on research and development and not on advertising when they are spending approximately eight percent more on advertising?

The answer may be that the pharmaceutical industry realizes that Americans will be more sympathetic to higher prescription drug prices if the high prices are attributable to the research and development costs associated with the drug and not the drugs' advertising costs. Americans have to see through these self-serving scare tactics and realize that the drug industry is driven by profit.¹³⁷ The pharmaceutical industry does not want to limit its advertising expenses because it knows advertising its products to consumers stimulates extensive profits.

To put this further in perspective, \$2.5 billion was spent on promoting prescription drugs directly to consumers in 2000.¹³⁸ Television advertising, which is the largest and fastest growing type of direct-to-consumer advertising, has grown from thirteen percent in 1994 to sixty-four percent in 2000.¹³⁹ While this is less than the amount automobile companies spend on advertising, it is comparable to the amount expended by the motion picture industry and the "computer-maker" industry.¹⁴⁰ Promoting drugs directly to consumers has proved so extremely profitable that some pharmaceutical companies invest more money in such promotions than they budget for informing physicians about their products.¹⁴¹

136. Hall, *supra* note 13.

137. Congressman Sherrod Brown, *Brown Blasts Drug Industry Ads*, (July 15, 2003) available at <http://www.house.gov/sherrodbrown/drugads71503.html>. Congressman Brown denounced the latest round of misleading ads from the pharmaceutical companies. *Id.*

138. The Henry J. Kaiser Family Foundation, *Direct-to-Consumer Prescription Drug Advertising*, (Jan. 18, 2004), available at http://www.kaisernetwork.org/adwatch/adwatch_index.cfm?display=detail&aw=285 (last visited Feb. 15, 2005). This was an increase of almost thirty-five percent over spending in 1999. *Id.*

139. *Id.* This represents an eighty-eight percent average annual increase in television advertising spending from 1994-2000. *Id.*

140. Jones, *supra* note 8. The article has the advertising figures, compiled by TNS Media Intelligence/CMR, of the prescription drug industry, the automobile industry, and the computer-maker industry. These figures are for the 2002 year and the midway point of the 2003 year. *Id.*

141. The American Council on Science and Health, Inc., *Does Direct-to-Consumer Prescription Drug Advertising benefit the Public's Health?* (1999) (Issue and answer from Dr. Phillip R. Alper), available at http://www.acsh.org/publications/priorities/1104/point_no.html (last visited Jan. 5, 2004).

These astounding advertising statistics do not even take into account the amount of money the pharmaceutical industry expends on lobbying. In the 2000 presidential election, the pharmaceutical industry made more than \$20 million in political expenditures.¹⁴² Since the election, the industry has contributed \$60 million in political donations and spent approximately \$38 million in lobbying in the first six months of this year.¹⁴³ Furthermore, the drug industry has set aside at least \$150 million dollars to spend in 2004.¹⁴⁴ All of these expenses, which add to the high price of prescription drugs in the United States, are aimed at influencing American thought on prescription drugs—making Americans believe that the high prices are attributable to researching and developing new drug innovations. In reality, according to the proponents of reimportation, the drug industry uses its money and power to keep its grip on the lucrative United States prescription drug market.¹⁴⁵

Instead of stressing its position that higher prescription drug prices are necessary to fund research and development, the proponents of reimportation believe that the pharmaceutical industry should limit these outrageous advertising and lobbying expenses. If the \$2.5 billion spent on advertising and the \$150 million set aside to lobby were used to reduce the price of prescription drugs, the need of Americans to reimport prescription drugs from foreign countries would be eliminated.¹⁴⁶ At the same time, the amount of money that goes into researching and developing newer drugs would not be affected. Until the drug industry pursues this course of action, it should not blame the high price of prescription drugs on the research and development of new innovations.¹⁴⁷

142. David Espo, *Lobbying Strong vs. Prescriptions Bill*, THE MIAMI HERALD, July 24, 2003, available at <http://www.miami.com/mld/miamiherald/6372599.htm> (last visited Feb. 15, 2005). Of the twenty million in political contributions by the pharmaceutical industry, roughly eight out of every ten dollars went to the Republicans. *Id.*

143. Ceci Connolly, *Drugmakers Protect Their Turf*, THE WASHINGTON POST, Nov. 21, 2003, at A04. The massive political contributions and lobbying was undertaken to keep reimportation illegal and to urge the passage of the new Medicare bill that adds prescription drug coverage to Medicare recipients. *Id.*

144. Congressman Sherrod Brown, *supra* note 137. Congressman Brown stated that the drug industry has set aside at least \$150 million for 2004 to influence American thought on prescription drugs. *Id.*

145. *Id.*

146. The author assumes these savings on advertising and lobbying would be passed onto the consumer, thereby reducing the price Americans pay for their prescription drugs.

147. While the author realizes that advertising directly to consumers may help people by giving them a means to ask questions about their health, he takes the position that the pharmaceutical industry goes above and beyond that necessary to inform the public. For instance, it really is not necessary for pharmaceutical companies to hire famous spokesman, such as baseball player Raphael Palmeiro, simply to market a drug. See Mike Huckman, *Arch Rivals: Glaxo vs. Pfizer, CNBC looks at the battle between top*

II. State Action

Certain states agree with the FDA and have taken action against the storefront distributors and Internet pharmacies promoting reimportation within their respective state.¹⁴⁸ A growing number of states, however, are taking the position that drug reimportation should be legalized because it is a safe, effective means of cutting the states' healthcare costs.¹⁴⁹ In fact, many of those states that were adamantly against drug reimportation have changed their tune and are now attempting to establish programs to sell prescription drugs reimported from Canada.¹⁵⁰ The following subsections will provide a brief overview of the specific actions states have taken on this complicated issue of drug reimportation.¹⁵¹

A. States Against Importation

The states that support the position of the FDA have taken the stance that the importation of prescription drugs is not only unsafe, but it is also illegal.¹⁵² The first state to take official action against a storefront distributor was Oklahoma, which filed a complaint in the District Court of Oklahoma County on March 27, 2003.¹⁵³ The complaint asked the

industry brands, Dec. 16, 2003, available at <http://msnbc.msn.com/id/3721062> (last visited Feb. 15, 2005). The author firmly believes that important health information can be passed on without the expenditure of paying a sports star.

148. National Association of Chain Drug Stores (NACDS), *FDA Actions and Positions*, available at <http://www.nacds.org/wmspage.cfm?parm1=2935> (last visited Feb. 15, 2005) [hereinafter NACDS]. The NACDS set up a Web page dedicated to drug importation. *Id.* It lists all of the actions states have taken against drug importation. *Id.*

149. Appleby, *supra* note 132. A growing number of cities, counties and states have stated that they want to allow employees, retirees and ordinary citizens to purchase prescription drugs from Canada. *Id.*

150. For instance, Oklahoma filed a complaint in the District Court of Oklahoma County on March 27, 2003 asking the District Court to enjoin a storefront distributor, Rx Depot, from violating the Oklahoma Pharmacy Act. The Oklahoma State Bd. of Pharmacy v. Rx Depot, No. CJ-2003-2643 (District of Oklahoma County filed March 27, 2003), available at http://www.nacds.org/user-assets/PDF_files/Oklahoma_BOP_Complaint.pdf (last visited February 3, 2005). More recently, Oklahoma is considering the establishment of "Rx for Oklahoma," which is a program that would provide a website allowing Oklahoma citizens to order cheaper prescription drugs from Canada and other industrialized countries. Carol Cole, *Steele, Hiatt Introduce 'Rx for Oklahoma'*, SHAWNEE NEWS-STAR, February 2, 2005, available at http://www.news-star.com/stories/020205/New_26.shtml (last visited February 14, 2005).

151. The states for and against reimportation refer to the same arguments that were extensively discussed in Part I of this Comment. This section of the Comment will simply discuss the specific actions taken by certain states.

152. While this subsection discusses certain state actions in opposition of reimportation, it is by no means exhaustive. For a more comprehensive discussion of State action taken against reimportation, see NACDS, *supra* note 148.

153. The Oklahoma State Bd. of Pharmacy v. Rx Depot, No. CJ-2003-2643 (District

District Court to enjoin a storefront distributor, Rx Depot, from violating the Oklahoma Pharmacy Act.¹⁵⁴ The Alabama¹⁵⁵ and North Carolina¹⁵⁶ Board of Pharmacy's filed similar complaints against storefront distributors in their respective states.

Other states have chosen to pursue other options in attempting to eliminate the storefront distributors residing within their jurisdiction.¹⁵⁷ For example, the Arizona Board of Pharmacy issued a letter to the Arizona Better Business Bureau asking it to warn consumers about the risks of purchasing prescription drugs from Canada.¹⁵⁸ The Arizona Board stressed its position that storefront distributors violate state and federal law.¹⁵⁹ Similarly, Oregon's Board of Pharmacy issued a statement regarding the illegality and danger of storefront distributors.¹⁶⁰ Both the Arizona and the Oregon Boards of Pharmacy stressed the need for consumers to contact their doctors or pharmacists for safe, cost-effective alternatives to drug importation.¹⁶¹

Kansas Attorney General, Phill Kline, sent a letter to Rx Depot, a storefront distributor, ordering it to cease operations because it exhibits the "Rx" symbol, which is an explicit violation of Kansas law.¹⁶² The letter gave Rx Depot fifteen days to comply before it would face further

of Oklahoma County filed March 27, 2003), available at http://www.nacds.org/user-assets/PDF_files/Oklahoma_BOP_Complaint.pdf (last visited Feb. 3, 2005).

154. *Id.* The Oklahoma Pharmacy Act is codified in 59 O.S.Supp.2002, Section 353 *et seq.*

155. Alabama State Bd. of Pharmacy v. Disc. Drugs of Canada, No CV 03-1742 (Circuit Court of Jefferson County Filed March 31, 2003), available at http://www.nacds.org/user-assets/PDF_files/AL_BOP_Complaint.pdf (last visited Feb. 3, 2005). The defendants consented to the Court issuing a Temporary Restraining Order to remain in full force until the hearing on the Plaintiff's request for a preliminary injunction.

156. North Carolina Bd. of Pharmacy v. Canada Drug Outlet, Inc., No. 3 CVS04986 (N.C. Superior Court Division filed Oct. 15, 2003), available at http://www.nacds.org/user-assets/PDF_files/NC_BOP_v_Canada.pdf (last visited Feb. 3, 2005).

157. NACDS, *supra* note 148.

158. Arizona Board of Pharmacy Urges Better Business Bureau to Warn Consumers About Prescription Drugs From Canada: You Can't Trust the Source; Letter Cites Repeat Felon Operating Canadian Drug Import Service, PR Newswire, May 9, 2003, available at http://www.findarticles.com/cf_dls/m4PRN/2003_May_9/101488124/p1/article.jhtml?term= (last visited Jan. 4, 2004). This article describes the actual letter sent by the Arizona Board of Pharmacy. *Id.*

159. *Id.*

160. Gary A. Schnabel, *Statement regarding Oregon storefront businesses that solicit drug therapy patients to hand over prescriptions to be filled in Canada*, Oregon Board of Pharmacy, Oct. 17, 2003, available at http://www.nacds.org/user-assets/Word_files/OR_Statement_Storefronts.DOC (last visited Feb. 3, 2005).

161. *Id.*

162. Theresa Agovino, *Rx Depot ordered to close stores*, THE KANSAS CITY STAR, Sept. 10, 2003, available at <http://www.kathrynpetro.com/mindfullife/archives/000035.html> (last visited Feb. 3, 2005).

action by the Attorney General or the Kansas Board of Pharmacy.¹⁶³

Lastly, in March of 2003, the Montana Board of Pharmacy sent Club Medzrx a letter ordering it to cease and desist its operations, as their practice of assisting Montana residents in obtaining drugs from RealFast Drugstore in Canada violates a number of state laws and regulations addressing appropriate licensure, advertising and use of pharmacy technicians.¹⁶⁴

B. *States for Importation*

A growing number of cities and states have been exploring ways to permit their residents to benefit from the cheaper prescription drugs existing in Canada.¹⁶⁵ A chief executive of CanaRx,¹⁶⁶ Tony Howard, actually stated that CanaRx was negotiating with approximately sixty cities and counties within the United States about instituting prescription drug importation programs.¹⁶⁷ One of the first cities to actually institute a program was Springfield, Massachusetts.¹⁶⁸ Its mayor, Michael J. Albano, has set up a voluntary Canadian mail-order option for city workers and retirees that he believes could cut the city's \$18 million annual prescription drug bill in half.¹⁶⁹ Mayor Albano believes so strongly in the safeness of the program that he uses it to purchase the prescription drugs he needs for his diabetic son.¹⁷⁰

The city of Montgomery, Alabama was actually the first city to institute a prescription drug importation program with Canada.¹⁷¹

163. *Id.*

164. Letter from Montana Board of Pharmacy to Club Medzrx, at http://www.nacds.org/user-assets/PDF_files/Club_Medz_Cease_Desist_MT.pdf (last visited Oct. 26, 2005).

165. Associated Press, *10 States seek prescriptions from Canada*, ST. PETERSBURG TIMES (Florida), Dec. 12, 2003, available at http://www.sptimes.com/2003/12/12/news_pf/Worldandnation/10_states_seek_prescr.shtml (last visited Feb. 3, 2005). Specifically, this article enumerates ten states that are exploring ways to buy cheap prescription drugs from Canada.

166. CanaRx is a Canadian pharmacy that sends prescription drugs into the United States. It currently provides prescription drugs for the city of Springfield's program.

167. Appleby, *supra* note 132.

168. MacDonald, *supra* note 11.

169. *Id.* The system set up by Mayor Albano allows city workers and retirees to choose whether they would like to order their drugs from Canada. It is a completely voluntary system. *Id.*

170. Trudy Tynan, *Mass. City Buying Drugs From Canada*, THE WASHINGTON POST, July 29, 2003, available at http://www.seacoastonline.com/2003news/07292003/south_of/42139.htm (last visited Feb. 3, 2005). Mayor Albano stated that he has purchased the prescription drugs for his diabetic son through Springfield's program and has, in turn, saved \$853 a year for the city. *Id.*

171. Appleby, *supra* note 132. Many people believe that Springfield, Massachusetts was the first to institute an importation program, but this is only because Montgomery, Alabama chose to keep its program quiet. *Id.*

Montgomery's program allows city employees and retirees to choose whether they want to purchase their prescription drugs from Canada.¹⁷² Those employees who decide to opt for the program essentially receive their prescription drugs for free because the city has saved so much money that it has dropped its fifteen percent co-payment.¹⁷³ The program, which started in December of 2002, has saved Montgomery approximately \$400,000-\$500,000 in the first year.¹⁷⁴

Minnesota governor, Tim Pawlenty, announced a five-phase plan that would allow its state residents to purchase prescription drugs from approved Canadian pharmacies.¹⁷⁵ Under the first phase, which is already underway, Minnesota established a Web site which allows its residents to gather information about prescription drug purchases, view a list of Minnesota-approved pharmacies, compare prescription drug prices, and learn about cost saving strategies.¹⁷⁶ To actually order prescription drugs, Minnesota residents simply must locate their medicine on the website, send it to a listed pharmacy (Canadian), and wait for the pharmacy to fill the prescription.¹⁷⁷ This innovative plan allows Minnesota to help its residents passively—this way the state is not a direct importer of drugs in violation of federal law.¹⁷⁸

Illinois governor Rod Blagojevich has been very active in pursuing affordable prescription drugs for Illinois residents. In October of 2003, Governor Blagojevich issued a report finding that Illinois residents could safely purchase drugs from Canada because the pharmacy practice in the Canadian provinces of Manitoba and Ontario is equal to or superior to the pharmacy practices in the State of Illinois.¹⁷⁹ The report further found that buying prescription drugs from Canada could save the State of

172. *Id.*

173. *Id.* The elimination of the co-payment applies only to those employees that opt for the reimportation program.

174. *Id.*

175. Tom Majeski, *Governor's Rx: Import drugs*, ST. PAUL PIONEER PRESS (Minnesota), Oct. 17, 2003, available at <http://www.twincities.com/ml3/pioneerpress/news/politics/7032399.htm> (last visited Feb. 3, 2005). The plan, however, was narrowed and now includes only three major phases. Tinsley, *supra* note 30, at 468.

176. *Id.* The program also provides for residents that do not have Internet access by allowing them to order prescription drugs by phone. Majeski, *supra* note 175.

177. Tinsley, *supra* note 30, at 470-71. The website does not allow direct purchases because this practice has already been ruled illegal in *U.S. v. Rx Depot*. *Id.* at 471.

178. At least three other states—New Hampshire, North Dakota and Wisconsin—have also established Web sites to help residents purchase prescription drugs from Canada. Monica Davey, *Illinois To Help Residents Buy Drugs From Canada, and Afar*, N.Y. TIMES, Aug. 17, 2004, at A21.

179. "Report of Feasibility of Employees and Retirees Safely And Effectively Purchasing Prescription Drugs From Canadian Pharmacies" available at <http://www.affordabledrugs.il.gov/pdf/SpecialAdvocateCanadian10-27-03Final.pdf> (last visited Oct. 26, 2005).

Illinois \$55 million annually.¹⁸⁰

In January of 2004, Governor Blagojevich started the “Illinois Rx Buying Club,”¹⁸¹ which allows the state to use its buying power to negotiate lower prices from *domestic* drug manufacturers.¹⁸² The purpose of the program is to solicit enough members to create a substantial buying power that enables the group to negotiate lower prices with pharmaceutical companies.¹⁸³ While this program has solicited about 74,400 participants, it has not reached its goal of 1.5 million participants.¹⁸⁴ Thus, the “Buying Club” has not been able to negotiate as strongly as it first anticipated.¹⁸⁵

Lastly, Governor Blagojevich, in mid-August of 2004, announced his intention to set up a program giving Illinois residents the ability to purchase prescription drugs from Canada, England, and Ireland.¹⁸⁶ The program allows Illinois residents to use a Web Site or a toll-free number to purchase about 100 products the state has determined can be safely shipped from outside the U.S.¹⁸⁷ Illinois residents simply need to enroll and submit a valid prescription and an in-state mailing address to enjoy twenty-five to fifty percent savings when compared to U.S. retail prices.¹⁸⁸

Vermont has decided to take a different route in making prescription drugs more affordable to its residents, becoming the first state to actually

180. *Id.* at pg 3-4.

181. This program allows Illinois residents, older than age 65 or with disabilities, to save an average twenty percent off the price of prescription drugs. Daily Health Policy Report, *Prescription Drugs: Illinois To Launch Program To Reimport Prescription Drugs From Canada, England and Ireland, Despite Warning from FDA*, Aug. 17, 2004, available at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=25297 (last visited Feb. 14, 2005) [hereinafter Daily Health Policy Report].

182. *Id.*

183. Tinsley, *supra* note 30, at 467. The program hopes to obtain enough participants to go to domestic pharmaceutical companies and say, “If you’ll provide a substantial discount on your products, we can deliver millions of Illinois customers through our state buying club. And if you refuse to give us all a good break on the price, we’ll take our business to your competitors.” *Id.*

184. Daily Health Policy Report, *supra* note 181.

185. *Id.*

186. Julie Appleby, *Illinois First to Help Buy Drugs Abroad*, USA TODAY, Aug. 17, 2004, available at http://www.usatoday.com/money/industries/health/drugs/2004-08-17-drugs_x.htm (last visited Feb. 14, 2005). Illinois is the first state to help its residents obtain prescription drugs from Europe. *Id.* Governor Blagojevich included European countries in the program to preempt any attempt by the drug companies to shut off supplies to Canada—believing that the drug companies cannot shut down supplies to the world only to keep prices high in the United States. Davey, *supra* note 178, at A21.

187. *Id.* The foreign pharmacies are inspected by state officials to help ensure safety. *Id.*

188. *Id.* The article includes a table that showcases the savings Illinois residents can expect when purchasing their prescription drugs through this program. *Id.*

sue the FDA to be able to import prescription drugs from Canada.¹⁸⁹ In November of 2003 Vermont officials asked the FDA to approve a pilot program under which the state would contract with a Canadian company that would take orders from Vermont residents and distribute the drugs by mail.¹⁹⁰ After receiving a letter denying the request, Vermont officials sued the FDA believing the FDA's denial to be "unsubstantiated" and in violation of the Administrative Procedure Act.¹⁹¹ Vermont's proposal would initially allow current and retired state employees and their dependents to import Canadian drugs, with the goal of expanding the plan to cover other Vermonters.¹⁹² Although the Vermont proposal called specifically for the FDA to work with Vermont to ensure safety, the FDA denied the request stating that "it would be extremely unlikely that the State of Vermont could ensure that all the Canadian drugs would be in full compliance with all laws and regulations applicable to the FDA."¹⁹³

Many other states have also announced that they are considering state instituted drug reimportation programs with Canada. These states include California,¹⁹⁴ West Virginia,¹⁹⁵ Delaware,¹⁹⁶ Louisiana,¹⁹⁷ and North Dakota.¹⁹⁸

189. A Chicago-area couple sued the FDA and the U.S. Department of health and human Services to permit the legalized import of prescription drugs from Canada, but Vermont is the first state to take action against the FDA. See Valerie Jablow, *Consumers, States Challenge Federal Ban on Drug Imports*, NEWS AND TREND, June 2004, at 40-JUN Trial 12 (citing *Andrews v. Dep't of Health & Human Servs.*, No. 1:04CV00307 (D.D.C. filed Feb. 26, 2004)).

190. Pam Belluck, *Vermont Will Sue U.S. for the Right to Import Drugs*, N.Y. TIMES, Aug. 11, 2004, at A13.

191. Statement on Vermont's Lawsuit on Importing Prescription Drugs From Canada, Aug. 20, 2004 <http://www.fda.gov/bbs/topics/news/2004/NEW01107.html>. The State of Vermont filed its complaint in the United States District Court for the District of Vermont. *Id.*

192. Belluck, *supra* note 190, at A13.

193. *Id.*

194. Jennifer Coleman, *California Legislature Eyes Meds From Canada*, THE WASHINGTON POST, Jan. 22, 2004. A bill introduced on January 22, 2003 by Senate President Pro Tempore John Burton would allow the state Department of General Services to consider Canadian pharmacies when seeking the best price for prescription medicines. *Id.*

195. Associated Press, *supra* note 165. Mr. Tom Susman, the acting administration secretary for West Virginia was quoted as saying, "Drugs are cheaper in Canada—how do we bring these drugs into the states. If they work better, and the cost is cheaper, I think it's legitimate." *Id.*

196. *Id.*

197. *Id.*

198. Mary Judice, *Kenner store defies order to close; Shop still brokering Canadian Drugs*, TIME-PICAYUNE (Louisiana), Nov. 8, 2003. Mayor Michael Bloomberg also stated that he will press federal officials to allow New York City to import drugs for city workers. *Id.*

III. FDA Action

On March, 21, 2003, the Food and Drug Administration (FDA) sent Rx Depot, an entity responsible for the creation of approximately eighty-five storefront distributors, a warning letter informing Rx Depot that its actions “present a significant risk to public health” and “mislead the public about the safety of the drugs” it provides.¹⁹⁹ Despite the warning, Rx Depot announced its intention to continue to provide access to Canadian drugs until ordered by a court to stop.²⁰⁰ The FDA, believing the continued operation of storefront distributors to create a significant potential health risk, filed a complaint in the United States District Court in the Northern District of Oklahoma.²⁰¹ The complaint seeks to enjoin Rx Depot and individual officers from directly or indirectly importing or causing the importation of U.S.-manufactured and unapproved foreign-manufactured prescription drugs into the U.S.²⁰² The following will extensively analyze the court’s analysis in deciding on the FDA’s request for an injunction.

A. *United States v. Rx Depot*²⁰³

United States v. Rx Depot arises from a complaint filed by the Department of Justice²⁰⁴ asking the court to enjoin the two storefront distributors, Rx Depot²⁰⁵ and Rx Canada,²⁰⁶ because they violate the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. Sections 331(d)²⁰⁷ and (t).²⁰⁸ The court ultimately granted the Department of Justice’s motion for preliminary injunction against Rx Depot finding the storefront distributors in violation of the FDCA because they created “an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or

199. FDA News, *FDA Takes Action Against Companies That Are Importing Unapproved, Potentially Unsafe Drugs*, Sept. 9, 2003, available at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00939.html> (last visited Feb. 15, 2005).

200. *Id.*

201. *Id.*

202. *Id.*

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

204. *Id.* at 1240. The Department of Justice filed this complaint on behalf of the FDA. *Id.*

205. *Id.* The Court consistently used “Rx Depot” in its analysis. *Id.* This was understood to also include Rx Canada and the other individual defendants Carl Moore and David Peoples. The same will be done for purposes of this Comment.

206. *Id.* at 1240-41.

207. *Id.* at 1245-46. The Department of Justice believes that 21 U.S.C. Section 331(d) is violated each time Rx Depot causes to be introduced or delivered for introduction into interstate commerce unapproved new drugs. *Id.*

208. *Id.* The Department of Justice believes that Rx Depot violates 21 U.S.C. Section 331(t) each time it causes the importation of prescription drugs because only the manufacturer of a drug can reimport that drug into the United States. *Id.*

expired drugs will be sold to American consumers.”²⁰⁹ While granting the Department of Justice’s claims, the court dismissed the five counter-claims of Rx Depot.²¹⁰

On the issue of safety, the court sided with the Department of Justice’s argument²¹¹ that prescription drugs imported from Canada are

209. *Id.* at 1248. To reach this finding the court had to evaluate the following four factors: 1) the movant has a substantial likelihood of success on the merits, 2) irreparable injury will occur if the injunction is not granted, 3) the injury that will occur outweighs any harm the injunction will cause the opposing party, and 4) the injunction is not adverse to the public interest. *Id.* at 1246. The court found the first factor was met because there was a substantial likelihood that the Department of Justice would succeed on the merits of its claim because the the court believed that by encouraging and facilitating individuals to illegally import drugs the requisite “causing” under 21 U.S.C. section 331 is met and that this alone is enough to constitute a substantial likelihood of success of the merits. *Id.* at 1247. The court did not have to assess the second and third factors, dealing with “irreparable injury,” because it has long been held that when an injunction is authorized by the statute, the passage of the statute itself is, in a sense, an implied finding that any violation will harm the public and ought, if necessary, be restrained. *Id.* at 1248. Therefore, the Department of Justice is only required to show that the defendants have violated the particular statute and that there exists “some cognizable danger of recurrent violation. *Id.* The court found that the danger of “recurrent violation” was present because Carl Moore or Rx Depot testified that he will not shut down Rx Depot unless a court orders him to do so. *Id.* at 1250. Lastly, the court found that the injunction was not adverse to the interest of the public. Although the court was “not unsympathetic to the predicament faced by individuals who cannot afford their prescription drugs at U.S. prices,” it recognized that Congress, by statute, has already determined that Rx Depot’s business practices harm the public interest. *Id.* at 1248.

210. The first claim asserted by Rx Depot was its belief that the FDA personal importation policy amounted to unconstitutional selective enforcement and represented “geographical” discrimination because individuals in the Northern United States are able to easily cross the border to obtain cheaper prescription drugs while individuals, farther from the Canadian border, are being enjoined from doing practically the same thing. *Id.* at 1249. The court found this argument to be unpersuasive and held that it was reasonable for the FDA to marshal its limited resources against large-scale, commercial operations rather than small-scale individual violators and, therefore, Rx Depot did not meet the requisite showing for selective enforcement. *Id.* Secondly, Rx Depot argued that the FDA’s enforcement action violated the Privileges and Immunities Clause, found in Article IV, Section 2 of the United States Constitution, which requires a state to accord residents and non-residents equal treatment when regulating the means of livelihood or doing business. *Id.* The court rejected this argument because Rx Depot did not show that it had a privilege or a fundamental right to facilitate illegal prescription drug importation. *Id.* Next, the court rejected Rx Depot’s assertion that its business practices are protected “speech” under the First Amendment, holding that any First Amendment interest in advertising a commercial transaction is “altogether absent when the commercial activity itself is illegal and the restriction on advertising is incidental to a valid limitation on economic activity.” *Id.* The last two arguments asserted by Rx Depot were also discarded by the court: The court held that the North American Free Trade Agreement (NAFTA) did not protect Rx Depot’s right to facilitate importation of drugs because it was conceded by Rx Depot that NAFTA does not provide a remedy to private citizens. *Id.* The court also declined Rx Depot’s request for the court to invoke its equitable powers holding that it would be an abuse of its power to ignore statutory law or to declare a statute invalid where there is no constitutional basis for doing so. *Id.* at 1250.

211. Obviously, the Department of Justice’s argument coincides with the FDA’s

unsafe because they are not under the constant regulation of the FDA.²¹² The court was very stern in its position that drugs reimported from foreign countries by someone other than the United States manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the FDA.²¹³ In addition, the court criticized Rx Depot's advertising of the availability of dispensing preset quantities of drugs regardless of the quantity prescribed by the United States physician, and without directions to take the drug for only the number of days prescribed by the physician.²¹⁴ This gives American patients the ability to take prescription drugs for a longer period than their United States physician intended them to do so, which can be dangerous in instances where drugs have potentially life-threatening side effects with continued use.²¹⁵

The preliminary injunction granted by the court, pursuant to 21 U.S.C. Section 332(a), restrained and enjoined Rx Depot from directly or indirectly causing the importation of any article of drug into interstate commerce.²¹⁶ It also barred Rx Depot from offering, advertising, or promoting any service that causes or facilitates the importation or assistance in importing articles of drug from any place outside the United States.²¹⁷

IV. Conclusion

This comment has attempted to comprehensively analyze the reimportation debate, discussing the major arguments provided by both

argument, which mirrors the arguments of those who oppose reimportation. See discussion *supra* Part I.A.

212. Rx Depot, 290 F.Supp.2d at 1241. The drugs are not subject to FDA oversight and are not continuously under the custody of a United States manufacturer or authorized distributor, which makes the drugs' quality less predictable than drugs obtained directly within the United States. *Id.* at 1241-42. For instance, the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent. *Id.*

213. *Id.* Even though the FDA is currently unaware of anyone harmed by prescription medications ordered through Rx Depot and reimported from Canada, the court believed that the legitimate safety concerns of the FDA are not diminished. *Id.* at 1242.

214. *Id.* at 1242.

215. *Id.* at 1242-43. An FDA agent made an undercover purchase through Rx Depot. Even though the agent had a prescription for one hundred pills, the agent was able to order a quantity of one hundred pills. In addition, the pills arrived without any instruction of how or how long the patient should take the pills.

216. *Id.*

217. *Id.* at 1251. This decision marked the beginning of the end to Carl Moore's (founder of Rx Depot) attempt to facilitate Americans in securing affordable prescription drugs by the use of storefront distributors. Associated Press, *Rx Depot Drops Drug Fight*, THE WASHINGTON POST, August 21, 2004, at A09. In August of 2004, almost a year after the decision, Carl Moore realized that he did not have a chance to prevail and finally consented to the decree making the court's order enjoining the storefront distributor's permanent. *Id.*

the proponents and the opponents of reimportation. Further, this comment presents an evaluation of where individual State's stand on reimportation and it discusses the action taken by the lone federal court to rule on the issue of reimportation. What does this all amount to? I believe it can be summed up in one statement; our government must realize that it is absolutely appalling that in a country as rich and powerful as the United States, approximately twenty-nine percent of its citizens are unable to afford some or all of their necessary prescription drugs.²¹⁸

This statement is especially true when looking at America's seniors, such as Ray Park,²¹⁹ who have helped make the United States the country it is today. These American seniors, mostly blue-collar workers, lived paycheck to paycheck relying on the fact that when they retired, they would have a full pension and a healthcare plan.²²⁰ Is it fair to leave these life-long, hardworking Americans in the cold simply because the company they worked forty-plus years for happened to file for bankruptcy? The majority of Americans, hopefully, would answer this question in the negative, which makes it even more unbelievable that the United States government has not adequately addressed this issue.

While the U.S. Government continually debates the appropriate action it wants to take in order to help Americans afford their necessary prescription drugs, individuals have been taking the matter into their own hands by turning to foreign countries, such as Canada, to obtain their prescription drug needs. Whatever channel of reimportation chosen—personally traveling across the border, ordering through the Internet, or by contacting a storefront distributor—Americans are finding out that by reimporting prescription drugs from foreign countries, they are finally able to afford their doctor-prescribed medications. Instead of choosing between prescription drugs and paying for food or rent, Americans are using reimportation to finally take a full dose of life-saving prescription drugs.

The United States Government, through the FDA, has criticized these practices of reimportation, labeling reimportation as very unsafe and a threat to the U.S. drug distribution system. In fact, the Department of Justice filed suit in the United States District Court in the Northern District of Oklahoma to enjoin Rx Depot, a storefront distributor, from helping Americans obtain affordable prescription drugs from Canada.²²¹ While was done with the intention of keeping the U.S. drug distribution

218. Hall, *supra* note 13.

219. See *supra* p.53 n.100.

220. Jones *supra* note 8.

221. See discussion *supra* Part III.A.

system safe, it has hurt those Americans who cannot afford to partake in the U.S. drug distribution system. These individuals believe an unaffordable drug is more dangerous than a reimported drug because the reimported drug at least gives them a chance to fulfill a doctor's prescription.

Seniors and other reimporters would prefer to stop reimporting drugs from foreign countries, but the Government has refused to offer an adequate alternative. An attempt was made with the enactment of the Medicare Prescription Drug Improvement and Modernization Act (The Act),²²² which adds Part D to Medicare and establishes a new voluntary prescription drug benefit program.²²³ The Act was enacted with the intent of cutting drug costs by about one-third for the average senior and to provide medicines virtually free to millions of low-income seniors. The plan, however, provides little relief for about three million people with moderate assets and incomes near the poverty level, and would cost seniors with drug expenses under \$835 a year more than they currently spend.²²⁴ It has actually been estimated that about one-quarter of all seniors became worse off the day the bill was enacted.²²⁵ Therefore, some, if not most, would say that the government has again failed to adequately address this issue.

Whether or not reimportation is the answer, something must be done to help Americans afford their necessary prescription drugs. In a country as rich as the U.S., there is no reason for Americans to compromise their safety by being forced to choose between reimporting prescription drugs or not taking the drugs at all. If the Federal Government steps up and somehow or someday provides American citizens access to safe, affordable prescription drugs, the entire reimportation issue would become moot. I, for one, cannot believe this issue has been ignored for so long. I only hope the U.S. Government comes to its senses and adequately address this issue by providing all Americans access to affordable prescription drugs.

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

223. Daniel Katz and Monica Deshpande, *An Rx for the Modification of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Toward a Reform with Results*, 14 ANNALS HEALTH L. 183, 185 (2005).

224. Alice Dembner, *Many win, some lose in Medicare drug bill*, THE BOSTON GLOBE, Nov. 18, 2003, available at 2003 WL 66477842 (last visited Feb. 15, 2005). This article believes that the bill is very adequate for those seniors that originally did not have any coverage, but those within the middle range will most likely be disappointed.

225. Marilyn Werber Serafini, *No Cure-All*, NAT'L J., Nov. 22, 2003, available at 2003 WL 65592514 (last visited Feb. 15, 2005).