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PRICE DISCRIMINATION IN THE UNITED STATES: WHY ARE PHARMACEUTICALS CHEAPER IN CANADA AND ARE AMERICANS SEIZING THE OPPORTUNITIES ACROSS THE BORDER?

*Farin Khosravi**

I. BACKGROUND

A group of elderly citizens climbs onto a bus that was sent by their U.S. senator. At first glance, it appears to be another political candidate's effort to ensure that these senior citizens make it to the polling booths. But as the bus crosses the U.S.-Canadian border, one realizes that these riders aren't headed to their precinct polling locations. Instead, they are traveling to Canada to purchase prescription drugs! When politicians focus campaign attention on the high cost of prescription drugs, they tend to aim their message at senior citizens because that group constitutes forty two percent of the prescription drug market.¹

Vermont Senator Bernard Sanders, inspired some of his political colleagues to organize bus trips to take senior citizens to Canada to purchase prescription medicines, in an effort to politicize, once again, the issue of rising prescription drug costs.² Recently, Senator Debbie Stabenow of Michigan organized such a trip. Hundreds of senior citizens from across the nation climbed aboard to ride the Rx Express from Detroit to Windsor, Canada to purchase medicines.³ Senator Tim Johnson of South Dakota also scheduled a bus trip for senior citizens in August of 2002 to visit

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1. News Release, AARP, *AARP Enters Three Federal Lawsuits to Bring Lower-Priced Drugs to Consumers* (May 29, 2002), available at <http://www.aarp.org/press/2002/nr052902drugs.html>.
2. See Curtis Koren, *How Far Would You Go for Cheaper Drugs?*, Lycos Health with WebMD (July 14, 2000), at http://webmd.lycos.com/content/article/1691_50450.
3. Press Release, Senator Debbie Stabenow, *U.S. Senator Debbie Stabenow and the Alliance for Retired Americans Kick off Rx Express Bus Trip to Canada* (June 10, 2002), at <http://stabenow.senate.gov/press/2002/061002rxexpress.htm>.

a doctor in Winnipeg, Canada and to have their prescriptions filled.⁴

Although many of these bus trips have been criticized as mere campaign ploys in election years, senior citizens do not seem to mind. Many senior citizens living on fixed incomes welcome the opportunity to go to Canada to fill prescriptions because it saves them money.⁵ Jane Hanlon, a 71-year-old hairdresser living in Vermont, was paying \$95 a month at a local pharmacy to purchase Tamoxifen which she takes for her breast cancer—now she gets it in Canada for \$10.42 a month.⁶ Seventy-four year old Viola Quirion of Waterville, Maine takes a bus trip to Canada every three months to purchase Prilosec to aid with stomach troubles and Relofen for arthritis.⁷ Other popular drugs are available at big savings as well: a three-month supply (180 pills) of Tamoxifen, a cancer-fighting drug, costs \$298 in the United States, but only \$26 in Canada;⁸ forty-five capsules of Prozac retails for \$115 in the United States, but only \$35 in Canada.⁹ During one trip in August 2002, a group of seniors saved, in aggregate, more than \$18,000 on prescriptions, according to Chellie Pingree, a U.S. Senate candidate from Maine.¹⁰ Pingree took several trips to Canada in 2002 with Maine seniors to raise awareness of the longstanding problem of high drug costs in the United States.¹¹ High prescription drug cost is an important issue that receives heightened attention during an election year, since an estimated sixty-five million Americans do not have prescription drug coverage.¹² This number includes both uninsured individuals and senior citizens who are Medicare beneficiaries, but not enrolled in any prescription drug program.¹³ An estimated 30 percent of all Medicare enrollees do not have drug coverage,¹⁴ which makes the high cost of drugs of particular importance to many senior citizens. As a result, politicians focus on the issue in election years.

4. Scott Waltman, *Johnson Schedules Another Bus Trip*, Democratic Senatorial Campaign Committee (Aug. 21, 2002), at <http://www.dscc.org/newsroom/inthenews082302>.

5. See, e.g., *Health Care: U.S. Seniors Travel to Canada by the Busloads for Deals. And Their Doctors are Helping Them*, L.A. TIMES (Dec. 4, 2000), available at <http://www.house.gov/bernie/publications/articles/2000-12-04-prescriptiondrugs-latimes.html>.

6. *Id.*

7. *Id.*

8. Robert Lenzner, *The Effects Could Be Devastating*, FORBES (Nov. 27, 2000), 2000 WL 25964120.

9. *Id.*

10. Jennifer John, *Head North for Prescriptions*, SOLIDARITY (Oct. 2002), at <http://www.uaw.org/solidarity/02/1002/features05.html>.

11. *Id.*

12. Families USA, *Profiting from Pain: Where Prescription Drug Dollars Go*, FAMILIES USA FOUNDATION (July 2002), at 14, at <http://www.familiesusa.org> [hereinafter *Profiting from Pain*].

13. Steven Findlay, *Prescription Drug Expenditures in 2000: The Upward Trend Continues*, 1 HEALTH CARE FOCUS 1, 1-3 (June 2001), at http://www.healthnet.com/brokers/pdf/A9851_FOCUS_June.pdf.

14. *Profiting from Pain*, *supra* note 12, at 15.

II. WHY ARE DRUGS APPRECIATIVELY MORE EXPENSIVE IN THE UNITED STATES THAN ELSEWHERE?

While it is generally accepted that prescription drugs cost too much in the United States, experts disagree on the reasons. As indicated above, drug prices are higher in the United States than for its neighbors to the north and south, and expenditures on prescription drugs are on the rise.¹⁵ Experts blame the high cost of prescription drugs on an array of factors: capital expenditures on research and development (R&D); the industry's quest for maximizing shareholder profits; heavy spending on advertising and marketing; high compensation for drug company executives; recapturing profits lost to compulsory discounts given to federal purchasers; and recapturing profits lost when drug companies are forced to charge lower prices in countries that heavily regulate the pharmaceutical industry, such as Canada.¹⁶

A. COSTS OF RESEARCH AND DEVELOPMENT

One reason cited for the high price of prescription drugs is that the pharmaceutical industry spends enormous capital on R&D. Brand-name pharmaceutical manufacturers spent more than \$30 billion on research in 2001.¹⁷ Developing a single drug costs in excess of \$800 million and takes an average of eleven years from creation to market.¹⁸

Although the pharmaceutical industry claims that its high expenditures on R&D are essential to discovering innovative and more effective drugs, independent studies show that the industry has not introduced many new and innovative drugs to the market in the last decade.¹⁹ According to National Institute for Health Care Management Research and Education Foundation, 65 percent of new drugs approved by the FDA from 1989 to 2000 contained active ingredients already present in products available on the market.²⁰ In fact, drug manufacturers are only marginally improving existing drugs and then selling them at a higher price.

R&D is clearly integral to discovering and manufacturing innovative drugs; however, drug companies, on average, allocate only 11 percent of total revenue to R&D.²¹ This number is seemingly inconsistent with the

15. See Findlay, *supra* note 13, at 3 (indicating that increases in spending for prescription drugs will be between 12 and 23% per year through 2004).

16. See generally, *Profiting from Pain*, *supra* note 12 (article explores in detail the reasons attributed to the high cost of drugs in America).

17. Joe Moser, *Link between Drug Company Profitability and Investments in Research: A Fact Sheet* (July 2, 2002), at <http://www.galen.org/news/070202.html>. This is a summary of a Tufts Center study.

18. *Id.*

19. Robert Dodge, *As Costs Soar, So Does Desire For Latest Drugs* (May 27, 2002), at <http://www.lef.org/newsarchive/aging/2002/05/27/krtbn/0000-0126-DA-PHARM.html>.

20. Michie Hunt, *Changing Patterns of Pharmaceutical Innovation*, NAT'L. INST. FOR HEALTH CARE MGMT. RESEARCH & EDUC. FOUND. 3 (May 2002), at <http://www.nihcm.org/innovations.pdf>.

21. *Profiting from Pain*, *supra* note 12, at 10.

pharmaceutical industry's claim that the main cause for the high cost of prescription drugs is the amount of capital spent on R&D. Furthermore, the industry's explanation that drug costs are a reflection of high R&D expenditures is not convincing given that 40 percent of most pharmaceutical companies' R&D budgets are paid by the National Institute of Health, whose budget is funded by U.S. taxpayers.²²

B. PROFITABILITY OF PHARMACEUTICAL COMPANIES

The pharmaceutical industry has been the most profitable industry in the United States for each of the last ten years, according to a report by Families USA.²³ On average, the pharmaceutical industry's profits have been one-and-one-half times that of the next most profitable industry.²⁴ The industry has been successful in continually maximizing shareholders' wealth. In the last five years, shareholders of pharmaceutical stocks have enjoyed an annual rate of return of 18.4 percent—twice the 9.2 percent average return to stockholders of the Fortune 500 companies.²⁵ The pharmaceutical industry leaders' position is that high drug prices are central to maintaining high levels of profitability, which are essential to attract new capital, which is necessary for R&D.²⁶

Proponents of the U.S. pharmaceutical industry point out that although the companies' profit margins are high, brand-name drug manufacturers pay more taxes than most other companies.²⁷ However, according to a 1999 report from the Congressional Research Service, the pharmaceutical industry's average tax rate of 16.2 percent is less than other industries, which average a tax rate of 23.7 percent.²⁸ The report also showed that in 1996, the pharmaceutical industry reduced its tax bill by almost \$3.8 billion,²⁹ by taking advantage of tax credits related to research investments.³⁰ Therefore, drug companies actually benefit from spending revenues on R&D since such spending allows the industry to avoid paying higher taxes and increasing net profits.

C. SPENDING ON MARKETING, ADVERTISING, AND ADMINISTRATION

As new drugs emerge, drug companies spend significant budgets on television and print ads targeting the general public. On average, pharmaceutical manufacturers spend 27 percent of their revenues on marketing, advertising, and administration.³¹ Also, on average, the top nine

22. Lenzner, *supra* note 8, at 3.

23. *Profiting from Pain*, *supra* note 12, at 13.

24. *Id.*

25. *Id.*

26. *Id.* at 14.

27. Moser, *supra* note 17, at 1.

28. *Pharmaceutical Companies Pay Lowest Tax Rate of Any Industry*, SOC. SEC. & MEDICARE ADVISOR (Apr. 2000); available at <http://www.tscl.org/NewContent/100048.asp> [hereinafter *Pharmaceutical Companies*].

29. *Id.*

30. See *id.*; *Profiting from Pain*, *supra* note 12, at 10.

31. *Profiting from Pain*, *supra* note 12, at 5.

brand-name drug manufacturers have a much higher number of employees committed to non-research activities: they employ 81 percent more people in marketing departments than in R&D.³² Between 1995 and 2000, research personnel in these nine companies declined by 2 percent, while marketing staff increased by 59 percent.³³ For example, Merck, the manufacturer of popular drugs such as Vioxx, Singular, and Zocor, had 85 percent of its 78,100 employees engaged in non-research activities in 2001.³⁴

D. EXECUTIVE COMPENSATION

Chief Executive Officers and other executive positions in the pharmaceutical industry are often paid much more than are those in commensurate positions in other industries. In 2001, the average annual income of the highest-paid executive in nine of the major brand-name pharmaceutical manufacturers was just shy of \$21 million.³⁵ That figure does not include unexercised stock options, which averaged \$48 million in 2001.³⁶ In 2001, the highest paid executive in the industry was Bristol-Myers Squibb's former Chairman and CEO, C.A. Heimbold, Jr., whose compensation exclusive of unexercised stock options was \$74,890,918.³⁷

E. RECOUPING PROFITS LOST TO DISCOUNTS GRANTED TO "MOST FAVORED PURCHASERS"

Pharmaceutical manufacturers are required by law to give the four largest federal customers a 24 percent discount.³⁸ In the private sector, pharmacy benefit managers (PBMs) of large insurance companies and health maintenance organizations (HMOs) negotiate with drug manufacturers for discounts, in return for granting the drugs preferred formulary status.³⁹ In accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA), manufacturers must give discounts to Medicaid.⁴⁰ Since pharmaceutical manufacturers are forced to sell at a cheaper price to these "most favored purchasers," costs are shifted to uninsured cash paying retail customers, many of whom are elderly.⁴¹ In 1999, a report was prepared for the House Committee on Government Reform comparing

32. *Id.* at 13.

33. Alan Sanger & Deborah Socolar, *Drug Industry Marketing Staff Soars While Research Staffing Stagnates*, BOSTON U. SCH. OF PUB. HEALTH REFORM PROGRAM (Dec. 6, 2001), available at <http://rxpolicy.com/studies/bu-rxpromotion-v-randd.pdf>.

34. *Profiting from Pain*, *supra* note 12, at 12.

35. *Id.* at 5.

36. *Id.* at 6.

37. *See id.* at 5 (Table 2).

38. Patricia M. Danzon, *Making Sense of Drug Prices: How to Make Drugs More Affordable without Stifling Beneficial Innovation and Competition*, 23 REG. 56, 59 (Spring 2000), available at <http://www.cato.org/pubs/regulation/regv23n1/danzon.pdf>.

39. *Id.* at 60.

40. *Id.*

41. *Id.* at 59-60.

the prices of drugs sold at retail price in pharmacies and the prices of drugs sold to HMOs and Medicaid.⁴² The report concluded that the average difference between the two prices was 106 percent⁴³ and that the drug manufacturers engaged in "price discrimination."⁴⁴

Some experts in the field justify differential pricing as an efficient mean of recovering the fixed costs of R&D.⁴⁵ They also explain that the alleged "price discrimination" stems from an economic theory known as "Ramsey pricing," where the price-sensitive customers (in this case PBMs and the federal government) are charged lower prices in comparison to price-insensitive buyers (cash-paying, uninsured prescription drug consumers). The experts claim that consumers as a whole are better off with "Ramsey pricing" than with uniform pricing.⁴⁶

F. RECOUPING PROFITS LOST TO FOREIGN PRICE REGULATIONS

Critics of the U.S. pharmaceutical industry allege that American consumers subsidize the rest of the world's prescription drugs. They blame the high prescription drug prices in the United States on price discrimination (to recover the cost of R&D, pharmaceutical companies charge citizens of prosperous nations more, while heavily discounting drugs for consumers in poorer countries).⁴⁷ Once manufacturers negotiate lower prices with countries that have imposed price regulations, they raise retail prices for consumers in the United States to make up the difference.⁴⁸

Proponents of the U.S. pharmaceutical industry deny that they engage in cost shifting to maximize revenues. They assert that cost shifting is simply inconsistent with profit-maximization goals of pharmaceutical firms.⁴⁹

III. WHY ARE DRUGS SO MUCH CHEAPER IN CANADA?

The General Accounting Office (GAO) reported in 1992 that prescription drugs in Canada cost much less than they do in the United States.⁵⁰ As stated in section I, prices of common drugs such as Prozac and Tamoxifen exemplify the cost differences between the two countries. One reason for Canada's lower drug prices is its government-imposed price

42. *Id.* at 60. See generally, Minority Staff Special Investigations Div. COMM. ON GOV'T. REFORM U.S. HOUSE OF REPRESENTATIVES, 106th CONG., *Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans* (Nov. 9, 1999), available at http://www.house.gov/reform/min/pdfs/pdf_inves/pdf_prescrip_pricing_us_rep.pdf [hereinafter MINORITY STAFF REPORT].

43. Danzon, *supra* note 38, at 59.

44. MINORITY STAFF REPORT, *supra* note 42, at 3.

45. For a discussion how the efficiency is achieved see Danzon, *supra* note 38, at 61.

46. See Danzon, *supra* note 38, at 61.

47. Lenzner, *supra* note 8, at 3.

48. See *Pharmaceutical Companies*, *supra* note 28.

49. Danzon, *supra* note 38, at 62.

50. See 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, 150 (1994).

regulatory scheme, controlling the price pharmaceutical manufacturers may charge.⁵¹ In the 1960s, drugs in Canada were among the highest priced in the world. The government saw that this was the result of its patent protection scheme.⁵² Canada passed an act requiring compulsory licensing of drug patents.⁵³ Compulsory licensing allows generic drug manufacturers to enter the market before the patent expires for a brand-name drug.⁵⁴ If the manufacturer did not accept the price set by the government, the government would force the drug-maker to license the product to a manufacturer who would produce a generic.⁵⁵ Some experts believe that the practice drives down prices so that manufacturers cannot recoup their R&D expenses.⁵⁶

As a result, in 1987 Parliament passed Bill C-22, which gave the Canadian patent-holder an exclusive right to market the drug for the first seven years of the patent term.⁵⁷ Then in anticipation of NAFTA, in 1993, Canada enacted Bill C-91 to eliminate compulsory licensing and extend patent protections in pharmaceuticals from seven to twenty years.⁵⁸ Bill C-91 contained a sunset provision, and in 1997 Parliament voted to retain the legislation.⁵⁹

Bill C-22 established the Patented Medicine Prices Review Board (PMPRB) to enforce price controls on patented medicines.⁶⁰ PMPRB is an independent, quasi-judicial body that has the authority to investigate and regulate excessive pricing of patented pharmaceutical products in Canada.⁶¹ In setting and limiting prices, the PMPRB considers the drug's Canadian price, the price in other markets, the price of similar medicines within Canada, Canada's Consumer Price Index, and the cost of making and marketing the drug.⁶² 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.⁶³

Another reason for lower-priced drugs in Canada is that Americans continue to be better off than Canadians financially.⁶⁴ Canadians have

51. Danzon, *supra* note 38, at 58.

52. Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L. REV. 215, 241 (1999).

53. Danzon, *supra* note 38, at 58.

54. Carter, *supra* note 52, at 241.

55. Danzon, *supra* note 38, at 58.

56. Carter, *supra* note 52, at 242.

57. *Id.*

58. *Id.* at 243.

59. *Id.* at 244.

60. *Id.* at 245.

61. John R. Graham, *Why the Difference between Canadian & American Prices for Prescription Drugs is Widening*, FRASER FORUM 32 (Sept. 2002).

62. See *Patented Medicines Prices Review Board: Background Paper on the Price Review Process for New Patented Drug Products 1* (June 1999), available at <http://www.pmprb-cepmb.gc.ca/pdf/wg/wg2002-a4e.pdf> [hereinafter PMPRB].

63. Carter, *supra* note 52, at 246.

64. See Graham, *supra* note 61.

become poorer than Americans in recent years. In 1987, Gross Domestic Product (GDP) per capita in the United States was 20 percent greater than Canada, but this gap widened to 55 percent in 2001.⁶⁵ Accordingly, not just prescription drugs, but almost all goods and services, such as automobiles and computer software, cost less in Canada because Canadians' incomes are decreasing relative to those of Americans.⁶⁶

In addition to governmental price regulations in Canada and the higher standard of living in the United States, there is another factor responsible for the price difference between the two countries. The United States is a more litigious country than Canada and the higher prices in the United States reflect the increased costs of legal liability. Many federal and state regulatory mandates for the healthcare industry impose greater risk of product liability litigation on pharmaceutical manufacturers in the United States;⁶⁷ hence the higher liability risks in the United States account for part of the price difference of pharmaceuticals in the two countries.

IV. OPTIONS FOR AMERICANS SEEKING CHEAPER MEDICINE

Until Congress implements measures to lower the burden on senior citizens and the uninsured, some Americans have come up with creative solutions to purchase their needed prescriptions while avoiding paying high domestic prices.

A. PURCHASING FROM INTERNET PHARMACIES

Many Americans have turned to purchasing prescriptions from online pharmacies. In 2000, there were between 300 and 400 Internet pharmacies, half of which were located outside the United States.⁶⁸ The Food and Drug Administration (FDA) estimates that about two million parcels containing regulated products enter the United States each year through the mail.⁶⁹ During a five-week pilot project with the FDA in 2000, customs officials in Carson City, California, received 16,500 suspect packages but were able to inspect fewer than 2,000 and seized only 720 of the suspect packages examined.⁷⁰ In 1999 alone, seizure of parcels containing controlled substances increased 450 percent, mainly due to an increase in online pharmacies.⁷¹

65. *Id.* at 32.

66. *Id.*

67. *Id.* at 33.

68. *Examining Prescription Drug Re-importation: A Review of a Proposal to Allow Third Parties to Re-import Prescription Drugs*, available at <http://www.energycommerce.house.gov/107/hearings/07252002Hearing677/Hubbard1147print.htm> [hereinafter Hubbard] (testimony of Mr. William Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, FDA at the hearing before the Subcommittee on Health of the House Committee on Energy and Commerce, 107th Cong. (2002)).

69. *Id.*

70. *Id.*

71. *Id.*

Internet pharmacies offer many conveniences. The consumer can access drug prices, comparison shop, and purchase from the cheaper provider.⁷² Online pharmacies eliminate the need to travel to a traditional pharmacy so the disabled and those living far away from a pharmacy have better access to prescriptions.⁷³ In addition, purchasing prescriptions online offers some anonymity; customers may talk with a pharmacist over the phone or via e-mail and not be concerned about bystanders overhearing.⁷⁴

Buying from online pharmacies has negative consequences as well. Since some Internet pharmacies provide drugs to patients without a prescription, consumers can self-medicate rather than receive proper direction from a licensed physician.⁷⁵ Many rogue pharmacies are currently operating online businesses, and consumers may be susceptible to getting out-of-date medicines or mislabeled dosage instructions.⁷⁶ The Attorney Generals of several states have filed suits against rogue pharmacies operating without licenses. Some of these suits have met success in Ohio, Missouri, Texas, and Kansas.⁷⁷

To ensure patient safety, the National Association of Boards of Pharmacy (NABP) established a program called Verified Internet Pharmacy Practice Sites (VIPPS).⁷⁸ This program is designed to assist the public in identifying properly licensed Internet pharmacies that have agreed to comply with federal and state laws. It is a voluntary program to which the online pharmacies may apply.⁷⁹ Consumers may want to choose pharmacies from the VIPPS list in order to benefit from the consumer protection plan. Online shoppers should price carefully, as well, because shipping charges might make the total price cost more than purchasing from a traditional pharmacy.

B. TRAVELING TO CANADA TO PURCHASE PRESCRIPTION DRUGS

Many U.S. consumers have turned to our northern neighbor to fulfill their prescription drug needs: Canadian pharmacies.⁸⁰ The data for 1998 indicated brand-name drug prices in the United States were 60 percent

72. Kerry Toth Rost, *Policing the "Wild West" World of Internet Pharmacies*, 55 FOOD DRUG L.J. 619, 622 (2000).

73. *Id.*

74. *Id.*

75. *Id.* at 623.

76. *Id.*

77. *See id.* at 632-33. Ohio Attorney General has filed cease-and-desist orders against several internet pharmacy cites; Missouri Attorney General has secured permanent injunction against an online clinic and a Texas-based internet pharmacy for providing prescription drugs without a license and only on the basis of information provided in online consultations; Kansas Attorney General has filed restraining orders against seven internet companies that were illegally selling prescription-only drugs over the internet.

78. Rost, *supra* note 72, at 629.

79. *Id.*

80. *See* Koren, *supra* note 2.

higher than Canada.⁸¹ The price difference between the two countries provides price-sensitive American citizens living close to the border, an advantageous venue for obtaining their prescription needs. Although many Americans, especially senior citizens, travel to Canada to fill their prescriptions, this is not a viable option for poorer Americans who do not have the resources to travel across the border to take advantage of the money saving opportunities.

Although purchasing prescription drugs from Canada and Mexico has been on the rise,⁸² under the Federal Food and Drug Cosmetic Act (FDCA), interstate shipment of any prescription drug that lacks required FDA approval is illegal.⁸³ Accordingly, importing drugs manufactured in a foreign country into the United States is against the law.⁸⁴ The FDCA, however, permits re-importation of prescription drugs made in the United States and exported to a foreign country only if the drug's original manufacturer imports the drug back into the United States.⁸⁵ Although the FDA warns Americans about the dangers of purchasing medications from foreign countries and consistently advises against the illegal practice, the FDA has issued an informal policy guide recognizing circumstances when FDA field agents can choose to take no action against the importation.⁸⁶ According to FDA's regulatory procedure manual, FDA inspectors may exercise enforcement discretion in allowing the importation only if the intended use of the drug is for a serious condition that does not have effective treatment domestically; the imported product does not pose unreasonable risk; it is for personal use and does not exceed a ninety day supply; it is not promoted to U.S. residents by those involved in the distribution of the product; the receiving individual affirms in writing that it is for her own use; and the individual provides a name and address of a U.S. doctor responsible for the patient's treatment with the product.⁸⁷

Insurance companies have jumped on the bandwagon by providing coverage of beneficiaries' drug purchases abroad. For example, UnitedHealth Group has waived its requirement that the drugs would be covered under the plan only if purchased in the United States.⁸⁸ In July

81. Graham, *supra* note 61, at 32.

82. Dennis Cauchon, *Americans Pay More for Medicine*, USA TODAY (Nov. 10, 1999), available at <http://www.usatoday.com/life/health/drugs/lhdru066.htm>.

83. *Id.*

84. Office of Regulatory Affairs, *Importation of Prescription Medicines/Drugs: Traveler Alert*, at http://www.fda.gov/ora/import/traveler_alert.htm (last visited Nov. 1, 2002).

85. Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER MAG. (Sept.-Oct. 2002), available at <http://www.fda.gov/fdac/features/2002/502.import.html>.

86. FDA Regulatory Procedure Manual, Ch. 9, *Subchapter Coverage of Personal Importations*, available at http://www.fda.gov/ora/compliance_ref/rpm_news2/ch9pers.html (last visited Nov. 3, 2002).

87. See Hubbard, *supra* note 68.

88. Sarah Lueck, *Upstart Texas Firm Makes Stir with Cheap Drugs from Canada*, WALL ST. J. (Oct. 21, 2002), available at <http://www.msnbc.com> (in Sept. 2002).

2002, SPC, Inc., a Texas company that processes insurance claims and designs health plans for unions, hospices, and managed-care companies, created a Canadian drug program.⁸⁹ Under this program, SPC, Inc. sends a list of 250 drugs that are cheaper in Canada to its member consumers. The patients obtain a prescription from their U.S. doctors, and order the drug through Expedite-Rx.⁹⁰ Orders are then placed with Cross Border Pharmacy in Calgary, which then forwards orders to Canadian doctors. The doctors re-write the prescriptions, send them back to Cross Border Pharmacy who fills them and mail the drugs to the patients.⁹¹ Since so many Americans, especially senior citizens, are resorting to obtaining drugs from Canada, insurance companies have decided not to penalize them for buying cheaper drugs, but rather to offer coverage of the drugs.

V. CURRENT LEGISLATION ADDRESSING HIGH DRUG PRICES

Congress has been receptive to the American public's concern for the consistent rise in the cost of prescription drugs. As a result, various popular solutions have emerged; some have avid supporters, and others have been criticized severely. Congress is attempting to pass legislation that would curb the rising price of prescription drugs in the United States.

A. LEGISLATION TO EASE ENTRY OF GENERIC DRUGS INTO THE MARKET

By an overwhelming majority vote of 78-21, on July 31, 2002, the Senate passed S.812, Greater Access to Affordable Pharmaceutical Act (GAAP), sponsored by Senators Charles Schumer of New York and John McCain of Arizona.⁹² During the past two years, about 45 percent of all prescriptions filled in the United States were generic drugs.⁹³ Generic

UnitedHealth Group told 97,000 of its insurers that it would cover the costs of drugs purchased in foreign countries).

89. *Id.*

90. *Id.*

91. *Id.*

92. See Markian Hawryluck, *Bill would ease Access to Generic Drugs*, AMEDNEWS.COM (Aug. 19, 2002), available at http://www.ama-assn.org/sci-pubs/amnews/pick_02/gvsb0819.htm; see also *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, 'Generic Drug Entry Prior to Patent Expiration'*, available at <http://www.energycommerce.house.gov/107/hearings/10092002Hearing745/Crawford1221print.htm> [hereinafter *Generic Drug Entry*] (statement of The Honorable Lester Crawford D.V.M., Ph.D, Deputy Commissioner of FDA at the hearing before the Subcommittee on Health of the House Committee on Energy and Commerce, 107th Cong. (Oct. 9, 2002)). For a detail view of the bill, see GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2002, S. 812, 107th Cong. (2002).

93. *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, 'Generic Drug Entry Prior to Patent Expiration'*, available at <http://energycommerce.houst.gov/107/hearings/10092002hearing745/Jaeger1223print.htm> [hereinafter *Jaeger*] (statement of Kathleen Jaeger, President and CEO of the Generic Pharmaceutical Association, at the hearing before the Subcommit-

drugs cost, on average, ten times less than their brand-name equivalent,⁹⁴ and patients, on average, save about 76 percent when a generic drug is substituted for a brand-name product.⁹⁵ Out of the 10,375 drugs listed in the FDA's Orange Book, 7,602 are available in generic form, and within the next three years, twenty-seven brand name drugs are scheduled to go off patent,⁹⁶ hence increasing the availability of cheaper generic drugs for the American consumers. Having passed the Senate, the bill was before the House of Representative's Committee on Energy and Commerce, and on October 9, 2002, the Subcommittee on Health held hearings to examine the issues surrounding the need for passing the measure.⁹⁷

The 1984 Hatch/Waxman Act⁹⁸ was enacted to achieve the dual objectives of guaranteeing a period of market exclusivity for the brand-drug manufacturers to recoup their investments in R&D, as well as to promote competition in the drug industry.⁹⁹ But, the Federal Trade Commission (FTC) has recently reported that drug companies are "filing frivolous lawsuits and invoking the act to fend off competition and keep generic drugs out of the marketplace."¹⁰⁰ Brand-name drug manufacturers take advantage of the protections the Hatch/Waxman Act affords them by suing generic drug manufacturers each time they attempt to introduce cheaper versions of a drug to the market. The incentive for filing a lawsuit is that the brand-name company is automatically granted a thirty-month stay, which means the FDA is barred from approving the generic competitor's product.¹⁰¹ Brand-name drug manufacturers thus benefit financially from the additional thirty months of market exclusivity.¹⁰² The abuse is indicated by the increased rate of patent challenges in recent years as more drug patents expired: 2 percent of all generic applications

tee on Health of the House Committee on Energy and Commerce, 107th Cong. (Oct. 9, 2002)).

94. *Id.* § 1 ¶ 4.

95. *Id.* § 1 ¶ 5.

96. *Id.* § 1 ¶ 7.

97. W.J. Tauzin, *Statement on Generic Drug Competition*, House Committee on Energy and Commerce (Oct. 9, 2002), available at http://energycommerce.house.gov/107/news/10092002_748print.htm.

98. Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C.S. § 505(j) (repealed); see also Markian Hawryluk, *Drugs without Borders: When Prescription Drugs Go Over the Line*, AMEDNEWS.COM (Oct. 22, 2001), available at http://www.ama-assn.org/sci-pubs/amnews/pick_01/gvsa1022.htm. (Under the Hatch/Waxman Act, brand-name drug makers are required to list the patents that apply to each drug. Rather than requiring a generic drug maker to repeat the extensive patent application process, the act allows the company to incorporate the original manufacturer's safety and efficacy data by showing the generic drug is equivalent to the brand-name product. Generics must certify equivalency for every patent listed for a drug, or assert that a patent is invalid or not infringed. If the original manufacturer sues to challenge those assertions, it triggers a thirty month protection against the generic competitor.)

99. Jaeger, *supra* note 93.

100. *Bush proposes rules to boost generic drugs*, CNN.COM. (Oct. 22, 2002), available at <http://www.cnn.com/2002/ALLPOLITICS/10/21/bush.generic.drugs.index.html>.

101. Jaeger, *supra* note 93.

102. *Id.* For a detailed description, refer to section B: The Current System is Being Abused to the Detriment of American Consumers.

were challenged in 1984-1989, whereas 28 percent were challenged in 2001.¹⁰³ The dramatic increase demonstrates the need for an immediate response by Congress to relieve the generic drug manufacturers from the brand-name drug makers invoking the Hatch/Waxman Act to delay the introduction of generic drugs into the market.¹⁰⁴

One of the main objectives of GAAP is to ease the introduction of generic drugs into the market upon the expiration of the brand-name manufacturer's patent by closing loopholes that the brand-name manufacturers are currently using to extend their patent protections.¹⁰⁵ Twenty-seven "blockbuster" drugs are scheduled to lose their patent protection in the next five years.¹⁰⁶ Advocates of GAAP urge Congress to pass the bill to prevent further attempts to delay production of generic drugs.¹⁰⁷

The main provisions of GAAP include: 1) limiting brand-name manufacturers to a single thirty-month stay upon filing suit against generic manufacturers; 2) banning collusion between a generic and brand-name manufacturers to prevent a generic alternative from coming to the market; 3) providing a means for competitors to challenge the relevancy of patents listed by brand-name manufacturers; and 4) allowing re-importation of U.S.-made drugs from Canada with the Health and Human Services Secretary's approval.¹⁰⁸ Congressional Budget Office reports that Americans will save \$60 billion dollars in the next ten years if Congress enacts GAAP into law.¹⁰⁹ The passage of GAAP could be an important move toward providing Americans with lower-price prescription drugs.

B. LEGISLATION TO LEGALIZE RE-IMPORTATION

During the long Senate debates over S.812 (GAAP), Senator Byron Dorgan of North Dakota succeeded in adding an amendment to S.812 that would allow re-importation of prescription drugs by pharmacists and wholesalers for resale.¹¹⁰ S.812 would allow for more drugs to be re-imported than is currently permitted under the Food Drug and Cosmetic Act, which allows only manufacturers to re-import.¹¹¹ An increase in re-

103. *Id.*

104. Jaeger, *supra* note 93. The FTC has concluded in its report that indeed there were no instances that the generic drug entering the market was later found to be infringing on the brand's patent.

105. Hawryluk, *supra* note 98.

106. Jaeger, *supra* note 93.

107. *Id.* The FTC issued its final report in July 2002, finding that the thirty month stay is being abused and delays competition.

108. Hawryluk, *supra* note 98.

109. Jaeger, *supra* note 93, at 7.

110. Markian Hawryluk, *Efforts Continue for Drug Reimportation*, AMEDNEWS.COM (Aug. 12, 2002), available at http://www.ama-assn.org/sci-pubs/amnews/pick_02/gvsc0812.htm.

111. Hubbard, *supra* note 68.

imported drugs should result in higher savings to American consumers.¹¹² The amendment was passed, along with GAAP, when the Senate voted in July 2002.

This is not the first time that Congress has enacted such a measure. In October 2000, during the Clinton administration, Congress enacted the Medicine Equity and Drug Safety Act (MEDSA), a measure similar to GAAP.¹¹³ A provision of MEDSA requires the Secretary of Health and Human Services (HHS) to certify, before the Act becomes effective, that implementation of the measure will achieve the goals of providing significant cost savings to Americans and ensuring the public's health and safety.¹¹⁴

Both the Clinton and Bush administrations have declined to implement MEDSA.¹¹⁵ In December 2000, HHS Secretary, Donna Shalala, stated that the legislation had too many weaknesses to be implemented.¹¹⁶ In July 2001, the Bush administration also refused to implement the measure due to safety concerns.¹¹⁷ The current re-importation legislation, GAAP, recently passed by the Senate, contains a verification provision similar to MEDSA. Senator Thad Cochran of Mississippi succeeded in adding an amendment to GAAP requiring the Secretary of Health and Human Services to certify before the law is implemented that re-importation is safe and cost effective.¹¹⁸

The Bush Administration is concerned that GAAP, in its current form, will compromise consumer safety.¹¹⁹ Another critic of the legislation is the current HHS Secretary, Tommy Thompson, who believes that the drug re-importation proposals introduced this year and in previous years "would create unacceptable risks of adulterated, outdated, mislabeled, or otherwise unsafe medications."¹²⁰ Drafters of GAAP changed several provisions in MEDSA to adjust for the concerns that Secretary Shalala expressed as central to her refusal to implement MEDSA.

Although MEDSA and GAAP are similar conceptually, they differ in two key aspects. MEDSA of 2000 allows "covered products" (prescrip-

112. Nat'l. Ass'n of Health Underwriters Washington Update, *Medicare Reform* (Aug. 2, 2002), available at http://www.nahu.org/goernment/newsletters/washington/washUpdate_08-01-02.htm [hereinafter *Medicare Reform*].

113. Hawryluk, *supra* note 98.

114. See Medicine Equity and Drug Safety Act, 21 U.S.C.S. § 384 (l) (2002).

115. Hawryluk, *supra* note 98.

116. *Examining Prescription Drug Reimportation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs*, available at <http://energycommerce.house.gov/107/hearings/07252002Hearing677/Hutt1150print.htm> (testimony of Mr. Peter Barton Hutt, partner in the law firm of Covington & Burling, at the hearing before the Subcommittee on Health of the House Committee on Energy and Commerce, 107th Cong. (July 25, 2002)).

117. Hawryluk, *supra* note 110.

118. *Medicare Reform*, *supra* note 112.

119. Office of Management and Budget, The Executive Office of the President, *Statement of Administration Policy on S. 812 - Greater Access to Affordable Pharmaceuticals*, (July 18, 2002), available at <http://www.whitehouse.gov/omb/legislative/sap/107-2/S812-s.html>.

120. Hawryluk, *supra* note 110.

tion drugs that are not controlled substances) to be imported from Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the European Union by wholesalers and pharmacies.¹²¹ GAAP on the other hand, in its current form, permits re-importation of drugs into the United States from Canada only.¹²²

GAAP also contains a clause that addresses personal importation of medicine from Canada.¹²³ GAAP would permit individuals to import prescription drugs for personal use, but not more than a ninety-day supply purchased from a licensed Canadian pharmacy registered with the Secretary of HHS and accompanied with a copy of a valid prescription.¹²⁴ MEDSA of 2000 does not contain a provision addressing personal importation.

Opponents of GAAP are concerned that patients will be at risk if such measures are implemented.¹²⁵ They believe that "no other country has as strong a regulatory structure protecting its pharmaceutical products as the United States."¹²⁶ The FDA resists implementing any measure that would legalize re-importation of prescription drugs because of fear of harm to Americans from drugs imported from other countries that do not subject drug companies to the "gold standard" used in the United States.¹²⁷ The Administration is concerned also with the broad provisions of the personal importation measures because their effect is to override the existing statutes that allow the FDA to refuse entry of prescription drugs from Canada if they are believed to be unsafe, adulterated, or counterfeit.¹²⁸

Alan Sager, Ph.D., professor of health services at the Boston University School of Public Health, believes that the pharmaceutical industry's reaction would retard the impact of any re-importation measures.¹²⁹ For one, it is unrealistic to think that the United States could purchase the necessary quantity of drugs from Canada, because the drug companies would be unwilling to first "ship to Canada the volume of drugs needed to support the much bigger U.S. market."¹³⁰

Supporters of the re-importation legislation believe that because so many people are already crossing the border to get prescription drugs, it makes sense to formally legalize the practice.¹³¹ It remains to be seen how the House of Representative will vote on the bill.

121. 21 U.S.C.S. § 384(f).

122. GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2002, S. 812, 107th Cong. § 804(b) (2002).

123. S. 812 § 804 (k)(3).

124. *See id.*

125. Hawryluk, *supra* note 110.

126. *Id.*

127. *See generally*, Hubbard *supra* note 68.

128. *Id.*

129. Hawryluk, *supra* note 110.

130. *Id.*

131. *Id.*

VI. CONCLUSION

With the advance of science in biomedicine and the discovery of innovative new medicines, comes a constant rise in prescription drug prices. Many uninsured Americans do not have access to life-saving, innovative drugs due to high prices. Although senior citizens and the uninsured have found alternatives to paying high retail prices for prescription drugs in the United States, most of these alternatives expose them to health or legal risks.

Legislators have begun to experiment with new ideas for resolving the problem of the high prescription drug prices in the United States, but it will be some time before a consensus is reached. In the meanwhile, some individuals who have the means will continue to purchase their medicines from our neighboring countries; and those who cannot, will suffer. Perhaps the United States could learn a lesson from its northern neighbor and other countries in how to successfully control drug prices and make prescription drugs accessible to its citizens. A further study of other health care systems may be a way to assist the United States in devising a prescription drug plan that better balances the demands of a free market, capitalism, equal access, and those in need of medication.

Articles

