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REIMPORTATION OF PRESCRIPTION DRUGS: LONG-LASTING RELIEF OR A SHORT-TERM ANALGESIC?

INTRODUCTION

As scientific advancement creates a higher standard of living, consumer demand for improved practices and products increases concurrently; however, the advancements often come with a large price tag.¹ For example, prescription drugs provide a variety of benefits to the public, yet the rising cost of prescription drug coverage is a hot topic of debate, often aired over the nightly news² and ubiquitous in popular newspapers³ and magazines.⁴ This debate also extends to the political arena, where the rising cost of prescriptions has been noted in several political campaign ads.⁵ Central to this debate is the tension between health and industrial policy, where the need to control prescription drug

1. For an insightful discussion of this medical paradox involving medical advances, see Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149 (2000). Stanton notes that medical advances only precipitate the further need for more significant medical advances. *Id.* at 149. That is, those people who survive life-threatening illnesses, or those who never are exposed to such an illness due to the modern marvels of medicine, tend to lead long lives, and as such, at some point, require advanced medical procedures and prescription drugs. *Id.*

2. See, e.g., NewsHour with Jim Lehrer: *Rx Drug Coverage* (PBS television broadcast, July 30, 2002), available at http://www.pbs.org/newshour/bb/health/july-dec02/drugs_7-30.html (last visited Oct. 19, 2004).

3. See, e.g., Joel Millman, *Not Your Generic Smugglers: American Seniors Flock to Border Town for Cheap Prescriptions*, WALL ST. J., Mar. 20, 2003, at D3; Paul Pringle, *Not-So Corner Drugstore: Canadian Web Firms are Supplying Low-Cost Prescriptions to Many Elderly Americans but Manufacturers and Regulators are Chafing*, L.A. TIMES, Feb. 21, 2003, at A1; David Schwab, *Primes: The Issues Behind the Battle Over Drug Prices*, SEATTLE TIMES, June 3, 2001, at D1; Robin Toner, *Major Battle Looms Over Medicare*, N.Y. TIMES, Feb. 11, 2001, at A34; Terry Frieden, *Judge Orders Internet Drug Firm Closed*, CNN.com, Nov. 7, 2003, at <http://www.cnn.com/2003/HEALTH/11/06/canada.drugs/index.html> (last visited Sept. 4, 2004).

4. Nathan Thornburgh, *Drug Costs: The Canadian Cure*, TIME, Nov. 24, 2003, at 19; David Noonan et al., *Why Drugs Cost So Much: High Stakes*, NEWSWEEK, Sept. 25, 2000, at 22; Donald L. Barlett & James B. Steele, *Why We Pay So Much for Drugs*, TIME, Feb. 2, 2004, at 44.

5. National political campaigns include television ads sponsored by MoveOn.org, attacking the Bush Administration's handling of health care reform. Press Release, MoveOn.org, MoveOn.org Voter Fund Takes Bush SOTU Medicare Ad into Five States (Jan. 22, 2004), <http://www.moveon.org/press/pr/release12004.pdf> (last visited Sept. 4, 2004). MoveOn.org Voter Fund spent \$1.9 million to carry this campaign in key battleground states, including Florida, Missouri, Nevada, Ohio, and West Virginia. *Id.* The ad featured voice-over of actual images of President Bush's State of the Union speech, with the voice-over suggesting that seniors will be paying substantially more under the new Medicare bill. *Id.* Local campaign ads include television and Internet ads sponsored by an Illinois Democratic Primary candidate for the United States Senate, Blair Hull. See M. Blair Hull, Democrat for U.S. Senate, <http://www.blairhull.com> (last visited Oct. 29, 2004).

spending directly competes with the need to provide incentives for an industry that provides significant health and economic benefits.⁶ This debate often centers around the substantial difference in the prices charged in the United States and those charged for the same drugs in other countries, most notably Canada.⁷ The debate also concerns balancing the need for affordable prescription drugs with the need to provide incentives for future research and development (R&D).⁸

On one side of this debate is the importance of preserving the free enterprise system that precipitates the newest and greatest advances in the health care industry.⁹ The pharmaceutical industry estimates that it costs between \$500 and \$800 million to bring a drug to market.¹⁰ However, while the R&D costs for bringing a single treatment to market can be quite high, the price actually paid for a single drug may be substantially less.¹¹ Additionally, investment in the pharmaceutical industry is consistently profitable,¹² and with continued increases in drug spending each year, it shows no signs of slowing down.¹³

On the other side of this debate is the importance of affordable prescription drugs for the American consumer. A substantial number of Americans have one or more chronic health conditions and require access

6. David Gross, *Prescription Drug Prices in Canada*, 62 AARP PUBLIC POLICY INSTITUTE BRIEF 1, 18 (2003), http://research.aarp.org/health/ib62_can_rx.pdf (last visited Oct. 18, 2004).

7. *Id.*

8. *Id.*

9. *International Prescription Drug Parity: Are Americans Being Protected or Gouged?: Hearing before the Subcomm. on Human Rights and Wellness of the Comm. on Government Reform*, 108th Cong. 1-5 (2003) [hereinafter *Hearing: International Prescription Drug Parity*] (statement of Rep. Dan Burton, Chairman, Subcomm. on Human Rights and Wellness).

10. *Id.* at 2.

11. *Id.* at 2. "Only ten to thirty percent of the products in development actually make it to the marketplace, so companies add the cost of failed products into the R&D costs of drugs that ultimately are approved." *Id.*

12. See Robert H. Ballance, *Market and Industrial Structure*, in CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS 95 (Peter Davis ed., 1996). Over the last three decades, the pharmaceutical industry experienced a return on equity over six percent greater than the average of other industries. *Id.* at 103-04. In the 2002 annual *Fortune 500* survey, the pharmaceutical industry topped the list of the most profitable industries, with a return of seventeen percent on revenue. Barlett & Steele, *supra* note 4, at 46-47.

13. Centers for Medicare and Medicaid Services (CMS), *National Health Care Expenditures Projections Tables, Table 2: National Health Expenditure amounts, and Average Annual Percent Change by type of Expenditure: Selected Calendar Years 1980-2012*, at <http://www.cms.hhs.gov/statistics/nhe/projections-2002/t2.asp> (last visited Sept. 4, 2004). Between 1990 and 2001, prescription drug spending in the United States grew by about twelve percent per year. *Id.* For another similar estimate of the increase in spending on prescription drugs, see Martha Ann Holt, *International Prescription Drug Cost Containment Strategies and Suggestions for Reform in the United States*, 26 B.C. INT'L & COMP. L. REV. 325 (2003) (noting an increase in drug spending in the United States of between sixteen and twenty percent per year).

to affordable prescription drugs in order to lead happy, healthy lives.¹⁴ The rising cost of prescription drug coverage has many American consumers—older American consumers in particular—looking for more affordable alternatives.¹⁵ Many Americans are uninsured or underinsured for the high cost of prescription drugs,¹⁶ and often fail to purchase necessary medication,¹⁷ even when they have serious medical conditions, such as heart disease.¹⁸

A third, and often ignored, aspect of this debate concerns the government's interest in regulating prescription drugs in order to ensure product safety and quality.¹⁹ Specifically, the Food and Drug Administration (FDA) is charged with ensuring that the protections afforded to consumers who purchase prescription drugs from their local pharmacy are extended to consumers who obtain prescriptions by alternative means.²⁰ As online pharmaceutical sales continue to increase, it becomes more challenging for the government to regulate the products dispensed, and, as such, the government cannot provide consumers with

14. *Hearing: International Prescription Drug Parity*, *supra* note 9, at 2. "As many as 108 million Americans have one or more chronic health conditions such as diabetes, high blood pressure, asthma, and heart disease, and many require prescription drugs to manage these conditions." *Id.* Seventy-five percent of Americans age fifty to sixty-four take at least one prescription drug, and fourteen percent of women aged sixty-five take five prescription drugs every week. *Id.*

15. See Patricia Barry, *More Americans Go North For Drugs*, AARP BULLETIN, Apr. 2003, at 3; see also Gross, *supra* note 6, at 1.

16. *Importation of Prescription Drugs from Canada*, MEDICARE RIGHTS CENTER POLICY BRIEF, Oct. 10, 2003, available at http://www.medicarerights.org/fairmedicare_reimportation.html (last visited Sept. 4, 2004). Seniors and the disabled often lack coverage and typically use more prescription drugs than younger, healthier Americans. *Id.* In 1999, thirty-eight percent of all people with Medicare had no coverage for prescription drugs, and even more had inadequate drug coverage. *Id.*

17. Karen Donelan et al., *The Cost of Health Care System Change: Public Discontent in Five Nations*, 18 HEALTH AFFAIRS, May–June 1999, at 206. Forty-two percent of uninsured Americans reported that they did not fill their prescriptions due to financial concerns. *Id.*

18. Alex D. Federman et al., *Supplemental Insurance and Use of Effective Cardiovascular Drugs Among Elderly Medicare Beneficiaries With Coronary Heart Disease*, 286 JAMA 1732 (2001).

19. In 2000, Congress passed, and "the President signed into law the MEDS Act to allow U.S. consumers, pharmacists, and wholesalers to purchase FDA-approved prescription drugs on the international market," but the FDA has not implemented the law, claiming that it cannot assure the safety of the products being shipped into the United States. *Hearing: International Prescription Drug Parity*, *supra* note 9, at 2. The FDA is charged with regulating products for the safety and protection of the American consumer under the Federal Food, Drug, and Cosmetic Act. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040, codified as amended at 21 U.S.C. § 301 et seq. (1938) [hereinafter FDCA]. The FDA has the legal authority to take action against the importation, sale, or distribution of an adulterated or misbranded drug; the importation, sale, or distribution of an unapproved new drug; the illegal promotion of a drug; the sale or dispensing of a prescription drug without a valid prescription; and counterfeit drugs. *Hearing: International Prescription Drug Parity*, *supra* note 9, at 40 (statement of William Hubbard, FDA Associate Commissioner for Policy, Planning and Legislation).

20. *Id.* at 38–39.

adequate assurance that prescription drugs purchased over the Internet are safe.²¹

For many Americans, the savings obtained from ordering prescription drugs from Canada can be quite substantial.²² Although U.S. law bars the importation of prescription drugs from Canada,²³ the FDA has often overlooked such actions and instead invoked a discretionary “personal use” exemption.²⁴ Consumers take advantage of this popular and often-publicized alternative in a variety of ways.²⁵ For example, American consumers may physically travel to Canada²⁶ to buy prescription drugs.²⁷ Alternatively, Americans not close enough to the border sometimes

21. *Id.* at 39. Although online pharmaceutical sales are important for many consumers, the FDA is concerned that some consumers may have difficulty identifying which Internet sites that sell legitimate products, thus placing their health and safety in jeopardy. *Id.*

22. *See, e.g.,* Jennifer Rak, *An RX for Reform: A Medicare Prescription Drug Benefit*, 12 HEALTH MATRIX 449 (2002). Seniors can save as much as ninety percent on needed medications, with a busload of fifty seniors saving as much as \$48,000 per year. *Id.* at 449.

23. FDCA, *supra* note 19, and accompanying text. The importation of prescription drugs from Canada into the United States contravenes various provisions of the FDCA. *E-drugs: Who Regulates Internet Pharmacies?: Hearing before the Comm. on Health, Education, Labor, and Pensions*, 106th Cong. 13-15 (2000) [hereinafter *Hearing: E-drugs*] (statement of Jane E. Henney, M.D., Commissioner of Food and Drugs, FDA).

24. Julius Melnitzer, *Glaxo Disrupts Canadian Drug Pipeline into United States: Canadian Trade Commission Supports Glaxo's Ban*, CORP. LEGAL TIMES, June 2003, at 34. This exemption is often narrowly construed to allow for prescription drugs shipped by Canadian pharmacists directly to American citizens. *Id.* Although the discretionary exemption has no statutory basis, a citizen has never been prosecuted for violating the law. *Id.* The “personal use” exemption usually consists of a ninety-day supply intended for personal use. *Id.*

25. The focus of this Note will be primarily confined to the reimportation of prescription drugs from Canada by personal reimportation: traveling to Canada, filling a prescription, and returning to the United States; or filling a prescription online and having the filled prescription shipped to the United States.

26. Similarly, many American consumers travel to Mexico to obtain prescription drug products due to their easy accessibility (most products do not require a prescription in Mexico), their lower cost, and because products are available in Mexico that are not available in the United States. *Examining Prescription Drug Importation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs: Hearing before the Subcomm. on Health of the Comm. on Energy and Commerce*, 107th Cong. 59 (2002) [hereinafter *Hearing: Examining Prescription Drug Importation*] (statement of Marv Shepherd, Director, Center for Pharmacoeconomic Studies, College of Pharmacy, University of Texas). The pharmaceutical business in Mexican border towns is indeed a huge tourist attraction that injects hundreds of millions of dollars into the Mexican economy. *Id.* at 62. This is evidenced by the fact that there are 1400 Farmacias in Tijuana, while in nearby San Diego there are just over 100 pharmacies. *Id.*

These lower prices exist because “Mexico is at a less advanced stage of economic development, has lower real wages and per capita incomes, and has lower prices for many goods and services.” PATRICIA M. DANZON, PRICE COMPARISONS FOR PHARMACEUTICALS: A REVIEW OF U.S. AND CROSS-NATIONAL STUDIES 32 (1999). Thus, it is no surprise that prices in Mexico are lower, given lower per capita gross domestic product, governmental use of monopsony power, weaker patent protection, and numerous price-sensitive consumers. *Id.* at 34.

27. *See generally* Barry, *supra* note 15 (describing elderly consumers traveling to Canada to fill prescriptions).

purchase prescription drugs by mail order, often via the Internet.²⁸ This trend of seeking out lower-cost prescription drugs will continue as Americans, especially older Americans, search for ways to pay for their ever-increasing prescription drug expenses.²⁹

The main reason that prescription drug prices are lower in other industrialized nations is that government-imposed price controls keep the cost down.³⁰ In comparison, the United States has struggled to preserve price parity, largely because pharmaceutical industry pricing is fundamentally unregulated.³¹ As the American public grows older, a longer, healthier life requires both affordable and innovative prescription drugs. To ensure that the American consumer has access to both, Congress needs to reevaluate the health care system. However, before deciding what legislation to pass in order to reform the health care system, Congress must balance the need to curb prescription drug spending with the need to maintain an economically healthy pharmaceutical industry.

Part I of this Note discusses the legislative history of the regulation of prescription drugs, as well as that of recent Congressional legislation aimed at establishing prescription drug price parity. Part II examines the historical disparity of the pharmaceutical industry's pricing structure on the national and international level, analyzing both methodology of price comparison and potential reasons for price disparity. Part III makes recommendations, based on the structure of the pharmaceutical industry and prescription drug coverage models from foreign countries, in particular Canada, for what the United States could, and should, do in response to the increasing cost of prescription drugs. Part IV proposes a balanced solution that incorporates regulatory methods taken from several countries. Finally, this Note concludes that without some balanced government intervention, either the American consumer will be forced to pay impossible amounts for prescriptions—requiring a choice between necessary medication and other living expenses—or the pharmaceutical industry will be unable to continue providing substantial health and

28. *Id.* See also Frieden, *supra* note 3.

29. Melnitzer, *supra* note 24, at 34. Overall, 1.2 million American consumers are spending \$2 billion every year to purchase prescription drugs from Canada, at thirty to ninety percent below American drugstore prices. *Id.* In Fall 2002, several insurers, including AARP, agreed to reimburse policyholders who filled their prescriptions in Canada. *Id.*

30. Michele L. Creech, *Make a Run for the Border: Why the United States Government is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 594 (2001). Other countries implement governmental regulations to negotiate the launch price of drugs with pharmaceutical manufacturers, limit price increases to inflation rates, or forbid price increases altogether. *Id.*

31. See Stanton, *supra* note 1, at 155.

economic benefits to not only the American public, but also to the global community at large.

I. LEGISLATIVE HISTORY

A. *History and Development of Current U.S. Regulation of Pharmaceuticals*

The long history of the regulation of pharmaceuticals³² began in the United States in 1902 with the Virus, Serum, and Antitoxin Act.³³ Shortly thereafter was the passage of the Pure Food and Drugs Act,³⁴ which took action against fraudulent remedies and unlabeled products.³⁵ The Federal Food, Drug, and Cosmetic Act (FDCA)³⁶ was the first attempt to require drugs to be tested for safety and labeled for use.³⁷ These acts were passed in order to ensure that the products were healthy and safe for consumers.³⁸

The Prescription Drug Marketing Act of 1987 (PDMA)³⁹ and the Prescription Drug Amendments of 1992⁴⁰ amended the FDCA to prohibit prescription drug reimportation.⁴¹ This legislation was proposed based on Congressional hearings regarding serious potential problems relating to the efficacy and accountability within the system of the reimportation of prescription pharmaceuticals to be sold to American consumers.⁴² After five days of hearings, a formal report issued by the subcommittee noted

32. For analysis of the history of biologics regulation, see, for example, Edward L. Korwek, *Human Biological Drug Regulation: Past, Present, and Beyond the Year 2000*, 50 FOOD & DRUG L.J. 123 (2000); PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW, CASES & MATERIALS 1–22 (2d ed. 1991).

33. Virus, Serum, and Antitoxin Act, Pub. L. No. 57-244, 32 Stat. 728 (1902).

34. Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. §§ 1–15 (1934) (repealed in 1938 by 21 U.S.C. § 392(a) (1988)).

35. JAMES NIELSEN, HANDBOOK OF FEDERAL DRUG LAW 4 (1992).

36. FDCA, *supra* note 19. Cf. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (original version).

37. NIELSEN, *supra* note 35, at 5–6.

38. *Id.*

39. Pub. L. No. 100-293, 102 Stat. 95 (1987) (codified at 21 U.S.C. §§ 301 note, 331(t), 333(v), 353(c)–(e), 381). Congress' intent in passing this legislation was to avoid "an unacceptable risk that counterfeit, adulterated, misbranded, subpotent or expired drugs will be sold to American consumers." 102 Stat. at 95–96.

40. Pub. L. No. 102-353, 106 Stat. 941 (1992) (codified at 21 U.S.C. §§ 301 note, 333, 353, 353 note, 381).

41. Guidelines for State Licensing of Wholesale Prescription Drug Distributors, 21 C.F.R. pt. 205 (2004). See also *supra* note 39 and accompanying text.

42. *Drug Diversion: Prescription Drug Diversion and the American Consumer: What You Think You See May Not Be What You Get: a Staff Report by the Subcomm. on Oversight and Investigations of the Comm. of Energy and Commerce*, 99th Cong. 1 (1985), Introduction. "American consumers can no longer purchase prescription drugs with the certainty that the products are safe and effective." *Id.*

the following concerns: (1) the existence and method of operation of a wholesale submarket that prevents effective control over the true sources of drugs; (2) the reimportation of drugs that may have become subpotent or adulterated during foreign handling and shipping; (3) the existing system of providing samples to physicians through manufacturers' sales representatives may encourage adulteration and/or misbranding; (4) the release of drugs by health care institutions helps fuel the diversion market; and (5) the counterfeiting of brand names by persons in foreign countries promotes the marketing of subpotent or impotent drugs, competes with American markets, and tarnishes the good name of legitimate products in those countries.⁴³

In 2000, the United States Congress passed, and then-President Clinton signed, the Medicine Equity and Drug Safety (MEDS) Act⁴⁴ to allow pharmacists and wholesalers to import covered products into the United States.⁴⁵ However, prior to implementation, the Secretary of Health and Human Services must demonstrate that implementation would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of covered products to the American consumer.⁴⁶

In December 2000, then-Secretary of Health and Human Services, Donna Shalala, refused to implement the MEDS Act, contending that reimportation of prescription drugs created serious health risks, and expressing doubt that reimportation would result in a substantial price reduction.⁴⁷ As such, the MEDS Act was deimplemented.⁴⁸

43. *Dangerous Medicine: The Risk to American Consumers from Prescription Drug Diversion and Counterfeiting*, Report by the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, 99th Cong. 2-4 (1986) (Chairman Dingell's letter of transmittal and Staff Report Findings).

44. The Medicine Equity and Drug Safety Act of 2000, 21 U.S.C. § 384 (2000) (deimplemented by the Secretary of Health & Human Services (HHS) Dec. 27, 2000) [hereinafter MEDS Act].

45. H.R. CONF. REP. NO. 106-948, at 39, 42 (2000). The definition of covered products includes prescription drugs other than controlled substances or biological products. *Id.*

46. *Id.* at 43. The statute also contained a sunset provision that would have canceled the legal effect of the regulations five years after going into effect. *Id.*

47. Marc Kaufman, *Shalala Rejects GOP Drug Price Law: Plan Won't Save Money, She Says*, WASH. POST, Dec. 27, 2000, at A1; Robert Pear, *In a Turnaround, White House Kills Drug-Import Plan*, N.Y. TIMES, Dec. 27, 2000, at A1.

48. *Id.*

B. Recent Legislation

Although the MEDS Act has not yet been reimplemented,⁴⁹ Congress has considered several bills that would permit reimportation of prescription drugs. In 2002, the Senate passed legislation that would permit importation of a ninety-day supply of prescription drugs for personal use from Canada.⁵⁰ This legislation, however, was not passed by the House of Representatives and did not become law.⁵¹

Congress has continued to consider bills that push for prescription drug pricing reform, with many legislators' campaigns heavily focused on prescription drug issues.⁵² Recently, the International Prescription Drug Parity Act⁵³ was introduced in response to the alarmingly high cost of pharmaceuticals in the United States, as compared to Mexico and Canada and other nations.⁵⁴ The Prescription Drug Fairness for Seniors Act⁵⁵ was recently introduced in response to studies that show drug manufacturers engage in price discrimination, charging seniors and others who buy their own prescription drugs more than twice as much as they charge their most favored customers, such as the federal government and large health maintenance organizations (HMOs).⁵⁶ The Health Care Research and Development and Taxpayer Protection Act⁵⁷ was introduced to prevent taxpayers from being charged twice for the same drug.⁵⁸ The

49. Tommy Thompson, the current Secretary of Health and Human Services, has described the legislation as "doubtful." Sara Fritz, *Election Over, Prescription Law Languishes*, ST. PETERSBURG TIMES, Apr. 8, 2001, at A1. As such, it is unlikely that the MEDS Act will be reconsidered and implemented any time soon. *Id.*

50. Gross, *supra* note 6, at 1.

51. *Id.*

52. See, e.g., Congressman Bernie Sanders (I-VT), Bills & Legislation: Legislation: Three Bills Push for Prescription Drug Pricing Reform, at <http://bernie.house.gov/prescriptions/bills.asp> (last visited Sept. 6, 2004); M. Blair Hull, Democrat for U.S. Senate, at <http://www.blairhull.com> (last visited Oct. 29, 2004).

53. International Prescription Drug Parity Act, H.R. 1885, 106th Cong. (1999), available at <http://bernie.house.gov/prescriptions/bills.asp> (last visited Sept. 6, 2004).

54. *Id.* H.R. 1885 would allow American distributors and pharmacists to reimport prescription drugs into the United States from Mexico and Canada as long as the drugs meet strict safety standards and are approved by the FDA. *Id.*

55. The Prescription Drug Fairness for Seniors Act, H.R. 664, 106th Cong. (1999), available at <http://bernie.house.gov/prescriptions/bills.asp> (last visited Sept. 6, 2004).

56. *Id.* The bill would protect seniors from drug price discrimination and make prescription drugs available to Medicare beneficiaries at substantially reduced prices. *Id.* This bill would allow pharmacies that serve Medicare beneficiaries to purchase prescription drugs at the low prices available to the federal government and other favored customers. *Id.*

57. The Health Care Research and Development and Taxpayer Protection Act, H.R. 626, 106th Cong. (1999), available at <http://bernie.house.gov/prescriptions/bills.asp> (last visited Sept. 6, 2004).

58. *Id.* The bill was introduced to prevent taxpayers from being charged twice; currently, taxpayers fund the development of drugs at the National Institutes of Health (NIH). The NIH then sells

Pharmaceutical Market Access Act of 2003⁵⁹ was introduced to allow the importation of drugs from twenty-five industrialized countries, including Canada.⁶⁰ However, none of these introduced bills have become law.

II. DISPARITY OF PRICING: UNITED STATES AND CANADA

Although the general consensus is that prescription drugs cost less in Canada than they do in the United States, the magnitude of the price difference is largely open to debate.⁶¹ This debate essentially stems from methodological differences in cross-national price comparisons for pharmaceuticals.⁶²

A. Methodology

A more complete understanding of methodological issues helps to clarify underlying themes in this debate regarding the magnitude of price differentials. First, methodological differences exist in calculating prescription drug prices at different points in the distribution chain.⁶³ For example, some studies examine prices charged by drug manufacturers, while other studies examine retail prices.⁶⁴ Second, within studies of only retail prices, differences exist regarding which consumer price is used.⁶⁵ For example, in the United States, cash-paying consumers often pay the highest prices, while insurers and HMOs are able to bargain for discounts and manufacturer rebates, and government programs are often able to negotiate the best prices.⁶⁶ Comparatively, Canadian consumers

the drug to a pharmaceutical company, from whom the drugs are ultimately purchased by consumers.
Id.

59. The Pharmaceutical Market Access Act, H.R. 2427, 108th Cong. (2003).

60. John Kasprak, *Prescription Drug Importation*, OLR RESEARCH REPORT, Oct. 7, 2003, available at <http://www.cga.state.ct.us/2003/olrdata/ph/rpt/2003-R-0713.htm> (last visited Sept. 6, 2004). This bill passed the House of Representatives on July 25, 2003, and is currently in the Senate. *Id.* Its intent is to direct the Department of Health and Human Services to adopt regulations concerning the importation of prescription drugs. *Id.*

61. Gross, *supra* note 6, at 6.

62. Patricia M. Danzon and Jeong D. Kim, *International Price Comparisons for Pharmaceuticals: Measurement and Policy Issues*, 14 (Supp. 1) PHARMACOECONOMICS 115 (1998). Danzon and Kim suggest that price comparisons are commonly used for one of two purposes. First, price comparisons based on a sample of products can be used to draw conclusions about differences in average price levels to evaluate drug prices. *Id.* at 116. Second, price comparisons can be examined cross-nationally to determine domestic prices for new products. *Id.* See also Gross, *supra* note 6, at 5.

63. *Id.*

64. *Id.* See generally DANZON, *supra* note 26, at 13–26 (comparing the retail price with the Federal Supply Schedule best price).

65. Gross, *supra* note 6, at 5.

66. *Id.* See generally WILLIAM VON OEHSSEN, PHARMACEUTICAL DISCOUNTS UNDER FEDERAL

experience little variation.⁶⁷ Third, the samples of prescription drugs compared vary widely.⁶⁸ And fourth, drug price comparisons on the international level lead to logistical problems, including choosing an exchange rate⁶⁹ and weighing each drug's price difference given its market share.⁷⁰

Because of the above methodological issues, measuring average price levels is difficult and often requires comparisons based on comprehensive, representative selections of products from the manufacturer.⁷¹ However, obtaining broad, comprehensive samples of products can be problematic because there is great variation across countries regarding product availability.⁷² This creates an inherent trade-off between the desire to compare only identical products and the reality of comparing a representative sample, which often includes generic and therapeutic substitutes.⁷³

LAW: STATE PROGRAM OPPORTUNITIES, PUBLIC HEALTH INSTITUTE: PHARMACEUTICALS AND INDIGENT CARE PROGRAM (2001), available at http://www.ppsv.com/issues/pharm_discounts.htm (last visited Oct. 19, 2004).

67. Steven Morgan et al., *Whither Seniors' Pharmacare: Lessons From (And For) Canada*, HEALTH AFFAIRS, May–June 2003, at 49–59.

68. Gross, *supra* note 6, at 5, 10. Some studies are designed to focus only on price differences of patented drugs, some studies consider price differences of all commonly used drugs, both patented and generic, and some studies focus only on drugs with high volume sales. *Id.*

69. *Id.* at 5. An ideal exchange rate is one that is not sensitive to day-to-day currency fluctuations but is still able to capture the costs and savings of a citizen of one country purchasing prescription drugs in the other country. *Id.* In particular, the extent to which the savings fluctuate when an American consumer purchases prescription drugs in Canada is dependent upon the exchange rate utilized. *Id.*

70. Gross, *supra* note 6, at 5, 11. In choosing a price index, or calculating an aggregate or average price differential, products can be weighted on the basis of their relative importance in the market based on volume of sales, or given an unweighted average, where each product is given equal weight in the calculation. *Id.*

71. Danzon & Kim, *supra* note 62, at 116. Comparisons of individual product prices should consider the manufacturer's entire product portfolio rather than focus on a single product, as production and R&D costs cannot be allocated to a particular product. *Id.* at 115–16. Moreover, appropriate weights of the sample products must be calculated in order to arrive at accurate calculations regarding the relative importance of different medicines as relative importance of various medicines varies across countries. DANZON, *supra* note 26, at 11.

72. Danzon & Kim, *supra* note 62, at 116. Variation across countries can be found in drug availability, dosage forms, strengths, and pack sizes. *Id.*

73. *Id.* A study that requires sample products to match on all dimensions, including compound, manufacturer, and strength, results in a very small and unrepresentative sample of the overall body of drugs available. *Id.* The alternative, which would allow generics and over-the-counter substitutes and allow different dosage forms, strengths, and pack sizes, would create a more valid comparison. *Id.*

B. Price Differentials

The practice of price discounting, or charging different prices to different consumers for the same goods and services, is a fairly common business practice.⁷⁴ Price discounting may be done on the basis of volume discounts or quality discounts, and is often driven by differences in the price sensitivity of the consumer.⁷⁵ However, in order to discount effectively the price of pharmaceuticals, three conditions are necessary:⁷⁶ first, resale potential must be limited;⁷⁷ second, sellers must maintain some degree of control of market prices;⁷⁸ and third, there must be demand, consisting of consumers with different price sensitivities.⁷⁹

There are several possible explanations for prescription drug price differences between the United States and Canada, but four reasons in particular seem to play a key role in price disparity.⁸⁰ These include governmental oversight by means of a review board, third-party purchasers, litigation fees, and R&D costs.⁸¹

74. DANZON, *supra* note 26, at 38–39. Price discounting is present in hospital, physician, and pharmacy services, and can also be seen in the senior citizen discounts offered by movie theaters, buses, and restaurants. *Id.*

75. *Id.* at 38. Volume discounts tend to reflect economies of scale, whereas quality discounts tend to reflect differences in service or convenience of a good or service. *Id.* By offering a lower price to consumers who are more price-sensitive, the producer is able to increase sales to these customers while continuing to collect typical revenues from less price-sensitive consumers. *Id.* at 39. As such, price discounting is one method of gaining incremental sales and increasing the market share of the particular drug. *Id.*

76. ERNST R. BERNDT, UNIFORM PHARMACEUTICAL PRICING: AN ECONOMIC ANALYSIS 7–11 (1994).

77. *Id.* at 8. If resale by a low-price buyer to a high-price buyer was effortless, profits would go to the low-price buyer rather than the producer. *Id.* As such, the potential for this type of resale tends to prevent effective price discounting. *Id.*

78. *Id.* In a perfectly competitive market, the producer is only able to charge the market price. *Id.* This price, however, may not be sufficient to cover sunk costs of discovery, research, and development. *Id.* Branded products and patent protection help the seller to maintain some control over price. *Id.* at 8–9.

79. *Id.* The seller's ability to identify potential consumers based on price responsiveness is necessary for effective price discounting. *Id.* For example, airline fares for last-minute flights are higher than fares for flights reserved weeks or months in advance because the desperate traveler has little opportunity for substitutes and, as such, is less price sensitive. *Id.* at 10.

80. For analysis of several secondary factors, see Creech, *supra* note 30. These secondary factors include an increase in the prescribing of drugs, patent protection, lobbying, and campaign contributions. *Id.* at 603–09.

81. See *infra* notes 82–114 and accompanying text.

1. Government Regulation of Price in Other Countries

First, Canada's federal Patented Medicine Prices Review Board (PMPRB) regulates the maximum prices that can be charged for patented drugs.⁸² Comparatively, no such regulations exist in the United States.⁸³ In Canada, all patented prescription drugs sold are subject to the PMPRB pricing guidelines, which regulate the price a manufacturer can charge for any patented drug sold in Canada.⁸⁴ The PMPRB determines maximum introductory prices for new patented drugs, as well as increases in the prices of existing drugs.⁸⁵ Instead of determining a drug's price before being marketed in Canada, the PMPRB reviews information on launch prices and sales of the same drugs in other countries.⁸⁶ Price disparity between the countries, then, can be partially attributed to Canada's regulatory PMPRB and the lack of a similar regulatory agency in the United States.

82. Patented Medicine Review Board, *Annual Report for the Year Ending December 31, 1999* (2000), available at <http://www.pmprb-cepmb.gc.ca/CMFiles/ar-96-e12tpo-472003-7097.pdf> (last visited Sept. 6, 2004). The PMPRB establishes and enforces guidelines that determine the maximum prices at which manufacturers can sell brand name drugs. *Id.* at 9. Under the guidelines, introductory prices of new drugs can not exceed the median of the prices of the same drugs in other industrialized countries. *Id.* at 27. Prices of patented drugs that do not provide a significant breakthrough in treating diseases must not exceed the maximum price of other drugs that treat the same disease, and once this introductory price is established, subsequent price increases are limited to changes in the Consumer Price Index (CPI). *Id.*

83. Gross, *supra* note 6, at 11.

84. *Id.* The PMPRB is a quasi-judicial body that regulates prices that a manufacturer of prescription drugs can charge. *Id.* at 11–12. The PMPRB has extensive jurisdiction, including authority over patented drugs sold by manufacturers to Canadian hospitals, wholesalers, retail pharmacies, and other bodies. *Id.* at 12.

85. *Id.* The PMPRB was established in 1987 to complement a change in Canadian law that strengthened patent protection on pharmaceutical products by providing greater market exclusivity. *Id.* Prior to the establishment of the PMPRB, patented pharmaceutical products sold in Canada had little right of market exclusivity free from generic drugs. *Id.*

86. *Id.* at 12–13. The prices of the drugs must conform to the following guidelines: (1) “[m]anufacturer prices for most new patented drugs are limited so that the cost of therapy using the new drug does not exceed the highest cost of therapy with existing drugs used to treat the same disease”; (2) “[m]anufacturer prices of breakthrough patented drugs and those that bring a substantial improvement are limited to the median of the prices charged for the same drug in other industrialized countries listed in the PMPRB’s *Regulations*,” which include France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States; (3) “[m]anufacturer price increases for patented medicines after launch are limited to changes in the general CPI”; and (4) “[m]anufacturer prices of a patented drug in Canada may at no time exceed the highest price for the same drug in the countries listed in the *Regulations*.” *Id.*

2. *Third-Party Purchasers*

Second, third-party purchasers in Canada have created competition among similar drugs.⁸⁷ The provincial drug benefit plans have successfully applied various cost management approaches that further restrain the cost of prescription drugs.⁸⁸ Cost management approaches include use of price information⁸⁹ and cost-effectiveness⁹⁰ to determine formulary inclusion, reference pricing,⁹¹ provincial price regulation,⁹² promotion of generics,⁹³

87. *Id.* at 14. Third-party purchasers, particularly the provincial drug benefit plans, use cost management approaches to further restrain prescription drug costs. *Id.* As large purchasers, these payers use price information, cost-effective evaluation, and reference pricing to determine formulary inclusion (or which drugs will be covered). *Id.* Additionally, Canada implements provincial price regulation, promotes generic substitution, and extensively reimburses for each prescription dispensed. *Id.*

88. *Id.* For a description of cost management tools, see Ake Blomqvist and Jing Xu, *Pharmacare in Canada: Issues and Options*, HEALTH CANADA (Sept. 2001), at 5–11, at http://www.fin.gc.ca/FIIQActualites/actualites/302_e.pdf. (last visited Oct. 24, 2004).

89. Gross, *supra* note 6, at 14. Each province in Canada has a formulary, or list of drugs that are covered under the plan, and there is variation between provinces as to which drugs are included. *Id.* The ability of a province's plan to exclude a drug altogether from the formulary or to require prior authorization may give drug manufacturers the incentive to set lower prices so that the provinces include the products in the plan. *Id.*

90. *Id.* A particular drug's cost-effectiveness is often used to determine whether to include the drug in the province's plan. *Id.* If a drug manufacturer wishes to have its product included on the provincial drug benefit plan, the manufacturer must submit a form that details the drug's clinical efficacy, as well as its cost-effectiveness. Thereafter, an independent committee of physicians and pharmacists review the submitted forms and make subsequent recommendations regarding coverage. *Id.* Based on the recommendations, the representative officials in each province determines whether the drug will be reimbursed for all patients with no restrictions, whether the drug will be reimbursed for those who meet certain clinical criteria, or whether it should not be reimbursed without a special written request specifically indicating why it is required for a particular patient. *Id.* Restrictions often occur when: the drug's effectiveness relative to currently available therapy is minimal; the drug offers only marginal benefit relative to alternative treatment but at a much higher price in instances where the manufacturer's data submission did not demonstrate its efficacy; or the drug is only cost-effective in a small subgroup of patients. *Id.* at 15.

91. *Id.* Reference pricing establishes reimbursement rates for categories of drugs and the conditions that the drugs treat. This approach seeks to set competitive pricing among therapeutically similar drugs. The reimbursement, or reference, price is set as the lowest cost of therapeutically similar products. *Id.* Those patients who are prescribed a different product are required to pay the difference between the cost of the prescribed drug and the reference drug price. *Id.* Studies of this reference price system have concluded that the result is substantial savings, and more importantly, the studies have not found adverse quality impacts or financial barriers to access. *Id.* For information regarding British Columbia's reference price system, see Government of British Columbia Ministry of Health Services, *Pharmacare: Reference Drug Program*, available at <http://www.hlth.gov.bc.ca/pharme/rdp/rdpindex.html> (last visited Sept. 24, 2004).

92. Gross, *supra* note 6, at 15. Some provinces regulate prices that they will pay for prescription drugs listed on their plans, and may prohibit price increases for those drugs that stay on the plan. *Id.*

93. *Id.* Closely tied to the above concept of reference pricing, promotion of generic substitution provides that the provincial drug benefit plans only pay the cost of the lowest priced generic drugs in situations where generics are available. *Id.*

and pharmacy reimbursement policies.⁹⁴ Because they are large purchasers, the third-party buyers can successfully negotiate the terms of their plans, including coverage and reimbursement, with the drug manufacturers and pharmacies.⁹⁵ As a result, patented drug prices are often below the maximum allowable prices set by the PMPRB.⁹⁶

3. *Products Liability Litigation Costs*

Third, products liability litigation in the United States creates higher prices for American, as compared to Canadian consumers.⁹⁷ Although the legal systems of the United States and Canada both evolved out of British common law,⁹⁸ they have since diverged. Nowhere is this more evident than in the area of tort law and liability.⁹⁹ Consequently, although the rules for pharmaceutical products liability in the United States are similar to Canadian negligence rules, Canadian courts have not been willing to hold manufacturers to the standards of care used in U.S. courts.¹⁰⁰ Therefore, a significant part of the variation in price between prescription drug prices in the United States and Canada is attributable to liability costs and in particular, anticipated liability cost,¹⁰¹ which is often calculated by the

94. *Id.* Regarding pharmacy reimbursement, the provinces often establish the amount that pharmacies will be paid for each prescription dispensed. Controlling this amount may be done by considering actual acquisition cost, lowest cost alternative, maximum allowable cost, and best available price. *Id.* The plans may further determine what dispensing fees will be paid to the pharmacists. *Id.*

95. *Id.* at 14.

96. *Id.* at 14. Additionally, the lower costs tend to promote the use of less costly versions of therapeutically similar drugs. *Id.*

97. *Id.* at 16. Various studies suggest that one-third to one-half of any prescription drug price differential between Canada and the United States is based on the higher cost of protection from legal liability. *Id.* In particular, Canada limits personal injury compensation to C\$250,000. *Id.* The cost of products liability litigation in the United States is substantially higher, and prescription drug prices in the United States reflect the added cost. *Id.*

98. GERAINT HOWELLS, *COMPARATIVE PRODUCT LIABILITY* 247 (1993) (indicating that eleven Canadian provinces and territories inherited English common law, while Quebec adopted the Civil Code of Lower Canada based on the French Napoleonic Code).

99. *Id.* at 248 (comparing the tort law principles of the United States and Canada). The complexity of Canadian law is further influenced by the United States, largely because Canada has closer social, economic, and cultural links with the United States than with United Kingdom. *Id.* See also Richard Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. ECON. 203, 206–07 (1997). Manning suggests that the past few decades have seen a drift away from common law roots, while the same drift in the United States is a great deal more pronounced. *Id.* In particular, Manning cites as examples the evolution of strict products liability and market share liability in the United States. *Id.*

100. *Id.* at 207–08. Manning argues that Canadian judges are reluctant to expand drug manufacturer liability. *Id.*

101. For an analysis regarding products liability and subsequent price differentials of prescription drugs in the United States and Canada, see Manning, *supra* note 99, at 234.

product's own litigation history.¹⁰² Pharmaceutical products liability both creates an incentive for companies to comply with regulations and promotes communication between manufacturers and physicians.¹⁰³

Procedural and substantive complications also contribute to higher products liability costs in the United States.¹⁰⁴ First, the rights of litigants are more limited in the Canadian system. For example, Canadian litigants have more limited rights of appeal than do American litigants,¹⁰⁵ and Canadian litigants do not have a right to a trial by jury in civil cases.¹⁰⁶ Second, differences in damage awards also contribute to higher prices in the United States. Punitive damages in Canada are rare, whereas in the United States they are increasingly common,¹⁰⁷ while damages in Canada are set by judges rather than by juries.¹⁰⁸ And third, there are differences in

102. *Id.* at 217. Often, summaries of litigation for various drugs are compiled, and the case histories of a variety of prescription drug products, including important cases, trial verdicts, and even settlements are studied in hopes of estimating future costs associated with litigation. *Id.* at 217–18. Manning's study concludes that the age of a product often plays an important role. *Id.* at 217. In particular, older drugs have significantly higher price differentials than do more recently introduced drugs because of the litigation history associated with the older drugs. *Id.*

103. For an analysis of liability as an incentive for compliance with FDA standards, see Steven Garber, *Product Liability, Punitive Damages, Business Decisions and Economic Outcomes*, 1998 Wis. L. REV. 237 (1998). An important reason for communication between the manufacturers and physicians, and the reason for a lack of communication between the manufacturers and patients, relates to products liability law for medical products. *Id.* at 266–67. Specifically, this lack of communication can be traced to the "learned intermediary rule," which requires that physicians receive warnings and act as the learned intermediaries between the manufacturers and patients. *Id.* Manufacturers can be held liable for failure to warn physicians; yet, with few exceptions, manufacturers have no duty to warn patients directly and will only be held liable for defective warnings given to patients." *Id.*

104. See, e.g., HOWELLS, *supra* note 98, at 247 (comparing the tort law principles of, among other countries, the United States and Canada).

105. For an explanation of how the possibility of appeals influences litigation, see Manning, *supra* note 99, at 208.

106. *Id.* See also HOWELLS, *supra* note 98, at 273. Many of the larger claims in the United States are often attributed to sympathetic juries, but in Canada, jury trials are less frequent. *Id.* An Ontario law practitioner estimated that only ten percent of cases used juries, and those that did were usually the result of the requests of defendants who believed juries are less generous than judges, not the plaintiffs, as is the case in the United States. *Id.*

107. *Id.* at 272. Punitive damages are awarded less frequently in Canada, and when awarded, are given in less dramatic amounts. *Id.* Moreover, Canada does not have the problem regarding excessive awards for non-pecuniary losses, largely due to a cap of C\$100,000 instituted by the Supreme Court of Canada in 1978. *Id.* at 273. Although this cap has increased to account for inflation, it still acts as a barrier against excessive claims. *Id.*

108. Manning, *supra* note 99, at 208. Manning assumes that even if juries are more willing than judges to favor plaintiffs when damages are awarded, damages will be higher in the United States because of the roles of judge and jury in Canada and the United States, respectively. *Id.* Even if Canadian judges are more willing to favor plaintiffs, the amount of damages that they can award is limited based on Canadian statutory limitations. *Id.*

the products liability environment, which are created by contingency fees and the availability of class action suits in the United States.¹⁰⁹

4. *Research and Development Costs*

A fourth reason for the price variation between the United States and Canada involves R&D costs.¹¹⁰ Because R&D serves all consumers in all countries that use the particular product, the cost cannot be attributed to any particular group.¹¹¹ Although many advocates argue for equal distribution of cost,¹¹² economic theory supports the opposite conclusion.¹¹³ Discovery, research, and development costs are sunk; incremental production costs for pharmaceuticals are modest; and drug profitability depends on the product's ability to generate revenue, often by using non-uniform pricing structures.¹¹⁴

III. RECOMMENDATIONS: A SURVEY OF OPTIONS

The actions that Congress deliberately avoids may be just as important as the actions Congress consciously undertakes.¹¹⁵ For example, although the implications for health care are not entirely clear, some regulatory policies are likely to be detrimental. Examples include certain forms of

109. HOWELLS, *supra* note 98, at 272. Contingency fees are rare in Canada, and banned in Ontario. *Id.* Moreover, Canada has a rule that costs are awarded against the losing party. *Id.* Howells suggests that if there were a similar rule in the United States, the prevailing attitude of "nothing ventured, nothing gained" would require considering the costs associated with a loss. *Id.*

110. See generally Stephen Latham, *Pharmaceutical Costs: An Overview and Analysis of Legal and Policy Responses by the States*, 24 J. LEGAL MED. 141 (2003). The increased cost of prescription drugs stems from R&D risks, and the industry has a tendency to build the cost into each pill, thus increasing the prices. *Id.* at 147.

111. DANZON, *supra* note 26, at 41.

112. See generally Latham, *supra* note 110. One argument advanced by opponents of differential pricing is that other countries are "free riders," declining to pay their fair share of R&D costs and hoping that the United States and other wealthier countries will pick up the slack. *Id.* at 147-48.

113. DANZON, *supra* note 26, at 41. "Ramsey pricing" concludes that charging different prices to different consumers based on the elasticity of demand is the most efficient way of recovering joint sunk costs. *Id.*

114. See BERNDT, *supra* note 76, at 11-12. R&D costs are estimated at over \$350-400 million, and production costs, due to economies of scale, are minimal. As such, differential pricing often creates increasing sales volumes and greater market share. *Id.* For other estimates regarding the high risk of pharmaceutical R&D, see Latham, *supra* note 110. Development of a new drug may take nearly twelve to fifteen years and cost hundreds of millions of dollars, and if investors cannot be convinced of the possibility of profit corresponding to the risk, the investors seek other investments. *Id.* at 150. Moreover, unequal pricing allows drugs to be sold at lower costs to buyers who could not otherwise afford to pay for a "per-pill" share of R&D. *Id.* at 148.

115. See, e.g., JOHN E. CALFEE, *PRICES, MARKETS, AND THE PHARMACEUTICAL REVOLUTION* (2000).

price controls and permitting continued sales of prescriptions over the Internet.¹¹⁶ While price controls may be inevitable without considerable changes in the pharmaceutical industry's behavior, there are price controls that likely would do more harm than good in the long-run.¹¹⁷ Suggested price controls include extending Medicaid discounts to neighborhood pharmacies, cutting United States prescription prices to match those charged in other countries, and imposing direct controls on the industry.¹¹⁸ However, these price controls would deter the pharmaceutical industry's development of new drugs,¹¹⁹ and its search for additional uses for existent drugs.¹²⁰ Burdened with these controls, the pharmaceutical industry would certainly forego financial incentives to research and develop new drugs, but may also lose the financial resources to do so. Moreover, if these controls were to be put in place and subsequently met with disfavor, dismantling such controls in the future would likely be difficult.¹²¹

While regulation of this industry must strike a delicate balance in order to maintain the benefits of the current system, it is worthwhile to consider alternatives. Different forms of price regulation that merit evaluation for use in the United States include uniform pricing, direct price regulation, manufacturer-specific budgets, reference price limits on reimbursement, rate-of-return regulation, physician drug budgets, drug reimbursement, patient co-payments, and managed health care.

A. Uniform Pricing

Uniform pricing of pharmaceutical products is an option to consider as a means of balancing competing concerns of prices and incentives. Under uniform pricing, one price is set for a particular product across the board.¹²²

116. *Id.* at 45–53.

117. *Id.* at 2–3.

118. *Id.* at 2.

119. PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION: NATIONAL POLICIES VERSUS GLOBAL INTERESTS 1–4 (1997). R&D costs make pharmaceuticals vulnerable to aggressive price regulation, and companies would be limited in future innovative R&D. *Id.* at 3–4.

120. *See, e.g.,* CALFEE, *supra* note 115, at 2. Fundamental changes in the industry over the past few decades include “scientific advances in pharmaceutical R&D and biotechnology, as well as institutional advances in drug testing, information processing, and dissemination of knowledge.” *Id.* at 2–3. This combination of providing new treatments to existing patients and offering existing treatments to new patients is a result of the advances and should not be stymied by arbitrary price controls. *Id.* at 3.

121. *See* CALFEE, *supra* note 115, at 3.

122. *See generally* BERNDT, *supra* note 76.

However, there are considerable arguments against this approach. For example, uniform pricing legislation often omits crucial details regarding the definition, implementation, and enforcement of uniform pricing policies.¹²³ Moreover, even if legislation promoting uniform pricing passed—certainly no simple proposition—several potential adverse consequences remain. These include greater uncertainty about the consistency of particular pricing policies,¹²⁴ increased litigation,¹²⁵ average price increases,¹²⁶ and enhanced possibilities for implicit price collusion.¹²⁷ Furthermore, uniform pricing disregards the realities of real-world manufacturing. Manufacturers charge prices to recover the costs of manufacturing, distributing, and R&D.¹²⁸ As such, manufacturers charge different prices to different consumers, based on each consumer's ability and willingness to pay.¹²⁹

B. Direct Price Regulation

Direct price regulation is another option to consider as a way to balance the competing concerns of prices and incentives. Direct price regulation takes several forms and often varies by country.¹³⁰ France, Italy, and Spain have strict governmental control over the pharmaceutical prices charged to insurers and consumers, and these countries use multiple criteria for

123. *Id.* That is, several important details would likely be omitted, such as the points in the distribution chain where prices must be uniform (i.e., initial point of sales or intermediate points), the length of time the prices must be the same (i.e., over the length of a multiyear contract, over a fiscal year, or on a daily basis), and whether preexisting multi-year contracts would be invalidated or grandfathered in. *Id.* at 13.

124. *Id.* at 14. During the period of uncertainty, pharmaceutical firms would likely be cautious in introducing innovative discounting policies because of confusion surrounding the precise interpretation of the legislation. *Id.*

125. *Id.* As a result of the greater uncertainty, there likely would be increased litigation over the proper interpretation of the legislation. *Id.* As such, any resolution through litigation would require substantial time and resources. *Id.*

126. *Id.* at 14–15. Firms would alter their pricing behavior because of changes on both the demand side and supply side of the market. *Id.* On the demand side, growth of managed-pharmacy provider services has led to greater non-uniform pricing in the industry. *Id.* at 15. On the supply side, there has been an increase in the number of drugs offered in recent years. *Id.*

127. *Id.* at 16. When active discounting is allowed and deal-making is encouraged, cooperation among pharmaceutical companies is difficult to achieve because of the desire for profit and market share. *Id.* By contrast, regulating prices to discourage vigorous competition creates an environment that facilitates the possibility of implicit collusion within the industry. *Id.*

128. John R. Graham, *Prescription Drug Prices in Canada and the United States—Part 2: Why the Difference*, THE FRASER INSTITUTE (Sept. 2000), at <http://www.fraserinstitute.ca/shared/readmore.asp?sNav=pb&rid=161> (last visited Oct. 15, 2004).

129. *Id.* When segmenting markets by country, manufacturers often use measures of national income to guide price structuring—that is, wealthier countries pay more. *Id.*

130. See, e.g., DANZON, *supra* note 119, at 16–29.

setting those prices.¹³¹ These countries require that introductory prices of new products and price increases of existing products be approved by the government if they are to be reimbursed by the social insurance system.¹³²

Canada utilizes a similar form of price control, using the PMPRB to monitor prices of pharmaceuticals and determine whether the prices being charged are reasonable.¹³³ The United States considered a similar proposal in then-President Clinton's Health Security Act, which proposed an advisory council to evaluate the reasonableness of the prices of new drugs.¹³⁴ However, none of these systems have considered the problem of global joint costs,¹³⁵ and, ultimately, they rely on negotiation and political discretion to establish costs for particular consumers.¹³⁶

C. Manufacturer-Specific Budgets

A limitation based on manufacturer-specific budgets, also known as revenue limits, is another option by which the competing concerns of prices and incentives can be balanced. In this option, the government sets a target growth rate for general pharmaceutical expenditures and then negotiates with each manufacturer a firm-specific limit on that firm's total sales (or revenue) for the year.¹³⁷ If the particular firm overshoots the set target, then its prices are reduced.¹³⁸ This system, in theory, gives

131. *Id.* at 16. For example, Italy had used a complex pricing formula based on total cost, with markups for therapeutic merit and contribution to the domestic economy. *Id.* France had considered internal comparisons with existing products, therapeutic merit, and contribution to the domestic economy, as well as comprehensive revenue limits and manufacture revenue limits. *Id.* at 16–17. For a discussion of comprehensive revenue limits and manufacture revenue limits, see *infra* notes 137–39 and accompanying text.

132. DANZON, *supra* note 119, at 16. Inflation adjustments are rarely granted, and price cuts are sometimes mandated. *Id.* Additionally, wholesale and retail distribution margins regulate the retail prices charged to insurers and consumers. *Id.*

133. *Id.* at 17. The reasonable benchmark price for innovative products is the median of prices charged in nine other countries. *Id.* Reasonable benchmark prices for products that offer only little or no therapeutic advance over existing products are tied to prices of existing drugs. *Id.* Post-launch price increases may not exceed the growth of the general consumer price index. *Id.*

134. *Id.* This proposal incorporated elements of several of the aforementioned foreign systems. *Id.*

135. *Id.* at 3. Global joint costs include costs that are essential to supply the drug but cannot be attributed to any individual consumer or country, but rather represent the cost that the whole world has to pay for a particular pharmaceutical product. *Id.*

136. *Id.* at 18. Even price negotiation carries problems of uncertainty and delay beyond that associated with obtaining approval of safety, efficacy, and quality. *Id.* Moreover, the delay in the launch of new products results in foregone benefits for consumers and loss of revenue for manufacturers that cannot be recovered. The loss to many facturers is due to the fact that the time left on the patent is not extended in situations where there has been a delay in pricing approval. *Id.*

137. *Id.* In 1994, France adopted this system, but the anticipated flexibility did not materialize as planned as individual negotiations remain for major drugs. *Id.* at 19.

138. *Id.* at 18.

manufacturers greater flexibility in pricing individual products, subject to a general revenue limit, and reduces the uncertainty and administrative cost of product-by-product price negotiations.¹³⁹

D. Reference Price Limits on Reimbursement

Another option to consider, reference price limits on reimbursement, is used in, among other countries, Canada.¹⁴⁰ Under this system, several drugs are grouped together based on therapeutically similar properties, and the government or insurer sets a single reimbursement price¹⁴¹ for all products in this cluster.¹⁴² With this system the manufacturer is permitted to charge more than the set reference price, but the patient must pay the difference as an out-of-pocket charge.¹⁴³

Problems are also apparent with this system. In reality, manufacturers rarely charge more than the reference price because patients are unwilling to pay excess co-payments.¹⁴⁴ Additionally, although reference pricing may create competition between products within the same category, reference pricing may actually reduce competition between products below the reference price.¹⁴⁵ Moreover, the impact of reference pricing on drug spending clearly depends on how broadly the groups of therapeutically similar drugs are defined, as well as on how the reference price is set.¹⁴⁶

139. *Id.* at 18–19. Similar restraints closely associated with revenue limits include restraint on promotional expenditures, improved informational systems, and attempts to limit prescribing products to medically appropriate uses. *Id.* However, the intended results have not yet been realized. *Id.*

140. *Id.* at 19. This system has been introduced in the Canadian province of British Columbia, as well as in Germany, the Netherlands, Denmark, and New Zealand. *Id.*

141. *Id.* This reimbursement price is also known as the reference price. *Id.*

142. *Id.*

143. *Id.* “Maximum allowable charge systems used in many Medicaid and managedcare programs in the United States are similar, but only apply to generic substitutes.” *Id.* at 19 n.1.

144. *Id.* at 19. This has been the case in Germany, where physicians are required by law to explain to patients why such a charge is necessary. *Id.* The result has been either a reluctance to make co-payments or the creation of highly elastic demand at prices above the reference price. *Id.*

145. *Id.* That is, manufacturers typically have an incentive to cut prices where demand is elastic. *Id.* But in a reference pricing system, demand is inelastic at prices below the reference price because any difference between the manufacturer price and the reference price credits the government, thus voiding the incentives of physicians, pharmacists, and patients to demand a change in volume. *Id.* at 19–20.

146. For an analysis of the impact of defining groups and setting initial reference prices, see *id.* at 20–21.

E. Rate-Of-Return Regulation

Another option to consider, rate-of-return regulation, regulates profits rather than prices.¹⁴⁷ The goals of this system are “to secure the provision of safe and effective medicines . . . at reasonable prices . . . and to promote a strong and profitable pharmaceutical industry . . . capable of such sustained R&D expenditures as should lead to the future availability of new and improved medicines.”¹⁴⁸ Each company negotiates with the government for an allowed total rate-of-return on capital (ROC).¹⁴⁹ “Any excess is ‘repaid’ either directly or through a price reduction. Conversely, companies that fail to meet their target ROC may apply for a price increase.”¹⁵⁰

Although this system explicitly recognizes the need for return on R&D, ROC has several potential problems. These include the creating of incentives for “creative accounting” and the distorting of real resource use.¹⁵¹ In response, the regulations associated with the allocation of costs and allowable promotional expenditures have become increasingly detailed.¹⁵² As such, these limits are detrimental to smaller companies introducing new products.¹⁵³

F. Physician Drug Budgets

Another option utilized to control drug spending involves physician drug budgets and physician accountability for their prescribing habits.¹⁵⁴ If

147. *Id.* at 21. Under this system “companies are free to set launch prices of new products, provided that the total rate-of-return on capital (ROC) . . . does not exceed a specified limit,” usually between seventeen and twenty-one percent. *Id.* There is a grey area within which the companies may retain some or part of any profit above the target, provided that they renegotiate. *Id.*

148. *Id.*

149. *Id.* This system is in effect in, among other countries, the United Kingdom. *Id.*

150. *Id.*

151. *Id.* Creative accounting strategies have tended to be used to maximize reimbursement, while real resource use is changed to maximize the rate base, and as such, the maximum allowed profit. *Id.* at 21–22. See also Harvey Averch & Leland Johnson, *Behavior of the Firm under Regulatory Constraint*, 52 AM. ECON. REV. 1052, 1068 (1962), available at <http://www.jstor.org/view/00028282/di950373/95p0073x/0> (last visited Sept. 4, 2004).

152. DANZON, *supra* note 119, at 22. Rules for allowable promotional expenditures are renegotiated with companies for the following year, and provisional targets are often set up two years in advance. *Id.* “The limits for promotion and R&D do not apply to actual expenditures but to the amount that can be included in the base of the ROC calculation.” *Id.*

153. *Id.* Smaller companies introducing new products face the difficulties of the high cost of application for marketing authorization and post-marketing surveillance. *Id.*

154. *Id.* at 24. This option is used in, among other countries, Germany. *Id.* “Even physicians who do not profit directly from dispensing drugs may use prescriptions as means to stimulate additional patient visits.” This system seeks to limit such excesses. *Id.*

total drug spending exceeds the target drug budget, the government charges the cost against the future budgets of physicians and drug manufacturers.¹⁵⁵

This system is flawed because it creates the wrong incentives. Office-based physicians, who are subject to the cap, often refer patients to hospitals that are not subject to the cap or avoid seeing high-cost patients altogether.¹⁵⁶ Moreover, simplistic budgetary limitations create a lack of information necessary to treat individual patients and create physician incentives to switch from newer, more innovative and costly drugs to older, less costly generics, without concern for therapeutic suitability.¹⁵⁷

G. Drug Reimbursement

Another option to consider is a system of drug reimbursement that incorporates both regulation and competition.¹⁵⁸ Under this system the government sets a reimbursement price for each drug, the dispensing physician or hospital receives the reimbursement payment from the social insurance program, and profits result from any margin between the reimbursement price and the manufacturer's price.¹⁵⁹ The government monitors the actual manufacturer prices charged and reduces the reimbursement price for those drugs that have excessive margins.¹⁶⁰

The effect of this system is to destroy R&D incentives, as it triggers price reductions from manufacturers, causing both actual manufacturer prices and government reimbursement prices to fall over a drug's life

155. *Id.* Individual physicians in Germany are assigned budgets based on their specialty, and deviations of more than twenty-five percent from the mean budget result in review and possible financial penalties. *Id.* "In Germany, if total drug spending exceeds the target drug budget, the first 280 million deutschemarks are charged to the physician budget for the following year. The next 280 million deutschemarks are charged to the drug manufacturers to reduce their incentives for drug promotion." *Id.*

156. *Id.* at 25. This results in a general increase in total cost because it only shifts the cost from a regulated group subject to a cap, to an unregulated group not subject to the cap. *Id.* For an in depth analysis of how firms seek to maximize profit but are subject to a constraint on rate of return, see generally Averch & Johnson, *supra* note 151.

157. DANZON, *supra* note 119, at 25. As such, this system passes the buck rather than fixing the underlying problem. *Id.*

158. *Id.* The system of drug reimbursement using both regulation and competition is associated with, among other countries, Japan and South Korea. *Id.*

159. *Id.* As such, "[d]rug manufacturers thus have incentives to cut their prices below the reimbursement price in order to increase the financial incentives of physicians to prescribe their drugs over those of their competitors." *Id.* at 25–26.

160. *Id.* at 26. In Japan, the government reevaluates the prices every two years. *Id.* The zone of reasonableness for which the reimbursement price can differ from the actual manufacturer's price is around thirteen percent. *Id.*

cycle.¹⁶¹ Consequently, the incentives for R&D are directed toward producing a high volume of new products, even if the new products contain only minor improvements over existing products.¹⁶²

H. Patient Co-Payments

A patient co-payment system factors patient cost-sharing into social insurance programs.¹⁶³ However, in actuality, cost-sharing is often limited by supplementary insurance¹⁶⁴ or exemptions.¹⁶⁵ Additionally, co-payments on physician visits, which factor into the total cost of obtaining a prescription, are often low in countries that follow the co-payment system.¹⁶⁶

Moreover, insurance in European countries traditionally covered a more extensive range of drugs, and as such, patient concern for prices has not limited demand for drugs.¹⁶⁷ In response, certain countries increased patient co-payments and “delisted” several drugs, thus making them ineligible for reimbursement.¹⁶⁸ However, the effects of these practices are uncertain at best and would adversely affect those who benefit from co-payments.¹⁶⁹

161. *Id.* This system passes savings to consumers only after a two-year lag, when prices are revised downward. *Id.*

162. *Id.* Although prices are subject to downward departure every two years, manufacturers can only obtain a price increase by introducing new products. *Id.* It is this incentive structure that has been credited for the Japanese R&D bias toward minor extensions of existing products rather than innovative significant therapeutic advances. *Id.*

163. *Id.* at 27. Many European countries use this system of requiring patient co-payments, where the patient pays expenditures on reimbursable products out of pocket. *Id.* For example, France has patient co-payments up to seventy percent depending on the class of drug, but only about three percent of expenditures on reimbursable products are actually paid by the patient because most people have supplementary insurance that covers the rest. *Id.*

164. *Id.* Moreover, insurance in European countries traditionally covered a more extensive range of drugs and, as such, cost-consciousness has not served as a constraint on demand for drugs. *Id.*

165. *Id.* For example, in the United Kingdom, “more than 80 percent of sales are exempt because of exemptions for the elderly, needy, and other categories.” *Id.*

166. *Id.*

167. *Id.* Traditional drug coverage in certain European countries has included, “cold and cough remedies, laxatives, and other preparations that U.S. consumers typically purchase over the counter and without reimbursement.” *Id.*

168. *Id.*

169. *Id.* at 27–28. Increasing co-payments is likely to be only a “minimal deterrent except for low-income patients or those on chronic medications.” *Id.* at 28.

I. *Managed Health Care*

A final option to consider is managed health care.¹⁷⁰ Recently, managed health care techniques have spread to pharmaceuticals through HMOs and specialty pharmacy benefit management companies that manage drug benefits for HMOs.¹⁷¹ These techniques include formularies of preferred drugs, physician education and monitoring, and generic and therapeutic substitution.¹⁷² These techniques move the market share toward preferred drugs, thereby giving the HMO managers leverage in negotiating discounts from manufacturers.¹⁷³

IV. PROPOSAL

Future American policies that determine drug prices must balance the need to control patients' health care costs with the need to preserve incentives for R&D innovation. Any single form of regulation has not been and will not be effective in balancing these interests.¹⁷⁴ State and local governments have defied the FDA ban on reimportation and will continue to do so.¹⁷⁵ The failure to prevent the reimportation of prescription drugs leads to the conclusion that long-term solutions must be implemented in order to fix the underlying problem. In order to balance the competing interests, a comprehensive solution is required for long-term success.

"The . . . high ratio of globally joint sunk costs . . . to user-specific marginal costs creates the opportunity and leverage for regulators and other major purchasers to force prices down to marginal costs."¹⁷⁶ However, although prices can be lowered with minimal short-term effects, over time this practice would hamper the development of innovative drugs.¹⁷⁷ Just as detrimental, however, is the amount, as a percentage of

170. *Id.* This system is used in, among other countries, the United States. *Id.*

171. *Id.* Insurance coverage for outpatient drugs is traditionally lower than for other ambulatory services. Moreover, prescription drug prices were unregulated and reimbursement under these traditional insurance plans gave the prescribing physician choice of which drugs to prescribe. *Id.*

172. *Id.* at 28–29.

173. *Id.*

174. Even with federal regulations and court rulings, state and local governments disregard federal regulations and reimport prescription drugs from, among other places, Canada. *See, e.g., supra* notes 4 and 5 and accompanying text.

175. *See* Thornburgh, *supra* note 4. Mayor Michael Albano made Springfield, Massachusetts, the first city in the nation to officially encourage its employees to buy prescription drugs from Canada, even though this is prohibited by federal law. *Id.*

176. DANZON, *supra* note 119, at 92.

177. *Id.* at 92–93. Short-term reduction of prices would have little effect on the supply of existing

total income, that some American consumers are forced to pay for prescription drug coverage.¹⁷⁸

Reimportation of prescription drugs from Canada does not address the pharmaceutical industry's need to come up with capital to pay for joint sunk costs. Moreover, reimportation of prescription drugs threatens both the health of the American consumer and the current system of price disparity, in which less wealthy countries are still able to receive medication.¹⁷⁹

Of the above-mentioned possibilities, a combination of two appears most viable. First, government subsidization of manufacturers' costs would promote innovations in R&D. This should be combined with a modified, managed healthcare program that would leverage favorable price discounts. In this proposed comprehensive solution the government would subsidize manufacturers' costs via tax breaks. Additionally, the government would need to appoint a primary purchaser of prescriptions, similar to Canada's PMPRB. Moreover, price controls must be avoided because they tend to discourage incentives for future investment and are ultimately a short term response to a larger problem.¹⁸⁰ Finally, the primary purchaser would use monopsonistic bargaining techniques to weaken the monopolistic power of the pharmaceutical industry.¹⁸¹ The end result would be that health care costs rise slightly in order to provide more expensive prescription drugs, yet the level would be somewhat controlled by a single purchaser exerting pressure on members of the industry to keep prices at a minimum.

drugs and likely would have little effect on drugs already being developed. *Id.* However, long-term results would be affected by the price regulations, as marginal cost pricing would cover only about thirty percent of total cost. *Id.* This effect, however, might not be noticed or felt for over a decade because the supply of innovative drugs depends on global revenues and has a lag time of several years. *Id.*

178. See *Importation of Prescription Drugs from Canada*, *supra* note 16.

179. The pharmaceutical industry's campaign to blacklist Canadian pharmacies that fill and sell prescription drugs to American consumers has taken a substantial toll. See, e.g., Graeme Smith, *Crackdown Taking Toll on Internet Pharmacies*, THE GLOBE AND MAIL, Apr. 24, 2004, at <http://health.workopolis.com/servlet/Content/fasttrack/20040424/INTERNET24?section=HR> (last visited Sept. 8, 2004).

180. See CALFEE, *supra* note 115, at 62.

181. For an explanation of monopsonistic bargaining techniques and how a single buyer can exercise power in a system that closely parallels the monopolistic power of a single seller, see generally DANZON, *supra* note 26.

CONCLUSION

As a final caveat, it is important to understand that Canada's success at restraining prices of patented drugs has not fully stemmed the growth of prescription drug spending but, rather, has helped control spending levels.¹⁸² Whether this proposed composite management system for health care will create an appropriate balance between cost control and incentives for innovation is uncertain, but it is certainly worth trying in order to fix the underlying problem.

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182. See Gross, *supra* note 6, at 18.

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