

Balancing Business & National Health: The Impact of Legislation on Pharmaceutical Drug Prices

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I. INTRODUCTION

The desire of both state and federal governments to regulate the drug market is understandable given that pharmaceutical prices are exorbitant. For instance, Americans spent \$1.6 trillion on healthcare needs in 2002, with eleven percent of that amount allocated to drug purchases.¹ This translated into each American citizen spending approximately \$5,440 for their healthcare costs in 2002.² From 1982 to 1988 alone, prescription drug costs increased at an annual rate of 9.5 percent, a greater price increase than any other sector of the healthcare system.³ These costs hit the elderly the hardest, a population that is most in need of prescription medication

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¹ See Fed. Trade Comm'n & U.S. Dep't of Justice, *Improving Health Care: A Dose of Competition*, at 2 (Washington, DC, 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> [hereinafter *Improving Health Care*](reporting also that the percentage of healthcare spending paid for prescription drugs has increased substantially over the past decade).

² See Sara Schaefer Munoz, *U.S. Health-Care Spending Rose 9.3 percent in 2002*, WALL ST. J., Jan. 9, 2004, at A2 (stating that 14.9 percent of the Gross Domestic Product for the United States was spent on healthcare).

³ Melvina Ford, U.S. Congressional Research Service, *Medicaid: Reimbursement for Outpatient Prescription Drugs*, CRS REP. FOR CONG., at 15 (Mar. 7, 1991).

yet least able to afford them.⁴ It is not uncommon for Americans to pay over twice as much for prescription drugs as compared to prices for the same drugs in foreign nations.⁵ The federal government, state governments, and private retailers have introduced various solutions to the prescription drug crisis.

Although government regulation of pharmaceutical products appears to be a panacea for those who cannot afford medication, the situation is complicated by the costs of research and development (hereinafter, "R&D"). Per year, approximately \$450 million is spent developing and marketing the branded drugs that are approved for patent.⁶ However, pharmaceutical companies actually expend billions of dollars yearly on R&D searching for novel prescription drugs that are marketable.⁷ Drug manufacturers claim that of 126,000 potential chemical formulas, only sixteen of these chemicals result in revenue-generating marketable drugs.⁸ Profits obtained from these drug sales are then funneled back into a manufacturer's R&D needs. The result is a conflict of interests: private companies have the right to turn a profit,⁹ but public concerns dictate that drugs be affordable in order to maintain a healthy lifestyle.

This comment will show how different institutions have addressed the issue of high healthcare costs in order to make prescription drugs more affordable. The first part will describe the federal system that was enacted in order to encourage pharmaceutical companies to research new drugs by protecting these companies when their products enter the market. It will further explain how the federal system works when generic manufacturers introduce cheaper versions of the branded products. The second part of this comment will discuss remedial statutes that have been passed in Maine, D.C., and other jurisdictions and how the private and public sector have reacted to these statutes. It will further discuss the judicial response to these statutes, specifically how federal patent laws sometimes preempt state legislation. This section will also analyze the federally-controlled healthcare systems in other nations such as France, Germany, Canada, and the United

⁴ See AMANDA MCCLOSKEY, *FAMILIES USA, BITTER PILL: THE RISING PRICES OF PRESCRIPTION DRUGS FOR OLDER AMERICANS* 1-2 (2002), <http://www.familiesusa.org/assets/pdfs/BitterPillreportf03c.pdf> (describing how in the year 2001 the cost of prescription drugs most frequently purchased by the elderly rose 7.8percent, nearly tripling the rate of inflation).

⁵ See Lana Kraus, *Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry*, 37 VAND. J. TRANSNAT'L L. 527, 535 (2004) (citing Tom Buerkle, *EU Weighs Lifting of Price Controls - Bid to End Market Distortions*, INT'L HERALD TRIB., Nov. 18, 1998, at 20).

⁶ See Jaclyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 103-04 (2002) (explaining how branded drug manufacturers have significant costs which generic manufacturers do not).

⁷ *Id.*

⁸ *Id.* at 103 (quoting Patent Term Extension and Pharmaceutical Innovation: Hearing before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, 97th Cong., 2d Sess. 18 (1982) (statement of Robert S. Walker, U.S. Representative, Pennsylvania)).

⁹ Interestingly, a recent study conducted by the consumer health organization, Families USA, examined the spending trends of nine pharmaceutical companies: Merck, Pfizer, Bristol-Myers Squibb, Pharmacia, Abbott Laboratories, American Home Products, Eli Lilly, Schering-Plough, and Allergan. Eight of these companies spent twice as much money yearly on marketing, advertising, and administration than on R&D. The executive director of Families USA opined that "the pharmaceutical industry's repetitious cry that research and development would be curtailed if drug prices are moderated is extraordinarily misleading." The Progress Report, *Why Prescription Drugs Cost So Much*, <http://www.progress.org/archive/pharma01.htm> (last visited Dec. 1, 2007).

Kingdom. The third part of this article will focus on how the private retailer Wal-Mart offers lower prices for generic drugs after federal patents for the branded drugs have expired. The final part will explore the advantages and weaknesses of different cost containment systems in order to determine how the system should be modified to effectively lower prescription drug prices in the U.S.

II. FEDERAL PROTECTION OF THE PHARMACEUTICAL INDUSTRY

a. The Balancing Act of Federal Patent Laws

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (otherwise known as the “Hatch-Waxman Act”) in order to protect investments in innovative and expensive pharmaceutical products while encouraging market competition from generic drugs.¹⁰ The Hatch-Waxman Act provides protection to a pharmaceutical company when it creates a novel drug by giving the drug exclusive manufacturing and distribution rights for a specified period of time.¹¹ The market exclusivity period typically lasts for six months, but may be extended for up to fourteen years.¹² While the exclusivity period is in effect, pharmaceutical companies may develop generic¹³ drugs in order to introduce competition into the market. The Hatch-Waxman Act then, in turn, confers a six-month period of market exclusivity to the first generic manufacturer of a particular drug.¹⁴ During this period, no other generic or branded manufacturer may introduce another generic copy of the specific drug that has market exclusivity.¹⁵ The exclusivity period

¹⁰ See Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure and Legacy*, 71 ANTITRUST L.J. 585, 585 (2003) (discussing the opposing concerns that Congress sought for the Hatch-Waxman Act to protect); see also H.R. Rep. No. 98-857, pt. 2, at 4 (1984), reprinted in 1984 U.S.C.C.A.N. (98 Stat. 1585) 2686.

¹¹ Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections Title of 15, 21, and 35 U.S.C.) (encouraging manufacturers to also produce generic drugs by sometimes providing protected markets through market exclusivity).

¹² 35 U.S.C.S. § 156(c) (LexisNexis 2000) (granting an extension to an expiring patent equivalent to the amount of time that was spent by the drug manufacturer preparing for required pre-market testing and approval).

¹³ A generic drug is defined as a drug which receives approval for an “abbreviated application” under 21 U.S.C. § 355(j) (2000). For a generic drug to be approved, an “abbreviated application” must supply information to show that: 1) “the conditions of use prescribed, recommended, or suggested in the labeling” are the same as an approved drug; 2) the active ingredient or ingredients are the same as an approved drug; 3) the route of administration, the dosage form, and the strength are the same as an approved drug; 4) the new drug is the bioequivalent to an approved drug; and 5) the labeling proposed for the new drug is the same as the labeling for an approved drug. *Id.*

A drug is “bioequivalent” to the listed drug when: “(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.” 21 U.S.C. § 355(j)(8)(B).

¹⁴ 21 U.S.C. § 355(j)(5)(A)(iv).

¹⁵ *Id.*

generates revenues for a drug manufacturer that it can use to offset the costs already expended on R&D. Excess revenues are then put into future R&D.

Competition generated in the market by the introduction of generic drugs reduces drug prices, allowing the public to purchase the equivalent of branded drugs for a fraction of the market price.¹⁶ Generic pharmaceutical manufacturers incur minimal costs from producing the generic drug because the branded company has already researched the chemical structure.¹⁷ The generic manufacturer can turn a sizable profit by selling its generic formula for a fraction of the branded drug price.¹⁸ Consequently, the Hatch-Waxman Act promotes public health by creating a process through which generic drug manufacturers can profitably sell drugs at cheaper prices than branded manufacturers.¹⁹ In 2003, a study comparing nine countries²⁰ found that the United States had one of the highest levels of generic drug use in comparison to the total volume of prescription drugs purchased.²¹ Generic drug prices were also lower in the U.S. than in any other surveyed nation, with the exception of Canada.²² However, pharmaceutical companies use numerous ways to bypass the Hatch-Waxman Act, actions which harm consumers by preventing competitive market forces from lowering the prices of prescription drugs.²³ Other companies have used underhanded tactics such as filing a petition with the Food and Drug Administration (“FDA”) to deny approval of the generic drugs.²⁴ This request is known as a citizen petition.²⁵ Although the FDA may eventually grant an exclusive marketing right to the generic drug maker, the process of reviewing petitions is time-consuming.²⁶ In a business where time means money, branded manufacturers are able to financially profit from the delay in other manufacturers being authorized to introduce generic drugs.²⁷

b. Authorized Generics Reducing Competition

A profitable strategy used by pharmaceutical companies to prevent competition

¹⁶ See Brian Porter, *Stopping the Practice of Authorized Generics: Mylan's Effort To Close the Gaping Black Hole in the Hatch-Waxman Act*, 22 J. CONTEMP. HEALTH L. & POL'Y 177, 178 (2005) (discussing the process by which generic drugs enter the market and reduce the high prices of prescription drugs).

¹⁷ See Miller, *supra* note 6, at 104.

¹⁸ *Id.*

¹⁹ See *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002) (suggesting that the Hatch-Waxman Act is beneficial because it encourages companies to invest in R&D for new products while encouraging generic companies to introduce low-cost drugs).

²⁰ See *Analyzing Brand-name and Generic Drug Costs in the U.S. and Eight Other Countries*, Knowledge@Wharton, (Nov. 19, 2003) <http://knowledge.wharton.upenn.edu/article.cfm?articleid=879> [hereinafter Knowledge@Wharton] (comparing the U.S. healthcare system to Canada, Mexico, Chile, Japan, France, Germany, Italy, and the United Kingdom).

²¹ *Id.*

²² *Id.* (finding generic prices in the U.S. to be lower than the other surveyed nations, with the exception of Canada, where generic drug prices are six percent lower).

²³ See Porter, *supra* note 16, at 177-78.

²⁴ According to 21 C.F.R. § 10.30 (2005), this petition is made to the Commissioner of the FDA, in part, in order to take or refrain from taking administrative action.

²⁵ *Id.*

²⁶ See Porter, *supra* note 16, at 181-82.

²⁷ *Id.* at 182.

from generic drugs demonstrates the flaws in the Hatch-Waxman Act.²⁸ Drug companies often market generic drugs to sell in place of the branded drugs on which they formerly held the exclusive patent.²⁹ These drugs are referred to as “authorized generics,” which prevent a generic competitor from entering the market with its own generic form of the branded drug.³⁰ The branded manufacturer introduces essentially the same chemical structure as the branded drug, relabeling and remarketing the drug as a generic version at a lower price.³¹ Several generic drug companies have challenged the legality of introducing authorized generics.³² These companies argued that allowing the manufacturer of the branded drug to then introduce a generic drug violates the Hatch-Waxman Act’s purpose of promoting drug competition that will lower prices.³³ Generic producer Teva Pharms., Indus., LTD sued the FDA for a declaration that authorized generics introduced by the branded drug company are prohibited during the generic exclusivity period.³⁴ The District Court concluded that the plain language of the Hatch-Waxman Act is silent as to the issue of authorized generics,³⁵ and therefore brand generics are permitted.³⁶

Congress has been criticized for leaving a “gaping hole” in the Hatch-Waxman Act that allows brand pharmaceutical companies to scoop up exclusive marketing rights to drugs as they become available.³⁷ One arguable consequence is that competition in the drug market is reduced, keeping drug prices high; one federal judge remarked that undermining fair competition in the drug market is a highly undesirable result.³⁸ In 2004, the generic manufacturer, Mylan, filed a citizen petition with the FDA that essentially proposed a compromise with branded manufacturers who seek to market authorized generics.³⁹ Mylan argued in its

²⁸ *Id.*

²⁹ See FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATIENT EXPIRATION: AN FTC STUDY (July 2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (explaining the process of how authorized generics enter the drug market). A similar tactic is for a pharmaceutical company to market a new drug with a very similar chemical makeup as the branded drug whose patent is about to expire. Once the FDA approves a patent for the new drug, competitors are prevented from introducing a generic drug to the original branded drug. See William Shieber, *State Antitrust Enforcement in Pharmaceutical Cases*, 18-SPG ANTITRUST 74, 75 (Spring 2004) (Westlaw) (describing the process by which pharmaceutical companies are able to submit a patent for a drug whose novelty is questionable, exposing competitor drug companies to a possible patent infringement lawsuit if they introduce a generic version of the branded drug).

³⁰ See Shieber, *supra* note 29, at 75.

³¹ *Id.*

³² *E.g.*, Teva Pharms., Indus., LTD v. FDA, 355 F. Supp. 2d 111, 118 (D.D.C. 2004) (lawsuit brought against the FDA for permitting branded companies to create generic drugs during the exclusivity period).

³³ *E.g.*, *id.* at 117.

³⁴ It was alleged that authorized generics introduced during the generic exclusivity period violated 21 U.S.C. § 355(j)(5)(B)(iv). *Teva Pharms., Indus., LTD*, 355 F. Supp. 2d at 115.

³⁵ The Court noted that authorized generics did not noticeably enter the market as a tool for reducing drug competition until after the provisions regarding exclusivity were amended by Congress. *Id.* at 118 n.7. Therefore, Congress could not address the problem of authorized generics because they did not yet exist. *Id.*

³⁶ *Id.* at 118.

³⁷ *E.g.*, Vicki Smith, Associated Press, *Mylan Lawsuit Warns of Looming Threat to Generic Drug Industry*, Aug. 27, 2004, available at http://www.siouxcityjournal.com/articles/2004/08/30/news_business/local/76a243fb0b1c1d5086256f0000151974.txt (citing negative comments made by U.S. District Judge Irene Keeley in response to the FDA allowing authorized generics to enter the market).

³⁸ *Id.*

³⁹ Letter from Stuart A. Williams, Chief Legal Officer, Mylan Pharmaceuticals, Inc., to Dockets

petition that because authorized generics are sold at a cheaper price than brand name products, generic manufacturers are hesitant to invest in R&D with the possibility that an authorized generic will beat them to the first market exclusivity right.⁴⁰ Mylan requested that the FDA prohibit authorized generics from entering the market until after a generic manufacturer's 180-day exclusivity period has ended; after this 180-day period, authorized generics would be allowed to compete with other generics.⁴¹ The FDA responded to Mylan's petition by asserting that authorized generics *increase* competition among pharmaceutical manufacturers.⁴² Such competition is consistent with the spirit of the Hatch-Waxman Act.⁴³ In its response letter to Mylan's petition, the FDA also stressed that it is charged solely with ensuring that drugs are safe and effective for human consumption.⁴⁴ Consequently, even if the FDA disagreed with the practice of introducing authorized generics, the agency would be powerless to regulate the competitive activities of the pharmaceutical industry.⁴⁵

III. STATE AND INTERNATIONAL LEGISLATIVE SOLUTIONS

a. The Maine Act and Similar Legislation

Maine is one of several states that devised a way to address the shortcomings of using a federal patent system that sometimes leads to high pharmaceutical prices during the periods of patent exclusivity. In 2001, Maine enacted the Maine Act to Establish Fairer Pricing for Prescription Drugs.⁴⁶ The Maine Rx Act sought to lower the cost of prescription drugs through manipulation of the powerful Medicaid system.⁴⁷ The federal Medicaid system was established in 1965, giving federal financial assistance to those states that choose to reimburse certain individuals for their medical needs.⁴⁸ However, the limitation of Medicaid is that individuals, in order to qualify, must be found "categorically needy."⁴⁹ The practical consequence

Management Branch, FDA, at 2 (Feb. 17, 2004) (on file with the author) [hereinafter Mylan Citizen Petition].

⁴⁰ *Id.*; see also Smith, *supra* note 37 (citing The Generic Pharmaceutical Association, which feels that fair competition is gravely threatened by authorized generics because brand-name producers are given "total control of the [pharmaceutical] market").

⁴¹ Mylan Citizen Petition, *supra* note 39, at 2.

⁴² Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Stuart A. Williams, Chief Legal Officer, Mylan Pharmaceuticals, Inc., and James N. Czaban, Heller Ehrman, at 12 (Jul. 2, 2004) (on file with author) [hereinafter FDA Letter to Mylan].

⁴³ See *id.* (explaining that one purpose in passing the Hatch-Waxman Act was to encourage competition among generic manufacturers).

⁴⁴ *Id.* at 2.

⁴⁵ *Id.*

⁴⁶ ME. REV. STAT. ANN., tit. 22, § 2681 (2004) (articulating the goals of the "Maine Rx Act").

⁴⁷ See *id.* (describing the purpose of the Maine Act).

⁴⁸ Social Security Amendments of 1965, Pub. L. No. 89-97, § 1901, 79 Stat. 343 (codified as amended at 42 U.S.C. § 1396 (2000)).

⁴⁹ 42 U.S.C. § 1396a (10)(A)(i)(I) (2000) (including as "categorically needy" those who are eligible for funds under the Aid to Families with Dependent Children [AFDC program]); 42 U.S.C. § 1381 (2000) (enumerating the aged, the blind, and the disabled receiving supplemental social security as eligible), and other low-income groups). Illinois, Wisconsin, South Carolina, Florida, Indiana, and Maryland have expanded the coverage of Medicaid to include senior citizens and the disabled with salaries up to 200

of reducing the pool eligible for Medicaid to those who are “categorically needy”⁵⁰ is that all individuals who do not qualify continue to pay premium rates for their medicine.

The state legislature enacted the Maine Rx Act in order to provide *all* Maine residents with an opportunity to purchase prescription medication at a reduced rate, regardless of whether or not the residents qualify for Medicaid.⁵¹ The Maine Rx Act established a system of negotiating rebates from drug manufacturers.⁵² The State Commissioner of Human Services is charged with negotiating the rebates.⁵³ Rebates are paid into a fund administered by the Commissioner, from which retail pharmacies are then compensated when the pharmacies offer discounted drugs.⁵⁴ These rebates enable residents to purchase drugs from retail pharmacies at discounted prices roughly equivalent to Medicaid prices.⁵⁵ According to the Medicaid statute, the negotiated rebate must be the higher price from: (1) the difference between the manufacturer’s average price for the drug and its “best price,”⁵⁶ or (2) 15.1 percent of the average manufacturer price for the particular drug.⁵⁷ The Maine Rx Act also put pressure on pharmaceutical companies who chose not to give rebates to the state; these companies would not be allowed to sell their products to Medicaid recipients without prior authorization from the state health department.⁵⁸

The Maine Rx Act met with considerable criticism from pharmaceutical companies, which were ultimately unsuccessful in overturning the statute.⁵⁹ Pharmaceutical companies argued that Medicaid recipients would be harmed if a drug company chose not to negotiate a rebate with the state, because the company would not be allowed to sell its drugs until authorization was obtained.⁶⁰ The Maine Rx Act was also attacked on the grounds that it violated the interstate commerce

percent of the poverty level. Nat’l Conf. of State Legislatures, States and “Pharmacy Plus” Medicaid Waiver Options, <http://www.ncsl.org/programs/health/pharmplus.htm> (last visited Dec. 1, 2007).

⁵⁰ 42 U.S.C. § 1396a(a)(10)(A)(i).

⁵¹ ME. REV. STAT. ANN. tit. 22, § 2681.

⁵² See *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 651 (2003) (discussing the constitutionality of the Maine Act on appeal to the United States Supreme Court).

⁵³ *Id.* at 654.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ “Best price” means “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity.” 42 U.S.C. § 1396r-8(c)(1)(C)(i) (2000).

⁵⁷ 42 U.S.C. § 1396r-8(c)(1)(B)(i). This price analysis applies to “single source” or “innovator multiple source” drugs. A “single source” drug has no generic alternative available. § 1396r-8(k)(7)(A)(iv). An “innovator multiple source” drug is a generic drug whose chemical structure was approved by the FDA when the drug’s branded equivalent was marketed. § 1396r-8(k)(7)(A)(ii). The negotiated rebate for all other types of drugs must be eleven percent of the average manufacturer price. § 1396r-8(c)(3)(B)(ii).

⁵⁸ *Walsh*, 538 U.S. at 654. “Prior authorization” is the process whereby a Medicaid recipient is reimbursed for a drug obtained under a doctor’s prescription only after a state agency has qualified that drug for reimbursement. The process is not mandated or regulated by federal law, but is used by states to reduce Medicaid costs. See, e.g., *Cowan v. Myers*, 187 Cal. App. 3d 968, 974-975 (Cal. Dist. Ct. App. 1986) (describing California’s Medicaid statute that requires prior authorization in order for Medicaid recipients to be reimbursed).

⁵⁹ *Walsh*, 538 U.S. at 655.

⁶⁰ *Id.* at 650.

clause by attempting to regulate commerce produced by out-of-state companies.⁶¹ In 2003, however, the United States Supreme Court in *Pharmaceutical Research and Manufacturers of America v. Walsh* affirmed the constitutionality of the Maine Rx Act.⁶² The Court found that requiring prior authorization before a Medicaid recipient may be reimbursed for a prescription is a permissible way for a state to curtail Medicaid costs.⁶³ The Court interpreted the Medicaid statute to give states broad latitude over the scope and limitations that apply to Medicaid recipients.⁶⁴ The sole caveat is that a state must ensure that “care and services are provided in the ‘best interest of the recipients.’”⁶⁵ The Court rejected the interpretation that Maine “threatens” drug companies into negotiating for drug rebates, lest the drugs be subject to the time-consuming process of prior authorization.⁶⁶ The Court also rejected the argument that the Maine Rx Act attempts to control the commerce of out-of-state manufacturers, concluding that any control that Maine has over interstate drug manufacturers is coincidental to lowering drug prices.⁶⁷ Consequently, the Supreme Court concluded that the Maine Rx Act accomplishes the purpose of lowering prescription drug costs without compromising the health of Maine residents or restricting the freedom of interstate commerce.⁶⁸

Despite the Supreme Court affirmation in *Walsh* that the Maine Rx Act is constitutional,⁶⁹ the Maine legislature chose to amend the Maine Rx Act in order to protect it against subsequent constitutional challenges.⁷⁰ The Maine Rx Act’s replacement is entitled “Maine Rx Plus,” reflecting several statutory modifications that addressed criticisms from pharmaceutical companies.⁷¹ The original Maine Rx Act endeavored to provide all uninsured and Medicaid-eligible citizens with drug coverage under a private or public insurance plan.⁷² With initial expenses for this insurance program being borne by the state, the Maine Rx Act’s plan was criticized for being prohibitively expensive.⁷³ It was estimated that the government would need to expend approximately \$4.5 million per year to sustain the program for the

⁶¹ The drug industry group Pharmaceutical Research and Manufacturers of America made this specific claim in their lawsuit against Maine. *Id.*

⁶² *Id.* at 669.

⁶³ *Id.* at 665.

⁶⁴ *Id.*

⁶⁵ *Id.* at 665 (citing *Alexander v. Choate*, 469 U.S. 287, 303 (1985)).

⁶⁶ *Walsh*, 538 U.S. at 662-663. The Court concluded that the Maine Rx Act serves several important Medicaid-related functions. These functions overshadow any apparent threats of coercion against drug manufacturers which refuse to negotiate with Maine for rebated drugs. *Id.* at 663.

⁶⁷ *Id.* at 669-670.

⁶⁸ *Id.* at 663-664, 669.

⁶⁹ *Id.* at 665.

⁷⁰ ME. REV. STAT. ANN. tit. 22, § 2681(2)(F) (West Supp. 2006).

⁷¹ *Id.*; see State of Maine Officer of the Governor, *Governor Balducci Announces Maine Rx Plus* (2003), <http://www.maine.gov/tools/whatsnew/index.php?topic=Gov+News&id=112&v=Article-2006>

(explaining that the Maine Rx Act was amended after a group of legislatures and advocates examined the Act and proposed changes that would make its implementation more effective).

⁷² ME. REV. STAT. ANN. tit. 22, § 2681 (2004).

⁷³ See Conrad F. Meier, *Governor Abandons Maine Rx Plan*, HEALTH CARE NEWS, Jul. 1, 2003, at 6, available at <http://www.heartland.org/Article.cfm?artId=12421> (explaining further that Governor John Balducci scrapped the original Maine Rx Act in favor of a plan that would save state expenditures by providing coverage to fewer residents).

325,000 eligible Maine residents.⁷⁴ Maine Rx Plus, on the other hand, restricts the expenses associated with operating the health insurance plan by setting an income cap as a guideline for determining which residents are eligible to receive health insurance.⁷⁵ Specifically, residents must earn no more than 350 percent of the federal poverty level in order to be eligible for Maine Rx Plus coverage.⁷⁶ In 2003, this translated into the income cap being set at about \$31,400 for an individual, \$42,000 for a couple, and \$64,000 for a family of four.⁷⁷ The number of eligible residents decreased from 325,000 to 275,000 as a result of the income cap.⁷⁸ Fortunately, Maine Rx Plus is able to provide significantly larger discounts to eligible residents than its predecessor.⁷⁹ Members of the program receive average discounts of twenty-six percent on branded drugs and fifty-one percent on generics drugs.⁸⁰

The Supreme Court judgment in *Walsh*⁸¹ provided validation to other states whose own pharmaceutical programs were highly criticized and has paved the way for new, innovative state regulations. Michigan,⁸² Ohio,⁸³ and Florida⁸⁴ have implemented similar statutes or policies that manipulate state Medicaid systems. In 2001, the Michigan Department of Community Health adopted a policy of refusing to subsidize drugs in state-funded plans such as Medicaid unless the manufacturer paid a rebate to the state.⁸⁵ The rebate would be accepted only if it reduced the drug's price to the price of the cheapest drug in its therapeutic class.⁸⁶ This tactic sought to reduce state drug costs in order to pass savings along to citizens enrolled in

⁷⁴ *Id.*

⁷⁵ In 2004, it cost approximately \$800,000 for the state government to operate Maine Rx Plus. *Id.* The cost in 2005 was \$2 million, less than half of the costs associated with operating the original Maine Rx Act. *Id.* The dramatic increase in cost from 2004 to 2005 is the result of a fund that was created by the Department of Health and Human Services to give greater reimbursement to small pharmacies. See IDAHO SENATE HEALTH & WELFARE COMMITTEE MINUTES: HEARING ON S. 1089 BEFORE THE S. HEALTH & WELFARE COMM., 2005 Sess. 1-5 (Feb. 10, 2005) [hereinafter IDAHO SENATE REPORT].

⁷⁶ ME. REV. STAT. ANN. tit., §2681(2)(F) (West Supp. 2006). The statute defines a resident qualified for Maine Rx Plus as "a resident of the State who has a family income equal to or less than 350% of the federal poverty level and who is enrolled in the program. 'Qualified resident' also means a resident of the State whose family incurs unreimbursed expenses for prescription drugs that equal 5% or more of family income or whose total unreimbursed medical expenses equal 15% or more of family income." *Id.*

⁷⁷ See State of Maine Office of the Governor, *supra* note 71 (explaining the operational details of Maine Rx Plus).

⁷⁸ *Id.*

⁷⁹ Compare ME. REV. STAT. ANN. tit. 22, § 2681(2)(F) (West Supp. 2006), with ME. REV. STAT. ANN. tit. 22, § 2681 (2004).

⁸⁰ See CENTER FOR POLICY ALTERNATIVES, PRESCRIPTION DRUG PRICING (2006), <http://www.stateaction.org/issues/issue.cfm/issue/PrescriptionDrugPricing.xml> (recommending, based on these statistics, that other states implement similar programs to Maine Rx Plus).

⁸¹ 538 U.S. at 651.

⁸² Pharm. Researcher & Mfrs. of Am. v. Dep't of Cmty. Health, 657 N.W.2d 162, 164 (Mich. Ct. App. 2002) [hereinafter Dep't of Cmty. Health] (describing the Michigan supplemental and basic rebate programs for prescription drugs).

⁸³ OHIO REV. CODE ANN. tit. 1, § 5110.05(A)(1)-(3) (West 2003) (current version at tit. 1, § 173 (West 2007)).

⁸⁴ Pharm. Research & Mfrs. of Am. v. Meadows, 304 F.3d 1197, 1198-99 (11th Cir. 2002) (discussing the Florida statute).

⁸⁵ See *Dep't of Cmty. Health*, 657 N.W.2d at 164-165.

⁸⁶ *Id.*

state-funded programs.⁸⁷ The Ohio pharmaceutical discount program, entitled Ohio's Best Rx, is similar to the Maine Act in that it restricts expenses associated with providing Medicaid by setting income and age restrictions for qualification purposes.⁸⁸ In order to restrict pharmaceutical prices, the state negotiates with manufacturers for lower prices, as well as receiving voluntary manufacturer rebates, then charges the Medicaid participant no more than the average price that other insurance plans charge for the drugs minus manufacturer rebates.⁸⁹

Florida passed a statute in 2001 that enables the Florida Medicaid Pharmaceutical and Therapeutics Committee to create a "preferred drug list."⁹⁰ Any drug not on this list requires prior authorization before it is covered by Medicaid.⁹¹ The Committee is authorized to withhold a drug from the preferred drug list if the drug lacks "cost-effectiveness."⁹² The statute is effective in reducing or offsetting state expenditures for Medicaid, savings that are passed onto citizens while in turn providing a benefit to drug manufacturers who are placed on the "preferred drug list."⁹³ The constitutionality of the Florida statute was upheld on appeal in *Meadows*.⁹⁴ The Court of Appeals for the Eleventh Circuit concluded that a state may place conditions on drugs eligible for state-provided Medicaid refunds.⁹⁵ These conditions could be economic, requiring manufacturers to negotiate rebates with the state, as long as they did not interfere with the purpose of the federal Medicaid Act.⁹⁶ The court applauded the statute by concluding that "by stretching its Medicaid dollars, the Florida law has the potential for providing more and better medical services to the target population."⁹⁷

b. The District of Columbia Act

A statute created by the District of Columbia in 2005 also tried to temper oppressive healthcare prices at the expense of pharmaceutical companies.⁹⁸ The Prescription Drug Excessive Pricing Act of 2005 (hereinafter, "D.C. Act"), as its

⁸⁷ *Id.*

⁸⁸ OHIO REV. CODE ANN. tit. 1, § 5110.05(A)(1)-(3). In order to qualify, an Ohio resident must either: (1) be over the age of 60, regardless of monthly income, or (2) be under the age of 60 with a monthly income no more than 300% of the federal poverty level. *Id.*, as amended by Am. Sub. H. B. 468 (2007). The monthly income requirement translates into earning no more than \$30,636 for a single person, \$41,076 for a family of two, or \$61,956 for a family of four. Ohio Dept. Of Aging, *Ohio's Best Rx* (2007), http://www.ohiobestrx.org/pdfs/OBRx_Fact_Sheet.pdf.

⁸⁹ The final amount charged to Medicaid participants is the "Best Rx Price," which saves participants about 34% on pharmaceutical products. Ohio Dept. Of Aging, *Ohio's Best Rx* (2007), http://www.ohiobestrx.org/pdfs/OBRx_Fact_Sheet.pdf.

⁹⁰ FLA. STAT. § 409.91195(9) (2001).

⁹¹ § 409.91195(8).

⁹² § 409.91195(9).

⁹³ *Meadows*, 304 F.3d at 1204 (stating that "the establishment of the 'preferred drug list' is directly tied to a 'supplemental rebate' program").

⁹⁴ *Id.* at 1208-09.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* at 1209.

⁹⁸ Prescription Drug Excessive Pricing Act of 2005, D.C. Code §§ 28-4551-4555, 52 D.C. Reg. 9061 (2005 Supp.), *invalidated by Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C., 2005).

name implies, created a blanket cap on drug prices deemed “excessive.”⁹⁹ Although the D.C. Act sought to achieve the admirable goal of ensuring “that all residents receive the health care they need,”¹⁰⁰ it was rapidly challenged in court and struck down.¹⁰¹ The statute prohibited a “drug manufacturer or any licensee . . . excluding a point of sale retail seller . . . to sell or supply for sale . . . a patented prescription drug” at excessive prices.¹⁰² The D.C. Act did not explicitly define what qualifies as an “excessive” price.¹⁰³ However, it was suggested that drugs not be priced at higher than thirty percent of the drug’s comparable price in the United Kingdom, Australia, Germany, or Canada.¹⁰⁴

The D.C. Act was struck down on the grounds that it conflicted with federal patent laws, particularly the Hatch-Waxman Act.¹⁰⁵ The D.C. Act would likely achieve its intended purpose of reducing the price of pharmaceutical drugs to no more than thirty percent greater than its comparable price in the four designated foreign countries.¹⁰⁶ However, the Court likened putting pressure on companies that charge an “excessive” amount for drugs to “punishing” the holders of pharmaceutical patents.¹⁰⁷ This is an economically-undesirable consequence because “[p]unishing the holders of pharmaceutical patents in this manner flies directly in the face of a system of rewards calculated by Congress to insure the continued strength of an industry vital to our national interests.”¹⁰⁸ The District Court consequently held the D.C. Act to be a “clear obstacle” to the protections that federal patent regulations are intended to provide.¹⁰⁹ Moreover, federal patenting is the healthcare process that Congress chose to balance the wellbeing of consumers with the high cost of drug production.¹¹⁰

The reaction to the D.C. Act’s invalidation has varied from concern to elation. The National Legislative Association on Prescription Drug Prices (NLARX), a nonprofit group, has hailed the now-defunct statute as “model legislation” because it strives to give all Americans the same opportunities to purchase medicine.¹¹¹ Conversely, others have pointed out that the market-based healthcare system in the United States is necessary because it “rewards innovation and drives future discovery.”¹¹² Creating endless regulations, it is argued, will stifle profits and

⁹⁹ D.C. Code § 28-4551(3).

¹⁰⁰ § 28-4551(1).

¹⁰¹ *Pharm. Research & Mfrs. of Am.*, 406 F. Supp. 2d at 58-59.

¹⁰² D.C. Act § 28-4553.

¹⁰³ D.C. Act § 28-4554(a).

¹⁰⁴ D.C. Act § 28-4552(2), 4554(a).

¹⁰⁵ *Pharm. Research & Mfrs. of Am.*, 406 F. Supp. 2d at 65-66.

¹⁰⁶ *Id.* at 66.

¹⁰⁷ *Id.* at 66-67.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 64, 67-71 (holding further that the Council of DC impermissibly sought to exercise its power over commerce that took place outside of its district, because presumably most drug manufacturers are out-of-state).

¹¹⁰ *Id.* at 67.

¹¹¹ See Susan Konig, *Court Rejects Prescription Drug Price Controls in D.C.*, HEALTH CARE NEWS, Feb. 1, 2006, available at <http://www.heartland.org/Article.cfm?artId=18479> (quoting an article that appeared on the NLARX website).

¹¹² The Pharmaceutical Research and Manufacturers of America [PhRMA], Press Release, *U.S. District Court Declares D.C. Price Control Law Unconstitutional* (Dec. 22, 2005), available at

consequently reduce investments in R&D.¹¹³

The D.C. Act was invalidated, in part, because its system made foreign prices the benchmark for what can be deemed “excessive” U.S. drug prices.¹¹⁴ In other words, the D.C. legislature sought with the D.C. Act to substitute federal regulations of the U.S. with federal regulations of other nations.¹¹⁵ Industrialized nations such as Germany and Canada were set as the benchmark for determining what prices are “excessive” in the United States.¹¹⁶ There is obvious conflict in comparing the United States’ market-based pricing system to the price-controlled systems in other countries.

c. Comparison to Price-Controlled Foreign Systems

Drugs in countries such as Canada, France, Germany, and the United Kingdom are priced lower because they are regulated by the federal government.¹¹⁷ For instance, Canada has forced pharmaceutical companies to share their medical innovations with other manufacturers since 1923.¹¹⁸ The cost of drugs consequently decreased as more companies competed for the same drug market.¹¹⁹ Unfortunately, companies also saw their profit margins vanish due to lower drug prices, resulting in a dramatic decline in R&D investment.¹²⁰ Germany and the United Kingdom engaged in similar price-control practices with similar results.¹²¹

i. National Health Insurance in France and Germany

France and Germany utilize a type of National Health Insurance System (NHI), whereby the government assumes primary responsibility for providing universal healthcare and regulating the healthcare system.¹²² In France, patients pay all

http://www.phrma.org/news_room/press_releases/u.s._district_court_declares_d.c._price_control_law_unconstitutional/. The statement was issued by Billy Tauzin, CEO and President of PhRMA. *Id.*

¹¹³ It is ironic that, although development of a drug is extremely expensive and time-consuming, drug manufacturing was the most profitable United States industry from 1995 to 2001. KAISER FAMILY FOUNDATION, TRENDS AND INDICATORS IN THE CHANGING HEALTH CARE MARKETPLACE (2002), available at, <http://www.health08.com/insurance/7031/ti2004-1-21.cfm>.

¹¹⁴ *Pharm. Research & Mfrs. of Am.*, 406 F. Supp. 2d at 66.

¹¹⁵ *Id.* at 67 (holding that Congress’ judgment is supreme, and therefore the D.C. Act is unconstitutional for trying to preempt Congress’ healthcare system).

¹¹⁶ Prescription Drug Excessive Pricing Act of 2005, D.C. Act 16-171, §28-4553 (Oct. 14, 2005).

¹¹⁷ See U.S. DEP’T OF COMMERCE INT’L TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION, at viii (2004), available at <http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf> (explaining the effective price regulatory systems of eleven countries who are members of the Organization for Economic Cooperation and Development [OECD]).

¹¹⁸ *Id.* (discussing a process referred to as “compulsory licensing”). The issuance of a compulsory license “authorize[s] a third party to make, use, or sell a patented invention[] without the patent owner’s consent.” See F.M. Scherer, *The Economics of Compulsory Drug Patent Licensing*, at 7, <http://www.patentmatics.org/pub2005/pub5f.pdf> (2003).

¹¹⁹ Scherer, *supra* note 118, at 8 (citing a study which found that drugs subject to Canadian compulsory licensing requirements in 1982 were priced on average 49% lower than their counterparts produced in the United States).

¹²⁰ *Id.*

¹²¹ *Id.* at 7.

¹²² See Martha Ann Holt, Comment: International Prescription Drug Cost Containment Strategies and Suggestions for Reform in the United States, 26 B.C. INT’L & COMP. L.REV. 325, 333 (2003).

medical fees directly to the healthcare providers and are subsequently reimbursed.¹²³ The government partially or fully reimburses patients from a health insurance fund.¹²⁴ This fund is comprised of mandatory taxes on earnings.¹²⁵ In contrast to numerous gatekeeper functions performed in the United States to reduce healthcare costs,¹²⁶ the French NHI imposes no restrictions on the quality or quantity of healthcare services provided to patients for which patients can be reimbursed.¹²⁷ However, patient reimbursement for prescription drugs is strictly regulated by an interministerial commission.¹²⁸ This commission determines whether a patient's purchase of specific pharmaceutical products will be reimbursed.¹²⁹ The majority of prescription drugs are actually approved by the commission for reimbursement; the government instead reduces the costs associated with running NHI by vesting the commission with the power to strictly regulate prescription drug prices.¹³⁰ Prices for pre-existing prescription drugs are set according to current market prices for the analogous drug.¹³¹ Interestingly, the system for setting prices on innovative drugs mirrors the system of how private manufacturers in the United States set prices.¹³² Prices reflect a reasonable monetary return for the manufacturer on the cost of production, including R&D.¹³³

Germany operates an NHI system similar to the one used in France.¹³⁴ This healthcare system provides prescription drugs (and every other medical treatment) to 100 percent of German citizens.¹³⁵ The German NHI for prescription drugs operates

¹²³ See Victor G. Rodwin, *The Health Care Under French National Health Insurance: Lessons for Health Reform in the United States*, AM. J. PUB. HEALTH, Jan. 2003 at 31, 32.

¹²⁴ *Id.* at 32. There are three primary NHI funds that are managed by the French social security administration: (1) for salaried workers [Caisse Nationale d'Assurance Maladie des Travailleurs Saliés, or CNAMTS], (2) for farmers and agricultural workers [Mutualité Sociale Agricole, or MSA], and (3) for the independent professions [Caisse Nationale d'Assurance Maladie des Professions Indépendantes, or CANAM]. *Id.*

¹²⁵ *Id.* at 34. In 2003, employers were required to pay 12.8% of the wage bill, while employees were taxed at 6.9% of their total earnings. The taxed wages were put into a fund to cover 74% of total healthcare costs. Interestingly, the French NHI system also taxes the pharmaceutical industry, earnings that are also placed into the fund. *Id.*

¹²⁶ See INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY*, at 23-24 (2001), available at http://books.nap.edu/catalog.php?record_id=10027#toc (listing several federal organizations which compile and analyze quality control data in order to monitor and improve healthcare standards).

¹²⁷ See Victor G. Rodwin & Simone Sandier, *Health Care under French National Health Insurance*, <http://www.nyu.edu/projects/rodwin/french.html> (last visited Feb. 2007).

¹²⁸ *Id.* (elaborating that this commission is comprised of representatives from the French Ministries of Health, Finance, and Industry).

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ See Holt, *supra* note 122, at 333-34. The NHI, although organized by the federal government, is actually administered by national and regional self-governing associations of payers and providers. These associations are responsible for negotiating prices. See Germany-National Health Insurance and Medical Care, <http://countrystudies.us/germany/119.htm> (last visited Feb. 2007).

¹³⁵ See Albert Wertheimer, et al., *Pharmacy in the Western World Health Care Systems*, in *CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS* 159, 164-65 (Peter Davis ed., 1996).

by suggesting market prices and encouraging competition.¹³⁶ Consequently, it is similar to the United States system in that pharmaceutical manufacturers are *encouraged*, but not required, to price their products at reasonable market prices. NHI associations establish reference prices for drugs, placing the reference prices on categories of drugs that are pharmacologically similar.¹³⁷ As with the French NHI system, patients pay upfront for prescription drugs and are subsequently reimbursed for their payments out of “sickness funds.”¹³⁸ However, the fund will only reimburse patients for the amount spent on drugs up to the reference price.¹³⁹ Reference prices are set with an understanding that innovative drugs are priced higher by manufacturers in order to offset the R&D costs they expended on creating the drugs.¹⁴⁰ Consequently, sickness funds will reimburse patients for *slightly* more expensive innovative products.¹⁴¹ Reference prices are set at only slightly higher than prices for generic drugs in order to encourage competition. The reasoning is that patients are more likely to select cheaper innovative drugs in order to ensure reimbursement from the sickness fund.¹⁴² Consumer selection of cheaper medication in turn encourages drug manufacturers to lower their prices.

Although France and Germany are commendable in their efforts to provide universal, quality healthcare to all citizens with an eye on cost containment, each NHI program has obvious weaknesses. The French system is criticized for sacrificing quality healthcare in order to provide all citizens with a minimum level of treatment.¹⁴³ The German NHI operates much like insurance plans in the United States, reimbursing patients for out-of-pocket expenses provided that the prescription drug is explicitly covered by the insurance plan.¹⁴⁴ Although Germany has guidelines in place to moderate the price of prescription drugs, these guidelines are *suggestions* which manufacturing companies need not follow when pricing their drugs.¹⁴⁵ The consequence of the German system mirrors the consequence of the United States market-based system: patients must shoulder the financial burdens of paying for drugs that their insurance plan does not cover.

ii. Price Containment in Canada

Canada is now able to offer prescription drugs at cheaper prices than in the United States because of price-control legislation passed in 1985.¹⁴⁶ The Patented Medicines Price Review Board (PMPRB) is a branch of the Canadian federal government that regulates the length of patents and then patented prescription drug prices.¹⁴⁷ The PMPRB is charged with reviewing a drug price when it is patented

¹³⁶ *Id.*

¹³⁷ *Id.* at 165.

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ See Rodwin, *supra* note 123, at 36.

¹⁴⁴ See Wertheimer et al., *supra* note 135, at 164-65.

¹⁴⁵ *Id.*

¹⁴⁶ Patent Act, R.S.C., ch. P 4, s. 1 (1985).

¹⁴⁷ *Id.*

and introduced into the market.¹⁴⁸ The Canadian government discovered that increasing patent terms from 6.5 years to 10 years would generate greater revenues for drug manufacturers.¹⁴⁹ Consequently, reported R&D investment by drug companies expanded from about \$165 million in 1988 to about \$1 billion in 2006.¹⁵⁰ The PMPBR determines the length of a drug patent, but may allow a generic drug manufacturer entry into the market before the patent expires.¹⁵¹ The generic manufacturer is allowed market entry during the patent exclusivity period by paying a form of royalty to the branded manufacturer.¹⁵²

There are several parts to the price-setting analysis of a new drug.¹⁵³ If the drug has similar therapeutic benefits to another drug already being sold in Canada, the new drug must be priced the same or lower than the former drug.¹⁵⁴ If the new patented drug is therapeutically unique, its price must be comparable to the median price charged in seven other nations.¹⁵⁵ In evaluating the fairness of a drug price, the PMPBR is also allowed to calculate whether profits are fair based on the pharmaceutical company's original investment.¹⁵⁶ Pharmaceutical companies in turn limit their spending budgets on marketing and advertising in order to have sufficient profits to channel back into R&D.¹⁵⁷ Consequently, the PMPBR has extensive negotiating power over pharmaceutical companies to drive down prices, since the board has ultimate discretion in approving patents and market exclusivity rights to generic manufacturers.¹⁵⁸ The PMPBR has negotiating power similar to that vested in the state health department of Maine under the Maine Rx Act.¹⁵⁹

c. State Access to Cheaper Foreign Medication

American citizens commonly obtain cheaper pharmaceutical products by purchasing them in Canada. Prescription drugs in Canada are priced from thirty-three to eighty percent lower than in the United States.¹⁶⁰ IMS Health reported that Americans purchased \$695 million worth of pharmaceutical products from Canadian

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Analysis of Research-and-Development Expenditures: Annual Report 2000, PMPBR 36, T.6 (2006). As per Canadian statute, only pharmaceutical companies that hold active Canadian patents for the sale of medicine in Canada are required to report R&D expenditures. *Id.* The figures represent expenditures for 66 companies in 1988 and 79 companies in 2000. *Id.*

¹⁵¹ See generally Patent Act, R.S.C. 1985, ch. P 4, s. 1 (Can).

¹⁵² *Id.*

¹⁵³ Patented Medicines Regulations, S.O.R./1994-688, s. 4(1)(e) (Can).

¹⁵⁴ *Id.* at s. 3-4.

¹⁵⁵ *Id.* at s. 4(1)(g) (the compared nations are Italy, France, Sweden, the United States, the United Kingdom, and Germany).

¹⁵⁶ See Luke W. Cleland, Comment: *Modern Bootlegging And The Prohibition On Fair Prices: Last Call For The "Repeal" Of Pharmaceutical Price Gouging*, 15 ALB. L.J. SCI. & TECH. 183, 201 (2004) (describing how the PMPBR limits drug prices at the expense of drug manufacturer profits).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ See generally *Walsh*, 538 U.S. at 649 (describing how the state health department can prevent pharmaceutical companies from selling their drugs to Medicaid recipients in Maine if the manufacturer does not give a rebate).

¹⁶⁰ Staff of Rep. Pol'y Comm., 108th Cong., There is a Better Way, Pharmaceutical Price Controls Abroad: An Unfair Trade Policy (Comm. Print 2003), available at <http://www.senate.gov/diff/rpc/index.cfm>.

internet pharmacies.¹⁶¹ Although Americans may travel to Canada to buy these products, the FDA attempted to preempt the sale of Canadian drugs in the United States by declaring Canadian drugs to be unsafe and potentially illegal if the drugs do not meet FDA safety standards. The Canadian government also expressed concern that the purchase of Canadian drugs by Americans would reduce the amount of drugs available to Canadian citizens.¹⁶² However, federal legislation was enacted in 2000 to permit importation of foreign prescription drugs to lower drug costs as long as these drugs are approved as safe by the Secretary of Health and Human Services.¹⁶³ Congress also passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which contains a similar provision allowing private citizens to import prescription drugs.¹⁶⁴ Consequently, beginning in 2003, several states brushed aside FDA warnings about the dangers of importing drugs and enacted their own importation programs.¹⁶⁵

New Hampshire established a state-sponsored website in order to provide all New Hampshire residents with access to Canadian internet pharmacies.¹⁶⁶ New Hampshire required only that: (1) Canadian drugs be certified as safe by the New Hampshire Department of Health and Human Services, (2) Canadian drugs be shipped in their original packaging to eliminate counterfeit products from being sold, and (3) American citizens present prescriptions signed by United States doctors to the Canadian sellers.¹⁶⁷ Despite FDA warnings of unsafe Canadian drugs, Governor Craig Benson declared that to have numerous citizens “not taking prescription drugs

¹⁶¹ IMS Health Canada reports that internet sales in 2003 were \$584 million Canadian dollars. IMS HEALTH CANADA, WHAT'S NEW AT IMS HEALTH (2005), available at http://www.imshealthcanada.com/htmen/1_0_16.htm. Using the Bank of Canada's average exchange rate 0.7135 from 2003 converts into \$416 million American dollars. Press Release, IMS Health Canada, *Growth in Retail Prescriptions Slows in 2004* (Mar. 7, 2005), http://www.imshealthcanada.com/vgn/images/portal/cit_40000873/0/35/78325956retail_prescription_growth_slows.pdf; Bank of Canada, *Exchange Rates, Annual Averages* (2005), <http://www.bankofcanada.ca/en/rates/exchange.html>.

¹⁶² *Canada Worried about Shortages Due to U.S. Reimportation*, WASH. DRUG LETTER (FDA News, Falls Church, Va.) Nov. 3, 2003, at 1.

¹⁶³ Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2001, Pub. L. No. 106-387, 114 Stat. 1549 (2000) (making appropriations for Agriculture, Rural Development, Food and Drug Administration and Related Agencies programs for the fiscal year ending September 30, 2001, and for other purposes).

¹⁶⁴ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1121, 117 Stat. 2066, 2464 (2003). For the importation of pharmaceutical drugs, the Act requires safety approval by the Secretary of Health and Human Services and that importing the foreign drug will create significant cost savings. It also created a task force to study the effect of importation on drug development in the United States. The task force reported its many negative findings in 2004, concluding that (1) United States regulations over domestic drugs are very effective at protecting public safety, (2) importing drugs is significantly dangerous, (3) national savings from allowing importation is small when compared with the costs spent on ensuring that importation is safe, (4) many drugs are the same price in foreign nations, (5) legalized drug importation will probably have adverse effects on domestic development of drugs, (6) legalized importation will probably harm intellectual property rights, and (7) consumers will have greater liability concerns when importing drugs. See *Importation of Prescription Drugs*, KANSAS LEGISLATIVE RESEARCH DEP'T, KANSAS LEGISLATOR BRIEFING BOOK, K-3, at 3 (2006) [hereinafter KANSAS LEGISLATOR BRIEFING BOOK].

¹⁶⁵ See generally Anna Wilde Mathews, *States to Help Citizens Import Canadian Drugs*, WALL ST. J., Dec. 18, 2003, at B1 (discussing drug importation programs in New Hampshire, Minnesota, West Virginia, and Massachusetts).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

because they [cannot] afford them” justified this bold program.¹⁶⁸ Numerous states, including Minnesota, New Jersey, and West Virginia, have followed New Hampshire by creating websites that allow Americans to import Canadian prescription drugs from pharmacies.¹⁶⁹ Further, thirteen states in total have enacted legislation to expressly permit certain drug importation from Canada or other industrialized nations for the health benefits of their citizens.¹⁷⁰

III. THE ROLE OF PRIVATE RETAILERS

a. Wal-Mart Pricing

Private retailers who are willing to offer lower prices on generic prescription drugs may provide the best solution to the crisis of high pharmaceutical prices. In September 2006, retail giant Wal-Mart Stores Inc. announced that it will sell about 300 generic drugs for \$4 per 30-day supply.¹⁷¹ Customers need only present a doctor’s prescription that can be filled with a generic drug in order to qualify for the reduced price; health insurance is not required.¹⁷² According to Wal-Mart’s current market strategy, 65 stores in Tampa, Florida offer the discounted drugs, with a nationwide distribution projected for 2008.¹⁷³ Savings to customers range from sixteen percent to sixty-seven percent.¹⁷⁴ Although Wal-Mart has been applauded for putting pressure on other pharmaceutical retailers to lower drug prices lest they lose customers, critics argue that Wal-Mart’s competition is not pressured because most of the drugs offered at the \$4 discount rate are old and cheaply priced anyway.¹⁷⁵ Drug industry analysts have concluded that the Wal-Mart program will have little effect on the nation’s overall healthcare costs because only fifteen percent of total healthcare revenues are derived from pharmaceutical sales.¹⁷⁶

The most crucial effect that Wal-Mart’s pharmaceutical plan may have on the drug market is simply showing that the price of numerous drugs can easily be reduced for both insured and non-insured individuals. Retailers are able to offer reduced prices on generic drugs because they have higher profit margins than branded drugs.¹⁷⁷ The savings that retailers pass on to consumers consequently have

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ The jurisdictions include California, Connecticut, District of Columbia, Hawaii, Nevada, Maine, Mississippi, Rhode Island, Texas, Vermont, Washington, West Virginia, and Wisconsin. KANSAS LEGISLATOR BRIEFING BOOK, *supra* note 164, at 4-6.

¹⁷¹ Wal-Mart, *Wal-Mart and Sam’s Club Accelerate Rollout of \$4 Generic Prescription Program* (Sept., 2007) <http://www.walmartfacts.com/articles/4495.aspx>. [hereinafter Wal-mart].

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ See Gary McWilliams & Barbara Martinez, *Wal-Mart Cuts Prices for Many Generic Drugs to \$4*, WALL ST. J., Sept. 22, 2006, at B1 (describing one of the most dramatic examples of savings for Wal-Mart customers: \$4 for 850 milligrams of diabetes drug Metformin as compared to \$28.19 for the same drug at competitor Walgreens).

¹⁷⁵ For example, Wal-Mart now offers the popular generic blood pressure drug Atenolol for \$4 per 30-day supply. Wal-Mart’s original price for the drug was \$8.62. However, competitor Costco Wholesale Corp. currently sells the same product for \$3.69 for a 30-day supply. *Id.* (discussing the effects of Wal-Mart’s drug plan on competitors).

¹⁷⁶ See *id.* (citing Tim van Biesen, partner at Bain & Co. and drug market analyst).

¹⁷⁷ *Id.* (describing how retail stores are often able to purchase generic drugs from manufacturers for as

little to no negative impact on the profits generated by stores such as Wal-Mart.¹⁷⁸ In fact, retailers ultimately profit from their reduced drug pricing plans by increasing customer loyalty.¹⁷⁹ For instance, the discounted generic drugs sold by Wal-Mart treat a wide range of ailments including allergies, high cholesterol, high blood pressure, diabetes, depression, and infections.¹⁸⁰ Therefore, many consumers choose a particular retailer because they greatly benefit from the retailer's drug plan by being able to purchase discounted products that treat a range of ailments. The obvious flaw to retailer drug plans is that they fail to offer newer, innovative drugs that enter the market under a patent.

IV. RECOMMENDED CHANGES TO THE PRESCRIPTION DRUG PRICING SYSTEM

An analysis of how the United States pharmaceutical industry should be regulated must take into account the goals and values that surround this industry. A high societal premium is placed on market competition and profit maximizing, reflected in a patent system that creates a short-term monopoly over innovative prescription drugs. Manufacturing companies operate for-profit and are allowed to set prices that will produce a reasonable return on R&D. Given that the U.S. pharmaceutical industry is estimated to earn approximately \$126 billion between 2005 and 2013,¹⁸¹ the U.S. patent system is clearly successful in protecting the profit margins of drug manufacturers.

Other nations such as France are praised for instituting national health policies that provide universal healthcare.¹⁸² However, the U.S. capitalistic drive for profits is distinct from France, which reflects the French pluralistic sense of community.¹⁸³ Consequently, drug manufacturers in the U.S. should not be faulted for seeking to maximize profits under the capitalist ideal. It is necessary that the U.S. also place a high premium on the health and safety of its citizens. At any given time there are about 40 million individuals uninsured in the U.S. who cannot afford the medications their doctors prescribe to them.¹⁸⁴ The issue, then, is what changes to

little as pennies per pill).

¹⁷⁸ *Id.*

¹⁷⁹ See Parija B. Kavilanz, *Generic Drugs Getting Cheaper at Wal-Mart: Number 1 Retailer Launches Program Selling Nearly 300 Common Medicines for as Low as \$4*, CNNMoney, Sept. 21, 2006, http://money.cnn.com/2006/09/21/news/companies/walmart_drugs/index.htm?cnn=yes (reporting the statement by Richard Hastings, senior analyst at Bernard Sands, that the marketing strategy will be a neutral financial event for Wal-Mart, but that it should greatly improve customer loyalty over time).

¹⁸⁰ Wal-Mart, *supra* note 171.

¹⁸¹ Michelle L. Kirsche, *Authorized Generics Yielding Controversy, Profits for Drug Makers*, DRUG STORE NEWS, Feb. 14, 2005, at 22, available at http://findarticles.com/p/articles/mi_m3374/is_2_27/ai_n10018289.

¹⁸² See Holt, *supra* note 122, at 333 (discussing how the French NHI system provides universal healthcare which is reimbursed by the federal government).

¹⁸³ Capitalism is an economic theory. It is defined as "an economic system characterized by private or corporate ownership of capital goods, by investments that are determined by private decision, and by prices, production, and the distribution of goods that are determined mainly by competition in a free market." Pluralism is a social theory. It is defined as "a state of society in which members of diverse ethnic, racial, religious, or social groups maintain an autonomous participation in and development of their traditional culture or special interest within the confines of a common civilization." MERRIAM-WEBSTER COLLEGIATE DICTIONARY (11th ed. 2005); see Rodwin, *supra* note 123, at 34 (describing how the French NHI system ensures that all citizens receive necessary healthcare, although the quality of such care is directly related to the wealth of the particular French region).

¹⁸⁴ See CDC: National Center for Health Statistics, *Early Release of Selected Estimates Based on Data*

the healthcare system may be made so that more Americans receive necessary medication without compromising capitalistic values.

Although the U.S. patent system meets its goal of protecting manufacturing profit margins, it has fallen short in its objective of lowering prescription drug prices. The Hatch-Waxman Act has numerous loopholes that allow branded manufacturers to undermine the entry of generic manufacturers into the market.¹⁸⁵ A popular delay mechanism is the introduction of authorized generics, a practice that the Hatch-Waxman Act is silent on.¹⁸⁶ The Hatch-Waxman Act's silence regarding the introduction of authorized generics,¹⁸⁷ coupled with the FDA's declaration that it is powerless to regulate the practice,¹⁸⁸ has motivated branded manufacturers to take a larger share of the market using authorized generics. For instance, from 1993 to 2002, only one authorized generic was introduced into the market per year.¹⁸⁹ In 2003, nine were introduced, with twelve introduced in 2004.¹⁹⁰ Only about 0.01 percent of pharmaceutical profits has been generated from the sale of authorized generics over the last few years.¹⁹¹

Based on the above statistics, the practice of selling authorized generics arguably is so rare that Congress need not concern itself with amending the Hatch-Waxman Act to discuss it. However, failure to amend the Hatch-Waxman Act places responsibility with courts to determine the scope of pharmaceutical competition. Judicial power has two negative consequences on pharmaceutical prices. First, generic manufacturers are obviously limited to one course of action in order to prevent an authorized generic from entering the market: manufacturers must file a time-consuming and costly anti-trust lawsuit. The expense of this process may discourage generic manufacturers from competing with authorized generic manufacturers (the branded manufacturers). Second, the time-consuming and risky nature of the judicial process may motivate branded manufacturers to seek an alternative entry into the market. The branded manufacturer may devote its time to creating a similar chemical structure to the original drug that can be patented as a unique drug. This unique drug is then approved for an FDA exclusivity period, keeping the price of the drug artificially high because no generic formula is allowed to enter the market during the exclusivity period. Consequently, the Hatch-Waxman Act should be amended to clearly reflect acceptance of authorized generics on the

from the 2005 National Health Interview Survey (June 21, 2006), available at <http://0-www.cdc.gov.mill1.sjlibrary.org/nchs/about/major/nhis/released200606.htm>. A study conducted by the government agency, Centers for Disease Control, reported that about 42 million Americans were uninsured in 2004. This translated into 14% of the population. The percentage and number of uninsured individuals has remained consistent over the past decade. *Id.*

¹⁸⁵ See Knowledge@Wharton, *supra* note 20, at 177-78 (describing how competition under the Hatch-Waxman Act occurs in relation to eight other foreign countries).

¹⁸⁶ The Hatch-Waxman Act was amended in 2003 without mention of whether authorized generics violate the Act. This has led scholars to argue that Congress' silence on the practice is akin to acceptance of the practice. See Porter, *supra* note 16, at 207 (stating further that the FDA should consider creating a separate approval process for authorized generics, but that such an approval process cannot be mandated unless the Hatch-Waxman Act is amended to address authorized generics).

¹⁸⁷ *Id.*

¹⁸⁸ See FDA Letter to Mylan, *supra* note 42 (declaring in a response letter to Mylan's Citizen Petition that the FDA is charged only with safeguarding public health and safety, not regulating competition).

¹⁸⁹ See Kirsche, *supra* note 181, at 21.

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

market. Authorized generics ultimately provide the consumer with greater choices, creating market forces that drive down prices.

Given that the federal government utilizes a pro-capitalism type of prescription drug scheme, states such as Maine,¹⁹² Michigan,¹⁹³ Ohio,¹⁹⁴ and Florida¹⁹⁵ have enacted their own health insurance statutes in order to exercise control over the pricing of pharmaceutical products. These statutes are commendable for actively involving state health departments in the process of negotiating lower prices with manufacturing companies. Unfortunately, statutes that benefit the community at the expense of business have several drawbacks. For instance, small, independently-owned pharmacies and large chain stores are often uninterested in passing along savings to their customers.¹⁹⁶

In Maine, blame for the failing prescription drug statute lies with the statutory process of negotiating rebates and then reimbursing the companies that give rebates. Maine Rx Plus empowers the State Commissioner of Human Services to negotiate with drug manufacturers to offer rebates on prescription drugs.¹⁹⁷ After the drug manufacturer approves a rebate on its product, private retailers *may* choose to keep the rebated price in mind when pricing the drugs sold in its stores.¹⁹⁸ Under Maine Rx Plus, the private retailer will be reimbursed by the state government if it chooses to set a retail price that reflects the rebated price from the manufacturer.¹⁹⁹ If the private retailer chooses not to participate in the rebate plan, the eligible customer does not receive a cheaper price on the drug from the store. In other words, the entire system of reducing prescription drug prices is undermined if the retailer rejects the system.

In Maine and in other states that have similar statutes, many retailers choose not to participate in the rebate plan for two economic reasons. First, retailers that give rebates to their customers are reimbursed only a few times per year.²⁰⁰ This imposes

¹⁹² Me. Rev. Stat. Ann tit. 22, § 2681 (2004 & Supp. 2006).

¹⁹³ See Dep't of Cmty. Health, 657 N.W.2d at 164 (describing the Michigan supplemental and basic rebate programs for prescription drugs).

¹⁹⁴ OHIO REV. CODE ANN. tit. 1, § 5110.05(A)(1)-(3).

¹⁹⁵ FLA. STAT. § 409.91195(9) (West 2005 & Supp. 2007); see also *Meadows*, 304 F.3d at 1198-99 (discussing the Florida statute).

¹⁹⁶ See IDAHO SENATE REPORT, *supra* note 75. The Idaho Senate in 2005 held a meeting to determine whether Idaho should pass a statute similar to Maine Rx Plus. Idaho Senator Compton reported that numerous small pharmacies from around the state expressed concern that selling discounted prescriptions drugs would induce their bankruptcy. Consequently, small pharmacies were more interested in protecting their business assets than in lowering prices for the benefit of the community. It was pointed out that small pharmacies are justified in protecting themselves because in many rural areas there are only one or two pharmacies. If these pharmacies close, members of the community will be forced to travel long distances to buy prescription drugs. A representative and pharmacist from Maine also reported that large, nationwide pharmacies including CVS, Wal-Mart, and Rite Aid rejected participation in the program. *Id.*

¹⁹⁷ ME. REV. STAT. ANN tit. 22, § 2681 (2004). Under the Maine Rx Plus program, rebates received from manufacturers and laborers are placed in a fund referred to as the "Maine Rx Plus Dedicated Fund." *Id.* One of the stated purposes of the fund is to "reimburse retail pharmacies for discounted prices provided to qualified residents." *Id.*

¹⁹⁸ No portion of Maine Rx Plus mandates that private retailers set prices that reflect the discounted rate received from manufacturers. Instead, title 22 § 2681(5) of the Maine Code states that "each participating retail pharmacy shall sell covered drugs to qualified residents at the lower of the initial discounted price and the secondary discounted price" (emphasis added).

¹⁹⁹ Maine Rx Plus Program, ME. REV. STAT. ANN tit. 22, § 2681(5) (2004).

²⁰⁰ See IDAHO SENATE REPORT, *supra* note 75 (describing concerns from Idaho Senators that Maine Rx

a great financial hardship on small community pharmacies that require immediate reimbursement in order to continue operating the pharmacy.²⁰¹ Second, the size of the reimbursement that pharmacies receive is tied to a state's Medicaid drug budget.²⁰² These budgets are approved by the state legislature.²⁰³ If that budget is cut, reimbursement rates decrease, consequently decreasing incentives for pharmacies to provide rebates to eligible customers. This situation nearly occurred in Maine, which would have caused devastating consequences to Maine Rx Plus.²⁰⁴ In January 2004, Maine's legislature approved a forty percent decrease of the state Medicaid budget, which would have given Maine the lowest Medicaid budget in the nation.²⁰⁵ Approximately seventy-five percent of pharmacies chose not to participate in Maine Rx Plus as a result.²⁰⁶ The President of large retailer Rite-Aid lamented that "pharmacies are necessary to help the state execute these long-term savings programs . . . So it's even harder to understand why [the legislature] would continue to cut [retailer] reimbursement, and as a result, the resources available to help [citizens] save on prescription costs."²⁰⁷

Despite several drawbacks, states should continue implementing statutes that put pressure on drug manufacturers to negotiate for lower prices. However, legislatures should put pressure by enacting statutes that require minimal state expenditures to operate the program. Maine Rx Plus reflects the devastating consequences that befall members of an insurance plan when a budget on which the plan is supported is reduced. Reimbursement plans such as those enacted in Maine and Ohio rely too heavily on both Medicaid funds and support from private retailers. The lack of either element renders the plan ineffective at reducing prescription drug prices. Consequently, state legislatures should mirror the type of statute implemented in Florida, which uses a preferred drug list and prior authorization.²⁰⁸ One flaw in the Florida statute is that it only implicates drugs that are covered by Medicaid. In other words, drug manufacturers are not pressured by the statute to lower the price on drugs that are not covered by Medicaid.²⁰⁹ Ultimately, the Florida statute is an

Plus requires reimbursements to be paid weekly to pharmacies, but that in practice reimbursements are being received quarterly).

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ See Martha King & Dianna Gordon, *Medicaid: 10 Fixes that Work: Of All the Reforms States Have Tried, These are the Ones that Hold the Most Promise*, State Legislatures, National Conference of State Legislatures, Mar. 2004, at 14, available at http://www.ncsl.org/programs/pubs/slmag/2004/04SLMar_medicaid.pdf (describing how states shrink Medicaid budgets in order to reduce overall expenditures).

²⁰⁴ See Idaho Senate Report, *supra* note 75. One State Representative lamented that "when [Maine] cut the reimbursement rate on the Medicaid program, it hurt the program because everything is tied to that reimbursement rate." *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ See James Frederick, *Maine pharmacy cuts ignite protests and threat of pullback by Rite Aid*, DRUG STORE NEWS, Jan. 19, 2004, at 58, available at http://findarticles.com/p/articles/mi_m3374/is_1_26/ai_112594047 (quoting an angry statement made by president and chief executive officer of Rite Aid, Mary Sammons).

²⁰⁸ See FLA. STAT. § 409.91195(9) (empowering physicians to approve drugs for the preferred drug list). Any Medicaid-covered drug that is not approved for the drug list must receive prior authorization before Medicaid will reimburse patients for using the drug. *Id.*

²⁰⁹ It is important to note that the Florida statute does not explicitly *exclude* non-Medicaid drugs from appearing on the preferred drug list. Instead, the statute broadly states that "the Medicaid Pharmaceutical and Therapeutics Committee shall develop its preferred drug list recommendations by

inexpensive, bold way for state health departments to motivate drug manufacturers to reduce prescription drug prices. As the Court of Appeals for the Eleventh Circuit stated in a judgment allowing the statute, "the Florida law operates to drive down the cost of prescription drugs under the Medicaid program by providing drug manufacturers with a strong economic incentive to offer the state a supplemental rebate."²¹⁰

Extensive attention has been focused on the prescription drug systems of foreign nations. As discussed previously, nations such as France and Germany provide universal healthcare.²¹¹ Canada, in addition to a system of universal healthcare, sells prescription drugs at prices that are thirty-three to eighty percent lower than in the U.S.²¹² In light of the extremely high volume of drugs that Americans purchase from Canadian pharmacies,²¹³ more states should sponsor websites that allow Americans to import Canadian medication. The benefits of creating state-sponsored importation websites are two-fold: more Americans can purchase affordable prescription drugs while giving state health departments supervisory control over the process. State legislatures should work to legalize foreign drug importations after it is determined that particular drugs are safe and effective.

Private retailers and individual states have effectively addressed the issue of exorbitant prescription drug prices, but for different motivations. Private retailers, such as Wal-Mart, are profit-driven and understand that customer loyalty is increased when prices are lowered.²¹⁴ Consequently, they are motivated to lower prices only when it is possible to do so without reducing profit margins. Wal-Mart has demonstrated that generic medication can be offered by private retailers for nominal prices with a consequent increase in customer loyalty. However, the majority of prescription drugs offered by the retailer are older formulas that are typically sold at much lower prices anyway. Individual states, on the other hand, are compelled to regulate prescription drug prices for the welfare of their citizens. Large private retailers will likely continue to reduce the prices on prescription drugs they offer if their market share increases from customer loyalty. In other words, whether private retailers continue offering large discounts on drugs will depend on profitability. States may want to consider providing economic incentives to stores such as CVS and Rite-Aid to encourage them to sell newer prescription drugs with discounts, in addition to their current line of generic drugs.

considering the clinical efficacy, safety, and *cost-effectiveness* of a product." FLA. STAT. § 409.91195(9) (emphasis added). The statute would be unconstitutional under the federal Medicaid Act if non-Medicaid drugs were explicitly excluded under all circumstances. *Meadows*, 304 F.3d at 1207-08.

²¹⁰ *Meadows*, 304 F.3d at 1207-08 (holding that the state has lawfully created a "prior authorization program" within the meaning of Medicaid Act, 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5), which permits a state Medicaid plan to "subject to prior authorization any covered outpatient drug").

²¹¹ See Holt, *supra* note 122, at 333-34 (describing differences in the National Health Insurance plans of France and Germany).

²¹² Rep. Pol'y Comm., 108th Cong., *supra* note 160.

²¹³ In 2003, Americans reportedly purchased about \$585 million worth of prescription drugs from Canadian pharmacies accessed on the internet. This volume of sales more than doubled the \$251 million in sales generated in 2002. *Retail Prescriptions Grow at Record Level in 2003*, IMS HEALTH CANADA, Mar. 25, 2004, http://www.imshealthcanada.com/web/content/0,3148,77303623_63872702_77770096_77809465,00.html.

²¹⁴ See Kavalanz, *supra* note 179.

V. CONCLUSION

Currently, prescription drug expenditures account for approximately eleven percent of healthcare costs.²¹⁵ This may appear to be a minimal amount of money, not worthy of consideration by legislatures. However, prescription drugs are extremely important to prolonging life, curing illnesses, and reducing pain of the terminally ill. Consequently, the issue of rising prescription drug costs must become a priority among legislatures. Despite attempts to contain the skyrocketing costs of pharmaceutical products, a significant portion of the population continues to search for alternate means to afford prescription medicine. Many have turned to Canada and other foreign nations to fill their prescriptions, creating a dangerous situation where drugs are often obtained that do not meet national safety standards.

It appears that the U.S. ideal of competition in the marketplace will continue indefinitely. Consequently, legislatures appear to be in the best position to continue modeling solutions that achieve a balance: providing pharmaceutical companies with reasonable profits while alleviating the heavy burden of affording prescription medicine. Federal and state legislatures must amend preexisting laws and mold new laws in order to contain the skyrocketing cost of prescription drugs. The American society should seek to institute healthcare plans that balance capitalism with social welfare. Specifically, a capitalist system that treats everyone differently can only be justified if those in the worst economic position are bettered by virtue of living under capitalism. Consequently, the health of Americans should be placed above the U.S. ideal of maximizing profits, if only to ensure that Americans are able to afford necessary medicine.

²¹⁵ See Improving Health Care, *supra* note 1.