Modern Bootlegging and the Prohibition on Fair Prices: Last Call for the "Repeal" of Pharmaceutical Price Gouging

Luke W. Cleland

Table of Contents.

I. Introduction

A seventy-two year-old woman in Oklahoma City, Oklahoma is willing to cut prescription pills in half or not take them at all, in order to stretch her dollar and prolong the amount of time she can spend with these precious little commodities.[1] If dissection of pills does not prolong her supply sufficiently, she is willing to travel to a foreign country to buy cheaper pills.[2] Another elderly person reflected on her choice to access the legal goods in a potentially illegal way by stating: "Life is sure more comfortable if you don't hurt so bad."[3] Pharmaceuticals are not only a desired good on an open market, but they are vital for the very survival of many individuals in the United States. However, the pharmaceutical companies' level of profit and success is directly correlated with the physical suffering and economic hardship experienced by most Americans who depend on pharmaceuticals for survival.

In 2002, nearly 15% of the Gross Domestic Product in the United States was spent on health care, which translates to approximately $5,440 for every citizen. [4] In fact, the Journal of Health Affairs reported that spending on health care in 2002 grew more than any other industry in the United States.[5] Congress has stated: "[d]espite increases in medical care spending that are greater than the rate of inflation, population growth, and Gross Domestic Product growth, there has not been a commensurate improvement in our health status as a nation."[6]

As a subspecies of the health care industry, pharmaceutical companies enjoy the largest profit margin of any industry in the United States.[7] The pharmaceutical industry has finally been able to surface from the quagmire of market restraint in order to meet society's insatiable appetite for health. Or is the pharmaceutical industries' experience in the United States an anomaly?

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[1] Brian Barber, *RxDepot Hearing Ends*, TULSA WORLD, Oct. 10, 2003, at A1.
[2] *Id.*
[3] *Id.*
[4] Sara Schaefer Munoz, *U.S. Health Care Spending Rose 9.3% in 2002*, WALL ST. J., Jan. 9, 2004, at A2.
[5] *Id.*
[6] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1014, 42 U.S.C. § 299(a)(3) (2003) [hereinafter Act of 2003].
[7] Shawna Lydon Woodward, Note, *Will Price Control Legislation Satisfactorily Address the Issue of High Prescription Drug Prices?: Several States Are Waiting in the Balance for PhRMA v. Concannon*, 26 SEATTLE U. L. REV. 169, 174-175 (2002).

Despite the pharmaceutical companies' profiteering triumph in the United States, the triumph is not necessarily representative of pharmaceutical companies' success the world round.[8] Arguably, the pharmaceutical companies do not operate under the harness of typical market restraints.[9] Distinguishing the United States further from the rest of the worlds, the brunt of the significant profit margin enjoyed by the pharmaceutical industry is borne directly by the consumer and not the government.[10] These costs are paid in the form of increased premiums for insurance and private pharmaceutical drug plans, or through increased tax monies that fund social legislation designed to provide prescription drug coverage for various impoverished sectors of American society. In 2003, employer sponsored health care plans rose in cost an average of 10% per employee, forcing employers to pass the increased costs onto their employees. Meanwhile, 19% fewer employers provide health care coverage to senior citizen retirees than just ten years ago.[11]

The search to find mechanisms to reduce the cost of pharmaceutical drugs is reaching a head, if the debate has not done so already. Various state legislatures have enacted mandatory rebate and prior authorization measures to deter physicians from prescribing high priced brand name pharmaceuticals to Medicaid recipients without a medically necessary reason as to why a cheaper generic solution could not be implemented.[12] For example, the state of Maine has not only threatened disclosure of the names of companies who refuse to participate in the program, but Maine has also increased the number of beneficiaries under the Maine Prescription statute to include a non-Medicare, non-Medicaid population of under or uninsured.[13] The beneficiaries under Maine's prescription drug plan now includes a suffering group of individuals whose personal insurance or pharmaceutical drug plans fail to adequately cover their

[8] Woodward, *supra* note 7, at 174. Although the pharmaceutical industry is one of the most profitable in the world, Americans pay more for their drugs than any other country in the world. Id.
[9] Michael B. Moore, *"Open Wide" (Your Pocketbook That Is!)- A Call For the Establishment in the United States of a Prescription Drug Price Regulatory Agency*, 1 SW. J. L. & TRADE AM. 149, 154-155 (Fall 1994).
[10] *See, e.g.*, Act of 2003, *supra* note 3.
[11] Vaness Fuhrmans, *Shifting Burden Helps Employers Cut Health Costs*, WALL ST. J., Dec. 8, 2003, at B1.
[12] 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, 340-42 (Spring 2003). Those state legislatures include: Maine, Wisconsin, and Michigan. See generally PhRMA v. Walsh, 123 S.Ct. 1855 (2003)(discussing Maine legislation); PhRMA v. Meadows, 304 F.3d 1197 (11th Cir. 2002)(discussing Florida legislation).
[13] 22 M.R.S.A. § 2681 (2002). As compared to other states with similar statutes. *See, e.g.* Marth Ann Holt, *supra* note 12, at 340-42.

prescription expenses and who do not qualify as traditional Medicaid recipients.[14] The Supreme Court upheld the constitutionality of the Maine Prescription statute, holding that the program did not place a disparate burden on interstate commerce and vacated a preliminary injunction barring the implementation of the state's statute.[15]

Likewise, frustrated by the lack of effective regulation of pharmaceutical prices in the U.S., individuals struggling to make ends meet have traveled, both physically and electronically, to foreign markets for relief.[16] One of the more popular of the foreign markets is Canada.[17] Within many states, officials on both the local and state governmental levels have, not only provided incentives for state and local employees to purchase drugs from Canadian pharmacies instead of American pharmacies,[18] but have also set up websites for the benefit of all citizens of a given state.[19] Although the private industry has attempted to facilitate international access to those who cannot physically travel, private industry facilitation of international access to pharmaceuticals has met some level of defeat.[20] The United States Congress has circumnavigated the individual states' ability to regulate the public welfare of their citizens by granting sole legislative discretion on the issue to the Secretary of Health and Human Services; a member of the executive branch.[21]

Parts II, III, and IV of this article examine the arguments surrounding possible free market price control mechanisms, in light of the pharmaceutical importation cases

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[14] See 22 M.R.S.A. § 2681, *supra* note 13. " '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."

[15] *Walsh*, 123 S.Ct. at 1873 (2003).

[16] Anne Wilde Mathews, *States to Help Citizens Import Canadian Drugs*, WALL ST. J., Dec. 18, 2003, at B1.

[17] *Id*.

[18] *Boston to Force Issue on Canadian Drugs*, WALL ST. J., December 10, 2003, page unavailable.

[19] Mathews, *supra* note 16, at B1.

[20] United States v. RxDepot, 290 F. Supp. 2d 1238, 1247 (2003). But see 21 U.S.C § 384 (2003) (allowing Secretary of Health and Human Services the capacity to approve re-importers of pharmaceuticals). *See also FDA Warns CanaRx Services About Its Illegal Internet Website & Mail Operation Obtaining Unapproved & Potentially Risky Drugs From Canada*, 13 BIOMEDICAL MKT. NEWSL. 14, Oct. 31, 2003 [hereinafter *FDA Warns*].

[21] Act of 2003, *supra* note 3. In fact, Congress wishes to grant the ability of the Secretary to "provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program…"; which would allow the executive the exclusive ability to decide on behalf of the aging American people what is in their best interest in procuring and accessing not only pharmaceutical drugs, but also the extent of health care coverage Medicare would practically have. *Id. See also* 42 U.S.C.A. § 1395hh NOTE (2003).

and state Medicaid initiatives both on the state level in the United States and elsewhere. Part V examines the provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Act") as they pertain to pharmaceutical importation possibilities. A workable price control mechanism may be the product of state initiatives to contain the ever-increasing burden on the under-insured and government dependants by exercising their bargaining power as public welfare police. This price control mechanism must include a certification by the Secretary of Health and Human Services to Congress that the importation regulations specified in the Act will "result in a significant reduction in the cost of covered products to the American consumer," thus allowing prescription drugs priced at lower foreign prices[22] to enter the United States pharmaceutical market.[23] The arguments are being exhausted. The American people still suffer.[24]

Price controls may be the only way to combat unchecked profit. If prices and profit margins continue to rise unchecked, how much money are Americans willing to hemorrhage? Now may be the last chance. The Secretary of Health and Human Services, Congress, and state legislatures must embrace current initiatives and perfect their implementation before high prices prohibit patients from meaningful access to pharmaceutical technology.

II. *RxDepot* and Others.

RxDepot is a Tulsa, Oklahoma company, that until November 6, 2003,[25] operated an online pharmacy through which customers with prescriptions for pharmaceuticals could purchase their drugs from a Canadian partner pharmacy.[26] RxDepot operated eighty-five locations in twenty-six states.[27] Upon submission of the relevant prescription to the local RxDepot store, customers were asked to fill out various forms concerning

[22] These lower prices are the product of foreign price control mechanisms not implemented in the United States. *See infra*, Part II.
[23] 21 U.S.C. § 384 (2004).
[24] Act of 2003, *supra* note 6.
[25] *See RxDepot*, 290 F. Supp. 2d at 1247.
[26] Brian Barber, *Judge Hears RxDepot Case*, TULSA WORLD, Oct. 9, 2003, at A1.
[27] *Id*.

their medical histories. [28] The customer's prescription, medical history, and payment information were forwarded to the partner pharmacy in Canada, where a Canadian medical doctor rewrote the prescription and the order was processed.[29]

On March 21, 2003 the Food and Drug Administration (FDA) sent a warning letter to RxDepot stating that the FDA believed that RxDepot was illegally re-importing manufactured drugs from foreign countries into the United States, as well as importing unapproved prescription drugs.[30] RxDepot issued a response to the FDA letter, stating that the company was merely importing pharmaceuticals that were manufactured within the United States.[31] Unsatisfied with the response, the FDA continued to send such letters to RxDepot warning legal action.[32]

On September 11, 2003, the United States filed a lawsuit against RxDepot alleging violations of the Federal, Food, Drug and Cosmetic Act (FDCA)[33] and sought an injunction as authorized by the FDCA.[34] The government presented, and the court adopted as fact, evidence of certain undercover FDA investigations which resulted in the receipt of: 1) an overfill of a prescription; 2) a generic version of a patent protected drug that was neither available nor manufactured in the U.S.; and 3) a non-FDA approved warning insert and packaging that failed to mention specific information about the possible occurrence of liver damage associated with the use of a particular drug.[35] Further, some purchases of re-imports were made from companies other than the U.S. manufacturer of the drug.[36] Additionally, the government presented evidence indicating that the Canadian pharmacy failed to validate the authenticity of certain ordered prescriptions.[37] However, the effectiveness and potency of the drugs were never tested, and no defect in the composition of the drugs themselves was ever alleged.[38]

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[28] *RxDepot*, 290 F. Supp. 2d at 1247.
[29] *Id*.
[30] *Id*.
[31] *Id*.
[32] The FDA has also threatened other companies similar to RxDepot, such as CanaRx Services, Inc. of Detroit, MI through this same letter campaign, citing risks to the public health. *Id. See FDA Warns*, *supra* note 19.
[33] *See* 21 U.S.C. §§ 331(d)(t), 381(d)(1)(2003).
[34] 290 F. Supp. 2d at 1239.
[35] *Id*.
[36] *Id*.
[37] Barber, *supra* note 26.
[38] *RxDepot*, 290 F. Supp. 2d 1243.

In its rebuttal of the results of the FDA investigations that the court adopted as fact, RxDepot argued three facts. [39] First, RxDepot argued that the allegedly overfilled prescriptions allowed for a refill amount in excess of the dose actually delivered.[40] Second, RxDepot argued that the generic version of the patent protected drug allegedly not manufactured in the U.S., was actually manufactured in Puerto Rico at an FDA approved facility.[41] Third, RxDepot argued that the alleged omitted liver information was included in a section of the packaging devoted to potential side effects, and thus not entirely absent.[42]

In finding importing drugs harmful to the consumer, the Northern District of Oklahoma stated that the quality of imported and re-imported drugs is "less predictable than drugs obtained in the United States" because the integrity of the drugs themselves may be compromised during their tenure outside the U.S.[43] Furthermore, the district court found that drugs imported in greater amounts than the prescription called for could be taken for longer periods of time and without the clinical supervision intended by the prescribing physician.[44] Finally, the court found that the failure to include specific FDA approved packaging endangered the patient.[45]

After finding that prescription drug costs were significantly higher in the United States than in other countries, and recognizing Congress as the "best" place to address the issues of price control on prescription drugs, the district court addressed the government's petition to grant a preliminary injunction against RxDepot.[46] The court held that RxDepot's operations constituted a per se violation of the FDCA.[47] Therefore, because RxDepot was in violation of the statute, the court held that the government was substantially likely to prevail against RxDepot in a full adjudication of the factual issues

[39] Barber, *supra* note 26.
[40] *Id*.
[41] *Id*.
[42] *Id*.
[43] *RxDepot*, 290 F. Supp. 2d, at 1240.
[44] *Id*.
[45] *Id*.
[46] *Id*. at 1242. When the injunction is authorized as part of a statutory scheme, the court must only find that there is a minimal chance of continued violation. Here, the court held that the absence of the injunction would allow the defendant to continue re-importing drugs. *Id.*
[47] *Id*. at 1244.

in the case.[48] The court stated that RxDepot's ability to offer lower prices, and whatever public health benefits were incidental from these lower prices, were best weighed against the benefits of the FDCA restriction in Congress and not through judicial opinion.[49] Additionally, because RxDepot's actions constituted a per se violation of a congressional act, injunction could only be avoided if the statute itself was unconstitutional.[50]

During its examination of the FDCA's constitutionality, the court held that the FDA's selective prosecution of importers of small quantities of prescription drugs was not selective enforcement barred by the constitution because RxDepot was a commercial entity operating to provide large quantities of drugs to a significant portion of the population.[51] Moreover, the court stated that because agencies such as the FDA are given great discretion in the prosecution of violations, selective prosecutions are only unconstitutional when they are based on arbitrary criteria.[52] Since the FDA is limited in resources, the court reasoned that selective enforcement against large-scale enterprises was a logical application of the FDA's efforts to reduce the risk of harm to the consumer arising from unauthorized re-importation of pharmaceuticals.[53] The court dismissed other constitutional challenges by finding that no entity can assert certain constitutional objections that arise from invalid, illegal activities.[54] Therefore, the court granted a preliminary injunction against RxDepot for the reasons stated above.[55]

On November 12, 2003 the Northern District of Oklahoma rejected an emergency plea to stay the preliminary injunction while the decision was on appeal.[56] In upholding its grant of the preliminary injunction, the court held that lost profits from engaging in an illegal activity could not constitute the irreparable harm necessary to circumvent preliminary injunction.[57] Additionally, the court reiterated that the government had a

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[48] *Id*.
[49] *Id*.
[50] *Id*.
[51] *Id*. at 1245.
[52] *Id*.
[53] *Id*.
[54] *Id*. Specifically, a violation of the Privileges and Immunities Clause, and the First Amendment right of free speech. *Id.*
[55] *Id*. at 1247.
[56] United States v. RxDepot, No. 03-CV-0616-EA, 2003 WL 23120030, at*1 (N.D. Okla. November 12, 2003).
[57] *Id*.

prevailing safety concern in preventing re-importation, which overrode any potential damage due to the high prices of pharmaceuticals in the United States.[58]

On November 21, 2003, the Tenth Circuit Court of Appeals refused to overturn the injunction.[59] In its appellee brief, the FDA argued that "RxDepot is facilitating violations of the [FDCA] on a massive and highly organized scale…unlike the activities of individual consumers…."[60] On November 23, 2003, frustrated RxDepot attorney Fred Stoops re-highlighted the ramifications that closing RxDepot storefronts nationwide would have on the elderly in a letter to the Tulsa World, a newspaper in Tulsa, Oklahoma:

> The FDA admitted that Health Canada has the same or similar standard to its own and is just as safe. All prescriptions filed through RxDepot came from a Health Canada pharmacy. . . .For a second time, the greatest generation is being asked to sacrifice -- but this time not to stop the onslaught of evil against freedom. This time it is just about money.[61]

Similarly, the plight of RxDepot repeats on other fronts. The FDA threatened legal action that may lead to the closure of CanaRx Services, Inc. of Detroit, Michigan.[62] In addition to providing cost savings to individuals, CanaRx provides employees of Springfield, Massachusetts access to reduced prescription drug prices; the first municipality in the United States to provide such benefits to its employees.[63] The FDA has sent several warning letters to the company.[64] The success of the government in *RxDepot*[65] and the enactment of the Medicare Act of 2003 indicate that this genus of pharmaceutical importer soon will no longer be able to operate in order to provide cost savings to the public.

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[58] *Id*.
[59] *See* Robert Boczkiewicz & Brian Barber, *Ruling to Keep RxDepot Closed*, TULSA WORLD, Nov. 22, 2003, at A15.
[60] *See* Robert Bocziewicz, *FDA Counters RxDepot's Request For Stay*, TULSA WORLD, Nov. 21, 2003, at A21.
[61] *The Truth of the Matter*, TULSA WORLD, Nov. 23, 2003, at G2.
[62] *See FDA Warns*, *supra* note 20.
[63] *Prescription Drug Importation; Canadian Drug Supplier Says Products Safe*, MED. LETTER ON CDC & FDA 35, Oct. 19, 2003.
[64] *Id*.
[65] *RxDepot*, 290 F. Supp. 2d at 1238.

III. The Maine Rx Program, the State Initiative, and Others.

In 2000, the state legislature of Maine enacted the Maine Rx Plus Program.[66] The program aims to establish affordable prescription drug access to the residents of Maine who fall within the state's Medicaid criteria.[67] Additionally, the program provides relief to those Maine residents who incur either, un-reimbursed expenses for prescription drugs equal to or greater than 5% of family income or, un-reimbursed medical expenses equal to or in excess of 15% of family income.[68]

Under the statute, all manufacturers or labelers of pharmaceuticals that sell their drugs within the state under publicly funded pharmaceutical drug plans must negotiate rebates with the state.[69] The proceeds from the rebates are then placed into a fund, which reimburses the participating pharmacies that sell the drugs at a reduced price.[70] When the act takes full effect on October 1, 2004, pharmacies within the state will sell the drugs at the prices reached through rebate negotiations with the pharmaceutical companies, minus any further discounts that the rebate fund is able to provide.[71] The Maine Board of Pharmacy must publish the discounted rates in participating pharmacies, indicating the amount of money saved by the initiative.[72]

Also, the statute provides that the state shall publish the names of the manufacturers and labelers who refuse to participate in the rebate arrangement to both the public and health care providers within the state.[73] In addition, physicians who desire to prescribe drugs manufactured by companies who refuse to enter into a rebate agreement are subject to prior authorization.[74] The prior authroization process requires the prescribing physician to verify the medical necessity of prescribing the drug of a non-

[66] 22 M.R.S.A. § 2681 (2003).
[67] *Id*. at §2681(2)(F).
[68] *Id*.
[69] *Id*. at §2681(3)(4). These rebates must at least be equal to the 15% rebates negotiated by the federal government under federal law. *Id*. *See* 28 U.S.C. § 2681(4).
[70] 22 M.R.S.A. § 2681(3)(4) (2003).
[71] *Id*. at §2681(5).
[72] *Id*. at §2681(6)(A).
[73] *Id*. at §2681(7).
[74] *Id*.

participating entity with a state appointed physician, who may then approve prescription of the drug.[75]

Drug company executives have expressed concerns with regard to prior authorization programs. [76] The concern is that the programs decrease the number of prescriptions written for drugs produced by those manufacturers who choose not to participate in the MaineRx program, thus directly affecting profits of those companies.[77] Drug companies also fear decreased profit margins, as lower prices are negotiated through rebate agreements, as well as a decrease in physician and patient loyalty.[78]

In *PhRMA v. Concannon*,[79] the Pharmaceutical Research & Manufacturers of America (PhRMA) brought suit against Maine's Commissioner of Human Services and the Attorney General of Maine alleging preemption under the federal Medicaid program, a violation of the Supremacy Clause, and violations of the dormant Commerce Clause.[80] The PhRMA contended that the program imposed a significant burden on Medicaid recipients by requiring recipients to go through the hassle of prior authorization without providing any valid Medicaid purpose, and that the statute regulated out of state commerce.[81] The district court upheld both of these contentions and issued a preliminary injunction against Maine, holding that the state statute conflicted with the purpose of the federal Medicaid statute, and finding that the Maine Rx Program regulated the revenues of out of state distributors and manufacturers of pharmaceutical drugs.[82]

On appeal, the First Circuit Court of Appeals reversed the trial court's grant of injunction.[83] The circuit court held that because the federal Medicaid statute explicitly granted states the authority to use prior authorization, no conflict existed between the Maine and federal statute.[84] The court iterated so long as the requirements under the federal statute were met, the purpose of the state, to provide access to medical services

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[75] *Id*; *see also* Jagan Nicholas Ranjan, *Medicaid and the Unconstitutional Dimensions of Prior Authorization*, 101 MICH. L. REV. 602 (2002) (outlining and critiquing the prior authorization process).
[76] *Walsh*, 123 S.Ct. at 1864.
[77] *Id*.
[78] *Id*.
[79] 249 F3d 66 (1st Cir. 2001).
[80] *Walsh*, 123 S.Ct. at 1860.
[81] *Id*.
[82] Woodward, *supra* note 7, at 180.
[83] PhRMA v. Concannon, 249 F.3d 66 (1st Cir. 2001).
[84] *Walsh*, 123 S.Ct. at 1865.

for those who could not afford them, was congruous with the purpose of the federal statute.[85] Further, the circuit court pointed out that the state might decrease long-term Medicaid expenditures arising from untreated conditions by providing prescription drug access to individuals that would not otherwise be able to afford the drugs for the treatment of deteriorating conditions.[86] However, the circuit court recognized that prior authorization may potentially affect the quality of medical care provided to Medicaid beneficiaries, thus, the court allowed the PhRMA to reserve the right to challenge preemption after the implementation of the Maine statute, in the event that prior authorization negatively affected medical care.[87]

The First Circuit Court of Appeals concluded that the statute did not violate the dormant commerce clause.[88] In so doing, the circuit court stated that, although the profit margins of pharmaceutical companies and distributors could experience incidental effects, the statute did not aim to regulate profits itself; nor did the statute regulate the prices in other states. [89] Rather, the circuit court stated that the statute only negotiated rebates for the benefit of the citizens of the state of Maine.[90] Moreover, the court found that all transactions policed under the Maine statute occurred within the state of Maine.[91] After balancing the local benefits against any burdens on interstate commerce, the circuit court held that the benefit derived from increased access to pharmaceutical drugs outweighed the loss of profits suffered by the producers of these drugs.[92]

The United States Supreme Court issued a writ of certiorari and affirmed the First Circuit Court of Appeal.[93] The Court affirmed in a plurality decision.[94] In its amicus brief, the government argued that the prior authorization allowed under the federal Medicaid statute was intended only to balance access with price, not to lower prescription

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[85] *Id*.
[86] *Id*; s*ee also Concannon,* 249 F.3d at 81.
[87] *Walsh,* 123 S.Ct. at 1866.
[88] *Id*.
[89] *Concannon,* 249 F.3d at 82.
[90] *Id.*.
[91] *Id*. These transactions included the purchase of the prescription drugs, the negotiation of the rebate, the prior authorization, and the release of the names of nonparticipating manufacturers. *Id*.
[92] *Id.* at 84.
[93] *Walsh,* 123 S.Ct. at 1855.
[94] *Id*.

drug costs for the benefit of all of the citizens of Maine.[95] Likewise, since a state must submit their proposal for change or amendment of its Medicaid scheme to the Secretary of Health and Human Services for approval,[96] the government argued that the Maine statute was either preempted by federal law or invalid due to of the state's failure to follow administrative procedures.[97]

However, in their amicus brief, thirty-eight sovereign states and Puerto Rico petitioned the Court as one to uphold the court of appeal's preemption analysis. [98] The brief argued that granting Medicaid recipients cheaper access to prescription drugs relieves long term medical costs to the Medicaid system that arise when patients allow ailments to go untreated simply because those patients cannot afford the pharmaceutical remedy.[99] The brief also encouraged the Court to uphold the negative commerce clause analysis because the statute did not control prices asked by manufacturers of pharmaceuticals in their dealings with drug distributors, the statute only regulates the drugs when they enter the state.[100] Likewise, the brief stated that Maine did not regulate the drugs to benefit state manufacturers or distributors at the expense of out of state interests.[101] Further, the brief urged that no pharmaceutical manufacturer or distributor was handicapped in their dealings with other states or entities therein.[102]

In its opinion, the Court limited its analysis to the lifting of the injunction and declined to resolve any factual disputes.[103] The Court also noted that the Maine Rx Plus Program may still be invalidated by the Secretary of Health and Human Services should the Secretary decide that the program is in fact an amendment to the state of Maine's Medicaid scheme, and thus subject to the Secretary's review.[104] The Court stated that although the Maine program did not limit benefits to Medicaid recipients only, the Maine program did not necessarily diminish the benefits that the statute provided to the

[95] Brief of Amici Curiae United States, et.al. at 9, PhRMA v. Concannon, 123 S.Ct. 1855 (2003)(No 01-188).
[96] *Id*. at 10.
[97] *Id*.
[98] Brief of Amici Curiae State of Massachusetts, et.al. at 22, PhRMA v. Concannon, 123 S.Ct. 1855 (2003)(No. 01-188).
[99] *Id*.
[100] *Id*. at 22-24.
[101] *Id*. at 22-29.
[102] *Id*. at 27-29.
[103] *Walsh*, 123 S.Ct. at 1855.
[104] *Id*. at 1866.

Medicaid population.[105] The Court also found that the Maine statute benefited the Medicaid population by reducing the overall costs of the program through increased access to the pharmaceuticals during early treatment of conditions, and that prior authorization substantially reduces the costs associated with the implementation of a Medicaid program.[106]

Additionally, the Court held that Maine's interest in promoting the health of its uninsured citizens was a valid justification for implementing its prior authorization requirement. The Court did not require that Maine's motivation to change Medicaid benefits relate to the Medicaid Act itself,[107] rather, the state must show only that the Medicaid patients' medical needs are not adversely affected.[108] The Court found that absent evidence to the contrary; Maine's prior authorization measures did not negatively affect the Medicaid patients' medical needs. [109] Thus, federal law did not preempt the Maine statute.[110] Moreover, the Court found that any impact on the profit margins of the pharmaceutical manufacturers was merely incidental to the cost savings enjoyed by the state in serving the medical needs of its underinsured population.[111]

In addressing the dormant Commerce Clause attack, the Court upheld the First Circuit Court of Appeals' opinion stating that the Maine statute did not regulate the price of pharmaceuticals negotiated in the transaction between the manufacturer and the wholesaler; nor did the Maine program control out of state prices through any in state pricing scheme.[112] Likewise, the Court found that the Maine statute created no disparate burdens.[113] Out-of-state manufacturers would not be able to avoid rebates by manufacturing within the state, nor would they benefit from in state reimbursement of local pharmacies;[114] therefore, the Court held that the Maine Rx Plus Program did not

[105] *Id*. at 1867.
[106] *Id*. at 1867-68.
[107] *Id.* at 1867.
[108] *Id*. at 1870.
[109] *Id*.
[110] *Id*.
[111] *Id*.
[112] *Id.* at 1871.
[113] *Id.*
[114] *Id.*

violate the Dormant Commerce Clause.[115] Thus, the Court held that the preliminary injunction was improperly granted by the district court.[116]

In a concurring opinion, Justice Breyer urged the district court to refer the questions that arose about the effects of the implementation of the Maine Rx Plus Program to the Secretary of Health and Human Services under the doctrine of primary jurisdiction, which allows a court to advantage a government agency's special expertise in a given area.[117] Likewise, Justices Scalia and Thomas, in separate concurring opinions, stated that the Secretary of Health and Human Services must address the issues presented in the case.[118] Additionally, Justice Thomas also questioned the standing of the PhRMA to challenge Spending Clause legislation when the PhRMA did not have a private right of action.[119]

However, Justices O'Connor and Kennedy, joined also by Chief Justice Rehnquist, dissented, stating that a state may not generate revenues using prior authorization mechanisms provided by the federal Medicaid Act and apply these revenues to purposes "wholly unrelated to its Medicaid program."[120] The dissent feared misappropriation of such funds to conduct tasks having no relation to Medicare, such as highway and school construction.[121] The dissent also questioned whether any Medicaid related benefits are actually produced by the Maine program.[122] Likewise, the dissenters questioned whether increased access to pharmaceuticals or prior authorization actually produces costs savings to the Medicaid program in its entirety.[123]

IV. The Best of the Rest.

Many other states have similar statutes providing for state sponsored prior authorization and drug rebate programs to benefit their own state Medicaid programs.[124]

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[115] *Id.*
[116] *Id*. at 1871.
[117] *Id.* at 1873.
[118] *Id* at 1874.
[119] *Id*. at 1878.
[120] *Id*. at 1879.
[121] *Id*.
[122] *Id*. at 1880.
[123] *Id*. The Justices feared a rush to judgment absent any evidence before the Court. *Id.*
[124] Holt, *supra* note 12, at 340-43 .

Michigan's statute negotiates rebates with pharmaceutical companies by breaking the prescription drugs into therapeutic categories and using these categories as reference prices, resulting in equitable post rebate prices.[125] Like Maine, the Wisconsin statute provides that the state Medicaid office is to negotiate rebates with manufacturers and publish lists of manufacturers who refuse to participate to the public.[126]

In 2001, Florida enacted a statute[127]requiring pharmaceutical drug manufacturers to discount the prices of pharmaceuticals by implementing mandatory10% rebates if the company desired to place a certain drug on a list of preferred drugs; otherwise, the manufacturers are a prior authorization process.[128] The PhRMA brought an action against Florida's Secretary of Medicaid Agency for Health Care Administration in *PhRMA v. Meadows*[129] alleging that the preferred drug list constituted a "formulary," as defined by the federal Medicaid Act;[130] and thus, was preempted by federal law.[131] In affirming the district court's decision granting summary judgment to the state, the Eleventh Circuit Court of Appeals held that the state's efforts to reduce Medicaid expenditures, by providing pecuniary incentives for manufacturers to offer rebates, was a valid exercise of their prior authorization power as authorized by the federal statue.[132] Further, the circuit court held that the preferred drug list was not a "formulary" as defined by the federal statute because the Florida list was not exclusive.[133] Any non-preferred drugs could be prescribed if it was determined, through a prior authorization procedure, that the drug was medically necessary to treat a given malady.[134]

Unlike the Maine statute, the Florida statute provides that the proceeds from the rebates be siphoned into other Medicaid programs promoting public health, instead of re-circulating funds into local pharmacies.[135] The circuit court followed the first circuit's

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[125] *Id*.
[126] *Id*.
[127] *See* Fla. Stat. §§ 409.91195, 409.912 (2001).
[128] *Id*.
[129] *See* PhRMA v. Meadows, 304 F.3d 1197, at 1205 (11th Cir. 2002), cert. den'd by 123 S.Ct. 2213 (2003).
[130] *See* 42 U.S.C. § 1396r-8(d)(4) (2003).
[131] *See Meadows* 304 F.3d at 1205.
[132] *Id*. at 1208-09.
[133] *Id*.
[134] *Id*. at 1209.
[135] *Id*. Maine's statute allows funds for drugs that are used for Medicaid patients to indirectly benefit under-insured citizens who are not covered by Medicaid criteria, even if marginally. *See* 22 M.R.S.A. § 2681(2)(F) (2003).

decision in *PhRMA v. Concannon*[136] by recognizing that the Secretary of Health and Human Services may invalidate the Florida statute if the Secretary determines that Florida's statute sufficiently amends Florida's Medicaid scheme.[137] Moreover, the United States Supreme Court denied a writ of certiorari to review *Meadows* just eight days after deciding the constitutionality of the Maine statute.[138] Thus, *PhRMA v. Walsh*[139] states the controlling principles governing state statutes instituting the negotiation of rebates and prior authorization procedures.

Throughout the world, other governments successfully negotiate reduced prices with the pharmaceutical industry. In the United Kingdom, the Department of Health and Social Security (DHSS) negotiates maximum profit margins with all pharmaceutical companies that sell their products in the country.[140] In addition to controlling research and development budgets, the British system negotiates limits on advertising.[141] The DHSS also establishes a list of drugs for which the government will not reimburse the institutions within their wholly funded government health care system.[142] Additionally, the DHSS provides a budget plan for doctors within the system that rewards a physician with surplus funds when that doctor efficiently and effectively prescribes available alternative generic drugs.[143]

In France and Germany, the government also reimburses all state owned facilities for covered pharmaceutical drugs by implementing a single buyer system.[144] In France, a government program determines which drugs are covered and the amount that the government will reimburse.[145] However, the French government does not hold patients or doctors responsible for the quantity or value of the medicines prescribed.[146] Unlike France, the German government decides for which drugs the participating health care

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[136] *PhRMA v. Concannon*, 249 F.3d 66, 72 (2001).
[137] *Meadows*, 304 F.3d at 1207.
[138] *PhRMA v. Walsh*, 123 S.Ct. 1855, 1871 (2003). *See also* Fla. Stat. §§ 409.91195, 409.912 (2001).
[139] *Walsh*, 123 S.Ct. at 1855.
[140] Holt, *supra* note 12, at 335.
[141] *Id*.
[142] *Id*.
[143] *Id*.
[144] *Id*. at 333. The government levies taxes to pay for the health care system, which includes purchasing pharmaceuticals from their manufacturers, and rations the proceeds accordingly. *Id.*
[145] *Id.*
[146] *Id*. at 345.

organizations will not be reimbursed.[147] Although it does not set prices for the drugs, the German government establishes a reference price by therapeutic category, in addition to establishing a maximum price that the government will reimburse for a certain drug.[148] The government audits physicians to ascertain an individual physician's ability to find medically equivalent generics, in addition to the physician's overall efficiency.[149] German citizens must also pay the difference between the reference price and the actual price they pay for their prescription.[150]

The Canadian model institutes a Patented Medicine Prices Review Board (PMPRB) that regulates the level of exclusivity a patent enjoys on the prescription drug market.[151] The PMPRB grants producers of generic drugs the opportunity to reach the market before the patent of a certain drug expires by requiring generic manufacturers to pay a type of royalty to the company that owns the patent.[152] The PMPRB also determines the fair return on a given investment that the pharmaceutical company makes and sets prices accordingly, thus, necessarily limiting marketing and advertising budgets.[153] The PMPRB also wields significant bargaining power in its negotiations with pharmaceutical companies. [154] This bargaining power arises from the PMPRB's ability to invalidate patents of pharmaceutical companies that refuse to negotiate with the government.[155]

V. The Medicare Prescription Drug, Modernization and Improvement Act of 2003.

On December 8, 2003, the 108th Congress passed the Medicare Prescription Drug, Modernization and Improvement Act of 2003 (the "Act").[156] The Act established a tax

[147] *Id*. at 334-35.
[148] *Id*.
[149] *Id*. at 335.
[150] *Id*. at 334.
[151] Moore, *supra* note 9, at 160.
[152] *Id*. The PMPRB program operates fairly analogous to the mechanism set forth in the Declaration on the TRIPS Agreement and Public Health, November 14, 2001 W.T.O. No. 01-5860; which permits developing nations to allow generic manufacturers to develop and produce generic forms of currently patented pharmaceuticals found to be necessary to effect public health crises in those nations. *Id*.
[153] *Id*. at 163.
[154] *Id*.
[155] *Id*.
[156] Act of 2003, *supra* note 6.

deduction for individuals who invest in savings accounts to provide for any future inadequacy or unavailability of health insurance, instituted a discount prescription drug program for Medicare recipients, and constructed barbed wire hoops for importers and re-importers of pharmaceutical drugs to jump through if they desire to import pharmaceuticals from Canada.[157] Congress also asked the American people to engage in a public debate to consider: 1) what health care services coverage they desire; 2) the extent of health coverage they desire; and 3) by what means they are willing to pay for coverage.[158]

The prescription drug program will be available as an additional policy to Medicare beneficiaries, or as a supplement to existing private health plans for Medicare-aged individuals.[159] However, until the Act goes into full effect in 2006, prescription drug cards can be purchased from participating manufacturers and authorized agencies to access discounted prices on brand name and pharmaceutical drugs.[160] The cards will also provide small allowances to very low-income seniors.[161]

Under the Act, individuals covered under Medicare, who spend more than $810 per year on prescription drugs, benefit from minor discounts.[162] Individuals paying between $2,250 and $5,100 per year on prescriptions drugs may save up to $1,080 under the sticker price.[163] Although they enjoy the greatest cost advantage, those whose yearly prescription drug dole costs more than $5,100 must pay at least $4,020 a year to take advantage of any cost savings.[164] Also, seniors who do not join the drug benefit program between November 15, 2005 and May 15, 2006, but still wish to join the program, must pay a penalty fee of a 1% increase of their annual premium for every month they delay

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[157] *Id*.
[158] 42 U.S.C.A. §299 Note (2003).
[159] Sarah Lueck, *Senate Clears Bill Expanding Medicare Coverage: Elderly Will Get Discounts on Prescription Drugs; Private Sector Role Widens*, WALL ST. J., Nov. 26, 2003, at A3.
[160] Tara Parker Pope, *New Medicare Drug-Discount Card May Just Add to Seniors' Frustration*, WALL ST. J., Dec. 16, 2003, at D1. This article also notes that seniors can get greater benefits on certain drugs by purchasing them online, or illegally from Canada. *Id*.
[161] *Id*.
[162] *Id*. However, the article states that these savings may be less than the current price of Canadian pharmaceuticals. *Id*.
[163] *Id*.
[164] *Id*. According to the article, this group of individuals includes close to 20% of all Medicare recipients. *Id*.

joining.[165] The penalty fee attaches to all yearly premiums throughout the life of the Medicare beneficiary.[166]

The Act's governance of the importation of drugs from Canada arguably has the greatest impact on the cost of available pharmaceuticals.[167] The Act subjects pharmacists and wholesalers to a number of safeguards that must be met before the Secretary of Health and Human Services may choose whether or not to certify a company to import pharmaceuticals from Canada.[168] The Act authorizes the Secretary to certify companies to import pharmaceuticals from Canada only, thereby implying that otherwise qualified pharmaceuticals from other countries would still remain a violation of the FDCA.[169]

In order to be considered by the Secretary for authorization to import pharmaceuticals from Canada, a company seeking to import pharmaceuticals must ultimately subject its plight to the complete discretion of the Secretary.[170] The company must provide information to the Secretary with regard to the quantity, quality, and batch history of the drug.[171] Similarly, the information provided to the Secretary must include similar documentation from the foreign seller of the pharmaceutical drug.[172] In the case of re-importation, the foreign company exporting the drug back into the United States must re-verify the quality[173] and quantity of a drug, as well as include scientific documentation to that effect.[174]

The importer or manufacturer must comply with all labeling and branding requirements under the FDCA.[175] The importer or manufacturer importing the drugs must also include all laboratory test records and other documentation verifying the identity and quality of the pharmaceuticals.[176] Moreover, if the importer is the entity conducting the laboratory tests, the importer must acquire FDCA compliant labels from

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[165] *Id*.
[166] *Id*.
[167] 21 U.S.C. § 384 (2003).
[168] *Id*.
[169] *See*, *e.g.*, Durousseau v. United States, 10 U.S. 307, 308 (1810) (describing the principle of implied exclusion in Congressional acts).
[170] 21 U.S.C. § 384(c) (2003).
[171] *Id*. at § 384(d).
[172] *Id*.
[173] *Id*. Such quality assurance includes chemical tests done to verify authenticity and an assessment of chemical degradation. *Id*.
[174] *Id*.
[175] *Id*.
[176] *Id*.

the manufacturer after verifying the quality of the drug.[177] Further, all foreign entities that wish to act as middlemen in the importation process described under the Act must register with the Secretary of Health and Human Services.[178] If any impropriety is discovered at any time, the Secretary may immediately suspend importation operation until the Secretary determines that the process is once again safe for the public.[179]

However, in direct contradiction of its intent to protect the public from the potential harms of imported drugs,[180] Congress granted the Secretary the authority to selectively enforce violations of the FDCA by granting specific waivers to individuals importing pharmaceuticals.[181] The Act provides that the Secretary must focus on prosecution of cases in which the drugs being imported pose a "significant threat to public health."[182] The Act commands the Secretary to overlook situations in which importation is clearly for personal use, and where the imported drug does not "appear to present an unreasonable risk to the individual."[183]

Individuals who are granted an express waiver to violate the Act, and who wish to import pharmaceuticals, must: 1) verify that their purchase is for personal use for no more than 90 days; 2) have a valid prescription; 3) import the drug from a seller registered with the Secretary; and 4) verify that the drug was manufactured in compliance with the FDCA.[184] At its own discretion, the Secretary may subject the waiver process to any and all other safeguards, in excess of those expressly mandated by the Act, if the Secretary feels such waivers are necessary to ensure the public safety.[185] Last, the Secretary can decide not to implement the waiver program at all, or do so only selectively.[186]

VI. The Cautionary Tale and A Response.

[177] *Id*. at § 384(e).
[178] *Id*. at § 384(f).
[179] *Id*. at § 384(g).
[180] *Id*. at § 384(c)(1).
[181] *Id*. at § 384(j).
[182] *Id* at § 384(j)(1)(A).
[183] *Id*. at § 384(j)(1)(B)(ii).
[184] *Id*.
[185] *Id*.
[186] 21 U.S.C.A. § 394(l) (2003). The opinion of the Secretary is not subjected to any proprietary review. *Id*.

Generally, the pharmaceutical industry opposes any form of price controls based largely on the valid arguments asserted by other free market industries.[187] Pharmaceutical companies believe that they should be free to make as much money as the market will bear.[188] However, the pharmaceutical industry is not subject to the same level of market restraint as that of other free market industry.[189] Oftentimes no viable alternative products exist for individuals suffering from a variety of maladies, thus, those individuals are unable to seek equivalent treatment elsewhere.[190] Further, insurance companies and government agencies that are able to negotiate lower prices with the pharmaceutical industry do so without the ability to walk away from the table because of this lack of viable treatment alternatives.[191]

Moreover, because illnesses affect all strata of social hierarchy, demand is consistent in all sectors.[192] However, the ability to pay is not static.[193] These commodities are often necessary to sustain life and cannot be foregone by those who cannot afford them without jeopardizing one's own health and well-being.[194] Therefore, the pharmaceutical companies exist in a vacuum devoid of typical market restraints.

In addition, pharmaceutical companies warn that controls on prices will decrease the monetary incentive for research and development.[195] Likewise, drug companies fear that price control will decrease the amount of money actually available for research and development.[196] However, as the pharmaceutical industry enjoys increasingly larger profit margins, the companies have not correspondingly increased research and development investments.[197] Rather, the federal government provides the pharmaceutical industry with a substantial amount of the research and development funds used by pharmaceutical companies in developing new drugs.[198] The pharmaceutical industry has also increased advertising spending to unprecedented levels, while research and

[187] Moore, *supra* note 9, at 149.
[188] *Id*.
[189] *Id*.
[190] *Id*. at 155.
[191] *Id*.
[192] Holt, *supra* note 12, at 327.
[193] *Id*.
[194] *Id*.
[195] Moore, *supra* note 9, at 155.
[196] *Id*.
[197] *Id*. at 156.
[198] *Id*. at 156-57.

development spending remains relatively stagnant.[199] Additionally, drug companies fix prices based on self-interested factors.[200]

Because the pharmaceutical industry has decided to promote individual drugs as a marketing strategy, instead of increasing spending on research and development to bring a greater variety of drugs to the market, a minimal level of price control would force the drug companies to increase development volume in order to increase profits. Some level of price control forces a mutually beneficial relationship between the pharmaceutical industry's need to prosper financially, and society's need to prosper physically. Last, price control mechanisms introduce certain barriers of market restraint that are currently absent from the pharmaceutical market in the United States.

So what to do now? The Medicare Act of 2003 and the plight of companies like RxDepot have constrained the ability of private industry to participate in accessing lower prices on prescription drugs in other markets.[201] Canada is the only foreign market from which companies could possibly obtain express authorization from the Secretary of Health and Human Services to import pharmaceuticals under the Act if they are seeking to import drugs legally.[202] However, the Canadian government fears its own citizens will experience a shortage of pharmaceuticals if importers buy pharmaceuticals for export.[203] In a corresponding act of chivalry, several drug companies are attempting to curtail the amount of drugs exported to Canada so that Americans cannot access lower prices.[204]

Perhaps a workable price control method involves the Maine model.[205] Like the several other states that have adopted similar statutes,[206] Maine exercised its bargaining power as an entity to provide for the pharmaceutical needs of the state's Medicaid population. Additionally, Maine also provides for the needs of its under-insured non-Medicaid population as well. By incorporating the Maine type of broad coverage with certain price referencing mechanisms, such as those instituted in the United Kingdom and

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[199] Woodward, *supra* note 7, at 175-177.
[200] *Id*.
[201] *See* Act of 2003, *supra* note 3; United States v. RxDepot, 290 F. Supp. 2d 1238, 1239 (N.D. Okla. 2003).
[202] Durousseau v. United States, 10 U.S. 307,308 (1810).
[203] *Canada Worried about Shortages Due to U.S. Reimportation*, WASH. DRUG LETTER, Nov. 3, 2003.
[204] Matthews, *supra* note 16, at B1.
[205] *See* 22 M.R.S.A. § 2681 (2003).
[206] *See* PhRMA v. Meadows, 304 F.3d 1197, 1202 (11th Cir. 2002).

Michigan that break pharmaceuticals down into therapeutic categories, state legislatures could increase their bargaining power to negotiate lower prices on pharmaceuticals to meet the needs of their state's population.

If states can effectively negotiate lower prices, the pharmaceutical industry will be forced to negotiate lower prices with the private insurance sector as well. As these negotiated prescription drug prices decrease the cost to the consumer, and approach the Canadian prices, the danger to the public arising from importation and re importation will likewise decrease due to the decreased consumer incentive to access foreign markets. The pharmaceutical industry will be forced to divert monies from advertising and marketing in order to generate a greater number of products and offset the "losses" suffered from decreasing profit margins. As the pharmaceutical companies rush to develop a greater variety of products, the flurry of development will allow the pharmaceutical industry to maintain its wealthy status among the nation's health care industries and will benefit the American people as new cures and treatments become available.

Although the Supreme Court upheld the constitutionality of the Maine statute, the Court also indicated that the final decision would rest with the Secretary of Health and Human Services.[207] This indication, in addition to Congress' express and exclusive authorization to the Secretary to certify companies to import drugs from Canada,[208] indicates that the Secretary serves as the ultimate arbiter of pharmaceutical prices in the United States. Although the Secretary has historically refused to approve such importation,[209] the sole responsibility for the fate of pharmaceutical prices in the United States nevertheless lies with the Secretary of Health and Human Services. Therefore, the opportunity to achieve the correlated benefit of an increased variety of cures and treatments lies with the Secretary as well as pharmaceutical companies would scramble to maintain profit levels through research and development, instead of single product advertising.

The Secretary must find and recommend that the new state Medicaid initiatives are valid amendments to individual states' Medicaid programs. Likewise, the Secretary must

[207] *See* PhRMA v. Walsh, 123 S.Ct. 1855, 1866 (2003).
[208] *See* 21 U.S.C. § 384(c) (2003).
[209] *Boston to Force Issue on Canadian Drugs*, WALL ST. J., Dec. 10, 2003.

authorize private industry companies that are in compliance with the terms of the Medicare Act of 2003 to begin re-importation of pharmaceuticals from Canada. By exposing the United States pharmaceutical market to entities that have the bargaining power to negotiate fair prices for their customers or constituents, the prescription drug industry will finally be subjected to a form of market constraint that is vital to a healthy free market.[210]

The FDA and Congress' aggressive regulation of pharmacists and wholesalers who import pharmaceuticals[211] (hereafter "pharmaceutical importers" or "importers") in the name of public safety is misplaced. In fact, the statute that purports to regulate the importation of pharmaceutical drugs alters the Federal Food, Drug, and Cosmetic Act (FDCA)[212] and grants the Secretary of Health and Human Services the power to implement an importation program only if such a program would "pose no additional risk to the public's health and safety".[213] The statute also extends to the executive branch the ability to waive enforcement of the law on individuals who import pharmaceuticals solely for personal use.[214] The effect of the statute clearly indicates that the only safeguarding the statute will do is to refortify the dam that prevents the pharmaceutical industry's profit margin from spilling into the valley of market restraint, where others attempting to provide quality drugs at quality prices lie in wait.

Through the Act, Congress mandates the Secretary to weigh the burdens and benefits of implementing pharmaceutical cost reducing procedures.[215] The benefits of pharmaceutical price reduction have traditionally been discussed in terms of increasing access to individual consumers.[216] However, providing basic access to individuals cannot be considered a benefit if the resulting access cripples individuals' ability to afford their daily bread,[217] let alone the ability to access the other pecuniary privileges and liberties that being a citizen of the United States entails. Therefore, the Secretary must acknowledge the preceding utility analysis to open the United States pharmaceutical

[210] Holt, *supra* note 12, at 327.
[211] 21 U.S.C. § 384 (2004).
[212] 21 U.S.C. § 381 (2004).
[213] 21 U.S.C. § 384 (2004).
[214] *Id*.
[215] 21 U.S.C.A. § 384(l)(2)(B)(IV)(bb)(iii)(II) (2003).
[216] *See* 22 M.R.S.A. § 2681 (2000).
[217] *See* Barber, *supra* note 1, at A1.

market to the world; thereby providing citizens meaningful access to the prescription drugs that fuel American prosperity and ingenuity.

VII. Conclusion.

The citizens of the United States are suffering at the hands of the pharmaceutical industry's profiteering machinery.[218] Congress acknowledges that, despite the overall wealth of the United States, all those who desire health care coverage cannot access health care coverage.[219] Likewise, Congress stated that: "Innovations in health care access, coverage, and quality of care, including the use of technology, have often come from the States, local communities, and private sector organization, but more creative policies could tap this potential."[220]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003[221] and the decision in *RxDepot*[222] prevent private industry from obtaining unfettered access to the price control mechanisms in foreign countries that could serve as one potential cost reduction mechanism. Similarly, athough the Supreme Court has upheld the constitutionality of state statutes promoting rebate negotiation and prior authorization procedures,[223] the ultimate decision on both the importation issue and the validity of state Medicaid amendments lies with the Secretary of Health and Human Services. All conjecture concerning the institution of price control mechanisms in the United States [224] ended with the enactment of the Medicare Act of 2003.

Now is truly the "last call" for price control measures in the United States, and the only "bartender" left to effectively implement such measures is the Secretary of Health and Human Services, a department of the executive branch. The legislative and judicial

[218] *See* Woodward, *supra* note 7, at 174.
[219] *See* 42 U.S.C.A. § 299 Note (2003).
[220] *Id*.
[221] *See* Act of 2003, *supra* note 3.
[222] United States v. RxDepot, 290 F.Supp.2d 1238, 1247 (2003).
[223] *See, e.g.*, PhRMA v. Walsh, 123 S.Ct. 1855 (2003).
[224] *See, e.g.*, Holt, *supra* note 12, at 325; Woodward, *supra* note 7 at 169; Moore, *supra* note 9, at 149.

branches have both deferred their questions to the executive branch.[225] Therefore, the Secretary must exercise both its authority and ability to take the essential steps to subject the pharmaceutical industry to the restraints of a true free market. The only alternative is to continue the suffering of individuals who hemorrhage substantial amounts of money to the most profitable industry in the United States.[226]

As attorney Fred Stoops aptly stated: "The only real safety issue in this case is the safety of the obscene profits of the pharmaceutical companies."[227]

[225] Brief of Amici Curiae State of Massachusetts, et.al. at 22, PhRMA v. Concannon, 123 S.Ct. 1855, 1860 (2003) (No.01-188); 21 U.S.C. § 384 (2003).
[226] *See* Barber, *supra* note 1. *See also* Woodward, *supra* at note 7, at 169.
[227] *The Truth of the Matter,* TULSA WORLD, Nov. 23, 2003, at G2.