COMMENT: A LITTLE BIT OF LEGISLATION HELPS THE MEDICINE GO DOWN—STATE PRESCRIPTION DRUG PROGRAMS IN THE ERA FOLLOWING *PHARM. RESEARCH AND MFRS. OF AM. V. CONCANNON.*

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I. INTRODUCTION

Over the past couple of years, prescription drug prices have been one of the most talked about political issues. Rising drug prices was a popular campaign issue in the 2000 elections, with some candidates providing would-be voters with bus trips to Canada,[1] where the American-made pharmaceuticals may be purchased at a significant discount over the price for the exact same drug in the United States.[2] With prices rising at staggering

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1. Patricia Lopez Baden, *Senate Candidates Follow Different Paths on Health Issues*, MPLS. STAR-TRIB., Oct. 26, 2000, *available at* http://www.startribune.com/stories/587/21311.html. Senator Mark Dayton, in his race against incumbent Rod Grams, received significant attention for his senior citizen-friendly position by paying for bus trips to Canada. *Id.*

2. *See infra* note 112 and accompanying text.

rates,[3] various levels of government have crafted different alternatives to make prescription drugs more affordable for those who do not have prescription drug coverage through a private healthcare provider or other public assistance program.

With the federal government slow to act, the most innovative proposals have been enacted at the state level. The most notable of these was in Maine, where, in 2000, the state enacted its Maine Rx program, which was designed to extend Medicaid prescription drug discounts to those without pharmaceutical coverage.[4] The Pharmaceutical Research and Manufacturers of America ("PhRMA") obtained an injunction to prevent the implementation of the Maine Rx program. Maine appealed to the First Circuit Court of Appeals, which reversed the district court in what is arguably the most significant healthcare holding in recent times.[5]

Section II of this comment looks at the problem of rising prescription drug costs and the pharmaceutical industry's response to the recent waive of criticism. Section III examines the facts and First Circuit's holding in *Pharm. Research & Mfrs. of Am. v. Concannon*. Section IV looks at Medicaid section 1115 waivers as another alternative to provide lower drug prices to those without drug coverage, which was tried and struck down in Vermont. Section V surveys prescription drug initiatives in several other states, and section VI looks at federal pharmaceutical legislation. Section VII provides an analysis of the federal court decision in Maine, other governmental alternatives, and the effects they will have on other states' attempts to slow rising drug costs.

This comment concludes that the First Circuit made a good decision and that it gives a green light for other states to enact similar legislation. Because the federal court in Maine left the door open to a post-implementation challenge by the drug industry, it remains to be seen what effect the Maine Rx program will have. Despite the uncertainty, the Maine Rx provides the best model for state action to control drug prices.

II. THE RISING COSTS OF PRESCRIPTION DRUGS

When enacting its prescription drug program, the Maine

3. *See infra* Part II.

4. *See infra* Part III.

5. Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66 (1st Cir. 2001).

legislature relied on the findings of a minority staff report for the United States House Committee on Government Reform ("Minority Staff Report").[6] The Minority Staff Report found over thirty-five percent of Medicare recipients do not have prescription drug insurance coverage.[7] The report also found that individuals pay substantially more for prescription drugs than favored customers, including the government and health maintenance organizations ("HMOs").[8]

In 2000, the prices for the top prescription drugs grew at an average rate of more than twice that of inflation.[9] This trend has raised concerns about seniors who live on fixed incomes, one-third of whom do not have insurance that covers prescription drugs.[10]

The problem of exorbitant increases in prescription drug prices is not new or unique to the past several years. During the ten-year period ending in 1994, prescription drug prices increased 148 percent.[11]

PhRMA has said one of the reasons prescription drug prices have risen is that it costs approximately $500 million over twelve to fifteen years to research and develop a drug before it is available to consumers.[12] Other reports, though, suggest this figure is far from

6. *Id.* at 71. *See* MINORITY STAFF OF HOUSE COMM. ON GOVERNMENT REFORM, 106TH CONG., PRESCRIPTION DRUG PRICING IN THE UNITED STATES: DRUG COMPANIES PROFIT AT THE EXPENSE OF OLDER AMERICANS (Nov. 9, 1999) [hereinafter MINORITY STAFF REPORT].

7. MINORITY STAFF REPORT, *supra* note 6, at 2 (citing *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, HEALTH AFF., Jan.-Feb. 1999, at 237). This equals over thirteen million senior citizens. *Id.*

8. *Id.* at 6. For the five prescription drugs with the highest sales to seniors, the average price differential between an individual purchaser and a most favored customer (i.e., HMO or the government) was 134%. *Id.*

9. FAMILIES USA, ENOUGH TO MAKE YOU SICK: PRESCRIPTION DRUG PRICES FOR THE ELDERLY, June 2001, at 2. From January 2000 to January 2001, the prices of the top fifty most frequently prescribed drugs rose 6.1%. *Id.* The rate of inflation for the same period was 2.7%. *Id.* Only eight of the top fifty drugs rose at a rate slower than inflation. *Id.* at 3.

10. *See id.*

11. Emile L. Loza, *Access to Pharmaceuticals Under Medicaid Managed Care: Federal Law Compiled and State Contracts Compared*, 55 FOOD & DRUG L.J. 449, 449 (2000). Twenty-one billion dollars was spent in 1985 and $52 billion was spent in 1994. *Id.*

12. Pharmaceutical Research and Manufacturers of America, *One New Drug=12-15 Years of R&D*, *at* www.phrma.org/publications/documents/factsheets//2001-03-01.210.phtml (Mar. 2001). During the first six and one-half years, scientists perform pre-clinical testing. *Id.* Over the next seven years, a drug is studied for how it works, its safety, and for effectiveness. *Id.* Finally the Food and Drug Administration reviews the

reality. A recent report by Public Citizen, a non-profit consumer watchdog group, indicates that drug companies spend only about $110 million to develop new drugs.[13] The lower figure can be attributed to the fact that a company's research and development costs are tax deductible.[14] Further, costs to drug companies is lower than the industry claims because a significant amount of new drug research is funded by the National Institutes of Health.[15] Currently, taxpayers subsidize approximately one-third of all pharmaceutical research.[16]

Critics of the pharmaceutical industry argue that one reason why prices have risen so much is because of the increase in direct-to-consumer advertising.[17] PhRMA has responded to those claims by claiming that marketing drugs is important to help physicians have enough information about new drugs.[18] The industry-representing group gives little explanation about the necessity for spending on direct-to-consumer advertising.

Another cause of high drug prices may be that the pharmaceutical industry is not subject to the same market forces that drive other sectors of the economy.[19] Naturally, manufacturers disagree for several reasons.[20] First, the industry insists that HMOs keep prices down by negotiating drug discounts and by using generic drugs as a substitute for name brand drugs.[21] Manufacturers also point to generic alternatives as a strong

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development and decides whether to grant approval. *Id.*

13. PUBLIC CITIZEN, RX R&D MYTHS: THE CASE AGAINST DRUG INDUSTRY'S R&D SCARE CARD, 4 (July 2001), *available at* http://dev.citizen.org/documents/ACFDC.PDF.

14. *Id.* at 3.

15. *Id.* Government-funded scientists conducted fifty-five percent of the research projects that led to the discovery and development of the top five drugs in 1995. *Id.* at i.

16. Press Release, Representative Bernie Sanders, *Sanders' Reasonable Pricing for Prescription Drugs Amendment Passes* (June 14, 2000), *available at* http://www.house.gov/bernie/press/2000/06-14-2000.html.

17. *Id.* at 21. In 1999, direct-to-consumer advertising of pharmaceuticals increased at a rate more than double the increase of spending on research and development. *Id.*

18. Pharmaceutical Research and Manufacturers of America, *Marketing and Promotion of Pharmaceuticals*, *at* http://www.phrma.org/publications/documents/backgrounders//2001-06-06.231.phtml (last visited Sept 30, 2001).

19. *See* Robin Elizabeth Margolis, *Prescription Drug Pricing: Do Competitive Forces Operate in the Pharmaceutical Marketplace?*, HEALTHSPAN, Feb. 1994, at 9, 11-12.

20. *Id.*

21. *Id.*

competitive force.[22]

Lastly, advocates for government control over prescription drug prices point to the average profitability of pharmaceutical companies compared to their counterparts in other industries.[23] In 2000, the average pharmaceutical company had an 18.9% profit-to-revenue ratio.[24] The next highest industry was the telecom industry, with an 11.7% profit-to-revenue ratio.[25]

A. *PhRMA-who?*

The Pharmaceutical Research and Manufacturers of America is an umbrella organization that represents many of the country's leading pharmaceutical companies.[26] PhRMA is the primary public policy advocate of the pharmaceutical industry.[27]

PhRMA is often a litigant in cases disputing state prescription drug programs, because the organization's members are "regulated by and make payments consistent with the provisions of the Medicaid prescription drug program."[28]

III. THE MAINE DECISION

A. *The Facts*

The Act to Establish Fairer Pricing for Prescription Drugs (the "Act") included the "Maine Rx Program" (the "Program").[29] The

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22. *Id.* In 1994, generic drugs represented half of all new prescriptions. *Id.*

23. Press Release, Representative Bernie Sanders, *New Figures Prove Pharmaceutical Continues to Fleece Americans*, *available at* http://bernie.house.gov/prescriptions/profits.asp (last visited Sept. 30, 2001).

24. *Id.*

25. *Id.*

26. Pharmaceutical Research and Manufacturers of America, *Who We Are*, *at* http://www.phrma.org/who (last visited Sept. 30, 2001). PhRMA's membership includes such notable companies as: Pfizer Inc., Merck & Co., Inc., GlaxoSmithKline, the Proctor & Gamble Company, Johnson & Johnson, Eli Lilly and Company, and Bristol-Myers Squibb Company. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, ANNUAL REPORT 2001-2002, *available at* http://www.phrma.org/publications/publications/annual2001/members.phtml (last visited Sept. 30, 2001) [hereinafter PHARMACEUTICAL ANNUAL REPORT].

27. PHARMACEUTICAL ANNUAL REPORT 2001-2002, *supra* note 26, *at* http://www.phrma.org/publications/publications/annual2001/mission.phtml (last visited Sept. 30, 2001).

28. *Concannon*, 249 F.3d at 87 (Keeton, J., concurring).

29. 2000 Me. Laws 786 (S.P. 1026) (L.D. 2599) (the "Act"). This law was enacted on May 11, 2000, by the Governor of Maine.

Program allows all Maine residents who enroll to purchase prescription drugs at a discounted price.[30] The State reimburses participating Maine pharmacies through a fund that was created through rebates from pharmaceutical manufacturers.

When a Program enrollee purchases a prescription drug, the State receives a rebate directly from the drug manufacturer.[31] These rebates are negotiated by the Commissioner of Maine's Department of Health Services with pharmaceutical manufacturers. While not directly tied to other rebate agreements between manufacturers and other buyers, the Act instructs the Commissioner to use his or her "best efforts" to obtain the rebate amount calculated under the Federal Medicaid Rebate Program.[32]

PhRMA brought an action against the Commissioner of the Maine Department of Human Services and the Maine Attorney General in United States District Court, alleging that the Act was unconstitutional on the grounds that the Act violated the dormant Commerce Clause.[33] Further, PhRMA claimed that the Act conflicted with the federal Medicaid statute and was therefore unconstitutional under the Supremacy Clause.[34] The district court agreed with both of PhRMA's arguments and granted PhRMA's request for a preliminary injunction.[35] In granting the injunction, the district court held that the Act violated the dormant Commerce Clause by regulating sales between out-of-state manufacturers and out-of-state distributors, creating an "impermissible extraterritorial reach."[36] The Act violated the Supremacy Clause, the district court reasoned, because of the Medicaid-conflicting effect on in-state distributors.[37]

30. ME. REV. STAT. ANN. tit. 22 § 2681 (West 2001).
31. ME. REV. STAT. ANN. tit. 22 § 2681(3).
32. ME. REV. STAT. ANN. tit. 22 § 2681(4). While manufacturers are not required to participate in the Program, the Act includes incentives for drug companies to enter into rebate agreements, including: releasing the names of nonparticipating manufacturers to health care providers and the public and subjecting manufacturers to prior authorization requirements. ME. REV. STAT. ANN. tit. 22 § 2681(7).
33. *Concannon*, 249 F.3d at 72.
34. *Id. See also* U.S. CONST. art. VI, cl. 2.
35. *Concannon*, 249 F.3d at 72.
36. *Id.*
37. *Id.*

B. The Court of Appeals Analysis

In *PhRMA*, the court of appeals reversed and vacated the district court's preliminary injunction.[38] The appellate court's review of the injunction dealt primarily with PhRMA's likelihood of success.[39]

After determining that PhRMA had prudential standing,[40] the court addressed PhRMA's challenge that the Act was preempted by the federal Medicaid program insofar as the prior authorization review requirement regulated sales to in-state distributors.[41] The district court concluded that the Act's prior authorization review requirement conflicted with the purposes of the Medicaid program.[42] Because the Medicaid statute does not explicitly forbid the Maine Rx Program,[43] the court of appeals only dealt with the issue of "implied conflict preemption."[44] The court of appeals held that the Maine Act is not inconsistent with the letter or intent of the Medicaid statute.[45] In its decision, the court noted that the Maine statute limits the prior authorization requirement by directing the Department of Human Services to impose such a requirement only "as permitted by law."[46] The court also dismissed

38. *Id.* at 71.

39. *Id.* at 72. The court noted the "familiar four" criteria for granting a preliminary injuction: "likelihood of success, risk of irreparable harm, the balance of equities and the public interest." *Id.* (citing Lanlois v. Abington Hous. Auth., 207 F.3d 43, 47 (1st Cir. 2000)).

40. *Id.* at 73.

41. *Id.* at 74. In *Pharm. Research & Mfrs. of Am. v. Concannon*, PhRMA's preemption claim was a threshold issue. The court limited its analysis of the preemption claim only to the regulation of sales to in-state distributors, because the district court held that the Commerce Clause would not bar such regulation. *Id.* Any analysis of the Commerce Clause claim would have become unnecessary, though, if the court of appeals affirmed the district court's preemption holding, because the Act would be invalid as to all distributors—in-state and out-of-state. *Id.*

42. *Id.*

43. *Id.* at 75, n.6. Rather than impliedly preventing the Act's prior authorization requirement, the statute explicitly permits such provisions. 42 U.S.C. § 1396r-8 (d)(1)(A).

44. *Concannon*, 249 F.3d at 74. A federal law preempts a state law either expressly or impliedly. *See* U.S. CONST. art. VI, cl. 2.

45. *Concannon*, 249 F.3d at 75. Medicaid's purpose is "to enable states to provide medical services to those whose income and resources are insufficient to meet the costs of necessary medical services. . . ." *Id.* (citing 42 U.S.C. § 1396 (2000)) (internal quotation marks omitted). The Medicaid statute dictates that these medical services are administered with "simplicity of administration" and in "the best interests of the recipients." 42 U.S.C. § 1396a (a)(19).

46. *Concannon*, 249 F.3d at 75 (citing ME. REV. STAT. ANN. tit. 22, § 2681(7)(West 2001)). Giving deference to the administering department, the

PhRMA's argument that, because a prior authorization offers no Medicaid-related purpose or benefit to Medicaid, the Medicaid program preempts the Program when a pharmaceutical manufacturer is subject to a prior authorization due to a company's refusal to enter into a rebate agreement with the state.[47] The First Circuit reasoned that although there may not be any "Medicaid purpose" for the prior authorization requirement, it does not actually conflict with the Medicaid program.[48] Next, the court discounted PhRMA's argument that the prior authorization requirement would limit doctors' abilities to prescribe their first choice medications, thereby harming Medicaid recipients.[49]

Because PhRMA's action raised a facial challenge of the Maine Rx Program, the court recognized the difficulty of evaluating any potential harm to Medicaid recipients.[50] Even though the court noted its own concern that the Program had the potential to harm Medicaid recipients by limiting access to first choice medications, there was insufficient proof that Maine's Medicaid plan conflicts with the requirement of providing care in the best interest of the recipients.[51]

The First Circuit then analyzed PhRMA's claim that the Act violates the dormant Commerce Clause. In doing so, the court applied three levels of analysis — evaluating the effect and reach of Maine's statute.[52] First, a court may find a statute a per se violation

court relied on the affidavit of Department of Human Services Commissioner Kevin Concannon as assurance that, when administering the Act, his department would not impose a prior authorization in conflict with the Medicaid statute. *Id.* at 75, n.7.

47. *Id.* at 76.

48. *Id.* The court continued by disagreeing with PhRMA's proposition that the Act does not have a Medicaid purpose. As is the intent of Medicaid, the Program attempts to provide medical services to low-income individuals. *Id.* Further, the court of appeals recognized evidence that the Maine Rx Program has the potential to reduce Medicaid expenditures. *Id.* By making prescription drugs available to those whose incomes are above the Medicaid guidelines, the Program could prevent these people's medical conditions as well as their economic situation from worsening; the result of such worsening would be more Medicaid recipients and greater subsequent expenditures. *Id.*

49. *Id.* at 77. While a patient may not always receive a first choice drug, the state argued that the Medicaid recipient would receive all drugs that are medically necessary. *Id.*

50. *Id.*

51. *Id.* The court stated that its decision was without prejudice to PhRMA's right to raise the issue of preemption after the Act was implemented. *Id.*

52. *Id.* at 79.

if it has an "extraterritorial reach."[53] Second, if a statute discriminates against interstate commerce, either facially or in effect, the state has the burden to demonstrate that the statute serves a legitimate local purpose that cannot be served by a nondiscriminatory alternative.[54] A court may strike down, without further analysis, a statute that favors in-state interests over out-of-state interests.[55] Third, the court may apply the *Pike* balancing test when a statute has an incidental effect on interstate commerce, but the statue does not discriminate between in-state and out-of-state interests.[56]

PhRMA argued that the Act is per se invalid under the dormant Commerce Clause.[57] Before proceeding to its analysis of the Act and the Commerce Clause, the court dismissed Maine's assertion that the state is a "market participant," a status that would have exempted Maine from any challenges under the dormant Commerce Clause.[58] Maine also argued for the court to use the *Pike* balancing test.[59]

The court first addressed the question of per se invalidity. PhRMA's argument, rooted in the proposition that a state may not dictate the terms of business between buyers and sellers outside of the state, was supported by three cases that involved price control schemes.[60] The court of appeals distinguished the Act from the

53. *Id.* (citing Healy v. Beer Inst., 491 U.S. 324, 336 (1989)). The court defined a statute to have "extraterritorial reach" if it "necessarily requires out-of-state commerce to be conducted according to in-state terms." *Id.* (citing Cotto Waxo Co. v. Williams, 46 F.3d 790, 794 (8th Cir. 1995)).

54. *Id.* at 79-80 (citations omitted). This strict level of scrutiny, which presumes the statute's invalidity, is known as the "virtually per se invalid rule." *Id.* at 79.

55. *Id.* at 80 (citing Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986)).

56. *Id.* at 80. *See also* Pike v. Bruce Church, Inc., 397 U.S. 137 (1970). In *Pike*, the Supreme Court held that an Arizona law requiring all cantaloupes grown in Arizona be packed in Arizona, thereby requiring an Arizona grower to build a local packing facility, was an unlawful burden on interstate commerce. *Id.* at 146. The Court balanced the statute's benefits (enhancing the reputation of Arizona growers) with its burdens on interstate commerce (compelling a grower to build an in-state packing facility costing $200,000). *Id.* at 143-45.

57. *Concannon*, 249 F.3d at 80. PhRMA contended that regulating transactions between drug manufacturers and distributors outside of Maine "is an impermissible exercise in extraterritorial regulation." *Id.*

58. *Id.* The court reasoned that because, under the Act, Maine is not a market buyer of prescription drugs and Program enrollees will purchase prescription drugs directly, Maine is not a market participant. *Id.*

59. *Id.*

60. *Id.* at 81. The cited cases' statutes-in-question tied prices charged in the

cases cited by PhRMA, because the Act, the court concluded, does not regulate prices in out-of-state transactions.[61] Rather than tying prices to those in other states, the Act instead instructs the Maine Commissioner of Human Services to obtain agreements with manufacturers that include rebates that are equal to or better than Medicaid program rebates.[62] The court also articulated that the Program is voluntary,[63] and the Act only regulates in-state transactions.[64] Therefore, the court concluded that the Act has no extraterritorial reach and is not per se invalid under the dormant Commerce Clause.[65] The court did not analyze the Act as a discriminatory statute.[66]

Lastly, the First Circuit applied the *Pike* balancing test to the

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home state to those in other states — producing a benefit for home state buyers and sellers while burdening the same in other states. *See Healy v. Beer Inst.*, 491 U.S. 324, 326; *Brown-Forman*, 476 U.S. at 575-76; Baldwin v. G.A.F. Seelig, 294 U.S. 511, 519 (1935). In *Healy*, under a state statute, out-of-state beer distributors were required to affirm that prices for products sold to Connecticut wholesalers were no higher than prices for products sold in bordering states, which unconstitutionally controlled prices and interfered with regulatory schemes in neighboring states. 491 U.S. at 326. In *Brown-Forman,* a New York statute required liquor distillers to affirm that, during a given month, their prices were no higher than the lowest price for the same product sold in any other state. 476 U.S. at 575-76. In effect, the state regulated interstate commerce by prohibiting distillers from lowering prices in other states after posting prices in New York. *See id.* In *Seelig*, a New York statute banned the sale of milk that had been purchased cheaper in another state, which effectively set out-of-state milk prices. 294 U.S. at 519.

61. *Concannon*, 249 F.3d at 81. The court stated that any effect on prices in out-of-state transactions was neither express in the statute, nor inevitable in effect. *Id.*

62. *Id.* at 82. The First Circuit also noted that the Act does not regulate wholly out-of-state transactions. *Id.* PhRMA further contended that the Act regulates profits. The court recognized the Act's potential of reducing drug company profits but states that such an effect does not necessarily amount to regulating profits. *Id.*

63. *Id.* In addition to the fact that entering into a rebate agreement is voluntary, either the state or participating company may withdraw from the Program. *Id.* The court left open the possibility of a challenge of the Program, after it takes effect, if the Commissioner's efforts become "coercive or otherwise inappropriate." *Id.* Because PhRMA raised a facial challenge, the court had no basis to conclude that the statute's language of "best efforts" by the commissioner include "regulating" prices rather than merely "negotiating" prices. *Id.*

64. *Id.* The court summarizes the Act's regulating effects to include: 1) purchase-triggered rebates; 2) rebate negotiation; and 3) drug prior authorization. *Id.* at 83-84.

65. *Id.*

66. *Id.* at 83. PhRMA did not argue that the Act is discriminatory on its face or in its effects. *Id.*

Act, which involves a low level of scrutiny.[67] Applying the elements from *Pike,* the court began by suggesting that the Act's only burden on interstate commerce is potential negative impacts on the profits of individual manufacturers.[68] Next, the court described the Program as having the potential to provide affordable prescription drugs to Maine citizens.[69] This benefit, the court held, outweighed the potential burden on interstate commerce.[70] Therefore, the court concluded, the Act is not invalid under the dormant Commerce Clause.[71]

The First Circuit concluded, invoking the words of Justice Brandeis, by praising the State of Maine for experimenting with a new idea.[72]

C. Judge Keeton, Concurring

Judge Keeton wrote a lengthy concurring opinion about the Maine Rx Program, paying more attention to the interests of liberty and order.[73] In his concurrence, Keeton began with discussing Madisonian principles of federalism, including "new and distinctive" ways to harmonize national and state governmental power.[74] Keeton recognized that Maine, as a sovereign, may act as a

67. *Id.* The district court did not apply the *Pike* balancing test, because it concluded the Act was per se invalid. *Id.* The appellate court included the *Pike* balancing test, because the Act does have an extraterritorial reach, it is not a discriminatory statute (which was not disputed), and it regulates evenhandedly with only incidental effects on interstate commerce — requiring the court to balance the factors of local benefits and burden on interstate commerce. *Id.*

68. *Id.* at 84. The court stated that economic effects on a particular firm does not rise to the level of a Commerce Clause burden. *Id.* (citing Instructional Sys., Inc., v. Computer Curriculum Corp., 35 F.3d 813, 827 (3d Cir. 1994)).

69. *Id.*

70. *Id.* At a minimum, the court added, the Act's burden on interstate commerce is not "clearly excessive" in relation to the benefits for Maine citizens. *Id.*

71. *Id.* In stating its decision, the court noted the challenge of applying the *Pike* balancing test to a facial challenge, because the court was forced to evaluate the Act's possible effects. *Id.*

72. *Id.* at 85. In cautioning about the "grave responsibility" of staying experimentation, Justice Brandeis wrote: "It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *Id.* (quoting New State Ice Co. v. Liebmann, 285 U.S. 262, 310 (1932) (Brandeis, J., dissenting)).

73. *Concannon*, 249 F.3d at 86.

74. *Id.* at 89. Madison's views are relevant, Keeton states, for resolving "disputes over supremacy of national legislation and associated issues of

participant in the pharmaceutical market and as a guardian for its citizens needing affordable prescription drugs.[75] It is in this role as guardian that Maine acted when enacting the Program.[76]

Keeton paid particular attention to interpreting the meaning of "best efforts," as the directive to the commissioner for obtaining a rebate agreement equal to Medicaid rebates.[77] Based on a pure statutory interpretation, the "best efforts" directive does not impose any administrative decisions or actions on the commissioner.[78] Keeton inferred that PhRMA's objections to the statute's language were based on concerns that a rebate program would not be in the best interest of PhRMA's pharmaceutical-manufacturing members, but he stated that the statute's language allows for negotiations between the state and manufacturers – which would serve the bests interests of Maine's residents and the manufacturers.[79]

Next, Keeton discussed the implications that PhRMA's facial challenge would have for federalism. Keeton advocated that courts faced with a similar facial challenge should make a "wait and see" decision rather than prohibiting a state from acting on behalf of its people out of fears that a state may overstep its authority.[80] A court acting on a facial challenge in advance of possible overstepping by state officials is contrary to recent constitutional holdings.[81]

Keeton's concurring opinion concluded with a discussion of the relationship between federalism and the Commerce Clause.[82] The ideals of federalism, Keeton explained, give deference to Maine's sovereignty and respect for the state's experimentation. The district court, therefore, acted beyond its authority and upset the balance between and state and federal power.[83]

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interpretation and associated issues of interpretation of the Maine statute . . . ." *Id.*

75. *Id.* at 90 (citing White v. Mass. Council of Const. Employers, 460 U.S. 204, 207 n.3 (1983)).

76. *Id.* Keeton notes that under the Program, Maine would act as a market participant in much the same way as a pharmacy benefit manager who purchases pharmacy products. *Id.*

77. *See id.* at 91.

78. *Id.* at 91-92.

79. *Id.* at 92.

80. *Id.* at 94.

81. *Id.* (citing United States v. Salerno, 481 U.S. 739, 745 (1987) ("[A] facial challenge to a legislative act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the act would be valid.")).

82. *Id.* at 95.

83. *See id.* at 97.

IV. SECTION 1115 WAIVER

Another option that states may utilize in attempting to make prescriptions drugs accessible and affordable is to obtain a Medicaid section 1115 waiver.[84] The Department of Health and Human Services (HHS) may approve "pilot" and "demonstration" projects that promote the objectives of Medicaid.[85] In doing so, the secretary of HHS may waive other Medicaid requirements.[86] While section 1115 waivers were originally granted on a selective, limited basis, HHS has granted more long-term and large-scale projects.[87]

A. *Vermont's Section 1115 Pharmacy Discount Program*

In March 2000, Vermont applied for a section 1115 waiver to operate its Pharmacy Discount Program as a demonstration

84. *See* Pharm. Research & Mfrs. of Am. v. Thompson, 251 F.3d 219, 220 (D.C. Cir. 2001). States increasingly needed to apply for section 1115 waivers in the mid-1990s after efforts to reform the health care system in the early years of the Clinton presidency failed, prompting states to address health care issues. Judith M. Rosenberg & David T. Zaring, *Managing Medicaid Waivers: Section 1115 and State Health Care Reform*, 32 HARV. J. ON LEGIS. 545, 545 (Summer 1995). Some of these state-initiated reforms hit Medicaid roadblocks, requiring that states apply for waivers. *Id.*

85. Public Welfare Amendments of 1962, Pub. L. No. 87-43, tit. XI, § 1115, 76 Stat. 173, 192 (1962) (codified as amended at 42 U.S.C. § 1315 (1994)). The cited Medicaid statute is part of the Social Security Act. *Id.*

86. 42 U.S.C. § 1315(a)(1). The secretary is limited to waiving Medicaid requirements and can do so only to the extent that it is necessary to carry out a pilot or demonstration project. *Id.* Before the secretary approves a waiver, a state must submit a project proposal, detailing what Medicaid restrictions would need to be waived, as well as the effect this would have on Medicaid expenditures and beneficiaries. Rosenberg & Zaring, *supra* note 84, at 547. Next, the Health Care Financing Agency (HCFA) (now known as the Center for Medicare and Medicaid), a division of HHS, reviews the proposal based on: methodology and design, objectives, costs, returns, and the applicant's experience in the relevant area. HCFA also evaluates the risks posed by the proposal before the agency gives its recommendation. *Id.* at 548. HCFA states that demonstration projects must be budget neutral. Health Care Financing Administration, *1115 Waiver Research and Demonstration Projects*, *at* http://medicare.hcfa.gov/medicaid/hpg5.htm (last visited Sept. 28, 2001).

87. Rosenberg & Zaring, *supra* note 84, at 551. *See also* National Association of State Medicaid Directors, *Medicaid 1115 Waivers*, *at* http://medicaid.aphsa.org/waivers/1115waivers.htm (last visited Sept. 28, 2001) ("Since 1993, the Health Care Financing Administration has approved 13 statewide comprehensive Medicaid 1115 waivers, for Delaware, Hawaii, Oklahoma, Oregon, Rhode Island, Tennessee, Vermont, Kentucky, Ohio, Illinois, Florida, Massachusetts, and Maryland.").

project.[88] In *Pharm. Research & Mfrs. of Am. v. Thompson*,[89] PhRMA sued the secretary of HHS, challenging the department's approval of the Vermont program.[90] Vermont proposed its demonstration Pharmacy Discount Program to extend Medicaid reduced-price prescription drug benefits to nearly 70,000 beneficiaries.[91] Program participants would pay the same price for prescriptions as Medicaid recipients.[92] The state proposed billing pharmaceutical manufacturers the cost of this discount to consumers.[93] The secretary of HHS approved Vermont's request.[94]

PhRMA filed suit in federal district court, seeking a preliminary injunction, claiming the program violated a Medicaid statute that requires manufacturers to issue rebates only for payments made under state drug plans.[95] The HHS secretary responded by arguing that, despite being reimbursed by manufacturers, Vermont was making a "payment," for the purposes of the Medicaid statute, and that PhRMA did not have standing to represent the interests of the program's beneficiaries.[96] The program went into effect on January 1, 2001, and the district court denied PhRMA's request for a preliminary injunction on January 17, 2001, from which PhRMA appealed.[97]

The circuit court did not address the merits of Vermont's program, but limited its review to whether HHS exceeded its authority to authorize Vermont to require manufacturers to make rebates to the state.[98] Reversing the lower court's decision, the circuit court held that under Vermont's program, the state did not

88. *Thompson*, 251 F.3d at 222.

89. *See supra* note 26 and accompanying text.

90. *Thompson*, 251 F.3d at 222.

91. *Id.*

92. *Id.* The average Medicaid rebate in Vermont was approximately eighteen percent in 2000. *Id.* In the proposal, Vermont planned to bankroll the program by first paying pharmacies the difference between what the beneficiary paid and pharmacies' retail price. *Id.*

93. *Id.* No public funds would be used to pay for the discounted drugs. *Id.*

94. *Id.* The approval was sent by letter dated November 3, 2000. *Id.* At the time, Donna Shalala was secretary of HHS under President Bill Clinton.

95. *Thompson*, 251 F.3d at 222 (citing 42 U.S.C. § 1396r-8(b)(1)(A) ("[P]harmaceutical manufacturers owe rebates only for drugs 'for which payment was made under the State plan.'")). PhRMA also alleged that states can only charge Medicaid beneficiaries a "nominal" amount, which is exceeded by requiring participants to pay eighty-two percent of the cost of a prescription. *Id.* (citing 42 U.S.C. § 1396o).

96. *Id.*

97. *Id.* at 223.

98. *Id.* at 221.

make "payments" to pharmacies.[99] In reaching its conclusion, the circuit court reasoned that the term "payment" only applied to state or federal funds appropriated for Medicaid expenditures.[100]

V. OTHER STATE PROGRAMS

Across the country, thirty states have enacted legislation to address rising drug prices.[101] This past year, twenty-seven state legislatures witnessed the introduction of bills that closely resembled the Maine Rx Program.[102]

Minnesota is among the states that have addressed the issue of rising costs for prescription drugs. In 1997, Minnesota enacted the Senior Citizen Drug Program, which assists low-income elderly with purchasing prescription drugs.[103] Replicating the Maine Rx Program, the Minnesota Fair Drug Pricing Act was proposed during the 2001 legislative session.[104] The Minnesota legislation was different from the Maine program, because the Minnesota bills would have required manufacturer participation merely because

99. *Id.* at 224.

100. *Id.* The secretary of HHS advocated for a broader reading of "payment," which would have included reimbursed expenditures. *Id.* The court, though, noted that Congress had originally enacted the legislation that required manufacturers to give rebates to "achieve significant Medicaid savings" at a time when the federal budget was stretched thin. *See id.* at 225. Because Vermont was acting merely as an intermediary, where the only state expenditure was forgone interest from the money used to pay pharmacies before manufacturers reimbursed the state, the rebate program would not reduce the cost of Medicaid. *Id.* at 226.

101. National Conference of State Legislatures, *2001 Prescription Drug Discount, Bulk Purchasing, and Price Related Legislation, at* http://www.ncsl.org/programs/health/drugdisc01.htm (Aug. 24, 2001).

102. CENTER FOR POLICY ALTERNATIVES, PRESCRIPTION DRUG FAIR PRICING LEGISLATIVE SUMMARY 1 (June 2001), *available at* www.stateaction.org/issues/healthcare/prescription/2001.pdf.

103. *See* MINN. STAT. § 256.955 (2000). The Minnesota program requires applicants to meet several criteria before enrolling, including having an income at or below 120 percent of the federal poverty guideline, not living in a nursing home, and not having prescription drug coverage for the preceding four months. *Id.*

104. *See* S.F. 765, 2001 Leg., 82d Sess. (Minn. 2001); H.F. 944, 2001 Leg., 82d Sess. (Minn. 2001). These proposals would have extended Medicaid prices for prescription drugs to approximately one million Minnesotans who are uninsured. Press Release, Mike Hatch, Attorney General, State of Minnesota, *State Senator John Hottinger and State Representative Ruth Johnson Propose the 2001 Fair Drug Pricing Act* (Feb. 7, 2001) (on file with the author) [hereinafter Hatch Press Release]. The proponents of this legislation sought to capture "the state's bargaining power to help the consumer with discounted prices and to also make sure local pharmacies are not financially hit by this discount." *Id.*

their drugs were prescribed in the state.[105] Consequently, with pharmaceutical companies having no option but to participate, the Minnesota legislation did not need to include the then-controversial question of a prior authorization requirement.[106] The bill's eligibility requirements would have required the applicant to be a permanent Minnesota resident, not be in another state public assistance prescription drug program, not have private drug coverage, and not have drug coverage under a supplemental Medicare plan.[107] The State Senate passed the bill,[108] but its House companion file did not receive a hearing and died in committee.[109]

VI. FEDERAL ALTERNATIVES

In the fall of 2000, as part of the annual agriculture appropriations bill, Congress passed the Medicine Equity and Drug Safety Act of 2000.[110] The bill, which was sponsored by Senator James Jeffords of Vermont, would have allowed the reimportation of prescription drugs from outside the United States.[111] This measure would have allowed pharmacists and wholesalers to buy drugs, which were manufactured in the United States and then exported, from countries that have prescription drug price controls.[112] Since the passage of the 1987 Prescription Drug

105. Minn. S.F. 765; Minn. H.F. 944.

106. Minn. S.F. 765; Minn. H.F. 944.

107. Minn. S.F. 765; Minn. H.F. 944.

108. Minn. S.F. 765. On May 14, 2001, the bill passed out of the senate chambers with a margin of 42 to 21 on a roll call vote.

109. Minn. H.F. 944. After H.F. 944 was introduced on February 15, 2001, it was immediately referred to the House Health and Human Services Policy Committee, where it sat idle for the remainder of the session. *Id.* On May 15, 2001, the Senate sent its amended and passed version of the bill to the House of Representatives. Like H.F. 944, when S.F. 765 was introduced in the House, it was referred to the Health and Human Services Policy Committee, where it died. *Id.*

110. Marc Kaufman, *Shalala Halts Bid to Lower Drug Costs*, WASH. POST, Dec. 27, 2000, at A1. *See also* FY 2001 Agriculture Appropriations Bill, Pub. L. No. 106-387, § 745, ___ Stat. ___, (2000). Proposals to allow drug reimportation have been around since 1999, when Rep. Bernie Sanders introduced the International Prescription Drug Parity Act. Press Release, Rep. Bernie Sanders, *Sanders Leads Bipartisan Coalition in Calling for Immediate Passage of Prescription Drug Reimportation Bill* (Sept. 14, 2000), *available at* http://www.house.gov/bernie/press/2000/09-14-2000.html. Since then, Rep. Sanders claims, drug manufacturers have spent millions of dollars influencing politicians with campaign contributions targeted at stopping Sanders' bill. *Id.*

111. Kaufman, *supra* note 110.

112. *Id.* Some drugs in the United States cost thirty to fifty percent more than they do in other countries. *Id.*

Marketing Act, it has been illegal for pharmacists and wholesalers to import a prescription drug.[113]

After President Clinton signed the bill, the program needed Health and Human Services Secretary Donna Shalala's approval.[114] On December 26, 2000, Secretary Shalala sent a letter to President Clinton in which she stated she would not approve the program.[115] PhRMA was active in lobbying against the proposal, raising concerns that reimported drugs could be dangerous or counterfeit.[116]

In July 2001, in response to a letter from Senator Jeffords, Tommy G. Thompson, the new HHS secretary in the Bush Administration, reaffirmed Secretary Shalala's decision not to allow the Medicine Equity and Drug Safety Act to take effect.[117] Secretary Thompson's reasons were much the same as Shalala's – reimportation would take pharmaceuticals out of the stream of the FDA's regulatory process and could pose safety risks.[118]

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113. Jane Cys, *Price Relief Coming? Congress Passes Drug Reimportation Bill*, AM. MED. NEWS, Nov. 6, 2000, *available at* http://www.ama-assn.org/sci-pubs/amnews/pick_00/gvsa1106.htm. Commercial shipments may be reimported only by the manufacturer of the drug. Letter from Tommy G. Thompson, Secretary, Department of Health and Human Services, to James Jeffords, Senator, United States Senate Attach. A (July 9, 2001), *available at* www.fda.gov/oc/po/thompson/medsact.html. In the case of some unapproved drugs, the Food and Drug Administration (FDA) does grant exemptions to the ban on importation, for small quantities of a drug for personal use on a case-by-case basis. Peter S. Reichertz and Melinda S. Friend, *Hiding Behind Agency Discretion: The Food and Drug Administration's Personal Use Drug Importation Policy*, 9 CORNELL J.L. & PUB. POL'Y 493, 493-94 (Winter 2000).

114. Kaufman, *supra* note 110, at A1.

115. *Id.* In the letter, Secretary Shalala stated: "Flaws and loopholes contained in the reimportation provision make it impossible for me to demonstrate that it is safe and cost effective." *Id.*

116. Press Release, Pharmaceutical Research and Manufacturers of America, *Eleven Former FDA Commissioners Warn of Dangers of Drug Reimportation to American Patients* (Aug. 31, 2000), *available at* www.phrma.org/org/press/newsreleases/2000-08-31.4.phtml. In its press release, PhRMA assembled every living FDA commissioner since 1969 to express their concerns that reimported drugs could be dangerous. *Id.*

117. Press Release, U.S. Department of Health and Human Services, *Secretary Thompson Determines that Safety Problems Make Drug Reimportation Unfeasible* (July 10, 2001), *available at* http://www.hhs.gov/news/2001pres/20010710.html [hereinafter Thompson Press Release].

118. *See id.* Secretary Thompson noted that the program included drug supply protections, including chain-of-sales documentation and product sampling and testing, but that these requirements were insufficient to ensure the same quality controls that exist today. *Id. See also* Kaufman, *supra* note 110, (discussing Shalala's refusal).

VII. ANALYSIS AND RECOMMENDATIONS

Skyrocketing prescription drug costs have captured the attention of policy-makers across the country. The failure by Congress to enact national legislation has prompted states to take action on the issue.[119] These state actions, though, have given rise to constitutional challenges from the pharmaceutical industry involving interstate commerce and the supremacy clause.[120] The judicial branch is then forced into the middle of a highly political debate to give final determination over whether a state's response to the drug price dilemma will ever see the light of day. In *Pharm. Research & Mfrs. of Am. v. Concannon*, the First Circuit Court of Appeals, after a well-reasoned analysis, made the correct decision by vacating the district court-imposed injuction and allowing the implementation of the Maine Rx Program.[121] In particular, the First Circuit's holding signals to other states that they may proceed with similar programs.

First, this decision significantly reduces a state's concerns that legislation similar to Maine's will conflict with the Medicaid statute, at least insofar as such a challenge that would be made prior to the implementation of a state-facilitated prescription drug program. While the Medicaid statute does not forbid the Maine Rx Program, the Maine drug plan abutted Congressionally-mandated restrictions on prior authorization.[122] Maine, though, prudently included in the Act language limiting prior authorization requirements only "as permitted by law."[123] This limitation proved to be a significant factor in the First Circuit's resistance to preventing the Program from being implemented.[124] With nothing to base its decision on besides the statutory text itself and statements by the commissioner charged with overseeing the program, the court had little choice but to give great deference to the commissioner's commitment to not overstepping Maine's limited authority vis a vis Medicaid.[125] Similarly, the court rightly held that it would have been improper to rule, based on a facial challenge, that the Program was not in the

119. *See* Rosenberg & Zaring, *supra* note 84, at 545.
120. *E.g. Concannon*, 249 F.3d at 72.
121. *Id.* at 71.
122. *See id.* at 75.
123. ME. REV. STAT. ANN. tit. 22, § 2681(7) (West 2001).
124. *See Concannon*, 249 F.3d at 75.
125. *Id.*

best interest of its recipients.[126]

Second, states wishing to follow Maine's lead will find the *Pharm. Research & Mfrs. of Am. v. Concannon* decision helpful to avoid, or at least prepare for, claims that allege violations of the dormant Commerce Clause. First and foremost, a state must be diligent to avoid the temptation of tying prices to those in other states.[127] As much as a state that pays more for pharmaceuticals, in the aggregate, than its neighbor would like to assist its citizens, this sort of response will not be able to pass the scrutiny under a per se challenge.[128] A state that wishes to be proactive on the issue will certainly want the opportunity to implement its program, and tying prices to those in other states will provide a basis to the pharmaceutical industry to stop a program from ever helping beneficiary number one.[129] Next, a state should aim to make the program voluntary. The First Circuit viewed this factor as part of the reason to allow Maine to proceed with the Program.[130] This is not to say that states should not include incentives that strongly push manufacturers toward participation in state programs.

Third, the court's application of the *Pike* balancing test to the Maine Rx Program should be encouraging to states wanting to follow Maine's lead.[131] As the court correctly applied, *Pike* calls for a low level of scrutiny, and the *Pike* balancing test is definitely supportive of a state that acts in the interests of its citizens.[132] Even if a state is confronted with a court challenge on its state drug program, assuming the state took measures to avoid per se violations, the *Pike* balancing test will only require a state to show that the state interests in enacting a drug program outweigh any potential impact the program would have on interstate commerce and pharmaceutical manufacturers.[133]

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126. *Id.* at 77.

127. *Compare Concannon*, 249 F.3d at 81, *with Healy*, 491 U.S. at 326, *Brown-Forman*, 476 U.S. at 575-76; *and G.A.F. Seelig*, 294 U.S. at 519. *See also supra* note 60 and accompanying text.

128. *See Concannon*, 249 F.3d at 81.

129. *Id.* Merely the fact alone that a state has not tied drug prices to prices in other states will not guarantee that the state will be allowed to implement its prescription drug program; rather, it will at least force a court to continue with its analysis under the less strict scrutiny imposed under the *Pike* balancing test. *Id.* at 83.

130. *Id.* at 82.

131. *See id.* at 83-84.

132. *Pike*, 397 U.S. at 142.

133. *See Concannon*, 249 F.3d at 84. The First Circuit noted that it was "forced

In its holding, the First Circuit recognized the significant interest that a state has in making lower cost prescription drugs available to its citizens.[134] At the same time, the court minimized the arguments of PhRMA, stating that the only potential adverse effect the Maine Act would have on interstate commerce is decreased drug company profits.[135] Essentially, the First Circuit's holding dismissed the drug industry's worn-out argument that Maine-like programs will dramatically slow the development of life-saving drugs. Further, the court puts pharmaceutical manufactures on notice that in future litigation claims of a decrease in money available for research will be seen as actually a concern about reduced profits – which will carry little weight when balanced, under *Pike*, against the significant interest of ensuring citizens have access to prescription drugs.[136]

Judge Keeton's concurrence, through the considerable attention that he paid to Madison and the fundamentals of federalism, provides further assurances to other states following in the footsteps of Maine. Keeton emphasized the important roles of states as sovereigns.[137] Rather than addressing concerns or reservations about Maine overstepping into interstate commerce, Keeton signaled to states that it is their duty as guardians to act on behalf of citizens needing affordable prescription drugs.[138] Keeton commented that negotiations over rebate agreements serve the interests of state residents and drug manufacturers[139] demonstrate that PhRMA's contention that state drug programs will restrain pharmaceutical advances are not accepted by all.

Despite PhRMA's successful challenge of Vermont's Pharmacy Discount Program,[140] Medicaid section 1115 waivers may still hold potential, albeit slim, for states looking to help their citizens access lower-cost prescription drugs. The holding in *Pharm. Research & Mfrs. of Am. v. Thompson* was limited to the issue of clarifying what a "payment" is for purposes of applying the Medicaid statute.[141] Even

to balance the *possible* effects, instead of the *actual* effects" of the Act, which could not be determined while evaluating a facial challenge. *Id.*

134. *Id.*
135. *Id.*
136. *Id.* Economic effects do not amount to a Commerce Clause burden. *Id.*
137. *Id.* at 89 (Keeton, J., concurring).
138. *Id.* at 90.
139. *Id.* at 92.
140. *See Thompson*, 251 F.3d at 224.
141. *Id.*

in this limited holding, the court's reasoning on this point is not entirely convincing. The circuit court reasoned that manufacturers would not have to pay rebates to Vermont because no federal or state dollars were expended.[142] If manufacturers did not give a rebate to the state, Vermont would indeed have had negative expenditures, because the state would have spent Medicare dollars by paying a discount to pharmacies.

Alternatively, the court could have held the rebate would have been paid (indirectly) to a private pharmacy. Pharmaceutical manufactures often engage in rebate agreements with the private sector.[143] If the court had followed this reasoning, the court could have found that the state was acting as a market participant along side the pharmacies, merely bankrolling a rebate plan for pharmacies.

Under the court's holding, another way a state could avoid the problems that Vermont faced is if a state acted as more than merely a conduit through which funds would travel;[144] this would allow the state to overcome the circuit court's "payment" issue. This may not be possible, noting the encouragement for budget-neutral waiver proposals.[145] Of course, a state could pursue creating another type of "pilot" or "demonstration" project that extended Medicaid drug prices to those without prescription drug coverage. One proposal might be to create a purchasing pool[146] for pharmacies and their patients and not allow the state to become entangled in the short-term financing of prescription purchases.[147] Also, a state could try

142. *Id. See supra* note 100 and accompanying text.

143. *See* Hatch Press Release, *supra* note 104.

144. *See Thompson*, 251 F.3d at 223.

145. *See* Health Care Financing Administration, *supra* note 86.

146. Press Release, Governor Jeanne Shaheen, State of New Hampshire, *Governors Shahee, King and Dean Joine Together to Create Tri-State Prescription Purchasing Pool* (May 24, 2001) (on file with the author). In May 2001, three New England governors announced that they were establishing the first multi-state prescription drug purchasing pool to reduce the costs of purchasing prescriptions for the states' 330,000 Medicaid recipients. *Id.* The purchasing pool united New Hampshire, Vermont, and Maine in an effort to combine the purchasing power of the three states, whose combined Medicaid spending on prescriptions drugs totaled $387 million. *Id.* The states estimated savings of around ten to fifteen percent. *Id.* Before beginning to administer the program, which would operate similar to an HMO with a prescription benefit manager, the states sought a section 1115 waiver. *Id.* While this initiative was designed to reduce states' Medicaid prescription drug costs, the program could serve as another model for statewide drug coverage.

147. Rosenberg & Zaring, *supra* note 84, at 551.

to obtain a section 1115 waiver for a Maine-like program.

Even if a state structured its section 1115 waiver proposal to avoid a challenge similar to that in Vermont, this option is not the best course a state could pursue. If a state enacted a section 1115 project, its prospects of a long-term solution to the prescription drug problem might be limited. While some current section 1115 projects have far exceeded any concept of a short-term, "demonstration" nature,[148] the federal government could reverse this trend in the next decade or two by returning to a stricter interpretation of the statute. After many years of operating its drug program, a state could be forced to shut down operations — returning its citizens to a brutal drug market.

Following the Maine decision, state legislatures should again try to implement similar prescription drug legislation, now armed with a court ruling in their favor. In Minnesota, the current Senior Citizen Drug Program is inadequate. As its title suggests, this program only assists the elderly,[149] whereas a Maine-style program would be available to a wider group of eligible enrollees.[150]

If Minnesota legislators try again to enact legislation like Maine's, they should restructure their proposal to more-closely resemble the Maine Rx Program. This includes changing the requirement that manufacturers participate.[151] The First Circuit's holding noted the fact that Maine's program was voluntary, which helped the court reach its decision.[152] If Minnesota proposals continued to include a mandatory participation requirement, this could provide fodder to a future court challenge by the pharmaceutical industry.

The past proposals' inclusion of the mandatory participation requirement made it unnecessary to address the then-pending challenge over prior authorization requirement in the Maine Rx Program. In future attempts in Minnesota, legislators will not need to shy away from the prior authorization issue. While not all manufacturers would necessarily participate in a Minnesota program, the state could garner significant manufacturer participation by including incentives such as prior authorization

148. *See* National Association of State Medicaid Directors, *supra* note 87.

149. MINN. STAT. § 256.955 (2000). Participants of the Senior Citizen Discount Program must be age 65 or older. *Id.*

150. *See* ME. REV. STAT. ANN. tit. 22 § 2681 (West 2001).

151. *See* S.F. 765; H.F. 944.

152. *See Concannon*, 249 F.3d at 82.

requirements. Including this type of incentive is a better alternative than prescribed mandatory manufacturer participation.

The federal plan to allow the reimportation of prescription drugs appears to be a reasonable step toward making drugs available at lowers costs, but the action also avoids the heart of the issue. In part, there is little sense in passing legislation that lifts a ban and allows Americans to buy back pharmaceuticals that originate from the United States. The prescription drug market, its two-tiered pricing system,[153] and the disparities in drug prices between nations,[154] raises questions about the pharmaceutical industry's use of public funding for drug research. The government, through the National Institutes of Health,[155] is essentially subsidizing sales of prescription drugs in other countries and to large drug purchasers, such as HMOs.

The current and past secretary of HHS may indeed have well-founded concerns that reimportation of drugs puts consumers at risk of receiving drugs that are dangerous or counterfeit.[156] Rather than not implementing the Medicine Equity and Drug Safety Act, the commissioners might have instead sought to ensure that reimported prescription drugs came from reputable distributors in other countries.

This has been Congress's most significant attempt to take action in the prescription drug price debate. It has been advocated that Congress enact a Medicare prescription drug benefit to give prescription drug coverage to those on Medicare.[157] The Medicare

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153. Hatch Press Release, *supra* note 104, at 2.

154. *See* Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 165 (2000) (noting the prices for pharmaceutical drugs are higher in the United States than in other countries). This paper has not addressed the option of traditional price controls such as those imposed in other countries such as Canada. *See id.* The mention of such action raises fierce opposition, although the opposition is generally based on the belief that price controls will hinder pharmaceutical innovation. *Id.* at 167.

155. PUBLIC CITIZEN, *supra* note 15, at 4.

156. Thompson Press Release, *supra* note 117.

157. *See* Am. Ass'n of Ret'd Pers., *Add the Missing Piece: Prescription Drugs in Medicare*, *at* http://www.aarp.org/prescriptiondrugs/medmonday.html (last visited October 21, 2001). The American Association of Retired Persons [herinafter "AARP"], is an advocacy organization for those over fifty-years-old and has been on the forefront of lobbying Congress to enact a Medicare prescription drug benefit. On the thirty-sixth anniversary of Medicare, AARP delivered birthday cakes to members of Congress. *Id.* The cakes had one piece missing, symbolizing the lack of a prescription drug benefit under Medicare. *Id.* AARP has called for a plan with low costs to enrollees, early enrollment, and operation by a pharmacy benefit manager to minimize costs. Press Release, AARP, *AARP*

drug benefit proposals have thus far failed to build momentum.

Surprisingly, there have been no serious proposals for a nationwide program similar to the Maine Rx Program. Such a plan seems like an obvious step toward addressing the drug pricing problem while avoiding interstate commerce and Supremacy Clause issues. The absence of a national Maine-like plan stands as a testament to the force yielded by PhRMA on Capitol Hill. Congress's failure to enact successful legislation to provide lower cost prescription drugs to those without drug coverage reaffirms the role of states in the battle against the pharmaceutical industry.

VIII. CONCLUSION

With a variety of options from which to choose, states will need to decide how to proceed with ensuring that lower cost prescription drugs availability to their citizens. For now, the federal government has all but left dealing with the issue to the states.[158] Although the federal government has given the authority to some states to pursue innovative methods of dealing with the problem,[159] the decision regarding the Vermont Pharmacy Discount Program establishes that the courts will place limits on what states may do.[160]

The First Circuit's holding from *Pharm. Research & Mfrs. of Am. v. Concannon* confirms that the Maine Rx Program is currently the best model available to states who wish to address the problem of rising drug prices. Besides the fact that it has withstood a court challenge, the program benefits participants by extending prescription drug prices that are comparable to those paid by the government and HMOs. The First Circuit made a sound legal decision while concurrently praising the efforts of Maine to address a pressing issue of wide concern. Maine is by no means free and clear from legal challenges over the Program, because the court left open the door to post-implementation challenges.[161] The court, though, prudently granted the state the opportunity to implement the Program and evaluate its effect.[162]

Commissioned Study Offers Policymakers Key Insights for Design of Medicare Drug Benefit (June 15, 2001), *at* http://www.aarp.org/press/2001/nr061501.html.

158. *See* Rosenberg & Zaring, *supra* note 84, at 545.

159. *See supra* section IV.

160. *See Thompson*, 251 F.3d at 224.

161. *Concannon*, 249 F.3d at 78 ("This decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act.").

162. *See id.*

Before the Program is implemented and operated for some time, it is pure conjecture how successful the Program will prove to be. It remains to be seen how many citizens will participate in Maine's program, whether manufacturers will participate, and what effect the Program will have on drug prices.[163] It also remains to be seen how other states will react to the First Circuit's holding.

163. *See* Pharm. Research & Mfrs. of Am. v. Concannon, 122 S.Ct. 340, 2001 WL 1181086 (2001). On October 9, 2001, in response to a petition for certiorari filed in July by PhRMA the Supreme Court invited the Solicitor General "to file briefs in this case expressing the views of the United States." *Id.* It is unclear what effect this will have on the Maine Rx Program.