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# **Maine's Battle in America's Other Drug War: *Pharmaceutical Research and Manufacturers of America v. Walsh***

**By Lynsey Mitchel\***

"To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation."<sup>1</sup>

## I. INTRODUCTION

At the time this article is being written, prescription drug policy is once again on the law-making agenda. President Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act into law on December 8, 2003.<sup>2</sup> The federal legislation contains a prescription drug discount for Medicare recipients that may impact the future of state-led initiatives regarding states' ability to lower the

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\*This article is dedicated to GLM, an excellent attorney, and even better father. The author wishes to thank Professor Ogden at Pepperdine University School of Law for suggesting this topic.

1. *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 85 (1st Cir. 2001) (quoting, *New State Ice. Co. v. Liebmann*, 285 U.S. 262, 310 (1932) (Brandeis, J., dissenting)).

2. Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.A.). The purpose of the act is to:

amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.

*Id.*

price of prescription drugs.<sup>3</sup> This idea will be explored in Part IV of this article.

The fight for cheaper prescription drugs has been termed America's other drug war. Almost four years ago, the Maine legislature started a battle for lower-cost prescription drugs that ended in the Supreme Court. On May 11, 2000, Maine legislators signed into law the Act to Establish Fairer Pricing for Prescription Drugs and established the Maine Rx Program, the nation's first state price control mechanism, to reduce prescription drug prices for those not qualified for Medicaid or who do not have another superior prescription drug plan.<sup>4</sup>

The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association that represents over one hundred pharmaceutical and biotechnology companies, challenged the legislation and won an injunction in October 2000.<sup>5</sup> A year later, the appeals court lifted the injunction but kept the legislation on hold awaiting Supreme Court review.<sup>6</sup> On May 19, 2003, the Supreme Court ruled against PhRMA.<sup>7</sup> Maine Rx Plus, a revamped program, is slated to go into effect in January 2004.<sup>8</sup>

Part II of this case note examines the background of prescription drug pricing, the relationship between Medicaid and the Maine Rx Program, PhRMA's constitutional challenges to the Maine legislation and a summary of the lower court opinions. Part III includes an analysis of the Supreme Court's opinion. Part IV discusses the impact of the case, including the revised program and the possible federal solution. Part V concludes the discussion of *Walsh*.

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3. *Id.*

4. 2000 Me. Laws 786.

5. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S. Ct. 1855, 1863-64 (2003).

6. *Id.* at 1865-66.

7. *Id.* at 1871.

8. ME. REV. STAT. ANN. Tit. 22, § 2681 (West 2004).

## II. HISTORICAL BACKGROUND

### A. *Same Drug, Different Price*

Prescription drug expenditure and retail prices in the United States have increased dramatically in recent decades.<sup>9</sup> Americans spent \$140.6 billion on outpatient prescription drugs in 2001, a 15.73% increase over 2000 spending and a tripling of 1990 figures.<sup>10</sup> Along with expenditure, retail and manufacturer prescription prices have increased.<sup>11</sup> Retail prescription prices have gone up 7.3% per year from 1992 to 2002, while manufacturer prices have gone up 3.6% per year during the same period.<sup>12</sup> Pharmaceutical company profits are also on the rise. In 2001, the pharmaceutical industry had the highest profit to revenue ratio of any industry.<sup>13</sup> Many perceive differential drug costs and high prices as unfair and have called for governmental drug cost regulations.<sup>14</sup> However, the pharmaceutical industry believes that the ultimate cost to be paid by governmental regulation is decreased innovation.<sup>15</sup>

Americans on the whole also pay higher prices for their drugs than other developed countries.<sup>16</sup> Maine's close proximity to Canada

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9. Stephen R. Latham, *Pharmaceutical Costs, An Overview and Analysis of Legal and Policy Responses by the States*, 24 J. LEGAL MED. 141, 141-44 (2003). Latham's article cites numerous factors for the increase in drug expenditures such as an aging population and that physicians are switching their patients to newer, higher priced drugs.

10. *Id.*

11. THE KAISER FAMILY FOUND., *PRESCRIPTION DRUG TRENDS* (May 2003), available at  
<http://www.kff.org/rxdrugs/loader.cfm?url=/commonspots/security/getfile.cfm&pageid=14267>. For comparison purposes, the report noted that the average inflation was 2.5%.

12. *Id.*

13. Latham, *supra* note 9, at 150.

14. See Martha Ann Holt, *International Prescription Drug Cost Containment Strategies and Suggestions for Reform in the United States*, 26 B.C. INT'L & COMP. L. REV. 325, 325-26 (2003).

15. *Id.*

16. Farin Khosravi, *Price Discrimination in the United States: Why are Pharmaceuticals Cheaper in Canada and are Americans Seizing the Opportunities Across the Border?*, 9 LAW & BUS. REV. AM. 427, 429 (2003).

highlighted the issue of differential prices of drugs. For example, Chellie Pingree, the Maine senator who sponsored the Maine legislation, accompanied Maine seniors to Canada and reported that the group saved \$18,000, in the aggregate, on their prescription drugs.<sup>17</sup> Health insurance companies, including managed care organizations, and government health plans are able to procure lower priced drugs since they can negotiate with drug manufacturers as large purchasers.<sup>18</sup> As a result, people without prescription drug benefits, either because they do not have health insurance or do not qualify for state programs such as Medicaid, pay the highest prices.

*B. The Federal Medicaid Statute, the Maine Rx Program and Prescription Drugs*

1. The Background of Medicaid and the Maine Rx Program

Medicaid became law in 1965 and finances health care for people with low-incomes defined as “families with dependent children and of aged, blind or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services.”<sup>19</sup> Since Medicare was mentioned earlier in this article, it should be clarified that Medicaid is a separate program than Medicare. Medicare provides financing for health care for persons over the age of sixty-five.<sup>20</sup> Entitlement to Medicare is based upon age, not need.<sup>21</sup> The Medicaid program is a federal/state partnership and provides states with the flexibility to set up their own eligibility requirements, payment for services and covered benefits.<sup>22</sup> In order to participate in the Medicaid program, a state must have their Medicaid plan approved by the Centers for Medicare and Medicaid, the agency who administers the program on behalf of the Secretary of

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17. *Id.* at 428.

18. John Rother, *Advocating for a Medicare Prescription Drug Benefit*, 3 YALE J. HEALTH POL'Y, L. & ETHICS 279, 281 (2003).

19. 42 U.S.C.A. § 1396 (West 2002).

20. STEPHEN J. WILLIAMS & PAUL R. TORRENS, *INTRODUCTION TO HEALTH SERVICES* 17 (Delmar Publishers 5th ed.) (1999).

21. *Id.*

22. 42 C.F.R. § 430 (2001).

the Department of Health and Human Services.<sup>23</sup> Although outpatient drugs are an optional benefit under Medicaid, all states provide them to their Medicaid-eligible citizens.<sup>24</sup>

The original Maine Rx Program was established for Maine citizens whose combined assets and income exceeded the qualifications for Medicaid, but yet who are also without another prescription drug benefit.<sup>25</sup> The Maine Rx Program was sweeping in who was allowed to take advantage of lower-priced drugs. Unlike Medicaid, there were no income ceilings and unlike Medicare, no age requirements.<sup>26</sup>

Although the Maine Rx Program was independent of Medicaid, it was nonetheless tied to Medicaid in two key ways. First, the actual cost to Medicaid for prescription drugs is reduced by rebates that manufacturers are compelled to pay to the states.<sup>27</sup> This federal rebate agreement is based on agreements between the manufacturer and the Secretary of Health and Human Services and is uniform across the states.<sup>28</sup> Had the Maine Rx Program been implemented, participating drug manufacturers would have been required to pay the same rebates to Maine Rx participants that they pay under the Medicaid program.<sup>29</sup> Second, drug manufacturers who did not elect to participate, essentially not entering into a rebate agreement with the state under the Maine Rx Program, would then have their drugs subject to prior authorization in Maine's Medicaid program.<sup>30</sup> Essentially, state legislators wanted to use Maine's leverage as a large purchaser of drugs in the Medicaid program to provide cheaper drugs for its other citizens without prescription drug coverage.

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23. 42 U.S.C.A. § 1396a (West 2002).

24. THE KAISER FAMILY FOUND., MEDICAID OUTPATIENT PRESCRIPTION DRUG BENEFITS: FINDINGS FROM A NATIONAL SURVEY, 2003 (December 2003), available at <http://www.kff.org/medicaid/loader.cfm?url=commonspot/security/getfile>

25. 2000 Me. Laws 786, § A-5(2).

26. *Id.*

27. 42 U.S.C.A. § 1396r-8 (West 2002). This section, titled "Payment for covered outpatient drugs," specifies that states are only eligible for federal payments if a drug manufacturer has entered into an agreement with the Secretary of the U.S. Department of Health and Human services or with the state itself.

28. *Id.*

29. *Walsh*, 123 S. Ct. at 1862.

30. *Id.* at 1863.

## 2. Rebate Agreements

The Federal Medicaid Rebate Program was passed by Congress in 1990 as a cost-saving measure so that state governments could reduce their costs for prescription drugs.<sup>31</sup> This legislation mandated that manufacturers had to enter into rebate agreements with either the federal government or with individual states in order to qualify for Medicaid payments.<sup>32</sup> Similarly, the Maine legislation directed the Commissioner of Maine's Department of Health Services to negotiate rebate agreements with manufacturers equal to the federal Medicaid rebates.<sup>33</sup>

The commissioner was to consider the rebate amount calculated under the Federal Medicaid Rebate Program and to then use his or her best efforts to obtain an initial rebate in the same amount.<sup>34</sup> Therefore, the Maine Rx Program would have allowed citizens of Maine, without any other prescription drug benefit, "to buy drugs from retail pharmacies at a discount roughly equal to the rebate on Medicaid purchases."<sup>35</sup> The participant would have been charged the discounted price set by the state and then the state would have used the funds obtained from the manufacturers to reimburse pharmacies for the discounts.<sup>36</sup>

## 3. The "Bite" of Prior Authorization

In order to create an incentive for manufacturers to participate in the Maine Rx Program, the statute provided that the names of manufacturers who did not enter into agreements be released to health care providers and the public.<sup>37</sup> Even more significant than negative publicity, the program required the drugs of non-participating manufactures to be subject to prior authorization when

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31. *Id.* at 1861.

32. *Id.* at 1862.

33. *Id.* at 1863.

34. *Id.* at 1863.

35. *Id.* at 1862.

36. *Id.* at 1863.

37. *Id.* at 1863.

prescribed for Medicaid program participants.<sup>38</sup> Subjecting a drug to prior authorization means that before a person can receive a prescription, a state agency must approve the request.<sup>39</sup> Prior authorization can be a "bite" or motivation to participate since subjecting a drug to prior authorization "sharply reduces the drug's market share and sales, as the prior authorization causes a shift of patients to competing drugs of other manufacturers that are not subject to a prior authorization."<sup>40</sup>

It is important to note that under the Medicaid program, the Social Security Act permits states to subject any Medicaid-covered outpatient drug to a requirement of prior authorization as long as the state complies with certain requirements.<sup>41</sup> These requirements include certain safeguards such as that prior authorization requests will receive a response within twenty-four hours, and that in emergency situations seventy-two hour supplies of drugs will be provided while requests are pending.<sup>42</sup> The Maine Rx Program was written to comply with these regulations.<sup>43</sup>

### *C. The Constitutional Challenges to the Rx Program*

The Pharmaceutical Research and Manufacturers of America (PhRMA) challenged the constitutionality of the Maine Rx legislation by asserting that the program violated the Supremacy Clause and the dormant Commerce Clause.<sup>44</sup> The background of

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38. *Id.*

39. Jagan Nicholas Ranjan, *Medicaid and the Unconstitutional Dimensions of Prior Authorization*, 101 MICH. L. REV. 602, 603 n.9 (2002). Ranjan stated that:

a state could declare Rogaine subject to prior authorization. As a consequence of this designation, any time a physician prescribed Rogaine she would have to make a telephone request to a state commission. Only after permission by the commission could the drug be prescribed. The commissioner must respond by telephone or another telecommunication device within 24 hours of the request.

See also 42 U.S.C.A. § 1396r-8(d)(5)(A) (West 2002).

40. *Walsh*, 123 S. Ct at 1864.

41. 42 U.S.C.A. § 1396r-8(d)(5)(A-B) (West 2002).

42. *Id.*

43. 2000 Me. Laws 786, § 7. The Act states that "[t]he department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law . . ." *Id.*

44. *Walsh*, 123 S. Ct. at 1860.



each of these areas of law will be discussed below.

## 1. Federal Preemption and Prior Authorization

PhRMA believed that imposing a prior authorization requirement on non-participating manufacturers was a threat to coerce manufacturers into reducing their prices on sales to non-Medicaid recipients.<sup>45</sup> The organization alleged that this portion of the Maine Rx Program was unconstitutional under the doctrine of federal preemption since the Maine Rx Program did not relate to Medicaid purposes, but instead imposed a significant burden on Medicaid recipients.<sup>46</sup> In their brief, the petitioners distinguished using prior authorization for Medicaid uses, such as policing quantity and refill limits for waste and preventing fraud, from using prior authorization as a way to make drug companies participate in the Maine Rx Program.<sup>47</sup>

The Supremacy Clause of the Constitution is the starting point for an analysis of whether or not the Maine Rx Program is preempted by the federal Medicaid statute. Article VI provides that “[t]his Constitution and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . .”<sup>48</sup> The Supremacy Clause mandates that federal law trumps any state regulation where there is an express conflict between the two sets of legislation.<sup>49</sup> However, there are other less overt types of preemption such as implied field and implied obstacle preemption.<sup>50</sup> Implied field preemption occurs where “Congress has legislated so comprehensively that it has left no room for supplementary state legislation.”<sup>51</sup> Since both Congress and the states maintain regulatory power over Medicaid, the relevant type of preemption in this case is

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45. *Id.* at 1867.

46. *Id.* at 1860.

47. Brief for Petitioner Walsh (No. 01-188) at 4.

48. U.S. CONST. art. VI, § 2.

49. RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW: SUBSTANCE AND PROCEDURE §§ 12.1-12.7 (3d ed. 1999).

50. Ranjan, *supra* note 39 at 606 & n.30.

51. R.J. Reynolds Tobacco Co. v. Durham Co., 479 U.S. 130, 140 (1986).

implied obstacle preemption.<sup>52</sup>

Under implied obstacle preemption, there is a presumption against preemption.<sup>53</sup> This presumption is especially powerful “[w]here coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes.”<sup>54</sup> The relevant standard is whether or not the Maine Rx Program is preempted by federal law because the “state law interposes an obstacle to the achievement of Congress’s discernable objectives.”<sup>55</sup> The key then to determining whether or not there is preemption is determining congressional intent. The Supreme Court ultimately had to determine whether or not Congress’s intent concerning Medicaid prior authorization should preempt the Maine Rx Program.<sup>56</sup>

## 2. The Dormant Commerce Clause

The Constitution provides Congress with the power “[t]o regulate commerce with foreign Nations, and among the several States.”<sup>57</sup> Therefore, when a state regulation concerning commerce is at odds with federal legislation, the supremacy clause holds that the federal statute dominates.<sup>58</sup> When Congress has not spoken clearly, the negative command, known as the dormant Commerce Clause, “prohibits states from acting in a manner that burdens the flow of interstate commerce.”<sup>59</sup> PhRMA argued that the rebate requirement violates the dormant Commerce Clause since it “constitutes

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52. *Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 15 (1st Cir. 2000).

53. *Walsh*, 123 S. Ct at 1869.

54. *Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 421 (1973).

55. *Grant's Dairy-Me.*, 232 F.3d at 15 (vacated by *Gibson v. Phillips*, 352 U.S. 874 (1956)).

56. For a more in depth discussion of the models of interpretation see R. Randall Kelso, *Statutory Interpretation Doctrine on the Modern Supreme Court and Four Doctrinal Approaches to Judicial Decision-Making*, 25 PEPP. L. REV. 37 (1997). See also Ranjan *supra* note 39 at 609-19.

57. U.S. CONST. art. I, § 8, cl. 3.

58. For an overview of the Commerce Clause see also ROTUNDA, *supra* note 49, at §§ 11.1, 11.10.

59. *Concannon*, 249 F.3d at 79.

impermissible extraterritorial regulation, and second that it discriminates against interstate commerce in order to subsidize in-state retail sales.”<sup>60</sup>

Statutes that violate the dormant Commerce Clause typically fall into one of these categories including 1) statutes that are per se violations of the Commerce Clause, 2) statutes that discriminate against interstate commerce, and 3) statutes that evenhandedly regulate commerce and have only incidental effects on interstate commerce.<sup>61</sup> PhRMA argued that the Maine Rx Program was a per se violation of the Commerce Clause. Per se violations result when a “statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority and is invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature.”<sup>62</sup> A state statute is subject to strict scrutiny if it discriminates against interstate commerce either on its face or in practical effect and will only be upheld if the state can “show that it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives.”<sup>63</sup>

PhRMA relied on the holdings of three cases, *Baldwin v. G.A.F. Seelig Inc.*, *Healy v. Beer Institute, Inc.*, and *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, to argue that the Maine Rx Program is a per se violation of the dormant Commerce Clause.<sup>64</sup> The Court found a per se violation of the price affirmation statute in *Seelig*.<sup>65</sup> In that case the Court struck down a New York statute that set minimum prices for milk purchased from producers, including producers within New York and other states, and banned the resale of milk that had been purchased for a lower price.<sup>66</sup> In this case, Seelig

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60. *Walsh*, 123 S. Ct. at 1870.

61. *Concannon*, 249 F.3d at 79.

62. *Id.* (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)).

63. *Oregon Waste Sys., Inc. v. Dep’t of Env’tl. Quality*, 511 U.S. 93, 100-01 (1994).

64. *Walsh*, 123 S. Ct. at 1870-71.

65. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). The Court held that “such a power, if exerted, will set a barrier to traffic between one state and another as effective as if customs duties, equal to the price differential, had been laid upon the thing transported.” *Id.*

66. *Id.*

a milk dealer in the city of New York, bought milk from producers in Vermont at lower prices than it would have had to buy from milk producers in New York.<sup>67</sup> Justice Cardozo wrote that "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there."<sup>68</sup>

The rule that came from *Seelig* was later applied in *Healy*.<sup>69</sup> In *Healy*, the Court struck down a Connecticut Liquor Control Act that required out-of-state shippers of beer to affirm that the prices at which the products were sold to Connecticut wholesalers were no higher than prices at which those same products were sold in bordering states.<sup>70</sup> Similarly, in *Brown-Forman*, a New York statute required liquor distillers to affirm that their prices were no higher than the lowest price at which the same product would be sold in any other state during the month.<sup>71</sup> The Court held that the statute violated the commerce clause since "[f]orcing a merchant to seek regulatory approval in one State before undertaking a transaction in another directly regulates interstate commerce."<sup>72</sup>

However, both the court of appeals and the Supreme Court found that these statutes, unlike the Maine statute, involved regulating prices charged in other states in order to benefit the buyers and sellers

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67. *Id.* at 520.

68. *Id.* at 521.

69. *Healy*, 491 U.S. 324.

70. *Id.* at 336. The Supreme Court also stated in *Healy* that:

Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions: First, the 'Commerce Clause. . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State. . . .' Second, a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.

*Id.*

71. *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 575-76 (1986).

72. *Id.* at 582.

in the home state, resulting in a direct burden on the non-home state buyers and sellers.<sup>73</sup> Part III will further illuminate how the Court determined that this rule did not apply in *Walsh*.

#### *D. Lower Court Opinions*

##### 1. United States District Court: *Pharmaceutical Research and Manufacturers of America v. Commissioner*

PhRMA filed a motion for a preliminary injunction in the United States District Court of Maine against the Commissioner of the Maine Department of Health Services and the Maine Attorney General in order to stop the Maine Rx Program from going into effect.<sup>74</sup> The district court concluded that the plaintiff's likelihood of success on both of their constitutional claims, including that the Maine program violated the dormant Commerce Clause and was preempted by the federal Medicaid Act, was "overwhelming."<sup>75</sup> As a result the court imposed an injunction against the state on October 26, 2000.<sup>76</sup> A court in determining whether or not to grant a preliminary injunction may consider the likelihood of success on the merits, the risk of irreparable harm, the balance of the inequities and the public interest.<sup>77</sup> The district court primarily ruled for PhRMA based upon its likelihood of success on the merits and briefly disposed of the remaining factors.<sup>78</sup>

First, the lower court examined whether or not the rebate program violated the Commerce Clause of the Constitution. Maine attempted to avoid the constitutional issue by claiming that they were not regulating, but were rather exercising their market power as a volume purchaser of prescription drugs in the Medicaid program.<sup>79</sup> The

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73. *Concannon*, 249 F.3d at 81; *Walsh* 123 S. Ct. at 1871.

74. *Pharm. Research & Mfrs. of America v. Commissioner*, CIV.00-157-B-H (D. Me. 2000) available at [http://www.med.uscourts.gov/site/opinions/hornby/2000/dbh\\_10262000\\_1-00cv157\\_pharma\\_v\\_commr\\_me.pdf](http://www.med.uscourts.gov/site/opinions/hornby/2000/dbh_10262000_1-00cv157_pharma_v_commr_me.pdf)

75. *Id.* at 16.

76. *Id.*

77. *Concannon*, 249 F.3d at 72.

78. *Commissioner*, at 16.

79. *Id.* at 6.

Supreme Court has ruled that states acting as buyers rather than regulators are not subject to the Commerce Clause and may "favor its citizens over others."<sup>80</sup> For example, in *South-Central Timber Dev., Inc. v. Wunnicke*, the Supreme Court held that Alaska ceased to be a participant in the market and became a regulator when Alaska attempted to use its leverage in the timber market, where it was a participant, in order to exert a regulatory effect in the processing market, in which it was not a participant.<sup>81</sup> The district court rejected Maine's argument and held that the state is subject to the Commerce Clause since Maine was acting in its regulatory capacity in trying to achieve a social, regulatory goal.<sup>82</sup>

Second, the court had to determine if the rebate program violated the Constitution's Commerce Clause.<sup>83</sup> The court concluded that Maine burdened interstate commerce since it attempted to regulate the prices paid in earlier transactions in other states.<sup>84</sup> The court agreed with PhRMA's analogy of the holdings in three cases, *Baldwin v. G.A.F. Seelig Inc.*, *Healy v. Beer Institute, Inc.*, and *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, to the Maine Rx Program.<sup>85</sup> The court reasoned that the Maine statute was similar to the New York statute in *Seelig* which attempted to regulate the price of milk in other states. The court held that "[i]f we change the names of the states, and substitute prescription medications for milk" the outcome is the same.<sup>86</sup>

Last, the court had to conclude if making drugs manufactured by non-participating companies subject to prior authorization was

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80. *Id.* See, e.g. *White v. Massachusetts*, 460 U.S. 204 (1983) (the state was not subject to the Commerce Clause in limiting its construction projects to firms that employ 50% Boston residents); *Reeves Inc. v. Stakes*, 447 U.S. 429 (1980) (the Court allowed South Dakota to sell its cement only to South Dakota residents).

81. *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 96-98 (1984).

82. *Id.*

83. *Commissioner*, at 8.

84. *Id.* at 9. Referring to distributors buying drugs from manufacturers located outside of Maine. The lower court stated that "the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." *Id.*

85. *Id.* at 9-10.

86. *Id.* at 9.

preempted by federal Medicaid law.<sup>87</sup> Since federal law did not expressly forbid the type of program that Maine passed, the court had to determine if there was implied preemption, essentially if Maine's legislation was inconsistent with Medicaid objectives.<sup>88</sup> The federal statute the court relied on states that drug distribution must "provide such safeguards as may be necessary to assure that . . . care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients."<sup>89</sup> The court determined that the program was inconsistent with Medicaid objectives since Congress had not suggested that the federal Medicaid program could be used to further the interests of non-Medicaid recipients.<sup>90</sup> The court held that "no matter how modest an obstacle the new prior authorization amounts to, it is an obstacle--drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed or prescribed."<sup>91</sup> The court reasoned that even if the Maine Rx Program would "not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy" it was preempted nonetheless.<sup>92</sup>

## 2. First Circuit Court of Appeals: Pharmaceutical Research and Manufacturers of America v. Concannon

A three-panel judge sitting for the First Circuit Court of Appeals in Boston, vacated the preliminary injunction based upon their conclusion that there was no conflict between the Medicaid Act and the Maine Rx Program since PhRMA did not establish that prior authorization would likely harm Medicaid recipients.<sup>93</sup> The court also concluded that Maine's statute did not violate the dormant Commerce Clause.<sup>94</sup>

The court of appeals first examined whether or not the prior

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87. *Id.* at 11.

88. *Id.*

89. *Id.* at 12 (quoting 42 U.S.C.A. § 1396a(a)(19) (West 2002)).

90. *Id.* at 12.

91. *Id.* at 13.

92. *Id.* at 12 (quoting Def. Mem. in Opp'n to Mot. for Prelim. Inj. at 29).

93. *Concannon*, 249 F.3d at 85.

94. *Id.*

authorization requirement conflicted with the purposes of the Medicaid program so as to violate the Supremacy Clause. Unlike the district court, the appeals court found “no conflict between the Maine Act and Medicaid’s structure and purpose.”<sup>95</sup> The court based its decision on the fact that the Medicaid statute explicitly permits covered outpatient drugs to be subject to prior authorization.<sup>96</sup> The court reasoned that Maine could subject all drugs in their Medicaid program to prior authorization if it so desired. The court found compelling the fact that when a state’s Medicaid Drug Utilization Review Committee subjects a drug to prior authorization they are guided by the principle that Medicaid recipients must be assured access to all medically necessary prescription drugs.<sup>97</sup>

The court dismissed PhRMA’s argument that interference, in this case prior authorization, is tolerable when performed within the confines of the Medicaid program, but unacceptable when used to motivate manufacturers for another program. The court concluded that the Medicaid statute “is [not] concerned with the motivation behind imposing prior authorization” as long as the program complies with the prior authorization guidelines.<sup>98</sup> Second, the court reasoned that even if motivation plays a role, there were still Medicaid purposes that the Maine Rx Program fulfilled. This reasoning negates the district court’s contention that “if Maine can use its authorization over Medicaid authorization to leverage drug manufacturers’ rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into a state program for highway and bridge construction or school funding.”<sup>99</sup> The appeals court laid out several Medicaid purposes that the Maine Rx legislation could have potentially accomplished which are discussed in full in Part III of this article.<sup>100</sup>

The court, after holding that the Maine Act was not preempted by

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95. *Id.* at 75.

96. *Id.* (citing 42 U.S.C.A. § 1396r-8(1)(A) (West 2002)).

97. *Id.* at 76. Kevin Concannon, the Commissioner of the Maine Department of Human Services, affirmed in an affidavit that the Department would not impose prior authorization that would conflict with the Medicaid requirements. *Id.*

98. *Id.* at 76.

99. *Commissioner*, at 13.

100. *Concannon*, 249 F.3d at 76; see *infra* Part III and accompanying notes.



the Medicaid statute, considered PhRMA's Commerce Clause challenge.<sup>101</sup> Unlike the district court, the appeals court distinguished the three cases that PhRMA relied upon (*Seelig*, *Healy and Brown-Forman*) as involving price control, price affirmation or price tying schemes unlike the Maine statute.<sup>102</sup> The court stated that the Maine Rx Program did not interfere with regulatory schemes in other states, but ultimately would have regulated activity that occurred in Maine. Unlike the statutes from these cases, Maine neither "requires the rebate to be a certain amount dependent upon the price of prescription drugs in other states," nor "impose[s] direct controls on a transaction that occurs wholly out-of-state."<sup>103</sup> The court concluded that there was no extraterritorial reach and therefore the program was not per se invalid under the Commerce Clause.<sup>104</sup>

After rejecting PhRMA's per se invalidation claim, the court considered if the statute still violated the Commerce Clause under the *Pike* balancing test.<sup>105</sup> The *Pike* balancing test is applied when a "statute regulates evenhandedly and has only incidental effects on interstate commerce."<sup>106</sup> Under the test, the court had to weigh the possible putative local benefits advanced by the statute against any possible burdens placed on interstate commerce.<sup>107</sup> The court identified the potential loss of profits for manufactures as one potential burden, but noted several possible local benefits including increased access to prescription drugs for citizens who could otherwise not afford them.<sup>108</sup>

The court of appeals lifted the injunction placed by the lower court since it concluded that PhRMA was not likely to succeed on the

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101. *Id.* at 79.

102. *Id.* at 81.

103. *Id.* at 82.

104. *Id.*

105. *Id.* at 83. The district court did not apply the test since it concluded that the statute was a per se violation of the Commerce Clause. *Id.*

106. *Concannon*, 249 F. 3d at 83.

107. *Id.* at 83-84 (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)). The court recognized the "difficulty in foreseeing what events actually will occur" and noted that this uncertainty made the *Pike* balancing test more challenging to apply. *Id.* at 84.

108. *Id.* at 84.

merits of their claims.<sup>109</sup> PhRMA petitioned the Supreme Court for review and the Court granted certiorari in June 2002.<sup>110</sup>

### III. ANALYSIS OF THE OPINION

On May 19, 2003, in a six to three decision, the Supreme Court affirmed the judgment of the appeals court and lifted the injunction against the Maine Rx Program.<sup>111</sup> Although most of the Justices agreed with the court of appeals, their justifications were diverse. Justice Stevens wrote the opinion of the court, and Justices Breyer, Scalia, and Thomas contributed concurring opinions for specific parts of the opinion.

In Parts I and II of the opinion, Justice Stevens summarized the Maine Rx Program, focusing on the prior authorization component, including the backdrop of rising prescription drug costs.<sup>112</sup> He noted that states, such as California and Georgia, as early as 1982 put in place prior authorization requirements in their Medicaid programs.<sup>113</sup> Since there were no federal laws or regulations concerning prior authorization, states included their prior authorization components in their Medicaid plans that were approved by the Secretary of the Department of Health and Human Services (HHS).<sup>114</sup> Congress sanctioned the practice of prior authorization when it created an amendment contained in the Omnibus Budget Reconciliation Act in 1990.<sup>115</sup> Since 1990, section 42 U.S.C. § 1396r-8(d)(1)(A) explicitly allows state Medicaid plans to have prior authorization components.<sup>116</sup>

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109. *Id.* at 84-85.

110. *Walsh*, 123 S. Ct. at 1860.

111. *Id.* at 1871.

112. *Id.* at 1861-63.

113. *Id.* at 1861. *See also* *Dodson v. Parham*, 427 F.Supp. 97, 100-01 (N.D. Ga. 1997); *Cowan v. Myers*, 232 Cal. Rptr. 299, 301-02 (Cal. Ct. App. 1986).

114. *Walsh*, 123 S. Ct. at 1861.

115. *Id.* (citing Omnibus Reconciliation Act of 1990, 104 Stat. 1388 (1990)).

116. 42 U.S.C.A. § 1396r-8(d)(1)(A), (5) (West 2002).

## A. Prior Authorization

### 1. Justice Stevens' Plurality Opinion

Justice Stevens, joined by Justices Souter, Ginsberg and Breyer, pointed out in Part IV of the opinion that because the Court was reviewing for an abuse of discretion concerning a preliminary injunction, the Court's decision did not determine the ultimate validity of the Maine Rx Program since there were no evidentiary hearings or fact findings.<sup>117</sup> Justice Stevens further tempered his opinion with the warning that "no matter how we answer the question whether petitioner's showing was sufficient to support the [preliminary] injunction, further proceedings in this case may lead to a contrary result."<sup>118</sup> "Further proceedings" includes a final ruling by the Secretary of Health and Human Services.<sup>119</sup> The issue before the Court concerned a preliminary injunction, and is "different from the question that would be presented if the Secretary, after a hearing, had held that the Maine Rx Program was an impermissible amendment of its Medicaid Plan."<sup>120</sup> Justice Stevens noted that a future determination by the Secretary that subjecting drugs to prior authorization under Maine's Medicaid program in order to secure rebates for the Maine Rx Program is impermissible, would be "presumptively valid."<sup>121</sup> But the Court could not rely upon an evidentiary hearing or a ruling by the Secretary, therefore the issue before the Court was "whether there is a probability that Maine's program was pre-empted by the federal statute's mere existence."<sup>122</sup>

In Part V of the opinion, Justice Stevens, joined by Justices Souter and Ginsburg, noted that the district court awarded the injunction because potential interference with the delivery of Medicaid benefits, without any benefit to the federal program, is prohibited by federal statute according to the doctrine of obstacle

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117. *Walsh*, 123 S. Ct. at 1866.

118. *Id.*

119. *Id.*

120. *Id.* at 1866-67.

121. *Id.* at 1867.

122. *Id.*

preemption.<sup>123</sup> The district court looked to the fact that Maine had “failed to identify any ‘Medicaid purpose’ in its new authorization requirement.”<sup>124</sup> Congressional intent is embodied in federal Medicaid law that requires state plans to comply with numerous requirements, including that they “provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients.”<sup>125</sup> However, Maine did not offer a Medicaid purpose because they thought it unnecessary since federal law already permitted Medicaid programs to have a prior authorization component.<sup>126</sup> Justice Stevens wrote that the district court erroneously relied on a waiver theory. PhRMA had the “burden of establishing, by a clear showing, a probability of success on the merits.”<sup>127</sup> It was PhRMA's burden to show that there was no Medicaid-related goal or purpose served by the Maine Rx Program.<sup>128</sup>

Justice Stevens remarked that the court of appeals identified two Medicaid-related purposes that the Maine Rx Program may have served.<sup>129</sup> First, the program would have provided lower priced pharmaceuticals to people who can be described as “medically needy” even if they do not qualify for Medicaid.<sup>130</sup> Second, the Maine Rx Program had the potential to lower Medicaid costs by enabling uninsured people to purchase prescription medicines.<sup>131</sup> Access to medications could prevent conditions from worsening and prevent further financial hardship making it less likely that Maine

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123. *Id.*

124. *Id.* (emphasis in the original).

125. 42 U.S.C.A. § 1396a(a)(19) (West 2002).

126. *Walsh*, 123 S. Ct. at 1867. *See also supra* note 116.

127. *Walsh*, 123 S. Ct. at 1867.

128. *Id.*

129. *Id.*

130. *Id.* The court acknowledged that there was “some factual dispute concerning the extent to which the program will also benefit no needy persons” *Id.* However, the court dismissed this concern since “the potential benefits for no needy persons would not nullify the benefits that would be provided to the neediest segment of the uninsured population.” *Id.*

131. *Id.*

residents would end up in the Medicaid program and require more expensive treatments.<sup>132</sup> Justice Stevens also noted that "[a] third rather obvious Medicaid purpose" is that prior authorization in the Medicaid program can protect beneficiaries from inappropriate prescriptions and save money by promoting the use of the most cost-effective prescription drugs.<sup>133</sup>

However, potential benefits to the Medicaid program would not justify the Maine Rx Program if it "severely curtailed Medicaid recipients' access to prescription drugs."<sup>134</sup> Justice Stevens wrote that it was appropriate for the district court to assume that the prior authorization component would fully comply with federal requirements of Medicaid and not severely curtail Medicaid recipients' access to prescription drugs.<sup>135</sup>

In addition, Justice Stevens noted that states do not have to be motivated by Medicaid-related goals in choosing the contours of their Medicaid program.<sup>136</sup> He wrote that states have "substantial discretion to choose the proper mix of amount, scope and duration limitations on coverage"<sup>137</sup> and the motivation of a state policy does not limit this scope.<sup>138</sup> For example, Pennsylvania can choose to exclude abortions from its Medicaid program based upon their state

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132. *Id.* at 1867-68.

133. *Walsh*, 123 S. Ct. at 1868. A doctor who testified for Maine stated that prior authorization can "ensure proper use of prescription drugs with a high potential for inappropriate use" and "encourage the use of cost-effective medications without diminishing safety or efficacy." *Id.* at 1864 n.23.

134. *Id.* at 1868.

135. *Id.* at 1869 The Court allowed the assumption even though in prior cases, the district court had made a fact finding that the state's Medicaid "care and services [were] provided in the 'best interest of the recipients.'" *Id.* (quoting *Alexander v. Choate*, 469 U.S. 287, 303 (1985) (quoting 42 U.S.C. § 1396a(a)(19)). The Medicaid Act allows states to "choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in 'the best interest of the recipients.'" *Id.* In *Alexander*, the Court examined a Tennessee Medicaid measure that reduced the number of annual inpatient hospital days and found that the reduction did not deny beneficiaries "meaningful access to medical services." *Alexander*, 469 U.S. at 302-03.

136. *Walsh*, 123 S. Ct. at 1869.

137. *Id.* (citing *Alexander*, 469 U.S. at 303).

138. *Id.*

policy interest in encouraging normal childbirth.<sup>139</sup> Likewise, Maine's state policy interest in protecting the health of its uninsured residents provides a justification for prior authorization since the Medicaid Act contains no "categorical prohibition against reliance on state interests unrelated to the Medicaid program itself."<sup>140</sup>

Justice Stevens stated that it was improper for the district court to impose an injunction against the Maine Rx Program on the determination that federal Medicaid law preempts the program as long as the prior authorization component posed some obstacle, no matter how modest, to realizing federal Medicaid goals.<sup>141</sup> A modest impediment to the accessibility of prescription drugs does not provide a sufficient basis for preemption of the Maine Rx Program.<sup>142</sup> Justice Stevens refers to the rule from *New York State Department of Social Services v. Dublino*.<sup>143</sup> In that case, there was a preemption challenge to a state statute that imposed employment requirements as conditions for continued eligibility for Aid to Families with Dependent Children (AFDC) benefits that went beyond the federal requirements.<sup>144</sup> The mere fact that the New York program imposed a nonfederal obstacle to continued eligibility for benefits did not provide a sufficient basis for preemption.<sup>145</sup> The Court wrote in *Dublino* that "[t]he problems confronting our society in these areas are severe, and state governments, in cooperation with the Federal Government, must be allowed considerable latitude in attempting their resolution."<sup>146</sup>

Justice Stevens then concluded Part V with a reiteration that the question of whether the Secretary's approval must be sought before the Maine Rx Program may go into effect was not before the Court.<sup>147</sup> He repeated that the Court offered no opinion as to whether

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139. *Id.* (citing *Beal v. Doe*, 432 U.S. 438, 445 (1977)).

140. *Id.*

141. *Id.* at 1870.

142. *Id.*

143. *Walsh*, 123 S. Ct. at 1869 (citing *New York State Dept. of Soc. Servs. v. Dublino*, 413 U.S. 405, 421 (1973)).

144. *Id.*

145. *Id.*

146. *Id.* (quoting *Dublino*, 413 U.S. at 413).

147. *Id.* at 1870.

it would be appropriate for the Secretary to approve or disapprove the Maine Rx Program.<sup>148</sup>

## 2. Justice Breyer's Concurring Opinion

Justice Breyer concurred in part and concurred in the judgment. In Justice Breyer's concurring opinion, he agreed with Justices Stevens, Souter and Ginsburg that a modest impediment standard was too low, but added that in order for PhRMA to prevail, they must demonstrate that Maine's program would seriously compromise important federal interests.<sup>149</sup> Therefore, the district court could not award an injunction to PhRMA simply by the showing that there may be a modest harm.<sup>150</sup> Justice Breyer noted that Congress "would not have intended to forbid prior authorization programs virtually *per se*—*i.e.*, on the showing of slight harm—even if no specific Medicaid-related benefit is apparent in a particular case."<sup>151</sup> He believed the injunction should be vacated since there was no in-depth examination of the Medicaid-related benefits and harms.<sup>152</sup> Justice Breyer commented that the Medicaid statute provides the framework for the analysis since it requires states to file their Medicaid plans for the Secretary's approval.<sup>153</sup>

Justice Breyer also suggested that the doctrine of primary jurisdiction should be invoked.<sup>154</sup> The doctrine of primary jurisdiction would allow the district court to refer the question to the

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148. *Walsh*, 123 S. Ct. at 1870.

149. *Id.* at 1872 (citing *Arkansas Elec. Cooperative Corp. v. Arkansas Pub. Serv. Comm'n*, 461 U.S. 374, 389 (1983)).

150. *Id.*

151. *Id.* (emphasis in the original).

152. *Id.*

153. *Walsh*, 123 S. Ct. at 1872.

154. *Id.* at 1873 (citing *United States v. Western Pacific R.R. Co.*, 352 U.S. 59, 63-65 (1956)). See also *Farmers Ins. Exch. v. Superior Court*, 826 P.2d 730, 735-42 (Cal. 1992). *Farmers Insurance Exchange* refers to two policy goals of invoking primary jurisdiction 1) to promote uniformity, and 2) the need for the agency's expertise. *Id.* at 737. The court also noted the doctrine serves a procedural goal as well since agency approval of a disputed practice may put an end to the conflict. *Id.*

Secretary.<sup>155</sup> Primary jurisdiction "seeks to produce better informed and uniform legal rulings by allowing courts to take advantage of an agency's specialized knowledge, expertise, and central position within a regulatory regime."<sup>156</sup> The HHS is institutionally better able to determine harm that may be caused to Medicaid beneficiaries and determine if the Maine Rx Program can further Medicaid-related goals.<sup>157</sup> The law would then grant significant weight to the Secretary's conclusions under *Chevron U.S.A. Inc., v. Natural Resources Defense Council, Inc.*<sup>158</sup>

### 3. Justice Scalia's Concurring Opinion

Justice Scalia also wrote a concurring opinion.<sup>159</sup> His opinion stated rather simply that PhRMA's remedy for Maine's failure to comply with the obligations it has agreed to undertake under the Medicaid Act is set forth in the statute itself.<sup>160</sup> PhRMA must seek enforcement of the Medicaid conditions by the HHS. He concluded his opinion by stating that PhRMA "may seek and obtain relief in the courts only when the denial of enforcement is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'"<sup>161</sup>

### 4. Justice Thomas's Concurring Opinion

Justice Thomas concurred in the judgment to overturn the injunction, but he wrote that the plurality glossed over the Medicaid

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155. *Walsh*, 123 S. Ct. at 1873.

156. *Id.*

157. *Id.* at 1872.

158. *Id.* (citing *Chevron U.S.A., Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837, (1984). See also *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). In *Chevron*, the Court held that "federal judges . . . have a duty to respect legitimate policy choices made by those who [have a constituency]." *Chevron*, 467 U.S. at 866. The Constitution vests the political branches with "[t]he responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest." *Id.*

159. *Walsh*, 123 S. Ct. at 1873.

160. *Id.* at 1874.

161. *Id.* at 1874 (quoting 5 U.S.C.A. § 706(2)(A) (West 2003)).



Act's complexity.<sup>162</sup> The Medicaid Act "represents a delicate balance Congress struck between competing interests—care and cost, mandates and flexibility, oversight and discretion."<sup>163</sup> Justice Thomas wrote that while PhRMA relies on federal law section 42 U.S.C. § 1396a(a)(19), which refers to the best interests of the recipients standard, there are other competing purposes such as cost control and the need for states to possess broad discretion in order to control access to prescription drugs.<sup>165</sup> Justice Thomas noted that it is too difficult to invoke obstacle preemption based upon an arbitrary selection of one purpose to the exclusion of others.<sup>166</sup> He determined that it is impossible to define purposes in "complex statutes at such a high level of abstraction."<sup>167</sup> Justice Thomas argued that "[b]oth the plurality and the dissent fail to explain how a State's purpose (and there may be many) in enacting a prior authorization program makes any difference in determining whether that program is in the 'best interests' of Medicaid beneficiaries".<sup>168</sup> He believed that a focus on the subjective intent of the state legislature in enacting the Maine Rx Program is an "irrelevant question."<sup>169</sup>

Justice Thomas then argued that the plurality and dissent did not give proper credence to the role of the Secretary.<sup>170</sup> The Secretary's mandate from Congress "is to conduct, with greater expertise and resources than courts, the inquiry into whether Maine Rx upsets the

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162. *Id.*

163. *Id.* at 1874.

165. *Walsh*, 123 S. Ct. at 1874.

166. *Id.* See also Note, *The Supreme Court, 2002 Term Leading Cases, Federal Statutes & Regulations*, 117 HARV. L. Rev. 449, 449-50 (2003). The note stated that "[w]hile most of the Justices were willing to compare the purposes behind the state and federal laws in deciding the preemption question, Justices Scalia and Thomas came up with an intriguing joinder." *Id.* The Justices determined that "because the federal Medicaid statute expressly authorizes the Secretary of Health and Human Services to approve or reject state Medicaid plans, courts lack authority to determine whether a state's plan poses an obstacle to the federal program's purposes." *Id.* The authority for such a determination "belongs instead to the Secretary." *Id.*

167. *Walsh*, 123 S. Ct. at 1874.

168. *Id.* (quoting 42 U.S.C.A. § 1396(a)(19) (West 2002)).

169. *Id.* at 1876.

170. *Id.*

balance contemplated by the Medicaid Act."<sup>171</sup> Justice Thomas noted that PhRMA should only seek judicial review if the Secretary approves the plan, like PhRMA has done in previous cases.<sup>172</sup> Thomas believed that the Court cannot use obstacle pre-emption to determine whether or not the Maine Rx Program serves Medicaid goals, stating "'it is Congress rather than the courts that pre-empts state law.'"<sup>173</sup>

In closing, Justice Thomas also raised the issue that based upon a contracts analogy and the Spending Clause, PhRMA has no standing to challenge the legislation, but noted that Maine did not pursue this type of challenge.<sup>174</sup> Under contract law, a third party can only sue if they are the intended beneficiary of the contract.<sup>175</sup> Therefore, Justice Thomas argued that PhRMA cannot challenge the law since PhRMA is not a beneficiary to the contract.<sup>176</sup>

#### 5. Justice O'Connor's Concurrence in part and Dissent in part Opinion

Justice O'Connor, joined by Chief Justice Rehnquist and Justice Kennedy, wrote an opinion concurring in part and dissenting in part with the majority opinion. Justice O'Connor agrees with the plurality that Maine cannot impose prior authorization without a Medicaid purpose.<sup>177</sup> She wrote that the starting point for a preemption analysis is determining Congressional intent.<sup>178</sup> Unlike Justice Thomas who believed that the subjective intent of Maine in imposing prior authorization was an irrelevant question, the dissent believed that intent controlled the case. Justice O'Connor stated the only

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171. *Id.* at 1877.

172. *Id.*; see also *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F.Supp.2d 39 (D.D.C. 2003).

173. *Walsh*, 123 S. Ct. at 1877-78 (quoting *Gade v. Nat'l Solid Waste Mgmt. Assn.*, 505 U.S. 88, 111 (1996)).

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.*

178. *Id.*

181. *Id.* at 1879.

purpose which can motivate a state to impose prior authorization is to reduce Medicaid costs, not to "generate revenue for purposes wholly unrelated to its Medicaid program."<sup>181</sup> She then concluded that although the Medicaid Act does not expressly prescribe that states cannot use prior authorization to accomplish goals for their non-Medicaid population, it is nonetheless an inherent prohibition in the structure of the Medicaid Act.<sup>182</sup>

Justice O'Connor and the other dissenting Justices did not believe it was an abuse of discretion for the district court to rule in favor of PhRMA.<sup>183</sup> An injunction was proper because, unlike the Court of Appeals, it was not the district court's *sua sponte* responsibility to brainstorm potential Medicaid-related purposes.<sup>184</sup> The plurality presented three possible Medicaid-related purposes that the Maine Rx Program may have furthered. The first two possible Medicaid-related purposes were that 1) people who do not qualify for Medicaid, but need coverage, will have access to medical benefits, and 2) Medicaid costs can be lowered if people have access to prescription drugs, thereby reducing the chance that they will end up in the Medicaid program needing more expensive treatments.<sup>185</sup> However, Justice O'Connor argued that this claim is an "attenuated causal chain" that was not presented before the district court.<sup>186</sup> The dissent also noted that the plurality's third potential Medicaid-related purpose lacked facts to support it in the record.<sup>187</sup> The plurality stated that the Maine Rx Program will necessarily produce cost savings for Maine's Medicaid program.<sup>188</sup> However, Justice O'Connor wrote that this conclusion is flawed since unlike prior authorization programs which are based upon efficacy and cost-effectiveness, the prior authorization component in this case would be solely based upon a manufacturer refusing a rebate agreement with the state.<sup>189</sup>

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182. *Id.* at 1879.

183. *Id.* at 1878.

184. *Id.* at 1881.

185. *Id.* at 1880-81.

186. *Id.* at 1881.

187. *Id.*

188. *Id.*

189. *Id.*

The dissent concluded their opinion with the statement that the district court had before it "concrete evidence of the burdens that Maine Rx's prior-authorization requirement would impose on Medicaid beneficiaries."<sup>190</sup> However, the district court had no evidence about potential Medicaid-related purposes. Therefore, the court did not abuse its discretion in enjoining the Maine Rx Program.<sup>191</sup>

### *B. Dormant Commerce Clause*

In Part VI of the opinion, Justice Stevens, joined by Chief Justice Rehnquist and Justices O'Connor, Kennedy, Souter, Ginsburg and Breyer, examined PhRMA's Commerce Clause challenge regarding the rebate agreement component of the Maine Rx Program. PhRMA argued that the rebate requirement constituted impermissible extraterritorial regulation and that it also discriminated against interstate commerce in order to subsidize in-state retail sales.<sup>192</sup> The Court did not find either of these arguments to be persuasive.<sup>193</sup>

The Court agreed with the court of appeals that "unlike price control or price affirmation statutes, 'the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect.'"<sup>194</sup> The Court also examined *West Lynn Creamery, Inc. v. Healy* for its applicability to the present case.<sup>195</sup> In *West Lynn*, the Court examined a Massachusetts statute that imposed an assessment on all milk sold by dealers to in-state retailers which was then distributed to Massachusetts dairy farmers.<sup>196</sup> The Court held that the statute "imposed a tax on out-of-state producers to subsidize production by their in-state competitors" and thus violated the Commerce Clause because of its discriminatory effect.<sup>197</sup> Unlike *West Lynn*, however, the Court held that the Maine Rx Program

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190. *Id.*

191. *Id.* at 1881-82.

192. *Id.* at 1857.

193. *Id.*

194. *Id.* at 1871.

195. *Id.* (citing *W. Lynn Creamery, Inc., v. Healy*, 512 U.S. 186 (1994)).

196. *Healy*, 512 U.S. at 186.

197. *Walsh*, 123 S. Ct. at 1871.

would not impose a disparate burden on any competitors. Justice Stevens concluded that “[a] manufacturer could not avoid its rebate obligation by opening production facilities in Maine and would receive no benefit from the rebates even if it did so.”<sup>198</sup>

Justice Scalia also concurred in rejecting PhRMA’s Commerce Clause challenge.<sup>199</sup> He opined that the dormant Commerce Clause has no text in the Constitution and “not lending itself to judicial application except in the invalidation of facially discriminatory action, should not be extended beyond such action and nondiscriminatory action of the precise sort hitherto invalidated.”<sup>200</sup>

#### IV. IMPACT

##### A. *The Maine Rx Plus Program*

Two weeks after the Supreme Court lifted the injunction placed against the Maine Rx Program, Governor John Baldacci unveiled a revised program named Maine Rx Plus.<sup>201</sup> Maine Rx Plus should go into effect in January 2004.<sup>202</sup> The Maine Rx Program was not revised, but rather completely revamped. The new Maine Rx Plus Program limits eligibility to individuals with incomes under 350% of the federal poverty level, instead of the sweeping eligibility of the former Maine Rx Program.<sup>203</sup> Additionally, the program is no longer tied to Medicaid by a prior authorization component. Instead, it permits participants to buy all drugs on the state's Medicaid preferred drug list at Medicaid cost. The program is entirely funded by the state. Maine estimates that 275,000 residents in 2004 will receive

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198. *Id.* For a more in-depth treatment of PhRMA's dormant Commerce Clause challenge see Brannon P. Denning, *The Maine Rx Prescription Drug Plan and the Dormant Commerce Clause Doctrine: The Case of the Missing Link[age]*, 29 AM. J.L. & MED. 7 (2003).

199. *Walsh*, 123 S. Ct. at 1873.

200. *Id.* at 1873-74.

201. Meg Haskell, *Maine Rx Plus Ready to Roll*, BANGOR DAILY NEWS, Jan. 14, 2004, available at [http://www.bangornews.com/editorialnews/articles/415082\\_011404mainerxplusready\\_mhaskell.cfm](http://www.bangornews.com/editorialnews/articles/415082_011404mainerxplusready_mhaskell.cfm).

202. *Id.*

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

discounts of up to 25% on name brand prescription drugs and 60% on generic prescription drugs.<sup>204</sup>

As soon as the Supreme Court lifted the injunction, predictions were not favorable that Tommy Thompson, Secretary of the Department of Health and Human Services, would approve the Maine Rx Program.<sup>205</sup> In a brief filed by the United States, the government argued that the prior authorization provision of the Maine Rx Program was invalid because the program was not tailored to low-income individuals, but was open to all Maine residents regardless of their financial or medical need.<sup>206</sup> Securities analysts predicted that if the brief was any indication of where Thompson stood on the issue, the odds appeared better than fifty-fifty that he would probably rule against the Maine Rx Program or at least tighten eligibility requirements.<sup>207</sup> Further, even if Thompson had been given a chance to approve the program, it would not have been protected from future legal battles. Indeed, PhRMA filed an amended suit September 25, 2003, in Maine District Court, where it continued to argue that Maine's plan violated the federal Medicaid statute because it offered no benefits to Medicaid beneficiaries.<sup>208</sup>

### B. A Federal Solution?

Maine citizens claim that measures such as the Maine Rx Plus Program, are not a real solution.<sup>209</sup> Legislators said that despite the recent passage of the Maine Rx Plus that was put into place to help

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204. FDA News.com, *Maine Rx Plus Launches; PhRMA Mounts New Challenge* (Jan. 28, 2004), available at [http://www.fdanews.com/cgi-bin/udt/sc.display.ppv?client\\_id=fdanews&inv\\_id=9035&sid=20943&view=V](http://www.fdanews.com/cgi-bin/udt/sc.display.ppv?client_id=fdanews&inv_id=9035&sid=20943&view=V).

205. THE KAISER FAMILY FOUND., *Prescription Drugs/Drug Companies Believe HHS Could Impose Limits on Maine Rx* (May 21, 2003), available at [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=17841](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=17841).

206. Brief for the United States as Amiciae Curiae at 20, *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001) (No. 31156279).

207. THE KAISER FAMILY FOUND., *supra* note 205.

208. FDA News.com, *supra* note 204..

209. The Maine Senate, *Maine Counsel of Senior Citizens Organizes Prescription Drug Bus Trip to Canada* (Nov. 4, 2003), available at <http://www.mainesenate.org/Press/2003-11-04%20RX%20Bus%20Trip%20to%20Canada.html>.

seniors and others seeking more affordable prescription drugs and health care, that “action at the federal level is needed to complete the job that Maine lawmakers have started.”<sup>210</sup> Senate Majority leader and sponsor of the revised program stated that “Maine legislators and the Governor have led the way nationally in acting to reduce drug prices, but we can’t do it alone. It’s time for the federal government to step up to the plate and take action.”<sup>211</sup>

Other states want solutions as well. In 2002, Shawna Woodward concluded her article about states waiting for the outcome of Maine’s program with the following quote: “[n]ow that the appeals court has wiped away the stigma of unconstitutionality, we expect the Maine approach to move like wildfire across the country.”<sup>212</sup> The prediction was correct as prescription drug policy remained at the forefront of state legislative agendas in 2003. During last year’s legislative session, forty-nine states had 290 bills pending that concerned some aspect of prescription drugs.<sup>213</sup> In addition, twenty-five states considered non-binding resolutions urging the U.S. Congress to take action.<sup>214</sup>

All sides of the debate, including PhRMA, state governments and consumers, have urged for a solution at the federal level. In a statement from Marjorie Powell, spokesperson for the PhRMA, she stated that “[r]eal solutions that help rather than hurt patients begin with passing a Medicare prescription drug benefit for seniors and disabled persons this year.”<sup>215</sup> Many believe that Medicare, rather than Medicaid, should “play the key role in providing prescription

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210. *Id.*

211. *Id.*

212. Shawna Lydon Woodward, *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, 194 (2002) (citing Physicians For a Nat’l Health Prog., *Court Rules in Favor of Maine Rx Price Controls*, at [http://www.pnhp.org/Press/2001/court\\_rules\\_6\\_4\\_01.htm](http://www.pnhp.org/Press/2001/court_rules_6_4_01.htm)).

213. Nat’l Conference of State Legislators, *2003 Prescription Drug State Legislation* (Jan. 22, 2004), available at <http://www.ncsl.org/programs/health/drugdisc03.htm>.

214. *Id.*

215. Press Release, PhRMA, Marjorie Powell, spokesperson for the PhRMA regarding the Supreme Court’s Ruling in *PhRMA v. Walsh* (May 19, 2003) available at <http://www.phrma.org/mediaroom/press/releases/19.05.2003.731.cfm>.

drug coverage to Medicare beneficiaries.”<sup>216</sup> Time will tell if the Medicare prescription drug bill signed into law by President Bush on December 8, 2003 is the cure.<sup>217</sup>

## V. CONCLUSION

How valuable are the lessons from *Pharmaceutical Research and Manufacturers of America v. Walsh*? After all, there was no majority opinion concerning the issue of preemption, and no evidentiary fact-finding since the Supreme Court reviewed an injunction put in place by the district court. Justice Stevens also tempered his opinion by stating “we offer no view as to whether it would be appropriate for the Secretary to disapprove this program if Maine had asked the Secretary to review it.”<sup>218</sup>

Nonetheless, if nothing else comes from *Walsh*, it has kept the nation discussing and brainstorming new solutions regarding prescription drugs. In America's other drug war, where important values are pitted against each other, including access versus innovation and free enterprise versus governmental assistance, it remains to be seen what a lasting solution will look like at the end of the day. The good news is that the Court's decision was in line with Justice Brandeis's quote, “[t]o stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation.”<sup>219</sup> There is no question that the issue of prescription drugs will not fade away.

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216. THE KAISER FAMILY FOUND., *Implications of the New Medicare Prescription Drug Benefit for State Medicaid Budgets* (May 2003), available at <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspots/security/getfile.cfm&PageID=14267>.

217. *Id.*

218. *Walsh*, 123 S. Ct. at 1870.

219. *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 85 (1st Cir. 2001) (quoting *New State Ice. Co. v. Liebermann*, 285 U.S. 262, 310 (1932) (Brandeis, J., dissenting)).



