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***Pharmaceutical Research and Manufacturers of America v. Walsh: The Supreme Court Allows the States To Proceed with Expanding Access to Drugs***

**Timothy Stoltzfus Jost, J.D.\***

INTRODUCTION

On May 19, 2003, the Supreme Court in *Pharmaceutical Research and Manufacturers of America v. Walsh* affirmed a court of appeals decision allowing for the implementation of the Maine Act to Establish Fairer Pricing for Prescription Drugs.<sup>1</sup> The Maine program attempted to leverage the considerable market power of the Medicaid program to force drug companies to offer the state a discount on pharmaceuticals. The state in turn would pass the savings on to its uninsured residents. Manufacturers that refused to negotiate a discount with the state would face the prospect of their products being available to Maine Medicaid recipients only with prior authorization, resulting in a considerable loss of market share for these manufacturers.<sup>2</sup>

The *Walsh* case permits states to use the market power they wield through their Medicaid programs to make prescription drugs more affordable to their residents, albeit subject to some constraints. The Court decisively rejected a broad constitutional challenge to the Maine program based on the prohibition against state interference with interstate commerce.<sup>3</sup> Had this challenge succeeded, it would have put at risk a wide range of state pharmaceutical programs. The badly splintered Court left unclear, however, the precise conditions under which states may use their Medicaid market power to benefit residents not covered by Medicaid. The Court established only that the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association that brought

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1. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. 1855 (2003).

2. 123 S.Ct. at 1863-64.

3. 123 S.Ct. at 1870-71.

the case, had not yet proven that the Maine program violated the Medicaid statute by imposing a state requirement lacking a “Medicaid purpose.”<sup>4</sup> The Court also suggested that states might do well to consult the Department of Health and Human Services (HHS) before proceeding with Medicaid-related drug programs.<sup>5</sup>

This Article begins by examining the scope and seriousness of the pharmaceutical access problem in America. It proceeds to describe briefly the range of programs that state governments currently employ or are considering to address this problem. Next, it discusses the opportunities states have to leverage their Medicaid market power to expand drug access among non-recipients of Medicaid. It then examines the Court’s decision in *Walsh* and how it affects these programs. The Article concludes by considering additional possibilities the *Walsh* decision opens up for states to expand access to drugs.

#### I. THE PROBLEM: MANY AMERICANS CANNOT AFFORD DRUGS

The problem addressed by the Maine program is a familiar one: The cost of pharmaceuticals has risen dramatically in the recent past. Expenditures for retail prescription drugs increased 16.4% in 2000 and another 15.7% in 2001, and are expected to increase at double-digit rates through the rest of this decade.<sup>6</sup> While drugs still represent a relatively small fraction of national health care expenditures (a little over 10%), the burden of drug costs falls disproportionately on a small number of individuals, most notably those with chronic diseases.<sup>7</sup> The median per capita drug expenditure for elderly persons in 1998 was \$895, but for the highest-spending one percent it was \$6,597.<sup>8</sup> The high cost of drugs often results in the inability of individuals to obtain needed medications. A recent eight-state study of Medicare beneficiaries found that 25% of uninsured beneficiaries failed to fill at least one prescription during 2001 due to cost, 27% skipped doses to make their medications last longer, and

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4. 123 S.Ct. at 1867-70.

5. 123 S.Ct. at 1870.

6. Stephen Heffler et al., *Health Spending Projections for 2001-2001: The Latest Outlook*, 21 HEALTH AFF. 207, 209 (2002); Katherine Levit et al., *Trends in U.S. Health Care Spending, 2001*, 22 HEALTH AFF. 154, 156 (2003).

7. John A. Poisal & Lauren Murray, *Growing Differences Between Medicare Beneficiaries with and Without Drug Coverage*, 29 HEALTH AFF. 74, 80 (2001).

8. Uwe Reinhardt, *Perspectives on the Pharmaceutical Industry*, 20 HEALTH AFF. 136, 140 (2001).

20% spent less on other basic needs to afford prescription drugs.<sup>9</sup> Though the prevalence of insurance coverage for drugs is much greater than it was two decades ago, it is still lower than coverage for other health care goods and services. In fact, some seventy million Americans have no insurance for prescription drugs.<sup>10</sup>

Most importantly, Medicare does not yet cover most outpatient drugs, and thus many senior citizens and disabled persons otherwise covered for health care costs lack drug coverage.<sup>11</sup> Although Congress recently adopted a Medicare prescription drug benefit, the program still leaves significant gaps in drug coverage for Medicare beneficiaries.<sup>12</sup> The legislation imposes a \$250 deductible and—once that is met—a 25% coinsurance obligation.<sup>13</sup> Moreover, a gap in coverage—commonly referred to as the “doughnut hole”—exists once total spending exceeds \$2,250.<sup>14</sup> Beyond this threshold, the beneficiary receives no further coverage until her total out-of-pocket spending reaches \$3,600 (referred to as the “stop-loss” level), after which the legislation covers 95% of drug costs.<sup>15</sup> Under the legislation, low-income beneficiaries (i.e., those under 150% of the poverty level) will face lower cost-sharing and will receive coverage in the “doughnut hole,” but only if they pass an asset test.<sup>16</sup> Furthermore, the new benefit will not take effect until 2006, leaving Medicare beneficiaries responsible for high drug costs for another two years, though perhaps assisted somewhat by pharmacy discount cards.<sup>17</sup> Expanding drug coverage to persons other than Medicare beneficiaries is not even on the congressional policy agenda.

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9. Dana Gelb Safran et al., *Prescription Drugs and Seniors: How Well are the States Closing the Gap?*, HEALTH AFF. W253, W265 (Web Exclusive, July 31, 2002), available at [http://www.healthaffairs.org/WebExclusives/Safran\\_Web\\_Excl\\_073102.htm](http://www.healthaffairs.org/WebExclusives/Safran_Web_Excl_073102.htm) (last visited Dec. 2003).

10. CTR. FOR POL’Y ALTERNATIVES, PLAYING FAIR, STATE ACTION TO LOWER PRESCRIPTION DRUG PRICES (2000), available at <http://www.stateaction.org/cpa/publications/pub.cfm?ID=112> (last visited Dec. 2003).

11. See KAISER FAMILY FOUND., MEDICARE AND PRESCRIPTION DRUGS FACT SHEET, available at <http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14186> (last visited Dec. 30, 2003).

12. Pub. L. 108-173, tit. I (2003).

13. Pub. L. 108-173 §§ 1860D-2(b)(1) & (2).

14. Pub. L. 108-173 § 1860D-2(b)(3).

15. Pub. L. 108-173 § 1860D-2(b)(4).

16. Pub. L. 108-173 § 1860D-14.

17. Pub. L. 108-173 § 1860D-31.

## II. THE PROPOSED SOLUTION: STATE PROGRAMS TO MAKE DRUGS MORE AFFORDABLE

For the immediate future, therefore, it appears that progress in expanding public programs to help cover drug costs is most likely to come at the state level.<sup>18</sup> The states have in fact been actively trying to address this problem, devising a diverse set of approaches that vary in the populations they serve, the extent of assistance they offer, and the mechanisms they employ to reach their access goals.

The most straightforward solution is simply to provide drug coverage for those most in need, either directly or through subsidized insurance plans. As of November 2003, thirty-five states had adopted laws to create pharmaceutical assistance programs, and twenty-nine such plans were operational.<sup>19</sup> All of these programs cover senior citizens, many cover disabled persons, and a few cover the uninsured generally.<sup>20</sup> Most impose income eligibility limits, which vary from 88% (in Florida) to 500% (in Massachusetts) of the federal poverty level.<sup>21</sup> However, the greatest disadvantage of these programs is that they must be paid for by the states, virtually all of which are under a constitutional obligation to balance their budget every year, and most of which are facing very tight budgets during the current economic downturn. Some states have financed these programs with tobacco settlement funds. However, funding remains tight, and it is unlikely that these direct state drug programs will expand in the immediate future. Most of the programs are still small (only five had more than 100,000 members in 2003).<sup>22</sup> Furthermore, even in states with well-established programs, many eligible persons do not participate because of low program awareness, complex and burdensome eligibility requirements and procedures, and limited benefits.<sup>23</sup>

Some states have also used their Medicaid programs to make drugs more available to the poor and uninsured, a strategy that allows them to

18. The Medicare prescription drug legislation also contemplates the continued existence of state pharmaceutical assistance programs to assist Medicare beneficiaries with premium or cost-sharing obligations imposed by the new drug benefit legislation. See Pub. L. 108-173, § 1860D-23.

19. NAT'L CONF. OF STATE LEGISLATURES, STATE PHARMACEUTICAL ASSISTANCE PROGRAMS (2003), <http://www.ncsl.org/programs/health/drugaid.htm> (last visited Dec. 2003).

20. *Id.*

21. *Id.* In 2003, the federal poverty level was \$8,980 for an individual. 68 Fed. Reg. 6456 (2003).

22. *Id.*

23. Safran et al., *supra* note 9.

take advantage of federal funds to help pay for the cost of the program. Although outpatient prescription drugs are an optional service under federal Medicaid law, all state Medicaid programs do in fact cover prescription drugs.<sup>24</sup> There are several ways in which states can use Medicaid to expand drug coverage. First, several states have simply expanded eligibility for their Medicaid programs, thus giving poor residents the full benefit of Medicaid coverage, including prescription drug coverage.<sup>25</sup> The federal Medicaid law offers states a broad menu of opportunities for Medicaid eligibility expansions beyond the minimum required federal coverage, including covering, for example, seniors and disabled persons with incomes up to the poverty level, working disabled persons up to 250% of the poverty level, or pregnant women and infants up to 185% of the poverty level.<sup>26</sup> Expanding Medicaid to cover all of the populations permitted optional coverage under federal law (or even the broader populations permitted coverage under federal Medicaid waiver provisions) can help to address the fact that drug coverage is unaffordable for many low-income persons. However, this option is very costly to states. Although the federal government funds approximately one half to four fifths of Medicaid costs,<sup>27</sup> the remainder must be paid for by the state, and when the state Medicaid program is expanded, the state must cover this cost for all mandatory services (including hospital and nursing home care), not just for drugs.<sup>28</sup>

Therefore, several states have applied for and received federal Medicaid waivers to provide drug benefits to an expanded population, usually senior citizens and disabled persons with incomes under 200% of the poverty level.<sup>29</sup> Drug-only Medicaid coverage is not an alternative

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24. THE HENRY J. KAISER FAM. FOUND., KAISER COMM'N ON MEDICAID & THE UNINSURED, MEDICAID AND PRESCRIPTION DRUGS (2002),

<http://www.kff.org/content/2002/20020213/1609-02.pdf> (last visited Dec. 2003).

25. See FAMILIES USA, EXPANDING MEDICAID: STATE OPTIONS, COULD YOUR STATE DO MORE TO EXPAND MEDICAID FOR SENIORS AND ADULTS WITH DISABILITIES? (2002),

<http://www.familiesusa.org/media/pdf/ExpandingMedicaid.pdf> (last visited Dec. 2002).

26. 42 U.S.C. § 1306a(a)(10)(A)(ii)(IX), (X), (XIII) (2000).

27. NAT'L HEALTH LAW PROGRAM, AN ADVOCATES GUIDE TO THE MEDICAID PROGRAM 2.4 (2001).

28. 42 U.S.C. §§ 1396a(1)(10)(B), 1396d(a) (2000).

29. As of May 2003, this included Illinois, Wisconsin, South Carolina, Florida, Indiana, and Maryland. These Medicaid expansions to cover optional populations offer only drug benefits. NAT'L CONF. OF STATE LEGISLATURES, STATES AND "PHARMACY PLUS" MEDICAID WAIVER OPTIONS (2003), <http://www.ncsl.org/programs/health/pharmplus.htm> (last visited Dec. 2003).

explicitly permitted by the Medicaid statute, but HHS has indicated its willingness to offer such waivers.<sup>30</sup> The federal Court of Appeals for the District of Columbia, however, held that such programs are permissible only if they involve a state contribution to the funding of the program, which could make this approach also costly to states.<sup>31</sup>

### III. THE WALSH ALTERNATIVE: USE MEDICAID MARKET POWER TO EXPAND ACCESS

Many states, reluctant to expand state-funded programs when their funds are scarce, have explored strategies that expand drug access by forcing down the prices charged by drug manufacturers. States justify this practice in a number of ways. Drug manufacturers garner famously high profit margins. During 2002, the top ten U.S. drug companies averaged profits as a percent of revenue of 17%, nearly five and half times the profits of the median Fortune 500 company.<sup>32</sup> These profits represented more than half the total net profits of all Fortune 500 companies combined.<sup>33</sup> Even if one considers return on assets, which might be a more accurate representation of their true profits, these top ten drug manufacturers earned 14.1% for 2002 when the Fortune 500 median return on assets was just 2.3%.<sup>34</sup> Because drug manufacturers are granted effective monopolies on new drugs both through patent protection and through statutory market exclusivity periods,<sup>35</sup> they are able to charge prices far above competitive levels. Once generics are finally introduced, the amounts consumers pay for drugs fall rapidly, with generics usually costing less than half as much as multiple-source brand name drugs.<sup>36</sup> However, until

30. See CTR. FOR MEDICARE & MEDICAID SERV., PHARMACY PLUS SECTION 1115 WAIVER RESEARCH AND DEMONSTRATION PROJECTS, TECHNICAL GUIDANCE AND FACT SHEET, <http://cms.hhs.gov/medicaid/1115/RXFACTSHEET41202.pdf> (last visited Dec. 2002).

31. *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001). In the challenged program, Vermont has attempted to use the drug rebate as the state matching funds, and thus contributed none of its own money.

32. PUB. CITIZEN CONG. WATCH 2003, 2002 DRUG INDUSTRY PROFITS: HEFTY PHARMACEUTICAL COMPANY MARGINS DWARF OTHER INDUSTRIES 1 (2003), [http://www.citizen.org/documents/Pharma\\_Report.pdf](http://www.citizen.org/documents/Pharma_Report.pdf) (last visited Dec. 2003).

33. *Id.*

34. *Id.*

35. Market exclusivity periods block FDA marketing approval for some generic substitutes even after patents expire or for products or uses that are not patentable. David G. Adams et al., 2 FUNDAMENTALS OF LAW AND REGULATION, 180-84 (1997).

36. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS

generics become available, the market does little to discipline prices.

Manufacturers justify their high returns by arguing that they are necessary to finance research and development. There is some truth in this: Drug research is very expensive and risky; the drug development process is protracted and often unsuccessful. Drug company research and development costs tend to track profits, and countries that have placed strict limits on drug prices have seen drug research lag.<sup>37</sup> Even so, the argument has been oversold. Drug companies currently spend far less on the research and development of new products than they do on administration and on the advertising and marketing of their existing products—including expensive but highly successful direct-to-consumer advertising of prescription drugs.<sup>38</sup> Moreover, more than one third of medical and health research and development in the United States is funded by the American taxpayer.<sup>39</sup> Pharmaceutical companies also gain from generous tax benefits, which heavily subsidize their research efforts.<sup>40</sup> Arguably then, it is only fair that the public, including those who cannot otherwise afford high-priced drugs, realize some of the benefits of its investment. States can thus reasonably claim that it is fair to compel drug companies to give up some of their profits to make drugs more available to those who cannot afford them.

Perhaps more to the point, states that attempt to limit the amount that the uninsured (or elderly, or poor) have to pay for drug products are simply trying to get for their constituents the same deal that drug manufacturers already offer in the private sector to high volume purchasers. Drug manufacturers face high front-end fixed costs (including research and development costs), but comparatively low variable costs, and

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AFFECTED PRICE AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 27-32 (1998).

37. See Patricia M. Danzon, *Making Sense of Drug Prices*, 23 REGULATION 56 (2000); F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending*, 20 HEALTH AFF. 216 (2001).

38. See FAMILIES USA, PROFITING FROM PAIN: WHERE PRESCRIPTION DRUG DOLLARS GO (2002), <http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249> (last visited Dec. 2003).

39. MICHAEL E. GLUCK, THE HENRY J. KAISER FAM. FOUND., FEDERAL POLICIES AFFECTING THE COST AND AVAILABILITY OF NEW PHARMACEUTICALS 40 (2002), <http://www.kff.org/rxdrugs/loader.cfm?url=/commonsot/security/getfile.cfm&PageID=14078> (last visited Dec. 2003). The National Institute of Health (NIH) funded, in part, the development of fifty-two of the seventy-seven cancer drugs approved by the FDA by 1996, and the NIH and FDA contributed to the development of forty-five of the fifty top-selling drugs approved by the FDA between 1992 and 1997. *Id.* at 20.

40. *Id.* at 23-25.



thus are ideally situated to engage in price discrimination.<sup>41</sup> They charge much less to high-volume purchasers in a position to refuse to purchase their product (e.g., managed care organizations or hospitals) than they do to low-volume purchasers (e.g., retail pharmacies or individual consumers paying out-of-pocket).<sup>42</sup> The drug industry's own advertising has claimed that private insurance companies pay 30% to 39% less for drugs than do the uninsured.<sup>43</sup> States would do their needy residents a great service if they could simply procure for them the same deal that the drug companies already offer to many other private purchasers.

The most obvious strategy for accomplishing this would be for states to use the approach already taken to drug pricing under the Medicaid program—mandating price discounts. Under the Omnibus Budget Reconciliation Act (OBRA) of 1990, drug manufacturers must, in most instances, provide state Medicaid programs with rebates for drugs sold to Medicaid beneficiaries.<sup>44</sup> The rebate equals the difference between the drug manufacturer's average wholesale price and the best price it offers to other buyers (other than the federal government), or at least 15.1%—essentially providing states the price discrimination benefit enjoyed by other large purchasers.<sup>45</sup> The federal government collects pricing information from drug manufacturers and uses it to determine the size of the rebate states can demand for particular drugs.<sup>46</sup>

The 1990 OBRA legislation also provided an important benefit for the drug manufacturers: It prohibited the states from excluding from a state drug formulary any of the products produced by a manufacturer that agreed to a rebate program.<sup>47</sup> Prior to the adoption of this legislation, several states had begun to exclude certain high cost drugs from their formularies. Since Medicaid is responsible for over 17% of drug expenditures,<sup>48</sup> exclusion from a Medicaid formulary posed a real threat to drug companies.

Though states are generally prohibited from excluding the drugs of

41. In this respect, they are like airlines or hotels.

42. ROY LEVY, FED. TRADE COMM'N, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST CHALLENGES IN AN ENVIRONMENT OF CHANGE* 73-95 (1999).

43. See CTR. FOR POL'Y ALTERNATIVES, *supra* note 10, at 8.

44. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (codified as amended at 42 U.S.C. § 1396r-8).

45. 42 U.S.C. § 1396r-8(c) (2000).

46. *Id.*

47. David Chavkin, *Medicaid and Viagra: Restoring Potency to an Old Program?*, 11 HEALTH MATRIX 190, 203 (2001).

48. Katherine Levit et al., *supra* note 6, at 158 (2003).

cooperating manufacturers from formularies, they are allowed to impose prior authorization requirements on some drugs subject to certain conditions.<sup>49</sup> Medicaid prior authorization programs must respond to an authorization request by telephone within twenty-four hours, and must also provide for the dispensing of a seventy-two-hour supply of drugs while awaiting authorization.<sup>50</sup> Nevertheless, requiring prior authorization for a drug frequently has the effect of denying patients access to it, often because they do not learn of the requirement until a pharmacy refuses to fill a prescription for which the physician did not obtain a prior authorization.<sup>51</sup> As a result, it has the effect of reducing the drug's sales.

Maine's program, at issue in *Walsh*, attempted to use this lever—the threat of requiring prior authorization—to make discounts available to all residents of the state who lacked insurance coverage for drugs, regardless of income.<sup>52</sup> The statute creating the program directed Maine's Commissioner of the Department of Health Services to enter into “voluntary” agreements with drug manufacturers to extend to the general population rebates on their drugs and to use his or her “best efforts” to secure rebates equal to those extended to the state under the Medicaid program.<sup>53</sup> These rebates were to be passed back to pharmacies that sell drugs to eligible Maine residents at discounts reflecting the rebates. Drug manufacturers who refused to extend voluntary rebates were to be sanctioned by having their identities released to the public and their products covered under the Medicaid program only on a “prior

49. 42 U.S.C. § 1396r-8(d) (2000).

50. 42 U.S.C. § 1396r-8(d)(5) (2000).

51. See Brief of Amicus Curiae Legal Services Organizations Representing Medicaid Beneficiaries at 4-13, *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. 1855 (2003) [hereinafter “Amicus Brief”].

52. ME. REV. STAT. ANN. tit. 22, §§ 2681(2)(F), (5) (West 2003). After the Supreme Court's decision, Maine enacted a more limited program, Maine Rx Plus, covering only persons whose income is below 350% of the poverty level, or who have drug costs exceeding 5% of household income or medical costs exceeding 15% of household income. See *Maine Governor Signs New State Prescription Drug Discount Program into Law*, KAISER DAILY POL'Y REPORT, June 26, 2003, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=18501](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=18501) (last visited Dec. 2003). The Maine Rx Plus program was finally implemented on January 17, 2004. See KAISER FAMILY FOUND., MAINE PRESCRIPTION DRUG DISCOUNT PROGRAM TO TAKE EFFECT SATURDAY (2004), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=21708](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=21708).

53. ME. REV. STAT. ANN. tit. 22, § 2681(3), (4) (West 2003).

authorization” basis.<sup>54</sup> Although the state argued that the prior authorization program would be operated so as to assure that Medicaid recipients had access to needed medications, it also acknowledged that the program might in some instances block recipients from receiving their doctors’ first choice of drug. In fact, other states that have implemented prior-authorization programs have seen dramatic reductions in use of pharmaceutical products placed on prior-authorization status.<sup>55</sup>

#### IV. THE SUPREME COURT’S RESPONSE: *PhRMA v. WALSH*

In the case that culminated in *PhRMA v. Walsh*, the trade association that represents most of the brand name drug manufacturers in the United States challenged the Maine program, arguing that the statute creating the program violated the United States Constitution in two respects. First, PhRMA contended that the statute violated the Supremacy Clause, which recognizes the preeminence of federal over state law, because the statute imposed a prior authorization requirement on drug coverage under the state Medicaid program—thus inflicting a significant burden on Medicaid recipients—for reasons unrelated to the purposes of the federal Medicaid statute.<sup>56</sup> In this argument, PhRMA was supported by amicus briefs filed by the United States Solicitor General and by organizations representing Medicaid recipients, which noted that Medicaid beneficiaries have indeed suffered in states with prior authorization programs.<sup>57</sup>

PhRMA also argued that the Maine program was unconstitutional because it violated the so-called dormant Commerce Clause. The dormant or negative Commerce Clause is a court-created doctrine implied by—rather than explicitly found in—the Constitution. Article one, section eight, clause three of the Constitution gives the federal government the authority to regulate commerce “among the several States.” In a series of cases, the Supreme Court has stated that this federal authority to regulate interstate commerce implies a prohibition against the states’ doing so.<sup>58</sup>

The dormant Commerce clause has generated a number of complex strands of doctrinal development over the years. Most successful dormant Commerce Clause cases, however, involve laws through which a state has

54. ME. REV. STAT. ANN. tit. 22, § 2681(7) (West 2003).

55. See Amicus Brief, *supra* note 51.

56. 123 S.Ct. at 1867.

57. *PhARMA v. Concannon*, Brief for the United States as Amicus Curiae Supporting Reversal, 2002 WL 31156279; *PhARMA v. Concannon*; Amicus Brief, *supra* note 51.

58. See, e.g., *Okla. Tax Comm’n v. Jefferson Lines, Inc.*, 514 U.S. 175 (1995); *Healy v. Beer Inst.*, 491 U.S. 324 (1989).

attempted to favor its own businesses at the expense of other states<sup>59</sup> or to regulate transactions that take place inside other states.<sup>60</sup> Where a state simply attempts to regulate transactions within its own borders (including regulating prices), the Clause has not been held to apply; and where a state attempts to further its own legitimate, non-protectionist interests through laws that incidentally impose burdens on interstate commerce, the laws are usually upheld under a balancing test.<sup>61</sup>

PhRMA argued that the Maine statute violated the dormant Commerce Clause because it 1) set prices for drugs sold by manufacturers and thus regulated transactions between manufacturers and wholesalers, which in most instances took place outside of Maine, and 2) favored Maine consumers at the expense of drug manufacturers located in other states.<sup>62</sup>

The federal district court accepted both of PhRMA's constitutional arguments, holding that the Maine drug program was inconsistent with both the federal Medicaid law and the dormant Commerce Clause.<sup>63</sup> The First Circuit Court of Appeals, however, reversed the district court judgment, holding that the program in fact promoted the purposes of the Medicaid program by making drugs available to low-income people and thus helping them to stay off of Medicaid.<sup>64</sup> It further held that the program did not violate the dormant Commerce Clause because it promoted an important state purpose while minimally burdening commerce and because it only governed transactions wholly within Maine.<sup>65</sup>

The Supreme Court upheld the court of appeals' decision rejecting the district court's preliminary injunction.<sup>66</sup> However, the Court was deeply divided in its reasoning, producing no single majority opinion. Justice Stevens announced the judgment of the Court in an opinion joined in its entirety by only two other Justices, Souter and Ginsburg.<sup>67</sup> Justice Breyer concurred in most of Justice Stevens' opinion, and in the judgment of the Court.<sup>68</sup> Justices Thomas and Scalia wrote their own opinions, agreeing

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59. *See* *Or. Waste Sys., Inc. v. Dep't of Envtl. Quality*, 511 U.S. 93 (1994).

60. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

61. *Id.*

62. 123 S.Ct. at 1870.

63. 123 S.Ct. 1865.

64. *Pharm. Research & Mfrs. Of Am. V. Concannon*, 249 F.3d 66, 74-79 (1st Cir. 2001).

65. 249 F.3d at 79-84.

66. *Pharm. Research & Mfrs. of Am. v. Walsh.*, 123 S.Ct. 1855 (2003).

67. *Id.* at 1860.

68. *Id.* at 1871. Justice Breyer wrote separately to opine that the district court should have been instructed to seek the view of the Secretary of Health and Human Services as to

with the result of the Court, but disagreeing with the reasoning of Justice Stevens' plurality opinion.<sup>69</sup> Finally, Justices O'Connor, Rehnquist, and Kennedy dissented from part of the Court's judgment.<sup>70</sup>

All of the Justices agreed on one thing: The dormant Commerce Clause does not prohibit Maine's program.<sup>71</sup> The Maine statute neither attempted to regulate prices of out-of-state transactions nor favored Maine manufacturers to the disadvantage of out-of-state competitors; thus, it did not fall within earlier decisions finding state legislation to violate the dormant Commerce Clause.<sup>72</sup>

On the Medicaid issue, however, the Court was divided. Six Justices agreed that the lower court should not have entered a preliminary injunction blocking the Maine program, but they offered four different opinions supporting this result. Justice Stevens, writing for himself and Justices Ginsburg and Souter, opined that the district court erred in holding that the Maine program served no Medicaid purpose.<sup>73</sup> Stevens agreed with the court of appeals that the program would provide services to some "medically needy" persons and also that Medicaid expenditures might be reduced because of early provision of drugs to "borderline" persons whose conditions might otherwise worsen, making them eventually a burden on the Medicaid program.<sup>74</sup> Stevens further argued that the prior authorization program itself might encourage the use of more cost-effective drugs, thus saving Medicaid money.<sup>75</sup> He also noted that each state has considerable discretion in administering its Medicaid program, and that PhRMA would have had to have shown that the Maine program had a more severe impact on the access of Medicaid recipients to drugs to overcome Maine's exercise of its discretion in this instance.<sup>76</sup> Stevens concluded that further proceedings would be necessary to resolve these issues, noting that the results might very well depend on actions that HHS might take as a result of the Maine scheme.<sup>77</sup>

Justices Breyer, Scalia, and Thomas each wrote separately, joining in the result, but not the reasoning, of the Court. Both Scalia and Thomas

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the permissibility of Maine's program.

69. *Id.* at 1873 (Scalia, J., concurring), 1874 (Thomas, J., concurring).

70. *Id.* at 1878.

71. *Id.* at 1870-71.

72. *Id.*

73. *Id.* at 1867-68.

74. *Id.*

75. *Id.* at 1868.

76. *Id.* at 1868-69.

77. *Id.* at 1869-70.

have little use for the dormant Commerce Clause, and gave short shift to that argument.<sup>78</sup> Both would also have thrown out the Medicaid case altogether, with Scalia taking the position that only HHS has the power to enforce the Medicaid statute through terminating state funding,<sup>79</sup> and Thomas arguing that there was no conflict between the Maine program and the Medicaid statute because the statute allows prior authorization programs without regard to the state's motive for adopting them. Thomas further pointed out that HHS, not the courts, is responsible for policing state compliance with Medicaid requirements.<sup>80</sup> Ultimately, both Thomas and Scalia saw the matter as primarily the concern of HHS, and did not believe that PhRMA's challenge was properly before the Court.

Justice Breyer, in his opinion, suggested that the appropriate course for the lower court on remand would be to stay the proceedings under the doctrine of primary jurisdiction, and to ask HHS for its views on the permissibility of the Maine plan.<sup>81</sup> Thus, Justice Breyer also believed that HHS should rule on the Maine plan.

Finally, Justices O'Connor, Rehnquist, and Kennedy dissented on the Medicaid issue, arguing that the Maine statute was preempted by the federal Medicaid law because it imposed a prior authorization requirement on Medicaid recipient for purposes unrelated to the Medicaid program.<sup>82</sup> The dissenters contended that there was no factual basis for the plurality's conclusion that the program furthered purposes related to the Medicaid

78. *Id.* at 1873-74 (Scalia, J., concurring), 1879 (Thomas, J., concurring).

79. *Id.* at 1874.

80. *Id.* at 1874-78. The fact that none of the other Justices joined Scalia and Thomas in their argument that courts have no role in overseeing the Medicaid program would seem to sound a death knell for the arguments raised by the district court in *Westside Mothers v. Haveman*, 133 F. Supp. 2d 549 (E.D. Mich. 2001). The lower court in that case held that the federal courts have no jurisdiction over the states in Medicaid cases under 42 U.S.C. § 1983, and that the Eleventh Amendment bars the courts from providing relief against states that violate Medicaid requirements. The district court was reversed on appeal, *Westside Mothers v. Haveman*, 289 F.3d 852 (6th Cir. 2002), and its position has been rejected by other courts. *See, e.g., Antrican v. Odom*, 290 F.3d 178 (4th Cir. 2002). Seven Justices in the *Walsh* case seem to have no problem with the Court permitting direct challenges to state administration of their Medicaid programs, though several suggest that it might be better if the Department of Health and Human Services take a first look at challenges to Medicaid programs, perhaps foreshadowing a future exhaustion requirement. *See Timothy S. Jost, The Tenuous Nature of the Medicaid Entitlement*, 22 HEALTH AFF. 145 (2003).

81. *Pharm. Research & Mfrs. of Am. v. Walsh.*, 123 S.Ct. at 1872-73.

82. *Id.* at 1878-82.

program.<sup>83</sup>

Three conclusions emerge from the multiple opinions when read together. First, the entire Court agreed that state attempts to leverage the Medicaid program to force discounts from drug companies do not violate the dormant Commerce Clause. Second, seven justices—all but Thomas and Scalia—agreed that a state should only be allowed to use the Medicaid program to obtain discounts for non-Medicaid recipients if it can show a “Medicaid purpose” for such a program, which some would explicitly tie to the statutory requirement that services be provided in a manner consistent with “the best interests of [Medicaid] recipients.”<sup>84</sup> Finally, six justices—all but the dissenters—agreed that the opinion of HHS regarding the permissibility of a state drug program that uses the state’s Medicaid purchasing power is important; and at least three—Thomas, Scalia, and Breyer—would regard it as well nigh decisive.

#### V. THE RAMIFICATIONS OF *WALSH* FOR STATE DRUG PROGRAMS

The most immediate result of *Walsh* is that it clears the way for states to move forward with adopting and implementing programs to expand access to drugs for the elderly and uninsured using their Medicaid market power. The drug manufacturers have been largely successful in blocking such programs through three years of litigation, but—with the ground rules for such programs now established by the Supreme Court—states can proceed.

Although the majority of the Justices in *Walsh* agreed that it was important that HHS review state plans to use the Medicaid program to secure drug rebates for their residents, this may not be an insurmountable barrier to the implementation of these plans. In fact, the Center for Medicare and Medicaid Services (CMS), a federal agency within HHS, has indicated its willingness to approve the use of Medicaid preauthorization programs to force drug companies to offer rebates for the benefit of non-Medicaid populations.<sup>85</sup> CMS approval of two such programs in Michigan covering low-income elderly persons and poor pregnant adolescents has already been upheld in a lower federal court decision that Justice Thomas described in his opinion as providing a “careful analysis” of the issue.<sup>86</sup>

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83. *Id.* at 1880-81.

84. 42 U.S.C. § 1396a(a)(19) (2000).

85. Letter from Dennis G. Smith, Director for Medicaid and State Operations, Centers for Medicare & Medicaid Services, to State Medicaid Directors (Sept. 18, 2002), on file with author and available at <http://www.cms.gov/states/letters/smd91802.pdf>.

86. *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F.Supp.2d 39 (D.D.C. 2003). *See Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. at 1877, n.5 (Thomas, J., concurring).

CMS based its approval of the Michigan program on its findings that the program was likely to save the Medicaid program money by keeping people whose income is marginally above Medicaid limits off of Medicaid, and that the Michigan prior authorization programs offered adequate protections for Medicaid recipients who needed a drug subject to prior authorization for a particular therapeutic reason.<sup>87</sup> HHS objected to the Maine program in its Supreme Court amicus brief primarily because Maine did not impose any income limits.<sup>88</sup> As this feature has now been changed,<sup>89</sup> HHS might well approve the plan.

In the end, of course, rebates at the 15% level, such as those available under Medicaid, may not be sufficient to make drugs available to many poor Americans. Because of this, the refusal of the Court to apply the dormant Commerce Clause in *Walsh* may be even more important in expanding the ways in which states can bring down drug prices for their residents. As long as state programs only regulate in-state transactions, and are not used to discriminate against out-of-state and in favor of in-state merchants or industries, states have considerable scope to bargain with pharmaceutical companies for lower drug prices.

A number of states are adopting aggressive strategies to bring down drug prices, perhaps even below the price levels enjoyed by the Medicaid program. Some, for example, are engaged in bulk drug purchasing of drugs at a state or regional level to force down drug prices for state employees and for Medicaid recipients, and could potentially expand this strategy to make drugs more affordable for uninsured residents.<sup>90</sup> Several states are also considering purchasing drugs from Canada, where prices are regulated, to make drugs more affordable for state employees<sup>91</sup>—

87. *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d at 74-75.

88. See Brief for the United States as Amicus Curiae Supporting Reversal at 21-22, *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001) (No. 01-188). As noted above, subsequent to *Thompson*, Maine amended its statute to impose limits on financial eligibility. See *Maine Governor Signs State New Prescription Drug Discount Program into Law*, *supra* note 52.

89. See *Maine Governor Signs New State Prescription Drug Discount Program into Law*, *supra* note 52.

90. See NAT'L CONF. OF STATE LEGISLATURES, PHARMACEUTICAL BULK PURCHASING: MULTI-STATE AND INTER-AGENCY PLANS (2003) <http://www.ncsl.org/programs/health/bulkrx.htm> (last visited Dec. 2003).

91. See THE HENRY J. KAISER FAM. FOUND., MINNESOTA TO EXPLORE BUYING PRESCRIPTION DRUGS FROM CANADA (2003), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=20033](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=20033) (last visited Dec. 2003).



another strategy that could potentially be expanded to cover the beneficiaries of state programs. Some states are even considering state maximum drug price controls.<sup>92</sup> Certainly, the *Walsh* dormant Commerce Clause ruling removes one important drug industry argument in opposing state drug price regulation programs.

#### CONCLUSION

In the absence of decisive federal action to make drugs available to Medicare recipients and the uninsured, a number of states are moving forward with state programs to expand drug availability. These programs have faced vigorous challenges from the drug industry. *PhRMA v. Walsh* gives the green light to one important strategy for making drugs more affordable—using state Medicaid market power to force down prices. Perhaps even more importantly, however, *Walsh's* Commerce Clause ruling opens the door to even more aggressive state actions to control drug costs. The case, therefore, marks an important milestone in efforts to make the benefits of modern pharmaceuticals available to all Americans, and not just to those fortunate enough to be insured.

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92. See NAT'L CONF. OF STATE LEGISLATURES, 2002 PRESCRIPTION DRUG DISCOUNT, BULK PURCHASING, AND PRICE-RELATED LEGISLATION (2003), <http://www.ncsl.org/programs/health/drugdisc02.htm> (last visited Dec. 2003).