


3-1-2006

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Recommended Citation

Brian Y. Furuya, *Getting It Right by Getting It Wrong: How the Supreme Court Helped Healthcare Reform by Incorrectly Applying the Standard of Review in Pharmaceutical Research and Manufacturers of America v. Walsh*, 20 BYU J. Pub. L. 549 (2006).
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Getting It Right by Getting It Wrong: How the Supreme Court Helped Healthcare Reform by Incorrectly Applying the Standard of Review in *Pharmaceutical Research and Manufacturers of America v. Walsh*

I. INTRODUCTION

Healthcare reform has proven to be a puzzling creature. As the number of citizens without healthcare coverage swells, and the specter of increasing healthcare costs looms large in the minds of nearly every person, it is fairly obvious why the topic of healthcare reform is a powerful and poignant issue today. Nearly forty-six million American citizens do not have any healthcare coverage, including coverage from public assistance programs such as Medicaid or Medicare.¹ Complementing this staggering number is a wide consensus amongst Americans that the system for providing healthcare coverage is broken and needs to be fixed.² And yet, despite overwhelming recognition that change is required, reform has come faltering, and has been largely ineffective.

This Note seeks to address one area of healthcare reform by examining the recent decision of the United States Supreme Court in *Pharmaceutical Research and Manufacturers of America v. Walsh*³ (hereafter called “*Walsh*”) in terms of its contribution to the healthcare reform debate. I first consider the issues that gave rise to the suit filed by Pharmaceutical Research and Manufacturers of America (hereafter called “PhRMA”), including an explanation of the Maine Rx Program, which stands at the core of the dispute. After a close examination of the reasoning set forth by the opinions of the *Walsh* decision, I propose that the plurality’s approach to addressing the case is procedurally unsound, given the controlling standard of review pointed out by the dissent. Nevertheless, the plurality’s decision to hold in favor of Maine Rx, even

1. U.S. CENSUS BUREAU, U.S. DEP’T OF COM., INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE U.S.: 2004, 16 (2005).

2. One public opinion poll placed healthcare reform as the fourth “most important problem for the government to address,” above taxes, the budget, terrorism, national security, education, and crime. THE HENRY J. KAISER FAMILY FOUNDATION, *March/April2005 Health Poll Report Survey*, Apr. 2005, at 4, available at <http://www.kff.org/kaiserpolls/upload/March-April-2005-Kaiser-Health-Poll-Report-Toplines.pdf>.

3. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003).

if only in the context of reviewing a preliminary injunction, is desirable because it ultimately provides support for the proposition that human lives are of greater value than lost profits. Furthermore, the Court's reaffirmation of presumptive constitutionality in the case of legislation involving Medicaid programs may aid effective healthcare reform by providing more ammunition to state legislatures as they assert their position as the proper forums for resolution of healthcare problems.⁴ Finally, this Note looks at subsequent treatment of the case in remand proceedings, noting especially the implications of the *Walsh* decision for the future, and concludes that the plurality's "inadvertence" may well aid healthcare reform more than many intentional undertakings.

II. MEDICAID, MAINE RX AND PRIOR APPROVAL PLANS

A. Medicaid⁵

Medicaid itself has long been a very controversial subject.⁶ Indeed, one author has observed that while the Medicare program has always enjoyed solid popularity, the Medicaid program has endured a tenuous and difficult existence since its passage as part of the Social Security Act in 1965.⁷ Medicaid's controversy is presumably due to public concerns about rising costs, as well as a certain apprehensiveness about socialized healthcare assistance programs.⁸

As set up by the "Medicaid Act,"⁹ Medicaid is a federally-subsidized healthcare coverage option for certain qualifying individuals, wherein each State administers its own version of the program. States largely determine for themselves what benefits to grant, and set eligibility requirements for determining which individuals will be covered, subject to certain federally imposed threshold requirements.¹⁰ Under those requirements, state Medicaid programs *must* extend healthcare coverage

4. I recognize that whether the states truly are the best forums for healthcare reform is a premise with which some might take issue. There are many compelling arguments for why states are better able to deal with healthcare reform than the federal government, but they are outside the immediate scope of this work, and I will not address them here. For a well-crafted treatment of five such arguments, see Carol S. Weissert's article, *Promise and Perils of State-Based Road to Universal Health Insurance in the U.S.*, 7 J. HEALTH CARE L. & POL'Y 42 (2004) (discussing healthcare reform in terms of moving towards universal health insurance).

5. This summary of the Medicaid system is distilled from BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 772-76 (West 2004) (1987).

6. FURROW ET AL., *supra* note 5, at 772.

7. *Id.*

8. *Id.*

9. 42 U.S.C. §§ 1396 *et seq.* (2000).

10. FURROW ET AL., *supra* note 5, at 773-75.

to citizens who are aged, blind, or permanently and totally disabled, and whose income is below or very near to the federal poverty line.¹¹ Agencies administering the Medicaid programs term this group of mandatory beneficiaries as the “categorically needy.”¹² In addition to providing for the “categorically needy,” States may choose to (and often do), extend eligibility for Medicaid coverage to a broader group based upon calculations of financial need.¹³ In this manner, States are given considerable leeway in defining the formulae used to calculate eligibility for Medicaid coverage.¹⁴ Historically, as long as the States crafted plans that extended benefits to the “categorically needy,” the federal government remained aloof from most other aspects of administration.¹⁵ Today, States do cover those with pressing medical needs, whose incomes, according to federally proscribed guidelines, are significantly depressed.¹⁶ However, States also cover a significant portion of individuals and families who would not otherwise be eligible under the federal minimum standards.¹⁷

Drug benefits under State Medicaid plans, like other covered benefits, are extended to qualifying applicants via the eligibility schemes of the various states, as described above.¹⁸ At first, there were only minimal federal guidelines for States to follow, mostly setting upper limits on state spending for prescription benefits.¹⁹ States took the liberty of instituting various regulatory plans to administer drug benefits to Medicaid beneficiaries. Many of these plans attempted to control increased drug spending, which was widely viewed as the product of rising drug costs.²⁰ One such program was the so-called “prior approval plan.”²¹ If a State chose to place a drug on a prior approval plan, all doctors prescribing that medication within that state had to obtain prior

11. *Id.* at 773–74. The federal poverty level is determined by reference to the size of a household, that household’s income, and location of the household in either the forty-eight contiguous states, Alaska, or Hawaii. The federal poverty level for a single-member household located within the contiguous states in 2006 is \$9,800.00 per year. For a household of four similarly located, the 2006 federal poverty level is \$20,000.00 per year. Annual Update of the HHS Poverty Guidelines, 71 Fed. Reg. 3848 (Jan. 24, 2006).

12. 42 U.S.C. § 1396a(a)(10)(A)(i).

13. FURROW ET AL., *supra* note 5, at 774–75.

14. *See id.* at 774, 779–81 (discussing state discretion in extending coverage to certain groups of applicants and in providing certain benefits).

15. *See id.*

16. *Id.* at 774–75.

17. *Id.* at 774.

18. *See id.* at 773–75.

19. *Walsh*, 538 U.S. at 651 (quoting M. Ford, Congressional Research Service Report to Congress, Medicaid: Reimbursement for Outpatient Prescription Drugs, CRS-1 (Mar. 7, 1991)).

20. *See id.*

21. *See id.* at 651–52.

approval from a state agency before the prescription could be filled.²² Such cost-saving measures had been implicitly sustained for quite some time, and without much controversy.²³ The first prior approval plans were simply approved by the Secretary of Health as a part of the States' Medicaid plans as a whole, rather than addressed in their own right.²⁴ This is presumably because the goal of these reforming states was to control Medicaid costs and they were not at that time directly regulated under the Medicaid Act.²⁵

Today, the Medicaid drug benefit is heavily supported by a provision of the Omnibus Budget Reconciliation Act of 1990,²⁶ which requires drug manufacturers to grant a rebate on all drugs purchased for Medicaid patients.²⁷ In return for the rebate, Congress forbids the States from excluding the drugs of participating manufacturers from their programs' coverage.²⁸ However, States are still allowed to place certain restrictions on the drugs of participating manufacturers, foremost amongst these being the prior approval plans, which Congress explicitly endorses.²⁹ Such regulatory plans were ostensibly ratified by Congress by amendment to the Medicaid Act.³⁰ At present, States' prior approval plans are specifically authorized by statute, so long as the States seeking to institute such plans maintain a reliable, quick, and efficient way of obtaining approval.³¹

Given Medicaid's turbulent and controversial development,³² it is clear that the roles of the federal government and the States are often undefined, and there is substantial overlap between their efforts and policies, which frequently results in confusion, waste, and most

22. *See id.*

23. *See id.* at 652.

24. The Secretary of Health is charged by statute with the duty of reviewing state Medicaid plans for compliance with federal mandates. 42 U.S.C. § 1396a(b).

25. *Walsh*, 538 U.S. at 652.

26. 104 Stat. 1388, 13880 143–59 (1990) (codified as amended at 42 U.S.C. § 1396r–8).

27. “The rebate on a ‘single source drug’ or an ‘innovator multiple source drug’ is the difference between the manufacturer’s average price and its ‘best price,’ or 15.1% of the average manufacturer price, whichever is greater. 42 U.S.C. §§ 1396r-8(c)(1), (2). The rebate for other drugs is 11.1% of the average manufacturer price. *See* [42 U.S.C.] § 1396r-8(c)(3).” *Walsh*, 538 U.S. at 652.

28. “[O]nce a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan” *Id.*

29. 42 U.S.C. § 1396r-8(d).

30. Until recently, it was unclear whether placing a drug on a prior approval plan could be done unilaterally by the states. However, in the aftermath of *Walsh*, the Secretary of the Department of Health and Human Services, who is charged with the task of administering federal involvement in, and supervision of, the Medicaid program, has suggested that such an action now needs approval from the Secretary. *See Walsh*, 538 U.S. at 662 n.30.

31. 42 U.S.C. § 1396r-8(d)(1)(A).

32. *See supra* text accompanying notes 6–8.

significantly, gaps in coverage.³³ The mixture of regulatory oversight and independence has left many deficiencies and many questions about what States may do to reform their healthcare programs to help residents with no healthcare coverage without endangering continued federal Medicaid subsidization. A large portion of the American population has no healthcare coverage at all, and, presumably, an even larger portion has inadequate coverage.³⁴ States are left on their own to determine how to address the healthcare needs of this substantial population. One particularly contentious issue is how States may use their Medicaid programs in connection with other State programs to solve this problem. This is a prominent point in the *Walsh* decision.

B. What is the Maine Rx Program?

Many individuals who do not have any healthcare coverage at all also have no way to offset staggering prescription drug costs. But the problem is much broader than just those who have no coverage. While many people have some form of health insurance, these same people do not always have adequate drug benefits; indeed, many have no drug benefits whatsoever.³⁵ The Maine Rx Program³⁶ (hereafter called “Maine Rx”) is one State’s attempt to use certain aspects of the Medicaid program to fill a gap left by Medicaid coverage.

33. The complete absence of specific provisions concerning prescription drug coverage between 1965 and 1990 serves as an ideal example of how the development of Medicaid has largely been an ad hoc enterprise, which development has seen both the creation of, and subsequent attending to, gaps in coverage. See *Walsh*, 538 U.S. at 651.

34. 45.8 million Americans were without any healthcare coverage for all or part of the year in 2004. U.S. CENSUS BUREAU, U.S. DEP’T OF COMMERCE, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE U.S.: 2004, 16 (2005). Additionally, a recent survey revealed that 61% of American adults who have had problems paying medical bills are covered by insurance, and a significant number of people [roughly 17% of American *non-senior* adults] reported not being able to pay for healthcare at all at some point in 2005, despite having some form of healthcare insurance. THE HENRY J. KAISER FAMILY FOUNDATION, HARVARD SCHOOL OF PUBLIC HEALTH & USA TODAY, *Health Care Costs Survey*, Aug. 2005, at 3, available at <http://www.kff.org/newsmedia/upload/7371.pdf>.

35. See U.S. CENSUS BUREAU, US DEP’T OF COMMERCE, CURRENT POPULATION REPORTS: HEALTH INSURANCE COVERAGE: 1996, at 1 (1997) (stating that in 1996, roughly 84.4% of the American population was covered by some type of insurance continuously throughout the entire year); THE HENRY J. KAISER FAMILY FOUNDATION, *Prescription Drug Trends*, Oct. 2004, at *2, available at <http://www.kff.org/rxdrugs/upload/Prescription-Drug-Trends-October-2004-UPDATE.pdf>. (“In 1996, 23% of nonelderly Americans [excludes children and Medicare eligible individuals] had no drug coverage (more recent data are not available), including those without any health insurance for some or all of the year”). Cf THE HENRY J. KAISER FAMILY FOUNDATION, *Health Care Costs Survey*, *supra* note 34, at 7 (“Nearly one-quarter (24%) of Americans report that they or someone in their household did not fill a prescription, cut pills or skipped doses in the past year because of the cost”).

36. Codified as currently amended at ME. REV. STAT. ANN. tit. 22, §§ 2681 *et seq.* (West Supp. 2005).

In an effort to provide some relief from rising drug costs to Maine residents, the Maine legislature created Maine Rx to grant a wide-reaching drug discount. Under Maine Rx, residents of Maine who do not have a comparable drug benefit could qualify for enrollment in the program and would thereafter be eligible³⁷ to receive a discount roughly equivalent to wholesale pricing. The program calls for Maine's Commissioner of Human Services to negotiate voluntary manufacturer rebates with pharmaceutical companies.³⁸ These rebates are to be at least as large as those that are granted to the federal government under the Medicaid program.³⁹ Maine then redistributes the rebates to participating pharmacies within the state, which sells the drugs at their discounted prices to enrollees.⁴⁰

If a pharmaceuticals manufacturer chooses not to participate in the program, the fact of such non-participation would be deemed "public knowledge," and Maine could "publicize" the name of the non-participating company, and the fact of its non-participation to practitioners, pharmacies, and the general public.⁴¹ In addition, Maine could also place the non-participating drug(s)⁴² on a prior approval plan for Maine's Medicaid population.⁴³ As discussed above, such an action means that practitioners would need to obtain prior approval from the State before prescriptions for the non-participating drug would be filled for Medicaid patients.⁴⁴ However, Maine also maintains rules exempting certain necessary drugs from the prior approval plan penalties, to ensure that Medicaid patients requiring essential medications are not unduly

37. Under the original Maine Rx statute, there was some controversy as to whether the program was open to all residents, or if it constrained enrollment in some way. Maine argued that enrollment was self-policing, as it would make no sense to use the program in lieu of a better private drug benefit, should one be available. *Walsh*, 538 U.S. at 655 n.14. Nevertheless, PhRMA argued that the bald language of the statute left enrollment wide open to all residents, thus requiring preemption by the Medicaid Act. *Id.* At that time, the statute read: "'Qualified resident' means a resident of the State who has obtained from the department a Maine Rx enrollment card." ME. REV. STAT. ANN. tit. 22, § 2681(2)(F) (West Supp. 2002). This point was important for the dissent's position that the statute did not facially promote any Medicaid related purpose, but is otherwise irrelevant to the topic of this Note. *See Walsh*, 538 U.S. at 685–90.

38. ME. REV. STAT. ANN. tit. 22, § 2681(4) (West Supp. 2002).

39. ME. REV. STAT. ANN. tit. 22, §§ 2681(3)–(4)(C) (West Supp. 2002). *See supra* text accompanying note 27.

40. ME. REV. STAT. ANN. tit. 22, §§ 2681(5)–(6) (West Supp. 2002).

41. ME. REV. STAT. ANN. tit. 22, § 2681(7) (West Supp. 2002) (re-codified as ME. REV. STAT. ANN. tit. 22, § 2681(7-A) (West Supp. 2005)).

42. It is conceivable that a pharmaceutical company would agree to grant a rebate on one drug and not another. *See id.*

43. *See id.*

44. *See* ME. REV. STAT. ANN. tit. 22, § 2681(7) (West Supp. 2002) (re-codified as ME. REV. STAT. ANN. tit. 22, § 2681(7-A) (West Supp. 2005)); *supra* text accompanying note 22.

burdened by the plan.⁴⁵

As can be seen from the prior discussion of early Medicaid provisions,⁴⁶ the device itself that Maine uses under Maine Rx to encourage manufacturers to grant rebates is nothing new. In fact, the Court in *Walsh* notes specifically that even before prior approval plans fell under the rubric of federal oversight, such regulatory tools were very common.⁴⁷ Before any litigation concerning Maine Rx began, prior approval plans had long been regarded as a perfectly acceptable way for States to control healthcare costs.⁴⁸ The question at the heart of the litigation that spawned *Walsh* is simply whether it is acceptable to use them in connection with non-Medicaid as well as Medicaid-related healthcare purposes.⁴⁹

III. HISTORY OF THE CASE

A. Facts

1. *Objections by pharmaceuticals manufacturers*

Unsurprisingly, pharmaceuticals manufacturers vigorously fought Maine Rx before it was even passed into law.⁵⁰ There are many points about the program that pharmaceuticals manufacturers could find objectionable, not least amongst these being the effect that Maine Rx inevitably has on their bottom line. Maine Rx, ultimately, is little more than a cost shifting device, in that it reallocates the cost of providing Maine residents with prescription drugs to the drug companies themselves. It would be extremely dubious to say that Maine Rx does anything but force drug companies to eat some profits in order to continue doing business in Maine.

Although reduced profits are most likely the single greatest compelling factor driving the subsequent litigation that has surrounded Maine Rx since its inception, it is not the only complaint that pharmaceutical companies have against the program. During legislative consideration of Maine Rx, PhRMA and other related groups took out full-page ads in Maine's largest newspapers, "calling the [program] 'a

45. ME. REV. STAT. ANN. tit. 22, §§ 2681(11), (13)–(14) (West Supp. 2002); Rules of the Dep't of Human Serv., § 15, Maine Rx Program (West Supp. 2002).

46. *See supra* text accompanying notes 20–31.

47. *Walsh*, 538 U.S. at 652.

48. *See id.*

49. *See Pharm. Research & Mfrs. of Am. v. Comm'r*, No. Civ. 00-157-B-H, 2000 WL 34290605, at *1 (D. Me. Oct. 26, 2000).

50. *See infra* text accompanying note 51.

cure that's worse than the disease.”⁵¹ PhRMA claimed that the bill would improperly restrict which drugs healthcare providers could prescribe, and could force Medicaid recipients and others to “take cheaper, less-effective medicines.”⁵² Additionally, the pharmaceutical manufacturers argued that the program would also “have a chilling effect on research and the development of new drugs.”⁵³ The validity of such contentions aside, PhRMA used these points extensively to bolster arguments against the program in its initial complaint filed in federal court.⁵⁴

In *Walsh*, PhRMA argues that Maine Rx should be permanently enjoined from taking effect for two reasons. First, PhRMA claims that provisions of Maine Rx conflict with the Medicaid Act by “constrict[ing] the flow of prescription drug benefits to Congress’s intended beneficiaries of Medicaid.”⁵⁵ To support its arguments in court, PhRMA uses much of the same hypothesizing and doom-casting it had conducted during ratification of the program during legislative consideration of Maine Rx. In particular, PhRMA calls upon expert witnesses to support its motion for injunction, who testify that, in their opinion, “prior authorization . . . for the purpose of influencing the manufacturer’s pricing behavior in another program . . . will lead to drugs being prescribed that are less safe and efficacious.”⁵⁶ Furthermore, PhRMA asserts that there is no Medicaid-related purpose advanced by the program, as it is merely a front for “holding Medicaid patients’ prescription drug benefits hostage to the State’s fundraising efforts on behalf of [non-Medicaid eligible residents of Maine].”⁵⁷ PhRMA concludes that since Maine Rx seeks to apply regulations that affect Medicaid recipients, and yet offers no Medicaid-related purpose within its text to suggest that it works in concert with Medicaid, it must therefore be in tension with the federal Medicaid statute.⁵⁸ PhRMA calls for the Court to permanently enjoin Maine Rx because, under the

51. A. J. Higgins, *Drug Bill Deal Reached: Compromise Aims to Cut Prices for Uninsured*, BANGOR DAILY NEWS, May 11, 2000, at 1, available at <http://proquest.umi.com/pqdweb?did=53679436&sid1&Fmt=3&clientId=9338&VName=PQD>.

52. *Id.*

53. *Id.*

54. *See, e.g., Walsh* 538 U.S. at 656–57 (citing PhRMA’s executives and experts presenting similar arguments in their affidavits to the district court).

55. Brief of Petitioner at 14, *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003) (No. 01-188).

56. *Walsh*, 538 U.S. at 657 (quoting affidavit of Dr. Howell of SmithKline Beecham Corporation).

57. *Id.*

58. *Id.* at 662.

Supremacy Clause of the U.S. Constitution,⁵⁹ federal law must prevail over state law when both attempt to regulate the same area.⁶⁰ Thus, says PhRMA, Maine Rx is pre-empted by the federal Medicaid Act and must be enjoined.⁶¹

Second, PhRMA alleges that Maine Rx must be permanently enjoined because it tramples on the dormant Commerce Clause powers reserved to Congress⁶² by attempting to regulate commercial actions that occur almost exclusively extraterritorially, and by favoring Maine citizens over citizens of other states at the expense of manufacturers located exclusively out-of-state.⁶³ It is important to note that PhRMA argues the rebate program is not voluntary, because penalties are attached to non-participation.⁶⁴ Thus, PhRMA views Maine Rx as coercive, rather than participatory. In support of this view, PhRMA points out that “virtually all manufacturers’ sales of prescription drugs occur outside of Maine in transactions with wholesalers and distributors.”⁶⁵ Given this fact, PhRMA insists that requiring them to give rebates would be tantamount to regulation of commercial transactions out-of-state.⁶⁶ PhRMA argues, since most of the commercial transactions that will be affected by Maine Rx take place out-of-state and will benefit only Maine residents, the program essentially discriminates against interstate commerce in order to exclusively fund in-state participants.⁶⁷

2. Procedural posture

The district court agreed with PhRMA on both⁶⁸ of its arguments, adopting its reasoning virtually wholesale. The Court granted an injunction enjoining Maine from “penalizing manufacturers, by placing

59. U.S. CONST. art. VI, § 2.

60. *See Walsh*, 538 U.S. at 662.

61. *See id.*

62. U.S. CONST. art. I, § 8, cl. 3. *See also* *Am. Trucking Ass’n v. Mich. Pub. Serv. Comm’n*, 125 S.Ct. 2419, 2422 (2005) (succinctly reviewing the dormant Commerce Clause and supporting case law).

63. Brief of Petitioner at 26–38, *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003) (No. 01-188).

64. *See supra* text accompanying notes 39–41.

65. Brief of Petitioner at 29, *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003) (No. 01-188) (internal citations omitted).

66. *See id.*

67. *See id.* at 35.

68. The district court also agreed with PhRMA on its arguments against Maine Rx’s anti-profiteering provisions, which the state later dropped when it appealed the Court’s decision, and will not be discussed further in this Note. *Pharm. Research & Mfrs. of Am. v. Comm’r*, No. Civ. 00-157-B-H, 2000 WL 34290605, at *2–*3 (D. Me. Oct. 26, 2000).

their drugs on [the prior approval plan], for refusing to negotiate or to pay a rebate to Maine's Rx program."⁶⁹ On appeal, the First Circuit Court of Appeals reversed the district court and vacated the injunction.⁷⁰

*B. The Decision of the United States Supreme Court*⁷¹

1. The plurality

Justices Stevens, writing for the Court, is joined by Justices Souter, Ginsburg, and Breyer. These four form the core of the plurality, which begins by stating that it is not required to rule on the validity of Maine Rx, pointing out that the district court had conducted neither evidentiary hearings, nor formally resolved any factual disputes.⁷² In so doing, the plurality attempts to confine its decision to the injunction, and leave the rest to later proceedings.⁷³

In addressing PhRMA's preemption argument, the plurality states that the question presented is, presuming that the state statute is valid, "whether there is a probability that Maine's program was preempted by the mere existence of the federal [Medicaid] statute."⁷⁴ The plurality rejects PhRMA's contention that, because Maine had not put forth any Medicaid-related purpose to justify Maine Rx's prior approval provisions before the district court, it had waived the existence of any such purposes.⁷⁵ Rather, the plurality holds that a waiver theory is inappropriate in this case because Maine had never represented that there were no Medicaid-related purposes. Given the presumption of validity to which the plurality suggests the statute is entitled, and by virtue of PhRMA's position as the party seeking the injunction, the burden is upon PhRMA to "establish[] by a clear showing, a probability of success on

69. *Id.* at *7.

70. *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 97 (1st Cir. 2001). However, the Circuit Court also recognized that some Medicaid beneficiaries might encounter some actionable harm as a result of Maine Rx's prior approval requirements, and thus reserved the right of such an aggrieved party to petition for a limited injunction at that point to readdress the matter in that context. *See id.* at 97–98. The Circuit Court's reasoning was extensively addressed (and largely accepted) by the Supreme Court on certiorari, and is noted, where relevant, in sub-section B *infra*.

71. The *Walsh* decision is highly fractured. In addition to the plurality's opinion, the Court offers three concurring and one dissenting opinion. The concurring opinions, offered by Justices Breyer, Scalia and Thomas, focus largely on substantive differences with the plurality's treatment of PhRMA's preemption argument. Because this Note is concerned with procedural aspects of the plurality's opinion, which are not treated by these concurrences, I will not discuss them further. *See Walsh*, 538 U.S. at 670–83.

72. *Id.* at 660.

73. *See id.* at 660, 668.

74. *Id.* at 661

75. *See id.* at 662–63.

the merits.”⁷⁶ Thus, if an injunction was to be granted, it is PhRMA’s duty to show the *absence* or *impossibility* of any Medicaid-related purposes, and not the other way around.⁷⁷ From these premises, the plurality reasons that “if [Maine Rx] on its face clearly serves some Medicaid-related goals, it would follow that the district court’s evaluation rested on an erroneous predicate,” and thus, should be reversed.⁷⁸ The plurality then proceeds to name three such facially apparent Medicaid-related purposes.

First, the plurality agrees with the First Circuit Court that Maine Rx will extend benefits to individuals who can be classified within the Medicaid statute as “medically needy,” even if they may not be “categorically needy.”⁷⁹ Justice Stevens reasons that the Medicaid statute explicitly authorizes States to extend benefits to this group of people.⁸⁰ He further notes that although PhRMA points to possible over-inclusiveness⁸¹ as a sure sign that Maine Rx does not have a Medicaid purpose, “the potential benefits for nonneedy persons would not nullify the benefits that would be provided to the neediest segment of the uninsured population.”⁸² Second, the plurality also agrees with the First Circuit Court that Maine Rx might reduce Medicaid spending by aiding people in addressing illnesses earlier, so that they are not forced to enroll in Medicaid later when their illnesses are advanced, and are then much more costly to treat.⁸³ Third, the plurality, *sua sponte*, presents a possible Medicaid-related purpose. The plurality argues that by simply using a prior approval plan for dispensing drug benefits to Medicaid patients, regardless of the State’s motivations therefore, the State will probably save money.⁸⁴ Such savings have been demonstrated by earlier prior approval plans conducted by managed care organizations.⁸⁵ The plurality suggests that controlling costs is a “rather obvious” Medicaid-related goal.⁸⁶

By way of qualification, the plurality admits that although Maine Rx may serve Medicaid-related purposes, such possibilities would not allow support of the program against an application for injunction if it

76. *Id.* at 662.

77. *See id.*

78. *Id.* at 662–63.

79. *Id.* at 663.

80. *Id.* at 651.

81. *See supra* text accompanying note 37.

82. *Walsh*, 538 U.S. at 663.

83. *See id.*

84. *Id.* at 663–64.

85. *See id.*

86. *Id.* at 663.

“severely curtailed Medicaid recipients’ access to prescription drugs.”⁸⁷ However, the district court’s reliance on the premise that “any impediment ‘[n]o matter how modest,’ to a patient’s ability to obtain the drug of her choice at state expense would invalidate [Maine Rx]” was misplaced, because minimal incursions on Medicaid beneficiaries’ benefits do not outweigh the State’s power of broad discretion in administering its own Medicaid plan.⁸⁸ Nor do they outweigh “Maine’s interest in protecting the health of its uninsured residents.”⁸⁹ As long as Maine assures “meaningful access” to its Medicaid beneficiaries, it does not truly matter what its motivations are for using its otherwise “broad discretion to define the package of benefits it will finance.”⁹⁰

Finally, the plurality holds that “the impact on manufacturers that Maine Rx is sure to have is not relevant because any transfer of business to less expensive products will produce savings for the Medicaid program.”⁹¹

With regard to PhRMA’s dormant Commerce Clause arguments, the plurality, this time joined by Chief Justice Rehnquist and Justices O’Connor, Kennedy, and Breyer, agrees with the First Circuit once more, holding that Maine Rx neither regulates prices of out-of-state sales transactions,⁹² nor does it tie the price of in-state products to out-of-state prices.⁹³ Maine Rx does not impose special burdens on certain manufacturers, while favoring others, nor do the rebates that Maine Rx grants provide “special benefit to competitors of rebate-paying manufacturers.”⁹⁴ Thus, Maine Rx does not violate the dormant Commerce Clause.

2. *The dissent*⁹⁵

Justice O’Connor, joined by Chief Justice Rehnquist and Justice Kennedy, form the dissent in *Walsh*. The dissent does not so much

87. *Id.* at 664.

88. *Id.* at 665.

89. *Id.* at 666.

90. *Id.*

91. *Id.* at 668.

92. Here, the plurality observes that Maine is not insisting that drug-makers sell their products to specific retailers or wholesalers for a certain price, but merely elicit a rebate from *all* manufacturers alike. *Id.* at 669.

93. *Id.*

94. *Id.* at 670.

95. The “dissent” in *Walsh* also concurred with the plurality’s reasoning concerning PhRMA’s dormant Commerce Clause argument. It is because of this concurrence that I do not address their response to the dormant Commerce Clause argument again here. *See supra* text accompanying notes 92–94.

disagree with the plurality's reasoning regarding PhRMA's preemption claims, as it objects to the plurality's conclusions and the means used to reach them. The dissent argues that the district court's decision to grant the injunction was not an abuse of discretion, because Maine Rx does not demonstrate any *prima facie* Medicaid-related purposes, the intention behind its creation being wholly unrelated to Medicaid goals.⁹⁶

The dissent adopts the "preemption test" articulated in *Glade v. National Solid Wastes Management Association*.⁹⁷ The dissent, following *Glade*'s lead, argues that the correct standard is to review the structure and purpose of each program in order to assess whether the intent of Maine's legislature in the passage of Maine Rx aligns sufficiently with Congress' intent in the passage of the Medicaid Act.⁹⁸ The dissent seems to suggest that under *Glade*, the key focus should be on the driving motives behind the programs' passage.⁹⁹ If Maine, in enacting Maine Rx, is pursuing the same ends that Congress pursued in the passage of the Medicaid Act, then the two programs are in conflict, and the Supremacy Clause mandates that the federal statute preempt that of the State.¹⁰⁰ Thus, the dissent concludes that "[a] State . . . may impose prior authorization to reduce Medicaid costs[,] but may not "impose prior authorization to generate revenue for purposes wholly unrelated to its Medicaid program."¹⁰¹ The dissent also argues that although there is no explicit prohibition on the use of prior authorization plans in the statutory language, the "purpose and structure" of the Medicaid Act inherently limits the usage of that mechanism for other-than-Medicaid-related ends.¹⁰²

As the dissent notes in *Walsh*, Maine Rx specifically states that its purpose is "to reduce prescription drug prices for residents of the State, and it accomplishes this goal by threatening to impose prior authorization on otherwise covered outpatient drugs."¹⁰³ The dissent assumes that Maine Rx operates regardless of financial need, and therefore the program's stated purpose reveals a motive incongruent with that of the Medicaid Act, which seeks to provide healthcare access to the *poor*.¹⁰⁴ Given that statutory language constituting Maine Rx does not evidence a

96. *Walsh*, 538 U.S. at 684 (O'Connor, J., dissenting).

97. *Glade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992).

98. *Walsh*, 538 U.S. at 684–85 (O'Connor, J., dissenting).

99. *Id.* at 685.

100. *Id.* at 684–85.

101. *Id.* at 685.

102. *Id.* at 685–86.

103. *Id.* at 687 (citing ME. REV. STAT. ANN. tit. 22, §§ 2681(1), (2)(F), (7) (West Supp. 2002)) (internal quotation marks omitted).

104. *See Walsh*, 538 U.S. at 687 (O'Connor, J., dissenting).

Medicaid-related purpose on its face, and that Maine did not advance any such purpose in the court below, and that there are no facts in the record supporting such purposes, the dissent concludes that the district court did not abuse its discretion in granting an injunction against Maine Rx.¹⁰⁵ The dissent notably points out that in evaluating the granting of an injunction on appeal, the Court is not to assume that the district court is required to do factual contortions to find Medicaid-related purposes when no party advanced such arguments below.¹⁰⁶

IV. ANALYSIS

Having thus explored the background behind *Walsh* and the reasoning behind the plurality's and dissent's arguments, I now turn to an examination of these opinions and their effect on the pressing need for healthcare reform. I will hereafter attempt to show that the plurality's assessment of the standard of review is incorrect, and as such, PhRMA should technically have prevailed in this case. However, I suggest that from a practical standpoint, the plurality's procedural mistake resulted in the best possible overall outcome, given pressing concerns about healthcare reform.

Nevertheless, despite the Court's procedural flaws, the decision is still defensible. At its core, *Walsh* presents an ethically charged issue. Subtle legal packaging aside, the case ultimately asks the Court to balance human lives against corporate profits. Given this rather perverse calculus, I submit that equity requires the result the plurality reaches, even in the face of technical mandates to the contrary. Additionally, the plurality's decision has great potential for encouraging state-sponsored healthcare reform, in that it affirms the right of the States to use their police powers to provide for their uninsured residents, even when the use of those powers implicates federal programs.

A. *The Plurality Stumbles on the Standard of Review*

1. *The plurality's shaky foundation*

As beneficial as the plurality's position may be, because it is based upon an improper application of the standard of review, it is procedurally flawed at its foundation. While initially presenting the correct standard of review,¹⁰⁷ the plurality thereafter seems to ignore that standard by

105. *See id.* at 689.

106. *See id.*

107. *See infra* text accompanying notes 108–18.

presuming the validity of Maine Rx on appeal. Despite the district court's prior judicial determination that the statute was invalid, the plurality incorrectly holds that the district court's grant of an injunction was erroneous because it did not raise Maine's arguments *sua sponte*.

a. *The statement of the standard.* Citing *Doran v. Salem Inn, Inc.*,¹⁰⁸ the plurality correctly recognizes that the standard of review here is whether the district court abused its discretion in awarding PhRMA an injunction.¹⁰⁹ *Doran* sets forth the familiar and demanding standard for granting a preliminary injunction, which requires a plaintiff to establish both irreparable injury, should the injunction not be issued, and likelihood of prevailing on the merits.¹¹⁰ *Doran* also states the standard of review for injunctions on appeal, specifically noting that "while the standard to be applied by the district court in deciding whether a plaintiff is entitled to a preliminary injunction is stringent, the standard of appellate review is simply whether the issuance of the injunction . . . constituted an abuse of discretion."¹¹¹ Since the Court is reviewing the award of an injunction in this case, the correct standard of review, as provided by *Doran*, is whether the district court abused its discretion in granting the injunction.¹¹²

It is well-established that acts of judicial discretion, such as the injunction at issue in *Walsh*, are given extreme deference upon review.¹¹³ The abuse of discretion standard is incredibly accommodating towards the trial judge's decision. By way of example, it is said that "a mere error of judgment is not abuse of discretion."¹¹⁴ Much more than this, in the context of appellate review, abuse of discretion is often characterized as resulting "manifest injustice," or decision-making that "is the result of partiality, prejudice, bias, or ill will[,]" or decisions that are "arbitrary or capricious," "against logic and the facts and reasonable deductions to be drawn therefrom," or so erroneous "as to shock reason and justice."¹¹⁵ Furthermore, a reviewing court may not overturn a grant of injunction merely because it would have decided the case differently.¹¹⁶ Indeed, "[a] reviewing court is never justified in substituting its discretion for that of the trial court."¹¹⁷ Positively stated, a reviewing court must affirm a trial

108. *Doran v. Salem Inn, Inc.*, 422 U.S. 922 (1975).

109. *Walsh*, 538 U.S. at 660.

110. *Doran*, 422 U.S. at 931.

111. *Id.* at 931–32.

112. *Id.*

113. See 5 C.J.S. *Appeal and Error* § 772 (1993).

114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.*

judge's grant of injunction if it "believes that a judicial mind could reasonably have reached the conclusion of the court below, or whether any reasonable person would agree with the trial court."¹¹⁸ Obviously, this standard is very difficult to meet. Yet, as will be shown hereafter, the plurality all but ignores the high bar set here by *Doran* in finding the district court's holding an abuse of discretion.

b. Presumptions of constitutionality on appeal. A central element of the plurality's justification of the standard of review in *Walsh* is its determination that the Maine Rx statute is entitled to a presumption of validity on appeal.¹¹⁹ The plurality relies upon *Davies Warehouse Co. v. Bowles*¹²⁰ in establishing that the Maine Rx statute is entitled to a presumption of validity.¹²¹ *Davies* stands, in relevant part, for the proposition that, in the context of a court reviewing potential preemption of state statutes on the merits, "[s]tate statutes . . . are entitled to the presumption of constitutionality *until their invalidity is judicially declared.*"¹²²

The plurality argues that since the Secretary of Health had not otherwise held the Maine Rx statute to be in conflict with the Medicaid Act, the statute is therefore entitled to a presumption of constitutional validity, even, so it seems, on appeal concerning merely an award of injunction.¹²³ However, it is highly questionable whether the presumption-of-validity principle in *Davies* is applicable to the current case. In *Davies*, the Court reviewed the preemption of state-legislated railroad regulation statutes by similar federal provisions.¹²⁴ It did so *on the merits*, and only after the specialty forums assigned to handle appeals specifically on those statutes had already passed their judgment on the same issue.¹²⁵ In *Walsh*, the Court is only reviewing a grant of an injunction, and not the substantial validity of Maine Rx itself. Furthermore, the Department of Health and Human Services (the specialty forum assigned to review the States' Medicaid plans) has not yet passed upon the validity of Maine Rx.¹²⁶ This is in stark contrast to the situation in *Davies*, where the merits of the preemption question had

118. *Id.*

119. *Walsh*, 538 U.S. at 661–62.

120. *Davies Warehouse Co. v. Bowles*, 321 U.S. 144 (1944).

121. *Walsh*, 538 U.S. at 661.

122. *Davies*, 321 U.S. at 153 (emphasis added).

123. *Walsh*, 538 U.S. at 661–62.

124. *Davies*, 321 U.S. at 147.

125. The merits of federal preemption of the state railroad regulation statutes were passed upon by both the federal Price Administrator and the then-extant U.S. Emergency Court of Appeals before the Supreme Court addressed the issue again on the merits. *Id.*

126. *Walsh*, 538 U.S. at 660.

already been passed upon by both of the forums assigned to hear challenges to railroad regulations.¹²⁷ There is no suggestion in the *Davies* case that the presumption of validity is applicable when the merits of the statute to be accorded the presumption are not even at issue.¹²⁸ Even if the *Davies* constitutional-presumption principle was applicable to interlocutory determinations at the trial level, at the appellate level, where a district court has already “judicially declared” the invalidity of the statute in question, that statute should be entitled to no such presumption.¹²⁹

In accepting *Doran*’s casting of the standard of review, the plurality should have presumed the validity of the district court’s holding concerning the invalidity of the Maine Rx statute. On appeal, the correct presumption applicable when reviewing injunctions should be in favor of the district court’s determination, in keeping with the abuse of discretion standard. However, the plurality sharply diverges from this established standard by presuming the validity of the Maine Rx statute. If the presumption had been correctly made in PhRMA’s favor, Maine could never have carried its burden on appeal of proving abuse of discretion, since the record was insufficient to support Medicaid-related purposes to overcome PhRMA’s preemption argument. In this manner, the plurality mistakenly held in favor of Maine.

c. The dissent and the arguments not made. In addition to the mistaken presumption of constitutional validity, the plurality’s decision is also based upon the very tenuous, and ultimately incorrect, conclusion that PhRMA failed to meet its burden by not making Maine’s arguments for it.¹³⁰ The plurality finds that the district court’s grant of an injunction

127. See *supra* text accompanying note 125.

128. Some may argue that when an appellate court reviews a grant of injunction, the underlying merits of the case in which the injunction is granted are brought into issue before the reviewing court as well. Such a contention is only partially accurate. In the context of an appellate review of a trial court’s grant of injunction, the abuse of discretion standard permits an inquiry into the underlying merits of the case only to the extent that such a review reveals that the trial judge did or did not abuse his discretion in finding that the moving party met its burden. See 36 C.J.S. *Federal Courts* § 598 (1993). Thus, the merits of the underlying case are only at issue at the appellate level inasmuch as the appellate court may examine them to determine whether, based upon the record developed before the trial court, a reasonable judge could find that the moving party met its burden. See 5 C.J.S. *Appeal and Error* §§ 716, 772 (1993); 36 C.J.S. *Federal Courts* § 598. In addition, the highly deferential abuse of discretion standard suggests that a reviewing court should not interfere with a trial court’s equitable discretion merely because they may disagree with the outcome. See *supra* text accompanying notes 116–17. In summary, it is the trial judge’s *evaluation* of the moving party’s efforts to show that it has a likelihood of prevailing on the merits that is at issue on appeal, and *not* the merits themselves. Given this severely limited sense in which a reviewing court may properly address the underlying merits on appeal of a grant of injunction, I submit that the merits of the case are not truly at issue at all.

129. See *supra* text accompanying note 122.

130. See *Walsh*, 538 U.S. at 662–63.

was an abuse of discretion because PhRMA did not carry its burden at the trial court level by establishing that there were no possible Medicaid-related purposes apparent from Maine Rx on its face.¹³¹ As the dissent rightly points out, this was likewise a misapplication of the abuse of discretion standard because the argument effectively shifts the burden to PhRMA and the district court to formulate, raise, and consider all of Maine's arguments on its behalf.¹³² Such an interpretation of the responsibilities of lower courts when considering motions for injunction is unreasonable, in that it requires judges to be partisan. In addition, its application on appeal does great violence to the deference normally accorded to their acts of judicial discretion when under appellate review. I argue that it also sets the burden on parties moving for injunctions unreasonably high and undermines the principal notions underpinning our adversarial system of justice.

On appeal, PhRMA argues that since Maine did not raise any Medicaid-related purposes for Maine Rx in the district court, they were barred from doing so on appeal.¹³³ The plurality maintains, however, that Maine's failure to present Medicaid-related purposes for Maine Rx to the district court did not constitute a waiver of their ability to raise such considerations on appeal.¹³⁴ According to its reasoning, since at the trial level PhRMA bore the heavy burden of "establishing, by a clear showing, a probability of success on the merits", waiver theories were inapplicable to Maine's appeal.¹³⁵ The "State never represented that there was no Medicaid purpose served by its program; it simply argued that it did not need to offer one."¹³⁶ The plurality argues that since it could conceive of three possible Medicaid-related purposes (which were not presented to the district court), the grant of injunction "rested on an erroneous predicate."¹³⁷ This characterization of both PhRMA's and the district court's burden on appeal is entirely against the standard of review, not to mention an unreasonable distortion of the test for an injunction.¹³⁸

131. *See id.*

132. *See id.* at 687–90.

133. *See id.* at 662–663.

134. *See id.*

135. *Id.* at 662.

136. *Id.*

137. *Id.* at 663.

138. I allude to the plurality's harsh interpretation of the test for an injunction. The *Walsh* plurality purports to adopt the injunction test from *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam). *Walsh*, 538 U.S. at 662. The *Mazurek* decision requires that the party moving for an injunction demonstrate, by a clear showing, that it is able to carry the burden of persuasion. *Mazurek*, 520 U.S. at 972. Although the requirement is undeniably high, ability to carry the burden of persuasion does not include the responsibility of proving *inevitability* of success, which seems to

The dissent offers some effective counters to the plurality's arguments. The dissent notes first that the Maine Rx statute did not reveal any Medicaid-related purpose on its face.¹³⁹ Far from it, Maine Rx's explicitly stated goal is "to reduce prescription drug prices for residents of the State," at the expense of benefits that would otherwise have been available to Medicaid beneficiaries without the statute's interference.¹⁴⁰ The dissent then argues that since Maine did not raise any other Medicaid-related purposes in the district court, it left the record void of any such arguments to evaluate on appeal for abuse of discretion.¹⁴¹ Therefore, the Medicaid-related purposes that the plurality suggests as possible candidates "rests on factual predicates that are not supported in the record."¹⁴² Additionally, the dissent argues that each of the three Medicaid purposes the plurality advances are at best speculative, and as such it could not have been properly expected of the district court to develop and make such guesses of its own accord, especially when Maine had failed to do so itself.¹⁴³ Expecting the district court to conceive of these arguments *sua sponte* is not in keeping with the abuse of discretion standard that the plurality purports to apply in this case. In fact, the dissent's position serves to highlight just how badly the plurality's arguments gore the deference usually due a district court when ruling on a discretionary act. As stated previously, the abuse of discretion standard should give substantial deference to the trial judge's opinion.¹⁴⁴ In this case, the plurality overturns the district court's holding not because it was biased or because it failed to consider relevant facts in the record, but because it did not create that record itself. Inasmuch as trial courts' discretionary acts are usually afforded very wide latitude, the plurality's opinion in this case tramples on an important assurance that the trial courts need to achieve just and equitable resolutions of difficult and complicated problems.

be what the plurality requires. *See Walsh*, 538 U.S. at 662–63. In other words, PhRMA's proper burden before the district court was demonstrating that, based upon the record before the Court, it will not lose. The district court believed that PhRMA did so. It is uncontested that PhRMA addressed and met every argument that Maine presented at the trial court proceedings, and that the district court was satisfied they could prevail on the merits based upon those proceedings. *See Walsh*, 538 U.S. at 658–59, 687–88. The *Walsh* plurality, however, would also require that PhRMA demonstrate success even beyond the record, requiring instead that PhRMA also counter arguments that its opponent never made. *See id. Mazurek* does not require such Herculean efforts. *Mazurek*, 520 U.S. at 972.

139. *Walsh*, 538 U.S. at 688.

140. *See id.* at 687 (quoting ME. REV. STAT. ANN. tit. 22 §§ 2681(1), (2)(F), (7) (West Supp. 2002)).

141. *See id.* at 688.

142. *Id.*

143. *See id.* at 688–89.

144. *See supra* text accompanying notes 113–18.

Furthermore, the plurality's insistence that PhRMA anticipate and counter every *possible* contingency within Maine Rx that could serve as a Medicaid-related purpose, regardless of whether Maine argued such or not, simply because PhRMA "bore the burden of establishing . . . a probability of success on the merits[.]"¹⁴⁵ places an unreasonably high burden on it, even given the already-stringent burden plaintiffs normally bear when seeking an injunction.¹⁴⁶ The plurality is mistaken in requiring such an exacting showing from PhRMA. Even given the plurality's test that PhRMA's burden before the district court was to establish by a clear showing that it had a probability of success on the merits,¹⁴⁷ this is still a different standard than requiring PhRMA to explore and counter every conceivable argument that Maine could make, which is truly what the plurality appears to expect.¹⁴⁸ Such a standard is unobtainable in most instances, because there are usually innumerable possible arguments that any party can make on any given issue. Many of these possible arguments may have little or no merit, because they might consider extremely remote factual possibilities. In proceedings on the merits of the issue, such remote possibilities would most likely be considered frivolous, and the plaintiff would not need to counter them to actually succeed on the merits, let alone demonstrate a probability of success against such arguments. Thus, it is a mistake for the plurality to interpret PhRMA's burden as requiring such an impossible and exacting showing at the district court level.

Finally, the plurality's expectation that either PhRMA or the district court anticipate and consider all of Maine's arguments for it, even those that the State did not make, and for which there is no support from facts in the record, is mistaken because it undermines our adversarial system of justice. In *Perry v. Leeke*, Justice Marshall observed that "[t]he paramount importance of vigorous representation follows from the nature of our adversarial system of justice. This system is premised on the well-tested principle that truth—as well as fairness—is best discovered by powerful statements on both sides of the question."¹⁴⁹ Our entire legal system is predicated upon the supposition that when two parties advocate their positions fervently before a neutral arbiter, the truth can be more clearly seen. Requiring one party to make the arguments for the other, or requiring such of the neutral arbiter, turns this system on its head, and

145. *Walsh*, 538 U.S. at 662.

146. *See supra* text accompanying note 138.

147. *See id.*

148. *See Walsh*, 538 U.S. at 662.

149. *Perry v. Leeke*, 488 U.S. 272, 291 (1989) (Marshall, J., dissenting) (internal quotation marks and citations omitted).

only lends confusion and inequality to an otherwise well-established process. Moreover, such requirements give the nonmoving party the perverse incentive to tread more frequently on the rights of the moving party. This is because under this system the nonmovant has virtually no responsibility to mount a defense, while the movant must himself shoulder the impossible burden of developing and addressing all of the defendant's arguments, or face a refusal of remedy. This absurd result could not possibly have been the plurality's intention, but its interpretation of the standard of review in *Walsh* suggests exactly this consequence. Therefore, the plurality's interpretation of the standard is wrong.

2. *No other justification for the plurality's standard*

Given the arguments above, I explore now whether the plurality could have more effectively ignored the standard of review altogether to achieve a sounder result. One possible approach, which I will explore below, has been used to completely overcome the standard of review. However, this device is strictly limited to certain circumstances that necessarily call for exception, and the facts at issue in *Walsh* do not justify deviance from the normal standard.

In *Thornburgh v. American College of Obstetricians & Gynecologists*, the Court held that the issues of the case were ripe for decision, even though it was still in the process of interlocutory appeal.¹⁵⁰ In bypassing the usual standard of review to reach the merits of the case, the Court made the unusual observation that "a court of appeals ordinarily will limit its review in a case of this kind to abuse of discretion is a rule of orderly judicial administration, not a limit on judicial power."¹⁵¹ However, the Court also strictly limited such an interpretation of the standard to cases where there is "an unusually complete factual record and legal presentation from which to address the important [] issues at stake."¹⁵² Thus, where the record is still underdeveloped, as in *Walsh*, this exception does not apply.¹⁵³

Thornburgh illustrates the extreme circumstances that are required for a court to ignore the abuse of discretion standard when reviewing a trial court's award of an injunction. It was not enough for the plurality in *Walsh* to disagree with the district court's decision to award PhRMA an

150. *Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 755–57 (1986) (overruled on other grounds by *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992)).

151. *Thornburgh*, 476 U.S. at 757.

152. *Id.*

153. *See id.* at 757 n.8.

injunction to overturn that decision. Indeed, it has been noted that “[t]he fact that the appellate court would have decided otherwise does not establish an abuse of discretion.”¹⁵⁴ Rather, to overcome the extremely deferential abuse of discretion standard, an extremely well-developed record and strictly circumscribed legal issues are required. As neither of these elements are present in *Walsh*,¹⁵⁵ the plurality has no existing justification for treating the abuse of discretion standard as a lower plenary review standard.

In light of the arguments made above, it is difficult to see how the plurality reached the holding that it did. Indeed, I submit that the only conclusion to be drawn from this discussion is that because the plurality is mistaken in the way it addresses the abuse of discretion standard, it should not have overturned the district court’s grant of injunction, but should have held in PhRMA’s favor.

B. Getting it Right by Getting it Wrong

Rather ironically, although the plurality, procedurally speaking, was incorrect in overturning the injunction against Maine Rx, and should have found in favor of PhRMA, this does not mean that its decision is wrong. Ultimately, the Court must balance the core interests clashing in *Walsh*, human lives and corporate profits. Faced with such a decision, equity and sound policy require a result in Maine’s favor. Furthermore, the plurality’s decision to hold in Maine’s favor opens a valuable door in the pressing area of healthcare reform. The aid that this decision will give to States as they work towards much-needed healthcare reforms has been, and will likely continue to be, invaluable in achieving greater access to healthcare services. For these two reasons, the plurality, in holding against the standard of review, arguably achieves a more just result than if it had correctly applied the standard.

1. Doing justice and equity

a. Healthcare and the problem of access. One of the most urgent problems facing healthcare in America is the problem of access. In 2004, 45.8 million Americans went without any health insurance for all or part of the year.¹⁵⁶ This number represents a trend in growth, especially among those who work part-time, where the number of uninsured rose by

154. 5 C.J.S. *Appeal and Error* § 772.

155. See *Walsh*, 538 U.S. at 660.

156. U.S. CENSUS BUREAU, U.S. DEP’T OF COMMERCE, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE U.S.: 2004, 16 (2005).

almost 3% in one year, and also amongst those households that had an annual income of between \$50,000 and \$75,000, where the number of uninsured rose by almost 10,000 in one year.¹⁵⁷ Worse than this, some 70 million Americans had no insurance for prescription drugs in 2004.¹⁵⁸ This number may be ameliorated in the future somewhat by the provision of the new Medicare drug benefit, albeit perhaps not as extensively as some previously believed it would.¹⁵⁹ In the end, however, these numbers reflect the reality that there is a sizable population that does not have any aid available to it to offset out-of-pocket expenditures on healthcare, especially on prescription drugs.

One recent study noted that “[e]xpenditures for prescription drugs in the United States are increasing much faster than total health spending.”¹⁶⁰ Indeed, the Kaiser Family Foundation reported that in 2002, spending on prescription drugs totaled \$162.4 billion, an increase of 15% from the previous year, reflecting a trend that has held substantially constant for eight years.¹⁶¹ Additionally, the prices of prescription drugs have continued to steadily climb at an average rate of 7.4% for the last decade, more than double the average inflation rate of 2.5%.¹⁶² This means that drug prices are continuing to increase at a dramatic rate, while prescription drug coverage continues to shrink. The logical result is that many of this population have to forego utilization of prescription drugs. One 2003 survey found that “37% of the uninsured said they did not fill a prescription because of cost, compared to 13% of the insured.”¹⁶³

It is now well-accepted that many medical conditions are easily treatable with access to the right medicines, and yet a growing number of people must do without, because they cannot afford the medicines they need, to the endangerment of their health and, in certain cases, their lives.

b. The pharmaceutical industry. In contrast, the pharmaceutical industry is, in all respects, very healthy. In 2004, the top twenty drug manufacturers made approximately \$332.5 billion in sales.¹⁶⁴ According

157. *Id.* at 18.

158. FURROW ET AL., *supra* note 5, at 805.

159. See Bruce Stuart, et al., *Assessing The Impact of Coverage Gaps in the Medicare Part D Drug Benefit*, HEALTH AFF., (2005) available at http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.167v1.**

160. AMERICAN PUBLIC HEALTH ASSOCIATION, *Making Medicines Affordable: the Price Factor* (2000) at *2, APHA Position Paper 20006, May 13, 2004, at *2, available at http://www.apha.org/legislative/testimonies/FDAimportComments5_13.pdf.

161. THE HENRY J. KAISER FAMILY FOUNDATION, *Prescription Drug Trends*, October 2004, at *1, <http://www.kff.org/rxdrugs/upload/Prescription-Drug-Trends-October-2004-UPDATE.pdf>.

162. *Id.*

163. *Id.* at *2.

164. M. Asif Ismail, *Special Report: Drug Lobby Second to None, How the Pharmaceutical*

to recent raw data, the pharmaceutical industry, as a whole, garnered \$20.3 billion dollars in net profits in 2004, outstripping every other American industry by at least \$5 billion.¹⁶⁵ The same data revealed that these earnings represent a profit-to-revenue ratio of 18.9%, the largest profit ratio of any industry in America, at almost 7% more than the next highest industry.¹⁶⁶ Of its total expenditures for 2004, the pharmaceutical industry spent nearly \$60 billion on marketing for its products, as opposed to the approximately \$30 billion it spent on research and development, undercutting the industry's arguments that programs like Maine Rx will do long-term harm to society because they will reduce available funds for research and development of new drugs.¹⁶⁷ These data demonstrate that pharmaceutical manufacturers, unlike the uninsured American public, are in excellent shape.

c. The balancing of equities. Procedural considerations aside, Maine's most powerful argument lies in equitable principles. Maine deserves a ruling in its favor not because it has the sounder legal argument, but because the stakes involved weigh heavier on the State's side. PhRMA's most pressing interest in opposing Maine Rx was its bottom line. By allowing Maine residents to purchase prescription drugs at reduced prices, which are funded by the rebates that the State leverages from the pharmaceutical manufacturers, Maine Rx requires those manufacturers to fund the drug benefit. The rebates that the manufacturers would have to pay the State would effectively reduce the amount of profits manufacturers could make otherwise. The drug companies stand to lose a significant amount of money in lost profits, due to the reduced profit margin imposed by the rebate program. At stake for Maine, however, is the ability to increase access to prescription drugs for its residents, and thereby improve, or even save, lives of residents. By offering reduced prices on needed drugs for those who are too poor to afford better health insurance, but who have too much to qualify for Medicaid assistance, Maine Rx offers a reasonable way to improve access. In the end, *Walsh* pitted human life against pharmaceutical manufacturers' profit. Given this calculus, it seems only natural that

Industry Gets its Way in Washington, Center for Public Integrity (July 7, 2005), available at <http://www.publicintegrity.org/rx/report.aspx?aid=723>.

165. Bernard Sanders, *New Figures Prove Pharmaceutical Industry Continues to Fleece Americans*, (Oct. 30, 2005). <http://bernie.house.gov/prescriptions/profits.asp>

166. *Id.*

167. Ismail, *supra* note 164. See also, THE HENRY J. KAISER FAMILY FOUNDATION, *Impact of Direct-to-Consumer Advertising on Prescription Drug Spending*, Jun. 2003, at 7, available at <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14378> (detailing how industry spending on certain forms of advertising is not essential to continued increases in drug spending).

Maine, with the more deserving equities hanging in the balance, should have prevailed, no matter what the procedural defects its case encountered. It is in light of these weightier considerations that the plurality's decision, although mistaken in application of the standard of review, nevertheless seems to be more in line with a sense of justice and equity, as well as better public policy.

2. *What was gained and what was lost*

a. *Reforming healthcare.* By deciding against the injunction against Maine Rx, the plurality afforded States greater ease and power in accomplishing healthcare reform. Given the number of Americans who believe that healthcare reform is a vital goal,¹⁶⁸ the plurality's decision is arguably justified by a compelling public policy to encourage effective reform. The plurality's decision encourages reform by sustaining the States' use of police powers to provide for their uninsured residents.

While it is true that the plurality attempted to limit the impact of its ruling specifically to injunction cases where the state healthcare action in question has not yet been reviewed by the Secretary of Health,¹⁶⁹ I believe that the inevitable result has been, and will continue to be, much more expansive in effect. For example, the plurality's ruling with regard to PhRMA's dormant Commerce Clause argument¹⁷⁰ found much greater support, with only Justices Scalia and Thomas abstaining therefrom.¹⁷¹ This showing of solidarity will most likely preclude future challenges to States' healthcare reform efforts (ala Maine Rx), through use of the dormant Commerce Clause.¹⁷² In addition, the plurality's arguments dealing with the issue of federal preemption provide reform-minded lower courts with some ammunition for upholding State healthcare reform efforts against challenges by drug companies seeking to protect their wide profit margins. For courts that are less "activist," the *Walsh*

168. See THE HENRY J. KAISER FAMILY FOUNDATION, *March/April 2005 Health Poll Report Survey*, Apr. 2005, at 4, available at <http://www.kff.org/kaiserpolls/upload/March-April-2005-Kaiser-Health-Poll-Report-Toplines.pdf>.

169. See *Walsh*, 538 U.S. at 660–61.

170. I have deliberately chosen not to widely discuss this already-well-explored area of the *Walsh* opinion, but the effect that this aspect of the opinion has, and will continue to have, on healthcare reform is too important to remain completely untouched. Thus, I recognize it here as perhaps the single greatest contribution of the opinion to state healthcare reform efforts.

171. *Walsh*, 538 U.S. at 683.

172. See e.g., Timothy Stoltzfus Jost, *Pharmaceutical Research and Manufacturers of America v. Walsh: The Supreme Court Allows States to Proceed with Expanding Access to Drugs*, 4 YALE J. HEALTH POL'Y L. & ETHICS 69, 83 (2004); Jessica S. Intermill, Note, *Take Two and Call Your Legislator in the Morning: What States Can Learn From Pharmaceutical Manufacturers of America v. Walsh*, 27 HAMLINE L. REV. 265, 293–95 (2004).

opinions, particularly the two concurrences, give some power to lower courts to aid state healthcare reform programs like Maine Rx by encouraging them to defer to the Secretary of Health whenever possible.¹⁷³ Perhaps most importantly, the plurality's opinion aides State healthcare reform by sustaining the States' use of their police powers to "protect[] the health of its uninsured residents" in the face of commercial challenges, even when the exercise of such powers overflows into areas governed by federal statutes.¹⁷⁴

b. Dilution of potency through procedural flaws and fracture. Inasmuch as the plurality's opinion is a boon to States' efforts at healthcare reform, its impact may still be muted somewhat for two reasons. First, the procedural flaws with the plurality's opinion take away from the force of its arguments by weakening its credibility. The dissent points out the most glaring problems with the plurality's application of the abuse of discretion standard,¹⁷⁵ and I have supplemented and expanded those arguments to illustrate the validity of the dissent's position in this regard. The procedural flaws of the plurality's position may weaken the impact that the decision could have. Nevertheless, in a choice between aiding state healthcare reform and protecting drug company profits, I believe that the plurality's decision ended up the wiser part, even if that decision costs some precedential weight through lack of credible procedural foundation. After all, such observations do not change the fact that the plurality's opinion remains, for all intents and purposes, the preeminent opinion of the case, which lower courts are bound to follow.

Second, *Walsh's* impact on healthcare reform may also lose potency simply because the Court was so fractured in its decision. A greater showing of solidarity could have done more to support the cause of state-initiated healthcare reform by giving challenging parties less incentive to bring suits that they know will most likely fail on appeal, given the definiteness of the Court's position on the matter. *Walsh's* efficacy may be diminished because challengers will see a weak and divided Supreme Court that may turn its way on the very next case.

C. Looking Toward a Brighter Future—Hope for Continued Reform

1. Minor changes and subsequent litigation

Immediately after the Court's decision in *Walsh*, the legislature of

173. *Walsh*, 538 U.S. at 660–61, 670–84.

174. *Id.* at 666.

175. *See Id.* at 684–90.

Maine, to avoid future litigation and the need to submit the program for approval by the Secretary of Health, altered Maine Rx somewhat to address some of the contentions PhRMA raised during the prior litigation.¹⁷⁶ A minor change that the Maine legislature made was the removal of the anti-racketeering provisions in the original Maine Rx statute, which the district court held unconstitutional in the prior litigation, and which the Maine legislature never appealed. The Maine legislature also changed eligibility provisions in the program, this time explicitly linking eligibility for enrollment with financial considerations.¹⁷⁷ To signify the new status of the program, the Maine legislature also renamed the program “Maine Rx Plus.”¹⁷⁸ Commenting on the changes, Maine’s Attorney General speculates that the new “program meets all the standards and guidelines of (Central Medical services, the agency that oversees the federal Medicare and Medicaid programs). We think there’s no need for prior approval.”¹⁷⁹

As it turns out, the changes did not discourage PhRMA from filing another suit against Maine, seeking to force the State to submit its program to the Secretary of Health for approval and also to enjoin it from implementing Maine Rx Plus pending the Secretary’s review.¹⁸⁰ This time, however, the district court denied PhRMA the injunction.¹⁸¹ The court accepted Maine’s reasoning that since Maine changed its statute, PhRMA’s claims were not yet ripe for review; especially considering that the new statute would not impose the prior approval provisions of the statute against nonparticipating drugs until October of 2005.¹⁸² Such a holding does not, of course, definitively decide the validity of Maine’s program. However, it may foreshadow a subtle shift in the district court’s view of programs like Maine Rx Plus. Only time will tell.

2. *The spread of Maine Rx Plus*

Other developments since *Walsh* are much more positive for state

176. Meg Haskell, *Maine Rx Plus Ready to Roll: 275,000 Eligible for Discount Drugs*, BANGOR DAILY NEWS, Jan. 14, 2004, at A1, available at <http://proquest.umi.com/pqdweb?did=529012371&sid=2&Fmt=3&clientid=9338&RQT=309&VName=PQD>.

177. The financial eligibility requirements under the new law are quite generous, much more so than for Medicaid enrollment. The statute extends eligibility to all residents who are 350% above the federal poverty level, or whose unreimbursed prescription drug costs total 5% of family income, or whose total unreimbursed medical expenses equal 15% or more of family income ME. REV. STAT. ANN. tit. 22 § 2681 (2)(F) (West Supp. 2005).

178. Haskell, *supra* note 176.

179. *Id.* (internal quotation marks omitted).

180. *Pharm. Research & Mfrs. of Am. v. Nicholas*, 353 F. Supp. 2d 231, 232 (D. R.I. 2005).

181. *See id.* at 246.

182. *See id.* at 239–46.

healthcare reform. In particular, the State of California is currently considering adopting a drug benefit program very similar to Maine Rx Plus.¹⁸³ Perhaps this development in the nation's most populous state indicates that States have been emboldened by the plurality's decision in *Walsh*, and are beginning to more fully exercise their police powers, now that they are free to do so without the fear of at least a dormant Commerce Clause challenge, and perhaps even some preemption challenges as well.

V. CONCLUSION

Although the plurality's reasoning in *Walsh* rests on a flawed procedural foundation, the future of healthcare reform is brighter because of its decision. The sustaining of States' use of their police powers to provide for the healthcare needs of their uninsured populations can only be a good thing, even despite technical inaccuracies that should have rendered a different decision.

Who is to say what the true effects of that decision will be? *Walsh* will at least stem some of the massive growth in prescription drug costs in certain jurisdictions, which may, in turn, improve overall health through the improvement of early access to necessary medications by those who could not otherwise afford them, and are otherwise ineligible for Medicaid. But maybe its influence will reach even further. Perhaps programs like Maine Rx Plus will be models for future programs that cover ambulatory care by promoting the solicitation of "rebates" from HMO's, MCO's and hospitals. *Walsh* allows States to use those tools at their disposal to provide for those who cannot afford health insurance or other drug benefits. Maybe, by reaffirming the use of police powers in fostering programs like Maine Rx Plus, *Walsh* will be the first of the necessary catalysts that will allow a jump to universal healthcare.¹⁸⁴

183. Jeff Tuttle, *Rx Plans Compete on Ballot in Calif.: One Initiative Like Maine Rx Plus*, BANGOR DAILY NEWS, Sept. 30, 2005, at A1, available at <http://proquest.umi.com/pqdweb?did=529012371&sid=2&Fmt=3&clientid=9338&RQT=309&VName=PQD>.

184. For the purposes of this note, I operate from the premise that universal healthcare is a desirable goal. I recognize, however, that the debate on the desirability and feasibility of universal healthcare is complex and often heated, and as such, a significant treatment of this topic is well beyond the scope of this note. For an interesting look at arguments concerning these issues, see James B. Roche, *Health Care in America: Why We Need Universal Health Care and Why We Need It Now*, 13 ST. THOMAS L. REV. 1013 (2001) (discussing arguments in favor of universal health care); Timothy Stoltzfus Jost, *Why Can't We Do What They Do? National Health Reform Abroad*, 32 J.L. MED. & ETHICS 433 (2004) (examining European universal health care models and how they facilitate similar reforms in the U.S.); William P. Gunnar, *The Fundamental Law That Shapes the United States Health Care System: Is Universal Health Care Realistic Within the Established Paradigm?*, 15 ANNALS HEALTH L. 151 (2006) (analyzing the feasibility of movement toward universal health care in the U.S.).

Wherever *Walsh* may lead in the future, in situations like this, I find it interesting that members of the Supreme Court can make the right decision, even when it is “wrong.”

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* JD Candidate, 2007. With thanks to Professor Susan Chasson for her encouragement, and with greatest love and appreciation to my Kate, for her fathomless support and patience.