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Preemption Doctrine - Preliminary Injunction Barring Implementation of State Prescription Drug Coverage Program Deemed Reversible Error - Pharmaceutical Research and Manufacturers of America v. Walsh, 123 S. CT. 1855 (2003)

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PREEMPTION DOCTRINE – PRELIMINARY INJUNCTION BARRING IMPLEMENTATION OF STATE PRESCRIPTION DRUG COVERAGE PROGRAM DEEMED REVERSIBLE ERROR – *PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA V. WALSH,* 123 S. CT. 1855 (2003).

As a fundamental tenet of Constitutional law, federal legislation may preempt conflicting state law.[1] In 2000, the Maine legislature passed the Maine Act to Establish Fairer Prices for Prescription Drugs ("Maine Rx"), creating a state-administered prescription drug coverage program for Maine residents, funded by pharmaceutical company rebates.[2] Maine Rx imposes Medicaid pre-authorization requirements on designated drugs marketed by pharmaceutical companies that refuse to enter into rebate agreements with the state.[3] In *Pharmaceutical Research and Manufacturers of America v. Walsh*,[4] the Supreme Court considered whether a district court properly enjoined enforcement of Maine Rx on a finding that the state program conflicted with federal Medicaid law by placing an unrea-

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[1] U.S. Const. art. VI, § 2. The Supremacy Clause states in pertinent part, "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof shall be the supreme law of the land ... and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." *Id. See* Hillsborough County v. Automated Med. Labs., 471 U.S. 707, 713 (1985) (holding determination of obstacle preemption requires analysis of legislative intent); Pac. Gas and Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n, 461 U.S. 190, 203 (1983) (affirming Congress' power to expressly preempt state law); Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (preempting state immigration law that presented obstacle to Congress' expressed immigration policies).

[2] ME. REV. STAT. ANN. tit. 22, § 2681 (West Supp. 2002). Through Maine Rx, the state of Maine bargains with pharmaceutical companies for price rebates on prescription drugs for Maine Rx subscribers. *See id.* § 2681(4).

[3] *See id.* § 2681(7-A). If a physician prescribes a drug on the prior authorization list, that physician must obtain approval from the State Medicaid administrator (or the administrator's agent) before that drug may be administered to Medicaid recipients. *See id* § 2681(4); *see also* Pharm. Research and Mfrs. of America v. Concannon, 249 F.3d 66, 72 (1st Cir. 2001) (stating pre-authorization by Medicaid Administrator required except in emergency situations), *aff'g sub nom.* Pharm. Research and Mfrs. of America v. Walsh, 123 S. Ct. 1855 (2003). In addition to requiring prior authorization for drugs produced by non-compliant manufacturers, the state will publish a list of the manufacturers' names. ME. REV. STAT. ANN. tit. 22, § 2681(7-A) (West Supp. 2002).

[4] 123 S. Ct. 1855 (2003) (affirming reversal of district court's preliminary injunction against state prescription drug coverage program).

sonable burden on Medicaid recipients.[5] The Court held that the district court abused its discretion in issuing a preliminary injunction and allowed Maine Rx to proceed.[6]

More than 325,000 Maine residents lack comprehensive health insurance coverage, and must pay out-of-pocket for prescription drugs.[7] Responding to citizen concern about the rising cost of pharmaceuticals, the Maine legislature created a prescription drug coverage program for Maine residents who do not receive drug coverage through their employer and who have incomes too high to qualify for Medicaid.[8] Maine Rx members

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[5] *See* Social Security Act Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified at 42 U.S.C. §§ 426, 1935—1936v (West 2003)). Medicaid was enacted as a component of the Social Security Act and is funded cooperatively by the federal and state governments. *See* 42 U.S.C. §§ 1396—1396v. Medicaid is a comprehensive health insurance program designed to provide qualifying low-income participants with necessary health care, including prescription drugs. *See id.* Medicaid provides federal matching funds to states that create health insurance plans satisfying criteria regulated by the Secretary of Health and Human Services. *See id.* States must offer coverage to individuals deemed "categorically needy." *See* 42 U.S.C. § 1396a(10)(A)(i)(I-VII) (West 2003). By definition, the categorically needy are citizens eligible for assistance under federal means-tested programs such as Supplemental Security Income. *See id.* A state may also opt to cover "medically needy" individuals who have incomes too high to qualify as categorically needy but who meet other non-financial eligibility requirements. *See* 42 U.S.C. § 1396a(10)(A)(ii)(I-XVIII). *See also* KAISER FAMILY FOUNDATION COMMISSION ON MEDICAID AND THE UNINSURED, THE UNINSURED: A PRIMER (2003) (outlining basics of Medicaid coverage and theories of reform), *available at* http://www.kff.org/uninsured/4085.cfm; ALEXANDER A. BOVE, JR., THE MEDICAID PLANNING HANDBOOK (1996) (explaining general guidelines for Medicaid eligibility for purposes of estate-planning).

[6] *Walsh*, 123 S. Ct. at 1871 (affirming appellate court reversal of preliminary injunction blocking implementation of prescription drug coverage program). The core of Petitioner's argument was that through Maine Rx, the Maine legislature exploited Medicaid patients in order to fund an insurance plan for non-indigent Maine residents. *See* Petitioner's Brief at 7, Pharm. Research and Mfrs. of America v. Walsh, 123 S. Ct. 1855 (2003) (No. 01-188) (arguing preauthorization requirements restrict drug access, harming low-income patients and drug manufacturers). *But see* Respondent's Brief at 9, Pharm. Research and Mfrs. of America v. Walsh, 123 S. Ct. 1855 (2003) (No. 01-188) (asserting existing Medicaid guidelines protect patients from arbitrary drug restrictions and promote economical care). *See generally* Timothy Cahill, Note, *Curing the Deficiencies of Proposed State and Federal Prescription Drug Discount Programs*, 70 U. CIN. L. REV. 1341, 1349 (2002) (concluding preauthorization was "hammer" through which Maine Rx program compelled pharmaceutical industry acceptance of rebate structure).

[7] *See* Janet Gemignani, Maine's Rx Drug Law Can Proceed, 19 Business & Health 14, June 1, 2001 (reciting statistics characterizing Maine's low-income population); *see also* Conrad J. Barrington, Note, Pharmaceutical Research and Manufacturers of America v. Concannon and Maine Prescription Drug Rebate Statute: *A 21st Century Solution to Medicaid Crisis*, 23 WHITTIER L. REV. 1127, 1131 (2002) (citing Maine governor's estimate that Maine Rx would reduce drug prices by 20 to 30 percent).

[8] *See* ME. REV. STAT. ANN. tit. 22, § 2681(1) (West Supp. 2002). Technically, the Maine Rx program is open to all Maine residents, although the aim of the Maine legislature is to provide affordable prescription drug coverage plan for Maine residents of low to moderate income. *See id.* "It is not the intention of the State to discourage employers from

use a discount card to purchase prescriptions from Maine pharmacies at below-retail prices.[9] Pharmacies submit bills to Maine for the difference between the Maine Rx price and the drug's retail price.[10] On a bi-weekly basis, the state reimburses pharmacies from a state fund comprised of drug company rebates.[11]

Maine Rx empowered the Commissioner of Maine's Department of Health Services to establish rebate arrangements with pharmaceutical companies selling prescription drugs in Maine.[12] To encourage drug company participation in Maine Rx, the state legislature used authority granted by the Federal Medicaid Act to impose restrictions on non-compliant drug companies.[13] Under the plan, drugs manufactured by non-compliant drug companies were to be placed on a Medicaid "prior authorization" list.[14] Physicians prescribing drugs on this list to Medicaid patients would have to receive permission from the state before the drugs would be administered.[15] As a general rule, pre-authorization requirements tend to discourage physicians from prescribing non-authorized drugs because physicians dislike having to go though an administrative process to obtain special authority to prescribe.[16] By influencing what physicians prescribe to their

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offering or paying for prescription drug benefits ... or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available ... under this subchapter." *Id; see* Pharm. Research and Mfrs. of America v. Concannon, 249 F.3d 66, 71 (1st Cir. 2001) (explaining Maine Rx not meant to augment existing drug coverage). The Maine Rx statute authorizes the Department of Health and Human Services to promulgate rules to govern the administration of the program. *See* ME. REV. STATE. ANN. tit., 22 § 2681(14). Proposed rules limit Maine Rx eligibility to persons who "do not have a comparable or superior prescription drug benefit plan." *Walsh,* 123 S. Ct. at 1863.

[9] *See Concannon,* 249 F.3d at 71 (delineating Maine Rx rebate structure as comparable to Medicaid).

[10] *See id.*

[11] *See* ME. REV. STAT. ANN. tit. 22, § 2681(5)(D) (West Supp. 2002) (outlining rebate structure from state to pharmacies).

[12] *See* ME. REV. STAT. ANN. tit. 22, § 2681 (West Supp. 2002).

[13] *See* Social Security Act Amendments of 1990, 42 U.S.C. § 1396r-8(d)(1)(A) (West 2003). Congress passed amendments to Medicaid in 1990 that encouraged states to take a more aggressive role in reducing Medicaid costs through prior authorization. *Id.* These amendments recognized the long-standing practice of some states to impose Medicaid service restrictions in order to limit expenses. *See* Dodson v. Parham, 427 F. Supp 97, 100 (D.C. Ga. 1977) (affirming state restriction of reimbursements to pharmacies for certain drugs prescribed to Medicaid patients); Cowan v. Myers, 187 Cal. App. 3d 968, 975 (1987) (affirming California's prior authorization requirement as permissible under federal Medicaid law).

[14] *See* ME. REV. STAT. ANN. tit. 22, § 2681(7) (2002) (subjecting manufacturers not agreeing to rebates to consequences for failure to comply).

[15] *See id; see also Walsh,* 123 S. Ct. at 1864 (citing affidavit of pharmaceutical executive that pre-authorization shifted "physician loyalty" to drugs without prior authorization).

[16] Petitioner and Respondent agreed that pre-authorization requirements are often used to influence which drugs physicians will prescribe to their patients. *See* Brief for

Medicaid patients, the Maine legislature intended to lower prices of prescription drugs for Maine Rx members.[17]

Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit in federal district court arguing that Maine Rx should be preempted because Medicaid pre-authorization restricts drug access and interferes with the administration of Medicaid.[18] The district court found

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Petitioner at 6, Pharm. Research and Mfrs. of America v. Walsh, 123 S. Ct. 1855 (2003) (No. 01-188). *See Walsh*, 123 S. Ct. at 1864 n.23 (2003) (quoting affidavit of Dr. Howell of SmithKline Beecham Corporation). "Prior authorization is often employed ... to enforce a drug formulary and is usually intended to limit the drugs to be prescribed by health care professionals ... . [P]rior authorization [is used] (1) to ensure proper use of drugs with high potential for inappropriate use, (2) to limit the use of prescription drugs with severe or life threatening side effects and/or drug interactions; and (3) to encourage the use of cost-effective medications without diminishing safety or efficacy." *Id. See also* Brief for Respondents at 21, Pharm. Research and Mfrs. of America v. Walsh, 123 S. Ct. 1855 (2003) (No. 01-188) (arguing criticisms of prior authorization stem from PhRMA's desire to promote expensive medications at public's expense). "PhRMA's case, therefore, rests on a general distain for prior authorization..." *Id.*

[17] *See Walsh*, 123 S. Ct at 1864-5 (explaining Respondent's argument that Maine Rx will not deter physicians from prescribing necessary medications). The State Medicaid Medical Director testified in an affidavit that Maine will protect Medicaid patients' right to the safest and most effective medication. *See id.* Under administrative regulations drafted for Maine Rx, a committee of physicians and pharmacists would make "final determinations of clinical appropriateness of any recommendation that a prior authorization requirement imposes with respect to a particular prescriptions drug." *Id.* at 1865.

[18] *See* Pharm. Research and Mfrs. of America v. Comm'r Me. Dep't of Human Servs., Civ. No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363 (D. Me. Oct. 26, 2000) (granting preliminary injunction blocking implementation of Maine Rx). PhRMA is the pharmaceutical industry's primary advocacy organization, representing approximately 75 percent of major American pharmaceutical companies. *See Walsh*, 123 S. Ct. at 1863 (explaining scope of PhRMA's influence); *see also* David Rubenstein, *PhRMA Uses Litigation for Leverage in Policy Fracas*, 11 CORP. LEGAL TIMES 22 (2001) (referencing PhRMA's legal interventions on behalf of pharmaceutical companies). The trial court did not consider whether PhRMA, as a trade organization, had standing to bring a lawsuit on behalf of Medicaid beneficiaries. *See* Pharm. Research and Mfrs. v. Comm'r Me. Dep't of Human Servs., Civ. No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363 (granting preliminary injunction to block implementation of Maine Rx) (D. Me. Oct. 26, 2000). On appeal, however, the court heard Maine's argument that PhRMA lacked standing. *See* Pharm. Research and Mfrs. of America v. Concannon, 249 F.3d 66, 73 (1st Cir. 2001) (considering elements of prudential standing in challenge to state statute). While recognizing a circuit split as to whether prudential standing can be raised for the first time on appeal, the court first determined that the "zone of interests" test was relevant, and found that PhRMA satisfied this test. *Id. Compare* Animal Legal Def. Fund v. Espy, 23 F.3d 496, 499 (D.C. Cir. 1994) (allowing prudential standing challenge on appeal) *with* Pershing Park Villas Homeowners Ass'n v. United Pac. Ins. Co., 219 F.3d 895, 899 (9th Cir. 2000) (refusing to entertain standing challenge on appeal). The zone of interest test requires an analysis of the interest to be protected by the statutory provision in question and a determination of whether the challenger's interests are among those sought to be protected. *See* Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co., 522 U.S. 479 (1998) (allowing banks to sue under Federal Credit Union Act to limit markets credit unions serve). On appeal to the First Circuit in the present case, Maine argued that nothing in the Medicaid statute was intended to protect sellers of pharmaceuti-

PhRMA's argument persuasive and enjoined enforcement of Maine Rx.[19] The First Circuit Court of Appeals reversed, holding that Medicaid expressly permits states to impose drug pre-authorizations as long as the restrictions do not actually harm Medicaid patients.[20] The court affirmed PhRMA's right to mount an as-applied challenge if Medicaid patients are denied access to necessary medications because of Maine Rx, but held that PhRMA had not shown Maine Rx's mere existence to be harmful to Medicaid patients.[21] The Supreme Court granted certiorari and agreed the district court should not have granted PhRMA's motion for a preliminary injunction.[22] The Court affirmed that the burden of showing preemption

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cal drugs, and therefore, PhRMA did not have the right to bring suit under the Medicaid Act. *See Concannon*, 249 F.3d at 73 (reversing preliminary injunction blocking implementation of Maine Rx). The appeals court disagreed with Maine, finding that PhRMA was seeking to enforce a preemption-based cause of action under the Supremacy Clause of the Constitution, not an express right granted under the Medicaid Act. *Id.* The court held that the Supremacy Clause creates an "implied right of action for injunctive relief against state officers who are threatening to violate federal law," and, "regardless of whether the Medicaid statute's relevant provisions were designed to benefit PhRMA, PhRMA can invoke the statute's preemptive force." *Id.*

[19] *See* Pharm. Research and Mfrs. v. Comm'r Me. Dep't of Human Servs., Civ. No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363 (granting preliminary injunction to block implementation of Maine Rx) (D. Me. Oct. 26, 2000). The court held:

> For purposes of the preliminary injunction motion, the record is essentially undisputed. On that record, I find the plaintiff's likelihood of success on the merits of most of its constitutional challenges to be overwhelming. That being so, the State's interest in forestalling the preliminary injunction is weak. The State has a strong interest in assisting its economically and medically needy citizens, but not through unconstitutional legislation ... Accordingly, the plaintiff is entitled to a preliminary injunction ... .

Id. at *24.

[20] *Concannon*, 249 F.3d at 75 (examining Medicaid statute for potential restrictions on state preauthorization authority). The First Circuit held that Maine Rx did not impose an obstacle to the objectives of the Federal Medicaid Act, because compliance with state law did not contravene the intent of federal regulations. *See id.* at 85. The appeals court stayed implementation of Maine Rx pending Supreme Court review. *See Walsh*, 123 S. Ct. at 1866 (reciting procedural posture of PhRMA's suit against Maine Rx.) Although the United States asked the Supreme Court to deny review in case the Secretary of Health and Human Services intended to review Maine Rx as an amendment to Maine's Medicaid program, the Court agreed to hear the case, seeking an Amicus Curiae brief from the United States and permitting the United States to give oral arguments. *See id.*

[21] *See Concannon*, 249 F.3d at 84. The court of appeals considered scholarly articles reporting negative health outcomes associated with an inability to pay for prescription drugs. *See* Stephen B. Soumera & Dennis Ross-Degnan, *Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action*, 340 NEW ENG. J. OF MED. (March 4, 1999) (arguing Medicare's lack of prescription drug coverage contributed to poor health among elderly).

[22] *See Walsh*, 123 S. Ct. at 1871 (affirming appellate court reversal of preliminary injunction based on petitioner's failure to meet burden).

rested on PhRMA as the petitioner, and held that PhRMA had not shown a likelihood of success at trial on their preemption argument.[23]

In considering whether to grant a preliminary injunction, a court must employ a balancing test.[24] This test evaluates the equitable interests involved by considering the merits of the petitioner's claim, the risk of irreparable harm that would result from not issuing the injunction, and the public interest.[25] The party seeking the injunction shoulders the burden of demonstrating a likelihood of success at trial on the merits of the claim.[26] Appellate courts review preliminary injunctions for abuse of discretion only; therefore, such injunctions are rarely reversed on appeal.[27] In *Langlois v. Abington Housing Authority*, indigent petitioners challenged a local housing authority plan to institute a lottery system for awarding places on a subsidized housing waiting list.[28] The court granted a preliminary injunction, finding it likely that the lottery violated a state statute reserving a certain percentage of subsidized housing for extremely low-income families.[29] The First Circuit Court of Appeals disagreed that a lottery necessarily violated the statute, but affirmed the preliminary injunction based upon its determination that the lower court's factual analysis was not plainly wrong.[30]

Although the Constitution provides that states retain all legislative power not expressly granted to the federal government, the Constitution requires federal law to preempt state law that either conflicts directly with federal law or obstructs the accomplishments of Congress.[31] Analyzing

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[23] *Id.* (affirming petitioner unlikely to succeed at trial on facts before Court).

[24] *See* Benten v. Kessler, 505 U.S. 1084, 1084 (1992) (enjoining petitioner from using illegal abortion drug because petitioner could not win at trial); Doran v. Salem Inn, Inc., 422 U.S. 922, 931 (1975) (affirming grant of preliminary injunction to bar topless dancing as per city ordinance); Langlois v. Abington Hous. Auth., 207 F.3d 43, 47 (1st Cir. 2000) (affirming temporary injunction to bar implementation of housing lottery).

[25] *See Langlois*, 207 F.3d at 47.

[26] *See Salem Inn, Inc.*, 422 U.S. at 931 (affirming grant of preliminary injunction to bar topless dancing as per city ordinance). "The traditional standard for granting a preliminary injunction requires the plaintiff to show that in the absence of its issuance he will suffer irreparable injury and also that he is likely the prevail on the merits." *Id.*

[27] *See Salem Inn, Inc.*, 422 U.S. at 931. An appellate court should review issues of fact leading to a preliminary injunction for plain error, but it may review judicial conclusions de novo. *See id.*

[28] *See Langlois*, 207 F.3d at 47 (affirming injunction barring implementation of lottery program as violative of state law).

[29] *See id.* at 46 (explaining housing authority plan to give lottery preferences to applicants living within town limits).

[30] *See id.* at 47 (conceding evidence tended to show that in practice, housing lottery might not violate statute).

[31] U.S. CONST. ART. VI, § 2. *See* Hillsborough County v. Automated Med. Labs., 471 U.S. 707, 715 (1985) (requiring examination of intent when preemption not stated in federal law and not obvious from text); Fidelity Fed. Savings and Loan Ass'n v. De la Custa, 458 U.S. 141, 153 (1982) (preempting state mortgage law in favor of federal Savings & Loan

obstacle preemption requires courts to determine Congress' intent in passing the federal law in question, applying preemption only if it is clear Congress intended to supercede state police power.[32] Because the authority to regulate health care has traditionally been vested in the state, there is a general presumption against preemption of state statutes designed to foster public health.[33] Historically, courts have been reluctant to preempt a state public health law – even one that imposes a burden on some citizens – if a state is acting reasonably to further some health-related objective.[34]

Medicaid is a joint federal and state program that provides health care to qualified indigents.[35] Many details of Medicaid administration are delegated to the states, and federal law affords states some leeway to design programs that meet localized health challenges.[36] Before a state may

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regulation); Jones v. Roth Packing Co., 430 U.S. 519, 525 (1977) (holding federal Whole Meat Act preempts state meat packing statue); Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (applying preemption when state law "obstructs" federal purposes). Federal law also preempts state law when a "scheme of federal regulation" is so pervasive that it is clear the federal government intends to occupy the entire field of law. *See* Pac. Gas and Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n, 461 U.S. 190, 212-15 (1983).

[32] *See Hines*, 312 U.S. at 67 (applying preemption when state law is "obstacle" to federal purpose.) To analyze obstacle preemption, courts may look to statutory history, expressed through legislative proceedings, or to extrinsic evidence such as speeches or contemporary events. *See id.* In *Hines*, the Court ruled that a state's registration policy for foreign nationals was an obstacle to federal immigration policy and jeopardized foreign relations because the state law, which required foreign nationals to register with the state every year and carry a special identification card, stigmatized immigrants living legally in the United States. *See id.* The Court held that the Pennsylvania law was an obstacle to the federal government's goal of establishing robust and positive relationships with foreign countries in order to protect the United States. *See id.*

[33] *See* Alexander v. Choate, 469 U.S. 287, 303 (1985) (affirming state discretion to choose proper mix of Medicaid services for state residents); Beal v. Doe, 432 U.S. 438, 447 (1977) (holding state interest in promoting childbirth justifies refusal to allow use of Medicaid funds for non-therapeutic abortions).

[34] *See Choate*, 469 U.S. at 303 (restricting inpatient days for Medicaid patients). "The 14-day limitation will not deny respondents meaningful access to Tennessee Medicaid services or exclude them from those services." *Id. See also* N.Y. State Dept. of Social Servs. v. Dublino, 413 U.S. 405, 421 (1973) (rejecting preemption of state law imposing employment requirement as condition of AFDC benefit eligibility). In *Walsh*, the plurality compares New York's AFDC work requirement to Maine Rx's imposition of prior-authorization for Medicaid patients. *See* 123 S. Ct. at 1869-70 "The problems confronting our society in these areas are severe, and state governments, in cooperation with the Federal Government, must be allowed considerable latitude in attempting their resolution." (quoting N.Y. State Dept. of Social Servs. v. Dublino, 413 U.S. 405, 421 (1973)).

[35] *See* Harris v. McRae, 448 U.S. 297, 308 (1980) (holding Medicaid does not require states to fully fund medical procedures). "The Medicaid program is a cooperative endeavor in which the Federal Government provides financial assistance to participating states to aid them in furnishing health care to needy persons." *Id.*

[36] *See* 42 U.S.C. § 1396r-8 (West 2003). In 1990, Medicaid amendments formally recognized state authority to restrict access to certain drugs via pre-authorization requirements in order to save money. *Id.*

implement substantive changes to its current Medicaid plan, however, the Secretary of Health and Human Services will review the changes to determine if the state plan still complies with federal Medicaid regulations.[37] If the Secretary finds that a state's amendments conflict with Medicaid, the Secretary has the power to terminate federal funding to the state program.[38] The Secretary's decision will stand unless a court determines that the decision was arbitrary and capricious.[39]

In *Pharmaceutical Research and Manufacturers of America v. Walsh*, the Supreme Court considered whether the district court erred in entering a preliminary injunction enjoining Maine Rx.[40] A majority of the Court held that the preliminary injunction was reversible error, although ideological differences between the justices prevented the decision from being a complete victory for Maine.[41] Affirming the presumption against preemption of a state public health statute, a plurality of four justices held PhRMA had not shown that Maine Rx imposed a significant obstacle to Medicaid.[42] According to the plurality, absent specific evidence that Maine Rx will prejudice Medicaid patients' access to necessary care, the petitioner did not establish facts sufficient to justify a preliminary injunction.[43] Concurring with the majority that the injunction was plain error, Justices Scalia and Thomas argued that Maine Rx is an amendment to Maine's Medicaid program and subject only to agency review by the Secretary of Health and Human Services.[44]

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[37] *See id.* § 1396a(b) (affording authority to Secretary to review state changes to Medicaid).

[38] *See id.* § 1396c. Because states would be unable to finance Medicaid without federal support, the Secretary essentially has the ultimate veto power for any Medicaid amendment. *Id. See generally* United States v. Western Pac. R.R. Co., 352 U.S. 59, 63 (1956) (establishing test for delegating authority to agency to make administrative decision).

[39] *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (affirming agency interpretation of statute will control when agency vested with authority to administer statute).

[40] *See Walsh*, 123 S. Ct. at 1855 (affirming state's prescription drug coverage program as non-violative of Medicaid).

[41] *See* Michelle M. Mello, David M. Studdert & Troyen A. Brennan, *The Pharmaceutical Industry versus Medicaid – Limits on State Initiatives to Control Prescription-Drug Costs*, 350 NEW ENG. J. MED. 608 (Feb. 5, 2004) (explaining efforts in Michigan and Maine to control Medicaid prescription drug costs through prior authorization techniques).

[42] See *Walsh*, 123 S. Ct. at 1871. Concurring in part with the plurality and concurring in the judgment, Justice Breyer concluded that in order to apply preemption, PhRMA needed to show that Maine's program would "seriously compromise important federal interests." *Id.*

[43] *Id.* The plurality also argued that Maine Rx will serve a distinct Medicaid purpose by defraying the cost of prescription drugs for low-income Maine residents which will keep many of them from becoming Medicaid eligible. *Id.* at 1872.

[44] *Walsh*, 123 S. Ct. at 1877 (Thomas, J., concurring) (arguing that the Secretary must look at Maine Rx's effect on Medicaid and determine if it is in the "best interest" of Medi-

Additionally, Justice Thomas did not perceive a direct conflict between Medicaid and Maine Rx.[45] He argued that it is impossible to deduce a singular purpose from the complex Medicaid statute, which represents a delicate balance of prescription costs and drug access.[46] Justice Thomas cautioned against "invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others."[47] In dissent, Justice O'Connor expressed an opposite view.[48] To O'Connor, the implicit intent of the Medicaid act is to permit preauthorization only if it serves a clear benefit to Medicaid patients.[49] Because Maine had argued no direct Medicaid benefit, O'Connor's dissent argued that "post-hoc justifications" offered by the Court were based on facts not supported in the record.[50] Based on this reading of the Medicaid act, O'Connor opined that she would have affirmed the preliminary injunction and allowed the case to proceed toward an adjudication on the merits.[51]

The district court predominantly considered the likelihood that PhRMA would succeed at trial on its claim that Medicaid preempts Maine Rx.[52] On certiorari, the Court appropriately limited its review to this element in determining whether the preliminary injunction should stand.[53] The Court's failure to agree in its reasoning should not detract from its ultimate decision that in order to obtain a preliminary injunction, a petitioner must show he would probably win at trial.[54] The Court correctly ruled that PhRMA has not made such a showing, because PhRMA has not demonstrated that Maine Rx is preempted by the federal Medicaid statute. In this case, PhRMA cannot demonstrate that preauthorization adversely affects Medicaid patients by denying them access to necessary prescription

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caid patients).

[45] *Id.* at 1874 (Thomas, J. concurring in the judgment).

[46] *Id.* at 1875 (Thomas, J. concurring in the judgment). Justice Thomas cites the text of the Medicaid statute that asserts "care and services will be provided, in a manner consistent with ... the best interests of the recipients" as evidence that the complexity of Medicaid belies the determination of a singular preeminent Medicaid goal. *Id.*

[47] *Id.* at 1875. (Thomas, J. concurring in the judgment).

[48] *Walsh*, 123 S. Ct. at 1872 (O'Connor, J., concurring in part and dissenting in part.) Justice O'Connor was joined in her dissent by Chief Justice Rehnquist and Justice Kennedy.

[49] *See id.* at 1881.

[50] *See id.*

[51] *Id.* (rejecting plurality's "predicate assumptions" finding that Maine Rx served Medicaid goals).

[52] Pharm. Research and Mfrs. of America v. Concannon, 249 F.3d 66, 72 (1st Cir. 2001) (reversing grant of preliminary injunction to pharmaceutical industry group). When reviewing a grant of preliminary injunction a likelihood of success at trial on the merits of the claim is generally accepted to be the most important element of the "familiar four" factors. *See* Weaver v. Henderson, 984 F.2d 11, 12, 14 n.5 (1st Cir. 1993) (concluding that upon determining success was not possible, consideration of other factors unnecessary).

[53] *See Walsh*, 123 S. Ct. at 1871.

[54] *See id.*

drugs.[55] Although preauthorization might block a Medicaid patient's access to his physician's brand-name drug of choice, there is no evidence that such a restriction will adversely impact care. Because PhRMA makes no showing that Maine Rx will adversely affect the standard of care, PhRMA cannot establish that Maine Rx conflicts with Medicaid's intent to provide necessary medical care to low-income Americans. [56] On the record presented to the Supreme Court, there was insufficient evidence to support a finding that Medicaid preempts Maine Rx.[57]

The Court was correct to narrowly tailor its review to the standard for a preliminary injunction, although Justice Thomas' textual analysis is too narrow to fully address the preemption issue.[58] Medicaid does not expressly preempt Maine Rx and, therefore, the question of whether Medicaid's purpose is frustrated by Maine Rx preauthorization necessarily requires a consideration of the motives belying the federal statute. This type of judicial analysis is well within the ability and the authority of the Supreme Court. Justice Scalia *may* be correct that the Court lacks the ultimate authority to adjudicate Maine Rx's validity.[59] If the Secretary of Health and Human Services decides that Maine Rx's preauthorization provision is an invalid Medicaid amendment, the Secretary could conceivably terminate federal funding to Maine's Medicaid program.[60] The possibility of further proceedings, however, does not affect the Court's authority to decide whether Maine Rx may proceed pending the Secretary's review.

In *Pharmaceutical Research and Manufacturers v. Walsh*, the Supreme Court refused to preliminarily enjoin Maine's prescription drug

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[55] *See id.*

[56] *See* United States v. Salerno, 481 U.S. 739, 745 (1987) (establishing facial challenge requires finding that law is not valid under any circumstance); United States v. Hilton, 167 F.3d 61, 71 (1st Cir.), *cert. denied*, 528 U.S. 844 (1999). "It makes little sense to strike down an entire statute in response to a facial attack when potential difficulties can be remedied in future cases through fact-specific as-applied challenges." *Id.*

[57] *See* Pharmaceutical Research and Mfrs. of America v. Medows, 184 F. Supp. 2d 1186 (N.D. Fla. 2001) (denying PhRMA's motion for preliminary injunction to enjoin mandatory Medicaid drug discount program).

[58] *Walsh*, 123 S. Ct. at 1871.

[59] *See id.*

[60] The plurality agreed that the success of Maine Rx may be a decision reserved for the Secretary of Health and Human Services. *See id.* at 1870. The plurality acknowledged that if the Secretary found Maine Rx to be an impermissible amendment to Medicaid, the Secretary's ruling would be presumptively valid. *See id.* at 1866-67.

> As the case comes to us, however, the question is whether there is a probability that Maine's program was pre-empted by the mere existence of the federal statute. We start therefore with a presumption that the state statute is valid ... and ask whether petitioner has shouldered the burden of overcoming that presumption.

Id. at 1877.

See Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984) (affording deference to agency interpretation of administrative provision).

coverage program. In allowing the program to proceed, the Court has implicitly affirmed Justice Brandeis' statement that "[i]t is one of the happy incidents of the federal system that a single courageous state may ... try novel social and economic experiments without risk to the rest of the country."[61] Sister states interested in attempting their own economic experiments in health care reform will closely watch the implementation of Maine Rx as a model for their own programs.[62]

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[61] New State Ice Co. v. Liebmann, 285 U.S. 262, 310 (1932) (holding statute barring manufacturing of ice impermissible state intrusion on private business) (Brandeis, J., dissenting).

[62] As this article goes to press, Maine Rx has not been implemented, and the Maine legislature has re-written the law to impose income restrictions on eligibility. *See* Maine Rx Plus Program, ME. REV. STAT. ANN. tit. 22, § 2681(2)(F) (West 2003) (restricting Maine Rx Plus membership to families living at or below 350% of the federal poverty level); *see* Mello, *supra* note 41. Still, state legislatures in Massachusetts and Vermont have expressed interest in the Maine Rx model. *See* National Conference of State Legislatures. (Accessed February 7, 2004, at http://ncsl.org/programs/health/drugaid.htm).