

FRUSTRATED WITH PREEMPTION: WHY COURTS SHOULD RARELY DISPLACE STATE LAW UNDER THE DOCTRINE OF FRUSTRATION PREEMPTION

KEVIN O. LESKE & DAN SCHWEITZER*

INTRODUCTION

In recent years, the Supreme Court's docket has been replete with preemption cases.¹ Indeed, it is fair to say that the preemption of state law by federal law has become the preeminent federalism issue in our courts. But the topic of preemption implicates far more than federalism; it also raises important separation of powers concerns and does so in at least two ways. First, when courts imply that federal statutes preempt state law, despite having no explicit preemption provisions, the courts risk judicial lawmaking. In Justice Thomas's words, it "leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies."² Second, when administrative agencies claim state laws are preempted, it raises the question of whether unelected executive branch officials can displace state law. Agencies often claim that state laws are preempted based either on their construction of an express preemption provision or their conclusion that the state law frustrates the achievement of federal statutory objectives.³

* Dan Schweitzer is the Supreme Court Counsel for the National Association of Attorneys General (NAAG). Kevin O. Leske is a Fellow at Harvard Law School's Emmett Environmental Law and Policy Clinic (ELPC). All views expressed herein are theirs personally, and do not reflect the views of the NAAG or its members or Harvard Law School. This Article is based on an amicus brief filed by the authors on behalf of Vermont and forty-six states in *Wyeth v. Levine*. See Brief of Vermont, et al. as Amici Curiae Supporting Respondent, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

1. See, e.g., *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Chamber of Commerce v. Brown*, 128 S. Ct. 2408 (2008); *Cuomo v. Clearing House Ass'n*, 129 S. Ct. 2710 (2009); *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008); *Rowe v. N.H. Motor Transp. Ass'n*, 552 U.S. 364 (2008); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1 (2007).

2. *Wyeth*, 129 S. Ct. at 1217 (Thomas, J., concurring).

3. See, e.g., *Average Fuel Economy Standards for Light Trucks Model Years 2008–2011*, 71 Fed. Reg. 17,566, 17,667 (Apr. 6, 2006) (to be codified at 16 C.F.R. pt. 163) (conclusion by the National Highway Traffic Safety Administration that

This Article explores how separation of powers concerns and related principles of statutory construction bear on the preemption inquiry. Our specific focus is on the type of preemption that presents the greatest separation of powers risks, namely, preemption based on the conclusion that state law frustrates “the accomplishment and execution of the full purposes and objectives of Congress.”⁴ The Article first explains why principles of statutory construction, separation of powers, and federalism require that courts should rarely displace state law under frustration preemption. When reasonable policy grounds both support and oppose preempting state law, courts should construe Congress’s decision *not* to include an express preemption provision as a decision *not* to displace state law. And when Congress did not intend to preempt state law on frustration preemption grounds, federal agencies lack the authority to decree otherwise.

Next, this Article explores the Supreme Court’s recent decision in *Wyeth v. Levine*,⁵ in which the Court’s reasoning aligned with many of the contentions in this Article. In *Wyeth*, the Court addressed the preemptive scope of the Federal Food, Drug, and Cosmetic Act (FDCA), which, as amended, does not contain an express preemption provision.⁶ The Court rejected the defendant’s frustration preemption argument that the FDCA displaced the plaintiff’s state tort law action because it presented an obstacle to the FDCA’s regulatory regime.⁷

state greenhouse gas standards “frustrate the objectives of Congress” in establishing the Corporate Average Fuel Economy program); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601) (conclusion by the Food and Drug Administration that “State law conflicts with and stands as an obstacle to achievement of the full objectives and purposes of Federal law if it purports to preclude a [pharmaceutical] firm from including in labeling or advertising a statement that is included in prescription drug labeling”); Final Rule: Standard for the Flammability (Open Flame) of Mattress Sets, 71 Fed. Reg. 13,472, 13,496–97 (Mar. 15, 2006) (to be codified at 49 C.F.R. pts. 523, 533, and 537) (conclusion by Consumer Product Safety Commission that “all non-identical state requirements which seek to reduce the risk of death or injury from mattress fires” are expressly preempted); *see also* Catherine M. Sharkey, *Preemption By Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 230–42 (2007).

4. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Preemption under *Hines* has several names, including “obstacle,” “frustration,” and “purposes and objectives” preemption. We will call it “frustration” preemption.

5. 129 S. Ct. 1187.

6. *Id.* at 1191.

7. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–97 (2006).

The concurring opinion of Justice Thomas more closely adopts the ideas set forth here, such as our argument that courts should not assume that Congress intends to accomplish its objectives at all costs. But the majority opinion of Justice Stevens accepts that the key inquiry in the frustration preemption analysis is whether Congress intended such preemption, and not whether courts can discern some tension between the federal and state schemes. The majority also recognized that, given the existence of express preemption provisions in other statutes, courts can, and should, view Congress's failure to include an express preemption provision as strong evidence that Congress did not intend it to preempt state law.

I.
PREEMPTION AND PRINCIPLES OF STATUTORY
CONSTRUCTION, SEPARATION OF
POWERS, AND FEDERALISM

When analyzing whether a federal statute displaces state law, the Supreme Court recognizes that the question is an issue of congressional intent.⁸ Thus, when defendants allege frustration preemption, the key inquiry is whether Congress intended to displace state laws that frustrate the full accomplishment of federal objectives.⁹ The answer is that Congress *sometimes* intends to remove every obstacle to federal objectives as quickly and completely as possible. But Congress often has competing objectives and crafts legislation as a product of compromise. For instance, Congress might conclude that a particular type of state tort action should proceed in order to provide remedies for injured consumers, even if it “frustrates” to some degree the federal goal of uniformity. Similarly, Congress might retain a state tort action as a compromise for having a less strict federal standard.

In the end, this paradigmatic policy decision is for Congress, not the courts, to make. Congress knows how to express its intent to displace state laws that it believes stand as obstacles to federal objectives. Hundreds of federal statutes contain express preemption provisions.¹⁰ Courts should respect Congress's decision not to

8. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“[T]he purpose of Congress is the ultimate touchstone in every pre-emption case.”) (internal quotation marks omitted); see also *Retail Clerks Int’l Ass’n v. Schermerhorn*, 375 U.S. 96, 103 (1963).

9. *Hines*, 312 U.S. at 67.

10. See JAMES T. O’REILLY, *FEDERAL PREEMPTION OF STATE AND LOCAL LAW* 2 (2006).

include such a provision. Adherence to the plain language of federal statutes requires no less. Just as the Supreme Court no longer finds implied private rights of action—except in rare cases¹¹—courts should no longer find frustration preemption (except in rare cases).

Several commentators have observed that the Supreme Court's implied preemption jurisprudence is in tension with its plain-language approach to statutory construction. For example, Professor John F. Manning notes that “the Court's approach to implied federal preemption of state law generally reflects premises more akin to those evident in its former purposivism.”¹² Likewise, Professor Daniel J. Meltzer argues that contrary to its default approach to statutory interpretation, the Court engages in significant interpretive lawmaking in implied preemption cases.¹³ This Article suggests that the Court should bring these two areas of the law into alignment.

Principles of federalism buttress this conclusion. The Commerce Clause gives Congress broad authority to preempt state law.¹⁴ If the political process is to serve as a genuine check on that power, states must receive notice when their authority is at risk. Frustration preemption undermines that check. It also amounts to a presumption *in favor* of preemption as courts presume Congress intended to displace state law. Our federal system should not countenance such a disregard of the states' reserved powers.

A. *Whether a federal statute preempts state law under the doctrine of frustration preemption depends on whether Congress intended it to displace state law.*

The Supremacy Clause¹⁵ is the constitutional choice-of-law provision which declares that federal law trumps state law when the two are in direct conflict. But the clause itself resolves few, if any, preemption disputes. Rather, as the Supreme Court has stated, the question in preemption cases “is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exer-

11. *Cort v. Ash*, 422 U.S. 66, 79–80 (1975); *see also infra* notes 42–48 and accompanying text.

12. John F. Manning, *Competing Presumptions about Statutory Coherence*, 74 *FORDHAM L. REV.* 2009, 2034 n.114 (2006).

13. Daniel J. Meltzer, *The Supreme Court's Judicial Passivity*, 2002 *SUP. CT. REV.* 343, 364–68 (2002).

14. *Gregory v. Ashcroft*, 501 U.S. 452, 501 (1991).

15. U.S. CONST. art. VI, cl. 2.

cise its constitutionally delegated authority to set aside the laws of a State?”¹⁶

That general statement masks critical nuances because the precise target of the statutory inquiry varies greatly depending on the type of preemption at issue. In particular, the inquiry differs depending on whether preemption allegedly arises from (1) a statutory provision that expressly preempts state laws; (2) a direct conflict between federal and state law such that it would be impossible to comply with both; or (3) the claim that operation of state law would frustrate achievement of the federal statute’s objectives.¹⁷ When a party claims a federal statute preempts state law based on frustration preemption, the key statutory construction inquiry is whether Congress—notwithstanding its silence on the issue—intended to displace state laws that frustrate certain purposes or objectives of the federal act.¹⁸

1. Express Preemption

When preemption is asserted based on an express preemption provision, the statutory construction inquiry concerns the meaning and scope of the provision. The presence of a saving clause, which preserves certain types of state laws from the force of the preemption provision, sometimes complicates this inquiry.¹⁹ But, critically, the inquiry in an express preemption case is *not* whether Congress intended to displace state law in the first place. The presence of an express preemption provision answers that question.

2. Impossibility Preemption

Preemption also occurs when “compliance with both federal and state regulations is a physical impossibility.”²⁰ The paradigmatic case of “impossibility preemption” occurs when a federal statute says “private entities must do X” and a state law says “private entities may not do X.” In this situation, direct operation of the Supremacy Clause gives the federal law precedence over a state law that would have nullified its operation. The statutory construction inquiry concerns the substantive meaning of the federal statute: What is the meaning of X? The inquiry, again, is *not* whether Congress intended to displace certain state laws.

16. *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996).

17. *See infra* text accompanying notes 19–32.

18. *See infra* note 31.

19. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867–74 (2000).

20. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963).

For example, to borrow from Professor Hart's famous example,²¹ if a federal statute declares that "no vehicles shall be permitted in public parks," and a state law provides that "bicycle riding is permitted in parks," the sole statutory construction inquiry would be the meaning of the substantive term "vehicles." If "vehicles" includes bicycles, the state law is preempted by operation of the Supremacy Clause—without any need for Congress to have specifically stated "we intend to displace state laws that directly contradict this statute."

3. Frustration Preemption

Even where there is no express preemption provision and it is possible to comply with both federal and state law, the Supreme Court asks whether the federal law nonetheless preempts the state law because it frustrates the full achievement of the federal objectives.²² In answering that question the statutory construction inquiry has two distinct focuses.

The first inquiry is the same one undertaken in impossibility preemption cases: What is the substantive meaning of the federal statute?²³ But, even if the court knows exactly what federal standards and rules Congress intended to adopt, there remains the separate question of whether Congress intended to displace state laws to better effectuate those standards and rules and their underlying purposes.

The Supremacy Clause tells us that *if* Congress intended to displace state laws when they frustrate the achievement of certain federal objectives, that federal command controls.²⁴ The predicate question of whether Congress intended such an effect is a matter of statutory construction.

Critically, Congress does not always, or even usually, intend to preempt any and all state laws that might somehow "frustrate" achievement of one of its objectives. For example, one goal of Congress might be to foster uniformity in regulations, but that objective

21. See H.L.A. Hart, *Positivism and the Separation of Law and Morals*, 71 HARV. L. REV. 593, 607 (1958).

22. See *Sprietsma v. Mercury Marine*, 537 U.S. 51, 70 (2002); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

23. See *Perez v. Campbell*, 402 U.S. 637, 644 (1971) ("Deciding whether a state statute is in conflict with a federal statute and hence invalid under the Supremacy Clause is essentially a two-step process of first ascertaining the construction of the two statutes and then determining the constitutional question whether they are in conflict.").

24. *Hines*, 312 U.S. at 66–68.

may not be “unyielding.”²⁵ For instance, a state tort action frustrating the goal of uniformity might possess the redeeming quality of advancing Congress’s expectation that injured consumers have access to remedies.²⁶ Similarly, Congress might conclude that state tort liability provides a necessary supplement to a regulatory regime by “spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators.”²⁷ Or a statute might reflect a compromise in which legislators who wanted stricter federal standards settled for laxer standards in exchange for *not* displacing state tort actions.²⁸

These examples, however, assume that courts can derive a single congressional intent. As Professor Nelson has explained, even if we “suppose that all members of Congress can agree on the ‘full purposes and objectives’ behind a particular federal statute[,] [t]here still is no reason to assume that they would want to displace whatever state law makes achieving those purposes more difficult.”²⁹ The Supreme Court “has acknowledged outside the realm of preemption, [that] ‘no legislation pursues its purposes at all costs,’ and ‘it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute’s primary objective must be the law.’”³⁰

In short, sometimes Congress decides as a policy matter that certain statutory ends warrant casting aside all state laws that hinder attainment of those ends. Sometimes, however, Congress decides as a policy matter (or as a compromise) that the competing interests served by state law outweigh the costs imposed on a particular federal objective. When assessing whether a federal statute

25. *Sprietsma*, 537 U.S. at 70.

26. *Id.* at 64 (saying state tort actions, “unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims”).

27. Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. AM. MED. ASS’N 308, 310 (2007); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) (saying “tort suits can serve as a catalyst” to improve industry and federal regulatory practices).

28. See *Landgraf v. USI Film Prods.*, 511 U.S. 244, 286 (1994) (“Statutes are seldom crafted to pursue a single goal, and compromises necessary to their enactment may require adopting means other than those that would most effectively pursue the main goal.”).

29. Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 280 (2000).

30. *Id.* (quoting *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987)).

preempts a state law based on frustration preemption, a court must decide how Congress resolved that policy question.³¹

As we explain below, ordinary tools of statutory construction dictate that when Congress has not spoken to the issue of preemption, courts should rarely conclude that Congress nonetheless intended to displace state laws that purportedly frustrate achievement of one of the federal statutory goals.³²

B. Standard tools of statutory construction militate against finding frustration preemption.

Statutory interpretation begins with the text. “When the statutory language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.”³³ Statutes, like the FDCA, that contain no preemption provisions express no apparent intent to displace state law.

When Congress wishes to displace state law to achieve federal objectives more efficiently, it knows how to do so. By one count, Congress has enacted 350 statutes that contain express preemption provisions.³⁴ The *absence* of a preemption provision is therefore telling and should create a strong presumption that Congress intended no preemption. Indeed, the Supreme Court routinely infers meaning from Congress’s failure to address a particular issue in

31. Some parties have asserted that congressional intent to displace state law is irrelevant to the frustration preemption inquiry. Brief of Prod. Liab. Advisory Council, Inc., as Amicus Curiae Supporting Petitioner at 3, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (“[C]onflict preemption analysis does not require a court to infer Congress’s preemptive intent.”). To be sure, it is irrelevant when a frustration preemption argument is premised on the impossibility of complying with both state and federal law. At that point, the Supremacy Clause kicks in and nullifies state law. But short of this type of impossibility preemption, the implied displacement of state law is not necessary; rather, it is a policy judgment. And Congress, not the courts, is the appropriate institution to make that policy judgment.

32. We recognize that the Supreme Court stated in *Geier v. Am. Honda Motor Co.* that it did not wish to “drive[] a legal wedge” between impossibility and frustration preemption. 529 U.S. 861, 873–74 (2000). But *Geier* cannot reasonably be construed as suggesting that there are no differences whatsoever between how the two types of preemption are analyzed.

33. *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (internal quotation marks omitted).

34. See O’REILLY, *supra* note 10, at 2.

a statute where Congress has expressly spoken on a similar issue in other statutes.³⁵

And when courts decline to read unexpressed preemptive intent into federal statutes, they act in a manner consistent with well-established statutory canons. First, one “cardinal principle of statutory construction” is that “a statute ought . . . to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.”³⁶ Although courts typically employ the anti-surplusage canon to understand the meaning of a single statute, its logic applies to construing separate statutes. Inferring frustration preemption makes surplusage out of many of Congress’s express preemption provisions.

Second, “[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”³⁷ Although, as with the anti-surplusage canon, this principle speaks to the “inclusion or exclusion” within a statute, its logic also applies when comparing statutes. When Congress includes preemption provisions in more than 350 statutes and does not include such provisions in other statutes, courts should presume Congress acted intentionally and purposefully.

35. *See, e.g.*, *Kimbrough v. United States*, 552 U.S. 85, 103 (2007) (“Drawing meaning from silence is particularly inappropriate here, for Congress has shown that it knows how to direct sentencing practices in express terms.”); *Whitfield v. United States*, 543 U.S. 209, 216–17 (2005) (“Congress has included an express overt-act requirement in at least 22 other current conspiracy statutes, clearly demonstrating that it knows how to impose such a requirement when it wishes to do so. Where Congress has chosen *not* to do so, we will not override that choice. . . .” (citation omitted)); *Dole Food Co. v. Patrickson*, 538 U.S. 468, 476 (2003) (“Where Congress intends to refer to ownership in other than the formal sense, it knows how to do so. Various federal statutes refer to ‘direct and indirect ownership.’ The absence of this language in 28 U.S.C. § 1603(b) instructs us that Congress did not intend to disregard structural ownership rules.” (citations omitted)); *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc.*, 484 U.S. 49, 57 (1987) (“Congress has demonstrated in . . . other statutory provisions that it knows how to avoid this prospective implication by using language that explicitly targets wholly past violations.”); *see also* *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1, 38 (2007) (Stevens, J., dissenting) (“To begin with, Congress knows how to authorize executive agencies to preempt state laws. It has not done so here.” (footnote omitted)).

36. *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (quotation marks and citations omitted).

37. *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation marks and citations omitted).

A further reason not to infer that Congress intended to displace certain state laws in the absence of a preemption provision is the difficulty of discerning Congress's precise goals and purposes in enacting a statute. Frustration preemption assumes the state law at issue is an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress."³⁸ What if, however, the federal statute was the product of a compromise or contains multiple "purposes and objectives" in some tension with each other?³⁹ A state law might simultaneously frustrate accomplishment of the "general objective," yet further the achievement of other desirable ends.⁴⁰ Only the statutory text can resolve whether Congress intended to preempt state law in such circumstances. Given these considerations, it is not surprising that members of the Supreme Court have expressed concern with the concept of frustration preemption.⁴¹

This approach to frustration preemption—focusing on text, not on furthering perceived congressional purpose—parallels the Supreme Court's approach to implied rights of action. Before 1975, the Court "placed considerable emphasis upon the desirability of implying private rights of action in order to provide remedies thought to effectuate the purposes of a given statute."⁴² As a result, the Court's "probe of the congressional mind . . . never focused squarely on private rights of action, as distinct from the substantive

38. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

39. See *Fitzgerald v. Racing Ass'n of Cent. Iowa*, 539 U.S. 103, 108 (2003) (noting that the state law under review, "like most laws, might predominantly serve one general objective . . . while containing subsidiary provisions that seek to achieve other desirable (perhaps even contrary) ends as well, thereby producing a law that balances objectives but still serves the general objective when seen as a whole").

40. *Id.*

41. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part) (approving "th[e] Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting) (discussing the importance of "prevent[ing] federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes"); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part, concurring in judgment) ("A free-wheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law.").

42. *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 15 (1979).

objects of the legislation.”⁴³ This changed in a series of cases beginning with *Cort v. Ash*.⁴⁴

The key inquiry now is whether Congress specifically intended to create a private right of action.⁴⁵ And “unless this congressional intent can be inferred from the language of the statute, the statutory structure, or some other source, the essential predicate for implication of a private remedy simply does not exist.”⁴⁶ Although not dispositive, “congressional silence . . . is thus a serious obstacle” to finding private rights of action.⁴⁷

The Supreme Court changed its approach to implying private rights of action for many reasons, one of which has particular resonance here. The Court observed in *Virginia Bankshares* that, while the text and legislative history of § 14(a) of the Securities Exchange Act of 1934 “carry the clear message that Congress meant to protect investors from misinformation[,] . . . it is just as true that Congress was reticent with indications of how far this protection might depend on self-help by private action.”⁴⁸ As this case indicates, Congress does not always pursue its objectives at all costs and through all means. It is up to Congress, not the courts, to specify the means, whether they be private rights of action or the displacement of state law.

C. Principles of federalism further militate against finding frustration preemption.

The Supreme Court has frequently recounted the reasons why the Framers adopted a federal structure of government and the advantages that accrue from it. Allowing states to exercise continued power ensures that government is

more sensitive to the diverse needs of a heterogeneous society[,] . . . increases opportunity for citizen involvement in democratic processes[,] . . . allows for more innovation and experimentation in government[,] . . . and makes government more responsive by putting the States in competition for a mobile citizenry.⁴⁹

43. *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1103 (1991).

44. 422 U.S. 66 (1975).

45. See *Virginia Bankshares*, 501 U.S. at 1104; *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 812 n.9 (1986) (collecting cases).

46. *Nw. Airlines, Inc. v. Transp. Workers*, 451 U.S. 77, 94 (1981).

47. *Virginia Bankshares*, 501 U.S. at 1104.

48. *Id.* at 1103–04; 15 U.S.C. § 78n(a) (1947).

49. *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

Preempting state laws, however, serves none of those interests. This concern may not have been paramount earlier in the Republic, when Congress's powers were viewed as narrower and federal law was "generally interstitial in its nature."⁵⁰ Now, however, with Congress's vast authority under the Commerce Clause,⁵¹ it has correspondingly broad opportunities to preempt state law.

Recognizing this concern, the Supreme Court adopted a series of clear-statement rules applicable when Congress encroaches upon state powers.⁵² These rules serve a crucial structural function: "[I]nasmuch as th[e] Court in *Garcia [v. San Antonio Metropolitan Transit Authority]*, 469 U.S. 528 (1985) has left primarily to the political process the protection of the States against intrusive exercises of Congress'[s] Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise."⁵³ In *Garcia*, the Court overruled *National League of Cities v. Usery*⁵⁴ and stated that the key mechanism to "ensure[] that laws that unduly burden the States will not be promulgated" is the states' participation in federal governmental action.⁵⁵ But states cannot protect their interests through the political process if Congress has not signaled that it intends to encroach on the states' domain.

The doctrine of frustration preemption is irreconcilable with that principle. Indeed, after the court concludes there is a conflict, the doctrine amounts to a presumption *in favor* of preemption because the court presumes that Congress, although silent on the issue, would have wanted state law displaced. This not only conflicts with basic canons of statutory construction and the judiciary's institutional role,⁵⁶ but also undermines the protections the political process affords the states. As then-Justice Stone wrote,

50. RICHARD H. FALLON, JR. ET AL., *THE FEDERAL COURTS AND THE FEDERAL SYSTEM* 494 (5th ed. 2003).

51. See *Gonzales v. Raich*, 545 U.S. 1, 17 (2005) (confirming "Congress'[s] power to regulate purely local activities" that substantially affect interstate commerce).

52. See, e.g., *Gregory*, 501 U.S. at 460–61 (adopting "plain statement" rule when Congress "would upset the usual constitutional balance of federal and state powers"); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985) (requiring plain statement before construing statute to abrogate states' sovereign immunity); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (stating "assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress").

53. *Gregory*, 501 U.S. at 464.

54. 426 U.S. 833 (1976).

55. *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 556 (1985).

56. See *supra* notes 32–48 and accompanying text.

At a time when the exercise of the federal power is being rapidly expanded through Congressional action, it is difficult to overstate the importance of safeguarding against such diminution of state power by vague inferences as to what Congress might have intended if it had considered the matter or by reference to our own conceptions of a policy which Congress has not expressed and which is not plainly to be inferred from the legislation which it has enacted.⁵⁷

The longstanding presumption against preemption is one tool for protecting the states' status as "independent sovereigns in our federal system."⁵⁸ "This assumption provides assurance that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts."⁵⁹ The arguments set forth above are independent from, but complementary to, the presumption against preemption. Principles of statutory construction and the proper institutional roles of Congress and the courts dictate that frustration preemption should rarely be found; federalism principles reinforce that conclusion. The federalism-based presumption against preemption, and its concomitant clear-statement rule, leads to the same result.

D. Inferring frustration preemption is only proper when no reasonable policy ground supports applying state law.

We do not suggest courts can *never* find frustration preemption. A state law might so undermine the achievement of manifest federal objectives that no reasonable legislator would have voted for the bill knowing that such a state law would continue to operate. Conversely, however, courts should not displace a state law when a reasonable policy ground supports its application. In other words, if a court can identify a legitimate reason why Congress would have *not* wanted a state law to be preempted, the court would be bound to uphold the state law.

This "reasonable policy ground" rule accounts for the statutory construction, separation-of-powers, and federalism concerns discussed above. The choice whether to preempt state law is for Congress to make. It knows how to express its intent to displace state laws; courts undermine the interests served by our federal system when they conclude federal acts implicitly preempt state laws.

57. *Hines v. Davidowitz*, 312 U.S. 52, 75 (1941) (Stone, J., dissenting).

58. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

59. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quotation marks and citation omitted).

Taken together, the general rule must be that courts should not “expand federal statutes beyond their terms through doctrines of implied pre-emption.”⁶⁰ If reasonable policy arguments can be asserted both for and against displacement of state law, congressional silence is properly construed as a decision *not* to displace state law.

E. Federal agencies lack the authority to deem state laws preempted under the doctrine of frustration preemption.

When the ordinary tools of statutory construction reveal Congress did not intend to displace state law, the frustration preemption inquiry ends. As occurred in *Wyeth*,⁶¹ however, sometimes courts consider the federal agency’s conclusions that a state law frustrates the achievement of federal objectives.⁶² Several scholars have comprehensively addressed the deference, if any, an agency should receive when it opines on preemption.⁶³ For present purposes, an additional observation is in order.

In *Alexander v. Sandoval*, the Supreme Court held that “it is most certainly incorrect to say that language in a regulation can conjure up a private cause of action that has not been authorized by Congress. Agencies may play the sorcerer’s apprentice but not the sorcerer himself.”⁶⁴ That holding fully applies to agency efforts to “conjure up” frustration preemption. It is one thing for an agency to exercise statutorily-delegated authority by promulgating a substantive regulation, and for that substantive regulation to preempt

60. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part).

61. *Wyeth v. Levine*, 129 S. Ct. 1187, 1201–04 (2009).

62. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601).

63. Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 Nw. U. L. REV. 695, 699 (2008) (suggesting that “especially with respect to a statute that contains no explicit preemptive language . . . courts should apply not only a presumption against preemption, but also an additional presumption against *agency* preemption”); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. REV. 727, 759–79 (2008) (concluding that agency interpretational rulings about the preemptive effect of federal law should be subject to a deference doctrine that is *sui generis* to preemption law); Ernest A. Young, *Executive Preemption*, 102 Nw. U. L. REV. 869, 891–93 (2008) (suggesting a preemption-specific version of *Skidmore* deference to prescribe deference to an agency’s interpretation of federal law); see also Mendelson, *supra*, at 698 (“Despite agencies’ expertise in implementing their own programs, no presumptive deference should be due because agencies lack both institutional expertise on important issues of state autonomy and federalism and adequate statutory guidance regarding preemption questions.”).

64. 532 U.S. 275, 291 (2001).

state laws that directly contradict it.⁶⁵ But, it is quite another thing for an agency to declare that, even though Congress did not intend to displace state laws that could frustrate full achievement of the federal objectives, the agency has authority to declare state laws preempted on that ground. In the former action, the agency is the sorcerer's apprentice; in the latter action, it is improperly playing the sorcerer. Put another way, "if Congress does not intend [frustration] preemption, Congress should be held not to intend agency [frustration] preemption."⁶⁶

For precisely this reason, an agency cannot manufacture preemption by declaring a standard it has adopted is both a "floor" and a "ceiling."⁶⁷ Such assertions are invariably followed by the contention that these standards preempt any state measures that impose stricter standards or additional requirements because they directly conflict with the federal ceiling.⁶⁸ The problem with this approach is that the agency's declaration that its standard is a ceiling is nothing more than a declaration that it is invoking frustration preemption.

As Professor Mendelson observes, Congress commonly charges agencies with accomplishing primary goals (e.g., providing a safe workplace, ensuring that drinking water is healthy, making automobiles safer) as well as "countervailing or moderating goals" (e.g., reducing costs to employers, increasing flexibility for manufacturers).⁶⁹ If agencies can declare their standards to be both floors (to achieve the primary goals) and ceilings (to achieve the countervailing secondary goals), "federal agencies would have the power to preempt nearly any state law operating in the same arena as the federal law."⁷⁰ For "[a]n agency can nearly always identify some statutory goal—perhaps opposed to or in tension with the statute's primary goal—with which the state law will conflict."⁷¹

65. See *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152–55 (1982) (agency rule permitting federal savings and loan associations to use "due-on-sale" clauses in mortgage contracts preempts California's prohibition of such clauses).

66. Mendelson, *supra* note 63, at 707.

67. See, e.g., 71 Fed. Reg. at 3935 (FDA's assertion that its labeling requirements "establish both a 'floor' and a 'ceiling'").

68. See, e.g., Brief of the United States as Amicus Curiae Supporting Petitioner at 19, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

69. Mendelson, *supra* note 63, at 711–14.

70. *Id.* at 714.

71. *Id.* at 713; see also *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646 (1990) ("[T]here are numerous federal statutes that could be said to embody countless policies.").

If Congress intends to grant agencies that massive power, it generally may do so. But where Congress does not express the intent to preempt state laws merely because those laws might frustrate the full accomplishment of a federal objective, Congress also does not intend to grant federal agencies the authority to do precisely that under the guise of setting floors and ceilings.

II. FRUSTRATION PREEMPTION UNDER THE FDCA: *WYETH V. LEVINE*

This part applies the reasoning set forth in Part I to demonstrate why the FDCA,⁷² which has no express preemption provision, does not impliedly preempt state tort actions. It then shows that the majority opinion of the Supreme Court and the concurring opinion of Justice Thomas in *Wyeth v. Levine*⁷³ reached the same conclusion through reasoning similar to that in this Article.

A. *Background of Wyeth v. Levine*

In 2001, Diane Levine sued Wyeth for its failure to warn of the dangers of injecting its nausea medication, Phenergan, directly into a patient's vein.⁷⁴ As a result of a direct injection, Ms. Levine suffered gangrene that required the amputation of part of her arm.⁷⁵

After a favorable verdict at the trial court, the Vermont Supreme Court affirmed Ms. Levine's jury award of \$7.4 million.⁷⁶ Throughout the litigation, Wyeth maintained that Ms. Levine's lawsuit was preempted under various theories, including frustration preemption. The question presented to the United States Supreme Court was "whether federal law preempt[ed] Levine's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration."⁷⁷

Wyeth presented two preemption arguments. It first argued that "it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law."⁷⁸ Second, Wyeth maintained that "recognition of Levine's

72. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–97 (2006).

73. *Wyeth*, 129 S. Ct. at 1204 (Thomas, J., concurring).

74. Joint Appendix at 14, *Wyeth*, 129 S. Ct. 1187 (2009).

75. *Wyeth*, 129 S. Ct. at 1191.

76. *Levine v. Wyeth*, 944 A.2d 179, 182–83 (Vt. 2006) (award reduced to \$6,774,000 by party stipulation).

77. *Wyeth*, 129 S. Ct. at 1194.

78. *Id.* at 1193 (citing *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)).

state tort action creates an unacceptable ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’ because it substitutes a lay jury’s decision about drug labeling for the expert judgment of the [Federal Drug Administration].”⁷⁹ Our focus is on that second argument.

With respect to frustration preemption, Wyeth’s argument was (1) that the FDCA, which broadly regulates foods, drugs, and cosmetics, operates identically to the Medical Device Amendments of 1976 (MDA),⁸⁰ which expressly preempts “different” or “addition[al]” state requirements with respect to medical devices;⁸¹ and (2) that Congress implicitly intended to preempt all state requirements “different from, or in addition to” the federal regulatory regime governing prescription drugs.⁸² Thus, Wyeth’s implied preemption argument boiled down to the proposition that the Supreme Court should construe the FDCA as though it had an express preemption provision like the MDA.

B. The principles set forth above demonstrate that state tort law does not frustrate Congress’s objectives in enacting the FDCA.

Because the FDCA does not contain an express preemption provision, the principles of statutory construction, separation of powers, and federalism set forth in Part I weigh heavily against inferring that Congress intended to displace state tort actions that do not present an “impossibility” conflict.

Congress’s treatment of state law as applied to other products regulated by the FDA reinforces this conclusion. Congress expressly preempted certain state actions based on injuries arising from medical devices⁸³ and vaccines,⁸⁴ and has preempted state re-

79. *Id.* at 1193–94 (citation omitted) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

80. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k (2006).

81. Brief for the Petitioner at 31, *Wyeth*, 129 S. Ct. 1187 (2009) (No. 06-1249).

82. 21 U.S.C. § 360k; Brief for the Petitioner, *supra* note 81, at 40–41. Under the FDCA, a drug manufacturer may not market a new drug before first submitting a new drug application to the FDA and receiving the agency’s approval. *See* § 355a. Essentially, Wyeth maintained that because the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices and because the Court had already held that the MDA preempts state law tort suits as being an impermissible “addition[al]” or “different” state requirement, Ms. Levine’s claim should similarly be preempted. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 (2008) (Ginsburg, J., dissenting).

83. 21 U.S.C. § 360k(a).

84. 42 U.S.C. §§ 300aa–22(b)(1) and (e) (2006).

quirements with respect to over-the-counter drugs.⁸⁵ In addition, Congress failed to include an express preemption provision in the FDCA despite the long history of state tort actions against drug manufacturers.⁸⁶ Indeed, Congress adopted a saving clause in 1962 to limit the FDCA's preemptive scope.⁸⁷ Congress's decision not to include an express preemption provision in the FDCA is therefore properly viewed as a decision not to displace state tort actions.

Congress's failure to include an express preemption provision combined with its decision to include a saving clause has additional implications. We noted earlier the principle that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."⁸⁸ Moreover, "[t]he long history of tort litigation against manufacturers" of prescription drugs, and Congress's refusal to amend the FDCA in response, adds force to the conclusion that Congress did not intend to preempt such litigation.⁸⁹ Drug manufacturers have been obligated to comply with both federal drug labeling obligations and state common law for seventy years.⁹⁰

When Congress crafted the preemption provision in the MDA, it was surely aware that "[j]udgments against manufacturers of various FDA-approved products were by no means rare."⁹¹ Nevertheless, Congress opted to preempt only state requirements with respect to medical devices—not state requirements with respect to

85. 21 U.S.C. § 379r(a).

86. *Wyeth*, 129 S. Ct. at 1200.

87. Drug Amendment of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (current version at 21 U.S.C. §§ 301–99(2006)). *See also Wyeth*, 129 S. Ct. at 1196 ("The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA.").

88. *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation marks and citations omitted).

89. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

90. *See, e.g., Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 981, 991–94 (8th Cir. 1969); *Abbott Labs. v. Lapp*, 78 F.2d 170, 175 (7th Cir. 1935); *Valmas Drug Co. v. Smoots*, 269 F. 356, 360 (6th Cir. 1920); *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 432, 451–52 (S.D.N.Y. 1968); *Incollingo v. Ewing*, 282 A.2d 206, 212, 219–20 (Pa. 1971); *Phillips v. Roux Labs.*, 145 N.Y.S.2d 449, 451–52 (App. Div. 1955); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 341 n.11 (2008) (Ginsburg, J., dissenting) (listing 14 state law tort actions brought between 1968 and 1975 involving FDA-approved drugs).

91. Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims after Medtronic*, 64 TENN. L. REV. 691, 704 (1997).

drugs. As the Supreme Court observed in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, “[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.”⁹²

Wyeth’s frustration preemption arguments should therefore prevail only if no reasonable policy arguments can be asserted against the displacement of state law. In *Riegel*, the Court “speculate[d]” that the reason Congress probably wanted the MDA’s preemption provision to cover state tort actions was “solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.”⁹³ That is a plausible policy justification for preempting state tort actions against prescription drug manufacturers as well. But there are plenty of plausible policy justifications for *not* preempting such actions.

Specifically, Congress may have wanted injured consumers to retain the right to bring tort actions against prescription drug manufacturers:

- to avoid the “harsh implications of foreclosing all judicial recourse for consumers injured” by defective drugs or inadequate drug labels;⁹⁴
- because tort suits “aid in the exposure of new dangers,” which leads manufacturers and federal regulators to address the problems;⁹⁵
- based on the concern that “pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies . . .”;⁹⁶

92. 489 U.S. 141, 166–67 (1989) (quotation marks omitted; second alteration in original).

93. *Riegel*, 552 U.S. at 326.

94. Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position*, 52 *FOOD & DRUG L.J.* 7, 9 (1997); see also *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (saying state tort actions, “unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims”).

95. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005).

96. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 *GEO. L.J.* 461, 471 (2008).

- based on the concern that the FDA is overworked and underfunded, and therefore cannot ensure that defective and dangerous devices will not reach consumers;⁹⁷ or
- based on the concern that the post-approval monitoring system is not up to the task of protecting consumers from drugs whose defects become apparent only after initial FDA approval.⁹⁸

In the end, Congress decides whether the policy considerations noted in *Riegel* outweigh the policy considerations outlined above. Congress's decision not to include an express preemption provision in the FDCA reflects a decision to accept the policy arguments opposed to displacing state tort actions against prescription drug manufacturers.

C. *The Majority Decision on Frustration Preemption in Wyeth v. Levine*

Justice Stevens, joined by Justices Kennedy, Souter, Ginsburg, and Breyer, issued the opinion of the Court, rejecting Wyeth's preemption claims.⁹⁹ Significantly, as in this Article, the majority concluded that in conflict preemption cases congressional intent matters and the presumption against preemption applies.

The Court first recognized that to answer the question "whether federal law preempts Levine's claim that Phenergan's label did not contain an adequate warning" it "must be guided by two cornerstones of [the Court's] pre-emption jurisprudence."¹⁰⁰ First, "the purpose of Congress is the ultimate touchstone in every pre-emption case,"¹⁰¹ and second, the presumption against preemption applies "[i]n all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied."¹⁰²

In holding that congressional intent is the key inquiry in implied preemption cases, the Court rejected the position set forth in Justice Alito's dissent (and advanced by several amici) that "the sole question is whether there is an 'actual conflict' between state and

97. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 499 (1997).

98. See Kessler & Vladeck, *supra* note 96, at 483–95.

99. *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

100. *Id.* at 1194.

101. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

102. *Id.* at 1194–95 (quoting *Lohr*, 518 U.S. at 485) (quotation marks and ellipses omitted, second alteration in original).

federal law; if so, then pre-emption follows automatically by operation of the Supremacy Clause.”¹⁰³

In addition, it reaffirmed that the “presumption against pre-emption” applies in conflict preemption cases.¹⁰⁴ In doing so, the Court rejected the theory presented in several amicus briefs, such as those by the Chamber of Commerce and the Product Liability Advisory Council, that the presumption against preemption does not apply in conflict preemption cases.¹⁰⁵ These parties argued that to determine whether state law conflicts with federal law, courts must interpret the *substantive* meaning of those laws without applying any such presumption.¹⁰⁶ The Court definitively rejected that argument, stating that “this Court has long held to the contrary.”¹⁰⁷

After rejecting Wyeth’s argument that it was impossible to comply with “both the state-law duties underlying [Levine’s] claims and its federal labeling duties,” the Court turned to Wyeth’s frustration preemption arguments.¹⁰⁸ Wyeth’s primary contention was that “the FDCA establishes both a floor and a ceiling for drug regulations” and that “[o]nce the FDA has approved a drug’s label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered [a] stronger warning.”¹⁰⁹ The Court squarely rejected this theory on the basis that “all evidence of Congress’[s] purposes is to the contrary.”¹¹⁰ Of significant importance to its conclusion that state tort suits did not frustrate federal objectives was the Court’s recognition that Congress “surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history.”¹¹¹

103. *Id.* at 1228 (Alito, J., dissenting); *see also* Brief of Prod. Liab. Advisory Council, Inc., *supra* note 31, at 3.

104. *Wyeth*, 129 S. Ct. at 1194–95.

105. Brief of Prod. Liab. Advisory Council, Inc., *supra* note 31, at 5–19; Brief of Chamber of Commerce of the United States as Amicus Curiae Supporting Petitioner at 27, *Wyeth*, 129 S. Ct. 1187 (No. 06-1249).

106. Brief of Prod. Liab. Advisory Council, Inc., *supra* note 31, at 16 (“Interpreting the federal statute’s substantive meaning is an inquiry that does not bring into play the presumption against preemption.”) (quotation marks omitted); Brief of Chamber of Commerce of the United States, *supra* note 105, at 23–24.

107. *Wyeth*, 129 S. Ct. at 1195 n.3 (citing cases). *But see id.* at 1229 n.14 (Alito, J., dissenting) (stating that it “remained an open question—before today—whether” the presumption against preemption “applied in conflict pre-emption cases”).

108. *Id.* at 1196–2000.

109. *Id.* at 1199.

110. *Id.*

111. *Id.* at 1200.

The Court highlighted that Congress had indeed enacted an express preemption provision for medical devices in its 1976 amendments of the FDCA, but had not done so for prescription drugs, such as Phenergan.¹¹² “Its silence on the issue, coupled with its awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”¹¹³ The majority reinforced its conclusion by citing to the presumption again preemption.¹¹⁴

Lastly, the Court addressed the impact of the FDA’s assertion that Levine’s claim is preempted. Although the Court recognized that agencies, such as the FDA, “do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’”¹¹⁵ it found that the weight of the FDA’s view received the deference accorded by *Skidmore v. Swift & Co.*,¹¹⁶ and thus depended on its “thoroughness, consistency, and persuasiveness.”¹¹⁷ Under this standard, the FDA’s view did not merit deference.¹¹⁸ The Court noted that not only was the FDA’s view (which was set forth in the preamble of an FDA final rule) “inherently suspect” because of its procedural failure to provide states and other parties with notice of its federalism impacts, but it was also at odds with Congress’s intent and the FDA’s previous long-standing position on the issue.¹¹⁹

The majority also cited several of the “reasonable policy arguments” identified above. For example, the Court noted that based on the FDA’s “limited resources” to monitor drugs, state tort actions could serve to uncover unknown drug hazards.¹²⁰ In addition, the majority suggested that state tort suits could “provide incentives for drug manufacturers to disclose safety risks promptly,” and such

112. *Id.* (citing *Riegel*, 552 U.S. at 327 (2008) (“Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.”)).

113. *Id.*

114. *Id.*

115. *Id.* at 1201 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

116. 323 U.S. 134 (1944).

117. *Wyeth*, 129 S. Ct. at 1201; *see also Skidmore*, 323 U.S. at 140.

118. *Wyeth*, 129 S. Ct. 1203.

119. *Id.* at 1199.

120. *Id.* at 1202.

suits “serve a distinct compensatory function that may motivate injured persons to come forward with information.”¹²¹

It concluded its decision by rejecting Wyeth’s (and the dissent’s) contention that the Court’s previous ruling in *Geier v. American Honda Motor Co.*¹²² compelled preemption here.¹²³ Distinguishing that case, it found that Wyeth had not persuaded the Court that “failure-to-warn claims like Levine’s obstruct the federal regulation of drug labeling.”¹²⁴

Thus, the majority did not fully embrace the arguments set forth here: that frustration preemption may only be found when no reasonable policy ground supports applying state law. It did, however, adopt the key test that congressional intent matters in conflict preemption cases and that Congress’s continued refusal to enact an express preemption provision is a significant element in determining whether Congress intended to displace state law.

D. *The Concurring Opinion of Justice Thomas*

Justice Thomas concurred in the judgment, agreeing with the Court that the FDA’s approval of the Phenergan label “does not pre-empt the state-law judgment” at issue.¹²⁵ He wrote separately, however, because he could not “join the majority’s implicit endorsement of far-reaching implied pre-emption doctrines.”¹²⁶ In fact, Justice Thomas rejected those doctrines altogether.

Justice Thomas identified many of the concerns presented in Part I, including that under our federalist system “the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause”¹²⁷ and that the Supremacy Clause thus ensures that “the Federal Government does not amass too much power at the expense of the States.”¹²⁸ The Court’s broad frustration preemption precedents, and particularly its frustration preemption jurisprudence, he reasoned, have “expanded federal statutes beyond their terms.”¹²⁹

In his view, this “potentially boundless” doctrine of frustration preemption, where the Court looked to “broad federal policy objec-

121. *Id.*

122. 529 U.S. 861 (2000).

123. *See Wyeth*, 129 S. Ct. at 1203.

124. *Id.* at 1204.

125. *Id.* at 1205 (Thomas, J., concurring).

126. *Id.*

127. *Id.*

128. *Id.* at 1206.

129. *Id.* at 1207.

tives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law,” does not satisfy constitutional requirements.¹³⁰ He explained that the Supremacy Clause only grants “supreme” status to federal laws “made in [p]ursuance”¹³¹ of the Constitution, and that the Constitution’s Bicameral and Presentment Clauses¹³² “prescribe and define the respective functions of the Congress and of the Executive in the legislative process.”¹³³ Because “[c]ongressional and agency musings . . . do not satisfy Art. 1, § 7 requirements for enactment of federal law . . . [they] do not pre-empt state law.”¹³⁴ Therefore, according to Justice Thomas (and as we posit above), “evidence of pre-emptive purpose must be sought in the text and structure of the provision at issue” when analyzing the preemptive effect of federal statutes and regulations.¹³⁵ Citing his concurring opinion in *Bates*, he asserted that the “[p]re-emption analysis should not be ‘a free-wheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict.’”¹³⁶ In short, “[p]re-emption must turn on whether state law conflicts with the text of the relevant federal statute or with the federal regulations authorized by that text.”¹³⁷

For these reasons, Justice Thomas views the “Court’s entire body of [frustration] pre-emption jurisprudence [a]s inherently flawed” because the cases “improperly rely on legislative history, broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law.”¹³⁸ As we propose here, “when statutory language is plain, it must be enforced according to its terms.”¹³⁹ Thus, the lack of an express preemption provision in the FDCA demonstrates it does not preempt state tort actions.

130. *Id.*

131. U.S. CONST. art. 6, cl. 2.

132. *Id.* art 1, § 7, cls. 2–3.

133. *Wyeth*, 129 S. Ct. at 1207 (Thomas, J., concurring) (quoting *INS v. Chadha*, 462 U.S. 919, 945–46 (1983)).

134. *Id.*

135. *Id.* (alterations in original) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)).

136. *Id.* at 1208 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005)).

137. *Id.*

138. *Id.* at 1211.

139. *Id.* at 1215; *see also id.* (“[N]o agency or individual Member of Congress can preempt a State’s judgment by merely musing about goals or intentions not found within or authorized by the statutory text.”).

Likewise, Justice Thomas recognized that attempting “to divine the broader purposes of the statute” leads courts “to assume that Congress wanted to pursue those policies ‘at all costs’—even when the text reflects a different balance.”¹⁴⁰ Because “[f]ederal legislation is often the result of compromise between legislators and ‘groups with marked but divergent interests,’ . . . a statute’s text might reflect a compromise between parties who wanted to pursue a particular goal to different extents.”¹⁴¹ Consequently, “it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute’s primary objective must be the law,”¹⁴² and preemption can only apply to “policies that are actually authorized by and effectuated through the statutory text.”¹⁴³

With respect to the FDCA, Justice Thomas agreed with the majority that it did not displace state tort law.¹⁴⁴ But he disagreed with the majority’s reliance on congressional silence to derive the motivations and policies of Congress.¹⁴⁵ To him, the relevance was that “no statute explicitly pre-empts the lawsuits.”¹⁴⁶ He concluded his concurrence with the warning that he “can no longer assent to a doctrine that pre-empts state laws merely because they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of federal law.”¹⁴⁷

In this respect, his opinion is significant because absent an express preemption provision, Justice Thomas will not find a state statute preempted unless it is “impossible” to comply with both state and federal law. This approach to frustration preemption therefore closely resembles the position advocated here—indeed, it goes further by not allowing frustration preemption even in the rare case where no plausible policy would justify the state law’s interference with federal objectives.

140. *Id.*

141. *Id.* (citing *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 93–94 (2002)).

142. *Id.*

143. *Id.* at 1216.

144. *Id.* at 1204.

145. *Id.* at 1216.

146. *Id.*; *see also id.* at 1217 (Court’s role “is merely to interpret the language of the statutes enacted by Congress”) (quotation marks and brackets omitted).

147. *Id.* at 1217 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (quotation marks and brackets omitted).

CONCLUSION

In *Wyeth*, the Supreme Court made clear that the question whether a federal statute displaces state law is an issue of congressional intent—even in frustration preemption cases. With this in mind, courts should look to principles of statutory construction, separation of powers, and federalism when determining whether a federal law preempts state law. As we have shown above, these principles dictate that courts should rarely displace state law under the doctrine of frustration preemption.