Federalism and Federal Agency Reform

Gillian E. Metzger
Columbia Law School, gmetzg1@law.columbia.edu

Follow this and additional works at: https://scholarship.law.columbia.edu/faculty_scholarship

Part of the Administrative Law Commons, and the Constitutional Law Commons

Recommended Citation
Available at: https://scholarship.law.columbia.edu/faculty_scholarship/1657

This Working Paper is brought to you for free and open access by the Faculty Publications at Scholarship Archive. It has been accepted for inclusion in Faculty Scholarship by an authorized administrator of Scholarship Archive. For more information, please contact cls2184@columbia.edu.
Federalism and Federal Agency Reform

Gillian E. Metzger
Columbia Law School

October 2010
FEDERALISM AND FEDERAL AGENCY REFORM

Gillian E. Metzger*

INTRODUCTION

Preemption has emerged as the contemporary federalism battleground. Struggles over preemption have surfaced repeatedly in recent years, first over aggressive use of agency preemption by the Bush administration,¹ and more recently in connection to the major healthcare and financial sector reforms and proposed climate change legislation.² Preemption’s dominance is as evident in the judicial sphere, with the federal courts regularly engaging preemption claims in a wide array of contexts. State and local governments increasingly have protested expansions of federal preemption, and legal scholars have sounded alarms over the impact of creeping preemption on state governance capacity.³


³ See, e.g., Thomas O. McGarity, The Preemption War: When Federal Bureaucracies Trump Local Juries 21 (2008) (“The preemption war is a manifestation of the latest and, in many ways, most threatening attempt to change state common law by replacing it with a body of
This was the background against which the Court in its 2008–2009 Term issued three major preemption decisions: Altria Group, Inc. v. Good,4 Wyeth v. Levine,5 and Cuomo v. Clearing House Ass’n.6 Notably, preemption claims failed in all three of these closely divided decisions, with the Court invoking federalism-based presumptions against preemption as well as the need to respect traditional federal and state functions to guide its analysis.7 These decisions, moreover, limit administrative agencies’ preemption powers in ways that could have significant prospective effect in protecting state law against displacement by executive branch actions. Further, the Court’s refusal to defer to the pro-preemption views of the administrative agencies involved in Wyeth and Cuomo indicates that a majority of Justices view preemption determinations as different from other statutory interpretation questions—a difference that appears to turn on the federalism effects of preemption.8 The impact of these decisions on tort litigation and preemption analysis generally is likely to be significant, at least in the short term. Wyeth is particularly portentous given its importance for failure to warn and other drug-related state law tort suits.9 More broadly, the decisions signal some judicial resistance


7. See Cuomo, 129 S. Ct. at 2717–18, 2720–21 (considering incursion on traditional state powers); Wyeth, 129 S. Ct. at 1194–95, 1199–1200 (invoking presumption against preemption); Altria, 129 S. Ct. at 543–44 & n.6 (considering clear statement rule especially important in “field traditionally occupied by the States”).
8. See infra text accompanying notes 56–64.
9. See Mason v. SmithKline Beecham Corp., 596 F.3d 387, 391–96 (7th Cir. 2010) (calling Wyeth “our intellectual anchor” in holding failure-to-warn claim was not preempted by federal regulation); Demahy v. Actavis, Inc., 593 F.3d 428 433–35, 437–39, 445–49 (5th Cir. 2010) (relying on Wyeth to hold FDA regulation did not preempt state failure-to-warn claims against drug manufacturer); Mensing v. Wyeth, Inc., 588 F.3d 603, 607–12 (8th Cir. 2009) (relying on Wyeth to conclude that “[t]he obligation [plaintiff] seeks to impose upon generic manufacturers does not obstruct the purposes and objectives of the Hatch-Waxman Amendments [to the FDCA]
toward statutory interpretations or other administrative efforts that aggressively expand the preemptive scope of federal action. In light of the close votes in these cases and Justice Stevens’s pivotal role in opposing preemption, whether these decisions have a longer lasting effect is harder to predict. The decisions themselves also leave open some important questions, such as the preemptive effect of a regulation with legal force. The Obama Administration’s greater resistance to preemption may mean that it will be a while before such questions are resolved.

Even more interesting, however, is how the decisions frame the relationship between the states and federal agencies and what they suggest about the role of the states in national administrative governance. A striking feature of the decisions is the extent to which they are centrally concerned with using state law and preemption analysis to improve federal agency performance—what I refer to here as federal agency reform. This focus is particularly salient in *Wyeth*, which argued that the potential for state liability assisted federal regulators by giving regulated entities an incentive to disclose evidence of potential risks. *Wyeth* also used judicial control over preemption determinations to encourage greater agency sensitivity to state interests. *Wyeth*’s concern with federal agency performance is also present in the other decisions, which portray state enforcement as complementing federal administration and serving to avoid regulatory gaps. Traditional federalism concerns about protecting the states from unjustified national intrusions clearly factored into the Court’s analysis as well. Yet, in the end, the decisions seem to treat the preservation of state authority less as a goal worth pursuing in its own right than instrumentally as an important mechanism for guarding against federal agency failure.

In arguing that the recent preemption decisions use preemption analysis to improve federal regulation and federal agency performance, I do not mean to suggest that this goal was consciously or actually animating the Court. It may have been, but other motivations are equally possible. To a significant degree, the Justices’ differing stances on preemption tracked the “liberal” and “conservative” division on the Court, suggesting that a major driver behind the decisions may be different ideological stances on tort reform and the benefits of regulation. At a minimum, the inconsistencies across recent preemption

---

10. Justice Stevens, who retired at the end of last Term, wrote both *Altria* and *Wyeth* and was one of the most consistent antipreemption votes on the Court.
11. See infra text accompanying notes 52–54.
12. See Obama Preemption Memo, supra note 1, at 24,693–94 (imposing restrictions on preemption assertions by heads of departments and agencies).
13. See infra text accompanying notes 68–69.
14. This account gains support not simply from the voting pattern in these decisions, in which the liberal Justices voted unanimously against preemption and the conservative Justices largely in favor, but also in scholarship documenting a probusiness trend on the Roberts Court.
precedent and among the positions of different Justices makes it clear that “the Court” itself lacks a coherent view on most questions relating to preemption. This area of jurisprudence is a prime occasion for remembering that the Court, like Congress, “is a they, not an it.”

Instead, my claim is that reading the decisions as fundamentally concerned with improving federal administration and the potential for federal agency failure offers the most analytically coherent account of the decisions, whatever the Justices’ actual motivations. At the same time, however, this account underscores tensions between the recent preemption decisions and other lines of the Court’s jurisprudence. In particular, the decisions stand in sharp contrast with other recent preemption precedent in which the Court has rejected efforts to use state tort law to police federal regulation. They are also at odds with administrative law decisions rejecting efforts to use the courts to broadly reform federal administration. To be sure, courts routinely entertain challenges to particular agency actions, often overturning agency determinations as contrary to statutory requirements, insufficiently reasoned, and the like. But lawsuits targeting agency performance more generally have found little judicial receptivity. In the recent decisions rejecting preemption, however, the Court underscored concerns about just such broader administrative performance. Unfortunately, the Court itself neither explained nor acknowledged these tensions in its jurisprudence, and thus offered little guidance for how we should make sense of the divergence.

This Article first explores the connection between the states and federal agency reform immanent in the preemption decisions and then assesses whether grounds exist to distinguish the recent preemption decisions from other precedent more hostile to policing federal administration through the courts. One possible explanation of the Court’s conflicting jurisprudence, and the one on which I focus here, is as reflecting a distinction between direct and indirect efforts at federal agency reform. The key difference between these

---

See, e.g., David L. Franklin, What Kind of Business-Friendly Court? Explaining the Chamber of Commerce’s Success at the Roberts Court, 49 Santa Clara L. Rev. 1019, 1019 (2009) (“[I]n the less than three full Terms of the Roberts Court, the Chamber [of Commerce] has been not only unusually active but unusually successful . . . .”). It should be noted, however, that the Court’s recent preemption jurisprudence is not entirely reducible to a liberal-conservative ideological dispute. For example, the voting patterns in Riegel v. Medtronic, 552 U.S. 312 (2008) (eight Justices supporting preemption of state tort suit) and Watters v. Wachovia Bank, N.A., 550 U.S. 1 (2007) (decision supporting preemption written by Justice Ginsburg and joined by “liberal” Justices Kennedy, Souter, Breyer, and Alito over dissent by Justice Stevens, joined by Chief Justice Roberts and Justice Scalia) do not fit the purely ideological story.

15. Kenneth A. Schepsle, Congress Is a “They,” Not an “It”: Legislative Intent as Oxymoron, 12 Int’l Rev. L. & Econ. 239, 244 (1992); see also Richard H. Fallon, Jr., Constitutional Constraints, 97 Calif. L. Rev. 975, 1020 (2009) (extrapolating to the context of the Court). For a discussion of some points of overall agreement among the Justices, see infra text accompanying note 55.

16. See infra Part II.A.

17. See infra Part II.B

18. See infra text accompanying notes 182–189.
two approaches is the extent to which federal administrative policies or actions are directly challenged or otherwise targeted. A suit seeking injunctive or declaratory relief against a federal agency for failing to meet its statutory responsibilities is the paradigmatic example of a direct agency reform effort, but direct targeting of federal agency action can take other forms as well. Thus, I include in this category other efforts that call the validity of federal administrative actions into question, such as tort actions against federal officers or tort actions between private parties alleging that federal administrative decisions were fraudulently obtained.\textsuperscript{19} Indeed, even a state statute that seeks to reinforce federal regulation by expressly tying state law liability to violation of federal requirements is arguably an instance of direct targeting and best viewed as a direct effort at federal agency reform.\textsuperscript{20} Indirect reform efforts, by contrast, are those that seek to influence how federal agencies function in a more roundabout way. As portrayed in \textit{Wyeth}, state law and judicial preemption analysis improve federal administration in an indirect fashion. They provide information and incentives to encourage better federal regulatory performance, but federal agencies retain control over whether they alter their behavior in response. Significantly, the Court’s resistance to efforts to improve federal administration has occurred in contexts in which federal agency performance was more directly targeted by the federal and state law claims involved.

A distinction between direct and indirect efforts to improve agency performance has some real bite, particularly in the federalism sphere. Independent state measures that affect federal agencies only indirectly have a strong intuitive claim to presumptive legitimacy, whereas certain state law efforts to directly challenge federal administration are appropriately viewed as presumptively preempted. I ultimately conclude, however, that drawing such a firm distinction is analytically and normatively unsatisfying. State measures do not clearly sort into direct and indirect categories, and even indisputably indirect measures can have a significant impact on federal agency operations. Nor, moreover, do direct state efforts to alter federal administration necessarily run afoul of constitutional federalism principles. Instead, in our contemporary world of concurrent federal and state authority and an ever-expanding national administrative state, some direct state targeting of federal agencies—including even state law claims that may call the validity of federal administrative decisions into question—seems both constitutionally legitimate and functionally necessary if states are to play a meaningful governance role.

This leaves the possibility of a more radical account of the relationship between the states and federal agencies, one which would assign the states a special role in policing and reforming federal administration—both directly and indirectly. Although this possibility gains some support from \textit{Wyeth} and other recent precedent, it potentially portends a dramatic departure from existing jurisprudence. More importantly, the Court has so far failed to

\textsuperscript{19} See infra text accompanying notes 210–216, 257–260.
\textsuperscript{20} See infra text accompanying notes 235–242.
provide crucial clarification for such an approach, both with respect to the scope of the states’ role and the underlying justification for assigning them special responsibilities to improve federal administration.

Part I of what follows outlines the three preemption decisions and briefly discusses their implications for current preemption debates. It then turns to assessing the extent to which the decisions are best viewed as an effort to vindicate the constitutional federal structure, concluding that federalism alone fails to fully explain the decisions. Instead, fears of agency failure appear a more central dynamic, with the decisions strategically using state law and preemption analysis as mechanisms for improving federal administrative performance. Part II contrasts this emphasis on improving federal performance with both the Court’s resistance to fraud-on-the-agency claims and its administrative law precedent rejecting challenges to agency policy and performance. It argues that what distinguishes the recent preemption decisions is their indirect regulatory approach. Part III then assesses the extent to which an indirect approach to improving federal agency performance is either functionally superior or constitutionally mandated. After finding the distinction between direct and indirect efforts at federal agency reform ultimately unsatisfying, Part III also considers the possibility of a broader role for the states in reforming federal administration.

I. FEDERALISM AS CORE OR FEDERALISM AS PERIPHERY?

Preemption disputes are a staple of the Supreme Court’s docket, resulting in both a substantial preemption jurisprudence and an ever-growing academic commentary. That commentary has been increasingly critical of late, as scholars have faulted the Court’s performance on preemption questions on a

number of grounds: for deviating from constitutional text and structure;\(^{22}\) for being insufficiently sensitive or overly sensitive to state interests;\(^{23}\) for ignoring important political or regulatory features;\(^{24}\) and for being inconsistent.\(^{25}\) Such claims of inconsistency have underscored the variation both in the Court’s stated analysis, especially in its invocation of the presumption against preemption, and in its application of governing doctrine in different cases.\(^{26}\) The Court’s most recent preemption decisions provide more fodder for those debates. The discussion below begins with a brief overview of the decisions and analysis of their import for preemption doctrine. It then assesses the extent to which the decisions are best explained by federalism principles rather than alternative concerns. Rejecting a straightforward federalism analysis, it concludes that agency failure is the central analytic theme in the decisions, with federalism in the form of state law and preemption analysis serving primarily as a mechanism for improving federal agency performance.

22. See, e.g., Viet D. Dinh, Reassessing the Law of Preemption, 88 Geo. L.J. 2085, 2096 (2000) (“[C]onstitutional text, structure, and history does not support the application of the assumption in all contexts as a general presumption against preemption.”); Caleb Nelson, Preemption, 86 Va. L. Rev. 225, 293 (2000) (“A general rule that express preemption clauses should be read ‘narrowly,’ so that they contradict the fewest potential state laws, is hard to square with the Supremacy Clause’s \textit{non obstante} provision.”). But see Bradford R. Clark, Separation of Powers as a Safeguard of Federalism, 79 Tex. L. Rev. 1321, 1429 (2001) (“[C]ontrary to Professor Dinh’s assessment, the constitutional structure appears to favor a presumption against preemption because the Constitution gives states a role in selecting Congress and the President, but not federal courts.”).

23. See, e.g., Dinh, supra note 22, at 2097 (arguing presumption against preemption is too sensitive to state interests); Young, Two Federalisms, supra note 3, at 130–33 (urging greater sensitivity to state interests); see also Samuel Issacharoff & Catherine A. Sharkey, Backdoor Federalization, 53 UCLA L. Rev. 1353, 1372 (2006) (describing trend toward greater federalization).


25. See, e.g., Dinh, supra note 22, at 2085 (“Notwithstanding its repeated claims to the contrary, the Supreme Court’s numerous preemption cases follow no predictable jurisprudential or analytical pattern.”); S. Candice Hoke, Preemption Pathologies and Civic Republican Values, 71 B.U. L. Rev. 685, 687–88 (1991) (“[T]he United States Supreme Court has failed to articulate a coherent standard for deciding preemption cases, and its haphazard approach fails to provide meaningful guidance to lower courts, legislators, and citizens.”); Nelson, supra note 22, at 232 (“Most commentators who write about preemption agree on at least one thing: Modern preemption jurisprudence is a muddle.”).

A. Setting the Stage: The 2008–2009 Term Preemption Decisions

In the ongoing debate over preemption, two issues have taken center stage: the authority of federal administrative agencies to preempt state law,27 and protections against preemption of state tort law.28 These two issues are often intertwined, as administrative action has become a prime basis for claims of state tort law preemption and administrative agencies have intentionally sought to wield their powers to that effect. Both administrative preemption and tort preemption have surfaced increasingly in recent preemption cases, but were often sidestepped by the Court in its opinions.29 In the 2008–2009 Term, however, the Court addressed both issues more directly in three major decisions: Altria v. Good, Wyeth v. Levine, and Cuomo v. Clearing House Ass’n. Each involved preemption claims based on federal agency action, with Altria and Wyeth also addressing the question of preemption in the context of state law tort claims. Notably, the Court rejected the preemption claims in all three decisions, a result somewhat at odds with the trend of the Court’s preemption jurisprudence over the last decade.30 Moreover, the results in these decisions arguably conflicted with several of the Court’s recent


29. See, e.g., Watters v. Wachovia Bank, N.A., 550 U.S. 1, 20 (2007) (“[U]nder our interpretation of the statute, the level of deference owed to the regulation is an academic question.”).

30. Jonathan Klick and Michael Greve report that the Rehnquist Court ruled in favor of preemption approximately half the time, though Catherine Sharkey has noted this rate increases to 60% in tort preemption cases. Compare Greve & Klick, supra note 21, at 57 tbl.5 (reporting 52% of Rehnquist Court’s 105 preemption rulings found state action preemption), with Sharkey, Products Liability Preemption, supra note 26, at 454 n.14 (noting Greve & Klick found “62.5% preemption rate in thirty-two cases involving preemption of state common-law tort claims from 1986 to 2004”). During its 2004 to 2008 Terms, the Court decided seventeen preemption cases, finding preemption in twelve (70%) of these cases. Although the recent trend has been toward preemption, the Court has also rejected preemption claims on several occasions, in particular Gonzales v. Oregon, 546 U.S. 243 (2006), and Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005).
preemption decisions—a point made by the dissent in each case.31

1. The Decisions: Altria, Wyeth, and Cuomo.—In Altria, Maine smokers brought an action under that state’s Unfair Trade Practices Act alleging that a tobacco company had deceived them with respect to the levels of tar and nicotine they would receive from smoking its light cigarettes. The essence of the smokers’ claim was that the company knew that smokers of light cigarettes unconsciously engage in compensating behaviors, such as blocking filter holes, which means they inhale more tar and nicotine than accounted for by measurements under the standard Cambridge Filter Method. The company responded by invoking both express and obstacle preemption. It argued that the suit was preempted both by the express preemption clause of the Federal Cigarette Labeling and Advertising Act and because liability would be an obstacle to a Federal Trade Commission (FTC) policy encouraging reliance on the Cambridge Filter Method for tar and nicotine yields.32

In a 5-4 decision written by Justice Stevens, the Court rejected both preemption arguments. Following the earlier plurality opinion in Cipollone v. Liggett Group, the majority held that the Labeling Act’s express preemption clause encompassed only state law rules targeted at smoking and health, and accordingly did not reach a state law claim alleging breach of a general duty not to deceive.33 Justice Thomas’s dissent contended that the majority’s approach was incapable of consistent application and represented an unduly narrow view of the clause.34 The majority further concluded that the FTC in fact had no such policy as the company described, leaving open whether “a regulatory policy could provide a basis for obstacle pre-emption.”35 According to the majority, the most the record revealed in support of the company’s argument was a “handful of industry guidances and consent orders” allowing use of the Cambridge Filter Method and “FTC[] inaction with regard to ‘light’ descriptors,” but “agency nonenforcement of a federal statute is not the same as a policy of approval.”36

Two grounds for preemption were also asserted in Wyeth. Wyeth began as a state court tort action in which a jury found a drug manufacturer liable for

32. Altria, 129 S. Ct. at 541–42.
33. Id. at 545–49 (citing Cipollone v. Liggett Grp., Inc., 505 U.S. 504 (1992)).
34. Id. at 555–58 (Thomas, J., dissenting).
35. Id. at 549–51 (majority opinion).
36. Id. at 550–51.
failing to warn about dangers associated with direct injection of an antinausea medication into patients’ veins. The manufacturer first asserted impossibility preemption, arguing that it could not comply with a state law duty to modify the label of the drug, Phenergan, without violating federal laws restricting a drug manufacturer’s ability to alter a drug label without prior approval from the Food and Drug Administration (FDA). It also invoked obstacle preemption, maintaining that allowing state law liability for failure to warn about dangers associated with a drug would pose an obstacle to achieving Congress’s objectives in the Food, Drug, and Cosmetic Act (FDCA) of assigning responsibility for drug labeling decisions to the FDA. In the preamble of a recently promulgated drug labeling regulation, the FDA had espoused a similar view, declaring that state law failure-to-warn actions “threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs” and therefore “FDA approval of labeling . . . preempts conflicting or contrary State law.”

Once again the Court rejected both arguments for preemption, this time by a 6-3 margin, with Justice Thomas concurring in the result. Justice Stevens’s majority opinion concluded that under governing regulations the manufacturer could have added a stronger warning in light of accumulating evidence of the dangers of direct intravenous administration and that the FDA had not prohibited strengthening the warning in such a fashion. The majority also rejected the view that state failure-to-warn suits would prove an obstacle to achieving Congress’s objectives for drug regulation in the FDCA, arguing that the claim of FDA exclusivity was not supported by the statute’s text, history, or purpose of furthering consumer protection. Particularly notable was the majority’s refusal to grant the FDA’s contrary view any weight as a result of procedural deficiencies and inconsistencies in the agency’s position over time. The dissenting Justices, in an opinion by Justice Alito, agreed with the manufacturer that preemption was appropriate on both impossibility and obstacle preemption grounds. The most radical view was that espoused by Justice Thomas, who contended in his concurrence that the very idea of obstacle preemption was constitutionally illegitimate.

_Cuomo_ differed from the others not only in arising outside the tort context, but also because it involved a state attorney general’s effort to enforce state law and a federal agency as a party seeking a declaration of preemption.

---

38. Id. at 1193, 1199.
40. Wyeth, 129 S. Ct. at 1196–204.
41. Id. at 1196–99.
42. Id. at 1199–200.
43. Id. at 1200–03.
44. Id. at 1220 (Alito, J., dissenting).
45. Id. at 1205, 1217 (Thomas, J., concurring).
The Office of the Comptroller of the Currency (OCC), along with a banking trade group, argued that state officials were preempted from seeking to enforce state laws against national banks by the general prohibition on state exercise of “visitorial powers” over national banks in the National Bank Act (NBA). The OCC had previously issued a regulation interpreting “visitorial powers” to include enforcing compliance with state and federal law. The Court in a 5-4 decision rejected the OCC’s broad claim of preemption. The majority opinion, this time authored by Justice Scalia, held that the OCC’s regulation interpreting visitorial powers to include suit by a state attorney general to enforce state law was not a credible reading of the statute. The majority agreed, however, that the NBA precluded state administrative investigatory and supervisory efforts unrelated to bringing a judicial enforcement action. Justice Thomas’s dissent contended that the OCC’s regulation represented a perfectly reasonable interpretation of an ambiguous statutory term by the agency charged with implementing the statute and deserved the Court’s deference.

2. The Decisions’ Import for Preemption Analysis.—The fact that these cases were all decided by close votes and contained vigorous dissents indicates that the Court remains quite divided about preemption. It is thus hard to assess the long-term impact the decisions will have, especially on highly disputed issues, such as how broadly or narrowly to read an express preemption clause, on which the Court seemed to deviate from recent precedent. Moreover, some key questions were left open, in particular the extent to which federal administrative regulations with the force of law—that is, substantive regulations or decisions that impose binding legal obligations, as opposed to regulations that simply interpret governing statutes or provide general guidance—can preempt state law. Also unclear is whether the Court will

48. Cuomo, 129 S. Ct. at 2715–19. The Court also rejected the OCC’s interpretation of its regulation as not preempting state enforcement of general legal requirements, such as state contract law, as at odds with the text of the regulation as well as the NBA. Id. at 2719–20.
49. Id. at 2721–22.
50. Id. at 2722–28 (Thomas, J., concurring in part and dissenting in part).
52. In Wyeth, the Court noted that it had previously held “an agency regulation with the force of law can pre-empt conflicting state requirements,” but emphasized that it was “faced with no such regulation” here and had “no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law,” distinguishing Geier on this ground. Wyeth v. Levine, 129 S. Ct. 1187, 1200–01, 1203 (2009). Although the majority appeared to leave this question open, Justice Breyer made clear in his concurrence that in his view agencies could issue specific regulations with legal force that have preemptive effect. Id. at 1204 (Breyer, J.,
require an express delegation by Congress of preemptive authority for such an agency regulation to have preemptive effect, and the extent to which an agency must have demonstrably considered an issue to support a claim of actual conflict.

Nonetheless, the decisions, especially Wyeth, mark a significant contribution to the Court’s preemption jurisprudence. To begin with, they indicate that the Court continues to believe that liability under state common

concurring). This was also the view of the three dissenting Justices in Wyeth, who argued that the relevant FDA actions in fact had legal force and defended the result in Geier. Id. at 1227–29 (Alito, J., dissenting).

Justice Thomas’s position on this issue is much harder to parse. He was the sole Justice expressly to renounce the Geier decision, but his objection to Geier—which also animed his concurrence in Wyeth—was opposition to obstacle preemption, under which state laws are displaced on the grounds that they are an obstacle to the achievement of general congressional purposes and objectives. Id. at 1211–17 (Thomas, J., concurring). As a result, it seems possible that Justice Thomas might support preemption when state law clearly conflicts with a valid regulation that has independent legal force, though it seems likely he would require clear congressional authorization of such preemptive authority. See id. at 1215 (“The Court’s ‘purposes and objectives’ pre-emption jurisprudence is . . . problematic because it encourages an overly expansive reading of statutory text.”); see also Cuomo, 129 S. Ct. at 2732–33 (Thomas, J., concurring in part and dissenting in part) (justifying deference to OCC’s view of NBA’s preemptive scope on grounds that statute includes express preemption clause and thus Congress made decision to preempt, not the agency).

53. In Wyeth, the majority emphasized the fact that “Congress has not authorized the FDA to pre-empt state law directly” as another reason why deference to the FDA’s views on preemption would be inappropriate. Wyeth, 129 S. Ct. at 1201. It did not specify, however, exactly how such an authorization would affect the preemption analysis and in particular whether clear congressional authorization is necessary for an agency regulation with the force of law to have preemptive effect. Justice Thomas would appear to require such clear authorization, see supra note 52, whereas the fact that Justice Breyer was willing to allow FDA regulations with legal force to have preemptive effect indicates he would not impose such a requirement, see Wyeth, 129 S. Ct. at 1204 (Breyer, J., concurring), and neither would the three dissenting Justices, see id. at 1220, 1227–30 (Alito, J., dissenting). Neither Cuomo nor Altria addressed the question—although the Cuomo majority’s refusal to defer to the OCC’s regulation interpreting the ambiguous term “visitorial powers,” combined with its insistence that this interpretation was in substance no different than a declaration of preemptive effect, suggests that more authorization of administrative preemption than simply an express preemption clause is needed for the agency’s views on preemption to get strong deference. See Cuomo, 129 S. Ct. at 2721 (describing OCC regulation at issue as interpretive and declaratory of the NBA’s preemptive force); see also William Funk, Judicial Deference and Regulatory Preemption by Federal Agencies, 84 Tul. L. Rev. 1233, 1242–49 (2010) [hereinafter Funk, Judicial Deference] (discussing role of statutory authorization in assessing whether agency views on preemption get deference). Some scholars have advocated requiring such clear authorization for agencies to have power to preempt. See, e.g., Mendelson, Presumption, supra note 27, at 699 (advocating clear statement rule); Merrill, Institutional Choice, supra note 27, at 767 (advocating “super-strong” clear statement rule). But see Metzger, New Federalism, supra note 27, at 2071–72 (arguing clear statement rule is at odds with current administrative law and “would create extraordinary obstacles to federal administrative governance”).

54. See Douglas G. Smith, Preemption After Wyeth v. Levine, 70 Ohio St. L.J. 1435, 1436–37 (2009) (arguing Wyeth suggests preemption is available when “the FDA has specifically considered the particular risks at issue”).
law can constitute a state law requirement or prohibition for purposes of an express preemption clause. That view was an unstated but necessary assumption of both Altria and Wyeth. It also is a point of growing consistency in recent preemption decisions; the Term before, in Riegel, the Court strongly adhered to the view that common law liability constitutes a requirement.\(^\text{55}\) The Court also remains committed to the possibility that state law liability might be impliedly preempted because it creates an impermissible obstacle to achievement of federal statutory objectives and purposes, even if such liability is not at odds with the text of governing federal laws. None of the other Justices in Wyeth joined Justice Thomas’s concurrence attacking the legitimacy of obstacle preemption. Their disagreement was not over the acceptability of obstacle preemption in principle, but rather over its application to the case at hand.

More important is Wyeth’s insistence that conclusions of preemptive effect are ultimately for the courts to make in their independent judgment, at least absent an express delegation to an agency of preemptive authority.\(^\text{56}\) Although a court may give weight to an agency’s “explanation of state law’s impact on the federal scheme,” it appears that without such an express delegation agencies generally receive at best limited deference of the Skidmore variety for their preemption determinations.\(^\text{57}\) In emphasizing the need for independent judicial determination of preemption and limited agency deference, Wyeth clarifies a frequent issue of dispute in preemption cases.\(^\text{58}\)


\(^{56}\) Wyeth, 129 S. Ct. at 1201.

\(^{57}\) Id.; see also Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) (“The weight of [the Administrator’s] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”). For a similar conclusion, see Funk, Judicial Deference, supra note 53, at 1251–52 (finding courts apply “weak or Skidmore deference”); see also Bhagwat, supra note 26, at 207 (“Note that adding up these votes, five of the current Justices have joined opinions disclaiming deference to agency findings of preemption.”).

\(^{58}\) See, e.g., Riegel, 552 U.S. at 326–27 (suggesting Skidmore deference); Watters v. Wachovia Bank, N.A., 550 U.S. 1, 20–21 & n.13 (2007) (refusing to address level of deference owed OCC regulation). The question of what deference, if any, to accord administrative interpretations of preemptive effects has received substantial academic commentary. See, e.g., Nina A. Mendelson, Chevron and Preemption, 102 Mich. L. Rev. 737, 758–98 (2004) [hereinafter Mendelson, Chevron] (arguing against Chevron deference for agency views on preemption and in favor of Skidmore on case-by-case basis); Merrill, Institutional Choice, supra note 27, at 769–79
Cuomo’s subsequent invocation of the Chevron framework instead of Skidmore surely muddies the waters a bit. This difference, however, may just reflect that preemption in Cuomo turned on the meaning of an express preemption clause rather than an implied preemption analysis assessing the impact of state law on the overall federal scheme.\(^{59}\)

In any event, what is more noteworthy about Cuomo is the extent to which the majority opinion deviates from ordinary Chevron review by refusing to defer to the OCC’s regulation interpreting “visitorial powers” in the NBA, despite acknowledging that this term was ambiguous and the regulation had been promulgated using full notice-and-comment procedures.\(^{60}\) Under established Chevron/Mead analysis, an agency interpretation of an ambiguous statutory term promulgated using full rulemaking procedures ordinarily receives substantial deference.\(^{61}\) That the Wyeth Court did not grant greater deference to the FDA’s view of FDCA’s preemptive effect is less surprising, given the procedural deficiencies that marred the FDA’s adoption of this view as part of the drug labeling rule and its inclusion only in the rule’s preamble.\(^{62}\) On the other hand, Wyeth’s insistence on independent judicial judgment on preemption, even with respect to agency regulations having the force of law, also marks a deviation from standard Chevron analysis.\(^{63}\)

It seems therefore that both Wyeth and Cuomo pull out administrative preemption determinations for different judicial treatment than administrative determinations usually receive.\(^{64}\) Also striking, however, is Wyeth’s use of

\(^{59}\). See Cuomo v. Clearing House Ass’n, 129 S. Ct. 2710, 2715 (2009); see also id. at 2732 (Thomas, J., concurring in part and dissenting in part) (emphasizing agency did not declare preemptive scope of NBA but instead interpreted term in statute’s preemption clause).

\(^{60}\). See id. at 2715 (majority opinion) (noting “some ambiguity as to the meaning of ‘visitorial powers’” and insisting that Court could nonetheless “discern the outer limits of the term . . . through the clouded lens of history”).

\(^{61}\). See United States v. Mead Corp., 533 U.S. 218, 226–27 (2001) (noting “an agency’s power to engage in adjudication or notice-and-comment rulemaking” is often good evidence Congress intended its statutory interpretations to receive deference); see also Metzger, New Federalism, supra note 27, at 2063–68 (describing other recent decisions in which Court appeared to engage in unusually searching statutory scrutiny in cases involving federalism issues).

\(^{62}\). See Wyeth, 129 S. Ct. at 1201 (outlining deficiencies); see also Mead, 533 U.S. at 228–31 (concluding classification rulings at issue “present a case far removed . . . from notice-and-comment process” and therefore not entitled to Chevron deference); cf. Riegel, 552 U.S. at 338 n.8 (Ginsburg, J., dissenting) (noting FDA’s “amicus brief interpreting a statute is entitled, at most,” to Skidmore deference).

\(^{63}\). See Mead, 533 U.S. at 226–27 (“[A]dministrative implementation of a particular statutory provision qualifies for Chevron deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.”).

\(^{64}\). Wyeth’s insistence on independent judicial determination of preemption supports my colleague Thomas Merrill’s suggestion that the Court is developing a special review doctrine for preemption. See Merrill, Institutional Choice, supra note 27, at 766–69.
administrative law to encourage more careful agency assessments of preemption—evident in the majority’s criticism of the FDA’s failure to provide states with notice and an opportunity to comment on its changed preemption views or a detailed defense of that change.65 These requirements of detailed explanation and justification for change are standard administrative law requirements for reasoned administrative decisionmaking, appearing under “hard look” arbitrary and capriciousness review as well as Skidmore scrutiny.66 Moreover, this use by the majority of ordinary administrative law to police administrative preemption determinations appears intentional, given the opinion’s statement that the Court would vary the degree of weight it assigned to an agency’s views based on the “thoroughness, consistency, and persuasiveness” of the agency’s account.67 The clear lesson for agencies is that they need to involve states in their preemption decisionmaking and offer well-reasoned, expertise-based justifications for their views, carefully explaining any change in their position on preemption over time, if they want those views to be given weight by a court.68

B. What’s Federalism Got to Do with It?

One way of understanding these decisions is that they reflect judicial unease over increasing federal displacement of state law and state regulatory authority. Elsewhere I have argued that several recent decisions appear to be using familiar administrative law doctrines, including a de facto more rigorous

65. See Wyeth, 129 S. Ct. at 1201–03.
68. A similar lesson is offered by Altria, albeit much more tacitly. The Court’s conclusion that an industry guidance and some consent orders did not translate into a potentially preemptive FTC policy encouraging use of the Cambridge Filter Method suggests that an agency seeking to adopt a position on preemption will need to use more formal procedures and to general effect. Altria Grp. Inc. v. Good, 129 S. Ct. 538, 549–51 (2008); see also Cuomo v. Clearing House Ass’n, 129 S. Ct. 2710, 2717–18 (2009) (emphasizing bizarre consequences of agency’s view as factor counting against it).
Chevron scrutiny, to address federalism concerns.69 Viewed in this light, the 2008–2009 Term preemption decisions appear of a piece with this trend in the Court’s precedent. While I ultimately conclude federalism is not the dynamic driving the decisions, it is undeniably an important factor in play.70 Both the Altria and Wyeth majorities prominently invoked the presumption against preemption at the outset of their analyses, emphasizing that “we begin our analysis ‘with the assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress.’”71 Altria’s invocation of the presumption was particularly notable given the presence of an express preemption clause in the Labeling Act, and the majority’s insistence that the presumption against preemption should apply even in cases of express preemption provoked sharp disagreement from the dissent.72 Similarly, the Wyeth majority rejected arguments that the presumption was inappropriate in contexts long regulated by the federal government (such as drug labeling), or in disputes over implied conflict preemption.73 Wyeth also emphasized the need to “respect . . . the States as ‘independent sovereigns in our federal system.’”74

Although it eschewed invocation of the presumption,75 the Cuomo majority gave perhaps even more extensive voice to federalism concerns. Emphasizing “the incursion that the Comptroller’s regulation makes upon traditional state powers,” the opinion noted that states had long enforced both general and banking-specific laws against national banks.76 It also characterized the OCC’s “bizarre” interpretation of the NBA—under which states could apply but not enforce their laws against national banks—as undermining the status of state enactments as law.77 Equally significant was the majority’s identification of the NBA as a “mixed state/federal regime[,] in which the Federal Government exercises general oversight while leaving state substantive law in place.”78 Perception of Cuomo as motivated by federalism

69. See Metzger, New Federalism, supra note 27, at 2067, 2069 (“[T]he searching scrutiny in these decisions provides evidence that the Court is using administrative law analysis to address federalism concerns . . . [and] the divide between ordinary and extraordinary [administrative law] here is far from stark.”).
72. See Altria, 129 S. Ct. at 543; id. at 556–58 (Thomas, J., dissenting) (noting Court had not expressly invoked presumption in such contexts of late).
73. Wyeth, 129 S. Ct. at 1195 n.3; see also id. at 1228 (Alito, J., dissenting) (arguing invocation of presumption was inappropriate).
74. Id. at 1195 n.3 (majority opinion) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).
76. Id.
77. Id. at 2718.
78. Id.
concerns is reinforced by the dissent, which took pains to refute federalism-based arguments against preemption.79

But cracks exist in this federalism story. One point to note at the outset is that federalism concerns are not leading the Court to dramatically transform its preemption analysis, even if they are affecting how that analysis is applied. Again, no one on the Court appears to question that common law duties can constitute state law requirements for preemption purposes, and eight Justices continue to accept the legitimacy of implied obstacle preemption in principle.80 The fact that the Wyeth Court expressly left open the question of how it would treat regulations with legal force is also significant, as a refusal to defer to agencies in that context would mark a more radical change from its precedent—both preemption precedent and general administrative law precedent—on how such regulations are reviewed.81 Thus, to some degree federalism concerns appear to be coming in at the margin.

Another reason for skepticism is encapsulated in the question: Why now? That federal preemption can significantly restrict state authority in areas of traditional state concern is hardly news. Nonetheless, as the Altria dissent noted, the Court has often failed to invoke the presumption against preemption in construing express preemption clauses, as recently as the preceding Term.82 Indeed, the 2007 decision in Watters v. Wachovia Bank appeared to apply a presumption in favor of preemption.83 The Court has also upheld claims of preemption even when compliance with both state and federal law was possible.84

It is true that the issue of administrative preemption has gained much more attention from the Court over the last few years, largely in response to federal agencies’ propreemption shift during the Bush Administration and the

---

79. See id. at 2731–33 (Thomas, J., concurring in part and dissenting in part).
80. See supra text accompanying notes 52, 55 (discussing obstacle preemption and common law duties as state law requirements, respectively).
81. See Metzger, New Federalism, supra note 27, at 2052, 2071–72 (discussing Court’s usual deference to substantive agency determinations and delegations of authority).
82. See Altria Grp., Inc. v. Good, 129 S. Ct. 538, 556 (2008) (Thomas, J., dissenting) (collecting cases). A number of scholars have underscored the Court’s inconsistency, particularly with respect to invoking the presumption. See Dinh, supra note 22, at 2105–07 (“[T]he Court’s application of obstacle preemption belies the insistence on a general presumption against preemption, of whatever weight.”); Sharkey, Products Liability Preemption, supra note 26, at 506–510 (arguing that presumption is inconsistently applied and is outcome determinative when invoked); see also Nelson, supra note 22, at 290–92 (discussing failure of Court’s presumption against preemption).
83. See Watters v. Wachovia Bank, N.A., 550 U.S. 1, 12 (2007) (noting Court has interpreted grants of power to national banks “not normally limited by, but rather ordinarily pre-empting, contrary state law” (internal quotation marks omitted)).
84. See Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 348 (2001) (finding “conflict” when “federal statutory scheme amply empowers the FDA to punish and deter fraud”); Geier v. Am. Honda Motor Co., 529 U.S. 861, 885 (2000) (“While we certainly accept the dissent’s basic position that a court should not find pre-emption too readily in the absence of clear evidence of a conflict . . . we find such evidence here.”); see also United States v. Locke, 529 U.S. 89, 108 (2000) (noting presumption against preemption “is not triggered when the State regulates in an area where there has been a history of significant federal presence”).
resultant political and scholarly outcry. Tort preemption has also increasingly risen to the fore, largely as a result of *Cipollone*, which held that common law duties could constitute state law requirements for preemption purposes. Some of the Court’s greater sensitivity to federalism may thus reflect growing awareness of the significant impact of these preemption trends on the states. Apparent variation in the Court’s sensitivity to federalism also may reflect the Court’s reading of different statutory regimes, or idiosyncratic voting by particular Justices.

Nevertheless, it is fair to say that the Court has not been consistently solicitous of state interests in preemption cases, even of late. A comparison of the Court’s two recent preemption decisions involving the NBA, *Cuomo* and *Watters*, demonstrates this point starkly. The concern with preserving the states’ historic role in enforcing state law against national banks emphasized in *Cuomo* made no appearance in *Watters*, which instead underscored the burdens put on national banks from having to comply with varied state regimes and duplicative oversight. Another notable contrast is between *Altria* and *Wyeth*, on the one hand, and *Riegel v. Medtronic, Inc.*, on the other. In *Riegel*, seven

---

85. See McGarity, supra note 3, at 3–5 (discussing Bush Administration’s controversial use of preemption to further “tort reform” agenda); Buzzee, Hard Look, supra note 27, at 1550–51 (characterizing lobbyist “entreaties for regulation” as attempts to “preempt additional state regulation and common law tort liabilities”); Sharkey, Preemption by Preamble, supra note 3, at 227–28 (calling Bush administration preemption policy “‘silent tort reform’” (quoting Stephen Labaton, “Silent Tort Reform” Is Overriding States’ Powers, N.Y. Times, Mar. 10, 2006, at C5); see also infra text accompanying note 130 (noting increased attention to and critique of this administrative trend in briefs).

86. *Cipollone* v. Liggett Grp., Inc., 505 U.S. 504, 521 (1992); see also Bates v. Dow Agrosciences LLC, 544 U.S. 431, 441 (2005) (“It was only after [*Cipollone*] . . . that a groundswell of federal and state decisions emerged holding that [FIFRA’s preemption provision] pre-empted claims like those advanced in this litigation.”); McGarity, supra note 3, at 60 (noting that, after “exceedingly influential” *Cipollone* decision, “federal preemption became the favored defense for regulated companies seeking to avoid liability and accountability for harm caused by their products and activities”).


88. Justice Kennedy joined the majority in rejecting preemption in *Altria*, 129 S. Ct. at 540–41, and *Wyeth* v. Levine, 129 S. Ct. 1187, 1190 (2009), but supported preemption in *Cuomo* v. Clearing House Ass’n, 129 S. Ct. 2710, 2722 (2009) (Thomas, J., concurring in part and dissenting in part), and in *Watters*, 550 U.S. at 4. Justice Scalia wrote the majority opinion rejecting preemption in *Cuomo*, 129 S. Ct. at 2714, but supported preemption in *Altria*, 129 S. Ct. at 551 (Thomas, J., dissenting), and *Wyeth*, 129 S. Ct. at 1217 (Alito, J., dissenting). Justice Ginsburg wrote the majority opinion in *Watters*, 550 U.S. at 4, which found preemption, but signed onto the majority opinion rejecting preemption in *Cuomo*, 129 S. Ct. at 2714. Justice Breyer wrote the majority opinion upholding preemption in *Geier*, 529 U.S. at 864, but in his concurrence in *Wyeth* he went out of his way to note that the Court did not have before it the question of whether an agency regulation with the force of law could preempt state tort law—a question he decided in the affirmative in *Wyeth*. 129 S. Ct. at 1204 (Breyer, J., concurring).

members of the Court signed on to Justice Scalia’s portrayal of state tort law as little different from state regulation and, if anything, meriting less protection given the limited expertise and perspective that jurors bring to bear.\textsuperscript{90} Another possible response to the “why now” question might be that the preemption challenges in these three recent decisions posed particular threats to state sovereignty. The majority opinions do at times suggest as much, with their references to the traditional state protective roles that preemption would eviscerate.\textsuperscript{91} But the state functions under attack—providing tort remedies for individuals injured by unlawful conduct or enforcing state laws—have been at issue in other recent cases and received a less protective response.\textsuperscript{92}

More importantly, the results in these cases produced limited protection for states as active legislators and regulators, with “active” here being the extent to which state officials are able to develop and implement state policies on specific issues of concern. All three decisions focused primarily on the ability to sue on state law claims in state or federal court, rather than on the ability of states to take legislative or administrative action. Underlying this point is the recognition that the “states” are not a single identifiable entity, but instead are comprised of a variety of institutions, officials, and functions.\textsuperscript{93} The preemption decisions protected two state institutions, state courts and state common law, but offered only limited room for actions by the states’ politically elected leaders.\textsuperscript{94}

States play a particularly passive role in the types of damages actions preserved in \textit{Altria} and \textit{Wyeth}, given that decisions to sue and decisions about liability are made by private individuals, whether as plaintiffs or as members of the jury. The only state official clearly involved is a state judge, and then only if the action is brought in state court. True, states can play a more active role by enacting statutes to address particular harms, rather than simply relying upon traditional judicially developed common law rules. Indeed, the damages action in \textit{Altria} arose under such a state statute.\textsuperscript{95} Of greater significance perhaps, the state statute at issue in \textit{Altria} expressly provides for enforcement by the state attorney general as well as private damages actions, and thus the decision could be said to also protect some enforcement role for state officials.\textsuperscript{96} On the other hand, \textit{Altria} offers a strong caution against states

\textsuperscript{91} See sources cited supra note 7.
\textsuperscript{92} See, e.g., \textit{Riegel}, 552 U.S. at 324–25 (finding state tort remedies preempted); \textit{Watters}, 550 U.S. at 7 (preempting state enforcement of state licensing and oversight of state-chartered subsidiaries of national banks).
\textsuperscript{93} See Roderick M. Hills, Jr., Dissecting the State: The Use of Federal Law to Free State and Local Officials from State Legislatures’ Control, 97 Mich. L. Rev. 1201, 1201 (1999) (“In discussions about American federalism, it is common to speak of a ‘state government’ as if it were a black box, an individual speaking with a single voice. . . . [A] ‘state’ actually incorporates a bundle of different subdivisions, branches, and agencies . . . .’’)
\textsuperscript{94} Nor is it at all clear which state actor best represents the interests served by state common law. See Sharkey, Federalism Accountability, supra note 66, at 2157 (“There is no a priori representative of state interests served by the common law . . . .’’).
\textsuperscript{96} See id. § 209 (2002 & Supp. 2009) (giving AG enforcement power); id. § 211 (giving
playing too much of a regulatory role, with the majority concluding that the state law at issue was not preempted precisely because it embodied a general duty not to deceive and was not aimed at smoking or health.\textsuperscript{97} Efforts by the attorney general to use the statute to address smoking-related harms thus might well be viewed more skeptically; indeed, the Court previously invalidated a similar attempt in this vein by the Massachusetts Attorney General.\textsuperscript{98}

\textit{Wyeth}, meanwhile, involved a traditional common law failure-to-warn claim. Thus, even the background state legislative involvement found in \textit{Altria} was lacking. Moreover, the \textit{Wyeth} majority justified its rejection of preemption in terms quite specific to common law suits. For example, it emphasized the compensatory functions and beneficial incentives associated with tort suits and concluded specifically “that Congress did not regard state tort litigation as an obstacle to achieving its purposes.”\textsuperscript{99} As a result, \textit{Wyeth}’s resistance toward preemption may well not extend to contexts involving more active and targeted state regulation, where the Court might perceive greater potential for conflict between federal and state requirements.

State officials were much more actively involved in \textit{Cuomo}, which upheld a state attorney general’s ability to sue to enforce state law. Equally important, \textit{Cuomo} rejected the OCC’s effort to restrict state enforcement to general state laws, emphasizing that Congress chose not to exempt national banks from state banking laws.\textsuperscript{100} \textit{Cuomo} thus affirms targeted state regulation of banking and more active state governance in this area. Strikingly, however, \textit{Cuomo} denied state officials access to their traditional administrative enforcement authority, insisting that a state’s enforcement of its banking laws against national banks could only occur in connection with a court proceeding.\textsuperscript{101} The net result is that, as a formal matter, state officials are denied the ability to exercise “any form of administrative oversight” over national banks, including the ability to issue administrative subpoenas targeted to identifying potential violations of state law.\textsuperscript{102} The majority justified this prohibition on administrative

\textsuperscript{97}. \textit{Altria Grp., Inc. v. Good}, 129 S. Ct. 538, 545–46 (2008).

\textsuperscript{98}. See \textit{Lorillard Tobacco Co. v. Reilly}, 533 U.S. 525, 548–51 (2001) (holding preempted state regulations addressing sale and advertising of cigarettes promulgated by Massachusetts Attorney General under state unfair and deceptive trade practices statute); see also \textit{Sprietsma v. Mercury Marine}, 537 U.S. 51, 63 (2002) (reading language “a law or regulation” in express preemption clause as “impl[y]ing] a discreteness—which is embodied in statutes and regulations—that is not present in the common law”); \textit{Medtronic, Inc. v. Lohr}, 518 U.S. 470, 489–90 (1996) (plurality opinion) (distinguishing between specific and general duties and holding only specific duties were preempted under statute at issue).


\textsuperscript{101}. Id. at 2718, 2721–22.

\textsuperscript{102}. Id. at 2721. In practice, “formally” may prove an important caveat, as banks may well prefer to voluntarily provide information sought by state officials as a means of forestalling suit.
enforcement as mandated by the NBA’s general bar on state exercise of “visitorial powers . . . except as . . . vested in the courts of justice.” Yet this conclusion seems contradicted by the majority’s own insistence that “a sovereign’s ‘visitorial powers’ and its power to enforce the law are two different things.” Nor, moreover, would allowing administrative enforcement of state law necessarily lead to the unconstrained discretion associated with visitorial powers, particularly if the limits on such administrative oversight were outlined by the Court.

In short, these decisions appear to assign the states a somewhat narrow and passive role, perhaps excessively so. To be sure, federalism can mean many things, and preserving state law’s traditional remedial function or state law enforcement in the courts certainly represents one account. But federalism is often understood as embracing more than this, in particular as protecting the ability of states to set policy and actively govern through their elected officials. Indeed, providing room for such active governance is critical if federalism is to achieve its purported benefits in our constitutional system. As Ernest Young observes: “[V]irtually all the values that federalism is supposed to promote—such as regulatory diversity, political participation, and restraints on tyranny—turn on the capacity of the states to exercise self-government.” The Court itself has identified the states’ ability to legislate

See Trevor W. Morrison, The State Attorney General and Preemption, in Preemption Choice, supra note 3, at 81, 87 (discussing use of visitorial power to generate information).


105. See Cuomo, 129 S. Ct. at 2719, 2721 (“Judges are trusted to prevent ‘fishing expeditions’ or an undirected rummaging through bank books and records for evidence of some unknown wrongdoing.”).

106. See Wyeth v. Levine, 129 S. Ct. 1187, 1194–95 & n.3 (2009) (noting “state-law causes of action” by which to deter harmful conduct and provide injured individuals with compensation are an exercise of “historic police powers of the States” and represent “a field which the States have traditionally occupied” (internal quotation marks omitted) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996))).

107. See Malcolm M. Feeley & Edward Rubin, Federalism: Political Identity & Tragic Compromise 12, 26–27 (2008) (defining federalism as entailing grant of partial autonomy to geographic subdivisions and identifying federalism’s insistence on “allow[ing] geographic subunits to choose divergent goals” as weakness of federalism compared to decentralization); Larry D. Kramer, Putting the Politics Back into the Political Safeguards of Federalism, 100 Colum. L. Rev. 215, 222 (2000) (“[F]ederalism is meant to preserve the regulatory authority of state and local institutions to legislate policy choices.”).

108. Young, Two Federalisms, supra note 3, at 4. Margaret Lemos has argued that this focus on state exercise of independent regulatory authority unduly ignores the federalism potential attendant simply on enforcement of federal law by state attorneys general. See Margaret H. Lemos, State Enforcement of Federal Law, 86 N.Y.U. L. Rev. (forthcoming 2011) (manuscript at 4, 24–28) (on file with the Columbia Law Review). Lemos’s criticism is apt and she rightly identifies such state enforcement as providing an opportunity for states to play a governance role.
and execute the law independently of federal direction as central to the constitutional federalist structure, but it has rejected such autonomy for the state courts. That the preemption decisions offer at best limited protection for state self-governance through state political branches thus reinforces doubts that federalism is the driving force underlying the decisions.

C. An Alternative Explanation: Agency Failure

Invocation of federalism in the preemption context is hardly surprising. More unusual is another analytic theme that surfaces repeatedly in the decisions: the Court’s concern that federal agencies may be systematically failing to meet their statutory responsibilities. An examination of the decisions suggests that such fear of federal agency failure, and the role of state law and state enforcement in improving federal regulatory performance, is central to the reasoning and results in these decisions. This emphasis on reforming and improving federal administrative performance is reinforced by the decisions’ emphasis on the regulatory role of tort law over its compensatory function.

1. Agency Failure’s Centrality.—Although present in all three decisions, concern about the potential for agency failure is particularly prominent in Wyeth. The majority there emphasized the resource constraints under which the FDA labors, noting that “[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.” Equally important, the opinion portrays state law liability as critical to encouraging information disclosure that is essential for FDA oversight: “State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also

But she does not dispute the importance of state regulation to federalism, and indeed suggests that state enforcement may be particularly relevant where states also enjoy some regulatory authority. See id. (manuscript at 34, 36). In any event, as noted above, a striking feature of the preemption decisions is the limited role played by state officials even in the enforcement arena, see supra text accompanying notes 95–105.


110. In structuring preemption analysis to improve federal agency performance, the Court has adopted a position in line with several tort scholars, who have argued in particular for improved information disclosure on risks as a necessary price of federal administrative preemption. See, e.g., Nagareda, supra note 28, at 7; Sharkey, Products Liability Preemption, supra note 26, at 513–20; see also Schuck, supra note 28, at 83 (favoring enhanced “manufacturers’ incentives to gather, analyze, and disclose all relevant risk information to the FDA, Congress, and the public in a timely fashion”).

111. Wyeth, 129 S. Ct. at 1202 (footnote omitted).
serve a distinct compensatory function that may motivate injured persons to come forward with information.”

The majority offered this account to explain why the FDA had “traditionally regarded state law as a complementary form of drug regulation” and thus its switch to viewing FDA regulation as exclusive represented “a dramatic change in position.” But the Court was equally concerned to demonstrate that the FDA’s new view was unreasonable. To that end, the majority included a lengthy footnote in which it quoted from several reports arguing that the FDA lacked the resources and staff to adequately protect consumers on its own.

The *Wyeth* majority thus invoked two separate instances of FDA failure. The first was the agency’s general inability to provide adequate postapproval monitoring of drugs and act against potential hazards. The second was the agency’s failure to appreciate its own limitations, combined with its adoption of a counterproductive new stance supporting preemption without justifying its change in view. The first form of agency failure was more overtly identified in the majority opinion, yet the second was likely as much of a driving force. What the second failure revealed was an unreliable and potentially captured agency, whose rules and understanding of its own actions were not grounded in agency expertise and therefore did not merit deference. In fact, some members of the Court may have perceived a third, more specific agency failure at issue in the case, namely the FDA’s failure to prohibit IV push administration of Phenergan. The majority opinion did not criticize the FDA on this front, but Justices Alito and Ginsburg both questioned the FDA’s decision at oral argument.

Similar concerns with agency performance are evident to some degree in *Altria*. *Altria* also made reference to a resource-strapped agency unable to fulfill its responsibilities without state assistance: “The FTC has long depended on cooperative state regulation to achieve its mission because, although one of the smallest administrative agencies, it is charged with policing an enormous amount of activity.” The majority also characterized the FTC’s stance as one of “inaction” and “agency nonenforcement of a federal statute” in allowing continued use of the Cambridge Filter Method. This

---

112. Id.
113. Id. at 1202–03.
114. Id. at 1202 n.11. A law review article cited by the *Wyeth* Court argues that the FDA’s view was based on “an unrealistic assessment of the agency’s practical ability—once it has approved the marketing of a drug—to detect unforeseen adverse effects of the drug and to take prompt and effective remedial action.” 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, 465 (2008); see also *Wyeth*, 129 S. Ct. at 1202-03 & n.12 (citing Kessler & Vladeck).
115. See Transcript of Oral Argument at 6–7, *Wyeth*, 129 S. Ct. 1187 (No. 06-1249) (Alito, J.) (“How could the FDA [have] concluded that IV push was safe and effective when on the benefit side of this you don’t have a life-saving drug, you have a drug that relieves nausea, and on the risk side you have a risk of gangrene?”); id. at 7 (Ginsburg, J.) (“The risk of gangrene and amputation is there. No matter what benefit there was, how could the benefit outweigh that substantial risk?”).
117. Id. at 550–51.
characterization was more generous to the FTC than describing it as affirmatively allowing reliance on a faulty test method, and the Court also emphasized that the FTC’s inaction resulted in part from the fact that tobacco companies did not provide test results demonstrating the Filter Method’s inadequacies. The Court further noted that the FTC itself “disavowed any policy authorizing the use of ‘light’ or ‘low tar’ descriptors,” and the agency’s occasional efforts to “police cigarette companies’ misleading results of test results.” Thus, the treatment of the FTC is more positive than that which the FDA received in Wyeth—perhaps in part due to the fact that the FTC, unlike the FDA, opposed preemption. Nonetheless, Altria is similar to Wyeth in portraying the FTC as unable to fulfill its statutory mandate and as having been inactive in the face of potential risks.

Federal agency failure loomed particularly large in the background of Cuomo, with the OCC repeatedly characterized as an agency captured by the entities it was charged with regulating, the classic example of agency failure. Notably, the Court did not invoke these allegations or in other ways expressly criticize the agency’s overall performance as it did in Wyeth. Moreover, the Court insisted that its decision in no way called into question its decision two years earlier in Watters, in which the Court had ruled in favor of preemption, notwithstanding strong allegations of OCC failure.

118. Id. at 551 n.14 (arguing “FTC’s inaction . . . [was] in part the result of petitioners’ failure to disclose” evidence of testing inaccuracy).
119. Id. at 549–50.
120. See Brief for United States as Amicus Curiae Supporting Respondents at 14–16, Altria, 129 S. Ct. 538 (No. 07-562) (arguing Respondents’ claims not preempted by FTC regulations); see also Sharkey, Product Liability Preemption, supra note 26, at 471–77 (emphasizing importance of agency’s position on preemption in understanding results in preemption cases).
Nonetheless, *Cuomo* still contains its share of allusions to deficient federal regulation. The majority insisted that preemption of state law enforcement would render state law de facto ineffectual, arguing that “[t]he bark remains, but the bite does not.”123 Implicit in this characterization is a rejection of the possibility that the OCC could be relied upon to enforce state law where applicable.124 The majority also repeatedly cast the OCC as overreaching and “attempt[ing] to do what Congress declined to do: Exempt national banks from all state banking laws, or at least state enforcement of those laws.”125 On this framing, the OCC appears as an agency that has fundamentally misunderstood the regulatory regime it is charged with enforcing and that has sought, by administrative fiat, to exempt national banks from longstanding legal constraints. *Cuomo*’s portrayal is also interesting because it implicitly recognizes that federal overregulation can be a form of federal agency failure—albeit in this case, the federal overregulation was aimed at limiting the regulatory oversight applied to national banks. Although *Cuomo* does not explicitly tie preservation of state enforcement to improved OCC regulation, its characterization of federal banking regulation as involving a “mixed state/federal regime[,]” as in *Wyeth*, similarly underscores the importance of state enforcement to effective implementation of the overall federal regulatory scheme.126 Preserving room for state enforcement thus ensured that the OCC would not be able to undermine the fundamental congressional choice of a dual national-state bank regulatory system.

This consistent theme of agency failures—be they failures of funding, performance, or reasoning—is notable. It marks a striking departure from previous preemption precedent, which at times portrayed agencies as carefully wielding their expertise to achieve the appropriate balance between state and federal regulation.127 Even before the Court’s most recent decisions, however, occasional suggestions of greater judicial skepticism of agencies had appeared

---

123. *Cuomo*, 129 S. Ct. at 2718.
124. See id. at 2718 n.3 (leaving open question of “whether converting the Comptroller’s visitorial power to assure compliance with all applicable laws . . . into an obligation to ensure compliance with certain state laws.” as Congress did in Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994, sufficed to preempt state enforcement of state law).
125. Id. at 2720; see also id. at 2715 (characterizing OCC regulation as “expansive”); id. at 2717 (stating “[t]here is not a credible argument” supporting equation of visitorial powers and law enforcement, as OCC’s regulation does).
126. Id. at 2718, 2720–21.
in preemption decisions. The Court’s sharply contested 2006 decision in Gonzales v. Oregon is a prime example; there, the majority refused to defer to the Attorney General’s interpretation of his own regulation, citing among other factors his lack of expertise and his failure to consult outside of his own department.\footnote{546 U.S. 243, 268–69, 274–75 (2006); see also id. at 257 (―An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.‖). Additionally, in Watters v. Wachovia Bank, N.A., 550 U.S. 1 (2007), the majority avoided discussing the agency’s view and any deference due it altogether, opting instead to engage in a fairly expansive reading of statutory text to find preemption plainly required. See Metzger, New Federalism, supra note 27, at 2042–45 (describing and critiquing reasoning in Watters); see also Riegel, 552 U.S. at 328–29 (critiquing agency’s reasoning in interpreting its own regulations with respect to preemption as “less than compelling”).} Such growing skepticism may have several roots, but an important likely contributing factor is the federal agencies’ dramatic shift to advocating for broad preemption during the Bush Administration.\footnote{See supra note 85 and accompanying text (discussing propreemption shift and resulting scholarly outcry).} This phenomenon, highlighted by amicus briefs in preemption cases and public debate, prompted increasing criticism of federal agencies as captured by regulated interests and as basing their decisions on ideology rather than expertise.\footnote{See, e.g., Metzger, New Federalism, supra note 27, at 2032–35 (discussing Attorney General Ashcroft’s implementation of Controlled Substances Act); Sharkey, Preemption by Preamble, supra note 3, at 237–42 (discussing FDA); Wilmarth, Supreme Court Responds, supra note 104, at 19–21, 24 (discussing OCC).} These complaints resonated with the Court outside of the preemption context as well; Massachusetts v. EPA paints a picture of unreasoned and flawed agency reasoning quite similar to that offered in Wyeth, Cuomo, and Gonzales.\footnote{See Massachusetts v. EPA, 549 U.S. 497, 534 (2007) (“EPA has offered no reasoned explanation for its refusal to decide whether greenhouse gases cause or contribute to climate change.”); Jody Freeman & Adrian Vermeule, Massachusetts v. EPA: From Politics to Expertise, 2007 Sup. Ct. Rev. 51, 85 (“There is [in Massachusetts] a conclusory assertion that EPA’s non-scientific ‘policy judgments’ do not ‘amount to a reasoned justification for declining to form a scientific judgment’ . . . .” (quoting Massachusetts, 549 U.S. at 533–34)); Metzger, New Federalism, supra note 27, at 2059 (“Massachusetts . . . repeatedly criticized the EPA . . . .”).} Also in the larger background were allegations of high-profile regulatory failures, such as the FDA’s delay in acting on Vioxx and other popular drugs found to pose unexpected postapproval risks, or the failure of financial regulators (including the OCC) to act on subprime mortgage abuses by national banks.\footnote{See Kessler & Vladeck, supra note 114, at 480 (“[T]he FDA acknowledges that it took over a year to force Merck, the manufacturer of Vioxx, to add a warning of the risks of heart attack and stroke to Vioxx’s label.”); Patricia A. McCoy, Andrey D. Pavlov & Susan M. Wachter, Systemic Risk Through Securitization: The Result of Deregulation and Regulatory Failure, 41 Conn. L. Rev. 1327, 1351–56 (2009) (discussing regulatory lapses by OCC and Office of Thrift Supervision in relation to subprime mortgage crisis); Nagare, supra note 28, at 43 (noting “widespread criticism of the FDA in connection with the controversy over the safety of prescription pain drugs,” including Vioxx).} The mortgage crisis is particularly relevant because that represented a context in which state attorneys general and

\footnote{See supra note 128 and accompanying text (discussing Attorney General John Ashcroft’s interpretation of Controlled Substances Act); see also id. at 257 (―An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.‖). Additionally, in Watters v. Wachovia Bank, N.A., 550 U.S. 1 (2007), the majority avoided discussing the agency’s view and any deference due it altogether, opting instead to engage in a fairly expansive reading of statutory text to find preemption plainly required. See Metzger, New Federalism, supra note 27, at 2042–45 (describing and critiquing reasoning in Watters); see also Riegel, 552 U.S. at 328–29 (critiquing agency’s reasoning in interpreting its own regulations with respect to preemption as “less than compelling”).}
other state officials were far more active than federal regulators in policing fraud, prompting efforts by the OCC to restrict state intervention.133

Focusing on agency failure also helps explain why federalism surfaces to the extent it does in the decisions. The decisions identify state law as a mechanism to guard against federal agency failure, and federalism presumptions represent an important analytical tool for ensuring that state law is preserved. Critically, however, federalism is invoked more as a means to improve federal agency performance than as a value in its own right.134 Put differently, federalism here means preserving state authority because of its benefits for national administration, not because of constitutional recognition of states as quasi-independent sovereigns or general systemic gains from having states serve as laboratories of experiment. Interestingly, this account of state law as a tool for policing and improving federal administration also explains why the decisions might preserve only a relatively limited state enforcement role. Robust authority to construct and pursue independent policies is less important when states are functioning as federal regulatory adjuncts rather than as more autonomous sovereigns. Indeed, more directed and active state regulation could complicate the tasks facing federal agencies by expanding the occasions of federal-state conflict.

Other scholars similarly have emphasized the extent to which poor federal administrative performance led the Court to resist preemption in these decisions. Arthur Wilmarth, for example, argues that Cuomo’s rejection of preemption is best explained by the subprime mortgage crisis and the Court’s concern “that the OCC’s preemption rules and regulatory failings contributed to the severity” of that crisis.135 David Vladeck has long contended that the FDA’s regulatory failures, particularly in postapproval monitoring of drugs and medical devices, strongly counseled against preemption of failure-to-warn suits.136 On these accounts, state law helps avoid the regulatory gaps and uncompensated harms that poor federal regulation otherwise could create.137 In addition, Catherine Sharkey has noted the reforming effect that Wyeth may

133. See Wilmarth, Supreme Court Responds, supra note 104, at 3, 19–21, 26 (arguing that states took greater efforts to address predatory lending and faulting federal regulatory oversight).

134. As a result, the preemption decisions represent a twist on the relationship between federalism and administrative law, evident in other recent precedent. As I have discussed elsewhere, of late the Court has increasingly used administrative law to protect state interests against undue federal intrusion. See Metzger, New Federalism, supra note 27, at 2063–69; supra note 69 and accompanying text. The preemption decisions similarly present a close intermingling of administrative law and federalism concerns, but the underlying dynamic between these two is reversed: Here federalism is serving more to meet administrative law concerns than the other way round.

135. Wilmarth, Supreme Court Responds, supra note 104, at 2, 31.

136. See Kessler & Vladeck, supra note 114, at 484–95 (emphasizing resource and information constraints on FDA); see also Vladeck, Preemption and Regulatory Failure Risks, in Preemption Choice, supra note 3, at 56–58 (identifying capture, information deficiencies, and limited resources as problems causing federal regulatory failure more generally).

137. See Vladeck, supra note 136, at 56 (describing “safety net of tort litigation” to fill “gaps that regulatory agencies cannot fill”); Wilmarth, Supreme Court Responds, supra note 104, at 3 (calling states “far more proactive” than federal agencies in protecting consumers).
have on agency preemption determinations, encouraging agencies to use notice-and-comment rulemaking and create a sufficient agency record in support. Less highlighted has been the extent to which the decisions portray state law as playing an important role in reforming and improving federal regulation more broadly. Writing before the recent decisions, however, Richard Nagareda and others emphasized the potential of using preemption to improve regulation by fostering greater information disclosure to the FDA. In like vein, David Barron has argued limited preemption helps protect against excessive federal agency politicization, and Amy Widman has defended state enforcement of federal regulations as a check on federal enforcement inaction.

2. Dominance of "Tort as Regulation" over "Tort as Compensation." — Agency failure’s centrality to the Court’s reasoning is also demonstrated by the decisions’ treatment of individual compensation. Concern with preserving injured individuals’ access to compensation has featured prominently in many of the Court’s prior decisions rejecting tort preemption claims. This consideration was notably lacking in the recent preemption decisions, where compensation concerns were expressly identified only in Wyeth and invoked there somewhat obliquely. Even more striking is the extent to which Wyeth

138. See Sharkey, Federalism Accountability, supra note 66, at 2179–80, 2186–89.
139. See Nagareda, supra note 28, at 40–49; see also Kessler & Vladeck, supra note 114, at 491–95 (noting, in course of discussing failure-to-warn litigation’s effectiveness in producing information of product risk, instances in which FDA responded to such information disclosures); Sharkey, Products Liability Preemption, supra note 26, at 519–20 (emphasizing greater information disclosure to FDA as benefit of limiting preemption to instances in which FDA has made determination on precise risk at issue). But see Schuck, supra note 28, at 99–100 (questioning information gains to FDA from litigation).
141. See Amy Widman, Advancing Federalism Concerns in Administrative Law Through a Revitalization of State Enforcement Powers—A Case Study of the Consumer Product Safety and Improvement Act of 2008, 29 Yale L. & Pol’y Rev. (forthcoming 2010) (manuscript at 4–6, 31–37) (on file with the Columbia Law Review) (portraying state enforcement as central to ensuring protection of state interests in federal administration and identifying such an approach as in keeping with federalism concerns of Cuomo); see also Lemos, supra note 108 (manuscript at 13–32) (discussing, from federalism perspective, benefits of such state enforcement).
142. See Sharkey, Products Liability Preemption, supra note 26, at 466–71 (discussing Court’s treatment of tort law as compensatory in preemption decisions).
143. The Court noted that “Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs” in the original FDCA or subsequent amendments, from which the Court inferred Congress had “determined that widely available state rights of action provided appropriate relief for injured consumers.” Wyeth v. Levine, 129 S. Ct. 1187, 1199 (2009). Underlying this conclusion was the assumption that Congress would not have left injured consumers without some avenue of relief. On other occasions, however, the Court has made this point expressly, stating “[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.” Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005); accord Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984) (finding it implausible that “Congress would, without comment, remove all
portrayed individual compensation less as a goal in its own right and more as simply a mechanism that can assist federal regulators by encouraging disclosure. According to the Court, “[s]tate tort suits . . . serve a distinct compensatory function that may motivate injured persons to come forward with information.”144 Put differently, state tort liability helps federal regulators identify where to target their regulatory efforts, thereby helping to ensure that potential hazards do not escape federal regulatory scrutiny. More generally, the decisions portray tort liability primarily in regulatory terms. This is again most evident in *Wyeth*, which repeatedly invoked the incentive effects of tort liability, such as its statement that Congress “may . . . have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.”145

Such a regulatory account of tort law has surfaced previously in the Court’s preemption decisions,146 but it usually did so in decisions finding preemption.147 The dominance of the regulatory tort model here, notwithstanding the failure of claims for preemption, underscores the extent to which improving federal regulation and federal agency performance lie at the decisions’ analytic core. Interestingly, *Wyeth* left unstated a seemingly more direct and obvious connection between agency failure and individual compensation: the point that poor agency performance increases the likelihood of injured individuals and thus intensifies the importance of state tort law’s compensatory function. One reason the Court may not have drawn this linkage is because doing so might seem to call into question specific agency regulatory decisions, such as the FDA’s decision to allow IV injection of Phenergan. But that this connection went unmentioned again reinforces the strongly regulatory means of judicial recourse for those injured by illegal conduct”). But see Riegel v. Medtronic, Inc., 552 U.S. 312, 326 (2008) (finding congressional intent to deny judicial recourse obvious because “this is exactly what a pre-emption clause for medical devices does by its terms”).

145. Id. at 1199–200; see also id. at 1202 (“State tort suits . . . provide incentives for drug manufacturers to disclose safety risks promptly.”).
146. This regulatory view of tort law was particularly evident in *Riegel*’s statement that “[s]tate tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than [a] state regulatory law to the same effect.” *Riegel*, 552 U.S. at 325.
147. Catherine Sharkey has made this point particularly well, identifying two distinct understandings of tort law in the Court’s tort preemption precedent—one emphasizing the regulatory role of tort and the other its corrective justice or compensatory function—and noting the correlation of the latter with decisions rejecting preemption claims. See Sharkey, Products Liability Preemption, supra note 26, at 459. These two alternative views in preemption precedent parallel two alternative theories of the function tort law plays in the academic literature: regulatory accounts and tort as corrective justice. See, e.g., Alexandra B. Klass, Tort Experiments in the Laboratories of Democracy, 50 Wm. & Mary L. Rev. 1501, 1508–09 (2009) (identifying scholars falling into both “camps”); Gary T. Schwartz, Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice, 75 Tex. L. Rev. 1801, 1801, 1802–11 (1997) (describing “two major camps” as those who “understand[] tort liability as an instrument aimed largely at the goal of deterrence” and those who “look[] at tort law as a way of achieving corrective justice between the parties”).
rather than compensatory view of tort law evident in the majority opinion. Additional evidence that improving regulatory outcomes is the decisions’ prime concern comes from the Court’s failure to emphasize the intersection between securing individual compensation and respecting federalism principles. One of the most problematic aspects of administrative preemption of tort law is that the agencies themselves lack the ability to create alternative compensatory mechanisms. Any public insurance fund, such as the programs used to assist 9/11 and vaccine victims, must be created by Congress. Agencies also lack the ability to provide for private rights of action not authorized by Congress in a governing statute. From an individual compensation perspective, therefore, an important reason to require that preemption decisions be made by Congress is that doing so may increase the chances that preemption will be tied to some alternative means for securing compensation. Requiring congressional action is also—and more commonly—justified on federalism grounds, as mandated by our federalist constitutional structure. As a result, the individual compensation and structural federalism perspectives dovetail in seeking clear congressional authorization of preemption. Federalism and individual compensation would seem closely interwoven in Wyeth and Altria in any event, given that the traditional state function at issue in both is precisely that of preserving injured individuals’ access to compensation. Yet the Court made little of these

148. See Schuck, supra note 28, at 93, 100–01 & n.114 (“The principal structural limitation of FDA regulation, [for example], is that it cannot directly compensate victims . . . .”).
151. See McGarity, supra note 3, at 47 (“Until quite recently . . . Congress never expressly preempted state common law without providing an alternative route to corrective justice by creating either a separate federal cause of action or an alternative administrative compensation regime.”); Klass, supra note 147, at 1537–40 (noting shift in 1990s whereby Congress was not providing “a federal substitute when it decide[d] to eliminate state tort lawsuits”).
152. See Stuart Minor Benjamin & Ernest A. Young, Tennis with the Net Down: Administrative Federalism Without Congress, 57 Duke L.J. 2111, 2116 (2008) (“[C]onstitutionalism means that we are simply not free to choose whatever normative principles and institutional strategies we think best.”); Bhagwat, supra note 26, at 225–26, 228–29 (“[E]fficiency is beside the point. The Constitution preserves state authority even when it is inefficient . . . .”); Clark, supra note 22, at 1427–30 (“The Supreme Court’s long-standing presumption against preemption . . . . functions to ensure that Congress . . . makes the crucial decision to displace state law” and such decisions “ensure[] that only actors subject to the political safeguards of federalism adopt ‘the supreme Law of the Land’.”).
connections between preserving individual compensation and federalism, focusing instead on the ways that individual compensation and state liability each separately serve to improve federal regulation.

II. CONFLICTING JUDICIAL RESPONSES TO ALLEGED AGENCY FAILURE

On this account, the preemption decisions are significantly about federal administration. They represent an effort by the Court to harness the power of state law and judicial preemption analysis to police and improve federal agency performance. Federalism and individual compensation concerns are also present, but they play a more ancillary or secondary role. Instead, what is really driving the analysis is fear of agency failure.

Viewed in this light, however, the decisions appear in some tension with at least some of the Court’s preemption and administrative law precedent. The Court has previously rejected state efforts to tie tort liability to the quality of federal administrative decisionmaking. It had also consistently resisted—including in a decision issued just one day before Wyeth—efforts to use the courts to address claims of general agency failure. The discussion below begins by describing the Court’s precedent holding state law claims alleging fraud on a federal agency preempted, and next describes the Court’s rejection of legal challenges targeting broad agency policy or performance. It then attempts to explain this divergence between the preemption decisions and other precedent addressing claims of agency failure. Because the Court itself never acknowledges this divergence, efforts to make sense of it are a hazardous enterprise. One factor that appears particularly salient, however, is that in the preemption decisions state law and preemption analysis target federal administration indirectly rather than directly.

A. Buckman and Fraud-on-the-Agency Claims

Concerns about federal agency failure are not new to the preemption context. But in the past the Court has shown far less receptivity to the idea of using state law to improve federal agency performance. The 2001 case of Buckman Co. v. Plaintiffs’ Legal Committee involved claims that a manufacturer of orthopedic bone screws had made fraudulent representations to the FDA to obtain FDA approval for the devices.154 The claims were brought as state law actions for fraud against the consulting company that had helped the manufacturer obtain FDA approval. The Court ruled such “fraud-on-the-FDA” claims were impliedly preempted, stating:

[T]he federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort

---

According to the Court, the possibility of fraud-on-the-FDA liability might discourage manufacturers from seeking FDA approval for products or lead them “to submit a deluge of information that the Administration neither wants nor needs.”\textsuperscript{156} Seven Justices held that, as a result, “[s]tate-law fraud-on-the-FDA claims inevitably conflict with . . . the Administration’s judgment and objectives” and were categorically preempted.\textsuperscript{157} Concurring in the judgment, Justice Stevens, joined by Justice Thomas, agreed that preemption was appropriate here but rejected the majority’s categorical ban. In his view, “[i]f the FDA determines both that fraud has occurred and that such fraud requires removal of a product from the market, state damages remedies would not encroach upon, but rather would . . . facilitate, the federal enforcement scheme.”\textsuperscript{158}

Three features of \textit{Buckman} stand in particular contrast to \textit{Wyeth}. First is the impressive consensus among the Justices; whereas \textit{Wyeth} was closely contested, \textit{Buckman} was unanimous in concluding that preemption was warranted. Second is \textit{Buckman}’s portrayal of the FDA. Rather than \textit{Wyeth}’s underresourced agency unable to obtain the information it needs to monitor the multitude of drugs and devices on the market, \textit{Buckman} viewed the FDA as a sophisticated and expert regulator that carefully balances conflicting goals and structures its processes to obtain the optimal amount of information.\textsuperscript{159} Third, and most relevant to my purposes here, is \textit{Buckman}’s resistance to state law playing a role in federal administration. \textit{Buckman} described the relationship between a federal agency and the entity it regulates as “inherently federal in character” and insisted that the state fraud claims at issue arose “solely from the violation of FDCA requirements.”\textsuperscript{160} This perception of federal administration and state law as inherently distinct is a basic assumption driving the Court’s analysis. It underlay \textit{Buckman}’s rejection of a presumption against preemption, because “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied.’”\textsuperscript{161} It also explains the disagreement between the majority and the concurrence; whereas the concurrence was willing to countenance state law fraud enforcement conditioned on an FDA determination that fraud had occurred, the majority was unwilling to allow states even that role. Instead, in the \textit{Buckman}
majority’s portrayal, state fraud-on-the-FDA claims represented an illegitimate state effort to interfere in a purely federal realm—the enforcement of federal law by the federal agency to which Congress had delegated enforcement responsibility.

Buckman’s insistence that the fraud claims involved there depended exclusively on federal law, as opposed to “traditional state tort law which had predated the federal enactments in questions [sic].” left open the question whether any state tort law referencing a manufacturer’s fraudulent actions vis-à-vis the FDA would be preempted, or only state actions that sought to impose liability for such fraud. This question arose in Desiano v. Warner-Lambert & Co., a Second Circuit decision addressing a Michigan statute that granted immunity from product liability actions for drugs approved by the FDA and in compliance with FDA requirements but denied such immunity when the drug’s manufacturer withheld or misrepresented required information and the FDA would not have approved the drug had it possessed complete and accurate information. The Second Circuit held that Michigan’s immunity exception was not preempted under Buckman because claims allowed as a result of the exception were “premised on traditional duties between a product manufacturer and Michigan consumers” and therefore not “based solely on the wrong of defrauding the FDA.” The Sixth Circuit meanwhile took a different view of Michigan’s statute, concluding that the immunity exception was impliedly preempted under Buckman to the extent its application was based on a state court finding of fraud on the FDA, rather than a finding of fraud by the FDA itself.

The Court granted certiorari to resolve this conflict but in the end simply affirmed the Second Circuit by an evenly divided vote, with Chief Justice Roberts recused. The much closer vote than in Buckman is notable, though it is impossible to tell whether that stemmed from the different claims in the two cases or instead reflected some Justices’ changing views on Buckman.

162. Id. at 353.
163. 467 F.3d 85 (2d Cir. 2006).
165. Desiano, 467 F.3d at 94-96; see also id. at 94 (arguing presumption against preemption applied here because, unlike Buckman, Michigan was not “attempt[ing] to police fraud against the FDA” but instead simply “to regulate and restrict when victims could continue to recover under preexisting state products liability law”).
168. Lower courts’ continued inconsistency on these issues may lead the Court to revisit this question. Compare In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 177 (1st Cir. 2009) (distinguishing Buckman and finding no preemption because suit did not involve “misrepresentations made directly to HCFA” and that “[a]lt issue here is a state law remedy for
The contrasts between *Buckman* and *Wyeth* suggest that to some extent such change may be occurring. Significantly, however, the failure-to-warn claims in *Wyeth* did not take issue with the FDA’s approval of Phenergan, and thus *Wyeth* does not necessarily signal that the Court has changed its view on state tort claims based on allegations of fraud against federal agencies.

**B. Administrative Law Challenges to Agency Failure**

*Wyeth*’s emphasis on how state liability can improve the FDA’s performance is also at odds with administrative law precedent rejecting efforts to challenge general agency functioning. These cases are based exclusively in federal law, such as the Administrative Procedure Act (APA) or substantive federal statutes, and they involve claims that an agency is pursuing policies or programmatic approaches at odds with governing requirements. The Court has been extremely reluctant to entertain such challenges, invoking standing, ripeness, and APA jurisdictional requirements as barriers to judicial involvement.

A prime example is *Lujan v. National Wildlife Federation*, a 1990 decision in which the Court rejected an environmental organization’s effort to challenge the Bureau of Land Management’s (BLM) program for determining when public lands could be opened up for additional uses such as mining. By a 5-4 vote, the Court insisted that the organization could not challenge the agency’s general approach to making such determinations; instead, it was limited to targeting final BLM decisions to open up specific lands, and only deceptive practices by a manufacturer against its customers”), with Pa. Emps. Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 251 (3d Cir. 2007) (holding state law claims preempted by FDA regulations although “the FDCA is not as clearly a ‘critical element’” as in *Buckman*), vacated, 129 S. Ct. 1578 (2009) (mem.).

169. *Wyeth* v. Levine, 129 S. Ct. 1187, 1194 (2009) (“[T]he jury verdict established only that Phenergan’s warning was insufficient. . . . We therefore need not decide whether a state rule proscribing [Phenergan’s] intravenous administration would be pre-empted.”).

170. Although my focus here is on challenges to federal agency action, for analogous decisions rejecting challenges to state or local policies on constitutional grounds, see, e.g., *City of Los Angeles v. Lyons*, 461 U.S. 95, 112 (1983) (denying standing to challenge police use of choke holds); *Rizzo v. Goode*, 423 U.S. 362, 380 (1976) (deeming district court injunction on municipal police department overbroad and, regardless, finding lack of justiciable case or controversy).

171. This reluctance has developed over time. In the 1960s and early 1970s, fears of agency capture fueled expansions in standing and development of more rigorous doctrines of judicial review. Although those decisions remain good law, over the ensuing decades the Court has demonstrated far greater skepticism about the appropriateness of using the courts as a mechanism to address broad agency failure. See *Merrill, Capture Theory*, supra note 121, at 1039–44, 1059–67 (“Starting in the late 1960s, many federal judges became convinced that agencies were prone to capture and related defects and—more importantly—that they were in a position to do something about it.”); id. at 1073–74 (noting literature and “today’s general climate” evidence “deep skepticism about all government institutions, combined with very little sense that judges have any tools that allow them to do something about it”).

then when the organization could show those decisions had an immediate or actual effect on the organization’s members.\textsuperscript{173} Noting the organization’s claim that violation of governing statutory requirements was “rampant” in the land review program, Justice Scalia’s majority opinion responded: “Perhaps so. But respondent cannot seek \textit{wholesale} improvement of this program by court decree, rather than in the offices of the Department or the halls of Congress, where programmatic improvements are normally made.”\textsuperscript{174}

The latest manifestation of this resistance to suits targeting general agency policies or performance came in \textit{Summers v. Earth Island Institute}, a decision issued just the day before \textit{Wyeth}.

\textit{Summers} involved a challenge brought by environmental organizations to the Forest Service’s policy, embodied in an agency regulation, of excluding certain limited timber sales from the notice, comment, and appeals processes statutorily mandated for Forest Service projects.\textsuperscript{176} The Court dismissed the challenge, again in a 5-4 decision with Justice Scalia writing for the majority, underscoring that the organizations had settled their claims with respect to the one specific project they had identified. According to the Court, absent an identifiable project they were challenging, the organizations could not establish sufficient actual and imminent injury to satisfy constitutional standing requirements.\textsuperscript{177}

This is all standard standing fare, and the result in \textit{Summers} is of a piece with existing precedent.\textsuperscript{178} To be sure, standing analysis is notoriously malleable, and the Court has at times found standing to challenge agency failure to comply with governing statutes despite complaints that the plaintiffs asserted only a generalized grievance and lacked the type of specific and

\begin{itemize}
  \item \textsuperscript{173} Id. at 889, 891–93.
  \item \textsuperscript{174} Id. at 891.
  \item \textsuperscript{175} Summers v. Earth Island Inst., 129 S. Ct. 1142 (2009). In \textit{Summers}, the Court denied standing to an environmental group and its members that sought to challenge the Forest Service’s acknowledged policy of exempting certain fire timber sales from statutorily required procedures. Id. at 1151.
  \item \textsuperscript{176} Id. at 1147–48.
  \item \textsuperscript{177} Id. at 1149–51.
  \item \textsuperscript{178} See Jonathan H. Adler, Standing Still in the Roberts Court 18 (Case Research Paper Series in Legal Studies, Working Paper No. 09-32, 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1497037 (on file with the Columbia Law Review) (“The Court may appear to have taken a slight step back from Massachusetts’ permissive approach to standing in \textit{Summers} . . .”). \textit{Summers} does help resolve debates over standing to sue on procedural violations. For instance, of the requirements laid out for notice-and-comment rulemaking in the APA, 5 U.S.C. § 553 (2006), the Court stated that “deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right \textit{in vacuo}—is insufficient to create Article III standing.” \textit{Summers}, 129 S. Ct. at 1151. But, as in its 1992 \textit{Lujan} decision, the result seems to turn on parsing a terse concurrence by Justice Kennedy. See \textit{Summers}, 129 S. Ct. at 1153 (Kennedy, J., concurring); Lujan v. Defenders of Wildlife, 504 U.S. 555, 579 (1992) (Kennedy, J., concurring). \textit{Summers} is also important to the question of when the possibility of harm to some of an organization’s members is sufficiently great to support organizational standing. See generally Bradford Mank, \textit{Summers v. Earth Island Institute} Rejects Probabilistic Standing, but a “Realistic Threat” of Harm Is a Better Standing Test, 40 Envtl. L. 89 (2010) (discussing this aspect of \textit{Summers}).
\end{itemize}
individualized injury the Constitution requires. However, the Court has been more consistent—and sometimes unanimous—in rejecting attempts to target general policies or programmatic approaches guiding federal administration, limiting its involvement to instances in which a specific agency decision is at issue. Underlying these decisions, including those which turn on an interpretation of the jurisdictional requirements of the APA, are separation of powers concerns about the appropriate limits on federal court oversight of governmental administration. According to the Court, “broad programmatic attack[s]” inappropriately “inject[] . . . [courts] into day-to-day agency management” and risk “judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve.”

For similar reasons, the Court also has been reluctant to entertain challenges to agency inaction and agency delay, holding even challenges to specific agency nonenforcement decisions presumptively nonreviewable.

One seeming outlier from this line of cases is the Court’s 2007 decision in Massachusetts v. EPA. There, the Court held that Massachusetts had standing to challenge the Environmental Protection Agency’s (EPA’s) refusal to regulate greenhouse gases as air pollutants under the Clean Air Act (CAA).

In so concluding, the Court put particular emphasis on Massachusetts’s status as “a sovereign State,” noting that “[w]hen a State enters the Union, it

179. See, e.g., Massachusetts v. EPA, 549 U.S. 497, 522, 524–525 (2007) (holding potential injury from climate change suffices for standing to challenge federal agency’s failure to regulate new auto emissions, notwithstanding “climate-change risks are ‘widely shared’” and fact that such emissions are only one contributor to global warming); FEC v. Akins, 524 U.S. 11, 25 (1998) (rejecting claim that informational harm to voters from federal agency’s nonenforcement of election law was too generalized to support standing because shared by all voters).


181. Norton, 542 U.S. at 64, 66–67; see also Summers, 129 S. Ct. at 1148 (stating “courts have no charter to review and revise legislative and executive action” except when part of their “traditional role of . . . redress[ing] or prevent[ing] actual or imminent threatened injury to persons caused by private or official violation of law”)

182. See Heckler v. Chaney, 470 U.S. 821, 831 (1985) (“This Court has recognized on several occasions over many years that an agency’s decision not to prosecute or enforce . . . is a decision generally committed to an agency’s absolute discretion.”); see also Massachusetts, 549 U.S. at 527 (distinguishing denial of rulemaking petitions from other forms of agency inaction). Summers itself did not go so far as that; instead, the majority acknowledged that the organizations could have standing to challenge the Forest Service’s failure to provide an opportunity for notice, comment, or appeal in conjunction with a specific project. Summers, 129 S. Ct. at 1151. Yet the majority erected a very high evidentiary burden for standing to be found, requiring the organizations to identify not only specific timber salvage sales exempt from such procedures under the Forest Service’s regulation, but also specific plans by particular members to use precisely those small parcels of the national forests where the sales would occur. Id. at 1150–53.


surrenders certain sovereign prerogatives” to the federal government.\textsuperscript{184} That transfer of authority, combined with Congress “ha[ving] ordered EPA to protect Massachusetts (among others) by prescribing [air pollutant] standards” and having provided a procedural right to challenge EPA’s rulemaking denial, meant that Massachusetts was “entitled to special solicitude in our standing analysis.”\textsuperscript{185} The Court supported its invocation of a special role for the states with citations to its parens patriae jurisprudence, under which the Court has long upheld the ability of a state to sue asserting “quasi-sovereign” interests, which include a state’s “interests in the health and well-being of its residents” and “in not being discriminatorily denied its rightful place within the federal system.”\textsuperscript{186} But the Court not only offered little clarification of how exactly Massachusetts’s status as a state factored into its ability to sue, it also proceeded to argue that Massachusetts had standing in terms typical of those used for private parties as well, such as the fact that Massachusetts owned substantial coastal property that could be affected by rising sea levels.\textsuperscript{187}

In any event, \textit{Massachusetts} differed from other administrative law decisions in this line by targeting a specific agency action: denial of a rulemaking petition. The Court itself emphasized this feature in finding the case justiciable.\textsuperscript{188} Thus, although \textit{Massachusetts} stands out as a relatively rare challenge to agency nonenforcement, the Court did not treat the decision as an exception to its prohibition on broad challenges to agency policy and performance.\textsuperscript{189}

This administrative law precedent rejecting broad challenges to agency policy and performance might appear at first glance to have little in common with \textit{Wyeth} and the recent preemption decisions. Most notably, the \textit{Summers} line of cases are fundamentally about separation of powers and the role of the federal courts in overseeing the functioning of federal agencies. Federalism does not factor into these cases which, other than \textit{Massachusetts}, do not involve the states or state law claims at all. Yet a central issue underlies and

\textsuperscript{184} Id. at 518–19.
\textsuperscript{185} Id. at 519–20.
\textsuperscript{187} See \textit{Massachusetts}, 549 U.S. at 521–23; Metzger, New Federalism, supra note 27, at 2037–39 & n.51, 2062–63 (discussing traditional standing elements and potential “special solicitude” for Massachusetts); see also Bradford Mank, Should States Have Greater Standing Rights than Ordinary Citizens?: \textit{Massachusetts} v. EPA’s New Standing Test for States, 49 Wm. & Mary L. Rev. 1701, 1746–47 (2008) [hereinafter Mank, States Standing] (arguing \textit{Massachusetts} does not provide clear test for state standing); Kathryn A. Watts & Amy J. Wildermuth, \textit{Massachusetts} v. EPA: Breaking New Ground on Issues Other than Global Warming, 102 Nw. U. L. Rev. 1029, 1030–31 (2008) (noting \textit{Massachusetts} v. EPA’s “somewhat unusual” approach to standing that “blended the conventional \textit{Lujan} analysis” with “standing analysis [based] on the state’s sovereign interest at stake in the litigation”).
\textsuperscript{188} See \textit{Massachusetts}, 549 U.S. at 516 (“Congress has moreover authorized this type of challenge to EPA action.”).
\textsuperscript{189} See id. at 527–28 (distinguishing Heckler v. Chaney, 470 U.S. 821 (1985) and noting “[t]here are key differences between a denial of a petition for rulemaking and an agency’s decision not to initiate an enforcement action”.)
links these seemingly disparate areas of jurisprudence. That issue is how the courts should respond to the potential for poor administrative performance and failure of federal agencies to fulfill their statutory responsibilities.

Moreover, *Summers* and the preemption decisions took notably different stances on this issue, albeit through different doctrinal rubrics that forestall any direct conflict. In *Summers*, the Court portrayed the claim that the Forest Service was failing to adhere to governing statutes as fundamentally off limits to judicial review because it was framed as a challenge to the agency’s general policy, divorced from any concrete application. The impact that largely precluding judicial review would have on agency decisionmaking—good or ill—was irrelevant and not discussed. By contrast, in the preemption decisions the Court invoked factors undermining general agency performance, such as insufficient resources and informational disadvantages, as centrally relevant considerations in assessing the strength of preemption claims. The Court did not demand evidence that these factors had played a role in producing the specific agency decisions at issue—the FTC’s position on the Cambridge Filter Method, the FDA’s approval of Phenergan, or the OCC’s regulation construing visitorial powers to include state law enforcement. Equally divergent was the Court’s focus on the incentive effects of state law liability and its willingness—expressly in *Wyeth*, more tacitly in *Altria* and *Cuomo*—to strategically employ judicial proceedings to improve the overall quality of federal agency decisionmaking. Left wholly unexplained is why, if policing general federal agency performance represents an illegitimate overstepping of the judicial role, the courts can consider general agency performance when determining whether state law should be deemed preempted.

To be sure, *Altria*, *Wyeth*, and *Cuomo* are individuated in precisely the way the Court found lacking in *Summers*, thereby forestalling any issue of satisfying Article III jurisdictional requirements. This is characteristic of preemption challenges generally; they emerge from discrete contexts involving allegedly conflicting federal and state law and thus involve a limited group of potential plaintiffs. Such individuation is particularly pronounced when preemption claims arise in conjunction with tort suits, which often involve specific injured plaintiffs. At the same time, preemption determinations frequently have a systemic flavor, because they require consideration of the overall relationship of federal and state law in a given regulatory context. Such overall assessments are particularly characteristic of implied preemption claims, which, as Justice Thomas protested, by their nature look beyond the

---

190. See supra note 177; see also supra text accompanying notes 180–181 (discussing Court’s consistent rejection of broad attack on agencies’ general policies or programmatic approaches).

191. See supra text accompanying notes 175–180.

192. See, e.g., *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) (“The FDA has limited resources to monitor the 11,000 drugs on the market . . . ”).
text of the federal statute. Further, the Court’s insistence that preemption is a question traditionally left for judicial resolution may help alleviate any separation of powers concerns that the courts are overstepping their constitutional role in considering systemic aspects of federal regulation in this context.

Although the simultaneously individuated and systemic character of preemption analysis no doubt contributed to the Court’s greater willingness to address overall agency performance in the preemption decisions than in *Summers*, this feature does not fully explain the Court’s different stance. *Summers*’s denial of standing seems more the result of the Court’s reluctance to police overall federal agency functioning than the other way around, and it is precisely the lack of a similar reluctance in the preemption decisions that requires explanation. Moreover, a broad view of federal agency performance necessarily downplays the details of specific cases and focuses instead on the general features of a regulatory scheme. This dynamic is strikingly present in *Wyeth*, in the majority’s unwillingness to delve into the particulars of the FDA’s assessment of Phenergan’s risk (particulars emphasized at length by the dissent) at the same time as it underscored the general information gains that state liability could bring. In addition, even if preemption claims require some broader assessment of the nature of the federal regulatory scheme, they surely do not necessitate consideration of whether in practice the federal agency will be able to fulfill its statutory responsibilities. And the more the Court seeks to use preemption to influence how federal agencies function, the more it would seem to be impinging upon agency programmatic choices and enforcement discretion, which *National Wildlife Federation* and similar

193. See id. at 1205 (Thomas, J., concurring) (“I have become increasingly skeptical of this Court’s ‘purposes and objectives’ pre-emption jurisprudence . . . in which the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law.”).

194. See Metzger, New Federalism, supra note 27, at 2094–96 (defending subconstitutional enforcement of federalism values as properly within judicial power).

195. Significantly, the agency’s policy was codified in a governing regulation, and the plaintiffs had submitted additional affidavits after settling their claims with respect to the specific project previously at issue that the Court refused to consider. See *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1147 (2009) (“[A]mendments to the Forest Service’s manual of implementing procedures . . . provided that fire-rehabilitation activities on areas of less than 4,200 acres, and salvage-timber sales of 250 acres or less, did not cause a significant environmental impact and thus would be categorically exempt from the requirement to file an EIS or EA.” (citing National Environmental Policy Act Documentation Needed for Cire Management Activities, 68 Fed. Reg. 33,815, 33,824 (June 5, 2003); National Environmental Policy Act Documentation Needed for Limited Timber Harvest, 68 Fed. Reg. 44,598, 44,607 (July 29, 2003))); id. at 1153 (rejecting dissent’s argument that Court “should also have considered the late-filed affidavits”). To be sure, the plaintiffs may have trouble demonstrating standing going forward, but that is because the Court is applying a very high threshold for showing standing in this context, see supra note 182, which appears to reflect the determination of a majority of Justices that this type of challenge does not belong in court.

196. Compare *Wyeth*, 129 S. Ct. at 1198–99 (emphasizing Vermont courts rejected *Wyeth*’s suggestion that FDA intended to prevent strengthening of Phenergan’s label), with id. at 1222–27 (Alito, J., dissenting) (detailing *Wyeth*’s interactions with FDA over Phenergan’s label).
decisions insist should be left to the political branches to control. In any event, neither the individuated nor systemic aspects of preemption analysis help clarify the contrast between the Court’s approach in Wyeth and its position in Buckman—also a preemption decision and thus sharing these individuated and systemic features.

C. Direct Versus Indirect Efforts at Agency Reform

Put simply, the Court was far more willing to address overall agency failure and to try to improve agency performance in the recent preemption decisions than it was in Buckman or its administrative law precedent. The puzzle is how to explain this difference. The Court itself offers no clarification. Plainly, an important factor is shifting majorities and the idiosyncratic preferences of swing Justices; the four Justices in dissent in Summers were in the majority in Wyeth, Altria, and Cuomo. Other contextual differences have been considered above. But is there anything else about the preemption decisions that might justify the Court’s varied responses?

One notable difference is that none of the state claims or laws at issue in the recent preemption decisions directly targeted federal agency decisionmaking. Instead, they affected federal regulation and federal agency performance indirectly—whether by influencing the behavior of regulated entities, supplementing federal oversight efforts, or compensating for failures in federal enforcement. As Catherine Sharkey has noted, this is true even of Wyeth, which involved a general state failure-to-warn claim that did not take issue with any FDA decision. Although the Court undertook to review the FDA’s position on the preemptive effect of drug labeling decisions, it did so only to determine what weight to assign to the agency’s position in the Court’s own independent assessment of preemption. As a result, the Court’s conclusion that the agency’s view on drug labeling preemption was procedurally and substantively unsound simply meant that the Court ignored

197. See Lujan v. Nat’l Wildlife Fed’n, 497 U.S. 871, 891 (1990); see also sources cited supra note 180 (demonstrating Court’s aversion to challenges to agency programmatic choices).
198. Justices Scalia and Kennedy switch positions among these cases; Justice Scalia wrote the majority opinions in Cuomo and Summers but dissented in the other two preemption cases, whereas Justice Kennedy joined the majority in Altria, Wyeth, and Summers but dissented in Cuomo. As noted above, the split summary affirmance in Desiano may also suggest some movement away from Buckman.
199. See supra notes 87–88 and accompanying text (discussing statutory interpretation contingencies and mapping Justices’ voting in these cases).
200. As Part III below makes clear, I ultimately conclude that such a direct-indirect distinction fails to justify the Court’s differential treatment of these lines of decision.
201. See Sharkey, Federalism Accountability, supra note 66, at 2185–88 (underscoring indirect aspect of Wyeth and viewing it as creating possibility for indirect challenges to agency rulemaking and other administrative decisionmaking); see also Wyeth v. Levine, 129 S. Ct. 1187, 1201 (2009) (“We are faced with no . . . regulation in this case, but rather with an agency’s mere assertion that state law is an obstacle to achieving its statutory objectives.”).
the agency’s view, rather than vacating or remanding the drug labeling regulation in which this view was put forward. Similarly, the Court did not directly question the FDA’s approval of Phenergan’s label, but instead emphasized the limited scope of this approval.\textsuperscript{202} Although Wyeth was centrally concerned with improving the FDA’s performance, the Court limited itself to indirect techniques by which to achieve this goal, such as fostering greater information disclosure or using deference as a carrot to incentivize better agency assessments of state law’s impact on federal regulation.

\textit{Altria} and \textit{Cuomo} were similarly indirect in their policing of federal agency action. Rather than directly challenging the FTC’s inaction on the Cambridge Filter Method, \textit{Altria} supplemented the FTC’s failed oversight with a potentially powerful state law incentive to offer more accurate assessments of tar and nicotine yields.\textsuperscript{203} The OCC’s regulation interpreting the NBA as preempting state law enforcement efforts was directly at issue in \textit{Cuomo}, and the decision rendered that provision in the OCC’s regulation essentially void.\textsuperscript{204} Again, however, the state law actions authorized in \textit{Cuomo} were not state law challenges to OCC regulatory decisions, but instead enforcement actions against national banks. To the extent \textit{Cuomo} serves to improve federal bank regulation, it will be by protecting against regulatory gaps resulting from OCC nonenforcement with state law enforcement, not by directly overturning any specific OCC decisions.\textsuperscript{205}

The indirect aspect of the preemption decisions was not emphasized by the Court. Nonetheless, it is a significant feature of these decisions—and of preemption challenges generally. Such challenges typically arise, as in \textit{Altria} and \textit{Wyeth}, out of disputes between two private parties rather than a suit against the federal government, with state and federal law intersecting only in their application to the same private conduct.\textsuperscript{206} Cases occur in which the federal government is a party, such as \textit{Cuomo}, but they are rare.\textsuperscript{207} Even when

\textsuperscript{202} Wyeth, 129 S. Ct. at 1194, 1196–99.


\textsuperscript{204} See supra text accompanying notes 46–48.

\textsuperscript{205} Although the state banking laws at issue in \textit{Cuomo} directly applied to national banks, the Court has long denied that their status as federally chartered corporations and federal instrumentalities entitles them to any particular exemption from state law. See First Nat’l Bank v. Missouri, 263 U.S. 640, 656 (1924) (“[N]ational banks are subject to the laws of a State in respect of their affairs . . . .”).

\textsuperscript{206} See Seth P. Waxman & Trevor W. Morrison, What Kind of Immunity? Federal Officers, State Criminal Law, and the Supremacy Clause, 112 Yale L.J. 2195, 2218 (2003) (“In most preemption cases, the federal and state governments do not confront each other directly.”); cf. Laurence H. Tribe, American Constitutional Law 1220 (3d ed. 2000) (“[T]he federal-state interaction has been indirect: the question has been how to allocate constitutional power as between the two levels of government when each seeks to deal with the same area of private conduct.”).

\textsuperscript{207} An ongoing prominent example of such involvement is the federal government’s suit to have Arizona’s new immigration law declared preempted. See United States v. Arizona, No. CV 10-1413-PHX-SRB, 2010 WL 2926157 (D. Ariz. July 28, 2010). Of course, the government often participates in preemption challenges before the Court as amicus curiae. See Sharkey,
the federal government is a party, it is still usually affected indirectly through the impact of state law on the behavior of federally regulated entities, rather than head-on. Indeed, this indirect aspect might be thought especially true of preemption challenges involving state tort law, given that tort law itself operates indirectly. As the Court stated in distinguishing between a jury verdict and a legal requirement: “A requirement is a rule of law that must be obeyed”; a jury verdict is “an event . . . that merely motivates an optional decision . . . . Whether a jury verdict will prompt the manufacturer to take any particular action” is a matter of speculation.

Equally important, the indirect character of these decisions offers a possible ground on which to distinguish the Court’s precedent that is resistant to efforts to police agency performance. In particular, the state law claim in Buckman targeted federal agency decisionmaking more directly than most state tort claims and preemption litigation. The only basis offered for liability was the company’s interactions with the FDA, and a finding of liability necessarily would have called the FDA’s approval of the bone screws into question. This direct targeting of the FDA’s decision was emphasized most in the concurrence, which concluded that the suit was preempted because the FDA had done nothing to remove the bone screws from the market. According to the concurrence, an FDA determination that “fraud has occurred and that such fraud requires the removal of a product from the market” was necessary to establish the causality element of the fraud claim “without second-guessing the [agency’s] decisionmaking or overburdening its personnel.” The majority, by contrast, focused primarily on the impact that such fraud claims would have on the FDA by dint of their effects on regulated parties’ behavior. Yet concerns about immediate effects on the FDA, such as the danger that regulated parties would deluge the FDA with unhelpful information, also surface in the majority opinion, leading it to insist that fraud-on-agency claims would have a “direct impact on the United States.”

Also revealing is the Buckman majority’s insistence that the fraud claims were not independently based in state law and instead represented an effort to enforce the disclosure requirements of the FDCA. The majority repeatedly underscored that this enforcement task was statutorily assigned to the FDA, thus portraying fraud-

Products Liability Preemption, supra note 26, at 471 & n.103 (noting outcome of preemption challenges frequently tracks position adopted by Solicitor General).

208. See Kessler & Vladeck, supra note 114, at 476 (“Failure-to-warn litigation does not undercut [the FDA’s] authority. Failure-to-warn litigation challenges the company’s failure to warn doctors and patients about a risk and seeks money damages for injuries caused by the lack of an adequate warning. Plaintiffs do not seek injunctions . . . .”).

209. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 445 (2005); see also Klass, supra note 147, at 1567–75 (faulting Court for “implicitly classifying all tort law as public law”).


211. Id. at 350–51 (majority opinion).

212. Id. at 351 n.6.
on-the-FDA claims as directly interfering with the agency’s regulatory role.\textsuperscript{213}

Administrative law challenges operate still more directly on federal agencies. Sustaining such a challenge generally results in vacatur of an agency decision and a remand to the agency for further action—or potentially in outright reversal when a court concludes the agency was acting outside of its authority.\textsuperscript{214} Even when an agency retains substantial discretion on remand, it cannot continue with its chosen course of action without responding to the court in some fashion. The direct aspect of administrative law challenges is evident in \textit{Summers}. The claim there was brought directly against the Forest Service, through its officers, and the lower court’s decision sustaining the environmental organizations’ challenge had resulted in a nationwide injunction against the Forest Service’s timber salvage regulation.\textsuperscript{215} Moreover, at issue was not a substantive requirement governing the behavior of third parties, but instead a question of the procedures that the Forest Service itself was required to follow in making forest management decisions.\textsuperscript{216}

In addition, a distinction between direct and indirect efforts at agency reform has considerable intuitive appeal from both a federalism and a separation of powers perspective. Direct state targeting of federal agency action through state law brings to the fore concerns about states overstepping their constitutional role and undermining the efficacy and supremacy of the federal government.\textsuperscript{217} Such fears of improper state involvement in federal affairs seem to animate \textit{Buckman}.\textsuperscript{218} The danger of improper state interference in federal regulation appears mitigated when state law operates

\textsuperscript{213} Id. at 348–50 & n.4.

\textsuperscript{214} 3 Richard J. Pierce, Jr., Administrative Law Treatise § 18.1, at 1675 (5th ed. 2010). The option of remand without vacatur is an important administrative law development, but does not alter the basic proposition here that agencies must respond to a reviewing court’s decision or face outright reversal, whether sooner or later.

\textsuperscript{215} See Earth Island Inst. v. Rutherbeck, 490 F.3d 687, 690–91 (9th Cir. 2007) (affirming nationwide injunction against two regulations and remanding on ripeness grounds as to regulations not applied to proposed project); see also Summers v. Earth Island Inst., 129 S. Ct. 1142, 1153 (2009) (“Since we have resolved this case on the ground of standing, we need not reach...the question whether, if respondents prevailed, a nationwide injunction would be appropriate.”).

\textsuperscript{216} \textit{Summers}, 129 S. Ct. at 1149. Similarly, the suit in \textit{National Wildlife Federation} was brought directly against the Secretary of the Interior, the Director of BLM, and the Interior Department; NWF sought to force the agency to change its approach to assessing whether public lands could be opened for additional uses and to invalidate specific agency decisions reclassifying particular lands. Nat’l Wildlife Fed’n v. Burford, 676 F. Supp. 271, 272–73 (D.D.C. 1985).

\textsuperscript{217} Even state suits targeting federal action under federal law have occasionally provoked such a reaction, although such suits are now well accepted. See infra text accompanying notes 268–272 (discussing evolution toward acceptance).

\textsuperscript{218} See \textit{Buckman}, 531 U.S. at 350 (“State-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.”); id. (“As a practical matter, complying with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA.”); see also Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004) (describing danger of state interference in federal administration as “inter-branch-meddling concerns”).
wholly independently of federal law and without directly targeting federal agencies. In such contexts, the states’ claims of sovereignty also appear at their strongest; they are acting within their traditional spheres rather than reaching out to insert themselves into purely federal arenas. Indeed, states as indirect instigators of federal agency reform maps well on a standard account of federalism’s benefits, under which states serve as laboratories of experimentation devising new regulatory strategies from which federal agencies—and other states—can learn if they choose. This indirect character also lends state law a less intrusive air: *Wyeth,* though acknowledging state law can have an impact, casts it not as displacing federal agency discretion but instead as affecting agency behavior around the edges.

The appearance of not stepping directly into the policy domains of the executive branch also helps explain why a Court that had just handed down *Summers* did not feel the same separation of powers concerns about assessing how state law claims could improve overall federal agency performance in *Wyeth.* Direct challenges that seek to change broad policy or overall aspects of agency performance seem to risk far greater intrusion on agencies’ operations and the policy-setting prerogatives of the political branches. Although *Wyeth* holds important lessons for the FDA about how to proceed if it wants to influence future preemption determinations, the agency remains free to ignore these lessons if it so chooses. Not so in the *Summers* context, where sustaining the challenge at issue would have forced the Forest Service to change its approach to salvage fire sales.

### III. The Role of the States in Reforming Federal Administration

In sum, the fact that the state laws involved in the preemption decisions did not directly target federal agency decisionmaking appears to be an important ingredient in the Court’s willingness to consider overall administrative performance in its analysis. Again, the Court itself does not distinguish between direct and indirect efforts at federal agency reform, so this account entails some reading between the lines. But such a distinction helps resolve the tension between the preemption decisions and other instances in which the Court has rejected both state and federal law efforts to police federal agency performance. The distinction also appears to resonate with federalism principles, and thus accords with the Court’s evident linkage of federalism and agency failure concerns in the preemption decisions.

Despite its attractiveness, however, a distinction between direct and indirect efforts at federal agency reform is ultimately unsatisfying, at least if it is posited as a categorical matter. As I argue below, the impact of indirect

---

219. See Richard S. Arnold, The Power of State Courts to Enjoin Federal Officers, 73 Yale L.J. 1385, 1394 (1964) (collecting cases supporting state court jurisdiction in areas involving “no direct interference with or obstruction of federal functions”).

220. See supra text accompanying notes 201–202 (discussing *Wyeth*).
reform measures on federal agencies can be very significant in practice, and it can be quite difficult to separate measures that directly target federal agencies from those that do so only indirectly. Moreover, efforts by states to directly regulate federal agencies and officials are not necessarily at odds with our constitutional structure. Indeed, once federal and state authority is recognized to be largely concurrent, states can have quite legitimate reasons for directly targeting federal agency decisionmaking. In fact, state efforts to directly challenge poor federal agency performance, albeit under federal law and in federal courts, may better accord with constitutional federalism principles than more indirect reform efforts.

The failure of the direct-indirect distinction to ultimately justify the Court’s divergent case law suggests a more radical possibility: Perhaps *Wyeth* and the preemption decisions should be read as assigning the states a special role in policing federal administration across the board, through both direct and indirect measures. Such an approach offers intriguing possibilities as a mechanism for further development of federalist principles within our contemporary national administrative state. This view of the decisions would represent a more significant reorientation of the Court’s jurisprudence, however. More importantly, much analytic work needs to be done to clarify what such a state role would mean in practice and to justify why the courts, rather than Congress, should be the ones to assign the states special responsibilities for monitoring federal administration.

A. *The Failure of Functional and Formalist Justifications of the Direct-Indirect Distinction*

As described above, the appeal of the direct-indirect distinction is twofold: Indirect state efforts at federal agency reform appear less intrusive and more reflective of the proper relationship between federal and state governments—and between agencies and the federal courts—than efforts that directly challenge agency performance. On greater scrutiny, however, these functional and formalist justifications of the direct-indirect distinction prove unavailing.

1. *Functional Limitations of a Direct-Indirect Distinction.*—Perhaps the most obvious critique of a distinction between direct and indirect efforts at agency reform is that the perception of indirect measures as unobtrusive is often quite clearly mistaken. In practice, indirect measures can have as great (or greater) an impact on agency functioning and discretion than direct reform efforts.

This critique, in fact, underlies arguments for broad implied administrative preemption, such as those made by the FDA in *Wyeth* and espoused by the *Wyeth* dissent. Under that view, state law liability seriously impairs the FDA’s efforts to create an optimal regulatory regime because it leads regulated entities to take greater precautions than the agency believes

---

221. See supra text accompanying notes 217-219.
appropriate.\textsuperscript{222} The \textit{Wyeth} majority downplayed such an impact, rejecting the proposition that FDA approvals represent a careful and up-to-date calibration of the various risks involved in the thousands of drugs the agency oversees.\textsuperscript{223} It is not necessary, however, to accept that proposition to conclude that the majority nonetheless paints an overly rosy account of \textit{Wyeth}’s impact on the FDA.\textsuperscript{224} What the majority ignores is the high likelihood that drug manufacturers may try to inoculate themselves against future liability by getting the FDA to reject alternative warnings.\textsuperscript{225} To put the point in \textit{Buckman}’s terms, manufacturers now have “an incentive to submit a deluge of information” on possible risks and to push for an agency response rejecting label changes.\textsuperscript{226} The result could well be substantial burdens on an already underresourced and overtaxed agency.\textsuperscript{227} Even a move seemingly quite

\begin{footnotesize}
\textsuperscript{222} See \textit{Wyeth} v. Levine, 129 S. Ct. 1187, 1218 (2009) (Alito, J., dissenting) (“[T]he real issue is whether a state tort jury can countermand the FDA’s considered judgment that Phenergan’s FDA-mandated warning label renders its . . . use ‘safe.’”); see also Schuck, supra note 28, at 78 (“The conflicting standards between state courts (and juries) and the federal agencies create inconsistent incentives for manufacturers.”).

\textsuperscript{223} \textit{Wyeth}, 129 S. Ct. at 1200–04.

\textsuperscript{224} For contrasting views of the FDA’s performance in this regard, compare Kessler & Vladeck, supra note 114, at 483 (“[W]e . . . have reservations about the FDA’s preemption position because it depends on the proposition that the FDA is capable of policing the marketplace effectively on its own.”), with Schuck, supra note 28, at 91, 113 (arguing that, in its drug safety decisions, “the FDA exercises an authority that is probably more comprehensive and technocratically rigorous than that exercised by any other federal regulator,” although also acknowledging information and resource disadvantages that hamper FDA). Recent reports on the FDA’s failures to monitor drugs adequately post-approval support Kessler & Vladeck’s more skeptical view. See Subcomm. on Sci. & Tech., FDA Sci. Bd., FDA Science and Mission at Risk 2, 6 (2007) (“[T]he Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities.”); U.S. Gov’t Accountability Office, GAO-06-402, Drug Safety: Improvement Needed in FDA’s Postmarket Decision-making and Oversight Process 5 (2006) (reporting management deficiency in postmarketing oversight); Comm. on the Assessment of the U.S. Drug Safety Sys., Inst. of Med. of the Nat’l Acads., The Future of Drug Safety: Promoting and Protecting the Health of the Public 193–94 (2007) (reporting general lack of resources preventing effective postmarketing drug safety); see also Citizens Advisory Comm. on the Food & Drug Admin., Report to the Secretary of Health, Education and Welfare, H.R. Doc. No. 84-227, at 53 (1st Sess. 1955) (reporting on budgetary and staffing deficiencies). For similar criticisms of the FDA’s preapproval review, see, e.g., Reed Abelson, Quickly Vetted, Treatment Is Offered to Cancer Patients, N.Y. Times, Oct. 27, 2008, at A1; Barry Meier, F.D.A. Seeks Better Data from Tests of Devices, N.Y. Times, Dec. 30, 2009, at B1.

\textsuperscript{225} Cf. Sharkey, Federalism Accountability, supra note 66, at 2186, 2189 (characterizing \textit{Wyeth} as consistent with agency reference model under which agencies should be required “to provide . . . comprehensive, written responses” to applications by drug manufacturers to change their labels, and arguing that “drug manufacturers, and other interested parties, should be able to challenge . . . refusals by the agency to create the necessary agency record” in order to “preserve their ability to mount a preemption defense”).


\textsuperscript{227} This situation might eventually inure to the agency’s benefit, insofar as it gains useful information or its inability to respond leads the pharmaceutical industry to lobby for increases in the FDA’s budget. See Schuck, supra note 28, at 108 (noting Professor Merrill’s speculation that “the industry . . . might press Congress to provide more resources to enable the agency to respond
deferential to agency decisionmaking, such as allowing state law fraud-on-the-agency claims to go forward only when the agency itself concludes that fraud occurred, could prove to have a substantial impact on agency functioning. The possibility of such liability seems likely to lead manufacturers to fight FDA fraud determinations vigorously and to result in the agency imposing weaker penalties.\footnote{228} The Arizona district court recently underscored this point in a decision that held much of Arizona’s new immigration law preempted. Although the law did not target federal immigration administration directly, the court concluded it would prove too burdensome on federal administration because it would lead to “an increase in the number of requests for determinations of immigration status, . . . [and thus] divert resources from the federal government’s other responsibilities and priorities.”\footnote{229}

That indirect regulatory approaches are powerful is, of course, not a novel point. To the contrary, it underlies much modern regulatory design, such as efforts to rely on market-based regulation rather than top-down, command-and-control approaches.\footnote{230} Indeed, the effectiveness of indirect approaches is heralded by the view of tort in regulatory rather than compensatory terms, as well as by Wyeth itself, which defends continued state law liability for inadequate drug labels in large part because of its indirect beneficial impact on federal regulation.\footnote{231}

to [its] requests”). But that potential outcome only underscores the impact preemption can have as an indirect tool for influencing behavior. See, e.g., Hills, Against Preemption, supra note 24, at 22 ("By giving nonfederal lawmakers a wider scope for entrepreneurial activity, a clear statement rule against federal preemption increases their capacity to influence congressional agendas in dramatic ways.").

\footnote{228. Some commentators already fault the FDA for its limited fraud enforcement efforts. See Derrick Price, FDCA Medical Device Amendments and Federal Preemption: Putting the Screws to Spinal Fusion Patients, 3 Hous. J. Health L. & Pol’y 83, 105–07 (2002) (describing criticisms of FDA enforcement efforts); see also Thomas O. McGarity, Beyond \textit{Buckman}: Wrongful Manipulation of the Regulatory Process in the Law of Torts, 41 Washburn L.J. 549, 563–70 (2002) (describing impediments to aggressive agency fraud enforcement). Commentators advocating this approach to the \textit{Desiano} and \textit{Buckman} situations largely have not discussed the potential impact subsequent tort liability could have on agency fraud determinations. See, e.g., Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004) (failing to discuss this dynamic); Sharkey, Fraud Caveat, supra note 166, at 850, 864–66 (same).


\footnote{231. See Wyeth v. Levine, 129 S. Ct. 1187, 1199–200 (2009) (“[Congress] may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.”). Another recent example of the powerful indirect effect of preemption determinations comes in the context of greenhouse gas regulation, where decisions rejecting preemption claims against state nuisance suits are an important force behind growing industry acceptance of new federal regulation. See Buzbee, State Greenhouse Gas Regulation, supra note 230, at 35 (“Polluters . . . see federal law as a means to
Further, direct regulatory approaches can be structured so that regulated entities retain substantial discretion over their actions. Performance-based regulation, which imposes outcome measures that regulated parties must meet but allows flexibility in how they do so, is a prime example. Perhaps more analogous to the agency reform efforts at issue here, direct legal relief intended to address widespread failure in the operations of government institutions can be structured to preserve substantial discretion on the part of the institutions involved. So, too, some direct challenges to general agency policies present less risk of intruding on agency prerogatives than others. Summers, for example, involved a relatively narrow question of statutory interpretation about which the agency had affirmatively adopted a position through notice-and-comment rulemaking. Although a decision against the agency would force it to comply with procedural requirements, resolution of such a challenge seems less likely to tread on legitimate agency operational discretion than one that challenges “general deficiencies in compliance” with a statutory mandate.

Equally important, no clear divide separates state measures that affect federal agencies directly from those that do so indirectly. Instead, an array of potential approaches exists with many measures blending both indirect and direct elements. This situation is most clearly illuminated by state statutes addressing tort liability for pharmaceutical products. A number of states have adopted statutory immunity measures that preclude liability to some degree for drugs approved by the FDA, provided the drug manufacturer complied with all regulations. “Without exception, all of these state statutes contain a fraud exception, disabling immunity where the drug manufacturer has deceived or defrauded the FDA.”

Michigan’s statute providing total immunity subject

undercut or preempt outright state and local law as well as common law litigation directed at climate change and its many contributing sources.”; see also Connecticut v. Am. Elec. Power Co., 582 F.3d 309, 369 (2d Cir. 2009) (holding city and private plaintiffs had standing to bring public nuisance cause of action against defendant polluters).

232. See Stephen D. Sugarman, Performance-Based Regulation: Enterprise Responsibility for Reducing Death, Injury, and Disease Caused by Consumer Products, 34 J. Health Pol. Pol’y & L. 1035, 1072 (2009) (“Performance-based regulation ties together the freedom to sell products with the responsibility for resulting negative consequences, leaving it to the firms to tailor the former in ways that minimize the latter.”).


235. See Sharkey, Fraud Caveat, supra note 166, at 850 (detailing different types of measures adopted by thirteen states); see also Pa. Emps. Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 242–47 (3d Cir. 2007) (analyzing exemption in Delaware Consumer Fraud Act, Del. Code Ann. tit. 6, § 2513(b) (2005), which states that “[t]his section shall not apply . . . [t]o any advertisement or merchandising practice which is subject to and complies with the rules and regulations, if[ ,] and the statutes administered by, the Federal Trade Commission”), vacated, 129 S. Ct. 1578 (2009) (mem.).

236. Sharkey, Fraud Caveat, supra note 166, at 850.
to such a fraud exception was the statute at issue in Desiano. 237

Are such measures best understood as directly targeting the FDA’s processes or as independent measures focused on determining the scope of state law immunity that take the FDA’s processes into account only indirectly? The most accurate answer would appear to be both; the direct-indirect distinction simply does not map well here. Perhaps for that reason, the scholarly commentary on the fraud exception does not tend to consider this distinction pivotal. Instead, general agreement exists on the need to provide some exception for fraud as the price of preemption or immunity, in large part to support FDA regulation and ensure that the beneficial information disclosing effects of tort liability are preserved. 238 Put differently, the fact that states are to some degree directly targeting FDA decisionmaking through these measures is not thought necessarily problematic. Indeed, some proposals to mitigate the impact of such fraud exemptions on the FDA would do so by making the exemption’s availability turn even more directly on the FDA’s actions, specifically on whether the FDA itself has determined that fraud has occurred. 239

Similar mixed indirect and direct approaches exist in other contexts. One example is state greenhouse gas measures that expressly seek to spur federal action but also independently govern emissions within state borders. 240 Another is state legislation that aims to take advantage of federal allowance for independent state law requirements that parallel those applicable under federal law. In Bates v. Dow Agrosciences, for example, the Court emphasized that preemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was

---

237. See supra text accompanying notes 163–168.

238. See Schuck, supra note 28, at 83 (“Like all other tort scholars, I favor an exception to both FDA preemption of tort claims and to any state law regulatory compliance defense that might survive this preemption . . . .”); Sharkey, Fraud Caveat, supra note 166, at 841 (“What I term the ‘fraud caveat’ to federal agency preemption has great intuitive appeal.”); Nagareda, supra note 28, at 46–47 (“[A] showing of . . . fraud [on the FDA] should suffice to defeat the preemptive effect that a given FDA assessment of a device or drug might otherwise have . . . .”).

239. See Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 353 (2001) (Stevens, J., concurring) (“The fact that the [FDA] has done nothing to remove the devices from the market, even though it is aware of the basis for the fraud allegations, convinces me that this essential element of the claim cannot be proved.”); Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004) (following Justice Stevens’s approach of allowing liability when FDA has determined fraud has occurred); Sharkey, Fraud Caveat, supra note 166, at 848–55 (calling Justice Stevens’s approach a “promising compromise”). Peter Schuck would seek to limit the exception’s scope by instead imposing high proof burdens. See Schuck, supra note 28, at 86 (noting that in his proposed exception “in order to survive a motion to dismiss, the tort plaintiff would have to meet a pleading standard requiring greater specificity with respect to both the allegations of disclosure deficit and supporting the factual evidence”).

240. See, e.g., Michael B. Gerrard, Climate Change and the Environmental Impact Review Process, Nat. Resources & Env’t, Winter 2008, at 20, 20 (“So far, as in most aspects of this issue, the states have been ahead of the federal government in considering climate change and are developing procedures that may be applied more broadly if a more sympathetic presidential administration comes into office.”); see also J.R. DeShazo & Jody Freeman, Timing and Form of Federal Regulation: The Case of Climate Change, 155 U. Pa. L. Rev. 1499, 1500 (2007) (discussing effect of state climate change initiatives on federal legislation).
(FIFRA) would not apply to state causes of action that were substantially equivalent to FIFRA’s because the statute limited preemption to state requirements that were “in addition to or different from those required under federal law.”

States seeking to avoid preemption thus would seem well advised to directly model their tort law and regulatory enactments on the requirements imposed by federal agencies, thereby once again blurring the line between state measures that directly target federal agency action and independent state law. That blurring is evident even in the context of administrative law challenges. Although such challenges—for example, the claim that an agency action was arbitrary and capricious—unquestionably involve direct agency targeting, in many ways their real power over time has stemmed more from their indirect impact on how agencies function in general than it has from their direct effect on the specific regulatory decision at issue.

2. Formal Constitutional Limits on State Efforts to Directly Target Federal Agencies and Federal Officials.—Viewed practically, therefore, the direct-indirect distinction has little to commend it; the distinction does not accurately identify more intrusive reform efforts and is likely to prove difficult to implement consistently. A harder question, however, is whether formal constitutional principles nonetheless require such a distinction.

In assessing this argument, I want to focus only on the federalism dimension and leave to the side the contention that direct federal judicial efforts to reform federal agencies violate separation of powers requirements. As a general principle, the latter proposition is unsustainable. The federal courts regularly undertake direct review of federal agency action, pursuant to congressional instructions, and since *Marbury* have asserted power to enforce constitutional requirements on other branches of federal government.


242. See William F. Pedersen, Jr., Formal Records and Informal Rulemaking, 85 Yale L.J. 38, 60 (1975) (“The effect of [thorough circuit court of appeals] judicial opinions within the agency reaches beyond those who were concerned with the specific regulations reviewed. They serve as a precedent for future rule-writers and give those who care about well-documented and well-reasoned decisionmaking a lever with which to move those who do not.”); Mark Seidenfeld, Bending the Rules: Flexible Regulation and Constraints on Agency Discretion, 51 Admin. L. Rev. 429, 458–59 (1999) (“[T]here are indications that ex-post review helps curb documented abuses of the regulatory system.”). Even critics of arbitrary and capricious review would seem to agree. The dominant complaint that such review ossifies rulemaking emphasizes the broader impact such challenges have on agencies and the incentives they create for agencies to act through other routes. See Jerry L. Mashaw & David L. Harfst, The Struggle for Auto Safety 9–26 (1990) (describing National Highway and Traffic Safety Administration’s change in regulatory strategy from rulemaking to recalls and identifying obstacles the legal system imposes on rulemaking as important culprit behind shift).

243. See Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803) (“It is emphatically the province and duty of the judicial department to say what the law is.”).
Summers is simply the last (as of this writing) in a long line of decisions acknowledging that such judicial scrutiny is appropriate so long as Article III’s requirements are met. The claim underlying the Summers line is instead that judicial efforts at wholesale agency reform go beyond the courts’ constitutional role and infringe on powers assigned to Congress and the President under Articles I and II. But more importantly here, if direct judicial efforts at broad agency reform are at odds with separation of powers, then judicial attempts to achieve that result indirectly would appear to be equally constitutionally suspect—particularly given the potential impact of indirect reform efforts on agency discretion. From a separation of powers perspective, therefore, the direct-indirect distinction has little formal bite.

From a federalism perspective, however, the situation initially appears quite different. Some indirect state impact on federal agencies and federal regulation is inevitable given overlapping federal and state regulatory authority. At a minimum, such concurrent authority means federal agencies need to regulate with an eye to the states to ensure that federal policies do not interact with state requirements in unintended and undesired ways. State regulatory actions may also lead federal agencies to change their policies and enforcement activities—whether by showcasing more effective strategies and the existence of federal regulatory gaps, or by prompting federal agencies to defend their turf. As the Court has remarked, the indirect impact of state law on federal agencies “is but the normal incident of the organization within the same territory of two governments.”

By contrast, state law that directly targets federal agencies and officers seems to fit uncomfortably with our formal constitutional federalist structure, in particular the principle of federal supremacy. Such targeting raises the danger that “the operations of the general government may at any time be

---

244. See Summers v. Earth Island Inst., 129 S. Ct. 1142, 1148–49 (2009) (noting courts have authority to “review and revise legislative and executive action” only when necessary “to redress or prevent actual or imminently threatened injury to persons caused by private or official violation of law”). Indeed, a case could be made that judicial review is a constitutional imperative of broad agency delegations. See Gillian E. Metzger, Ordinary Administrative Law as Constitutional Common Law, 110 Colum. L. Rev. 479, 522 (2010) (“The Court has made clear that broad congressional delegations of authority to administrative agencies are constitutional, but it has failed to adequately consider whether such delegations should come with constitutional strings attached.”).

245. See sources cited supra notes 180, 197 (documenting Summers line of cases). Similar concerns with excessively broad judicial remedies surface in cases in which the federal courts have mandated at times quite sweeping changes in state and local agencies to cure violations of constitutional and federal statutory rights. Yet here, too, the Court has reaffirmed the federal courts’ power to order relief necessary to cure specific constitutional violations. See Lewis v. Casey, 518 U.S. 343, 349–50 (1996) (“It is the role of courts to provide relief to claimants . . . who have suffered, or will imminently suffer, actual harm; it is not the role of courts . . . to shape the institutions of government in such fashion as to comply with the laws and the Constitution.”).


arrested at the will of one of its members.”248 In Tarble’s Case, for example—an 1871 decision denying state courts habeas jurisdiction over federal officials to challenge military custody of an allegedly underage soldier—the Court proclaimed that from “the distinct and independent character of the two governments, within their respective spheres of action, it follows that neither can intrude with its judicial process into the domain of the other, except so far as such intrusion may be necessary . . . [for] the National government to preserve its rightful supremacy.”249 Similarly, fifty years earlier the Court denied the states mandamus power over federal officials, holding in McClung v. Silliman that the conduct of a federal government or agent “can only be controlled by the power that created him” and emphasizing the extraordinary character of mandamus.250 The Court also initially voiced strong concerns about the extent to which application of state law might unduly interfere with


249. 80 U.S. (13 Wall.) 397, 407 (1871); see also id. at 409 (“It is manifest that the powers of the National government could not be exercised with energy and efficiency at all times, if its acts could be interfered with and controlled for any period by officers or tribunals of another sovereignty.”); Ableman v. Booth, 62 U.S. (21 How.) 506, 526 (1858) (holding unconstitutional state habeas relief against federal officer that contradicted prior federal court decision). As noted below, see infra text accompanying note 269, Tarble’s Case has received substantial criticism, but its prohibition on state habeas over federal officials is generally acknowledged to remain the governing rule, at least as long as the federal courts stand open for federal habeas claims and Congress has not sanctioned such state relief. See, e.g., Richard H. Fallon, Jr., Applying the Suspension Clause to Immigration Cases, 98 Colum. L. Rev. 1068, 1074 n.31 (1998) (noting “implied exclusion of state jurisdiction [over habeas claims] would vanish” if federal statutes withdrew federal jurisdiction); Todd E. Pettys, State Habeas Relief for Federal Extrajudicial Detainees, 92 Minn. L. Rev. 265, 268 (2007) (calling prohibition on state habeas over federal officials “too widely accepted to be seriously questioned”).

250. 19 U.S. (6 Wheat.) 598, 605 (1821). The extent to which the Court meant in McClung to adopt a general rule against state mandamus is unclear; much of the Court’s reasoning appears to turn on its previous determination that the federal courts lacked power of mandamus in the same dispute, which involved efforts to force a federal land office official to issue a deed. See id. at 599–601, 605 (discussing McIntire v. Wood, 11 U.S. (7 Cranch) 504 (1813) and emphasizing that federal government had “withh[eld] from its own Courts[] the exercise of this controlling power over its ministerial officers”). However, “McClung has been interpreted to exclude state court mandamus against federal officials under any circumstances.” Richard H. Fallon, Jr. et al., Hart and Wechsler’s The Federal Courts and the Federal System 406 (6th ed. 2009) [hereinafter Fallon et al., Hart & Wechsler]; see also Arnold, supra note 219, at 1392 (“McClung has been deemed controlling . . . when state courts have been asked or have attempted to mandamus federal officers.”). The Court has never addressed whether the states have power to enjoin federal officials, but several other courts have concluded from McClung and Tarble’s Case that states lack injunctive power as well. See, e.g., Armand Schmoll, Inc. v. Fed. Reserve Bank, 37 N.E.2d 225, 226–27 (N.Y. 1941); see also Arnold, supra note 219, at 1393–1406 (discussing cases and arguing in favor of state court jurisdiction over injunctive suits); Martin H. Redish & Curtis E. Woods, Congressional Power to Control the Jurisdiction of Lower Federal Courts: A Critical Review and a New Synthesis, 124 U. Pa. L. Rev. 45, 88 (1975) (“[A] stronger case exists for forbidding [state court] injunctive power [against federal officials] than for disallowing habeas power.”).
the operations of federal agencies and instrumentalities. Much of the resultant doctrine of federal intergovernmental immunity has been cut back over time, with such concerns now addressed largely under the aegis of preemption. Still, some prohibitions remain that underscore the importance of a direct-indirect distinction, such as the rule that “the States can never tax the United States directly but can tax any private parties with whom it does business, even though the financial burden falls on the United States, as long as the tax” is nondiscriminatory. And at times federal officers have been held exempt from state criminal law for actions within the scope of their federal duties, even absent a preempting federal statute, on grounds of federal supremacy.

In the end, however, a categorical constitutional bar to direct state law targeting of federal agencies and officers cannot be sustained. To begin with, federal officers have never been deemed automatically exempt from state substantive law, including state criminal law. Instead, the availability of immunity depends on the scope of the officials’ authority under federal law. More importantly, federal officers have long been subject to state tort suits for their unlawful actions. Indeed, tort liability represented a basic mechanism

251. See, e.g., McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 326–30 (1819) (“[T]he law of Congress . . . must have its full and complete effects and “cannot be either defeated or impeded by acts of State legislation.”). 252. See, e.g., North Dakota v. United States, 495 U.S. 423, 434–35 (1990) (“Claims to any further degree of immunity must be resolved under principles of congressional pre-emption.”); South Carolina v. Baker, 485 U.S. 505, 520–23 (1988) (“[G]overnment contract immunities recognized under prior doctrine were, one by one, eliminated.”). 253. Baker, 485 U.S. at 523; see also North Dakota, 495 U.S. at 435 (“A state regulation is invalid only if it regulates the United States directly or discriminates against the Federal Government or those with whom it deals.”); Graves v. New York ex rel. O’Keefe, 306 U.S. 466, 487 (1939) (emphasizing “any indirect or incidental” burden borne by federal or state government by other government’s taxation of its employees “is but the normal incident of the organization within the same territory of two governments” and is constitutional). 254. See In re Neagle, 135 U.S. 1, 75 (1889) (holding federal marshal immune from state criminal prosecution for actions undertaken to protect federal official and stating “if in doing that act he did no more than what was necessary and proper for him to do, he cannot be guilty of a crime under [state] law”); see also Johnson v. Maryland, 254 U.S. 51, 56–57 (1920) (overturning federal mail truck driver’s conviction and fine for failing to obtain state license, stating “[s]uch a requirement does not merely touch the Government servants remotely by a general rule of conduct; it lays hold of them in their specific attempt to obey orders and requires qualifications in addition to those that the Government has pronounced sufficient”); Waxman & Morrison, supra note 206, at 2232–37 (discussing Neagle’s approach to Supremacy Clause immunity). 255. See Waxman & Morrison, supra note 206, at 2202 (“Although the relevant case law is limited, it does establish that an officer’s entitlement to immunity is determined by examining the reasonableness of his actions in light of his federal powers and duties alone, irrespective of the requirements of state criminal law.”). 256. See, e.g., Teal v. Felton, 53 U.S. (12 How.) 284, 286–87 (1851) (allowing state court trover action against postmaster); see also Arnold, supra note 219, at 1394 (discussing cases in which federal officials sued for damages in state courts); Redish & Woods, supra note 250, at 81–82 (same). In addition, the Court upheld the power of state courts to issue writs of replevin and ejectment against federal officers. See United States v. Lee, 106 U.S. 196, 218 (1882) (ejectment); Slocum v. Mayberry, 15 U.S. (2 Wheat.) 1, 12–13 (1817) (replevin); Arnold, supra note 219, at 1394–95 (discussing ejectment and replevin cases).
by which federal officers were held accountable for exceeding their authority.\footnote{257} Rather than serving as a bar to jurisdiction, federal officers had to show federal statutory authority as an affirmative defense, and they were liable for damages under state law if their actions were found unauthorized.\footnote{258} Such state tort suits against federal officers based on their official conduct represent a direct targeting of federal administrative action.\footnote{259} Although today direct state tort liability for federal officers is largely precluded under the Federal Tort Claims Act (FTCA),\footnote{260} this immunity is the result of congressional action rather than constitutional dictate. Moreover, the extent and scope of a federal officer’s tort liability still turns on state substantive law under the FTCA, albeit now based on the federal statute’s incorporation of state law as the governing rule.\footnote{261}


\footnote{258} See Louis L. Jaffe, Judicial Control of Administrative Action 194–96 & ch. 7 (1965) (describing rule that officer could defend against damages actions if he “acted within his colorable authority”); James E. Pfander & David Baltmanis, Rethinking Bivens: Legitimacy and Constitutional Adjudication, 98 Geo. L.J. 117, 134 (2009) (noting that in response to suit “[t]he official could respond by trying to show that the search was authorized by federal law”).

\footnote{259} Jerry Mashaw appears to disagree, including these suits in the category of actions to obtain indirect review of federal administrative action, along with tort actions involving two private parties. See Jerry L. Mashaw, Federal Administration and Administrative Law in the Gilded Age, 199 Yale L.J. 1362, 1399–1402, 1407 (2010) [hereinafter Mashaw, Federal Administration]; cf. Redish & Woods, supra note 250, at 82 (“Any resultant impingement of the official duties of federal officers [from state tort suits] is, at most, indirect.”). As discussed below, however, Mashaw’s prime focus is on distinguishing such tort actions from suits that sought to directly control the actions of federal officials through injunctions or writs of mandamus. See infra text accompanying notes 263–264. I agree that tort actions operate more “indirectly” on federal agencies than injunctions or mandamus. See supra text accompanying notes 206–209. But I disagree that such state actions against federal officers based on their official conduct are best viewed as indirect challenges to federal agency action. Although state tort actions do not seek to control future actions by federal officers, the substance and legality of officers’ past actions are nonetheless directly at issue.

\footnote{260} Under the Federal Tort Claims Act (FTCA), the United States is substituted for federal employees found to be acting within the scope of their employment, 28 U.S.C. § 2679(d)(1) (2006), and suit under the FTCA is the exclusive remedy allowed for nonconstitutional torts committed by federal officers, id. § 2679(b)(1); see also Waxman & Morrison, supra note 206, at 2242–43 (discussing FTCA). The FTCA also prohibits liability for actions taken by federal employees involving performance or nonperformance of a discretionary function. 28 U.S.C. § 2680(a); see also Pfander & Baltmanis, supra note 258, at 123 (“Congress, by transforming claims for law enforcement (and other) torts into claims against the United States under the FTCA, has largely eliminated state common law remedies as a relevant source of relief for individuals who have suffered a constitutional injury.” (footnote omitted)). For discussion of other statutes allowing recovery for tortious misconduct, see Lester S. Jayson & Robert C. Longstreth, Handling Federal Tort Claims § 2.05 (2004).

\footnote{261} See 28 U.S.C. § 2672 (stating liability is determined “in accordance with the law of the place where the act or omission occurred”).
Two distinctions are critical to understanding the Court’s varied jurisprudence here. The first is between efforts to control federal actions in the future and efforts to remedy past federal misconduct. Both Tarble’s Case and McClung involved the former; they were efforts to force federal officials to undertake particular actions.262 Jerry Mashaw has underscored that, until the twentieth century, such judicial relief was only narrowly available in federal court: “Direct review of administrative action by mandamus or injunction was sharply limited by the Supreme Court’s position that mandamus was inappropriate whenever the Administrator was engaged in anything more than a ministerial, nondiscretionary task.”263 But, as Mashaw notes, courts were much more receptive to common law actions seeking simply to remedy past agency action alleged to have violated individuals’ rights.264 The Court’s precedent prohibiting state efforts in the form of injunctive relief yet allowing state tort actions thus accords with views about the propriety of certain forms of judicial relief that existed independent of the federal-state context. Thus, for example, in Johnson v. Towsley, a suit over the validity of a land patent between two private parties in which the Court defended the ability of the courts of equity to correct mistakes in federal Land Office determinations, the fact that the decision it was affirming was that of the Nebraska Supreme Court did not factor into the Court’s analysis.265

The second, and perhaps even more important distinction, is between a constitutional prohibition on direct state targeting of federal officials and restrictions that rest on congressional statutes. As a matter of constitutional structure, a categorical, constitutionally grounded prohibition would be at odds with the Madisonian Compromise, under which “state courts would always be open to hear cases not given by Congress to the federal courts.”266 The ultimate residual availability of the state courts to hear federal claims is viewed today as fundamental to understanding the Constitution’s grant to Congress of control over the jurisdiction of the federal courts.267 But it is hard to see how

262. See Tarble’s Case, 80 U.S. (13 Wall.) 397, 401–02 (1871) (describing question presented as “whether a State court commissioner has jurisdiction . . . to inquire into the validity of . . . [soldiers’] enlistment . . . and to discharge them from such service”); McClung v. Silliman, 19 U.S. (6 Wheat.) 598, 604 (1821) (addressing how “a State tribunal can . . . issue[] a mandamus to the [federal] register of a land office”); see also McIntire v. Wood, 11 U.S. (7 Cranch) 504, 505 (1813) (predecessor case to McClung in federal court describing claim as mandamus action to force register to grant plaintiff certificates of purchase for particular lands).


264. 80 U.S. (13 Wall.) 72, 83–84, 91 (1871); see also Mashaw, Federal Administration, supra note 259, at 1409–10 (discussing Johnson).


the state courts could play this role—at least in cases involving state enforcement of federal laws, such as Tarble’s Case and McClung268—if as a constitutional matter state courts lacked jurisdiction to grant relief against federal officials. Indeed, Tarble’s Case has been much criticized as fundamentally at odds with the Madisonian Compromise, as well as with original practice under which state courts regularly entertained habeas challenges.269

Little dispute exists, however, that Congress has authority to preempt state action targeting federal agencies or federal officials.270 In fact, the overarching theme of commentary in this area is that it is ultimately up to Congress to decide what role the states are to play in monitoring and controlling the actions of federal officers.271 Unsurprisingly, therefore, Tarble’s Case and McClung are often thought best understood as concluding that Congress had prohibited the types of state action involved, rather than as invoking a constitutional prohibition.272 Congress, moreover, has acted, adopting several statutes that either preclude or significantly limit direct application of state law to federal agencies and officers. Prime among these are the FTCA’s preclusion of state tort actions against federal officers found to be acting within the scope of their employment;273 the APA’s waiver of

268. See Tarble’s Case, 80 U.S. (13 Wall.) 397, 409–12 (1871); McClung v. Silliman, 19 U.S. (6 Wheat.) 598, 604–05 (1821); see also Armand Schmoll, Inc. v. Fed. Reserve Bank, 37 N.E.2d 225, 226 (1941) (denying states have power to “control the manner in which a Federal agency performs or attempts to perform its functions and duties under the Tariff Act or other Federal statute where the Federal government has exclusive jurisdiction”).

269. See Fallon et al., Hart & Wechsler, supra note 250, at 402–03, 437–39 (scrutinizing Tarble’s Case on these grounds); Pettys, supra note 249, at 294–96 (same). But see Redish & Woods, supra note 250, at 50, 81–92 (concluding Tarble’s Case represents constitutional bar to certain forms of state relief against federal officers and remains good law).

270. Fallon et al., Hart & Wechsler, supra note 250, at 390–91. Such congressional restrictions on state action are quite different from the congressional efforts to force or “commandeer” the states to implement federal regulation that the Court has invalidated on federalism grounds. See Printz v. United States, 521 U.S. 898, 935 (1997) (prohibiting federal commandeering of state executive officers); New York v. United States, 505 U.S. 144, 166 (1992) (prohibiting federal commandeering of state legislatures).

271. See Pettys, supra note 249, at 296 & n.177 (collecting sources).

272. For arguments to this effect on Tarble’s Case, see Amar, supra note 257, at 1509–10 (arguing Court’s analysis in Tarble’s Case and Ableman v. Booth, the pre-Civil War decision on which Tarble’s Case relied, “was shaky, and its language quite sloppy” and concluding these decisions “can be justified only if they are understood simply as attributing to Congress a desire for exclusive federal court jurisdiction in habeas proceedings against federal officers”); Waxman & Morrison, supra note 206, at 2224–27 (concluding similarly Tarble’s Case is best read as reflecting congressional determination to limit habeas jurisdiction over federal officers to federal courts). But see Arnold, supra note 219, at 1390–93 (noting statutory basis of McClung but arguing that in Tarble’s Case “Justice Field’s language indicates that the Constitution forbids state jurisdiction ex proprio vigore”); Collins, supra note 267, at 98–104 (concluding both Tarble’s Case and McClung were originally based in Constitution but noting statutory view avoids problems with constitutional account); Redish & Woods, supra note 250, at 96–102 (defending Tarble’s Case as constitutionally based).

sovereign immunity for nonmonetary actions against federal agencies brought in federal court;\textsuperscript{274} and the federal removal statute’s grant of broad powers to federal officers to remove to federal court state civil and criminal actions filed against them for acts committed under color of their office.\textsuperscript{275} As a statutory matter, the comprehensive scheme that Congress has provided for remedying federal administrative transgressions leaves little room or need for resort to state remedial measures.

Congress’s central role in structuring state involvement in federal regulation suggests that a potentially fruitful way of understanding the direct-indirect distinction is in terms of its operation as a constitutionally inspired default rule, trumpable by Congress.\textsuperscript{276} Under this approach, absent congressional indication to the contrary, state measures directly targeting federal agency decisions or seeking to control the actions of federal officials would be presumptively preempted, whereas indirect state measures would be presumptively valid. This formulation accords nicely with the preemption decisions, which invoked presumptions against preemption in the context of measures affecting federal agencies indirectly, as well as with \textit{Buckman}, which deemed a presumption against preemption inappropriate precisely because of the federal nature of the activities targeted by state law.\textsuperscript{277} Yet even a presumptive direct-indirect distinction is ultimately unsustainable across the board. The problem is not the presumptive validity of indirect state measures, but rather condemning as presumptively illegitimate all direct state targeting of federal agencies. That would go well beyond existing precedent and statutory measures, which focus instead on protecting the federal government from state law intrusions that would impede the ability of federal agents to function.\textsuperscript{278} Thus, they prohibit efforts by states to “interrupt the acts of the general government itself,”\textsuperscript{279} and limit the extent to which federal officers and agencies face state law liability for their actions.\textsuperscript{280} To be sure, a concern with

\begin{footnotesize}
\begin{enumerate}
\item[275.] See 28 U.S.C. § 1442(a)(1); see also Arnold, supra note 219, at 1405 (“[F]ederal officers have the protection of removal.”); Waxman & Morrison, supra note 206, at 2228–30 (discussing removal statute).
\item[276.] For a similar constitutional-default-rule account of prohibitions on interstate discrimination, see Gillian E. Metzger, Congress, Article IV, and Interstate Relations, 120 Harv. L. Rev. 1468, 1475 (2007) (“[T]he antidiscrimination provisions of Article IV are best understood, like the dormant commerce clause, as constitutional default rules.”).
\item[277.] See Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 347–48 (2001) (“[T]he relationship between a federal agency and the entity it regulates is inherently federal in character . . . .”).
\item[278.] See, e.g., Tafflin v. Levitt, 493 U.S. 455, 458–460 (1990) (noting, in suit between private parties, state courts are “presumptively competent . . . to adjudicate claims arising under the laws of the United States” and thus “have concurrent jurisdiction ‘where it is not excluded by express provision, or by incompatibility in its exercise arising from the nature of the particular case’” (quoting Claflin v. Houseman, 93 U.S. 130, 136 (1876))). For a skeptical view of implied preemption defenses of limits on state habeas jurisdiction over federal officers, see Pettys, supra note 249, at 297–307.
\item[279.] Johnson v. Maryland, 254 U.S. 51, 55 (1920).
\end{enumerate}
\end{footnotesize}
protecting against state law prohibitions and restrictions on the actions of federal officials supports viewing state law efforts that seek to overturn or enjoin federal administrative actions as presumptively preempted.281 These actions might well be deemed actually preempted by the APA and other federal statutes granting rights of action to remedy arbitrary and unlawful agency action in federal court. This rationale, however, could not justify a presumption of preemption in the Buckman situation, in which state law directly targeted federal agency decisionmaking but did not (a) impose liability on any federal actor; (b) render any federal decision legally invalid, or (c) purport to control future federal agency action. Preemption of such actions could still result from the substantive regulatory statute at issue (the FDCA in Buckman), but certainly not from general federalism principles alone.

Even more plainly, these precedents and statutes do not support a presumption against direct state targeting of federal administrative action that takes the form of suits brought by state actors in federal court and under federal law. A strong case could be made that such state conduct is preferable to state efforts to influence federal agencies more indirectly. Dangers of a single state imposing its policy preferences on the nation as a whole are assuaged by the need to prove a claim under federal law to a federal tribunal. At a minimum, barring statutory language to the contrary, states should be equally able to sue under statutes that provide rights of action against federal officers or agencies in federal court, such as the APA. Moreover, such state suits are regularly entertained, at least when the state asserts an injury to its sovereign or proprietary interests, such as federal imposition of unconstitutional requirements or federal action that harms state property.282

1988 U.S.C.C.A.N. 5945, 5947 (“The possible exposure of Federal employees to personal liability could lead to a substantial diminution in the vigor of Federal law enforcement and implementation.”); see also Springer v. Bryant, 897 F.2d 1085, 1086–87 (11th Cir. 1990) (noting Congress passed Westfall Act creating absolute immunity for federal employees who commit common law torts as a result of the “immediate crisis in which all federal employees were confronted with the prospect of being held personally liable for actions taken within the scope of their employment” and because Congress feared “that this potential threat of personal liability and protracted tort litigation could undermine the morale of federal employees and the effectiveness of the agencies in which they were employed”). Insofar as state court suits target federal agencies rather than federal officers, they likely would be barred by federal sovereign immunity, as the APA’s waiver of sovereign immunity would not apply. See 5 U.S.C. §702 (2006) (waiving sovereign immunity for certain claims against the United States brought “in a court of the United States”).

281. Akhil Amar and Richard Arnold have rejected this proposition, arguing that such state law actions against federal officials should be deemed constitutional and questioning the correctness of decisions such as Tarble’s Case to the contrary. See Amar supra note 257, at 1504–17; Arnold, supra note 219, at 1401–03 (defending state court power to enjoin federal officials).

The situation is somewhat different when a state sues the federal government in its parens patriae capacity asserting quasi-sovereign interests, including interests in obtaining benefits to which its residents are entitled under federal law. In the past, the Court has rejected state parens patriae suits against the federal government on the grounds that “the United States, not the State, represents the citizens as parens patriae in their relations to the federal government.” The recent decision in *Massachusetts v. EPA* calls this limit on such suits into question, however, with the Court there not only upholding a state’s suit against a federal agency’s failure to regulate but further invoking its parens patriae jurisprudence to justify its assertion of “special solicitude” for the states in standing analysis. According to the *Massachusetts* majority, the Court’s precedents at most bar state parens patriae suits that seek to protect state residents from the operation of federal laws, not suits in which states seek to assert rights under those federal laws. In any event, the undeniable ability of states to sue federal agencies in federal court in other contexts suffices to preclude any across-the-board presumption against states directly targeting federal administrative action through federal court litigation.

In sum, an approach that views direct state targeting of federal action as presumptively preempted may well be appropriate as applied to some state measures, such as suits in state court (based on either state or federal law) that seek to control the future actions of federal officers or federal agencies. But a presumptive approach is not justified across the board; in particular, it is not sustainable as applied to contexts such as *Buckman* (in which state law may directly target federal decisionmaking without seeking to overturn agency decisions or impose liability on federal officers) or *Summers* (in which federal agencies are directly sued under federal law in federal court). Thus, even this more modest approach fails to vindicate the direct-indirect distinction as a full

---


284. Georgia v. Pa. R.R. Co., 324 U.S. 439, 445–46, 450–52 (1945); see also Massachusetts v. Mellon, 262 U.S. 447, 485–86 (1923) (“While the state, under some circumstances, may sue in that capacity for the protection of its citizens, it is no part of its duty or power to enforce their rights in respect of their relations with the federal government. In that field it is the United States, and not the state, which represents them as parens patriae . . . .”). For a defense of the traditional approach, see Alexander M. Bickel, The Voting Rights Cases, 1966 Sup. Ct. Rev. 79, 86–90.


explanation for the tension between the preemption decisions and these other lines of jurisprudence.

3. Lessons from the Past: The Repeated Failure of Federalism-Based Direct-Indirect Distinctions.—The difficulty involved in justifying a categorical federalism-based distinction between direct and indirect efforts to improve federal agencies should come as no surprise. Previous attempts to use formalistic direct-indirect distinctions to navigate federal and state relationships have also failed, and for many of the same reasons. Perhaps the most prominent of these was the Court’s effort to confine exercise of Congress’s commerce power to measures that directly targeted the movement of goods and services in interstate commerce and its prohibition on congressional regulation of activities (such as manufacturing, mining, or agriculture) that affected interstate commerce indirectly. This effort was combined with a less well-known mirror restriction on the states, under which the Court invalidated state measures that it concluded directly targeted interstate commerce but sustained state legislation that was deemed to affect interstate commerce only indirectly. Both of these direct-indirect distinctions failed to hold, for familiar reasons: the lack of a clear divide between activities said to affect interstate commerce directly as opposed to indirectly; and the extent to which supposedly indirect effects could vitiate federal efforts to regulate interstate commerce. As a result, it became clear that these direct-indirect distinctions artificially constrained the legitimate sphere of federal and state regulation.

Similarly here, the direct-indirect distinction suggested by the Court’s case law fits poorly with both practical reality and constitutional principle. Of

287. See Carter v. Carter Coal Co., 298 U.S. 238, 309 (1936) (finding act unconstitutional that sought to “regulate and minimize . . . local controversies and evils affecting local work” and that “[s]uch effect as they may have upon commerce, however extensive it may be, is secondary and indirect”); A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 546 (1935) (“In determining how far the federal government may go in controlling intrastate transactions upon the ground that they ‘affect’ interstate commerce, there is a necessary and well-established distinction between direct and indirect effects.”).


289. See Wickard v. Filburn, 317 U.S. 111, 125 (1942) (holding commerce power can reach purely intrastate activities); NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 37, 40 (1937) (holding commerce power extends to intrastate activities that have “close and substantial relation to interstate commerce”). See generally Cushman, supra note 288, at 1094–100 (tracing development of direct-indirect distinction).

290. See Cushman, supra note 288, at 1094 (noting direct-indirect distinction “appears artificial, wooden, even silly”); see also United States v. Lopez, 514 U.S. 549, 605 (Souter, J., dissenting) (describing direct-indirect cases as “applying highly formalistic notions of ‘commerce’”).
particular importance, the distinction embodies an unduly narrow view of the states’ legitimate scope of concern. The image of the federal and state governments as occupying separate and independent spheres of action articulated in Tarble’s Case was cast aside by the New Deal. 291 The Court has now long acknowledged that the central federalism dynamic is one of concurrent and overlapping jurisdiction—precisely the reason that preemption has risen so prominently to the fore. 292 As the range of legitimate federal regulatory authority has expanded, so too has the scope of legitimate state interest and involvement in federal regulation. The success or failure of federal regulatory efforts has a profound effect upon the “States qua States.” 293 Federal agency failures can result in the states themselves having to undertake regulatory action or face substantial public expenditures, in part given the states’ roles in federal regulatory programs. 294 States also have a significant interest in the success of federal regulatory efforts because those efforts often displace state measures and render the states unable to regulate in their own right. 295 Massachusetts emphasized this point, noting the possibility of preemption as one reason why states are “entitled to special solicitude in our standing analysis.” 296


292. Cf. Metzger, New Federalism, supra note 27, at 2072 (“Given the overlapping character of federal and state regulatory power, most substantive determinations by federal agencies hold the potential to displace state law . . . .”).


294. For example, northeastern states challenged the Bush Administration’s ozone standards as too lax, arguing that the effect was to increase these states’ burdens in meeting emissions standards under the CAA. See, e.g., West Virginia v. EPA, 362 F.3d 861, 865 (D.C. Cir. 2004) (“Evidence in the record demonstrates that states in the eastern United States have difficulty attaining ozone standards because of ozone . . . emissions in upwind states.”). States have also sued the Department of Health and Human Services to prohibit its adoption of more restrictive regulations under the SCHIP program. See Christopher Lee, N.J. Wants Rules for Health Plan Blocked: Lawsuit Says Children Would Suffer, Wash. Post, Oct. 2, 2007, at A3 (describing state suit challenging federal implementation of SCHIP program). Even outside of such cooperative programs, federal regulatory failures can force state responses; states today are faced with communities devastated by the subprime mortgage scandal and failure of federal oversight. See Nicholas Bagley, Subprime Safeguards We Needed, Wash. Post, Jan. 25, 2008, at A19 (“To combat this surge in predatory lending, some state legislatures decided to stanch the flow of easy credit to subprime lenders.”); Michael Powell, Federal Judge Rejects Suit by Baltimore Against Bank, N.Y. Times, Jan. 9, 2010, at A11 (noting federal judge dismissed Baltimore’s lawsuit against Wells Fargo because “the city could not prove that the bank’s lending practices had resulted in broad damage to poor neighborhoods”).

295. See Brief of the States of New York et al. as Amicus Curiae in Support of the Petitioner at 2, Watters v. Wachovia Bank, N.A., 550 U.S. 1 (2007) (No. 05-1342) (arguing if regulation at issue “is allowed to stand, it would render States powerless to protect their residents from abusive and discriminatory consumer practices” and that “OCC would usurp that function, even though it is ill-equipped to perform it”); Brief of the States of Arizona et al. as Amici Curiae in Support of Petitioners at 21, Massachusetts v. EPA, 549 U.S. 497 (2007) (No.05-1120) (“When administrative decisions have the potential to preempt state law and thus interfere with the State’s interest in creating and enforcing its own legal code, States are injured, and it is the administrative decision that causes that injury.”).

B. Federalism for the Future: A Special State Role in Monitoring and Improving Federal Administration?

The inadequacies of the direct-indirect distinction in explaining the Court’s varying jurisprudence leaves open a more radical possibility: Rather than attempting to fit the recent preemption decisions within the Court’s existing precedent, perhaps they are better understood as representing a shift in the Court’s views. Along with Massachusetts v. EPA, the decisions could signal that the Court has adopted a new understanding of federal-state relations under which the states have a special role in monitoring and improving federal administration.

The idea that the states may have such a role to play in checking and reforming federal administration is intriguing. But substantial analytic and normative work remains to be done for such an account to be viable. The Court itself has provided little clarification of what such a role for the states might mean in practice or of its implications for existing jurisprudence. In addition, it has almost wholly failed to justify why the states should be assigned any such role—and more specifically, why the responsibility for assigning them a role falls to the Court rather than to Congress.

1. The Scope and Implications of a Special State Role.—The strongest support for the view that the Court may be assigning the states a special role in reforming federal administration comes in Massachusetts. There, the Court repeatedly invoked the “special position and interest” of the states in concluding that the states are “entitled to special solicitude in our standing analysis.” Massachusetts indicates the states should be accorded special access to federal court in order to challenge federal agency action. But the exact contours of this access remain obscure.

On the one hand, it seems unlikely that the Court intended to free the states entirely from traditional standing requirements when they seek to challenge federal agency action. After emphasizing the importance of state status, the majority proceeded to analyze whether Massachusetts, like a private litigant, had demonstrated sufficient injury, causation, and redressability to have standing. Moreover, freeing the states from these requirements entirely would set up a stark contest between federalism and separation of powers principles, as the Court has held they represent the minima necessary

297. Id. at 518, 520.
298. See Watts & Wildermuth, supra note 187, at 1033, 1036 (concluding Massachusetts still requires satisfaction of traditional standing requirements, but using less restrictive analysis); see also Mank, States Standing, supra note 187, at 1779 (“It is unlikely that the Court meant to abolish standing for states . . . .”); Massey, supra note 285, at 261–62, 271–72 (arguing Massachusetts allows states to sue on generalizable interests, but some injury requirement remains). But see Robert A. Weinstock, Note, The Lorax State: Parens Patriae and the Provision of Public Goods, 109 Colum. L. Rev. 798, 826–30 (2009) (arguing parens patriae and Lujan analyses in Massachusetts were separate and suggesting traditional standing analysis does not apply to state assertion of quasi-sovereign interests).
for a challenge to satisfy Article III’s “case or controversy” limitation on federal jurisdiction. Even the parens patriae jurisprudence on which the Court relies necessitates some showing beyond “[t]he mere fact that a state is the plaintiff” for suit to lie. A state must demonstrate that its quasi-sovereign interests are implicated, which would appear to necessitate some showing of at least potential harm to the health and economic well-being of its residents or their ability to obtain the benefits of federal law. Not surprisingly, lower court decisions since Massachusetts have held that the decision does not excuse states from meeting the traditional Article III requirements for standing.

On the other hand, the Court’s treatment of whether Massachusetts met these requirements was notably lenient. It sustained Massachusetts’s right to sue based on fairly generalized and speculative claims of injury and causation, expressly tying its analysis of these requirements to Massachusetts’s state status. Equally important is Massachusetts’s holding that states could sue federal agencies as parens patriae to assert the rights of their residents under federal statutes. Further, Massachusetts’s lenient approach to satisfying Article III requirements suggests that states may be able to bring such parens patriae suits without having to show that their residents had suffered identifiable harms clearly traceable to federal regulatory failure or redressable by regulatory action.

Thus, Massachusetts may presage dramatically expanded access to the federal courts for state suits challenging federal administrative action, assuming a majority of Justices continue to adhere to its approach. Wyeth, in turn, may push this access even further, with its approval of state efforts to improve the overall functioning of federal agencies. Combined, these decisions could lead to a significant qualification on the Summers line of precedent, with states being found to have standing to bring the kind of overall challenges to agency functioning and policy that the federal courts have previously refused to entertain. To be sure, several of the decisions holding such challenges nonjusticiable have rested on grounds other than standing.

---

304. See supra text accompanying notes 283–286.
305. See Mank, States Standing, supra note 187, at 1775–80 (arguing for this as result of Massachusetts); Massey, supra note 285, at 268–71 (arguing, post-Massachusetts, “generalized injury is sufficient to constitute quasi-sovereign injury”); Weinstock, supra note 298, at 826–28 (arguing Massachusetts “treated damage to state-owned property as surplus to a parens patriae action”).
306. Cf. Freeman & Vermeule, supra note 131, at 70, 92–96 (arguing decision in Massachusetts is driven by Court’s perception of politicized decisionmaking in context of urgent regulatory need and special state standing may not expand much beyond that case).
specifically a lack of ripeness or of final agency action. But it is hard to see why a special solicitude for the states that allows them greater ease in satisfying constitutional standing requirements would not result in the states being granted more leeway with respect to these jurisdictional obstacles as well.

For example, it is not hard to imagine that states would be able to sue to challenge an agency’s policy on preemption, even prior to a specific preemption challenge arising. Such a suit—which could be seen as asserting either a state’s sovereign interest in its own power to govern or its quasi-sovereign interest in protecting its citizens from harms—draws particular support from Massachusetts’s reference to preemption as a basis for according states special solicitude in assessing standing. But in addition, states might be able to challenge an agency’s general failure to comply with statutory requirements or perform its statutorily assigned responsibilities adequately. To use the statutory context of Wyeth as an example, perhaps states could sue the FDA over its poor record in monitoring drugs post-approval. Agency failure of this sort could pose a threat to the well-being of state residents, supporting standing under Massachusetts, and Wyeth sanctioned the use of state law to achieve a similar agency-reforming effect.

Wyeth also suggests that a special state role in monitoring and improving federal administration might not be limited to the federal court context, but instead could extend to efforts to reform federal agencies through use of state law. Recognizing such a state role might lead the Court to uphold state law measures like the fraud-on-the-FDA claims at issue in Buckman, which aim to use state law liability to protect federal agency decisionmaking or reinforce federal standards. It might also support taking a broad view of the states’


308. In particular, deference to a state’s assessment of when its quasi-sovereign interests are implicated may make it easier for states to demonstrate that their claims are ripe and also that an agency action sufficiently represents the agency’s official position to allow for challenge. For examples of private litigants hindered by these jurisdictional obstacles, see Nat’l Park Hospitality Ass’n v. Dep’t of the Interior, 538 U.S. 803, 808–12 (2003) (concluding that challenge to agency policy statement was unripe due to lack of hardship, even though policy statement was final agency action); Bennett v. Spear, 520 U.S. 154, 177–78 (1997) (requiring final agency action subject to suit under APA to be “consummation of the agency’s decisionmaking process” and “one by which . . . legal consequences will flow” (internal quotation marks omitted) (quoting Port of Bos. Marine Terminal Ass’n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970))).

ability to enforce federal standards. A special state role conceivably could extend even further to authorizing state court efforts seeking directly to control federal agency decisionmaking, such as the state habeas and mandamus actions at issue in \textit{Tarble’s Case} and \textit{McClung}, though such a move would represent quite a dramatic departure from current practice. Of course, Congress could preempt any state law effort to police federal agency action, and thus, cast as interpretations of the federal statutes at issue, \textit{Buckman} and these earlier precedents might still stand. Yet to the extent these decisions embody the broader proposition that policing federal agency action is not an appropriate state function, the Court’s view would now be quite different. State law targeting of federal agency action could become presumptively available, absent express preemption or a relatively clear case of federal-state law conflict.

As a result, assigning the states a special role with respect to reforming federal administration has the potential to work a dramatic change in existing practice and precedent. That is perhaps reason enough to proceed cautiously before reading the preemption decisions in this fashion, absent clearer indications from the Court that it intends such a move.

2. Justifying a Special State Role.—An equally serious weakness is the Court’s failure so far to provide a justification for assigning the states such a special role. One might defend such a role on several different grounds. One possible basis is the belief that states are likely to be particularly effective monitors of agencies and instigators of administrative change. States gain special knowledge about federal administrative deficiencies from frequent involvement in implementing federal programs, as well as from their own independent regulatory undertakings. States may have substantial access to Congress through their state representatives, allowing them to raise concerns about federal agency actions and perhaps prompt federal oversight. States also have the capacity to sue if needed, particularly when they partner with

310. See Widman, supra note 141 (manuscript at 4–5, 36–40) (advocating state enforcement of federal regulations).

311. As noted above, the contrast between \textit{Wyeth} and \textit{Buckman}, as well as the split summary affirmance in \textit{Desiano}, suggest some movement away from such a strong view of \textit{Buckman}. See supra text accompanying notes 168–169.

312. See supra text accompanying notes 293–296; see also Jessica Bulman-Pozen & Heather K. Gerken, Uncooperative Federalism, 118 Yale L.J. 1256, 1288 (2009) (advocating “uncooperative federalism” in which “states can take advantage of the connective ties that bind them to federal officials” which in turn “yield[s] knowledge of the system and personal relations with the people best positioned to change the policy”); Philip J. Weiser, Federal Common Law, Cooperative Federalism, and the Enforcement of the Telecom Act, 76 N.Y.U. L. Rev. 1692, 1698–1703 (2001) (discussing rationales for cooperative enforcement of national regulatory regimes).

313. See Carol F. Lee, The Political Safeguards of Federalism? Congressional Responses to Supreme Court Decisions on State and Local Liability, 20 Urb. Law. 301, 335–36 (1988) (“[I]nstitutional linkages help to secure access and attention for state and local concerns.”); see also Mendelson, \textit{Chevron}, supra note 58, at 762 (noting state organizations, such as National Governors’ Association and National Conference of State Legislatures, “seem well-positioned to have their voices heard in [congressional] decisionmaking”).
other states.\footnote{314} Yet although these features could empower states as federal agency overseers, they do not suffice to differentiate all states in all contexts. States may lack any special knowledge in areas in which they are inactive, and inevitably some states will have far superior expertise and resources than others. Moreover, public interest organizations—like the environmental groups who initially petitioned the EPA to regulate greenhouse gases in \textit{Massachusetts} or who sought to challenge the Forest Service’s practices in \textit{Summers}—also often have extensive expertise, deep knowledge of how federal programs are operating, substantial litigating capacity, and close connections to Congress.\footnote{315}

What does differentiate the states from private litigants is their political accountability. State challenges to federal administrative action are overwhelmingly brought by state attorneys general who are accountable to the voters in their states for how they direct the resources of their offices.\footnote{316} However, political accountability is very much a two-edged sword. It may act as a constraint on excessive litigation, thus limiting the disruptive potential on federal agencies of allowing states special court access.\footnote{317} Alternatively, as the current healthcare reform litigation demonstrates, their political accountability may also prompt state officials to bring suit to challenge federal actions that are unpopular in their states.\footnote{318} The political accountability of

\footnotesize

315. See, e.g., Oliver A. Houck, Standing on the Wrong Foot: A Case for Equal Protection, 58 Syracuse L. Rev. 1, 43 (2007) (“[P]ublic interest organizations are far and away the best plaintiffs in environmental cases for the relatively greater resources and expertise they can bring to the court on . . . highly complex issues.”). But see Peter M. Lavigne, The Movement for American Ecosystem Restoration and Interactive Environmental Decisionmaking: Quagmire, Diversion, or Our Last, Best Hope?, 17 Tul. Envtl. L.J. 1, 44 (2003) (“[M]ost environmental NGOs do not have the resources to match business interests in expertise, training, or staff time.”).

316. See Mank, States Standing, supra note 187, at 1783–85 (“State AGs must respond to a broad range of constituents and therefore have incentive to serve the public interest.”); Massey, supra note 285, at 274–75 & n.103 (“State attorneys general have limited resources and are politically constrained.”).

317. See Lemos, supra note 108, at 37 (arguing that “state enforcement seems significantly less prone to overenforcement than . . . private enforcement”); Massey, supra note 285, at 279 (“An attorney general who devotes inordinate attention to litigation of public rights in federal court . . . may encounter voter discontent.”). Moreover, the political accountability of states need not undermine the effectiveness of states as a check on federal agency failure or capture by regulated interests, as the political constituencies to which the states respond may be different from those which are most effective at the federal level. See Hills, Against Preemption, supra note 24, at 23 (noting different mix of constituencies at state and federal level); Widman, supra note 141 (manuscript at 43) (same).

318. See Editorial, Health Care Reform and the Courts, N.Y. Times, May 20, 2010, at A26 (noting “many of the [attorneys general] behind these suits are running for re-election or higher office,” including lead plaintiff, Florida’s Attorney General Bill McCollum); see also Mank, States Standing, supra note 187, at 1783–84 (discussing political impact of \textit{Massachusetts} on state
state officials also underscores that states’ views about what constitutes agency failure are likely to be ideologically driven. Thus states will often disagree on this question, and allowing states a special agency-policing role may well result in legal challenges with different states on opposing sides.\textsuperscript{319}

In any event, even if states were particularly effective monitors of federal agencies, that fact alone does not suffice to justify a decision by the Court to assign them a special agency-reforming role. Functional calculations of this sort fall within the purview of the political branches. As a result, the Court needs some basis in federal law—statutory, regulatory, or constitutional—for injecting states into this role. Not surprisingly, therefore, in \textit{Massachusetts} the Court invoked constitutional federalism as authority for special state standing, emphasizing the “sovereign prerogatives” states surrender to the federal government—including the ability to protect their interests through force, foreign negotiations, and in some instances domestic regulation.\textsuperscript{320} A state’s inability to use force against sister states to protect itself is a common justification for parens patriae jurisdiction in the federal courts.\textsuperscript{321} Substantial support similarly exists for concluding the Framers intended the federal courts to serve as an alternative forum for resolving interstate disputes, including Article III’s provision for diversity jurisdiction and for disputes involving a state as a party to come within the Court’s original jurisdiction.\textsuperscript{322} But Congress was also expected to play a central—indeed, \textit{the} central—role in resolving interstate disputes,\textsuperscript{323} and political safeguards of state interests in Congress are acknowledged to form their primary protection against harmful federal enactments.\textsuperscript{324} Thus, simply the fact that the states have ceded sovereign prerogatives to the federal government does not necessarily translate into greater access to federal court for states seeking to challenge federal action.

A stronger constitutional argument, both for expanded federal court access and for a special role for the states in policing federal administration more broadly, is that the delegation of extensive policymaking responsibilities to agencies eviscerates the political checks traditionally relied upon to defend

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{319} Cf. Levy & Glicksman, supra note 153, at 12–17 (detailing how various states may have incentives to over- or underregulate, depending on their relationship to activity being regulated).
\item \textsuperscript{320} \textit{Massachusetts} v. \textit{EPA}, 549 U.S. 497, 519 (2007).
\item \textsuperscript{321} See, e.g., \textit{Georgia v. Tenn. Copper Co.}, 206 U.S. 230, 237 (1907); \textit{Missouri v. Illinois}, 180 U.S. 208, 241 (1901).
\item \textsuperscript{322} See \textit{U.S. Const.}, art. III, § 2 (defining jurisdiction of federal courts); see also \textit{Martin v. Hunter’s Lessee}, 14 U.S. (1 Wheat.) 304, 347 (1816) (discussing these various provisions for federal jurisdiction); \textit{The Federalist No. 80}, at 361–62 (Alexander Hamilton) (Ernest O’Dell ed., 2010) (same).
\item \textsuperscript{323} See \textit{Metzger, Congress, Article IV}, supra note 276, at 1475–76, 1479 (explaining Congress’s central role as justified by “precedent, federalism values, functional concerns, and history”).
\end{itemize}
\end{footnotesize}
state interests. On this account, ensuring states access to federal court to challenge federal administrative action is necessary to preserve constitutional federalism in the administrative era.\textsuperscript{325} This argument has surfaced most forcefully in the administrative preemption debate, with scholars justifying independent judicial determination of preemption issues on the grounds that agencies lack sensitivity to state interests.\textsuperscript{326} I have elsewhere questioned whether federal agencies are actually as unresponsive and opposed to state interests as these arguments suggest, but part of what ensures agency attentiveness to the states is the potential for judicial review and reversal.\textsuperscript{327} More generally, it makes sense to conclude that special protections for the states must develop in the administrative realm if federalism is to have continuing relevance in the world of national administrative governance that increasingly dominates today.\textsuperscript{328}

Importantly, however, this justification assumes a critical point: that courts can legitimately update the federal-state relationship to take account of modern administrative realities on their own, rather than leaving that task to Congress. To be sure, constitutional federalism norms may well provide some justification for such a move, and courts regularly interpret federal statutes with an eye toward constitutional values, with the doctrine of constitutional avoidance being a prime example.\textsuperscript{329} But constitutional avoidance has come in for substantial criticism as judicial aggrandizement precisely because of its free-floating constitutionalism.\textsuperscript{330} Hence, at a minimum judicial authority to

\textsuperscript{325} See, e.g., Massey, supra note 285, at 267 (“[T]he question of who has standing to challenge the exercise of that discretion should be informed by the disconnection between Congress and administrative agencies.”); see also Watts & Wildermuth, supra note 187, at 1036–37 (describing protection of state laws “from being trumped by federal agency action” as “possible sovereign interest”).

\textsuperscript{326} See, e.g., Mendelson, Presumption, supra note 27, at 721–22; Merrill, Institutional Choice, supra note 27, at 755–57.

\textsuperscript{327} See Metzger, New Federalism, supra note 27, at 2072–91. For similar skepticism and defense of agencies as attentive to state interests, see Galle & Seidenfeld, supra note 27, at 1948–83; Sharkey, Federalism Accountability, supra note 66, at 2146–55.

\textsuperscript{328} Cf. Metzger, New Federalism, supra note 27, at 2090–100 (defending use of administrative law to address federalism concerns).


import federalism values into administrative contexts requires a defense that the Court has yet to supply—indeed, it has not articulated an administrative federalism argument along these lines at all.\footnote{331}{Metzger, New Federalism, supra note 27, at 2101, 2107–09.}

Such a defense is especially needed because of the separation of powers implications of assigning the states a special agency-policing role. As noted above, animating the Summers line are concerns about restricting judicial intrusion into administrative policysetting and management, on the grounds that administrative decisions of this sort are the responsibility of elected officials and involve issues the courts are institutionally ill-equipped to resolve.\footnote{332}{See supra notes 181–182 and accompanying text.} Allowing states greater access to challenge federal agency policy and functioning in federal court thus would entail potentially significant trumping of these separation of powers concerns in the name of federalism.\footnote{333}{Cf. Bickel, supra note 284, at 89–90 ("It would make a mockery of the constitutional requirement of case or controversy… to countenance automatic litigation—and automatic it would surely become—by states…. The consequent agrandizement of the judicial function is something to contemplate.").} That separation of powers requirements may need to bend to accommodate federalism is certainly a possible constitutional outcome; these are, after all, both core constitutional structural principles.\footnote{334}{See Massey, supra note 285, at 273–76 (noting “both separation of powers and federalism are structural doctrines designed to check concentration of power” and should “join” in reaching that end).} But the appropriate balance between federalism and separation of powers concerns, and the responsibility of the courts in striking that balance as opposed to Congress, are central issues that the Court must address if indeed it intends to assign the states this role.

An alternative approach that focused more centrally on Congress would at least mitigate many of these concerns about judicial overstepping. Congress clearly has power to assign states a special role in particular federal regulatory schemes, as is evident in recent enactments authorizing expanded state enforcement of federal regulatory requirements.\footnote{335}{See Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Pub. L. No. 111-203, § 1042, 124 Stat. 1376, 2012–2014 (to be codified at 12 U.S.C. § 5552) (providing that state attorneys general may bring suit in federal district court to enforce statutory requirements or regulations issued under the Act); Widman, supra note 141 (manuscript at 16–17) (describing provisions for state enforcement in Consumer Product Safety Improvement Act of 2008); see also Lemos, supra note 108, at 8–9 (listing other federal statutes authorizing state enforcement).} Congress also can provide that “broad regulations… [are] to be the object of judicial review directly, even before the concrete effects normally required for APA review are felt.”\footnote{336}{Lujan v. Nat’l Wildlife Fed’n, 497 U.S. 871, 891 (1990).} Moreover, Congress has some leeway to provide for suits that, absent such authorization, would be deemed to involve too generalized a grievance to be appropriately raised in federal court.\footnote{337}{See Massachusetts v. EPA, 549 U.S. 497, 516 (2007) (finding congressional “power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before” (quoting Lujan v. Defenders of Wildlife, 504 U.S 555, 580 (1992)).}
Whether this emphasis on Congress represents a plausible account of the Court’s recent decisions is another matter, however. In fact, it is hard to view *Massachusetts* in this vein, given that the Court there made no mention of the central role Congress assigned the states in implementing the CAA and instead justified the states’ special standing on their position in our constitutional order. In addition, this approach leaves unanswered why the Court concluded that Congress intended the states to play an agency-policing role in *Wyeth* and the recent preemption decisions, but not in *Buckman*. Thus, even for this alternative account to work the Court must provide greater clarification about the basis on which it will infer that Congress intended the states to serve as federal agency reformers.

**CONCLUSION**

The recent preemption decisions reveal a Court struggling to forge a coherent doctrinal account of the relationship between the states and federal agencies. The decisions are notable for their willingness to consider federal agency failure in preemption analysis. But the Court offers little explanation of why it is more comfortable using state law to reform overall agency performance here than in other contexts. Although a distinction between direct and indirect efforts at agency reform seems at first to offer an appealing justification for the Court’s approach, on more sustained analysis it proves inadequate. As a result, defending the preemption decisions may require invoking a more radical conception of the states as having a special role to play in reforming federal administration. But for now that suggestion remains implicit and inchoate. Future decisions—particularly in the preemption context, but also those at the intersection of federalism and separation of powers—will reveal whether this view of the states’ role becomes a more vibrant part of the Court’s federalism and administrative law jurisprudence.