

2010

## *Wyeth v. Levine* and Agency Preemption More Muddle or Creeping to Clarity?

Ashutosh Bhagwat

UC Hastings College of the Law, aabhagwat@ucdavis.edu

Follow this and additional works at: [http://repository.uchastings.edu/faculty\\_scholarship](http://repository.uchastings.edu/faculty_scholarship)

---

### Recommended Citation

Ashutosh Bhagwat, *Wyeth v. Levine and Agency Preemption More Muddle or Creeping to Clarity?*, 44 *Tulsa Law Review* \_\_\_\_ (2010).  
Available at: [http://repository.uchastings.edu/faculty\\_scholarship/1000](http://repository.uchastings.edu/faculty_scholarship/1000)

This Article is brought to you for free and open access by UC Hastings Scholarship Repository. It has been accepted for inclusion in Faculty Scholarship by an authorized administrator of UC Hastings Scholarship Repository. For more information, please contact [marcusc@uchastings.edu](mailto:marcusc@uchastings.edu).

## **WYETH V. LEVINE AND AGENCY PREEMPTION: MORE MUDDLE, OR CREEPING TO CLARITY?**

Ashutosh Bhagwat\*

In *Wyeth v. Levine*,<sup>1</sup> the Supreme Court held that a decision by the federal Food and Drug Administration (FDA) (made pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA)) to approve the marketing of the drug Phenergan and its specific labeling, did not preempt a tort suit brought pursuant to Vermont state law in which the plaintiff, Diana Levine, claimed that the manufacturer of Phenergan, Wyeth, had not provided adequate warnings regarding the risks posed by a particular method of administration of the drug. The Court's decision has a great deal of practical significance because it permits a potentially vast number of failure-to-warn products liability suits against pharmaceutical manufacturers with respect to drugs and labels approved by the FDA. The case also represents the Court's latest pronouncement in a broader area of intense public and academic dispute which concerns the power of federal regulatory agencies to preempt state law.<sup>2</sup> The law of preemption generally, and the law of agency preemption in particular, is infamous for its vagueness and unpredictability. Does *Wyeth v. Levine* provide any clarity to this important but frustrating area of law? Or is it just more muddle? And what insight does *Wyeth* provide regarding the larger questions lurking behind this area of law, such as what the relative roles should be of Congress and administrative agencies in determining the appropriate balance of state and federal power, and what the role of the courts should be in policing those roles and boundaries? The short answer is that *Wyeth* provides some clarity, and a few answers, but it also continues to a substantial extent along the ambiguous, under-theorized, and frankly muddled path that the Court has followed in this area. The long answer is, well, long, and is the subject of the rest of this article. Part I provides background regarding the law of preemption, the significance of administrative agencies in this area, the *Wyeth* decision, and its aftermath. Part II discusses the institutional roles of agencies and Congress in this area. Finally, Part III discusses the role of the courts vis-à-vis both agencies and Congress.

---

\* Professor of Law, University of California, Hastings College of the Law (bhagwata@uchastings.edu). Thanks to Marsha Cohen for extremely helpful comments.

1. 129 S. Ct. 1187 (2009).

2. Some evidence of the significance of this dispute is that just weeks after *Wyeth* was decided, President Obama issued an Executive Memorandum on the subject. Memo. from Pres. Barak Obama, to the Heads of Executive Departments and Agencies, *Preemption*, (May 20, 2009) (available at [http://www.whitehouse.gov/the\\_press\\_office/Presidential-Memorandum-Regarding-Preemption/](http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/)) [hereinafter *Preemption*]. This memorandum and its significance will be discussed in Part I(D).

I. PREEMPTION, AGENCIES, AND *WYETH*A. *The "Law" of Preemption*

The Supremacy Clause of Article VI of the Constitution states that

[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.<sup>3</sup>

This language is understood to provide that, in the event of any sort of conflict between federal laws adopted by Congress and the law of any State, federal law shall triumph. It is also understood to empower Congress to enact legislation which explicitly nullifies state law in a particular area which Congress believes should be subject to exclusively federal regulatory control. In either case, the term used to describe the supremacy of federal law is "preemption."

That, at least, is the conventional story. As Caleb Nelson has pointed out, however, the truth is rather more complex.<sup>4</sup> By its terms, the Supremacy Clause says very little about state law and certainly does not explicitly authorize Congress to displace state law.<sup>5</sup> Instead, Nelson points out, the primary work done by the Clause is to establish that federal law is in fact the law of the land, fully enforceable in both state and federal courts,<sup>6</sup> and that in case of repugnance—what Nelson calls a "logical contradiction" between state and federal law—judges are directed to follow federal law.<sup>7</sup> Stephen Gardbaum has further argued that while the Supremacy Clause does provide for the "supremacy" of federal law in case of conflict, it does *not* authorize Congress to literally preempt state law, displacing it by express statutory language, because the Supremacy Clause does not by its terms convey any power to Congress.<sup>8</sup> The power of preemption, which is to say, the power to completely displace state law from a field, Gardbaum argues, must derive from the Necessary and Proper Clause of Article I, § 8 (though it remains true that once Congress has exercised its power, it is the Supremacy Clause which acts to invalidate all conflicting state law—meaning all state law in the area that Congress has preempted).<sup>9</sup> Indeed, Gardbaum provides evidence that the power of Congress to preempt state law which does *not* actually conflict with federal law was highly controversial for the first century of the Republic, and did not become clearly established until the twentieth century.<sup>10</sup> On this view, much of modern preemption law is confused because it fails to distinguish between two very distinct inquiries, one

---

3. U.S. Const. art. VI, § 2.

4. Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225 (2000).

5. *Id.* at 251–252.

6. *Id.* at 247–249.

7. *Id.* at 260.

8. Stephen A. Gardbaum, *The Nature of Preemption*, 79 Cornell L. Rev. 767, 770–773 (1994). It should be noted that Thomas Merrill has expressed his disagreement with this conclusion. Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. Rev. 727, 733–736 (2008).

9. Gardbaum, *supra* n. 8, at 773–783.

10. *Id.* at 785–807.

directed at congressional power and intent, the other directed at whether a conflict exists between state and federal law, a question having little to do with congressional intent. Nelson's and Gardbaum's critiques are both quite persuasive and have, as we shall see, important implications for preemption doctrine.

Whatever the merit of the above arguments, the modern law of preemption, as articulated by the Supreme Court, is not based on them. Instead, current preemption doctrine starts off from very different premises. It presumes that the Supremacy Clause is the source of all preemption. It is also (at least purportedly) based on the fundamental premise that "the purpose of Congress is the ultimate touchstone in every pre-emption case[.]"<sup>11</sup> a statement that has guided the Court's preemption analysis at least since 1963.<sup>12</sup> Finally, and perhaps most significantly, since 1947 the Court has insisted that

[i]n all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," . . . we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."<sup>13</sup>

In other words, there should be a "presumption against preemption." As we will discuss in more detail later, there is some dispute regarding the exact scope of this presumption, and there are serious doubts about whether the Court in fact follows such a presumption with any consistency. But at least in principle, this presumption underlies modern preemption law.

From these first principles, the Court has constructed an elaborate doctrinal structure within which preemption claims are to be analyzed. The Court has identified three, or really four, distinct forms of preemption.<sup>14</sup> The first, "express preemption," occurs when Congress enacts explicit language preempting state law. The scope of express preemption is, of course, defined by the language adopted. The second form of preemption is called "field" preemption. It occurs when Congress has enacted a regulatory scheme that is so pervasive in scope that it is reasonable to infer that Congress left no room for supplemental state regulation. Finally, preemption occurs when there is an "actual conflict" between state and federal law. As it happens, however, the Court has identified two quite distinct forms of conflict preemption, thereby increasing the forms of preemption to four. The first form of conflict preemption occurs when it is physically impossible to comply with both federal and state law—we might call this "impossibility" preemption. The second occurs where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"<sup>15</sup>—we might call this "purpose" or "obstacle" preemption (both terms appear to be in use).

From just this brief summary of the current doctrinal rules in this area, some of the inconsistencies and ambiguities in preemption doctrine should already be apparent. First

---

11. *Wyeth*, 129 S. Ct. at 1194 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

12. See *Lohr*, 518 U.S. at 485 (citing *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Similar language appears even earlier, in *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

13. *Wyeth*, 129 S. Ct. at 1194–1195 (quoting *Lohr*, 518 U.S. at 485 (quoting *Rice*, 331 U.S. at 230)).

14. See Nelson, *supra* n. 4, at 226–229, and cases cited therein, for a more detailed summary of the preemption doctrine.

15. *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

of all, despite the Court's insistence that Congress's intent be the "touchstone in every pre-emption case," in fact, at least some preemption analysis, notably "impossibility" analysis, has absolutely nothing to do with discerning Congress's intent (except for the unexpressed, though logical, assumption that Congress intends to preempt state laws that make compliance with federal laws impossible). Second, the clean dividing lines of the categories of preemption are somewhat deceptive.<sup>16</sup> In at least one modern decision, the Justices divided over whether a statute created express or implied preemption.<sup>17</sup> In that same decision, the Court acknowledged a great deal of overlap between field and purpose/obstacle preemption since a finding that a state law is an obstacle to federal purposes, which most typically occurs when the Court discerns a congressional purpose of exclusive federal regulation, is really no different from a finding of field preemption with respect to the specific subject matter as to which Congress intended to prohibit duplicative regulation.<sup>18</sup> Finally, and most broadly, it should be noted that of the four forms of preemption, only one—express preemption—flows directly from statutory language. The others are all forms of "implied preemption," which means that the Court is discerning congressional intent from the broader structure of statutes. Moreover, realistically in many implied preemption cases, the "congressional intent" that the Court discerns is much more a product of judicial construction than any actual congressional intent—indeed, since by definition all implied preemption cases involve situations where Congress did *not* include statutory language addressing preemption, it is reasonable to believe that Congress had absolutely no formed intent on the preemption question. Among the three forms of implied preemption, impossibility preemption is uncontroversial and unproblematic because, while it derives from congressional "intent" in an essentially fictional sense, it does flow quite naturally from the language of the Supremacy Clause. Field and purpose/obstacle preemption, however, flow from the language of *neither* a statute nor the Constitution, raising serious questions about their provenance. Indeed, the combination of the Court's two founding principles, that preemption flows from Congress and that there is a presumption against preemption, arguably suggests that neither form of preemption should exist. If Congress has not spoken to the subject, and if compliance with both state and federal law is possible, on what authority do courts find preemption?

In short, preemption doctrine is, on its face, a complex, well-established body of doctrine. Look under the surface, however, and both logic and clarity vanish. Even the surface logic that characterizes preemption doctrine disappears, however, when one examines our next topic, which is the role of administrative agencies in preempting state law.

#### B. *Preemption and Agencies—The Issues*

The description of preemption law and doctrine set forth above is based on a vision

---

16. See generally Karen A. Jordan, *Agency Preemption and the Shimer Analysis: Unmasking Strategic Characterization by Agencies and Giving Effect to the Presumption Against Preemption*, 2008 Wis. L. Rev. 69, 78–79.

17. *Gade v. Natl. Solid Wastes Mgt. Assn.*, 505 U.S. 88 (1992).

18. *Id.* at 104 n. 2.

of federal law as constituting statutes passed by Congress. That premise, however, is thoroughly out of date. Since the New Deal revolution of the 1930s, most federal law is, in fact, made by administrative agencies. The typical model for modern federal lawmaking is for Congress to pass a statute of greater or less specificity depending on the circumstances, and then empowering an administrative agency such as the Federal Communications Commission (FCC) or the Environmental Protection Agency (EPA) to implement the statute through regulations. In practice, it is those agency's regulations which constitute the binding "law" that citizens must follow.

Where do those agency regulations fall within the law of preemption? The conventional wisdom, as stated by the Supreme Court, is that "[f]ederal regulations have no less pre-emptive effect than federal statutes."<sup>19</sup> Behind this bland statement, however, lurk many questions and uncertainties. To better understand these issues, it is useful to set forth a typology of the different ways in which agencies can become involved in preemption issues.

First, it is possible for Congress to explicitly delegate to an agency power to preempt state law (as it sometimes does, though not with great frequency), and an agency can exercise that power to adopt a regulation expressly preempting state law.<sup>20</sup> Currently, it seems almost universally accepted that, given the demise of the Nondelegation Doctrine, this is permissible (though Bradford Clark raises some questions<sup>21</sup>).

Second, Congress can grant to an agency general rulemaking power—i.e., the power to adopt regulations with the force of law—without any mention of preemption, and the agency can exercise that power to adopt a regulation expressly preempting state law.<sup>22</sup> There is an ongoing academic debate, discussed in the next section, regarding the permissibility of such regulations. The Supreme Court has never explicitly resolved this question, though Justice Stevens's dissent (joined by Chief Justice Roberts and Justice Scalia) in the recent *Watters v. Wachovia Bank, N.A.* strongly suggests that he would not permit agencies to preempt state law using general rulemaking authority.<sup>23</sup>

Third, Congress can enact a statute which itself contains an express preemption clause and the administrative agency charged with administering the statutory scheme can interpret the scope of that clause. Again, there is an ongoing academic debate over the level of deference (if any) that courts should accord to such interpretations. In particular, there is disagreement about whether such interpretations should be accorded the very high level of deference, called *Chevron* deference,<sup>24</sup> the lower level of deference, termed *Skidmore* deference,<sup>25</sup> or no deference at all. The Supreme Court has

---

19. *Fidelity Fed. Sav. & Loan Assn. v. de la Cuesta*, 458 U.S. 141, 153 (1982); see also *La. Pub. Serv. Commn. v. FCC*, 476 U.S. 355, 369 (1986) ("Pre-emption may result not only from action taken by Congress itself; a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation"); *N.Y.C. v. FCC*, 486 U.S. 57, 63–64 (1988).

20. See e.g. 47 U.S.C. § 253(d) (2009).

21. Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 Tex. L. Rev. 1321, 1433–1435 (2001).

22. See e.g. *N.Y. v. FCC*, 486 U.S. 57 (1988).

23. 550 U.S. 1, 40 (2007) (Stevens, J., dissenting).

24. See *Chevron U.S.A. v. NRDC*, 467 U.S. 837 (1984).

25. See *Skidmore v. Swift*, 323 U.S. 134 (1944).

not yet clearly resolved this issue.<sup>26</sup>

Fourth, it might be that neither a statute nor agency regulations expressly mention preemption, but an agency expresses its views regarding the scope of implied preemption, typically purpose/obstacle implied preemption (though, in principle, also field preemption), created by the governing statute that it administers. Such agency pronouncements are typically expressed through relatively informal modes, such as preambles to regulations, policy statements, memorandums, amicus briefs, or interpretative rules, all of which lack the force of law. The question of whether courts should defer to such agency views is a highly contentious one, on which commentators sharply disagree, and on which the Court has given extremely mixed signals.<sup>27</sup> This issue was raised again in the *Wyeth* case and again the Court failed to clearly resolve it.

Fifth, an agency might adopt a substantive regulation, and a state law might conflict with that regulation.<sup>28</sup> In this situation, it is well established that preemption does follow. Note that in many cases involving conflicts with agency regulations, state laws can also be said to conflict with the congressional statute authorizing the regulation. In that situation, preemption is, of course, completely unproblematic. But the Court has made clear (in the quotes beginning this section) that even when a state law conflicts only with a regulation and not a statute, preemption still follows. Again, there is some academic debate over the propriety of such preemption,<sup>29</sup> but it is well accepted by the Court and seemingly by most commentators.

That, then, is a brief summary of the difficult, unresolved, and highly contested issues that arise when administrative agencies become involved in preemption. Let us turn now to a brief summary of the current academic debates in this area.

### C. Preemption and Agencies—The Academic Debate

In recent years, preemption generally, and the role of agencies in preemption in particular, have become the subject of intense academic interest. Caleb Nelson's path breaking article on the textual and historical roots of preemption doctrine, published in 2000,<sup>30</sup> probably represents the beginning of this trend, but it was several years later that the scholarship on agencies and preemption began to burgeon.<sup>31</sup> In 2008 alone, both the Duke Law Journal and the Northwestern Law Review published symposium issues

---

26. See *Watters*, 550 U.S. at 20–21 n.13 (refusing to resolve the question); but see *id.* at 41–42 (Stevens, J., dissenting) (arguing against *Chevron* deference); *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 744 (1996) (“We may assume (without deciding) that the latter question [of whether a statute is pre-emptive] must always be decided *de novo* by the courts”).

27. Compare *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000) (“We place some weight upon DOT’s interpretation of FMVSS 208’s objectives and its conclusion, as set forth in the Government’s brief, that a tort suit such as this one would ‘stand as an obstacle to the accomplishment and execution’ of those objectives”) and *Lohr*, 518 U.S. at 495–496 with *Bates v. Dow Agrosciences, L.L.C.*, 544 U.S. 431, 449–452 (2005) (finding no preemption despite the contrary position of the agency) and *Wyeth*, 129 S. Ct. at 1201 (declining to defer to the agency’s position).

28. See e.g. *U.S. v. Shimer*, 367 U.S. 374 (1961).

29. See generally Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 Duke L.J. 2023, 2069 n. 175 (2008).

30. Nelson, *supra* n. 4.

31. See generally Stuart Minor Benjamin & Ernest A. Young, *Tennis with the Net Down: Administrative Federalism Without Congress*, 57 Duke L.J. 2111, 2131 n. 79 (2008) (citing scholarship).

dedicated to the topic of preemption;<sup>32</sup> several other major articles on the topic were published that year as well.<sup>33</sup> Clearly, something is in the air (not least the Supreme Court's decision to decide the *Wyeth v. Levine* case, one suspects).

The academic debate on agencies and preemption touches upon, and demonstrates disagreement over, many of the specific issues regarding the role of agencies in preempting state law noted above. Underlying these specific points, however, is an overarching debate about institutional strengths and weaknesses. At its core, this debate concerns whether Congress or administrative agencies (or, for that matter, federal courts) are best placed to determine the proper balance between federal and state regulatory authority, which is of course the core concern triggered by preemption. A number of scholars, including Nina Mendelson,<sup>34</sup> Thomas Merrill,<sup>35</sup> Stuart Benjamin,<sup>36</sup> Ernest Young,<sup>37</sup> and Scott Keller,<sup>38</sup> favor Congress (though there is some disagreement within this group about whether agencies have any institutional strengths in this area at all). The essential argument made by these scholars harkens back to Herbert Wechsler's famous article on the political safeguards of federalism.<sup>39</sup> Wechsler's argument, in essence, was that judicial enforcement of federalism-based limits on Congress's power was unnecessary because state representation in Congress ensured that Congress itself would adequately take account of and protect the interests of the sovereign states. The group of scholars noted above turn this argument on its head by pointing out that the safeguards that Wechsler attributes to Congress do *not* exist within administrative agencies. Ernest Young in particular (drawing on previous work by Bradford Clark) identifies two different kinds of safeguards for state interests and autonomy in Congress: political safeguards, arising from the fact that states are represented in Congress, and procedural safeguards, arising from the sheer difficulty of enacting federal legislation.<sup>40</sup> As Young points out, neither of these safeguards exist at the agency level. States are obviously not represented within agencies, which are purely national, unelected institutions, and agency action faces far fewer barriers than legislative action (that is, of course, the whole point of having agencies in the first place).<sup>41</sup> Young also rejects the argument, made by Larry Kramer,<sup>42</sup> that the involvement of state officials in implementing cooperative federalism programs provides some assurance against federal administrative overreaching, pointing out that such cooperative programs may actually have the reverse

---

32. *Thirty-Eighth Annual Administrative Law Issue*, 57 Duke L.J. 1933 et seq. (2008); *Symposium on Ordering State-Federal Relations Through Federal Preemption Doctrine*, 102 Nw. U. L. Rev. 503 (2008).

33. See Scott A. Keller, *How Courts Can Protect State Autonomy from Federal Administrative Encroachment*, 82 S. Cal. L. Rev. 45 (2008); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 Geo. Wash. L. Rev. 449 (2008); Jordan, *supra* n. 16.

34. Nina A. Mendelson, *Chevron and Preemption*, 102 Mich. L. Rev. 737, 779–791 (2004) [hereinafter Mendelson, *Chevron and Preemption*]; Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 Nw. U. L. Rev. 695, 717–722 (2008) [hereinafter Mendelson, *A Presumption*].

35. Merrill, *supra* n. 8 at 755–756.

36. Benjamin & Young, *supra* n. 31, at 2146–2147.

37. *Id.*; Ernest A. Young, *Executive Preemption*, 102 Nw. U. L. Rev. 869, 876–878 (2008).

38. Keller, *supra* n. 33, at 62.

39. Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 Colum. L. Rev. 543 (1954).

40. Young, *supra* n. 37, at 876 n. 44 (citing Clark, *supra* n. 21).

41. *Id.* at 878.

42. Larry Kramer, *Understanding Federalism*, 47 Vand. L. Rev. 1485, 1544 (1994).



effect, that of eroding state officials' loyalty to localism.<sup>43</sup> Nina Mendelson and Thomas Merrill build on this argument by pointing out that the institutional structure of agencies might in fact make them particularly ill-suited to consider the benefits of preserving state autonomy because of agencies' narrow focus on achieving particular regulatory goals rather than preserving the broader structure of our system of government.<sup>44</sup> All of these are powerful arguments and make intuitive sense. Congress, after all, is made up of locally elected politicians who continue to have political roots and alliances in local jurisdictions throughout this nation. Agencies, on the other hand, are centralized, national, and unelected entities whose senior officials inevitably live and work in and around Washington, D.C. Such organizations have no particular links to the states and have an obvious bias in favor of expanding federal and, hence, their authority. In short, this argument goes, if agencies are authorized to preempt state law, they will do so far more often and more broadly than would be optimum from an overall perspective because agencies have no incentives to value continuing local control and state autonomy, despite the fact that these are important values in our constitutional system.

Despite the intuitive power of the arguments set forth above, there is an admittedly smaller, but significant group of scholars who argue to the contrary, that under modern circumstances it is agencies, and not Congress, who are best situated to determine the appropriate balance between national and state power. This argument has been advanced most clearly and strongly by Brian Galle and Mark Seidenfeld.<sup>45</sup> Galle and Seidenfeld argue that, on the criteria of transparency, deliberation, and accountability, agencies outperform Congress and, indeed, the courts (though I will focus on Congress) in their capacity to evaluate issues regarding the proper delineation of state and federal authority.<sup>46</sup> Regarding transparency, they argue that the notice-and-comment process for rulemaking which agencies must follow under the Administrative Procedure Act (APA) (as interpreted by the courts) ensures that agencies are highly transparent in the sense that agencies are obliged to disclose their thinking, and the reasons and data behind their thinking, to the public, and it is relatively easy for members of the public to communicate with agency staff.<sup>47</sup> With respect to Congress, on the other hand, though Congress operates in the public light, its actual decision-making process is often shrouded in secrecy and members of the public, other than well-organized interest groups, have effectively no access to members of Congress. With respect to deliberation, Galle and Seidenfeld emphasize the impact of modern "hard look" judicial review on agency decision-making.<sup>48</sup> Under hard look review, as articulated in Supreme Court cases such as *Citizens to Preserve Overton Park v. Volpe*<sup>49</sup> and *Motor Vehicle Manufacturers Association of the United States v. State Farm Mutual Automobile*

---

43. Young, *supra* n. 37, at 879–880.

44. Mendelson, *A Presumption*, *supra* n. 34, at 717–718; Mendelson, *Chevron and Preemption*, *supra* n. 34, at 779–791; Merrill, *supra* n. 8, at 755–756.

45. Brian Galle & Mark Seidenfeld, *Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 *Duke L.J.* 1933 (2008).

46. *Id.* at 1948–1984.

47. *Id.* at 1955.

48. *See id.*

49. 401 U.S. 402 (1971).

*Insurance Company*,<sup>50</sup> courts reviewing a final agency decision under the APA's "arbitrary and capricious" standard of review<sup>51</sup> must carefully evaluate the agency's decision and reasoning to ensure that the agency considered the relevant factors and acted rationally. The threat of such review, in turn, requires agencies to act carefully and deliberatively in their decision-making process. Congress, on the other hand, is notoriously undeliberative and also lacks the expertise that agency staff enjoy which imbues agency decision-making with a sophistication that Congress necessarily lacks.<sup>52</sup> Finally, Galle and Seidenfeld conclude, rather counter-intuitively, that even on the question of political accountability, agencies outperform Congress. Congress is of course directly elected, suggesting a high level of accountability, but in fact Galle and Seidenfeld argue, the enormous benefits of incumbency and voters' lack of knowledge makes that accountability somewhat illusory, especially in the regulatory arena where voter knowledge is often extremely limited. Agencies, on the other hand, though not elected, are subject to substantial oversight by Congress and the President, creating substantial political accountability, especially because of presidential oversight. In addition, agencies' ability to act quickly means that their decisions are more likely to reflect *current* political preferences, while congressional statutes because of inertia may well reflect preferences that have since changed.<sup>53</sup> In short, Galle and Seidenfeld argue that in the world of the modern, administrative state, administrative agencies are not only capable of properly taking into account state interests, they are better placed to do so than Congress.

Galle and Seidenfeld are not the only modern scholars touting the strengths of agencies. Gillian Metzger has likewise defended agencies' incentives and ability to properly consider state interests. She emphasizes the deep relationships between agencies and state officials through lobbying, cooperative federalism programs, and contacts in local offices, as an important avenue for the assertion of state interests. She also argues that agency expertise makes them especially well qualified to assess how state and federal authority interact in particular areas, a critical factor in determining the need for preemption.<sup>54</sup> Catherine Sharkey similarly emphasizes the significance of agency expertise in permitting administrative agencies to provide guidance regarding the need for uniform federal regulation of a particular subject (which would necessitate preemption of state regulation).<sup>55</sup> Indeed, even Nina Mendelson, who is generally hostile to agency preemption, has conceded that agencies do have some incentives to consider state interests in their decision-making process and that agencies have valuable insights to provide regarding the need for preemption.<sup>56</sup>

In short, we find in the recent scholarship two starkly different visions of the institutional competency and incentives of administrative agencies to consider the

---

50. 463 U.S. 29 (1983).

51. See 5 U.S.C. § 706(2)(A) (2009).

52. Galle & Seidenfeld, *supra* n. 45, at 1962–1979.

53. *Id.* at 1979–1984.

54. Metzger, *supra* n. 29, at 2074–2083.

55. Sharkey, *supra* n. 33, at 485–490.

56. Mendelson, *A Presumption*, *supra* n. 34, at 717–718; Mendelson, *Chevron and Preemption*, *supra* n. 34 at 769–778.

interests of the states and to preserve state autonomy. Unsurprisingly, these differences in institutional outlooks result in very different prescriptions regarding agency authority to preempt. A number of scholarly proponents of congressional authority (and opponents of agency authority), for example, have argued in favor of “clear statement” rules, under which agencies would be able to preempt state law *only* if Congress has enacted legislation which clearly and unambiguously authorizes such preemption. Thomas Merrill, for example, would require a “super-strong clear statement” before agencies could preempt state law.<sup>57</sup> Nina Mendelson similarly advocates “a showing that Congress clearly wishes to preempt state law” before an agency can preempt state law,<sup>58</sup> and Ernest Young suggests that a high level of clarity be required before agencies preempt state law.<sup>59</sup> I read these arguments as limited to *express* preemptions of state law by agency regulation, not to implied preemption, especially actual conflict preemption, since presumably there is widespread agreement that, when it is impossible for a regulated entity to comply with both a substantive federal regulation and a state law, the state law must yield (any other rule would permit the states to hamstring federal regulatory efforts). Nonetheless, the impact of these scholars’ proposals would be to eliminate the second category of agency preemption discussed above<sup>60</sup> and to narrow the first category to instances where Congress has spoken with exceptional clarity. Scott Keller would go one step further and create a “clear statement canon” which would require Congress to clearly state its intent to authorize such agency action before an agency could even substantively regulate—much less preempt—in an area of traditional state authority.<sup>61</sup> The impact of his proposal on preemption would be to substantially narrow even the fifth category of agency preemption, which is actual conflict preemption between regulations and state law, because it would eliminate many substantive agency regulations.<sup>62</sup>

In addition to clear statement requirements, scholars hostile to administrative preemption also tend to favor reduced, or no, deference to agency interpretations regarding the preemptive scope of congressional statutes or of substantive agency regulations. Nina Mendelson, for example, has argued that agency preemption interpretations should receive the lower, *Skidmore* level of deference from courts, not *Chevron* deference.<sup>63</sup> Stuart Benjamin and Ernest Young, writing together, similarly conclude that agency statements regarding the preemptive effect of federal law “would add relatively little to a preemption inquiry; the preemptive effect of federal law would have to be grounded in actions by Congress, not the agency’s judgment.”<sup>64</sup> Finally, Thomas Merrill and Ernest Young (writing alone) both advocate an approach to

---

57. Merrill, *supra* n. 8, at 767.

58. Mendelson, *A Presumption*, *supra* n. 34, at 710.

59. Young, *supra* n. 37, at 897–898.

60. See *supra* pt. I(B).

61. Keller, *supra* n. 33, at 90–91.

62. In truth, the ambiguity of the phrase “area of traditional state authority” probably makes Keller’s proposal impractical because its impact would be to disempower federal agencies from regulating vast areas of human activity. A narrower focus on clear statement requirements for preemption, on the other hand, is much more practical.

63. Mendelson, *Chevron and Preemption*, *supra* n. 34 at 797–798.

64. Benjamin & Young, *supra* n. 31, at 2140–2141.

deference on preemption issues which is *sui generis* and which modulates the level of deference courts give to agencies depending on such factors as the extent to which the agency permitted state actors to participate in its decision-making and to which it explicitly considered state interests.<sup>65</sup> On its face, thus, there appears to be quite broad-ranging agreement among this group of scholars on the deference question, and none of the scholars appear to distinguish, on the question of deference, between agency interpretations of express preemption provisions and agency interpretations of the implied preemptive scope of a statute (or for that matter, a regulation). Giving some support to this approach to deference is the fact that in a dissenting opinion in 2000's *Geier v. American Honda Motor Company* case, Justice Stevens (joined by Justices Souter, Thomas, and Ginsburg) argued that because of institutional differences between agencies and Congress, agency claims of preemption should not be accorded deference unless they were adopted through a "formal notice-and-comment rulemaking," which agency interpretations of preemptive effect almost never are.<sup>66</sup> And in his 2007 dissent in *Watters v. Wachovia Bank, N.A.* (this time joined by Chief Justice Roberts and Justice Scalia), Justice Stevens reiterated his view that agency conclusions regarding the preemptive scope of a federal statute should not receive *Chevron* deference.<sup>67</sup> Note that adding up these votes, five of the current Justices have joined opinions disclaiming deference to agency findings of preemption.

Despite this seeming consensus, however, there are, in fact, some interesting divisions, even among scholars who are generally suspicious of agency preemption, regarding the scope of deference, or non-deference, due agencies. With respect to agency interpretations of express statutory preemption provisions, all these scholars seem to agree that only reduced deference is due. With respect to implied purpose/obstacle preemption, this group seems to agree that no deference is due on the ultimate question of whether preemption exists. For some scholars, such as Scott Keller and Bradford Clark,<sup>68</sup> that seems to be the end of the matter given agencies' institutional weaknesses. However, several other scholars *would* accord deference to agencies regarding the meaning and substantive reach of a statute, even though that interpretation has obvious implications for the implied preemptive effect of the statute. Ernest Young, for example, believes that an agency's substantive interpretations must be accorded *Chevron* deference even when such interpretations have preemptive implications and (quite reasonably) he reads the Supreme Court's decision in *Smiley v. Citibank (S.D.)* as supporting this distinction.<sup>69</sup> Nina Mendelson also concedes that, because of their expertise, agencies have important contributions to make regarding the meaning of federal law and the extent to which overlapping state law might interfere with achieving

---

65. Merrill, *supra* n. 8, at 775–776; Young, *supra* n. 37, at 891–894.

66. *Geier*, 529 U.S. at 912. The reason that agency interpretations are typically announced informally rather than through notice-and-comment rulemaking is that a regulation/interpretation adopted through notice and comment itself has the force of law and can directly preempt state law, rather than merely interpret the preemptive scope of a statute (this assumes, of course, that the agency has been properly delegated preemptive power by Congress, a topic discussed earlier).

67. *Watters*, 550 U.S. at 41 (Stevens, J., dissenting).

68. See Keller, *supra* n. 33; Clark, *supra* n. 21.

69. Young, *supra* n. 37, at 885 (citing *Smiley*, 517 U.S. at 744).

federal goals.<sup>70</sup> Thomas Merrill, on the other hand, explicitly rejects the *Smiley* approach of granting *Chevron* deference on substantive but not preemptive questions,<sup>71</sup> yet even he concedes that agencies have a great deal of institutional expertise, and some important comparative advantages, in assessing pragmatic factors such as how federal and state law actually interact in an area.<sup>72</sup> Interestingly, the ultimate position adopted by these scholars has marked similarities to Catherine Sharkey's ultimate conclusions, reflecting as they do a distinction between agency views on regulatory issues and agency views on ultimate preemption questions<sup>73</sup> despite the fact that Sharkey seems generally less hostile to agency preemption.

There is thus a range of opinions, even among scholars generally hostile to agency preemption, regarding the role agencies may play in this area. On the other side, Brian Galle, Mark Seidenfeld, and Gillian Metzger are much more clear in their position, which is that there should be no special barriers to agency preemption. Preemption, in their view, is an exercise of federal power like any other and, in the modern, post-New Deal world, with the demise of the Nondelegation Doctrine, agencies are freely permitted to exercise federal power so long as a proper congressional delegation exists. Moreover, as discussed above, these authors believe that, in light of the state of modern administrative law and the requirements that it imposes on agencies, agencies are *better* placed than other federal institutions to assess the optimum balance between federal and state power. Given these views, Galle and Seidenfeld not surprisingly completely reject any "clear statement" requirement for Congress to delegate preemptive power to agencies.<sup>74</sup> In their view, any such requirement is too limiting on agency authority and unnecessary. They would require agencies to exercise delegated preemptive power only through notice-and-comment rulemaking, subject to hard look judicial review,<sup>75</sup> but that is a minor limitation since agency rules with the force of law are typically the product of such a process.<sup>76</sup> On the question of deference to agency interpretations regarding preemptive effect, Galle and Seidenfeld's view is more nuanced. They concede that *Chevron* deference may be too inflexible, but they also think that *Skidmore* deference denies agencies too much power, in particular the power to reconsider judicial pronouncements regarding the preemptive effect of statutes. Ultimately, they advocate a multifactor test which has similarities to the tests proposed by scholars such as Thomas Merrill and Ernest Young, but which does seem, on the whole, to grant agencies significantly more discretion.<sup>77</sup> Gillian Metzger is less explicit than Galle and Seidenfeld on the specific issues discussed here, but if anything, she seems to have even fewer

---

70. Mendelson, *A Presumption*, *supra* n. 34, at 718.

71. Merrill, *supra* n. 8, at 773–774.

72. *Id.* at 755–756, 775–776.

73. Sharkey, *supra* n. 33, at 491.

74. Galle & Seidenfeld, *supra* n. 45, at 2006–2009.

75. *Id.* at 2011.

76. This leaves open the question of the preemptive force of agency adjudications, whether formal or informal, since such actions have the force of law but (especially in the case of informal adjudications) are not the product of a formal process. In truth, however, it is hard to see how an agency adjudication, which is typically binding only on the parties, can have broad preemptive effect except as effectuated by a statute or substantive regulations.

77. *Id.* at 1996–2005.

qualms about agency preemption. For example, Metzger clearly rejects any clear statement rules in this area on the grounds that they would interfere excessively with federal regulatory programs.<sup>78</sup> And her general view that ordinary administrative law is sufficient to protect state interests in the federal administrative process<sup>79</sup> suggests strongly that, in her view, ordinary deference principles should be applied in this area with no special rules reducing deference on preemption issues.<sup>80</sup>

What explains these sharp differences regarding the scope of agency authority to preempt state law? Part of the explanation, as noted earlier, lies in differing views regarding the institutional capacity of agencies to properly take into account the interests of the states. But that is not the full story. A deeper, underlying difference animating the divisions among these scholars relates to their views of federalism itself, its nature, and the reasons for preserving it. Defenders of agency authority such as Brian Galle, Mark Seidenfeld, and Gillian Metzger tend to view federalism in functional and pragmatic terms, as an institutional mechanism for achieving optimum public policy. Galle and Seidenfeld are quite explicit on this matter. The following paragraph, which is worth quoting in its entirety, illustrates their view quite clearly:

At the outset, it deserves mention that this Article views the aims of federalism, whether in its abstract or economic sense, as improving the regulatory process, not the preservation of state regulatory prerogatives per se. Hence, the issue is not which institution best enables state influence over regulation, but rather which institution fosters state influence that will enhance public welfare, and not simply state officials' opportunities for rent seeking. This view, however, does not universally discount the value of having a sovereign independent of the federal government with the power to regulate. Rather, it credits the availability of dual sovereignty only as a functional matter—that is, only when that availability is related to regulatory outcomes and not simply out of some posited formalistic preference for protection of dual sovereignty.<sup>81</sup>

Metzger similarly insists that the question of whether administrative agencies “can offer adequate protection to state regulatory interests” should be answered *not* by requiring actual “success in derailing proposed administrative actions that adversely impact the states,” but only by ensuring “that state regulatory interests receive careful consideration by federal officials[.]”<sup>82</sup> The reason, she explains, is that insisting on the actual preservation of state authority is inconsistent with the modern assumption that Congress and agencies do possess the power to regulate activities and to preempt state law in the process. Thus Metzger, like Galle and Seidenfeld, seems to place little value in the actual preservation of state regulatory authority. Instead, her focus is on the efficiency of the federal administrative process.

Scholars generally hostile to agency preemption have a very different view of federalism. Instead of focusing on functional roles and pragmatic policy outcomes, they tend to see federalism as a formal, structural principle, to be adhered to regardless of its

---

78. Metzger, *supra* n. 29, at 2071–2072.

79. *Id.* at 2083–2086, 2108–2109.

80. *Cf. id.* at 2071 (noting scholarly arguments against deference in this area, and implying, without stating explicitly, that they are misplaced).

81. Galle & Seidenfeld, *supra* n. 45, at 1949 (footnote omitted); *see also id.* at 1971–1972.

82. Metzger, *supra* n. 29, at 2072–2073.

efficacy. Stuart Benjamin and Ernest Young, for example, forthrightly acknowledge that their approach to federalism is “formalist” in the sense that it requires adherence to a particular set of institutional rules (in this case, congressional primacy on matters of preemption) regardless of whether those rules best advance particular values.<sup>83</sup> Writing on his own, Ernest Young is even more explicit that at the core of federalism doctrine “is a general commitment to balance between national and state authority. That commitment is grounded not in the capacity of federalism to promote various policy values . . . but rather in constitutional fidelity.”<sup>84</sup> And Tom Merrill, describing the basic principles of federalism, emphasizes not the practical value of a federal system, but rather the structural principle that “the state governments are the locus of general sovereignty in the American federal system.”<sup>85</sup> In short, the scholarly debate over agency preemptive authority reveals fissures not only on institutional details, but also on basic principles of American constitutionalism.

#### D. *The Wyeth v. Levine Decision*

Into this maelstrom of doctrinal confusion and scholarly divisions, the Supreme Court leapt with its decision in *Wyeth v. Levine*. *Wyeth* is perhaps the most significant Supreme Court preemption decision since the groundbreaking 1992 case *Cipollone v. Liggett Group, Inc.*<sup>86</sup> which inaugurated the modern trend of finding state common law tort claims preempted by federal law.

##### 1. Facts and Regulatory Background

Diana Levine, the plaintiff in this case, was a professional musician and a resident of Vermont who suffered from serious migraine headaches. On April 7, 2000, she visited her local clinic to obtain treatment for a severe migraine. She was originally given intramuscular injections of Demerol for her headache and Phenergan, a drug manufactured by defendant Wyeth, for her nausea. Because this treatment did not work, she returned later in the day and received second doses of both drugs. This time, the drugs were administered intravenously, using the “IV-push” method under which a drug is directly injected into a patient’s veins. For reasons that are not entirely clear, however, the Phenergan escaped from Levine’s vein and came into contact with arterial blood. Phenergan is known to cause irreversible gangrene if it enters an artery, and Levine developed gangrene. Doctors were forced to amputate first her right hand, and then her entire forearm, to prevent the spread of the gangrene, as a consequence of which Levine was no longer able to pursue her musical career and, of course, incurred pain and suffering.<sup>87</sup> Levine sued her clinic, which settled her claim, and also sued Wyeth in state court on the theory that Phenergan’s labeling did not adequately warn of the dangers associated with IV-push administration of Phenergan and, more broadly, that Phenergan was not safe for intravenous administration. Wyeth raised the defense that Levine’s

---

83. Benjamin & Young, *supra* n. 31, at 2130.

84. Young, *supra* n. 34, at 872 (footnote omitted).

85. Merrill, *supra* n. 8, at 745.

86. 505 U.S. 504 (1992).

87. *Wyeth*, 129 S. Ct. at 1190–1191.

failure-to-warn claims were preempted by federal law, as a matter of both field and conflict preemption. The trial judge rejected Wyeth's defense and a jury ultimately awarded Levine \$7,400,000 in damages on her failure-to-warn claim. The Vermont Supreme Court affirmed the jury verdict, as well as the trial judge's rejection of Wyeth's preemption defense, and the United States Supreme Court granted certiorari on the preemption issue.<sup>88</sup>

To understand the nature of Wyeth's preemption claim, some understanding is necessary of the drug Phenergan and the federal regulatory scheme governing drugs. Phenergan is a brand name for promethazine hydrochloride, an antihistamine used to treat allergies and nausea. It has been approved for use in the United States since 1955. Phenergan may be administered either intramuscularly or intravenously, and if intravenously, either through the IV-push method or through the IV-drip method whereby the drug is added to a saline solution which enters the patient's veins through an already inserted IV catheter. Evidence at Levine's trial indicated that the risk of gangrene posed by Phenergan can be almost entirely eliminated through the use of IV-drip (or intramuscular injection) rather than the IV-push method.<sup>89</sup> Based on this evidence, Levine argued that Wyeth should have included stronger warnings on the Phenergan label (as discussed below, Wyeth did include some warnings) against the use of the IV-push method, and that the failure to do so made the product defective. The jury accepted these arguments and also found that Wyeth's failure to warn was the cause of Levine's injury—findings which were of course binding on the United States Supreme Court in the course of its review.<sup>90</sup>

Wyeth's preemption defense was based on the nature of the regulatory scheme governing the sale of drugs in this country. Under the FDCA, before a new drug can be sold in the United States, it must be approved for sale by the FDA. During this approval process the FDA reviews both evidence that the drug is safe and effective and the adequacy of the warning labels accompanying the drug. Injectable Phenergan was first approved by the FDA for sale in 1955. During the 1970s and 1980s, Wyeth and the FDA corresponded regarding the need for stricter warnings on the risks of gangrene resulting from IV-push administration and Wyeth duly added such labels.<sup>91</sup> It should be noted, though, that the majority and dissenting Justices in *Wyeth* appear to disagree on the amount of attention the FDA gave to these issues: the majority cites the trial judge's finding that the FDA "paid no more than passing attention to the question whether to warn against IV-push administration of Phenergan[,]"<sup>92</sup> while the dissent specifically rejects this finding.<sup>93</sup> Regardless, it is undisputed that when Levine's accident occurred in 2000, Phenergan's labeling did contain extensive language warning of the risk of gangrene associated with intravenous administration of Phenergan and also contained language stating that IV-drip administration is "usually preferable" to IV-push administration. According to the Supreme Court majority, however, Phenergan's

---

88. *Id.* at 1191–1193.

89. *Id.* at 1190, 1192.

90. *Id.* at 1193.

91. *Id.* at 1192.

92. *Wyeth*, 129 S. Ct. at 1193, 1199.

93. *Id.* at 1226 (Alito, J., dissenting).



“labeling did not contain a specific warning about the risks of IV-push administration[.]”<sup>94</sup> another finding that the dissent rejects.<sup>95</sup>

Two final and critical facts regarding the FDA regulatory scheme complete this regulatory background. The first is that FDA regulations permit drug companies to add or strengthen warnings on already-approved drugs *without* prior approval by the FDA so long as the company files a supplemental application with the FDA.<sup>96</sup> The second is that while historically (including in 2000 when the accident occurred) the FDA had taken the position that its regulation of new drugs did *not* preempt state tort law claims,<sup>97</sup> that changed in 2006. That year, the FDA issued new regulations regarding the content and form of drug labels and attached to those regulations a Preamble which stated that, in the view of the agency, FDA approval of a drug label preempted contrary state law tort claims because the FDCA made an approved label both a “floor” and a “ceiling,” thereby prohibiting states from requiring stricter warnings.<sup>98</sup> In particular, the FDA Preamble stated that state law failure-to-warn claims “threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.”<sup>99</sup> This Preamble, it should be noted, was *not* adopted through notice and comment rulemaking because it was added to the regulations after the rulemaking process had been completed—to the contrary, the FDA’s original notice of proposed rulemaking in this proceeding specifically disclaimed any preemptive effect.<sup>100</sup> Nonetheless, when the Supreme Court considered the *Wyeth* case during the October, 2008 Term, it was faced with an official agency interpretation, reiterated in an amicus brief filed by the United States, that the FDCA preempted Levine’s claims.

Based on this regulatory structure and history, Wyeth argued that the FDCA, combined with the FDA’s approval of Wyeth’s label for Phenergan, preempted Levine’s claims. In the U.S. Supreme Court, Wyeth pursued two different conflict preemption claims:<sup>101</sup> first, that it was physically impossible to comply with both federal law and the state law duty implied by the jury verdict; and second, that in any event the state law tort action was an “obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>102</sup> We now turn to the Court’s analysis of these claims.

## 2. Majority Opinion

In the U.S. Supreme Court, *Wyeth v. Levine* produced four opinions: a majority opinion by Justice Stevens, joined by Justices Kennedy, Souter, Ginsburg, and Breyer; a short concurring opinion by Justice Breyer; a lengthy opinion by Justice Thomas concurring in the judgment only; and a dissenting opinion by Justice Alito, joined by

---

94. *Id.* at 1192 (majority).

95. *Id.* at 1225–1226 (Alito, J., dissenting).

96. *Id.* at 1196 (majority).

97. *Wyeth*, 129 S. Ct. at 1202–1203.

98. 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006).

99. *Id.*

100. *Wyeth*, 129 S. Ct. at 1201.

101. In state court, Wyeth had also argued field preemption, but abandoned that claim in the U.S. Supreme Court. *Id.* at 1192.

102. *Id.* at 1193 (quoting *Hines*, 312 U.S. at 67).

Chief Justice Roberts and Justice Scalia. We begin with the majority opinion.

After setting forth the facts and regulatory background, Justice Stevens begins his preemption analysis with what he calls the “two cornerstones of our pre-emption analysis. First, ‘the purpose of Congress is the ultimate touchstone in every pre-emption case.’”<sup>103</sup> The second “cornerstone” he cites is the so-called presumption against preemption, the principle that especially when Congress legislates in a field traditionally occupied by the States, preemption should be found only if that was “the clear and manifest purpose of Congress.”<sup>104</sup> This last statement, while seemingly boilerplate, actually has a great deal of significance because, prior to the *Wyeth* decision, there was serious doubt about whether the presumption against preemption applied in cases involving implied preemption.<sup>105</sup> The *Wyeth* majority, however, unambiguously holds that the presumption applies to both express and implied preemption, rejecting the dissent’s arguments to the contrary.<sup>106</sup>

Turning then to the substantive analysis, the majority begins by quickly rejecting Wyeth’s physical impossibility claim based on its conclusion, noted above, that FDA regulations permitted Wyeth to supplement its warning label without prior FDA approval. Given this fact, the majority held, it was not physically impossible for Wyeth to provide stronger warnings for Phenergan and comply with the FDCA.<sup>107</sup> Notably, neither Justice Thomas concurring separately<sup>108</sup> nor Justice Alito in dissent<sup>109</sup> appeared to question the majority’s reading of the relevant statute and regulations in this respect (though as we’ll see, Justice Thomas did phrase the conflict analysis a bit differently from the majority).

Wyeth’s purpose/obstacle preemption claim elicited a more lengthy analysis (and some sharp disagreements among the justices, as we shall see). The majority begins its discussion by reviewing the history of the FDCA, noting that throughout its 70 year history Congress had never provided a federal monetary remedy for consumers injured by unsafe drugs and had never expressly preempted state tort law despite Congress’s awareness of its continuing existence. From this, the Court concluded that Congress did not view state tort litigation as an obstacle to federal regulation.<sup>110</sup> The majority then turned its attention to the FDA’s 2006 regulatory Preamble endorsing preemption, and how it should influence the Court’s analysis. Justice Stevens begins by noting that the FDA in this case had *not* issued a regulation with the force of law which conflicts with state law (though he notes that even in that situation “the Court has performed its own conflict determinations” without relying on agency “proclamations of pre-emption”).<sup>111</sup> He also notes that Congress has not explicitly authorized the FDA to preempt state law,

---

103. *Wyeth*, 129 S. Ct. at 1194 (quoting *Lohr*, 518 U.S. at 485).

104. *Id.* at 1194–1195 (quoting *Lohr*, 518 U.S. at 485).

105. See Young, *supra* n. 37, at 882–883 (arguing that presumption applies only in express preemption cases).

106. *Wyeth*, 129 S. Ct. at 1195 n. 3.

107. *Id.* at 1196–1199.

108. *Id.* at 1208–1211 (Thomas, J., concurring in the judgment).

109. *Id.* at 1221 (Roberts, C.J., Alito & Scalia, JJ., dissenting) (“[t]o be sure, federal law does not prohibit Wyeth from contraindicating IV push”).

110. *Id.* at 1199–1200.

111. *Wyeth*, 129 S. Ct. at 1200–1201.

suggesting that this fact has some relevance to the question of judicial deference to the agency's pronouncements. Next, in a critical passage, the majority concedes that in past cases the Court has given "some weight" to "an agency's views about the impact of tort law on federal objectives," but insists that the Court has never "deferred to an agency's conclusion that state law is pre-empted."<sup>112</sup> In other words, the *Wyeth* majority seems to clearly adopt the distinction (advocated by commentators such as Ernest Young, Nina Mendelson, and Catherine Sharkey) between deference to agency views regarding the substantive impact of state law on a federal regulation and deference regarding the ultimate question of preemption, rejecting any sort of deference on the latter issue (at least absent an agency regulation with the force of law).

Having accepted this distinction, that then left Justice Stevens with the question of whether the Court should defer to the view expressed by the FDA that state tort law interfered with the FDCA's regulatory scheme. Citing *United States v. Mead Corp.*<sup>113</sup> and *Skidmore v. Swift & Co.*,<sup>114</sup> the Court held that the FDA's views would receive *Skidmore* deference, meaning that the weight the Court would "accord the agency's explanation . . . depends on its thoroughness, consistency, and persuasiveness."<sup>115</sup> Applying this standard, the Court concluded that absolutely no deference was due to the FDA's interpretive position. The Court gives many reasons for this lack of deference, including: (a) that the 2006 Preamble was issued without notice or comment, and so without input from States or other parties; (b) that the preamble is at odds with Congress's apparent purpose; and (c) that the Preamble represents a "dramatic change in position" because for decades prior to 2006 the FDA had indicated that it did not consider state tort law to interfere with federal regulation, a position which it indeed held in 2000 when Levine was injured (the Court also cited the FDA's change in position as the reason it did not defer to the United States' amicus brief urging a finding of preemption).<sup>116</sup> Having concluded that Congress did not intend to preempt state law and having rejected deference to the agency's arguments to the contrary, the Court of course rejected *Wyeth's* purpose/obstacle preemption claim.<sup>117</sup>

### 3. Concurring Opinions

Although he joined the majority opinion in its entirety, Justice Breyer authored a

---

112. *Id.* at 1201 (citation omitted) (emphasis in original).

113. 533 U.S. 218, 234–235 (2001).

114. 323 U.S. at 140.

115. *Wyeth*, 129 S. Ct. at 1201. Under the Court's holding in *Mead Corp.*, *Skidmore* deference and *Chevron* deference would appear to be appropriate here because the FDA Preamble did not have the force of law. *Mead Corp.*, 533 U.S. at 226–227. Of course, the Court's later decision in *Barnhart v. Walton* creates some serious uncertainties about what exactly the holding of *Mead* was, but in *Wyeth* at least, the Court appears to have adhered to a fairly simple "force of law" interpretation of *Mead*. See *Barnhart v. Walton*, 535 U.S. 122 (2002); see generally Cass R. Sunstein, *Chevron Step Zero*, 92 Va. L. Rev. 187 (2006).

116. *Wyeth*, 129 S. Ct. at 1201–1202.

117. *Id.* at 1204. In an intriguing footnote towards the end of its opinion, the majority reiterates that the FDA had not, during the regulatory proceedings, considered and rejected a stronger warning against IV-push. *Id.* at 1203 n. 14. This suggests that if the FDA had in fact rejected such a warning, the Court might have found preemption here—though the majority is admittedly ambiguous on this point. If this is a fair reading of the majority opinion, it bears noting that *Wyeth* may be a narrower decision than it first appeared to be because, on slightly different facts, it might have turned out differently.

brief concurring opinion as well in which he emphasized that an agency such as the FDA may well have expertise regarding the extent to which state law interfered with federal regulation. However, Breyer insisted that if the FDA wished to implement its expert judgment on such issues, it should do so though “lawful specific regulations,” presumably with the force of law.<sup>118</sup> Such regulations might well, according to Breyer, have preemptive effect, but no such regulation existed here.

Justice Thomas wrote a lengthy separate opinion concurring in the judgment only. The opinion begins with a brief exposition of (and ode to) basic principles of federalism. The opinion then proceeds to analyze each of Wyeth’s conflict preemption claims. Regarding the impossibility claim, Thomas’s analysis largely parallels the majority’s, with one major difference. Drawing on Caleb Nelson’s work, Thomas argues that, rather than focusing on physical impossibility, conflict preemption analysis should ask whether there is a “direct conflict” between state and federal law.<sup>119</sup> Such a conflict might exist even if it was physically possible to comply with both laws if, for example, federal law creates a right (but not a duty) to engage in particular behavior which state law forbids. On the facts of *Wyeth*, however, Thomas finds no direct conflict because the FDCA and FDA regulations do not forbid drug manufacturers from changing their warning labels without FDA preapproval and they also “do not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA.”<sup>120</sup> His reading of the statute, as noted above, matches the majority’s.

It is on Wyeth’s second purpose/conflict preemption claim that Thomas departs sharply from the majority (and, perforce, the dissent). In short, Thomas states that he has come to consider the entire category of purpose/obstacle implied conflict preemption to be illegitimate because it permits courts to find preemption based on broad-based conclusions about congressional purposes which are not rooted in statutory text.<sup>121</sup> The Supremacy Clause, however, only permits federal law enacted pursuant to Article I, § 7 of the Constitution (as well as federal treaties and the federal Constitution itself) to preempt state law, a requirement which Thomas argues is not satisfied by nontextual congressional purposes discovered or constructed by courts. Having stated his basic conclusion, the bulk of the separate opinion traces the history of the purpose/obstacle prong of the Court’s preemption analysis from the 1941 *Hines v. Davidowitz* decision<sup>122</sup> through the 2000 *Geier* decision.<sup>123</sup> The thrust of Thomas’s analysis is that purpose/obstacle preemption is inherently illegitimate because it permits courts to find preemption even when Congress has *not* expressly preempted state law and there is no direct conflict between federal and state law. Indeed, Thomas goes so far as to question the entire underlying assumption of this form of analysis, which is that statutes have single, overarching “purposes” which can be frustrated by state law. As Thomas sensibly

---

118. *Id.* at 1204 (Breyer, J., concurring).

119. *Id.* at 2109 (Thomas, J., concurring in the judgment) (citing Nelson, *supra* n. 4, at 260–261).

120. *Wyeth*, 129 S. Ct. at 1210.

121. It should be noted that Thomas’s rejection of purpose/obstacle preemption mirrors Caleb Nelson’s conclusion on this point, though following a somewhat different line of analysis. See Nelson, *supra* n. 4, at 265.

122. 312 U.S. at 67.

123. *Geier*, 529 U.S. 861.

points out, statutes are often the product of legislative compromises and so often reflect multiple, even conflicting purposes such as, for example, a desire to create an effective federal regulatory program *and* to preserve state tort remedies, even if they somewhat interfere with that program.<sup>124</sup> This stark fact, Thomas argues persuasively, makes much purpose/obstacle analysis frankly incoherent. Thomas concludes by castigating the majority for relying on factors such as congressional silence to ferret out a congressional purpose to retain state tort law, which Thomas doubts exists, and which, in any event, is not relevant to proper preemption analysis.<sup>125</sup>

#### 4. Dissenting Opinion

Justice Alito wrote a lengthy and vigorous dissenting opinion which was joined by Chief Justice Roberts and Justice Scalia. As noted above, the dissent disagrees with the majority's reading of the facts in a few respects. (Notably, the dissent states its beliefs, contrary to the majority, that the FDA had given close attention to whether Wyeth's warnings regarding IV-push administration were adequate and that the Phenergan warnings in effect in 2000 specifically warned about the risks of IV-push administration.)<sup>126</sup> More importantly, however, the dissent views the case in fundamentally different terms than the majority. From the dissent's perspective, the issue raised by the case is "whether a state tort jury can countermand the FDA's considered judgment that Phenergan's FDA-mandated warning label renders its intravenous (IV) use 'safe.'" <sup>127</sup> Phrased that way, and given its factual assumptions, the dissent thought the answer obvious: surely a state jury cannot second-guess the FDA's expert judgment in this matter, and the majority's conclusion to the contrary undermines the FDA's conclusion that IV-push administration of Phenergan was safe and effective given the labeling that Wyeth used and the FDA had approved.

Much of the disagreement between the majority and dissent centers around their different readings of the factual record in this case, particularly the degree to which the FDA had made a considered judgment to reject stronger warnings for Phenergan regarding IV-push administration as well as disagreements about whether this case could be distinguished from the Court's earlier *Geier* decision. In addition, the dissent was clearly influenced to some extent by its doubts about the jury's conclusion that inadequate warning was causally related to Levine's injury,<sup>128</sup> doubts which the majority correctly points out are not truly relevant to the preemption issue.<sup>129</sup> These are all relatively narrow disagreements which are not truly relevant to our topic. There are also, however, several broader issues regarding agency preemption authority where the dissent sharply disagrees with the majority. First of all, the dissent rejects the majority's suggestion that conflict preemption should be limited to situations where an agency expresses its preemptive intent through notice-and-comment rulemaking.<sup>130</sup> Second, the

---

124. *Wyeth*, 129 S. Ct. at 1215 (Thomas, J., concurring in the judgment).

125. *Id.* at 1215–1216.

126. *Id.* at 1225–1226 (Roberts, C.J., Alito & Scalia, JJ., dissenting).

127. *Id.* at 1218.

128. *Id.* at 1217–1218.

129. *Wyeth*, 129 S. Ct. at 1194 n. 2 (majority).

130. *Id.* at 1227–1228 (Roberts, C.J., Alito & Scalia, JJ., dissenting).

dissent argues (quoting previous opinions by Justice Breyer) that the FDA's expert determination, published in its regulatory preamble, that state duty-to-warn tort liability would interfere with the FDA's regulatory program, was entitled to judicial deference, as was the amicus brief filed by the agency to the same end.<sup>131</sup> Regarding the majority's argument that the preamble did not have the "force of law" (a point obviously related to the lack of notice-and-comment rulemaking), the dissent argues that this is irrelevant since the FDA's decision to approve Phenergan's label was an adjudicatory decision which *did* have the force of law and which preempted Levine's tort claim.<sup>132</sup> It might be noted in passing that this part of the dissent's reasoning seems incorrect; because an adjudication cannot have future, binding force on non-parties,<sup>133</sup> it is difficult to see how the FDA's adjudication of Wyeth's new drug application could preempt Levine's later-arising tort claims. Third, the dissent (as noted earlier) flatly rejects the majority's conclusion that the "presumption against preemption" should apply in cases involving conflict preemption.<sup>134</sup> Finally, the dissent objects to the majority's refusal to defer to the FDA because its current argument in favor of preemption represents a change in the agency's position, pointing out that in other preemption cases the Court has tended to defer to an agency's current, not its past, positions.<sup>135</sup>

All in all, then, there are obvious and deep differences between the majority and dissenting opinions regarding the preemptive power of agencies. Where the majority seemed to insist on fairly formal agency action, ideally notice-and-comment rulemaking, for an agency to express its preemptive intent, the dissent would impose no such requirement. Where the majority rejects deference, the dissent strongly favors it. And where the majority generally expresses hostility towards preemption, but especially towards preemption by administrative agencies, the dissent expresses no such hostility. In conclusion, then, the broader theoretical questions raised by agency preemption were aired more clearly, and more explicitly, in the various opinions in *Wyeth v. Levine* than in most recent preemption cases. In the next Part, we will explore the impact of this decision on the law of agency preemption. Before turning to those questions, however, we need to explore one more recent development in the area of agency preemption, a development which occurred not in the courts, but in the executive branch.

#### E. Enter the President

On May 20, 2009, two months and sixteen days after *Wyeth* was decided by the Supreme Court, President Barack Obama issued a "Memorandum for the Heads of Executive Departments and Agencies" on the subject of preemption.<sup>136</sup> Building on President Bill Clinton's Executive Order (E.O.) 13132,<sup>137</sup> (on which more later), in his Memorandum President Obama announced his Administration's policy "that preemption of State law by executive departments and agencies should be undertaken only with full

---

131. *Id.* at 1228–1229.

132. *Id.* at 1228.

133. See generally *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759 (1969); *supra* n. 70.

134. *Wyeth*, 129 S. Ct. at 1228–1229, 1229 n. 14 (Roberts, C.J., Alito & Scalia, JJ., dissenting).

135. *Id.* at 1229.

136. *Preemption*, *supra* n. 2.

137. Exec. Or. 13132, 64 Fed. Reg. 43255 (1999).

consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.” The substantive provisions of the Memorandum read as follows:

To ensure that executive departments and agencies include statements of preemption in regulations only when such statements have a sufficient legal basis:

1. Heads of departments and agencies should not include in regulatory preambles statements that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation.
2. Heads of departments and agencies should not include preemption provisions in codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132.
3. Heads of departments and agencies should review regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption. Where the head of a department or agency determines that a regulatory statement of preemption or codified regulatory provision cannot be so justified, the head of that department or agency should initiate appropriate action, which may include amendment of the relevant regulation.<sup>138</sup>

This Memorandum has some immediate and dramatic implications for agency preemption. First and foremost, it flatly bans the practice, followed by the FDA in 2006, of announcing preemptive intent in regulatory preambles, and it orders agency heads to review any such preambles issued in the past decade (i.e., during the second Bush Administration). Second, it orders agencies to preempt state law only when justified by legal principles, including principles outlined in E.O. 13132. To understand the significance of this requirement (surely requiring agencies to follow “legal principles” is not controversial?), a closer look at E.O. 13132 is necessary.

President Bill Clinton issued E.O.13132, titled simply *Federalism*, on August 4, 1999. Most of the Order recites general principles of federalism, orders agencies to interfere with state discretion to the minimum extent possible, and requires agencies to consult with state and local officials when their actions have federalism implications (interestingly, Nina Mendelson provides quite compelling empirical evidence that federal agencies have largely ignored E.O. 13132 and its predecessor during both the Clinton and second Bush administrations<sup>139</sup>). Section Four of the Order deals specifically with preemption. The most important of its requirements are: (a) that agencies shall construe statutes to preempt state law “only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where [state law] conflicts with . . . the Federal statute”; and (b) if the statute does not preempt, “agencies shall construe any authorization [to issue regulations] as authorizing preemption of State law by rulemaking only when the exercise of State authority directly conflicts with the exercise of Federal authority . . . or there is clear evidence to conclude that the Congress intended the agency to have the authority to preempt state law.”<sup>140</sup>

---

138. *Preemption*, *supra* n. 2.

139. Mendelson, *A Presumption*, *supra* n. 34, at 718–719.

140. Exec. Or. 13132, 64 Fed. Reg. at 43257.

Between them, the Obama Memorandum and E.O. 13132 (which has never been revoked, though it was mostly honored in the breach during the second Bush Administration) appear to resolve many of the specific issues and concerns discussed above. By requiring codification of preemptive regulations, the Memorandum bans the sort of preemption-by-stealth attempted by the FDA in 2006. E.O. 13132 appears to go even further by permitting agencies to interpret statutes to preempt state law only if “clear evidence” exists of Congress’s preemptive intent, and by permitting agencies to themselves preempt state law only in instances of a “direct conflict” between federal and state law or where there is “clear evidence” that Congress intended to authorize agency preemption. If the Obama Administration follows through on the President’s expressed resolve to adhere to E.O. 13132, it would seem that many of the conflicts regarding the appropriate scope of agency preemptive authority have been resolved. In fact, however, it is probably too early to declare the battles resolved because the Obama Memorandum and E.O. 13132 have important limitations.<sup>141</sup>

The most important limitation of the Obama Memorandum and E.O. 13132 is that they directly constrain only *executive* agencies and departments, not independent agencies. The Obama Memorandum, by its terms, is directed only to executive departments and agencies, and while E.O. 13132 does state that independent agencies are “encouraged” to comply with the Order,<sup>142</sup> that is an implicit admission that they have no obligation to do so. As such, the possibility remains open that independent agencies will continue to claim expansive preemptive authority during the coming years.

Second, the debate over whether a “clear statement” by Congress should be required before agencies claim express preemptive authority is not quite resolved by E.O. 13132 or the Obama Memorandum. E.O. 13132 does require “clear evidence” of congressional intent to authorize agency preemption, but that is not quite the same as a clear statement rule, which would require an express and unambiguous authorization of preemption. “Clear evidence” is a pliable standard, and it is quite easy to envision agencies finding such evidence in statutory structure, even absent plain language mentioning preemption. Thus, the question of whether a grant of general rulemaking power by Congress authorizes agency preemption remains unresolved.

Third, E.O. 13132 continues to permit agencies to construe a statute to preempt state law in case of a “conflict.”<sup>143</sup> The term “conflict” would appear to incorporate not only physical impossibility, but also purpose/obstacle preemption (which, remember, is a branch of implied conflict preemption). Thus, an agency remains empowered to interpret a federal statute to preempt state law if it concludes that state law stands as an obstacle to Congress’s purposes. This, however, is precisely what the FDA did in its 2006 Preamble.<sup>144</sup> Of course, under the Obama Memorandum, the FDA can no longer make such an argument in a preamble; but it remains able to do so in a codified regulation or, for that matter, in an amicus brief.

---

141. For simple political reasons, conflicts over agency preemption are, of course, likely to arise less frequently during the Obama Administration than during the second Bush Administration.

142. Exec. Or. 13132, 64 F.R. at 43259.

143. *Id.* at 43257.

144. 71 Fed. Reg. at 3934–3936.



Fourth, E.O. 13132 permits agencies to preempt state law themselves in case of a “direct[ ] conflict[ ]” between federal and state law.<sup>145</sup> The phrase “direct conflict” *might* be read to include only physical impossibility, but that is not an inevitable reading. Admittedly, equating “direct conflict” with physical impossibility is probably the better understanding, and in *Wyeth*, Justice Thomas argues that the Court has generally used the term “direct conflict” interchangeably with physical impossibility. But then Thomas himself goes on to suggest that “direct conflict” should be a broader category than impossibility.<sup>146</sup> Moreover, on a few occasions the Court does appear to have used the phrase “direct conflict” to refer to both impossibility and purpose/obstacle preemption.<sup>147</sup> Thus there is enough play in the joints of this part of E.O. 13132 that it may not fully foreclose the possibility that an agency, on its own authority, might preempt state law on the basis of a conclusion that state law stands as an obstacle to the purposes of a federal regulatory scheme. Given the capaciousness of purpose/obstacle preemption, this is a broad power indeed.

Finally, the most obvious limitation of the Obama Memorandum and E.O. 13132 is that they can always be revoked by a future administration or ignored by agencies.<sup>148</sup> Presidential revocation of the Obama Memorandum is certainly a real, albeit not imminent possibility, and the history of administrative flouting of E.O. 13132 recited by Nina Mendelson<sup>149</sup> suggests that ignoring these presidential commands is also quite plausible. For all of these reasons, the issue of agency preemption has likely not gone away, though it may enter a period of short-term abeyance. Continued attention to the these issues is therefore quite justified.

## II. AGENCIES AND CONGRESS

As discussed in the previous Part, underlying the debate about agency preemption are large, institutional questions regarding the relative institutional competencies of Congress and administrative agencies in determining the ideal division of authority between the federal and state governments. What insights does the *Wyeth* decision offer on these issues? It is to that question that we now turn.

### A. *The Impact of Wyeth*

Let us begin with the relatively narrow question of what *doctrinal* impact *Wyeth v. Levine* is likely to have on the law of agency preemption. It is of course difficult to know for certain what that impact will be without knowing how future courts will use and cite the opinion, but some educated guesses are possible. First of all, it does seem relatively clear that *Wyeth* has resolved one doctrinal question, holding that the presumption against preemption applies in implied conflict preemption cases as well as in express

---

145. Exec. Or. 13132, 64 F.R. at 43257.

146. *Wyeth*, 129 S. Ct. at 1209 (Thomas, J., concurring in the judgment).

147. See e.g. *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504 (1988); *Rose v. Rose*, 481 U.S. 619, 632 (1987); *Philko Aviation v. Shacket*, 462 U.S. 406, 410–411 (1983).

148. Since neither the Memorandum nor the E.O. create judicially enforceable rights, an agency’s ignoring of either provision would not assist a litigant challenging agency preemption.

149. Mendelson, *A Presumption*, *supra* n. 34, at 718–719.

preemption cases. The majority explicitly so holds, much to the dissent's chagrin. Of course, there is some doubt about the significance of this holding—commentators point out that the Court's invocation and use of the presumption against preemption has been quite inconsistent.<sup>150</sup> Nonetheless, even if at the Supreme Court level this holding may not have great significance, it is likely to have some impact on decisions in the lower federal courts and in state courts where, after all, most cases are actually decided.

On more specific issues relating to agency preemptive authority, however, *Wyeth* is rather less clear. The first set of such questions tends to revolve around agency regulations which seek expressly to preempt state law, and in particular about agency authority to issue such regulations. *Wyeth*, of course, did not directly address this area because the FDA had not adopted preemptive regulations (the FDA Preamble was not, to reiterate, a regulation with the force of law). Nonetheless, the *Wyeth* majority does evince a distinct tone towards agency preemption, and that tone is generally hostile. For example, in deciding what weight to give the FDA's views on preemption, the majority relies heavily on the fact that "Congress has not authorized the FDA to pre-empt state law directly," contrasting the FDA's lack of express preemptive authority with other agencies to whom Congress has expressly delegated preemptive power.<sup>151</sup> While not rising to the level of a holding, this reasoning does suggest that an admittedly bare majority of the Justices is endorsing the view that agency preemptive authority requires an express delegation of preemptive power by Congress, not just a general delegation of rulemaking authority. Again, the jury is still out on this issue, but perhaps the writing is on the wall (to happily mix a metaphor).

That leaves the question of conflict preemption. *Wyeth* leaves untouched the basic proposition that "an agency regulation with the force of law can pre-empt conflicting state requirements,"<sup>152</sup> a proposition which, as noted above, is not truly controversial. Importantly, however, *Wyeth* unambiguously states that when an agency expresses its views on whether state law conflicts with federal law (presumably either a statute or an agency regulation), courts do *not* defer to the "agency's conclusion that state law is pre-empted."<sup>153</sup> Instead, deference, if any, is given only to the "agency's explanation of how state law affects the regulatory scheme."<sup>154</sup> Again, this is an important clarification of existing law, adopting, as noted earlier, a dichotomy generally favored by scholars.

The final, probably critical question, is *what* level of deference is due to the agency's views regarding the interaction of state and federal law. Here, unfortunately, the *Wyeth* decision is less than crystal clear. The Court clearly applies *Skidmore* rather than *Chevron* deference, but that decision may have been driven more by the informal nature of the FDA Preamble than by the preemption context—i.e., the Court does not foreclose the possibility that a future, more formal statement of the agency's views on deference (perhaps as the result of a formal adjudication) might deserve *Chevron*

---

150. See Sharkey, *supra* n. 33, at 458–459, 458 n. 30; see also *Cuomo v. Clearing House Assn., L.L.C.*, 129 S. Ct. 2710, 2720 (2009) (declining to invoke presumption, in a case decided less than four months after *Wyeth*).

151. *Wyeth*, 129 S. Ct. at 1201, 1201 n. 9.

152. *Id.* at 1200.

153. *Id.* at 1201.

154. *Id.*

deference. Moreover, the Court's application of *Skidmore* deference is also somewhat perplexing. The majority's bottom line, of course, is clear: "the FDA's 2006 preamble does not merit deference."<sup>155</sup> However, the Court had earlier conceded that agency views on the impact of state law on federal regulation merited "some weight," especially in highly technical areas (which FDA regulation of drugs surely is).<sup>156</sup> Why, then, the Court did not give *any* weight to the FDA's views here is rather unclear. One reason given by the Court is that the FDA's views are "at odds with what evidence we have of Congress' purposes"<sup>157</sup>; but that is nonsensical since the question of whether state tort law interferes with federal regulation is surely independent of whether Congress intended to tolerate such interference. The Court also heavily emphasizes the fact that the FDA Preamble represents a change in position for the agency.<sup>158</sup> Again, however it is not quite clear why that is significant. In another administrative law case decided just two months after *Wyeth*, the Court explicitly held that an agency change of position does not elicit any special judicial review or suspicion,<sup>159</sup> and the FDA's 2006 Preamble provided a quite thorough explanation of why it considered recent state tort decisions to threaten the balance drawn by the FDCA.<sup>160</sup> Finally, the majority also relies heavily on the fact that the FDA had not enacted a regulation with the force of law to reject deference and as the primary means to distinguish the Court's earlier *Geier* decision.<sup>161</sup> Once more, however, the Court shoots and misses. In *Geier*, the question had been whether state tort law interfered with federal policies expressed in an agency regulation with the force of law. In *Wyeth*, the question was whether state tort law interfered with federal policies expressed in the FDCA and in the FDA's decision to approve Wyeth's Phenergan warning label, an adjudicatory decision with the force of law. But in both cases, the agency's views regarding whether such interference occurred were not expressed in regulations, they were expressed less formally, including (as Justice Alito's dissent points out) in amicus briefs.<sup>162</sup> In short, while the tone of the *Wyeth* majority towards deference is an unrelentingly hostile one, Justice Stevens's opinion notably fails to explain *when* deference is justified and when it is not.

The *Wyeth v. Levine* decision thus provides some, but only limited clarity on issues relating to agency preemption. One way of reading *Wyeth*, a reading clearly hinted at by the dissent, is that, in writing this opinion, Justice Stevens was converting into holdings views about (and hostility to) agency preemption expressed in his earlier dissents in the *Geier* and *Watters* cases. Some support for this position can be found in the fact that the *Geier* dissent was joined by Justices Souter, Thomas, and Ginsburg, all of whom also voted for the result in *Wyeth*. This view, while somewhat convincing, raises as many questions as it answers. For one thing, it cannot explain why Justices Kennedy and Breyer joined Stevens's opinion. More oddly, Stevens's dissent in *Watters* was joined by

---

155. *Id.*

156. *Wyeth*, 129 S. Ct. at 1201 (quoting *Geier*, 529 U.S. at 883).

157. *Id.* at 1201.

158. *Id.* at 1201–1203.

159. *FCC v. Fox TV Stations, Inc.*, 129 S. Ct. 1800, 1810–1811 (2009).

160. 71 Fed. Reg. at 3934–3936.

161. *Wyeth*, 129 S. Ct. at 1203.

162. *Id.* at 1228–1229 (Roberts, C.J., Alito & Scalia, JJ., dissenting) (citing *Geier*, 529 U.S. at 881, 883).

Chief Justice Roberts and Justice Scalia, the same pair that joined Justice Alito's *Wyeth* dissent. In short, while Justice Stevens has quite consistently, for the past decade at least, expressed views hostile to agency preemption, the other justices do not seem to take any consistent position on this matter, often joining opinions which seem to flatly contradict each other. Given the uncertainties noted above regarding the precise scope of the holding in *Wyeth*, this situation seems to promise more muddle to come.

### B. Institutional Competencies and Federalism

*Wyeth's* contributions to doctrinal transparency in the area of agency preemption, then, are real, but limited. What of the deeper institutional and constitutional issues lurking here—does *Wyeth* provide any clarity? Again, the answers are mixed. As discussed above, one of the fundamental divisions driving views about agency preemptive authority revolve around the relative institutional capacities of Congress and agencies to properly consider the interests of the sovereign states in making preemptive decisions. Unsurprisingly, the Justices in *Wyeth* do not directly confront these questions. There are, however, undoubtedly clear tones expressed in the opinions on this issue which may be of some relevance in later decisions.<sup>163</sup> The five justice majority, lead by Justice Stevens, clearly has doubts about agency capacity to consider state interests. Justice Stevens made this point explicitly in his earlier dissent in *Geier*,<sup>164</sup> and his hostility to the FDA in *Wyeth* appears to reflect a similar view of agencies. Justice Thomas avoids the question by rejecting the doctrinal framework on which the FDA's support of preemption was built, but Justice Alito's opinion clearly endorses the contrary view that agencies enjoy expertise and so should be deferred to even when the result is preemption of state law, implicitly assuming that agencies will give adequate consideration to states' sovereign interests.

Case closed then, three justices in favor of agency expertise, five justices opposed? Unfortunately, not. For one thing, while Justice Breyer joins Justice Stevens's opinion in full, he also writes separately to emphasize the FDA's expertise. His opinion suggests that the reason he is not deferring to the FDA in this case is because the FDA did not enact specific regulations.<sup>165</sup> This explanation is belied (or at least obfuscated) by the fact that Justice Breyer himself, in an earlier decision *involving FDA preemption*, wrote a separate opinion endorsing agency expertise as expressed in regulations *and* "through statements in 'regulations, preambles, interpretive statements, and responses to comments',"<sup>166</sup> and even more confusingly, Justice Breyer was the author of the *Geier* majority opinion which deferred to some extent to an agency amicus brief. On the flip side, as noted above, just two years before *Wyeth*, Chief Justice Roberts and Justice

---

163. Cf. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487 (1951) ("It is fair to say that in all this Congress expressed a mood.").

164. *Geier*, 529 U.S. at 908 (Stevens, Souter, Thomas & Ginsburg, JJ., dissenting) ("Unlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed regulations that have broad pre-emption ramifications for state law.").

165. *Wyeth*, 129 S. Ct. at 1204 (Breyer, J., concurring).

166. *Lohr*, 518 U.S. at 506 (Breyer, J., concurring in part and concurring in the judgment) (quoting *Hillsborough Co. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 721 (1985)).

Scalia, Justice Alito's fellow dissenters, joined a dissenting opinion by Justice Stevens which explicitly and powerfully objected to agency preemptive authority because of agencies' institutional inability to properly value federalism.<sup>167</sup> As with deference, then, the bottom line would appear to be that, with respect to the justices' views on larger institutional questions, all is chaos.

Perhaps it is time, then, to step back and consider the bigger picture along with a dose of realism. The scholarly debate regarding the institutional merits of Congress and agencies turns, in essence, on the relative values of the political representation of states within Congress as opposed to the expertise and more open rulemaking procedures of agencies. The truth is, however, that the relentless expansion of national authority since the New Deal, across the decades, enacted through statutes and regulations, and regardless of which political party controls either Congress or the Presidency, leaves one with grave doubts that *any* national entity has any serious incentives or desire to protect state autonomy. As Ernest Young and Stuart Benjamin point out, in practice, administrative agencies have demonstrated little inclination to preserve state power.<sup>168</sup> At the same time, it is hard to argue with a straight face that either Congress or the President has seriously prioritized the preservation of state authority over any length of time. To the extent that Congress appears less inclined to preempt state tort law than agencies or the President (which it does), it is far from clear that this is because Congress is responding to the interests of the states as opposed to the plaintiffs' bar. In short, the true answer to the institutional debate may well be that there are no winners here, that *no* federal institution can be trusted to protect state interests.

If one accepts this bleak but plausible conclusion, then a difficult question arises. Historically, state autonomy was protected by limiting the scope of national power. National power, in turn, was limited through two mechanisms: enforcing limits on the scope of the national government's enumerated powers, especially the commerce clause,<sup>169</sup> and restricting the power of Congress to delegate its authority to administrative agencies through the Nondelegation Doctrine, thereby limiting the effective reach of federal law.<sup>170</sup> Both of those restrictions, however, were essentially eliminated after 1937 and, other than a brief and inconsequential flirtation with reviving commerce clause restrictions from 1995 through 2000,<sup>171</sup> there are no signs that the modern Supreme Court has any intention of restoring those limits.<sup>172</sup> Finally, at least since 1984, it has been a fundamental tenet of our system that administrative agencies acting within their spheres of authority are entitled to substantial deference from courts.<sup>173</sup> The result is a system of government with essentially unlimited national authority, almost all of which is wielded by administrative agencies. This governmental

---

167. *Watters*, 550 U.S. at 41 (Stevens, J., Roberts, C.J. & Scalia, J., dissenting).

168. Benjamin & Young, *supra* n. 31, at 2154.

169. See e.g. *Hammer v. Dagenhart*, 247 U.S. 251 (1918); *A.L.A. Schechter Poultry Corp. v. U.S.*, 295 U.S. 495 (1935).

170. See *Panama Refining Corp. v. Ryan*, 293 U.S. 388 (1935); *Schechter Poultry*, 295 U.S. 495.

171. See e.g. *U.S. v. Lopez*, 514 U.S. 549 (1995); *U.S. v. Morrison*, 529 U.S. 598 (2000).

172. See *Gonzales v. Raich*, 545 U.S. 1 (2005) (rejecting a commerce clause challenge to a congressional statute regulating the growing of marijuana at home for medical purposes); *Whitman v. Am. Truckers Assn.*, 531 U.S. 457 (2001) (largely acknowledging the modern demise of the Nondelegation Doctrine).

173. See *Chevron*, 467 U.S. 837.

structure was born of the perceived need, under modern circumstances, for expeditious, expert, and centralized regulatory authority. The question then arises, if citizens and the courts have accepted the need for this structure in all other areas, at the expense of structural federalism, why should there be any special rules regarding preemption? Nowhere else do courts insist on specific delegations of authority, and nowhere else do courts deny deference to the expert opinions of agencies, so why in the area of preemption?

The answer to this question, if one exists, must lie in some vision of why preemption is special, which, in turn, derives from an understanding of why federalism matters. Much of the discussion of federalism in our society focuses on the supposed practical benefits of federalism such as efficiency, maximizing individual choice by permitting local majorities to decide issues, and permitting experimentation.<sup>174</sup> In fact, however, as *The Federalist Papers* (and, for that matter, the context of the American Revolution) make quite clear, the original goal of a federal system of dual sovereigns was neither efficiency nor other perceived utilitarian benefits, it was to restrict the power of the government, especially the federal government, by creating competing *loci* of power within our society. James Madison made this point explicitly in *Federalist No. 51*<sup>175</sup> and in *Federalist No. 46*, where he set forth in detail the mechanisms by which state governments could resist national tyranny or usurpations of power.<sup>176</sup> And there is, of course, also the Second Amendment with its vision of state militias resisting national military authority, which further confirms this understanding. Such resistance, along with the division of authority between separate sovereigns and the competition for political favor between different levels of officials, is not particularly likely to yield an efficient government or optimal public policy outcomes, but it is nonetheless a fundamental aspect of our structure of government for completely separate, structural reasons.

Consider now administrative agencies. Scholars such as Brian Galle, Mark Seidenfeld, and Gillian Metzger are drawn to agencies because, in their view (and their view is quite persuasive in this regard), agencies are best placed to determine the allocation of authority between national and state governments which is likely to yield the most efficient and best public policy outcomes. The reason is that agencies are experts and they are efficient. The problem is, of course, that efficiency is beside the point. The Constitution preserves state authority even when it is inefficient; indeed, in some sense it divides authority because it *is* inefficient and so limits the reach of federal power. Our system of government is not particularly designed to make the trains run on time, with all that that implies. Insofar as administrative agencies represent the epitome of centralized, efficient government, it is precisely this fact which makes them such a threat to the structural functions of federalism. Of course, since the New Deal we have to some extent accepted that threat by permitting national, administrative authority to

---

174. See generally Geoffrey R. Stone, Louis Michael Seidman, Cass R. Sunstein, Mark V. Tushnet & Pamela S. Karlan, *Constitutional Law* 169–171 (6<sup>th</sup> ed., Aspen 2009).

175. James Madison, *The Federalist No. 51*, in *The Federalist Papers* 261 (Garry Wills ed., Bantam Books 1982).

176. James Madison, *The Federalist No. 46*, in *The Federalist Papers*, *supra* n. 175, at 237. For a more detailed examination of these issues, see Ashutosh Bhagwat, *Cooper v. Aaron and the Faces of Federalism*, 52 St. Louis U. L.J. 1087, 1097–1099 (2008).

expand enormously. Preemption, however, may be one step too far. The reason is that preemption poses an especially direct threat to structural federalism. When federal law preempts state law, it completely eliminates state governments as a source of competing authority in a way that neither the expansion of federal authority alone nor even cooperative federalism programs accomplish. Preemption, in other words, completely eliminates state governments as competing *loci* of power in particular areas, and as preemption proceeds apace, it threatens to eliminate state governments as *loci* of power altogether. That, of course, is an arrow to the heart of structural federalism.

The threat posed by preemption is well demonstrated by the facts of *Wyeth v. Levine* and by the increase in federal preemption of state tort law more generally.<sup>177</sup> Federal regulation of industries such as the pharmaceutical industry typically proceeds on the presumption that expert administrators can create and enforce sufficiently effective regulatory rules to protect the public from harm. The focus of such programs is on technical standards, expertise, and command-and-control measures. It is *not* on providing compensation for individuals harmed by industry actions. Compensation, rather, has traditionally been the function of state tort law.<sup>178</sup> Moreover, federal agencies are, of course, potentially subject to industry capture, creating a risk that firms in a particular industry will be subject to no effective oversight, while also, if preemption is found, being freed from any obligation to compensate victims. State tort juries, for all of their faults, cannot be captured. All of which is to say that federal regulation and state tort law act as competing forms of regulation which, when overlapping, provide alternative models of how particular problems should be addressed by government. Such competition can sometimes lead to inefficiency, but within limits that is one of the costs of federalism.

Of course, all of the objections to preemption stated above apply equally to congressional as to agency preemption. Why then should there be any special rules limiting agency preemption? Part of the answer must lie in the fact that the text of the Supremacy Clause expressly states that laws passed by Congress (but not regulations passed by agencies) will displace state law. Yet another part of the answer must lie in Congress's greater (albeit still limited) accountability, which restricts the extent to which it is likely to preempt truly popular state law. Another important, and related, part of the answer must lie in Congress's greater *legitimacy*. When Congress acts to preempt state law, such a decision can meaningfully be described as a choice by the People of the United States to repose their confidence in federal rather than state officials, a choice that Madison argues in the *Federalist* should be available to them (though only within limits).<sup>179</sup> But perhaps most importantly, it may well be that it is the sheer inertia and inefficiency of Congress, what Ernest Young, citing Bradford Clark, calls the

---

177. See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 De Paul L. Rev. 227 (2007).

178. See *Wyeth*, 129 S. Ct. at 1202 (noting the "distinct compensatory function" of state tort law). Of course, compensation is not the only function of tort law. Regulation of primary conduct is also an effect and objective of a tort system. In the context of *Wyeth*, such regulatory effects can interfere with federal policy, but they can also complement it by providing pharmaceutical firms with incentives to strengthen label warnings without FDA prodding (which will often not be forthcoming, given limited agency resources).

179. Madison, *supra* n. 175, at 237–238.

“procedural safeguard” of federalism,<sup>180</sup> that provides the strongest answer for trusting Congress more. Even if Congress had the will to eliminate large swathes of state authority, this argument goes, it will be unable to do so because of its difficulty in acting, especially on controversial topics. All of these arguments have some merit, and provide some practical basis for preferring Congress to agencies as the source of preemption. It must be conceded, though, that congressional preemption remains a potent threat to federalism, and that therefore, absent a revival of substantive limits on national power, all of this debate over agency preemption may be a minor sideshow, fiddling while Rome burns.

### III. WYETH AND THE COURTS

In the previous Part, we discussed the relative roles of Congress and agencies in preempting state law, and concluded (rather gloomily) that while neither institution is likely to be particularly committed to protecting state autonomy, on balance, placing greater responsibility on Congress is probably the best outcome that we can hope for. We now consider the role of the third branch of government, the judiciary, in protecting state interests when making preemption decisions. As we shall see, the *Wyeth* decision, and Justice Thomas’s separate opinion in particular, provides some interesting insights on the role of the courts in this area.

Just as the question of whether a clear statement rule should be imposed on congressional delegations of preemptive authority to agencies can be analyzed based on the comparative institutional advantages of Congress and agencies, the question of judicial deference to agency preemptive pronouncements can be considered from the vantage of the comparative institutional strengths of agencies and courts. The greatest comparative strength of agencies is, of course, their expertise and their familiarity with the intricacies of federal regulatory programs. In addition, agencies are probably *more* politically accountable than courts because of presidential influence, because of congressional influence, and because agency heads lack life tenure. As a consequence, agencies may be somewhat more responsive to state interests. On the other hand, courts also have some comparative strengths. For one, their lack of accountability makes them less prone to capture by industry and the consequent devaluing of state interests. In addition, agencies often have incentives to expand their own sphere of authority by supplanting state law, incentives which are much less relevant to the work of courts. Finally, and most significantly, judges, unlike agency administrators, are trained to, and are relatively well placed to, give attention to fundamental constitutional concerns such as the importance of retaining a strong system of structural federalism.

Arguably, these comparative strengths and weaknesses played out well in the *Wyeth* decision. For example, the majority’s holding that agencies should be granted some deference on technical questions regarding the interaction between federal and state law, while not receiving any deference on ultimate conclusions regarding deference, nicely balances agencies’ expertise with their tendency to undervalue structural federalism. In addition, the *Wyeth* majority’s ultimate decision *not* to defer to the FDA’s

---

180. Young, *supra* n. 37, at 876, 876 n. 44 (citing Clark, *supra* n. 21).



2006 Preamble also probably reflects institutional factors, in particular a perception on the part of the majority that the FDA's decision to support preemption was driven not by its expert judgment, but rather by politics and perhaps capture. Such a reading certainly explains the majority's emphasis of the fact that the FDA's 2006 Preamble represented an unexplained change of position for the agency. Indeed, the Court's special concerns about agency flip-flops here, which are not necessarily followed in other administrative contexts even when those flip-flops appear to have been influenced by politics,<sup>181</sup> may well be a product of special judicial sensitivity to underlying federalism values.

All of this, however, may be a bit too sanguine. As Justice Thomas's separate opinion in *Wyeth* argues, there is a strong argument to be made that, in recent years, courts in fact have *not* been sufficiently sensitive to state interests and have been far too willing to find preemption without clear authorization from Congress. Thomas traces the problem to the development and expansion of the purpose/obstacle prong of preemption analysis, and he makes a compelling case. As Thomas points out, criticism of this doctrine goes back to its very roots in the 1941 *Hines v. Davidowitz* decision.<sup>182</sup> More recently, Justice Kennedy sharply criticized the doctrine in his separate opinion in *Gade v. National Solid Waste Management Association*, describing the doctrine as creating the danger of a "judicial inquiry into whether a state statute is in tension with federal objectives."<sup>183</sup> Thomas adds to this by pointing out that the Court's application of the purpose/obstacle doctrine in the 2000 *Geier* case permitted the Court to find preemption even in the face of an express statutory savings clause addressed to state tort law.<sup>184</sup> Indeed, the Court's decision in *Geier* has obvious and troubling similarities to the FDA's actions in *Wyeth*, preempting (or, in the FDA's case, seeking to preempt) state law without any direct conflict between federal and state law or any indication that Congress so intended.

If purpose/obstacle preemption is understood as preemption by the courts, then the problems with it become obvious. Justice Thomas criticizes the purpose/obstacle doctrine on the grounds that it permits a finding of preemption completely untethered to any statutory text enacted by Congress, a result which he says violates the Supremacy Clause's limitation that only laws made pursuant to the Constitution can preempt state law. Whether or not this textual argument is convincing, there are serious institutional reasons to be concerned about purely judicial preemption. Judges, like agencies, are not constituted to represent state interests, and while judges are perhaps more sensitive to constitutional principles than agencies, that does not ensure that in individual cases they will place value in retaining particular state laws to which they might otherwise be ideologically hostile. Moreover, the complete lack of political accountability of judges means that the States, and citizens, have no practical way (beyond amicus briefs) to exert influence on courts to preserve state autonomy. Finally, judges, while perhaps not as efficient as agencies, are far more efficient than Congress. It is true that they play a

---

181. See e.g. *Fox TV*, 129 S. Ct. at 1810–1811; *Chevron*, 467 U.S. at 863–864.

182. *Wyeth*, 129 S. Ct. at 1212–1213 (Thomas, J., concurring in the judgment) (citing *Hines*, 312 U.S. at 75–79 (Stone, J., dissenting)).

183. 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment).

184. *Wyeth*, 129 S. Ct. at 1213–1215 (Thomas, J., concurring in the judgment).

relatively passive role, since they can only act when litigation is initiated; but in our complex, litigious society, that is not a particularly high barrier, especially in areas like preemption where the financial stakes are often extremely high. And once a case is initiated, it is essentially trivial for a judge to find state law preempted.

In short, there seems a strong argument that Justice Thomas was right on the mark in *Wyeth* in suggesting that the real culprit in the preemption area is not the administrative state, but rather the doctrine of purpose/obstacle preemption itself. It is this doctrine which empowers courts *and* agencies to seek to preempt state law relatively easily without any evidence of congressional intent—thereby turning the political and procedural safeguards of federalism on their head—and without any evidence of a direct conflict (or as Caleb Nelson puts it, “logical contradiction”<sup>185</sup>) between state and federal law. Nelson, indeed, makes quite a compelling argument that the purpose/obstacle prong of preemption analysis has no textual or historical support,<sup>186</sup> and Nina Mendelson argues convincingly that purpose/obstacle preemption presents by far the most serious problems of overbroad agency preemption.<sup>187</sup> Finally, the abandonment of this prong of preemption doctrine need not impose a serious burden on the ability of the federal government to achieve its goals. Express preemption by Congress, and when done pursuant to a congressional delegation by agencies, remains available. In addition, both Nelson and Justice Thomas propose a loosening of the impossibility prong of conflict preemption analysis to capture those situations where state and federal law are truly in opposition, and so preemption is justified even without an expressly stated congressional desire to do so.<sup>188</sup> Justice Thomas has pointed the way; perhaps it is time for the other justices to at least explore whether that road might lead to a safer haven for federalism.

#### IV. CONCLUSION

The law of agency preemption is a muddle. Basic questions, such as the clarity with which Congress must delegate preemptive power to administrative agencies and the level of deference courts should provide to agency statements regarding the preemptive effect of federal law remain unresolved by the Supreme Court. The Court’s recent *Wyeth v. Levine* decision provides a bit of clarity on some specific matters, such as the level and nature of judicial deference, and provides some hints of the Court’s future direction, but, in truth, muddle still dominates over clarity. Ultimately, however, this article argues that much of the debate over agency preemption may be beside the point. While there may be reasons to somewhat prefer Congress to agencies, or to the courts, as the institution with the authority to preempt state law, the truth is that *no* institution of the federal government appears to have either the incentives, or the will, to truly preserve state law and state autonomy in a way consistent with maintaining structural federalism.

Nonetheless, if we are to maintain fidelity to our constitutional structure, some commitment must be retained to preserving states as autonomous and competing sources of power to the federal government. One promising step in this direction is pointed to by

---

185. Nelson, *supra* n. 4, at 260.

186. *Id.* at 265.

187. Mendelson, *A Presumption*, *supra* n. 34, at 699–701.

188. Nelson, *supra* n. 4, at 260; *Wyeth*, 129 S. Ct. at 1209.

Justice Thomas's concurring opinion in *Wyeth*. Thomas argues that the Court should abandon one of the prongs of the Supreme Court's preemption doctrine, what I call the purpose/obstacle prong, which preempts state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."<sup>189</sup> Justice Thomas, building on the work of Professor Caleb Nelson, makes a convincing argument that this prong is dangerous and illegitimate, a conclusion which is bolstered by a consideration of institutional factors. Here, at least, the Court, if it is so inclined, has the ability to take some concrete measures to preserve and restore the balance of federalism.

What is most frustrating about the debate over preemption generally, and agency preemption in particular, is that so few actors in the area, either agencies, commentators, or even Justices of the Supreme Court, appear to take seriously the structural significance of federalism in the preemption context. The underlying concerns raised by federal preemption of state law are not the efficiency of government or the advancement of public policy, it is the need to retain states as independent *loci* of authority within our system. The threat of preemption is the threat of leaving states as withered hulks, perhaps cooperating in the implementation of federal programs, but lacking the power and the means to meet their citizens' needs autonomously. Such a path undermines the very existence of states as a counterbalance to the national government. States can play this role only insofar as citizens look to, and participate in, state government, a process which will inevitably weaken as state authority shrinks. The truth is that despite the New Deal, until recently state governments have retained their broad authority and historical dominance in areas of criminal and private law, including consumer protection and tort law. The recent federal preemptive onslaught threatens these last bastions of state power, leaving what remains of "Our Federalism" at great risk.

---

189. *English*, 496 U.S. at 79 (quoting *Hines*, 312 U.S. at 67).