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Inside Agency Preemption

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INSIDE AGENCY PREEMPTION[†]

Catherine M. Sharkey*

A subtle shift has taken place in the mechanics of preemption, the doctrine that determines when federal law displaces state law. In the past, Congress was the leading actor, and courts and commentators focused almost exclusively on the precise wording of its statutory directives as a clue to its intent to displace state law. Federal agencies were, if not ignored, certainly no more than supporting players. But the twenty-first century has witnessed a role reversal. Federal agencies now play the dominant role in statutory interpretation. The U.S. Supreme Court has recognized the ascendancy of federal agencies in preemption disputes—an ascendancy unchecked by the change in presidential administrations.

This Article confronts the profound implications for the administrative rulemaking process caused by the ascendancy of federal agencies in the preemption realm. Stakeholders with vested interests in preemption disputes, such as state governmental organizations, state attorneys general, consumer- and business-oriented organizations, and private litigants, can continue to ignore the preemptive rulemaking processes within federal agencies only at their peril. As this Article further shows, those processes are, in and of themselves, rich areas for investigation. Taking a unique perspective “inside” the preemptive rulemaking processes within five major federal agencies that regulate in areas as diverse as health and safety, banking, and the environment, this Article presents the first look at agencies’ responses to President Obama’s Memorandum on Preemption and their efforts to ensure compliance with the relevant provisions of Federalism Executive Order 13132, which governs preemptive rulemaking.

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* Crystal Eastman Professor of Law, New York University School of Law; John Simon Guggenheim Memorial Fellow (2011–12). This Article draws extensively from a December 2010 Report that I prepared as an academic consultant to the Administrative Conference of the United States, which adopted Recommendation 2010–1, Agency Procedures for Considering Preemption of State Law, based on the Report. *See* Adoption of Recommendation, 76 Fed. Reg. 81 (Jan. 3, 2011). For discussion and comments, I am grateful to Daniel Farber, Abbe Gluck, Sally Katzen, Gillian Metzger, Nina Mendelson, Richard Pierce, Richard Revesz, Stuart Shapiro, Jonathan Siegel, Paul Verkuil, Arthur Wilmarth, and Nicholas Wittner. Matthew Shahabian (NYU 2011) provided extraordinary research assistance, and Robert Keele (NYU 2012) assisted diligently with final revisions.

As part of this project, I conducted in-depth interviews with agency officials at the Consumer Product Safety Commission (“CPSC”), Environmental Protection Agency (“EPA”), Food and Drug Administration (“FDA”), Office of the Comptroller of the Currency (“OCC”), Office of Information and Regulatory Affairs (“OIRA”), Office of Management and Budget (“OMB”), and National Highway Traffic Safety Administration (“NHTSA”). My thanks to the agency officials who are named and cited in the Article, and especially to three officials who gave me additional helpful feedback: Neil Eisner (Department of Transportation), Ken Munis (EPA), and Steve Wood (NHTSA).

With this empirical grounding in agency practice, the Article addresses possibilities for reform, including a novel attorney general preemption notification provision and a blueprint for external review of newly proposed internal oversight procedures. The specific reform measures are guided by the overarching goals of (1) creating a “home” within agencies for consideration of the federalism values at stake in preemptive rulemaking and ensuring participation in the rulemaking process by suitable representatives of state regulatory interests; and (2) establishing a system of internal agency policing of the empirical and factual predicates to arguments for preemption, coupled with external oversight.

This journey inside agency preemption charts preemption’s future path.

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INTRODUCTION

A subtle shift has taken place in the mechanics of preemption, the doctrine that determines when federal law displaces state law. In the past, Congress was the leading actor, and courts and commentators focused almost exclusively on the precise wording of its statutory directives as a clue to its intent to displace state law. Federal agencies were, if not ignored, certainly no more than supporting players. But the twenty-first century has witnessed a role reversal. Federal agencies now play the dominant role in statutory interpretation. While Congress, with the stroke of a pen, could definitively resolve preemption questions by specifying the impact of its legislation on state law, in reality it often does not, but rather leaves open a wide interpretive space for courts to fill.¹ And while courts reiterate that congressional intent is the touchstone of preemption analysis, they increasingly rely on the views propounded by federal agencies either in regulations or else in preambles or litigation briefs.

At a superficial level, this shift might be attributable to mere politics—namely, the efforts of a conservative administration (under George W. Bush)

1. Some legislation—such as the Motor Vehicle Safety Act (“MVSA”) and the Consumer Product Safety Act—is marked by Congress’s inclusion of *both* an express preemption provision that would seem to oust competing state law and an express “savings” provision that would seem to have the opposite effect. *See* 15 U.S.C. § 2074(a) (2006) (Consumer Product Safety Act savings clause); *id.* § 2075(a) (Consumer Product Safety Act preemption clause); 49 U.S.C. § 30103(b) (2006) (MVSA preemption clause); *id.* § 30103(e) (MVSA savings clause).

to accomplish indirectly, via federal agencies, such tort reform goals as eliminating common law tort liability that could not be achieved directly via Congress.² Thus, with the change in administration (from George W. Bush to Barack Obama), the story goes, we should expect a reversal, a power shift away from agencies and back to Congress. But this political story obscures more than it reveals about emerging jurisprudential trends.

The U.S. Supreme Court has recognized the ascendancy of federal agencies in preemption disputes—an ascendancy unchecked by the change in presidential administrations. And the ever-growing role of agencies gives scholars the coherent analytical framework for the Court’s preemption jurisprudence—often characterized as a “muddle”³—that they have long sought.⁴ The Court’s pronouncement on preemption in *Williamson v. Mazda Motor of America, Inc.*⁵ provides the clearest illustration to date. There, the majority’s holding that a federal safety regulation did not preempt a state tort lawsuit rested fundamentally on “the promulgating agency’s contemporaneous explanation of its objectives, and the agency’s current views of the regulation’s pre-emptive effect.”⁶ That seven justices signed on to an opinion relying principally on the regulatory agency’s current and past view of whether the federal regulation should operate as a floor (compatible with more stringent state law standards) or a ceiling (in conflict with additional state law requirements) is momentous.⁷ Justice Clarence Thomas stood alone in his objection to this agency-centric approach, chastising the Court for “wad[ing] into a sea of agency musings and Government litigating positions

2. See, e.g., *Oversight Hearing on Passenger Vehicle Roof Strength: Hearing Before the Subcomm. on Consumer Affairs, Ins. & Auto. Safety of the S. Comm. on Commerce, Sci. & Transp.*, 110th Cong. (2008) (statement of Sen. Claire McCaskill) [hereinafter *Oversight Hearing on Roof Strength*], available at http://commerce.senate.gov/public/index.cfm?p=Hearings&ContentRecord_id=50f68af1-c5f8-4494-907a-4af5d734a78d&ContentType_id=14f995b9-dfa5-407a-9d35-56cc7152a7ed&Group_id=b06c39af-e033-4cba-9221-de668ca1978a&MonthDisplay=6&YearDisplay=2008 (suggesting Bush Administration White House’s involvement in a preemption “plot” to “wipe out” people’s access to courts); AM. ASS’N FOR JUSTICE, GET OUT OF JAIL FREE: HOW THE BUSH ADMINISTRATION HELPS CORPORATIONS ESCAPE ACCOUNTABILITY (2008), available at http://www.atlanet.org/cps/rde/xbcr/justice/Preemption_Rpt.pdf.

3. Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 232 (2000) (“Most commentators who write about preemption agree on at least one thing: Modern preemption jurisprudence is a muddle.”).

4. See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 477 (2008) [hereinafter Sharkey, *Products Liability Preemption*] (“Out of the preemption muddle, then, a glimmer of clarity emerges at least with respect to the products liability cases—the Court’s final decisions line up with the positions urged by the agency.”).

5. No. 08-1314, slip op. (U.S. Feb. 23, 2011).

6. *Williamson*, slip op. at 6.

7. Justice Clarence Thomas concurred separately in the judgment, and Justice Elena Kagan recused herself.

and fish[ing] for what the agency may have been thinking 20 years ago when it drafted the relevant provision.”⁸

Justice Stephen Breyer (author of the *Williamson* majority opinion) tipped his hand during oral argument, asking rhetorically:

Who is most likely to know what 40,000 pages of agency record actually mean and say? People in the agency. And the second most likely is the [Solicitor General’s] office, because they will have to go tell them. . . . So if the government continuously says, this is what the agency means and the agency is telling them, yes, this is what it means, the chances are they will come to a better, correct conclusion than I will with my law clerks⁹

Justice Breyer characterized this agency-centric view as the triumph of the “practical” over the “theoretical” perspective on preemption.¹⁰

The Court’s embrace of this practical, agency-centric approach to preemption comes against a backdrop of considerable concern over controversial agency interpretations of preemption. In 2009, the U.S. Supreme Court decided *Wyeth v. Levine*, which held that a state tort lawsuit brought by a woman injured by a drug approved by the Food and Drug Administration (“FDA”) was not impliedly preempted by the Food Drug and Cosmetic Act or FDA regulations.¹¹ In *Levine*, the Court looked with particular disdain on the procedural irregularities that accompanied FDA’s inclusion of its preemptive intent statement in the preamble to the drug labeling rule:

When the FDA issued its notice of proposed rulemaking in December 2000, it explained that the rule would “not contain policies that have federalism implications or that preempt State law.” In 2006, the agency finalized the rule and, without offering States or other interested parties notice or opportunity for comment, articulated a sweeping position on the FDCA’s

8. *Williamson*, slip op. at 4 (Thomas, J., concurring). Seen in this light, Justice Thomas’s opinion for a sharply divided Court in *PLIVA, Inc. v. Mensing*, a generic drug preemption case from that same term, *see infra* notes 149–171 and accompanying text, could be read to signal a retreat from the *Williamson* supermajority’s deference to the agency’s position on preemption. *See PLIVA, Inc. v. Mensing*, No. 09-993, slip op. at 6 n.3 (U.S. June 23, 2011) (“Although we defer to the agency’s interpretation of its regulations, we do not defer to an agency’s ultimate conclusion about whether state law should be pre-empted.”). But Justice Thomas nonetheless joined a unanimous Court in according dispositive deference to an agency’s interpretation of its own regulations. *See Chase Bank USA, N.A. v. McCoy*, 131 S. Ct. 871, 880 (2011) (“[W]e defer to an agency’s interpretation of its own regulation, advanced in a legal brief, unless that interpretation is ‘plainly erroneous or inconsistent with the regulation.’” (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997))). And the *Mensing* majority’s pro-preemption conclusion (though contrary to the position taken by FDA, the underlying agency) rests squarely on the agency’s interpretation of its regulations, which FDA could revise at any time to square with its antipreemption position. In other words, the fate of preemption lies equally in the hands of the agency under *Mensing* as it does under *Williamson*. *Mensing* is thus fully consistent with this Article’s premise of the ascendancy of federal agencies in the preemption realm.

9. Transcript of Oral Argument at 30, *Williamson*, slip op.

10. *See id.* at 29–30.

11. 129 S. Ct. 1187 (2009). Preemption is implied, as opposed to express, when the statute does not contain an explicit preemption provision.

pre-emptive effect in the regulatory preamble. The agency's views on state law are inherently suspect in light of this procedural failure.¹²

FDA's approach to "preemption by preamble" did not comply with the notice-and-comment rulemaking process or the state consultation mandates of Federalism Executive Order 13132 ("E.O. 13132" or "the Federalism Executive Order");¹³ accordingly, the Court did not accord deference to FDA's pro-preemption position. The disregard shown by FDA (and other federal agencies) toward procedural and consultative requirements for preemption determinations highlights the risks of agency interpretation supplanting congressional intent.

Scholars have, to some degree, taken note of the pros and cons of the ascendancy of federal agencies in the preemption realm, prompting a robust, emergent debate of the comparative institutional competencies among Congress, courts, and agencies in resolving the statutory interpretation, federalism, and regulatory policy issues that are embedded in preemption disputes.¹⁴ But these scholars have only begun to appreciate the full extent of the transformation in process. Most significantly, they have yet to recognize how the shift from Congress to the administrative rulemaking process calls for a comprehensive overhaul of internal agency preemption procedures.

This Article confronts the profound implications for the administrative rulemaking process caused by the ascendancy of federal agencies in the interpretive realm. First, courts will increasingly look to the rulemaking process and interrogate the agency record—as signaled by the Court in *Levine* and even more directly in *Williamson*. Second, stakeholders in preemption debates, including groups representing state and local elected officials, consumer advocates, or business interest groups, should focus their lobbying efforts on agencies and the rulemaking process, not (as is the current dominant strategy) exclusively on Congress.

Given this transformation, an overhaul of agency preemption procedures is not only timely, but imperative. There appears to be consensus that the requirements of the preemption provisions of E.O. 13132—including

12. *Levine*, 129 S. Ct. at 1201 (citations omitted).

13. E.O. 13132 identifies federalism principles that bear consideration in policymaking and specifies procedures for intergovernmental consultation, emphasizing consultations with state and local governments and enhanced sensitivity to their concerns. *See infra* notes 24–43 and accompanying text.

14. *See, e.g.*, Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. 1 (2007); Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 Nw. U. L. REV. 695 (2008) [hereinafter Mendelson, *Presumption*]; Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004) [hereinafter Mendelson, *Chevron*]; Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. REV. 727 (2008); Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 DUKE L.J. 2023 (2008); Catherine M. Sharkey, *Federalism Accountability: "Agency-Forcing" Measures*, 58 DUKE L.J. 2125 (2009) [hereinafter Sharkey, *Federalism Accountability*].

consultation with the states and “federalism impact statements”¹⁵—are sound. But compliance with these provisions has been inconsistent, and difficulties have persisted across administrations of both political parties. A 1999 Government Accountability Office (“GAO”) Report identified only five rules—out of a total of 11,000 issued from April 1996 to December 1998—that included a federalism impact statement.¹⁶ Case studies of particular rulemaking proceedings have revealed failures to comply with E.O. 13132.¹⁷

This Article presents a unique perspective “inside” agency preemption, first as a descriptive matter by focusing on agency practice and second as a normative matter with an eye toward reform measures. It begins in Part I by explaining the White House’s efforts to exercise control over the agency preemption process, both through E.O. 13132 and President Obama’s May 2009 Presidential Memorandum on Preemption (the “Presidential Memorandum on Preemption” or “Preemption Memorandum”)—which, in addition to articulating the new administration’s policy on preemption, condemned the practice of “preemption by preamble” and contained a directive to agencies to conduct a ten-year retrospective review of all preemptive rulemakings to ensure that they were legally justified and comported with the administration’s principles.¹⁸

Part II is an on-the-ground empirical assessment of what federal agencies are doing with respect to preemption in the rulemaking and litigation realms. The Article presents the first look at agencies’ responses to the Presidential Memorandum on Preemption and their efforts to comply with the relevant provisions of E.O. 13132 governing preemptive rulemaking. This empirical work, focusing on agencies’ awareness of the issue of preemptive rulemaking and their compliance efforts, draws from my extensive interviews with high-level agency officials at the National Highway Traffic Safety Administration (“NHTSA”), FDA, Office of the Comptroller of the Currency (“OCC”), Consumer Product Safety Commission (“CPSC”), Environmental Protection Agency (“EPA”), and Office of Information and Regulatory Affairs (“OIRA”), within the Office of Management and Budget (“OMB”), as well as my own independent review of the agencies’ respective rulemaking dockets and interventions in litigation. My findings contradict commentators’ claims that the Preemption Memorandum was merely a political act without any discernible practical effect.¹⁹ Instead, the

15. See *infra* text accompanying notes 31–34.

16. U.S. GEN. ACCOUNTING OFFICE, GAO/T-GGD-99-93, FEDERALISM: IMPLEMENTATION OF EXECUTIVE ORDER 12612 IN THE RULEMAKING PROCESS 1 (1999). Executive Order 12612 is the precursor to E.O. 13132. See *infra* note 25 and accompanying text.

17. See Mendelson, *Presumption*, *supra* note 14, at 719; Sharkey, *Federalism Accountability*, *supra* note 14, at 2131–39.

18. Preemption: Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24,693, 24,693–94 (May 20, 2009) [hereinafter *Preemption Memorandum*], available at <http://www.gpo.gov/fdsys/pkg/FR-2009-05-22/pdf/E9-12250.pdf#page=1>.

19. Lawrence S. Ebner, *President Obama’s “Preemption Memo”: Much To Do About Very Little*, LEGAL BACKGROUNDER (Washington Legal Found., Washington, D.C.), June 19,

memorandum not only put an end to the “preemption by preamble” trend but has also triggered real transformations within some federal agencies, which, in turn, has revealed the continuing significance of agency participation in preemption, especially in the rulemaking context.

With this empirical grounding in agency practice, Part III of the Article addresses possibilities for reform. The specific reform measures are guided by the overarching goals of (1) creating a “home” within agencies for consideration of the federalism values at stake in preemptive rulemaking and ensuring participation in the rulemaking process by suitable representatives of state regulatory interests; and (2) establishing a system of internal agency policing of the empirical and factual predicates to arguments for preemption, coupled with external oversight exercised by OIRA.

I. EXECUTIVE DIRECTIVES ON PREEMPTION AND FEDERALISM

A. *May 2009 Presidential Memorandum on Preemption*

On May 20, 2009, President Obama issued a presidential memorandum announcing his administration’s official policy on preemption: “[P]reemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.”²⁰ The memorandum specifically admonished department and agency heads to cease the practice of “preemption by preamble”—in which preemption statements are included in the preamble, but not in the codified regulation.²¹ Moreover, the memorandum directed agencies to employ preemption provisions in codified regulations only to the extent “justified under legal principles governing preemption, including the principles outlined in Executive Order 13132.”²²

The Preemption Memorandum calls for agencies to “review regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to

2009, available at http://www.wlf.org/publishing/publication_detail.asp?id=2084 (arguing that the memorandum will have little impact on preemption beyond forcing agencies to conduct “vague review” of regulations); Lauren Williamson, *Agency Appraisal: President Obama Orders Review of Federal Pre-emption Clauses*, INSIDE COUNS. MAG., Aug. 2009, at 30 available at <http://www.insidecounsel.com/Issues/2009/August-2009/Pages/Agency-Appraisal.aspx> (noting some commentators’ arguments that the memorandum is a “purely political” move); see also Victor E. Schwartz & Cary Silverman, *Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance That Protects Public Safety*, 84 TUL. L. REV. 1203, 1221 (2010) (“The memorandum does not fundamentally alter preemption principles or the analysis undertaken.”).

20. *Preemption Memorandum*, *supra* note 18, at 24,693.

21. *Id.* (“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.”).

22. *Id.*

preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption.”²³

B. *Federalism Executive Order 13132*

E.O. 13132, “Federalism,” which President Clinton issued on August 4, 1999,²⁴ is adverted to in Obama’s Preemption Memorandum and also serves as the centerpiece of numerous reform proposals for agency preemption of state law. E.O. 13132 is an amended version of E.O. 12612, President Reagan’s Executive Order on Federalism.²⁵ E.O. 13132 identifies federalism principles and policymaking criteria and designates specific procedures for intergovernmental consultation. The Order designates special requirements for agencies in taking action that preempts state law. It emphasizes consultations with state and local governments and enhanced sensitivity to their concerns. And the Order applies to all federal agencies—except for independent regulatory agencies,²⁶ which are nonetheless encouraged to comply voluntarily with its provisions.²⁷

1. Consultation Process

E.O. 13132 directs that agencies have “an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.”²⁸ The Order establishes specific procedures for intergovernmental consultation if a rule

23. *Id.*

24. Exec. Order No. 13,132, 3 C.F.R. 206 (1999).

25. President Clinton had previously issued short-lived Executive Order 13083, a comprehensive rewrite of the Reagan Federalism Order. Exec. Order No. 13,083, 3 C.F.R. 146 (1998). But E.O. 13083, which stated that federal action was justified “[w]hen there is a need for uniform national standards”; “[w]hen decentralization increases the costs of government”; or “[w]hen States would be reluctant to impose necessary regulations because of fears that regulated business activity will relocate to other States,” *id.* § 3(d), 3 C.F.R. at 148, was suspended after a “firestorm of criticism,” including charges that President Clinton failed to consult with state and local elected governmental officials, John Dinan, *Strengthening the Political Safeguards of Federalism: The Fate of Recent Federalism Legislation in the U.S. Congress*, PUBLIUS, Summer 2004, at 55, 64. President Clinton issued E.O. 13132 after consulting with the “Big Seven” national organizations of state and local elected officials. *See Summary of Executive Order 13132 on Federalism Issued by Clinton Administration*, NAT’L CONF. ST. LEGISLATURES (Aug. 31, 1999), <http://web.archive.org/web/20051118212006/http://www.ncsl.org/statefed/federalism/exec13132.htm> (describing “extensive negotiations between the White House and seven national organizations . . . representing state and local government officials”).

26. *See* Exec. Order No. 13,132, § 1(c), 3 C.F.R. at 207.

27. *Id.* § 9, 3 C.F.R. at 211.

28. *Id.* § 6(a), 3 C.F.R. at 209. The Order defines “State and local officials” as “elected officials of State and local governments or their representative national organizations.” *Id.* § 1(d), 3 C.F.R. at 207.

preempts state law.²⁹ Each agency must consult with state and local officials “early in the process of developing the proposed regulation.”³⁰

2. Federalism Impact Statements

E.O. 13132 also requires agencies to provide a federalism impact statement (“FIS”) whenever regulations will have federalism implications³¹ and preempt state law.³² Prior to the formal promulgation of the regulation, the agency must provide OMB with a “federalism summary impact statement” in “a separately identified portion of the preamble to the regulation.”³³

The FIS must include (1) “a description of the extent of the agency’s prior consultation with State and local officials”; (2) “a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation”; and (3) “a statement of the extent to which the concerns of State and local officials have been met.”³⁴

3. Enforcement

Within OMB, OIRA has “primary responsibility for implementing [E.O. 13132].”³⁵ In October, 1999, OIRA Administrator John Spotila circulated “Guidance for Implementing E.O. 13132” to all heads of executive departments and agencies and to independent regulatory agencies.³⁶ The guidelines are procedural in nature, focusing on “what agencies should do to comply with the Order and how they should document that compliance to OMB.”³⁷

29. *Id.* § 6(c), 3 C.F.R. at 210 (establishing procedures for “any regulation that has federalism implications and that preempts State law”).

30. *Id.* § 6(c)(1), 3 C.F.R. at 210.

31. *Id.* § 1(a), 3 C.F.R. at 206 (defining federalism implications as “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government”).

32. *Id.* § 6(c)(2), 3 C.F.R. at 210.

33. *Id.*

34. *Id.* The agency must also submit to OMB at that time a copy of any formal policy-related correspondence from state and local officials. *Id.* § 6(c)(3), 3 C.F.R. at 210.

35. See Memorandum from Jacob J. Lew, Director, Office of Mgmt. & Budget, to the Heads of Exec. Dep’ts & Agencies & Indep. Regulatory Agencies: Guidance for Implementing E.O. 13132, “Federalism” (Oct. 28, 1999) [hereinafter OMB Guidance for E.O. 13132], available at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/m00-02.pdf> (cover letter). As the OMB Guidance states: “Under Executive Order 12866, [OIRA] already coordinates our regulatory review and planning functions.” *Id.*; see also Exec. Order No. 12,866, 3 C.F.R. 638 (1993) (“Regulatory Planning and Review”), amended by Exec. Order No. 13,422, 3 C.F.R. 191 (2007).

36. OMB Guidance for E.O. 13132, *supra* note 35, at 1 (letter from John T. Spotila, Adm’r, Office of Info. & Regulatory Affairs, to Heads of Exec. Dep’ts & Agencies & Indep. Regulatory Agencies).

37. *Id.*

Pursuant to the guidelines, each agency and department designates a federalism official with primary responsibility for the agency's implementation of the Order.³⁸ Federalism officials are to (1) "ensure that the agency considers federalism principles in its development of regulatory and legislative policies with federalism implications"; (2) "ensure that the agency has an accountable process for meaningful and timely intergovernmental consultation in the development of regulatory policies that have federalism implications"; and (3) "provide certification of compliance to OMB."³⁹

The federalism official must submit to OMB "a description of the agency's consultation process."⁴⁰ The description "should indicate how the agency identifies those policies with federalism implications and the procedures the agency will use to ensure meaningful and timely consultation with affected State and local officials."⁴¹

For any draft final regulation with federalism implications that is submitted for OIRA review under Executive Order 12866 ("E.O. 12866"), titled "Regulatory Planning and Review,"⁴² the federalism official must certify that the requirements of E.O. 13132 concerning both the evaluation of federalism policies and consultation have been met in a meaningful and timely manner.⁴³

II. AGENCY PRACTICE: RULEMAKING AND LITIGATION

The May 2009 Presidential Memorandum on Preemption caught federal agencies' attention and prompted serious internal review, at least for the majority of agencies surveyed.⁴⁴ Moreover, both the change in administration and the Presidential Memorandum on Preemption have had wider-ranging effects on preemption policy within the agencies. The policy shift, both in

38. See Exec. Order No. 13,132, § 6(a), 3 C.F.R. at 209. Each agency was directed to notify OIRA of its designated federalism official. OMB Guidance for E.O. 13132, *supra* note 35, at 2.

39. OMB Guidance for E.O. 13132, *supra* note 35, at 2.

40. Exec. Order No. 13,132, § 6(a), 3 C.F.R. at 209; OMB Guidance for E.O. 13132, *supra* note 35, at 2.

41. OMB Guidance for E.O. 13132, *supra* note 35, at 5.

42. There are four criteria for regulations that trigger OMB review under E.O. 12866: (1) have an annual effect on the economy of at least \$100 million or adversely affect the economy in a "material" way; (2) create a "serious" inconsistency between the proposed action and another federal agency action; (3) "[m]aterially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof"; or (4) "[r]aise novel legal or policy issues." Exec. Order No. 12,866, § 3(f), 3 C.F.R. 638, 641-42 (1993) (defining "significant regulatory action"), *amended by* Exec. Order No. 13,422, 3 C.F.R. 191 (2007).

43. Exec. Order No. 13,132, § 8(a), 3 C.F.R. at 209.

44. Officials at NHTSA, OCC, CPSC, and EPA provided me with either a report or information regarding their respective agency's ten-year retrospective review of all rules intended to preempt state law. FDA did not provide this information; however, the agency published its ten-year retrospective review while this Article was in production. Preemption Review, 76 Fed. Reg. 61,565 (Oct. 5, 2011), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-10-05/html/2011-25479.htm>.

rulemakings and litigation positions, has been most pronounced at NHTSA and CPSC, and more difficult to evaluate at FDA and OCC.

EPA stands apart. Preemption in EPA rules is relatively rare and always occurs pursuant to express statutory provisions. Moreover, EPA has a unique relationship with the states as coregulators.

A. National Highway Traffic Safety Administration

Of all the agencies surveyed, NHTSA's preemption policy shift under the Obama Administration was the most dramatic.⁴⁵ A June 2010 rule on electric-powered vehicles contained a lengthy discussion of the evolution of the agency's preemption approach, including its disavowal of the preemptive language contained in three 2005 notices of proposed rulemaking; ("NPRMs") and, since 2007, its ever-weakening embrace of implied preemption, as shown in its revisions to its boilerplate preemption language in rulemakings. Beginning with its November 2010 proposed rule on child restraint systems (and continuing to the present), NHTSA has further disclaimed any preemptive intent and affirmatively asserts that state tort law may impose standards above and beyond NHTSA's "minimum" safety standards without creating any conflict.⁴⁶

In the midst of this period of NHTSA's refinement of its boilerplate preemption language, in August 2010 the solicitor general submitted an amicus brief (on behalf of NHTSA) to the U.S. Supreme Court in *Williamson v. Mazda Motor of America, Inc.*⁴⁷ Arguing against preemption, the solicitor general outlined a sharply circumscribed view of implied preemption under *Geier v. American Honda Motor Co.*, whereby NHTSA safety standards should generally be read as minimum standards unless the regulatory history demonstrates the agency's contrary affirmative policy.⁴⁸

45. I conducted extensive in-person interviews with NHTSA and DOT officials. Interview with Kevin Vincent, Chief Counsel, Nat'l Highway Traffic Safety Admin., in Washington, D.C. (June 30, 2010); Interview with Steve Wood, Assistant Chief Counsel, Nat'l Highway Traffic Safety Admin., in Washington, D.C. (June 30, 2010); Interview with Neil Eisner, Assistant Gen. Counsel for Regulation & Enforcement, U.S. Dep't of Transp., in Washington, D.C. (June 30, 2010); Interview with Paul Geier, Assistant Gen. Counsel for Litig., U.S. Dep't of Transp., in Washington, D.C. (July 6, 2010).

46. Federal Motor Vehicle Safety Standards, Child Restraint Systems; Hybrid III 10-Year-Old Child Test Dummy, 75 Fed. Reg. 71,648, 71,661 (proposed Nov. 24, 2010) (to be codified at 49 C.F.R. pt. 571).

47. No. 08-1314, slip op. (U.S. Feb. 23, 2011).

48. Brief for the United States as Amicus Curiae Supporting Petitioners at 10–31, *Williamson*, slip op. (No. 08-1314) [hereinafter U.S. *Williamson* Brief]. In *Geier v. American Honda Motor Co.*, the U.S. Supreme Court held, notwithstanding the existence of an express "savings" clause in the MVSA, that the statute and attendant NHTSA regulation governing passive restraints in automobiles impliedly preempted a state tort lawsuit alleging that an automobile was defective because the manufacturer had not installed an airbag. 529 U.S. 861, 866, 873 (2000). The Court held that the tort lawsuit would interfere with the menu of options offered by the regulation and, as such, would conflict with the "purposes and objectives" of the federal regulatory scheme. *Id.* at 873, 881. *Geier* remains the seminal Court pronouncement on what is known as implied obstacle preemption.

The correspondence and feedback between the agency's litigating position and its rulemaking considerations of preemption seemed to be stronger at NHTSA than at any of the other agencies that I surveyed. Not only did NHTSA's boilerplate language in its rulemakings since November 2010 mirror the government's articulated position in *Williamson*, but, of all the agencies surveyed, NHTSA seemed the most cognizant of the link between its rulemaking and the course of future tort litigation.

The agency's appreciation and assertion of its preemptive authority has likewise evolved over time. In its June 2010 Electric-Powered Vehicles Rule, NHTSA characterized implied preemption under *Geier* as resting upon "finding implied preemption of State tort law on the basis of a conflict discerned by *the court*, not on the basis of an intent to preempt asserted by the agency itself."⁴⁹ With its November 2010 Child Restraint Systems Rule, NHTSA incorporated a bolder position on its own influence as part of its revised boilerplate language: "The agency's ability to announce its conclusion regarding the preemptive effect of one of its rules reduces the likelihood that preemption will be an issue in any subsequent tort litigation."⁵⁰ While this development has largely escaped commentary (from NHTSA itself or from others), tort litigants have begun to take note.⁵¹

1. Response to May 2009 Presidential Memorandum on Preemption

In response to the President's Memorandum on Preemption, the Department of Transportation ("DOT") sent OIRA a list of all current DOT rulemakings asserting preemptive effect, along with what corrective action would be taken, if any.⁵² For NHTSA, DOT identified six rules with preemptive effect: Designated Seating Positions,⁵³ Air Bag Labeling,⁵⁴

49. Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,525 (June 14, 2010) (to be codified at 49 C.F.R. pt. 571) (emphasis added).

50. Federal Motor Vehicle Safety Standards, Child Restraint Systems; Hybrid III 10-Year-Old Child Test Dummy, 75 Fed. Reg. at 71,661.

51. See, e.g., Supplemental Brief of Appellant at 9, *Priester v. Cromer*, No. 06-CP-38-1071 (S.C. May 15, 2011) ("[I]n NHTSA's view . . . a lawsuit like this one seeking to hold a manufacturer liable for failing to install advanced glazing in the side windows of a passenger vehicle would *not* be preempted by federal law."); *id.* at 18 ("NHTSA does not intend this rule to preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by today's rule." (emphasis omitted) (quoting Federal Motor Vehicle Safety Standards, Ejection Mitigation; Phase-In Reporting Requirements; Incorporation by Reference, 76 Fed. Reg. 3212, 3295 (Jan. 19, 2011) (to be codified at 49 C.F.R. pts. 571 & 585))).

52. Letter from Robert S. Rivkin, Office of Gen. Counsel, U.S. Dep't of Transp., to Kevin Neyland, Acting Adm'r, Office of Info. & Reg. Affairs (Aug. 17, 2009) [hereinafter Letter from Robert S. Rivkin] (on file with the *Michigan Law Review*).

53. Federal Motor Vehicle Safety Standards; Designated Seating Positions and Seat Belt Assembly Anchorages, 73 Fed. Reg. 58,887 (Oct. 8, 2008) (to be codified at 49 C.F.R. pt. 571).

54. Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 66 Fed. Reg. 65,376 (Dec. 18, 2001) (to be codified at 49 C.F.R. pt. 571).

Detachable Seat Belts,⁵⁵ Event Data Recorders,⁵⁶ and two Average Fuel Economy Standards.⁵⁷ Only one of these rules, the Designated Seating Positions Rule, was listed as including a preemptive provision in the codified regulation.⁵⁸ That rule is also the only rule for which NHTSA believed further action was warranted. NHTSA began with a list of only those notices that either contained a statement that the agency intended to preempt tort civil actions, or identified a specific factual situation in which such actions would create a conflict or frustrate a federal purpose. It then removed those notices whose statements had already been rendered inoperative by a subsequent notice.⁵⁹

NHTSA's identification of only six preemptive rules and just a single one in need of further action may, at first glance, seem surprising in light of the charges—from Congress, stakeholder groups, and legal academics—of aggressive preemptive rulemaking during the George W. Bush Administration. According to the American Association for Justice's ("AAJ") 2008 Report, over the period from 2001 to 2008 NHTSA issued more notices claiming preemption than any other federal agency, accounting for nearly half of all rulemakings (twenty-four of fifty-three) that AAJ characterized as preemptive rulemakings.⁶⁰ Moreover, as of July 2010, AAJ compiled a list of seven NHTSA proposed rules and seven final rules from 2005 to 2008 that it claimed "still contain preemption language."⁶¹ By NHTSA's count, only three of the twenty-four notices listed in AAJ's 2008 report, and none of the fourteen notices listed in AAJ's July 2010 email, identified a conflict or stated an intent to preempt, and thus the notices should not be characterized as "preemptive rulemakings." Two factors explain the discrepancy

55. Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 69 Fed. Reg. 70,904 (Dec. 8, 2004) (to be codified at 49 C.F.R. pts. 571, 585, 586, 589, 590, 596 & 597).

56. Event Data Recorders, 71 Fed. Reg. 50,998 (Aug. 28, 2006) (to be codified at 49 C.F.R. pt. 563).

57. Average Fuel Economy Standards, Passenger Cars and Light Trucks; Model Years 2011–2015, 73 Fed. Reg. 24,352 (proposed May 2, 2008) (to be codified at 49 C.F.R. pts. 523, 531, 533, 534, 536 & 537); Average Fuel Economy Standards for Light Trucks Model Years 2008–2011, 71 Fed. Reg. 17,566 (Apr. 6, 2006) (to be codified at 49 C.F.R. pts. 523, 533 & 537).

58. Letter from Robert S. Rivkin, *supra* note 52, at 7.

59. Email from Steve Wood, Assistant Chief Counsel, Nat'l Highway Traffic Safety Admin., to Catherine M. Sharkey, Professor of Law, N.Y. Univ. Sch. of Law (Oct. 13, 2010, 01:55 EST) (on file with the *Michigan Law Review*) [hereinafter Email from Steve Wood].

60. AM. ASS'N FOR JUSTICE, *supra* note 2, app. B at 28–33. In my tally of preemptive rulemakings, I grouped together as one all proposed, final, or amended rules on the same subject (which AAJ listed as separate entries). If either the proposed, final, or amended rule claimed preemption, I counted it as a preemptive rulemaking (but not more than one). Note, too, that the AAJ report listed proposed rules that had not yet resulted in a final (or interim final) rule.

61. NHTSA Preemptive Regulations Issued from 2005–2008 Memorandum attached to Email from Sarah Rooney, Regulatory Counsel, Am. Ass'n for Justice, to Catherine M. Sharkey, Professor of Law, N.Y. Univ. Sch. of Law (July 20, 2010, 15:31 EST) [hereinafter Email from Sarah Rooney] (on file with the *Michigan Law Review*).

between NHTSA and AAJ. First, several rules that contained aggressive assertions of preemption in the NPRMs did not contain preemption language in their final versions. Second—and the source of continuing disagreement between NHTSA and AAJ—NHTSA did not include rules that contain a “boilerplate” discussion of preemption.⁶² In its 2010 rulemaking on electric-powered vehicles, NHTSA responded to AAJ’s charges of further preemptive rulemakings by stating that the boilerplate language was not intended to preempt state law because it did not include any finding of a conflict and did not state any intent to preempt. The agency also provided the history of the evolutionary changes it made to the language over time to make the absence of conflict identification and of any preemptive statements or intent increasingly clear.⁶³ According to NHTSA, the boilerplate simply describes the possibility that preemption could occur if there were an actual conflict between state and federal law, as was the case in *Geier*, and no more.⁶⁴ On NHTSA’s account, the boilerplate makes no effort to identify or serve as a warning of preemption but simply serves as a notice for potential future conflicts in the courts.⁶⁵ Given that the Presidential Memorandum on Preemption directs agencies to review all rules “intended by the department or agency to preempt State law,”⁶⁶ NHTSA concluded that the boilerplate language did not fall within the memorandum and thus did not include for review the rules with the boilerplate language.⁶⁷

2. Rulemaking

NHTSA has acknowledged a policy shift on preemption under the Obama Administration. At a congressional hearing in 2010 on proposed amendments to the Motor Vehicle Safety Act (“MVSA”), NHTSA Administrator David Strickland made clear that the era of “preemption by preamble” in rulemakings was over:

[REP. BRALEY:] All right. Now, one of the concerns that I had and many people had during the period of the Bush Administration and its operation

62. Each of the rules on AAJ’s July 2010 list from 2005 through 2008, *see* Email from Sarah Rooney, *supra* note 61, contain such “boilerplate” language—with the exception of one rule that seems to have been listed in error. AAJ lists the Windshield Zone Intrusion Rule, 73 Fed. Reg. 38,372 (July 7, 2008) (to be codified at 49 C.F.R. pt. 571), as asserting preemptive effect. The rule, however, states that NHTSA tentatively concluded that states are free to regulate in this area and that the rule would not preempt state law. *Id.* at 38,373–74.

63. Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,524 (June 14, 2010) (to be codified at 49 C.F.R. pt. 571) (stating that AAJ’s discerning of preemptive intent in the boilerplate “fundamental[ly] misunderstand[s]” NHTSA’s intent and noting that AAJ had not pointed to any specific language that identified a conflict that could be the basis for preemption or that stated an intent to preempt).

64. *Id.* (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)).

65. *Id.*

66. *Preemption Memorandum*, *supra* note 18, at 24,693 (emphasis added).

67. Email from Steve Wood, *supra* note 59.

of NHTSA was that the agency during that period specifically from 2005 to 2008 seemed to many of us to usurp its own regulatory authority and take on the role of Congress by including in many of its preambles issued in response to regulations language pre-empting state law claims. Are you familiar with that practice?

[MR. STRICKLAND:] Yes, sir, I am.

[REP. BRALEY:] And I know that the President himself at the beginning of his Administration took a strong position rolling back some of those statements made by agency representatives in those preambles and in the regulations themselves. Are you able here today as a representative of the Administration . . . to assure us that those practices will not continue while you are Administrator?

[MR. STRICKLAND:] I can make that obligation, absolutely. There is a notion that state's rights are incredibly important and those preambles that were placed not only in NHTSA's rules but there were several rules throughout executive branch agencies and safety agencies which undermine safety, and I know the Obama Administration felt very strongly that those should not be used to undercut the notion of safety whether by the federal government or in the states.⁶⁸

NHTSA's clarifying actions in the preemption realm began in late summer 2008 (i.e., before the issuance of the May 20, 2009 Presidential Memorandum on Preemption).⁶⁹ But only in its 2010 rulemaking on electric-powered vehicles did NHTSA provide an explicit description of the evolution of changes it made in preemptive rulemakings. Recent revisions to the boilerplate—including the agency's specific disavowal of preemptive intent and explicit statement that "[e]stablishment of a higher standard by means of State tort law would not conflict with the minimum standard proposed here"—have been introduced without any official commentary from NHTSA.⁷⁰

a. *Removal of Preemptive Language*

In three 2005 rulemakings—the Rearview Mirror Rule, the Roof Crush Rule, and the Designated Seating Positions Rule—NHTSA gave an extended discussion of preemption and claimed the safety standard preempted state

68. *Motor Vehicle Safety Act: Hearing on H.R. 5381 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 111th Cong. 62–63 (preliminary transcript of hearing) (2010). This sentiment was echoed by NHTSA chief counsel, who maintained that “the 2005 policy is not the 2010 policy.” Interview with Kevin Vincent, *supra* note 45.

69. See Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. at 33,524–25 (June 14, 2010) (to be codified at 49 C.F.R. pt. 571) (describing NHTSA's clarification efforts).

70. Federal Motor Vehicle Safety Standards; Side Impact Protection, 76 Fed. Reg. 52,883 (Aug. 24, 2011).

tort law.⁷¹ For each of the 2005 proposed rulemakings, NHTSA identified a potential conflict or obstacle posed by state tort law. In its 2010 rulemaking on electric-powered vehicles, NHTSA noted that these earlier three 2005 NPRMs “contrast markedly” with its other 2007–2008 rules that use boilerplate language.⁷²

i. Rearview Mirror Rule

The 2005 NPRM for the Rearview Mirror Rule paradoxically asserted preemption while disclaiming any federalism implications warranting consultation with state and local officials. This NPRM not only stated that the proposed amendments “would preempt all state statutes, regulations and common law requirements that differ with it,” but also specifically named New Jersey, New York, and Washington as states whose statutes would be preempted under the rule.⁷³ Despite this explicit, targeted preemption, the NPRM asserted the rule “would not have sufficient Federalism implications to warrant consultations with State and local officials or the preparation of a Federalism summary impact statement.”⁷⁴

Before the final rule was promulgated, Congress passed the Cameron Gulbranson Kids Transportation Safety Act of 2007, which required NHTSA to issue new rules expanding the driver’s field of vision behind certain vehicles.⁷⁵ The Act applied only to cars and light trucks, while NHTSA’s rule targeted heavier trucks.⁷⁶ For that reason, and because post-NPRM data and analysis indicated that the class of vehicles covered by the NPRM accounted for only four of the annual deaths resulting from backover

71. Federal Motor Vehicle Safety Standards; Rearview Mirrors, 70 Fed. Reg. 53,753, 53,768–69 (proposed Sept. 12, 2005) (to be codified at 49 C.F.R. pt. 571) (rearview mirrors on trucks); Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,245–46 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571) (NPRM for roof crush resistance); Federal Motor Vehicle Safety Standards; Designated Seating Positions and Seat Belt Assembly Anchorages, 70 Fed. Reg. 36,094, 36,101–02 (proposed June 22, 2005) (to be codified at 49 C.F.R. pt. 571) (amending the definition of a “[d]esignated seating position” (emphasis omitted)).

72. See Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. at 33,524.

73. Federal Motor Vehicle Safety Standards; Rearview Mirrors, 70 Fed. Reg. at 53,768 & nn.22–24 (citing N.J. STAT. ANN. § 39:3-71.1 (West 2004); N.Y. VEH. & TRAF. LAW § 375(9)(e) (McKinney 2003); and WASH. REV. CODE ANN. § 46.37.400 (West 2004)).

74. *Id.* at 53,768. NHTSA noted, however, that New York commented on the Advanced NPRM, and NHTSA responded to New York’s comments. *Id.* at 53,764–65, 53,768.

75. Cameron Gulbranson Kids Transportation Safety Act of 2007, Pub. L. No. 110-189, § 2(b), 122 Stat. 639 (2008) (to be codified at 42 U.S.C. § 30111).

76. See *id.* § 2(e)(2) (excluding from the Act motor vehicles weighing more than 10,000 pounds); 70 Fed. Reg. 53,753 (Sept. 12, 2005). Light trucks include sport utility vehicles and vans (both passenger and cargo) under 10,000 pounds gross vehicle weight rating (“GVWR”); NHTSA’s rule applied to straight trucks with GVWRs between 10,000 and 26,000 pounds.

accidents, NHTSA decided to withdraw the NPRM in order to take a “comprehensive look at backing safety for all types of motor vehicles.”⁷⁷

In March 2009, NHTSA issued a revised Advanced NPRM (“ANPRM”) for rearview mirrors.⁷⁸ This revised ANPRM replaced the language discussing preemption with boilerplate language that stated there was a “possibility” the MVSA would preempt state law, but NHTSA claimed that it did not “know of any State laws or regulations that currently exist that are potentially at risk of being preempted.”⁷⁹ For implied preemption, NHTSA said it had “considered today’s ANPRM and [did] not currently foresee any potential State requirements that might conflict with it. Without any conflict, there could not be any implied preemption.”⁸⁰ In its December 2010 NPRM, NHTSA further disclaimed any preemptive intent in its revised boilerplate language that stated, “NHTSA does not intend that this proposal preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by today’s proposal.”⁸¹

ii. Roof Crush Rule

In the NPRM for the Roof Crush Rule, NHTSA was clear that “if the proposal were adopted as a final rule, it would preempt all conflicting State common law requirements, including rules of tort law.”⁸² As it did in the rearview mirror NPRM, NHTSA also asserted—paradoxically, given the preemptive intent of the rule—that the new rule “would not have any substantial impact on the States” and therefore did “not have sufficient federal implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement.”⁸³

NHTSA received twenty-five comments in response to the preemption discussion, including objections from National Conference of State Legislatures (“NCSL”), Public Citizen, and twenty-seven state attorneys general. During the comment period, Jeffrey Rosen, DOT General Counsel, and Steve Wood, a NHTSA attorney, met with representatives of NCSL and the National Association of Attorneys General (“NAAG”) at their request and discussed the proposal and its preemptive effects.⁸⁴

77. Federal Motor Vehicle Safety Standards; Rearview Mirrors, 73 Fed. Reg. 42,309, 42,312 (withdrawal of rulemaking on July 21, 2008) (to be codified at 49 C.F.R. pt. 571).

78. Federal Motor Vehicle Safety Standard; Rearview Mirrors, 74 Fed. Reg. 9478 (proposed Mar. 4, 2009) (to be codified at 49 C.F.R. pt. 571).

79. *Id.* at 9516.

80. *Id.*

81. Federal Motor Vehicle Safety Standard, Rearview Mirrors; Federal Motor Vehicle Safety Standard, Low-Speed Vehicles Phase-In Reporting Requirements, 75 Fed. Reg. 76,186, 76,242 (proposed Dec. 7, 2010) (to be codified at 49 C.F.R. pts. 571 & 585).

82. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,246 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571).

83. *Id.* at 49,245.

84. Jeffrey Rosen and Steve Wood met with NAAG and NCSL at a meeting at OMB. Interview with Steve Wood, *supra* note 45.

The Roof Crush Rule also caught Congress's attention. NHTSA's preemptive rule was touched on during Congress's wide ranging 2007 hearing on regulatory preemption.⁸⁵ Then, in 2008, the Senate held a hearing on the Roof Crush Rule, during which it confronted NHTSA Deputy Administrator James Ports with questions about preemption.⁸⁶ Members from both sides of the aisle criticized NHTSA. Republican Senator Coburn stated he had "heartburn" over the lack of transparency in this rulemaking, and Democratic Senator Pryor warned NHTSA that preemption was a "bad idea" and that NHTSA was "overstepping its bounds" into the legislative arena.⁸⁷

After the hearing, the Roof Crush Rule was shelved. Following the change in administration, and just before the issuance of the Presidential Memorandum on Preemption, NHTSA promulgated the final rule. The May 12, 2009 final rule "reconsidered" the tentative position presented in the NPRM: "We do not foresee any potential State tort requirements that might conflict with today's final rule. Without any conflict, there could not be any implied preemption."⁸⁸

iii. *Designated Seating Positions Rule*

The Designated Seating Positions Rule was the sole rule that NHTSA identified in its response to the Presidential Memorandum on Preemption as warranting further action. Subsequently, in a December 2009 final rule (in response to petitions for reconsideration), NHTSA removed the preemptive regulatory text.⁸⁹

The original final rule was issued in October 2008 and included preemptive regulatory text. Both AAJ and Public Citizen petitioned NHTSA to reconsider the 2008 rule. AAJ argued that neither express nor implied preemption was warranted: express preemption was contrary to congressional intent, and *Geier* was an "unusual, fact driven case" that upheld implied preemption on the basis of the particular range of options intended to remain available under the rule and on the basis of its lengthy regulatory history that supported the agency's intent.⁹⁰ Public Citizen (with the Consumer

85. *See Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?: Hearing Before S. Comm. on the Judiciary*, 110th Cong. 7 (2007) [hereinafter *Hearing on Regulatory Preemption*] (statement of Donna Stone, State Rep., Delaware General Assembly, Pres., NCSL). Representative Donna Stone, on behalf of NCSL, criticized NHTSA for defying E.O. 13132 in its Roof Crush Rule by preempting state tort law in the rule, while simultaneously disclaiming any federalism implications. *Id.* at 11.

86. *Oversight Hearing on Roof Strength*, *supra* note 2.

87. *Id.*

88. Federal Motor Vehicle Safety Standards; Roof Crush Resistance; Phase-In Reporting Requirements, 74 Fed. Reg. 22,348, 22,349 (May 12, 2009) (to be codified at 49 C.F.R. pts. 571 & 585).

89. Federal Motor Vehicle Safety Standards; Designated Seating Positions, 74 Fed. Reg. 68,185, 68,189 (Dec. 23, 2009) (to be codified at 49 C.F.R. pt. 571).

90. Letter from Les Weisbrod, President, Am. Ass'n for Justice, to David Kelly, Acting Admin., NHTSA (Nov. 24, 2008), available at <http://www.regulations.gov/#!documentDetail;D=NHTSA-2008-0059-0008>.

Federation of America) argued that NHTSA's preemption statements were "harmful and unnecessary," that tort law did not "frustrate" the purposes of the rule, and that *Geier* was "fact-specific," and it disputed NHTSA's claims that tort law would reduce safety by forcing automakers to install "more seat belts than are necessary."⁹¹

After reconsideration and further analysis, NHTSA removed the preemptive regulatory text in its December 2009 rule, stating that it agreed with Public Citizen's argument that it was "unlikely" tort law would actually conflict with the Designated Seating Positions Rule.⁹² In making this determination, NHTSA researched state tort law and pending litigation and consulted with organizations representing the interests of state and local governments and officials.⁹³

NHTSA replaced the preemptive text in the preamble with boilerplate language stating that while conflict preemption was theoretically possible, NHTSA could discern no potential for a conflict.⁹⁴ The agency included a lengthy explanation of "How NHTSA's Regulations May Give Rise to a *Judicial Finding of Preemption*"⁹⁵ as well as a detailed explanation of how it believed *Geier* should be interpreted. NHTSA's bottom line was that "[a] court should not find preemption too readily in the absence of clear evidence of a conflict."⁹⁶

b. *Evolution of Boilerplate Language on the Issue of Preemption*

In most of its rulemakings in 2007 through 2008, NHTSA included a boilerplate discussion of preemption indicating that state law could potentially conflict with the federal standard, but that NHTSA had not "outlined" any conflicts at the present time.⁹⁷ NHTSA's rulemakings from 2008 to 2010 included a variation on the boilerplate language.

In its 2010 Electric-Powered Vehicles Rule, NHTSA described modifications in the boilerplate language from the 2007–2008 NPRMs up until

91. Letter from Joan Claybrook, President, Pub. Citizen, and Jack Gillis, Dir. of Pub. Affairs, Consumer Fed'n of Am., to David Kelly, Acting Admin., NHTSA (Nov. 24, 2008) (internal quotation mark omitted from first quotation), available at <http://www.regulations.gov/#!documentDetail;D=NHTSA-2008-0059-0015>.

92. Federal Motor Vehicle Safety Standards; Designated Seating Positions, 74 Fed. Reg. at 68,188–89.

93. *Id.* NHTSA engaged in this consultation outside of E.O. 13132, because it determined that the rule did not raise sufficient federalism implications to warrant a federalism impact statement. *Id.* at 68,189. NCSL, which had actively opposed the Roof Crush Rule and which took part in the notice-and-comment process, did not submit any comment on the Designated Seating Positions Rule.

94. *Id.* at 68,187–88.

95. *Id.* at 68,187 (emphasis added).

96. *Id.* at 68,188.

97. See, e.g., WILLIAM FUNK ET AL., CTR. FOR PROGRESSIVE REFORM, WHITE PAPER NO. 804, THE TRUTH ABOUT TORTS: REGULATORY PREEMPTION AT THE NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION 6 (2008), available at http://www.progressivereform.org/articles/NHTSA_Preemption_804.pdf.

June 2010 as an ongoing attempt to clarify its position.⁹⁸ NHTSA examined whether there was any *potential* to preempt and succinctly determined that “[w]ithout any conflict, there could not be any implied preemption.”⁹⁹

Beginning with its November 2010 proposed Child Restraint Systems Rule, NHTSA has gone even further to disclaim any preemptive intent in its boilerplate language: “[NHTSA] finds that this proposal, like many NHTSA rules, prescribes only a minimum safety standard. As such, NHTSA does not intend that this proposal preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by today’s proposal.”¹⁰⁰

i. Implied Preemption Language

In its 2008 NPRM on Seat Belt Lockability, the agency changed its language on implied preemption from “NHTSA has not outlined such potential [conflicts]” to “NHTSA has not *discerned* any conflict.”¹⁰¹ The agency’s March 2009 Air Brakes Rule added language stating that “NHTSA has considered today’s interim final rule and does not currently foresee any potential State requirements that might conflict with it. Without any conflict, there could not be any implied preemption.”¹⁰² According to NHTSA, this revision was in response to AAJ’s petitions to NHTSA.

In August 2009, NHTSA laid out how it assesses potential conflicts and obstacles for implied preemption, while retaining the language about not discerning any conflict.¹⁰³ The 2010 Electric-Powered Vehicles Rule used

98. In subsequent rulemakings, NHTSA referred readers to the 2010 Electric-Powered Vehicles Rule, which “explained that the agency has increasingly clarified and amplified its discussion responding to E.O. 13132 in an attempt to end the misunderstandings and assuage concerns about the preemption discussion.” Federal Motor Vehicle Safety Standards; Seat Belt Assembly Anchorages, School Bus Passenger Seating and Crash Protection, 75 Fed. Reg. 66,686, 66,695 (Oct. 29, 2010) (to be codified at 49 C.F.R. pt. 571).

99. Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,525–26 (June 14, 2010) (to be codified at 49 C.F.R. pt. 571).

100. Federal Motor Vehicle Safety Standards, Child Restraint Systems; Hybrid III 10-Year Old Child Test Dummy, 75 Fed. Reg. 71,648, 71,661 (proposed Nov. 24, 2010) (to be codified at 49 C.F.R. pt. 571).

101. *Compare* Federal Motor Vehicle Safety Standards; Occupant Crash Protection in Interior Impact, 72 Fed. Reg. 50,900, 50,905 (Sept. 5, 2007) (to be codified at 49 C.F.R. pt. 571), *with* Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 73 Fed. Reg. 52,939, 52,941 (proposed Sept. 12, 2008) (to be codified at 49 C.F.R. pt. 571) (emphasis added). At this time, NHTSA’s language on express preemption remained unchanged. *See* Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 73 Fed. Reg. at 52,941.

102. *See* Federal Motor Vehicle Safety Standard; Air Brake Systems, 74 Fed. Reg. 9173, 9175 (Mar. 3, 2009) (to be codified at 49 C.F.R. pt. 571), *cited in* Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. at 33,525 & nn.26–27.

103. *See* Federal Motor Vehicle Safety Standards; Controls, Telltales, and Indicators, 74 Fed. Reg. 40,760, 40,763–64 (Aug. 13, 2009) (to be codified at 49 C.F.R. pt. 571) (“However, NHTSA has considered *the nature and purpose* of today’s rule and does not currently foresee

similar language, expanding slightly on NHTSA's conflict analysis: "NHTSA has considered the nature (*e.g.*, the language and structure of the regulatory text) and objectives of today's final rule and does not discern any existing State requirements that conflict with the rule or the potential for any future State requirements that might conflict with it."¹⁰⁴

NHTSA and AAJ continued to disagree over the interpretation of the boilerplate language.¹⁰⁵ NHTSA argued that its inclusion of this boilerplate discussion under the section of its preambles discussing E.O. 13132 was not intended to preempt state tort law. AAJ disagreed. I identified twenty-nine NHTSA rules with boilerplate language discussing preemption that NHTSA did not include in its list to OIRA.¹⁰⁶ These rules can be grouped into three broad categories of NHTSA's evolving boilerplate. Eleven rules follow NHTSA's tack (as seen in the June 2010 Electric-Powered Vehicles Rule) of stating that it cannot discern any conflict with state law and concluding that "[w]ithout any conflict, there could not be any implied preemption."¹⁰⁷ Five rules from 2008 state that NHTSA "cannot completely rule out the possibility that such a conflict might become apparent."¹⁰⁸ And eleven rules from mid-2007 through mid-2008 state that while NHTSA had not identified a conflict, a conflict-creating preemption was "conceivable."¹⁰⁹

With its November 2010 proposed Child Restraints Rule, NHTSA made an even more emphatic disclaimer of preemptive intent or effect of its rule-making as part of its further revised boilerplate. As a general matter, NHTSA explained, conflicts between its federal safety standards and state tort law should be few and far between: "Because most NHTSA standards established by [Federal Motor Vehicle Safety Standards] are minimum standards, a State common law tort cause of action that seeks to impose a

any potential [conflicts]. Without any conflict, there could not be any implied preemption." (emphasis added)).

104. See Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. at 33,525–26.

105. See, *e.g.*, Federal Motor Vehicle Safety Standards; Seat Belt Assembly Anchorages, School Bus Passenger Seating and Crash Protection, 75 Fed. Reg. 66,686, 66,695 (Oct. 29, 2010) (to be codified at 49 C.F.R. pt. 571) ("AAJ has mistakenly characterized the agency's discussion of implied preemption, a discussion that we included in approximately two dozen other Federal motor vehicle safety standard rulemaking notices issued from February 2007 to November 2008.").

106. NHTSA reiterated its position that none of the notices in any of the categories identifies a conflict or states an intent to preempt and thus cannot be accurately characterized as a "preemptive rulemaking." Email from Steve Wood, *supra* note 59.

107. See, *e.g.*, Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. at 33,524–26 (including the most detailed discussion of boilerplate evolution).

108. *E.g.*, Federal Motor Vehicle Safety Standards; Seating Systems, Occupant Crash Protection, Seat Belt Assembly Anchorages, School Bus Passenger Seating and Crash Protection, 73 Fed. Reg. 62,744, 62,778 (Oct. 21, 2008) (to be codified at 49 C.F.R. pt. 571).

109. *E.g.*, Federal Motor Vehicle Safety Standards; Power-Operated Window, Partition, and Roof Panel Systems, 73 Fed. Reg. 38,331, 38,338 (July 7, 2008) (to be codified at 49 C.F.R. pt. 571).

higher standard on motor vehicle manufacturers will generally not be preempted.”¹¹⁰ With respect to the specific proposal, NHTSA remarked that it, “like many NHTSA rules, prescribes only a minimum safety standard. . . . Establishment of a higher standard by means of State tort law would not conflict with the minimum standard proposed here.”¹¹¹ NHTSA, moreover, specifically stated that it “does not intend that this proposal preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by today’s proposal.”¹¹² And, for the first time in a rulemaking, it made plain that “[t]he agency’s ability to announce its conclusion regarding the preemptive effect of one of its rules reduces the likelihood that preemption will be an issue in any subsequent tort litigation.”¹¹³

Unlike its long elaboration in the June 2010 Electric-Powered Vehicles Rule, NHTSA has not commented on this latest revision to its boilerplate language on preemption, which it incorporated into its 2011 proposed rulemakings.¹¹⁴ Although it should quell AAJ and Public Citizen’s complaints about the boilerplate language, the revision will likely subject NHTSA to criticism for trying to disclaim the preemptive effect of its rules so emphatically.

ii. *Express Preemption Language*

In addition to its evolving boilerplate discussion of implied preemption, NHTSA altered its boilerplate language on express preemption under the MVSA—although this latter change was not acknowledged or discussed by NHTSA in its lengthy comments in the 2010 Electric-Powered Vehicles Rule. Throughout 2007 and 2008, as NHTSA altered the implied preemption boilerplate, the express preemption boilerplate’s unqualified statement

110. Federal Motor Vehicle Safety Standards; Child Restraint Systems; Hybrid III 10-Year Old Child Test Dummy, 75 Fed. Reg. 71,648, 71,661 (proposed Nov. 24, 2010) (to be codified at 49 C.F.R. pt. 571). NHTSA did reserve a narrow category of rules where implied preemption would be appropriate: “[I]f and when such a conflict does exist—for example, when the standard at issue is both a minimum and a maximum standard—the State common law tort cause of action is impliedly preempted.” *Id.* (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)).

111. *Id.*

112. *Id.*

113. *Id.*

114. *See, e.g.*, Make Inoperative Exemptions; Vehicle Modifications to Accommodate People with Disabilities, Side Impact Protection, 76 Fed. Reg. 37,025, 37,027 (June 24, 2011) (to be codified at 49 C.F.R. pt. 595); Federal Motor Vehicle Safety Standards; Motorcycle Helmets, 76 Fed. Reg. 28,132, 28,159 (May 13, 2011) (to be codified at 49 C.F.R. pt. 571); Federal Motor Vehicle Safety Standards, Ejection Mitigation; Phase-In Reporting Requirements; Incorporation by Reference, 76 Fed. Reg. 3212, 3294–95 (Jan. 19, 2011) (to be codified at 49 C.F.R. pts. 571 & 585).

that the MVSA preempted “State law” that was not identical to the NHTSA standard remained untouched.¹¹⁵

Then, in the March 2009 Air Brake Rule, NHTSA limited its claim of express preemption to state positive law: “It is this statutory command [49 U.S.C. § 30103(b)(1)] that unavoidably preempts State *legislative and administrative law*, not today’s rulemaking, so consultation would be unnecessary.”¹¹⁶ The clear import is that state common law does not fall within the purview of express preemption claims.¹¹⁷ NHTSA made this implication explicit in its November 2010 proposed Child Restraint Systems Rule:

The express preemption provision . . . is subject to a savings clause under which “[c]ompliance with a motor vehicle safety standard . . . does not exempt a person from liability at common law.” Pursuant to this provision, State common law tort causes of action against motor vehicle manufacturers that might otherwise be preempted by the express preemption provision are generally preserved.¹¹⁸

3. Litigation

NHTSA took an antipreemption position in *Williamson v. Mazda Motor of America, Inc.*,¹¹⁹ the 2010 U.S. Supreme Court case that defined the scope of the Court’s implied preemption holding in *Geier*. According to the solicitor general’s amicus brief (submitted in August 2010), since *Geier* lower courts around the country have misread the Supreme Court’s holding and rather have created a much broader standard of preemption in which they find implied preemption “even though the federal agency that promulgated and administers that regulation disagrees.”¹²⁰ The brief, signed by Paul Geier, Assistant General Counsel for Litigation at DOT, argued that lower courts have incorrectly read *Geier* to suggest that any time NHTSA gives manufacturers different options to satisfy a safety standard, state tort law is preempted.¹²¹ Because of this broadening of *Geier* preemption, the brief

115. See, e.g., Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 73 Fed. Reg. 52,939, 52,941 (proposed Sept. 12, 2008) (to be codified at 49 C.F.R. pt. 571) (“It is this statutory command [49 U.S.C. § 30103(b)(1)] that preempts State law, not today’s rulemaking, so consultation would be inappropriate.”).

116. Federal Motor Vehicle Safety Standard; Air Brake Systems, 74 Fed. Reg. 9173, 9175 (Mar. 3, 2009) (to be codified at 49 C.F.R. pt. 571) (emphasis added).

117. According to Steve Wood, although he had not previously thought anyone would reasonably read “state law” to include tort law—especially in light of *Geier*’s holding of no express preemption of state tort law—he decided to add qualifying language to ensure that no one could henceforth interpret NHTSA’s express preemption discussion as extending to tort law. Email from Steve Wood, *supra* note 59.

118. Federal Motor Vehicle Safety Standards; Child Restraint Systems; Hybrid III 10-Year Old Child Test Dummy, 75 Fed. Reg. 71,648, 71,661 (proposed Nov. 24, 2010) (to be codified at 49 C.F.R. pt. 571) (alteration in original).

119. No. 08-1314, slip op. (U.S. Feb. 23, 2011).

120. U.S. *Williamson* Brief, *supra* note 48, at 17.

121. *Id.* at 17–18 (citing many federal and state cases).

sought, like NHTSA's rulemaking shift,¹²² to clarify the "acknowledged confusion" and "widespread error in the lower courts over the decade since *Geier*."¹²³

The rule at issue in *Williamson* allowed manufacturers to choose between lap-belts and shoulder-belts for the middle seat position in cars.¹²⁴ When the plaintiff sought to hold Mazda liable for its decision to use a lap-belt in its minivan, which contributed to the death of a passenger, Mazda claimed, and the trial court agreed, that the claim was preempted by the NHTSA safety standard.¹²⁵ Affirming the trial court, the California state appellate court held that the same policy concerns of testing multiple forms of passive restraints (e.g., airbags) that led to preemption in *Geier* also applied to seatbelts, and the California Supreme Court denied certiorari.¹²⁶

The United States and NHTSA argued to the Court that, unlike in *Geier*, there was no "affirmative[] encourag[ing]" of diverse forms of seatbelts, and a Federal Motor Vehicle Safety Standard should normally be read to be no more than a "minimum standard."¹²⁷ NHTSA appears to favor a standard whereby courts should defer to its judgment when it states that a rule does *not* have preemptive effect. Moreover, according to NHTSA, the agency's "longstanding" position is that its standards do not generally preempt state tort law, aside from situations in which the agency's affirmative policy presents an outright conflict, as in *Geier*.¹²⁸ The U.S. Supreme Court unanimously held that the NHTSA regulation did not preempt state common law and seven justices expressly endorsed the views of the agency and the solicitor general, relying on "the regulation's history, the agency's contemporaneous explanation, and its consistently held interpretive views."¹²⁹

122. Specifically, in NHTSA's December 2009 Designated Seating Positions Rule, the agency set forth a similar interpretation of *Geier*. Federal Motor Vehicle Safety Standards; Designated Seating Positions, 74 Fed. Reg. 68,185, 68,188 (Dec. 23, 2009) (to be codified at 49 C.F.R. pt. 571).

123. U.S. *Williamson* Brief, *supra* note 48, at 21.

124. *Williamson*, slip op. at 1.

125. *Williamson v. Mazda Motor of Am., Inc.*, 167 Cal. Rptr. 4th 905, 907–10 (Ct. App. 2008) (describing trial court order), *rev'd*, No. 08-1314, slip op. (U.S. Feb. 23, 2011).

126. *Id.* at 919; U.S. *Williamson* Brief, *supra* note 48, at 6–8.

127. U.S. *Williamson* Brief, *supra* note 48, at 9 (citing 49 U.S.C. § 30102(a)(9) (2010)).

128. Indeed, NHTSA has consistently taken this position in cases before the U.S. Supreme Court. *See id.* at 30–31 (detailing the government's position set forth in a series of amicus briefs submitted to the Court in cases dating back to 1990, including *Wood v. General Motors Corp.*, 494 U.S. 1065 (1990), and *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995)). While this position stands in some tension with NHTSA's rulemaking during the period of use of the preemption preambles in 2005 and arguably with some of the later rulemakings in 2007–2008, it is now squarely aligned with NHTSA's more recent rulemakings since November 2010. *See supra* notes 110–114 and accompanying text.

129. *Williamson*, slip op. at 12.

B. Food and Drug Administration

Of the agencies surveyed, FDA is the most difficult to assess. Like NHTSA, FDA came under sharp attack during the George W. Bush Administration for its efforts to preempt state tort law while skirting the requirements of E.O. 13132.¹³⁰ According to the AAJ study, from 2001 to 2008, FDA issued twenty of the fifty-three total notices issued by federal agencies claiming preemption, second only to NHTSA.¹³¹ Most notably, the FDA preempted state tort law for drug labeling through the preamble of a regulation, even after it had previously disclaimed any preemptive intent in the initial proposed rulemaking.¹³² The U.S. Supreme Court criticized the FDA's conduct in *Wyeth v. Levine* and refused to defer to the FDA's position on preemption.¹³³

There is some evidence from the regulatory record and intervention in litigation that indicates that FDA has revised its preemption policy under the Obama Administration. My interview with FDA's chief counsel provided some (albeit limited) evidence of a change in tone on preemption at the agency.¹³⁴ Then-pending litigation—and FDA's attempts to keep its preemption position close to the vest until it had fully analyzed the issues—likely explains the opacity of FDA's position.

Whereas NHTSA appears to have staked out a fairly categorical stance rejecting implied obstacle preemption (at least with respect to state tort law) in both its rulemaking and intervention in litigation, FDA seems to have adopted a more neutral position, based on the fact-intensive nature of obstacle preemption that is likely to vary across different scenarios. FDA, for example, removed all references to implied obstacle preemption in a recent rulemaking on the ground that the doctrine is necessarily “case specific,” whereas NHTSA, in its recent rulemakings, has incorporated what amounts to an express disclaimer of preemptive intent or effect of its rules. Somewhat more subtly, differences can be teased out of the positions of the respective agencies in litigation before the Supreme Court. Unlike the solicitor general's amicus brief in *Williamson*, which clearly articulated NHTSA's antipreemption position in the case (and requested deference to its views), the solicitor general did not take a similar opportunity to elabo-

130. See, e.g., Sharkey, *Federalism Accountability*, *supra* note 14, at 2131–41.

131. See AM. ASS'N FOR JUSTICE, *supra* note 2, app. B at 28–33.

132. Sharkey, *Federalism Accountability*, *supra* note 14, at 2131–34.

133. 129 S. Ct. 1187, 1201 (2009) (“In 2006, the agency finalized the rule and, without offering States or other interested parties notice or opportunity for comment, articulated a sweeping position on the FDCA's pre-emptive effect in the regulatory preamble. The agency's views on state law are inherently suspect in light of this procedural failure.”); Sharkey, *Federalism Accountability*, *supra* note 14, at 2173–74 (“[T]he Court looked askance at the FDA's ‘proclamations of pre-emption’ in its 2006 preemption preamble. The Court specifically mentioned that the FDA's failure to ‘offer[] States or other interested parties notice or opportunity for comment’ rendered its views on state law ‘inherently suspect.’” (alteration in original) (footnote omitted)).

134. Interview with Ralph Tyler, Chief Counsel, FDA, in Silver Spring, Md. (July 6, 2010).

rate fully on FDA's general position on preemption in its amicus submission in *PLIVA, Inc. v. Mensing*, a generic drug preemption case that same term.¹³⁵

1. Response to May 2009 Presidential Memorandum on Preemption

In response to whether FDA conducted the ten-year retrospective review of preemptive rulemakings, FDA chief counsel stated that the agency performed an extensive review, as requested by the Preemption Memorandum, and explained that FDA anticipates issuing the results of its review after appropriate clearance.¹³⁶ Prospectively, the chief counsel explained that "we seek to avoid finding preemption when we can in a principled way."¹³⁷

2. Rulemaking

Searches of recent FDA rulemakings did not turn up the kind of extensive commentary on an evolving position on preemption that NHTSA, for example, included in its 2010 Electric-Powered Vehicles Rule. FDA, however, administers myriad statutory schemes (some of which include express preemption provisions), and the agency therefore does not have the same opportunity as does NHTSA to opine on preemption across the different areas in which it regulates.

The rulemaking record, nonetheless, contains some hints that FDA may have retreated from its aggressive pro-preemption stance. One example is the Food, Drug and Cosmetic Act's ("FDCA") non-prescription-drug express preemption provision, 21 U.S.C. § 379r(a). While the prepublication version of the FDA's over-the-counter ("OTC") labeling rule contained a preemption provision (which was quickly removed from the Federal Register

135. Compare U.S. *Williamson* Brief, *supra* note 48, at 29–31 (arguing that the Court should defer to its position on preemption in addition to its interpretation of its regulations), with Brief for the United States as Amicus Curiae Supporting Respondents at 15, *PLIVA, Inc. v. Mensing*, No. 09-993, slip op. (U.S. June 23, 2011) [hereinafter U.S. *Mensing* Merits Brief] (arguing for deference to FDA's interpretation of its regulations but not to its position on preemption). Interestingly, the solicitor general also invoked the "presumption against preemption" in *Williamson*, but not in *Mensing*. See U.S. *Williamson* Brief, *supra* note, 48, at 11.

136. Telephone Interview with Ralph Tyler, Chief Counsel, FDA; Ann Wion, Deputy Chief Counsel for Program Review, FDA; and Leslie Kux, Acting Assistant Comm'r for Policy, FDA (Oct. 4, 2010). While this Article was in production, FDA published its ten-year retrospective review of preemptive regulations. See *supra* note 44.

137. Interview with Ralph Tyler, *supra* note 134.

website),¹³⁸ the limited discussion of express preemption in the final rule does not preempt state law as clearly as the NPRM.¹³⁹

On the other hand, FDA has continued to assert statutory preemption in its rules—for example, the Skin Protectant and Bottled Water Rules.¹⁴⁰ The Skin Protectant Rule, issued one month before the OTC Drug Labeling Rule, likewise interprets preemption under § 379r(a).¹⁴¹ The rule claims express preemption under 379r(a) with a justification similar to the NPRM in the OTC Drug Labeling Rule, and also claims implied preemption under *Geier*.¹⁴² The rule mentions that FDA reached out to state and local officials on preemption but received no comment.¹⁴³

The Bottled Water Rule asserts preemption under a different provision of the FDCA: preemption of misbranded food regulation in § 403A.¹⁴⁴ The rule quotes § 403A and explains:

Although this rule has a preemptive effect in that it will preclude States from issuing requirements . . . that are not identical to the requirements . . . as set forth in this rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(1) of the act displaces both State legislative requirements and State common law duties.¹⁴⁵

The final rule actually appears to go further than the NPRM, which did not assert that 403A(a)(1) preempted state common law duties.¹⁴⁶ As the first FDA rule claiming preemption since President Obama's Preemption

138. Kurt R. Karst, *Change in FDA Preemption Position? New Rule Largely Eliminates Preemption Discussion*, FDA L. BLOG (Apr. 29, 2009, 10:41 AM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2009/04/change-in-fda-preemption-position-new-rule-largely-eliminates-preemption-discussion.html. I also interviewed Kurt Karst, author of FDA Law Blog, by telephone on July 8, 2010.

139. See Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling, 71 Fed. Reg. 77,314, 77,345 (proposed Dec. 26, 2006) (to be codified at 21 C.F.R. pts. 201 & 343).

140. See, e.g., Beverages: Bottled Water, 74 Fed. Reg. 25,651, 25,664 (May 29, 2009) (to be codified at 21 C.F.R. pts. 129 & 165); Astringent Drug Products that Produce Aluminum Acetate; Skin Protectant Drug Products for Over-the-Counter Human Use; Technical Amendment, 74 Fed. Reg. 9759, 9763–64 (Mar. 6, 2009) (to be codified at 21 C.F.R. pts. 310 & 347).

141. 21 U.S.C. § 379r(a) (2006).

142. Astringent Drug Products that Produce Aluminum Acetate; Skin Protectant Drug Products for Over-the-Counter Human Use; Technical Amendment, 74 Fed. Reg. at 9763–64 (claiming express and implied preemption). The rule is a “technical amendment” that updates a 1993 rule on skin protectants; there was no preemption provision in the 1993 rule. See Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products, 58 Fed. Reg. 54,458 (Oct. 21, 1993) (to be codified at 21 C.F.R. pts. 310 & 347).

143. Astringent Drug Products that Produce Aluminum Acetate; Skin Protectant Drug Products for Over-the-Counter Human Use; Technical Amendment, 74 Fed. Reg. at 9764.

144. See Beverages: Bottled Water, 74 Fed. Reg. at 25,664.

145. *Id.* (citation omitted).

146. See Beverages; Bottled Water, 73 Fed. Reg. 53,775, 53,791–92 (proposed Sept. 17, 2008) (to be codified at 21 C.F.R. pts. 129 & 165).

Memorandum, however, the rule states that it is now treating preemption “in light of the President’s Memorandum.”¹⁴⁷

FDA appears to rely exclusively on express preemption principles, with no reliance on *Geier* implied preemption. Guided by this approach, in a 2011 Sunscreen Drug Products Rule, FDA removed statements regarding implied preemption that it had included in the 2007 proposed rule. As FDA explained: “[W]e have omitted any statement regarding implied preemption because, although implied preemption may arise, such scenarios are necessarily case-specific.”¹⁴⁸

3. Litigation

In 2011, the U.S. Supreme Court decided *PLIVA, Inc. v. Mensing*, which held that state law failure-to-warn claims against generic drug manufacturers were preempted, notwithstanding the Court’s refusal in *Wyeth v. Levine* to preempt similar claims against brand name prescription drug companies.¹⁴⁹ The Court held that the federal regulations applicable to generic drug manufacturers directly conflict with, and thus preempt, state law failure-to-warn claims.¹⁵⁰

In its amicus briefs to the Court,¹⁵¹ the solicitor general (joined by agency officials from the Department of Health and Human Services¹⁵²) argued against preemption of the state tort claim. FDA conceded that generic drug manufacturers are constrained in their ability to alter their labels, which by

147. Beverages; Bottled Water, 74 Fed. Reg. at 25,664 n.3.

148. Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35,620, 35,624 (June 17, 2011) (to be codified at 21 C.F.R. pts. 201 & 310).

149. *PLIVA, Inc. v. Mensing*, No. 09-993, slip op. (U.S. June 23, 2011). The precise question presented in *Mensing* was “[w]hether the [court] abrogated the Hatch-Waxman Amendments by allowing state tort liability for failure to warn in direct contravention of the Act’s requirement that a generic drug’s labeling be the same as the FDA-approved labeling for the listed (or branded) drug.” Petition for Writ of Certiorari at i, *Mensing*, slip op. (No. 09-993), available at http://www.scotusblog.com/wp-content/uploads/2010/05/09-993_pet.pdf.

Both of the federal courts of appeals (and the majority of lower federal courts) that addressed the issue rejected preemption. *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *rev’d, Mensing*, slip op. at 6, *reh’g denied, remand to, Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir.); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), *rev’d, Mensing*, slip op. at 6, *remand to, Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir.).

150. Until 1984, the same federal regulations applied to both brand name and generic drugs. In 1984, Congress passed the Hatch-Waxman Amendments, which streamlined requirements for generic drug manufacturers to gain FDA approval simply by showing the generic’s equivalence (including active ingredients as well as labeling) to the brand name drug. 21 U.S.C. § 355(j)(2)(A) (2006).

151. Before granting certiorari, the Court requested the views of the solicitor general on the petition for writ of certiorari. See Brief for the United States as Amicus Curiae, *Mensing*, slip op. (No. 09-993) [hereinafter U.S. *Mensing* Cert. Brief]. The solicitor general also filed an amicus brief at the merits stage. U.S. *Mensing* Merits Brief, *supra* note 135.

152. Ralph Tyler, Chief Counsel of FDA, signed the briefs in his capacity as Associate General Counsel of the Department of Health and Human Services. U.S. *Mensing* Merits Brief, *supra* note 135; U.S. *Mensing* Cert. Brief, *supra* note 151.

statutory mandate must be identical to those approved for the brand name drug.¹⁵³ Unlike a brand name manufacturer, a generic drug manufacturer cannot unilaterally change its approved labeling under the “changes being effected” (“CBE”) process.¹⁵⁴ Moreover, should a generic drug manufacturer unilaterally send out a “Dear Health Care Professional” letter (as brand name drug manufacturers may do),¹⁵⁵ it risks having its generic drug deemed “misbranded.”¹⁵⁶ Nonetheless, FDA maintained that generic drug manufacturers are obliged to provide FDA with any new information about risks and may do so by proposing either labeling changes or “Dear Health Care Professional” letters to FDA, which can then modify the existing warnings as appropriate.¹⁵⁷

The Supreme Court deferred to FDA’s interpretations of its regulations, finding its views “controlling unless plainly erroneous or inconsistent with the regulation[s]’ or there is any other reason to doubt that they reflect the FDA’s fair and considered judgment.”¹⁵⁸ But the Court disagreed with FDA’s

153. U.S. *Mensing* Merits Brief, *supra* note 135, at 3, 15–16 (stating that generic drugs must bear labeling “the same as the labeling approved for the [name brand drug]” (quoting 21 U.S.C. § 355(j)(2)(A)(v)) (internal quotation marks omitted)).

154. *Id.* at 7, 16 (citation omitted) (internal quotation marks omitted) (“FDA has consistently taken the position that [a generic drug manufacturer] may not unilaterally change its approved labeling.”). The Eighth Circuit did not weigh in on this issue in *Mensing*. The Fifth Circuit, however, concluded that the CBE process was available to generic drug manufacturers. *Demahy*, 593 F.3d at 439–44. According to the solicitor general, the Fifth Circuit’s holding “misunderstands FDA’s regulations.” U.S. *Mensing* Cert. Brief, *supra* note 151, at 22 n.10.

155. These letters describe important information about a drug, including updated warnings, and are occasionally mailed out by drug manufacturers and distributors to physicians, nurses, and other members of the professional health care community. *See* 21 C.F.R. § 200.5 (2011) (setting standards for such correspondence).

156. For this reason, “[s]tate law may not impose liability on [a generic drug manufacturer] for failing to send such a letter unilaterally.” U.S. *Mensing* Cert. Brief, *supra* note 151, at 18.

157. *See id.* (“[E]ither would have involved bringing the relevant information to FDA’s attention with a view to providing consistent warnings for the [brand name drug] and its generic equivalents.”); *id.* at 13 (“[Generic drug manufacturers] were nonetheless required to provide FDA with new information about risks, and FDA would have acted on such information if appropriate”); *id.* at 15 (declaring that generic drug manufacturers are “obligated to provide FDA with information about labeling concerns”); *see also* U.S. *Mensing* Merits Brief, *supra* note 135, at 9.

158. *PLIVA, Inc. v. Mensing*, No. 09-993, slip op. at 6 (U.S. June 23, 2011) (alteration in original) (quoting *Auer v. Robbins*, 519 U.S. 452, 461–62 (1997)); *see id.* at 8 (“We defer to the FDA’s interpretation of its CBE and generic labeling regulations.”); *id.* (“As with the CBE regulation, we defer to the FDA [regarding generic drug manufacturer’s ability to send ‘Dear Health Care Professional’ letters].”). The Court found it unnecessary to decide whether, as the FDA claimed, a preamble to its regulations implementing the Hatch-Waxman Amendments created a federal duty for generic manufacturers, in light of new safety risk information, to request that FDA take steps to strengthen the label for both brand-name and generic drugs. *Id.* at 10 (“Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter.”).

bottom-line conclusion that state law was not preempted.¹⁵⁹ Instead, the Court found “impossibility” preemption on the ground that the generic drug manufacturers could not simultaneously satisfy their state law duty to provide additional warnings and their federal law duty to provide the same labeling as the brand name drug.¹⁶⁰ Moreover, the Court widened the scope of impossibility preemption by refusing to take into account possible interventions by FDA to reconcile federal and state law duties.¹⁶¹

The solicitor general’s amicus briefs in *Mensing* are FDA’s first expression of its position on implied preemption under the Obama Administration. FDA claims that its interpretations of its regulations governing drug labeling are entitled to deference.¹⁶² Perhaps of even greater significance, and despite its opposition to the generic drug manufacturers’ impossibility preemption argument, FDA would nonetheless preserve its own potential preemptive authority: “A fully informed, actual decision by FDA that a particular warning would be inconsistent with the FDCA or FDA’s regulations would presumably preempt a state law claim predicated on the necessity of such a warning.”¹⁶³ On FDA’s account, the key to the implied preemption

159. *Id.* at 6–7 n.3 (“Although we defer to the agency’s interpretation of its regulations, we do not defer to an agency’s ultimate conclusion about whether state law should be preempted.” (citation omitted)). The Court’s treatment here of the agency’s position contrasts with its heavy reliance in *Williamson v. Mazda Motor of Am., Inc.* on “the promulgating agency’s contemporaneous explanation of its objectives, and the agency’s current views of the regulation’s pre-emptive effect.” No. 08-1314, slip op. at 6 (U.S. Feb. 23, 2011). Justice Thomas was the lone objector to the agency-centric view espoused by the majority in *Williamson*; writing for the Court in *Mensing*, he steered the majority toward a more limited and structured approach, focusing on the text of the relevant federal regulations (as interpreted by FDA). *Mensing* may signal a backpedaling from the *Williamson* approach to agency deference on preemption; however, it may be distinguishable given that it was resolved solely on implied impossibility preemption and thus did not consider the wider obstacle (or frustration of purposes) preemption. *See Mensing*, slip op. at 18 n.7 (“[T]hat type of pre-emption [obstacle] is not argued here.”). In that regard, the Court’s analysis in *Mensing* shares more affinities with express preemption cases—where the Court’s task is to interpret the language of the explicit preemption provision—than with implied obstacle preemption cases, which require resort to extratextual sources, chief among them the agency’s stated objectives, regulatory record, and views on preemption.

160. *Mensing*, slip op. at 12 (“[I]t was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.”).

161. *See id.* at 13 (“The question for ‘impossibility’ is whether the private party could independently do under federal law what state law requires of it.” (emphasis added)); *id.* at 17 (“[W]hen a party cannot satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes.”). The dissent vehemently objected to this “independent” requirement, charging that the majority “invents new principles of pre-emption law out of thin air to justify its dilution of the impossibility standard.” *Id.* at 2 (Sotomayor, J., dissenting).

162. U.S. *Mensing* Cert. Brief, *supra* note 151, at 13 (citing *Auer v. Robbins*, 519 U.S. 452, 462 (1997), and *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984)).

163. *Id.* at 19 n.9 (citing *Wyeth v. Levine*, 129 S. Ct. 1187, 1203 & n.14 (2009)); *see also Wyeth v. Levine*, 129 S. Ct. 1187, 1204 (2009) (Breyer, J., concurring); U.S. *Mensing*

determination (and a factual issue that must be addressed in the litigation) is “what action FDA would have taken in response to a hypothetical warning proposal”;¹⁶⁴ and here, FDA argues that the drug manufacturers will have to continue to shoulder the preemption defense burden by demonstrating “the likelihood of FDA *inaction*.”¹⁶⁵

FDA likewise signaled (in its amicus brief at the certiorari petition stage) that the scope of obstacle (i.e., frustration of purposes) preemption was narrow.¹⁶⁶ First, FDA reiterated the *Levine* Court’s characterization of the proconsumer purpose of the FDCA to “bolster consumer protection against harmful products,” which it said reflected Congress’s “determin[ation] that widely available state rights of action provide[] appropriate [compensatory] relief for injured consumers.”¹⁶⁷ Next, FDA reasoned that it would not make sense for Congress to have deprived consumers injured by generic drugs of state law remedies against the manufacturer while similarly situated consumers injured by brand name drugs would have recourse.¹⁶⁸ If Congress had actually intended to do so, FDA argued, it “surely would have enacted an express preemption provision if it believed that all state-law suits posed an obstacle to its objectives.”¹⁶⁹ Finally, FDA concluded that the mod-

Merits Brief, *supra* note 135, at 32 (“If FDA had actually rejected a labeling change proposed by [a generic drug manufacturer] . . . [that] might well operate to bar a jury from revisiting FDA’s decision.”).

164. U.S. *Mensing* Cert. Brief, *supra* note 151, at 19.

165. *Id.* (internal quotation marks omitted). It remains elusive precisely what kind of evidence would suffice to indicate that FDA considered the new risk information but declined to take further action to alter the labeling, and thus preempt a state failure-to-warn claim. FDA nonetheless takes the position that such clashes, wherein it is impossible for the defendant manufacturer to comply with both the state law duty and the federal regulatory requirements, “arise infrequently, and when they do, there tend to be unique, fact-specific considerations at issue.” *Id.* at 16.

166. At the merits stage, the generic drug manufacturers abandoned their obstacle preemption argument. See Brief for Respondents Gladys Mensing and Julie Demahy at 48, *Mensing*, slip op. (No. 09-993) (“[Petitioners] appear to have largely abandoned [the argument that state tort liability would obstruct Congress’s purposes and objectives in enacting the Hatch-Waxman Amendments].”). Thus, the government omitted its obstacle preemption argument from its merits-stage amicus brief. The government nonetheless briefly mentioned obstacle preemption, citing *Williamson* and *Levine* but not further elaborating on its position: “Even if compliance with both state and federal law is not impossible, the state-law duty underlying a tort claim is preempted if it would frustrate the purposes and objectives of federal statutes and regulations.” U.S. *Mensing* Merits Brief, *supra* note 135, at 14 (citing *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314, slip op. at 5 (U.S. Feb. 23, 2011), and *Levine*, 129 S. Ct. at 1199).

167. U.S. *Mensing* Cert. Brief, *supra* note 151, at 21 (alteration in original) (quoting *Levine*, 129 S. Ct. at 1199) (internal quotation marks omitted); U.S. *Mensing* Merits Brief, *supra* note 135, at 28.

168. U.S. *Mensing* Cert. Brief, *supra* note 151, at 21.

169. *Id.* (quoting *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009) (internal quotation marks omitted)).

est state law duty to provide information to FDA “seems unlikely to affect the availability of generic pharmaceuticals.”¹⁷⁰

Overall, however, FDA’s position on implied obstacle preemption in the certiorari-stage amicus brief is cursory, and FDA does not request deference to its antipreemption position (as NHTSA did in *Williamson*¹⁷¹). And because obstacle preemption dropped out of the case altogether, FDA had no further opportunity to elaborate.

C. Office of the Comptroller of the Currency

The U.S. Supreme Court has considered OCC’s preemptive rulemakings on a number of occasions. In *Cuomo v. Clearing House Ass’n*, the Court held that the National Banking Act (“NBA”) does not preempt a state attorney general’s action to enforce consumer protection laws preventing discriminatory or predatory lending against a national bank.¹⁷² More specifically, the Court considered whether OCC’s Visitorial Powers Rule, which preempted state law enforcement,¹⁷³ was a reasonable interpretation of the NBA, which shields national banks from states’ exercises of “[v]isitorial powers.”¹⁷⁴ The Court rejected OCC’s position as contrary to the plain terms of the NBA, which would permit state enforcement of nonpreempted state law.¹⁷⁵ OCC had wielded the same Visitorial Powers Rule to preempt state laws regulating mortgage lending as applied to state-chartered subsidiaries of national banks, an action that the Supreme Court upheld two years earlier in *Watters v. Wachovia Bank, N.A.*¹⁷⁶

OCC’s preemptive Visitorial Powers Rule was issued in 2004, along with a broader rule preempting all state laws that “‘obstruct, impair, or condition a national bank’s ability to fully exercise its Federally authorized powers’ in four broadly-defined areas—real estate lending, lending not

170. *Id.* at 22. At the same time, FDA recognized that “imposing on a generic manufacturer a state law duty not to market its product without developing for itself knowledge as comprehensive as FDA’s or the [brand name manufacturer’s] could pose [different] preemption questions.” *Id.*

171. *See* U.S. *Williamson* Brief, *supra* note 48, at 29–31.

172. 129 S. Ct. 2710 (2009).

173. *See* 12 C.F.R. § 7.4000 (2011). The exercise of visitorial powers is the power to inspect or make decisions about an entity’s operations. *Id.*

174. 12 U.S.C. § 484(a) (2006).

175. *See Cuomo*, 129 S. Ct. at 2715. The Court did, however, conclude that state attorneys general cannot investigate national banks’ conduct or practices using administrative subpoenas, which the Court characterized as impermissible visitations preempted by the NBA. *Id.* at 2721–22.

176. 550 U.S. 1 (2007). Unlike *Cuomo*, which focused on the scope of *express* preemption inherent in the statutory term “visitorial powers,” the Court found *implied* conflict preemption in *Watters*, holding that state supervision of state-chartered subsidiaries of national banks would conflict with the exercise of the national bank’s federally authorized powers under the NBA. *Watters*, 550 U.S. at 20–21. *But see infra* note 209 and accompanying text (discussing how Congress overturned *Watters* in the Dodd-Frank Wall Street Reform and Consumer Protection Act).

secured by real estate, deposit-taking, and other ‘operations.’”¹⁷⁷ When OCC considered these rules, members of Congress wrote to OCC to ask for a delay in promulgating these rules, because they wanted to consider whether to clarify congressional intent to OCC after Congress returned from recess.¹⁷⁸ OCC did not wait. In response, both the House and Senate committees conducted hearings on whether OCC’s actions exceeded the boundaries of what Congress intended.¹⁷⁹

Additionally, Congress commissioned GAO to study OCC’s rulemaking process, to review OCC’s capacity to handle consumer complaints, and to assess the potential impact of OCC’s rules on consumer protection and the dual banking system.¹⁸⁰ The 2005 GAO Report evaluated OCC’s apparent disregard of state interests in passing the preemptive rules at issue in *Cuomo* and *Watters*, and concluded that OCC had opportunities to enhance its consultative efforts.¹⁸¹ Because GAO found that OCC had followed the requirements of E.O. 13132, GAO did not make formal recommendations to Congress.¹⁸² GAO cautioned, however, that it “could not fully determine the basis for some of the other agency actions or assess the extent of its consultations with stakeholders because OCC did not always document its actions and lacked written guidance and procedures detailing the rulemaking process.”¹⁸³ GAO criticized OCC’s lack of documentation of both its consultations and procedures, warning that “[w]ithout such documentation, it may not

177. Arthur E. Wilmarth, Jr., *Cuomo v. Clearing House: The Supreme Court Responds to the Subprime Financial Crisis and Delivers a Major Victory for the Dual Banking System and Consumer Protection*, in *THE PANIC OF 2008: CAUSES, CONSEQUENCES AND IMPLICATIONS FOR REFORM* 295, 335 n.89 (Lawrence E. Mitchell & Arthur E. Wilmarth, Jr. eds., 2010) (citing 12 C.F.R. §§ 7.4007–.4009, 34.4).

178. See *Congressional Review of OCC Preemption: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Fin. Servs.*, 108th Cong. 274–89 (2004) (letters from various members of Congress to Hon. John D. Hawke, Jr., Comptroller of the Currency).

179. See *id.*; *Review of the National Bank Preemption Rules: Hearings Before the S. Comm. on Banking, Hous., and Urban Affairs*, 108th Cong. 864 (2004).

180. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-06-387, OCC PREEMPTION RULES: OCC SHOULD FURTHER CLARIFY THE APPLICABILITY OF STATE CONSUMER PROTECTION LAWS TO NATIONAL BANKS 2 (2006), available at www.gao.gov/new.items/d06387.pdf.

181. The Report stated:

In the face of an executive order [13132] specifically calling for state and local consultation on preemption rules, OCC’s limited additional effort may have contributed to an impression that it did not genuinely seek or consider input from [state bank supervisors]. Stakeholders representing such diverse interests as consumer protection advocates, state bank regulators, state attorneys general, and some Members of Congress continue to maintain that the agency did not genuinely seek their input.

U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-06-8, OCC PREEMPTION RULEMAKING: OPPORTUNITIES EXISTED TO ENHANCE THE CONSULTATIVE EFFORTS AND BETTER DOCUMENT THE RULEMAKING PROCESS 45 (2005) [hereinafter 2005 GAO REPORT], available at <http://www.gao.gov/new.items/d068.pdf>.

182. *Id.* at “Highlights.”

183. *Id.* at 5.

be clear—to agency management, auditors, or oversight committees—that an agency followed applicable requirements.”¹⁸⁴

From the perspective of OCC officials,¹⁸⁵ preemption is a “tool for conducting nationwide business.”¹⁸⁶ Others have made the point more pejoratively, claiming that preemption is a “selling point” used by OCC to market charters. Competing with state banking charters, OCC has used preemption as an inducement to persuade banks to incorporate under national charters, thereby increasing its revenues and its budget.¹⁸⁷ Assessment fees collected from nationally chartered banks are OCC’s primary source of revenue.¹⁸⁸ Congress believed that because OCC admitted that preemption was about attracting additional charters, which in turn increased the size of OCC’s budget, reform was needed.¹⁸⁹

Largely overshadowing any developments in the rulemaking or litigation realms at OCC is the 2010 Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act” or “the Act”). Pursuant to this Act, OCC

184. *Id.*; see also *id.* at 46 (“Without documentation about matters such as how decisions were reached, who was consulted, and what their views were, we were not able to present information in this report that might have contributed to a better understanding of OCC’s process.”).

185. I conducted a telephone interview with a group of OCC officials on August 5, 2010. Participants in the telephone interview were: Horace Sneed, Director of the Litigation Division; Karen Solomon, Director of the Legislative and Regulatory Activities Division; Michele Meyer, Assistant Director of the Legislative and Regulatory Activities Division; Ursula Bass, Counsel in the Legislative and Regulatory Activities Division; and Douglas Jordan, Senior Counsel in the Litigation Division. Telephone Interview with Horace Sneed, Dir. of Litig. Div., OCC; Karen Solomon, Dir., Legislative & Regulatory Activities Div., OCC; Michele Meyer, Assistant Dir., Legislative & Regulatory Activities Div., OCC; Ursula Bass, Counsel, Legislative & Regulatory Activities Div.; and Douglas Jordan, Senior Counsel, Litig. Div., OCC (Aug. 5, 2010) [hereinafter OCC Telephone Interview].

186. *Id.*

187. See Wilmarth, Jr., *supra* note 177, at 308 (“A former head of the OCC described preemption as ‘a significant benefit of the national [bank] charter—a benefit that the OCC has fought hard over the years to preserve.’” (alteration in original) (quoting John D. Hawke, Jr., Comptroller of the Currency, Remarks Before the Women in Housing and Finance (Feb. 12, 2002))).

188. See Oren Bar-Gill & Elizabeth Warren, *Making Credit Safer*, 157 U. PA. L. REV. 1, 93 (2008) (“Assessments compromise 95% of the OCC’s budget . . .”).

189. S. COMM. ON BANKING, HOUS., AND URBAN AFFAIRS, THE RESTORING FINANCIAL STABILITY ACT OF 2010, S. REP. NO. 111-176, at 16 (2010), available at <http://www.gpo.gov/fdsys/pkg/CRPT-111srpt176/pdf/CRPT-111srpt176.pdf> (“At a hearing on the OCC’s preemption rule, Comptroller Hawke acknowledged, in response to questioning from Senator Sarbanes, that one reason Hawke issued the preemption rule was to attract additional charters, which helps to bolster the budget of the OCC.”). In the hearing that the Senate Report cites, Comptroller Hawke, responding to Senator Sarbanes, stated: “[P]reemption is an important attribute of the national bank charter, and I am a strong believer in the quality of the national bank charter.” *Review of the National Bank Preemption Rules: Hearings Before the S. Comm. on Banking, Hous., and Urban Affairs*, 108th Cong. 37 (2004) (statement of John D. Hawke, Jr., Comptroller of the Currency, U.S. Dep’t of the Treasury) (discussing Jess Bravin & Paul Beckett, *Friendly Watchdog: Federal Regulator Often Helps Banks Fighting Consumers*, WALL ST. J., Jan. 28, 2002, at A1).

is classified as an independent agency, no longer subject to the mandates of E.O. 13132.¹⁹⁰

1. Congressional Response: Dodd-Frank Wall Street Reform and Consumer Protection Act

Legislative activity has dominated preemption policy developments at OCC over rulemaking and litigation efforts.¹⁹¹ Under the 2010 Dodd-Frank Act,¹⁹² OCC is designated as an independent regulatory agency within the Department of the Treasury, and assumes the functions of the Office of Thrift Supervision (“OTS”) relating to federal savings associations and the OTS’s rulemaking authority for all savings associations.¹⁹³ The Act also creates a Bureau of Consumer Financial Protection to promulgate and enforce federal financial consumer protection laws.¹⁹⁴ For financial consumer protection, Congress inserted a general preemption standard provision that mirrors the provisions in some of the Federal Trade Commission acts: federal law sets a floor, state law that extends beyond federal law should not be preempted,¹⁹⁵ and state law that is “inconsistent” with federal law is only preempted to the extent of the inconsistency.¹⁹⁶ The Bureau has the authority to determine whether state law is inconsistent with federal law, either on its own motion or in response to a petition.¹⁹⁷

In the Act’s highly contentious “*Barnett* paragraph,” Congress set forth the preemption standard for how state consumer financial protection laws apply to national banks. A state consumer law is preempted only if: (1) it discriminates against national banks;¹⁹⁸ (2) in accordance with *Barnett Bank v. Nelson*,¹⁹⁹ it “prevents or significantly interferes with the exercise by the national bank of its powers”;²⁰⁰ or (3) it is preempted by another federal law.

190. Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 315, 124 Stat. 1376, 1524 (2010) (amending the definition of “independent regulatory agency,” 44 U.S.C. § 3502(5) (2006), to include OCC); *see also* OCC Telephone Interview, *supra* note 185 (confirming change).

191. OCC deferred revisiting its Visitorial Powers Rule until the conclusion of the legislative process. *See infra* note 215.

192. Pub. L. No. 111-203, 124 Stat. 1376.

193. *Id.* §§ 312(b)(2)(B), 314.

194. *Id.* § 1011. The Bureau is likewise an independent regulatory agency, and therefore is not subject to E.O. 13132. *Id.* § 1100D(a).

195. *Id.* § 1041(a)(2).

196. *Id.* § 1041(a)(1).

197. *Id.* § 1041(a)(2).

198. *Id.* § 1044(a) (adding 12 U.S.C. § 5136C(b)(1)(A)).

199. 517 U.S. 25 (1996).

200. Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (emphasis added) (adding 12 U.S.C. § 5136C(b)(1)(B)). The final bill added the language “significantly interferes,” as opposed to merely citing *Barnett*. *Id.* There is a debate over whether OCC, over the past decade, has gone further than the original *Barnett* standard in its preemption determinations and whether the Act changes the substantive preemption standard. Compare Stacy Kaper & Cheyenne Hopkins, *Regulatory Reform Conferees Clip Preemption*, AM. BANKER,

Preemption determinations under the *Barnett* standard can be made by courts or by regulation or order of OCC “on a case-by-case basis.”²⁰¹ “Case-by-case basis” is defined as evaluating one specific state law at a time, rather than affording blanket preemption.²⁰² OCC may attempt to preempt more than one state’s law at a time if it determines that the laws of multiple states are “substantively equivalent,” but OCC must consult with the Bureau when determining whether state law is “substantively equivalent.”²⁰³

According to OCC officials, the *Barnett* paragraph does not alter the status quo because OCC’s preemptive rulemakings have explicitly cited *Barnett*.²⁰⁴ Nor, in their opinion, does the “case-by-case basis” language exclude categorical preemptive rulemakings because of the “substantively equivalent” provision.²⁰⁵ But portions of the Act’s legislative history, including key commentators, suggest that OCC was stripped of authority to enact blanket preemption provisions.²⁰⁶

That said, the “case-by-case” provision applies only to “[s]tate consumer financial law[s],” which are narrowly defined as “State law[s] that do[] not directly or indirectly discriminate against national banks and that directly and specifically regulate[] the manner, content, or terms and conditions of any financial transaction (as may be authorized for national banks to engage in), or any account related thereto, with respect to a consumer.”²⁰⁷ Thus,

June 23, 2010 (quoting various scholars and commentators as stating that *Barnett*’s “significantly interferes” standard is higher than the mere “obstructs” or “impairs” standard used by OCC in its 2004 rulemakings), with *New Financial Regulatory Reform Act: Has It Materially Altered the Preemption Landscape for Federally Chartered Institutions?*, FIN. REG. REFORM ADVISORY (Arnold & Porter LLP, Washington, D.C.), July 2010, at 4 [hereinafter *New Financial Regulatory Reform Act*], available at http://www.aporter.net/public_document.cfm?u=NewFinancialRegulatoryReformActHasItMateriallyAlteredthePreemptionLandscapeforFederallyCharteredInstitutions&id=16154&key=6E2 (stating *Barnett* standard’s impact on national banks “will to some extent be limited by the fact that the . . . amendments primarily codify existing precedent,” but will greatly affect the standards for thrifts and savings banks as it moves away from OTS’s “field preemption” standard).

201. Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (adding 12 U.S.C. § 5136C(b)(1)(B)).

202. *See id.* (adding 12 U.S.C. § 5136C(b)(3)(A)).

203. *Id.* (adding 12 U.S.C. § 5136C(b)(3)(B)).

204. OCC Telephone Interview, *supra* note 185. *But see supra* note 200 (presenting debate on this issue).

205. OCC Telephone Interview, *supra* note 185.

206. The Act’s legislative history suggests that the “case-by-case” provision was a compromise provision that gave OCC some preemptive power, whereas earlier versions of the bill would have stripped OCC of preemptive power entirely. *See* 156 CONG. REC. H14,678 (daily ed. Dec. 10, 2009) (statement of Rep. Melissa Bean). Moreover, former OCC Comptroller John Hawke is listed as a contact on a client report on the Dodd-Frank Act for his law firm, Arnold & Porter, which states that preemption of state consumer financial laws by OCC “must be made on a ‘case-by-case’ basis.” *New Financial Regulatory Reform Act*, *supra* note 200, at 2–3.

207. Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (internal quotation marks omitted) (adding 12 U.S.C. § 5136C(a)(2)).

preemption of state laws regulating issues like bank registration would not be subject to this provision.²⁰⁸

Congress also included a savings clause in the Act, which reverses *Watters v. Wachovia* with respect to the applicability of state law to state-chartered subsidiaries of national banks.²⁰⁹

Finally, OCC must conduct a periodic review (through notice-and-comment rulemaking proceedings) of any regulations or orders with preemptive effect every five years after promulgating such a regulation.²¹⁰ This list must be forwarded to both the House Committee on Financial Services and the Senate Committee on Banking, Housing and Urban Affairs.²¹¹ Given OCC's new designation as an independent regulatory agency, the Dodd-Frank Act shifts review of OCC rulemaking from the executive to Congress. OCC is also required to publish and update quarterly a list of all agency determinations with preemptive effect.²¹²

2. Response to May 2009 Presidential Memorandum on Preemption

OCC's law department conducted a review of its preemptive rulemaking and submitted it to OIRA in August 2009.²¹³ OCC identified eight preemptive rulemakings since 1999 and concluded that, with one exception, all were "justified under the established legal principles that govern national bank preemption, including the principles in E.O. 13132."²¹⁴ OCC deemed the one exception—the Visitorial Powers Rule—in need of further revision in light of *Cuomo*.²¹⁵

With respect to compliance with E.O. 13132, OCC stated:

OCC complied with the principles and requirements of E.O. 13132 in promulgating each of the 8 preemption rules . . . Each rule was issued using the notice-and-comment procedures prescribed by the Administrative Procedure Act. We received detailed and thoughtful comments from state officials individually and collectively on many of the proposals and, in some cases, we met with state representatives to discuss them. We considered those comments fully, and summarized and responded to them in the

208. *New Financial Regulatory Reform Act*, *supra* note 200, at 2.

209. *See* Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (adding 12 U.S.C. §§ 5136C(b)(2), 5136C(e)).

210. *Id.* (adding 12 U.S.C. § 5136C(d)(1)).

211. *Id.* (adding 12 U.S.C. § 5136C(d)(2)).

212. *Id.* (adding 12 U.S.C. § 5136C(g) ("Transparency of OCC Preemption Determinations")).

213. *See* Memorandum from Julie L. Williams, First Senior Deputy Comptroller and Chief Counsel, Office of the Comptroller of the Currency, to Kevin F. Neyland, Deputy Adm'r, Office of Info. and Regulatory Affairs, 2–3 (Aug. 13, 2009) [hereinafter Williams Memorandum to Neyland] (on file with the *Michigan Law Review*).

214. *Id.* at 1.

215. *Id.* ("We are currently preparing revisions to that regulation to conform with the Court's decision in *Cuomo*."). According to OCC officials, OCC determined that, prior to undertaking revisions to rules, it would await the end of the legislative process (which culminated in the Dodd-Frank Act). OCC Telephone Interview, *supra* note 185.

preambles to the final rules. We prepared and published with each final rule a federalism summary impact statement specific to that rule. The preambles to those rules, including the federalism summary impact statements, demonstrate the OCC's adherence to the applicable constitutional and legal principles, detail the comments and concerns submitted by state and local officials, and provide the OCC's response to those comments.²¹⁶

OCC's response to the Preemption Memorandum was comprehensive. In light of the Dodd-Frank Act, however, an additional rule—the Bank Operations Rule—may warrant revisiting. The rule adopts a loose interpretation of the *Barnett* standard for preempting state law. Under that standard, state laws are deemed preempted if they “interfere with or impair” a national bank's ability to perform certain acts. The Bank Operations Rule omits the “significantly interferes” language from the standard for conflict preemption.²¹⁷ Thus, although OCC claims in the review it submitted to OIRA that the preemption standard used in the Bank Operations Rule was “confirmed” by the Supreme Court's interpretation of banking preemption in *Watters*,²¹⁸ OCC's interpretation of *Barnett* may not be appropriate in light of Congress's reiteration of the “significantly interferes” language as part of the *Barnett* standard in the Dodd-Frank Act.

3. Rulemaking

OCC issued a final rule to implement provisions of the Dodd-Frank Act, including revisions to OCC's rules on preemption and its Visitorial Powers Rule. In its May 2011 NPRM, OCC asserted—consistently with the views expressed earlier by OCC officials²¹⁹—that the Act did not impart a more stringent preemption standard in the “*Barnett* paragraph.”²²⁰ Thus, according to OCC, Congress's inclusion of “significantly” in the Act was of little moment.²²¹ OCC therefore reiterated that all of its previous rulemakings

216. Williams Memorandum to Neyland, *supra* note 213, at 4 (footnote omitted).

217. Bank Activities and Operations; Real Estate Lending and Appraisals, 69 Fed. Reg. 1904, 1910 (Jan. 13, 2004) (to be codified at 12 C.F.R. pts. 7 & 34) (internal quotation marks omitted). *But see id.* (“The OCC intends this phrase [‘interfere with or impair’] as the distillation of the various preemption constructs articulated by the Supreme Court, as recognized in . . . *Barnett*, and not as a replacement construct that is in any way inconsistent with those standards.”).

218. Williams Memorandum to Neyland, *supra* note 213, at 2–3.

219. *See supra* text accompanying note 204.

220. The NPRM asserts that “prevents and significantly interferes” is merely a “touchstone” in the Court's conflict preemption analysis in *Barnett*: “It is not the only formulation; it is not set apart from the others; and it is not presented as a test different from the others.” Office of Thrift Supervision Integration; Dodd-Frank Act Implementation, Notice of Proposed Rulemaking, 76 Fed. Reg. 30,557, 30,562 (May 26, 2011).

221. The NPRM reasons that the Act merely requires preemptive rulemaking to be in line with the Supreme Court's *Barnett* decision. *Id.* And, given that the language “prevents or significantly interferes” is not part of the *Barnett* holding, but is merely “exemplary” of the *Barnett* standard, OCC claims that it can continue to rely on *Barnett* itself to justify preemptive rules. *Id.*

that had relied on its own formulations of the *Barnett* standard—that is, “obstruct, impair, or condition” a national bank’s power—remained valid.²²² In its NPRM, OCC modified the Visitorial Powers Rule (again, as OCC officials had previewed) in light of the Dodd-Frank Act’s endorsement of *Cuomo*. Acknowledging that states are free to enforce their consumer protection laws by filing suits in court, OCC added language that “an action against a national bank . . . brought by a state attorney general . . . to enforce a non-preempted state law against the national bank . . . is not an exercise of visitorial powers.”²²³

Finally, OCC acknowledged in the NPRM that Congress overturned the Supreme Court’s *Watters* decision and proposed to rescind its regulation preempting state law for subsidiaries of national banks.²²⁴

In response to its NPRM, OCC received forty-five public comments, including submissions from state and local officials, a U.S. Senator, and various financial and consumer protection institutions.²²⁵ Far more unusual, the U.S. Treasury Department submitted a trenchant critique.²²⁶

While OCC’s final rule devotes considerable space to addressing the public comments and critiques, it largely hewed to the position espoused in the NPRM.²²⁷ Significantly, OCC maintained its position on the *Barnett*

222. 76 Fed. Reg. at 30,563 (“[A]ll existing precedents (including judicial decisions and interpretations) consistent with [the *Barnett* conflict preemption] analysis are . . . preserved.”). Nonetheless, due to potential “ambiguities and misunderstandings” surrounding the “obstruct, impair, or condition” standard, OCC proposed to delete that language from OCC rules, leaving the unadorned citation to *Barnett* as the relevant preemption standard. *Id.* at 30,563–64.

223. *Id.* at 30,564.

224. *Id.* at 30,562.

225. These comments can be found at www.regulations.gov by searching for the proposed rule with the following docket identification number: OCC-2011-0006.

226. Letter from George Madison, General Counsel, Dep’t of the Treasury, to the Hon. John Walsh, Acting Comptroller of the Currency, Office of the Comptroller of the Currency, June 27, 2011 [hereinafter Treasury Letter]; see V. Gerard Comizio & Helen Y. Lee, *Unclear Whether Latest Preemption Developments Create Clear Path or Muddy Waters for Federally Chartered Banks*, PAUL HASTINGS, July 5, 2011, at 1, available at <http://www.paulhastings.com/assets/publications/1948.pdf> (describing Treasury Letter as “unprecedented”).

The Treasury Department raised three main objections. First, it expressed concern that OCC was attempting to broaden the Dodd-Frank Act’s preemption standard by reading “prevents or significantly interferes” out of the Act. Second, it disagreed that the Act had no effect on the preemption standard and likewise disagreed that OCC’s preexisting rules based on the “obstruct, impair, or condition” standard continued to be valid. Third, Treasury wanted OCC to clarify that it would not pursue categorical preemption. Treasury Letter, *supra*, at 1–3.

Recall that OCC is, per the Dodd-Frank Act, an independent regulatory agency. Notwithstanding its lack of official power over OCC, the Treasury Department decided to publicly call out what it perceived to be OCC’s errors of judgment.

227. See Office of Thrift Supervision Integration; Dodd-Frank Act Implementation, Final Rule, 76 Fed. Reg. 43,549, 43,553–58 (July 21, 2011).

standard and its position that the Dodd-Frank Act did not alter that standard.²²⁸

D. Consumer Product Safety Commission

CPSC is an independent regulatory agency (thus not bound by E.O. 13132) that took advantage of preamble preemption, notwithstanding its lack of historical precedent for issuing preemptive rules. CPSC included language in the preamble to a rule on flammability standards for mattress sets that preempted any “inconsistent” state law—both in the form of statutory law and tort law.²²⁹ In the Senate Judiciary Committee’s hearing on regulatory preemption, senators criticized CPSC’s inclusion of the preemptive preamble in its Mattress Flammability Rule.²³⁰

The statute that CPSC used to assert preemption, the Flammable Fabrics Act of 1953 (“FFA”), is one of four product safety statutes that were transferred to the Commission’s jurisdiction when it was created in 1972; the other three statutes are the Federal Hazardous Substances Act of 1960 (“FHSA”), the Poison Prevention Packaging Act of 1970 (“PPPA”), and the Refrigerator Safety Act of 1956 (“RSA”).²³¹ Three of the four transferred acts contain express preemption clauses.²³² Courts have been inconsistent regarding which statutes preempt state law and which do not: “[C]ourts have generally found that the FHSA preempts state common law, [but] the opposite is true of the FFA, and the cases are mixed with respect to preemption of common law under the PPPA.”²³³

The main statute under CPSC’s jurisdiction, the Consumer Product Safety Act, contains both a preemption clause²³⁴ and a savings clause.²³⁵

228. *Id.* at 43,555–56. At the same time, OCC acknowledged that the Act’s “prevents or significantly interferes” language is likely a direct rebuke of OCC’s “obstructs, impairs, or conditions” standard. *See id.* at 43,566 (“We also recognize that inclusion of the ‘prevents or significantly interferes’ conflict preemption formulation in the *Barnett* standard preemption provision may have been intended to change OCC’s approach by shifting the basis of preemption back to the decision itself, rather than placing reliance on the OCC’s efforts to distill the *Barnett* principles in this manner [i.e., with the “obstructs, impairs, or conditions” standard].”).

229. Final Rule: Standard for the Flammability (Open-Flame) of Mattress Sets, 71 Fed. Reg. 13,472, 13,496 (Mar. 15, 2006) (to be codified at 16 C.F.R. pt. 1633).

230. *Hearing on Regulatory Preemption, supra* note 85, at 3 (statement of Sen. Specter); *id.* at 16 (statement of Sen. Leahy, Chairman, S. Comm. on the Judiciary).

231. WILLIAM FUNK ET AL., CTR. FOR PROGRESSIVE REFORM, WHITE PAPER No. 807, THE TRUTH ABOUT TORTS: REGULATORY PREEMPTION AT THE CONSUMER PRODUCT SAFETY COMMISSION 5–6 (2008), available at http://progressivereform.org/articles/Truth_About_Torts_CPSC_807.pdf [hereinafter FUNK ET AL., CPSC] (citing 15 U.S.C. § 1203 (FFA); 15 U.S.C. § 1211 (RSA); 15 U.S.C. § 1261 note (Effect upon Federal and State Law) (FHSA); and 15 U.S.C. § 1476 (PPPA)).

232. The RSA does not. *See* 15 U.S.C. §§ 1211–14 (2006).

233. FUNK ET AL., CPSC, *supra* note 231, at 6–7 (footnotes omitted).

234. 15 U.S.C. §§ 2074–75 (2006).

235. *Id.* § 2074(a).

Several courts, following the Supreme Court's reading of the interplay between preemption and savings clauses in *Geier*, have found state tort law preempted.²³⁶ Against the backdrop of these preemption decisions and CPSC's preemption preamble, Congress passed the Consumer Product Safety Improvement Act of 2008 ("CPSIA"),²³⁷ which explicitly stated that state tort law should not be construed as preempted by CPSC's rulemaking and which disclaimed any preemptive rulemaking authority in the CPSC itself.²³⁸

While Congress's statutory direction has had the most pronounced effect on CPSC's rulemaking and intervention in litigation, the change in administration and the Presidential Memorandum on Preemption likewise seem to have had some impact. Compared to its activities under the George W. Bush Administration, CPSC has been less inclined to offer any interpretive gloss on preemption in rulemakings beyond simply citing relevant statutory express preemption provisions. Likewise, CPSC has been more hesitant to enter the litigation fray where preemption is at issue.

1. Congressional Response: Consumer Product Safety Improvement Act of 2008

The CPSIA was less a response to CPSC preemption than a response to the implosion of the agency and the fever pitch of recalls in 2007 that forced Congress to strengthen product safety protections.²³⁹ Congress also attempted to clarify preemption as it applies to CPSC. The Act explicitly states that the Commission "may not construe any such Act [under its jurisdiction] as preempting any cause of action under State or local common law or State statutory law regarding damage claims."²⁴⁰

CPSC general counsel suggested that the CPSIA simply "slaps the hand" of CPSC with respect to its past preemption by preamble (e.g., the Mattress Flammability Rule), while leaving general preemption standards alone (or even buttressing them).²⁴¹ The CPSIA's legislative history confirms the general counsel's view that Congress pursued a compromise, "split the baby" approach. Congressional Democrats championed the bill's protection

236. See, e.g., *Bic Pen Corp. v. Carter ex rel. Carter*, 251 S.W.3d 500, 505–06 (Tex. 2008) (recounting several cases in which preemption was found).

237. Pub. L. No. 110-314, 122 Stat. 3016 (2008).

238. *Id.* § 231(a).

239. See Amy Widman, *Advancing Federalism Concerns in Administrative Law Through a Revitalization of State Enforcement Powers: A Case Study of the Consumer Product Safety and Improvement Act of 2008*, 29 YALE L. & POL'Y REV. 165, 180–84 (2010).

240. Consumer Product Safety Improvement Act of 2008 § 231(a). Victor Schwartz and Cary Silverman construe this provision as a "gag order" on the agency that "deprive[s] courts of guidance that they come to expect from the entity in the best position to understand whether federal health and safety objectives would be impeded by application of inconsistent state tort claims." Schwartz & Silverman, *supra* note 19, at 1223.

241. I conducted an interview with CPSC General Counsel. Interview with Cheryl Falvey, Gen. Counsel, Consumer Prod. Safety Comm'n, in Bethesda, Md. (July 7, 2010).

of state labeling laws that regulate product safety (in its § 231(b) provision),²⁴² while Republicans were pleased that the bill preempted the “confusing” patchwork of state laws on lead regulation.²⁴³ The conference report noted that the bill “reiterat[ed]” existing preemption standards while “preserv[ing]” state laws.²⁴⁴

Unlike the Dodd-Frank Act,²⁴⁵ the CPSIA does not attempt to clarify the relationship between state law and federal law for the courts, but is only specifically directed toward CPSC.²⁴⁶ Professor William Funk nonetheless suggests that, in slapping the hand of CPSC with respect to preemption, the CPSIA may cause courts to hesitate before finding preemption.²⁴⁷

2. Response to May 2009 Presidential Memorandum on Preemption

According to the general counsel, in response to the Preemption Memorandum, the office surveyed.²⁴⁸ CPSC identified sixteen rules issued over the past ten years that contained preemptive language. Of the sixteen, the general counsel stated, only two rules “appear to go beyond what the statute says.”²⁴⁹ The first, a rule on bunk bed safety standards issued in 1999, cited the preemption provisions of the CPSA and the FHSA.²⁵⁰ The rule went on to state that rules promulgated by California and Oklahoma differ from the federal rule and would thus be preempted in accord with congressional intent under the issuing statutes, and that failure to preempt state law “could

242. See, e.g., 153 CONG. REC. H16,884 (daily ed. Dec. 19, 2007) (statement of Rep. Henry Waxman).

243. See, e.g., 154 CONG. REC. H7581 (daily ed. July 30, 2008) (statement of Rep. Joe Barton) (“[O]ne of the compromises in the bill is that there is Federal preemption, that there is one standard for all the States, and I am very pleased that that is in the bill.”); *id.* at H7586 (statement of Rep. Ed Whitfield) (“I am glad that this conference report preempts State standards—notably for lead, lead paint and the phthalates I mentioned—and that the authority of the State Attorneys General is appropriately limited to ensure that enforcement is swift, efficient, and consistent across the country.”).

244. H. REP. NO. 110-787, at 74 (2008) (Conf. Rep. on H.R. 4040), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_reports&docid=f:hr787.110.pdf.

245. See *infra* notes 358–361 and accompanying text.

246. See *supra* note 240 and accompanying text; H. REP. NO. 110-501, at 15 (2008) (Comm. Rep. on H.R. 4040).

247. FUNK ET AL., CPSC, *supra* note 231, at 8.

248. Interview with Cheryl Falvey, *supra* note 241. According to the general counsel, although CPSC did the retrospective analysis required by the memorandum, they did not submit a formal report to OMB. Email from Cheryl Falvey, Gen. Counsel, Consumer Prod. Safety Comm’n, to Catherine M. Sharkey, Professor of Law, N.Y. Univ. Sch. of Law (Nov. 1, 2010, 13:49 EST) (on file with the *Michigan Law Review*) [hereinafter Email from Cheryl Falvey].

249. Email from Cheryl Falvey, Gen. Counsel, Consumer Prod. Safety Comm’n, to Catherine M. Sharkey, Professor of Law, N.Y. Univ. Sch. of Law (Oct. 12, 2010, 21:41 EST) (on file with *Michigan Law Review*).

250. See Safety Standard for Bunk Beds, 64 Fed. Reg. 71,888, 71,899 (Dec. 22, 1999) (to be codified at 16 C.F.R. pts. 1213, 1500, & 1513).

have an adverse economic effect on manufacturers and distributors.”²⁵¹ Because the CPSIA requires the Commission to update the Bunk Bed Rule, the Commission plans to defer addressing the preemption asserted in the current rule until the update is issued.²⁵²

The second rule identified by the general counsel is the previously discussed Mattress Flammability Rule.²⁵³ It is the only rule that explicitly preempts state tort law.²⁵⁴ According to the general counsel, because of the amount of regulatory activity currently on CPSC’s agenda, and given that the language of CPSIA would prevent a court from giving preemptive effect to the Mattress Flammability Rule, revoking the preemption language in the rule “hasn’t been a priority.”²⁵⁵

Of the remaining fourteen rules, ten identified by the CPSC follow the same basic boilerplate structure: they first quote the applicable preemption clause from the statute, and then state that the rule would preempt nonidentical state and local laws under the statute. For example, rules issued under the FFA preempt nonidentical “standards or regulations,”²⁵⁶ rules issued under the PPPA preempt nonidentical “special packaging standards,”²⁵⁷ and rules issued under the FHSA preempt nonidentical “requirements.”²⁵⁸ Several of these rules also mention that, although the CPSC is not bound by E.O. 13132, the Commission evaluated preemption “in light of the principles” stated in E.O. 13132.²⁵⁹

Two rules on safety standards for garage door openers simply quote the relevant preemption provision without offering any interpretation or application to the rule.²⁶⁰ A 2007 rule on portable generator labeling requirements disclaims express preemption under the relevant statute, but reserves the

251. *Id.*

252. Email from Cheryl Falvey, *supra* note 248.

253. *See* Final Rule: Standard for the Flammability (Open Flame) of Mattress Sets, 71 Fed. Reg. 13,472 (Mar. 15, 2006) (to be codified at 16 C.F.R. pt. 1633).

254. *See id.* at 13,496–97.

255. Interview with Cheryl Falvey, *supra* note 241; Email from Cheryl Falvey, *supra* note 248.

256. Standard for the Flammability of Mattresses and Mattress Pads, 65 Fed. Reg. 12,935, 12,937–38 (Mar. 10, 2000) (to be codified at 16 C.F.R. pt. 1632).

257. Poison Prevention Packaging Requirements; Exemption of Hormone Replacement Therapy Products, 67 Fed. Reg. 66,550, 66,552 (Nov. 1, 2002) (to be codified at 16 C.F.R. pt. 1700).

258. Exemptions from Classification as Banned Hazardous Substances; Exemption for Certain Model Rocket Propellant Devices for Use with Rocket-Powered Model Cars, 68 Fed. Reg. 4697, 4698–99 (Jan. 30, 2003) (to be codified at 16 C.F.R. pt. 1500); Dive Sticks; Final Rule, 66 Fed. Reg. 13,645, 13,650 (Mar. 7, 2001) (to be codified at 16 C.F.R. pt. 1500).

259. *E.g.*, Exemptions from Classification as Banned Hazardous Substances; Exemption for Certain Model Rocket Propellant Devices for Use with Rocket-Powered Model Cars, 68 Fed. Reg. at 4698–99 (discussing E.O. 13132).

260. Safety Standard for Automatic Residential Garage Door Operators, 72 Fed. Reg. 54,816, 54,817 (Sept. 27, 2007) (to be codified at 16 C.F.R. pt. 1211); Safety Standard for Automatic Residential Garage Door Operators, 65 Fed. Reg. 70,656, 70,656 (Nov. 27, 2000) (to be codified at 16 C.F.R. pt. 1211).

possibility of conflict preemption where it would be impossible for a manufacturer to comply with both the federal rule and a state requirement.²⁶¹ Finally, a 2008 rule on certificates of compliance cites the relevant preemption provision but punts on its interpretation, stating that “the preemptive effect of this rule would be determined in an appropriate proceeding in a court of competent jurisdiction.”²⁶²

According to the general counsel, the agency, going forward, would reference the relevant statute(s) in its rulemakings, but would not offer any interpretive gloss, especially where state common law was at issue.²⁶³

3. Rulemaking

In response to the Presidential Memorandum on Preemption, CPSC has deliberately included a more passive statement regarding preemption in recent rulemakings.²⁶⁴ Five 2010 preemptive rulemakings—each of which addresses nursery products—use the same boilerplate language:

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a “consumer product safety standard under [the CPSA]” is in effect and applies to a product, no State or political subdivision of a State may either establish or continue in effect a requirement dealing with the same risk of injury unless the State requirement is identical to the Federal standard.²⁶⁵

The boilerplate language is limited to the express preemption provisions of the CPSA and cites the CPSIA for further preemptive support.

Other rules issued before 2010 but after the CPSIA only briefly touch on preemption, if at all. CPSC’s rule on lead content limits for children’s toys states: “According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this proposal is stated in section 18 of the FHSA. 15 U.S.C. 1261n.”²⁶⁶ The rule on labeling for children’s toy advertisements does not address preemption.²⁶⁷

CPSC has not ventured an interpretive gloss on preemption even in areas that are of particular concern to it, such as whether states could enact different

261. Portable Generators; Final Rule; Labeling Requirements, 72 Fed. Reg. 1443, 1445 (Jan. 12, 2007) (to be codified at 16 C.F.R. pt. 1407).

262. Certificates of Compliance, 73 Fed. Reg. 68,328, 68,331 (Nov. 18, 2008) (to be codified at 16 C.F.R. pt. 1110).

263. Interview with Cheryl Falvey, *supra* note 241.

264. *Id.*

265. Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs; Notice of Proposed Rulemaking, 75 Fed. Reg. 43,308, 43,321 (proposed July 23, 2010) (to be codified at 16 C.F.R. pts. 1219, 1220, & 1500) (alterations in original).

266. Children’s Products Containing Lead; Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule, 74 Fed. Reg. 43,031, 43,041 (Aug. 26, 2009) (to be codified at 16 C.F.R. pt. 1500).

267. Labeling Requirement for Toy and Game Advertisements; Final Rule, 73 Fed. Reg. 67,730 (Nov. 17, 2008) (to be codified at 16 C.F.R. pt. 1500).

testing regime requirements.²⁶⁸ A 2010 rule on testing punts on this preemption question:

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, of new regulations. The proposed regulation would be issued under authority of the CPSA and the CPSIA. The CPSA provision on preemption appears at section 26 of the CPSA. The CPSIA provision on preemption appears at section 231 of the CPSIA. The preemptive effect of this rule would be determined in an appropriate proceeding by a court of competent jurisdiction.²⁶⁹

4. Litigation

According to the general counsel, under the Obama Administration the agency has been extremely reluctant to “step into the fray” of litigation surrounding preemption issues, whereas under the George W. Bush Administration the agency likely would have taken a position.²⁷⁰ The general counsel mentioned the example of an Illinois statute, the Lead Poisoning Prevention Act of 2010,²⁷¹ that prescribes a labeling requirement for lead in toys. If CPSC issues warning labels for lead, state labeling requirements are preempted.²⁷² Proponents of the Illinois statute argue that, because there is no current federal lead labeling standard for children’s toys, the FHSIA preemption provision is not triggered.²⁷³ Commentators have noted that this statute will likely be challenged.²⁷⁴ According to the general counsel, while the toy industry has urged CPSC to challenge the statute, the agency’s current position is not to engage, but instead to wait for the toy industry to sue on its own.²⁷⁵

E. Environmental Protection Agency

In contrast to the aggressive preemptive efforts in the past by NHTSA, FDA, and OCC, the policies of EPA stand as a possible springboard to develop a model for “best practices” involving state and local government

268. Interview with Cheryl Falvey, *supra* note 241.

269. Testing and Labeling Pertaining to Product Certification, 75 Fed. Reg. 28,336, 28,361 (proposed May 20, 2010) (to be codified at 16 C.F.R. pt. 1107).

270. Interview with Cheryl Falvey, *supra* note 241.

271. 410 ILL. COMP. STAT. ANN. 45 (West 2010).

272. 15 U.S.C. § 1261 note (Effect upon Federal and State Law) (2006).

273. See *Illinois Lead Warning Label Required in 2010*, UL-STR (Sept. 8, 2011), <http://www.strquality.com/en-us/newsevents/Pages/illinois-lead-warning-label-required-in-2010.aspx>; John W. Moss, *New State Labeling Laws: Preempted?*, LAW 360, Apr. 9, 2009, available at http://www.winston.com/siteFiles/Publications/New_State_Product_Labeling_Laws_Preempted.pdf.

274. See, e.g., Greenberg Traurig, Presentation to American Apparel & Footwear Ass’n, State Law Updates, 9 (Oct. 29, 2009), available at <https://www.apparelandfootwear.org/UserFiles/File/Presentations/102909cpsia/citera.pdf>.

275. Interview with Cheryl Falvey, *supra* note 241.

officials in the federal regulatory process.²⁷⁶ Whereas other federal agencies sidestepped the consultation and reporting requirements of E.O. 13132, EPA published its official policies on how to comply with E.O. 13132.²⁷⁷ For this reason, I analyze recent EPA rulemaking in the context of the recommendations in Part III.

Here, I consider the extent to which the relationship between EPA and the states is unique, and therefore potentially less generalizable to other federal agencies. Because environmental protection laws mandate enforcement of federal law by state regulatory agencies, EPA has gained knowledge, experience, and practice cooperating with state authorities and being sensitive to state interests.²⁷⁸

1. Response to May 2009 Presidential Memorandum on Preemption

EPA's memo to OMB lists nine rules that EPA's Office of Policy, Economics and Innovation and EPA's Office of General Counsel determined preempt state law.²⁷⁹ All nine of these rules preempted state law through express statutory preemption, not through implied conflict preemption or preamble preemption. The four Clean Air Act ("CAA") rules listed, for example, preempted state regulation of air pollution (except for California) under the CAA's express preemption provisions by setting federal standards for nonroad emission controls²⁸⁰ and sulfur fuel controls.²⁸¹ Out of the four CAA rules, only the most recent rule from 2008 found that promulgating a

276. I conducted in-person interviews with several EPA officials. Interview with Ken Munis, Assoc. Dir., Office of Regulatory Policy & Mgmt.; Eileen McGovern, Office of Regulatory Policy & Mgmt.; David Coursen, Attorney Advisor, Cross-Cutting Issues Law Office, Office of Gen. Counsel; and Sonja Rodman, Attorney, Cross-Cutting Issues Law Office, Office of Gen. Counsel in Washington, D.C. (July 14, 2010) (group interview) [hereinafter Interview with EPA Officials]; Interview with Carol Ann Siciliano, Assoc. Gen. Counsel, Cross-Cutting Issues Law Office, Office of General Counsel, in Washington, D.C. (July 15, 2010).

277. U.S. ENVTL. PROT. AGENCY, EPA'S ACTION DEVELOPMENT PROCESS: GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM (2008) [hereinafter EPA GUIDANCE].

278. See Sharkey, *Federalism Accountability*, *supra* note 14, at 2159–60; see also Abbe R. Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 YALE L.J. 534 (2011) (recognizing that states can have significant roles in implementing federal statutes, especially environmental statutes like the Clean Air Act and the Clean Water Act).

279. Email from Nicole Owens, Envtl. Prot. Agency, to Dominic J. Mancini, Office of Mgmt. & Budget (Aug. 4, 2009, 08:24 EST) (on file with the *Michigan Law Review*); see also Memorandum from Ken Munis, Assoc. Dir., Office of Regulatory Policy & Mgmt., on EPA Process for Identifying "Preemption" per President's Memo (on file with the *Michigan Law Review*).

280. Control of Emissions from Nonroad Spark-Ignition Engines and Equipment, 73 Fed. Reg. 59,034, 59,038–39 (Oct. 8, 2008) (to be codified at 40 C.F.R. pts. 9, 60, 80, 85, 86, 89, 90, 91, 92, 94, 1027, 1033, 1039, 1042, 1045, 1048, 1051, 1054, 1060, 1065, 1068 & 1074).

281. Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements, 66 Fed. Reg. 5002, 5084–85 (Jan. 18, 2001) (to be codified at 40 C.F.R. pts. 69, 80 & 86) (promulgating under Clean Air Act § 211(c)(4)).

rule that triggered statutory preemption invoked the “federalism implications” provision of E.O. 13132.²⁸² The other three rules, whose preambles explained their effect on state law, nevertheless disclaimed significant federalism implications. Instead, they simply relied on continuing statutory preemption that triggered E.O. 13132 under express preemption.²⁸³ For all four CAA rules, EPA noted that it met and consulted with state and local officials in developing each rule.²⁸⁴

EPA listed two rules that preempted state regulation of hazardous materials under the Toxic Substances Control Act (“TSCA”).²⁸⁵ Similar to the CAA rules, these rules did not assert preemption on their own accord, but simply referred to the statutory preemption provision in the TSCA.²⁸⁶ EPA did not meet with state and local officials, however, stating that the notice-and-comment process gave state and local officials sufficient opportunity to participate in the rulemaking in compliance with E.O. 13132.²⁸⁷

EPA listed two rules regulating the transportation of hazardous materials that it promulgated with DOT.²⁸⁸ The first rule, which reduced the paper-

282. Control of Emissions from Nonroad Spark-Ignition Engines and Equipment, 73 Fed. Reg. at 59,172 (citing Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999)).

283. Control of Air Pollution from New Motor Vehicles: Heavy Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements, 66 Fed. Reg. at 5134 (citing Exec. Order No. 13,132, 64 Fed. Reg. 43,255) (“This final rule does not have federalism implications.”); Phase 2 Emission Standards for New Nonroad Spark-Ignition Handheld Engines at or Below 19 Kilowatts and Minor Amendments to Emission Requirements Applicable to Small Spark-Ignition Engines and Marine Spark-Ignition Engines, 65 Fed. Reg. 24,268, 24,304 (Apr. 25, 2000) (to be codified at 40 C.F.R. pts. 90 & 91) (same); Control of Air Pollution from New Motor Vehicles: Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements, 65 Fed. Reg. 6698, 6821 (Feb. 10, 2000) (to be codified at 40 C.F.R. pts. 80, 85 & 86) (same).

284. Control of Emissions from Nonroad Spark-Ignition Engines and Equipment, 73 Fed. Reg. at 59,172 (describing consultation with the National Association of Clean Air Agencies and with states that asked EPA to tighten federal standards if under new statutory preemption they would be unable to piggyback on California standards); Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements, 66 Fed. Reg. at 5134 (noting consultation with California and Alaska to develop diesel sulfur rules exempted from federal standard); Phase 2 Emission Standards for New Nonroad Spark-Ignition Handheld Engines at or Below 19 Kilowatts and Minor Amendments to Emission Requirements Applicable to Small Spark-Ignition Engines and Marine Spark-Ignition Engines, 65 Fed. Reg. at 24,304 (describing consultation with California to develop “harmonized requirements,” because California was already regulating in this area under its CAA preemption exemption); Control of Air Pollution from New Motor Vehicles: Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements, 65 Fed. Reg. at 6821 (noting that it “consult[ed]” with states in developing rule).

285. Reclassification of PCB and PCB-Contaminated Electrical Equipment, 66 Fed. Reg. 17,602, 17,616 (Apr. 2, 2001) (to be codified at 40 C.F.R. pt. 761); Asbestos Worker Protection, 65 Fed. Reg. 69,210, 69,215 (Nov. 15, 2000) (to be codified at 40 C.F.R. pt. 763).

286. Reclassification of PCB and PCB-Contaminated Electrical Equipment, 66 Fed. Reg. at 17,616; Asbestos Worker Protection, 65 Fed. Reg. at 69,215.

287. *Id.*

288. Hazardous Waste Management System; Modification of the Hazardous Waste Manifest System, 70 Fed. Reg. 10,776 (Mar. 4, 2005) (to be codified at 40 C.F.R. pts. 260, 261,

work required for transporting hazardous material, preempted any state laws that required different documentation for hazmat manifests under the Hazardous Material Transportation Act (“HMTA”).²⁸⁹ Though the rule described the changes to manifest requirements as “minor,” EPA and DOT still held two public meetings for state and local officials, which twenty-three states and territories attended.²⁹⁰ State and local officials were also invited to participate in the EPA workgroup charged with developing the rule.²⁹¹ The other HMTA rule, promulgated before E.O. 13132 took effect, preempted state law by clarifying the interaction between the HMTA and the CAA.²⁹² EPA, interpreting the CAA, said that states could not use the more lenient preemption standards in the CAA to promulgate rules for hazardous materials that would otherwise be preempted by the HMTA.²⁹³

Finally, EPA also listed a rule preempting state law under the Clean Water Act (“CWA”).²⁹⁴ Another pre-E.O. 13132 rule, this rule again used statutory preemption, because the CWA preempts state law regulating discharges from vessels once EPA sets standards.²⁹⁵ In developing this discharge standard for armed forces vessels, EPA noted that it consulted with both the Environmental Council of the States (“ECOS”)²⁹⁶ and the armed forces, and also that “representatives from the Navy (as the lead for the [Department of Defense]), EPA, and the Coast Guard met with each State expressing an interest in the [rule’s] development.”²⁹⁷

2. Uniqueness of the Environmental Protection Agency: Agency and States as Coregulators

EPA and the states have developed a collaborative relationship as coregulators, particularly over the past twenty years. EPA has an internal Office of Congressional and Intergovernmental Relations (“OCIR”) that coordinates a variety of state-EPA performance partnerships, such as the

262, 263, 264, 265 & 271); Accidental Release Prevention Requirements: Risk Management Programs Under Clean Air Act Section 112(r)(7); Amendments to the Worst-Case Release Scenario Analysis for Flammable Substances, 64 Fed. Reg. 28,696 (May 26, 1999) (to be codified at 40 C.F.R. pt. 68).

289. Hazardous Waste Management System; Modification of the Hazardous Waste Manifest System, 70 Fed. Reg. at 10,813.

290. *Id.*

291. *Id.*

292. Accidental Release Prevention Requirements: Risk Management Programs Under Clean Air Act Section 112(r)(7); Amendments to the Worst-Case Release Scenario Analysis for Flammable Substances, 64 Fed. Reg. at 28,698.

293. *Id.*

294. *See* Uniform National Discharge Standards for Vessels of the Armed Forces, 64 Fed. Reg. 25,126 (May 10, 1999) (to be codified at 40 C.F.R. pt. 69 & Ch. VII).

295. *Id.* at 25,131.

296. For more information on the involvement of ECOS, see *infra* notes 338 & 392 and accompanying text.

297. Uniform National Discharge Standards for Vessels of the Armed Forces, 64 Fed. Reg. at 25,129.

National Environmental Performance Partnership System (“NEPPS”).²⁹⁸ The most current iteration of the NEPPS plan (FY 2011) lists several objectives for the partnership between EPA and the states.²⁹⁹ These objectives, which target strengthening communication and information flow, include “[c]onduct[ing] joint strategic planning that reflects Performance Partnership principles in [the Performance Partnership Agreements]” and “[a]dvanc[ing] Performance Partnership principles through effective collaboration with states on policy and implementation issues.”³⁰⁰

* * *

This close look at the responses to the Presidential Memorandum on Preemption within NHTSA, FDA, OCC, CPSC, and EPA, and these agencies’ partially successful efforts to ensure compliance with E.O. 13132, reveal various avenues for reform.

III. AGENCY REFORM

Despite near consensus that the procedural requirements of the Federalism Executive Order are sound, compliance with those requirements has been spotty at best. A 1999 GAO Report, analyzing compliance with the Reagan-era Federalism Executive Order (E.O. 12612),³⁰¹ identified only five rules out of 11,000 issued between April 1996 and December 1998 that included a federalism impact statement.³⁰² Compliance scarcely improved

298. OFFICE OF CONG. & INTERGOVERNMENTAL RELATIONS, U.S. ENVTL. PROT. AGENCY, NATIONAL ENVIRONMENTAL PERFORMANCE PARTNERSHIP SYSTEM: FY 2011 NATIONAL GUIDANCE 7 (2011) (“EPA and states and tribes set priorities, design strategies, and negotiate grant agreements together . . .”).

Many of the more formal EPA/state coordination efforts began in earnest during the early years of the Clinton Administration. See DENISE SCHEBERLE, FEDERALISM AND ENVIRONMENTAL POLICY: TRUST AND THE POLITICS OF IMPLEMENTATION 2–7 (2d ed. rev. and updated 2004) (describing initial outreach efforts by EPA and organization efforts by states to negotiate implementation with EPA). For example, the discussions at the State/EPA Capacity Steering Committee, which formed in 1993, led to the 1995 NEPPS Plan, “which uses negotiated state performance agreements ‘to increase state participation and flexibility, while improving EPA’s working relationship with the states and reducing the costs of implementing federal environmental statutes.’” Christopher Terranova, *Challenging Agency Preemption* 8 n.40 (Working Paper, May 12, 2009) (quoting FLA. CTR. FOR PUB. MGMT., NATIONAL ENVIRONMENTAL PERFORMANCE PARTNERSHIP SYSTEM (NEPPS) 1), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1403628.

299. OFFICE OF CONG. & INTERGOVERNMENTAL RELATIONS, *supra* note 298, at 3–4.

300. *Id.* at 3–6.

301. Exec. Order No. 12,612, 3 C.F.R. 252 (1987).

302. U.S. GEN. ACCOUNTING OFFICE, *supra* note 16, at 1. GAO found that 26 percent of all rules issued over this period of time cited E.O. 12612. *Id.* at 4. Not counting the five rules that included an FIS, those 26 percent that cited E.O. 12612 included only “‘boilerplate’ certifications with little or no discussion of why the rule did not trigger the executive order’s requirements.” *Id.*

under the Clinton-era E.O. 13132 (continued under the Bush and Obama Administrations), as Professor Mendelson and I have documented.³⁰³

Why is this? Professors Donahue and Pollack offer one astute explanation: “Federalism criteria . . . do not have a natural home in agencies.”³⁰⁴ Another key problem that my research and investigation reveals is that, in the context of federal preemption of state tort law (as opposed to state regulations), it is unclear who best represents the state interest at hand, which, in turn, impedes meaningful participation by the states in the agency decisionmaking process.³⁰⁵

303. See Mendelson, *Chevron*, *supra* note 14, at 784 n.192 (estimating that for proposed rules during one quarter in 1998, FISs were included in only 9 of 2,456 agency rulemakings); *id.* at 783 (finding six FISs in one quarter of 2003, a time period in which roughly 600 final and proposed rules were issued); *id.* at 783–84 (demonstrating that FISs are relatively rare and of “poor quality”); Mendelson, *Presumption*, *supra* note 14, at 719 (reporting results from a study of 2006 preemptive rules, which disclosed only a single substantive FIS out of six preemptive rules); Sharkey, *Federalism Accountability*, *supra* note 14, at 2139 (“The story is one of outright contradictions—agencies initially claimed that the proposed rule would not have a substantial effect on the federal-state balance, only to assert the preemptive effect upon promulgation of the final rule—coupled with cavalier denials of any impact on federalism, even where the preemptive intent of the agency’s rule was apparent.”); *id.* at 2139–43 (providing numerous examples of FDA and NHTSA rulemakings whereby the agency disclaimed any federalism implications in a proposed or interim rule, followed by an assertion of preemption in the final rule, or else the agency denied the federalism impact of a clearly preemptive rule).

304. John D. Donahue & Mark A. Pollack, *Centralization and Its Discontents: The Rhythms of Federalism in the United States and the European Union*, in *THE FEDERAL VISION: LEGITIMACY AND LEVELS OF GOVERNANCE IN THE UNITED STATES AND THE EUROPEAN UNION* 73, 131 (Kalypso Nicolaidis & Robert Howse eds., 2001); see also *id.* (“Further, unlike benefit-cost analysis, they do not have a natural home in OMB. This, combined with a lack of attention by the Reagan, Bush, and Clinton administrations, made [the Federalism Executive Order] a non-priority.”).

305. Because I appreciated this issue at the outset, see Sharkey, *Federalism Accountability*, *supra* note 14, at 2158–63, I made considerable efforts to identify and interview an array of interested stakeholders that included, but was not limited to, the “Big Seven” national organizations that OMB singled out as the appropriate consultants on E.O. 13132. I solicited additional input from representatives of state judges, state attorneys general, and various consumer- and business-oriented groups.

I conducted a roundtable discussion with the so-called “Big Seven” national organizations of state and local governmental officials in Washington, D.C. on July 6, 2010. Participants included Carolyn Coleman, National League of Cities (“NLC”); Edward Ferguson, National Association of Counties; Susan Parnas Frederick, National Conference of State Legislatures; Elizabeth Kellar, International City/County Management Association; David Parkhurst, National Governors Association (“NGA”); David Quam, NGA; Stephanie Spierer, NLC; and Chris Whatley, Council of State Governments. A representative from the U.S. Conference of Mayors was invited, but did not attend. Interview with the “Big Seven,” in Washington, D.C. (July 6, 2010).

I interviewed Judge Gregory Mize, Judicial Fellow, National Center for State Courts, on July 7, 2010. Interview with Judge Gregory Mize, Judicial Fellow, Nat’l Ctr. for State Courts, in Bethesda, Md. (July 7, 2010). Judge Mize monitors policy proposals in the federal government that likely raise federalism issues for state courts. He was my liaison with the Conference of Chief Justices (“CCJ”), an association of the presiding officers of every state supreme court, which “has traditionally adopted formal positions to defend against proposed policies that threaten principles of federalism or that seek to preempt state court authority.” Letter from Jean Hoefler Toal, President, Conference of Chief Justices, to Div. of Dockets

This Part describes the reforms I have devised in an effort to enhance agency compliance with the Federalism Executive Order, reforms that directly confront the absence of a “natural home” issue and the state-interest representative issue. More specifically, I recommend the following:

1. The development of internal agency guidelines specifying how an agency is to determine if a rulemaking implicates federalism concerns. Such guidelines will create a structure—that is, a “home”—within agencies for compliance with the Federalism Executive Order. Part and parcel of such internal reform within agencies is the development of internal standards for evaluating evidence asserted in support of a preemptive rulemaking. Under this proposed system, agencies would be required to support their preemption conclusions with empirical data, which would then be scrutinized within the agencies themselves before the conclusions could be incorporated into proposed rules.

2. Enhancement of the process by which agencies consult with the states. My recommendations here take several forms: First, there should be an expanded view of who are the appropriate representatives of state interests. Improved outreach to the “Big Seven”³⁰⁶ is a key first step, but a first step only. Second, agency-specific liaison groups should be developed and fostered. Third, a mandatory notification procedure should be introduced whereby state attorneys general and NAAG are automatically notified of proposed rulemakings by agencies, and who, in turn, can then notify the relevant representatives of the potentially affected state interests. This novel recommendation is designed to enhance participation by state interests in the rulemaking process by delegating to state attorneys general the task of identifying the relevant representatives—a task that they, relative to federal agencies, are better poised to carry out. Fourth, procedures should be developed whereby agencies are encouraged to consult with state representatives early in the rulemaking process.

This Part also describes reforms that should be implemented within OMB and OIRA. These agency-oversight departments of the federal gov-

Mgmt., FDA 1 (Mar. 17, 2008), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0032-0019>. CCJ has occasionally responded to outreach from federal agencies. See, e.g., *id.*

For input on the role of state attorneys general, I interviewed James McPherson, Executive Director of National Association of Attorneys General, by telephone on November 2, 2010 and November 10, 2010, and Dan Schweitzer, Supreme Court Counsel, National Association of Attorneys General, in person on July 19, 2010. Telephone Interview with James McPherson, Exec. Dir., Nat'l Ass'n of Attorneys Gen. (Nov. 2, 2010) [hereinafter November 2 Interview with James McPherson]; Telephone Interview with James McPherson, Exec. Dir., Nat'l Ass'n of Attorneys Gen. (Nov. 10, 2010) [hereinafter November 10 Interview with James McPherson]; Interview with Dan Schweitzer, Supreme Court Counsel, Nat'l Ass'n of Attorneys Gen., in Washington, D.C. (July 19, 2010). I also interviewed James Tierney, Director of the National State Attorneys General Program at Columbia Law School, by telephone on October 20, 2010. Telephone Interview with James Tierney, Dir., Nat'l State Attorneys Gen. Program at Columbia Law Sch. (Oct. 20, 2010).

306. The “Big Seven” include NGA, National Conference of State Legislatures, Council of State Governments, U.S. Conference of Mayors, National League of Cities, International City/County Management Association, and National Association of Counties.

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ernment can play a key role in enhancing agency compliance with the Federalism Executive Order by doing the following:

1. Directing agencies to publish reports of their compliance with the 2009 Presidential Memorandum on Preemption;
2. Updating the OMB Guidance Document to include the most current information about state consultation groups; and
3. Improving the ways that OIRA oversees agency compliance with E.O. 13132.

A. Agencies

1. Internal Guidelines for Implementing the Preemption Provisions of Federalism Executive Order 13132 and Evaluating Evidence in Support of Preemption

a. *Internal Guidelines*

Internal agency guidelines for implementing the preemption provisions will provide structure to the agency's compliance with the Federalism Executive Order. Agencies should be able to cite their own internal guidelines in federalism impact statements to explain whether or not a specific rulemaking implicates federalism concerns and, if so, to justify the specific actions taken in response. Such internal guidelines would foster consistency in the agency's federalism review. In addition to the practical function, the existence and dissemination of such internal guidelines would also help foster an internal agency culture that is committed to ensuring compliance with the Federalism Executive Order.

EPA's November 2008 "Guidance on Executive Order 13132: Federalism" provides a model of an easy-to-follow, comprehensive set of internal guidelines. EPA's guidance document goes beyond what E.O. 13132 requires, "reflecting EPA's commitment to early and meaningful intergovernmental consultation,"³⁰⁷ but is consistent with my further recommendations on state consultation below.

EPA's comprehensive, fifty-six page guidance document gives direction for implementing E.O. 13132 for rules, proposed legislation, informal policy statements, adjudications, and waivers.³⁰⁸ The guidance document provides flowcharts for determining if a rule has federalism implications under E.O. 13132.³⁰⁹ The guidelines provide answers to regulatory questions such as "What do I do if my rule does *not* have [federalism implications] . . . but [it

307. EPA GUIDANCE, *supra* note 277, at 2; *see also id.* at 11 ("Even if your rule does not have [federalism implications], if it has any adverse impact on [state or local] governments above a minimal level, then you are subject to EPA's consultation requirements. . . . This internal policy is broader than EO 13132.").

308. *See id. passim.*

309. *See id.* attachment B at 36-42.

has more than minimal adverse impacts on [state or local] governments[?]"³¹⁰ With respect to the federalism implications of a preemptive rule, the EPA is notably clear: "EPA rules would have [federalism implications] because they . . . preempt [state or local] law."³¹¹

EPA's guidance document proceeds step-by-step through the rulemaking process, from "tiering" the rule, to convening a federalism workgroup within EPA, to preparing a consultation plan, to consulting, to drafting the preamble, to agency and OMB review, to preparing an "Action memo," and finally to publishing a proposed rule.³¹² EPA has formalized many aspects of the regulatory review process, and lists what is expected of agency officials who shepherd a rule through the regulatory process. The guidance document states at many points that an official attempting to determine whether a rule has federalism implications is required to "[c]onsult with [the official's Office of General Counsel] workgroup representative and [the official's] Regulatory Steering Committee Representative."³¹³ These standing representatives should be consulted to determine if the rule preempts state law and has federalism implications,³¹⁴ to prepare a consultation plan, and to review draft FISs.³¹⁵

The guidance document also gives direction and advice on interacting with state and local officials. It includes a list of contact information for the "Big Ten" organizations that EPA mandates be contacted.³¹⁶ While inclusion of such contact information may seem basic, it is apparently missing at other agencies. Members of the "Big Seven" told anecdotes about misdirected correspondence from agencies.³¹⁷

The EPA document addresses questions like, "How much consultation is enough?"³¹⁸ Moreover, it provides further advice by highlighting the common concerns of elected officials as expressed to EPA: money required for program implementation; requiring the state or local government to comply as a regulated party; interference with division of responsibilities between levels of government; command and control rules; and impact on local in-

310. *Id.* at 11.

311. *Id.* at 5.

312. *See id.* at 13–18.

313. *See, e.g., id.* at 7.

314. *See id.* at 7, 14, 18.

315. *See id.* at 19–20.

316. *Id.* at 4, attachment C at 45–46, attachment D (listing "Big 10" and "More Forums for Contacting Elected Officials"). The "Big Ten" include the more traditional "Big Seven" state and local organizations, as well as the National Association of Towns and Townships, County Executives of America, and ECOS. *See id.* at 4 n.3.

317. At the roundtable discussion with the "Big Seven," representatives told of mail addressed to former officials of their organization, instances where the agency claimed contact was made but could not verify to whom correspondence was sent, and the like. Interview with the "Big Seven," *supra* note 305.

318. EPA GUIDANCE, *supra* note 277, at 21 ("For rules with [federalism implications] . . . at a minimum you should consult . . . with *each* of the relevant representative national organizations in the Big 10.").

dustry, employment, or land use.³¹⁹ To develop a consultation plan for state and local officials, the document provides an appendix with three pages of factors to consider in building the plan.³²⁰

EPA's guidance document also tries to address the problem of enforcing agency procedures that concern federalism issues. The guidance document states that, to ensure compliance with E.O. 13132, EPA's Office of Policy, Economics, and Innovation should collect and analyze key information, including all existing and contemplated rules with any federalism impact, the status of federalism consultation plans, and any problems in carrying out the consultation plan that would affect the federalism official's ability to certify that EPA is in compliance with E.O. 13132.³²¹

With EPA's guidance document as a benchmark, each of the other agencies surveyed came up short. Some agencies, such as FDA—which apparently does not have any published guidelines³²²—must begin at square one, whereas others, such as NHTSA and OCC, should focus on updating and expanding their existing guidelines.

DOT (within which NHTSA lies) uses a 1988 document—"DOT Guidance: Federalism"³²³—which provides some constructive direction on improving the rulemaking process. It states that agencies should include federalism notices in notices of proposed rulemaking.³²⁴ And it suggests that agencies should err on the side of including a federalism assessment, even if the impact is "borderline."³²⁵

That said, the DOT guidance document leaves much to be desired. As an initial matter, it is out-of-date. The 1988 guidance document is based on President Reagan's 1987 Executive Order,³²⁶ which was superseded in 1999 by E.O. 13132. Several provisions from E.O. 13132 are missing from the DOT document,³²⁷ which (unlike EPA's guidance document) is thus not a stand-alone, self-contained manual that includes all of the relevant information necessary for agency officials to conduct a federalism analysis and to ensure compliance with E.O. 13132. Moreover, its direction—especially as compared to EPA's guidance document—is vague and

319. *Id.* at 23–24.

320. *Id.* attachment E.

321. *Id.* at 24. EPA publishes a listing of all rules under development with any federalism impact in its semiannual Regulatory Agenda. *See id.*

322. Interview with Ralph Tyler, *supra* note 134.

323. OFFICE OF GEN. COUNSEL, U.S. DEP'T OF TRANSP., DOT GUIDANCE: FEDERALISM (1988) [hereinafter DOT GUIDANCE].

324. *See id.* ¶ VIII.A.1 (stating consultation should take place through notice-and-comment proceedings).

325. *See id.* ¶ III.B.3.

326. *Id.* ¶ I.

327. Compare *id.*, with Exec. Order No. 13,132, § 6(b)–(c), 3 C.F.R. 206, 209–10 (1999). For example, section 6 of E.O. 13132 mandates that agencies engage in "meaningful and timely" consultation with the states "early in the process of developing the proposed regulation." *Id.* § 6(a)–(b), 3 C.F.R. at 209.

unspecific at times. For example, in describing the depth of a federalism assessment, the document states:

The Assessment should be of whatever length and analytic justification are necessary to describe the likely effects, possible alternatives, and the rationale for the position chosen. Although the approach and depth of the document will vary according to the circumstances, it is not anticipated that in most cases it will substantially increase the amount of analysis already being performed.³²⁸

From this guideline, it is not clear what type of federalism review is “necessary,” nor whether an official is even supposed to do anything at all if the assessment is not supposed to “substantially increase” the analysis being performed. Additionally, the definition of “sufficient” federalism implications is too vague to provide definitive guidance.³²⁹

OCC operates with a description of E.O. 13132 contained within its 2005 “Guide to OCC Rulemaking Procedures: A Staff Manual.”³³⁰ In a 2005 report investigating OCC preemption, GAO criticized OCC’s lack of a detailed regulatory process and singled out the fact that OCC did not have written guidance, policies, or procedures for the rulemaking process, but instead relied on a barebones “rulemaking checklist.”³³¹ The OCC guide, dated December 2005, two months after the 2005 GAO Report, does not advance much further than the “checklist” approach—at least as it concerns E.O. 13132. The guide to E.O. 13132 is about a single page; it names OCC’s federalism official, states that the project attorney makes an initial federalism assessment that is checked by the federalism official, states generally what to include in an FIS, and denotes the Conference of State Bank Supervisors (“CSBS”) as the main state contact for federalism issues (primarily through the notice-and-comment process, but occasionally through meetings when OCC determines that it is “appropriate”).³³²

OCC officials explained that all rulemaking is centralized within the Division of Legislative and Regulatory Activities. There is no separate track for preemptive rulemakings; the federalism compliance review is done as part of the general rulemaking process. OCC officials conceded that, as a formal matter, in terms of internal guidelines for compliance with E.O. 13132, the procedures are “a bit out of date.” They explained that there is a

328. DOT GUIDANCE, *supra* note 323, ¶ V.D.

329. *See id.* ¶ IV.A. (“The same kind of analysis that is used to determine whether an action is ‘major’ under E.O. 12291, ‘significant’ under the Department’s Regulatory Policies and Procedures, or has a ‘significant economic impact on a substantial number of small entities’ under the Regulatory Flexibility Act should generally be used to determine the sufficiency of the federalism implications.”).

330. OFFICE OF THE COMPTROLLER OF THE CURRENCY, GUIDE TO OCC RULEMAKING PROCEDURES: A STAFF MANUAL 17–18 (2005) [hereinafter OCC GUIDE].

331. 2005 GAO REPORT, *supra* note 181, at 5 (internal quotation marks omitted). For its report, GAO reviewed the relevant documents for proposed and final preemption rules, interviewed OCC officials who participated in promulgation of the rules, and analyzed documents from its docket files. *Id.* at 4.

332. OCC GUIDE, *supra* note 330, at 17–18.

checklist and narrative description of aspects of rulemaking that should be considered and that the requirements of E.O. 13132 are described. OCC officials emphasized that, because the law department is a relatively small office, the supervisor for any particular rulemaking ensures that a federalism analysis is conducted—albeit informally—where necessary.³³³

Of the agencies surveyed that are subject to E.O. 13132, only EPA provides a publicly available, comprehensive document providing step-by-step direction to its officials in conducting federalism review pursuant to E.O. 13132. The other agencies should devise and implement (and make publicly available) similar internal guidelines. The focus should be on development of a simple, easy-to-follow, comprehensive document that can be cited in the agency's FIS. Publicly available internal guidelines would go a long way toward reassuring the state-interest stakeholders as well as the public at large that agencies are taking compliance with E.O. 13132 seriously. Internal guidelines, moreover, can have a significant practical effect. EPA has cited its guidance document in recent rulemakings. In its Coal Rule, for example, EPA referenced its guidance document when it noted that even though the rule did not preempt state law, EPA included an FIS because the rule would impose “substantial compliance cost[s]” (defined as greater than \$25 million) on the states.³³⁴ EPA cited its guidance document to explain other actions it took under the rule, such as sending letters to the “Big Ten” organizations that EPA and OMB identified as representing state and local interests.³³⁵

The existence of publicly available guidelines can also serve as an accountability check on an agency. For example, in promulgating its 2009 Stormwater Rule, EPA acknowledged that the rule had federalism implications,³³⁶ but nonetheless neglected to consult with state and local officials or ECOS as instructed under its internal guidelines.³³⁷ These groups were then able to direct EPA's attention to this lapse in following its own guidelines—which prompted an apology and explanation from EPA.³³⁸

The creation of comprehensive internal guidelines provides consistency in an agency's federalism review, which in turn ensures that adequate measures are taken to meet the requirements of E.O. 13132. It is the first

333. OCC Telephone Interview, *supra* note 185. The above paragraph is based on the interview.

334. Hazardous and Solid Waste Management System; Identification and Listing of Special Wastes; Disposal of Coal Combustion Residuals from Electric Utilities, 75 Fed. Reg. 35,128, 35,226 (proposed June 21, 2010) (to be codified at 40 C.F.R. pts. 257, 261, 264, 265, 268, 271, & 302) (internal quotation marks omitted).

335. *Id.*

336. Effluent Limitations Guidelines and Standards for the Construction and Development Point Source Category, 74 Fed. Reg. 62,996, 63,055 (Dec. 1, 2009) (to be codified at 40 C.F.R. pt. 450) (internal quotation marks omitted).

337. *See id.* at 63,055–56.

338. Email from R. Steven Brown, Exec. Dir., Envtl. Council of the States, to Catherine M. Sharkey, Professor of Law, N.Y. Univ. Sch. of Law (Oct. 12, 2010, 15:15 EST) (on file with the *Michigan Law Review*).

necessary step in creating a “home” for federalism review of preemptive rulemakings within federal agencies.

b. *Internal Oversight*

Federal agencies should develop an internal standard for evaluating the evidence asserted in support of a preemptive rulemaking. This standard should be akin to the “agency reference model” standard that I have proposed for court review of agency positions on preemption, which is premised on judicial scrutiny of the contemporaneous agency record to determine precisely the risks weighed by the agency.³³⁹

The core idea is to force the agency to provide documented empirical evidence that supports its preemption conclusion and then to submit the factual predicate to some systematic scrutiny within the agency. The agency should be required to identify and analyze the data that support the asserted conflict between state law and the federal regulatory scheme.³⁴⁰ This empir-

339. In a series of articles, I have set forth the agency reference model for preemption decisionmaking. There is an internal agency piece:

Behind agency decisions to regulate or to refrain from regulating is a rich body of empirical cost-benefit (or increasingly risk-risk) analyses. These analyses made by the agency at the time of its action (or inaction), as well as the nature of the agency action and the contemporaneous reasons given by the agency to justify it, can guide courts' judgments regarding the need for, and equally significantly, the present feasibility of, uniform national regulatory standards.

Sharkey, *Products Liability Preemption*, *supra* note 4, at 453; *id.* at 477–521. Moreover, there is an equally important judicial review component:

Courts have an opportunity to scrutinize both the empirical substrate of the regulatory record compiled by the agency as well as its articulated reasons underlying any interpretive policy. Anticipation of such judicial review at this stage would force agencies . . . not only to adhere to the strictures of the [Federalism Executive Order], but also to compile a diligent agency record that would serve as the basis of the court's evaluation of whether the state tort action seeks to “redo” the analysis conducted by the agency and should therefore be ousted.

Sharkey, *Federalism Accountability*, *supra* note 14, at 2130; *see also id.* at 2188–89.

340. The American Bar Association (“ABA”) has adopted a resolution recommending that federal agencies subject to E.O. 13132 should have to provide:

(a) [F]actual support in the record for any assertions that state tort law has in the past interfered or is currently interfering with the operation of federal laws or regulations, or (b) reasoning to support any predictions or concerns that state tort law would in the future interfere with the operation of federal laws or regulations.

Am. Bar Ass'n, Res. 117, § 3 (2010) [hereinafter ABA Res. 117], *available at* http://www.abanow.org/wordpress/wp-content/files_flutter/1282164714Resolution117Summary080910.doc (passing resolution). Part (a) is akin to the factual predicate recommended here (and in my “agency reference model”). Although the ABA specifically limited its focus to agency preemption of state tort law, my recommendation applies more generally to preemption of state law (including state statutes and regulations). My recommendation goes even further by calling for this factual predicate evidence to be included in a document signed by the head of the program office and to be made part of the public rulemaking docket for comments.

ical evidence should be included in a document signed by the head of the program office and inserted into the public docket for the rulemaking.³⁴¹ The rulemaking notice should draw attention to the document and specifically invite comment on it.³⁴²

Exhibit A for the need for such an internal agency standard and review process is FDA's 2006 Drug Labeling Rule. The FDA asserted its preemptive intent in the preamble to the final rule: "FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law."³⁴³ The main thrust of FDA's federalism impact statement was that FDA had legal authority to preempt state law in this area.³⁴⁴ Such purely legalistic determinations would not suffice to satisfy the proposed factual predicate standard. Moreover, as the U.S. Supreme Court remarked in *Levine*:

[T]he Office of Chief Counsel ignored the warnings from FDA scientists and career officials that the preemption language [of the 2006 preamble] was based on erroneous assertions about the ability of the drug approval process to ensure accurate and up-to-date drug labels.³⁴⁵

This scenario suggests the need for a counterbalance to the Office of the Chief Counsel, which the proposed empirical evidentiary requirement could provide.

Exhibit B for the need for such internal oversight is NHTSA's 2005 Roof Crush Rule. As its 2009 rewrite of the rule makes clear, the factual predicates for NHTSA's preemption conclusion simply did not hold up. In

341. Attention must be paid to the practical realities of how different offices in an agency function in relation to each other. See Elizabeth Magill & Adrian Vermeule, *Allocating Power Within Agencies*, 120 YALE L.J. 1032, 1035 (2011) (examining "how administrative law allocates power *within* agencies and how arguments from expertise, legalism, and politics apply inside agencies rather than across institutions").

342. The agency should have to go through the same internal procedure with respect to any rule with potential preemptive effect. In other words, the agency would have to document the empirical evidence—via a report signed by the head of the program office and inserted into the public rulemaking docket—not only when the agency asserts preemptive effect, but also when it disclaims preemption. Concededly, a one-way ratchet effect (which is a wider judicial review phenomenon) may nonetheless exist here: the agency will have an easier time evading judicial review due to its "inaction"—disclaiming preemption—as compared to its "action"—invoking preemption. But, at least where an agency revokes a prior preemptive rulemaking, the requirements should stick. For an example of an agency disclaiming a rulemaking's preemptive effect, see "Exhibit B" on NHTSA's Roof Crush Rule, *infra* text accompanying notes 346–350.

343. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, & 601).

344. *Id.* at 3969 ("If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness [of labels] . . . the federal system for regulation of drugs would be disrupted.").

345. *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 n.11 (2009) (alterations in original) (quoting H. COMM. ON OVERSIGHT & GOV'T REFORM, 110TH CONG., MAJ. STAFF REP., FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES 4 (2008)) (internal quotation marks omitted).

a relatively lengthy three-page discussion, NHTSA took apart the earlier asserted factual predicates one by one.³⁴⁶ First, after further testing by NHTSA, the final rule disclaimed the NPRM's argument that improving roof safety would also increase rollover propensity.³⁴⁷ Second, where the NPRM asserted that state tort laws requiring improved roof crush resistance would divert resources away from developing new technologies to avoid rollovers in the first instance, the final rule rebuked that assertion, stating that "there is not a basis to conclude that such [diverted] resources would otherwise have been used for improving rollover resistance or improving safety."³⁴⁸ Third, the final rule disagreed with the automotive industry's argument that increased roof crush resistance from state tort law would create dangerous disparities in vehicle mass, stating that the industry "did not provide technical analysis addressing . . . the issue."³⁴⁹ NHTSA Assistant Chief Counsel for Vehicle Rulemaking and Harmonization—who has been involved with preemption policymaking at NHTSA for more than twenty years—likewise agreed that the original Roof Crush Rule would not have survived scrutiny by NHTSA engineers and statisticians.³⁵⁰

Exhibit C for this kind of reform is the 2004 OCC Visitorial Powers Rule that was revised in light of *Cuomo*.³⁵¹ In *Cuomo*, the Second Circuit commented that "OCC does not appear to have found any facts at all in promulgating its visitorial powers regulation. It accretes a great deal of regulatory authority to itself at the expense of the states through rulemaking

346. Federal Motor Vehicle Safety Standards; Roof Crush Resistance; Phase-In Reporting Requirements, 74 Fed. Reg. 22,348, 22,380–83 (May 12, 2009) (to be codified at 49 C.F.R. pts. 571 & 585). I therefore take issue with Schwartz and Silverman's characterization of NHTSA's shift in preemption policy as an unprincipled "abrupt[] change[] [of] course." Schwartz & Silverman, *supra* note 19, at 1221. They claim NHTSA reversed preemption in the Roof Crush Rule with only a "two-sentence explanation." *Id.* It appears that the authors looked only at the Executive Summary's description of "*How This Final Rule Differs from the NPRM . . .*" Federal Motor Vehicle Safety Standards; Roof Crush Resistance; Phase-In Reporting Requirements, 74 Fed. Reg. at 22,349, as opposed to the federalism discussion thirty pages later, which spans three pages, *id.* at 22,380–83. Compare Federal Motor Vehicle Safety Standards; Designated Seating Positions, 74 Fed. Reg. 68,185, 68,187–89 (Dec. 23, 2009) (to be codified at 49 C.F.R. pt. 571) (including NHTSA's explanation of how it interprets preemption and its analysis of state law and why it would not conflict, and soliciting comment from state and local officials), with Schwartz & Silverman, *supra* note 19, at 1222 ("The agency's explanation for this turn was only that it later found such conflicts 'unlikely,' speculating that manufacturers would reduce seat width or install an impediment or void in vehicles rather than undertake the additional expenses of providing an additional seat belt.").

347. Federal Motor Vehicle Safety Standards; Roof Crush Resistance; Phase-In Reporting Requirements, 74 Fed. Reg. at 22,382.

348. *Id.*

349. *Id.* at 22,383.

350. Interview with Steve Wood, *supra* note 45.

351. For a description of the the Visitorial Powers Rule, see *supra* notes 172–179 and accompanying text.

that lacks any real intellectual rigor or depth.”³⁵² Indeed, both the final rule³⁵³ and the NPRM³⁵⁴ read like legal briefs (complete with argument subheadings), not like agency rulemakings.³⁵⁵ There were no factual findings in either rule explaining why preemption was necessary in the specific case or what conflicts between state authorities and federal banks justified preemption. There was nothing to suggest that state law “significantly interfere[d]” with national bank activities under the relevant *Barnett* preemption standard.³⁵⁶ Rather, the rule laid out an argument for why OCC was legally allowed to preempt state law, and responded to CSBS’s arguments that OCC was not authorized to preempt state law and that preemption would undermine the dual state/federal banking system.³⁵⁷

In response, the Dodd-Frank Act requires agency preemption determinations to be evaluated under a “substantial evidence” standard.³⁵⁸ The Act mandates that evidence be made “on the record,” which supports the “specific finding regarding the preemption” under the *Barnett* standard.³⁵⁹ The Act further directs courts evaluating agency preemption determinations by OCC to assess their validity based on “thoroughness evident in the consideration,” “validity of the reasoning,” and “consistency with other valid determinations.”³⁶⁰ This *Skidmore* standard for review is likewise consistent with the agency reference model.³⁶¹

352. *Clearing House Ass’n v. Cuomo*, 510 F.3d 105, 119 (2d Cir. 2007), *aff’d in part, rev’d in part*, 129 S. Ct. 2710 (2009).

353. *Bank Activities and Operations*, 69 Fed. Reg. 1895 (Jan. 13, 2004) (to be codified at 12 C.F.R. pt. 7).

354. *Rules, Policies, and Procedures for Corporate Activities; Bank Activities and Operations; Real Estate Lending and Appraisals*, 68 Fed. Reg. 6363 (proposed Feb. 7, 2003) (to be codified at 12 C.F.R. pts. 3, 5, 6, 7, 9, 28, & 34).

355. *Clearing House Ass’n*, 510 F.3d at 118 (“The administrative record here consists almost entirely of the agency’s interpretation of case law, legislative history, and statutory text.”).

356. *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1044, 124 Stat. 1376, 2014 (2010) (adding 12 U.S.C. § 5136C(b)(1)(B)) (codifying *Barnett* as preemption standard for banking preemption); *see also* *Barnett Bank of Marion Cnty. v. Nelson*, 517 U.S. 25, 33 (1996).

357. *Bank Activities and Operations*, 69 Fed. Reg. at 1896–1903.

358. Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (adding 12 U.S.C. § 5136C(c)).

359. *Id.* The *Barnett* standard requires a finding that the state law “prevents or significantly interferes with” the national bank’s exercise of its national bank powers. *Id.*; *see supra* text accompanying notes 198–204.

360. Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (adding 12 U.S.C. § 5136C(c)).

361. *See* Sharkey, *Products Liability Preemption*, *supra* note 4, at 491–98 (making the case for *Skidmore*, not *Chevron*, deference to agency determinations of preemption); *id.* at 498 (“[T]he choice of granting *Skidmore* as opposed to *Chevron* deference would fuel the agency reference model by encouraging agencies to engage in . . . notice-and-comment rulemaking processes that, arguably, vet the agency decisionmaking process and make the agency respond to substantive concerns raised by all affected parties.”); *see also* Sharkey, *Federalism Accountability*, *supra* note 14, at 2180 (“My own view has been that the agency’s views should be

OCC officials expressed skepticism that the “substantial evidence” standard would appreciably affect their rulemakings, aside from perhaps mandating explicit reference to the new standard.³⁶² But OCC is aware that proffering evidence in support of preemption enhances the likelihood that a court will adopt its preemption conclusions. An OCC attorney specifically cited *American Bankers Ass’n v. Lockyer*³⁶³ as an example where OCC made factual findings to support its preemption determinations and garnered a favorable result.³⁶⁴ In *Lockyer*, California passed statutes requiring banks to give more information to credit card customers about the implications of carrying credit card debt and to provide options for customers to phone in for explanations and to receive referrals for credit counseling.³⁶⁵ In its amicus brief, OCC argued that the requirements should be preempted because they imposed significant operating costs on national banks and therefore on customers, and because they interfered with national banks’ abilities to exercise their powers to set terms, conditions, and interest rates for credit cards.³⁶⁶ The court agreed with OCC’s interpretation and found California law preempted.³⁶⁷ The high level of specificity and the significant factual findings made by OCC in *Lockyer*, including the precise cost of the state rule on national banks, poses an extremely sharp contrast to the complete absence of a factual record in the Visitorial Powers Rule.

2. Consultation with the States

Federal agencies are consistently criticized for falling short in their efforts to consult with the states during the rulemaking process, especially where preemptive rules are at issue. Congressional hearings on regulatory preemption highlighted FDA’s failure to consult with state and local officials pursuant to E.O. 13132.³⁶⁸ NHTSA likewise came under fire for bypassing state consultation.³⁶⁹ And finally, the 2005 GAO Report criticized OCC for

accorded *Skidmore* ‘power to persuade’ (not *Chevron* mandatory) deference—a position apparently endorsed by the Court in [*Levine*].”).

362. OCC Telephone Interview, *supra* note 185.

363. 239 F. Supp. 2d 1000 (E.D. Cal. 2002).

364. OCC Telephone Interview, *supra* note 185.

365. *Lockyer*, 239 F. Supp. 2d at 1002–04.

366. *Id.* at 1013–15. The court also cited an OCC opinion letter that found portions of a West Virginia statute preempted under the Gramm-Leach-Bliley Act because they imposed significant operating costs on national banks. *Id.* at 1015. It is notable that OCC’s West Virginia opinion letter distinguished between preempting the “significant” provisions and not preempting West Virginia’s requirement that credit and insurance documents for a loan be processed separately when the insurance was a condition for the loan because it imposed only paperwork burdens and some administrative costs. *Id.*

367. *Id.* at 1022.

368. See *Hearing on Regulatory Preemption*, *supra* note 85, at 144–45 (2007).

369. See Sharkey, *Federalism Accountability*, *supra* note 14, at 2141 (criticizing NHTSA’s defense of its decision to forego state consultation in its preemptive rulemaking on head restraint requirements); see also Letter from Carl Tubbesing, Deputy Exec. Dir., Nat’l Conference of State Legislatures, to William Schoonover, Docket Operations, U.S. Dep’t of

failing to document any of its consultations with state representatives and officials during the rulemaking process.³⁷⁰ GAO also noted that the representative state groups complained that OCC did not adequately consult with them in the rulemaking process.³⁷¹ Although OCC disputed most of GAO's factual findings and asserted that they complied with the requirements of E.O. 13132, OCC stated they intended to make improvements to their consultation process and told GAO they had already held several meetings to further this goal.³⁷²

Two separate, albeit related, issues present formidable challenges to the Federalism Executive Order's state consultation mandate. First, it is not at all clear who best represents state regulatory interests, particularly in the context of consumer health and safety issues. OMB has specifically designated the "Big Seven" national organizations as representative of state and local government officials for purposes of complying with the consultative requirements of E.O. 13132.³⁷³ At least in OMB's view, such elected officials are appropriate representatives of states and are best equipped to assess the impact of a federal regulation on a state statute or regulation. But because preemption determinations increasingly displace state common law liability, in addition to state legislative or regulatory standards, it is unclear who represents the interests served by state tort law. State tort law wears at least two hats: one compensatory, the other regulatory. Should the suitable representatives of state regulatory interests be those who represent injured victims (potential and actual), those who are engaged in health and safety regulation at the state level, or both?

Second, the consultative process breaks down at both ends: while federal agencies have rightly been criticized for bypassing consultation with the states, at the same time it appears as though at times the state representatives have not held up their end of the bargain, because participation in the rulemaking process by state and local government representatives is sparse.³⁷⁴

Transp. (May 16, 2008) ("NCSL does not believe that one mailing constitutes meaningful consultation as contemplated by E.O. 13132. In sum, [the agency's] attempts at meaningful consultation were feeble at best and disingenuous at worst."); *Oversight Hearing on Roof Strength*, *supra* note 2 (criticizing NHTSA's use of preamble preemption in its Roof Crush Rule).

370. 2005 GAO REPORT, *supra* note 181, at 5.

371. *Id.* at 6–7.

372. *Id.* at 46–47, 53. OCC officials were not able to identify specific reforms that had been undertaken in response to the 2005 GAO Report. OCC Telephone Interview, *supra* note 185.

373. Letter from Mickey Ibarra, Assistant to the President & Dir. of Intergovernmental Affairs, to Donald J. Borut, Chair, Big 7 Orgs. (Mar. 9, 2000), *reprinted in* EPA GUIDANCE, *supra* note 277, attachment C ("White House Letter on Consultation and List of 'Representative National Organizations' Contacts").

374. See Sharkey, *Federalism Accountability*, *supra* note 14, at 2168 ("Some responsibility . . . lies with the state governmental groups who may have opted out of engaging with the federal agencies."); *id.* at 2166–67 (providing some examples where federal agencies reached out to consult with the state governmental groups but received no comments back); see also *supra* notes 93, 143 and accompanying text (providing more examples). Moreover, when state

Most rules with potential preemptive effect receive no comments from state or local government officials or their representatives. Granted, of the fifty-three preemptive notices included in AAJ's study, twenty inserted preemptive language into the final rule only after the notice-and-comment period had closed.³⁷⁵ But, in the remaining thirty-three proposed rules, state representatives only submitted comments in four rulemakings: NCSL submitted a comment to a proposed chemical facility security regulation promulgated by the Department of Homeland Security and to NHTSA's proposed Roof Crush Rule.³⁷⁶ NAAG also voiced its objection to NHTSA's proposed Roof Crush Rule.³⁷⁷ State attorneys general filed comments in two additional NHTSA rules addressing fuel economy standards for passenger vehicles and standards for light trucks.³⁷⁸ The reforms described here aim to address both of these issues.

a. Expand Appropriate Representatives of State Regulatory Interests

i. Reach Out to the "Big Seven"

Of the agencies surveyed, EPA and NHTSA appear to be making concerted, good faith efforts to reach out to the "Big Seven" to establish good working relations. By contrast, OCC maintains that they do no specific outreach to the "Big Seven," but instead hear from governors and state legislators during the notice-and-comment process.³⁷⁹

As mentioned above, EPA's guidance document contains a list of contact information for the "Big Ten" organizations. Moreover, EPA Office of Congressional and Intergovernmental Relations hosts quarterly meetings with the "Big Ten."³⁸⁰ It would behoove the other federal agencies to compile updated contact lists of relevant individuals within the "Big Seven" and also to consider establishing some form of regularized personal contact in order to build relationships.

Given the structure of the federal statutes that EPA implements, the agency conducts relatively few formal consultations with the states pursuant to E.O. 13132. From 2007 to 2010, EPA determined that a rule invoked E.O.

government groups do intervene in preemption disputes, they generally assert an antipreemption position that focuses on protection of state autonomy and issues of structural concern to all states but does not stake out narrower policy positions on specific conflicts between state and federal law.

375. See AM. ASS'N FOR JUSTICE, *supra* note 2, app. B at 28–33.

376. Michael Jo, Who Represents the States? State Government Groups, Preemption, and Horizontal Federalism 26 & app. II (Fall 2009) (unpublished directed research paper, New York University, supervised by Professor Sharkey) (on file with the *Michigan Law Review*). For NCSL's efforts to defeat the Roof Crush Rule, see *supra* notes 84–85 and accompanying text.

377. Jo, *supra* note 376, app. II.

378. *Id.*

379. OCC Telephone Interview, *supra* note 185.

380. Interview with EPA Officials, *supra* note 276.

13132 in two final regulations and in one NPRM.³⁸¹ For each of these rules (save the Stormwater Rule discussed above³⁸²), EPA noted the steps it took to consult with state and local officials and to meet E.O. 13132's requirements. For the NPRM on National Emissions Standards for Hazardous Air Pollutants for Area Sources, EPA said the proposed rule "may" have federalism implications, included a brief FIS, and stated:

EPA consulted with State and local officials in the process of developing the proposed action to permit them to have meaningful and timely input into its development. EPA met with 10 national organizations representing State and local elected officials to provide general background on the proposal, answer questions, and solicit input from State/local governments. . . . In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.³⁸³

For the Regulation of Fuels and Fuel Additives in the Denver area, EPA noted its regulation would have federalism implications and "may preempt State law."³⁸⁴ Accordingly, EPA consulted with Colorado state and local government "early in the process . . . to permit them to have meaningful and timely input."³⁸⁵ Based on this consultation, the final rule incorporated material requested by the state as "necessary to ensure the success of Colorado's ozone action plan."³⁸⁶

NHTSA likewise appears to be making renewed efforts to reach out and consult with state and local officials. In a rulemaking on tire fuel efficiency information for consumers, NHTSA expressly sought comment on preemption from state and local officials.³⁸⁷ NHTSA stated that it "sought public comment on the scope of [the rule] generally, and in particular on whether, and to what extent, [the rule] would or would not preempt tire fuel consumer information regulations that the administrative agencies of the State of

381. National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial, and Institutional Boilers, 75 Fed. Reg. 31,896, 31,922 (June 4, 2010); EPA Regulation of Fuels and Fuel Additives: Federal Volatility Control Program in the Denver-Boulder-Greeley-Ft. Collins-Loveland, CO, 1997 8-Hour Ozone Nonattainment Area, 75 Fed. Reg. 9107, 9110 (Mar. 1, 2010); Effluent Limitations Guidelines and Standards for the Construction and Development Point Source Category, 74 Fed. Reg. 62,996, 63,055 (Dec. 1, 2009) (Stormwater Rule).

382. See *supra* notes 336–338 and accompanying text.

383. National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial, and Institutional Boilers, 75 Fed. Reg. 31,896, 31,922 (proposed June 4, 2010) (to be codified at 40 C.F.R. pt. 63).

384. Regulation of Fuels and Fuel Additives: Federal Volatility Control Program in the Denver-Boulder-Greeley-Ft. Collins-Loveland, CO, 1997 8-Hour Ozone Nonattainment Area, 75 Fed. Reg. at 9110.

385. *Id.*

386. *Id.*

387. Tire Fuel Efficiency Consumer Information Program, 75 Fed. Reg. 15,894, 15,941 (Mar. 30, 2010) (to be codified at 49 C.F.R. pt. 575).

California may promulgate in the future.”³⁸⁸ To address “ambiguity” in the statute’s preemptive language, NHTSA sent a copy of the NPRM to “the State of California, the National Governor’s Association, the National Conference of State Legislatures, the Council of State Governments, and the National Association of Attorneys General.”³⁸⁹ Only the California Energy Commission responded.³⁹⁰ NHTSA, in turn, issued a statement that “NHTSA believes that it is premature to consider the applicability of the . . . preemption provision. Moreover, NHTSA notes that it is ultimately a court, not NHTSA, which would determine whether or not future regulations established by the State of California are preempted under Federal law.”³⁹¹

Given the limited response it received, NHTSA’s statement was the responsible course. But this example shows that more work needs to be done to identify the appropriate representatives of state interests and to ensure that they respond when asked for comment.

ii. Encourage Development of Agency-Specific Liaison Groups

Several of the agencies have added organizations with relevant expertise to the list of consultative groups. As mentioned above, EPA has expanded the “Big Seven” to the “Big Ten.” ECOS plays a particularly influential role. Indeed, it was through dialogue with ECOS that EPA decided to lower its threshold for federalism impact from \$100 million to \$25 million at the time it issued its November 2008 guidance document.³⁹²

Like EPA, OCC reaches out to the representatives of its state regulatory counterparts. The Conference of State Bank Supervisors is a trade association of state banking regulators. According to OCC officials, OCC shares draft proposals with CSBS shortly before they are published; CSBS then distributes the draft proposals to state bank supervisors. In 1999, OCC established by way of a series of letters regarding E.O. 13132 that CSBS would serve as the liaison between OCC and states with respect to rulemaking.³⁹³ With OCC, CSBS developed the model consumer complaint forms to standardize information sharing.³⁹⁴ For state-chartered banks that establish interstate branches, CSBS helped negotiate a nationwide state-federal agreement for overlapping regulatory spheres, and has negotiated several other agreements and understandings with federal regulators involved in

388. *Id.*

389. *Id.*

390. *Id.*

391. *Id.* at 15,942.

392. Interview with EPA Officials, *supra* note 276; Telephone Interview with Steven Brown, Exec. Dir., Env’tl. Council of the States (July 30, 2010).

393. OCC Telephone Interview, *supra* note 185.

394. See CONFERENCE OF STATE BANK SUPERVISORS, CONSUMER COMPLAINT MANAGEMENT: BEST PRACTICES 3, available at <http://www.csbs.org/regulatory/Cooperative-Agreements/Documents/CSBS-ConsumerComplaintBestPractices.pdf>.

banking.³⁹⁵ CSBS frequently comments on regulatory proposals from federal agencies involved in banking,³⁹⁶ and also occasionally files amicus briefs on behalf of state banking regulators.³⁹⁷ However, it appears that OCC has focused on CSBS to the exclusion of state and local elected officials. The 2005 GAO Report noted that “[a]lthough OCC did send the drafts of the proposed rules to CSBS, the extent to which it consulted with state officials appeared limited.”³⁹⁸

Like EPA and OCC—albeit the information is buried in its website as opposed to in its guidance document—DOT lists three organizations on its contact list in addition to the “Big Seven”: the American Association of State Highway and Transportation Officials, the Association of Metropolitan Planning Organizations, and the National Association of Regional Councils.³⁹⁹ NHTSA has also experimented with a kind of focus group, comprised not only of state officials, but also industry representatives and others representing state regulatory interests (including tort law). For example, in the course of deciding whether to amend crash safety protection requirements in school buses, NHTSA “convened a ‘roundtable of State and local government policymakers, school bus and seat manufacturers, pupil transportation associations and consumer associations to address . . . [s]tate and local policy perspectives’ on the feasibility and desirability of a national uniform requirement” before issuing the NPRM.⁴⁰⁰ Roundtable participants included “representatives from states with compulsory seatbelt requirements, individuals with expertise in seatbelt installation (and effects on passenger capacity), and a representative from the National School Transportation Association.”⁴⁰¹

395. See, e.g., Memorandum of Understanding Between the U.S. Dep’t of Treas., Financial Crimes Enforcement Network and [State Agency] (Apr. 28, 2005), available at <http://www.csbs.org/regulatory/Cooperative-Agreements/Documents/MOU-DOT-FINCEN.pdf>.

396. See *CSBS Comment Letters*, CONF. ST. BANK SUPERVISORS, <http://www.csbs.org/regulatory/policy/Pages/CSBS%20Comment%20Letters.aspx> (last visited Oct. 21, 2011) (listing twenty-five comment letters in 2011).

397. See, e.g., Brief of the Conference of State Bank Supervisors as Amicus Curiae in Support of the Petitioner, *Cuomo v. Clearing House Ass’n*, 129 S. Ct. 2710 (2009) (No. 08-453), 2009 WL 685656.

398. 2005 GAO REPORT, *supra* note 181, at 19.

399. *Governmental Affairs, State & Local Organizations*, OFFICE SEC. TRANSP., U.S. DEP’T TRANSP., <http://www.dot.gov/ost/govaffairs/statelocal.htm> (last visited Oct. 8, 2011).

400. Sharkey, *Federalism Accountability*, *supra* note 14, at 2171–72 (alterations in original) (citing Federal Motor Vehicle Safety Standards; Seating Systems, Occupant Crash Protection, Seat Belt Assembly Anchorages, School Bus Passenger Seating and Crash Protection, 72 Fed. Reg. 65,509, 65,511 (proposed Nov. 21, 2007) (to be codified at 49 C.F.R. pt. 571)).

401. *Id.* at 2172 (citing Federal Motor Vehicle Safety Standards; Seating Systems, Occupant Crash Protection, Seat Belt Assembly Anchorages, School Bus Passenger Seating and Crash Protection, 72 Fed. Reg. 65,509, 65,511 (proposed Nov. 21, 2007) (to be codified at 49 C.F.R. pt. 571)).

iii. Introduce an Attorney General Notification Provision

Given the twin problems of identifying appropriate representatives of state regulatory interests and the paucity of comments received from state governmental organizations during the rulemaking process, I propose the introduction of a novel notification provision to the state attorneys general⁴⁰² and to the National Association of Attorneys General.⁴⁰³ The proposal borrows from the Class Action Fairness Act (“CAFA”) settlement notice provision, which mandates that notice of every class action settlement within CAFA’s purview be provided to “appropriate” federal and state officials and provides, by default, that the state representative be the attorney general of any state in which any class member lives.⁴⁰⁴ The intuition behind this approach is that the top legal officer of the state ought to be able to distribute information relevant to a determination whether a certain proposed rulemaking advances or impedes state interests to the relevant state agencies, officials, or other appropriate representatives.

The addition of an attorney general notification provision would provide a formal mechanism to notify those well positioned to alert any and all interested participants in the rulemaking process.⁴⁰⁵ After all, not every interested participant combs the Federal Register for relevant rulemakings, and the exclusive singling out of the “Big Seven” organizations for notification may no longer make sense, particularly in light of the rise of rulemakings that preempt state tort law.

Indeed, the potential that state attorneys general represent has already been recognized.⁴⁰⁶ They are given a special role in the new Dodd-Frank Act: the *states* can force the new Bureau of Consumer Financial Protection to take regulatory action on consumer protection issues. If a majority of the states passes a resolution in support of establishing or modifying a Bureau regulation, the Bureau must issue a notice of proposed rulemaking on the

402. All fifty state AGs have permanent email addresses. For a current listing of all AGs and contact information, see *Current Attorneys General*, NAT’L ASS’N ATT’YS GEN., <http://www.naag.org/current-attorneys-general.php> (last visited Oct. 8, 2011).

403. James McPherson, Executive Director of NAAG, indicated his willingness to serve as the point of contact for the federal agencies. Depending on the subject matter of the regulation, he would first send it to a relevant NAAG staff member, who would then forward it on to his or her relevant contact person in each of the AG offices. November 10 Interview with James McPherson, *supra* note 305.

404. 28 U.S.C. § 1715(a)(2) (2006). For an analysis of this provision and its early implications, see Catherine M. Sharkey, *CAFA Settlement Notification Provision: Optimal Regulatory Policy?*, 156 U. PENN. L. REV. 1971 (2008).

405. The AG might function simply as a conduit for passing along the information to the relevant state agency, which would not require any significant investment of resources, financial or human.

406. For a comprehensive list of federal acts that authorize state AG enforcement, see Margaret H. Lemos, *State Enforcement of Federal Law*, 86 N.Y.U. L. REV. 698, 708–11 (2011).

issue.⁴⁰⁷ This provision also requires the Bureau to publish findings on certain specific considerations in response to a state petition, and it must send copies of those findings to the House and Senate finance committees.⁴⁰⁸ Under the Act, state attorneys general also have the power to bring lawsuits against banks in order to *enforce* federal regulations issued by the Bureau.⁴⁰⁹

CPSC has also come to recognize how useful state attorneys general can be as vehicles for improving state participation. The general counsel explained that the CPSC chairman instituted a monthly call with the state attorneys general offices.⁴¹⁰ Anywhere from twenty to thirty-five participants from state attorney general offices with consumer protection responsibilities typically participate in these calls.⁴¹¹ According to the general counsel, “[t]his direct line of communication has proven very useful in engendering state participation in rulemakings with preemptive effect.”⁴¹² This CPSC state attorney general initiative supports both focusing on reaching out to states early in the rulemaking process and providing notification to state attorney general offices.

Over the years, attorneys general, sometimes coordinated by NAAG, have challenged federal agencies’ decisions to preempt state law, often via amicus briefs. Historically, the attorneys general have focused their opposition to preemption in areas of robust state regulation, such as environmental law, banking, and consumer protection.⁴¹³ But over time, states have become increasingly interested in the preemption of state common law claims because of their experience with preemption in other realms, such as banking, where state agencies are explicitly at risk.⁴¹⁴

407. Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1041(c), 124 Stat. 1376, 2011 (2010).

408. *Id.* § 1041(c)(2)–(3).

409. *Id.* § 1042(a)(1). If an AG wishes to bring an action under section 1042, he or she must first consult with the Bureau. *Id.* § 1042(b). Moreover, the AGs may enforce only those rules, not the statute itself. *Id.* § 1042(a)(2). As OCC officials pointed out, this was a deliberate omission to prevent states from creating fifty different interpretations of the statute. OCC Telephone Interview, *supra* note 185; *see also* 156 CONG. REC. S3868–72 (daily ed. May 18, 2010) (containing a debate on state AG enforcement provision discussing how amendments “strike[] a balance” and “compromise” to allow supplemental enforcement from states without creating conflicting authorities).

410. Email from Cheryl Falvey, *supra* note 248.

411. *Id.*

412. *Id.*

413. Interview with Dan Schweitzer, *supra* note 305. State AGs have tended to be most engaged in OCC preemption, where the focus is on enforcement of state consumer financial protection laws.

414. *See* Daniel Schweitzer, Supreme Court Counsel, Nat’l Ass’n of Attorneys Gen., Panelist Remarks at the New York University Annual Survey of American Law: Tort Law in the Shadow of Agency Preemption (Feb. 27, 2009); *see also* Kevin O. Leske & Dan Schweitzer, *Frustrated with Preemption: Why Courts Should Rarely Displace State Law Under the Doctrine of Frustration Preemption*, 65 N.Y.U. ANN. SURV. AM. L. 585 (2009).

State attorneys general have intervened in lawsuits to protest preemption of state common law.⁴¹⁵ The attorney general notification provision would capitalize on this burgeoning development and further expand the role of state attorneys general in identifying the relevant state regulatory interests at stake in preemptive rulemakings.

b. *Focus on Earlier Outreach to States*

An effort should be made to encourage agencies to consult with state representatives early in the rulemaking process. The 1999 OMB guidance document suggests that consultation should take place before the NPRM and that the results of that consultation should be discussed in an FIS preamble to the NPRM.⁴¹⁶

However, most of the agencies still focus primarily, if not exclusively, on state consultation during the notice-and-comment process. DOT's guidance document focuses on the notice-and-comment process, directing that states should receive copies of NPRMs with preemptive effects and that agencies should respond to any comment submitted by a state during notice-and-comment proceedings.⁴¹⁷ There are no provisions for any "meaningful" consultation outside of the notice-and-comment process or before an NPRM is published.⁴¹⁸ OCC likewise maintains that the primary mechanism of consultation with the states is the notice-and-comment procedure.⁴¹⁹

Such exclusive focus on notice-and-comment proceedings denies states substantial opportunities to contribute meaningfully to the development of regulations, because they can only respond once NPRMs have already been published.

415. For example, one brief asserted:

The forty-seven amici states, as separate sovereigns in our federal system . . . have a fundamental interest in preserving the appropriate balance of authority between the states and the federal government. . . . In our view, courts should only rarely infer that Congress, although silent on the issue, nonetheless intended to displace state law where it is possible to comply with both state and federal law.

Brief of Amici Curiae Vermont et al. in Support of Respondent at 1, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 3851613, at *1.

416. OMB Guidance for E.O. 13132, *supra* note 35.

417. DOT GUIDANCE, *supra* note 323, ¶ VII–VIII.

418. There is just a cryptic addendum: "To the extent additional consultation is believed to be warranted, contact should be made with the Office of the General or Chief Counsel, as appropriate, for advice and approval . . ." *Id.* ¶ VIII.A.1. There is no discussion of when additional consultation is warranted or how DOT determines if it should be approved.

419. OCC Telephone Interview, *supra* note 185.

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*B. Office of Information and Regulatory Affairs/Office
of Management and Budget*

1. Direct Agencies to Publish Reports of Agency Compliance
with May 2009 Presidential Memorandum on Preemption

OIRA/OMB should direct agencies to publish their responses to the Preemption Memorandum's directive to conduct a ten-year retrospective review of preemptive rulemaking. Doing so would correct the perception that the Preemption Memorandum has been largely ignored.⁴²⁰ Publication of these reports would, along with individual agencies' publication of internal guidelines on compliance with E.O. 13132, signal renewed focus and attention on the part of agencies to issues of federalism and agency preemption of state law.

2. Update the Office of Management and Budget Guidance Document

OMB's 1999 guidance document (and E.O. 13132) directs agencies to send OMB the names of their designated federalism officials as well as consultation plans that describe how the agencies identify policies with federalism implications and the procedures agencies use to ensure meaningful and timely consultation.⁴²¹ OIRA/OMB should bring this document up to date, and include an updated list of state consultation groups and their contact information.⁴²²

In an effort to encourage greater transparency with respect to agency compliance with E.O. 13132, OIRA/OMB should also direct agencies to publish the names of their designated federalism officials and their consultation plans (along with the agencies' internal guidelines for compliance with E.O. 13132).⁴²³

My survey of federal agencies revealed spotty compliance with the OMB guidance documents. I did not uncover any evidence that OIRA/OMB took steps to monitor agencies' submissions of required federalism official designations or consultation plans, nor was this information generally publicly available. Apart from EPA, which incorporates its consultation plan in its publicly available guidance document, DOT was the only agency to provide an explicit consultation plan that was submitted to OMB.⁴²⁴ The "plan,"

420. See *supra* note 19 and accompanying text.

421. OMB Guidance for E.O. 13132, *supra* note 35, at 4–5; Exec. Order No. 13,132, § 6(a), 3 C.F.R. 206, 209 (1999).

422. At a minimum, OIRA/OMB should inform agencies whom to contact in order to submit the names of their designated federalism officials and their consultation plans.

423. OIRA/OMB should encourage agencies to post their relevant information in a fairly consistent manner, such that the information is easy for interested parties to compile, assess, and compare.

424. Letter from Nancy E. McFadden, Gen. Counsel, U.S. Dep't of Transp., to John Spotilla, Office of Mgmt. & Budget (Mar. 13, 2000) [hereinafter DOT 3/13/00 Letter]. OCC

however, merely states: “The Department intends to expand its efforts [to consult] by proactively soliciting the involvement of the Big Seven or elected officials in those actions it identifies as warranting such participation.”⁴²⁵ This statement is followed by three pages of examples of agency consultation and working groups set up by the various DOT agencies on their own accord.⁴²⁶ There is no general plan that explains how consultation should happen, and, notably, the plan mentions NHTSA only once: “[NHTSA] meets annually with State Highway Safety Offices to share information and solicit ideas on grant projects.”⁴²⁷

3. Include a More Thorough Review of Preemption in the Regulatory Review Process

At present, OIRA is responsible for monitoring agencies’ compliance with E.O. 13132.⁴²⁸ Under E.O. 12866, OIRA reviews “significant” proposed regulations on a transactional, or rule-by-rule, basis.⁴²⁹

According to OIRA officials, preemption and other federalism issues are given significant attention in the regulatory review process.⁴³⁰ But OIRA’s review is hampered when agencies evade the requirements of E.O. 13132.⁴³¹ The 2003 GAO Report—examining a subset of eighty-five rules over a year-long period—casts some doubt on the vigor of OIRA’s policing of agency compliance with E.O. 13132, finding only a single instance in which OMB questioned an agency’s conclusion regarding the absence of federalism implications in a rule.⁴³² Stuart Shapiro, who worked on federalism issues as

has no record of sending any such description to OIRA/OMB. OCC Telephone Interview, *supra* note 185.

425. DOT 3/13/00 Letter, *supra* note 424, at 1.

426. *Id.* at 1–4.

427. *Id.* at 3.

428. *See supra* note 35 and accompanying text.

429. *See supra* notes 42–43 (outlining four criteria triggering OIRA review under E.O. 12866 and certification for compliance with E.O. 13132).

430. I conducted an interview with Kevin Neyland, OIRA Deputy Administrator, on July 14, 2010. Interview with Kevin Neyland, Deputy Adm’r, Office of Info. & Regulatory Affairs, in Washington, D.C. (July 14, 2010). I followed up with Neyland and Michael Fitzpatrick, OIRA Associate Administrator, by telephone conversations on November 1, 2010, November 9, 2010, and November 12, 2010. Telephone Interviews with Kevin Neyland, Deputy Adm’r, Office of Info. & Regulatory Affairs, and Michael Fitzpatrick, Assoc. Adm’r, Office of Info. & Regulatory Affairs (Nov. 1, 9 & 12, 2010). I also conducted an interview with Preeta Bansal, OMB General Counsel and Senior Policy Advisor, and Boris Bershteyn, OMB Deputy General Counsel, on June 30, 2010. Interview with Preeta Bansal, Gen. Counsel & Senior Policy Advisor, Office of Mgmt. & Budget, and Boris Bershteyn, Deputy Gen. Counsel, Office of Mgmt. & Budget, in Washington, D.C. (June 30, 2010).

431. Sharkey, *Federalism Accountability*, *supra* note 14, at 2177–78 (“[S]uch theoretical [OMB] review provides cold comfort in the face of a reality in which agencies evade the requirements to produce [Federalism Impact Statements].”); *see Mendelson, Chevron*, *supra* note 14, at 783–86 (describing poor record of agency compliance with E.O. 13132).

432. The 2003 GAO Report examined a subset of eighty-five health, safety, or environmental rules that were submitted to OMB for review between July 2001 and June 2002. Only a single

assistant branch chief at OIRA in the late 1990s and early 2000s, confirmed the impression left by the 2003 GAO Report:

These [federalism] issues were a lower priority at OIRA than those more central to the analytical mission of the agency. If OIRA were to be able to exercise meaningful oversight of federalism issues, the staff would have to be expanded to include a couple of individuals with expertise in this area.⁴³³

In response to the increasing aggressiveness of federal agencies in preempting state law, several scholars have proposed strengthening OIRA's role to directly oversee federal regulatory policy and better ensure compliance with E.O. 13132.⁴³⁴ The ABA has adopted a resolution that "urges the President to improve agency compliance with E.O. 13132 by requiring inclusion of an entity independent of the agency regulatory office with sufficient autonomy, authority, and resources to conduct an effective review in the rule-making process before a preemptive rule is adopted."⁴³⁵

rule was cited in which OMB was "concerned with EPA's conclusion that th[e] proposed rule did not have federalism implications." U.S. GEN. ACCOUNTING OFFICE, GAO-03-929, RULEMAKING: OMB'S ROLE IN REVIEWS OF AGENCIES' DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS app. II at 182 (2003), available at www.gao.gov/new.items/d03929.pdf. In one other case, OMB changed the language in the federalism section in a rule's preamble, but did not require further agency action. *Id.* app. II at 139.

433. Email from Stuart Shapiro, Assoc. Professor & Dir. of Pub. Policy Program, Rutgers Univ., to Catherine M. Sharkey, Professor of Law, N.Y. Univ. Sch. of Law (Nov. 2, 2010, 10:32 EST) (on file with the *Michigan Law Review*). I conducted telephone interviews with Professor Shapiro on May 28, 2010 and October 21, 2010. Telephone Interviews with Stuart Shapiro, Assoc. Professor & Dir. of Pub. Policy Program, Rutgers Univ. (May 28, 2010 & Oct. 21, 2010). Shapiro may understate the extant legal expertise at OIRA, where both the Administrator (Cass Sunstein) and Associate Administrator (Michael Fitzpatrick) are lawyers. Moreover, OIRA could take advantage of the legal expertise within OMB's General Counsel Office by having that office review agency preemptive regulations as a matter of course.

According to some scholars, however, OMB sees its primary role as cost reduction, not regulatory oversight. *See, e.g.*, Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1263-68 (2006) (describing how OIRA focused on cost reduction at the expense of regulatory coordination).

434. *See, e.g.*, WILLIAM FUNK ET AL., CTR. FOR PROGRESSIVE REFORM, WHITE PAPER NO. 809, LIMITING FEDERAL AGENCY PREEMPTION: RECOMMENDATIONS FOR A NEW FEDERALISM EXECUTIVE ORDER 5-6 (2008) ("President Obama could use the new Federalism Executive Order to establish an office within OIRA that would have the legal expertise to review agencies' compliance with the Order."), available at http://www.progressivereform.org/articles/ExecOrder_Preemption_809.pdf; Sharkey, *Federalism Accountability*, *supra* note 14, at 2178 & n.209 (describing OIRA review under E.O. 12866 as a potential "template" for expanded review under E.O. 13132); Memorandum from Authors of *Advancing the Public Interest Through Regulatory Reform* to Michael Fitzpatrick, Assoc. Admin'r, Office of Info. & Regulatory Affairs, and Kevin Neyland, Deputy Adm'r & Acting Adm'r, Office of Info. & Regulatory Affairs (Mar. 31, 2009) (commenting on relationship between OIRA and federal agencies), available at http://www.reginfo.gov/public/jsp/EO/fedRegReview/advancing_attachment.pdf.

435. ABA Res. 117, *supra* note 340. The accompanying ABA Report explains that "[s]uch an independent entity might be OIRA, an office in the Department of Justice, or simply an office in the agency proposing the rule if that office has sufficient autonomy, authority, and resources for effective review." AM. BAR ASS'N, REPORT ON RES. 117, at 8 (2010), available

OIRA, as the central coordination locus for regulatory review, is well positioned to more thoroughly review agency proposals to preempt state law. For certain regulations—those subject to OMB review under E.O. 12866⁴³⁶—the Federalism Executive Order requires a designated federalism official in each agency to certify that the order’s requirements “have been met in a meaningful and timely manner” in developing regulations with federalism implications.⁴³⁷ But OMB is given little to review;⁴³⁸ it is asked simply for a vote of confidence in the federalism officer’s conclusion. If my recommendations are followed, however, agencies would have their own internal review of the factual predicates supporting preemption, and their analyses could then be reviewed by OIRA. This would go a long way toward enhancing OIRA’s level of trust and confidence in the agency’s submissions.

As an initial matter, OIRA should also include review of the federalism implications of agency preemptive rules within its checklists under the A-4 circular.⁴³⁹ Moreover, OIRA should consider the feasibility of requiring agency certification of compliance with E.O. 13132’s consultation and FIS mandates for *all* agency rulemakings that preempt state law (not just those subject to E.O. 12866).⁴⁴⁰

at http://www.americanbar.org/content/dam/aba/migrated/2011_build/medical_liability/med_mal_resolution117.authcheckdam.pdf.

436. Certification to OMB is required only for “significant” regulations. *See supra* note 42.

437. Exec. Order No. 13,132, § 8(a), 3 C.F.R. 206, 210 (1999); *see also* OMB Guidance for E.O. 13132, *supra* note 35, at 3 (“For any draft final regulation with federalism implications that is submitted for OIRA review under E.O. 12866, the federalism official must certify that the requirements of E.O. 13132 concerning both the evaluation of federalism policies and consultation have been met in a meaningful and timely manner.”).

438. *See* OMB Guidance for E.O. 13132, *supra* note 35, at 15 app. B (“Recommended Format for Section 8(a) Certification”). The recommended certification reads in its entirety: “I certify that [agency] complied with the requirements of E.O. 13132 for the attached draft final regulation, [title, RIN #].” *Id.*

439. Circular A-4 from Office of Mgmt. & Budget to Heads of Exec. Agencies & Establishments: Regulatory Analysis (Sept. 17, 2003), *available at* http://www.whitehouse.gov/omb/circulars_a004_a-4/. The A-4 circular “provides [OMB’s] guidance to Federal agencies on the development of regulatory analysis.” *Id.* Nowhere in the A-4 circular is there direction to ensure that agencies have met the procedural requirements of the preemption provisions of E.O. 13132.

Note that the A-4 circular applies only to economically significant rules under section 3(f)(1) of E.O. 12866 (defined as having an annual effect on the economy of at least \$100 million) and would therefore not apply to rules reviewed under other provisions, such as the “novel legal/policy” review. *See supra* note 42. According to an empirical study of OMB regulatory review during the period 1981–2000, 5 percent of the rules OMB reviewed met the “economically major/significant” criterion (i.e., section 3(f)(1)); the remaining 95 percent were “otherwise major/significant” (i.e., section 3(f)(2)–(4)). Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 846 (2003).

440. OIRA review under any of the four criteria for E.O. 12866 review listed in section 3(f), *see supra* note 42, should trigger a certification of compliance with E.O. 13132 by the agency per E.O. 13132 section 8(a). But it remains unclear whether *every* preemptive

CONCLUSION

Federal agencies hold the key to preemption decisionmaking in the future. Until very recently, their regulatory actions and interpretive positions have exerted a sub rosa influence on judicial decisions, which have instead emphasized Congress's direction. But the U.S. Supreme Court has now made federal agencies' role overt. This shift in institutional power has the potential to reshape the preemption landscape, by directing efforts away from Congress and the courts and toward the administrative rulemaking process within federal agencies. Stakeholders with vested interests in preemption disputes, such as state governmental organizations and other representatives of state interests, state attorneys general, consumer- and business-oriented organizations, and private litigants, can continue to ignore the preemptive rulemaking processes within federal agencies only at their peril.

As this Article further shows, those processes are, in and of themselves, rich areas of investigation. I have taken a close and in-depth view of the preemptive rulemaking processes within five significant federal agencies that regulate in areas as diverse as health and safety, banking, and the environment. In so doing, I have uncovered key areas for reform and have devised specific solutions, including a novel attorney general preemption notification provision and a blueprint for external OIRA/OMB review of newly proposed internal oversight procedures. This journey inside agency preemption charts preemption's future path.

rulemaking—for which agencies are required to submit a federalism impact statement to OMB per section 6(c)—would meet the E.O. 12866 section 3(f) criteria.

One possibility would be for OIRA to interpret E.O. 12866 section 3(f)(4) (“[r]aise novel legal or policy issues”) to apply categorically to agency preemptive rulemakings and to so instruct the agencies.

