

FEDERAL AGENCY PREEMPTION OF STATE LAW

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INTRODUCTION

Federal agency preemption of state law is a significant, high-profile issue. The Administrative Conference of the United States (ACUS) last considered the topic in 1984 and issued several recommendations. The Reagan Executive Order on Federalism (E.O. 12612) incorporated two of the procedural requirements ACUS recommended.¹ In 1988, the American Bar Association (ABA) adopted the ACUS recommendations almost verbatim.² At that time, the most pressing concern was federal preemption of state regulations and whether agencies had authority to preempt those state regulations via notice-and-comment rulemaking. Since that time, the major controversy has become federal preemption of state tort law. In 1992, the U.S. Supreme Court held in *Cipollone v. Liggett Group*³ that state law “requirements” subject to preemption by federal statutes (in this case, one regulating cigarette labeling) could be read to include common law tort actions (in addition to state statutes and regulations).

Federal preemption of state tort law has become one of the most high-profile issues today, arising in a variety of contexts ranging from health, safety and environmental regulation to banking regulation and consumer protection. During the George W. Bush Administration, executive department agencies and independent regulatory agencies aggressively pursued preemption.⁴ The United States Supreme Court has decided a rash of preemption cases in recent years.⁵ Congress has held hearings on

¹ Section 4 (“Special Requirements for Preemption”) of E.O. 12612 reads:

(d) As soon as an Executive department or agency foresees the possibility of a conflict between State law and Federally protected interests within its area of regulatory responsibility, the department or agency shall consult, to the extent practicable, with appropriate officials and organizations representing the States in an effort to avoid such a conflict.

(e) When an Executive department or agency proposes to act through adjudication or rule-making to preempt State law, the department or agency shall provide all affected States notice and an opportunity for appropriate participation in the proceedings.

Exec. Order No. 12,612, 3 C.F.R. 252 (1988), *reprinted in* 5 U.S.C. § 601 (1994). These subsections copy (almost verbatim) 1984 ACUS recommendations #3 and #4. ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, RECOMMENDATION NO. 84-5, PREEMPTION OF STATE REGULATION BY FEDERAL AGENCIES (1984).

² Arthur E. Bonfield, *Preemption Recommendation*, 113 ANN. REP. A.B.A. 291 (1988).

³ 505 U.S. 504 (1992).

⁴ For elaboration, see Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) [hereinafter Sharkey, *Preemption by Preamble*].

⁵ See *Cuomo v. Clearing House Ass’n*, 129 S. Ct. 2710 (2009) (holding that the National Banking Act does not preempt a state attorney general’s action to enforce state fair lending laws against a national bank); *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009) (holding that FDA

proposed legislation that would undo the Court's preemption decision in the realm of medical devices,⁶ and the issue of preemption is at the forefront of debates surrounding the Motor Vehicle Safety Act⁷ and the newly created Consumer Financial Protection Agency.⁸ In May 2009, President Obama issued a Presidential Memorandum on Preemption.⁹

Federal agencies play a significant role in statutory interpretation. While Congress, with the stroke of a pen, could definitively resolve preemption questions, simply by clearly specifying the fate of state law when it enacts legislation, the reality is that Congress often falls short of this benchmark. Some legislation—such as the Motor Vehicle Safety Act and the Consumer Product Safety Act—are marked by Congress' inclusion of *both* an express preemption provision that would seem to oust competing

approval of warnings on a pharmaceutical company's label did not provide a complete defense to state tort claims); *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 551 (2008) (holding that a state fraud claim against a cigarette manufacturer was not preempted by federal law); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 87 (2d Cir. 2006) (holding that federal law did not preempt a state tort law providing a "fraud-on-the-FDA" exception to state immunity for drug manufacturers whose drugs are approved by the FDA), *aff'd by an equally divided court*, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1011 (2008) (holding that a federal statute regulating medical devices preempts state tort law when the device at issue had received FDA premarket approval). The Supreme Court has two additional preemption cases on its docket this Term. In *Williamson v. Mazda Motor of Am., Inc.*, the Court will decide whether compliance with a motor vehicle safety standard preempts state common law liability. See United States Supreme Court, Order List: 560 U.S. at 2 (May 24, 2010) (granting cert), *available at* <http://www.supremecourt.gov/orders/courtorders/052410zor.pdf>. And in *Bruesewitz v. Wyeth*, the Court will determine whether the National Childhood Vaccine Injury Act of 1986 preempts all design defect claims against vaccine manufacturers. See United States Supreme Court, Order List: 559 U.S. at 3 (Mar. 8, 2010) (granting cert), *available at* <http://www.supremecourt.gov/orders/courtorders/030810zor.pdf>; Brief for Petitioners, *Bruesewitz v. Wyeth*, No. 09-152, at i (May 24, 2010) (question presented).

⁶ But "it appears that legislative attempts to curtail the scope of the MDA's pre-emption clause in the wake of *Riegel* have lost momentum, at least for the time being." See John A. Tartaglia III, *Guest Post - H.R. 6381: Will Congress Strip Class III Medical Device Manufacturers of Their Pre-Emption Defenses?*, DRUG & DEVICE L. (May 5, 2010), <http://druganddevicelaw.blogspot.com/2010/05/guest-post-hr-6381-will-congress-strip.html>.

⁷ The House Energy and Commerce Committee has reported out a bill, H.R. 5381, that amends the Motor Vehicle Safety Act by adding language to end federal preemption for motor vehicle safety regulations. See Motor Vehicle Safety Act of 2010, H.R. 5381, 111th Cong. (2010).

⁸ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 § 315 (2010).

⁹ Memorandum for the Heads of Executive Departments and Agencies (May 20, 2009), 74 Fed. Reg. 24,693, 24,693-94 (May 22, 2009), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2009-05-22/pdf/E9-12250.pdf#page=1>.

state law and an express “savings” provision that would seem to have the opposite effect. Other legislation, such as the provisions of the Food, Drug, and Cosmetic Act pertaining to pharmaceutical drugs, is silent on the question. Where Congress is less than pellucid, courts play an increasing role in deciding preemption questions that come before them. And while courts reiterate that congressional intent is the touchstone of preemption analysis, even in express preemption cases, let alone in implied preemption cases, there is vast interpretive room. It is here that the views propounded by federal agencies—either in regulations or else in preambles or litigation briefs—have held sway in the courts.

Agency interpretations of preemption have come under enhanced scrutiny in the past few years. The Presidential Memorandum on Preemption came close on the heels of the U.S. Supreme Court’s decision in *Wyeth v. Levine*, which held that a state tort lawsuit brought by a woman injured by an FDA-approved drug was not impliedly preempted by the Food Drug and Cosmetic Act or FDA regulations. Moreover, the U.S. Supreme Court looked with particular disdain upon the procedural irregularities that accompanied the FDA’s inclusion of its statement of preemptive intent 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.” 65 Fed. Reg. 81103; see also 71 *id.*, at 3969 (noting that the “proposed rule did not propose to 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 pre-emptive effect in the regulatory preamble. The agency’s views on state law are inherently suspect in light of this procedural failure.¹⁰

The FDA’s approach to “preemption by preamble” bypassed vetting under the notice-and-comment process as well as the state consultation mandates of the Federalism Executive Order 13132; accordingly, the Court did not accord deference to the FDA’s pro-preemption position. The disregard shown by the FDA (and other federal agencies) towards procedural and consultative requirements for preemption determinations highlights the concern of an agency’s interpretation of preemption substituting for congressional intent.¹¹

¹⁰ *Wyeth v. Levine*, 129 S. Ct 1187, 1201 (2009).

¹¹ In August 2010, the American Bar Association adopted a resolution proposed by its Task Force on Federal Agency Preemption of State Tort Law, which calls upon the President to “require three particular procedures . . . before an agency regulation should be able to preempt state law.” AM. BAR ASS’N, TASK FORCE ON FEDERAL AGENCY PREEMPTION OF STATE TORT LAWS 8 (2010) [hereinafter ABA TASK FORCE REPORT]; Am. Bar Ass’n, H.R. 117, Tort Law Preemption Issues § 3 (2010), available at http://www.abanow.org/wordpress/wp-content/files_flutter/1282164714Resolution117Summary080910.doc [hereinafter ABA H.R. 117] (passing resolution). The Task Force’s recommendations were issued against a backdrop where, “[d]espite the [Executive Order 13132], some have asserted that executive agencies are not consistently following its directions.” ABA TASK FORCE REPORT, *supra*, at 6.

The Supreme Court has not, however, precisely specified the level of deference to give to agency preemptive rulemakings, or positions embedded in preambles to rules or briefs in litigation. Since *Chevron* was decided in 1984,¹² courts defer to agency interpretations of ambiguous statutory language.¹³ But whether courts should similarly to defer to agency interpretations that *preempt* state law has been the subject of an ongoing debate.¹⁴ In *Cuomo v. Clearing House Association*,¹⁵ the Court held that the OCC's interpretation of visitorial powers to preempt state enforcement of state law went beyond the "outer limits" of the ambiguity inherent in the term and was therefore not entitled to *Chevron* deference.¹⁶ Together, *Wyeth* and *Cuomo* illustrate the Supreme Court's reluctance to confer *Chevron* deference to agency preemption determinations. But, at the same time, the Court has only intimated (albeit not consistently) that the lesser form of *Skidmore* "power to persuade" deference should apply.

This Report presents the first look at federal agency compliance with the Presidential Memorandum on Preemption, 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 rulemakings¹⁷ to ensure that they were legally justified and comported with the Administration's principles.

As the Supreme Court has recognized, preemption determinations may be unique, in part because of the federalism values at stake when state law is pitted against federal

¹² *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

¹³ *See id.* at 840–41, 866 (holding EPA interpretation as a "permissible construction of the statute").

¹⁴ *See, e.g.*, Catherine M. Sharkey, *Federalism Accountability: "Agency Forcing" Measures*, 58 DUKE L.J. 2125, 2180 (2009) [hereinafter Sharkey, *Federalism Accountability*]; Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. L. REV. 695 (2008) [hereinafter Mendelson, *Presumption*]; Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U.L. REV. 727 (2008); Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004) [hereinafter Mendelson, *Chevron*]; William Funk, *Judicial Deference and Regulatory Preemption by Federal Agencies*, 84 TULANE L. REV. (forthcoming 2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1586955; 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 (manuscript at 20) (Lawrence E. Mitchell & Arthur E. Wilmarth, Jr. eds., forthcoming 2010), available at <http://ssrn.com/abstract=1499216>.

¹⁵ *Cuomo v. Clearing House Ass'n*, 129 S. Ct. 2710 (2009).

¹⁶ *Id.* at 2715.

¹⁷ The Presidential Memorandum defines "preemptive rulemaking" as one that contains "statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law."

law and must cede ground. The recommendations included in this ACUS Report are directed towards federal agencies with the twofold 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 the 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 the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB).

I. EXECUTIVE DIRECTIVES ON PREEMPTION AND FEDERALISM

A. *May 2009 Presidential Memorandum on Preemption*

On May 20, 2009, President Barack 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.”¹⁸ The memorandum specifically admonished department and agency heads to cease the practice of “preemption by preamble”—where preemption statements are included in the preamble, but not in the codified regulation.¹⁹ 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.”²⁰

The Preemption Memo asks 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 preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption.”²¹

B. *Federalism Executive Order 13132*

Executive Order 13132, “Federalism,” issued by President Clinton on August 4, 1999,²² is adverted to in Obama’s Presidential Memorandum and also serves as the centerpiece of numerous reform proposals for agency preemption of state law. E.O.

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

¹⁹ *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.”).

²⁰ *Id.*

²¹ *Id.*

²² Exec. Order No. 13,132, 3 C.F.R. 206 (2000), *reprinted in* 3 U.S.C. § 301 (2006).

13132 is an amended version of E.O. 12612, President Reagan's Executive Order on Federalism.²³ 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.²⁴ The Order emphasizes consultations with State and local governments and enhanced sensitivity to their concerns. The Order applies to all federal agencies, except for independent regulatory agencies,²⁵ which are nonetheless encouraged to comply voluntarily with its provisions.²⁶

1. Consultation Process

E.O. 13132 directs that agencies must 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.”²⁷ The Order establishes specific procedures

²³ President Clinton issued a short-lived order (E.O. 13083) that attempted a more comprehensive rewriting of the Reagan Federalism Order. *See* Exec. Order No. 13,083, 63 Fed. Reg. 27,651 (May 19, 1998). Clinton's order stated that problems of national scope would arise in numerous circumstances and provided nine examples. The Order stated that federal action was justified “[w]hen there is a need for uniform national standards”; “[w]hen decentralization increases the cost 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.* at 27,652. President Clinton suspended his order after a “firestorm of criticism,” including charges that he 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*, 34 PUBLIUS 55, 64 (2004). He then 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 CONFERENCE OF STATE LEGISLATURES (last updated Nov. 18, 2005), <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”).

²⁴ Exec. Order No. 13,132 § 4 (“Special Requirements for Preemption”). The Order also furthers the policies of the Unfunded Mandates Reform Act, which is not the focus of this Report. Section 6(b) establishes procedures for unfunded mandates, defined as “any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, and that is not required by statute.” *Id.* § 6(b). That said, the specific procedures outlined for intergovernmental consultation are identical for regulations that impose unfunded mandates and those that preempt state law.

²⁵ Exec. Order No. 13,132 § 1(c).

²⁶ *Id.* § 9.

²⁷ *Id.* § 6(a). The consultation process must involve “elected officials of State and local governments or their representative national organizations.” *Id.* §§ 1(d), 6(a).

for intergovernmental consultation if a rule preempts state law.²⁸ Each agency must consult with state and local officials “early in the process of developing the proposed regulation.”²⁹

2. *Federalism Impact Statements*

E.O. 13132 also requires agencies to provide a federalism impact statement (FIS) whenever regulations will have federalism implications³⁰ and preempt state law.³¹ 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.”³²

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.”³³

3. *Enforcement*

Within OMB, OIRA has “primary responsibility for implementing . . . [Executive] Order 13132.”³⁴ In October, 1999, OIRA Administrator John Spotila

²⁸ Section 6(c) establishes procedures for “any regulation that has federalism implications and that preempts State law.” *Id.* § 6(c).

²⁹ *Id.* § 6(c)(1).

³⁰ *Id.* § 1(a) (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”).

³¹ *Id.* § 6(c)(2) (requiring FIS for regulations and orders with “federalism implications and that preempt[] State law”).

³² *Id.* OIRA has urged agencies to include FIS earlier, as part of the Notice of Proposed Rulemaking (NPRM). *See* Memorandum from Jacob J. Lew, Director, Office of Mgmt. & Budget, to the Heads of Executive Departments and Agencies, and Independent Regulatory Agencies, Guidance for Implementing E.O. 13132, “Federalism” (Oct. 28, 1999), at 6, *available* at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/m00-02.pdf> [hereinafter OMB Guidance for E.O. 13132] (“To the extent that an agency has carried out intergovernmental consultations prior to publication of the [NPRM], we strongly recommend that the agency help State and local governments, and the public as a whole, by including a ‘federalism summary impact statement’ in its preamble to the NPRM.”).

³³ Exec. Order No. 13,132 § 6(c)(2). 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).

³⁴ OMB Guidance for E.O. 13132, *supra* note 32 (cover sheet). As the OMB Guidance states: “Under Executive Order 12866, [OIRA] already coordinates our regulatory review and

circulated to all heads of executive departments and agencies and independent regulatory agencies “Guidance for Implementing E.O. 13132”³⁵ 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.”³⁶

Pursuant to the Guidelines, each agency and department was to designate a federalism official with primary responsibility for the agency’s implementation of the Order.³⁷ 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.”³⁸

The federalism official must submit to OMB “a description of the agency’s consultation process.”³⁹ 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.”⁴⁰

For any draft final regulation with federalism implications that is submitted for OIRA review under Executive Order 12866 (“Regulatory Planning and Review”),⁴¹ 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.⁴²

planning functions.” *Id.*; see also Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), amended by Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007).

³⁵ OMB Guidance for E.O. 13132, *supra* note 32.

³⁶ *Id.* at 1.

³⁷ Exec. Order No. 13,132 § 6(a). Each agency was to notify OIRA of the designated federalism official. OMB Guidance for E.O. 13132, *supra* note 32, at 2.

³⁸ *Id.*

³⁹ Exec. Order No. 13,132 § 6(a); OMB Guidance for E.O. 13132, *supra* note 32, at 2.

⁴⁰ OMB Guidance for E.O. 13132, *supra* note 32, at 4–5.

⁴¹ There are four criteria 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) “Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof” or; 4) “Raise novel legal or policy issues” Exec. Order No. 12,866 § 3(f) (defining “significant regulatory action”).

⁴² Exec. Order No. 13,132 § 8(a).

II. FEDERAL AGENCY RESPONSE: RULEMAKING AND LITIGATION

A central contribution of this Report is an evaluation of agencies' responses to President Obama's Memorandum on Preemption and efforts taken to ensure compliance with the relevant provisions of Executive Order 13132 ("Federalism") governing preemptive rulemaking. This empirical work, focusing on agencies' awareness of the issue and their compliance efforts, draws from extensive interviews with agency officials as well as an independent review of the agencies' respective rulemaking docket and intervention in litigation. In the past, some have noted that whether agencies follow E.O. 13132 is a matter of "culture" within the agency. This Report probes inter-agency differences in their responses to the Presidential Memorandum and E.O. 13132.

Sharkey conducted sets of in-person and telephone interviews with officials at each of the federal agencies surveyed. At these interviews (or shortly thereafter), Sharkey requested various documents to support information gleaned from the interviews. She also extensively reviewed the respective federal agency's rulemaking and intervention in litigation over the past decade in publicly available databases. Where possible, the Report cites to documents (published and unpublished) as opposed to the unrecorded informal interviews. Nonetheless, the interviews were pivotal in terms of steering the inquiries as well as in confirming and/or raising questions about ambiguities in the documented record.

The May 2009 Presidential Memorandum on Preemption caught the attention of federal agencies and led to serious internal review, at least in the majority of agencies surveyed. Officials at National Highway Traffic Safety Administration (NHTSA), Office of the Comptroller of the Currency (OCC), Consumer Product Safety Commission (CPSC), and Environmental Protection Agency (EPA) provided Sharkey with either a report or information regarding the agency's ten-year retrospective review of all rules intended to preempt state law.

Moreover, both the change in Administration and the Presidential Memorandum on Preemption have had wider-ranging effects in terms of shifts in preemption policy within the agencies. This policy shift has been most pronounced at NHTSA. On the rulemaking front, NHTSA removed the preemptive language in two 2005 rulemakings⁴³ and, beginning in 2008 but especially in 2009, has drafted increasingly toned down "boilerplate" language on the possibility of preemption which has evolved over the past several years. NHTSA's revised position in rulemakings is mirrored by its recent litigation stances. Perhaps most significantly, NHTSA argued against preemption in the *Williamson v. Mazda* case (now pending before the U.S. Supreme Court), and gave its most tepid embrace of *Geier*'s implied preemption holding, which the Court will revisit in *Williamson*.

CPSC—an independent regulatory agency, technically not bound by E.O. 13132—has also experienced a significant shift in its rulemaking and intervention in litigation, largely at the behest of Congressional direction. CPSC has adopted an extremely cautious stance. In its rulemakings, the agency refrains from offering its interpretive gloss on preemption, choosing instead mere recitation of governing express

⁴³ A third 2005 rulemaking was withdrawn in July 2008. 73 Fed. Reg. 42,309 (July 21, 2008).

statutory preemption provisions. CPSC is likewise hesitant to intervene in litigation where preemption is at stake.

The Food and Drug Administration (FDA) is more difficult to evaluate. Due to the then-pending invitation for the Solicitor General to submit its views on implied preemption to the U.S. Supreme Court, which is considering granting certiorari in a pair of generic drug preemption cases, agency officials were less forthcoming with information.⁴⁴ There is some evidence from the regulatory record and intervention in pending litigation from which to infer that FDA has revised its preemption policy under the new Administration. In its most recent rulemakings, the agency appears to be proceeding full speed ahead with respect to express statutory preemption, but pulling back from its prior reliance on *Geier* implied preemption.

At the OCC, the recently enacted Dodd-Frank Wall Street Reform and Consumer Protection Act has occluded any developments in the rulemaking or litigation realms. Pursuant to this Act, OCC will be classified as an independent agency, no longer subject to the mandates of E.O. 13132, and review of OCC rulemaking has effectively shifted from the Executive to Congress.

The Federal Trade Commission (FTC), like CPSC (and now OCC), is an independent regulatory agency, and as such, is not formally required to submit to the provisions of E.O. 13132. In contrast with both the CPSC and OCC, however, the FTC has consistently refrained from preemption.

Finally, like FTC, EPA stands in fairly sharp relief against the background of the history of preemptive actions by NHTSA, FDA, and OCC. Preemption in EPA rules is relatively rare, and always pursuant to express statutory provisions. Moreover, EPA has a unique relationship with the states as co-regulators.

A. NHTSA

Of all the agencies surveyed in this Report, NHTSA showed the most evidence of a shift in policy on preemption under the Obama Administration. A recent 2010 rule on Electric-Powered Vehicles contains a lengthy discussion of the evolution of the agency's thinking on preemption, including a disavowal of the preemptive language contained in three 2005 Notice of Proposed Rulemakings (NPRMs) as well as a lengthy adumbration of the agency's revisions to its boilerplate language discussing the issue of preemption since 2007, culminating in its weakest embrace of implied preemption to date in more recent rulemakings. These policy shifts in the rulemaking process are echoed in its recent participation in litigation. In two high-profile cases—one now pending before the U.S. Supreme Court and another decided by the Second Circuit—NHTSA submitted amicus briefs arguing against implied preemption and outlining a sharply circumscribed view of

⁴⁴ On November 2, 2010, the Solicitor General submitted its brief (co-signed by officials at the Department of Health and Human Services) arguing against a grant of certiorari. Brief for the United States as Amicus Curiae, *PLIVA, Inc. v. Mensing*, No. 09-993 (U.S. Nov. 2, 2010).

implied preemption under the Motor Vehicle Safety Act and Energy Policy and Conservation Act, respectively.

Sharkey conducted extensive in-person interviews with NHTSA and DOT officials.⁴⁵

1. *Response to May 2009 Presidential Memorandum on Preemption*

In response to the President's Memorandum on Preemption, the Department of Transportation sent OIRA a list of all current DOT rulemakings asserting preemptive effect, along with what corrective action should be taken, if any.⁴⁶ For NHTSA, DOT identified six rules with preemptive effect: Designated Seating Positions,⁴⁷ Air Bag Labeling,⁴⁸ Detachable Seat Belts,⁴⁹ Event Data Recorders,⁵⁰ and two Average Fuel Economy standards.⁵¹ Only one of these rules, Designated Seating Positions, was listed as including a preemptive provision in the codified regulation.⁵² That rule is also the only

⁴⁵ Sharkey conducted separate interviews with Kevin Vincent, NHTSA Chief Counsel (June 30, 2010), Steve Wood, NHTSA Assistant Chief Counsel (June 30, 2010), Neil Eisner, DOT Assistant General Counsel for Regulation and Enforcement (June 30, 2010), and Paul Geier, DOT Assistant General Counsel for Litigation (July 6, 2010). Moreover, Sharkey had corresponded independently via email with Steve Wood (who was "Acting Chief Counsel" of NHTSA for the first seven months in 2009) between 2006-10 during which time Sharkey was working on various research projects concerning agency preemption of state law.

⁴⁶ Letter from Robert S. Rivkin, Office of Gen. Counsel, U.S. Dep't of Transp., to Kevin Neyland, Acting Admin., Office of Info. & Reg. Affairs (Aug. 17, 2009). This document was provided to Sharkey by Neil Eisner.

⁴⁷ Federal Motor Vehicle Safety Standards; Designated Seating Positions and Seat Belt Assembly Anchorages, 73 Fed. Reg. 58,887 (Oct. 8, 2008). Note that this is the pre-reconsideration rule. For a discussion of the post-reconsideration rule (issued after NHTSA's letter to OIRA), see *infra* notes 80–87 and accompanying text.

⁴⁸ Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 66 Fed. Reg. 65,376, 65,402 (Dec. 18, 2001).

⁴⁹ Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 69 Fed. Reg. 70,904, 70,912 (Dec. 8, 2004).

⁵⁰ Event Data Recorders, 71 Fed. Reg. 50,998, 51,029–30 (Aug. 28, 2006).

⁵¹ Average Fuel Economy Standards for Light Trucks, MY 2008-2011, 71 Fed. Reg. 17,566 (Apr. 6, 2006); Average Fuel Economy Standards, Passenger Cars and Light Trucks; MY 2011-2015, *available at* <http://www.regulations.gov/search/Regs/contentStreamer?objectId=09000064807a98a5&disposition=attachment&contentType=pdf>. (This is a notice of proposed rulemaking; for discussion of the final rule, see *infra* notes 121–125 and accompanying text).

⁵² Letter from Robert S. Rivkin, *supra* note 46, at 7.

rule listed where NHTSA believed further action was warranted.⁵³ NHTSA said that it 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.⁵⁴

NHTSA's identification of only six preemptive rules and just a single one in need of further action may, at first, seem surprising in light of the charges—from Congress, stakeholder groups and in the legal academic literature—of aggressive preemptive rulemaking during the George W. Bush Administration. According to the American Association for Justice 2008 Report, over the period from 2001 to 2008, NHTSA issued more notices claiming preemption than any other federal agency, accounting for nearly half (twenty-four of fifty-three) of all rulemakings characterized by AAJ as preemptive rulemakings.⁵⁵ Moreover, as of July 2010, AAJ compiled a list of seven proposed NHTSA rules and seven final rules from 2007 to 2009 that it claims “still contain preemption language.”⁵⁶ By NHTSA's count, only 3 of the 24 notices listed in AAJ's 2008 report and none of the 14 notices listed in AAJ's July 2010 email identified a conflict or stated an intent to preempt and thus can be accurately characterized as “preemptive rulemakings.” In the agency's view, notices that simply contain the boilerplate discussion of the issue of preemption do not meet either of those criteria and thus are not in any sense “preemptive rulemakings.”

The discrepancy between NHTSA and AAJ is explained by two factors. 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

⁵³ For the Air Bag Labeling rule, NHTSA stated that preemption was limited solely to impossibility preemption, *i.e.* a state tort judgment would require labeling standards such that a manufacturer could not meet both the NHTSA requirements and the state requirement. *Id.* at 7–8. For the Detachable Seat Belts rule, the preemption provision is limited to preempting state tort suits where NHTSA affirmatively stated that Type 2 seatbelts could be used in Type 2 approved vehicles. *Id.* at 8. For the Event Data Recorders (EDRs) rule, NHTSA offered a lengthy explanation for why, though it saw no conflicts at the time, it needed to proactively assert that state regulation of data recorders should be preempted: conflicting regulation would reduce the benefits of standardized data and operation and make it less likely that manufacturers would voluntarily develop EDRs and improve the technology. *Id.* at 9–12. For the two Average Fuel Economy rules, NHTSA cited DOJ Civil's advice that no comments on preemption were necessary, as greenhouse gas regulation will be national in nature. *Id.* at 12–13.

⁵⁴ Email from Steve Wood to Catherine M. Sharkey, Oct. 13, 2010, 1:55 A.M.

⁵⁵ 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.

⁵⁶ Email from Sarah Rooney, Regulatory Counsel, American Association for Justice, to Catherine M. Sharkey, July 20, 2010, 3:30 P.M.

contain “boilerplate” discussion of the issue of preemption.⁵⁷ In a recent 2010 rulemaking on Electric-Powered Vehicles, in response to AAJ, NHTSA stated that the boilerplate language was not intended to preempt state law, noting that the language did not include any finding of a conflict and did not state any intent to preempt. The agency also relayed 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.⁵⁸ According to NHTSA, the boilerplate simply describes the possibility that preemption could occur if there is an actual conflict between state and federal law, as was the case in *Geier*, and no more.⁵⁹ The boilerplate makes no effort to identify or serve warning of preemption, and simply serves as a notice for potential future conflicts in the courts.⁶⁰ Given that the Presidential Memorandum on Preemption directs agencies to review all rules “intended by the department or agency to preempt state law,”⁶¹ it is not surprising that NHTSA concluded that the boilerplate language did not fall within the Memorandum and thus did not include the rules with the boilerplate language.

2. Rulemaking

NHTSA has acknowledged a policy shift on preemption under the Obama Administration. At a recent Congressional hearing on proposed amendments to the Motor Vehicle Safety Act, 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 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 regulation language preempting state law claims. Are you familiar with that?

⁵⁷ Each of the rules on AAJ’s July 2010 list from 2007-09, *see supra* note 56, 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), 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.

⁵⁸ Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,524 (June 14, 2010) (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).

⁵⁹ *Id.* (citing *Geier v. Am. Honda Corp.*, 529 U.S. 861 (2000)).

⁶⁰ *Id.*

⁶¹ Presidential Memorandum on Preemption, *supra* note 21.

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 decisions—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 in your capacity able to assure us that those practices will not continue while you are administering?

MR. STRICKLAND: I can make that obligation, absolutely. There is a notion that states' rights are incredibly important and those preambles that will place not only in districts rules, but there were several rules throughout executive branch agencies and safety agencies which undermined 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.⁶²

NHTSA's clarifying actions in the preemption realm began in late summer 2008, and in fact preceded the May 20, 2009 Presidential Memorandum on Preemption.⁶³ But only in its recent 2010 rulemaking on Electric-Powered Vehicles did NHTSA provide a comprehensive account of the 2009 removal of preemptive language from two of the three 2005 rulemakings and the 2008 withdrawal of the third 2005 rulemaking and the evolution of the boilerplate language on the issue of preemption that continues to date.

(a) *Removal of Preemptive Language*

In three 2005 rulemakings, NHTSA gave an extended discussion of preemption and claimed the safety standard preempted state tort law.⁶⁴ In its recent 2010 rulemaking on Electric-Powered Vehicles, NHTSA noted that the three 2005 NPRMs “contrast markedly” with their other 2007-09 rules that use boilerplate language.⁶⁵ For each rule, NHTSA had identified a specific potential conflict or obstacle state tort law would pose for each of the federal standards.

⁶² *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. (2010). This sentiment was echoed by NHTSA Chief Counsel, who maintained that “the 2005 policy is not the 2010 policy.” Sharkey Interview with Kevin Vincent.

⁶³ Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,524–25 (June 14, 2010).

⁶⁴ The three rules were: the NPRM for roof crush resistance, 70 Fed. Reg. 49,223, 49,245-46 (Aug. 23, 2005), rearview mirrors on trucks, 70 Fed. Reg. 53,753, 53,768-69 (Sept. 12, 2005), and amending the definition of a “designated seating position,” 70 Fed. Reg. 36,094, 36,101-02 (June 22, 2005).

⁶⁵ See Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,524 (June 14, 2010).

(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 from it,” but also specifically named New Jersey, New York, and Washington as states whose statutes would be preempted under the rule.⁶⁶ 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.”⁶⁷

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.⁶⁸ The Act applied only to cars and light trucks (light trucks include SUVs and vans (both passenger and cargo) under 10,000 pounds, gross vehicle weight rating (GVWR) while NHTSA’s rule was targeted at straight trucks with GVWRs between 10,000 and 26,000 pounds. 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 accidents, NHTSA decided to withdraw the NPRM in order to take a “comprehensive look at backing safety for all types of motor vehicles.”⁶⁹

In March 2009, NHTSA issued a revised Advanced NPRM for rearview mirrors.⁷⁰ This revised ANPRM replaced the language discussing preemption with boilerplate stating there was a “possibility” the MVSA would preempt state law, but, according to NHTSA, “we do not know of any State laws or regulations that currently exist that are potentially at risk of being preempted.”⁷¹ For implied preemption, NHTSA said it had “considered today’s ANPRM and [did] not currently foresee any potential

⁶⁶ Federal Motor Vehicle Safety Standards; Rearview Mirrors, 70 Fed. Reg. 53,753, 53,768 & nn.23–24 (Sept. 12, 2005) (citing N.J. Stat. Ann. § 39:3-71.1 (West 2004); N.Y. Vehicle and Traffic Law § 375(9)(e) (McKinney 2003); Wash. Rev. Code Ann. § 46.37.400 (West 2004)).

⁶⁷ *Id.* at 53,768. NHTSA, however, noted that New York commented on the Advanced NPRM, and NHTSA responded to New York’s comments. *See id.* at 53,764–65, 53,768.

⁶⁸ Cameron Gulbranson Kids Transportation Safety Act of 2007, Pub. L. No. 110-189 § 2(b).

⁶⁹ *See* Federal Motor Vehicle Safety Standards; Rearview Mirrors, 73 Fed. Reg. 42,309, 42,312 (July 21, 2008).

⁷⁰ Federal Motor Vehicle Safety Standard; Rearview Mirrors; Proposed Rule, 74 Fed. Reg. 9477 (Mar. 4, 2009).

⁷¹ *Id.* at 9516.

State requirements that might conflict with it. Without any conflict, there could not be any implied preemption.”⁷²

(ii) *Roof Crush Rule*

In the NPRM for the Roof Crush Rule, NHTSA was clear that: “[I]f the proposal were adopted as a final rule, it would preempt all conflicting State common law requirements, including rules of tort law.”⁷³ NHTSA also asserted (just as it did in the rearview mirror NPRM)—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 federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement.”⁷⁴

NHTSA received twenty-five comments in response to the preemption discussion, including comments from National Conference of State Legislatures (NCSL), Public Citizen, and twenty-seven attorneys general. Also, during the comment period, Jeffrey Rosen, Department of Transportation General Counsel, and Steve Wood, a NHTSA attorney, met with representatives of NCSL and National Association of Attorneys General (NAAG) at their request and discussed the proposal and preemptive effects.⁷⁵

The Roof Crush Rule also caught Congress’ attention. NHTSA’s preemptive rule was touched upon during Congress’ wide ranging 2007 hearing on regulatory preemption.⁷⁶ Then, in 2008, the Senate held a hearing on the Roof Crush Rule, during which it confronted NHTSA Deputy Administrator James Ports with questions on preemption.⁷⁷ Members from both sides of the aisle criticized NHTSA. Senator Coburn

⁷² *Id.*

⁷³ Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,246 (Aug. 23, 2005).

⁷⁴ *Id.* at 49,245.

⁷⁵ Jeffrey Rosen and Steve Wood met with NAAG and NCSL at a meeting at OMB. Sharkey Interview with Wood, June 30, 2010.

⁷⁶ *See Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?: Hearing Before S. Comm. on the Judiciary*, 110th Cong. (2007). Donna Stone, on behalf of the NCSL, criticized the NHTSA as being the first agency to skirt E.O. 13132 in its roof crush rule by claiming no federalism implications but preempting state tort law in the rule. *Id.* at 11 (statement of Hon. Donna Stone, State Rep., Dela. Gen. Assembly, President, Nat’l Conf. of State Legis.). Professor David Vladeck also discussed the irony of a roof crush rule that would have little practical impact because tort litigation that should be protected by the Motor Vehicle Safety Act’s savings clause had already forced carmakers to increase rollover protection. *Id.* at 21.

⁷⁷ *Oversight Hearing on Passenger Vehicle Roof Strength: Hearing before the Subcomm. on Consumer Affairs, Ins., & Auto. Safety of the S. Comm. on Commerce, Science, & Transp.*, 110th Cong. (2008), available at http://commerce.senate.gov/public/index.cfm?p=Hearings&ContentRecord_id=50f68af1-c5f8-4494-907a-4af5d734a78d&ContentType_id=14f995b9-dfa5-407a-9d35-

(R) stated he had “heartburn” over the lack of transparency in this rulemaking. Senator Pryor (D) warned NHTSA that preemption was a “bad idea” and that NHTSA was “overstepping its bounds” into the legislative arena.⁷⁸

After the hearing, the Roof Crush rule was shelved. After 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.”⁷⁹

(iii) *Designated Seating Position Amendment*

The Designated Seating Position Amendment was the sole rule warranting further action that NHTSA identified in its response to the Presidential Memorandum on Preemption. Subsequently, in a December 2009 final rule (in response to petitions for reconsideration), NHTSA removed the preemptive regulatory text.⁸⁰

The original final rule was issued in October 2008 and added preemptive regulatory text. After the 2008 rule, both AAJ and Public Citizen petitioned NHTSA to reconsider. AAJ argued that neither express nor implied preemption was warranted:

56cc7152a7ed&Group_id=b06c39af-e033-4cba-9221-de668ca1978a&MonthDisplay=6&YearDisplay=2008 [hereinafter *Oversight Hearing on Roof Strength*]; see also WILLIAM BUZBEE ET AL., THE TRUTH ABOUT TORTS: RETHINKING REGULATORY PREEMPTION AND ITS IMPACT ON PUBLIC HEALTH 8 (Ctr. for Progressive Reform White Paper #902, 2009), available at <http://www.cprblog.org/articles/RethinkingPreemption902.pdf> (describing how “[m]embers of both political parties present at the hearing sought to persuade NHTSA to remove a provision of the proposed rule that indicated the agency believed the rule would preempt state tort law”).

⁷⁸ Moreover, Senator Pryor warned NHTSA that if they kept the preemptive language in the final rule, Congress would take action. He cited Senator Coburn’s unease with the rulemaking as evidence that there would be bipartisan support for action by Congress to countermand NHTSA’s actions. Senator McCaskill (D) likewise made her dissatisfaction known. She pointed out that the last rule on roof crush standards was issued thirty years ago, and that preemption forces the rest of the country to wait around for NHTSA to update the rule. NHTSA responded by stating that preemption language was included because NHTSA had a comprehensive plan on balancing roof strength with stability. Senator McCaskill retorted by pressing NHTSA on when it started preempting state law through boilerplate preamble preemption. She wanted to know who ordered preemption boilerplate in NHTSA rules. Specifically, she wanted to know if it was the White House and when this practice began. She said, “There’s preemption popping up everywhere like spring flowers!” She feared there was a “plot” in the Bush administration to wipe out people’s access to courts. *Oversight Hearing on Roof Strength, supra* note 77.

⁷⁹ 74 Fed. Reg. 22,348, 22,382 (May 12, 2009).

⁸⁰ 74 Fed. Reg. 68,7185 (Dec. 29, 2009).

express preemption was contrary to congressional intent and *Geier* was an “unusual, fact driven case” that rested on a range of options available under the rule and its lengthy history.⁸¹ Public Citizen (with the Consumer Federation of America) argued that NHTSA’s preemption statements were “harmful and unnecessary,” that tort law did not “frustrate” the purposes of the rule, that *Geier* was “fact-specific,” and disputed NHTSA’s claims that tort law would force automakers to install “more seatbelts than necessary,” which NHTSA argued would reduce safety.⁸²

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 Seat Position amendment.⁸³ 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.⁸⁴

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.⁸⁵ The agency included a lengthy explanation of “How NHTSA’s Regulations May Give Rise to a *Judicial* Finding of Preemption”⁸⁶ as well as a detailed explanation of how it believed *Geier* should be interpreted.⁸⁷ NHTSA’s bottom

⁸¹ See Letter from Les Weisbrod, Pres., Am. Ass’n for Justice et al., to David Kelly, Acting Admin., NHTSA (Nov. 24, 2008), *available at* http://www.atlanet.org/resources/NHTSA_dsp_petition.pdf.

⁸² Letter from Joan Claybrook, Pres., Pub. Citizen, to David Kelly, Acting Admin., NHTSA (Nov. 24, 2008), *available at* <http://www.regulations.gov/search/Regs/contentStreamer?objectId=090000648095315a&disposition=attachment&contentType=pdf>.

⁸³ 74 Fed. Reg. at 68,188-89. While Public Citizen argued vociferously against preemption, it did not specifically argue that it was “unlikely” that tort law would conflict with the federal regulation. See Letter from Joan Claybrook, *supra* note 82.

⁸⁴ 74 Fed. Reg. at 68,188-89. NHTSA engaged in this consultation outside of E.O. 13132, as 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 took part in the notice-and-comment process, did not submit any comment on the seating designated seating position rule. *Id.*

⁸⁵ *Id.* at 68,187-88.

⁸⁶ *Id.* at 68,187-88 (emphasis added).

⁸⁷ The basic summary of NHTSA’s interpretation of *Geier* is: The savings clause allows state tort law to go beyond NHTSA standards but the savings clause does not bar conflict preemption principles. According to NHTSA, in *Geier*, the Supreme Court paid careful attention to NHTSA’s “detailed explanation of the ‘significant considerations’ underlying the multiple approaches in the airbag rule.” *Id.*

line was that “[a] court should not find preemption too readily in the absence of clear evidence of a conflict.”⁸⁸

(b) *Evolution of Boilerplate Language on the Issue of Preemption*

In most of its rulemakings in 2007-08, 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.⁸⁹ NHTSA’s recent rulemakings from 2008 to 2010 include a variation on the boilerplate language.⁹⁰

In its recent 2010 Electric-Powered Vehicles rule, NHTSA describes modifications in the boilerplate language from the 2007-2008 NPRMs to present as an ongoing attempt to clarify its position as one simply of notice of the results of its examination whether there was any *potential* to preempt, succinctly stating “Without any conflict, there could not be any implied preemption.”⁹¹

(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.”⁹²

According to NHTSA, because AAJ kept petitioning the agency to change its preemption language, the agency’s March 2009 Air Brakes Rule added language stating “NHTSA has considered today’s interim final rule and does not currently foresee any

⁸⁸ *Id.* at 68,188.

⁸⁹ WILLIAM FUNK ET AL., THE TRUTH ABOUT TORTS: REGULATORY PREEMPTION AT THE NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION 6 (Ctr. for Progressive Reform White Paper #804, 2008), *available at* http://www.progressivereform.org/articles/NHTSA_Preemption_804.pdf (citing Federal Motor Vehicle Safety Standards: Door Locks and Door Retention Components, 72 Fed. Reg. 5385, 5397 (Feb. 5, 2007)).

⁹⁰ My research assistant, Matthew Shahabian, searched the regulations.gov database for NHTSA’s rules from 2008 to 2010. He was unable to find any recent rules that used anything other than the boilerplate. To search through the database, he went to the view all rules section, then limited to “NHTSA” and “Rules.” He then clicked on each Federal Motor Vehicle Safety Standard rule from November 2008 to July 2010 and searched within the rule for “preempt” to see whether the rule addressed preemption with anything other than the boilerplate language.

⁹¹ 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).

⁹² *Compare id.*, with Federal Motor Vehicle Safety Standard; Seat Belt Lockability, 73 Fed. Reg. 52,939, 52,941 (Sept. 12, 2008) (emphasis added). At this time, NHTSA’s language on express preemption remained unchanged. *See* 73 Fed. Reg. 52,941.

potential State requirements that might conflict with it. Without any conflict, there could not be implied preemption.”⁹³

In August 2009, NHTSA began outlining how it assesses potential conflicts and obstacles for implied preemption, while retaining the language on not “discerning” any conflict.⁹⁴ The 2010 Electric-Powered Vehicles Rule uses 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.”⁹⁵

NHTSA and AAJ continue to disagree over the interpretation of the boilerplate language. According to NHTSA, its inclusion of boilerplate discussion under the section of its preambles discussing Executive Order 13,132 issues was not intended to preempt State tort law, while AAJ contends that it was so intended. This Report has identified twenty-nine NHTSA rules with boilerplate language discussing the issue of preemption that NHTSA did not include in its list to OIRA.⁹⁶ These rules can be grouped into three broad categories of NHTSA’s evolving boilerplate.⁹⁷ Eleven rules follow NHTSA’s most

⁹³ 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), *as cited in* Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,525 & nn.26–27 (June 14, 2010).

⁹⁴ See Federal Motor Vehicle Safety Standards; Controls, Telltales, and Indicators, 74 Fed. Reg. 40,760, 40,7063-64 (Aug. 13, 2009) (“However, NHTSA has considered *the nature and purpose* of today’s rule and does not currently foresee any potential [conflicts].”).

⁹⁵ See 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).

⁹⁶ My research assistant, Matthew Shahabian, used the LEXIS Federal Register database to search for NHTSA rules from the past ten years. His search terms were: “Department of Transportation (DOT)” /2 “National Highway Traffic Safety Administration (NHTSA)” [this screened out non-NHTSA authored rules] & 13132 & preemp! (249 results). He also used the docket numbers to search in the regulations.gov database to see if there were more recent responses to petitions for reconsideration not reflected in the LEXIS search results. He focused on the most recent disposition of each rule, *e.g.*, he ignored rules that were modified after reconsideration.

NHTSA reiterated its point 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 to Catherine M. Sharkey, Oct. 13, 2010, 1:55 A.M.

⁹⁷ Two rules did not fit in any of these categories. The Lamp and Reflective Devices rule states that “NHTSA does not believe that such conflicts are likely to arise from today’s rulemaking, because this final rule only results in an administrative rewrite of the existing requirements of FMVSS No. 108. However, if such a conflict were to become evident, NHTSA may opine on such conflicts in the future, if warranted.” Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices, and Associated Equipment, 72 Fed. Reg. 68,234, 68,265 (Dec. 4, 2007). NHTSA did not suggest that a conflict was likely to become

recent tack (as seen in the 2010 Electric-Powered Vehicles rule) of stating that it cannot discern any conflict with state law and concluding “Without any conflict, there could not be any implied preemption.”⁹⁸ Five rules from 2008 state that NHTSA “cannot completely rule out the possibility that conflict might become apparent.”⁹⁹ And eleven rules from mid-2007 through mid-2008 state that while NHTSA had not identified a conflict, a conflict creating preemption was “conceivable.”¹⁰⁰

evident. The second rule, the Fuel System Integrity Rule, mentions the Supreme Court’s *Geier* implied preemption standard without expressing an opinion as to how *Geier* applies to that specific rule. Occupant Crash Protection; Fuel System Integrity 72 Fed. Reg. 62,135, 62,139 (Nov. 2, 2007).

⁹⁸ See Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515 (June 14, 2010) (including most detailed discussion of boilerplate evolution); Theft Protection and Rollaway Prevention, 75 Fed. Reg. 15,621 (Mar. 30, 2010); Final Rule, Federal Motor Vehicle Safety Standards; Door Locks and Door Retention Components, 75 Fed. Reg. 7370 (Feb. 19, 2010); Motor Vehicle Brake Fluids, 75 Fed. Reg. 5553 (Feb. 3, 2010); Bus Emergency Exits and Window Retention and Release, 74 Fed. Reg. 68,558 (Dec. 28, 2009); Ejection Mitigation; Phase-In Reporting Requirements, 74 Fed. Reg. 63,180 (Dec. 2, 2009); New Pneumatic and Certain Specialty Tires, 74 Fed. Reg. 56,166 (Oct. 30, 2009); Federal Motor Vehicle Safety Standards; Air Brake Systems 74 Fed. Reg. 42,781 (Aug. 25, 2009); Federal Motor Vehicle Safety Standards; Controls, Telltales and Indicators, 74 Fed. Reg. 40,759 (Aug. 13, 2009); Federal Motor Vehicle Safety Standard; Rearview Mirrors, 74 Fed. Reg. 9478 (Mar. 4, 2009).

⁹⁹ 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 (Oct. 21, 2008); Federal Motor Vehicle Safety Standards; Motorcycle Helmets, 73 Fed. Reg. 57,297 (Oct. 2, 2008); Electronic Stability Control Systems, Controls and Displays, 73 Fed. Reg. 54,526 (Sept. 22, 2008) (Response to reconsideration petition), 72 Fed. Reg. 17,236 (Apr. 6, 2007) (final rule); Federal Motor Vehicle Safety Standards; Motorcycle Brake Systems, 73 Fed. Reg. 54,020 (Sept. 17, 2008); Occupant Crash Protection, 73 Fed. Reg. 52,939 (Sept. 12, 2008) (seat belt lockability).

¹⁰⁰ Federal Motor Vehicle Safety Standards; Power-Operated Window, Partition, and Roof Panel Systems, 73 Fed. Reg. 38,331 (July 7, 2008); Occupant Protection in Interior Impact; Side Impact Protection; Side Impact Phase-In Reporting Requirements, 73 Fed. Reg. 32,470 (June 9, 2008); Vehicle Identification Number Requirements, 73 Fed. Reg. 23,367 (Apr. 30, 2008); Federal Motor Vehicle Safety Standards, Child Restraint Systems; Anthropomorphic Test Devices (Hybrid III 10-Year-Old and Hybrid III 6-Year-Old Child Dummies), 73 Fed. Reg. 3901 (Jan. 23, 2008); Federal Motor Vehicle Safety Standards; Platform Lifts for Motor Vehicles; Platform Lift Installations in Motor Vehicles, 72 Fed. Reg. 72,326 (Dec. 20, 2007); Cargo Carrying Capacity, 72 Fed. Reg. 68,422 (Dec. 4, 2007); Federal Motor Vehicle Safety Standards; Brake Hoses, 72 Fed. Reg. 57,459 (Oct. 9, 2007); Federal Motor Vehicle Safety Standards; Occupant Protection in Interior Impact, 72 Fed. Reg. 50,900 (Sept. 5, 2007); Occupant Crash Protection, 72 Fed. Reg. 40,252 (July 24, 2007); Federal Motor Vehicle Safety Standards; Tire Pressure Monitoring Systems, 72 Fed. Reg. 38,017 (July 12, 2007); Federal Motor Vehicle Safety Standards; Head Restraints, 72 Fed. Reg. 25,483 (May 4, 2007).

(ii) *Express Preemption Language*

In addition to its evolving boilerplate discussion of implied preemption, NHTSA altered its boilerplate language on express preemption under the Motor Vehicle Safety Act—although this latter change was not acknowledged or discussed by NHTSA in its lengthy comments in the Electric-Powered Vehicle rule. Throughout 2007-08, as NHTSA altered the implied preemption boilerplate, the express preemption boilerplate remained untouched with an unqualified statement that the Motor Vehicle Safety Act preempted “State law” that was not identical to the NHTSA standard.¹⁰¹

Then, in the March 2009 Air Brake Rule, NHTSA limited its claim of express preemption to state positive law, stating “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.”¹⁰² The clear import is that state common law does not fall within the purview of express preemption claims.¹⁰³

3. *Litigation*

(a) *Automobile Safety Standards*

NHTSA has taken an anti-preemption position in *Williamson v. Mazda Motor of America, Inc.*,¹⁰⁴ a case pending this Term before the U.S. Supreme Court that will define

¹⁰¹ See, e.g., Federal Motor Vehicle Safety Standards, Occupant Crash Protection, 73 Fed. Reg. 52,939, 52,941 (Sept. 12, 2008) (“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.”).

¹⁰² Federal Motor Vehicle Safety Standard; Air Brake Systems, 74 Fed. Reg. 9173, 9175 (emphasis added).

¹⁰³ 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 to Catherine M. Sharkey, Oct. 13, 2010, 1:55 A.M.

¹⁰⁴ See United States Supreme Court, Order List: 560 U.S. at 2 (May 24, 2010) (granting cert), available at <http://www.supremecourt.gov/orders/courtorders/052410zor.pdf>; Petition for Cert., *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314 (Apr. 22, 2009). The question presented is:

Where Congress has provided that compliance with a federal motor vehicle safety standard “does not exempt a person from liability at common law,” 49 U.S.C. § 30103(e), does a federal minimum safety standard allowing vehicle manufacturers to install either lap-only or lap/shoulder seatbelts in certain seating positions preempt a state common-law claim alleging that the manufacturer should have installed a lap/shoulder belt in one of those seating positions?

Id. at i.

the scope of the Court’s implied preemption holding in *Geier*.¹⁰⁵ According to the Solicitor General’s amicus brief, since *Geier*, lower courts around the country have misread the Supreme Court’s holding to create a much broader standard of preemption, finding implied preemption “even though the federal agency that promulgated and administers that regulation disagrees.”¹⁰⁶ The brief, signed by Paul Geier, Assistant General Counsel for Litigation at NHTSA, argues 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.¹⁰⁷ Because of this broadening of *Geier* preemption, the brief seeks, like NHTSA’s rulemaking shift,¹⁰⁸ to clarify the “acknowledged confusion” and “widespread error in lower courts over the decade since *Geier*”¹⁰⁹

The rule at issue in *Williamson* allowed manufacturers to choose between lap-belts and shoulder-belts for the middle seat position in cars.¹¹⁰ When the plaintiff sought to hold Mazda liable for its decision to use a lap-belt in its minivan, contributing to the death of a passenger, Mazda claimed, and the trial court agreed, that the claim was preempted by the NHTSA safety standard.¹¹¹ 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 affirmed, and the California Supreme Court denied certiorari.¹¹²

The United States and NHTSA argue that, unlike in *Geier*, there is 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.”¹¹³ 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 has been that NHTSA standards do not generally

¹⁰⁵ *Geier v. Am. Honda Corp.*, 529 U.S. 861 (2000).

¹⁰⁶ Brief for the United States as Amicus Curiae at 17, *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314 (U.S. Apr. 2010).

¹⁰⁷ *Id.* at 17-18 (citing many federal and state cases).

¹⁰⁸ Specifically, in NHTSA’s December 2009 Designated Seating Position Amendment rule, the agency set forth a similar interpretation of *Geier*. See *supra* note 87 and accompanying text.

¹⁰⁹ Brief for the United States as Amicus Curiae at 21, *Williamson*, No. 08-1314.

¹¹⁰ *Id.* at 1-4.

¹¹¹ See *Williamson v. Mazda Motor of Am., Inc.*, 167 Cal. App. 4th 905, 908–910 (2008) (describing trial court order).

¹¹² *Id.* at 919; Brief for the United States as Amicus Curiae at 6–8, *Williamson*, No. 08-1314.

¹¹³ Brief for the United States as Amicus Curiae at 9, *Williamson*, No. 08-1314 (citing 49 U.S.C. § 30102(a)(9) (2010)).

preempt state tort law, aside from situations where the agency's affirmative policy presents an outright conflict, as in *Geier*.¹¹⁴

(b) *Fuel Economy Standards*

In addition to the Motor Vehicle Safety Act, NHTSA also administers average fuel economy standards under the Energy Policy and Conservation Act (EPCA).¹¹⁵ In *Metropolitan Taxicab Board of Trade v. City of New York*, the Second Circuit affirmed the trial court's ruling that New York City's regulation of the fares taxis could charge for hybrid vs. non-hybrid vehicles was preempted by the EPCA (and the Clean Air Act), as it "related to" fuel economy standards.¹¹⁶ In the Second Circuit appeal, the United States, joined by NHTSA, filed an amicus brief asking the court to reverse the trial court's interpretation of the EPCA as preempting local taxi regulation.¹¹⁷ NHTSA argued that Congress did not intend to preempt local taxi regulation when it passed the EPCA in the 1970s, given the widespread local regulation that existed both before and after its passage.¹¹⁸

NHTSA appears to be trying to craft a fine line for EPCA preemption between regulation that "directly" regulates fuel economy standards and regulation that only

¹¹⁴ Indeed, NHTSA has consistently taken this position in cases before the U.S. Supreme Court. However, it is in some tension with its rulemaking, at least during the period of use of the preemption preambles in 2005 and arguably with some of the later rulemakings in 2007-08. For example, in its Response to an AAJ comment on Electronic Stability Control Systems, NHTSA declined to disavow its boilerplate discussion of preemption, arguing that the discussion neither asserted the existence of a conflict giving rise to implied preemption nor stated an intent to preempt. NHTSA also rejected AAJ's contention that *Geier* was an "unusual, fact-driven case." See Federal Motor Vehicle Safety Standards; Electronic Stability Control Systems; Controls and Displays, 73 Fed. Reg. 54,526, 54,536 (Sept. 22, 2008). As this was a pre-"boilerplate evolution" rule, NHTSA did not distinguish between state tort law and positive law when it discussed how state requirements could be preempted expressly through the Motor Vehicle Safety Act or impliedly through *Geier*.

However, according to NHTSA, *Geier* had long settled the issue of whether there was an express preemption of state tort law under the Motor Vehicle Safety Act and that therefore the reference to "state law," while inartful, could not reasonably be interpreted as including state tort law. Email from Steve Wood to Catherine M. Sharkey, Oct. 13, 2010, 1:55 A.M.

¹¹⁵ 49 U.S.C. § 32902(a); 49 C.F.R. §§ 1.50(f), 501.2(a)(8).

¹¹⁶ See *Metropolitan Taxicab Board of Trade v. City of New York*, No. 09-2901-CV, 2010 WL 2902501 (2d Cir. July 27, 2010). A case in the District of Massachusetts held similarly for Boston's taxi regulation. See *Ophir v. City of Boston*, 647 F.Supp.2d 86 (D. Mass. 2009) (citing *Metropolitan Taxicab*, 633 F. Supp. 2d 83).

¹¹⁷ See Brief for the United States as Amicus Curiae at 9, *Metropolitan Taxicab Board of Trade v. City of New York*, No. 09-2901-CV (2d Cir. Jan. 15, 2010).

¹¹⁸ *Id.* at 9-12 (quoting *Buck v. California*, 343 U.S. 99, 102 (1952)) ("The operation of taxicabs is a local business,' and 'Congress has left the field largely to the states.'").

“indirectly” affects fuel economy standards. Its amicus brief argued that “indirect” regulation like taxicab lease rates should not be preempted, but did not take a position on “direct” regulation.¹¹⁹ Moreover, NHTSA has not stated a clear position on how it determines which regulations “directly” regulate fuel economy standards and which ones merely “indirectly” regulate fuel economy, but its amicus brief suggests the significance of the actual impact of the state rule on federal objectives may drive NHTSA’s position.¹²⁰

NHTSA’s position also appears to be in line with a recent shift in policy. Originally, the text of NHTSA’s 2006 NPRM on Average Fuel Economy Standards for Light Trucks Model Years 2008-2011¹²¹ claimed “broad preemption” under the EPCA of all state laws related to fuel economy standards, including those regulating greenhouse gases.¹²² In contrast, in its 2009 Final Rule for Average Fuel Economy Standards, Passenger Cars and Light Trucks, MY 2011, NHTSA decided to defer any decision to preempt under the EPCA for MY 2011.¹²³ NHTSA noted that this deferral was in response to President Obama’s request for NHTSA to reconsider preemption in light of how to implement the Energy Independence and Security Act of 2007 and the Supreme Court’s decision in *Massachusetts v. EPA*.¹²⁴ And in its 2009 NPRM for fuel economy standards for MY 2011-2015, NHTSA notes that the issue of preempting state emissions standards remains “an ongoing public dialogue,” and meanwhile, NHTSA had been in consultation with the States.¹²⁵

¹¹⁹ See *id.* at 12 & n.3.

¹²⁰ See Brief for the United States as Amicus Curiae at 14, *Metropolitan Taxicab*, No. 09-2901-CV (“The Supreme Court has observed that, even in statutes containing the broad ‘relating to’ language, the ‘significan[ce]’ of the actual impact of a state rule on federal ‘pre-emption-related objectives’ has some bearing on a court’s inquiry.” (quoting *Rowe v. N.H. Motor Transport Ass’n*, 128 S. Ct. 989, 995 (2008))).

¹²¹ See 71 Fed Reg. 17,566 (Apr. 6, 2006).

¹²² See *id.* at 17,654-70 (stating that regulating carbon dioxide emissions from vehicles has “direct effect” of regulating fuel consumption and is “related to” fuel economy standards); see also *Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1181 n.1 (9th Cir. 2008) (not addressing preamble preemption because rule was not yet final).

¹²³ See Final Rule, Average Fuel Economy Standards, Passenger Cars and Light Trucks, MY 2011, at 43-44, 818, available at http://www.nhtsa.gov/DOT/NHTSA/Rulemaking/Rules/Associated%20Files/CAFE_Update_d_Final_Rule_MY2011.pdf (“As noted above, NHTSA has decided not to include any preemption provisions in the regulatory text at this time and will re-examine the issue of preemption in the context of the rulemaking for MY 2012 and later years.”).

¹²⁴ *Id.* at 787-88.

¹²⁵ See Notice of Proposed Rulemaking, Average Fuel Economy Standards, Passenger Cars and Light Trucks, MY2011-2015, at 374-75, available at http://www.nhtsa.gov/DOT/NHTSA/Rulemaking/Rules/Associated%20Files/CAFE_11-15_NPRM_April_21.pdf (referring to *Green Mountain Chrysler Plymouth Dodge Jeep v.*

In affirming the district court’s decision in *Metropolitan Taxicab*, the Second Circuit implicitly rejected NHTSA’s argument that the EPCA does not preempt NYC’s favorable lease rates for hybrid cabs. The court, however, did not even address NHTSA’s argument that Congress intended to leave taxi regulation alone. It instead relied on the analogy to ERISA preemption standards that preempt state laws directly “related to” the subject matter of the federal standard. The court held that the regulations “directly relate” to fuel economy standards “because they rely on fuel economy, and nothing else, as the criterion for determining the applicable lease cap.”¹²⁶

B. FDA

Of the agencies surveyed in this Report, FDA has been the most difficult one 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. 13132.¹²⁷ 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.¹²⁸ Most notably, the FDA preempted state tort law for drug labeling through the preamble of a regulation, after it had previously disclaimed any preemptive intent in the initial proposed rulemaking.¹²⁹ The U.S. Supreme Court refused to rely upon the preemption preamble in *Wyeth v. Levine*.¹³⁰

There is some evidence from the regulatory record and intervention in pending litigation that indicates that the FDA has revised its preemption policy under the Obama

Crombie, 508 F. Supp. 2d 295 (D. Vt. 2007); Cent. Valley Chrysler-Jeep, Inc. v. Goldstone, 529 F. Supp. 2d 1151 (E.D. Cal. 2007)).

After its reconsideration, NHTSA noted that its position on tailpipe emissions remained “unchanged,” and maintained that state regulation of CO2 emissions is preempted by the EPCA, despite two district court cases to the contrary. *Id.* at 374-79.

¹²⁶ *Metropolitan Taxicab Board of Trade v. City of New York*, No. 09-2901-CV, 2010 WL 2902501, at *5 (2d Cir. July 27, 2010).

¹²⁷ See, e.g., Sharkey, *Federalism Accountability*, *supra* note 14, at 2131–41.

¹²⁸ See AM. ASS’N FOR JUSTICE, *supra* note 55 (note that this total included proposed rules that had not yet resulted in a final or interim final rule).

¹²⁹ Sharkey, *Federalism Accountability*, *supra* note 14, at 2131-34.

¹³⁰ 129 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.’”).

Administration. Sharkey's interview with FDA's Chief Counsel provided some (albeit limited) evidence of a change in tone on preemption at the agency.¹³¹

Fuller exposition of the FDA's position on preemption is expected now that the Solicitor General has responded to the U.S. Supreme Court's call for its views in two generic drug preemption cases.¹³²

1. *Response to May 2009 Presidential Memorandum on Preemption*

In response to whether FDA had conducted the ten-year retrospective review of preemptive rulemakings, FDA Chief Counsel stated that the agency has conducted an extensive review, as requested by the Presidential Memorandum, and explained that FDA anticipates issuing the results of its review after appropriate clearance.¹³³

Prospectively, the Chief Counsel explained that "we seek to avoid finding preemption when we can in a principled way."¹³⁴

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 recent 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 they regulate.

The rulemaking record, nonetheless, contains some hints that FDA may have retreated from its aggressive pro-preemption stance. For example, in the context of the Federal Food, Drug and Cosmetic Act's (FDCA) non-prescription drug express preemption provision, 21 U.S.C. § 379r(a), while the pre-publication version of the FDA's over-the-counter (OTC) labeling rule contained a preemption provision (which was quickly removed from the Fed. Reg. website),¹³⁵ the Final Rule contained only

¹³¹ Sharkey Interview with Ralph Tyler, Chief Counsel, FDA, July 6, 2010, 4–5 PM.

¹³² See Brief for the United States as Amicus Curiae, *PLIVA, Inc. v. Mensing*, No. 09-993 (U.S. Nov. 2, 2010); Supreme Court of the United States, Order List, 560 U.S. at 2 (May 24, 2010) (inviting the Solicitor General to file briefs in *PLIVA, Inc. v. Mensing*, No. 09-993 and *Actavis Elizabeth, LLC v. Mensing*, No. 09-1039).

¹³³ Sharkey Telephone Interview with Ralph Tyler, Chief Counsel, FDA, Ann Wion, Deputy Chief Counsel for Program Review, FDA, and Leslie Kux, Acting Assistant Commissioner for Policy, FDA, October 4, 2010, 5–5:30 PM.

¹³⁴ Sharkey Interview with Ralph Tyler, Chief Counsel, FDA, July 6, 2010, 4-5 PM.

¹³⁵ See Kurt R. Kast, *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-

limited discussion of express preemption that does not preempt state law as clearly as the NPRM did.¹³⁶

On the other hand, FDA has continued to assert statutory preemption in its rules—for example, the recent Skin Protectant and Bottled Water rules.¹³⁷ The Skin Protectant rule, issued one month before the over-the-counter drug labeling rule, likewise interprets preemption under § 379r(a).¹³⁸ The rule claims express preemption under

preemption-position-new-rule-largely-eliminates-preemption-discussion.html. Sharkey also interviewed Kurt Karst, author of FDA Law Blog, by telephone on July 8, 2010.

¹³⁶ The NPRM's section on express preemption stated: "FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized as proposed, would have a preemptive effect on State law." It then quotes 21 U.S.C. § 379r(a) and explains: "Currently, this provision operates to preempt States from imposing requirements related to the regulation of nonprescription drug products. (See section 751(b), (c), (d), and (e) of the act for the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision.)" 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 (Dec. 26, 2006).

In contrast, the final rule says only:

"On December 27, 2006, FDA's Division of Federal and State Relations provided notice via email transmission of a letter to elected officials of State governments and their representatives. The letter advised the States of the publication of the proposed rule and stated that when published as a final rule, this regulation would preempt State law in accordance with section 751 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379r(a)). The letter encouraged State and local governments to review the proposed rule and to provide any comments to the docket (Docket No. 1977N-0094L) by May 25, 2007, or to contact certain named individuals. FDA did not receive any comments in response to this notice, or any comments from the States in response to the publication of the proposed rule." Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph, 74 Fed. Reg. 19,385, 19,406 (Apr. 29, 2009).

Unlike the NPRM, this discussion in the final rule merely cites the letter to the states, and provides no context as to how § 379r applies to the OTC rule. The final rule does include language saying, "In conclusion, we believe that we have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effects of this rule are consistent with Executive Order 13132." *Id.* The rule, however, never explains what the preemptive effect is, other than citing its mention of § 379r in the letter to the states.

¹³⁷ See, e.g., Final Rule on Beverages: Bottled Water, 74 Fed. Reg. 25,651, 25,664 (May 28, 2009); Final Rule on 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).

¹³⁸ 21 U.S.C. § 379r(a) (2006).

379r(a) with a justification similar to the NPRM in the OTC Drug rule, and also claims implied preemption under *Geier*.¹³⁹ The rule also mentions that FDA reached out to state and local officials on preemption and received no comment.¹⁴⁰

The Bottled Water rule asserts preemption under a different provision of the FDCA: § 403A’s preemption of misbranded food regulation.¹⁴¹ The rule quotes 403A and explains:

FDA has determined that the revisions to the standard of quality for bottled water relating to microbiological quality (§ 165.110(b)(2)) will have a preemptive effect on State law. Although this rule has a preemptive effect in that it will preclude States from issuing requirements for microbiological testing in bottled water that are not identical to the requirements for microbiological testing in bottled water 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 (*Riegel v. Medtronic*, 128 S. Ct. 999 (2008)).¹⁴²

The Final Rule actually appears to go further than the NPRM, which did not include the last portion asserting 403A(a)(1) preempted state common law duties.¹⁴³ As the first FDA rule claiming preemption since President Obama’s Memorandum on preemption, however, the rule states it is now treating preemption “in light of the President’s Memorandum.”¹⁴⁴ The FDA appears to be relying exclusively on express preemption principles, with no reliance on *Geier* implied preemption.

3. *Litigation*

Pending litigation—and FDA’s attempts to keep its preemption position close to the vest until it had fully analyzed the issues—may explain the opacity of FDA’s position to date.

The U.S. Supreme Court called for the views of the Solicitor General on whether to grant certiorari in two circuit court cases,¹⁴⁵ raising the issue whether *Wyeth*’s holding

¹³⁹ 74 Fed. Reg. 9759, 9763-64 (claiming express and implied preemption). The rule is a “technical amendment” updating a 1993 rule on skin protectants; there was no preemption provision in the 1993 rule. *See* 58 Fed. Reg. 54458 (Oct. 21, 1993).

¹⁴⁰ *Id.*

¹⁴¹ *See* Final Rule on Beverages: Bottled Water, 74 Fed. Reg. 25,651, 25,664.

¹⁴² *Id.*

¹⁴³ *See* 73 Fed. Reg. 53,775, 53,791–92 (Sept. 17, 2008).

¹⁴⁴ 74 Fed. Reg. 25,651, 25,664 n.3.

¹⁴⁵ *See* *PLIVA, Inc. v. Mensing*, No. 09-993 (2010); *Actavis Elizabeth v. Mensing*, No. 09-1039 (2010); *see also* SCOTUSWIKI,

extends to blocking preemption claims by *generic* drug manufacturers.¹⁴⁶ The question presented in the cert petition is:

Whether 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 Federal Drug Administration-approved labeling for the listed (or branded) drug.¹⁴⁷

Both of the federal courts of appeals¹⁴⁸ (and the majority of lower federal courts¹⁴⁹) that have addressed the issue rejected preemption. In *Mensing v. Wyeth*, the Eighth Circuit held that because generic manufacturers could have proposed a labeling change to the

http://www.scotuswiki.com/index.php?title=PLIVA%2C_Inc._v._Mensing%3B_Actavis_Elizabeth_v._Mensing (last visited Aug. 25, 2010).

¹⁴⁶ See SUPREME CT. OF THE U.S., <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/09-993.htm> (last visited Aug. 25, 2010); see also Kurt R. Kast, *U.S. Supreme Court Invites Solicitor General to Express the Views of the United States in Generic Drug Preemption Cases*, FDA L. BLOG (May 25, 2010, 12:51 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/05/us-supreme-court-invites-solicitor-general-to-express-the-views-of-the-united-states-in-generic-drug.html.

Ralph Tyler, FDA's Chief Counsel, and Lou Bograd, Senior Litigation Counsel for the Center for Constitutional Rights and lead appellate counsel for plaintiffs in *Mensing*, confirmed that FDA had meetings with plaintiffs and representatives from the generic drug industry to hear their arguments. Sharkey Interview with Ralph Tyler; Sharkey Telephone Interview with Lou Bograd (July 12, 2010).

¹⁴⁷ Petition for certiorari, *PLIVA, Inc. v. Mensing*, No. 09-993 (Feb. 19, 2010), available at http://www.scotusblog.com/wp-content/uploads/2010/05/09-993_pet.pdf.

¹⁴⁸ See *Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009); *Demahy v. Actavis, Inc.*, 593 F.3d 428, 436–39, 444–45 (5th Cir. 2010).

¹⁴⁹ See *Bartlett v. Mut. Pharm., Co., Inc.*, 659 F. Supp. 2d 279 (D.N.H. 2009); *Stacel v. Teva Pharm.*, 620 F. Supp. 2d 899 (N.D. Ill. 2009); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262 (W.D. Okla. 2009). But see *Morris v. Wyeth, Inc.*, 582 F. Supp. 2d 861 (W.D. Ky 2008) (allowing preemption because generics cannot unilaterally heighten labeling requirements under CBE procedures without FDA approval), *motion for reconsideration denied*, 642 F. Supp. 2d 677 (W.D. Ky 2009) (appeal pending in 6th Cir.); *Gaeta v. Perrigo Pharm. Co.*, 672 F. Supp. 2d 1017 (N.D. Cal. 2009) (appeal pending in 9th Cir.).

The Sixth Circuit (where *Morris v. Wyeth* is pending) asked the FDA for its opinion. DOJ (along with official from Department of Health and Human Services, including Ralph Tyler, Chief Counsel of FDA) filed an amicus brief that set forth the same position as the United States' amicus brief in the *Mensing* cases (discussed below in text). Brief for Amicus Curiae U.S. Food and Drug Administration at 12 n.5, *Morris v. Wyeth*, No. 09-5509 (6th Cir. Nov. 16, 2010) (“On November 2, 2010, at the Supreme Court’s invitation, the United States filed an amicus brief in the *Mensing* cases recommending the certiorari be denied, reflecting the same position on the preemption question as this brief.”).

FDA or requested that the FDA send out a warning letter, there was no conflict between the state law tort claim and federal standards that warranted preempting the plaintiff's claims.¹⁵⁰

In its amicus brief submitted at the request of the U.S. Supreme Court, the Solicitor General (joined by agency officials from Department of Health and Human Services¹⁵¹) opined that the Eighth Circuit “correctly held that FDA mediates the channels available to an ANDA [abbreviated new drug application for generic drug manufacturers] holder under federal law for disseminating strengthened warnings (though the court misunderstood precisely which processes were appropriate).”¹⁵² According to the FDA, generic drug manufacturers are constrained in their ability to alter their labels, which by statutory mandate must be exactly the same as that 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), it risks having its generic drug deemed “misbranded.”¹⁵⁵ Nonetheless, FDA maintains that generic drug manufacturers are obliged to provide the FDA with any new information about risks and can do so by proposing either labeling changes or “Dear Health Care Professional” letters to the FDA, who can then act as appropriate.¹⁵⁶

¹⁵⁰ See *Mensing*, 588 F.3d at 608–12 (rejecting both impossibility and obstacle preemption arguments).

¹⁵¹ Ralph Tyler, Chief Counsel of FDA, signed the brief in his capacity as Associate General Counsel of the Department of Health and Human Services.

¹⁵² Brief for the United States as Amicus Curiae at 18, *PLIVA, Inc. v. Mensing*, No. 09-993 (U.S. Nov. 2, 2010).

¹⁵³ 21 U.S.C. § 355(j)(4)(G) (generic drugs must bear labeling “the same as the labeling approved for the [name brand drug]”).

¹⁵⁴ 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 SG, the Fifth Circuit’s holding “misunderstands FDA’s regulations.” Brief for the United States as Amicus Curiae at 22 n.10, *PLIVA*, No. 09-993.

¹⁵⁵ For this reason, “[s]tate law may not impose liability on an ANDA holder for failing to send such a letter unilaterally.” *Id.* at 18.

¹⁵⁶ *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 (“ANDA holders were nonetheless required to provide FDA with new information about risks, and FDA would have acted on such information if appropriate”); *id.* at 15 (generic drug manufacturers are “obligated to provide FDA with information about labeling concerns”).

The Solicitor General’s (and FDA’s) response to the U.S. Supreme Court is the first statement of the FDA’s position on implied preemption under the Obama Administration.¹⁵⁷ FDA claims that its interpretations of its regulations governing drug labeling are entitled to deference.¹⁵⁸ Perhaps of even greater significance, FDA would preserve its own 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.”¹⁵⁹ Key to the preemption determination, then (and an issue that must be addressed in the litigation) is “what action FDA would have taken in response to a hypothetical warning proposal”,¹⁶⁰ and here, FDA suggests that the drug manufacturers will have to shoulder the burden of demonstrating “the likelihood of FDA inaction.”¹⁶¹

What remains elusive is precisely what kind of evidence that FDA considered the new risk information but declined to take further action to alter the labeling would suffice to preempt a state failure to warn claim.¹⁶² FDA nonetheless takes the position that such

¹⁵⁷ The FDA gave an earlier hint that its position might be different than that under the previous George W. Bush Administration. Beginning in 2000, FDA intervened as amicus in numerous pharmaceutical cases, taking the position that the Supremacy Clause bars state tort liability for failure to include a warning in a drug label that is in conflict with, or contrary to, warnings approved by the FDA. See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 505 n.267 (2008) [hereinafter Sharkey, *Products Liability Preemption*] (citing cases in which FDA intervened).

But, shortly after the Obama Administration took office, DOJ withdrew an amicus brief submitted by FDA espousing a pro-preemption position in *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), *vacated*, *Colacicco v. Apotex Inc.*, 129 S.Ct. 1578 (2009) (mem.).

¹⁵⁸ Brief for the United States as Amicus Curiae at 13, *PLIVA*, No. 09-993 (citing *Auer v. Robbins*, 519 U.S. 452, 462 (1997); *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984)).

¹⁵⁹ *Id.* at 19 n.9 (citing *Wyeth*, 129 S. Ct. at 1203 & n.14; *id.* at 1204 (Breyer, J., concurring)).

¹⁶⁰ *Id.* at 19.

¹⁶¹ *Id.*

¹⁶² This issue was front and center in an earlier case. *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), *vacated*, *Colacicco v. Apotex Inc.*, 129 S.Ct. 1578 (2009) (mem.). In *Colacicco*, the Third Circuit preempted state-law failure to warn claims against the manufacturer of selective serotonin reuptake inhibitors, or SSRI, drugs, finding that “a state-law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA’s oft-repeated conclusion that the evidence did not support such an association.” *Id.* at 271. The court accorded the FDA’s pro-preemption position *Skidmore* deference, finding it persuasive on account of the consistency, care, formality, and relative expertise of the agency. *Id.* at 274–75 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134 (1994)).

clashes, whereby 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.”¹⁶³

FDA likewise signaled that the scope of obstacle, or frustration of purposes, implied preemption was narrow. First, FDA reiterated the *Wyeth* Court’s characterization of the pro-consumer purpose of the FDCA to “bolster consumer protection against harmful products,” which it said reflected Congress’ “determin[ation] that widely available state rights of action provide[] appropriate [compensatory] relief for injured consumers.”¹⁶⁴ 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 whereas similarly situated consumers injured by brand name drugs would

The United States argued before the Third Circuit that it was not the preemption preamble of the FDA’s drug labeling rule that preempted plaintiffs’ claims, but rather the FDA’s repeated findings that there was insufficient scientific evidence of an association between adult use of antidepressants and suicidality to permit a warning on the labeling for those drugs. Brief of the United States as Amicus Curiae in Support of Defendants-Appellants at 28–29, *Colacicco*, 521 F.3d 253 (No. 08-437), 2006 WL 5691532.

The U.S. Supreme Court vacated and remanded *Colacicco* in light of *Wyeth*. *Colacicco*, 129 S. Ct. 1578. The Third Circuit then remanded the consolidated cases back to their respective district courts.

The U.S. rescinded its amicus brief in support of defendants-appellees, stating that “[t]he [FDA] has not yet conducted the sort of reexamination of various preemption issues following the Supreme Court’s decision in *Wyeth* that would be necessary to inform a position of the United States in this case.” Letter from Sharon Swingle, U.S. Dep’t of Justice, Civil Div., Appellate Staff, to Marcia M. Waldron, Clerk, U.S. Court of Appeals for the Third Circuit (Apr. 28, 2009).

The district court removed GlaxoSmithKline as a party after it dismissed claims against GSK unrelated to preemption. *See Colacicco v. Apotex, Inc.*, No. 05-CV-5500, 2009 WL 4729883, at *1 (E.D. Pa. Dec. 10, 2009). The case against Apotex, the generic drug manufacturer, later settled. *Colacicco v. Apotex, Inc.*, No. 05-CV-5500, 2010 WL 1707003 (E.D. Pa. Mar. 5, 2010) (“Stipulation of All Parties for Voluntary Dismissal of Entire Action”).

The U.S. rescinded its amicus brief in support of defendants-appellees, stating that “[t]he [FDA] has not yet conducted the sort of reexamination of various preemption issues following the Supreme Court’s decision in *Wyeth* that would be necessary to inform a position of the United States in this case.” Letter from Sharon Swingle, U.S. Dep’t of Justice, Civil Div., Appellate Staff, to Marcia M. Waldron, Clerk, U.S. Court of Appeals for the Third Circuit (Apr. 28, 2009).

¹⁶³ Brief for the United States as Amicus Curiae at 16, *PLIVA*, No. 09-993. According to FDA, “[f]or that and other reasons, FDA has not promulgated a formal regulation for this process.” *Id.*

¹⁶⁴ *Id.* at 21

have recourse.¹⁶⁵ Finally, FDA concluded that the modest state law duty to provide information to the FDA “seems unlikely to affect the availability of generic pharmaceuticals.”¹⁶⁶ 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 NDA holder’s could pose [different] preemption questions.”¹⁶⁷

C. OCC

The Supreme Court addressed the OCC’s preemption positions on a number of occasions. Most recently, in 2009, the Court considered whether the OCC’s visitorial powers rule, claiming preemption through its interpretation of the National Bank Act (NBA),¹⁶⁸ prevented states from enforcing their consumer protection laws against national banks, thwarting the states’ asserted interest in protecting consumers from discrimination and predatory lending.¹⁶⁹ In *Cuomo v. Clearing House Association*, the Supreme Court held that the National Bank Act (NBA) provision addressing visitation could not be construed to preempt the ability of state attorneys general to bring legal action against a national bank in order to enforce an otherwise valid state law.¹⁷⁰ The Court did, however, conclude that state attorneys general may not investigate national banks’ conduct or practices using administrative subpoenas (the action attempted by the New York Attorney General) because it would be an impermissible visitation preempted by the NBA.¹⁷¹ In 2007, the OCC had used the same preemptive rule to preempt states from exercising supervisory powers over state-chartered subsidiaries of national banks, an action that was upheld by the Supreme Court in *Watters v. Wachovia Bank, N.A.*¹⁷²

¹⁶⁵ *Id.* (“[I]ndividuals harmed by inadequately labeled generic drugs would (on petitioner’s view) have no remedy, while individuals who took the same drug with the same labeling in its brand-name form would (by virtue of *Wyeth*) have a state tort remedy.”).

¹⁶⁶ *Id.* at 22.

¹⁶⁷ *Id.*

¹⁶⁸ 12 C.F.R. § 7.4000.

¹⁶⁹ *See Clearing House Ass’n v. Cuomo*, 510 F.3d 105, 119 (2d Cir. 2007).

¹⁷⁰ 129 S. Ct. 2710 (2009).

¹⁷¹ *Id.* at 2721–22.

¹⁷² 550 U.S. 1 (2007). Unlike *Cuomo*, which focused on the scope of the express preemption inherent in the 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. *See Watters*, 550 U.S. at 20–21. *But see infra* note 216 (discussing how Congress overturned *Watters* in the Dodd-Frank Act).

The visitorial powers preemptive rule in *Cuomo* 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 secured by real estate, deposit-taking, and other ‘operations.’”¹⁷³ At the time of OCC’s consideration of these rules, members of Congress wrote to OCC to ask for a delay in promulgating the rule, as they wanted to consider whether to clarify Congressional intent to the OCC after Congress returned from recess.¹⁷⁴ 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.¹⁷⁵

Additionally Congress commissioned the Government Accountability Office (GAO) to study the OCC’s rulemaking process, its process and its capacity to handle consumer complaints, and to assess the potential impact of the rules on consumer protection and the dual banking system.¹⁷⁶ The 2005 GAO Report evaluated the OCC’s apparent disregard of state interests in passing the preemptive rules at issue in *Cuomo* and *Watters*, and concluded that “opportunities existed to enhance [OCC’s] consultative efforts.”¹⁷⁷ Because GAO found that OCC had followed the requirements of E.O. 13132,

¹⁷³ 12 C.F.R. §§ 7.4007-7.4009, 34.4; see Wilmarth, Jr., *supra* note 14, at 20 n.89.

¹⁷⁴ 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). The OCC stated it failed to heed Congress’ request because of a “compelling reason”—namely, new state consumer protection laws that were about to become effective. See *id.* at 20-21 (colloquy between Hon. Sue Kelly (Chair of Subcomm. on Oversight and Investigations) and Hon. Julie L. Williams (Chief Counsel of OCC)); see also *id.* at 52 (statement of Chairwoman Sue Kelly) (“Unfortunately, this is not the first time that Congress has had difficulty working with the OCC, which indicates to me that there may be larger systemic problems at the agency. Congress must, and will, take all necessary steps to ensure that the interests of the American people come first—even if means a ‘culture of change’ at the OCC.”).

¹⁷⁵ See generally *id.*; *Review of the National Bank Preemption Rules: Hearings Before the S. Comm. on Banking, Hous., and Urban Affairs*, 108th Cong. (2004).

¹⁷⁶ 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). The GAO addressed each of these questions in three separate reports.

¹⁷⁷ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-06-08, OCC PREEMPTION RULEMAKING: OPPORTUNITIES EXISTED TO ENHANCE THE CONSULTATIVE EFFORTS AND BETTER DOCUMENT THE RULEMAKING PROCESS 45 (2005), available at <http://www.gao.gov/new.items/d068.pdf> [hereinafter 2005 GAO REPORT] (“In the face of an executive order [13,132] 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

GAO did not make formal recommendations to Congress.¹⁷⁸ 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.”¹⁷⁹ The GAO criticized both the lack of documentation for consultative efforts and procedural requirements, warning “Without such documentation, it may not be clear—to agency management, auditors, or oversight committees—that an agency followed applicable requirements.”¹⁸⁰

Sharkey conducted a telephone interview with a group of OCC officials.¹⁸¹ From the perspective of the OCC officials, preemption is a “tool for conducting nationwide business.”¹⁸² Others have made the point more pejoratively, claiming that preemption was a “selling point” used by the OCC to market charters. Competing with state banking charters, the OCC has used preemption as an inducement to persuade banks to incorporate under national charters, increasing its revenues and its budget.¹⁸³ Assessment fees collected from nationally chartered banks are OCC’s primary source of revenue.¹⁸⁴ Congress believed that because OCC admitted that preemption was about attracting

such diverse interests as consumer protection advocates, state bank regulators, state attorneys general, and some Members of Congress continue to maintain that the agency genuinely did not seek their input.”).

¹⁷⁸ *Id.* at “Highlights.”

¹⁷⁹ *Id.* at 5.

¹⁸⁰ *Id.* at 5, 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.”).

¹⁸¹ Participants in the telephone interview conducted by Sharkey (August 5, 2010) 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 [hereinafter OCC Telephone Interview].

¹⁸² OCC Telephone Interview.

¹⁸³ See Wilmarth, Jr., *supra* note 14, at 20 (“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.’” (quoting John D. Hawke, Jr., Comptroller of the Currency, Remarks Before the Women in Housing and Finance (Feb. 12, 2002))).

¹⁸⁴ See Oren Bar-Gill & Elizabeth Warren, *Making Credit Safer*, 157 U. PA. L. REV. 1, 93–94 (2007) (“Assessments compromise 95% of the OCC’s budget . . .”).

additional charters, which in turn increased the size of OCC's budget, reform was needed.¹⁸⁵

Largely overshadowing any developments in the rulemaking or litigation realms at the OCC is the recently enacted Dodd-Frank Wall Street Reform and Consumer Protection Act. Pursuant to this Act, OCC will be classified as an independent agency, no longer subject to the mandates of E.O. 13132.¹⁸⁶

I. Response to May 2009 Presidential Memorandum on Preemption

The OCC's law department conducted a review and submitted it to OIRA in August 2009.¹⁸⁷ OCC identified eight preemptive rulemakings since 1999 and concluded that, with one exception, all were "justified under the established legal principles that

¹⁸⁵ 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 the Senate Report cites, Comptroller Hawke, responding to Senator Sarbanes, stated: "Preemption 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: Hearing Before the S. Comm. on Banking, Hous., and Urban Affairs*, 108th Cong., at 37 (2004) (discussing Jess Bravin & Paul Beckett, *Friendly Watchdog: Federal Regulator Often Helps Banks Fighting Consumers*, WALL ST. J., Jan. 28, 2002, at A1).

¹⁸⁶ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 § 315 (2010) (amending the definition of "independent regulatory agency, 44 U.S.C. § 3502(5) (2006), to include OCC); *see also* OCC Telephone Interview (confirming change). Interestingly, this section of the Act is merely titled "Federal Information Policy," and gives no indication of this change in OCC's status other than amending the relevant section of the U.S. Code, unlike the section of the Dodd-Frank Act that states the new Bureau of Consumer Financial Protection will be an independent agency. *Compare* § 315, *with* § 1100D(a) (titled "Designation as an Independent Agency"). Prior to this legislative change, OCC was not considered an "independent regulatory agency," under § 3502(5), exempt from E.O. 13132. *See, e.g.*, Bank Activities and Operations, Final Rule, 69 Fed. Reg. 1895, 1903 (Jan. 13, 2004). It has always had, however, some semblance of independence within the Executive. OCC's enabling statute states: "[T]he chief officer of which bureau shall be called the Comptroller of the Currency and shall perform his duties under the general directions of the Secretary of the Treasury." 12 U.S.C. § 1. The statute continues: "The Secretary of the Treasury may not delay or prevent the issuance of any rule or the promulgation of any regulation by the Comptroller of the Currency," *id.*, giving OCC some insulation from political influence even before the Dodd-Frank Act was passed.

¹⁸⁷ *See* Julie L. Williams, First Senior Deputy Comptroller and Chief Counsel of OCC, Memorandum to Kevin F. Neyland, Deputy Administrator, Office of Info. and Reg. Affairs, at 2-3 & n.9 (Aug. 13, 2009) [hereinafter Williams Memorandum to Neyland]. This document was provided to Sharkey by the OCC.

govern national bank preemption, including the principles in E.O. 13132.”¹⁸⁸ The one exception—the Visitorial Powers rule—was deemed in need of further revision in light of *Cuomo*.¹⁸⁹ But, according to OCC officials, OCC determined that, prior to undertaking revisions to rules, it would await the end of the legislative process.¹⁹⁰

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

The 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 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.¹⁹¹

OCC’s response to the Presidential Memorandum was comprehensive.¹⁹² In light of the Dodd-Frank Act, however, an additional rule—the Bank Operations Preemption rule—may warrant revisiting. The rule adopts a loose interpretation of the *Barnett* standard for preempting state law, omitting “significantly impairs” from the standard for

¹⁸⁸ *Id.* The rules identified were: Operating Subsidiary Rule, 12 C.F.R. 7.4006; Deposit-Taking, 12 C.F.R. 7.4007; Non-Real Estate Lending, 12 C.F.R. 7.4008; National Bank Operations, 7.4009; Real Estate Lending, 12 C.F.R. 34.4; Fiduciary Powers, 12 C.F.R. 9.7(e); Debt Cancellation Contracts, 12 C.F.R. 37.1(c); and Visitorial Powers, 12 C.F.R. 7.4000.

¹⁸⁹ *Id.* (“We are currently preparing revisions to that regulation to conform with the Court’s decision in *Cuomo*.”).

¹⁹⁰ OCC Telephone Interview. At the time, an Administrative Regulatory Reform proposal was on the table, calling for an evaluation of federal preemption with respect to national banks. *Id.*

¹⁹¹ Williams Memorandum to Neyland, *supra* note 187, at 4.

¹⁹² A parallel Lexis search conducted by my research assistant, Matthew Shahabian, did not turn up any additional preemptive rules. In fact, OCC’s listing of preemptive rules was perhaps even more inclusive than necessary. For example, the Debt Cancellation Contracts (DCCs) and Debt Suspension Agreements (DSAs) Rule, 67 Fed. Reg. 58,962, 58,975 (Sept. 19, 2002), classifies DCCs and DSAs as banking products as opposed to insurance products, and the preemption comes from the statutory and regulatory implications of declaring them banking products, not from preemptive language in the rule itself. The review did not include OCC opinion letters that preempt state law on a case-by-case basis, *e.g.*, 68 Fed. Reg. 46264 (Aug. 5, 2003), but the Presidential Memorandum only targets preemptive regulations.

conflict preemption.¹⁹³ Thus, though the OCC claims in its Review of Preemption Regulations Pursuant to the Presidential Memorandum to OMB that the preemption standard used in this rule was “confirmed” by the Supreme Court’s interpretation of banking preemption in *Watters*,¹⁹⁴ it is not clear whether OCC’s interpretation of *Barnett* is still appropriate in light of Congress’s reiteration of “significantly” as part of the *Barnett* standard in the Dodd-Frank Act.¹⁹⁵

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

As mentioned above, legislative activity has dominated preemption policy developments at the OCC to the exclusion of rulemaking and litigation efforts. OCC deferred revisiting its Visitorial Powers rule until the conclusion of the legislative process.¹⁹⁶ Congress recently passed the Dodd-Frank Wall Street Reform and Consumer Protection Act.¹⁹⁷ Under the Dodd-Frank Act, OCC is designated as an independent regulatory agency within the Department of the Treasury¹⁹⁸ 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.¹⁹⁹

Additionally, the Act creates a “Bureau of Consumer Financial Protection” to promulgate and enforce federal financial consumer protection laws.²⁰⁰ For financial consumer protection, Congress inserted a general preemption standard provision that

¹⁹³ See Bank Activities and Operations; Real Estate Lending and Appraisals, 69 Fed. Reg. 1904, 1910 (Jan. 13, 2004) (using only “obstruct” or “impair”). *But see id.* (“The OCC intends this phrase as the distillation of the various preemption constructs articulated by the Supreme Court, as recognized in *Hines* and *Barnett*, and not as a replacement construct that is in any way inconsistent with those standards.”).

¹⁹⁴ See Williams Memorandum to Neyland, *supra* note 187, at 2–3 & n.9 (Aug. 13, 2009). Lower federal courts have also upheld this regulation. See *Rose v. Chase Bank USA, N.A.*, 513 F.3d 1032 (9th Cir. 2008); *Aguayo v. U.S. Bank*, 658 F. Supp. 2d 1226, 1233 (S.D. Cal. 2009) (finding conflict preemption using OCC’s interpretation of *Barnett*).

¹⁹⁵ See *infra* notes 204–213 and accompanying text.

¹⁹⁶ In the Dodd-Frank Act, Congress endorsed the *Cuomo* standard on visitorial powers. Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 § 1047(a) (2010) (modifying 12 U.S.C. § 5136C(i)(1)). OCC will presumably now revise that rule.

¹⁹⁷ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).

¹⁹⁸ See *supra* note 186 and accompanying text.

¹⁹⁹ Dodd-Frank Wall Street Reform and Consumer Protection Act §§ 312(b)(2)(B), 314.

²⁰⁰ *Id.* § 1011. The Bureau will likewise be an independent regulatory agency, and therefore not subject to E.O. 13132. *Id.* § 1100D(a).

mirrors the provisions in some of the Federal Trade Commission acts—federal law sets a floor, and state law that goes beyond federal law should not be preempted,²⁰¹ and state law that is “inconsistent” with federal law is only preempted to the extent of the inconsistency.²⁰² 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.²⁰³

In the highly contentious “*Barnett* paragraph,” Congress set forth the preemption standard for how state consumer financial protection laws apply to national banks. State consumer laws are preempted only if: (1) the state law discriminates against national banks;²⁰⁴ (2) in accordance with *Barnett Bank v. Nelson*,²⁰⁵ state law “prevents or significantly interferes with the exercise by the national bank of its powers”;²⁰⁶ or (3) state consumer law is preempted by another federal law. Preemption determinations under the *Barnett* standard can be made by courts, or by regulation or order of the OCC “on a case-by-case basis.”²⁰⁷ “Case-by-case basis” is defined as evaluating one specific

²⁰¹ *Id.* § 1041(a)(2).

²⁰² *Id.* § 1041(a)(1).

²⁰³ *Id.* § 1041(a)(2).

²⁰⁴ *Id.* § 1044(a) (modifying 12 U.S.C. § 5136C(b)(1)(A)).

²⁰⁵ 517 U.S. 25 (1996).

²⁰⁶ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying § 5136C(b)(1)(B)). There is a debate over whether the OCC, over the past decade, has gone further than the original *Barnett* standard in its preemption determinations, and whether the bill will actually change the substantive preemption standard. See Stacy Kaper & Cheyenne Hopkins, *Regulatory Reform Conferees Clip Preemption*, AM. BANKER, 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); A. PATRICK DOYLE, HOWARD N. CAYNE, JOHN D. HAWKE, JR. & LAWRENCE J. HUTT, ARNOLD & PORTER LLP, NEW FINANCIAL REGULATORY REFORM ACT: HAS IT MATERIALLY ALTERED THE PREEMPTION LANDSCAPE FOR FEDERALLY CHARTERED INSTITUTIONS? 4 (July 2010), 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 bank as it moves away from OTS’s “field preemption” standard); see also Cheyenne Hopkins, *Bad to Worse: OCC Sees Flaws in Dodd Reform Bill*, AM. BANKER, Mar. 18, 2010, available at <http://www.banking.state.ny.us/art100318.htm> (explaining debate between simply citing *Barnett* in bill and actually codifying a standard, as “[t]he OCC has always interpreted *Barnett* to give it more flexibility to applying preemption”). The final bill added the standard of “significantly interferes,” as opposed to merely citing *Barnett*. Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying § 5136C(b)(1)(B)).

²⁰⁷ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying 12 U.S.C. § 5136C(b)(1)(B)).

state law at a time, not blanket preemption.²⁰⁸ The OCC may, however, 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.”²⁰⁹

According to the OCC officials, the *Barnett* paragraph does not alter the status quo because OCC’s preemptive rulemakings have explicitly cited *Barnett*.²¹⁰ Nor, in their opinion does the “case-by-case basis” language exclude categorical preemptive rulemakings because of the “substantively equivalent” provision.²¹¹ The legislative history, however, 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.²¹² Moreover, former OCC Comptroller John Hawke coauthored a client report on the financial reform bill for his law firm, Arnold &

²⁰⁸ *Id.* (modifying 12 U.S.C. § 5136C(b)(3)(A)).

²⁰⁹ *Id.* (modifying 12 U.S.C. § 5136C(b)(3)(B)); *see also* S. COMM. ON BANKING, HOUS., AND URBAN AFFAIRS, THE RESTORING FINANCIAL STABILITY ACT OF 2010, S. Rep. No. 111-176, at 176 (2010), *available at* <http://www.gpo.gov/fdsys/pkg/CRPT-111srpt176/pdf/CRPT-111srpt176.pdf> (“The term ‘case-by-case basis’ is defined to permit the OCC to make a single determination concerning multiple States’ consumer financial laws, so long as the law contains substantively equivalent terms.”).

²¹⁰ OCC Telephone Interview. *But see supra* note 206 (presenting debate on this issue).

²¹¹ *Id.* Though the “substantively equivalent” provision does allow the OCC to issue a preemptive rule that applies to more than one state, functionally OCC must still make the case-by-case determination, in consultation with the BCFP, that each state’s law is “substantively equivalent” in terms to the others’. *See supra* note 209 and accompanying text.

²¹² *See* 156 Cong. Rec. H14496, 14678 (Dec. 10, 2009) (statement of Rep. Bean (D-IL)) (“The manager’s amendment addresses key concerns many of my colleagues and I had with the underlying text, which included changes to existing law in preemption standard and judicial deference. The compromise allows for the national bank regulator to make case-by-case preemption determinations on an individual State’s consumer financial laws and then apply that determination to categories of State consumer financial laws that have equivalent terms.”). *Compare* Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (final bill preemption standard), *with* H.R. 3126 § 143 (modifying § 5136C(b)) (proposed bill) (“State Consumer Laws of General Application—Notwithstanding any other provision of Federal law and except as provided in subsection (d), any consumer protection provision in State consumer laws of general application, including any law relating to unfair or deceptive acts or practices, any consumer fraud law and repossession, foreclosure, and collection law, shall apply to any national bank.”), *and id.* § 5136C(d) (limiting exceptions to “inconsistencies” where state law provides *less* protection than federal law according to new consumer protection agency, not OCC).

Porter, in which he wrote that preemption of state consumer financial laws by OCC “must be made on a ‘case-by-case’ basis.”²¹³

That said, the “case-by-case” provision applies only to “state consumer financial laws,” 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.”²¹⁴ Thus, preemption of state laws regulating issues like bank registration would not be subject to this provision.²¹⁵

Congress also included a savings clause in the Act, which appears to reverse *Watters v. Wachovia* with respect to the applicability of state law to state-chartered subsidiaries of national banks.²¹⁶

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 that regulation.²¹⁷ This list must be forwarded to both the House Committee on Financial Services and the Senate Committee on Banking, Housing and Urban Affairs.²¹⁸ Given the OCC’s new designation as an independent regulatory agency,²¹⁹ the Dodd-Frank Act shifts review of OCC rulemaking from the Executive to Congress. The OCC is also required to publish and update quarterly a list of all agency determinations with preemptive effect.²²⁰

²¹³ Doyle et al., *supra* note 206, at 2–3 (stating that OCC has “leeway” for broader preemption under the substantively equivalent/consultation provision).

²¹⁴ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying 12 U.S.C. § 5136C(a)(2)).

²¹⁵ See Doyle et al., *supra* note 206, at 2.

²¹⁶ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying 12 U.S.C. §§ 5136C(b)(2), 5136C(e)); see also Doyle et al., *supra* note 206, at 2 (“As amended, the NBA [National Banking Act] and the HOLA [Home Owners Loan Act] will no longer preempt state law as applied to state-chartered subsidiaries and affiliates of national banks or federal savings banks (unless such entities are themselves national banks or federal savings banks). This is a highly significant change in the law and effectively reverses the holding of *Watters v. Wachovia Bank* . . .”).

²¹⁷ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying § 5136C(d)(1)).

²¹⁸ *Id.* (modifying § 5136C(d)(2)) (“The report submitted to the respective committees shall address whether the agency intends to continue, rescind, or propose to amend any determination that a provision of Federal law preempts a State consumer financial law, and the reasons therefore.”).

²¹⁹ See *supra* note 186 and accompanying text.

²²⁰ *Id.* (modifying § 5136C(G) (“Transparency of OCC Preemption Determinations”)).

D. CPSC

The Consumer Product Safety Commission (CPSC) is an example of an independent regulatory agency (and thus not bound by E.O. 13132) that took advantage of preamble preemption, notwithstanding its lack of historical precedent for issuing preemptive rules. The CPSC, issuing a rule on flammability standards for mattress sets, included language in the rule's preamble that preempted any "inconsistent" state law—both in the form of statutory law and tort law.²²¹ In the Senate Judiciary Committee's hearing on regulatory preemption, Senators criticized the CPSC's inclusion of the preemptive preamble in its mattress rule.²²²

The statute 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).²²³ Three of the four "transferred acts" contain express preemption clauses.²²⁴ Courts have been inconsistent over which statutes preempt state law, and which do not. "[C]ourts have generally found that the FHSA preempts state common law,²²⁵ [but] the opposite is true of the FFA,²²⁶ and the cases are mixed with respect to preemption of common law under the PPPA."²²⁷

²²¹ Final Rule: Standard for the Flammability (Open-Flame) of Mattress Sets, 71 Fed. Reg. 13,471, 13,496. (Mar. 15, 2006); see Sharkey, *Preemption by Preamble*, *supra* note 4, at 227, 230-33.

²²² *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?: Hearing Before S. Comm. on the Judiciary*, 110th Cong. 3 (2007) (statement of Sen. Specter); *id.* at 16 (statement of Sen. Leahy).

²²³ WILLIAM FUNK ET AL., THE TRUTH ABOUT TORTS: REGULATORY PREEMPTION AT CPSC 5–6 (Ctr. for Progressive Reform White Paper #807, 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. § 1261 note (b)(1)(A) (FHSA); 15 U.S.C. § 1476 (PPPA); 15 U.S.C. § 1211 (RSA)).

²²⁴ The Refrigerator Safety Act does not. See 15 U.S.C. §§ 1211–1214.

²²⁵ FUNK ET AL., CPSC, *supra* note 223, at 6–7 (citing *Busch v. Graphic Color Corp.*, 662 N.E.2d 397 (Ill. 1996), *cert. denied*, 519 U.S. 810 (1996); *Sherman v. Sunsong Am., Inc.*, 485 F. Supp. 2d 1070 (D. Neb. 2007)).

²²⁶ *Id.* (citing *Wilson v. Bradlees of New Eng., Inc.*, 96 F.3d 552 (1st Cir. 1996), *cert. denied* 519 U.S. 1149 (1999); *O'Donnell v. Big Yank, Inc.*, 696 A.2d 846 (Pa. Super. 1997); *Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727 (Minn. 1980)).

Somewhat ironically, then, the CPSC chose to preempt state common law through the FFA when it issued its mattress flammability rule—the one statute courts generally hold to *not* preempt state common law. Professor Funk and his coauthors suggest this blatant contradiction may help explain why the CPSC backed away from preemption under the FFA when it issued its

The main statute under CPSC’s jurisdiction, the Consumer Product Safety Act, contains both a preemption clause²²⁸ and a savings clause.²²⁹ Several courts, following the Supreme Court’s reading of the interplay between preemption and savings clauses in *Geier*, have found state tort law preempted.²³⁰ Against the backdrop of these court preemption decisions and the CPSC’s preemption preamble, Congress passed the Consumer Product Safety Improvement Act of 2008,²³¹ which explicitly stated that state tort law was not to be construed as preempted by CPSC’s rulemaking and disclaimed any preemptive rulemaking authority in the CPSC itself.²³²

Sharkey conducted an interview with the General Counsel at CPSC.²³³ While Congress’ statutory direction has had the most pronounced effect on rulemaking and intervention in litigation at the CPSC, 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 seems less inclined to offer any interpretive gloss on preemption in rulemakings, beyond simply citing relevant express statutory preemption provisions and likewise is more hesitant to enter the litigation fray where preemption is at issue.

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

The Consumer Product Safety Improvement Act of 2008 (CPSIA)²³⁴ was less a response to CPSC preemption and more a response to the “implosion” of the agency and

more recent clothing textile rulemaking. FUNK ET AL., CPSC, *supra* note 223, at 7 (citing Standard for the Flammability of Clothing Textiles, 73 Fed. Reg. 15,636 (Mar. 25, 2008)).

²²⁷ *Id.* (citing *Miles v. S.C. Johnson & Son, Inc.*, 2002 WL 31655188 (N.D. Ill. Nov. 25, 2002) (holding that the PPPA preempts any common law claims that “seek to impose . . . packaging requirements that are different from those imposed by [the] statute”); *Hunnings v. Texaco, Inc.*, 29 F.3d 1480, 1488 (11th Cir. 1994) (holding that PPPA did not preempt common law claim because the suit was filed against a bulk packager, not a packager of retail products)).

²²⁸ 15 U.S.C. §§ 2074-2075.

²²⁹ § 2074(a).

²³⁰ *See, e.g., Bic Pen Corp. v. Carter*, 251 S.W.3d 500, 505-06 (Tex. 2008) (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869-73 (2000)); *see also* FUNK ET AL., CPSC, *supra* note 223, at 4-5 & nn.6-12 (describing various court decisions).

²³¹ Pub. L. No. 110-314, 122 Stat. 3016 (Aug. 14, 2008).

²³² *Id.* at § 231(a); *see also* FUNK ET AL., CPSC, *supra* note 223, at 8.

²³³ Sharkey interview with Cheryl Falvey, General Counsel, CPSC, July 7, 2010.

²³⁴ Pub. L. No. 110-314, 122 Stat. 3016.

the “fever pitch” of recalls in 2007 that forced Congress to act to strengthen product safety protection generally.²³⁵ In addition to strengthening product safety regulation, Congress also attempted to clarify preemption as it applies to the 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.”²³⁶

CPSC General Counsel suggested that the CPSIA simply “slaps the hand” of the CPSC with respect to its past preemption by preamble (e.g., the mattress rule), while leaving general preemption standards alone (or even buttressing them).²³⁷ The CPSIA’s legislative history confirms the General Counsel’s view that Congress pursued a compromise, “split the baby” approach. Democratic members of Congress championed that the bill protected state labeling laws regulating product safety (through the § 231(b) provision),²³⁸ while Republicans were pleased that the bill preempts the “confusing”

²³⁵ Amy Widman, *Advancing Federalism Concerns in Administrative Law Through a Revitalization of Enforcement Powers – A Case Study of the Consumer Product Safety and Improvement Act of 2008*, 29 YALE L. & POL’Y REV. (forthcoming Fall 2010) (manuscript at 14–16), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1588884.

Reasons proffered for the compromised state of CPSC include agency capture by industry, limited resources, and excessive procedural requirements that stymied quick recalls and bans. FUNK ET AL., *supra* note 223, at 9-11; Widman, *supra*, at 12–16 (describing Bush CPSC as “a shell of an agency”).

²³⁶ CPSIA § 231(a). Schwartz and 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.” Victor E. Schwartz & Cary Silverman, *Preemption of State Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety*, 84 TULANE L. REV. 1203, 1223 (2010).

²³⁷ Sharkey Interview with Falvey. For example, while the CPSIA does not change the preemption *standard*, by prescribing safety standards for lead, the statute affects the *scope* of preemption by triggering the FHSA preemption provisions. See Doug Farquhar & Scott Hendrick, *State Authority to Regulate Toxins in Children’s Consumer Products* (unpublished manuscript), at 12 (2009), available at http://works.bepress.com/doug_farquhar/1.

Those FHSA provisions that preempt state law affecting performance are triggered when the federal government issues a performance standard, as the CPSIA does for lead. See, FHSA, 15 U.S.C. § 1261 n. (b)(1)(A); *Toy Mfgs. of Am. v. Blumenthal*, 986 F.2d 615 (2d Cir. 1992) (holding because CPSC standard only regulated toys for children younger than three, it was not a standard applying to toys for children older than three that would preempt Connecticut’s safety standard).

²³⁸ See, e.g., 153 CONG. REC. H16882 (2007) (colloquy between Rep. Waxman (D-CA), and Rep. Dingell (D-MI)) (noting that bill protects state labeling laws like California’s Prop 65).

The CPSIA includes a provision for states to apply directly to the CPSC for an exemption from any preemption of state positive law specifically regulating toy safety *performance* standards, through notice and comment proceedings. CPSIA § 106(h). According to the

patchwork of state laws on lead regulation.²³⁹ The conference report notes that the bill “reiterat[es]” existing preemption standards while “preserv[ing]” state laws.²⁴⁰

Unlike the Dodd-Frank financial reform bill,²⁴¹ with one exception, the Act does not attempt to clarify the relationship between state law and federal law for the courts, but is only specifically directed towards the CPSC.²⁴² Professor William Funk nonetheless suggests that, in slapping the hand of the CPSC with respect to preemption, the CPSIA may lead courts to hesitate to find preemption.²⁴³

2. Response to May 2009 Presidential Memorandum on Preemption

According to the General Counsel, the office surveyed its attorneys about the existence of any preemptive rules.²⁴⁴ The CPSC identified sixteen rules issued over the past ten years that contained preemptive language. Of the sixteen, the General Counsel

CPSC, four states applied for an exemption by the November 12, 2008 deadline: Arizona, California, Illinois, and New York. *See* FAQs for Section 231: Preemption, CPSC, <http://www.cpsc.gov/about/cpsia/faq/231faq.html>.

²³⁹ *See, e.g.*, 154 CONG. REC. H7581 (2008) (statement of Rep. Barton (R-TX)) (“[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. Whitfield (R-KY)) (“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.”).

²⁴⁰ H. REP. NO. 110-787, at 74 (2008) (conf. report on H.R. 4040), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_reports&docid=f:hr787.110.pdf.

²⁴¹ *See, e.g.*, Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010). For discussion of the “*Skidmore* deference” provision directed to reviewing courts, *see infra* notes 421–422 and accompanying text.

²⁴² *See id.*; H. REP. NO. 110-501, at 15 (2008) (committee report on H.R. 4040). The exception, added only after the conference committee, is for the Federal Hazardous Substances Act, and states the FHSA is *not* to be interpreted as preempting warning requirements established pursuant to state law in effect as of August 31, 2003. *Compare id.*, with Pub. L. No. 110-314, § 231(b). This provision was intended to exempt California Proposition 65, California’s Safe Drinking Water Act of 1986, from preemption. H. REP. NO. 110-787, at 74 (2008) (Conf. Rep.).

²⁴³ FUNK ET AL., *supra* note 223, at 8.

²⁴⁴ Sharkey Interview with Falvey. According to the General Counsel, though CPSC did the retrospective analysis required by the Memorandum, they did not submit a formal report to OMB. Email from Cheryl Falvey to Catherine Sharkey, Nov. 1, 2010, 1:49 P.M.

stated they identified only two rules that “appear to go beyond what the statute says.”²⁴⁵ The first, a rule on bunk bed safety standards issued in 1999, started by quoting the preemption provisions of the CPSA and the FHSA.²⁴⁶ 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 have an adverse economic effect on manufacturers and distributors.”²⁴⁷ 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.²⁴⁸ The second rule identified by the General Counsel is the previously discussed mattress flammability rule.²⁴⁹ The mattress flammability rule is the only rule that explicitly preempts state tort law.²⁵⁰ According to the General Counsel, because of the amount of regulatory activity currently on the CPSC’s plate, and because 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.”²⁵¹

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 therefore preempt non-identical state and local laws under the statute. For example, rules issued under the FFA preempt non-identical “standards or regulations,”²⁵² rules issued under the PPPA preempt non-identical “special

²⁴⁵ Email from Cheryl Falvey, to Catherine Sharkey, Oct. 12, 2010, 9:41 P.M.

²⁴⁶ See Safety Standard for Bunk Beds, 64 Fed. Reg. 71,887, 71,899 (Dec. 22, 1999).

²⁴⁷ *Id.*

²⁴⁸ Email from Cheryl Falvey to Catherine Sharkey, Nov. 1, 2010, 1:49 P.M.

²⁴⁹ See Standard for the Flammability (Open Flame) of Mattress Sets; Final Rule, 71 Fed. Reg. 13,471, 13,496 (Mar. 15, 2006); *supra* notes 221–226 and accompanying text.

²⁵⁰ Standard for the Flammability (Open Flame) of Mattress Sets; Final Rule, 71 Fed. Reg. at 13,496 (“The Commission intends and expects that the new mattress flammability standard will preempt inconsistent state standards and requirements, *whether in the form of positive enactments or court created requirements.*”) (emphasis added).

²⁵¹ Email from Cheryl Falvey to Catherine Sharkey, Nov. 1, 2010, 1:49 P.M.

²⁵² Standard for the Flammability of Mattresses and Mattress Pads, 65 Fed. Reg. 12,935, 12,937–38 (Mar. 10, 2000); Standard for the Surface Flammability of Carpets and Rugs; Standard for the Surface Flammability of Small Carpets and Rugs, 65 Fed. Reg. 12,929, 12,932 (Mar. 10, 2000); Standard for the Flammability of Children’s Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children’s Sleepwear: Sizes 7 Through 14, 65 Fed. Reg. 12,924, 12,926–27 (Mar. 10, 2000); Final Technical Changes; Standard for the Flammability of Children’s Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children’s Sleepwear: Sizes 7 Through 14, 64 Fed. Reg. 2833, 2838 (Jan. 19, 1999).

packaging standards,²⁵³ and rules issued under the FHSA preempt non-identical “requirements.”²⁵⁴ Several of these rules also mentioned that, although the CPSC is not bound by E.O. 13,132, the Commission evaluated preemption “in light of the principles” stated in E.O. 13,132.²⁵⁵

Two rules on safety standards for garage door openers simply quote the relevant preemption provision without offering any interpretation or application to the rule.²⁵⁶ A 2007 rule on portable generator labeling requirements disclaims express preemption under the relevant statute, but reserves the possibility of conflict preemption where it would be impossible for a manufacturer to comply with both the federal rule and a state requirement.²⁵⁷ Finally, a 2008 rule on certificates of compliance cites (but does not

²⁵³ Poison Prevention Packaging Requirements; Exemption of Hormone Replacement Therapy Products, 67 Fed. Reg. 66,550, 66,552 (Nov. 1, 2002); Household Products Containing Hydrocarbons; Final Rules, 66 Fed. Reg. 53,951, 53,956 (Oct. 25, 2001); Child-Resistant Packaging for Certain Over-The-Counter Drug Products, 66 Fed. Reg. 40,111, 40,115 (Aug. 2, 2001); Final Rule: Requirements for Child-Resistant Packaging; Household Products Containing Methacrylic Acid, 64 Fed. Reg. 32,799, 32,803 (June 18, 1999).

²⁵⁴ 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); Dive Sticks; Final Rule, 66 Fed. Reg. 13,645, 13,650 (Mar. 7, 2001).

²⁵⁵ *Compare* 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 (citing 13,132); Dive Sticks; Final Rule, 66 Fed. Reg. at 13,650 (same); Standard for the Flammability of Mattresses and Mattress Pads, 65 Fed. Reg. at 12,937–38 (same); Standard for the Surface Flammability of Carpets and Rugs; Standard for the Surface Flammability of Small Carpets and Rugs, 65 Fed. Reg. at 12,932 (same); Standard for the Flammability of Children’s Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children’s Sleepwear: Sizes 7 Through 14, 65 Fed. Reg. at 12,926–27 (same); Final Technical Changes; Standard for the Flammability of Children’s Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children’s Sleepwear: Sizes 7 Through 14, 64 Fed. Reg. at 2838 (same); Safety Standard for Bunk Beds, 64 Fed. Reg. at 71,899 (same), *with* Standard for the Flammability (Open Flame) of Mattress Sets; Final Rule, 71 Fed. Reg. at 13,496 (not citing 13,132); Household Products Containing Hydrocarbons; Final Rules, 66 Fed. Reg. at 53,956 (same); Child-Resistant Packaging for Certain Over-The-Counter Drug Products, 66 Fed. Reg. at 40,115 (same); Final Rule: Requirements for Child-Resistant Packaging; Household Products Containing Methacrylic Acid, 64 Fed. Reg. at 32,803 (same).

There does not seem to be any reason why some rules cite E.O. 13,132 and others do not.

²⁵⁶ Safety Standard for Automatic Residential Garage Door Operators, 72 Fed. Reg. 54,816, 54,817 (Sept. 27, 2007); Safety Standard for Automatic Residential Garage Door Operators, 65 Fed. Reg. 70,656, 70,656 (Nov. 27, 2000).

²⁵⁷ Portable Generators; Final Rule; Labeling Requirements, 72 Fed. Reg. 1443, 1445 (Jan. 12, 2007).

quote) the relevant preemption provision, and punts on its interpretation, stating “the preemptive effect of this rule would be determined in an appropriate proceeding in a court of competent jurisdiction.”²⁵⁸

On a prospective basis, according to the General Counsel, the agency would reference the relevant statute(s) in its rulemakings, but would not offer any interpretive gloss, especially where state common law was at issue.²⁵⁹

3. *Rulemaking*

According to the General Counsel, in response to the Presidential Memorandum on Preemption, the agency has deliberately included a more passive statement regarding preemption in recent rulemakings.²⁶⁰ Five recent 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. (Section 26(c) of the CPSA also provides that States or political subdivisions of States may apply to the Commission for an exemption from this preemption under certain circumstances.) Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.²⁶¹

The boilerplate language is limited to the express preemption provisions of the CPSA, in addition to citing the CPSIA for further preemptive support.

²⁵⁸ Certificates of Compliance, 73 Fed. Reg. 68,328, 68,331 (Nov. 18, 2008).

²⁵⁹ Sharkey Interview with Falvey.

²⁶⁰ *Id.*

²⁶¹ Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs; Notice of Proposed Rulemaking, 75 Fed. Reg. 43,307, 43,321 (July 23, 2010); Draft Notice of Proposed Rulemaking (“NPR”) for Full-Size and Non-Full Size Cribs, at 55 (July 12, 2010), *available at* <http://www.cpsc.gov/library/foia/foia10/brief/104cribsRev.pdf>; Safety Standard for Infant Walkers: Final Rule, 75 Fed. Reg. 35,266, 35,272–73 (June 21, 2010); Safety Standard for Infant Bath Seats: Final Rule, 75 Fed. Reg. 31,691, 31,697–98 (June 4, 2010); *see also* Safety Standard for Bassinets and Cradles; 16 CFR Part 1218 - Notice of Proposed Rulemaking, 75 Fed. Reg. 22,303, 22,311 (Apr. 28, 2010) (using same boilerplate language, but adding citation to federal district court opinion that was not included in the other four rules).

Other rules issued before 2010 but after the CPSIA only briefly touch on preemption, if at all. The 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.”²⁶² The rule on labeling for children’s toy advertisements does not address preemption.²⁶³

According to the General Counsel, the CPSC is not venturing an interpretive gloss on preemption even in areas that are of particular concern to it, such as whether states could enact different testing regime requirements.²⁶⁴ The most recent 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.²⁶⁵

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.²⁶⁶ The General Counsel mentioned the example of a recent Illinois statute, the Lead Poisoning Prevention Act of 2010,²⁶⁷ which prescribes a labeling requirement for lead in toys. If the CPSC issues warning labels for lead, state labeling requirements are preempted.²⁶⁸ Proponents of the Illinois statute argue that, because

²⁶² 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).

²⁶³ Labeling Requirement for Toy and Game Advertisements; Final Rule, 73 Fed. Reg. 67,730 (Nov. 17, 2008).

²⁶⁴ Sharkey Interview with Falvey.

²⁶⁵ Testing and Labeling Pertaining to Product Certification [Children’s Toys], 75 Fed. Reg. 28,336, 28,361 (May 20, 2010).

²⁶⁶ Sharkey Interview with Falvey.

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

²⁶⁸ See 15 U.S.C. § 1261 n. (b)(1)(A). This preemption provision is subject to the grandfathering clause in § 231(b) of the CPSIA, which grandfathers warning requirements issued under state *statutes* that were passed before August 31, 2003. This means California can continue to issue *new* warning regulations for lead under its grandfathered statute (Proposition 65).

there is no current federal lead labeling standard for children's toys, the FHSA preemption provision is not triggered.²⁶⁹ Commentators have noted that this statute is likely to be challenged.²⁷⁰ 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 wait for the toy industry to sue on its own.²⁷¹

E. FTC

The Federal Trade Commission (FTC), like CPSC, is an independent regulatory agency,²⁷² and as such, is not formally required to submit to the provisions of E.O. 13132.²⁷³ In contrast with the CPSC, however, the FTC has consistently refrained from preemption.

²⁶⁹ See John W. Moss, Winston & Strawn LLP, *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 (discussing arguments for and against preemption of Ill. law); Illinois Lead Warning Label Required in 2010, STR TECH. RES., <http://www.strquality.com/en-us/newsevents/Pages/illinois-lead-warning-label-required-in-2010.aspx> (“Illinois Attorney General Lisa Madigan maintains that the CPSIA does not preempt the Illinois Lead Poisoning Prevention Act on the basis that the Illinois law merely prescribes a warning and does not impose actual lead limits.”).

This “absence of regulation” argument is similar to the argument the Second Circuit upheld in *Toy Mfgs. of Am. v. Blumenthal*, 986 F.2d 615 (2d Cir. 1992). The court held that the FHSA did not preempt Connecticut's law requiring choking warnings on toys designed for children aged three to seven. The existing CPSC standard only regulated labeling requirements for toys designed for children under three and there was no standard for toys on children between three and seven years old. The court held that because CPSC did not demonstrate a “clear and manifest” intent to preempt state law by deciding not to regulate toys for children older than three years, the court would not find express preemption. *Id.* at 621–23. Moreover, because the express preemption of the FHSA provides “a reliable indicium of congressional intent with respect to state authority,” the court declined to engage in implied preemption analysis outside of the express preemption provision. *Id.* at 623–24.

²⁷⁰ See, e.g., Greenberg Taurig, Presentation to American Apparel & Footwear Ass'n, State Law Updates, at 10 (Oct. 29, 2009), available at <https://www.apparelandfootwear.org/UserFiles/File/Presentations/102909cpsia/citera.pdf>.

²⁷¹ Sharkey Interview with Falvey.

²⁷² 44 U.S.C. § 3502(5) (2006)

²⁷³ See Exec. Order No. 13,132, 3 C.F.R. 206 § 1(c) (2000), reprinted in 3 U.S.C. § 301 (2006) (defining “agency” subject to E.O. 13132 as “any authority of the United States that is an ‘agency’ under 44 U.S.C. § 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. § 3502(5)).

The FTC administers many statutes within the purview of consumer protection. Some of these statutes contain express preemption provisions from Congress,²⁷⁴ others give the FTC express authority to preempt “inconsistent” state law.²⁷⁵ FTC also has the power to issue rules to enforce its mandate. For the statutes where the FTC is given the power to preempt, the statute typically states that state law shall be preserved, “except to the extent that such [law] is inconsistent with the provisions of this chapter, and then only to the extent of the inconsistency.”²⁷⁶ Additionally, the preemption provision explicitly only preempts *weaker* state laws, as the statute allows the FTC to save state law that provides stronger protection.²⁷⁷

Despite this broad range of power over different consumer protection areas, coupled with express preemptive authority, the FTC has shown little interest in preempting state law.²⁷⁸ For example, after nearly a decade of privacy regulation, the FTC has yet to rule that federal law preempts a state’s privacy law as “inconsistent” with federal law under the Gramm-Leach-Bliley Act.²⁷⁹ Members of Congress have at times expressed frustration with the FTC’s indifference towards preemption of state law.²⁸⁰

²⁷⁴ *E.g.* Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(b) (2006).

²⁷⁵ *E.g.* Fair Credit Reporting Act, 15 U.S.C. § 1681t; Gramm-Leach-Bliley Act, 15 U.S.C. § 6807; Fair Debt Collection Practices Act (FDCPA), 15 U.S.C. § 1692n; *see also* Fair Debt Collection Practices Act, 15 U.S.C. § 1692o (allowing FTC to exempt state regulation entirely from FDCPA where state regulation is “substantially similar” to federal requirements).

²⁷⁶ *E.g.* Gramm-Leach-Bliley Act, 15 U.S.C. § 6807(a).

²⁷⁷ § 6807(b).

²⁷⁸ *See* Arnold & Porter LLP, *Farewell Federal Preemption: Effect on FTC Likely Minimal*, CONSUMER ADVERTISING L. BLOG (May 29, 2009), <http://www.consumeradvertisinglawblog.com/2009/05/farewell-federal-preemption-obama-clears-the-path-for-state-suits.html> (“While most agency heads are busy parsing through regs [in response to President Obama’s Memorandum on Preemption], the folks over at the Consumer Protection Bureau at the FTC should have little to do. For the most part the FTC has opted not to preempt state and local regulation of advertising and marketing claims.”).

²⁷⁹ 15 U.S.C. §§ 6801-6809 (2006). *See, e.g.*, Fed. Trade Comm’n, Letter to Flagstar Bank, May 12, 2005, *available at* <http://www.ftc.gov/os/2005/05/052405flagstarbankletter.pdf> (finding no preemption of California Online Privacy Protection Act of 2003); Fed. Trade Comm’n, Letter to Connecticut re Preemption Issues, June 7, 2002, *available at* <http://www.ftc.gov/privacy/glbact/conn020607.htm> (finding no preemption of Connecticut privacy laws); *cf.* Fed. Trade Comm’n, Committee Advisory Opinion Concerning Section 809 of the FDCPA (Mar. 31, 2000), *available at* <http://www.ftc.gov/os/2000/04/fdcpaadvisoryopinion.htm> (finding that the Fair Debt Collection Practices Act requiring validation notice of debt collection did not preempt state laws that forbid including validation notices in court documents).

²⁸⁰ *See, e.g.*, *Fair Credit Reporting Act and Issues Presented by Reauthorization of the Expiring Preemption Provisions: Hearing Before S. Comm. on Banking, Housing, and Urban Affairs*, 108th Cong. 13 (2003) (statement of Sen. Tim Johnson) (telling former FTC Director of

And, even when pressed by members of Congress about the FTC’s stance on preemption, the FTC has at times been unwilling to express an opinion.²⁸¹

Sharkey conducted an interview with the Director of the Consumer Protection Bureau at the FTC.²⁸² The Director takes the position—relying upon a law review article by Paul Verkuil²⁸³— that the FTC has very limited power to preempt state law via rulemaking: in the 1970s, Congress enacted a statute that governs how the FTC must exercise its preemptive authority; namely, it subjected FTC rules defining “unfair or deceptive practices” to stricter procedural requirements than the Administrative Procedure Act requires of other agencies.²⁸⁴

Consumer Protection Bureau J. Howard Beales, III, he has been “disappointed” with Administration’s “unwillingness” to push for renewal of credit reporting preemption).

²⁸¹ Testifying in front of Congress in 2003, former Director of the Consumer Protection Bureau J. Howard Beales simply outlined the case in favor of preemption (national uniformity) and the competing position in favor of encouraging states to develop new ways to protect consumers:

The Commission hasn’t taken a position on [renewing preemption of credit reporting]. I think that the failure to renew the preemptions runs the risk that what is now a national system begins to fragment, that it does so in ways that make it harder to share information across state lines and within what are increasingly national credit markets. I believe the potential benefit of allowing the preemption to expire, would be letting States innovate with different approaches and try out different schemes to try to protect consumers or to try to balance these conflicting interests in slightly different ways. And as I say, the downside of that is we may not like some of those experiments and they may interfere with the uniformity that we currently enjoy in credit markets.

Id. at 11 (statement of J. Howard Beales, III)

²⁸² Sharkey Interview with David Vladeck, Director, Bureau of Consumer Protection, Federal Trade Commission, July 1, 2010.

²⁸³ Paul R. Verkuil, *Preemption of State Law by the Federal Trade Commission*, 1976 DUKE L.J. 225, 243. According to Verkuil, the statute imposed three main requirements: additional hearing procedures for states that allowed for oral presentation and cross-examination on factual issues; expanded scope of review by the courts “to ensure that the courts look[ed] closely at [a rule’s] basis and rationale”; and exemptions for the states from a rule’s effect. *Id.* at 242–43.

²⁸⁴ Sharkey Interview with Vladeck. Vladeck elaborated this position in an amicus brief in *Altria* on behalf of the Tobacco Control Legal Consortium. See Brief of Amici Curiae Tobacco Control Legal Consortium, AARP, and Public Justice in Support of Respondents at *31, *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008) (No. 07-562), 2008 WL 2472392 (arguing that Congress enacted heightened procedures “designed to provide notice to the states and ‘to ensure the preemption decision will be carefully made’”; see also Brief of Amicus Curiae Constitutional and Administrative Law Scholars in Support of Respondents, *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008) (No. 07-562), 2008 WL 2489869 (arguing that an FTC policy statement that fails to follow the §57a procedures lacks force of law and thus could not be used to preempt state law); *id.* at *32–35 (“We are unaware of any cases where

1. *Response to May 2009 Presidential Memorandum on Preemption*

FTC apparently did not file a report with OMB in response to the Presidential Memorandum on Preemption.²⁸⁵ FTC has included, in its semiannual regulatory agendas, boilerplate language on E.O. 13132:

In addition, the Agency has responded to the optional information question that corresponds to Executive Order 13132 . . . which does not apply to independent regulatory agencies. The Commission believes to the extent that any of the rules in this agenda may have “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” within the meaning of E.O. 13132, it has consulted with the affected entities. The Commission continues to work closely with the States and other governmental units in its rulemaking process, which explicitly considers the effect of the Agency’s rules on these governmental entities.²⁸⁶

2. *Rulemaking*

FTC cited the Presidential Memorandum on Preemption in its 2009 rule on disclosing breaches of patient information confidentiality under HIPAA.²⁸⁷ In the section

preemptive effect has been accorded to agency “policies” not embodied in rules that have the force of law . . .”).

Vladeck (in his previous position as a law professor) has consistently been a strong opponent of federal preemption, filing an amicus brief in *Cipollone* on behalf of the American Cancer Society arguing against preemption, *see* Brief of Amicus Curiae of the American Cancer Society, American College of Cardiology, American Heart Association, American Lung Association, American Public Health Association, and Public Citizen in Support of Petitioner, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (No. 90-1038), 1991 WL 11003930, and an amicus brief arguing against preemption in *Wyeth* on behalf of former FDA Commissioners Donald Kennedy and David Kessler, *see* Brief of Amici Curiae Former FDA Commissioners Dr. Donald Kennedy & Dr. David A. Kessler in Support of Respondent, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249). *See also*, David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts To Preempt Failure-To-Warn Claims*, 96 GEO. L. J. 461, 463 (2008); David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95 (2005).

²⁸⁵ Sharkey Interview with Vladeck.

²⁸⁶ *See, e.g.*, 75 Fed. Reg. 21,951 (Apr. 26, 2010); 72 Fed. Reg. 70,199 (Dec. 10, 2007).

²⁸⁷ Final Rule, Health Breach Notification Rule, 74 Fed. Reg. 42,962, 42,965-66 (Aug. 25, 2009). The rule was promulgated jointly with HHS. It regulates what constitutes a breach of personal information that must be disclosed. The rule was prompted by a provision of the 2009 stimulus bill that heightened HIPAA enforcement. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009); 74 Fed. Reg. 42,962.

on preemption, FTC noted that the stimulus bill incorporated the Social Security Act's express preemption provision.²⁸⁸ In response to comments questioning the preemptive effect of the FTC's regulation, FTC stated that the rule would only preempt "contrary" state law, and would *not* preempt state laws that impose requirements in addition to federal law.²⁸⁹ FTC noted that because an entity could set forth all the required information on a disclosure notice even if a state imposes additional requirements, there was no impossibility preemption and "because it is possible to comply with both laws, and the state laws do not thwart the objectives of the federal law, there is no conflict between state and federal law."²⁹⁰

More recently, the FTC issued a rule amending acceptable practices for telemarketing sales, particularly focusing on debt settlement practices.²⁹¹ In response to comments about whether state regulation is preferable to FTC regulation, the rule discusses the preemption of existing state laws regulating debt settlement practices in a footnote.²⁹² The footnote states that in this context "Congress has not totally foreclosed state regulation," and thus the preemptive effect of the FTC rule is limited to conflict preemption.²⁹³ The rule also asserts that state statutes are preempted only to the extent of a conflict with the federal regulation, defining conflict as either an impossibility conflict or an obstacle conflict.²⁹⁴ Citing an earlier version of the Telemarketing Sales Rule from the mid-90s, "The Commission has emphasized that state laws can impose additional requirements as long as they do not directly conflict with the [federal Telemarketing Sales Rule]."²⁹⁵ The FTC seems to take a very narrow definition of conflict preemption, as even though the FTC rule bans "advance fees" entirely, the footnote points out that a

HHS is given the lead on enforcing HIPAA, but the stimulus bill gives FTC the power to enforce "temporary" breach requirements (which this rule implements) until HHS has a chance to study the issue (in consultation with FTC) and present a report to Congress, which will then enact final legislation. *See* 74 Fed. Reg. 42,962; Pub. L. No. 111-5 § 13407 (temporary enforcement and sunset provision conditioned on new legislation).

²⁸⁸ 12 U.S.C. § 1320d-7.

²⁸⁹ 74 Fed. Reg. 42,962, 42,966.

²⁹⁰ *Id.* (citing *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), for "a discussion of the issue of federal preemption when state laws frustrate federal objectives").

²⁹¹ Telemarketing Sales Rule, 75 Fed. Reg. 48,458 (Aug. 10, 2010).

²⁹² *Id.* at 48,480 n.312.

²⁹³ *Id.* (citing *Ray v. Atl. Richfield Co.*, 435 U.S. 151, 158 (1978)).

²⁹⁴ *Id.*

²⁹⁵ *Id.* (citing Telemarketing Sales Rule, 60 Fed. Reg. 43,842, 43,862–63 (Aug. 23, 1995)). The mid-90s rule discusses the FTC rule as setting a federal floor, but allows states to regulate beyond federal regulations. 60 Fed. Reg. at 43,862–63.

state law setting merely a cap on advance fees is not technically preempted, since compliance is possible with both state and federal law (by charging no fee).²⁹⁶

3. *Litigation*

In the past, the FTC has intervened in preemption disputes in the tobacco context. In the Supreme Court’s most recent tobacco preemption case, *Altria Group, Inc. v. Good*, the tobacco companies asserted that the Federal Cigarette Labeling and Advertising Act expressly preempted fraud claims asserted under Maine’s deceptive practice statute against the tobacco companies’ promotion of “light” or “low tar” cigarettes,²⁹⁷ and that FTC regulation of cigarette advertising and labeling impliedly preempted the plaintiffs’ claims.²⁹⁸ The United States filed an amicus brief, which the FTC joined, on behalf of the plaintiffs.²⁹⁹ The FTC took the position that its regulation of cigarette advertising and labeling did *not* impliedly preempt state tort law.³⁰⁰

In *Altria*, the Court held that “the FTC’s various decisions with respect to statements of tar and nicotine content do not impliedly pre-empt respondents’ [consumer fraud] claim.”³⁰¹ The Court reasoned that “even if such a regulatory policy could provide a basis for obstacle pre-emption, petitioner’s description of the FTC’s actions in this regard are inaccurate. The Government itself disavows any policy authorizing the use of ‘light’ and ‘low tar’ descriptors.”³⁰²

²⁹⁶ 75 Fed. Reg. at 48,480 n.312.

²⁹⁷ See *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 542 (2008).

²⁹⁸ See *id.* at 549.

²⁹⁹ Brief for the United States Amicus Curiae Supporting Respondents, *Altria*, 129 S. Ct. 538 (No. 07-562).

³⁰⁰ See *id.* at 14-33. The FTC took no position on the express preemption question. See *Altria*, 129 S. Ct. at 561 n.5 (Thomas, J., dissenting) (“The United States, in its *amicus* brief and at oral argument, conspicuously declined to address express pre-emption or defend the *Cipollone* opinion’s reasoning.”) (internal citations omitted); see also Transcript of Oral Argument, at *42-43, *Altria*, 129 S. Ct. 538 (No. 07-562) (“MR. HALLWARD-DRIEMEIER: Your Honor, the United States has not taken a position on the bottom line of the first question presented.”).

³⁰¹ 129 S. Ct. 538, 551. With respect to express preemption, the Court distinguished a prior tobacco case (not involving the FTC) that preempted state common law that imposed a “requirement or prohibition based on smoking and health . . . with respect to . . . advertising or promotion.” *Altria*, 129 S. Ct. at 545 (majority op.) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524 (1992)). Because fraud claims only depend on falsity, not “smoking and health,” the court held the cigarette labeling act did not preempt those claims. *Id.* at 545, 551.

³⁰² *Id.* at 559 (citing Brief for the United States as Amicus Curiae at 16–33).

F. EPA

In contrast to the aggressive preemptive efforts in the past by NHTSA, FDA, and OCC, the policies of the Environmental Protection Agency (EPA) stand as a possible springboard to develop a model “best practices” for involving state and local government officials in the federal regulatory process.³⁰³ Whereas other federal agencies sidestepped the consultation and reporting requirements of E.O. 13132, the EPA published its official policies on how to comply with E.O. 13132.³⁰⁴ For this reason, this Report will analyze recent EPA rulemaking in the context of its recommendations in Part IV.

Here, the Report considers 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, the EPA has gained knowledge, experience, and practice cooperating with state authorities and being sensitive to state interests.³⁰⁵

Sharkey conducted in-person interviews with several EPA officials.³⁰⁶

1. Response to May 2009 Presidential Memorandum on Preemption

The EPA’s memo to OMB lists nine rules the EPA’s Office of Policy, Economics and Innovation and the Office of General Counsel determined preempt state law.³⁰⁷ All

³⁰³ See Sharkey, *Federalism Accountability*, *supra* note 14, at 2159-60.

³⁰⁴ U.S. ENVTL. PROT. AGENCY, EPA’S ACTION DEVELOPMENT PROCESS: GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM (2008).

Although EPA is sometimes referred to as an independent agency, it is not considered an “independent regulatory agency” under 44 U.S.C. § 3502(5), and is thus subject to E.O. 13132. Exec. Order No. 13,132 § 1(c) (defining “agencies” subject to order).

³⁰⁵ See Sharkey, *Federalism Accountability*, *supra* note 14, at 2159-60.

³⁰⁶ In one group setting, on July 14, 2010, Sharkey interviewed Ken Munis, Associate Director of the Office of Regulatory Policy and Management; Eileen McGovern, Office of Regulatory Policy and Management; David Coursen, Attorney Advisor, Cross-Cutting Issues Law Office, Office of General Counsel; Sonja Rodman, Attorney, Cross-Cutting Issues Law Office, Office of General Counsel.

Sharkey interviewed Carol Ann Siciliano, Associate General Counsel, Cross-Cutting Issues Law Office, Office of General Counsel on July 15, 2010.

³⁰⁷ Email from Nicole Owens, EPA to Dominic J. Mancini, OMB, “Re: Preemption guidance,” Aug. 4, 2009, 08:24 A.M.; *see also* EPA Process for Identifying “Preemption” per President’s Memo, at 1. These documents were provided to Sharkey by Ken Munis.

EPA described its review process as follows:

In order to respond to the President’s request, EPA searched the Federal Register database on LEXIS for any final EPA rule in the last ten years that contained the

nine of these rules preempted state law through express statutory preemption, not using 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 controls³⁰⁸ and sulfur fuel controls.³⁰⁹ Out of the four CAA rules, only the most recent rule from 2008 found that promulgating a rule that triggered statutory preemption invoked the "federalism implications" provision E.O. 13132.³¹⁰ The other three rules, though they explained the rules' effect on state law in the preamble, stated that the rules did not have significant federalism implications and simply relied on continuing statutory preemption that triggered E.O. 13132 under the "preemption"

word preempt (and its derivatives such as preempted, preemption, etc). Our search term was: AGENCY(epa)and ACTION(Final) and TEXT(PREEMPT!) and date geq (1/1/1999). This query returned 1892 final rules that contained the term preempt, or a derivative of that word.

EPA then used CFR part numbers to eliminate, from the total search result, those classes of rules that did not preempt state law. For example, EPA approvals of Clean Air Act state implementation plans (SIP) do not preempt state law, rather such actions approve (or disapprove) state law as consistent (or inconsistent) with federal requirements. Of the remaining 166 rules, the Office of Policy, Economics and Innovation and the Office of General Council reviewed the actions to determine which rules preempted state law

EPA Process for Identifying "Preemption" per President's Memo, *supra*, at 1.

³⁰⁸ Control of Emissions From Nonroad Spark-Ignition Engines and Equipment, 73 Fed. Reg. 59,034 (Oct. 8, 2008) (promulgating under Clean Air Act § 209(e)(2)); 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 (Apr. 25, 2000) (same).

³⁰⁹ 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 (Jan. 18, 2001) (promulgating under Clean Air Act § 211(c)(4)); Control of Air Pollution From New Motor Vehicles: Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements, 65 Fed. Reg. 6698 (Feb. 10, 2000) (same).

³¹⁰ 73 Fed. Reg. 59,034, 59,172 (citing Exec. Order No. 13,132 § 6) ("This final rule has federalism implications because it preempts State law. It does not include any significant revisions from current statutory and regulatory requirements, but it codifies existing statutory requirements.").

provision.³¹¹ For all four of the CAA rules, EPA noted that it met and consulted with state and local officials in developing each rule.³¹²

EPA listed two rules that preempted state regulation of hazardous materials under the Toxic Substances Control Act (TSCA).³¹³ 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.³¹⁴ In terms of consulting with the states, EPA did not meet with state and local officials, stating that the notice and comment process gave state and local officials sufficient opportunity to participate in the rulemaking in compliance with E.O. 13132.³¹⁵

EPA listed two rules regulating the transportation of hazardous materials, promulgated with the Department of Transportation.³¹⁶ The first rule, which reduced the paperwork required for transporting hazardous material, preempted any state laws requiring different documentation for hazmat manifests under the Hazardous Material Transportation Act (HMTA).³¹⁷ 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 attended.³¹⁸ State and local officials were also invited to participate in the EPA workgroup developing the rule.³¹⁹ The other HMTA rule,

³¹¹ 65 Fed. Reg. 24,268, 24,304 (citing Exec. Order No. 13,132 § 4) (“This final rule does not have federalism implications.”); 66 Fed. Reg. 5002, 5134 (same); 65 Fed. Reg. 6698, 6821 (same).

³¹² 73 Fed. Reg. 59,034, 59,172 (describing consultation with Nat’l Ass’n 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); 65 Fed. Reg. 24,268, 24,304 (describing consultation with California to develop “harmonized regulations” since California was already regulating in this area under their CAA preemption exemption); 66 Fed. Reg. 5002, 5134 (noting consultation with California and Alaska to develop diesel sulfur rules exempted from federal standard); 65 Fed. Reg. 6698, 6821 (noting “consulted” with states in developing rule).

³¹³ Reclassification of PCB and PCB-Contaminated Electrical Equipment, 66 Fed. Reg. 17,602 (Apr. 2, 2001); Asbestos Worker Protection, 65 Fed. Reg. 69,210 (Nov. 15, 2000).

³¹⁴ 66 Fed. Reg. 17,602, 17,616; 65 Fed. Reg. 69,210, 69,215.

³¹⁵ *Id.*

³¹⁶ Hazardous Waste Management System; Modification of the Hazardous Waste Manifest System, 70 Fed. Reg. 10,776 (Mar. 4, 2005); 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).

³¹⁷ 70 Fed. Reg. 10,776, 10,813.

³¹⁸ *Id.*

³¹⁹ *Id.*

promulgated before E.O. 13132 took effect, preempted state law by clarifying the interaction between the HMTA and the CAA.³²⁰ EPA, interpreting the CAA, said that states could not use the lighter preemption standards in the CAA to promulgate rules for hazardous materials that fall under the CAA that would otherwise be preempted by the HMTA.³²¹

Finally, EPA also listed a rule preempting state law under the Clean Water Act.³²² Another pre-E.O. 13132 rule, this rule again used statutory preemption, as the CWA preempts state law regulating discharges from vessels once the EPA sets standards.³²³ In developing this discharge standard for Armed Forces vessels, EPA noted it consulted with both the Environmental Council of the States and the Armed Forces, and also “representatives from the Navy (as the lead for the DOD), EPA, and the Coast Guard met with each State expressing an interest in the [rule’s] development.”³²⁴

2. *Uniqueness of EPA: Agency and States as Co-regulators*

EPA and the states have developed a collaborative relationship as co-regulators, particularly over the past twenty years. EPA has an internal Office of Congressional and Intergovernmental Relations (OCIR), which coordinates a variety of state-EPA performance partnerships. For example, as a result of the National Environmental Performance Partnership System (NEPPS), environmental policies are designed using a collaborative process: “EPA and states set priorities, design strategies, and negotiate grant agreements *together*.”³²⁵ As Denise Scheberle explains, many of the more formal EPA/state coordination efforts began in earnest during the early years of the Clinton

³²⁰ 64 Fed. Reg. 28,696, 28,698

³²¹ *Id.*

³²² Uniform National Discharge Standards for Vessels of the Armed Forces, 64 Fed. Reg. 25,126 (May 10, 1999).

³²³ *Id.* at 25,131 (“[S]ection 312(n)(6) of the CWA preempts States from regulating these discharges once the UNDS regulations are effective, including issuing a wasteload allocation (WLA) for these discharges. A State, however, may avail itself of the provisions in CWA section 312(n)(7) to establish a no-discharge zone, either through State prohibition or EPA prohibition . . .”).

³²⁴ *Id.* at 25,129.

³²⁵ OFFICE OF CONG. & INTERGOVERNMENTAL RELATIONS, U.S. ENVT’L PROT. AGENCY, NATIONAL ENVIRONMENTAL PERFORMANCE PARTNERSHIP SYSTEM: FY 2008-2011 NATIONAL GUIDANCE 9-10 (2008), *available at* http://www.epa.gov/cfo/npmguidance/ocir/2009/nepps_2009_npm_guidance_final.pdf (emphasis in original).

administration.³²⁶ For example, the discussions at the State/EPA Capacity Steering Committee, 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.’”³²⁷ The most current iteration of the NEPPS plan (FY 2008-2011) lists several objectives for the partnership between EPA and the states.³²⁸ These objectives, targeted at strengthening communication and information flow, include “[c]onduct[ing] joint strategic planning and reflect[ing] the results in the Performance Partnership Agreements,” “[a]dvance partnership principles through effective collaboration with states on policy and implementation issues,” “[f]ocus[ing] state reporting on information needed to set goals and objectives, measur[ing] progress in achieving them, and ensur[ing] accountability,” and “[s]et[ting] the future direction for performance partnerships.”³²⁹

III. RECOMMENDATIONS

There appears to be a near-consensus that the procedural requirements of the Federalism Executive Order—including consultation with the states and the requirement for “federalism impact statements”—are sound. But the Federalism Executive Order has been a perennial source of discontent. A 1999 GAO Report identified a paltry five rules—out of a total of 11,000 issued between April 1996 and December 1998 while the Reagan-era Federalism Executive Order (E.O. 12612) was in effect³³⁰—that included a federalism impact statement.³³¹ Nor has agency compliance under the Clinton-era

³²⁶ See DENISE SCHEBERLE, FEDERALISM AND ENVIRONMENTAL POLICY: TRUST AND THE POLITICS OF IMPLEMENTATION 2-7 (1997) (describing initial outreach efforts by EPA and organization efforts by states to negotiate implementation with EPA).

³²⁷ Christopher Terranova, Challenging Agency Preemption 8 n.40 (Working Paper) (May 12, 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1403628 (quoting Fla. Ctr. For Pub. Mgmt., National Environmental Performance Partnership System (NEPPS) 1).

³²⁸ See OFFICE OF CONG. & INTERGOVERNMENTAL RELATIONS, *supra* note 325, at 3-4.

³²⁹ *Id.* Each objective provides a brief, but clear picture of how EPA thinks the collaborative relationship in this cooperative federalism scheme can be improved. For example, objective 3, “advancing partnership principles through effective collaboration” lists strategies for collaboration, the history of developing policy, remaining challenges, and the key contacts and infrastructure to accomplish the objective. *See id.* at 22-24.

³³⁰ Exec. Order No. 12,612, 52 Fed. Reg. 41,685 (Oct. 26, 1987).

³³¹ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO/T-GGD-99-93, IMPLEMENTATION OF EXECUTIVE ORDER 12612 IN THE RULEMAKING PROCESS 1 (1999). According to the report, the GAO found that 27% of all rules issued over this period of time cited E.O. 12612. *Id.* at 4. Not counting the five rules that included a FIS, those 27% 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.*

(continued under the Bush and Obama administrations) E.O. 13132 escaped criticism. Professors Mendelson and Sharkey have documented empirical evidence and case examples of agencies' disregard of their responsibility to conduct federalism impact statements.³³²

Any reform recommendation must confront this backdrop of decades of dissatisfaction with the enforcement of the federalism mandates. Professors Nicolaides and Howse astutely commented:

This lack of impact by 12612 is unsurprising. Federalism criteria, like benefit-cost, do not have a natural home in agencies. 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 12612 a non-priority.³³³

The goal of any reform effort directed at federal agency preemptive rulemaking should be to create a suitable "home" for federalism analysis to take place within federal agencies. As a threshold matter, agencies should be encouraged to develop comprehensive internal guidelines on compliance with the preemption provisions of the Federalism Executive Order. Such internal guidelines should be coupled with an internal oversight procedure, whereby the agency scrutinizes the underlying factual predicate or empirical claims in support of any preemptive stance. Moreover, to the extent possible, this internal agency scrutiny must be insulated from political pressures.

This Report makes recommendations for how best to secure meaningful participation in the agency decisionmaking process by state and local governmental officials (and the organizations that represent them) as well as other key constituencies. Sharkey conducted a roundtable discussion with the so-called "Big Seven" national organizations of state and local governmental officials.³³⁴ Given that with respect to the

³³² See Mendelson, *Chevron*, *supra* note 14, at 784 n. 192 (estimating that for proposed rules during one quarter in 1998, FISs are included in only 9 of 2456 agency rulemakings); *id.* at 783 (finding six FISs in one quarter of 2003, a time period in which roughly 600 final rules were issued); *id.* at 783-84 (demonstrating that federalism impact statements are relatively rare and of "poor quality"); Mendelson, *Presumption*, *supra* note 14, at 719 (reporting results from a further study of 2006 preemptive rules, which disclosed only a single substantive federalism impact statement 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 federalism impact of a clearly preemptive rule).

³³³ KALYPSO NICOLAIDES & ROBERT HOWSE, *THE FEDERAL VISION: LEGITIMACY AND LEVELS OF GOVERNANCE IN THE UNITED STATES* 131 (2001).

³³⁴ The "Big Seven" include the National Governors Association (NGA), National Conference of State Legislatures (NCSL), Council of State Governments (CSG), U.S. Conference of

issue of federal preemption of state tort law (as opposed to state regulations), it is not altogether clear who best represents the “state interest” at hand,³³⁵ additional input was solicited from representatives of state judges,³³⁶ state attorneys general,³³⁷ and various consumer- and business-oriented groups. The Report recommends a novel Attorney General notification procedure, modeled after the Class Action Fairness Act settlement Attorney General notification provision.

Finally, the Report recommends that OIRA/OMB (a) direct agencies to publish their reports on compliance with the Presidential Memorandum on Preemption; (b) update its guidance document on compliance with the preemption provisions of E.O. 13132; and (c) include a more thorough review of the federalism implications of agency proposals to preempt state law as part of its regulatory review process.

A. Agencies

1. Internal Guidelines on Procedures for Implementing the Preemption Provisions of the Federalism Executive Order (13132)

Internal agency guidelines on procedures for implementing the preemption provisions serve a practical function in terms of structuring the agency’s compliance with the Federalism Executive Order. Agencies should be able to cite their own internal

Mayors, National League of Cities (NLC), International City/County Management Association (ICMA), and National Association of Counties (NAC).

Sharkey met with the following individuals on July 6, 2010: Carolyn Coleman, NLC; Edward Ferguson, NAC; Susan Parnas Frederick, NCSL; Elizabeth Kellar, ICMA; David Parkhurst, NGA; David Quam, NGA; Stephanie Spiner, NLC; Chris Whatley, CSG. A representative from U.S. Conference of Mayors was invited, but did not attend.

³³⁵ See Sharkey, *Federalism Accountability*, *supra* note 14, at 2158-63.

³³⁶ The Conference of Chief Justices, an association of the presiding officers of every state supreme court, 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 Hoeffler Toal, President, Conf. of Chief Justices, to Div. of Docket Mgmt., FDA 1 (Mar. 17, 2008), *available at* <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064803ff415&disposition=attachment&contentType=pdf>. It has occasionally responded to outreach from federal agencies. See, e.g., *id.* at 2–3. Sharkey interviewed Judge Gregory Mize, Judicial Fellow, National Center for State Courts on July 7, 2010. Judge Mize monitors policy proposals in the federal government that likely raise federalism issues for state courts.

³³⁷ Sharkey interviewed James McPherson, Executive Director of NAAG, 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. Sharkey also interviewed James Tierney, Director of the National State Attorneys General Program at Columbia Law School, by telephone on October 20, 2010.

guidelines in federalism impact statements (FIS) to explain whether or not a specific rulemaking implicates federalism concerns, what specific actions were taken, and to justify why those decisions were made. 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,"³³⁸ but is consistent with this Report's further recommendations on state consultation below.

EPA's Guidance document presents logical step-by-step questions that an agency desk officer could follow to ensure compliance with E.O. 13132.³³⁹ This step-by-step process is organized both textually and with flow charts that make it useful for staff on the ground implementing E.O. 13132. Moreover, all the information necessary to write the FIS and comply with E.O. 13132 is contained in this one document.

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.³⁴⁰ The Guidance document provides flowcharts for determining if a rule has federalism implications under E.O. 13132.³⁴¹ The guidelines provide answers to regulatory questions like "What do I do if my rule does not have [federalism implications] . . . but [it] has more than minimal adverse impacts on [state

³³⁸ U.S. ENVT'L PROT. AGENCY, EPA'S ACTION DEVELOPMENT PROCESS: GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM at 2 (2008) [hereinafter EPA GUIDANCE]; *see also id.* at 11 ("Even if your rule does not have [federalism implications], if it has any adverse impact on [state/local] governments above a minimal level, then you are subject to EPA's consultation requirements. . . . This internal policy is broader than EO 13132.").

³³⁹ For example, Part 1 (Regulations) proceeds as follows:

1. "How will I know if my rule is subject to the Order?"
2. "What are the thresholds for determining if my rule has Federalism Implications (FI)?"
3. "What do I do if my rule has FI?"
4. "What do I do if my rule does *not* have FI?"
5. "What steps do I follow for my rule?"
6. "What help and participation can I expect from OCIR [Office of Congressional and Intergovernmental Relations] as I develop my rule?"
7. "About consulting with S[tate]/L[ocal] elected officials"
8. "How will EPA ensure compliance with the order?"

Id. at i-ii.

³⁴⁰ *See id.*

³⁴¹ *See id.* at 36-39.

and local] governments[?]”³⁴² 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.”³⁴³

EPA’s Guidance document goes 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.³⁴⁴ EPA has formalized many aspects of the regulatory review process, and lists what is expected of agency officials shepherding a rule through the regulatory process. The Guidance document states at many points that officials attempting to determine whether their rule has federalism implications are required to consult with “your [Office of General Counsel] workgroup representative and your Regulatory Steering Committee Representative.”³⁴⁵ These standing representatives are to be consulted to determine if the rule preempts state law and has federalism implications,³⁴⁶ to prepare a consultation plan, and to review draft FISs.³⁴⁷

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.³⁴⁸ While inclusion of such contact information may seem basic, it is apparently missing at other agencies. Members of the “Big Seven” frequently tell anecdotes about misdirected correspondence from agencies.³⁴⁹

³⁴² *Id.* at 11. Answer: “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 consultations requirements. *In the spirit of EO 13132*, it is EPA’s policy to promote communications between EPA and [state and local] governments and solicit input from [state and local] government representatives *This internal policy is broader than EO 13132.*” *Id.* (emphases added).

³⁴³ *Id.* at 5.

³⁴⁴ *Id.* at 14–18.

³⁴⁵ *See, e.g., id.* at 7.

³⁴⁶ *See id.* at 7, 14, 18.

³⁴⁷ *See id.* at 19–20.

³⁴⁸ *Id.* at 4, 45–47 (listing “Big 10” and “more forums for contacting elected officials”). According to the EPA, the “Big 10” include the more traditional “Big 7” state and local organizations, plus the National Association of Towns and Townships, County Executives of America, and the Environmental Council of the States. *Id.* at 4 n.3.

³⁴⁹ 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. Sharkey Interview with “Big Seven,” July 6, 2010.

The EPA document addresses questions like “How much consultation is enough?”³⁵⁰ Moreover, it provides further advice by highlighting the main concerns of elected officials as expressed to the EPA: money required for program implementation; requiring the state/local government to comply as a regulated party; interfering with division of responsibilities between levels of government; command and control rules; impact on local industry, employment, or land use.³⁵¹ 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.³⁵²

EPA’s Guidance document also tries to address the biggest problem with agency procedures for considering federalism issues: enforcement of those procedures. The Guidance document states that, to ensure compliance with E.O. 13132, EPA’s Office of Policy, Economics, and Innovation will gather information for EPA’s semi-annual Regulatory Agenda, including a listing of all rules with any adverse impact on state and local governments, all rules under development with federalism impact, status of federalism consultation plans, and any problems in carrying out the consultation plan that would affect the Federalism Official’s ability to certify EPA is in compliance with E.O. 13132.³⁵³

With EPA’s Guidance document as a benchmark, each of the other agencies surveyed in this Report came up short. Some agencies, such as FDA—which apparently does not have any published guidelines³⁵⁴—must begin at square one, whereas others, such as NHTSA and OCC, should focus on updating and expanding upon their existing guidelines. Moreover, EPA’s Guidance document is the only one that is publicly available. It would go a long way towards reassuring the state interest stakeholders as well as the public at large for agencies to make their internal guidelines publicly available.

Of the agencies surveyed subject to E.O. 13132, only the 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 a simple, easy-to-follow, comprehensive document that can be cited in the agency’s FIS.

Internal guidelines, moreover, can have a significant practical effect. In recent rulemakings, the EPA has cited its Guidance document. In its recent Coal Rule, for example, EPA noted that even though the rule did not preempt state law, EPA included

³⁵⁰ EPA GUIDANCE, *supra* note 338, at 21 (“For rules with FI . . . at a minimum you should consult . . . with *each* of the relevant representative national organizations in the Big 10.”).

³⁵¹ *Id.* 23–24.

³⁵² *Id.* at 49–51 (“Attachment E”).

³⁵³ *Id.* at 24.

³⁵⁴ Sharkey Interview with Ralph Tyler, Chief Counsel, FDA.

an FIS because the rule would impose “substantial compliance costs” on the states (defined as greater than \$25 million), citing its Guidance document.³⁵⁵ EPA frequently cited the document to explain other actions it took under the rule, like sending letters to the “Big Ten” organizations EPA and OMB identified that represent state and local interests.³⁵⁶

The existence of publicly available guidelines can also serve as an accountability check on the agency. For example, in promulgating its recent Stormwater Rule, EPA acknowledged that the rule had “federalism implications,”³⁵⁷ but nonetheless neglected to consult with state and local officials or the Environmental Council of the States (ECOS) as per its internal guidelines.³⁵⁸ These groups were then able to direct the EPA’s attention to this lapse in following its own guidelines—which prompted an apology/explanation from EPA.³⁵⁹

In sum, the provision of comprehensive internal guidelines creates consistency in an agency’s federalism review, which in turn creates a culture that internally ensures adequate measures are taken to meet the requirements of E.O. 13132. It is the first necessary step in creating a “home” for federalism review of preemptive rulemakings within federal agencies.

2. *Consultation with the States*

Federal agencies have come under consistent criticism 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. 13132.³⁶⁰ NHTSA likewise came under fire for bypassing state consultation.³⁶¹ And

³⁵⁵ Hazardous and Solid Waste Management System; Identification and Listing of Special Wastes; Disposal of Coal Combustion Residuals From Electric Utilities; Proposed Rule, 75 Fed. Reg. 35,128, 35,226 (June 21, 2010).

³⁵⁶ *Id.*

³⁵⁷ See Effluent Limitations Guidelines and Standards for the Construction and Development Point Source Category, 74 Fed. Reg. 62,996, 63,055 (Dec. 1, 2009).

³⁵⁸ See *id.* at 63,055–56 (*While EPA did not consult with State and local elected officials, the Agency did consult with all of the state Stormwater Coordinators in attendance at EPA’s Annual Stormwater Coordinator’s conferences in 2008 and 2009. EPA also attended several conferences where governmental officials were present, such as the International Erosion Control Association (IECA) conference in February 2009, the MAC-IECA conference in September 2009, and the Northwest Environmental Business Council meeting in March of 2009.*) (emphasis added).

³⁵⁹ Email from Steve Brown, Executive Director, ECOS, to Catherine M. Sharkey, Oct. 12, 2010, 3:15 P.M.

³⁶⁰ *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 144 (2007); see also Letter from

finally the 2005 GAO Report criticized OCC for failing to document any of its consultation with state representatives and officials during the rulemaking process.³⁶² GAO also noted that the representative state groups felt OCC did not do an adequate job in consulting them in the rulemaking process.³⁶³ Though the OCC disputed most of the 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.³⁶⁴

Two separate, albeit related, issues present formidable challenges with respect 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 being representative of state and local government officials for purposes of complying with the consultative requirements of E.O. 13132.³⁶⁵ Such elected officials

Ill. State Senator Steven J. Rauschenberger, President, Nat'l Conference of State Legislatures, to Michael O. Leavitt, Sec'y, U.S. Dep't Health & Human Servs. (Jan. 13, 2006) ("It is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide.").

³⁶¹ 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 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 Passenger Vehicle Roof Strength: Hearing Before the Subcomm. on Consumer Affairs, Ins., and Automotive Safety of the S. Comm. on Science, Commerce and Transp.*, 110th Cong. (2008) (criticizing NHTSA's use of preamble preemption in its roof crush rule).

³⁶² 2005 GAO REPORT, *supra* note 177, at 1.

³⁶³ *Id.* at 6-7; see also *Congressional Review of OCC Preemption: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Fin. Servs.*, 108th Cong. 16 (2004) (statement of Thomas J. Miller, Attorney Gen., State of Iowa, on Behalf of the Nat'l Ass'n of Attorneys Gen.) (stating it "does not make any sense at all" to take states out of consumer protection when OCC has only been administering laws for three years); *Review of the National Bank Preemption Rules: Hearings Before the S. Comm. on Banking, Hous., and Urban Affairs*, 108th Cong. 2-3 (2004) (statement of Sen. Paul S. Sarbanes) (quoting from comment letters from the NAAG, letters from other commenters, and newspaper articles) (describing reaction of interested parties as claiming OCC's preemption is "self-serving").

³⁶⁴ See 2005 GAO REPORT, *supra* note 177, at 46-47, 53. OCC officials were not able to identify specific reforms that had been undertaken in response to the 2005 GAO Report. Sharkey Interview with OCC Officials.

³⁶⁵ Letter from Micky Ibarra, Assistant to the President and Director of Intergovernmental Affairs to Donald J. Borut, Chair, Big 7 Organizations (Mar. 9, 2000), *reprinted in* EPA GUIDANCE, *supra* note 338, at 43-46 ("White House Letter on Consultation and List of 'Representative National Organizations' Contacts"); see also EPA GUIDANCE, *supra* note 338, at 4. The

may seem the natural representatives of states, and best equipped to assess the impact of a federal regulation on a state statute or regulation. But, increasingly, preemption determinations displace state common law liability, as opposed to state legislative or regulatory standards. And it is by no means clear who represents the interests served by state tort law. State tort law wears at least two hats—one compensatory, the other regulatory. With respect to suitable representatives of state regulatory interests, should it be those who represent injured victims (potential and actual) or those who are engaged in health and safety regulation at the state level, or both?

Second, the consultative process breaks down at both ends; namely, while federal agencies have rightly been criticized for bypassing consultation with the states, at the same time, it appears as though some of the state representatives have not held up their end of the bargain.³⁶⁶ When state government groups intervene in preemption disputes, they generally assert an anti-preemption agenda, focusing on protection of state autonomy and issues of structural concern to all states, eschewing policy positions on specific regulations. Participation in the rulemaking process by state and local government representatives is, however, sparse. Most rules with potential preemptive power receive no comments from state or local government officials or their representatives. Granted, of the fifty-three preemptive notices included in AAJ's study,³⁶⁷ twenty of them inserted preemptive language into the final rule only after the notice-and-comment period had closed. But, in the remaining thirty-three proposed rules, the state representatives only submitted comments in four rulemakings: one by the Department of Homeland Security (chemical facility security regulation) and three by NHTSA (fuel economy standards for passenger vehicles; standards for light trucks; vehicle roof crush strength).³⁶⁸ NCSL submitted two comments and the state attorneys

“Big 7” include the National Governors Association, 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.

³⁶⁶ 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 agency reached out to consult with the state governmental groups but received no comments back). See also *supra* note 84 (mentioning that NCSL failed to submit any comment to NHTSA during its reconsideration of the Designated Seating Position Amendment rule); *supra* note 136 (mentioning lack of comments from the states, after providing “notice via email transmission of a letter to elected officials of State governments and their representatives,” in FDA over-the-counter labeling rule); *supra* note 140 (mentioning that no states commented on FDA Skin Protectant rule).

³⁶⁷ See AM. ASS'N FOR JUSTICE, *supra* note 55.

³⁶⁸ Michael Jo, Who Represents the States? State Government Groups, Preemption, and Horizontal Federalism 27 (Fall 2009) (unpublished directed research paper, supervised by Professor Catherine Sharkey).

general submitted three (one under the auspices of the National Association of Attorneys General (NAAG)).³⁶⁹

(a) *Expand Appropriate Representatives of State Regulatory Interests*

(i) *The Big Seven*

Of the agencies surveyed in this Report, EPA and NHTSA appear to be making concerted, good faith efforts to reach out to the “Big Seven” to reestablish good working relations. By contrast, the 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.³⁷⁰ (FDA did not provide any relevant information and there were no relevant examples in its recent rulemakings.)

As mentioned above, EPA’s Guidance document contains a list of contact information for the “Big Ten” organizations.³⁷¹ Moreover, the EPA Office of Congressional and Intergovernmental Relations hosts quarterly meetings with the Big Ten.³⁷² It would behoove the other federal agencies to compile an updated contact list for reaching out to the “Big Seven” and also to consider establishing some form of regularized personal contact in order to build relationships.³⁷³

Given the structure of the federal statutes that it implements, the EPA conducts relatively few formal consultations with the states pursuant to E.O. 13132. In a case study, Terranova noted that EPA formally consulted with the states under E.O. 13132 in only two of thirty Clean Air Act regulations it had issued.³⁷⁴ In the two regulations where it did solicit comment from the states, the EPA noted E.O. 13132 did not mandate consultation, “[r]ather, the EPA merely felt it would be good policy to consult with state representatives because of their ‘substantial interest’ in the rule.”³⁷⁵ Terranova also identified three examples of NPRMs where EPA solicited comment from state and local

³⁶⁹ *Id.*

³⁷⁰ Sharkey Interview with OCC Officials.

³⁷¹ *See supra* note 348.

³⁷² Sharkey Interview with EPA Officials.

³⁷³ *See* Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 81–82 (1997) (recommending agencies designate staff advocate or ombudsman to help develop meaningful participation in rulemaking process).

³⁷⁴ Terranova, *supra* note 327, at 11 (describing this as an unsurprising function of the fact that Congress, not EPA, already set the distribution of power between the states and federal government when it passed the CAA).

³⁷⁵ *Id.* at 12 & n.61 (citing 71 Fed. Reg. 60,612 (2006) (Regional Haze Regulations); 72 Fed. Reg. 20,586 (2007) (Clean Air Fine Particle Implementation Rule)).

officials.³⁷⁶ According to EPA, these consultations have led to direct implementation of specific recommendations from the states.³⁷⁷

Over the past three years, EPA determined that a rule invoked E.O. 13132 in two final regulations and one NPRM.³⁷⁸ For each of these rules (save the Stormwater Rule discussed above), EPA noted the steps it took to consult with state and local officials and meet the E.O. 13132 requirements. For the NPRM on National Emissions Standards for Hazardous Air Pollutants for Area Sources: Boilers, EPA said the NPRM “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.³⁷⁹

³⁷⁶ *Id.* (citing 71 Fed. Reg. 5985 (Feb. 6, 2006) (Protection of Stratospheric Ozone); 71 Fed. Reg. 61,144 (Oct. 17, 2006) (National Ambient Air Quality Standards for Particulate Matter); 73 Fed. Reg. 3567 (Jan. 18, 2008) (National Emissions Standards for Reciprocating Internal Combustion Engines)).

³⁷⁷ *See, e.g.*, 71 Fed. Reg. 60,612, 60,629-30 (Oct. 13, 2006) (Regional Haze Regulations).

³⁷⁸ My research assistant, Matthew Shahabian, took advantage of EPA’s “Gateway” website for searches. According to Ken Munis:

The EPA Regulatory Gateway, (<http://yosemite.epa.gov/opei/rulegate.nsf/content/index.html?opendocument>), represents one advancement that we launched earlier this year. The “Gateway” enables the public and those affected by our regulations to better track EPA action on priority rulemakings. For example, the Gateway enables the public to see which actions the Agency believes may have federalism effects. We hope this additional information will facilitate timely consultation and help us provide meaningful opportunities for participation by outside parties. The Gateway also enables the public to track our actions as they relate to key areas such as federalism.

Email from Ken Munis, EPA, to Catherine M. Sharkey, Aug. 15, 2010, 10:44 A.M.

³⁷⁹ 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).

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.”³⁸⁰ Accordingly, EPA consulted with Colorado state and local government “early in the process . . . to permit meaningful and timely input”³⁸¹ Based on this consultation, the final rule reflected what the state requested EPA enact as “necessary to ensure the success of Colorado’s ozone action plan.”³⁸²

NHTSA likewise appears to be making renewed efforts to reach out and consult with state and local officials. In a recent rulemaking on tire fuel efficiency information for consumers, which does not currently have preemptive effect, NHTSA expressly sought comment on preemption from state and local officials.³⁸³ NHTSA stated:

In the NPRM, NHTSA sought public comment on the scope of Section 111 generally, and in particular on whether, and to what extent, Section 111 would or would not preempt tire fuel consumer information regulations that the administrative agencies of the State of California may promulgate in the future pursuant to California’s Assembly Bill 844 (AB 844). Given the ambiguity of the statutory language regarding preemption, the agency sent a copy of the NPRM directly 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. Of these organizations, only the California Energy Commission submitted comments on the NPRM. A summary of all comments the agency received on this issue is presented here. . . . Given that California has not promulgated final regulations yet, NHTSA believes that it is premature to consider the applicability of the EISA section 111 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.³⁸⁴

³⁸⁰ 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).

³⁸¹ *Id.*

³⁸² *Id.*

³⁸³ Tire Fuel Efficiency Consumer Information Program, 75 Fed. Reg. 15,894 (Mar. 30, 2010). *See also supra* note 84 (describing NHTSA’s consultation outside of E.O. 13132 with state and local officials during its reconsideration of the Designated Seating Position Amendment rule).

³⁸⁴ *Id.* at 15,941–42.

(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. The Environmental Council of the States (ECOS) plays a particularly influential role. Indeed, it was in 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.³⁸⁵

Like EPA, OCC reaches out to the representative of its state regulatory counterparts. The Conference of State Bank Supervisors (CSBS) 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.³⁸⁶ With OCC, CSBS developed the model consumer complaint forms to standardize information sharing.³⁸⁷ For state chartered banks that establish interstate branches, CSBS helped negotiate a nationwide state/federal agreement for overlapping regulatory spheres,³⁸⁸ and has negotiated several other agreements and understandings

³⁸⁵ Sharkey Interview with EPA Officials; Sharkey Telephone Interview with Steve Brown, Executive Director, ECOS, July 30, 2010.

³⁸⁶ OCC Telephone Interview. Moreover, OCC has expanded its collaborative outreach to CSBS over the years. In 2006, Comptroller Dugan and the head of CSBS drafted joint procedures for consumer complaint information; 43 states have entered into a similar model. And in that same year, a designee from CSBS was added to the Federal Financial Institution Examination Council, the coordinating body of federal banking regulators. *Id.*

³⁸⁷ 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> (stating recommendations are based on state experience and “CSBS’s ongoing work with the federal banking agencies to develop referral procedures and a Common Consumer Complaint Form”); CSBS, Model Complaint Form, available at <http://www.csbs.org/regulatory/Cooperative-Agreements/Documents/ModelComplaintFormMaster.doc>; *Testimony of John G. Walsh, Chief of Staff and Public Affairs, Office of the Comptroller of the Currency, Before the Subcomm. on Fin. Insts. and Consumer Credit of the H. Comm. on Fin. Servs.*, at 4–5 (Dec. 12, 2007) (describing OCC’s collaboration with CSBS on consumer complaint form), available at <http://www.occ.treas.gov/ftp/release/2007-133b.pdf>.

³⁸⁸ NATIONWIDE COOPERATIVE AGREEMENT (Dec. 9, 1997), available at http://www.csbs.org/regulatory/Cooperative-Agreements/Documents/nationwide_coop_agrmnt.pdf; NATIONWIDE FEDERAL/STATE SUPERVISORY AGREEMENT (Nov. 14, 1996), available at http://www.csbs.org/regulatory/Cooperative-Agreements/Documents/nationwide_state_fed_supervisory_agrmnt.pdf.

with federal regulators involved in banking.³⁸⁹ CSBS frequently comments on regulatory proposals from federal agencies involved in banking,³⁹⁰ and also occasionally files amicus briefs on behalf of state banking regulators.³⁹¹ 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 sent the drafts of the proposed rules to CSBS, the extent to which it consulted with state officials appears limited.”³⁹²

Like EPA and OCC—albeit with the information buried in the Department of Transportation 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.³⁹³ 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):

NHTSA initiated a rulemaking process to determine whether to amend requirements for crash safety protection in small and large school buses. Early in the process, prior to the issuance of the notice of proposed rulemaking, 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. Participants at the roundtable included representatives from states with compulsory seatbelt requirements, individuals with expertise in seatbelt installation (and effects on

³⁸⁹ 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>.

³⁹⁰ CSBS COMMENT LETTERS, <http://www.csbs.org/regulatory/policy/Pages/CSBS%20Comment%20Letters.aspx> (last visited Aug. 25, 2010) (listing ten comment letters so far this year).

³⁹¹ See, e.g., Brief of CSBS as Amicus Curiae in Support of the Petitioner, *Cuomo v. Clearing House Ass’n*, No. 08-453, 129 S. Ct. 2710 (2009), 2009 WL 685656; Brief of Amicus Curiae, CSBS, in Support of Appellee, *Urging Affirmance, State Farm Bank, FSB v. Reardon*, No. 07-4260, 539 F.3d 336 (6th Cir. 2008), 2008 WL 2740657; Brief of the Big 7, Joined by the CSBS, as Amici Curiae Supporting Petitioner, *Watters v. Wachovia Bank, N.A.*, No. 05-1342, 550 U.S. 1 (2006), 2006 WL 2570993.

It is worth mentioning that state banking regulators and the OCC compete for chartering fees from banks, and given that competition, it is not surprising to see CSBS is one of the more aggressive representatives of state interests in regulations, legislation, and court battles.

³⁹² 2005 GAO REPORT, *supra* note 177, at 19.

³⁹³ Gov’t Affairs, Office of the Sec. of Transp., U.S. Dep’t of Transp., State & Local Organizations, <http://www.dot.gov/ost/govaffairs/statelocal.htm>.

passenger capacity), and a representative from the National School Transportation Association.³⁹⁴

(iii) *Introduce Attorney General Notification Provision*

Given the twin problems of identifying appropriate representatives of state regulatory interests and the paucity of comments during the rulemaking process from state governmental organizations, this Report proposes the introduction of a novel notification provision to the Attorneys General³⁹⁵ and to the National Association of Attorneys General (NAAG).³⁹⁶ 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 must 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.³⁹⁷ The intuition behind this approach is that the top legal officer of the state ought to be able to distribute the information to the relevant state agencies or officials or other appropriate representatives of the state interest.

The addition of an Attorney General notification provision would provide a formal mechanism to a party that is well positioned to alert any and all interested participants in the rulemaking process. It is premised on the intuition that not all interested participants comb the Federal Register for relevant rulemakings and the exclusive singling out of the Big Seven organizations may no longer make sense, particularly in light of the rise of rulemakings that preempt state tort law.

State AGs are given a special role in the new Dodd-Frank Wall Street Reform and Consumer Protection 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 pass a resolution in support of establishing or modifying a Bureau regulation, the

³⁹⁴ Sharkey, *Federalism Accountability*, *supra* note 14, at 2171-72 (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 (Nov. 21, 2007)); *see also* 73 Fed. Reg. 62,744, 62,777-78 (Oct. 21, 2008) (describing consultation in final rule as "discuss[ing] the safety, policy and economic issues related to seat belts on school buses").

³⁹⁵ All fifty state AGs have general permanent email addresses. For a current listing of all AGs and contact information, see <http://www.naag.org/current-attorneys-general.php>.

³⁹⁶ James McPherson, Executive Director of NAAG, indicated his willingness to serve as the point of contact for the federal agencies. Depending upon 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 AGs offices. Telephone Interview with McPherson, November 10, 2010.

³⁹⁷ 28 U.S.C. § 1715 (a) (2) (Supp. V 2005). 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).

Bureau must issue a notice of proposed rulemaking on the issue.³⁹⁸ This provision also requires the Bureau to publish findings on certain specific considerations in response a State petition, and it must send copies of those findings to the House and Senate Finance committees.³⁹⁹ Under the Act, state AGs also have the power to bring lawsuits against banks in order to *enforce* federal regulations issued by the Bureau.⁴⁰⁰

The Chairman of the CPSC, according to its General Counsel, instituted a monthly call with the state attorneys general offices.⁴⁰¹ Anywhere from twenty to thirty-five participants from state AG offices with consumer protection responsibilities typically participate in these calls.⁴⁰² According to the General Counsel, “This direct line of communication has proven very useful in engendering state participation in rulemakings with preemptive effect.”⁴⁰³ This CPSC state AG initiative supports both focusing on reaching out to states early in the rulemaking process and providing notification to state attorneys 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.⁴⁰⁴

³⁹⁸ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 § 1041(c) (2010).

³⁹⁹ *Id.* § 1041(c)(2)-(3).

⁴⁰⁰ *Id.* § 1042(a)(1). If an AG wishes to bring an action under § 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 the OCC officials pointed out, this was a deliberate omission to prevent states from creating fifty different interpretations of the statute. OCC Telephone Interview; *see also* 156 Cong. Rec. S3868–72 (May 18, 2010) (debate on State AG enforcement provision discussing how amendments “strike a balance” and “compromise” to allow supplemental enforcement from states without creating conflicting authorities).

⁴⁰¹ Email from Cheryl Falvey to Catherine Sharkey, Nov. 1, 2010, 1:49 P.M.

⁴⁰² *Id.*

⁴⁰³ *Id.*

⁴⁰⁴ Sharkey Interview with Dan Schweitzer, Supreme Court Counsel, NAAG, July 19, 2010. State AGs have tended to be most engaged in OCC preemption, where the focus is on enforcement of state laws. NAAG’s Interim Brief for the Transition team highlighted consumer protection as one of their priorities. NAT’L ASS’N OF ATT’YS GEN., INTERIM BRIEFING PAPER PREPARED FOR PRESIDENT-ELECT BARACK OBAMA TRANSITION TEAM 7 (2009), *available at* http://www.naag.org/assets/files/pdf/policy/Transition_Team_Briefing_Paper_20090110.pdf Specifically, they requested that the new administration roll back preemption of consumer

In addition to advocating state interests in preserving state positive law, state AGs have also intervened to protest preemption of state common law.⁴⁰⁵ The AG notification provision would capitalize on this burgeoning development and further expand the role of state AGs in identifying the relevant state regulatory interest at stake in preemptive rulemakings.

(b) *Focus on Earlier Outreach to States*

An effort should be made in terms of encouraging 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 in the NPRM.⁴⁰⁶

However, most of the agencies still focus primarily, if not exclusively, on state consultation during the notice-and-comment process. The DOT Guidance document focuses on notice and comment process, directing that states should receive copies of NPRM with preemptive effects and that agencies should respond to any comment submitted by a state during notice and comment proceedings.⁴⁰⁷ There are no provisions for any “meaningful” consultation outside of the notice-and-comment process or before

protection laws as asserted by both OCC and the soon-to-be-defunct Office of Thrift Supervision. *Id.*

⁴⁰⁵ See, e.g., Brief for Vermont et al. as Amici Curiae Supporting Respondent at *1, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 3851613 (“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.”); see also Daniel Schweitzer, Supreme Court Counsel, Nat’l Ass’n of Att’ys Gen., Panelist Remarks at the New York University Annual Survey of American Law: Tort Law in the Shadow of Agency Preemption (Feb. 27, 2009) (noting that, over time, states have gotten 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).

⁴⁰⁶ OMB Guidance for E.O. 13132, *supra* note 32.

⁴⁰⁷ U.S. DEP’T OF TRANSP., DOT GUIDANCE: FEDERALISM 6 (1988) [hereinafter DOT GUIDANCE] (“The consultation is generally met with respect to rulemaking through the use of the notice and comment process. . . . In addition, for the rulemakings [that invoke federalism implications] the agency should make a special effort to ensure that the document is distributed directly to the States . . .”). This document was provided to Sharkey by Neil Eisner, Ass’t General Counsel for Regulation and Enforcement, Dep’t of Transportation.

the NPRM is published.⁴⁰⁸ OCC likewise maintains that the primary mechanism of consultation with the states is the notice-and-comment procedure.⁴⁰⁹

This focus only on notice and comment proceedings denies States substantial opportunities to contribute meaningfully to the development of the regulation, as they can only respond once the NPRM has already been published.⁴¹⁰

3. *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 Sharkey has proposed for court review of agency positions on preemption, which is premised upon judicial scrutiny of the contemporaneous agency record to determine precisely the risks weighed by the agency.⁴¹¹

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

⁴⁰⁸ 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 or approval” *Id.* There is no discussion of when additional consultation is warranted or how DOT determines if it should be approved.

⁴⁰⁹ Sharkey Interview with OCC Officials.

⁴¹⁰ *See, e.g.,* Freeman, *supra* note 373, at 12 (“[T]he notice-and-comment process often fails to make the best use of available data and information. This is in part a product of timing: only after the Notice of Proposed Rule Making (NPRM) do parties supply detailed arguments about the technical and practical difficulties of implementing a rule, instead of much earlier when the information might be more valuable to the agency in formulating the proposed rule.”).

⁴¹¹ Sharkey, *Products Liability Preemption*, *supra* note 157, at 453 (“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.”); *id.* at 477–521 (developing agency reference model); *see also* Sharkey, *Federalism Accountability*, *supra* note 14, at 2130 (“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 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.”); *id.* at 2188–89 (elaborating on the “agency record” necessary to justify preemption).

analyze the data that demonstrates the existence of the asserted factual predicate of a conflict between state law and the federal regulatory scheme.⁴¹² This empirical evidence should be included in a document signed by the head of the program office and inserted into the public docket for the rulemaking.⁴¹³ The rulemaking notice should note the existence of the document and invite comment on it.

Exhibit A for the need for such an internal agency standard and review process is the 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." The main thrust of the FDA's federalism impact statement was that the FDA had legal authority to preempt state law in this area.⁴¹⁴ Such purely legalistic determinations would not suffice to satisfy the proposed factual predicate standard. Moreover, as the U.S. Supreme Court complained in *Wyeth*:

[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.⁴¹⁵

⁴¹² The ABA has adopted a resolution recommending that federal agencies subject to E.O. 13132 should have to provide: "(a) factual 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." ABA H.R. 117, *supra* note 11. Part (a) is akin to the factual predicate recommended here (and in Sharkey's "agency reference model"). Though the ABA specifically limited its focus to agency preemption of state tort law, this Report applies more generally to preemption of state law (including state statutes and regulations).

This Report's 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.

⁴¹³ Attention must be paid to the practical realities of how different offices in an agency function in relation to each other. *Cf.* Elizabeth Magill & Adrian Vermeule, *Allocating Power Within Agencies*, YALE L.J. (forthcoming 2010) ("In this essay, we will examine how administrative law allocates power within agencies, and how arguments from expertise, legalism and politics apply inside agencies rather than across institutions."), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1577723.

⁴¹⁴ 71 Fed. Reg. 3922, 3969 (Jan. 24, 2006) ("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.").

⁴¹⁵ *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 n.11 (2009) (quoting H. COMM. ON OVERSIGHT & GOV'T REFORM, MAJ. STAFF REP., FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES 4 (2008)).

It seems that in at least that instance there was a need for a counterbalance to the Office of the Chief Counsel.

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 a relatively lengthy three-page discussion, NHTSA took apart the earlier asserted factual predicates one-by-one.⁴¹⁶ First, after further testing by NHTSA, the Final Rule disclaimed the NPRM's argument that improving roof safety would also increase rollover propensity.⁴¹⁷ Additionally, where the NPRM asserted 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 "there is not a basis to conclude that such [diverted] resources would otherwise have been used for improving rollover resistance or improving safety."⁴¹⁸ The Final Rule also disagreed with the automotive industry's argument that increased roof crush resistance from state tort law would create dangerous disparities in vehicle mass, stating the industry "did not provide technical analysis addressing . . . the issue."⁴¹⁹ NHTSA Assistant Chief Counsel, 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.⁴²⁰

The "substantial evidence" provision in the Dodd-Frank Wall Street Reform and Consumer Protection Act—which requires agency preemption determinations to be

⁴¹⁶ 74 Fed. Reg. 22,348, 22,380–83 (May 12, 2009).

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 236, 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," 74 Fed. Reg. 22,348, 22,349 (May 12, 2009), as opposed to the Federalism discussion thirty pages later, which spans three pages. *See id.* at 22,380–83. The authors also give short shrift to NHTSA's explanation of its policy shift in the Designated Seating Position Rule. *Compare* 74 Fed. Reg. 68,185, 68,187–89 (Dec. 23, 2009) (NHTSA's two-page explanation of how it interprets preemption and its analysis of state law, why it would not conflict, and soliciting comment from state and local officials), *with* Schwartz & Silverman, *supra* note 236, at 1221–22 ("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.").

⁴¹⁷ 74 Fed. Reg. 22,382.

⁴¹⁸ *Id.*

⁴¹⁹ *Id.* at 22,382–83.

⁴²⁰ Sharkey Interview with Steve Wood, June 30, 2010.

evaluated under a “substantial evidence” standard⁴²¹—is also instructive. The Act requires the evidence to be made “on the record,” supporting the “specific finding of preemption” under the *Barnett* standard, which requires a finding that the state law “significantly interfere or impair” the national bank’s exercise of its national bank powers. The Act further directs courts evaluating agency preemption determinations by OCC to assess their validity based on “thoroughness of consideration,” “validity of reasoning,” and “consistency with other determinations.”⁴²² This *Skidmore* standard for review is likewise consistent with the agency reference model.⁴²³

Exhibit C here would be the 2004 OCC preemptive rule that will have to be rescinded in light of *Cuomo*. In *Cuomo*, the Second Circuit commented that “the 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 lacking any real intellectual rigor or depth.”⁴²⁴ Indeed, both the Final Rule⁴²⁵ and the NPRM⁴²⁶ read like legal briefs (complete with argument subheadings), not like agency rulemakings.⁴²⁷ 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 this “clarification” that resulted in preemption. There was nothing to suggest that state law “significantly interfered” with national bank activities under the relevant banking preemption standard.⁴²⁸ Rather, the

⁴²¹ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 § 1044(a) (2010) (modifying 12 U.S.C. § 5136C(c)).

⁴²² *Id.* (modifying § 5136C(b)(5)(A)).

⁴²³ Sharkey, *Products Liability Preemption*, *supra* note 157, 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 accorded *Skidmore* ‘power to persuade’ (not *Chevron* mandatory) deference—a position apparently endorsed by the Court in *Wyeth*.”).

⁴²⁴ *Clearing House Ass’n v. Cuomo*, 510 F.3d 105, 119 (2d Cir. 2007).

⁴²⁵ *Bank Activities and Operations*, Final Rule, 69 Fed. Reg. 1895 (Jan. 13, 2004).

⁴²⁶ *Rules, Policies, and Procedures for Corporate Activities; Bank Activities and Operations; Real Estate Lending and Appraisals*, NPRM, 68 Fed. Reg. 6363 (Feb. 7, 2003).

⁴²⁷ *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.”).

⁴²⁸ *See Barnett Bank v. Nelson*, 517 U.S. 25 (1996); *see also* Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044 (modifying 12 U.S.C. 5136C(b)(1)(B)) (codifying *Barnett* as preemption standard for banking preemption).

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.⁴²⁹

OCC officials expressed skepticism that the "substantial evidence" standard would appreciably affect their rulemakings, apart from perhaps mandating explicit reference to the new standard.⁴³⁰ One of the OCC attorneys specifically cited *American Bankers Association v. Lockyer*,⁴³¹ as an example where the OCC has made factual findings to support preemption determinations in the past. 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 receive referrals for credit counseling.⁴³² 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 interfered with national banks' ability to exercise their powers to set terms, conditions, and interest rates for credit cards.⁴³³ The court agreed with OCC's interpretation and found California law preempted.⁴³⁴ Additionally, the court 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.⁴³⁵ 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, as it imposed only paperwork burdens and some administrative costs.⁴³⁶ Given this level of specificity and the significant factual findings made by the OCC in *Lockyer*, including the precise cost of the state rule on national banks, the complete absence of a factual record in the visitorial powers rule could hardly pose a sharper contrast.⁴³⁷

⁴²⁹ 69 Fed. Reg. 1896–1903.

⁴³⁰ Sharkey Interview with OCC Officials.

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

⁴³² *Id.* at 1002–04.

⁴³³ *Id.* at 1013–15.

⁴³⁴ *Id.* at 1022.

⁴³⁵ *See id.* at 1015.

⁴³⁶ *Id.*

⁴³⁷ The other OCC rulemaking issued contemporaneously with the Visitorial Powers (VP) Rule, which preempted various state regulations affecting national bank operations, seems significantly more justified than the VP rule. Bank Activities and Operations; Real Estate Lending and Appraisals, 69 Fed. Reg. 1904 (Jan. 13, 2004). The OCC spent a considerable amount of time in the preamble explaining why the regulation preempts state law, arguing that banking is now more national in nature and crosses state-boundaries on a regular basis.

B. OIRA/OMB

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

Publication of the reports of agency responses to the Presidential Memorandum's directive to conduct a 10-year retrospective review of preemptive rulemaking would, at least in part, debunk one view that the Presidential Memorandum on Preemption has not induced any significant agency action or follow-up with respect to the 10-year retrospective review.⁴³⁸

Publication of these reports would—along with individual agency's 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.

Too many different state laws were arguably preventing national banks from exercising the full extent of their powers under federal charters, reducing the availability of credit to consumers and increasing the price of banking services. *Id.* at 1907–08. The OCC pointed to its case-by-case preemption of the Georgia Fair Lending Act (GFLA), 68 Fed. Reg. 462,64 (Aug. 5, 2003), as a justification for blanket preemption, arguing in the Georgia case mortgage lenders simply were not making loans to Georgia consumers because the costs imposed by the GFLA were too high. 69 Fed. Reg. at 1908. (This GFLA justification was also asserted by former Comptroller Hawke in his prepared testimony for the Financial Crisis Inquiry Commission. *See Statement of John D. Hawke, Former Comptroller of the Currency, Before the Financial Crisis Inquiry Commission* 5 (Apr. 8, 2010), available at <http://www.fcic.gov/hearings/pdfs/2010-0408-Hawke.pdf>.) Though OCC still made legal arguments explaining why it had preemptive power in the first instance, 69 Fed. Reg. at 1908–11, this rule was at least supported with factual arguments and justifications, unlike the VP rule.

⁴³⁸ Ashutosh Avinash Bhagwat, *Wyeth v. Levine and Agency Preemption: More Muddle or Creeping to Clarity?* 44 TULSA L. REV. (forthcoming 2010) (manuscript at 36–42), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1474470 (arguing it remains to be seen whether Memorandum will have lasting effect); *Agency Appraisal: President Obama Orders Review of Federal Pre-emption Clauses*, INSIDE COUNSEL MAG., Aug. 8, 2009, <http://www.insidecounsel.com/Issues/2009/August-2009/Pages/Agency-Appraisal.aspx> (quoting law firm partners as stating memorandum is “purely political” move); Lawrence S. Ebner, *President Obama's "Preemption Memo": Much To Do About Very Little*, 24 LEGAL BACKGROUNDER, June 19, 2009, http://www.wlf.org/publishing/publication_detail.asp?id=2084 (arguing Memo will have little impact on preemption beyond forcing agencies to conduct “vague review” of regulations).

2. Update OMB Guidance Document

OMB's 1999 Guidance document (and E.O. 13132) directs agencies to send OMB their designated "federalism official" as well as a "consultation plan" that describes how agencies identify policies with federalism implications and the procedures agencies will use to ensure meaningful and timely consultation.⁴³⁹

OMB/OIRA should bring this document up to date.⁴⁴⁰ Here would be an appropriate place to include a current list of state consultation groups and their contact information.

In an effort to encourage greater transparency with respect to agency compliance with E.O. 13132, OMB/OIRA should also direct agencies to publish their designated federalism officials and consultation plans (along with the agencies' internal guidelines for compliance with E.O. 13132).⁴⁴¹

This Report's survey of federal agencies found spotty compliance with these mandates. The Report did not uncover any evidence that OMB/OIRA took steps to monitor agencies' provision 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 had been submitted to OMB.⁴⁴² The "plan," however, is merely a statement that says "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."⁴⁴³ This statement is followed by four pages of examples of agency consultation and working groups set up by the various DOT agencies on their own

⁴³⁹ Exec. Order No. 13,132 § 6(a); OMB Guidance for E.O. 13132, *supra* note 32, at 4–5.

⁴⁴⁰ At a minimum, OIRA should inform the agencies whom to contact with respect to submission of the name of their designated federalism official and the description of the agency's consultation process. The current document lists Stuart Shapiro (who is currently an associate professor at Rutgers University, *see infra* note 451) as the contact person for this and any other questions relating to E.O. 13132. *See* OMB Guidance for E.O. 13132, *supra* note 32, at 2, 4, 7.

⁴⁴¹ OIRA 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.

⁴⁴² 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]. This document was provided to Sharkey by Neil Eisner.

OCC has no record of sending any such description to OMB/OIRA. Sharkey Telephone Interview with OCC Officials.

⁴⁴³ DOT 3/13/00 Letter, *supra* note 442, at 1.

accord.⁴⁴⁴ There is no general plan that explains how consultation should happen, and notably, NHTSA is mentioned only once in the entire plan: “The [NHTSA] meets annually with State Highway Safety Offices to share information and solicit ideas on grant projects.”⁴⁴⁵

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

At present, OIRA is responsible for monitoring agencies’ compliance with E.O. 13132.⁴⁴⁶ Under Executive Order 12866, OIRA reviews “significant” proposed regulations on a transactional, or rule-by-rule, basis.⁴⁴⁷

According to OIRA officials, preemption and other federalism issues are given significant attention in the regulatory review process.⁴⁴⁸ But OIRA’s review is hampered when agencies evade the requirements of E.O. 13132.⁴⁴⁹ A 2003 GAO Report cast some doubt on the vigor of OIRA’s policing of agency compliance with E.O. 13132, finding only a single instance—examining a subset of 85 rules over a year-long period—in which OMB questioned an agency’s conclusion regarding the absence of federalism implications in a rule.⁴⁵⁰ Moreover, this impression was confirmed by Stuart Shapiro,

⁴⁴⁴ *Id.* at 1–4.

⁴⁴⁵ *Id.* at 3.

⁴⁴⁶ *See supra* note 34.

⁴⁴⁷ *See supra* notes 41–42 (outlining four criteria triggering OIRA review under E.O. 12866 and certification for compliance with E.O. 13132).

⁴⁴⁸ Sharkey conducted an interview with Kevin Neyland, OIRA Deputy Administrator, on July 14, 2010. Sharkey followed up with Neyland and Michael Fitzpatrick, OIRA Associate Administrator, by telephone conversations on November 1, 2010, November 9, 2010, and November 12, 2010. Sharkey 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.

⁴⁴⁹ *See 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.]”); Mendelson, *Chevron, supra* note 14, at 783–86 (describing poor record of agency compliance with E.O. 13132).

⁴⁵⁰ In a study by U.S. General Accounting Office that looked at a subset of eighty-five health, safety, or environmental rules that were submitted to OMB for review between July 2001 and June 2002, only one 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-03-989, RULEMAKING: OMB’S ROLE IN REVIEW OF AGENCIES’ DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS 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.* at 139.

who worked on federalism issues as assistant branch chief at OIRA in the late 1990s and early 2000s:

These 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.⁴⁵¹

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. 13132.⁴⁵² The American Bar Association has adopted a resolution that "urges the President to improve agency compliance with Executive Order 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."⁴⁵³ 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

⁴⁵¹ Email from Stuart Shapiro, Associate Professor and Director of Public Policy Program, Rutgers University, to Catherine M. Sharkey, Nov. 2, 2010, 10:32 A.M. Sharkey conducted telephone interviews with Professor Shapiro on May 28, 2010 and October 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).

⁴⁵² *See, e.g.,* Memorandum from Authors of Advancing the Public Interest through Regulatory Reform to Michael Fitzpatrick, OIRA Associate Administrator (Mar. 31, 2009) (comments on the relationship between OIRA and federal agencies), *available at* http://www.reginfo.gov/public/jsp/EO/fedRegReview/advancing_attachment.pdf; Sharkey, *Federalism Accountability*, *supra* note 14, at 2178 & n.209 (citing RICHARD L. REVESZ & MICHAEL A. LIVERMORE, INST. FOR POLICY INTEGRITY, N.Y.U. SCHOOL OF LAW, FIXING REGULATORY REVIEW, RECOMMENDATIONS FOR THE NEXT ADMINISTRATION 4-5 (2008)) (describing OIRA review under E.O. 12866 as a potential "template" for expanded review under E.O. 13132); WILLIAM FUNK ET AL., LIMITING FEDERAL AGENCY PREEMPTION RECOMMENDATIONS FOR A NEW FEDERALISM EXECUTIVE ORDER 5-6 (Ctr. For Progressive Reform White Paper #809, 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.

⁴⁵³ ABA H.R. 117, *supra* note 11.

agency proposing the rule if that office has sufficient autonomy, authority, and resources for effective review.”⁴⁵⁴

OIRA, as the central coordination locus for regulatory review, is well positioned to be the entity charged with a more thorough review of agency proposals to preempt state law. For certain regulations—those subject to OMB review under E.O. 12866⁴⁵⁵—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.⁴⁵⁶ But OMB is given little to review;⁴⁵⁷ it is asked simply for a vote of confidence in the federalism officer’s conclusion. If the recommendations in this Report are followed, however, agencies would have their own internal review of the factual predicates supporting preemption and their analyses could 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.⁴⁵⁸

⁴⁵⁴ ABA TASK FORCE REPORT, *supra* note 11, at 8.

⁴⁵⁵ Certification to OMB is required only for “significant” regulations. *See supra* notes 41–42.

⁴⁵⁶ Exec. Order No. 13,132 § 8(a). *See also* OMB Guidance for E.O. 13132, *supra* note 32, 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.”).

⁴⁵⁷ *See* OMB Guidance for E.O. 13132, *supra* note 32, at Appendix 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.*

⁴⁵⁸ *See* OFFICE OF INFO. & REGULATORY AFFAIRS, CIRCULAR A-4 ON REGULATORY ANALYSIS (2003), *available at* http://www.whitehouse.gov/omb/circulars_a004_a-4/. The A-4 circular “provides the [OMB’s] guidance to Federal agencies on the development of regulatory analysis.” *Id.* The A-4 checklist includes a designation for “effect on state and local government.” But the description implies that it is focused primarily on costs imposed on state and local government (the focus of UMRA) and not on agency assertions of preemption. *See id.* (“Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth. You need to identify the portions of benefits, costs, and transfers received by State, local, and tribal governments.”). 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 § 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, for example the “novel legal/policy” review. *See supra* note 41. 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.*, § 3(f)(1)); the remaining 95% were

Moreover, OIRA should consider the feasibility of requiring agency certification of compliance with the consultation and FIS mandates of E.O. 13132 for *all* agency rulemakings that preempt state law (not just those subject to E.O. 12866).⁴⁵⁹

“otherwise major/significant” (*i.e.*, § 3(f)(2)-(4)). See Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 846 (2003)

⁴⁵⁹ OIRA review under any of the four criteria for E.O. 12866 review (listed in § 3(f), *see supra* note 41, should trigger a certification of compliance with E.O. 13132 by the agency per E.O. 13132 § 8(a). But it remains unclear whether *every* preemptive rulemaking—for which agencies are required to submit a federalism impact statement to OMB per E.O. § 6 (c)—would meet the E.O. 12866 § 3(f) criteria.

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