

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

FEDERAL AGENCY PREEMPTION OF STATE LAW

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Introduction..... 3

I. Executive Directives on Preemption and Federalism..... 6

 A. May 2009 Presidential Memorandum on Preemption..... 6

 B. Federalism Executive Order 13132..... 7

 1. Consultation Process..... 8

 2. Federalism Impact Statements..... 8

 3. Enforcement..... 9

II. Federal Agency Response: Rulemaking and Litigation..... 10

 A. NHTSA..... 11

 1. Response to May 2009 Presidential Memorandum on Preemption..... 12

 2. Rulemaking..... 14

 (a) Removal of Preemptive Language..... 15

 (i) Rearview Mirror Rule..... 15

 (ii) Roof Crush Rule..... 16

 (iii) Designated Seating Position Amendment..... 18

 (b) Evolution of Boilerplate Preemption Language..... 19

 (i) Implied Preemption Language..... 20

 (ii) Express Preemption Language..... 22

 3. Litigation..... 22

 (a) Automobile Safety Standards..... 22

 (b) Fuel Economy Standards..... 24

 B. FDA..... 26

 1. Response to May 2009 Presidential Memorandum on Preemption..... 27

 2. Rulemaking..... 27

 3. Litigation..... 29

 C. OCC..... 32

 1. Response to May 2009 Presidential Memorandum on Preemption..... 34

 2. Congressional Response: Dodd-Frank Wall Street Reform and Consumer Protection Act..... 36

 D. CPSC..... 39

 1. Congressional Response: Consumer Product Safety Improvement Act of 2008..... 41

 2. Response to May 2009 Presidential Memorandum on Preemption..... 43

 3. Rulemaking..... 43

 4. Litigation..... 45

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PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

- E. FTC..... 46
 - 1. Response to May 2009 Presidential Memorandum on Preemption..... 48
 - 2. Rulemaking..... 49
 - 3. Litigation..... 50
- F. EPA..... 51
 - 1. Response to May 2009 Presidential Memorandum on Preemption..... 51
 - 2. Uniqueness of EPA: Agency and States as Co-regulators..... 54
- III. Recommendations..... 55
 - A. Agencies 57
 - 1. Internal Guidelines on Federalism Executive Order (13132)..... 57
 - 2. Consultation with the States..... 62
 - (a) Expand Appropriate Representatives of State Regulatory Interests..... 64
 - (i) The Big Seven..... 64
 - (ii) Encourage Development of Agency-Specific Liaison Groups 67
 - (iii) Introduce NAAG Notification Provision 69
 - (b) Focus on Earlier Outreach to States 71
 - 3. Internal Oversight 72
 - B. OIRA/OMB 75
 - 1. Publish Reports of Agency Compliance with May 2009 Presidential Memorandum..... 75
 - 2. Update OMB Guidance Document..... 76
 - 3. Include Review of Federalism Implications in Regulatory Review Process 76

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 February 2009, the Office of Management and Budget (OMB) sought public comments on reform proposals for a new Executive Order on regulatory review procedures,⁹ and in May 2009, President Obama issued a Presidential Memorandum on Preemption.¹⁰

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 stating the fate of state law when it enacts legislation, the reality is that

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). Next Term, the Supreme Court will hear *Williamson v. Mazda Motor of Am., Inc.* to 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>. The Court will also hear *Bruesewitz v. Wyeth*, to 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 74 Fed. Reg. 8819 (Feb. 26, 2009) (requesting comments on new Executive Order on Federal Regulatory Review).

¹⁰ 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>.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 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 even more enhanced scrutiny in just 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 FDA’s inclusion of its statement of preemptive intent in the preamble to the drug labeling rule, and not in the codified rule. This “preemption by preamble” approach 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.¹¹ 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.

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

¹¹ Nor did the FDA stand alone in the preemption by preamble practice. NHTSA and CPSC were also complicit during the George W. Bush Administration. These three agencies, then, were prime candidates for inclusion in this Report.

¹² *Chevron, U.S.A., Inc. v. Nat. 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*

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 rulemakings 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 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 federalism values 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 OIRA/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.”¹⁷ The memorandum specifically admonished department and agency

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 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>.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

heads to cease the practice of “preemption by preamble”—where preemption statements are included in the preamble, but not in the codified regulation.¹⁸ 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.”¹⁹

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.”²⁰

B. Federalism Executive Order 13132

Executive Order 13132, “Federalism,” issued by President Clinton on August 4, 1999,²¹ is adverted to in Obama’s Presidential Memorandum and also serves as the centerpiece of numerous reform proposals. E.O. 13132 is an amended version of E.O. 12612, President Reagan’s Executive Order on Federalism.²² E.O. 13132 identifies federalism principles and policymaking criteria and designates specific procedures for intergovernmental consultation. 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,²³ which are nonetheless encouraged to comply voluntarily with its provisions.²⁴

¹⁸ *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.”).

¹⁹ *Id.*

²⁰ The White House, Presidential Memorandum on Preemption (May 20, 2009), *available at* http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.

²¹ Exec. Order No. 13,132, 3 C.F.R. 206 (2000), *reprinted in* 3 U.S.C. § 301 (2006).

²² 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.

²³ Exec. Order No. 13,132 § 1(c).

²⁴ *Id.* § 9.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.”²⁵ The Order establishes specific procedures for intergovernmental consultation if a rule preempts state law.²⁶ Each agency must consult with state and local officials “early in the process of developing the proposed regulation.”²⁷

2. Federalism Impact Statements

E.O. 13132 also requires agencies to provide a federalism impact statement (FIS) whenever regulations will 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.”²⁸ For any “major” regulation (defined as having an annual effect on the economy of at least \$100 million) subject to Executive Order 12866,²⁹ the agency must submit with its final draft regulation a “federalism summary impact statement” in “a separately identified portion of the preamble to the regulation.”³⁰

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

²⁵ *Id.* § 6(a). Consultation process must involve “elected officials of State and local governments or their representative national organizations.” *Id.* §§ 1(d), 6(a).

²⁶ Section 6(c) establishes procedures for “any regulation that has federalism implications and that preempts State law.” *Id.* § 6(c).

²⁷ *Id.* § 6(c)(1).

²⁸ *Id.* § 6(c)(2) (requiring FIS for regulations and orders with “federalism implications and that preempts State law”); *id.* § 1(a) (defining federalism implications).

²⁹ From 1981-2000 only five percent of federal rules were reviewed by OMB under this standard. See Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 846 (2003).

³⁰ Exec. Order No. 13,132 § 6(c)(2). 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 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.”).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.³¹

3. *Enforcement*

Within OMB, OIRA has primary responsibility for implementing the Executive Order.³² In October, 1999, OIRA Administrator John Spotila circulated to all heads of executive departments and agencies and independent regulatory agencies "Guidance for Implementing E.O. 13132, 'Federalism.'"³³ 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."³⁴

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.³⁵ 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.³⁶

The federalism official must submit to OMB "a description of the agency's consultation process."³⁷ 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."³⁸

For any draft final regulation with federalism implications that is submitted for OIRA review under 12866, the federalism official must certify that the requirements of

³¹ Exec. Order No. 13,132 § 6(c)(2). The agency must also submit at that time, a copy of any formal policy-related correspondence from State and local officials. *Id.* § 6(c)(3).

³² Under Executive Order 12866, OIRA coordinates regulatory review and planning functions. 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).

³³ OMB Guidance for 13132, *supra* note 30.

³⁴ *Id.* at 1.

³⁵ Exec. Order No. 13,132 § 6(a). Each agency was to notify OIRA of the designated federalism official.

³⁶ OMB Guidance for 13132, *supra* note 30, at 2.

³⁷ Exec. Order No. 13,132 § 6(a); OMB Guidance for 13132, *supra* note 30, at 2.

³⁸ OMB Guidance for 13132, *supra* note 30, at 4–5.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

E.O. 13132 concerning both the evaluation of federalism policies and consultation have been met in a meaningful and timely manner.³⁹

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 Executive Order 13132 ("Federalism"). This empirical work, focusing on agencies' awareness of the issue and their compliance efforts, draws from extensive interviews with agency officials as well as 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, 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 three prior 2005 rulemakings and has drafted new 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. CPSC has adopted an extremely cautious stance. In its rulemakings, the

³⁹ Exec. Order No. 13,132 § 8(a).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

agency refrains from offering its interpretive gloss on preemption, choosing instead mere recitation of governing express 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. ~~Perhaps in light of~~ Due to the 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. There is, at best, subtle 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 EO 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. 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 most aggressive stance of "preemption by preamble" contained in three 2005 Notice of Proposed Rulemakings (NPRMs) as well as a lengthy adumbration of the agency's revisions to its boilerplate preemption language 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 implied preemption under the Motor Vehicle Safety Act and Energy Policy and Conservation Act, respectively.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Sharkey conducted extensive in-person interviews with NHTSA and DOT officials.⁴⁰

I. 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.⁴¹ For NHTSA, DOT identified six rules with preemptive effect: Designated Seating Positions,⁴² Air Bag Labeling,⁴³ Detachable Seat Belts,⁴⁴ Event Data Recorders,⁴⁵ and two Average Fuel Economy standards.⁴⁶ Only one of these rules, Designated Seating Positions, was listed as including a preemptive provision in the codified regulation.⁴⁷ That rule is also the only rule listed where NHTSA believed further action was warranted.⁴⁸

⁴⁰ 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 in 2009) between 2006-10 during which time Sharkey was working on various research projects concerning agency preemption of state law.

⁴¹ 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.

⁴² 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 74–81 and accompanying text.

⁴³ Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 66 Fed. Reg. 65,376, 65,402 (Dec. 18, 2001).

⁴⁴ Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 69 Fed. Reg. 70,904, 70,912 (Dec. 8, 2004).

⁴⁵ Event Data Recorders, 71 Fed. Reg. 50,998, 51,029–30 (Aug. 28, 2006).

⁴⁶ 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 115–119 and accompanying text).

⁴⁷ Letter from Robert S. Rivkin, *supra* note 32, at 7.

⁴⁸ 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.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 the academy—of aggressive preemptive rulemaking during the Bush II Administration. According to the American Association for Justice 2008 Report, over the period from 2001 to 2008, NHTSA issued more regulations claiming preemption than any other federal agency, accounting for nearly half (twenty-four of fifty-three) of all preemptive rulemakings.⁴⁹ Moreover, as of July 2010, AAJ compiled a list of seven proposed NHTSA rules and seven final rules from 2007 to 2009 that “still contain preemption language.”⁵⁰

The discrepancy between NHTSA's own report and that of 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 contain “boilerplate” language on preemption.⁵¹ In a recent 2010 rulemaking on Electric-Powered Vehicles, in response to AAJ, NHTSA denied that the boilerplate language was intended to preempt state law and relayed the history of the evolution of the language over time to make this clear.⁵² According to NHTSA, the boilerplate simply describes the possibility that preemption could occur if there is an actual “conflict”

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.

⁴⁹ 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.

⁵⁰ Email from Sarah Rooney, AAJ, to Professor Catherine M. Sharkey (July 20, 2010) (on file with author).

⁵¹ Each of the rules on AAJ's list from 2007-09, *see supra* note 50, 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.

⁵² Federal Motor Vehicle Safety Standards; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection, 75 Fed. Reg. 33,515, 33,524 (June 14, 2010) (claiming that AAJ's discerning of preemptive intent in the boilerplate “fundamental[ly] misunderstand[s]” NHTSA's intent).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

between state and federal law, as was the case in *Geier*, and no more.⁵³ 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.⁵⁴ Given that the Presidential Memorandum on Preemption directs agencies to review all rules “intended by the department or agency to preempt state law,”⁵⁵ it is not surprising that NHTSA 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?

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.⁵⁶

What NHTSA terms its “clarifying” actions in the preemption realm began in late summer 2008, and in fact preceded the May 20, 2009 Presidential Memorandum on

⁵³ *Id.* (citing *Geier v. Am. Honda Corp.*, 529 U.S. 861 (2000)).

⁵⁴ *Id.*

⁵⁵ Presidential Memorandum on Preemption, *supra* note 20.

⁵⁶ *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.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Preemption.⁵⁷ But only in its recent 2010 rulemaking on Electric-Powered Vehicles did NHTSA provide a comprehensive account of the removal of preemptive language from three 2005 rulemakings and the evolution of the boilerplate preemption language 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.⁵⁸ NHTSA now admits that the three 2005 NPRMs “contrast markedly” with their other 2007-09 rules that use boilerplate language.⁵⁹ For each rule, NHTSA had identified a specific potential conflict or obstacle state tort law would pose for each of the federal standards.

(i) *Rearview Mirror Rule*

The 2005 NPRM for the Rearview Mirror Rule paradoxically asserted preemption while disclaiming any federalism impacts 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.⁶⁰ 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.”⁶¹

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 vehicles.⁶² Though the Act applied only to cars whereas NHTSA’s rule was targeted at straight trucks, NHTSA

⁵⁷ 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).

⁵⁸ 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).

⁵⁹ 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).

⁶⁰ 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)).

⁶¹ *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.

⁶² Cameron Gulbranson Kids Transportation Safety Act of 2007, Pub. L. No. 110-189 § 2(b).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

decided to withdraw the NPRM in order to take a “comprehensive look at backing safety for all types of motor vehicles.”⁶³

In March 2009, NHTSA issued a revised Advanced NPRM for rearview mirrors.⁶⁴ This revised ANPRM replaced the preemption language with boilerplate stating there was a “possibility” the MVSA would preempt state law, but NHTSA stated “we do not know of any State laws or regulations that currently exist that are potentially at risk of being preempted.”⁶⁵ For implied preemption, NHTSA said it had “considered today’s ANPRM and [did] not currently foresee any potential State requirements that might conflict with it. Without any conflict, there could not be any implied preemption.”⁶⁶

(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.”⁶⁷ 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.”⁶⁸

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, OMB 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.⁶⁹

The Roof Crush Rule also caught Congress’ attention. NHTSA’s preemptive rule was touched upon during Congress’ wide ranging 2007 hearing on regulatory

⁶³ See Federal Motor Vehicle Safety Standards; Rearview Mirrors, 73 Fed. Reg. 42,309, 42,312 (July 21, 2008).

⁶⁴ Federal Motor Vehicle Safety Standard; Rearview Mirrors; Proposed Rule, 74 Fed. Reg. 9477 (Mar. 4, 2009).

⁶⁵ *Id.* at 9516.

⁶⁶ *Id.*

⁶⁷ Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,246 (Aug. 23, 2005).

⁶⁸ *Id.* at 49,245.

⁶⁹ Jeffrey Rosen and Steve Wood met with NAAG and NCSL at a meeting at OMB. Sharkey Interview with Wood, June 30, 2010.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

preemption.⁷⁰ 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.⁷¹ Members from both sides of the aisle criticized NHTSA. Senator Coburn (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.⁷²

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

⁷⁰ 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 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.

⁷¹ *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-9d35-56cc7152a7ed&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”).

⁷² 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. 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 71.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

“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.”⁷³

(iii) *Designated Seating Position Amendment*

The Designated Seating Position Amendment is 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 language.⁷⁴

The original final rule was issued in October 2008 and still contained the preemptive text. After the 2008 rule, both AAJ and Public Citizen petitioned NHTSA to reconsider. AAJ argued that neither express nor implied preemption was warranted: express preemption was contrary to congressional intent and *Geier* was an “unusual, fact driven case” that rested on a range of options available under the rule and its lengthy history.⁷⁵ 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.⁷⁶

After reconsideration, NHTSA removed the preemptive 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.⁷⁷ 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.⁷⁸

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

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

⁷⁵ 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.

⁷⁶ 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>.

⁷⁷ 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 76.

⁷⁸ 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

NHTSA replaced the preemptive text with boilerplate language claiming conflict preemption was theoretically possible, but that NHTSA could discern none.⁷⁹ The agency included a lengthy explanation of “How NHTSA’s Regulations May Give Rise to a *Judicial Finding of Preemption*”⁸⁰ as well as a detailed explanation of how it believes *Geier* should be interpreted.⁸¹ NHTSA’s bottom line was that “[a] court should not find preemption too readily in the absence of clear evidence of a conflict.”⁸²

(b) *Evolution of Boilerplate Preemption Language*

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.⁸³ NHTSA’s recent rulemakings from 2008 to 2010 include a variation on the boilerplate language.⁸⁴

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 *potential* to preempt, succinctly stating “Without any conflict, there could not be any implied preemption.”⁸⁵

crush rule and took part in the notice-and-comment process, did not submit any comment on the seating designated seating position rule. *Id.*

⁷⁹ *Id.* at 68,187-88.

⁸⁰ *Id.* at 68,187-88 (emphasis added).

⁸¹ 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.*

⁸² *Id.* at 68,188.

⁸³ 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)).

⁸⁴ 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.

⁸⁵ 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).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

(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.”⁸⁶

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 potential State requirements that might conflict with it. Without any conflict, there could not be implied preemption.”⁸⁷

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.⁸⁸ 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.”⁸⁹

NHTSA and AAJ continue to disagree over the interpretation of the boilerplate language. This ACUS Report has identified twenty-nine NHTSA rules with preemption boilerplate language that NHTSA did not include in its list to OIRA.⁹⁰ These rules can be

⁸⁶ 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.

⁸⁷ 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).

⁸⁸ 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].”).

⁸⁹ 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).

⁹⁰ 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.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

grouped into three broad categories of NHTSA’s evolving boilerplate.⁹¹ Eleven rules follow NHTSA’s most 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.”⁹² Five rules from 2008 state that NHTSA “cannot completely rule out the possibility that conflict might become apparent.”⁹³ And eleven rules from mid-2007 through mid-2008 state that while NHTSA had not identified a conflict, a conflict creating preemption was “conceivable.”⁹⁴

⁹¹ 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). 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).

⁹² 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).

⁹³ 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).

⁹⁴ 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,

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

(ii) *Express Preemption Language*

In addition to its evolving boilerplate implied preemption language, 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 unequivocal statement that the Motor Vehicle Safety Act preempted all “State law” that was not identical to the NHTSA standard.⁹⁵

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.”⁹⁶ The clear import is that state common law does not fall within the purview of express preemption claims.

NHTSA officials were not able to explain the reasoning behind this shift in language.⁹⁷

3. *Litigation*

(a) *Automobile Safety Standards*

NHTSA has taken an anti-preemption position in *Williamson v. Mazda Motor of America, Inc.*,⁹⁸ a case pending this Term before the U.S. Supreme Court that will define

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).

⁹⁵ 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.”).

⁹⁶ Federal Motor Vehicle Safety Standard; Air Brake Systems, 74 Fed. Reg. 9173, 9175 (emphasis added).

⁹⁷ Sharkey Interview with Wood; follow-up emails.

⁹⁸ 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

the scope of the Court’s implied preemption holding in *Geier*.⁹⁹ 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.”¹⁰⁰ 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.¹⁰¹ Because of this broadening of *Geier* preemption, the brief seeks, like NHTSA’s rulemaking shift,¹⁰² to clarify the “acknowledged confusion” and “widespread error in lower courts over the decade since *Geier*”¹⁰³

The rule at issue in *Williamson* allowed manufacturers to choose between lap-belts and shoulder-belts for the middle seat position in cars.¹⁰⁴ 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.¹⁰⁵ The California state appellate court held that 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 cert.¹⁰⁶

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.”¹⁰⁷

state common-law claim alleging that the manufacturer should have installed a lap/shoulder belt in one of those seating positions?

Id. at i.

⁹⁹ *Geier v. Am. Honda Corp.*, 529 U.S. 861 (2000).

¹⁰⁰ Brief for the United States as Amicus Curiae, *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314, at 17 (Apr. 2010).

¹⁰¹ *Id.* at 17-18 (citing many federal and state cases).

¹⁰² Specifically, in NHTSA’s December 2009 Designated Seating Position Amendment rule, the agency set forth a similar interpretation of *Geier*. See *supra* note 81 and accompanying text.

¹⁰³ Brief for the United States as Amicus Curiae, *Williamson*, No. 08-1314, at 21.

¹⁰⁴ *Id.* at 1-4.

¹⁰⁵ See *Williamson v. Mazda Motor of Am., Inc.*, 167 Cal. App. 4th 905, 908–910 (2008) (describing trial court order).

¹⁰⁶ *Id.* at 919; Brief for the United States as Amicus Curiae, *Williamson*, No. 08-1314, at 6–8.

¹⁰⁷ Brief for the United States as Amicus Curiae, *Williamson*, No. 08-1314, at 9 (citing 49 U.S.C. § 30102(a)(9) (2010)).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 preempt state tort law, aside from situations where the agency's affirmative policy presents an outright conflict, as in *Geier*.¹⁰⁸

(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).¹⁰⁹ 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.¹¹⁰ 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.¹¹¹ 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.¹¹²

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 "indirectly" affects fuel economy standards. Its amicus brief argued that "indirect" regulation like taxicab lease rates should not be preempted, but does not take a position on "direct" regulation.¹¹³ Moreover, NHTSA has not stated a clear position on how it

¹⁰⁸ 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 refused to disavow its boilerplate preemption language, rejecting 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*.

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

¹¹⁰ 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).

¹¹¹ See Brief for the United States as Amicus Curiae, *Metropolitan Taxicab Board of Trade v. City of New York*, No. 09-2901-CV, at 9 (2d Cir. Jan. 15, 2010).

¹¹² *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.'").

¹¹³ See *id.* at 12 & n.3.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 may drive NHTSA’s position.¹¹⁴

NHTSA’s position also appears to be in line with a recent shift in policy. Originally, the text of the NHTSA’s 2006 NPRM on Average Fuel Economy Standards for Light Trucks Model Years 2008-2011¹¹⁵ claimed “broad preemption” under the EPCA of all state laws related to fuel economy standards, including those regulating greenhouse gases.¹¹⁶ 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 2011.¹¹⁷ 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*.¹¹⁸ 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.¹¹⁹

¹¹⁴ See Brief for the United States as Amicus Curiae, *Metropolitan Taxicab*, No. 09-2901-CV, at 14 (“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))).

¹¹⁵ See 71 Fed Reg. 17,566 (Apr. 6, 2006).

¹¹⁶ See *id.* at 17,654-70 (stating that regulating CO2 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).

¹¹⁷ 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.”).

¹¹⁸ *Id.* at 787-88.

¹¹⁹ 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. Crombie*, 508 F. Supp. 2d 295 (D. Vt. 2007); *Cent. Valley Chrysler-Jeep, Inc. v. Goldstene*, 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.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

In affirming the district court’s decision, 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.”¹²⁰

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 Bush II Administration for its efforts to preempt state tort law while skirting the requirements of E.O. 13132.¹²¹ According to the AAJ study, from 2001 to 2008, FDA issued twenty of the fifty-three total regulations issued by federal agencies claiming preemption, second only to NHTSA.¹²² 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.¹²³ The U.S. Supreme Court refused to rely upon the preemption preamble in *Wyeth v. Levine*.¹²⁴

But unlike the case of NHTSA, there is at best subtle evidence from the regulatory record and intervention in pending litigation from which to assess whether FDA has revised its preemption policy under the Obama Administration. Sharkey’s interview with FDA’s Chief Counsel provided some (albeit limited) evidence of a change in tone on preemption at the agency.¹²⁵

¹²⁰ *Metropolitan Taxicab Board of Trade v. City of New York*, No. 09-2901-CV, 2010 WL 2902501, at *5 (2d Cir. July 27, 2010).

¹²¹ See, e.g., Sharkey, *Federalism Accountability*, *supra* note 14, at 2131–41.

¹²² See AM. ASS’N FOR JUSTICE, *supra* note 49 (note that this total included proposed rules that had not yet resulted in a final or interim final rule).

¹²³ Sharkey, *Federalism Accountability*, *supra* note 14, at 2131-34.

¹²⁴ 129 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.’”).

¹²⁵ Sharkey Interview with Ralph Tyler, Chief Counsel, FDA, July 6, 2010, 4–5 PM. ~~Sharkey made numerous attempts to reach additional officials at FDA, but none was willing to talk with her. (Sharkey did speak with one FDA employee, but it was to conduct an interview with her in her capacity as former Regulatory Counsel at AAJ.)~~

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Fuller exposition of the FDA's position on preemption is expected when the Solicitor General responds to the U.S. Supreme Court's call for its views in two generic drug preemption cases.¹²⁶

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.~~there was "no systematic retrospective look under way."~~¹²⁷

Prospectively, the Chief Counsel explained that "we seek to avoid finding preemption when we can in a principled way."¹²⁸

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), the FDA Law Blog points out that 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),¹²⁹ the

¹²⁶ See 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).

¹²⁷ 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, July 6, 2010, 45-5:30 PM.~~Sharkey attempted to confirm this information speaking with other officials in FDA who may have additional information that pre-dates the Chief Counsel's tenure at FDA. To date, she had not received responses to her numerous emails and telephone calls. Sharkey also requested information and/or a copy of any such report from Kevin Neyland at OIRA, who referred her back to the agency.~~

¹²⁸ Sharkey Interview with Ralph Tyler, Chief Counsel, FDA, July 6, 2010, 4-5 PM.~~Id.~~

¹²⁹ 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-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.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Final Rule contained only limited discussion of express preemption that does not preempt state law as clearly as the NPRM did.¹³⁰

On the other hand, FDA has continued to assert some preemptive effect in its rules—most recently the Skin Protectant and Bottled Water rules.¹³¹ The Skin Protectant rule, issued one month before the over-the-counter drug labeling rule, likewise interprets preemption under § 379r(a).¹³² The rule claims express preemption under 379r(a) with a justification similar to the NPRM in the OTC Drug rule, and also claims implied

¹³⁰ 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.

¹³¹ 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).

¹³² 21 U.S.C. § 379r(a) (2006).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

preemption under *Geier*.¹³³ The rule also mentions that FDA reached out to state and local officials on preemption and received no comment.¹³⁴

The Bottled Water rule asserts preemption under a different provision of the FDCA: § 403A’s preemption of misbranded food regulation.¹³⁵ 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)).¹³⁶

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.¹³⁷ 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.”¹³⁸ 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 has fully analyzed the issues—may explain the opacity of FDA’s position to date.

The U.S. Supreme Court has called for the views of the Solicitor General on whether to grant certiorari in two circuit court cases,¹³⁹ raising the issue whether *Wyeth*’s

¹³³ 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).

¹³⁴ *Id.*

¹³⁵ *See* Final Rule on Beverages: Bottled Water, 74 Fed. Reg. 25,651, 25,664.

¹³⁶ *Id.*

¹³⁷ *See* 73 Fed. Reg. 53,775, 53,791-92 (Sept. 17, 2008).

¹³⁸ 74 Fed. Reg. 25,651, 25,664 n.3.

¹³⁹ *See* *PLIVA, Inc. v. Mensing*, No. 09-993 (2010); *Actavis Elizabeth v. Mensing*, No. 09-1039 (2010); *see also* SCOTUSWIKI, http://www.scotuswiki.com/index.php?title=PLIVA%2C_Inc._v._Mensing%3B_Actavis_Elizabeth_v._Mensing (last visited Aug. 25, 2010).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

holding extends to blocking preemption claims by *generic* drug manufacturers.¹⁴⁰ 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.¹⁴¹

The lower courts¹⁴² (and the majority of courts addressing the issue¹⁴³) rejected preemption. In *Mensing v. Wyeth*, the Eighth Circuit held that because generic manufacturers could have proposed a labeling change to the 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.¹⁴⁴

In a separate consolidated appeal in the Sixth Circuit raising the same generic drug preemption issue,¹⁴⁵ the court asked the FDA for its opinion by July 29, 2010. DOJ

¹⁴⁰ 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 has 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).

¹⁴¹ 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.

¹⁴² See *Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009); *Demahy v. Actavis, Inc.*, 2010 WL 46513 (5th Cir. Jan. 8, 2010).

¹⁴³ 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).

¹⁴⁴ See *Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009).

¹⁴⁵ *Smith v. Wyeth*, No. 09-5460 (6th Cir.); *Wilson v. Pliva*, No. 09-5466 (6th Cir.); *Morris v. Wyeth*, No. 09-5509 (6th Cir.).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

responded, however, that the court would have to await the Solicitor General's response to the Supreme Court.¹⁴⁶

The Solicitor General's (and presumably FDA's) response to the U.S. Supreme Court will be the first statement of the FDA's position on preemption under the Obama Administration. The FDA gave an earlier hint that its position might be different than that under the previous Bush II Administration. Shortly after the Obama Administration took office, DOJ withdrew an amicus brief submitted by FDA in *Colacicco v. Apotex, Inc.*¹⁴⁷

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."¹⁴⁸ 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.¹⁴⁹ The United States argued before the Third Circuit that it is not the preamble that preempts 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.¹⁵⁰

¹⁴⁶ DOJ responded:

The Acting Solicitor General intends to file an amicus brief with the Supreme Court setting forth the Government's view on the preemption issues raised in the *Mensing* cases, which are the same issues as those in the above-captioned cases pending before this Court.

In view of this, the Government respectfully requests 14 days from the date it files a brief with the Supreme Court to respond to this Court's request.

See David Walk, *Preemption and Generic Drugs: the Department of Justice Tells the Sixth Circuit to Get in Line Behind the Supreme Court*, DRUG & DEVICE L. (July 29, 2010, 5:10 PM), <http://druganddevicelaw.blogspot.com/2010/07/preemption-and-generic-drugs-department.html>.

¹⁴⁷ 521 F.3d 253 (3d Cir. 2008), *vacated*, *Colacicco v. Apotex Inc.*, 129 S.Ct. 1578 (2009) (mem.).

¹⁴⁸ *Id.* at 271.

¹⁴⁹ *Id.* at 274–75 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134 (1994)).

¹⁵⁰ 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.

Beginning in 2000, FDA has 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

The U.S. Supreme Court vacated and remanded *Colacicco* in light of *Wyeth*.¹⁵¹ 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.”¹⁵²

C. OCC

In 2009, the Office of the Comptroller of the Currency (OCC), using a rule it had issued claiming preemption through its interpretation of the National Bank Act (NBA),¹⁵³ preempted states from enforcing their consumer protection laws against national banks, thwarting the states’ asserted interest in protecting consumers from discrimination and predatory lending.¹⁵⁴ The Supreme Court invalidated this preemptive action in *Cuomo v. Clearing House Association*.¹⁵⁵ 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.*¹⁵⁶

The Visitorial Powers preemptive rule in *Cuomo* was first proposed in 2004, along with a broader preemption 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.’”¹⁵⁷ 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

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).

¹⁵¹ *Colacicco*, 129 S. Ct. 1578. The Third Circuit then remanded the consolidated cases back to their respective district courts. The district court removed GlaxoSmithKline as a party after it dismissed claims against GSK unrelated to preemption. *See Colacicco v. Apotex, Inc.*, Civ. Action No. 05-5500, 2009 WL 4729883, at *1 (E.D. Pa. Dec. 10, 2009). The case against Apotex, the generic drug manufacturer, remains pending. *See id.* at *5 (denying motion to transfer venue to the Eastern District of New York).

¹⁵² 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).

¹⁵³ 12 C.F.R. § 7.4000.

¹⁵⁴ *See Clearing House Ass’n v. Cuomo*, 510 F.3d 105, 119 (2d Cir. 2007).

¹⁵⁵ 129 S. Ct. 2170 (2009).

¹⁵⁶ 550 U.S. 1 (2007).

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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

returned from recess.¹⁵⁸ 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.¹⁵⁹ 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.¹⁶⁰ A 2005 GAO Report criticized the OCC's disregard of state interests in passing the preemptive rules at issue in *Cuomo* and *Watters*.¹⁶¹

Sharkey conducted a telephone interview with a group of OCC officials.¹⁶² From the perspective of the OCC officials, preemption is a "tool for conducting nationwide business."¹⁶³ 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

¹⁵⁸ 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.").

¹⁵⁹ See generally *id.*; *Review of the National Bank Preemption Rules: Hearings Before the S. Comm. on Banking, Hous., and Urban Affairs*, 108th Cong. (2004).

¹⁶⁰ 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.

¹⁶¹ 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 (2005), available at <http://www.gao.gov/new.items/d068.pdf> [hereinafter 2005 GAO REPORT]

¹⁶² Participants in the telephone interview conducted by Sharkey (August 5, 2010) were: Horace Sneed, Director of the Litigation Division; Karen Solomon, Director for Legislative and Regulatory Activities; Michele Meyer, Assistant Director for Legislative and Regulatory Activities; Ursula Bass, Counsel for Legislative and Regulatory Activities; and Michael Jordan, Senior Counsel in the Litigation Division [hereinafter OCC Telephone Interview].

¹⁶³ OCC Telephone Interview.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

incorporate under national charters, increasing its revenues and its budget.¹⁶⁴ Chartering fees are OCC's primary source of revenue.¹⁶⁵ Congress recognized that the OCC itself admitted that preemption was about chartering fees, and reform was needed.¹⁶⁶

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. 13132.¹⁶⁷

I. Response to May 2009 Presidential Memorandum on Preemption

The OCC's law department conducted a review and submitted it to OIRA in August 2009.¹⁶⁸ OCC identified eight preemptive rulemakings since 1999 and concluded that, with one exception, all were "justified under the established legal principles that

¹⁶⁴ See Wilmarth, Jr., *supra* note 14, at 20.

¹⁶⁵ See Oren Bar-Gill & Elizabeth Warren, *Making Credit Safer*, 157 U. PA. L. REV. 1, 93-94 (2007).

¹⁶⁶ 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.").

¹⁶⁷ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 § 315 (2010) (amending 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.

¹⁶⁸ 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 Horace Sneed.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

govern national bank preemption, including the principles in E.O. 13132.”¹⁶⁹ The one exception—the Visitorial Powers rule—was deemed in need of further revision in light of *Cuomo*.¹⁷⁰ But, according to OCC officials, OCC determined that, prior to undertaking revisions to rules, it would await the end of the legislative process.¹⁷¹

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.¹⁷²

OCC’s response to the Presidential Memorandum was comprehensive.¹⁷³ 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*

¹⁶⁹ *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.

¹⁷⁰ *Id.* (“We are currently preparing revisions to that regulation to conform with the Court’s decision in *Cuomo*.”).

¹⁷¹ 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.

¹⁷² Williams Memorandum to Neyland, *supra* note 168, at 4.

¹⁷³ A parallel Lexis search conducted by my research assistant, Matthew Shahabian, did not turn up any additional preemption 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 asks only for preemptive regulations.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

standard for preempting state law, omitting “significantly impairs” from the standard for conflict preemption.¹⁷⁴ 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*,¹⁷⁵ it is not clear this standard is still appropriate after Congress’s addition of “significantly” to the *Barnett* standard in the Dodd-Frank Act.¹⁷⁶

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.¹⁷⁷ Congress recently passed the Dodd-Frank Wall Street Reform and Consumer Protection Act.¹⁷⁸ Under the Dodd-Frank Act, OCC is reformed as an independent regulatory agency within the Department of the Treasury¹⁷⁹ and assumes some of the powers of the Office of Thrift Supervision (OTS).¹⁸⁰

Additionally, the Act creates a “Bureau of Consumer Financial Protection” to promulgate and enforce federal financial consumer protection laws.¹⁸¹ For financial consumer protection, Congress inserted a general preemption standard provision that

¹⁷⁴ 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.”).

¹⁷⁵ See Williams Memorandum to Neyland, *supra* note 168, 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*).

¹⁷⁶ See *infra* notes 185–194 and accompanying text.

¹⁷⁷ 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.

¹⁷⁸ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).

¹⁷⁹ See *supra* note 167 and accompanying text.

¹⁸⁰ Dodd-Frank Wall Street Reform and Consumer Protection Act §§ 312(b)(2)(B), 314.

¹⁸¹ *Id.* § 1011. The Bureau will likewise be an independent regulatory agency, and therefore not subject to EO 13132. *Id.* § 1100D(a).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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,¹⁸² and state law that is “inconsistent” with federal law is only preempted to the extent of the inconsistency.¹⁸³ 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.¹⁸⁴

In the highly contentious “*Barnett* paragraph,” Congress modified 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;¹⁸⁵ (2) in accordance with *Barnett Bank v. Nelson*,¹⁸⁶ state law “prevents or significantly interferes with the exercise by the national bank of its powers”;¹⁸⁷ 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

¹⁸² *Id.* § 1041(a)(2).

¹⁸³ *Id.* § 1041(a)(1).

¹⁸⁴ *Id.* § 1041(a)(2).

¹⁸⁵ *Id.* § 1044(a) (modifying 12 U.S.C. § 5136C(b)(1)(A)).

¹⁸⁶ 517 U.S. 25 (1996).

¹⁸⁷ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying § 5136C(b)(1)(B)). There is debate on 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)).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

“on a case-by-case basis.”¹⁸⁸ “Case-by-case basis” is defined as evaluating one specific state law at a time, not blanket preemption.¹⁸⁹ The OCC can attempt to preempt more than one state’s law at a time if it determines the laws of multiple states are “substantively equivalent,” but OCC must consult with the Bureau when determining whether state law is “substantively equivalent.”¹⁹⁰

According to the OCC officials, the *Barnett* paragraph does not alter the status quo because OCC’s preemptive rulemakings have explicitly cited *Barnett*.¹⁹¹ Nor, in their opinion does the “case-by-case basis” language exclude categorical preemptive rulemakings.¹⁹² 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.¹⁹³ Moreover, former OCC Comptroller John Hawke coauthored a client report on the financial reform bill for his law firm, Arnold & Porter, in which he wrote that preemption of state consumer financial laws by OCC “must be made on a ‘case-by-case’ basis.”¹⁹⁴

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

¹⁸⁸ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying 12 U.S.C. § 5136C(b)(1)(B)).

¹⁸⁹ *Id.* (modifying 12 U.S.C. § 5136C(b)(3)(A)).

¹⁹⁰ *Id.* (modifying 12 U.S.C. § 5136C(b)(3)(B)).

¹⁹¹ OCC Telephone Interview. *But see supra* note 187 (presenting debate on this issue).

¹⁹² *Id.*

¹⁹³ *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).

¹⁹⁴ Doyle et al., *supra* note 187, at 2–3 (stating that OCC has “leeway” for broader preemption under the substantively equivalent/consultation provision).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.”¹⁹⁵ Thus, preemption of state laws regulating issues like bank registration would not be subject to this provision.¹⁹⁶

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.¹⁹⁷

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.¹⁹⁸ This list must be forwarded to both the House Committee on Financial Services and the Senate Committee on Banking, Housing and Urban Affairs.¹⁹⁹ Given the OCC’s new designation as an independent regulatory agency,²⁰⁰ 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.²⁰¹

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—

¹⁹⁵ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying 12 U.S.C. § 5136C(a)(2)).

¹⁹⁶ See Doyle et al, *supra* note 187, at 2.

¹⁹⁷ 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 187, 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* . . .”).

¹⁹⁸ Dodd-Frank Wall Street Reform and Consumer Protection Act § 1044(a) (modifying § 5136C(d)(1)).

¹⁹⁹ *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.”).

²⁰⁰ See *supra* note 167 and accompanying text.

²⁰¹ *Id.* (modifying § 5136C(G) (“Transparency of OCC Preemption Determinations”)).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

both in the form of statutory law and tort law.²⁰² In the Senate Judiciary Committee’s hearing on regulatory preemption, Senators criticized the CPSC’s inclusion of the preemptive preamble in its mattress rule.²⁰³

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).²⁰⁴ Three of the four “transferred acts” contain express preemption clauses.²⁰⁵ 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,²⁰⁶ [but] the opposite is true of the FFA,²⁰⁷ and the cases are mixed with respect to preemption of common law under the PPPA.”²⁰⁸

²⁰² Final Rule: Standard for the Flammability (Open-Flame) of Mattress Sets, 71 Fed. Reg. 13,472, 13,496. (Mar. 15, 2006); *see* Sharkey, *Preemption by Preamble*, *supra* note 4, at 227, 230-33.

²⁰³ *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).

²⁰⁴ 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)).

²⁰⁵ The Refrigerator Safety Act does not. *See* 15 U.S.C. §§ 1211–1214.

²⁰⁶ FUNK ET AL., CPSC, *supra* note 204, 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)).

²⁰⁷ *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 more recent clothing textile rulemaking. FUNK ET AL., CPSC, *supra* note 204, at 7 (citing *Standard for the Flammability of Clothing Textiles*, 73 Fed. Reg. 15,636 (Mar. 25, 2008)).

²⁰⁸ *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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

The main statute under CPSC's jurisdiction, the Consumer Product Safety Act, contains both a preemption clause²⁰⁹ and a savings clause.²¹⁰ Several courts, following the Supreme Court's reading of the interplay between preemption and savings clauses in *Geier*, have found state tort law preempted.²¹¹ Against the backdrop of these court preemption decisions and the CPSC's preemption preamble, Congress passed the Consumer Product Safety Improvement Act of 2008,²¹² 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.²¹³

Sharkey conducted an interview with the General Counsel at CPSC.²¹⁴ Similar to the experience with NHTSA, the change in Administration and the Presidential Memorandum on Preemption seem to have had a pronounced effect on rulemaking and intervention in litigation at the CPSC. In sum, compared to its activities under the Bush II 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.

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

As Amy Widman explains, the Consumer Product Safety Improvement Act of 2008 (CPSIA)²¹⁵ was less a response to CPSC preemption and more a response to the "implosion" of the agency and the "fever pitch" of recalls in 2007 that forced Congress to act to strengthen product safety protection generally.²¹⁶ In addition to strengthening

common law claim because the suit was filed against a bulk packager, not a packager of retail products)).

²⁰⁹ 15 U.S.C. §§ 2074-2075.

²¹⁰ § 2074(a).

²¹¹ 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 204, at 4-5 & nn.6-12 (describing various court decisions).

²¹² Pub. L. No. 110-314, 122 Stat. 3016 (Aug. 14, 2008).

²¹³ *Id.* at § 231(a); see also *FUNK ET AL.*, CPSC, *supra* note 204, at 8.

²¹⁴ Sharkey interview with Cheryl Falvey, General Counsel, CPSC, July 7, 2010.

²¹⁵ Pub. L. No. 110-314, 122 Stat. 3016.

²¹⁶ See 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.”²¹⁷

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).²¹⁸ 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),²¹⁹ while Republicans were pleased that the bill preempts the “confusing” patchwork of state laws on lead regulation.²²⁰ The conference report notes that the bill “reiterat[es]” existing preemption standards while “preserv[ing]” state laws.²²¹

bans. FUNK ET AL., *supra* note 204, at 9-11; Widman, *supra*, at 12–16 (describing Bush CPSC as “a shell of an agency”).

²¹⁷ 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).

²¹⁸ 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).

²¹⁹ 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 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>.

²²⁰ 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Unlike the Dodd-Frank financial reform bill,²²² 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.²²³ 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.²²⁴

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.²²⁵ They identified five or six rules, including the mattress flammability rule, which were marked for the agency to go back and remove the preemptive language (which had yet to be done).²²⁶

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.²²⁷

3. *Rulemaking*

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.”).

²²¹ 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.

²²² *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 381–382 and accompanying text.

²²³ *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.).

²²⁴ FUNK ET AL., *supra* note 204, at 8.

²²⁵ Sharkey Interview with Falvey. Repeated requests via email and telephone by Sharkey for the actual report submitted to OMB were not answered.

²²⁶ *Id.*

²²⁷ *Id.*

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.²²⁸ 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.²²⁹

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

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.”²³⁰ The rule on labeling for children’s toy advertisements does not address preemption.²³¹

²²⁸ *Id.* Again, repeated requests by Sharkey for a listing of the relevant rules were not answered.

²²⁹ 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).

²³⁰ 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).

²³¹ Labeling Requirement for Toy and Game Advertisements; Final Rule, 73 Fed. Reg. 67,730 (Nov. 17, 2008).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.²³² 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.²³³

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 Bush Administration, the agency likely would have taken a position.²³⁴ The General Counsel mentioned the example of a recent Illinois statute, the Lead Poisoning Prevention Act of 2010,²³⁵ which prescribes a labeling requirement for lead in toys. If the CPSC issues warning labels for lead, state labeling requirements are preempted.²³⁶ Proponents of the Illinois statute argue that, because there is no current federal lead labeling standard for children’s toys, the FHSA preemption provision is not triggered.²³⁷ Commentators have noted that this statute is likely to be challenged.²³⁸

²³² Sharkey Interview with Falvey.

²³³ Testing and Labeling Pertaining to Product Certification [Children’s Toys], 75 Fed. Reg. 28,336, 28,361 (May 20, 2010).

²³⁴ Sharkey Interview with Falvey.

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

²³⁶ 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).

²³⁷ 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.²³⁹

E. FTC

The Federal Trade Commission (FTC), like CPSC, is an independent regulatory agency,²⁴⁰ and as such, is not formally required to submit to the provisions of EO 13132.²⁴¹ In contrast with the CPSC, however, the FTC has consistently refrained from preemption.

The FTC administers many statutes within the purview of consumer protection. Some of these statutes contain express preemption provisions from Congress,²⁴² others give the FTC express authority to preempt "inconsistent" state law.²⁴³ 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."²⁴⁴ Additionally, the preemption explicitly only

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.

²³⁸ 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>.

²³⁹ Sharkey Interview with Falvey.

²⁴⁰ 44 U.S.C. § 3502(5) (2006)

²⁴¹ 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 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)).

²⁴² E.g. Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(b) (2006).

²⁴³ 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).

²⁴⁴ E.g. Gramm-Leach-Bliley Act, 15 U.S.C. § 6807(a).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

preempts *weaker* state laws, as the statute allows the FTC to save state law that provides stronger protection.²⁴⁵

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.²⁴⁶ 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.²⁴⁷ Members of Congress have at times expressed frustration with the FTC's indifference towards preemption of state law.²⁴⁸ 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.²⁴⁹

²⁴⁵ § 6807(b).

²⁴⁶ 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.").

²⁴⁷ 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).

²⁴⁸ 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 Consumer Protection Bureau J. Howard Beales, III, he has been "disappointed" with Administration's "unwillingness" to push for renewal of credit reporting preemption).

²⁴⁹ Testifying in front of Congress in 2003, former Director of the Consumer Protection Bureau J. Howard Beales simply outlined the positives of preemption (national uniformity) and the positives 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Sharkey conducted an interview with the Director of the Consumer Protection Bureau at the FTC.²⁵⁰ The Director takes the position—relying upon a law review article by Paul Verkuil²⁵¹—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.²⁵²

I. Response to May 2009 Presidential Memorandum on Preemption

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)

²⁵⁰ Sharkey Interview with David Vladeck, Director, Bureau of Consumer Protection, Federal Trade Commission, July 1, 2010.

²⁵¹ 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.

²⁵² 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 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. 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; see also, e.g., David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95 (2005).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

FTC apparently did not file a report with OMB in response to the Presidential Memorandum on Preemption.²⁵³ 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.²⁵⁴

2. *Rulemaking*

FTC cited the Presidential Memorandum on Preemption in its 2009 rule on disclosing breaches of patient information confidentiality under HIPAA.²⁵⁵ In the section on preemption, FTC noted that the stimulus bill incorporated the Social Security Act’s express preemption provision.²⁵⁶ 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.²⁵⁷ 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,

²⁵³ Sharkey Interview with Vladeck.

²⁵⁴ *See, e.g.*, 75 Fed. Reg. 21,951 (Apr. 26, 2010); 72 Fed. Reg. 70,199 (Dec. 10, 2007).

²⁵⁵ 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.

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).

²⁵⁶ 12 U.S.C. § 1320d-7.

²⁵⁷ 74 Fed. Reg. 42,962, 42,966.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

and the state laws do not thwart the objectives of the federal law, there is no conflict between state and federal law.”²⁵⁸

3. *Litigation*

In the past, 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,²⁵⁹ and that FTC regulation of cigarette advertising and labeling impliedly preempted the plaintiffs’ claims.²⁶⁰ The United States filed an amicus brief, which the FTC joined, on behalf of the plaintiffs.²⁶¹ The FTC took the position that its regulation of cigarette advertising and labeling did *not* impliedly preempt state tort law.²⁶²

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.”²⁶³ 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.”²⁶⁴

²⁵⁸ *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”).

²⁵⁹ *See Altria Group, Inc. v. Good*, 129 S. Ct. 538, 542 (2008).

²⁶⁰ *See id.* at 549.

²⁶¹ Brief for the United States Amicus Curiae Supporting Respondents, *Altria*, 129 S. Ct. 538 (No. 07-562).

²⁶² *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.”).

²⁶³ 129 S. Ct. 538, 551 (2008). 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.

²⁶⁴ *Id.* at 559 (citing Brief for the United States as Amicus Curiae, at 16–33).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.²⁶⁵ Whereas other federal agencies blatantly sidestepped the consultation and reporting requirements of E.O. 13132, the EPA published its official policies on how to comply with 13132.²⁶⁶ 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.²⁶⁷

Sharkey conducted in-person interviews with several EPA officials.²⁶⁸

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.²⁶⁹ All

²⁶⁵ See Sharkey, *Federalism Accountability*, *supra* note 14, at 2159-60.

²⁶⁶ 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).

²⁶⁷ See Sharkey, *Federalism Accountability*, *supra* note 14, at 2159-60.

²⁶⁸ 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, ~~Associate General Counsel~~ Attorney Advisor, Cross-Cutting Issues Law Office, Office of General Counsel; Sonja ~~Roedman~~, 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.

²⁶⁹ Email from Nicole Owens, EPA to Dominic J. Mancini, OMB, “Re: Preemption guidance,” Aug. 4, 2009, 08:24 AM; *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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

nine of these rules preempted state law through express statutory preemption, not using 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 controls²⁷⁰ and sulfur fuel controls.²⁷¹ 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 EO 13132.²⁷² 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 13132 under the "preemption" provision.²⁷³ For all four of the

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.

²⁷⁰ 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).

²⁷¹ 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).

²⁷² 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.").

²⁷³ 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).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

CAA rules, EPA noted that it met and consulted with state and local officials in developing each rule.²⁷⁴

EPA listed two rules that preempted state regulation of hazardous materials under the Toxic Substances Control Act (TSCA).²⁷⁵ 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.²⁷⁶ 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 13132.²⁷⁷

EPA listed two rules regulating the transportation of hazardous materials, promulgated with the Department of Transportation.²⁷⁸ 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).²⁷⁹ 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.²⁸⁰ State and local officials were also invited to participate in the EPA work group developing the rule.²⁸¹ The other HMTA rule, promulgated before EO 13132 took effect, preempted state law by clarifying the interaction between the HMTA and the CAA.²⁸² EPA, interpreting the CAA, said that

²⁷⁴ 73 Fed. Reg. 59,034, 59,172 (describing consultation with Nat’l Ass’n of Clean Air Agencies and that states 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).

²⁷⁵ 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).

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

²⁷⁷ *Id.*

²⁷⁸ 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).

²⁷⁹ 70 Fed. Reg. 10,776, 10,813.

²⁸⁰ *Id.*

²⁸¹ *Id.*

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.²⁸³

Finally, EPA also listed a rule preempting state law under the Clean Water Act.²⁸⁴ Another pre-13132 rule, this rule again used statutory preemption, as the CWA preempts state law regulating discharges once the EPA sets standards.²⁸⁵ 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.”²⁸⁶

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*.”²⁸⁷ As Denise Scheberle explains, many of the more formal EPA/state coordination efforts began in earnest during the early years of the Clinton administration.²⁸⁸ 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

²⁸² 64 Fed. Reg. 28,696, 28,698

²⁸³ *Id.*

²⁸⁴ Uniform National Discharge Standards for Vessels of the Armed Forces, 64 Fed. Reg. 25,126 (May 10, 1999).

²⁸⁵ *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 . . .”).

²⁸⁶ *Id.* at 25,129.

²⁸⁷ 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).

²⁸⁸ *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).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

EPA’s working relationship with the states and reducing the costs of implementing federal environmental statutes.”²⁸⁹ The most current iteration of the NEPPS plan (FY 2008-2011) lists several objectives for the partnership between EPA and the states.²⁹⁰ 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.”²⁹¹

III. RECOMMENDATIONS

There appears to be 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 while the Reagan-era Federalism Executive Order (E.O. 12612) was in effect²⁹²—that included a federalism impact statement.²⁹³ The Clinton-era (continued under the Bush and Obama administrations) E.O. 13132 has been met with similar indifference and neglect. Professors Mendelson and Sharkey have documented striking evidence of agencies’ flouting their responsibility to conduct federalism impact statements.²⁹⁴

²⁸⁹ 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).

²⁹⁰ See OFFICE OF CONG. & INTERGOVERNMENTAL RELATIONS, *supra* note 287, at 3-4.

²⁹¹ *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.

²⁹² Exec. Order No. 12,612, 52 Fed. Reg. 41,685 (Oct. 26, 1987).

²⁹³ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO/T-GGD-99-93, IMPLEMENTATION OF EXECUTIVE ORDER 12612 IN THE RULEMAKING PROCESS 1 (1999).

²⁹⁴ See 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.”); Mendelson, *Chevron*, *supra* note 14, at 783–84 (demonstrating that federalism impact statements are relatively rare and of “poor quality”); see also Mendelson, *Presumption*, *supra* note 14, at 719 (reporting

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Any reform recommendation must confront this backdrop of decades of dissatisfaction with the enforcement of the federalism mandates. Professors Nicolaidis 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.²⁹⁵

The goal of any reform effort 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 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.

This ACUS 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 “Big 7.”²⁹⁶ Given that with respect to the 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,²⁹⁷ additional input was solicited from representatives of state judges, state attorneys general, and various consumer groups. The Report recommends a novel NAAG notification procedure, modeled after the Class Action Fairness Act settlement Attorney General notification provision.

Finally, the Report recommends that OIRA/OMB publish the agency reports on compliance with the Presidential Memorandum on Preemption and update its guidance document on compliance with E.O. 13132. A more robust reform is proposed whereby OIRA would include review of federalism implications as part of its regulatory review process.

results from a further study of 2006 preemptive rules, which disclosed only a single substantive federalism impact statement out of six preemptive rules).

²⁹⁵ KALYPSO NICOLAIDES & ROBERT HOWSE, *THE FEDERAL VISION: LEGITIMACY AND LEVELS OF GOVERNANCE IN THE UNITED STATES* 131 (2001).

²⁹⁶ The “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.

²⁹⁷ See Sharkey, *Federalism Accountability*, *supra* note 14, at 2158-63.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

A. Agencies

1. Internal Guidelines on Federalism Executive Order (13132)

Internal agency guidelines on federalism 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 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,"²⁹⁸ 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. 13132.²⁹⁹ This step-by-step process is organized both textually and with flow charts that make it useful for staff on the ground implementing EO 13132. Moreover, all the information necessary to write the FIS and comply with 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.³⁰⁰ The Guidance document provides flowcharts for

²⁹⁸ U.S. ENV'T'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.").

²⁹⁹ 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.

³⁰⁰ *See id.* at i-ii.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

determining if a rule has federalism implications under 13132.³⁰¹ It explains how to calculate costs to determine if the rule has substantial federalism effects.³⁰² 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 and local] governments[?]”³⁰³ 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.”³⁰⁴

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.³⁰⁵ 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.”³⁰⁶ These standing representatives are to be consulted to determine if the rule preempts state law and has federalism implications,³⁰⁷ to prepare a consultation plan, and to review draft FISs.³⁰⁸

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.³⁰⁹ While inclusion of such contact

³⁰¹ See *id.* at 36-39.

³⁰² *Id.* at 32–34 (“Guidance for Implementing the Federalism ‘1% Test’”).

³⁰³ *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).

³⁰⁴ *Id.* at 5.

³⁰⁵ *Id.* at 14–18.

³⁰⁶ See, e.g., *id.* at 7.

³⁰⁷ See *id.* at 7, 14, 18.

³⁰⁸ See *id.* at 19–20.

³⁰⁹ *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.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

information may seem basic, it is apparently missing at other agencies. Members of the “Big Seven” frequently tell anecdotes about misdirected correspondence from agencies.³¹⁰

The EPA document addresses questions like “How much consultation is enough?”³¹¹ 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.³¹² 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.³¹³

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. 13132.³¹⁴

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 guidelines³¹⁵—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.

³¹⁰ 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.

³¹¹ EPA GUIDANCE, *supra* note 298, at 21 (“For rules with FI . . . at a minimum you should consult . . . with *each* of the relevant representative national organizations in the Big 10.”).

³¹² *Id.* 23–24.

³¹³ *Id.* at 49–51 (“Attachment E”).

³¹⁴ *Id.* at 24.

³¹⁵ Sharkey Interview with Ralph Tyler, Chief Counsel, FDA.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

The Department of Transportation (within which NHTSA lies) uses a 1988 document “DOT Guidance: Federalism,”³¹⁶ which provides some constructive direction on improving the rulemaking process. It suggests agencies should include federalism notices in the notice of proposed rulemaking (NPRM).³¹⁷ And it suggests that agencies should err on the side of including a federalism assessment, even if the impact is “borderline.”³¹⁸

That said, the DOT Guidance document leaves much to be desired. As an initial matter, it is out-of-date. The 1988 Guidance document is based on President Reagan’s 1987 E.O. 12612, which was superseded in 1999 by E.O. 13132. Several provisions from E.O. 13132 are therefore not reflected in the DOT Guidance document. For example, Section 6 of E.O. 13132 mandates that agencies engage in “meaningful and timely” consultation with the States “early in the process of developing the proposed regulation.”³¹⁹

The DOT Guidance document is therefore not a stand-alone, self-contained manual with all of the relevant information for agency officials to conduct a federalism analysis and to ensure compliance with E.O. 13132. Moreover, its direction is—especially as compared to EPA’s Guidance document—vague and unspecific at times. For example, in describing the depth of a federalism assessment, the document states:

The Assessment should be of whatever length and analytic justification are necessary to describe the likely effects, possible alternatives, and the rationale for each position chosen. Although the approach and depth of the document will vary according to the circumstance, it is not anticipated that in most cases it will substantially increase the amount of analysis already being performed.³²⁰

From this guideline, it is not clear how much is “necessary,” or whether an official is even supposed to do anything at all if the assessment is not supposed to “substantially increase” the analysis being performed. Additionally, the definition of “sufficient” federalism implications is too vague to provide definitive guidance.³²¹

³¹⁶ U.S. DEP’T OF TRANSP., DOT GUIDANCE: FEDERALISM (1988) [hereinafter DOT GUIDANCE]. This document was provided to Sharkey by Neil Eisner, Ass’t General Counsel for Regulation and Enforcement, Dep’t of Transportation.

³¹⁷ *See id.* at VIII.A.1 (stating consultation should take place through notice and comment proceedings).

³¹⁸ *Id.* at III.B.3.

³¹⁹ Exec. Order No. 13,132 §6(b)–(c).

³²⁰ DOT GUIDANCE, *supra* note 316, at V.D.

³²¹ *Id.* at V.A. (“The same kind of analysis that is used to determine whether an action is ‘major’ under E.O. 12291, ‘significant’ under the Department’s Regulatory Policies and Procedures, or has a ‘significant economic impact on a substantial number of small entities’ under the Regulatory Flexibility Act should generally be used to determine the sufficiency of the federalism implications.”).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

OCC operates with a one-page excerpt on E.O. 13132 contained within its 2005 “Guide to OCC Rulemaking Procedures: A Staff Manual.”³²² In a 2005 report investigating OCC preemption, GAO criticized OCC’s lack of a detailed regulatory process and singled out the fact that OCC did not have written guidance, policies or procedures for the rulemaking process, but instead relied upon a barebones “rulemaking checklist.”³²³ The OCC Guide, dated December 2005, two months after the GAO Report, does not seem to advance much beyond the “checklist” approach—at least as concerns E.O. 13132. The guide to E.O. 13132 is a single page: it explains who the OCC’s Federalism official is, states that the project attorney makes an initial federalism assessment which is checked by the federalism official, states generally what to include in an FIS, and explains that the Conference of State Bank Supervisors (CSBS) is the main state contact for federalism issues (primarily through the notice-and-comment process, occasionally through meetings when OCC determines it is “appropriate”).³²⁴

OCC officials explained that all rulemaking is centralized within the Division of Legislative and Regulatory Activities.³²⁵ There is no separate track for preemptive rulemakings; the federalism compliance review is done as part of the rulemaking documents. OCC officials conceded that, as a formal matter, in terms of internal guidelines for compliance with Executive Order 13132, the procedures are “a bit out of date.” As they described, there is a checklist and narrative description of aspects of rulemaking that should be considered and the requirements of E.O. 13132 are described. The OCC officials emphasized that, informally, because the law department is a relatively small office, the supervisor for any particular rulemaking ensures that a federalism analysis is conducted where necessary.

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

³²² OFFICE OF THE COMPTROLLER OF THE CURRENCY, GUIDE TO OCC RULEMAKING PROCEDURES: A STAFF MANUAL (2005) [hereinafter OCC GUIDE]. This document was provided to Sharkey by Horace Sneed, Director for Litigation, OCC.

³²³ 2005 GAO REPORT, *supra* note 161, at 5. For its report, the GAO reviewed the relevant documents for the proposed and final preemption rules, interviewed OCC officials who participated in OCC’s promulgation of the rules and analyzed documents from its docket files. *Id.* at 4.

³²⁴ OCC GUIDE, *supra* note 322, at 17–18.

³²⁵ OCC Telephone Interview. This ensuing paragraph is based upon the interview.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

an FIS because the rule would impose “substantial compliance costs” on the states (defined as greater than \$25 million), citing its Guidance document.³²⁶ 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.³²⁷ Moreover, 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 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. 13132.³²⁸ NHTSA likewise came under fire for bypassing state consultation.³²⁹ And finally the 2005 GAO Report criticized OCC for failing to document any of its consultation with state representatives and officials during the rulemaking process.³³⁰ GAO also noted that the representative state groups felt OCC did not do an adequate job in consulting them in the rulemaking process.³³¹ Though the OCC disputed most of the

³²⁶ 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).

³²⁷ *Id.*

³²⁸ *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 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.”).

³²⁹ 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).

³³⁰ 2005 GAO REPORT, *supra* note 161, at 1.

³³¹ *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)

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

GAO's factual findings, they did agree the E.O. 13132 consultation process needed to be improved and stated they were already making reforms.³³²

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 nine national organizations as being representative of state and local government officials for purposes of complying with the consultative requirements of E.O. 13132.³³³ Such elected officials 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.³³⁴ When state government groups intervene in preemption disputes,

(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").

³³² See 2005 GAO REPORT, *supra* note 161, at 46-47. 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.

³³³ The "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. The additional two include the National Association of Towns and Townships and the County Executives of America.

³³⁴ 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 78 (mentioning that NCSL failed to submit any comment to NHTSA during its reconsideration of the Designated Seating Position Amendment rule); *supra* note 130 (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-

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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 rulemakings included in AAJ's study,³³⁵ 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).³³⁶ NCSL submitted two comments and the state attorneys general submitted three (one under the auspices of the National Association of Attorneys General (NAAG)).³³⁷

(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.³³⁸ (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.³³⁹ Moreover, the EPA Office of Congressional and Intergovernmental Relations hosts quarterly meetings with the Big Ten.³⁴⁰ It would behoove the other federal agencies to compile an updated contact list for

the-counter labeling rule); *supra* note 134 (mentioning that no states commented on FDA Skin Protectant rule).

³³⁵ See AM. ASS'N FOR JUSTICE, *supra* note 49.

³³⁶ 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).

³³⁷ *Id.*

³³⁸ Sharkey Interview with OCC Officials.

³³⁹ See *supra* note 309.

³⁴⁰ Sharkey Interview with EPA Officials.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

reaching out to the “Big Seven” and also to consider establishing some form of regularized personal contact in order to build relationships.³⁴¹

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 notes that EPA formally consulted with the states under E.O. 13132 in only two of thirty Clean Air Act regulations it had issued.³⁴² 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.”³⁴³ Terranova also notes three examples of NPRMs where EPA solicited comment from state and local officials.³⁴⁴ According to EPA, these consultations have led to direct implementation of specific recommendations from the states.³⁴⁵

Over the past three years, EPA determined that a rule invoked E.O. 13132 in two final regulations and one NPRM.³⁴⁶ For each of these rules, EPA noted the steps it took

³⁴¹ 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).

³⁴² Terranova, *supra* note 289, 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).

³⁴³ *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)).

³⁴⁴ *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)).

³⁴⁵ See, e.g., 71 Fed. Reg. 60,612, 60,629–30 (Oct. 13, 2006) (Regional Haze Regulations).

³⁴⁶ 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.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.³⁴⁷

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.”³⁴⁸ Accordingly, EPA consulted with Colorado state and local government “early in the process . . . to permit meaningful and timely input”³⁴⁹ 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.”³⁵⁰ Also, EPA similarly consulted with the appropriate state coordinators at various conferences to regulate pollution from stormwater discharges.³⁵¹

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.³⁵² 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

³⁴⁷ 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).

³⁴⁸ 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).

³⁴⁹ *Id.*

³⁵⁰ *Id.*

³⁵¹ *See* Effluent Limitations Guidelines and Standards for the Construction and Development Point Source Category, 74 Fed. Reg. 62,966, 63,055–56 (Dec. 1, 2009).

³⁵² Tire Fuel Efficiency Consumer Information Program, 75 Fed. Reg. 15,894 (Mar. 30, 2010). *See also supra* note 78 (describing NHTSA’s consultation outside of E.O. 13132 with state and local officials during its reconsideration of the Designated Seating Position Amendment rule).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.³⁵³

(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.³⁵⁴

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.³⁵⁵ With OCC, CSBS developed the model consumer complaint forms to standardize information sharing.³⁵⁶ For state chartered banks that establish interstate

³⁵³ *Id.* at 15,941–42 (emphasis added).

³⁵⁴ Sharkey Interview with EPA Officials; Sharkey Telephone Interview with Steve Brown, Executive Director, ECOS, July 30, 2010.

³⁵⁵ 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.*

³⁵⁶ 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

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

branches, CSBS helped negotiate a nationwide state/federal agreement for overlapping regulatory spheres,³⁵⁷ and has negotiated several other agreements and understandings with federal regulators involved in banking.³⁵⁸ CSBS frequently comments on regulatory proposals from federal agencies involved in banking,³⁵⁹ and also occasionally files amicus briefs on behalf of state banking regulators.³⁶⁰ 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 [the Conference of State Bank Supervisors], the extent to which it consulted with state officials appears limited.”³⁶¹

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>.

³⁵⁷ 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.

³⁵⁸ *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>.

³⁵⁹ 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).

³⁶⁰ *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.

³⁶¹ 2005 GAO REPORT, *supra* note 161, at 19.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.³⁶² 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 passenger capacity), and a representative from the National School Transportation Association.³⁶³

(iii) *Introduce NAAG 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 National Association of Attorneys General (NAAG). 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.³⁶⁴ 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.

³⁶² 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>.

³⁶³ 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”).

³⁶⁴ 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).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

The addition of a NAAG 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.

NAAG has challenged federal agencies' decisions to preempt state law, often via amicus briefs. Historically, NAAG, too, has focused its opposition to preemption in areas of robust state regulation, such as environmental law, banking, and consumer protection.³⁶⁵ 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 Bureau must issue a notice of proposed rulemaking on the issue.³⁶⁶ 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.³⁶⁷ Under the Act, state AGs also have the power to bring lawsuits against banks in order to *enforce* federal regulations issued by the Bureau.³⁶⁸

³⁶⁵ 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 protection laws as asserted by both OCC and the soon-to-be-defunct Office of Thrift Supervision. *Id.*

CPSC Chairman has a monthly call with state AGs on consumer protection issues. Sharkey Interview with Falvey.

³⁶⁶ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 § 1041(c) (2010).

³⁶⁷ *Id.* § 1041(c)(2)-(3).

³⁶⁸ *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).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

But in addition to advocating state interests in preserving state positive law, NAAG has also intervened to protest preemption of state common law.³⁶⁹ The NAAG 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.³⁷⁰

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.³⁷¹ There are no provisions for any “meaningful” consultation outside of the notice-and-comment process or before the NPRM is published.³⁷² OCC likewise maintains that the primary mechanism of consultation with the states is the notice-and-comment procedure.³⁷³

³⁶⁹ 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).

³⁷⁰ OMB Guidance for Implementing 13132, *supra* note 30.

³⁷¹ DOT GUIDANCE, *supra* note 316, at 6 (“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 . . .”).

³⁷² 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.

³⁷³ Sharkey Interview with OCC Officials.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.³⁷⁴

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.³⁷⁵ 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.

Exhibit A 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.³⁷⁶ First,

³⁷⁴ See, e.g., Freeman, *supra* note 341, 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.”).

³⁷⁵ Sharkey, *Products Liability Preemption*, *supra* note 150, at 477–521 (developing agency reference model); see also Sharkey, *Federalism Accountability*, *supra* note 14, at 2130 (“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.”).

³⁷⁶ 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 217, 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 217, 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.”).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

after further testing by NHTSA, the Final Rule disclaimed the NPRM’s argument that improving roof safety would also increase rollover propensity.³⁷⁷ 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.”³⁷⁸ 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.”³⁷⁹ 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 under the “hard look” review standard of the agency reference model.³⁸⁰

The “substantial evidence” provision in the Dodd-Frank Wall Street Reform and Consumer Protection Act—which requires agency preemption determinations to be evaluated under a “substantial evidence” standard³⁸¹—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.”³⁸² This *Skidmore* standard for review is likewise consistent with the agency reference model.

Exhibit B 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.”³⁸³ Indeed, both the Final Rule³⁸⁴ and the NPRM³⁸⁵ read like legal briefs (complete with argument

³⁷⁷ 74 Fed. Reg. 22,382.

³⁷⁸ *Id.*

³⁷⁹ *Id.* at 22,382–83.

³⁸⁰ Sharkey Interview with Steve Wood, June 30, 2010.

³⁸¹ 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)).

³⁸² *Id.* (modifying § 5136C(b)(5)(A)).

³⁸³ *Clearing House Ass’n v. Cuomo*, 510 F.3d 105, 119 (2d Cir. 2007).

³⁸⁴ *Bank Activities and Operations*, Final Rule, 69 Fed. Reg. 1895 (Jan. 13, 2004).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

subheadings), not like agency rulemakings.³⁸⁶ 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.³⁸⁷ Rather, the rule laid out an argument for why OCC was legally allowed to preempt state law, and responded to CSBS’s arguments that OCC was not authorized to preempt state law and that preemption would undermine the dual state/federal banking system.³⁸⁸

OCC officials expressed skepticism that the “substantial evidence” standard would appreciably affect their rulemakings, apart from perhaps mandating explicit reference to the new standard.³⁸⁹ One of the OCC attorneys specifically cited *American Bankers Association v. Lockyear*,³⁹⁰ as an example where the OCC has made factual findings to support preemption determinations in the past. In *Lockyear*, 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.³⁹¹ 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.³⁹² The court agreed with OCC’s interpretation and found California law preempted.³⁹³ 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.³⁹⁴ It is notable that OCC’s West

³⁸⁵ Rules, Policies, and Procedures for Corporate Activities; Bank Activities and Operations; Real Estate Lending and Appraisals, NPRM, 68 Fed. Reg. 6363 (Feb. 7, 2003).

³⁸⁶ *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.”).

³⁸⁷ 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).

³⁸⁸ 69 Fed. Reg. 1896–1903.

³⁸⁹ Sharkey Interview with OCC Officials.

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

³⁹¹ *Id.* at 1002–04.

³⁹² *Id.* at 1013–15.

³⁹³ *Id.* at 1022.

³⁹⁴ See *id.* at 1015.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

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.³⁹⁵ Given this level of specificity and the significant factual findings made by the OCC in *Lockyear*, 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.³⁹⁶

B. OIRA/OMB

1. *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 prevailing view that the Presidential Memorandum on Preemption was simply a political statement, not really intended to induce any significant agency action or follow-up with respect to the 10-year retrospective review.³⁹⁷

³⁹⁵ *Id.*

³⁹⁶ 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. 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.

³⁹⁷ 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,

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

Moreover, publication of these reports would—along with publication of agency’s internal guidelines on compliance with E.O. 13132—signal renewed focus and attention on the part of agencies to issues of federalism and agency preemption of state law.

2. *Update 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.³⁹⁸ OMB/OIRA should bring this document up to date. Here would be an appropriate place to include a current list of state consultation groups and their contact information. OMB/OIRA should also publish the designated federalism officials and consultation plans from each of the agencies, along with the agencies’ internal guidelines for compliance with E.O. 13132.

This Report’s survey of federal agencies found spotty compliance with these mandates and no evidence of OMB/OIRA review. 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.³⁹⁹ 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.”⁴⁰⁰ 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 accord.⁴⁰¹ 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.”⁴⁰² This summary offers little by way of guidance.

3. *Include Review of Federalism Implications in Regulatory Review Process*

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).

³⁹⁸ Exec. Order No. 13,132 § 6(a); OMB Guidance for 13132, *supra* note 30, at 4–5.

³⁹⁹ 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.

⁴⁰⁰ DOT 3/13/00 letter, *supra* note 399, at 1.

⁴⁰¹ *Id.* at 1–4.

⁴⁰² *Id.* at 3.

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

At present, OIRA is responsible for monitoring agencies' compliance with E.O. 13132. To date, OIRA's enforcement efforts have been limited at best.⁴⁰³ Some scholars have suggested that this is because OMB sees its primary role as cost reduction, not regulatory oversight.⁴⁰⁴ 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. 13132.⁴⁰⁵ The American Bar Association has proposed coordinated review of agency preemption decisions by OMB, OIRA, the Department of Justice, or some other unspecified agency.⁴⁰⁶

⁴⁰³ 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).

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.

⁴⁰⁴ See 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). Certification to OIRA for compliance with E.O. 13132 is limited to “significant” rules of at least \$100 million in impact as defined by E.O. 12866. Compare Sharkey, *Federalism Accountability*, *supra* note 14, at 2177 & n.207, with *id.* at n.207 (describing EPA implementation threshold at only \$25 million).

⁴⁰⁵ 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 EO 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), *available at* http://www.progressivereform.org/articles/ExecOrder_Preemption_809.pdf.

⁴⁰⁶ AM. BAR ASS’N, TASK FORCE ON PREEMPTION RECOMMENDATION REPORT (manuscript at 8) (2010); see also Am. Bar Ass’n, H.R. 117, Tort Law Preemption Issues (2010), *available at* http://www.abanow.org/wordpress/wp-content/files_flutter/1282164714Resolution117Summary080910.doc (passing resolution on preemption).

PRELIMINARY DRAFT: FOR COMMITTEE REVIEW

OIRA's inclusion of review of federalism implications in its regulatory review process is likely to be the most effective enforcement mechanism for independent regulatory review. For certain regulations—those subject to OMB review under the cost-benefit order (E.O. 12866)⁴⁰⁷—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.⁴⁰⁸ But OMB is given little to review; 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. Moreover, OIRA could review the federalism impact statements required for all rulemakings with “federalism implications.” The recommendation is that OIRA include review of federalism implications within its checklists under the A-4 circular.⁴⁰⁹

⁴⁰⁷ The required certification to OMB is required only for “significant” regulations, defined as having an annual effect on the economy of at least \$100 million.

⁴⁰⁸ Exec. Order No. 13,132 § 6(a).

⁴⁰⁹ See OFFICE OF INFO. & REGULATORY AFFAIRS, CIRCULAR A-4 ON REGULATORY ANALYSIS (2003), available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.