

# FEDERAL AGENCY PREEMPTION OF STATE LAW

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## EXECUTIVE SUMMARY

### Background

Federal agency preemption of state law (including common law) is a significant, high-profile issue. Federal preemption can be *express*, i.e., Congress has included an explicit preemption provision in a statute, or *implied* by the overall structure and purpose of the regulatory scheme. Implied preemption has two further categories: *field*, whereby the federal regulation leaves no room for any state regulation in the defined area or field, or *conflict*, whereby only state law that is incompatible with the federal regulation is displaced. Finally, implied conflict preemption comes in two varieties: *impossibility*, denoting that it is impossible to comply with the mandates of the competing state and federal law requirements, and *obstacle*, which characterizes a broader form of displacement of state law that frustrates the purpose or goals of the federal regulatory scheme.

Federal agencies play a significant role in determinations of federal preemption of state law by promulgating federal regulations with preemptive effect and by proffering their views on the extent to which state law conflicts with federal regulatory goals. Federal agencies play a significant role in statutory interpretation. While Congress, with the stroke of a pen, could definitively resolve preemption questions, simply by clearly specifying the fate of state law when it enacts legislation, the reality is that Congress often falls short of this benchmark. Where Congress is less than pellucid, courts play an increasing role in deciding preemption questions. 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—in regulations, in regulatory preambles, or in litigation briefs—have held sway in the courts.

Agency interpretations of preemption have come under enhanced scrutiny in the past few years. 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, the U.S. Supreme Court looked with particular disdain upon the procedural irregularities that accompanied the FDA's inclusion of its statement of preemptive intent in the preamble to its drug labeling rule. The FDA's approach to "preemption by preamble" bypassed vetting the agency's position through the notice-and-comment process as well as the state consultation mandates of the Federalism Executive Order 13132. Accordingly, the Court did not accord deference to the FDA's pro-preemption position. The disregard shown by the FDA (and other federal agencies) towards procedural and consultative requirements for preemption determinations increases 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. Courts defer to agency interpretations of ambiguous statutory language under the *Chevron* doctrine, but whether

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courts should similarly to defer to agency interpretations that *preempt* state law has been the subject of an ongoing debate.

On May 20, 2009, President Barack Obama issued a Presidential Memorandum which, in addition to articulating the new Administration's policy on preemption, condemned the practice of "preemption by preamble" (where preemption statements are included in the preamble, but not in the codified regulation) 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.

The Federalism Executive Order 13132 is adverted to in Obama's Presidential Memorandum and also serves as the centerpiece of numerous reform proposals for agency preemption of state law. E.O. 13132 identifies federalism principles and policymaking criteria and designates specific procedures for intergovernmental consultation. The Order designates special requirements for agencies in taking action that preempts state law. The Order emphasizes consultations with State and local governments and enhanced sensitivity to their concerns. E.O. 13132 also requires agencies to provide a federalism impact statement (FIS) whenever regulations will have federalism implications and preempt state law. The Order applies to all federal agencies, except for independent regulatory agencies, which are nonetheless encouraged to comply voluntarily with its provisions.

There appears to be a near-consensus that the procedural requirements of the Federalism Executive Order—including consultation with the states and the requirement for FISs—are sound. But the E.O. 13132 has been a perennial source of discontent. A 1999 GAO Report identified a paltry five rules—out of a total of 11,000 issued between April 1996 and December 1998—that included a federalism impact statement. Professors Mendelson and Sharkey have documented further empirical evidence and case examples of agencies' disregard of their responsibility to conduct federalism impact statements.

### **Federal Agency Case Studies: NHTSA, FDA, OCC, CPSC, FTC, EPA**

A central contribution of this Report is an evaluation of agencies' responses to President Obama's Memorandum on Preemption and efforts taken to ensure compliance with the relevant provisions of E.O. 13132 governing preemptive rulemaking. This empirical work, focusing on agencies' awareness of the issue and their compliance efforts, draws from extensive interviews with agency officials as well as an independent review of the agencies' respective rulemaking docket and intervention in litigation. Sharkey conducted sets of in-person and telephone interviews with officials at each of the federal agencies surveyed (NHTSA, FDA, OCC, CPSC, FTC, EPA). Sharkey also extensively reviewed the respective federal agency's rulemaking and intervention in litigation over the past decade in publicly available databases.

The May 2009 Presidential Memorandum on Preemption garnered the attention of federal agencies and led to serious internal review, at least in the majority of agencies surveyed. Officials at NHTSA, OCC, CPSC, and EPA provided Sharkey with either a report or information regarding the agency's ten-year retrospective review of all rules intended to preempt state law.

Moreover, both the change in Administration and the Presidential Memorandum on Preemption have had wider-ranging effects in terms of shifts in preemption policy within the agencies.

- This policy shift has been most pronounced at the National Highway Traffic Safety Administration (NHTSA). On the rulemaking front, NHTSA removed the preemptive language in two 2005 rulemakings and, beginning in 2008 but especially in 2009, has drafted increasingly

toned down “boilerplate” language on the possibility of preemption that 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 the Court’s previous implied preemption holding in *Geier v. American Honda Motor Co.*, which the Court will revisit in *Williamson*.

- The Consumer Product Safety Commission (CPSC)—an independent regulatory agency, technically not bound by E.O. 13132—has also experienced a significant shift in its rulemaking and intervention in litigation, largely at the behest of Congressional direction. CPSC has adopted an extremely cautious stance on preemption. In its rulemakings, the 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. Due to the then-pending invitation for the Solicitor General to submit its views on implied preemption to the U.S. Supreme Court, which is considering granting certiorari in a pair of generic drug preemption cases, agency officials were less forthcoming with information. There is some evidence from the regulatory record and intervention in pending litigation from which to infer that FDA has revised its preemption policy under the new Administration. In its most recent rulemakings, the agency appears to be proceeding full speed ahead with respect to express statutory preemption, but pulling back from its prior reliance on *Geier* implied preemption.
- At the Office of the Comptroller of the Currency (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 the Act effectively shifts review of OCC rulemaking from the Executive to Congress.
- The Federal Trade Commission (FTC), like CPSC (and now OCC), is an independent regulatory agency, and as such, is not formally required to submit to the provisions of E.O. 13132. In contrast with both the CPSC and OCC, however, the FTC has consistently refrained from preemption.
- Finally, like FTC, the Environmental Protection Agency (EPA) stands in fairly sharp relief against the background of the history of preemptive actions by NHTSA, FDA, and OCC. Preemption in EPA rules is relatively rare, and always pursuant to express statutory provisions. Moreover, EPA has a unique relationship with the states as co-regulators that has facilitated a more careful, deliberative stance on preemption.

## **Recommendations**

The Report’s recommendations are directed towards federal agencies with the twofold goals of (1) creating a “home” within agencies for consideration of the federalism values at stake in preemptive rulemaking and ensuring participation in the rulemaking process by suitable representatives of the state regulatory interests; and (2) establishing a system of internal agency policing of the empirical and factual predicates to arguments for preemption, coupled with external oversight exercised by the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB).

### *Agency Internal Guidelines on Procedures for Implementing the Preemption Provisions of the Federalism Executive Order 13132*

Agencies should be encouraged to develop comprehensive internal guidelines on compliance with the preemption provisions of E.O. 13132. Of the agencies surveyed, 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. Agencies should cite their own internal guidelines in federalism impact statements 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.

### *Agency Internal Oversight*

Such internal guidelines should be coupled with an internal oversight procedure, whereby the agency scrutinizes the underlying factual predicate or empirical claims in support of any preemptive stance. Moreover, to the extent possible, this internal agency scrutiny must be insulated from political pressures.

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. The core idea is to force the agency to provide documented empirical evidence that supports its preemption conclusion and then to submit the factual predicate to some systematic scrutiny within the agency. The agency should be required to identify and analyze the data that demonstrates the existence of the asserted factual predicate of a conflict between state law and the federal regulatory scheme. This empirical evidence should be included in a document signed by the head of the program office and inserted into the public docket for the rulemaking. The rulemaking notice should note the existence of the document and invite comment on it.

### *Agency Consultation with the States*

Two separate, albeit related, issues present formidable challenges with respect to E.O. 13132's state consultation mandate. First, it is not at all clear who best represents state regulatory interests, particularly in the context of consumer health and safety issues. OMB has specifically designated "The Big Seven" national organizations as being representative of state and local government officials for purposes of complying with the consultative requirements of E.O. 13132. And the Report recommends that agencies reach out to the "Big Seven," ideally earlier in the rulemaking process than the notice-and-comment phase. 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. It is by no means clear who represents the interests served by state tort law. Further, 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. Most rules with potential preemptive power receive no comments from state or local government officials or their representatives.

Given the twin problems of identifying appropriate representatives of state regulatory interests and the paucity of comments during the rulemaking process from state governmental organizations, this Report proposes the introduction of a novel notification provision to the Attorneys General and to the National Association of Attorneys General (NAAG). The addition of an Attorney General notification provision would provide a formal mechanism to a party that is well positioned to alert any and all interested participants in the rulemaking process. It is premised on the intuition that not all interested participants comb the Federal Register for relevant rulemakings and the exclusive singling out of the Big Seven organizations may no longer make sense, particularly in light of the rise of rulemakings that preempt state tort law.

### *OIRA's Role*

Within OMB, OIRA has primary responsibility for implementing E.O. 13132.

#### *1. Direct Agencies to Publish Reports of Agency Compliance with the Presidential Memorandum*

Publication of the reports of agency responses to the Presidential Memorandum's directive to conduct a 10-year retrospective review of preemptive rulemaking would, at least in part, debunk one view that the Presidential Memorandum on Preemption 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. Publication of these reports would—along with individual agency's publication of internal guidelines on compliance with E.O. 13132—signal renewed focus and attention on the part of agencies to issues of federalism and agency preemption of state law.

#### *2. Update OMB Guidance Document*

OMB's 1999 Guidance document for implementing 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. OMB/OIRA should bring this document up to date. In an effort to encourage greater transparency with respect to agency compliance with E.O. 13132, OMB/OIRA should also direct agencies to publish their designated federalism officials and consultation plans (along with the agencies' internal guidelines for compliance with E.O. 13132). Here would be an appropriate place to include a current list of state consultation groups and their contact information.

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

OIRA, as the central coordination locus for regulatory review, is well positioned to be the entity charged with a more thorough review of agency proposals to preempt state law. For certain regulations—those subject to OMB review under E.O. 12866—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. 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. This would go a long way toward enhancing OIRA's level of trust and confidence in the agency's submissions.

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