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Preemption by Preamble: Federal Agencies and the Federalization of Tort Law

Catherine M. Sharkey

PREEMPTION BY PREAMBLE: FEDERAL AGENCIES AND THE FEDERALIZATION OF TORT LAW

*Catherine M. Sharkey**

INTRODUCTION

In the preamble to its January 2006 prescription drug labeling rule, the Food and Drug Administration (FDA) asserted that "FDA approval of labeling under the act . . . preempts conflicting or contrary State law."[1] The latest rule handed down by the Consumer Product Safety Commission (CPSC)—strengthening the requirements for bedding mattresses' ability to withstand fires caused by open flames, such as candles, matches, and lighters—includes a sweeping preamble stating that the new federal standard preempts "inconsistent state standards and requirements, whether in the form of positive enactments or court created requirements."[2] And, if the National Highway Traffic Safety Administration (NHTSA) has its way, a new safety standard for roofs on sport-utility vehicles will include language immunizing auto manufacturers from state tort lawsuits over defective roofs if their autos meet federal safety standards.[3] Dubbed "silent tort reform,"[4] these preemption preambles may be only the tip of the iceberg—a harbinger of a future where federal agency regulations come

* Professor of Law, Columbia Law School; Visiting Professor of Law, Harvard Law School (Spring 2007). I presented earlier versions of this Article at the Twelfth Annual Clifford Symposium at DePaul University College of Law, at law faculty workshops at Chicago-Kent, Iowa, and Tel Aviv Universities, and at a panel at the 2006 Federalist Society National Convention, where participants offered helpful comments. I am especially grateful to Robert Rabin for an insightful oral commentary at the Clifford Symposium. For additional comments and criticisms, I thank Michael Dorf, Jared Goldstein, Roderick Hills, Samuel Issacharoff, Nina Mendelson, Gillian Metzger, Henry Monaghan, Theodore Ruger, Daniel Schweitzer, Peter Strauss, John Witt, and Stephen Wood. Rodman Forter, Aaron Leiderman, and Jaime Sneider provided excellent research assistance.

1. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (effective June 30, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

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

3. *See* Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,247–48 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571).

4. Stephen Labaton, *"Silent Tort Reform" Is Overriding States' Powers*, N.Y. TIMES, Mar. 10, 2006, at C5 ("Supporters and detractors call it the 'silent tort reform' movement, and it has quietly and quickly been gaining ground."); *see also* Kenneth M. Suggs, *Warped Washington*, 42

armed with directives that displace competing or conflicting state regulations or common law as a matter of course.[5]

Federal agency momentum towards increased preemption—evidenced by clear statements in the preambles of issued regulations—fits the broader pattern of what Professor Samuel Issacharoff and I have termed "backdoor federalization."[6] Just as our prior account complicated the characterization of the Rehnquist Court as a staunch ally of states' rights, the agency account I present here also tempers the conventional view.[7] In the "tale of three agencies" that follows, I place the recent aggressive stances adopted by the CPSC, the NHTSA, and the FDA in sharp relief against a historical backdrop of more mixed (and often muted) preemption positions.

Next, analyzing what is at stake in the agency preemption debate, I highlight a discernible trend—both in the U.S. Supreme Court and in lower courts—towards deference to agency preemption determinations. Given the momentum in this direction, I expose a potentially troubling asymmetry: courts appear to grant agencies fairly expansive discretion to interpret or declare the preemptive scope of the regulations they promulgate,[8] but when it comes to inferring private rights of

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TRIAL, Mar. 2006, at 9 ("The other new attack on safety and responsibility is coming from administrative agencies—controlled, of course, by the White House.").

5. Lest this seem hyperbolic, consider this statement by Consumer Product Safety Commissioner Thomas Moore:

> To some, this new preemption language may not seem of much consequence in the mattress context, but it (or something very like it) will be inserted in every new regulation the Commission issues. The consumer's right to sue a manufacturer, potentially any manufacturer of a regulated consumer product, for injuries from that product, may be seriously curtailed. That surely is not without consequence.

U.S. Consumer Product Safety Commission, Statement of the Honorable Thomas H. Moore on the Final Rule and Preamble for the Flammability (Open-Flame) of Mattress Sets (Feb. 16, 2006), http://www.cpsc.gov/cpscpub/prerel/prhtml06/06091.html [hereinafter CPSC Commissioner Moore Statement on the Final Rule and Preamble].

6. Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353 (2006). Our collaborative project offered a positive, analytic account of the momentum towards the federalization of substantive law and forum—as seen by the Rehnquist Court's opinions regarding preemption and federal question subject-matter jurisdiction, and indirectly by its punitive damages jurisprudence. By detailing its jurisprudence in these areas, we portrayed the Court as a willing partner of Congress in providing federal oversight of state interference with the national market. To the extent our project was descriptive of the general momentum towards federalization, the recent federal agency actions essentially confirm our account. To the extent that our account was predictive in the sense that broad product markets increasingly will tend to be regulated nationally, not locally, we seem to be on equally sure footing.

7. *See, e.g.*, Nicholas Bagley, Note, *The Unwarranted Regulatory Preemption of Predatory Lending Laws*, 79 N.Y.U. L. REV. 2274, 2292–93 (2004) ("[T]he Rehnquist Court's revitalization of federalism principles has rendered judicial deference to preemption 'by administrative fiat' increasingly less likely . . . ." (citations omitted)).

8. The Supreme Court's grant of certiorari in *Watters v. Wachovia Bank, N.A.*, 126 S. Ct. 2900 (2006), *argued* Nov. 29, 2006, may provide the Court an opportunity to clarify this area, but it

action under those same regulations, the agencies' hands are tied by judicial tether. Justice Antonin Scalia has colorfully remarked that agencies cannot create causes of action: "Agencies may play the sorcerer's apprentice but not the sorcerer himself."[9] Why can an agency play the role of the sorcerer in the context of preemption, but must remain a lowly apprentice with respect to implied rights of action? At the extreme, a disconcerting scenario emerges, whereby aggressive regulatory preemption, combined with a renewed vigor for eviscerating federal private causes of action, could lead to a nearly complete substitution of public for private enforcement of the law.

Even if the inexorable momentum towards federalization continues, agencies and courts may have means at their disposal to harness this development in service of transparency and, more ambitiously, a new era of accountability. Agencies themselves might foster federalism values by forcing Congress to confront the preemption question it has repeatedly dodged when it regulates products. Alternatively, agencies might emerge as effective representatives of state interests, the situs for a rich, deliberative dialogue regarding the interplay of state law and federal regulatory schemes. Courts might condition deference to agency interpretations of the preemptive scope of regulations on compliance with various congressional and executive measures designed to increase the public participation of states, the legislature, and outside political groups. Consultation mandates, "federalism impact statements,"[10] or even notice-and-comment periods could be required for all preemption statements. Such information-forcing reforms would, at a bare minimum, shed light on what has hitherto been an all-too-quiet, backdoor movement in need of further scrutiny and debate.

II. FEDERALIZING AGENTS: A TALE OF THREE AGENCIES

With the issuance of a series of controversial preambles, federal agencies have recently thrust themselves into the preemption spotlight. What follows is an account of the forays into the preemption debate by three agencies (CPSC, NHTSA, FDA), which I examine in the context of the broader framework of the "backdoor federaliza-

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may be just as likely that the Court instead focuses on the particularities of the National Banking Act. *See infra* Part III.A.

9. Alexander v. Sandoval, 532 U.S. 275, 291 (2001).

10. "Federalism implications" include federal actions that "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." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (proposed Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201).

tion" of products liability. I begin with the relatively obscure CPSC. I then turn briefly to the NHTSA and the FDA, which are not only well-known administrative agencies, but ones whose regulations have been implicated in major preemption decisions before the Supreme Court.

A. *Consumer Product Safety Commission*

Created as an independent federal regulatory agency in 1972 by the Consumer Product Safety Act (CPSA)[11] "to protect the public against unreasonable risks of injuries associated with consumer products,"[12] the CPSC was conceived as a "super-agency" with "authority to regulate all food, drugs, and common household products."[13] The CPSA was "the first legislation since the . . . New Deal to create an independent commission for the purpose of imposing federal regulation on an established area of commercial activity."[14] Against a patchwork of piecemeal federal product safety regulations, industry self-regulation, common-law standards and remedies, and state and local agency regulations, Congress perceived the need for a federal agency to oversee the increasingly national product market.[15] The CPSC emphasizes its role in creating national standards: "[O]ur work ensures a uniform level of safety for the nation's families. Similarly, our product safety work and safety guidance provide businesses with a national level playing-field for domestic and imported consumer products."[16]

At the time of its creation, the CPSC was expected to be a beacon of product safety, with wide discretion to establish mandatory safety standards, including requirements for product performance, design, labeling, warnings, and instructions.[17] With jurisdiction over more than 15,000 types of consumer products, the CPSC's role was (and

11. 15 U.S.C. §§ 2051–2084 (2000).

12. *Id.* § 2051(b).

13. S. REP. NO. 92-835, at 1 (1972), *as reprinted in* 1972 U.S.C.C.A.N. 4573, 4574. This new "super-agency" was to exercise areas of regulatory control previously under the authority of the FDA, Center for Disease Control, Department of Commerce, Federal Trade Commission, and Department of Agriculture. *See* Chad D. Emerson, *The Continuing Showdown over Who Should Regulate Amusement Attraction Safety: A Critical Analysis of Why Fixed-Site Amusement Attraction Safety Should Remain State-Governed*, 28 SETON HALL LEGIS. J. 1, 18 (2003).

14. Antonin Scalia & Frank Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 UCLA L. REV. 899, 899 (1973).

15. *See id.* at 900–01.

16. U.S. CONSUMER PROD. SAFETY COMM'N, 2007 PERFORMANCE BUDGET REQUEST: SAVING LIVES AND KEEPING FAMILIES SAFE iv (2006), *available at* http://www.cpsc.gov/cpscpub/pubs/reports/2007plan.pdf [hereinafter CPSC, 2007 PERFORMANCE BUDGET REQUEST].

17. *See* 15 U.S.C. § 2056(a) (authorizing the CPSC to set mandatory performance and labeling requirements); *see also* Geraint G. Howells, *The Relationship Between Product Liability and Product Safety—Understanding a Necessary Element in European Product Liability Through a*

remains) to "identify and assess hazards, [and then] use a wide range of tools to address them: the voluntary standards process; consumer information; safety guidelines; cooperative product recalls and corrective actions; and, as a last resort, mandatory rulemaking and litigation."[18] But with the onset of the Reagan-era deregulatory thrust,[19] the CPSC shifted gears away from mandatory regulations towards voluntary standards.[20] The rhetoric of the CPSC persists in full force today: "The CPSC's work to ensure the safety of consumer products—such as toys, cribs, power tools, cigarette lighters, and household chemicals—contributed significantly to the 30 percent decline in the rate of deaths and injuries associated with consumer products over the past 30 years."[21] But its influence on the product safety landscape in the United States has certainly waned.[22]

Given this background, the flammability standard for mattresses recently promulgated by the CPSC[23] is noteworthy because it is mandatory.[24] It is, moreover, the first "major" regulation passed by

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Comparison with the U.S. Position, 39 WASHBURN L.J. 305, 309 (2000) (describing the CPSC's original mandate).

18. CPSC, 2007 PERFORMANCE BUDGET REQUEST, *supra* note 16, at iv. Notwithstanding the CPSC's sweeping language regarding its jurisdiction, a wide array of products falls outside its purview: automobiles and other on-road vehicles, tires, boats, alcohol, tobacco, firearms, food, drugs, cosmetics, pesticides, and medical devices produced by any manufacturer, retailer, importer, and distributor of consumer products, regardless of their size. Nor does its jurisdiction include false advertising, fraud, or poor product quality unrelated to safety. *See* U.S. Consumer Product Safety Commission, Frequently Asked Questions, http://www.cpsc.gov/about/faq.html (last visited Jan. 10, 2007).

19. *See* Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1318–19 (1986) ("[T]he Reagan administration appeared to pursue a broader-based de facto deregulation policy by appointing unsympathetic agency administrators and proposing drastic budget cuts in regulatory programs untainted by congressional disapproval. . . . [This] might suggest a far more ambitious ideological aim, namely, to reassess the need for regulatory institutions as a mechanism for policing the market." (citing GEORGE C. EADS & MICHAEL FIX, RELIEF OR REFORM?: REAGAN'S REGULATORY DILEMMA 139–62 (1983)).

20. Howells, *supra* note 17, at 310 ("[T]he U.S. system has forgone mandatory regulations and is left to rely upon free standing voluntary standards."). The revised CPSA reflects this shift in regulatory approach. The Act was amended in 1981 to permit mandatory standards only where compliance with voluntary standards would be unlikely "to result in the elimination or adequate reduction of the risk of injury." *Id.* at 309 (citing 15 U.S.C. § 2058(f)(3)(D) (1994 & Supp. IV 1998)).

21. Press Release, CPSC, CPSC Signs Cooperative Agreement with Chinese Government to Improve Safety of U.S. Imports (Apr. 21, 2004), http://www.cpsc.gov/cpscpub/prerel/prhtml04/04124.html.

22. *See, e.g.*, Robert L. Rabin, *The Politics of Tort Reform*, 26 VAL. U. L. REV. 709, 712 (1992) ("The present patchwork [regulatory] system does fairly well in some areas, such as food and drug regulation, and dismally in others; witness the twenty year track record of the Consumer Product Safety Commission.").

23. *See supra* note 2 and accompanying text.

24. The CPSC currently "works on eight to fourteen mandatory standards per year and forty to fifty voluntary standards." Howells, *supra* note 17, at 310.

the CPSC in its history.[25] But above all, what has attracted attention—and criticism—is the section of the Rule's preamble that reads as follows: "The Commission intends and expects that the new mattress flammability standard will preempt inconsistent state standards and requirements, whether in the form of positive enactments or court created requirements."[26] By making clear that "requirements" include not only positive statutory or regulatory provisions but also court-imposed liability rules, the CPSC weighed in on an issue that has bedeviled courts, including the Supreme Court.[27] To justify its action, the CPSC once again highlighted its interest in promoting uniform, federal standards:

> State requirements intended to reduce the risk of mattress fire, no matter how well intentioned, have the potential to undercut the Commission's uniform national flammability standard, create impediments for manufacturers whose mattress products enter the stream of interstate commerce, establish requirements that make dual state and federal compliance physically impossible, and cause

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25. A "major" rule is defined as "one that has more than a $100 million annual impact on the economy." Press Release, CPSC, CPSC Approves New Flammability Standard for Mattresses (Feb. 16, 2006), http://www.cpsc.gov/cpscpub/prerel/prhtml06/06091.html. The CPSC estimates that an average of 270 lives will be saved and 1330 injuries will be prevented annually once the standard is fully effective. *Id.*

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

27. *Compare, e.g.*, Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992) ("The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules." (alteration omitted)), *with, e.g.*, Bates v. Dow Agrosciences L.L.C., 544 U.S. 431, 443 (2005) ("An occurrence that merely motivates an optional decision does not qualify as a requirement. The Court of Appeals was therefore quite wrong when it assumed that any event, such as a jury verdict, that might 'induce' a pesticide manufacturer to change its label should be viewed as a requirement.").

As is fairly typical, the preemption provision contained in the Flammable Fabrics Act, the statute invoked by the preamble as authority, uses the terms "standard" and "regulation" without being explicit as to the fate of common-law remedies:

> [W]henever a flammability standard or other regulation for a fabric . . . is in effect under this [Act], no State . . . may establish or continue in effect a flammability standard or other regulation for such fabric . . . if the standard or other regulation is designed to protect against the same risk of occurrence of fire with respect to which the standard or other regulation under this [Act] is in effect unless the State . . . standard or other regulation is identical to the Federal standard or other regulation.

15 U.S.C. § 1203(a) (2000). This language parallels the preemption provision included within the CPSA. *Id.* § 2075(a) ("[N]o State or political subdivision of a State [may establish] . . . any provision of a safety standard or regulation which . . . [is] designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.").

> confusion among consumers seeking to understand differing state and federal mattress fire requirements.[28]

The inclusion of a preemption provision in the preamble statement was unprecedented: "[It] was the first instance in the agency's 33-year history of the commission's voting to limit the ability of consumers to bring cases in state courts."[29] And it has sparked controversy, both internally and with outside critics. From within, one of the CPSC's Commissioners has lamented the sacrifice of the value of experimentation: "States are often pioneers in consumer protection, providing the impetus for new or improved federal regulation and California is usually in the forefront on consumer issues."[30] Moreover, the same Commissioner has expressed doubt in the CPSC's ability to create proper liability standards: "If we have gotten this standard right, then [lawsuits] against manufacturers should be a rarity and prevailing ones even less common. But if we have gotten it wrong, the fastest way we will find out is through people bringing lawsuits that challenge our conclusions."[31] Senator Daniel Inouye has echoed the concern about the ossification of safety standards:

> I would hazard to guess that after this rule is finalized, the issue of home fire safety may not be addressed for several more decades, while science and the ability to make mattresses even safer will continue to evolve. Removing a significant incentive for industries to improve outside of meeting the federal standard may have a chilling effect on industries integrating new safety technology into their products.[32]

B. National Highway Traffic Safety Administration

The NHTSA is a more familiar and more active federal regulatory agency.[33] Located within the Department of Transportation (DOT),

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28. Final Rule: Standard for the Flammability (Open-Flame) of Mattress Sets, 71 Fed. Reg. at 13,496. The CPSC invoked its authority under the Flammable Fabrics Act. *See supra* note 27.

29. Labaton, *supra* note 4.

30. CPSC Commissioner Moore Statement on the Final Rule and Preamble, *supra* note 5. In this particular instance regarding the flammability standard, Commissioner Moore acknowledged the contribution of California's Bureau of Home Furnishings and Thermal Insulation. *See id.*; *see also* PREEMPTION ALERT (PIRG), Mar. 2006, at 1 [hereinafter PREEMPTION ALERT], *available at* www.uspirg.org/html/preemptionalert/march06.pdf ("States have long been the laboratories for innovative public policy. Over the last three decades, states have become more active in passing strong laws to protect the environment and consumers.").

31. CPSC Commissioner Moore Statement on the Final Rule and Preamble, *supra* note 5.

32. PREEMPTION ALERT, *supra* note 30, at 2–3 (quoting Letter from Senator Inouye to CPSC Chairman Hal Stratton (Feb. 13, 2006)).

33. For a comprehensive descriptive and normative account of the development of the NHTSA's regulatory policy over the first two decades of its existence, see Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. ON REG. 257 (1987).

with over 600 employees and an annual budget exceeding $400 million, the "NHTSA's stated mission is to 'save lives, prevent injuries and reduce traffic-related health care and other economic costs.'"[34]

A NHTSA regulation was front and center in *Geier v. American Honda Motor Co.*,[35] a pivotal preemption case before the Supreme Court. The Court was asked to decide whether Federal Motor Vehicle Safety Standard 208 (FMVSS 208), promulgated under the National Traffic and Motor Vehicle Safety Act (VSA), preempted a state common-law tort action against a defendant auto manufacturer.[36] The VSA is in some sense a quintessential example of the contradictory signals sent by Congress.[37] Its preemption clause provides that "no State . . . shall have any authority . . . to establish . . . any safety standard . . . which is not identical to the Federal standard."[38] Yet the accompanying "savings clause" reads as follows: "Compliance with any Federal motor vehicle safety standard . . . does not exempt any person from any liability under common law."[39]

The state tort action was premised on the manufacturer's negligence in failing to equip its cars with certain passive restraints, including airbags.[40] The Court held that the regulation preempted state common-law tort actions premised on the failure to provide state-of-the-

34. Kevin M. McDonald, *Shifting out of Neutral: A New Approach to Global Road Safety*, 38 VAND. J. TRANSNAT'L L. 743, 773–74 (2005) (quoting Long Range Strategic Planning, 69 Fed. Reg. 39,542, 39,543 (June 30, 2004)). McDonald, an attorney for Volkswagen of America, further noted that "[a]s of December 2004, NHTSA had eighty-four active rulemaking proceedings." *Id.* at 778 (citing Harry Stoffer, *No Longer a Rule for Every Problem: NHTSA Focuses on Fewer, Broader Areas*, AUTOMOTIVE NEWS, Dec. 6, 2004, at 4)).

Professor Jerry Mashaw and Attorney David Harfst document a major paradigm shift that pre-dates the Reagan Administration's deregulatory thrust:

> Established as a rulemaking agency to force the technology of automobile safety design, NHTSA indeed functioned in a rulemaking mode from roughly its inception in 1966 until about 1974. . . . Since the mid-1970's, NHTSA has instead concentrated on its alternative statutory power to force the recall of motor vehicles that contain "defects" related to safety performance.

Mashaw & Harfst, *supra* note 33, at 263. They remark upon the parallel to the CPSC. *Id.* at 310–11 ("Like NHTSA, the CPSC's rulemaking power has atrophied while its primary regulatory activity has become product recalls.").

35. 529 U.S. 861 (2000).

36. *Id.* at 864–65.

37. Indeed, "Congress demonstrates its capacity for creating ambiguity in the preemption area." Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2058 (2000) [hereinafter Rabin, *Reassessing Regulatory Compliance*]; *accord* Robert L. Rabin, *Federalism and the Tort System*, 50 RUTGERS L. REV. 1, 28 (1997) ("To say that the Court's signals in the preemption area have been indistinct regarding the appropriate degree of deference to be afforded federalism concerns would be a major understatement.").

38. 15 U.S.C. § 1392(d) (1988), *amended by* 49 U.S.C. § 30103 (1994).

39. *Id.* § 1397(k).

40. *Geier*, 529 U.S. at 865.

art passenger protection, reasoning that, absent preemption, "state law could impose legal duties that would conflict directly with federal regulatory mandates."[41] The regulatory standard "deliberately provided the manufacturer with a range of choices among different passive restraint devices,"[42] and state law "would have presented an obstacle to the variety and mix of devices that the federal regulation sought."[43]

In that case, neither Congress nor the Secretary of Transportation had explicitly made this preemption judgment by statute or regulation. But according to the Court, "[t]he failure of the Federal Register to address pre-emption explicitly [was] not determinative."[44] The Solicitor General, moreover, argued that the NHTSA's promulgation of FMVSS 208 embodied an affirmative "policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car."[45] The Court "place[d] some weight"[46] on the agency's interpretation: "We have no reason to suspect that the Solicitor General's representation of DOT's views reflects anything other than 'the agency's fair and considered judgment on the matter.'"[47]

Its pro-preemption position in *Geier* notwithstanding, it seems fair to conclude that the NHTSA has not been particularly aggressive in asserting the preemptive force of its enactments. For example, when state officials in Massachusetts and New York asked for an advisory opinion as to whether their respective defect notification programs were preempted by the VSA, the NHTSA concluded that they were not preempted because Congress did not intend to occupy the field of

41. *Id.* at 871. More precisely, the Court held that the suit was not expressly preempted by the Act; but under implied conflict preemption principles, the Court found that because the suit was based on requiring airbags, it conflicted with the regulation. *Id.* at 869, 874.

42. *Id.* at 875.

43. *Id.* at 881. In promulgating FMVSS 208, the NHTSA went through a detailed analysis of what an "airbag only" standard would accomplish and what degrees of compliance would be achieved. It then determined that a gradual approach, one that utilized a "mix" of safety devices, was the preferable course. *See id.* at 874–75.

44. *Geier*, 529 U.S. at 884.

45. *Id.* at 881 (quoting Brief for the United States as Amicus Curiae Supporting Affirmance at *25, *Geier*, 529 U.S. 861 (No. 98-1811), 1999 WL 1045115 [hereinafter United States *Geier* Brief]).

46. *Id.* at 883 ("We place some weight upon DOT's interpretation of FMVSS 208's objectives and its conclusion, as set forth in the Government's brief, that a tort suit such as this one would 'stan[d] as an obstacle to the accomplishment and execution' of those objectives." (alterations in original) (internal quotation marks omitted) (quoting United States *Geier* Brief, *supra* note 45, at *25–26)).

47. *Id.* at 884 (quoting Auer v. Robbins, 519 U.S. 452, 462 (1997)).

motor vehicle defect notification.[48] Moreover, because it would be possible to comply with state law without violating the federal law, and the state law did not frustrate the purpose of the federal regulatory regime, the NHTSA concluded that there was no conflict or obstacle preemption.[49]

Against this historical backdrop, the NHTSA's most recent proposal, which combines a uniform national safety standard with specific preemptive language, may indicate a sea change. This proposal would impose higher safety standards for motor vehicles; specifically, the proposed rule would require automobile roofs to withstand direct pressure of two and a half times the vehicle's weight.[50] The NHTSA's promulgation of a uniform national standard is "part of a comprehensive plan for reducing the risk of death and serious injury from rollover crashes."[51]

The proposed rule includes language immunizing car manufacturers from state tort lawsuits over defective roofs if their cars meet the federal safety standard: "[I]f the proposal were adopted as a final rule, it would preempt all conflicting State common law requirements, including rules of tort law."[52] The NHTSA defended the inclusion of an exemption from state personal injury law on the ground that carmakers, fearful of lawsuits, would strengthen car roofs to the point that vehicles would become top-heavy and more likely to roll over. This would compromise the balance the federal standard sought to achieve between roof strength and rollover propensity.[53]

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48. Kevin M. McDonald, *Federal Preemption of Automotive Recalls: A Case of Too Many Backseat Drivers?*, 71 TENN. L. REV. 471, 484–87 (2004).

49. *Id.* at 484–85. Courts have reached mixed results with respect to recalls based upon state law. *See id.* at 487–88 (reporting an even split among eight courts: "three federal district courts and one state court have held that the [VSA] preempts state-law-based recall orders"; one federal district court and three state courts reached the opposite conclusion).

50. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,247 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571). This new standard represents an increase over the one and one half weight ratio currently required. Standard No. 216, Roof Crush Resistance—Passenger Cars, 49 C.F.R. § 571.216 (1973).

51. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. at 49,224. The call for national uniformity in safety standards has been echoed by some commentators as well. For example, in the context of analyzing whether state-based recall orders are preempted by the VSA, McDonald reasons as follows:

> [S]tate-law-based recalls would interfere with the *methods* by which the federal statute was designed to reach the goal of promoting vehicle safety. . . . Potentially *fifty* different notification requirements and differing recall actions, in particular when the NHTSA has decided *not* to act, could create the confusion, "undue public alarm," and harmful economic effects that Congress specifically wished to avoid.

McDonald, *supra* note 48, at 507–08 (citation omitted).

52. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. at 49,246.

53. *Id.* at 49,245–46.

The proposed preemption language has sparked controversy. Senators Arlen Specter and Patrick Leahy submitted a letter demanding that the NHTSA explain its broad preemption language in light of the absence of any express indication by Congress that it intended to preempt state laws in this area.[54] For its part, the NHTSA insists this is not a new phenomenon, citing the situation in *Geier*, where the agency joined automakers in arguing that they should not be sued for not installing airbags at a time when the agency allowed either airbags or automatic seatbelts.[55]

C. *Food and Drug Administration*

The third tale addresses the FDA, an agency that has historically (if somewhat inconsistently) asserted the preemptive force of its regulations and is the subject of the most scholarly debate.[56] Housed within the Department of Health and Human Services, and consisting of eight separate divisions, the FDA has a broad mission:

> The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based in-

54. Specifically, the Senators' letter challenges "how NHTSA concluded that preemption of State law was the intent of Congress when it passed the Transportation Equity Act" given the directive of "Executive Order 13132, which states: 'Agencies shall construe, in regulations and otherwise, a Federal statute to preempt State law *only where the statute contains an express preemption provision or there is clear evidence that the Congress intended preemption of State law.*'" Letter from Senators Arlen Specter and Patrick Leahy to Jacqueline Glassman, Acting Director of NHTSA (Nov. 17, 2005). The Senators' letter omits the Executive Order's reference to conflict preemption. *See infra* note 75.

55. *See, e.g.*, Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000) ("DOT has explained FMVSS 208's objectives, and the interference that 'no airbag' suits pose thereto, consistently over time." (citing Brief for the United States as Amicus Curiae Supporting Respondents at 28–29, Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) (No. 94-286); Brief for United States as Amicus Curiae at 7, 11–16, Wood v. Gen. Motors Corp., 494 U.S. 1065 (1990) (No. 89-46)); *see also supra* note 46.

56. Professor Robert Rabin provides an illuminating analysis of preemption and the regulatory compliance defense (in the pre-2000 era) in the context of FDA regulation of prescription drugs—the subject matter of the most recent FDA proposal. Rabin, *Reassessing Regulatory Compliance*, *supra* note 37, at 2082 (concluding that "the case for a strong regulatory compliance defense, along the lines envisioned by Peter Huber or Kip Viscusi, is seriously compromised by real-world considerations"); *see also* Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. (2006), http://www.bepress.com/jtl; Mary J. Davis, Discovering the Boundaries: Federal Preemption of Prescription Drug Labeling Product Liability Actions (May 22, 2006) (unpublished draft), *available at* http://ssrn.com/abstract=903757.

> formation they need to use medicines and foods to improve their health.[57]

The FDA is often singled out as an exemplar of the ex ante regulatory approach.[58] It oversees an exhaustive process under the Federal Food Drug and Cosmetic Act (FDCA) of pre-approval investigation of new drugs.[59] Indeed, "the regulations imposed by the [FDA] are generally considered the world's most demanding."[60] Thus, the practice of allowing state tort awards against drug companies whose products have received FDA approval has drawn harsh criticism.[61]

Preemption under the Medical Devices Amendments (MDA) to the FDCA was at issue in *Medtronic, Inc. v. Lohr*.[62] *Medtronic* involved negligence and strict liability claims by a plaintiff who was injured by a pacemaker that had been approved by the FDA pursuant to the MDA.[63] As is typical, and consistent with the NHTSA example above, neither the statutory language nor the legislative history of the MDA explicitly bars tort claims.[64]

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57. U.S. Food and Drug Administration, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Jan. 10, 2007).

58. *See* Samuel Issacharoff, *Regulating After the Fact*, 56 DEPAUL L. REV. 375, 378 (2007).

59. 21 U.S.C. § 355(b), (d) (2000).

60. Joan E. Shreffler, Comment, *Bad Medicine: Good-Faith FDA Approval as a Recommended Bar to Punitive Damages in Pharmaceutical Products Liability Cases*, 84 N.C. L. REV. 737, 753 (2006) (citing MARK MATHIEU, NEW DRUG DEVELOPMENT: A REGULATORY OVERVIEW 1 (5th ed. 2000)).

61. *See, e.g.*, Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of* Chevron *Deference and a Response to Richard Nagareda*, 1 J. TORT L. (2006), http://www.bepress.com/jtl ("What possible reason is there not to preempt litigation which on balance is worse than useless?"); David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 396–97 (1996) (contending that tort liability, subsequent to FDA drug approval, constitutes "retrospective jury nullification" of FDA regulations and "is contrary to public policy"); W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1480 (1994) ("Tort law in the pharmaceutical context has proven to be an extraordinarily expensive regime that suffers from institutional constraints limiting its accuracy. . . . [W]here the manufacturer has complied with the FDCA and its implementing regulations, tort law does not appear to have significant ability to generate safer drugs.").

62. 518 U.S. 470 (1996).

63. *Id.* at 480–81 (describing the expedited premarket notification procedure for "substantially equivalent" medical devices).

64. Congress merely prohibited states from requiring medical device manufacturers to comply with standards or requirements that are "different from, or in addition to" federal standards. 21 U.S.C. § 360k(a); *see, e.g.*, Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 923–24 (1994) ("[W]e note that there is no absolutely dispositive language in the MDA regarding preemption and the common law. That is, nowhere in the amendments or in the legislative history of the amendments does Congress indicate that state common law tort claims are preempted or are not preempted." (citation omitted)).

A sharply divided Court held that common-law claims concerning the design of medical devices were not preempted:[65] "[P]re-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'"[66] The FDA adopted a fairly constricted view of its preemptive power in *Medtronic*. In fact, the Solicitor General filed a brief in support of respondent Lohr:

> The FDA has consistently, and reasonably, construed the term "requirement" to refer to substantive, but not remedial, provisions. Applying that approach here, a substantive obligation created by state tort law, such as the duty to use due care, may constitute a "requirement" . . . but that term does not encompass a state tort principle entitling a plaintiff to recover damages for the defendant's breach of a substantive common-law obligation.[67]

In other words, the FDA interpreted the term "requirement" specifically *not* to preempt state tort remedies or other state remedial provisions; moreover, according to the Solicitor General, this was the long-standing view of the FDA.[68]

Buckman Co. v. Plaintiffs' Legal Committee[69] pushes in another direction for both the Court and the FDA, with each showing far greater concern for the potential balkanization of federal regulatory authority. The state common-law claim in *Buckman* was premised upon allegedly false representations made to the FDA in the course of obtaining approval for orthopedic bone screws.[70] The screws were approved by the FDA as a predicate device, but the approval was based on representations that these screws would be marketed for legs and arms, not spines.[71] Claiming that the FDA would not have approved

65. *Medtronic*, 518 U.S. at 493–94.

66. *Id.* at 496.

67. Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners at *9–10, *Medtronic*, 518 U.S. 470 (Nos. 95-754, 95-886), 1996 WL 118035.

68. The Solicitor General pointed to FDA proposed regulations from June 1977, which included a preamble that made clear that the preemption provision "does not preempt 'general State or local law provisions governing the enforcement of requirements applicable to medical devices,' because '[s]uch general enforcement provisions are not themselves requirements.'" *Id.* at *12 (alteration in original) (quoting Exemptions from Federal Preemption of State and Local Device Requirements, 42 Fed. Reg. 30,383, 30,384 (June 14, 1977)).

Following the *Medtronic* decision, then-Chief Counsel of the FDA, Margaret Porter, agreed that the Supreme Court's ruling was consistent with the FDA's "long-standing presumption against preemption." Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 7 (1997).

69. 531 U.S. 341 (2001).

70. *Id.* at 344.

71. *Id.* at 346–47.

the screws absent the fraudulent representation, plaintiffs sought damages under state tort law.[72]

The Solicitor General, in an amicus brief submitted on behalf of itself, the Chief Counsel for the FDA, and the Department of Justice (DOJ), took the position that the common-law fraud-on-the-FDA claims were impliedly preempted.[73] In this context, the Government was not content with the substantive-remedial distinction it had previously embraced in *Medtronic*. Instead, the Solicitor General highlighted the need for consistency at both the remedial and substantive ends:

> Even if juries in different States applied the same substantive standards as FDA, it would not eliminate that conflict. As this Court has explained, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law."[74]

Understanding that "remedies form an ingredient of any integrated scheme of regulation"[75]—in other words, that remedies cannot be blithely separated from substantive common-law requirements—is critical to this view.[76] Moreover, the Court's pro-preemption ruling retained the essence of the Solicitor General's reasoning:

> As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants . . . . Would-be applicants may be discouraged from seeking . . . approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates . . . to unpredictable civil liability.[77]

This line of argument is remarkably similar to the FDA's reasoning in the preemption preamble to its most recently codified rule gov-

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72. *Id.* The suit claimed that the misrepresentations were the "but for" cause of the injuries that the plaintiffs sustained from the implantation of these devices. *Id.* at 343.

73. Brief for the United States as Amicus Curiae Supporting Petitioner at *16–18, *Buckman Co.*, 531 U.S. 341 (No. 98-1768), 2000 WL 1364441.

74. *Id.* at *23 (alteration in original) (quoting Garner v. Teamsters, Chauffeurs & Helpers Local Union No. 776, 346 U.S. 485, 490–91 (1953)).

75. *Id.* (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959)).

76. The FDA attempted to reconcile its seemingly contradictory stance by distinguishing the areas of "traditional state concern" involved in *Medtronic*—device design and failure to warn—from the federal issue at stake in *Buckman*—fraud. *Id.* at *19 ("[W]hen state law implicates an area of preeminent federal concern, the presumption against preemption disappears and the likelihood of a fatal conflict between state and federal law significantly increases.").

77. *Buckman*, 531 U.S. at 350. Arguably, the Court could have rested its decision exclusively on an alternate ground: "Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied' . . . . To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347.

erning the format and content of drug labeling. The final rule, published on January 24, 2006 in the Federal Register, includes a preamble asserting broad preemption of state drug labeling, advertising, and product liability laws: "[The] FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law."[78]

The FDA justified its position on implied conflict preemption in the interests of uniformity, expertise, and safety concerns:

> Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.[79]

Once again, Congress has been silent on the issue of whether state law may coexist with federal regulatory law in the case of new drug approvals.[80] Does the FDA's action constitute the dawn of a new era of aggressive regulatory preemption? Not according to the FDA, which remains emphatic that its preemption preamble is representative of "the government's long standing views on preemption."[81] But,

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

At the same time, and injecting considerable ambiguity, the comments to the preamble assert that the "FDA's regulation of drug labeling will not preempt all State law actions"; specifically, "certain State law requirements that parallel FDA requirements may not be preempted." *Id.* at 3936. This "parallel requirements" exception is complicated by the juxtaposition of supporting and contrary authority cited by the FDA. *See id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S 470, 495 (1996) for supporting its position that "the presence of a State law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but 'merely provides another reason for manufacturers to comply with . . . federal law,'" and contrasting the holdings of *Buckman*, 531 U.S. 341 and *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817, 824 (3d Cir. 1998)).

79. *Id.* at 3935. The FDA explains further that, unlike state regulators, the FDA's regulatory decisions are "characterized by centralized expert evaluation" and would avoid "defensive labeling" that would result from disparate state liability regimes. *Id.*

80. Unlike the MDA, there is no preemption provision at all in the prescription drug provisions of the FDCA. *Compare supra* note 64, *with* 21 U.S.C. §§ 301–397 (2000). There is, however, a "savings clause." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).

81. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934. In support of this assertion, the FDA lists three examples of previous efforts to preempt state law requirements relating to drugs via rulemakings: (1) preemption preambles included in 1982 regulations requiring tamper-resistant packaging for over-the-counter drugs; (2) 1986 regulations requiring aspirin labels to include a warning against use in treating chicken pox or flu symptoms in children due to the risk of Reye's Syndrome; and

as illustrated above, the consistency and tenacity of the FDA's position on preemption over time is subject to dispute.

III. SORCERER'S APPRENTICE?

Congressional intent is at the heart of conventional preemption analysis. Thus, it would seem that federal agencies, as the bodies to which Congress delegates statutory authority to carry out its objectives, should naturally have a role. As Professor Einer Elhauge reminds us, "in the modern administrative state most statutory interpretations are done by agencies."[82] Until recently, however, agencies had been more reticent about including forceful preemptive statements in their regulations. Will the sea change in agency action have an impact? In order to answer this question, it is first necessary to wade into the larger unsettled debate regarding the level of deference courts ought to accord agency preemption determinations—an issue the Supreme Court has recently taken up. Meanwhile, litigation implicating the status of the FDA preemption preamble has proceeded apace in state and federal courts, where there is an emergent and discernible trend, if not a dominant position, towards deference to agency preemption determinations. Should this regulatory preemption trend continue, the implications for what is broadly termed "access to justice" are potentially profound. Agencies would be selectively empowered to act in one direction only—to oust competing state power—but denied the corresponding power to augment enforcement by inferring private rights of action under the regulations they administer. This asymmetry challenges the conventional view of the subservient agency acting consistently in the role of "sorcerer's apprentice."

A. The Stakes of the Agency Preemption Debate

A 1996 Executive Order issued by President Bill Clinton mandates that a federal regulation "specif[y] in clear language the preemptive effect, if any, to be given to the law."[83] Why, then, the controversy?

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(3) 1994 amendments to regulations related to over-the-counter drug pregnancy-nursing warning requirements. *Id.* at 3935.

82. EINER ELHAUGE, STATUTORY DEFAULT RULES (forthcoming 2007) (manuscript at 153, on file with author) ("Because most statutory interpretations today are administrative ones, understanding the proper justification for, and limits on, the *Chevron* doctrine is vital to understanding modern interpretive practice.").

83. Exec. Order No. 12,988, 61 Fed. Reg. 4729, 4731 (Feb. 7, 1996). Executive Order 13,132, issued in 1999, instructs agencies to construe federal statutes as preempting state law "only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority

The regulatory preemption debate centers on the extent to which the preambles go beyond simply reciting the preemptive effect of the governing statute or regulation promulgated within the agency's delegated authority, and instead attempt to discern the proper scope of preemption with little or no direction from Congress.[84] Controversy surrounds the appropriate weight to be accorded agency views: Should courts grant *Chevron* deference,[85] weaker *Skidmore* deference,[86] or no deference at all to agency preemption determinations, whether embodied in formal rules or informal preamble statements and agency interpretations?[87] Here, the Court's "presumption against preemption" canon of interpretation would seem to clash with the *Chevron* principle, which accords deference to an agency's reasonable interpretation of ambiguous laws.[88]

The Supreme Court has hitherto been rather cryptic regarding *Chevron* deference in its products liability preemption decisions; by its actions, however, it implicitly seems to have granted agency determi-

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conflicts with the exercise of Federal authority under the Federal statute." Exec. Order. No. 13,132, 64 Fed. Reg. 43,255, 43,257 (Aug. 10, 1999).

84. It is beyond peradventure that an agency acting within its delegated authority may pass legislative regulations that have full preemptive effect. *See, e.g.*, Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141 (1982); United States v. Shimer, 367 U.S. 374 (1961). It is equally well settled that Congress may expressly delegate authority to an agency to issue preemptive regulations. The issue here is whether the agency's legal determination regarding the scope of preemption provisions falls within its delegated power.

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

86. Skidmore v. Swift & Co., 323 U.S. 134 (1944).

87. *See* United States v. Mead Corp., 533 U.S. 218, 226–28 (2001) (outlining the factors relevant to *Skidmore* deference, including degree of agency expertise, persuasiveness, and consistency over time and noting that "administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of such authority").

Although she explicitly brackets the issue of regulatory preemption, Professor Nina Mendelson argues that courts should have "discretion to take account of an agency interpretation on preemption under a regime such as *Skidmore v. Swift*"; she concludes that *Chevron* deference to agency preemption interpretations would be ill-advised in part because "[o]ther institutions . . . may better assess issues such as the overall distribution of governmental authority and the intrinsic value of preserving core state regulatory authority." Nina A. Mendelson, Chevron *and Preemption*, 102 MICH. L. REV. 737, 742 (2004).

88. Several commentators have noted this tension:

> Deference to administrative rulemaking is normally justified by the presumption that when Congress has expressed no particular intent on a subject, it meant to leave its resolution to the agency. The force of that presumption is undercut in the context of agency preemption, however, by the contrary presumption that Congress does not normally intend to preempt state law unless it explicitly says so.

Bagley, *supra* note 7, at 2293–94 (citation omitted); *accord* Jack W. Campbell IV, *Regulatory Preemption in the* Garcia/Chevron *Era*, 59 U. PITT. L. REV. 805, 806 (1998); Paul E. McGreal, *Some* Rice *with Your* Chevron*?: Presumption and Deference in Regulatory Preemption*, 45 CASE W. RES. L. REV. 823, 824 (1995).

nations a type of *Skidmore* deference. For example, writing for the majority in *Geier* that upheld the preemptive effect of a DOT airbag regulation, Justice Stephen Breyer appeared to apply *Skidmore* factors:

> We place *some weight* upon [the agency's] interpretation of [its regulation's] objectives and its conclusion, as set forth in the Government's brief, that a tort suit such as this one would "stan[d] as an obstacle to the accomplishment and execution" of those objectives. Congress has delegated to [the agency] authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is "uniquely qualified" to comprehend the likely impact of state requirements.[89]

The bottom line was that "[i]n these circumstances, the agency's own views should make a difference."[90]

Justice Breyer had previously tipped his hand in a separate concurrence in *Medtronic*:

> [T]his Court has previously suggested that, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect. . . . It can communicate those intentions, for example, through statements in "regulations, preambles, interpretive statements, and responses to comments" . . . .[91]

Justice Sandra Day O'Connor was provoked to respond: "Apparently recognizing that *Chevron* deference is unwarranted here, the Court does not admit to deferring to these regulations, but merely permits them to 'infor[m]' the Court's interpretation. It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference . . . ."[92]

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89. Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000) (emphasis added) (third alteration in original) (citations omitted) (internal quotation marks omitted). The Court relied on the DOT's explanation in an amicus brief regarding the agency's regulatory objectives and the agency's bottom-line conclusion that state tort liability would interfere with the accomplishment of those objectives. *Id.*; *see supra* note 46.

90. *Geier*, 529 U.S. at 883.

91. 518 U.S. 470, 505–06 (1996) (Breyer, J., concurring) (quoting Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 718 (1985)). In the Court's most recent products liability preemption decision, *Bates v. Dow Agrosciences L.L.C.*, Justice Breyer reiterated his view that the Environmental Protection Agency "ha[s] the legal authority . . . to determine the pre-emptive effect of [its] rules in light of the agency's special understanding of 'whether (or the extent to which) state requirements may interfere with federal objectives.'" 544 U.S. 431, 454 (2005) (Breyer, J., concurring) (quoting *Medtronic*, 518 U.S. at 506 (Breyer, J., concurring)).

92. *Medtronic*, 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part) (alterations in original) (citations omitted). Justice O'Connor's opinion was joined by Chief Justice Rehnquist, and Justices Scalia and Thomas. *Id.* at 509.

The issue of what level of deference courts ought to accord to agency preemption determinations remains unsettled. More precisely, the issue is whether courts should apply *Chevron* or some lesser form of deference to an agency's assertion of preemptive authority—whether in regulations (legislative, interpretive, or policy) or stated views (as articulated, for example, in amicus briefs or preambles).[93] The Supreme Court granted certiorari in *Watters v. Wachovia Bank, N.A.*[94] to decide whether to grant *Chevron* deference to an agency's interpretation that its regulation, promulgated under the National Banking Act, preempts state mortgage lending laws as applied to wholly owned subsidiaries of a national bank.[95]

The *Watters* case appears to have implications beyond the banking context.[96] Indeed, there is a split in authority as to whether the Fed-

93. As Professor Cass Sunstein proclaims, "More than at any time in recent years, a threshold question—the scope of judicial review—has become one of the most vexing in regulatory cases." Cass R. Sunstein, Chevron *Step Zero*, 92 VA. L. REV. 187, 190 (2006). The issue beguiles courts and academics alike. *See, e.g.*, City of N.Y. v. FCC, 814 F.2d 720, 726 (D.C. Cir. 1987) ("[W]hether *Chevron* deference is required in, or appropriate to, judicial review of an agency's assertion of preemption authority is unsettled."), *aff'd*, 486 U.S. 57 (1988) (deferring to the FCC's decision to prohibit states and municipalities from imposing more stringent standards to govern cable television signals—without invoking *Chevron*); Thomas W. Merrill, *Rethinking Article I, Section 1: From Nondelegation to Exclusive Delegation*, 104 COLUM. L. REV. 2097, 2173–75 (2004) (arguing that agency determinations of the scope of their regulatory power should be given *Skidmore*, rather than *Chevron*, deference); Thomas W. Merrill & Kristin E. Hickman, Chevron*'s Domain*, 89 GEO. L.J. 833, 836 (2001) (proposing a "*Chevron* Step Zero" threshold inquiry into whether *Chevron* framework should apply at all); Cass R. Sunstein, *Law and Administration After* Chevron, 90 COLUM. L. REV. 2071, 2097–101 (1990) (suggesting that courts have refused to defer to agency determinations of their own jurisdiction when change implicates "a large category of cases" or when bias or self-dealing is likely to be at work).

94. 126 S. Ct. 2900 (2006), *argued*, Nov. 29, 2006.

95. Two other federal court of appeals cases raise the same issue:

> [T]he Supreme Court has made it clear that a "pre-emptive regulation's force does not depend on express congressional authorization to displace state law" and that a "narrow focus" on Congress' intent to supersede state law is "misdirected." The proper focus is on whether the agency effecting preemption "has exceeded [its] statutory authority or acted arbitrarily."

Wachovia Bank, N.A. v. Burke, 414 F.3d 305, 314 (2d Cir. 2005) (quoting Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1982) (alteration in original) (citation omitted)). *petition for cert. filed*, 74 U.S.L.W. 3233 (U.S. Sept. 30, 2005) (No. 05-431); *accord* Wells Fargo Bank N.A. v. Boutris, 419 F.3d 949, 954 (9th Cir. 2005) (holding that the National Banking Act "preempt[s] the California Commissioner of Corporations' . . . exercise of investigative and licensing authority over 'operating subsidiaries' of national banks").

96. Many arguments urged by the parties and amici in *Watters* apply to preemption questions outside of the banking context. For example, the petitioner in *Watters* contends that *Chevron* deference to agency preemption determinations is unwarranted "[g]ive[n] the obvious self-interest that undergirds an agency's expansion of its own powers," the Court's capacity to resolve preemption disputes based on its own "intricate body of law delineating the various types of preemption," and the effects such determinations would have on federalism. Brief for the Petitioner at 32, Watters v. Wachovia Bank, N.A., No. 05-1342 (Sept. 1, 2006), 2006 WL 2570336. Similarly, an amicus brief submitted by forty-nine states, Puerto Rico, and the District of Colum-

eral Food, Drug and Cosmetic Act (FDCA) preempts state common-law claims for design defect and failure to warn against pharmaceutical manufacturers; this split neatly tracks courts' divergent positions on the level of deference to accord to the FDA's preemption preamble.[97] In *Colacicco v. Apotex, Inc.*,[98] a federal district court's determination that the plaintiff's failure-to-warn claims were impliedly preempted by the FDCA and FDA regulations was in sync with the FDA's position.[99] Emphasizing the centrality of the FDA's view to its

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bia argued that granting *Chevron* deference to such determinations would permit an agency to "confer power upon itself," thereby raising separation of powers and federalism concerns. Brief of the States of New York et al. as Amicus Curiae in Support of the Petitioner at 7, Watters v. Wachovia Bank, N.A., No. 05-1342 (Sept. 1, 2006), 2006 WL 2570992 (quoting La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986)). The respondents in *Watters* replied that "the real issue is not whether Congress specifically intended to preempt, but instead whether the agency was authorized to issue the preemptive regulation." Brief in Opposition at 14, Watters v. Wachovia Bank, N.A., 126 S. Ct. 2900 (2006) (No. 05-1342).

97. Although no federal court of appeals has addressed the preemption issue presented since the FDA issued the preamble, the Third Circuit currently has two cases before it on this very question. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 528 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. 2006); McNellis *ex rel.* DeAngelis v. Pfizer, Inc., No. Civ. 05-1286(JBS), 2006 WL 2819046, at *3 (D.N.J. Sept. 29, 2006), *appeal docketed*, No. 06-5148 (3d Cir. 2006). District courts are divided on the issue. For pro-preemption rulings that take the position that the FDA's preamble is entitled to deference, see *In re* Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., No. M: 05-1699 CRB, 2006 WL 2374742, at *6–7 (N.D. Cal. Aug. 16, 2006); *Colacicco*, 432 F. Supp. 2d at 525; Abramowitz v. Cephalon, Inc., No. BER-L-617-04, 2006 WL 560639, at *3 (N.J. Super. Ct. Law Div. Mar. 3, 2006); and Conte v. Wyeth, Inc., No. CGC-04-437382, 2006 WL 2692469, at *6 (Cal. App. Dep't Super. Ct. Sept. 14, 2006). For anti-preemption rulings that take the position that the FDA preamble is not entitled to deference, see Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 968 & n.3 (D. Neb. 2006); *McNellis*, 2006 WL 2819046, at *3; Coutu v. Tracy, No. C.A. PC/00-3720, 2006 WL 1314261, at *3 (R.I. Super. May 11, 2006); and Levine v. Wyeth, No. 2004-384, 2006 WL 3041078, at ¶ 32 (Vt. Oct. 27, 2006).

98. 432 F. Supp. 2d 514. The plaintiff in *Colacicco* sued GlaxoSmithKline because his wife committed suicide after ingesting a generic version of its antidepressant drug, Paxil. *Id.* at 518. The plaintiff asserted a failure-to-warn claim, arguing that the warnings (published by GlaxoSmithKline and adopted verbatim by Apotex, the generic manufacturer) regarding suicide risk were inadequate. *Id.*

99. The Government's amicus brief, filed at the request of the court, reaffirmed its view that the plaintiff's failure-to-warn claims were preempted. Brief for Amicus Curiae the United States of America, at 1, 13, 15, *Colacicco*, 432 F. Supp. 2d 514 (No. 05-CV-05500-MMB). The Government points out that, at least since 2000, the FDA has intervened in pharmaceutical cases, taking a consistent 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. *Id.* at 19 (citing Government briefs filed in Motus v. Pfizer Inc., 358 F.3d 659 (9th Cir. 2004); Kallas v. Pfizer, Inc., No. 2:04CV0998 PGC, 2005 WL 4030146 (D. Utah Sept. 29, 2005); Bernhardt v. Pfizer, Inc., Nos. 00 Civ. 4042 LMM, 00 Civ. 4379 LMM, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000)).

Courts, moreover, have previously deferred to the FDA's preemption position expressed in its amicus briefs. *See, e.g.*, Needleman v. Pfizer Inc., No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697, at *4 (N.D. Tex. Aug. 6, 2004) ("[T]he Court places weight on the FDA's unambiguous statement that it would view any statement describing a relationship between Zoloft use and suicide as 'false and misleading,' and it would deem any state warning requirement preempted."); Dusek v.

analysis, the court was prepared to accord *Chevron* deference to the FDA's preemption preamble "because Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference."[100] A handful of additional courts have followed suit, according deference to the FDA's preemption position.[101] Given the traction of the *Chevron* deference position to date, it is worth considering the implications of this strong form of regulatory preemption.

B. "Access to Justice"

What, if any, relationship exists, or should exist, between regulatory preemption and what is broadly termed "access to justice"? It is perhaps ironic that the stated purpose of Executive Order 12,988—which calls for specific agency statements as to the preemptive effect of promulgated regulations—is "to improve *access to justice* for all persons who wish to avail themselves of court and administrative adjudicatory tribunals."[102] To begin, the bedrock of the civil justice system in the United States is private enforcement.[103] Democratic Representative Jan Schakowsky of Illinois has commented on the recent spate of preemption preambles:

> [I]t appears that there may have been an Administration-wide directive for agencies to promote tort reform through rule changes. . . . When so many agencies are understaffed and unable to enforce existing law, *the private right of action is more important*

Pfizer Inc., No. Civ.A. H-02-3559, 2004 WL 2191804, at *5 n.7 (S.D. Tex. Feb. 20, 2004) ("The Court does, however, place weight, though not dispositive weight, on the agency's view as expressed in the *amicus* brief.").

100. *Colacicco*, 432 F. Supp. 2d at 525 (citing Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837, 844 (1984)); *id.* at 529 ("[I]t is abundantly clear that the FDA's position is entitled to significant deference." (citing Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000) and *Chevron*, 467 U.S. at 844)).

101. *See, e.g.*, *In re Bextra & Celebrex*, 2006 WL 2374742, at *8 ("[T]he FDA's view of the preemptive effect of its own regulations is not 'plainly erroneous or inconsistent with the regulation.'" (quoting Auer v. Robbins, 519 U.S. 452, 461 (1997)); *Abramowitz*, 2006 WL 560639, at *4 ("While recognizing that the FDA is not a judicial body, this court must respect its decision with regard to preemption of state claims for failure to warn . . . .").

102. Exec. Order No. 12,988, 61 Fed. Reg. 4729, 4729 (Feb. 7, 1996) (emphasis added).

103. *See, e.g.*, Howells, *supra* note 17, at 308 (contrasting "the European commitment to regulation, rather than, litigation as a means of promoting product safety," with the focus in the United States on products liability litigation with a more peripheral role for "voluntary standards[ ] established by private actors"); *see also* John C. Coffee, Jr., *Reforming the Securities Class Action: An Essay on Deterrence and Its Implementation*, 106 COLUM. L. REV. 1534, 1542–43 (2006) (summarizing research demonstrating that "the majority of the total monetary sanctions recently imposed in the United States were obtained through private, not public, enforcement [of securities laws]"); Issacharoff, *supra* note 58, at 380–84.

> *than ever* in ensuring that unsafe practices and products are identified and kept out of the market.[104]

Of course, one could separate the establishment of national liability standards at the federal regulatory level from their enforcement, which might remain largely in private hands.[105] But a darker scenario lurks in the background. Indeed, taken to an extreme, regulatory preemption, combined with renewed vigor towards evisceration of federal private causes of action, could lead to a nearly complete substitution of public for private enforcement of the law.[106]

Here I wish to press a potentially troublesome asymmetry: agencies are given significant discretion to interpret or declare the preemptive scope of the regulations they promulgate, but when it comes to conferring private rights of action under those same regulations, courts tie their hands. In *Alexander v. Sandoval*,[107] the Court rejected the claim that there was a private right of action to enforce disparate impact regulations promulgated by the DOJ and the DOT pursuant to Title VI of the Civil Rights Act of 1964, on the ground that "[l]anguage in a regulation may invoke a private right of action that Congress through statutory text created, but it may not create a right that Congress has not."[108] Here, the Court showed no hesitation in rejecting the agencies' contrary view; it was up front with the fact that "[b]oth the Government and respondents argue[d] that the *regulations* contain rights-creating language and so must be privately enforceable."[109] Justice Scalia famously remarked that "[a]gencies may play the sorcerer's apprentice but not the sorcerer himself."[110] The clear import is that when agencies promulgate rules, private rights of action to enforce

104. Letter from Representative Jan Schakowsky to President George W. Bush (Feb. 16, 2006) (emphasis added), *available at* http://www.house.gov/schakowsky/PressRelease_2_16_06_BushLetters.html.

105. For example, the securities laws are privately enforced even if under federal regulatory standards. *See, e.g.*, Coffee, *supra* note 103, at 1542–43.

106. A fuller analysis of the interplay between private rights of action and federal regulatory schemes is beyond the scope of this Article. Elsewhere, I argue that the necessity of private rights of action varies inversely with the comprehensiveness of the federal regulatory scheme. Catherine M. Sharkey, Remedial and Regulatory Voids: Products Liability Preemption in the Modern Administrative State (2007) (unpublished manuscript) (on file with author).

107. 532 U.S. 275 (2001).

108. *Id.* at 291 (citing Touche Ross & Co. v. Redington, 442 U.S. 560, 577 n.18 (1979) ("[T]he language of the statute and not the rules must control." (alteration in original)).

109. *Id.* (citing Brief for United States at 19–20, *Sandoval*, 532 U.S. 275 (No. 99-1908); Brief for Respondents at 31, *Sandoval*, 532 U.S. 275 (No. 99-1908)).

110. *Id.* ("[W]hen a statute has provided a general authorization for private enforcement of regulations, it may perhaps be correct that the intent displayed in each regulation can determine whether or not it is privately enforceable. But it is most certainly incorrect to say that language in a regulation can conjure up a private cause of action that has not been authorized by Congress.").

those rules will not be available unless the underlying statute meets the stringent congressional intent requirement of *Sandoval*.[111]

Relatedly, the Court has held that where Congress itself has created a private right of action, it has assigned the primary responsibility for interpreting the statute to the *courts*—not the enforcing agency. In *Adams Fruit Co. v. Barrett*,[112] a unanimous Court held that the private right of action expressly conferred on migrant workers under the Migrant and Seasonal Agricultural Worker Protection Act (AWPA) was not restricted by the exclusivity provisions in the state workers' compensation law.[113] The Court, relying on the AWPA's language and structure, refused to defer to the contrary view expressed in the Department of Labor's regulations.[114] Taken together, *Adams Fruit* and *Sandoval* suggest that, to create or remove private rights of action, Congress must expressly delegate the power to the agency.[115]

At a theoretical level, there is no disconnect between the realms of implied preemption and implied rights of action. For each, there is a similar initial threshold query: Did Congress intend to preempt state regulations or common-law tort causes of action? Did Congress intend to create a private cause of action to enforce the rights or duties created by its federal scheme? Why, then, does it seem that the agency can no longer be distinguished from the sorcerer in the context of preemption, while it remains a lowly apprentice with respect to implied rights of action?[116]

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111. To be fair, while the import of Justice Scalia's rhetorical flourish is clear, *Sandoval* itself does not tell us much about an agency's power to infer private causes of action, except in the unusual posture of a valid agency regulation that is utterly inconsistent with the underlying statute. For an elaboration of this point, see Epstein, *supra* note 61.

112. 494 U.S. 638 (1990).

113. *Id.* at 650–51.

114. *See id.* at 649–50.

115. Professor Thomas Merrill has criticized *Adams Fruit* as a "wooden product of a conceptual scheme that all too often forecloses potentially valuable lines of inquiry." Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 1023 (1992). In contrast, Merrill argues that courts should defer to agencies which "often have specialized knowledge about the operations of a particular industry and the way it is affected by a statutory scheme." *Id.* at 1022. For an argument that agencies should be granted *Chevron* deference when determining whether a private right of action exists, see Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 159 (2005).

116. Symmetry, of course, could be achieved by restraining the agency in the former context, as opposed to expanding its authority in the latter. Indeed, not all courts acquiesce in the agency's assumption of the sorcerer's role in preemption. *See, e.g.*, Desiano v. Warner-Lambert & Co., 467 F.3d 85, 97 n.9 (2d Cir. 2006) ("[A]n agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption."); Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 683 (E.D. Pa. 2006) (suggesting that the distinction between addressing statutory ambiguities and supplying a legislative statement of intent to overcome a presumption against preemption is precisely the difference between

A finding that no federal private right of action exists will usually not preclude a state from providing a right of action.[117] As reflected in the *Restatement (Third) of Torts*, "The violation of federal statutes and regulations is commonly given negligence per se effect in state tort proceedings."[118] Most state courts follow suit; as courts of general jurisdiction, they recognize that, even absent a federal right of action, state tort law may provide an enforcement mechanism for the violation of federal standards.[119] But other state courts have refused to recognize a state tort action based on a violation of the federal liability standard where there is no express or implied federal cause of action.[120] Courts have relied on various grounds relating to the fact that "the congressional decision not to provide a private cause of action under the [federal statute] becomes quite important in considering the propriety of a state negligence per se action."[121] The bottom line, then, is that there is a right but no private remedy.[122] Public enforcement will have to take up the slack.

"play[ing] the sorcerer's apprentice" and "the sorcerer himself" (quoting Alexander v. Sandoval, 532 U.S. 275, 291 (2001)).

117. *See* Note, *State Incorporation of Federal Law: A Response to the Demise of Implied Federal Rights of Action*, 94 YALE L.J. 1144, 1155–56 (1985).

118. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 14 reporter's cmt. a (Proposed Final Draft No. 1, 2005); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (1998) ("[A] product's noncompliance with an applicable product safety statute . . . renders the product defective . . . .").

119. *See, e.g.*, Lowe v. Gen. Motors Corp., 624 F.2d 1373, 1379 (5th Cir. 1980) ("This Court has often held that violation of a Federal law or regulation can be evidence of negligence, and even evidence of negligence per se."); Hofbauer v. Nw. Nat'l Bank of Rochester, Minn., 700 F.2d 1197, 1201 (8th Cir. 1993) ("Even though the [plaintiffs] cannot assert a private cause of action arising under federal law, the federal statutes may create a standard of conduct which, if broken, would give rise to an action for common-law negligence.").

120. *See, e.g.*, Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 554 (E.D. Pa. 2006) (accepting defendant's contention that plaintiff's negligence per se claim was impliedly preempted on the ground "that there is no private right of action under the FDCA"); Miller v. E.I. Du Pont de Nemours & Co., 880 F. Supp. 474, 480 (S.D. Miss. 1994) ("This court concludes that since Congress did not intend to create a private right of action under [the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)], then any alleged violation of that statute by defendant cannot provide a basis for a negligence per se claim."); Dine v. W. Exterminating Co., CIV. A. No. 86-1857-OG, 1988 WL 25511, at *4 (D.D.C. Mar. 9, 1988) (holding that "plaintiffs may not invoke the principle of negligence per se" based on a FIFRA violation).

121. *In re* Bendectin Litig., 857 F.2d 290, 314 (6th Cir. 1988) (observing that "preemption could be yet another obstacle to plaintiffs' reliance on a theory of negligence per se"); *accord* R.B.J. Apartments, Inc. v. Gade City Sav. & Loan Ass'n, 315 N.W.2d 284, 290 (N.D. 1982) ("The separation-of-powers doctrine and principles of federalism militate against the adoption of the federal statute as the standard of care in a state negligence action when no private cause of action, either explicit or implicit, exists in the federal statute.").

122. The Supreme Court has eloquently proclaimed the need for a remedy:

> [T]he power to enforce the performance of [an] act must rest somewhere, or it will present a case which has often been said to involve a monstrous absurdity in a well

IV. FEDERALISM VALUES

Agencies' active participation in preemption determinations, fueling the momentum towards federalization of product liability standards, raises fundamental issues of institutional choice and competence. With the stroke of a pen, Congress could definitively answer the question of state common-law preemption in each of the product areas in which it has regulated. Few would challenge Congress' ultimate constitutional authority in the realm of products liability preemption. Indeed, most would argue further that Congress—as the sole constitutional body that effectively represents state interests—should exercise its powers to decide critical issues of policy, lest important federalism values fall by the wayside.[123]

The interesting question here, then, is how to handle the situation presented in each of the product realms examined above where Congress is anything but clear and resolute. Congress punts on the key question: To what extent do federal "standards" and "regulations" preempt common-law remedies determined by judges and juries?[124] Agencies and courts, then, vie to fill this interpretive gap.[125] At this

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organized government, that there should be no remedy, although a clear and undeniable right should be shown to exist.

Kendall v. United States, 37 U.S. (12 Pet.) 524, 624 (1838).

123. *See, e.g.*, Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 331 (2000) (analyzing the use of nondelegation canons, which require legislative deliberation on the issue in question on the ground that Congress, not executive agencies, should decide the issue because state interests are effectively represented in Congress (citing Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 COLUM. L. REV. 543 (1954))). The vigorous dissent in *Geier*, penned by Justice John Paul Stevens, and joined by Justices David Souter, Clarence Thomas, and Ruth Bader Ginsburg, echoed this view: "Unlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed regulations that have broad pre-emption ramifications for state law." 529 U.S. 861, 908 (2000) (Stevens, J., dissenting).

124. What explains Congress' failure to weigh in on this critical issue, time and again? According to Professors James Henderson and Aaron Twerski, there is a simple political answer:

> Congress quite clearly has sought to placate both industry and consumers by speaking out of both sides of its mouth. And in the event that no one should understand how both [preemption and saving clauses] can work in tandem, that job is left to the United States Supreme Court, which does not have to face the wrath of political constituencies.

JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 424 (5th ed. 2004).

This abdication of responsibility, in turn, masks a deeper set of issues regarding Congress' asymmetric focus on liability standards, rather than remedial schemes, in promulgating federal legislation—a topic that I take up elsewhere. *See* Sharkey, *supra* note 106.

125. *Cf.* Mendelson, *supra* note 87, at 800 ("Ultimately, the source of the tension between *Chevron* and the presumption against preemption is that Congress has failed to define explicitly whether it believes a statute preempts state law or whether it wishes an administrative agency to decide that question.").

point, the debate shifts to whether agencies or courts are more likely to protect the values of federalism.[126]

Agencies might further federalism values in one of two ways. First, they might serve as a catalyst for congressional action. Second, agencies themselves might emerge as the institutional actor of choice, to the extent that they effectively represent state interests in our modern administrative state. With respect to each of these aims, the "back-door" nature of federal agencies' recent actions should give us pause.[127] I take as given that federal agencies are an ingrained component of the modern regulatory state. What follows is an attempt to sketch out a forward-looking, federalism-inspired model for agency and court participation in preemption determinations.

A. Agencies: Accountability, Dialogue, and Mobilization

Given their unique understanding of the ways in which state law interacts with a federal regulatory scheme, federal agencies may have a critical role to play in preemption determinations, either directly or in forcing Congress to confront the vexing issue of the displacement of state common law. Recent agency action is in marked contrast with the pre-2000 era, when, as aptly characterized by Professor Lars Noah, agencies' formal pronouncements on the preemption subject, typically disclaiming any preemptive intent, "contributed to the courts' confusion by disavowing any intent to influence tort litigation through [their] regulatory decisions."[128] Legal scholar Peter Huber explained the seeming inconsistency as follows: "Administrative agencies may find it politically convenient to disclaim final responsibility for [their]

126. The conventional view is that courts, which generally apply a presumption against preemption, are more likely than federal agencies to protect federalism values. *But see* William N. Eskridge, Jr. & Kevin S. Schwartz, Chevron *and Agency Norm-Entrepreneurship*, 115 YALE L.J. 2623, 2626 (2006) ("[A]dministrative norm-entrepreneurship is potentially more democratically accountable than judicial value elaboration."); Mendelson, *supra* note 87, at 741 (arguing that "[a]gencies are politically accountable through the President" and also frequently desire to maintain cooperative working relationships with the states).

127. Others have charged that federal agencies are undemocratic because rulemakings—let alone the filing of amicus briefs—draw far less public attention than pending legislation. *See, e.g.*, Theodore Ruger, *Left to Their Own Devices*, LEGAL AFF., Sept.–Oct. 2005, at 24 ("[R]ather than make its case and risk opposition before elected officials in Congress, the FDA has engaged in the stealth tactic of intervening in private lawsuits."); Margaret H. Clune, *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers* 10 (Ctr. for Progressive Regulation White Paper No. 403, Oct. 2004) ("The Bush Administration has pursued its tort reform agenda through arcane legal vehicles that are largely hidden from public view, and it has enlisted the industry to alert it to chances to do so.").

128. Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2158 (2000) (citing regulations).

public risk choices . . . ."[129] This point was taken up by Noah, who suggested that the FDA historically failed to oppose judicial review of agency standards because the tort system served as a convenient "safety valve" for deflecting adverse publicity when FDA-approved products were subsequently demonstrated to be defective.[130] Might then the recent promulgation of preemption preambles by federal agencies mark the dawn of a new sense of accountability?

Agency accountability, however, means more than seizing the preemption reins. In filling out Congress' statutory schemes, agencies are called upon to judge how the continuation of state laws alongside federal legislation might skew congressional objectives.[131] This evaluative process does not take place in a vacuum. Agencies are "subject to a combination of political influences by the executive, legislature, and outside political groups."[132] Indeed, "agencies have become an important situs for the expression and testing of public norms."[133]

At least in theory, there should be room in this process for a federal-state dialogue. Under Executive Order 13,132, federal agencies are obliged to consult with state and local authorities regarding the

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129. Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 334 (1985).

130. *See* Noah, *supra* note 128, at 2158.

131. In this vein, the *Medtronic* Court focused upon the FDA's expertise:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and, therefore, whether it should be pre-empted. For example, Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA—an authority that necessarily requires the FDA to assess the pre-emptive effect that the Act and its own regulations will have on state laws.

518 U.S. 470, 496 (1996) (citations omitted).

132. ELHAUGE, *supra* note 82 (manuscript at 154) (citing Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2254–60, 2264–69, 2274–319 (2001)). Elhauge's current preferences default rule theory provides an illuminating angle on the debate. Elhauge takes the position that "agencies in fact are subject not only to presidential influence but to various forms of influence by Congress and outside political groups." *Id.* (manuscript at 172). Elhauge provides a significant caveat:

> If agency action can largely be directed by the President, then its actions are more likely to reflect only presidential preferences. Such agency action is more likely to take positions that create sharp conflicts with Congress. More importantly, such agency action is less likely to reflect current enactable preferences because the President's views reflect only one piece of the political puzzle necessary to create enactments.

Id. (manuscript at 173).

133. Eskridge & Schwartz, *supra* note 126, at 2624–25 ("Administrative norm-entrepreneurship through statutory interpretation can enrich our national discourse about fundamental values.").

effects of the regulations they issue.[134] The CPSA specifically provides for cooperation between the Commission and state agencies, including the commissioning of state employees as CPSC officers for purposes of conducting examinations, investigations, and inspections.[135] The NHTSA and the FDA are likewise directed to foster open exchanges with state and local agencies.[136]

But the recent controversy over the agency preemption preambles has led to charges that agencies are thumbing their noses at these congressional and executive mandates. In its recent Notice of Proposed Rulemaking on roof standards, the NHTSA asserted that the new rule "would not have any substantial impact on the States," and therefore did "not have sufficient federal implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement."[137] The FDA, at the time of its December 2000 initial notice of its intent to revise the prescription drug labeling regulations, stated its view in the preamble that its regulations were *minimum* standards and did not preempt state tort claims.[138] Moreover, the FDA expressly stated that "this proposed rule *does not contain policies that have federalism implications or that preempt State law.*"[139] The FDA's issuance of a final rule with preemptive language inserted in the preamble thus provoked charges that it had flouted its obligation to consult with State and local authorities and circumvented the proper notice-and-comment process.

The question remains, however, whether the aggressive pro-preemption posture taken by the agencies (coupled perhaps with their

134. *See* Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,257 (Aug. 10, 1999) (requiring agencies to provide notice and opportunity to participate to potentially affected states); *see also* Geier v. Am. Honda Motor Co., 529 U.S. 861, 909–10 (2000) (Stevens, J., dissenting) (stressing the significance of notice-and-comment rulemaking to "ensure that States will be able to have a dialog with agencies regarding pre-emption decisions *ex ante*").

135. *See* 15 U.S.C. § 2078 (2000) (requiring Commission to "establish a program to promote Federal-State cooperation" by commissioning state and local authorities to assist in "data collection, investigation, and educational programs" so long as states and localities are "able and willing to provide [such services] and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance").

136. *See, e.g.*, FDA INVESTIGATIONS OPERATIONS MANUAL 71 (2006) ("The scope of consumer protection is extended by cooperative efforts of federal, state, and local agencies and international cooperation. Procedures to appropriately share responsibilities and cooperate with our consumer protection partners are essential. Federal, state, and local cooperation shall be fostered whenever possible.").

137. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,245 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571).

138. *See* Requirements on Content and Format of Labeling for Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (proposed Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201).

139. *Id.* (emphasis added).

flouting of these mandates) will nonetheless serve as a catalyst to mobilize congressional action.[140] A group of state attorneys general and the National Conference of State Legislatures have voiced sharp criticisms of the preemption preambles issued by the NHTSA and the FDA;[141] Oregon Governor Theodore Kulongoski has joined the chorus of protest.[142] The American Trial Lawyers' Association (recently renamed the American Association for Justice) has used the issue to energize its base;[143] the issue nearly came to a head at the 2006 annual meeting of the American Bar Association.[144] Public Citizen, a con-

140. Here, I am drawing upon Professor Roderick Hills' provocative argument in favor of a strong presumption against preemption not based on the merits of the anti-preemption position, but instead upon the hypothesis that it will serve as a catalyst for mobilizing the public and generating bills before Congress, which would then be forced to confront the issue directly. *See* Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. (forthcoming 2007). As a theoretical matter, however, one could employ either a strong pro- or anti-preemption default (or presumption) for court decisionmaking. Noah, for example, has hypothesized that agency preemption, in the form of a regulatory compliance defense enforced by courts, raises all parties' incentives to take part in agencies' notice-and-comment rulemaking procedures. Noah, *supra* note 128, at 2164 n.71. Ultimately, it is an empirical claim whether one or the other default position would lead to greater mobilization of the public, leading to some congressional action. Here, I merely trace some of the actors prompted into action in response to courts' actual (or predicted) deference to agency preemption preambles.

141. *See* Letter from Office of the Attorneys General of Twenty-Six States to NHTSA (Dec. 23, 2005) (criticizing the NHTSA's alleged flouting of the specific mandates of Executive Order 13,132); Letter from National Conference of State Legislatures to the Secretary of the U.S. Department of Health and Human Services (Jan. 13, 2006), *available at* http://www.ncsl.org/programs/press/2006/060113Leavitt.htm (assailing the FDA's actions as "an abuse of agency process and a complete disregard for our dual system of government"); *see also Federal Preemption of State Authority a Disturbing and Growing Trend*, NCSL NEWS, Apr. 6, 2006, http://www.ncsl.org/programs/press/2006/pr060406.htm.

142. *See* Rob Ammons & David George, *Tort Reform by Regulation: The National Highway Traffic Safety Administration Attempts to Preempt State-Tort Lawsuits with Its Proposed Roof-Strength Regulation*, 58 ADMIN. L. REV. 709, 729 n.144 (2006) ("Oregon Governor Theodore R. Kulongoski objected to NHTSA's claim that Proposed Safety Standard 216 does not raise sufficient federalism concerns to warrant consultation with state officials of a federalism summary impact statement." (citing Letter from Governor of Oregon Theodore R. Kulongoski to Jacqueline Glassman, Acting Administrator of NHTSA (Nov. 21, 2005), *available at* http://dmses.dot.gov/docimages/pdf94/372927_web.pdf)).

143. ATLA's President Kenneth Suggs has accused the FDA of underhandedness, given the lack of transparency in its rulemaking process. Suggs, *supra* note 4, at 9 ("The final rule is the polar opposite of the one that was originally proposed . . . . The FDA even admitted at a January press conference announcing the rule that the provisions were added behind the scenes after consulting with the drug industry.").

144. Reacting to what it perceived as a "silent tort reform" movement, the Tort Trial and Insurance Practice Section of the American Bar Association House of Delegates proposed, but then subsequently withdrew, the following resolution: "That, absent Congressional authorization, the American Bar Association opposes the promulgation by federal agencies of rules or regulations that pre-empt state tort and consumer protection laws in instances where the state laws hold parties to a higher or stricter standard than that being promulgated by a federal

sumer advocacy group, has pressed opposition to preemption in court as well as in the press.[145]

This agitation, moreover, has reverberated throughout the chambers of Congress. Senators Edward Kennedy and Christopher Dodd, and Representatives Sherrod Brown, Henry Waxman, and John Dingell voiced angry criticism of the FDA for its failure to comply with its consultation mandate.[146] And Senator Kennedy and Representative Maurice Hinchey have threatened to introduce legislation if necessary to thwart the agency's preemption coup.[147]

In sum, the issuance of preemption preambles might galvanize a variety of stakeholder groups—including those representing states and the public interest—to take responsive action, including lobbying Congress for legislation to address preemption explicitly. Courts' deference to agency preemption determinations might then serve as a strong pro-preemption default, leading to mobilization of interests before Congress. But in light of Congress' track record to date, it is worthwhile to consider whether courts might play a different sort of information-forcing role in a world where Congress, even in the face of increased agitation, continues to punt on the key preemption determination.

B. Courts: Penalty Defaults and Information-Forcing Rules

Given the twin aims of mobilization and robust exchanges between federal agencies and state and public stakeholders, courts, too, might play an enhanced role. Consistent with Executive Order 13,132,[148] courts might condition deference to agency interpretations of the preemptive scope of regulations on compliance with various congres-

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agency." Sandra R. McCandless, 2006 A.B.A. TORT TRIAL & INS. PRAC. SEC. 1; Leigh Jones, *Plan Causes Sharp Divide Before Being Pulled*, NAT'L L.J., July 31, 2006.

145. *See, e.g.*, Brief of Amici Curiae Public Citizen et al., Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 06-3107) (pending appeal in the Third Circuit); Allison M. Zieve & Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why It Is Wrong and Warrants No Deference*, 21 TOXICS L. REP. 516 (2006); FDA's Drug Label Rule Fails to Guarantee Access to Vital Information and Includes "Sneak Attack" on Patients' Legal Rights (Jan. 18, 2006), http://www.citizen.org/pressroom/print_release.cfm?ID=2114.

146. Letter from Senators Edward M. Kennedy and Christopher J. Dodd to The Honorable Michael O. Leavitt, Secretary of Health and Human Services (Feb. 23, 2006); Letter from Representatives Sherrod Brown, Henry A. Waxman, and John D. Dingell, members of the House Committees on Government Reform and Energy and Commerce, to The Honorable Michael O. Leavitt, Secretary of Health and Human Services (Feb. 23, 2006).

147. *See* John P. Lavelle, Jr. & Anne G. Sweeny, *Preemption of Failure-to-Warn Claims: The Battle Inside and Outside the Courtroom*, 14 METROPOLITAN CORP. COUNS., Oct. 2006, at 25.

148. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999). The Executive Order does not give rise to any rights enforceable in court, so it is controversial to suggest that courts give dispositive weight to any failure to comply with its mandates.

sional and executive measures designed to increase the public participation of states, the legislature, and outside political groups: consultation mandates, "federalism impact statements," or even notice-and-comment periods could be required for all preemption statements. An express declaration of preemptive intent and effect in the required federalism impact statement,[149] for example, might be a prerequisite to court deference to an agency interpretation of the preemptive scope of a particular regulation.[150] In a similar vein, courts might mandate notice-and-comment periods for any preemption statement.[151] The goal of such procedural reforms would be to require the agencies to engage directly with the preemption issue, leading to more deliberate, well-informed, and publicly accountable decision-making.[152]

Some recent cases illustrate such a hard-line stance taken by courts. In *Jackson v. Pfizer, Inc.*,[153] a federal district court rejected the defendant's claim that common-law failure-to-warn claims were preempted by the FDA. In so doing, the court opined that "[t]he recent notice issued by the FDA claiming preemption is not persuasive" on the ground that "[t]he FDA failed to comply with its requirements [under Executive Order 13,132] to communicate with the states and to allow

149. *Id.* at 43,258.

150. As Mendelson documents, currently it is rare in practice to see federalism impact assessments from agencies. Mendelson, *supra* note 87, at 783. A 1999 GAO report corroborates this observation, finding that "agencies have prepared federalism assessments for only 5 of the more than 11,000 final rules issued in recent years" and otherwise only include "'boilerplate' certifications with little or no explanation of why the executive order's requirements were not applicable to the rules." U.S. GEN. ACCOUNTING OFFICE, FEDERALISM: IMPLEMENTATION OF EXECUTIVE ORDER 12612 IN THE RULEMAKING PROCESS 8, 11–13 (1999) (suggesting that agencies' high thresholds for what constitutes a significant federalism impact explain this phenomenon).

151. Interpretive rules and statements of policy, however, are ordinarily exempted from the APA's notice-and-comment procedure. *See* United States v. Mead Corp., 533 U.S. 218 (2001). Policy statements are "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." Lincoln v. Vigil, 508 U.S. 182, 197 (1993) (internal quotation marks omitted) (quoting Chrysler Corp. v. Brown, 441 U.S. 281, 302 n.31 (1979)). It is not obvious whether the preemption preamble is an "interpretive rule" or a "statement of policy." *See, e.g.*, Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 532–34 (2006).

152. Notice-and-comment rulemaking is at the heart of many scholars' embrace of administrative statutory interpretation. *See, e.g.*, ELHAUGE, *supra* note 82 (manuscript at 165) ("While different forms of rulemaking have equally coercive effects on third parties, it is only rulemaking that is conducted after notice and comment that gives some reasonable assurance that the agency surveyed the current political preferences before acting."); Eskridge & Schwartz, *supra* note 126, at 2626 (describing the notice-and-comment process as "[i]llustrating a republican virtue absent in judicial norm elaboration, citizens and groups are able to present their evidence and arguments to public officials who are required to take their input seriously").

153. 432 F. Supp. 2d 964 (D. Neb. 2006). The plaintiffs in *Jackson* sued Pfizer and Wyeth for strict liability and negligence, alleging that ingestion of the antidepressant drugs Zoloft and Effexor caused their son to commit suicide. *Id.* at 965.

the states an opportunity to participate in the proceedings prior to a preemption decision."[154] In similar fashion, the federal district court in *McNellis ex rel. DeAngelis v. Pfizer, Inc.*[155] refused to defer to the FDA's assessment of the preemptive effect of its rule based not only upon its failure to comply with Executive Order 13,132, but also on the ground that "the 2006 Preamble was a novation, not subjected to prior public notice or comment."[156]

Each of these courts refused to accord mandatory *Chevron* deference to the agency's statement of its preemption position in a preamble that in some way evaded the procedural process for agency rulemaking.[157] By conditioning deference (whether of the mandatory *Chevron* variety, or more plausibly, of the *Skidmore* "power to persuade" variety) on full compliance with the congressional and executive mandates designed to ensure robust dialogue and debate among state and federal stakeholders, courts would force agencies, at a minimum, to account for any divergence between their stated purposes to promote uniformity and enhanced safety, and the consequences flowing from evisceration of state common-law causes of action.

V. CONCLUSION

Agency preemption preambles represent the latest manifestation of a broader trend of the increasing federalization of law governing products regulated in a national market. This inexorable momentum towards federalization raises a potentially troublesome asymmetry with respect to agency decisionmaking: courts appear to grant agencies expansive discretion to interpret or declare the preemptive scope of the regulations they promulgate, whereas agencies are not given corresponding latitude to infer private rights of action under those

154. *Id.* at 968 & n.3 (citing Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999)). The court likewise declined to give the FDA's amicus briefs "force of law." *Id.* at 968 n.4. The Supreme Court has held that, in order to get *Chevron* deference, agency action must have the "force of law." *Mead*, 533 U.S. at 229–31.

155. No. Civ. 05-1286(JBS), 2006 WL 2819046, at *3 (D.N.J. Sept. 29, 2006), *appeal docketed*, No. 06-5148 (3d Cir. 2006).

156. *Id.* at *9 ("While an agency's explanatory statement, composed after receiving comment upon the duly-published proposed regulations, is admittedly not itself subject to notice and comment before final publication, the abrupt rejection of the agency's own prior interpretation (while the regulations themselves are unchanged) suggests a degree of informality yielding an interpretation unhinged from the text and original intent of the regulations themselves.").

157. *But see In re* Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., No. M: 05-1699 CRB, 2006 WL 2374742, at *7 (N.D. Cal. Aug. 16, 2006) ("[T]he FDA's failure to comply with Executive Order 13132 regarding consultation with local officials about a possible conflict with state law does not mean that this Court cannot consider the FDA's view of how certain state laws stand as an obstacle to the accomplishment of the objectives of Federal law.").

same regulations. Moreover, the "backdoor" nature of recent agency action is in sharp tension with the conventional notion of a democratically accountable, broadly representative body (e.g., Congress) taking the lead in politically charged areas that implicate the balance of federal-state relations. To transcend these various difficulties, I have sketched some court-enforced default rules that might alternatively mobilize Congress to address preemption questions directly or else motivate agencies to replace Congress as the situs for a rich and deliberative debate surrounding the displacement of state common law by a federal regulatory scheme. In a world where Congress is likely to continue to punt key preemption questions to agencies and courts, it is worth considering such federalism-inspired models, designed to foster an informed dialogue amongst the institutional actors. The goal here is not that such information-forcing reforms would inevitably lead to substantive policy changes within the agencies,[158] but instead that they would shed light on what has hitherto been an all-too-quiet, backdoor movement, in need of further scrutiny and debate.

158. Of course, an agency "high on hubris" (to quote from Robert Rabin's oral commentary on this Article) could easily evade any such requirements with "empty symbolic gestures." Moreover, the politics involved in this area are significant. *Cf.* Anna Wilde Mathews, *FDA Plan Would Aid Drug Makers in Liability Suits*, WALL ST. J., Jan. 14, 2006, at A1 ("Inclusion of the new FDA policy in the long-awaited drug-labeling rule has sparked disagreements between FDA career officials and Bush administration appointees, according to people with knowledge of the matter. Some FDA career staffers have argued internally that it isn't relevant to the rule's focus on drug-labeling reform, and may draw controversy to an important regulatory improvement that isn't itself politically divisive.").