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FEDERALISM ACCOUNTABILITY: “AGENCY-FORCING” MEASURES

CATHERINE M. SHARKEY†

ABSTRACT

This Article takes as its starting point the “agency reference model” for judicial preemption decisions, adopting the foundational premise that courts should take advantage of what federal agencies, which are uniquely positioned to evaluate the impact of state regulation and common law liability upon federal regulatory schemes, have to offer. The Article’s main focus is on the federalism dimension of the debate: Congress’s and federal agencies’ respective ability to serve as loci of meaningful debate with state governmental entities about the impact of federal regulatory schemes on state regulatory interests. Notwithstanding the dismal track record of federal agencies, which seems to be characterized by total neglect of states’ regulatory interests, the Article sides with agencies over Congress and trains its focus on reform of the agency rulemaking process. Given that the 1999 Federalism Executive Order provides a blueprint for timely and meaningful consultation with the states, issuance of federalism impact statements, and robust interchanges during the notice-and-comment period, what is needed now is an effective enforcement mechanism.

The Article advocates a variety of “agency-forcing” measures designed to enhance the ability of Congress, the executive, and

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especially the courts, to ensure that agencies abide by executive mandates and other reforms, and to provide a check on overt politicization or inaction on agencies' part. The Article introduces the concept of "indirect challenges" to agency rulemaking, arising outside of the Administrative Procedure Act's domain of direct challenges to agency action at a later juncture when a defendant asserts a preemption defense to state common law tort actions.

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INTRODUCTION

Federal preemption of state tort law has emerged on the modern political and judicial scene with a vengeance. Federal agencies have

promulgated myriad regulations asserting preemptive authority,¹ the U.S. Supreme Court has decided a rash of products liability preemption cases,² and Congress has gotten in on the game, holding hearings to consider legislation designed to undo the Court's handiwork in the realm of medical devices and food products.³

The change in administration presents a ripe opportunity to reevaluate the organization of the regulatory state and the appropriate roles of Congress and federal agencies. This Article concludes that the roles of Congress and federal agencies with regard to health and safety regulation preemption determinations are, and should be, precisely the opposite of what scholars and critics conventionally think. Congress—the institutional actor typically heralded as democratically accountable, and thus willing to heed states' interests—proves, in actuality, to be nearly indifferent to those committed to state regulatory interests and, in any event, relatively powerless to advance them. And federal agencies—typically

1. See *infra* Part I.

2. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009) (holding that FDA approval of warnings on a pharmaceutical company's label did not provide a complete defense to state tort claims); *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 551 (2008) (holding that a state fraud claim against a cigarette manufacturer was not preempted by federal law); *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), *affg by an equally divided Court* *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 87 (2d Cir. 2006) (holding that federal law did not preempt a state tort law providing a "fraud-on-the-FDA" exception to state immunity for drug manufacturers whose drugs are approved by the FDA); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1011 (2008) (holding that a federal statute regulating medical devices preempts state tort law when the device at issue had received FDA premarket approval).

3. See Food and Drug Administration Globalization Act of 2009, H.R. 759, 111th Cong. § 2 (2009) (providing "savings" language to the FDCA to the effect that neither the Act nor any amendments thereto "may . . . be construed as modifying or otherwise affecting any action or the liability of any person . . . under the law of any State"); see also Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (introduced Mar. 5, 2009 and referred to the Subcommittee on Health Mar. 6, 2009); Medical Device Safety Act of 2008, S. 3398, 110th Cong. (2008) (providing a savings clause and effectively overturning *Riegel*); Medical Device Safety Act of 2008, H.R. 6381, 110th Cong. (2008) (same); Barry Meier, *Life, Death and Liability: An Effort to Restore the Right to Sue Device Makers*, N.Y. TIMES, Feb. 20, 2009, at B1 ("Two House Democrats, Henry A. Waxman of California, the chairman of the House Energy and Commerce Committee, and Frank Pallone Jr. of New Jersey, the head of its health subcommittee, plan to reintroduce soon legislation that would effectively nullify the Supreme Court decision. A similar Senate bill, sponsored last year by Edward M. Kennedy, Democrat of Massachusetts, and Patrick J. Leahy, Democrat of Vermont, is expected to be reintroduced in coming months."); Letter from H. Thomas Wells, Jr., President, Am. Bar Ass'n, to Rep. Frank Pallone, Jr., Chairman, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Representatives (Dec. 29, 2008), available at http://www.abanet.org/poladv/letters/tortlaw/2008dec29_medicaldeviceh_1.pdf (urging the sponsor of H.R. 6381 to reintroduce it in the next Congress).

understood as insulated, undemocratic institutions, that are, moreover, tools of the reigning political party—surprisingly emerge as the best possible protectors of state regulatory interests.

What emerges from this reassessment of institutional roles? Given that federal agencies have become the real decisionmakers in preemption controversies, state governmental entities cannot assume that Congress will be a receptive or effective audience. It is indeed understandable that state entities have looked to Congress for sympathy, particularly during the George W. Bush (Bush II) administration, when federal agencies acted in blatant disregard of state regulatory interests. The Food and Drug Administration's (FDA) machinations surrounding the issuance of a preemption preamble to a 2006 prescription drug labeling rule exemplifies a wider pattern of neglect of states' regulatory interests.⁴ But now that Congress has taken a back seat to federal agencies on critical questions of preemption, it is not useful to yearn for a (perhaps fictional) time when Congress reigned supreme. Instead, a wise strategy would be to embrace the primacy of federal agencies and to focus on reforming them to ensure they can become a rich forum for participation by state governmental entities.

Part I explores the federal agencies' dismal track record on accountability and highlights why reform is necessary. A close look at the circumstances behind the FDA's issuance of the 2006 drug labeling preemption preamble reveals a lack of transparency, procedural irregularity, and utter indifference toward state governmental entities. This, moreover, is but one example of federal agencies' documented disregard of congressional and executive mandates to incorporate into their rulemaking process consultation with relevant state entities and investigation of the potential consequences of their rules on state regulatory schemes. The FDA's 2008 drug labeling regulation addresses circumstances in which drug manufacturers can unilaterally (that is, prior to FDA approval) change drug labels in light of newly acquired information.⁵ The regulation signaled a measured step in the right direction, but it provides meager confidence that reform is headed inevitably in that direction.

4. *See infra* Part I.A.1.

5. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814).

Against this rather bleak background, Part II presents a comparative institutional analysis of Congress and federal agencies with respect to preemption determinations. As I have argued previously, in making preemption decisions, courts should take advantage of what federal agencies, which are uniquely positioned to evaluate the impact of state regulation and common law liability upon federal regulatory schemes, have to offer.⁶ The “agency reference model”⁷ that I have proposed would be “information-forcing” in the sense that it would require product manufacturers to come forward to the FDA with new safety risk information, including clinical studies, adverse event reports and the like, as a precondition for court determinations of preemption.⁸ In this Article, I address a new dimension of the debate: Congress’s and federal agencies’ respective ability to serve as loci of meaningful debate with state governmental entities about the impact of federal regulatory schemes on state regulatory interests.

Part III launches an imaginative rethinking of the institutional role played by federal agencies. A brighter future, giving voice to state regulatory interests in preemption decisionmaking can only happen in the wake of fundamental reforms to the agency rulemaking process, as well as to the general approach that agencies take toward those who represent state regulatory interests. A threshold question is precisely who represents these state interests, a vexing issue in the sphere of consumer health and safety, where typically preemption involves the displacement of state common law and there is no state-level agency or regulatory apparatus to serve as a natural representative. State governmental entities emerge as likely (albeit imperfect) contenders.

The 1999 Federalism Executive Order (No. 13,132) provides a blueprint for reform: timely and meaningful consultation with the states throughout the process, issuance of federalism impact statements that detail the effects upon the states and changes in the federal-state balance, robust interchanges during the notice-and-comment period, including solicitation of comments and responses thereto. The spirit of the executive order is even more far-sighted,

6. E.g., Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 452–53 (2008) [hereinafter Sharkey, *Products Liability Preemption*].

7. *Id.* at 477–502.

8. *See id.* at 520.

envisioning a cooperative partnership between states and agencies in the development of rules and regulations. Critical to the success of any such reforms, however, is an effective enforcement mechanism—a serious drawback of the existing executive order.

Part IV takes up a variety of “agency-forcing” measures designed to enhance the ability of Congress, the executive, and especially the courts, to ensure that agencies abide by executive mandates and other reforms, and to provide a check on overt politicization or inaction on agencies’ part. Previous attempts to urge Congress to codify the federalism executive order have not been successful, nor have scholarly calls for the executive to seize the reins to harmonize enforcement via centralized review by its Office of Information and Regulatory Affairs been heeded. This Article revisits the enforcement potential of each of these institutional actors before turning to innovative proposals centering upon courts. The absence of direct challenges to preemptive health and safety regulations has contributed to a failure of the imagination on the part of scholars to harness administrative law process in service of reform. This Article introduces the concept of indirect challenges to agency rulemaking, arising outside of the Administrative Procedure Act’s domain of direct challenges to agency action at a later juncture when a defendant asserts a preemption defense to state common law tort actions. Courts have an opportunity to scrutinize both the empirical substrate of the regulatory record compiled by the agency as well as its articulated reasons underlying any interpretive policy. Anticipation of such judicial review at this stage would force agencies (prodded by interested parties, such as drug manufacturers) not only to adhere to the strictures of the executive order, but also to compile a diligent agency record that would serve as the basis of the court’s evaluation of whether the state tort action seeks to “redo” the analysis conducted by the agency and should therefore be ousted. Finally, agencies would be dissuaded from operating on the basis of politically motivated “proclamations of pre-emption”⁹ that would not withstand judicial scrutiny and would instead be goaded toward

9. *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009). *Wyeth* stands as a prominent example of an indirect challenge to an agency regulation—in this case, the FDA’s preemption preamble—with dire consequences for the defendant manufacturer. For discussion, see *infra* notes 247–52 and accompanying text.

notice-and-comment rulemaking, which “offer[] States or other interested parties notice or opportunity for comment.”¹⁰

I. AGENCY DISREGARD OF STATE REGULATORY INTERESTS

In a 2007 article, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, I began with a tale of three agencies—the FDA, the National Highway Transportation and Safety Administration (NHTSA), and the Consumer Product Safety Commission (CPSC)—each of which had promulgated a preamble to a proposed rule, stating that the rule would displace competing state tort claims.¹¹ The nascent trend I identified—of federal agencies issuing express directives that oust state tort law claims—has picked up steam in the ensuing years. Agencies—particularly the FDA and NHTSA—are disregarding and even defying state regulatory interests, stooping so low as to engage in bait-and-switch tactics: publicly disclaiming preemptive effect during the notice-and-comment rulemaking period, and then, without warning, eviscerating that disclaimer with a resolute preemption provision in the final rule. Against this backdrop of stealth maneuvers and deceptive communications with state governmental entities, an agenda of reinvigorated agency accountability might seem dubious, if not outright naïve. A small glimmer of hope is provided by the 2008 FDA drug labeling regulation, which was ushered through the notice-and-comment process with a modicum of procedural regularity. Yet this example bears many of the same distressing signs: distrust between federal agencies and state governmental agencies, dysfunction in the notice-and-comment rulemaking process, and missed opportunities for agency reform. This is the sobering backdrop for the reform measures I propose in Parts III and IV.

A. *The FDA’s Dismal Record*

1. *FDA 2006 Drug Labeling Rule.* Agency skeptics’ worst fears were realized in the FDA’s handling of the rulemaking process leading up to its 2006 rule on the format and content of prescription drug labels. To begin, in its notice of proposed rulemaking in

10. *Wyeth*, 129 S. Ct. at 1201.

11. Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 228 (2007) [hereinafter Sharkey, *Preemption by Preamble*].

December 2000, the FDA disclaimed any potential preemptive effect, stating clearly that “this proposed rule does not contain policies that have federalism implications or that preempt State law.”¹² With this denial, the FDA relieved itself from the further requirements of the executive mandate on federalism (Executive Order 13,132), which requires consultation with relevant state organizations.¹³ Any interested parties that followed FDA involvement in pharmaceutical regulation—particularly those monitoring agency rules with the potential to oust existing state law regulations and common law tort liability—would, moreover, take this as a signal to focus antipreemption efforts elsewhere.

It therefore came as a surprise—unwelcome, to say the least—that the final rule issued by the FDA in January 2006 contained an express statement of preemptive intent.¹⁴ The FDA’s preemption statement, moreover, materialized in the rule’s preamble, thus eluding detection via the transparent and public process of notice-and-comment rulemaking.¹⁵

In an act of breathtaking hubris, the FDA included a federalism impact statement (as required by Executive Order 13,132) that defended its actions¹⁶ and subtly held state governmental groups to blame:

FDA sought input from all stakeholders on new requirements for the content and format of prescription drug labeling through publication of the proposed rule in the Federal Register. Although the proposed rule did not propose to preempt state law, it did solicit

12. 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).

13. For a full discussion of Executive Order 13,132, see *infra* notes 122–27 and accompanying text.

14. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601) (“FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.”).

15. *Id.*

16. The main thrust of the FDA’s federalism impact statement (FIS) was that the FDA had authority to preempt state law in this area. *Id.* at 3967–69. According to the FDA, “[i]f State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness [of labels] . . . the federal system for regulation of drugs would be disrupted.” *Id.* at 3969. The FDA acknowledged its obligation under Executive Order 13,132 to preempt state law as minimally as possible, but claimed that “[t]his final rule meets the preceding requirement because . . . it preempts state law only to the extent required to preserve Federal interests.” *Id.*

comment on product liability issues. FDA received no comments on the proposed rule from State and local governmental entities.¹⁷

Perhaps in an effort to camouflage its duplicitous, 180-degree change in its position on the rule's preemptive effect, which it deliberately set out in a preamble and without public comment, the FDA dared to suggest that it consulted with state governmental officials and entities:

Officials at FDA consulted with a number of organizations representing the interests of state and local governments and officials about the interaction between FDA regulation of prescription drug labeling (including this rule) and state law.¹⁸

At best, the FDA was referring to its solicitation of comments during the notice-and-comment period—although it was during that period that the FDA disclaimed any preemptive effect. At worst, the FDA was being disingenuous.

State representatives take the latter view. Susan Frederick, Federal Affairs Counsel for the National Conference of State Legislatures (NCSL), recounts a telephone call she received late in the day on December 30, 2005, from an FDA intergovernmental staff member, who informed her that the FDA planned to issue its “long-dormant labeling rule” in early January 2006 and that it would include a statement preempting state laws.¹⁹ The FDA's general counsel's office then informed Ms. Frederick that “NCSL could not review this proposed language in advance of its publication, that this telephone call constituted the consultation under Executive Order 13,132, and that the comment period was closed and would not be reopened to permit NCSL to submit comments on the new language.”²⁰ Donna Stone, president of the NCSL and Delaware State Representative, likewise tried to set the record straight in her September 2007 testimony before the Senate Judiciary Committee:

NCSL approached FDA officials and asked for three things: a consultation meeting pursuant to the Federalism Executive Order, a copy of the proposed language, and that the FDA re-open the comment period to allow NCSL to file formal comments on this very

17. *Id.* at 3969.

18. *Id.*

19. Brief of the National Conference of State Legislatures as Amicus Curiae Supporting Respondents at 9–10, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 3851606.

20. *Id.* at 10 (quoting the Affidavit of Susan Parnas Frederick).

significant and preemptive change. The FDA ignored the first request. The second and third requests were denied.²¹

In a letter to the secretary of Health and Human Services, NCSL expressed its outrage at the lack of transparency of the FDA's process and, even more so, at its stifling of participation by the states' representatives: "It is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide."²² Several members of Congress echoed this sense of outrage given that "neither [the] affected state and local entities . . . nor the general public were given an opportunity to comment."²³

2. *FDA 2008 Drug Labeling Rule.* The FDA's 2008 notice-and-comment rulemaking procedure to amend its drug labeling regulations stands in fairly sharp contrast to the procedurally flawed process of its 2006 promulgation of the drug labeling preemption preamble.²⁴ The regulation, which amends the "changes being

21. *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 144 (2007) [hereinafter *Sen. Hearing on Regulatory Preemption*] (statement of Donna D. Stone, President, National Conference of State Legislatures), available at http://judiciary.senate.gov/hearings/testimony.cfm?id=2935&wit_id=6641. Stone further charged that "during this rule's 5-year dormancy period, the FDA had allowed certain large pharmaceutical companies to submit comments pertaining to preemption after the expiration of the comment period." *Id.* at 144-45.

22. Letter from Ill. State Senator Steven J. Rauschenberger, President, Nat'l Conference of State Legislatures, to Michael O. Leavitt, Sec'y, U.S. Dep't Health & Human Servs. (Jan. 13, 2006) (emphasis omitted), available at <http://www.ncsl.org/programs/press/2006/060113Leavitt.htm>. The letter also sharply criticized the FDA's justification of its action:

NCSL understands that FDA now intends to finalize this rule and include a policy statement that provisions of the Labeling Rule would now preempt state product liability laws. NCSL recently asked FDA officials why it was including this harmful language. References to several recent court cases wherein FDA filed amicus briefs and in which FDA's position on federal preemption of state laws did not prevail were offered. FDA further informed NCSL it would not re-publish the Labeling Rule and open it up for comments based on this very significant change, nor would it share the proposed language with NCSL.

Id.

23. Letter from Representative Henry A. Waxman et al., to Michael O. Leavitt, Sec'y, U.S. Dep't Health & Human Servs. (Feb. 23, 2006), available at <http://dodd.senate.gov/index.php?q=node/3381>; see also Letter from Edward M. Kennedy & Christopher J. Dodd, Senators, U.S. Senate, to Michael O. Leavitt, Sec'y, U.S. Dep't Health & Human Servs. (Feb. 23, 2006), available at <http://dodd.senate.gov/index.php?q=node/3381> ("We strongly believe that states have an important role to play in protecting consumers and patients from unsafe drugs, and question the notion that the FDA alone can provide this protection.").

24. The proposed regulation was published in the Federal Register on January 16, 2008, the FDA solicited comments, and the final rule was published on August 22, 2008 (effective

effected” (CBE) supplements rule, governs the circumstances under which a pharmaceutical or medical device manufacturer may alter a warning when new risks come to light, without the FDA having to preapprove the revision.²⁵ The regulation clarifies that the CBE rule applies only to situations where “newly acquired information” has come to light; moreover, it requires the existence of “sufficient evidence of a causal association” between the risk and an adverse outcome before the manufacturer can unilaterally revise the warning.²⁶

The FDA considers its latest CBE regulation to be consistent with the 2006 drug labeling preemption preamble. In both, the FDA “interprets the [Food Drug and Cosmetics] Act to establish both a ‘floor’ and a ‘ceiling,’ such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading.”²⁷ Since the inauguration of the drug labeling preemption preamble, the FDA has pushed its view that public health and safety are threatened by the prospect of overwarning: “This amendment is intended to clarify FDA’s existing policies and is intended to ensure that scientifically valid and appropriately worded warnings will be provided in the approved labeling for medical products, and to prevent overwarning, which may deter appropriate use of medical products, or overshadow more important warnings.”²⁸

Numerous parties—including consumer advocacy groups, individuals, law firms, law professors, pharmaceutical companies, trade associations, and members of Congress—commented upon the

September 22, 2008). Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814).

25. *Id.* at 49,603–04.

26. *Id.* at 49,604. “Newly acquired information” is defined in the final rule as “data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.” *Id.* at 49,609.

27. *Id.* at 49,605 (quoting Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 CFR pts. 201, 314, 601) (drug labeling preemption preamble)).

28. *Id.* at 49,605–06; *see also* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935 (“State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product’s risks, thereby potentially discouraging safe and effective use of approved products . . .”).

proposed regulation during the notice-and-comment period.²⁹ Several objectors, including a panel of Congress members, filed scathing remarks that accused the FDA of politically motivated and disingenuous action.³⁰ Others questioned why “an agency that is clearly in crisis would seek to limit consumers’ access to information about crucial health and safety risks.”³¹ More specifically, several House Representatives charged that the FDA “suffers from a high turnover rate of scientists, an inadequate information technology system, a weak organizational structure, and a rapidly declining inspection force.”³²

Most relevant for present purposes, states were given an explicit opportunity to comment on the rule’s impact “(1) [o]n the States, (2) on the relationship between the national government and the States, or (3) on the distribution of power and responsibilities among the

29. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. at 49,604–05 (“FDA received approximately 20 comments to the January 2008 proposed rule.”).

30. See, e.g., Letter from Henry A. Waxman, Chairman, House Comm. on Oversight & Gov’t Reform, to Andrew C. von Eschenbach, Comm’r, FDA 1 (Jan. 23, 2008) [hereinafter Waxman Letter], available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=0900006480401a97&disposition=attachment&contentType=pdf> (claiming the CBE rule was not “an isolated case, but part of a pattern of actions in the Bush Administration’s final months to permanently insulate the drug and device industry from liability”). The letter was cosigned by a number of other congressmen, including Senator Edward M. Kennedy, Chairman of the Senate Committee on Health, Education, Labor, and Pensions. *Id.* at 6; see also Letter from Ronald Goldman, Esquire, Baum, Hedlund, Aristei & Goldman, to Div. of Dockets Mgmt., FDA 6 (Mar. 17, 2008), available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064803ff31e&disposition=attachment&contentType=pdf> (“[S]ince the arrival of the Bush administration, FDA policy-makers seem to have forgotten the FDA’s objectives and obligations. Rather, the agency appears to be more concerned with protecting the profits of the pharmaceutical industry.”); Letter from Peter Lurie, Deputy Dir., & Sydney M. Wolfe, Dir. of Health Research, Public Citizen, to Div. of Dockets Mgmt., FDA 3 (Mar. 17, 2008), available at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=FDA-2008-N-0032> (noting that the FDA’s proreemption policy stance emerged only in the last few years).

31. Letter from Bart Stupak et al., U.S. House of Reps., to Andrew C. von Eschenbach, Comm’r, FDA 1 (Feb. 29, 2008) [hereinafter House of Representatives Letter], available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=0900006480401990&disposition=attachment&contentType=pdf>; see also Letter from Kathleen Flynn Peterson, President, Am. Ass’n for Justice, to Div. of Dockets Mgmt., FDA 3 (Mar. 17, 2008), available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064803fab4b&disposition=attachment&contentType=pdf> (claiming that the FDA’s proposal would limit dissemination of risk information “at a time when every independent evaluation has shown that the FDA is woefully incapable of acting timely to provide this information”); Waxman Letter, *supra* note 30, at 1 (questioning whether an agency would spend its already-strapped resources to promulgate a rule “that will serve only to deprive American consumers of critically important and timely information”).

32. House of Representatives Letter, *supra* note 31, at 1–2.

various levels of government.”³³ In response to this outreach to states, the FDA received only a single comment from the Conference of Chief Justices (CCJ).³⁴ The CCJ is a group composed of the highest judicial officers in each of the fifty states. It has “traditionally adopted formal positions to defend against proposed policies that threaten principles of federalism or that seek to preempt state court authority.”³⁵ The CCJ charged that the proposed rule lacked “sufficient statement of actual, irreconcilable conflict to justify the FDA’s broad assertion of implied preemption of all state law”³⁶ based upon “an unwarranted and abstract assumption that state statutes and traditional tort litigation invariably cause conflict with federal regulatory policy.”³⁷

The evolution of the CBE regulation presents a paradigmatic example of mutual breakdown or dysfunction in the notice-and-comment process.³⁸ On the one hand, state governmental bodies (such as the NCSL) failed to take advantage of the opportunity to comment; by absenting themselves, they ensured that they would not play a role in shaping the ultimate regulation. On the other hand, the FDA’s cursory rejection of the bulk of the comments and suggestions it actually received during the notice-and-comment period suggests that such participation by states would have been futile at best—thus reinforcing those groups’ views that their energies are best directed elsewhere.

33. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,609 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814) (“FDA issued a ‘Dear Colleague’ letter . . . [t]he purpose of [which] was to alert officials in various organizations within the fifty States about the rulemaking, including officials with State pharmacy boards, State medical boards, health commissioners, and drug program directors.”).

34. *Id.*

35. Letter from Jean Hoeffler Toal, President, Conf. of Chief Justices, to Div. of Docket Mgmt., FDA 1 (Mar. 17, 2008), available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064803ff415&disposition=attachment&contentType=pdf>.

36. *Id.* at 2.

37. *Id.* at 3.

38. Here, I put to one side the fact that the FDA’s decision to amend the CBE regulation seemed motivated by a desire to affect pending litigation in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). The FDA cited the U.S. government’s amicus brief in *Wyeth* twice in promulgating its final rule. See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. at 49,605–06. In *Wyeth*, the Solicitor General argued for a rule preempting any state law claims that “challenge labeling that FDA approved after being informed of the relevant risk.” *Id.* at 49,606 (quoting Brief for the United States as Amicus Curiae Supporting Petitioner at 7, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 2308908).

The FDA's machinations in 2006 do not appear to be an isolated event. Although one of the more egregious examples, the promulgation of the drug label preemption preamble fits a wider empirical pattern of federal agencies' shunting of state regulatory interests.

B. Empirical Evidence of Widespread Agency Pattern and Practice

The FDA case study in drug labeling is but an extreme example of a sufficiently entrenched pattern of disregard for state interests. The pattern of agency defiance of, or superficial compliance with, congressional and executive mandates to consider states' interests has been the subject of limited empirical study. For example, Nina Mendelson has collected evidence of agencies' flouting their responsibility to conduct federalism impact statements (FISs).³⁹ As Mendelson detailed in 2004, FISs are few and far between in the annals of the Federal Register. From 1996–1998, only five of the more than 11,000 final rules issued contained an FIS.⁴⁰ Mendelson estimated that for proposed rules during one quarter in 1998, FISs are included in only 9 of 2546 agency rulemakings.⁴¹ For 2003, the rate of agency issuance of FISs seemed to pick up slightly. Mendelson turned up six FISs in one quarter of 2003, a time period in which six hundred final rules were issued.⁴²

Besides being relatively rare, FISs also tend to be, in Mendelson's words, of "poor quality."⁴³ The prototypical FIS, should it train its focus on preemption at all, simply attempts to justify the agency's authority to preempt state law on the basis of delegated (usually implied) statutory authority, without expounding broader federalism values.⁴⁴ Most of the FISs in 2003 simply affirmed the agency's authority to preempt without any acknowledgement of the

39. Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737, 783–84 (2004).

40. *Id.* at 783–84. Mendelson's figure is taken from H.R. 2245, *The Federalism Act of 1999: Hearing Before the Subcomm. on Nat'l Econ. Growth, Natural Res., and Regulatory Affairs of the H. Comm. on Gov't Reform*, 106th Cong. 101 (1999) (statement of Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, General Accounting Office).

41. Mendelson, *supra* note 39, at 784 n.192.

42. *Id.* at 783. Mendelson performed the following search: "Executive Order 13132" and not (%) ((no or not) /s federalism). *Id.* at 783 n.191. She then examined the remaining rules individually and found five that included an FIS of some sort and one which claimed an FIS would be available if requested. *Id.*

43. *Id.* at 783.

44. *Id.* at 784.

values endorsed by the executive order mandating them.⁴⁵ According to Mendelson, examples of irresponsible agency action dominate the few instances in which FISs are provided.⁴⁶ Take, for instance, the FIS proffered in conjunction with the Department of Homeland Security's issuance of chemical security rules. Evidently, the agency believed that an obligatory citation to the Supremacy Clause setting forth its authority to preempt sufficed in terms of discussion of relevant state interests.⁴⁷

My own study of the track records of the FDA and NHTSA over the last several years reaffirms this general pattern.⁴⁸ The story is one of outright contradictions—agencies initially claimed that the proposed rule would not have a substantial effect on the federal-state balance, only to assert the preemptive effect upon promulgation of the final rule—coupled with cavalier denials of any impact on federalism, even where the preemptive intent of the agency's rule was apparent.

1. *Bait-and-Switch*. With the benefit of hindsight, the FDA's 2006 preemption preamble to the drug labeling rule can be seen as but one example of agency bait-and-switch tactics. Just one year after the FDA rolled out an interim final rule on soluble fibers, which stated in no uncertain terms that the rule had no substantial effect on the states and did not "contain policies that have federalism implications, as defined in [Executive Order 13,132],"⁴⁹ the FDA "determined that the [final] rule will have a preemptive effect on State law," inserting boilerplate preemptive language prohibiting states from "issuing any health claim labeling requirements for

45. *Id.* ("Only one of the five [FISs] . . . even acknowledged the interests of states in protecting their in-state residents . . .").

46. In a further study, Mendelson turned up six rules or proposed rules with preemptive effects in 2006. Of these, only three concluded that FISs were required, and only a single FIS was substantive. Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 719 (2008).

47. *Id.* at 720–21.

48. I am grateful to journalist Pete Yost of the Associated Press for providing me with a list of proposed and final rules containing preemption provisions—issued by the FDA, NHTSA, CPSC, Federal Railroad Administration, and Department of Homeland Security—which was a useful starting point for my research. See E-mail from Pete Yost to Catherine Sharkey, Professor of Law, New York Univ. Sch. of Law (May 5, 2008, 12:31 EST) (on file with *Duke Law Journal*).

49. Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Coronary Heart Disease, 70 Fed. Reg. 76,150, 76,161 (interim final rule Dec. 23, 2005).

barley . . . that are not identical to those required by this final rule.”⁵⁰ The FDA has followed this pattern again and again in both the drug and food contexts. For example, with rulemakings involving laxative drug products, adverse event reporting on drugs, and dandruff shampoos, the FDA has disclaimed any preemption or federalism implications in the proposed or interim rule, only to follow up in short order with a final rule that clearly spells out the preemptive effect and seeks to justify it on legal grounds.⁵¹ In other instances, arising in the context of rulemakings for foods and over-the-counter drugs, the FDA tentatively concluded that the proposed rule would have no effect on states (thus, according to the agency, negating the need for consultation with the states), only to follow up with a definitive assertion of preemptive effect in the final rule.⁵²

50. Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Coronary Heart Disease, 71 Fed. Reg. 29,248, 29,250 (May 22, 2006) (codified at 21 C.F.R. pt. 101).

51. *Compare* Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph, 68 Fed. Reg. 46,133, 46,137 (proposed Aug. 5, 2003) (to be codified at 21 C.F.R. pts. 310, 334) (stating that the proposal did not contain policies that would affect the federal-state balance), *with* Laxative Drug Products for Over-the-Counter Human Use; Psyllium Ingredients in Granular Dosage Forms, 72 Fed. Reg. 14,669, 14,673 (Mar. 29, 2007) (codified at 21 C.F.R. pts. 201, 310) (asserting that the agency’s policy decision carried preemptive effect); *compare* Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products, 69 Fed. Reg. 21,778, 21,792 (proposed Apr. 22, 2004) (to be codified at 21 C.F.R. pts. 201, 208, 209) (stating that the rule would not alter the federal-state balance), *with* Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products, 73 Fed. Reg. 63,886, 63,896 (Oct. 28, 2008) (to be codified at 21 C.F.R. pts. 201, 208, 209) (stating that the rule preempts state law); *compare* Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products Containing Coal Tar and Menthol for Over-the-Counter Human Use; Proposed Amendment to the Monograph, 70 Fed. Reg. 73,178, 73,180 (proposed Dec. 9, 2005) (to be codified at 21 C.F.R. pts. 310, 358) (stating that the proposal did not have federalism implications), *with* Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products Containing Coal Tar and Menthol for Over-the-Counter Human Use; Amendment to the Monograph, 72 Fed. Reg. 9849, 9851 (Mar. 6, 2007) (codified at 21 C.F.R. pts. 310, 358) (stating that the rule would preempt state law).

52. *Compare* Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim “Lean,” 70 Fed. Reg. 71,041, 71,056 (proposed Nov. 25, 2005) (to be codified at 21 C.F.R. pt. 101) (stating that the rule “does not contain policies 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 “tentatively conclud[ing] that the rule [did] not contain policies that have federalism implications,” thus negating the need for a federalism impact statement), *with* Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim “Lean,” 72 Fed. Reg. 1455, 1459 (Jan. 12, 2007) (codified at 21 C.F.R. pt. 101) (prohibiting states from “promulgating any nutrient content claim labeling requirements for the claim ‘lean’ that are not identical” to those in the final rule); *compare* Over-the-Counter Vaginal Contraceptive Drug Products Containing Nonoxynol 9; Required Labeling, 68 Fed. Reg. 2254, 2261 (proposed Jan. 16, 2003) (to be codified at 21 C.F.R. pt. 201) (stating that the FDA “tentatively concludes that

The FDA is not the only culprit. In 2007, NHTSA reversed its position on preemption when it issued a final rule responding to a petition for reconsideration of its head restraint requirements.⁵³ The earlier 2004 final rule stated in no uncertain terms: “The final rule is not intended to preempt State tort civil actions.”⁵⁴ Without any consultation with the states, NHTSA suddenly reversed course, asserting that the 2007 rule preempted state law.⁵⁵

NHTSA’s defense of its decision to bypass state consultation rings hollow. First, NHTSA quixotically proclaimed that, despite preempting state law, its rule had no “substantial direct effects on the States” or the relationship between the federal and state governments.⁵⁶ NHTSA further reasoned that “consultation [with States, local governments or other representatives] would be inappropriate” because the Motor Vehicle Safety Act contains an express preemption provision, and that provision, as opposed to the agency’s rulemaking, was the real source of preemption.⁵⁷ This flatly contradicted the U.S. Supreme Court’s determination that the Motor Vehicle Safety Act and an accompanying regulation did not expressly preempt state common law liability. In *Geier v. American Honda*

the proposed rule does not contain policies that have federalism implications as defined in the Executive order [13,132]”), *with* Over-the-Counter Vaginal Contraceptive and Spermicide Drug Products Containing Nonoxynol 9; Required Labeling, 72 Fed. Reg. 71,769, 71,783–84 (Dec. 19, 2007) (codified at 21 C.F.R. pt. 201) (asserting preemptive effect using boilerplate language); *compare* Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph for Over-the-Counter Nasal Decongestant Drug Products, 69 Fed. Reg. 63,482, 63,486 (proposed Nov. 2, 2004) (noting that the FDA “tentatively conclude[d] that the proposed rule [did] not contain policies that have federalism implications”), *with* Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products, 71 Fed. Reg. 43,358, 43,361 (Aug. 1, 2006) (codified at 21 C.F.R. pt. 341) (claiming preemption). In each of these cases, in the final rule, the FDA relies almost exclusively on the express preemption provisions of the FDCA pertaining to foods and over-the-counter drugs, respectively, 21 U.S.C. § 343-1 (2006) and 21 U.S.C. § 379r (2006). But even if that authority were airtight, it would still beg the question of why the FDA’s earlier conclusions published in the proposed rules were only “tentative.”

53. Federal Motor Vehicle Safety Standards; Head Restraints, 72 Fed. Reg. 25,484, 25,512 (May 4, 2007) (to be codified at 49 C.F.R. pts. 571, 585).

54. Federal Motor Vehicle Safety Standards; Head Restraints, 69 Fed. Reg. 74,848, 74,880 (Dec. 14, 2004) (codified at 49 C.F.R. pt. 571).

55. Federal Motor Vehicle Safety Standards; Head Restraints, 72 Fed. Reg. at 25,512. Further, the record displays no opportunity for comment on this point, nor does it indicate that the agency had disclosed its preemptive intent at any time prior to the final rule. *See id.* (“[N]o consultation is needed to discuss the preemptive effect of today’s rule.”).

56. *Id.*

57. *Id.*

Motor Co.,⁵⁸ which is the only products liability preemption decision involving the Motor Vehicle Safety Act, the Court found *implied*, but not *express*, preemption,⁵⁹ recognizing that a primary obstacle to express preemption is the Safety Act's express "saving clause" that purports to "save" existing common law actions.⁶⁰

NHTSA thus presents a strained reading of *Geier* to support its aggressive campaign to assert express preemption in its promulgated rules. More disingenuously, NHTSA inserts what has become its boilerplate preemption language into final rules, while denying any federalism impact in the notices of proposed rulemaking.⁶¹

2. *Denying "Federalism Impact" of Preemption.* It is difficult to imagine a more serious threat to the state-federal regulatory balance than the outright denial of any federalism impact of a federal rule that ousts competing state tort law. Notwithstanding the contradiction, NHTSA has forged ahead down this path of obfuscation.

In a 2007 final rule governing labeling requirements for cargo-carrying capacity on motor homes and vehicle trailers, NHTSA clearly asserts that the rule preempts state law—both

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

59. *Id.* at 867–69. Nor does NHTSA's add-on to the effect that "the Supreme Court has also recognized that State requirements . . . can stand as an obstacle to the accomplishment and execution of a NHTSA safety standard" rehabilitate NHTSA's stance. Federal Motor Vehicle Safety Standards; Head Restraints, 72 Fed. Reg. at 25,512 (citing *Geier*, 529 U.S. 861).

60. *Geier*, 529 U.S. at 867–68.

61. *See, e.g.*, Federal Motor Vehicle Safety Standards; Occupant Crash Protection in Interior Impact, 72 Fed. Reg. 50,900, 50,905 (Sept. 5, 2007) (to be codified at 49 C.F.R. pt. 571) ("NHTSA has examined today's final rule pursuant to Executive Order 13132 . . . and concluded that no additional consultation with States, local governments or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rulemaking would not have federalism implications because a final rule, if issued, would not 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.' Further, no consultation is needed to discuss the preemptive effect of today's rulemaking." (quoting Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,255 (Aug. 4, 1999))). In the notice of proposed rulemaking, NHTSA stated that the rule "would not have any substantial impact on the States, or on the current Federal-State relationship," and that consultation with the states was not required. Federal Motor Vehicle Safety Standards; Occupant Protection in Interior Impact, 71 Fed. Reg. 20,932, 20,939–40 (proposed Apr. 24, 2006) (to be codified at 49 C.F.R. pt. 571). In the final rule, NHTSA also expressly reserved for itself the opportunity to comment on specific instances of preemption down the road. Federal Motor Vehicle Safety Standards; Occupant Crash Protection in Interior Impact, 72 Fed. Reg. at 50,905.

regulatory/statutory and common law.⁶² At the same time, it curiously denies that the rule has any direct impact upon the states or the balance of power between the federal and state governments.⁶³ Its bizarre rationale is that the rule operates entirely outside the confines of Executive Order 13,132, because it “would apply to motor home manufacturers and to travel trailer manufacturers, not to the States or local governments.”⁶⁴ Although it is true that the regulation is being imposed upon manufacturers, not the states, that is the case with respect to most (if not all) agency-directed regulations. Given the clear assertion of preemption in the final rule, it appears that NHTSA engaged in some fancy (and unconvincing) interpretive footwork with an eye toward bypassing Executive Order 13,132.

II. POLITICAL SAFEGUARDS OF FEDERALISM

The agencies’ aggressive assertion of preemption, combined with the apparent stonewalling of, and refusal to engage with, state governmental bodies, has been an easy target for renewed arguments against the shift of decisionmaking power from Congress to federal agencies. Scholars who argue against the preemption of state tort law also invariably urge that “[c]ourts should be particularly wary of deferring to an agency’s determination of the preemptive effects of its regulations or governing statutes. Federal agencies do not represent the states, and their interests do not always align.”⁶⁵ The states are especially dubious of statutory delegation of authority (express or implied) to agencies: “States cannot protect their interests through the political process if Congress has not signaled that it intends to trench on the states’ domain.”⁶⁶ Herbert Wechsler’s “political safeguards of federalism”⁶⁷ refrain reverberates: “The political branches are . . . in the best position to give due weight to the

62. Federal Motor Vehicle Safety Standards; Cargo Carrying Capacity, 72 Fed. Reg. 68,442, 68,458 (Dec. 4, 2007) (to be codified at 49 C.F.R. pt. 571).

63. *Id.*

64. Federal Motor Vehicle Safety Standards; Cargo Carrying Capacity, 70 Fed. Reg. 51,707, 51,713–14 (proposed Aug. 31, 2005) (to be codified at 49 C.F.R. pt. 571).

65. Brief of Amicus Curiae Constitutional and Administrative Law Scholars in Support of Respondent at 32, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 3851604.

66. Brief of Amici Curiae Vermont et al. in Support of Respondent at 25, *Wyeth*, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 3851613 [hereinafter States’ *Wyeth* Amicus Brief].

67. Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of National Government*, 54 COLUM. L. REV. 543 (1954).

fundamental federalism concerns that would be raised by any effort to preempt such basic and well-established state-law tort principles.”⁶⁸

A. *Congress: States’ Battleground*

In 1954, Herbert Wechsler famously heralded Congress as accountable to states’ interests, and thus the keystone to “the political safeguards of federalism.”⁶⁹ Central to this model is the fact that states have a voice in Congress, in which “[l]egislation rests in practice on a balancing of interests.”⁷⁰ In the House of Representatives, members are representatives of “the people of the states,”⁷¹ and in the Senate, only one half of the states are needed to constitute a majority and “one-third plus one” of the states banding together can defeat a treaty.⁷² The electoral and legislative processes, then, hold Congress’s feet to the fire where issues of state and local import are concerned. Wechsler’s model has captured the legal imagination. Although academics have criticized aspects of the model or transformed it in significant ways,⁷³ the model remains at the core of the conventional belief of the comparative superiority of Congress in the realm of federalism, or accountability to state regulatory interests.⁷⁴ The model

68. Brief of Torts Professors Mark P. Gergen and Michael D. Green as Amici Curiae in Support of Respondent at 33, *Wyeth*, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 3851610.

69. Wechsler, *supra* note 67.

70. *Id.* at 548.

71. *Id.* at 546 (emphasis omitted).

72. *Id.* at 547. According to Wechsler, in both houses of Congress, “the states are the strategic yardsticks for the measurement of interest and opinion, the special centers of political activity, the separate geographical determinants of national as well as local politics.” *Id.* at 546.

73. Larry Kramer, for example, argues that the safeguards of federalism are secured by political parties, not the structure of the electoral process. Larry D. Kramer, *Putting the Politics Back into the Political Safeguards of Federalism*, 100 COLUM. L. REV. 215, 215 (2000). According to Kramer, political parties are characterized by being neither programmatic nor centralized. *Id.* at 278–79. National politicians, therefore, often rely heavily on local and state politicians for getting out the vote and for other electoral benefits. *See id.* at 279 (describing America’s “political culture in which members of local, state, and national networks are encouraged, indeed expected, to work for election of candidates at every level” that encourages “mutual dependency among party and elected officials at different levels”). In addition, political parties are the mechanism by which politicians translate their local and state experience to a national platform. *See id.* at 285 (“Fully half of the members of the House of Representatives, for example, began their careers as state legislators, and men and women recruited and trained at the state level are found throughout the federal bureaucracy.”). In other words, Kramer substitutes the forces of localized political parties for the disciplining force of the electoral process of Wechsler’s model.

74. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting) (“The signal virtues of this presumption [against preemption include] its placement of the power of pre-emption squarely in the hands of Congress, which is far more suited . . . to

in its “pure” form is self-executing, guided by the “invisible hand” of the structural features of political institutions.⁷⁵

Some scholars have adeptly unmasked instances in which Congress seems to have fallen short of the ideal of taking states’ interests to heart.⁷⁶ This body of scholarship identifies examples of political process failure that lead to a call to the judiciary to force Congress to address its shortcoming. Roderick Hills, for instance, observes that “diseconomies of scale” plague the federal legislative process, preventing representatives from addressing important issues.⁷⁷ Hills’s normative endorsement of the “presumption against preemption” statutory canon reflects his belief that the presumption would improve the legislative process as a whole,⁷⁸ and thus his view

strike the appropriate state/federal balance (particularly in areas of traditional state regulation) . . .”); Mendelson, *supra* note 39, at 768 (“[T]he fact that members of Congress come from particular districts and states probably does give them a particular incentive to focus on state interests that have especially regional aspects.”); Mark D. Rosen, *Contextualizing Preemption*, 102 NW. U. L. REV. 781, 797 (2008) (“[W]hether state law should be preempted is best characterized as a subjective ‘political’ decision that is most appropriately made by Congress, the most politically representative branch.”); Peter J. Smith, Pennhurst, Chevron, and the Spending Power, 110 YALE L.J. 1187, 1202 (2001) (arguing that the reliance on state voter support makes federal congressional representatives, “whom the voters may remove from office if they fail adequately to respect state prerogatives,” accountable to the states in federalism determinations); Ernest A. Young, *Two Cheers for Process Federalism*, 46 VILL. L. REV. 1349, 1385 (2001) (asserting that the presumption against preemption protects federalism by “forc[ing] Congress to make a deliberative political decision about how far it wants to intrude on state autonomy, and . . . mak[ing] sure that all the states’ potential defenders have notice of what is at stake,” and by “reinforc[ing] institutional checks by requiring Congress to make the decision, with all the procedural hurdles and roadblocks that process entails”).

75. In this vein, Kramer has challenged “those who would persist in defending judicial intervention . . . to explain why institutional arrangements that have worked for more than two centuries have suddenly ceased to do so.” Kramer, *supra* note 73, at 290.

76. For such an argument in a different field, see Peter H. Schuck & John Williams, *Removing Criminal Aliens: The Pitfalls and Promises of Federalism*, 22 HARV. J.L. & PUB. POL’Y 367, 422–54 (1999).

77. Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. 1, 10 (2007) (quoting VINCENT OSTROM, ROBERT BISH & ELINOR OSTROM, *LOCAL GOVERNMENT IN THE UNITED STATES* 97–98 (1988)). Hills argues that a large and politically diverse body can be prone to counterproductive gridlock on important issues. *Id.* at 10–16.

78. See *id.* at 1 (arguing that “an anti-preemption rule of statutory construction has benefits for the national lawmaking process”). But see Sharkey, *Preemption by Preamble*, *supra* note 11, at 255 n.140 (“As a theoretical matter . . . one could employ either a strong pro- or anti-preemption default (or presumption) for court decisionmaking. . . . 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.”); Sharkey, *Products Liability Preemption*, *supra* note 6, at 450–51 n.4 (“While Hills’s account might explain issues that fail to reach the congressional agenda, such as bills that die in committee, it has far less explanatory power in the situation—

departs from the conventional view that such a default rule simply protects “state interests,” however defined. Hills has faith that such an antipreemption presumption (akin to Einer Elhauge’s “preference-eliciting default rules,” which Hills endorses) would promote “an open and vigorous debate on the floor of Congress.”⁷⁹

Ultimately, these scholars share Wechsler’s unwavering faith in Congress—in theory if not in practice—as the institution best positioned to guard states’ interests. Some scholars attribute Congress’s comparative superiority to legislative inertia, a natural safeguard against too much federal law.⁸⁰ For others, Congress truly represents the aspirational goal of robust engagement with state regulatory interests.⁸¹

B. Agencies: States’ New Turf

The flip side of the Wechsler-inspired celebration of Congress—as an institution whose actions are both public and accountable, encouraging widespread participation of all interested parties—is the pillorying of agencies. On this view, agencies often act swiftly, hidden from public view, in a process largely impenetrable to interested parties. Nina Mendelson, for example, charges that, unlike Congress, agencies are specialized institutions.⁸² Thus, even when interested parties are represented in the agency decisionmaking process,

dominant in products liability preemption—where the issue is squarely before Congress (on a repeat basis no less) and Congress manages to speak out of both sides of its mouth. Instead, it seems more plausible that Congress affirmatively punts the issue to courts and/or agencies.”).

79. Hills, *supra* note 77, at 28; *see also* EINER ELHAUGE, STATUTORY DEFAULT RULES: HOW TO INTERPRET UNCLEAR LEGISLATION 152–53 (2008) (advocating for the use of “preference-eliciting default rules”).

80. Young, *supra* note 74, at 1361–62 (citing Bradford R. Clark, *Federal Common Law: A Structural Reinterpretation*, 144 U. PA. L. REV. 1245, 1261 (1996)); *see also* Bradford R. Clark, *Constitutional Compromise and the Supremacy Clause*, 83 NOTRE DAME L. REV. 1421, 1422 (2008) (“[Congressional] procedures were designed to preserve the governance prerogatives of the states both by making federal law relatively difficult to adopt and by assigning this task solely to actors subject to the political safeguards of federalism.”).

81. *See, e.g.*, Hills, *supra* note 77, at 28–36 (arguing in favor of a “presumption against preemption” to force Congress to act by mobilizing business groups to lobby Congress to act, leading to a robust national debate of preemption issues); Young, *supra* note 74, at 1389 (arguing that “resistance norms” such as requiring a clear statement rule before countenancing preemption will force Congress to debate what exactly is at stake, giving notice to those impacted); *see also* Mendelson, *supra* note 46, at 710 (making the point that requiring Congress to get involved will mitigate the risk that federalism interests would be eviscerated incidentally).

82. Mendelson, *supra* note 46, at 717.

agencies take little heed of interests outside their expertise.⁸³ Cass Sunstein, appointed by President Barack Obama as head of the Office of Information and Regulatory Affairs (OIRA), has captured the collective unease toward agency decisionmaking: “While there is no good reason to think that a reinvigorated nondelegation doctrine would improve the operation of modern regulation, it is entirely reasonable to think that for certain kinds of decisions, merely executive decisions are not enough.”⁸⁴

Most of the comparative institutional debate—especially those voices that extol the virtues of Congress over agencies on federalism grounds—focuses on so-called “abstract federalism”⁸⁵ values. Consider, for example, Thomas Merrill’s trenchant critique of agencies:

Agencies are specialized institutions, intensely focused on the details of the particular statutory regimes they are charged with administering. By design and tradition, they are not expected to ponder larger structural issues such as the relative balance of authority between the federal and state governments, the importance of preserving state autonomy, the value of allowing policy to vary in accordance with local conditions, or the systemic advantages of permitting state experimentation with divergent approaches to social problems.⁸⁶

Agencies in the pursuit of narrow policy goals, in other words, are blind to the import of the greater structure of governance.

My focus instead is on a more concrete federalism value, namely, giving heed to state regulatory interests and how they interact with

83. *Id.* at 717–18; *see also* Mendelson, *supra* note 39, at 787–89 (arguing that agencies are not well equipped to evaluate the overall distribution of governmental authority as compared to Congress and the Judiciary); Robert R.M. Verchick & Nina Mendelson, *Preemption and Theories of Federalism*, in *PREEMPTION CHOICE* 13, 27 (William W. Buzbee ed., 2009) (“[A]gencies lack the expertise to evaluate the federal-state balance . . .”).

84. Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 338 (2000). Sunstein also points out that “certain decisions are ordinarily expected to be made by the national legislature, with its various institutional safeguards, and not via the executive alone.” *Id.* at 343; *see also* Lisa Schultz Bressman, *Deference and Democracy*, 75 GEO. WASH. L. REV. 761, 765 (2007) (suggesting that courts should not defer to agencies for “extraordinary questions”).

85. *See* Mendelson, *supra* note 39, at 782; *see also id.* at 741 (“Federalism values, such as ensuring core state regulatory authority and autonomy, are important and can be protected through political processes.”).

86. Brief of the Center for State Enforcement of Antitrust and Consumer Protection Laws, Inc. as Amicus Curiae in Support of Respondent at 23, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 3851615.

federal regulatory schemes. Focusing on these interests, it is not so clear, as either a positive or normative matter, that states are better off fighting on Congress's turf, as opposed to that of agencies. For starters, Congress has essentially sat on the sideline of the products liability preemption debate. One might easily argue that Congress has altogether abdicated responsibility in this realm. Particularly in the area of health and safety, where the preemption issue is squarely before Congress (on a repeat basis no less), Congress tends to "speak[] out of both sides of its mouth"⁸⁷—simultaneously promulgating preemption clauses along with "savings clauses," which, for all intents and purposes, is tantamount to inaction.⁸⁸

When Congress does weigh in on the debate in a more resolute fashion, it is likely to decide preemption on an all-or-nothing basis.⁸⁹

87. Sharkey, *Products Liability Preemption*, *supra* note 6, at 450–51 n.4.

88. *Id.* at 450. Nor is there reason to be sanguine about the possibility that Congress, though initially ambiguous, will react more decisively following judicial decisions. See Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 HARV. L. REV. 1604, 1612–13 (2007) (examining congressional responses to Supreme Court preemption decisions between 1983 and 2003 and finding that, of 127 Court cases pertaining to preemption of state law, Congress overruled only two of the decisions, and partially overruled a third).

Whereas relatively unexplored (with a few notable exceptions) in the legal literature, congressional inaction, or calculated ambiguity, is a subject of robust discussion in the political science literature. See, e.g., Daryl J. Levinson & Richard H. Pildes, *Separation of Parties, Not Powers*, 119 HARV. L. REV. 2312, 2353–54 (2006) (describing how political parties encourage Congress to abstain from action when both the executive and legislative branches are controlled by the same party); Richard H. Pildes, *Political Avoidance, Constitutional Theory, and the VRA*, 117 YALE L.J. POCKET PART 148 (2007), <http://thepocketpart.org/2007/12/10/pildes.html> (arguing that reauthorization of the Voting Rights Act in 2006 was a prime example of congressional abdication); see also Morris P. Fiorina, *Legislative Choice of Regulatory Forms: Legal Process or Administrative Process?*, 39 PUB. CHOICE 33, 47 (1982) (examining congressional incentives to delegate decisionmaking power to agencies and noting that, under the "shift the responsibility model," "[b]y charging an agency with the implementation of a general regulatory mandate, legislators . . . avoid or at least disguise their responsibility for the consequences of the decisions ultimately made" (internal quotation marks omitted)); Kenneth A. Shepsle, *The Strategy of Ambiguity: Uncertainty and Electoral Competition*, 66 AM. POL. SCI. REV. 555, 567 (1972) (analyzing the argument that politicians are most likely to retain voter support by adopting equivocal platforms, and concluding that that theory may be true only when "a majority of voters is risk-acceptant (and . . . possesses intense preferences, thus rendering the issue 'critical')").

89. See MINORITY STAFF OF H. COMM. ON GOV'T REFORM, SPECIAL INVESTIGATIONS DIV., 109TH CONG., CONGRESSIONAL PREEMPTION OF STATE LAWS AND REGULATIONS 17–38 (2006) (describing preemption provisions Congress has added to twenty-seven laws since 2001). The vast majority of the provisions cited in the survey simply provide absolute preemption of state action or common law. See, e.g., Law Enforcement Officers Safety Act of 2004, 18 U.S.C. §§ 926B–C (2006) (preempting concealed weapons laws for former and off-duty law enforcement officers); Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d

Legislative pronouncements on preemption (or nonpreemption) are sledgehammers where sharp scalpels are more appropriate.⁹⁰ Congress's blanket antipreemption provisions in the context of health and safety regulations⁹¹ might, in the end, prove to be Pyrrhic victories for state regulatory interests. Such resolute pronouncements of the minimal nature of federal regulation—which thereby provides a “floor” as opposed to a “ceiling” or “optimal” standard—create an accountability loophole, enabling the regulating federal agency to disclaim ultimate responsibility for health and safety.⁹² Conversely, preemptive federal standards might hold the agency's feet to the fire, and deference to state regulatory standards (which may, themselves, fall short of “optimal”) may be traded off in favor of ultimate responsibility and accountability.

Given Congress's proclivity to protect national prerogatives, such absolute responses are (at least in theory) equally likely to cut against state interests as to favor them.⁹³ Agency experts at the policy and

(2006) (providing full immunity for producers of certain vaccines); Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, 118 Stat. 418 (preempting certain standards for limiting pollution from small engines).

90. David Shapiro kindly supplied several early uses of the quip:

The Book of Psalms: “Lord grant me the wisdom not to use a sledgehammer when the task bespeaketh the need of a scalpel.”

Hamlet to Polonius: “I can tell a sledgehammer from a scalpel when the wind is north, northwest.”

Hart & Wechsler's First Edition: “It is clear, is it not, that the occasion calls not for a sledgehammer but a scalpel?”

E-mail from David Shapiro, William Nelson Cromwell Professor of Law Emeritus, Harvard Law Sch., to Catherine Sharkey, Professor of Law, New York Univ. Sch. of Law (Feb. 13, 2009, 15:11 EST) (on file with *Duke Law Journal*).

91. See, e.g., Medical Device Safety Act of 2008, S. 3398, 110th Cong. (2008) (explaining the proposed “savings clause” to overturn *Riegel* preemption for medical devices).

92. Cf. Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 334 (1985) (“Administrative agencies may find it politically convenient to disclaim final responsibility for [their] public risk choices . . .”); Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2158 (2000) (discussing the historic practice of the FDA not 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).

93. See Lynn A. Baker, *Putting the Safeguards Back into the Political Safeguards of Federalism*, 46 VILL. L. REV. 951, 956–61 (2001) (detailing the congressional interests in expanding federal power); Lynn A. Baker & Ernest A. Young, *Federalism and the Double Standard of Judicial Review*, 51 DUKE L.J. 75, 113–14 (2001) (arguing that congressional representatives may be hostile to state regulatory interests because federal representatives compete with state politicians for support from their shared constituency and “any official seeking to maximize his own support would seek to maximize his own [federal] regulatory

enforcement levels may better be able to engage with state actors in a more meaningful and substantive way than congressional staffers.⁹⁴

The story of the Department of Homeland Security (DHS) and its regulatory process pursuant to Congress's REAL ID Act of 2005⁹⁵ illustrates how agencies may very well surpass Congress on the accountability front. Under the REAL ID Act of 2005, a state must comply with various requirements before the drivers' licenses it issues are deemed valid forms of federal identification.⁹⁶ The Act, which does not contain an express preemption provision, grants regulatory authority to DHS but directs the secretary to consult with the states before issuing the requirements that the states must meet.⁹⁷ In January 2008, the Secretary of DHS promulgated these requirements for the first time.⁹⁸

In tandem with doing so, DHS provided a relatively robust federalism impact statement, detailing the interaction and consultation process with state governmental entities that it had undertaken "in the spirit of Federalism."⁹⁹ More specifically, DHS described the fairly extensive consultation process that preceded the issuance of the final rule as follows:

jurisdiction at the expense of other [state] public officials seeking support from the same constituents").

94. See Brian Galle & Mark Seidenfeld, *Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 1971 (2008) ("Agencies have the potential to be both deliberative and responsive to political preferences, both because of their relationship to the courts and the political branches and because of their composition and the motivation of their staff members."). Agency officials may have relevant backgrounds for taking state actors' concerns seriously. Agency officials may also have worked with or in state government, providing them with a state-side perspective of relevant regulatory issues. See *id.* at 1975 ("[T]o satisfy judicial review, agencies need staff members from a multitude of professions who can understand the views of all greatly affected interest groups.").

95. REAL ID Act of 2005, Pub. L. No. 109-13, 119 Stat. 302 (codified in scattered sections of 8 and 49 U.S.C. (2006)).

96. 49 U.S.C. § 30301 note (2006) (Improved Security Requirements for Drivers' Licenses and Personal Identification Cards).

97. *Id.* ("All authority to issue regulations, set standards, and issue grants under this title shall be carried out by the Secretary, *in consultation with* the Secretary of Transportation and the States." (emphasis added)). A prior statute (which the 2005 Act replaced) had instead required a negotiated rulemaking procedure.

98. See *id.*

99. Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Official Purposes, 73 Fed. Reg. 5272, 5329-30 (Jan. 29, 2008) (to be codified at 6 C.F.R. pt. 37).

DHS held meetings and solicited input from various States and such stakeholders as the National Governors Association [NGA] and the National Conference of State Legislatures [NCSL].

In particular, during the comment period, DHS hosted sessions that were available via webcast across the country to engage State Governors' chiefs of staff, homeland security directors in the States, and motor vehicles administrators, as well as a separate session with State legislators.¹⁰⁰

The REAL ID Negotiated Rulemaking Comment Session of April 16, 2007 generated a three-hundred-page transcript, which includes, in addition to input from the NCSL and NGA, commentary from the Texas Department of Public Safety, the Massachusetts Registry of Motor Vehicles, the California Governor's Office, the American Association of Motor Vehicle Administrators, the Maine Secretary of State's Office, the Michigan Secretary of State's Office, the California Department of Motor Vehicles, the International Association of the Chiefs of Police, and the Florida Department of Highway Safety and Motor Vehicles.¹⁰¹

But DHS's ostensibly active engagement with state governmental entities could not mask what these governmental entities perceived to be Congress's trouncing of state regulatory interests in the structure of the Act itself.¹⁰² Before the Senate Judiciary Committee hearing on preemption, NCSL stated:

The Real ID Act of 2005 was added to a must-pass supplemental spending bill for the war on terrorism and tsunami relief. With its enactment, the Real ID Act repealed an existing negotiated rulemaking process for establishing [driver's license/identification] standards, in which NCSL participated, and instead put into statute prescriptive mandates. The negotiated rulemaking process would

100. *Id.* at 5330.

101. The transcript is available online at Regulations.gov. U.S. DEP'T OF HOMELAND SECURITY, DHS-2006-0030-1839, REAL ID NEGOTIATED RULEMAKING COMMENT SESSION (2007), available at <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=090000648023072e>.

102. See Nat'l Conference of State Legislatures, Count Down to Real ID, <http://www.ncsl.org/RealID/> (last visited Mar. 7, 2009) (counting down to the date REAL ID becomes effective and providing a number of resources detailing state opposition to the law).

have made the development of standards a partnership instead of a preemption of existing state practices.¹⁰³

NCSL was thus nostalgic for the institutional arrangement of negotiated agency rulemaking under the previous statute. Presumably, at least on this issue, NCSL was confident that it could have had more influence over the agency than over Congress. The NGA likewise touted the agency, writing in a letter to leaders in the House and Senate, “DHS listened to governors and other state stakeholders and improved its draft regulations.”¹⁰⁴ Indeed, the agency did more than simply listen; according to NCSL, the proposed rules “incorporated a number of recommendations made to DHS by NCSL, governors and motor vehicle administrators.”¹⁰⁵

This example invites a more generalized analysis of the comparative capacity of Congress and agencies to engage in an accountable decisionmaking process, and to respond to state

103. *Sen. Hearing on Regulatory Preemption*, *supra* note 21, at 148–49 (statement of Donna Stone, President, National Conference of State Legislatures).

104. Letter from Governors Tim Pawlenty & Edward G. Rendell to Senator Harry Reid, Majority Leader, U.S. Senate, et al. (Mar. 20, 2008), *available at* <http://www.nga.org/portal/site/nga/menuitem.cb6e7818b34088d18a278110501010a0/?vgnnextoid=e9986c653ecc8110VgnVCM100001a01010aRCRD>. The governors did, however, voice criticisms of Congress:

Governors supported initial legislation to enhance driver’s licenses through a cooperative negotiated rulemaking. When that legislation was repealed and replaced with REAL ID, governors objected and called on the Department of Homeland Security (DHS) and Congress to fix and fund REAL ID by fashioning reasonable rules and providing adequate funding to cover the cost of this new national mandate. . . . Now, if REAL ID is to become a reality, Congress and the Administration must provide sufficient funding to cover states’ cost[s] and preserve flexibility for states to manage their unique systems.

Id. That sizeable costs are imposed on the states is a significant issue. A study conducted by the NCSL, NGA, and the American Association of Motor Vehicle Administrators estimates that the cost to the states will exceed eleven billion dollars. NAT’L GOVERNOR’S ASS’N, NAT’L CONFERENCE OF STATE LEGISLATURES & AM. ASS’N OF MOTOR VEHICLE MFRS., *THE REAL ID ACT: NATIONAL IMPACT ANALYSIS 3* (2006), http://www.ncsl.org/print/statefed/Real_ID_Impact_Report_FINAL_Sept19.pdf.

105. Nat’l Conference of State Legislatures, *The History of Federal Requirements for State Issued Driver’s Licenses and Identification Cards*, http://www.ncsl.org/standcomm/sctran/History_of_DL_Reform.htm (last visited Mar. 19, 2009); *see also Understanding the Realities of REAL ID: A Review of Efforts to Secure Drivers’ Licenses and Identification Cards: Hearing Before the Subcomm. on Oversight of Government Management, the Federal Workforce, & the District of Columbia of the S. Comm. on Homeland Security and Governmental Affairs*, 110th Cong. 22 (2007), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_senate_hearings&docid=f:34415.pdf (statement of Leticia Van de Putte, President, National Conference of State Legislatures, and State Senator, Texas) (“NCSL acknowledges that the draft regulations incorporate a number of our recommendations made in the September 2006 report.”).

regulatory concerns raised by governmental entities. I have argued that “[w]ith respect to answering the key regulatory policy issue at the heart of the preemption query—namely, whether there in fact should be a uniform federal regulatory policy—federal agencies emerge as the institutional actor best equipped to provide the answer.”¹⁰⁶ Specifically, I proposed an “agency reference model” that

directs attention to a repository of agency information—ideally reflecting a broad range of views, having been vetted by expert and public opinion—focusing on the precise nature of the agency’s regulatory cost-benefit (or risk-risk) determinations as well as the economic consequences of various determinations and the effects of state regulation on federal regulatory schemes.¹⁰⁷

With respect to promoting federalism values, “agencies . . . emerge as the institutional actor of choice, to the extent that they effectively represent state interests in our modern administrative state.”¹⁰⁸

Several other scholars have echoed the suggestion that states’ federalism interests may fare relatively well in the hands of agencies as compared to Congress.¹⁰⁹ Brian Galle and Mark Seidenfeld dissect three common arguments for congressional superiority—transparency, deliberative processes, and accountability—and contend, contra conventional wisdom, that agencies, as measured by

106. Sharkey, *Products Liability Preemption*, *supra* note 6, at 477.

107. *Id.* at 485.

108. Sharkey, *Preemption by Preamble*, *supra* note 11, at 252, 252–53 (sketching out a “federalism-inspired” model for agency participation in preemption decisions, based upon a “federal-state dialogue” pursuant to congressional and executive agency mandates to consult with state and local authorities).

109. See, e.g., Peter H. Schuck, *Delegation and Democracy: Comments on David Schoenbrod*, 20 *CARDOZO L. REV.* 775, 781–90 (1999) (arguing that agencies are superior venues for accountability in a number of important respects).

Scholars—perhaps most prominently Cass Sunstein—have previously argued that the courts and Congress play essential roles in guiding and ensuring accountability on the part of agencies. See, e.g., Cass R. Sunstein, *Changing Conceptions of Administration*, 1987 *BYU L. REV.* 927, 941 (Congress is capable of providing “relatively clear guidelines” that ensure that agencies remain accountable and that “statutes [will not] be defeated in the implementation process”); Cass R. Sunstein, *Factions, Self-Interest and the APA: Four Lessons Since 1946*, 72 *VA. L. REV.* 271, 272–77 (1986) (arguing that, since the passage of the Administrative Procedure Act, courts have taken advantage of an improved understanding of the purposes of regulation and the function of agencies to monitor and prod agencies in the direction of efficiency, effectiveness, and accountability); Cass R. Sunstein, *Law and Administration After Chevron*, 90 *COLUM. L. REV.* 2071, 2110–12 (1990) (embracing courts’ use of “[c]lear statement” rules designed, as a quasi substitute for the nondelegation doctrine, either to ensure clear congressional statements on issues that have constitutional dimensions or to ensure that Congress deliberates on the issue).

these criteria, do better.¹¹⁰ On transparency, Galle and Seidenfeld compare the opacity of congressional decisionmaking, often the product of logrolling and backroom lobbying, to the relative visibility of the decisionmaking process of agencies, governed by statutes mandating transparent determination and reasoned explanation.¹¹¹ As for deliberative process, Galle and Seidenfeld contend that the legislative process “generally is not as conducive to deliberation as it is to compromise and division of spoils.”¹¹² In the face of the rampant practice of logrolling coupled with the high cost to congressional committees of obtaining accurate information, true legislative deliberation is an ideal rather than a reality.¹¹³ By contrast, the administrative process, coupled with the prospect of judicial review, forces agencies to consider counterarguments and alternatives.¹¹⁴ Finally, Galle and Seidenfeld tackle accountability, which they measure by responsiveness to states’ interests, broadly defined.¹¹⁵ They chip away at the Wechslerian armor by pointing out that, although Congress is directly elected, the spread between voters’ true preferences and a representative legislator’s particular votes may be quite large.¹¹⁶ And they advert to the numerous political checks on agency action by both Congress and the president.¹¹⁷

Gillian Metzger has likewise challenged the wisdom that “Congress offers significantly more sensitivity to state regulatory prerogatives than federal agencies.”¹¹⁸ Nor is there any reason—in

110. Galle & Seidenfeld, *supra* note 94, at 1948–83. Mark Seidenfeld has long been an advocate of broad delegations of authority to agencies. *See, e.g.*, Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1551 (1992) (“I believe that civic republicanism provides a strong justification for the assignment of broad policymaking discretion to administrative agencies.”).

111. Galle & Seidenfeld, *supra* note 94, at 1949–61.

112. *Id.* at 1962.

113. *Id.* at 1962–68.

114. *Id.* at 1971–79.

115. *Id.* at 1979–84.

116. *Id.* at 1980 n.194 (describing how voters’ information is imperfect, causing legislators’ positions to differ substantially from their constituents’ preferences on any particular issue).

117. *Id.* at 1980–84 (generally describing the various mechanisms of executive and legislative control of agencies); *see also* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2284–303 (2001) (describing three techniques of presidential control: “review,” “directives,” and “appropriation”); Charles Tiefer, *Congressional Oversight of the Clinton Administration and Congressional Procedure*, 50 ADMIN. L. REV. 199, 205–15 (1998) (describing congressional controls over agencies including: Senate floor procedures, committee jurisdictions, appropriation procedures, and the congressional budget process).

118. Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 DUKE L.J. 2023, 2080–81 (2008).

theory or practice—to presume that agencies will be bent on eroding state power.¹¹⁹ Furthermore, as Metzger reminds, Congress simply cannot resolve all federal-state questions; on sheer practical grounds, agencies must bear at least some of this burden. Recognizing that “questions about the appropriate federal-state balance are not easily separated from substantive policy determinations on which agencies do have expertise,” she concludes this is not necessarily a bad state of affairs.¹²⁰

III. AGENCY ACCOUNTABILITY

Agencies, at least in theory, are equipped to make nuanced, flexible determinations regarding federal-state regulatory balance, based upon underlying policy considerations that may vary by regulatory context. If one believes, as I do, that preemption is warranted in certain narrow contexts, such as where the relevant federal agency has carefully considered the relevant health or safety risk at issue, but not as a blanket rule, then the record of the agency’s regulatory review must play a pivotal role in the analysis. These are

119. This is a frequent claim in the legal literature. *See, e.g.*, Einer Elhauge, *Preference-Estimating Statutory Default Rules*, 102 COLUM. L. REV. 2027, 2127 (2002) (“[A]gencies have certain biases (such as a bias in favor of expanding their power) that might distort their interpretations [of vague statutory delegations.]”); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 756 (2008) (“Not every agency is bent on empire building or is captured by the firms it regulates. But these phenomena are not unheard of and warrant caution before automatically deferring to agency judgments about the need for preemption. Agencies may also resent the implicit competition from other sources of regulatory authority like states.”); Rosen, *supra* note 74, at 801–02 (“[T]here are good reasons to be skeptical of a bureaucracy’s decision regarding its own powers.”).

But the claim of agency self-aggrandizement stands empirically on shaky ground; moreover, it does not appear to hold even in the preemption context. *See, e.g.*, Sharkey, *Products Liability Preemption*, *supra* note 6, at 475 (“Counterintuitively, federal agencies have been just as likely, if not more likely, to argue *against* preemption in the products liability realm.”); *id.* at 475–77, 486–90 (discussing numerous examples); *see also* Daryl J. Levinson, *Empire-Building Government in Constitutional Law*, 118 HARV. L. REV. 915, 932–34 (2005) (pointing to a litany of scholarship that suggests that agency bureaucrats do not necessarily try to expand their own power but are rather controlled by a combination of self-interest, professionalism, and political oversight); Metzger, *supra* note 118, at 2078–79 (“Too many instances exist of federal agencies refusing to preempt or seeking to expand state regulatory autonomy to conclude that federal agencies are categorically insensitive or hostile to preserving a state regulatory role.” (citing Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 SUPREME CT. ECON. REV. 43, 73 (2006))); Greve & Klick, *supra*, at 73 (observing that, during the Rehnquist Court, the Solicitor General took “a pro-preemption position in [only] 39 of 95 preemption cases, or about 40 percent.”).

120. Metzger, *supra* note 118, at 2082.

the underpinnings of my “agency reference model” for judicial preemption determinations.¹²¹

Part IV of this Article addresses “agency-forcing” reform measures, so called because the substantive blueprint for action—which I explore in this Part—already exists. Executive Order 13,132, titled “Federalism,” was issued by President William Clinton in August 1999 to “ensure that the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies.”¹²² It recognized that “the States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy.”¹²³ The Executive Order requires that federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking action that might restrict states’ policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope.¹²⁴

In addition to such lofty rhetoric, the Executive Order outlines specific requirements to be met before an agency may issue a preemptive regulation. An agency shall be clear in stating the preemptive effect of its policies in the notice of proposed rulemaking and, should it change position, the agency shall reopen the comment period before issuing a final rule. The agency is to “provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.”¹²⁵ The aim of the

121. See Sharkey, *Products Liability Preemption*, *supra* note 6, at 477–502; Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437, 440–62 (2009) [hereinafter Sharkey, *What Riegel Portends*] (extending the agency reference model by prescribing searching judicial review of evidence taken from the FDA’s regulatory record to substantiate implied preemption findings).

Moreover, the United States Supreme Court (I would argue) embraced this approach in *Wyeth v. Levine*. See *infra* notes 188–90 and accompanying text.

122. Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,255 (Aug. 4, 1999). Executive Order 13,132 applies to all agencies, save independent agencies, such as the CPSC, which nonetheless are “encouraged to comply.” Independent agencies, moreover, are subject to Executive Order 12,988, signed into effect by President Clinton in February 1996, which directs agencies to “specif[y] in clear language the preemptive effect, if any, to be given to the law.” Exec. Order No. 12,988, 61 Fed. Reg. 4729, 4731 (Feb. 5, 1996).

123. Exec. Order No. 13,132, 64 Fed. Reg. at 43,255.

124. *Id.* at 43,256. Further, section 4(a) requires agencies to “construe . . . a Federal statute to preempt 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 conflicts with the exercise of Federal authority under the Federal statute.” *Id.* at 43,257.

125. *Id.* at 43,257.

Executive Order reaches beyond establishing a robust notice-and-comment process; the goal is to engage states on the most fundamental threshold issue of whether there should be a preemptive rule—that is, a national rule that sets an optimal standard that serves as both a floor and ceiling on regulation. The overarching goal, then, is to facilitate a dialogue with the states concerning the nature of preemptive rules and the form they should take. Agencies are charged with the duty to establish an “accountable process to ensure meaningful and timely input” from the states.¹²⁶ Before issuing a proposed rule, agencies must consult with appropriate state and local officials to avoid conflicts between state and federal laws.¹²⁷

As Part I vividly demonstrated, agencies have employed myriad crafty strategies to bypass the executive federalism mandate, including the most deceptive bait-and-switch tactics. But, as explored in Part II, any response to federal agency overreaching in the preemption context that calls for simply pushing the decision back to Congress is misguided on normative grounds and untenable for practical purposes.

This Part first addresses the question of who represents state regulatory interests—a threshold question that, ironically, is all too often ignored in debates centering on abstract federalism values such as autonomy and democratic accountability. With respect to regulation of consumer health and safety, the representation issue is especially thorny. Typically, preemption in this realm involves the displacement of state common law (and state regulations to a lesser degree). There is no a priori representative of state interests served by the common law, nor is there any consensus on whether the relevant interests are regulatory or compensatory in nature. Several contenders, including drug safety divisions within state-level departments of health, state attorneys general (and their umbrella coordinating association, the National Association of Attorneys General (NAAG)), and state governmental entities such as the National Conference of State Legislatures (NCSL) (and the other “Big Seven” organizations) are put forward.

With potential vanquishers of state regulatory interests identified, this Part then proposes reforms in line with Executive Order 13,132, taking up an overhaul of notice-and-comment

126. *Id.*

127. *Id.* at 43,256 (stating that agencies should, “to the extent practicable,” consult with state and local authorities “before any such action is implemented”).

rulemaking, followed by guidelines for establishing an effective partnership between federal agencies and the states.

A. *Who Represents State Regulatory Interests?*

A prerequisite to any discussion of effective agency consultation and collaboration with the states is identification of the relevant stakeholders: Who precisely represents state regulatory interests? In the context of the regulation of consumer health and safety, this is a formidable issue.¹²⁸ The absence of any well-developed regulatory apparatus at the state level, similar to that which exists, for example, in the context of environmental regulation or banking regulation, has two significant implications.¹²⁹ First, by and large, preemption determinations will displace state common law liability, as opposed to state legislative or regulatory standards. Second, and relatedly, it is by no means clear who represents the interests served by state tort law. State tort law wears at least two hats—one compensatory, the other regulatory.¹³⁰ The increasingly dominant law and economics view posits a regulatory role for tort law: namely, that it deters excessive risk taking on the part of manufacturers by forcing them to internalize the costs of the harms they inflict upon others in situations in which they fail to take cost-justified preventative measures. Compensation of injured victims is a significant component of the tort system, but, on this view, it is the mechanism whereby optimal deterrence is achieved and not an independent goal, at least untethered from the deterrence objective. A threshold question arises, then, with respect to suitable representatives of state regulatory interests: should it be those who represent injured victims (potential and actual) or those who are engaged in health and safety regulation at the state level, or both?

128. It may also go a long way toward explaining the absence of any models of “cooperative federalism” in this realm. Cf. Philip J. Weiser, *Federal Common Law, Cooperative Federalism, and the Enforcement of the Telecom Act*, 76 N.Y.U. L. REV. 1692, 1695–703 (2001) (presenting a model whereby state agencies play a role exercising discretion within a federal regulatory regime). In other words, a precondition for such cooperative federalism is likely the existence of intricately linked state and federal agencies, with built-in incentives and opportunities for communication as well as constructive collaboration.

129. The existence of state regulatory agencies by no means assures that their resistance to preemption will be successful; the more modest point is simply that it is easier to locate the representatives of competing state interests in that context.

130. For an elaboration of “the two faces of tort law,” see Sharkey, *Products Liability Preemption*, *supra* note 6, at 459–71.

The realm of environmental regulation, as administered by the Environmental Protection Agency (EPA), provides a constructive contrast. First, congressional acts mandate enforcement by state regulatory agencies, establishing an institutional framework for agency-state cooperation.¹³¹ As Brian Galle has noted, “federal dependence on the knowledge and resources of cooperating state regulators” ensures a certain degree of federal agency sensitivity to state interests.¹³² State environmental agencies have presumably become more adept by virtue of this “cooperative federalism.”¹³³

131. The Clean Air Act, for example, requires that states establish plans to help ensure that each state implements and enforces the statute’s target emissions reductions. 42 U.S.C. § 7410(a)(1) (2006). State environmental agencies enforce these policies under this statutory mandate. And under the Clean Water Act, state environmental agencies can be deputized to issue federal permits in lieu of the EPA. 42 U.S.C. § 7410(a)(2)(a) (2006); *see also* DENISE SCHEBERLE, *FEDERALISM AND ENVIRONMENTAL POLICY: TRUST AND THE POLITICS OF IMPLEMENTATION 7–10* (1997) [hereinafter SCHEBERLE, *FEDERALISM AND ENVIRONMENTAL POLICY*] (describing ways that states implement federal environmental statutes); Envr. Council of States, *Delegation by Environmental Act*, http://www.ecos.org/section/states/enviro_actlist (last visited May 13, 2009) (noting that “[a]s of 2001, over 75% of the federal environmental programs that can be delegated have been delegated to the States” and that the Clean Air Act has been delegated by the EPA to all fifty states).

Congressional mandates in the environmental regulation context set the parameters of “a matrix composed of distributed powers and necessary interdependencies,” through which “state and federal actors find bargaining and negotiation standard fare.” Denise Scheberle, *The Evolving Matrix of Environmental Federalism and Intergovernmental Relationships*, 35 *PUBLIUS* 69, 70 (2005) [hereinafter Scheberle, *The Evolving Matrix*] (citing DANIEL J. ELAZAR, *AMERICAN FEDERALISM: A VIEW FROM THE STATES* (3d ed. 1984)); *id.* (“[T]he collaborative matrix has not disappeared but has been reconstructed by the prevalence of bargaining, growing managerial sophistication on the part of state and local actors, the opening of more venues for collaboration, and real limits on federal enforcement ability.”).

The EPA’s internal guidelines on Executive Order 13,132 make explicit reference to this federal-state interdependence. EPA’S ACTION DEVELOPMENT PROCESS, GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM 21 (2008), available at <http://www.govexec.com/pdfs/111908rb1.pdf> (emphasizing the importance of agency consultation with state and local government officials given that “[state and local] governments carry out most of the day-to-day administration of many national environmental programs.”).

132. Brian Galle, *Getting Spending: How to Replace Clear Statement Rules with Clear Thinking About Conditional Grants of Federal Funds*, 37 *CONN. L. REV.* 155, 193 (2004); *see also* Brian D. Galle, *Can Federal Agencies Authorize Private Suits Under Section 1983?: A Theoretical Approach*, 69 *BROOK. L. REV.* 163, 198 (2003) (describing agency-state interaction as a “collaborative enterprise between federal and state bureaucrats”); David Freeman Engstrom, *Drawing Lines Between Chevron and Pennhurst: A Functional Analysis of the Spending Power, Federalism, and the Administrative State*, 82 *TEX. L. REV.* 1197, 1235–36 (2004) (arguing that federal agencies may be soliticious of state interests given that field-level administrators frequently rely on participation by state agencies and personnel). *But see* Roderick M. Hills, Jr., *The Eleventh Amendment as Curb on Bureaucratic Power*, 53 *STAN. L. REV.* 1225, 1227 (2001) (“The state bureaucrat cannot be trusted to lobby vigorously against federal mandates in the federal administrative process.”). Hills also explains that state and

The Food Drug and Cosmetic Act, by contrast, does not mandate any form of state participation. And, unlike the EPA, which has state-level counterpart agencies with which it can partner, the FDA has no specific state-level counterpart. A few states do appear to have agencies that complement the FDA through inspection, research, and regulation of drugs and devices within the state. California has an extensive network of such agencies, many of which focus narrowly enough to provide thoughtful input on quick notice in the event of solicitation from the FDA. In the realm of drugs, California's Department of Public Health has its own Drug Safety Program division, which monitors the drug, cosmetic, and "other consumer product industries" to ensure that "products are not adulterated, misbranded or falsely advertised."¹³⁴ New York, although it does not have an equally strong drug and device monitoring framework in place,¹³⁵ does have a strong food safety regulatory framework that would seem to be equally appropriate for targeted

federal regulators "often share more in common with each other than they do with the level of government by which they are employed." *Id.*

133. Another distinguishing factor may be the culture within the agency. Apparently, in the late 1990s, the EPA highlighted the executive order on federalism, assigned an ombudsman-like role to a designated federalism liaison to oversee compliance with the order, held meetings about how to deal with the executive order, and developed internal guidelines for compliance. Telephone Interview with Susan Frederick, Fed. Affairs Counsel for the Nat'l Conference of State Legislatures (July 17, 2008).

In 1993, the EPA formed the State/EPA Capacity Steering Committee to improve the federal-state partnership in environmental programs. *See* SCHEBERLE, FEDERALISM AND ENVIRONMENTAL POLICY, *supra* note 131, at 13; *see also* Scherberle, *The Evolving Matrix*, *supra* note 131, at 74-75 (noting the existence of the State/EPA Capacity Steering Committee, designed to "lead a federal-state dialog on creating and maintaining an environmental 'partnership' between state and federal officials").

Consistent with this past practice, the EPA issued internal guidelines on compliance with Executive Order 13,132 in November 2008. *See* EPA'S ACTION DEVELOPMENT PROCESS, GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM, *supra* note 131, at 2 ("For some actions, including those which may not have federalism implications . . . EPA policy is broader than the Executive Order, reflecting EPA's commitment to early and meaningful intergovernmental consultation.").

134. Cal. Dep't of Pub. Health, Drug Safety Program, <http://www.cdph.ca.gov/certlic/manfprocdistrib/Pages/Drug.aspx> (last visited Mar. 19, 2009).

135. *See generally* New York State Dep't of Health, <http://www.health.state.ny.us/> (last visited Apr. 22, 2009). Most of New York's health-related agencies seem more targeted toward providing services to patients, such as the state's drug pricing program, which provides consumers with information and pricing on the leading prescriptions for given ailments. *See* New York State Dep't of Health, Prescription Drug Price Website, <http://rx.nyhealth.gov/pdpw/> (last visited Apr. 22, 2009).

solicitations on the part of the FDA.¹³⁶ Although all states have a health commission of some kind, the scope and reach of that agency's authority and, in turn, its efficacy as a contributor to rulemaking procedures at the federal level, varies from state to state.¹³⁷

Every state, moreover, has a codified version of the Food Drug and Cosmetic Act that attorneys general may enforce at the state level. The National Association of Attorneys General (NAAG) is the central agency for the coordination of legal policymaking and federal litigation by state attorneys general. In addition, NAAG organizes standing committees on particular areas of state concern, such as environmental protection, consumer protection, securities regulation, and regulation of the insurance industry.¹³⁸

Existing state governmental bodies are also potential partners with the federal agencies. The "Big Seven"—consisting of NCSL, the National Governors Association, the National Association of Counties, the National League of Cities, the U.S. Conference of

136. As the Department of Agriculture and Markets' largest division, New York's Division of Food Safety and Inspection monitors, among other things, food labeling and advertising, and hosts information seminars for the food industry on safety and labeling. N.Y. State Dep't of Agric. & Mkts., Div. of Food Safety & Inspection, <http://www.agmkt.state.ny.us/FS/FSHome.html> (last visited Mar. 19, 2009). It samples products for safety and provides services similar to those of the FDA's Center for Food Safety and Applied Nutrition. See Food & Drug Admin., Center for Food Safety and Applied Nutrition: Overview, <http://www.cfsan.fda.gov/~lrd/cfsan4.html> (last visited Apr. 22, 2009).

137. For links to all state health departments, see State & Local Gov't on the Net, State Health Dep'ts and Servs., <http://www.statelocalgov.net/50states-health.cfm> (last visited Mar. 19, 2009). All states appear to have some agency body geared toward prescription drug tracking and monitoring. The health commissioner or director typically oversees the state's public health program, which may include a drug program and food inspection program. The title "drug program director" is a position usually held at the county level within certain states. Most state agencies, however, are primarily directed at enforcement; it is unclear whether they would have the incentive or resources to respond to requests from the FDA for comment on issues pertaining to preemption.

138. See Cornell W. Clayton, *Law, Politics and the New Federalism: State Attorneys General as National Policymakers*, 56 REV. POL. 525, 540 (1994) ("These committees encourage standardization of state enforcement standards under federal laws and draft model state statutes. Environmental protection, public land management, antitrust law, consumer protection, charitable trusts and solicitations... securities regulation, regulation of the insurance industry, and utility rate-making are some of the areas addressed by NAAG standing committees since 1980.").

NAAG, moreover, also lobbies to affect national legislation. Judith Resnik provides one example whereby NAAG mobilized to influence the 2005 Class Action Fairness Act. See Judith Resnik, *Lessons in Federalism from the 1960s Class Action Rule and the 2005 Class Action Fairness Act: "The Political Safeguards" of Aggregate Translocal Actions*, 156 U. PA. L. REV. 1929, 1961-63 (2008) (describing how NAAG's proposal to protect state actors and expand opportunities for state attorney general participation was implemented).

Mayors, the Council of State Governments, and the International City/County Management Association—are voluntary organizations of government officials that meet on a regular basis with the goal of influencing lawmaking and law enforcement at the national level.¹³⁹ These organizations are poised to comment, at a collective level that accounts for all (or some critical number of) states' perspectives, rather than represent the unique (and perhaps idiosyncratic) interests of any one.¹⁴⁰ Such an aggregate perspective has much to recommend it, especially when a key concern in the debate is whether a particular state seeks to exploit its regulatory framework to impose negative externalities upon other states.¹⁴¹

NAAG has challenged federal agencies' decisions to preempt state law, often via amicus briefs.¹⁴² Historically, NAAG has focused its opposition to preemption in areas of robust state regulation, such as environmental law, banking, and consumer protection. But it has

139. Resnik et al. have similarly argued in favor of giving such governmental entities, which they refer to as "TOGAS," or translocal organizations of government actors, regulatory power through consultation with agencies and inclusion in the policymaking process. See Judith Resnik, Joshua Civin & Joseph Frueh, *Ratifying Kyoto at the Local Level: Sovereigntism, Federalism, and Translocal Organizations of Government Actors (TOGAS)*, 50 ARIZ. L. REV. 709, 776–80 (2008). Resnik et al. come down decidedly against preemption, to spur local experimentation. *Id.* But so long as these powerful governmental bodies play an active role in regulatory policymaking, I see no reason why preemption need be taken off the table in all circumstances.

140. Collective actions taken by these state intergovernmental organizations have been described as "bottom up" federalism, through which local initiatives—once they reach a critical threshold—promote parallel action by state actors. See, e.g., Charles R. Shipan & Craig Volden, *Bottom-Up Federalism: The Diffusion of Antismoking Policies from U.S. Cities to States*, 50 AM. J. POL. SCI. 825, 828, 840 (2006) (attributing the emergence of anti-smoking initiatives at the state and federal levels, in part, to strong anti-smoking advocacy at the local level); Judith Resnik, *The Internationalism of American Federalism: Missouri and Holland*, 73 MO. L. REV. 1105, 1122 (2008) (discussing the more than eight hundred mayors who signed onto a U.S. Conference of Mayors' agreement that sets target dates for compliance with Kyoto Protocol air quality standards).

141. See Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353, 1370 (2006) ("Congress frequently regulates activities because state regulation, or lack of regulation, of those activities imposes external costs on neighboring states.").

Critics counter that such an aggregate approach sacrifices local and state experimentation—a core principle of federalism. Moreover, some contend that such state intergovernmental organizations are prone to suppression of minority views as well as susceptible to capture by outside interests. Cf. Clayton, *supra* note 138, at 543–44; Michael S. Greve, *Cartel Federalism?: Antitrust Enforcement by State Attorneys General*, 72 U. CHI. L. REV. 99, 100–01 (2005) (suggesting that the "extraordinary extent of state consensus" on antitrust actions has led to "a partial *surrender* of state regulatory autonomy" and a concomitant refusal to challenge sister states' anticompetitive conduct).

142. See, e.g., Clayton, *supra* note 138, at 548–52.

also intervened to protest preemption of state common law.¹⁴³ Moreover, groups like NCSL rely on plaintiff and consumer advocacy groups—like trial lawyers, Public Citizen, and the American Civil Liberties Union—to communicate their interests, which enhances their capacity to effectively represent both the state regulatory interest as well as the interests of injured victims.

More attention is due to this vexing issue of who represents state regulatory interests. It is critical to the success of a reform agenda centered on notice-and-comment rulemaking and, more broadly, on forging effective agency-state partnerships.

B. Notice-and-Comment Rulemaking

Notice-and-comment rulemaking is the means by which federal agencies solicit and incorporate the views of all “interested persons” before issuing final rules.¹⁴⁴ It remains the case that “[a]ttitudes about the utility of the notice and comment process and the behavior of parties are likely to vary with different agencies and across different regulatory contexts.”¹⁴⁵ The pessimistic view holds that the process is much sound and fury—leading to “voluminous comments that include multiple objections, criticisms, and proposed alternatives, each supported by lengthy studies and arguments . . . including many conflicting studies that challenged the major factual predicates for the proposed rule”¹⁴⁶—with little constructive substance. But it strikes me that it is far too soon to give up on the process’s potential to force agencies, in line with Executive Order 13,132, to contend with competing regulatory interests and empirical claims.

143. See generally *States’ Wyeth Amicus Brief*, *supra* note 66, at *1 (“The forty-seven amici states, as separate sovereigns in our federal system . . . have a fundamental interest in preserving the appropriate balance of authority between the states and the federal government. . . . In our view, courts should only rarely infer that Congress, although silent on the issue, nonetheless intended to displace state law where it is possible to comply with both state and federal law.”); see also Dan Schweitzer, Supreme Court Counsel, Nat’l Ass’n of Att’y’s Gen., Panelist Remarks at the New York University Annual Survey of American Law: Tort Law in the Shadow of Agency Preemption (Feb. 27, 2009) (noting that, over time, states have gotten increasingly interested in the preemption of state common law claims because of their experience with preemption in other realms, such as banking, where state agencies are explicitly at risk).

144. 5 U.S.C. § 553 (2006).

145. Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 11 n.27 (1997).

146. Richard J. Pierce, Jr., *Rulemaking and the Administrative Procedure Act*, 32 TULSA L.J. 185, 192–93 (1996).

1. *Federalism Impact Statements.* Executive Order 13,132 requires agencies to provide a federalism impact statement (FIS) whenever regulations will have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”¹⁴⁷ An FIS should “consist[] of a description of the extent of the agency’s prior consultation with State and local officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met.”¹⁴⁸

The mandate is recognized primarily in its breach. As detailed above in Part I.B, federal agencies have either blithely ignored their responsibility to provide FISs or have gone to great lengths to obfuscate whether their preemption determinations have any federalism impact whatsoever.¹⁴⁹

Executive Order 13,132, in sharp contrast, envisions a robust exchange between officials on the federal, state, and local levels. What this suggests is that more than a simple call for state participation via the agency’s provision of an FIS is needed.

2. *Solicitation of Comments.* For starters, the agency-provided FIS should be viewed as the beginning, not the end, of an agency’s consideration of affected state regulatory interests. Brazenly enough, the FDA has defended its failure to consult with the states on the grounds that it had “provided the States with an opportunity for appropriate participation in [one particular] rulemaking when it sought input from all stakeholders through publication of the proposed rule in the Federal Register.”¹⁵⁰ In other words, the FDA makes the unlikely assumption that state representatives can and will comb through the Federal Register on a regular basis to search for potential preemption clashes. The chance that these individuals will

147. Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,255 (Aug. 4, 1999).

148. *Id.* at 43,258.

149. The EPA stands as a counterexample. It has been at the forefront in terms of providing internal guidance on how to conduct a suitable FIS consistent with the principles embodied in Executive Order 13,132. See EPA’S ACTION DEVELOPMENT PROCESS, GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM, *supra* note 131, at 9.

150. Food Labeling: Nutrition Labeling of Dietary Supplements on a “Per Day” Basis, 71 Fed. Reg. 74,785, 74,790 (Dec. 13, 2006) (codified at 21 C.F.R. pt. 101); Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim “Lean,” 72 Fed. Reg. 1455, 1459 (Jan. 12, 2007) (to be codified at 21 C.F.R. pt. 101).

take on this significant burden is particularly slim where the proposed rule disclaims emphatically (or even tentatively) any preemptive effect.¹⁵¹ The FDA's inconsistent stance regarding preemption thus likely undermines states' incentives to engage in the rulemaking process.

Several examples in which the FDA took the initiative to reach out to the states, however, provide some modest optimism for the scope of potential reform in this area. Agencies typically reserve direct requests for comments for situations in which the agency has determined that the proposed rule has an impact on federalism and, as such, is required under Executive Order 13,132 to seek state input.¹⁵² In several instances, the FDA reports that it sent notice via fax and email to the states to make them aware of the proposed rule, and gave them some period (typically one month) to respond.¹⁵³ The FDA also cites examples of more targeted outreach, directing its requests for comment to "State health commissioners, State agriculture commissioners, food program directors, and drug program

151. See *supra* notes 49–52 and accompanying text. For example, recall the FDA rule on nonoxynol/vaginal contraceptives, in which, contrary to the proposed rule's tentative disclaimer, the final rule asserted preemptive effect. In that case, the FDA solicited comments from the states on May 12, 2006, via fax and email to "elected officials of State governments and their representatives of national organization[s]." Over-the-Counter Vaginal Contraceptive and Spermicide Drug Products Containing Nonoxynol 9; Required Labeling, 72 Fed. Reg. 71,769, 71,783 (Dec. 19, 2007) (to be codified at 21 C.F.R. pt. 201); see also Skin Protectant Drug Products for Over-the-Counter Human Use; Reduced Labeling; Technical Amendment, 73 Fed. Reg. 6014, 6017 (Feb. 1, 2008) (to be codified at 21 C.F.R. pt. 347) (noting that no state commented during the public notice-and-comment period and that FDA reached out to states on December 10, 2007, but received no response).

152. Exec. Order No. 13,132, 64 Fed. Reg. at 43,257.

153. See, e.g., Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling, 71 Fed. Reg. 77,314, 77,345 (proposed Dec. 12, 2006) (to be codified at 21 C.F.R. pts. 201, 343) (asserting the preemptive effect of the proposed rule and noting that "FDA is providing an opportunity for State and local officials to comment on this rulemaking, and will conduct outreach to State and local government or organizations representing them"); see also Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim "Lean," 72 Fed. Reg. at 1459 (noting that states had been contacted in addition to the general notice provided to all stakeholders via publication in the Federal Register); Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Heart Disease, 71 Fed. Reg. 29,248, 29,250 (May 22, 2006) (to be codified at 21 C.F.R. pt. 101) (noting that the agency contacted the states via fax and email about the intended amendment and gave nearly a two-month window to respond). In these latter two examples, however, the FDA had denied that there were federalism impacts under the proposed rules.

directors.”¹⁵⁴ In most of these instances, however, the FDA reports that it received no responses.¹⁵⁵

A few examples of FDA outreach demonstrate further measures the agency should take to reach relevant state officials. Before promulgating a rule specifying labeling requirements for health claims concerning barley beta-fiber, the FDA appears to have made considerable effort to solicit relevant state input.¹⁵⁶ A proposed rule approved claims that whole oat and whole grain barley products lowered the risk of coronary heart disease and stated that the rule, if adopted, would preempt state law claims regarding soluble fiber’s health claims to the extent that they were not identical to the federal regulation.¹⁵⁷ Following the standard notice-and-comment period, the FDA reached out to states by faxing and emailing state health commissioners, food program directors, and drug program directors to “advise[] the States of FDA’s possible action and encourage[] the States and local government to review the petition and to provide any comments to the docket.”¹⁵⁸ States were given one month to respond.¹⁵⁹ After receiving no responses, the FDA once again invited state and local officials to comment on the interim rule.¹⁶⁰ In response to its second call for comments, the FDA received a single, brief

154. Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim “Lean,” 72 Fed. Reg. at 1459; Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Heart Disease, 71 Fed. Reg. at 29,250.

155. *E.g.*, Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim “Lean,” 72 Fed. Reg. at 1456; Food Labeling: Health Claims; Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease, 73 Fed. Reg. 9938, 9946 (interim final rule Feb. 25, 2008) (codified at 21 C.F.R. pt. 101).

156. The barley rule is one of three instances mentioned by Mendelson in which agencies solicited comments from states. *See* Mendelson, *supra* note 46, at 719 n.127 (citing Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Coronary Heart Disease, 71 Fed. Reg. 29,248, 29,250 (May 22, 2006) (codified at 21 C.F.R. pt. 101)); *id.* at 719 n.126 (citing Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Drivers’ License, 71 Fed. Reg. 29,396 (proposed May 22, 2006)); *id.* at 719 n.127 (citing Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan (ALWTRP), 71 Fed. Reg. 26,702, 26,704 (temporary rule May 8, 2006)).

157. Food Labeling: Health Claims; Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease, 72 Fed. Reg. 5367, 5373 (proposed Feb. 6, 2007) (to be codified at 21 C.F.R. pt. 101).

158. Food Labeling: Health Claims; Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease, 73 Fed. Reg. at 9946 (Feb. 25, 2008).

159. *Id.*

160. *Id.*

comment from the Secretary of Health and Family Services of the State of Kentucky.¹⁶¹

The FDA made similar efforts to prompt state response with a 2007 proposed FDA rule regarding osteoporosis health claims for calcium and vitamin D combination milk products. Following the notice of proposed rulemaking, in which it asserted preemptive effect, the FDA “provided notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors.”¹⁶² Having received no state response at the end of the comment period, the FDA invited states to comment on the proposed rule yet again.¹⁶³

It is difficult to know how to interpret the states’ seeming lack of interest to engage the relevant federal agency, in this case the FDA. The NCSL has raised concerns regarding the agency consultation process. For example, NCSL blamed the U.S. Department of Transportation for forgoing follow-up: “NCSL does not believe that one mailing constitutes meaningful consultation as contemplated by E.O. 13132. In sum, [the agency’s] attempts at meaningful consultation were feeble at best and disingenuous at worst.”¹⁶⁴ Instead, according to NCSL,

it was incumbent on [the agency] to follow-up with public sector organizations by phone or e-mail to verify that the information was sent to the correct address and to establish a point of contact with our organization. . . . [The agency] did not conduct any follow-up contact with any of these organizations [(“Big Seven” members of state and local government coalitions)] and then construed our silence as some sort of acquiescence.¹⁶⁵

161. The Secretary thanked the FDA for the opportunity to participate in the process and responded that “Kentucky conducts all labeling reviews in accordance with the [FDCA]; therefore, this ruling will not adversely affect our state’s actions or conflict with any state laws.” Letter from Janie Miller, Sec’y, Cabinet for Health and Family Servs., Ky., to Div. of Dockets Mgmt., FDA 1 (Mar. 14, 2008), available at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=FDA-2008-N-0032>.

162. Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis, 72 Fed. Reg. 497, 516 (proposed Jan. 5, 2007) (to be codified at 21 C.F.R. pt. 101).

163. *Id.*

164. Letter from Carl Tubbesing, Deputy Exec. Dir., Nat’l Conference of State Legislatures, to William Schoonover, Docket Operations, U.S. Dep’t of Transp. (May 16, 2008) (on file with *Duke Law Journal*).

165. *Id.*

Some responsibility, however, lies with the state governmental groups who may have opted out of engaging with the federal agencies. Part of the disaffection or despair experienced by these groups may stem from their lack of faith that participation in the process can meaningfully shape the agency's rulemaking. This dissatisfaction may stem from the nature of agencies' responses to the comments they do provide.

3. *Response to Comments.* How do agencies respond, if at all, when state actors do submit comments? It appears that the agencies' responses to questions and objections raised by stakeholder groups are often pro forma, which is perhaps not surprising given the general climate of nonengagement.

Some narrow counterexamples give hope. In one situation, NAAG, on behalf of forty-six state attorneys general, sent a letter to the Secretary of Health and Human Services objecting to a proposed regulation that would have permitted drug manufacturers to purge certain records relating to a Medicaid rebate program after three years.¹⁶⁶ The letter was submitted as part of the regulatory process¹⁶⁷ and, in this particular case, the intervention was successful—the regulation was withdrawn.¹⁶⁸

Groups such as NCSL, moreover, have the capacity to take further independent actions to conduct studies and to intervene in the agency rulemaking process. An example from a 2005 NHTSA proposed rule on roof crush resistance is instructive. Notwithstanding

166. A subsection of NAAG, the National Association of Medicaid Fraud Control Unit, sent out an alert that the proposed regulation had been published in the Federal Register. The state attorneys general were concerned that the regulation would undermine their ability to enforce the Medicaid program requirements; many state attorneys general have ongoing investigations concerning the rebate program and the three-year time window seemed unduly short. See Letter from Peter Heed, Att'y Gen. of N.H. et al. to Tommy G. Thompson, Sec'y, Dep't of Health & Human Servs., et al. (Oct. 28, 2003) [hereinafter Heed Letter] (on file with *Duke Law Journal*) (raising concerns that a three-year recordkeeping requirement would be too short for the purposes of state law enforcement); see also Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program, 69 Fed. Reg. 508, 511 (interim final rule Jan. 6, 2004) (to be codified at 42 C.F.R. pt. 447) (recognizing concerns raised in NAAG letter and agreeing to change policy from a three-year requirement to a ten-year requirement). My research assistant, Benjamin Heidlage, deserves credit for bringing this example to my attention.

167. Heed Letter, *supra* note 166.

168. Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program, 69 Fed. Reg. at 508 ("In this interim final rule with comment period we are removing the 3-year recordkeeping requirements, replacing them with 10-year recordkeeping requirements on a temporary basis, and soliciting comments on the 10-year requirements.").

the fact that the rule stated that it “would preempt all conflicting State common law requirements, including rules of tort law,”¹⁶⁹ consistent with its pattern and practice of denial (detailed above in Part I.B), NHTSA disclaimed any federalism impact: “the proposal would not have any substantial impact on the States, or on the current Federal-State relationship.”¹⁷⁰ NHTSA also bypassed any consultation with relevant state organizations on the ground that the proposed rule lacked “sufficient federal implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement.”¹⁷¹ NCSL contracted with the Pacific Institution for Research and Analysis to conduct an analysis of the financial impact of NHTSA’s proposed rule on the states. The study reported a projected increased annual financial burden of between \$49 to \$71 million dollars, primarily due to increased state-paid medical and disability costs for rollover crash victims who could no longer recover from automobile manufacturers.¹⁷² Although NHTSA has not taken any official action to rescind the proposed rule, according to Susan Frederick, Federal Affairs Counsel for NCSL, it is “dead,” largely due to the empirical findings presented to the agency by NCSL.¹⁷³

Scant counterexamples do not a success story make. But they do, at a minimum, suggest that the process of federal agency engagement with governmental entities representing state regulatory interests does not have to remain as it is. That said, effective communication between the agency and the relevant state governmental bodies is a key prerequisite for success.¹⁷⁴ And establishing such communication

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

170. *Id.*

171. *Id.*

172. See TED R. MILLER & EDUARD ZALOSHINJA, PACIFIC INSTITUTE FOR RESEARCH AND EVALUATION, STATE, LOCAL, AND TRIBAL GOVERNMENTS’ BENEFITS AND COSTS FROM NHTSA’S PROPOSED RULEMAKING ON ROOF CRUSH RESISTANCE 2 (2006) (“[T]he preemption of all conflicting State common law requirements, including rules of tort law, would prevent some permanently disabled victims in rollover crashes from recovering losses. As a result, the more seriously disabled could end up on Medicaid, which is partially funded by States.”).

173. Susan Frederick, Dir. of the Law & Justice Comm., Nat’l Conference of State Legislatures, Panelist Remarks at the New York University Annual Survey of American Law: Tort Law in the Shadow of Agency Preemption (Feb. 27, 2009).

174. During the Bush II administration, the pattern of nonconsultation coupled with the informal nature of the agency decisions, see *supra* note 30, made it extraordinarily difficult even for state groups that were in contact with an agency to keep abreast of preemption determinations.

and cooperation will be part and parcel of building a new agency-state partnership.

C. Partnership with the States

Compliance with Executive Order 13,132's strictures regarding the notice-and-comment process is a crucial first step, but far more important, and more difficult to implement, will be compliance with its broader spirit of agency-state interchange. How will it be possible to transform the existing relationship between states and federal agencies into a true partnership?

One key to such a transformation entails ensuring a meaningful consultation process with impacted stakeholders.¹⁷⁵ Consultation with the states must take place on a regular basis, even when the agency thinks that there is no federalism impact or obligation to issue an FIS.¹⁷⁶ Moreover, the consultation must take place much earlier in the

175. This is part and parcel of the Executive Order's direction that "no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation . . . consulted with State and local officials early in the process of developing the proposed regulation." Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,258 (Aug. 4, 1999).

The EPA Guidelines elaborate: "Your consultation should be 'meaningful and timely.' Generally, we interpret 'meaningful and timely' to mean that consultation should begin as early as possible and continue as you develop the proposed rule." EPA'S ACTION DEVELOPMENT PROCESS, GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM, *supra* note 131, at 9. EPA's Office of Congressional and Intergovernmental Relations (OCIR) offers logistical support: "OCIR staff can help you assess issues of concern to other government entities, identify interested government officials, suggest ways for achieving their education and involvement, tailor information about rules for [state and local] government audiences, and develop and implement consultation plans." *Id.* at 19.

176. Again, the EPA is exemplary. On several occasions, it has engaged in such consultation with the states. *See, e.g.*, Water Quality Standards for Puerto Rico, 72 Fed. Reg. 70,517, 70,523 (Dec. 12, 2007) (to be codified at 40 C.F.R. pt. 131) ("Although . . . Executive Order 13132 does not apply to this final rule, EPA did consult with the Commonwealth of Puerto Rico in developing this rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials."); Component Durability Procedures for New Light-Duty Vehicles, Light-Duty Trucks and Heavy-Duty Vehicles, 71 Fed. Reg. 2843, 2852 (proposed Jan. 17, 2006) (to be codified at 40 C.F.R. pt. 86) ("In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials."); *see also* EPA'S ACTION DEVELOPMENT PROCESS, GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM, *supra* note 131, at 11 ("In the spirit of EO 13132, it is EPA's policy to promote communications between EPA and [state and local] governments and solicit input from [state and local] government representatives when developing a regulation that will have any adverse impact above a minimal level on [state and local] governments. This internal policy is broader than EO 13132.").

process.¹⁷⁷ States must receive notice early on—well in advance of the agency’s imminent publication of a final rule—to have a hand in shaping the contours of a national rule. As a formal matter, such consultation is recognized by Executive Order 13,132, which urges agencies “[i]n determining whether to establish uniform national standards, [to] consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority.”¹⁷⁸ Moreover, agencies are to “consult with appropriate State and local officials to determine whether Federal objectives can be attained by other means.”¹⁷⁹ For cases in which the need for national policy is recognized or required by federal statute, the agency is to “consult with the appropriate State and local officials in developing those standards.”¹⁸⁰ Targeted outreach to states may be an effective way to gather state input on the optimal level of certain regulations and on the need for uniform national programs.¹⁸¹

A case example from a NHTSA rulemaking shows that beneficial dialogue can occur when state officials and individuals representing state interests are involved in the rulemaking process at an earlier stage. NHTSA initiated a rulemaking process to determine whether to amend requirements for crash safety protection in small

177. Notice-and-comment rulemaking has been subject to a more generalized critique along these lines. *See, e.g.*, Freeman, *supra* note 145, at 12 (“[T]he notice and comment process often fails to make the best use of available data and information. This is in part a product of timing: only after the Notice of Proposed Rule Making (NPRM) do parties supply detailed arguments about the technical and practical difficulties of implementing a rule, instead of much earlier when the information might be more valuable to the agency in formulating the proposed rule.”).

178. Exec. Order No. 13,132, 64 Fed. Reg. at 43,256.

179. *Id.*

180. *Id.*

181. One idea, suggested to me by Phil Weiser, would be for each federal agency to have some type of ombudsperson committed to state outreach. Executive Order 13,132 in fact requires agencies to designate a “federalism official,” who is charged with certifying compliance with the order. *See infra* note 206 and accompanying text; *see also* EPA’s ACTION DEVELOPMENT PROCESS, GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM, *supra* note 131, at 19 n.7 (highlighting the role of the “Regulatory Steering Committee Representative” of EPA’s Office of Congressional and Intergovernmental Relations in assisting with outreach to EPA’s intergovernmental partners).

Another idea, suggested by my student Christopher Terranova, is for each agency to create a working group of interested parties with which it can consult. *See* Christopher Terranova, Challenging Agency Preemption 19–20 (May 12, 2009) (unpublished manuscript, on file with *Duke Law Journal*). The Federal Railroad Administration regularly consulted with such a working group before issuing its preemptive rules. *See id.* (manuscript at 9–10).

and large school buses. Early in the process, prior to the issuance of the notice of proposed rulemaking, NHTSA convened a “roundtable of State and local government policymakers, school bus and seat manufacturers, pupil transportation associations and consumer associations to address . . . [s]tate and local policy perspectives” on the feasibility and desirability of a national uniform requirement.¹⁸² Participants at the roundtable included representatives from states with compulsory seatbelt requirements, individuals with expertise in seatbelt installation (and the effects on passenger capacity), and a representative from the National School Transportation Association.¹⁸³ A consensus emerged that the costs of installing belts would outweigh the benefits.¹⁸⁴

This situation was unique because the invitation to participate was extended to several representative local and state interest groups when the rule was at a preliminary proposal stage; this was not a perfunctory request for comment once much of the shape of the rule was already determined. Such early-stage participation shapes the outcome of the rule and affords the states an opportunity to participate in the federalism debate.

IV. “AGENCY-FORCING” MEASURES

Policy groups and academics interested in protecting state regulatory interests from an onslaught of national expansion should engage in the discussion of how agency policymaking can be structured to be more responsive to federalism concerns.¹⁸⁵ Although (as discussed above in Part III) Executive Order 13,132 provides a blueprint for reform, success would seem to turn entirely on the question of enforcement. “Agency-forcing” accountability measures are required given that the Executive Order is not enforceable against

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

183. *Id.*

184. *Id.*

185. Several of the reforms posited here, moreover, fit within a broader regulatory reform agenda. Cf. Philip J. Weiser, *Institutional Design, FCC Reform, and the Hidden Side of the Administrative State* 38 (Univ. of Colo. Law Sch. Legal Studies Research Paper Series, Working Paper No. 09-01, 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1336820 (outlining a reform agenda for the FCC to “seek to obtain better information, elicit more effective public input, and, finally, enable the public to play a more constructive role in the agency’s work”).

the agencies,¹⁸⁶ which, as detailed above in Part I, are thus prone to ignore it. Such agency-forcing measures admittedly face formidable barriers, but they have enormous, hitherto untapped, potential to transform agencies into loci for rich, deliberative dialogue regarding the interplay of state law and federal regulatory schemes.

A variety of institutional actors could take the lead. First, Congress could codify the strictures of the Executive Order. Second, the White House could use its Office of Information and Regulatory Affairs' (OIRA) centralized review to enforce the Executive Order. Each of these avenues has been proposed before in this (or similar) context—thus far, to no avail—and while they may be worth revisiting, my main focus will be on the comparatively underexplored realm of judicial enforcement.

The innovative proposal is to think about how courts might force agencies into action. Although it is oft-repeated that courts can do little to spur agency action,¹⁸⁷ judicial enforcement holds the greatest promise. Admittedly, one searches in vain for traces of direct challenges to preemptive rules in the health and safety arena. The status quo may be explained either by deliberate strategic choices or by standing and ripeness barriers. Regardless of whether direct challenges can get off the ground, courts can play an effective agency-forcing role at a later juncture, when called upon to rule on the assertion of preemption—typically in a motion to dismiss or for summary judgment—as a defense to a state products liability claim. The United States Supreme Court implicitly gave its imprimatur to such an “indirect challenge” to agency rulemaking in *Wyeth v. Levine*.¹⁸⁸ In rejecting a drug manufacturer’s assertion of implied preemption of state failure-to-warn claims, the Court looked askance at the FDA’s “proclamations of pre-emption” in its 2006 preemption

186. Exec. Order No. 13,132, § 11, 64 Fed. Reg. at 43,259 (stating that the Executive Order “is intended only to improve the internal management of the executive branch, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person”).

187. See, e.g., Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1276 (2006) (“[C]ourts generally cannot spur agency action.”). Agency inaction is notoriously difficult to police. *Heckler v. Chaney*, 470 U.S. 821 (1985), established that an agency’s refusal to initiate enforcement proceedings is not ordinarily subject to judicial review. *Id.* at 831. Agencies, moreover, enjoy a wide berth of discretion “to choose how best to marshal [their] limited resources and personnel to carry out [their] delegated responsibilities.” *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007) (citing *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–45 (1984)).

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

preamble.¹⁸⁹ The Court specifically mentioned that the FDA's failure to "offer[] States or other interested parties notice or opportunity for comment" rendered its views on state law "inherently suspect."¹⁹⁰

One effect of *Wyeth* will be to encourage agencies to shepherd preemption provisions through notice and comment—thus expanding the domain for direct challenges to such provisions through the APA framework. Even more significantly, *Wyeth* could augur the dawn of a new form of indirect challenge, arising when the preemption defense is raised to state tort causes of action, with far-reaching implications.

A. Congressional

Congress should codify Executive Order 13,132 to require agencies to consult with public officials and prepare federalism impact statements for all rules that impact federalism.¹⁹¹ The bills proposed thus far have failed, but this may have had something to do with their arguably overbroad nature; the proposed bills tried to impose accountability requirements on Congress as well as on federal agencies.¹⁹²

The Federalism Accountability Act of 1999 (1999 FAA) (introduced in the 106th Congress) required federal agencies to consult with potentially affected state and local governments and to prepare "federalism assessments" explaining the reason for any

189. *Id.* at 1201. For a description of the 2006 preamble, see *supra* Part I.A.1.

190. *Wyeth*, 129 S. Ct. at 1201.

191. There is surprisingly little academic commentary addressing the merits of congressional codification of Executive Order 13,132 (or its precursors). For at least a mention, see Nina A. Mendelson, *The California Greenhouse Gas Waiver Decision and Agency Interpretation: A Response to Professors Galle and Seidenfeld*, 57 DUKE L.J. 2157, 2172 (2008). Professor Mendelson noted the unenforceability of Executive Order 13,132 and stated that "[c]ongressional action is clearly required here." *Id.* For a more pessimistic assessment, see Patricia L. Donze, *Legislating Comity: Can Congress Enforce Federalism Constraints Through Restrictions on Preemption Doctrine?*, 4 N.Y.U. J. LEGIS. & PUB. POL'Y 239, 275 (2000–01). As Ms. Donze notes, "Almost every single phrase of the proposed bills would conceivably spur litigation, and there is no assurance that the bills would do anything more than require boilerplate federalism assessments by agencies . . . already under stress due to scarce time and resources." *Id.*

192. Moreover, they have included more than simply a codification of Executive Order 13,132. For example, the proposed bill from the 106th Congress included a "rule of construction relating to preemption" for use by federal, state, and local court judges that tipped the balance decidedly against preemption—in essence codifying the presumption against preemption. S. 1214, 106th Cong. §§ 4, 6 (1999). *But see* Federalism Preservation Act of 1999, H.R. 2960, 106th Cong. §2(a) (codifying the terms of Executive Order 12,612).

preemptive determination.¹⁹³ In addition, the FAA would have required each congressional committee report to state explicitly whether the bill preempted state law and, if so, the reasons that such preemption was necessary.¹⁹⁴

The politics of enactment are complicated. The proposed 1999 FAA initially received broad support in the Senate; the bill was positively recommended by the Committee on Governmental Affairs by a bipartisan 8 to 2 vote.¹⁹⁵ The bill nonetheless failed to make it to the Senate floor (companion bills in the House met a similar fate¹⁹⁶),

193. S. 1214, 106th Cong. § 7 (1999). These provisions codified President Ronald Reagan's Executive Order 12,612, Executive Order 13,132's predecessor. Executive Order 12,612 (similar to E.O. 13,132) listed federalism principles for agencies to follow and required a designated federalism official to complete a "federalism assessment."

President Clinton's proposed 1998 Executive Order 13,083 (to replace the Reagan order), "which was viewed as a significant retreat from previous executive orders regarding federal preemption," gave additional momentum to backers of the bills. John Dinan, *Strengthening the Political Safeguards of Federalism: The Fate of Recent Federalism Legislation in the U.S. Congress*, 34 PUBLIUS 55, 64 (2004). President Clinton suspended his order after a "firestorm of criticism"—including charges that, ironically, he failed to consult with state groups. *Id.* But "state and local officials were by this point convinced" that they could no longer rely on executive orders and needed statutory protection. *Id.*; see also David S. Broder, *Executive Order Urged Consulting, but Didn't; State, Local Officials Want Federalism Say*, WASH. POST, July 16, 1998, at A15.

One day after the FAA cleared a Senate committee, President Clinton issued Executive Order 13,132, perhaps to quell the momentum from the bill's supporters. See Donze, *supra* note 191, at 269–70 n.176; see also Nat'l Conference of State Legislatures, Summary of Executive Order 13132 on Federalism Issued by Clinton Administration, <http://www.ncsl.org/statefed/federalism/exec13132.htm> (last visited May 13, 2009) (describing "extensive negotiations between the White House and seven national organizations . . . representing state and local government officials").

194. S. 1214, 106th Cong. § 5.

195. S. REP. NO. 106-159, at 13 (1999). Among the original ten sponsors of the bill, five were Democrats (Bayh (Ind.), Robb (Va.), Breaux (La.), Levin (Mich.), and Lincoln (Ark.)). S. 1214, 106th Cong. The two dissenters in the Committee, however, were both Democrats—Senators Durbin (Ill.) and Cleland (Ga.). S. REP. NO. 106-159, at 13.

The House bills, meanwhile, had a much stronger Republican tilt in terms of sponsorship. The Federalism Act, which closely tracked the 1999 FAA (S. 1214)—both included a rule of statutory construction against preemption, a requirement that agencies promulgate a federalism impact statement accompanying proposed rules, and requirements for Congress to state explicitly the preemptive consequences of bills in committee reports—ended up with thirty Republican sponsors and five Democratic sponsors (Condit (Cal.), Moran (Va.), McCarthy (Mo.), Danner (Mo.), and Shows (Miss.)). H.R. 2245, 106th Cong. (1999).

The Federalism Preservation Act of 1999, which simply required all federal departments and agencies to comply with Executive Order 12,612, had twenty-four cosponsors—all Republicans. The chief sponsor of that bill was Bob Barr (Ga.). H.R. 2960, 106th Cong. (1999).

196. Neither of the House bill counterparts, H.R. 2245 and H.R. 2960, made it out of Committee.

and it has never been reintroduced. Strange bedfellows—the U.S. Chamber of Commerce joined by proregulatory environmental, labor, and consumer organizations—opposed the bill. The Chamber of Commerce “waged a major campaign to kill or substantially weaken the measures,” fearing that the bill would thwart the imposition of national standards.¹⁹⁷ At the same time, a group of 300 environmental, labor, consumer, and other groups opposed the legislation for fear that it could impede federal action.¹⁹⁸ Donna Shalala, then-director of Health and Human Services, voiced a similar concern that the Act could weaken consumer protection programs, which depend on national uniform rules to be effective, and that burdensome procedural requirements for agencies would increase cost and cause delay.¹⁹⁹

During 2007 Senate Judiciary Committee hearings on regulatory preemption, Donna Stone, representing the NCSL, proposed an updated version, the Federalism Accountability Act of 2007 (2007 FAA).²⁰⁰ The legislation, which largely replicates the failed 1999 Act, would require an agency to conduct notice and comment as to the preemptive effect of a rule.²⁰¹ A key provision of the proposed bill specifically authorizes judicial enforcement: should an agency fail to perform a federalism impact statement, “a court may . . . delay the effective date of such rule until the federalism assessment and consultation are completed.”²⁰²

The success of congressional mandates for agency-state cooperation in the REAL ID experience,²⁰³ as well as in the realm of environmental law,²⁰⁴ provides some modicum of hope that, assuming the political hurdles could be overcome, codification of the Executive Order would pave the way toward more fruitful agency-state cooperation and interaction in setting regulatory policy.

197. Stephen Labaton, *Anti-Federalism Measures Have Bipartisan Support*, N.Y. TIMES, Sept. 6, 1999, at A12.

198. *Id.*; see also Dinan, *supra* note 193, at 66 (“[H]ealth, labor, and environmental groups . . . strongly opposed [the federalism bills] on the ground that they would prevent the enactment of numerous beneficial statutes and regulations.”).

199. S. REP. NO. 106-159, at 27.

200. *Sen. Hearing on Regulatory Preemption*, *supra* note 21, at 7–8.

201. Telephone Interview with Susan Frederick, *supra* note 133. Ms. Frederick kindly provided a copy of the proposed draft bill, which was never introduced into Congress. Draft Bill (on file with the *Duke Law Journal*). The notice-and-comment provision is in section 7.

202. Draft Bill § 6(f)(4) (“Court Action”).

203. See *supra* notes 95–105 and accompanying text.

204. See *supra* notes 131–33 and accompanying text.

B. Executive

Another tack would be for the executive to take the lead, directing OIRA (housed within the Office of Management and Budget (OMB)) to conduct centralized review of agency compliance with Executive Order 13,132.²⁰⁵

For certain regulations—those subject to OMB review under the cost-benefit executive order (Executive Order 12,866)—the federalism executive order requires a designated federalism official in each agency to certify that the order’s requirements “have been met in a meaningful and timely manner” in developing regulations with federalism implications.²⁰⁶ Two limitations surface at the outset. First, the required certification to OMB is required only for “significant” regulations (defined as having an annual effect on the economy of at least \$100 million) subject to Executive Order 12,866.²⁰⁷ Second, OMB is given little to review; it is asked simply for a vote of confidence in the federalism officer’s conclusion. In theory, OMB could review the federalism impact statements required for all rulemakings with “federalism implications.”²⁰⁸ But, such theoretical review provides

205. In 2009, the Director of the OMB set out to “develop[] a set of recommendations to the President for a new Executive Order on Federal Regulatory Review” and, as part of the process, invited “public comments on how to improve the process and principles governing regulation.” 74 Fed. Reg. 8819 (Feb. 26, 2009). The preexisting guidelines on implementation of Executive Order 13,132 are procedural in nature, focusing on “what agencies should do to comply with [the Order] and how they should document that compliance to OMB.” Memorandum from Jacob J. Lew, Director, Office of Mgmt. & Budget, to the Heads of Executive Departments and Agencies, and Independent Regulatory Agencies, Guidance for Implementing E.O. 13132, “Federalism” (Oct. 28, 1999), available at <http://www.whitehouse.gov/omb/memoranda/m00-02.pdf>.

206. Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,258–59 (Aug. 4, 1999).

207. Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), amended by Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007); see also Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,258 (Aug. 4, 1999) (providing for certification of compliance to OMB when “transmitting any draft final regulation that has federalism implications to [OMB] pursuant to Executive Order 12866”). Executive Order 12,866 defines a “significant regulatory action” in terms of an “annual effect on the economy of \$100 million or more.” Exec. Order No. 12,866, § 3(f), 58 Fed. Reg. 51,735; *id.* at § 6(a)(3)(A), 58 Fed. Reg. 51,735 (“[Regulations] not designated as significant will not be subject to [OMB] review.”). According to an empirical study by Steven Croley, only 5 percent of federal rules met this standard for OMB review during the period 1981–2000. Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 846 (2003).

The EPA’s federalism guidelines propose a lower dollar figure (\$25 million) for establishing reviewability under Executive Order 13,132. See EPA’S ACTION DEVELOPMENT PROCESS, GUIDANCE ON EXECUTIVE ORDER 13132: FEDERALISM, *supra* note 131, at 6.

208. See *supra* note 147.

cold comfort in the face of a reality in which agencies evade the requirement to produce FISs.

OIRA's centralized review of agencies' compliance with cost-benefit analysis pursuant to Executive Order 12,866 provides a potential template.²⁰⁹ Agencies, moreover, have guidelines for how to conduct cost-benefit analyses.²¹⁰ Similar guidelines should be developed for federalism impact statements.

OIRA enforcement cannot escape politics.²¹¹ For this reason, judicial review will remain an important policing mechanism.

C. *Judicial*

Courts review administrative agency rulemaking under the Administrative Procedure Act. In the realm of health and safety, however, direct challenges to agency action (or inaction) have been few and far between. The time has come for a broader set of "agency-forcing" measures.

Outside of the APA framework of direct challenges to agency rulemaking, courts can play an "agency-forcing" role in the context of adjudicating whether federal law preempts state common law actions. The idea that preemption controversies before state and federal courts provide such an opportunity for an indirect challenge to agency

209. See, e.g., RICHARD L. REVESZ & MICHAEL A. LIVERMORE, INST. FOR POLICY INTEGRITY, N.Y.U. SCHOOL OF LAW, FIXING REGULATORY REVIEW: RECOMMENDATIONS FOR THE NEXT ADMINISTRATION 4-5 (2008) [hereinafter REVESZ & LIVERMORE, RECOMMENDATIONS]; see also RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH 31-32 (2008) (stating that the message of Executive Order 12,866 was that "centralized review and cost-benefit analysis could serve as a neutral tool"); Bagley & Revesz, *supra* note 187, at 1267 ("In recent years, the functional appropriateness of Executive Order 12,866 as a template for executive control of the administrative process has not been seriously challenged.").

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

211. REVESZ & LIVERMORE, RECOMMENDATIONS, *supra* note 209, at 7 ("The history of federal regulatory review has shown that OIRA's role easily shifts to reflect changing administrative ideologies: starting as a secretive and blunt instrument under President Reagan, changing to more of a facilitator under President Clinton, and reverting to a regulatory gatekeeper under President George W. Bush."); *id.* at 9 ("A 2003 study by the U.S. General Accounting Office (now called the Government Accountability Office) found that, over the last eight years, OIRA has acted more as a gatekeeper—aggressively imposing its will at the expense of reasoned analysis and science—whereas during the Clinton Administration it played the role of a facilitator."). Revesz and Livermore's recommendations are "geared towards making durable changes in OIRA's roles so that it can become a stabilizing force in regulatory review, rather than merely a mirror of the latest and mercurial administrative agenda." *Id.* at 7.

rulemaking may seem counterintuitive. But it makes sense once one recognizes the centrality of the agency's input to courts' preemption decisions—particularly with respect to how state law affects the federal regulatory scheme. Even the Court's antipreemption decision in *Wyeth v. Levine* (in which the FDA's preemption preamble received especially harsh treatment) recognized the significance of input from the relevant federal agency.²¹²

Wyeth stands as an intriguing exemplar of how courts can play an agency-forcing role. Bent on reconciling its implied preemption holdings, the Court contrasted its propreemption *Geier* decision, in which the Department of Transportation had promulgated a regulation with “force of law,”²¹³ with the situation in *Wyeth*, in which the FDA had put forth its views in a preamble that evaded the notice-and-comment rulemaking procedures.²¹⁴ Justice Stephen Breyer concurred separately to emphasize the majority's concession that agency regulations with “force of law” can preempt.²¹⁵ Justice Breyer spelled out that the FDA “may seek to embody [its] determinations [whether and when state tort law acts as a help or hindrance to federal regulatory goals] in lawful specific regulations describing, for example, when labeling requirements serve as a ceiling as well as a floor.”²¹⁶

In the wake of *Wyeth*, agencies have an incentive to put preemption provisions through notice-and-comment rulemaking.

212. *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009) (Agencies have “a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941))); *id.* (“[W]e have attended to an agency's explanation of how state law affects the regulatory scheme.”). To be sure, the Court emphasized that preemption is a *judicial* decision that is informed by agency input. *Id.* at 1203 (“After conducting our own pre-emption analysis [in *Geier*], we considered the agency's explanation of how state law interfered with its regulation, regarding it as further support for our independent conclusion that the plaintiff's tort claim obstructed the federal regime.”).

213. *Id.* at 1200.

214. *Id.* at 1203 (“By contrast, we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law.”).

215. *Id.* at 1200 (“This Court has recognized that an agency regulation with the force of law can pre-empt conflicting state requirements.” (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985))). Even in such situations, “the Court has performed its own conflict determination, relying on the substance of state and federal law and not on agency proclamations of pre-emption.” *Id.* at 1200–01.

216. *Id.* at 1204 (Breyer, J., concurring) (“[I]t is possible that such determinations would have pre-emptive effect.”).

Such direct regulations would be more likely to pass judicial muster at the preemption juncture, but they would also be more susceptible to direct challenges during the rulemaking process.²¹⁷

But the reach of *Wyeth* goes even further—into contexts where either Congress has not authorized the agency to preempt state law directly,²¹⁸ or the agency has not promulgated regulations with “force of law.” In these situations, the Court still looks to the agency’s explanation of how state law affects the regulatory regime. The question becomes “what weight [the Court] should accord the FDA’s opinion.”²¹⁹ The Court had previously given a nod (if not outright deference) to agency proclamations of preemption in “regulations, preambles, interpretive statements, and responses to comments.”²²⁰ My own view has been that the agency’s views should be accorded *Skidmore* “power to persuade” (not *Chevron* mandatory) deference²²¹—a position apparently endorsed by the Court in *Wyeth*.²²² By virtue of subjecting agency action and interpretation to *Skidmore* deference at the preemption juncture, courts establish a framework for indirect challenges to agency rulemaking.

217. See *infra* text accompanying note 232.

218. See, e.g., *Wyeth*, 129 S. Ct. at 1201 (comparing *Wyeth* with 21 U.S.C. § 360k, which “authoriz[es] the FDA to determine the scope of the [Medical Device Amendment’s] preemption clause”). In this respect, Brian Galle and Mark Seidenfeld have, in my view, interpreted *Wyeth* too broadly by suggesting that it holds that Congress must clearly delegate the power to preempt before an agency can exercise that power. See Brian Galle & Mark Seidenfeld, *Preemption and Federal Administrative Law*, 34 ADMIN. & REG. L. NEWS (2009) (abstract).

219. *Wyeth*, 129 S. Ct. at 1201.

220. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 505–06 (1996) (Breyer, J., concurring); *id.* at 495–96 (majority opinion) (“The FDA regulations interpreting the scope of [the statute’s] preemptive effect support the [antipreemption] view, and our interpretation of the preemption statute is *substantially informed* by those regulations.” (emphasis added)); see also *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2000) (“We place some weight upon DOT’s interpretation of [the regulation’s] objectives and its conclusion, as set forth in the Government’s brief, that a tort suit such as this one would stand as an obstacle to the accomplishment and execution of those objectives.”).

In these cases, the Court studiously avoided specifying the level of deference owed agency interpretations on preemption. Several lower courts gave *Chevron*, or mandatory, deference to the FDA’s preemption preamble. See, e.g., Sharkey, *Products Liability Preemption*, *supra* note 6, at 512 n.304 (citing cases).

221. See Sharkey, *Products Liability Preemption*, *supra* note 6, at 491–98.

222. *Wyeth*, 129 S. Ct. at 1201 (“The weight we accord the agency’s explanation of state law’s impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness.”) (comparing *United States v. Mead Corp.*, 533 U.S. 218, 234–35 (2001) and *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

1. *Direct Challenges to Agency Rulemaking.* Courts already have tools to ensure that agencies disclose relevant data and provide reasoned responses to material objections raised during the rulemaking process. *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*²²³ articulates a standard of “hard look” review in the context of determining whether a regulation is “arbitrary and capricious” under § 706 of the APA.²²⁴ *State Farm* solidifies previously articulated agency standards imposed by lower courts (under § 553 of the APA), such as the *United States v. Nova Scotia Food Products Corp.*²²⁵ obligation to respond to significant comments during the notice-and-comment period:²²⁶

It is not in keeping with the rational process to leave vital questions, raised by comments which are of cogent materiality, completely unanswered. The agencies certainly have a good deal of discretion in expressing the basis of a rule, but the agencies do not have quite the prerogative of obscurantism reserved to legislatures.²²⁷

Direct challenges to preemptive rules in the health and safety arena are, however, few and far between. This is in marked contrast to other areas, such as environmental regulation, where nonprofit and governmental organizations take an active role in challenging rules adverse to state regulatory interests.²²⁸ What explains this seeming market failure?

First, as a threshold matter (explored above in Part III.A), it is not altogether clear who most effectively represents the state regulatory interests in the health and safety context. It is a bit of a puzzle why groups such as NCSL and NAAG have not asserted state

223. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

224. *Id.* at 34.

225. *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240 (2d Cir. 1977).

226. *State Farm*, 463 U.S. at 42–44.

227. *Nova Scotia*, 568 F.2d at 252. An agency is not expected to respond to each and every comment. *See, e.g., MCI WorldCom, Inc. v. FCC*, 209 F.3d 760, 765 (D.C. Cir. 2000) (“An agency is not obliged to respond to every comment, only those that can be thought to challenge a fundamental premise.”).

228. *See, e.g.,* Letter from Henry A. Waxman, Chairman of Comm. on Oversight & Gov. Reform, to Stephen L. Johnson, Administrator of EPA 3 (Oct. 21, 2008), available at <http://oversight.house.gov/documents/20081021110039.pdf> (reporting that during the Bush II Administration, the D.C. Circuit and the U.S. Supreme Court rejected an EPA regulation in 18 of 27 Clean Air Act cases); Chris Bowman, *Bush Team Battered by Courts on Environment*, SAC. BEE, May 19, 2008, at A1 (“[T]he Bush administration won just one” case out of “78 federal court rulings and settlements in [Endangered Species Act] cases resolved since January 2001”).

regulatory interests as strongly in this area as in others. After all, courts have deferred to informal agency proclamations of preemption, such as that embodied in the preemption preamble.²²⁹ Cognizant of these developments, which could lead to foreclosing state tort suits down the road, state governmental entities and public interest groups would have an incentive to challenge procedural failures in the rulemaking process. But such direct agency challenges have not materialized. Why not?

Perhaps only a direct, sizeable financial stake will be sufficient to galvanize state participation.²³⁰ Moreover, some state governmental entities (representing both state courts and legislatures) may have succumbed to the “tort reform” spirit, which has led to a variety of substantive and procedural measures to cabin tort liability and limit the remedies afforded to injured victims.²³¹

Second, agencies’ insertion of preemptive provisions into preambles to rules may provide part of the answer. Such stealth maneuvers simultaneously diverted the attention of the watchdogs and also may have insulated the rules from direct judicial challenge.²³² As a strategic matter, moreover, consumer advocates may have consciously avoided any invitation to the courts to find that an agency

229. See *supra* note 220.

230. Consider in this regard the vociferous outcry by the states regarding the REAL ID Act. See *supra* notes 99–101 and accompanying text; see also *supra* note 104 and accompanying text.

231. Certain state legislative tort reform measures—such as caps on punitive and noneconomic damages—have made strong inroads. See, e.g., Jonathan Klick & Catherine M. Sharkey, *What Drives the Passage of Damage Caps?*, in *EMPIRICAL STUDIES OF JUDICIAL SYSTEMS AROUND THE GLOBE* (forthcoming 2009) (“A number of states have passed caps on non-economic and punitive damage awards in civil cases.”); Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damages Caps*, 80 N.Y.U. L. REV. 391, 396 (2005) (“A majority of states have imposed some kind of cap or limitation on the amount of damages that plaintiffs can recover in a lawsuit.”). By contrast, however, tort reform efforts to establish regulatory compliance as an absolute defense to state tort claims have been an abject failure. See Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL’Y 1013, 1022–23 (2007) (“It is hardly an exaggeration to claim that the push for a strong regulatory compliance defense to tort liability . . . advocated by a host of scholars and policymakers has been an abject failure. Today, Michigan stands alone in having adopted, by statute, blanket immunity based upon federal regulatory compliance.” (footnote omitted)).

232. The United States has taken the position that “[n]either the Administrative Procedure Act nor Executive Order 13,132 requires FDA to provide notice of and an opportunity to comment on responses to public comments about a proposed rule, setting forth the agency’s view of principles of implied conflict preemption in a preamble that is not part of the codified final rule.” Brief for Amicus Curiae the United States of America at 19 n.8, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (Civ. No. 05-CV-05500-MMB), 2006 WL 1724170.

did have authority to issue the preemption statement or, even worse, that the agency statement was correct or warranted deference. Instead, such advocates may have focused exclusively on injured consumers seeking to litigate their tort suits afterward.

Finally, standing and ripeness problems loom large. The Food Drug and Cosmetic Act does not create a private right of action for individuals to challenge FDA decisions or to enforce on behalf of the FDA.²³³ Who would be the appropriate party to challenge a preemption preamble via the Administrative Procedure Act, in advance of federal enforcement based upon deference to the agency's interpretation contained therein? And at what juncture would a dispute be of sufficient immediacy to be ripe for judicial consideration? There is no brightline doctrinal rule here nor any categorical bar to judicial review of preambles.²³⁴ The Court of Appeals for the D.C. Circuit, for example, will entertain direct challenges to preambles of final regulations, albeit in the limited context in which the preamble has "independent legal effect, which in turn is a function of the agency's intention to bind either itself or regulated parties."²³⁵ But even so, the challenging party would have to demonstrate a "direct and immediate" effect—a formidable standard to meet.²³⁶

Given these stumbling blocks, it is usually not until defendants wield these rules in the context of asserting preemption defenses against state common law products claims that the clash of state and federal regulatory interests comes to a head. It is, nonetheless, worth

233. 21 U.S.C. § 337 (2006); *see also In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well settled . . . that the FDCA creates no private right of action).

234. For an insightful discussion of these standing and ripeness challenges, see Terranova, *supra* note 181 (manuscript at 28–30). My discussion in this paragraph borrows from Terranova's discussion.

235. *Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1223 (D.C. Cir. 1996). A preamble that was "an interpretation of an identified statutory provision, [or] a clarification of an otherwise binding regulation," would likely pass this test. *Id.*; *see also NRDC v. EPA*, 559 F.3d 561, 564–65 (D.C. Cir. 2009) ("While preamble statements may in some unique cases constitute binding, final agency action susceptible to judicial review, this is not the norm. Agency statements 'having general applicability and legal effect' are to be published in the Code of Federal Regulations." (quoting Federal Register Act, 44 U.S.C. § 1510(a) (citation omitted))).

236. In *Kennecott*, for example, the D.C. Circuit dismissed the challenge on ripeness grounds, concluding that "[u]nless and until [the Department of the] Interior or another trustee invokes the preamble in an attempt to affect the outcome of a real dispute, there is little need for and no factual basis to inform our inquiry into its validity." *Kennecott*, 88 F.3d at 1223.

contemplating whether legal developments might bolster the effectiveness of direct rulemaking challenges.

In *Massachusetts v. EPA*,²³⁷ the U.S. Supreme Court bestowed “special solicitude” upon the state in its analysis of standing in the context of a challenge to an EPA order denying a petition for rulemaking to regulate greenhouse gas emissions from motor vehicles under the Clean Air Act.²³⁸ The Court reaffirmed that “[w]hen a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.”²³⁹ Even as scholars debate the precise contours of special solicitude for states,²⁴⁰ courts might accord similar latitude for standing to challenge the rulemaking procedures of some group deputized to represent state regulatory interests.²⁴¹

Jody Freeman and Adrian Vermeule, moreover, heralded *Massachusetts v. EPA* as “*State Farm* for a new generation.”²⁴² At a minimum, the Court’s prior claim that agencies receive heightened deference even when they have refused to initiate rulemaking proceedings has been called into question. It remains to be seen the extent to which courts will reinvigorate and expand “hard look” review of agency action. *Wyeth v. Levine* could expand the domain of direct challenges to preemption provisions in notice-and-comment rulemakings should agencies be spurred in that direction. It also stands as a progenitor of a new form of indirect challenge, arising

237. *Massachusetts v. EPA*, 549 U.S. 497 (2007).

238. *Id.* at 520.

239. *Id.* at 518.

240. See, e.g., Metzger, *supra* note 118, at 2062–63 (“[W]hat the majority intends by its invocation of ‘special solicitude’ for the states in standing analysis is not obvious; such solicitude might mean a generous stance in determining whether the traditional trio of requirements for standing is met, or exempting the states from the traditional analysis altogether when their sovereignty interests are implicated.”).

241. Dru Stevenson links the Court’s standing innovation with the evolving role of state attorneys general. See Dru Stevenson, *Special Solicitude for State Standing: Massachusetts v. EPA*, 112 PENN ST. L. REV. 1, 38 (2007) (“Standing is one additional obstacle that every AG must consider before commencing an action. Relaxing the standing requirements for states means that there will be one less hurdle—a significant hurdle that itself could otherwise consume costly litigation resources—for policy-oriented litigation by the state AG’s. Now that the costs are lower and the chances of success are greater, proceeding to litigation will be a rational decision for AG’s more frequently.” (footnote omitted)).

242. Jody Freeman & Adrian Vermeule, *Massachusetts v. EPA: From Politics to Expertise*, 2007 SUP. CT. REV. 51, 52.

when the preemption defense is raised against state tort causes of action.

2. *Indirect Challenges to Agency Rulemaking.* The extent to which courts can play an agency-forcing role at a later juncture—namely in the context of a preemption defense to a state products liability claim raised in court—has been relatively unexplored.

I have suggested that courts could play a role here by conditioning any deference to an agency's preemption position on that agency's compliance with the strictures of Executive Order 13,132.²⁴³ A few federal district courts have taken such a hard-line position, rejecting preemption defenses based upon the FDA's assertion of preemption in the drug labeling context.²⁴⁴ I have also urged *Skidmore* "power to persuade" deference (as opposed to mandatory *Chevron* deference) as a means to "encourag[e] agencies to engage in formal notice-and-comment rulemaking processes that, arguably, vet the agency decisionmaking process and make the agency respond to substantive concerns raised by all affected parties."²⁴⁵

I now want to extend that view and suggest that preemption decisions might provide an apt avenue for a new form of indirect challenge to agency rulemaking and regulatory actions with wider applicability. What I have in mind is an extension of the *Nova Scotia-*

243. See Sharkey, *Preemption by Preamble*, *supra* note 11, at 256–57.

244. See, e.g., *Kellogg v. Wyeth*, No. 2:07-cv-82, 2008 WL 5272715, at *10 (D. Vt. Dec. 10, 2008) (finding that procedural defects indicate that the FDA's position was not "promulgated in the exercise of [agency] authority" (quoting *Gonzales v. Oregon*, 546 U.S. 243, 256 (2006))); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 275 (E.D.N.Y. 2007) ("The FDA cannot be allowed to usher in such a sweeping change in substantive law through the back door."); *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 968 & n.3 (D. Neb. 2006) ("The FDA failed to comply with its requirements [under Executive Order 13,132] to communicate with the states and to allow the states an opportunity to participate in the proceedings prior to a preemption decision."); *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 (JBS), 2006 WL 2819046, at *9 (D.N.J. Sept. 29, 2006) ("[T]he 2006 [FDA Drug Labeling] Preamble was a novation, not subjected to prior public notice or comment . . ."), *rev'd sub nom.* *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), *cert. granted, vacated, and remanded*, 129 S. Ct. 1578 (2009) (mem.). *But see* *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 315 n.27 (E.D. Pa. 2007) (rejecting the court's reasoning in *Jackson v. Pfizer, Inc.*); *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.")

245. Sharkey, *Products Liability Preemption*, *supra* note 6, at 498.

State Farm framework of hard look review in the context of court preemption decisions.²⁴⁶ Courts are well poised to police agencies' flouting of their responsibilities in the domains of regulatory review and interpretation.

Wyeth v. Levine implicitly endorses the "agency reference model" with the corresponding heightened judicial scrutiny that I have propounded. What is perhaps most striking about the decision is the fact that the majority *and* dissent embrace at least one dimension of the agency reference model: namely an examination of the contemporaneous agency record to determine precisely the risks weighed by the FDA.²⁴⁷ Implied preemption rests on the critical significance of agency attention to the question of dangers posed by the particular administration of the drug at issue in *Wyeth*.²⁴⁸

246. *But see* Mendelson, *supra* note 191, at 2164 n.42 (suggesting that the *Nova Scotia* "obligation to respond to 'significant comments' that courts have imposed as a gloss on Section 553 of the APA" would not seem to extend outside of the rulemaking context proper).

247. The majority relies upon the trial court's finding that "the agency had paid no more than passing attention to the question whether to warn against IV-push administration of Phenergan." *Wyeth v. Levine*, 129 S. Ct. 1187, 1193 (2009); *see also id.* at 1199 ("[T]he trial court found 'no evidence in this record that either the FDA or the manufacturer gave more than passing attention to the issue of' IV-push versus IV-drip administration." (quoting the appendix)). The majority in no way distances itself from similar agency reliance in *Geier*, indeed, the majority contrasts the situation in *Wyeth* with that in *Geier*, where the "contemporaneous record . . . revealed the factors the agency had weighed and the balance it had struck." *Id.* at 1203.

The dissent responds that "[t]he FDA has long known about the risks associated with IV push in general and its use to administer Phenergan in particular." *Id.* at 1218 (Alito, J., dissenting). The majority, however, accuses the dissent of creative parsing and reconstruction of the record to "suggest greater agency attention to the question" *Id.* at 1199 n.6 (majority opinion).

The majority concedes that the agency record is incomplete, commenting upon the "sparse correspondence between *Wyeth* and the FDA about Phenergan's labeling," *id.* at 1192, and the "limited" record regarding any newly acquired information in *Wyeth's* hands, *id.* at 1197 ("The record is limited concerning what newly required information *Wyeth* had or should have had about the risks of IV-push administration of Phenergan . . ."). Furthermore, *Wyeth* has the "burden in establishing a pre-emption defense" *Id.* at 1196.

248. *Wyeth* makes clear that "[i]mpossibility pre-emption is a demanding defense" and "the mere fact that the FDA approved [the drug's] label does not establish" impossibility preemption. *Id.* at 1199. It provides far less constructive guidance on what would suffice. At times, the Court seems to suggest nothing short of an explicit rejection by the FDA of a proposed warning would do. *See id.* at 1198 ("[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for *Wyeth* to comply with both federal and state requirements."); *id.* at 1203 n.14 ("[T]he FDA did not consider and reject a stronger warning against IV-push injection of Phenergan"). But, in other places, the Court proposes a lesser burden of coming forward with relevant information regarding the risks. *See id.* at 1199 ("*Wyeth* does not argue that it supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method.").

Turning from the agency's regulatory record to its interpretive sphere, the Court by no means suggests that the agency's view is irrelevant. To the contrary, the majority not only concedes that "some state-law claims might well frustrate the achievement of congressional objectives," but also embraces *Geier*, as a case in which (as the dissent points out, with more than a twinge of irony):

[n]otwithstanding the [National Traffic and Motor Safety Vehicle Act's] saving clause, and notwithstanding the fact that Congress gave the Secretary authority to set only 'minimum' safety standards, we held *Geier*'s state tort suit pre-empted. In reaching that result, we relied heavily on the view of the Secretary of Transportation . . . expressed in an amicus brief²⁴⁹

The majority's embrace is more tepid,²⁵⁰ but the point remains that the Court is willing to accord *Skidmore*, or "power to persuade"

Defining a necessary and sufficient agency record to establish impossibility preemption will dominate the next wave of litigation. In *Colacicco*, the Third Circuit Court of Appeals preempted state-law failure to warn claims against the manufacturer of selective serotonin reuptake inhibitors, or SSRI, drugs, finding that "a state-law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA's oft-repeated conclusion that the evidence did not support such an association." *Colacicco v. Apotex Inc.*, 521 F.3d 253, 271 (3d Cir. 2008). The court accorded the FDA's position *Skidmore* deference, finding it persuasive on account of the consistency, care, formality, and relative expertise of the agency. *Id.* at 275. The United States argued before the Third Circuit that it is not the preamble that preempts plaintiffs' claims, but rather the FDA's repeated findings that there was insufficient scientific evidence of an association between adult use of antidepressants and suicidality to permit a warning on the labeling for those drugs. Brief of the United States as Amicus Curiae in Support of Defendants-Appellants at 28–29, *Colacicco*, 521 F.3d 253 (No. 08-437), 2006 WL 5691532.

The U.S. Supreme Court vacated and remanded *Colacicco* in light of *Wyeth*. *Colacicco v. Apotex, Inc.*, 129 S. Ct. 1578 (2009) (mem.). The Third Circuit then remanded the consolidated cases back to their respective district courts. The U.S. has since rescinded its amicus brief in support of defendants-appellees, stating that "[t]he [FDA] has not yet conducted the sort of reexamination of various preemption issues following the Supreme Court's decision in *Wyeth* that would be necessary to inform a position of the United States in this case." Letter from Sharon Swingle, U.S. Dep't of Justice, Civil Div., Appellate Staff, to Marcia M. Waldron, Clerk, U.S. Court of Appeals for the Third Circuit (Apr. 28, 2009). Consistent with my argument here, the FDA's regulatory record with respect to SSRI drugs should be front and center. For a review of the FDA regulatory record with respect to SSRI drugs—including findings from internal scientific reviews and several advisory committees convened to study the matter as well as denials of numerous citizen petitions seeking review, see Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. 1, 27–30 (2006).

249. *Wyeth*, 129 S. Ct. at 1221 (Alito, J., dissenting).

250. *Id.* at 1201 (majority opinion) ("In prior cases, we have given 'some weight' to an agency's views about the impact of tort law on federal objectives when 'the subject matter is technical[] and the relevant history and background are complex and extensive.'" (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000))).

deference, to the position espoused by the agency.²⁵¹ The FDA's preemption preamble miserably fails this standard—the Court was unpersuaded by what the agency “said” when it seemed contrary to what it “did.” Put differently, deficits in the agency regulatory record cannot be overcome by embellishment by the agency in the interpretive sphere.²⁵²

a. Agency Record. Building upon the agency reference model, here I give a concrete example of precisely how a court might scrutinize the agency record in making its preemption determination. Recall the FDA's 2008 CBE (changes being effected) drug regulation that governs when manufacturers can unilaterally change their labels in response to new risk evidence.²⁵³ During the notice-and-comment period, members of Congress (including Senator Edward Kennedy) challenged the proposed CBE rule on empirical grounds. The group requested data on the number of CBE supplements submitted to the FDA since 1982, as well as examples of any cases where a CBE supplement was used to the detriment of the public health.²⁵⁴ In a similar vein, the Consumers Union charged that the FDA had presented no evidence that overwarning presents a problem to public health.²⁵⁵

The FDA responded in writing to Senator Kennedy and his colleagues. Its response, however, hardly instills confidence in its claims regarding the impending dangers of overwarning: of more than 3000 CBEs,²⁵⁶ the FDA noted four relevant examples in which the

251. *Id.* (“The weight we accord the agency’s explanation of state law’s impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness.” (comparing *United States v. Mead Corp.*, 533 U.S. 218, 234–35 (2001) and *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))).

252. *Id.* at 1203 (“[T]he ‘complex and extensive’ regulatory history and background relevant to this case undercut the FDA’s recent pronouncements of pre-emption, as they reveal the longstanding co-existence of state and federal law and the FDA’s traditional recognition of state-law remedies—a recognition in place each time the agency reviewed Wyeth’s Phenergan label.” (citation omitted)).

253. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814); *see also supra* Part I.A.2.

254. Waxman Letter, *supra* note 30, at 4.

255. Letter from Consumers Union to Div. of Dockets Mgmt., FDA 6 (Mar. 17, 2008), available at <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=09000064803fb60f>.

256. The FDA reports 2711, 550, and 789 CBEs for drugs, biologics, and medical devices, respectively. Letter from Stephen R. Mason, Acting Assistant Comm’r for Legislation, FDA to Hon. Edward M. Kennedy, Chairman, Comm. on Health, Educ., Labor, & Pensions, U.S.

FDA rejected manufacturers' CBE supplemental applications—none of which offered evidence of threatened harm to the public.²⁵⁷ Under my proposed model, the empirical backing for the FDA's position would be scrutinized by a court, and, in turn, the FDA's position would likely fail under hard look review.

Consider, too, drug manufacturer Johnson & Johnson's request that the agency "reaffirm its practice to provide a full and complete written response to all CBE supplements... [t]o enhance transparency and accountability in the safety labeling process."²⁵⁸ Johnson & Johnson urged the FDA to "provide a comprehensive, written response to the sponsor describing FDA's grounds for approval, disapproval, or request for modifications to the CBE supplement."²⁵⁹ The FDA declined to do so, and issued a quick dismissal without elaboration.²⁶⁰

The framework I have proposed would, in fact, require the FDA to provide such comprehensive, written responses that would become part of the official agency record reviewable by courts making preemption determinations.²⁶¹ To preserve their ability to mount a preemption defense, drug manufacturers, and other interested parties, should be able to challenge such refusals by the agency to create the necessary agency record.

Senate 2–3 (Mar. 7, 2008), available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064804019ec&disposition=attachment&contentType=pdf>.

257. See *id.* at 4. A 2008 report by Representative Waxman, moreover, suggests that FDA career officials raised this same objection internally. MAJORITY STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 110TH CONG., FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES 14 (2008) [hereinafter MAJORITY STAFF REPORT ON PREEMPTION], available at <http://oversight.house.gov/documents/20081029102934.pdf> ("The rule is not, as it purports to be, consistent with the agency's role in protecting the public health. We have not experienced problems with sponsors' use of CBE supplements to over warn, and this rule tips the balance against early warnings by using vague and confusing terms such as 'causal association' and 'reasonable time' that will be difficult for staff and sponsors to apply." (quoting Email from Jane Axelrad to Dr. John Jenkins et al. (June 17, 2008))).

258. Letter from Kathy Schroeder, Assoc. General Counsel, Johnson & Johnson, to Div. of Dockets Mgmt., FDA, at 1 (Mar. 13, 2008), available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064803fbc40&disposition=attachment&contentType=pdf>.

259. *Id.* at 4.

260. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,607 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814) ("FDA disagrees with this comment [from Johnson & Johnson]. The comment failed to provide a compelling justification for this proposal.").

261. See Sharkey, *Products Liability Preemption*, *supra* note 6, at 491–502; Sharkey, *What Riegel Portends*, *supra* note 121, at 446–50.

b. Change of Agency Position. The judicial review component of the agency reference model is useful for another reason: it will cabin political forces and stave off the prospect of agency political flip-flop.²⁶² Lurking just beneath the surface of the *Wyeth* majority opinion is deep suspicion that the FDA changed its position on preemption for political as opposed to scientific or risk management reasons.²⁶³

Scholars have argued that the perception of the politicization of federal agencies has decreased the level of deference that an agency receives from courts.²⁶⁴ Prior to *Wyeth*, lower courts cited the FDA's inconsistency as reason to grant the agency's position lesser deference.²⁶⁵ But *Wyeth* put the last nail in the coffin. Defendant manufacturer Wyeth's implied obstacle preemption argument was,

262. Jody Freeman and Adrian Vermeule have called "expertise-forcing" the attempt by courts to ensure that agencies exercise expert judgment free from outside political pressures from the White House or political appointees in agencies. Freeman & Vermeule, *supra* note 242, at 52 ("[T]he Court majority[] increasing[ly] worries about the politicization of administrative expertise . . ."); see also David J. Barron, *From Takeover to Merger: Reforming Administrative Law in an Age of Agency Politicization*, 76 GEO. WASH. L. REV. 1095, 1148 (2008) (arguing that judicial review should be "expertise forcing" to "preclude federal agencies from preempting state and local regulators without first demonstrating to the courts that such preemption decisions are not themselves strongly influenced by political considerations.").

263. See MAJORITY STAFF REPORT ON PREEMPTION, *supra* note 257, at 14–15 (noting that officials in the White House and political appointees in the FDA threatened to block the Physician Labeling Rule unless the preemption changes were included); AM. ASS'N FOR JUSTICE, GET OUT OF JAIL FREE: HOW THE BUSH ADMINISTRATION HELPS CORPORATIONS ESCAPE ACCOUNTABILITY 7–15 (2008), available at http://www.justice.org/resources/Preemption_Rpt.pdf (summarizing findings from Freedom of Information Act requests that allegedly show a concerted effort during the Bush II administration, in part organized by the Office of Management and Budget, to preempt state laws through agency action without consultation with the states); see also James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 969 (2008) ("The FDA's [preemption preamble] was the culmination of the Bush Administration's lobbying effort."); David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 991 (2008) ("[T]he Agency effected its dramatic change in position on preemption for political reasons, as opposed to scientific or public policy concerns.").

264. See O'Reilly, *supra* note 263. In a different context, Freeman and Vermeule have situated *Massachusetts v. EPA* as "part of a trend in which the Court has at least temporarily become disenchanted with executive power and the idea of political accountability, and is now concerned to protect administrative expertise from political intrusion." Freeman & Vermeule, *supra* note 242, at 54.

265. *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007); *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 968 & n.3 (D. Neb. 2006); see also *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 (JBS), 2006 WL 2819046, at *9 (D.N.J. Sept. 29, 2006) (finding that the FDA preamble constitutes an "unexplained change in position"), *rev'd sub nom.* *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), *cert. granted, vacated, and remanded*, 129 S. Ct. 1578 (2009) (mem.).

according to the majority, “[l]argely based on the FDA’s *new position*”²⁶⁶—built upon the edifice of the agency’s 2006 preemption preamble, which represented “a dramatic change in position.”²⁶⁷ The majority did not mince words in expressing its disdain for the FDA’s “newfound opinion,”²⁶⁸ finding it “entitled to no weight.”²⁶⁹

This is not to say that agencies should never change their mind or switch their positions. Nor is it realistic to think that such decisions can (or should) be altogether divorced from politics. In fact, agencies, as arms of the executive branch, are supposed to reflect the political aims and policies of the President. What courts must scrutinize, instead, is ideologically-driven changes in position—especially those that are at odds with the nature and content of the agency regulatory record, and the scientific or other data of which that record is comprised.²⁷⁰ In this respect, the *Wyeth* majority gets to the heart of the issue when it complains that the FDA’s preemption preamble “reverses the FDA’s own longstanding position *without providing a reasoned explanation*, including any discussion of how state law has interfered with the FDA’s regulation of drug labeling during decades of coexistence.”²⁷¹ *Skidmore* deference provides courts with an appropriate tool to scrutinize the “reasoned explanations” provided by agencies.

CONCLUSION

A surge in federal agency regulatory preemption coupled with some egregious examples of agency disregard of state regulatory interests during the Bush II administration has shaped the debate on

266. *Wyeth v. Levine*, 129 S. Ct. 1187, 1203 (2009) (emphasis added).

267. *Id.*

268. *Id.*

269. *Id.* at 1204.

270. The majority opinion calls the U.S. amicus brief “undeserving of deference” given that “[t]he Government’s explanation of federal drug regulation departs markedly from the FDA’s understanding at all times relevant to this case.” *Id.* at 1203 n.13.

271. *Id.* at 1201 (emphasis added); *see also id.* at 1202 (“[T]he FDA traditionally regarded state law as a complementary form of drug regulation.”). There is evidence of a prior antipreemption position: in 1998, the FDA stated that it was “establishing ‘minimal standards’ for drug labels [and] did not intend ‘to preclude the states from imposing additional labeling requirements.’” *Id.* at 1202 & n. 10 (quoting 63 Fed. Reg. at 66,384) (citing 44 Fed. Reg. 37,437 (1979); 59 Fed. Reg. 3948 (1994)).

The dissent, by contrast, interprets the FDA’s change in position as a natural and expected shift away from a “decade-old and now-repudiated” statement. *Id.* at 1229 (Alito, J., dissenting).

the proper institutional role for federal agencies in determining the boundaries of federal law and the outcome of clashes with state law. One might conclude that the skepticism (bordering on hostility) with which judges and scholars assail agency input on these key federalism matters is ephemeral—shifts in the political winds leading to oscillation by agencies in the extent to which they assert federal power.

That said, it is worth considering whether a power shift has, in fact, taken place—a shift that will be seen to transcend a switch in political administrations.²⁷² My own view is that Congress has ceded significant ground to federal agencies. Changes in administration might, nonetheless, create more or less amenable climates for reforming the agency decisionmaking process along the lines that I have suggested.

In this Article I advance two basic normative claims—albeit against a backdrop that seems to be in considerable tension with achieving them. First, agency disregard of states' interests is by no means inevitable. Second, and more fundamentally, Congress, the executive, and, most significantly, the courts can ensure that these state regulatory interests are no longer ignored, by implementing agency-forcing measures that will steer agencies toward a more responsive, and responsible, course.

272. Cf. Kagan, *supra* note 117, at 2248 (demonstrating the continuation of an expanded federal power from the Reagan and Bush years into the Clinton administration, albeit for different political ends).