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WHO DECIDES WHO DECIDES: FEDERAL REGULATORY PREEMPTION OF STATE TORT LAW

*MARK SEIDENFELD**

INTRODUCTION

In this paper, I contend that there is no universal answer to whether common law courts provide a valuable function as a backstop to agency regulation for setting standards of care within an industry, with which a provider of goods or services must comply.¹ Rather, the potential benefits of having courts as a backstop will depend on particular characteristics of the market in which a producer operates. These include, among other things, efficiencies of uniformity of production, the risks of uncertainty facing the producer about the standard of care, the information reasonably available prior to the producer's commitment to market a product, and the likely reaction of consumers to knowledge about the product if they are fully informed of its risks.

Given this premise about the value of tort law as a regulatory backstop, the crucial question becomes: Which institution is best suited to decide, in the context of a particular regulatory action, whether tort suits are preempted? Here the choice is not only between agency and court, but also Congress, which can, if it chooses, preclude state tort suits with respect to virtually any mass tort. My thesis is that agencies are the preferable institution for deciding whether state tort law should be preempted by regulation and that

* Patricia A. Dore Professor of Administrative Law, Florida State University College of Law. Thanks to the Florida State University Foundation for supporting this research. Thanks also to Cathy Sharkey for inviting me to the symposium, which motivated me to write this Article; the other participants at the symposium for a great discussion that informed the final version; the faculty at the University of Richmond Law School for feedback on a presentation of this Article; Beth Burch and Brian Galle for insightful comments; and Jesse Unruh for assistance with research for this Article.

1. This paper limits its consideration to regulation of consumer goods and services which can threaten health and safety, which are the kinds of commercial activity that generate the mass tort actions that have garnered the attention of the public, regulators and scholars alike.

therefore courts should recognize agencies' authority to preempt state law under general rulemaking authority granted by Congress.²

At the outset, I need to clarify the scope of this thesis. I do not address directly the question that has arisen of late in tort preemption cases—the role of agencies in determining whether a statute itself preempts common law tort suits either directly or by occupying the regulatory field. Others have thoughtfully written on this question, addressing whether agency input is appropriate and, if so, how best to structure that input in the context of interpreting potentially preempting statutes.³ Instead, this paper addresses the issue of agency preemption in the absence of statutory instruction.⁴

My proposal may seem radical because it unmoors preemption from any reliance, whether actual or imagined, on a congressional decision on this issue. Those who value federalism for its own sake might therefore find my proposal disconcerting as it facilitates preemption by circumventing the checks of the legislative process.⁵ Of

2. I am not alone in having reached this conclusion. Cathy Sharkey recently advocated a similar switch in focus from Congress to agencies for preemption decisions. See Catherine Sharkey, *Federalism Accountability: "Agency-Forcing" Measures*, 58 DUKE L.J. 2125, 2129 (2009) [hereinafter Sharkey, *Federalism Accountability*]. See generally William W. Buzbee, *Preemption Hard Look Review: Regulatory Interaction, and the Quest for Stewardship and Intergenerational Equity*, 77 GEO. WASH. L. REV. 1521 (2009) (accepting that agencies can preempt state law but arguing that such action should be subject to hard look review).

3. See generally Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004). See also Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 491–502 (2008) [hereinafter Sharkey, *Products Liability Preemption*]; Thomas Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 769–79 (2008) [hereinafter Merrill, *Preemption*]; cf. Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 DUKE L.J. 2023, 2069–72 (2008) (discussing the role of ordinary doctrines of administrative law as a means of implementing federalism concerns in preemption cases).

4. My conclusion that agencies should have primary responsibility for deciding when tort suits are preempted does bear on the question of whether a statute calls for preemption. In order to preserve room for the agency to exercise this responsibility, I conclude that courts should not interpret statutes definitively either to preempt or to save tort suits except when the statute so provides explicitly and clearly. See discussion *infra* Section IIIA.

5. See William N. Eskridge, *Vetogates, Chevron, Preemption*, 83 NOTRE DAME L. REV. 1441, 1470 (2007) (opining that because agency rulemaking circumvents the vetogates involved in the legislative process, "the Court should require a targeted (preemption-specific) statement from Congress when it is delegating preemptive authority to an agency"); Merrill, *Preemption*, *supra* note 3, at 750–51 (2008). Those concerned with circumvention of the limits on preemption often call for "presumptions against preemption" or "clear statement rules." See Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1425 (2001); Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the*

course, courts ultimately rejected that concern with respect to rulemaking in general, allowing broad delegations by Congress.⁶ If one values federalism instrumentally, rather than as an end in itself, the same arguments for allowing the regulatory process to be more flexible than the legislative process also support allowing such flexibility for preemption decisions.⁷ Even unabashed federalists might take heart, however, because my proposal reduces the pressure on courts to find statutory preemption on the slimmest of interpretive reeds⁸ and imposes significant procedural and substantive burdens before an agency could preempt tort law. The hope is that this proposal will encourage wiser preemption, not simply more preemption.

I. COMPARATIVE ADVANTAGES OF PREEMPTIVE REGULATION

Agencies can act in a variety of ways to establish regulation. If authorized by Congress they can adopt rules that govern industry

National Legislative Process, 82 N.Y.U. L. REV. 1, 17, 32–39 (2007); Earnest A. Young, *Federal Preemption and State Autonomy*, in *FEDERAL PREEMPTION: STATE'S POWERS, NATIONAL INTERESTS* 249, 254 267–68 (Richard A. Epstein & Michael S. Greve eds., 2007). Such doctrines are examples of “resistance norms”—rules that discourage particular government action by raising the cost of that action. See Ernest A. Young, *Constitutional Avoidance, Resistance Norms, and the Preservation of Judicial Review*, 78 TEX. L. REV. 1549, 1585 (2000).

6. See Heidi Kitrosser, *The Accountable Executive*, 93 MINN. L. REV. 1741, 1756 (2009) (stating that “the Court has come to accept broad policymaking delegations from Congress to the administrative state”).

7. For some, like Brad Clark and Cass Sunstein, the non-delegation doctrine remains vital in theory, foundering only in the lack of administrability of a distinction between enacting and executing the law. See Clark, *supra* note 5, at 1374; Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 338 (2000). For them, the canon requiring a statutory clear statement of intent to preempt state law would reflect a limit on Congress’s authority to delegate preemption power to agencies. Hence, presumably they would find my proposal unconstitutional. For those who take the more usual view that Congress can delegate legislative functions to agencies as long as it does so with sufficient safeguards, duly adopted regulations are laws enacted pursuant to the Constitution and hence can preempt state law under the Supremacy Clause.

8. See Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437, 438–41 (2009) [hereinafter Sharkey, *What Riegel Portends*] (criticizing the Supreme Court Justices’ approaches to interpreting preemption provisions as removed from analysis of statutory text, and perhaps outcome driven).

conduct.⁹ Some agencies are also charged with the responsibility to approve products before they come on the market.¹⁰ Approval is often based on imprecise standards set by statute or regulation, with the agency filling gaps in the standards on a case-by-case basis¹¹ or by interpretive rule or policy statement.¹² At times agencies regulate ex post by monitoring industry conduct and ordering a regulated entity to cease and desist from conduct that the agency determines to be contrary to statutory or regulatory standards.¹³ Regardless of how an agency sets initial standards, it usually has significant enforcement discretion that allows it to refrain from penalizing an entity that has transgressed an agency standard. To the extent enforcement discretion is exercised in accordance with predictable criteria, it modifies any regulatory standard because those criteria define the conduct that will trigger a regulatory response.¹⁴

Tort suits, like agency regulatory action, come in a variety of forms and can develop in a variety of manners. Some suits result from isolated events that cause the conduct of one person to harm

9. See 1 RICHARD J. PIERCE, JR., *ADMINISTRATIVE LAW TREATISE* § 6.2, at 306 (4th ed. 2002).

10. The FDA (Food and Drug Administration) has recently been highlighted as an agency with such authority in several recent Supreme Court preemption decisions. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 87 (2d Cir. 2006), *aff'd per curiam* *Warner-Lambert & Co. v. Kent*, 552 U.S. 440 (2008) (evenly divided court); *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009); see also *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. §§ 301–99 (2006).

11. See *SEC v. Chenery*, 332 U.S. 194, 201–03 (1947) (approving SEC authority to establish policy by adjudication as well as rulemaking).

12. See Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 *ADMIN. L. REV.* 803, 808 (2001) [hereinafter Strauss, *Publication Rules*]. The extent to which interpretive rules and statements of policy have “legal effect” is controversial, although it is clear that they do not have the same binding force of law of legislative rules. See Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like—Should Federal Agencies Use Them to Bind the Public?*, 41 *DUKE L.J.* 1311, 1315 (1992).

13. See, e.g., 15 U.S.C. § 45(b) (2006) (authorizing the Federal Trade Commission to order a company to cease and desist from unfair trade practices).

14. See Jeannette L. Austin, Comment, *The Rise of Citizen-Suit Enforcement in Environmental Law: Reconciling Private and Public Attorneys General*, 81 *NW. U. L. REV.* 220, 234–35 (1987) (articulating a sophisticated view of administrative law in which “[e]nforcement efforts . . . are an integral part of the policymaking process”); cf. Matthew C. Stephenson, *Public Regulation Of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 *VA. L. REV.* 93, 116 (2005) (noting that agencies often adopt overly broad regulations and use enforcement discretion to tailor them to optimize the social goals of the agency’s regulatory program).

another in a manner that is unique to their precise interaction;¹⁵ others may involve isolated incidents that injure numerous people.¹⁶ Of late, tort suits that have generated the most controversy about preemptive regulation have been products liability cases—based on injuries, either realized or latent, caused by the use of a product which may be a good or a service.¹⁷ Injuries in such cases are traceable to similar causes and threaten similar potential injuries to each victim.¹⁸

Along another dimension, tort suits can go to trial where a jury ultimately may decide whether the injurers' conduct was unreasonable, thereby establishing the standard of care to the extent the case provides controlling or persuasive precedent.¹⁹ Alternatively, suits can settle, in which case the attorneys play a more significant role in determining what conduct is reasonable and the cost the defendant bears for its actions.²⁰ To be sure, the strength of the attorneys' positions will depend on their predictions of how a jury is

15. These correspond to typical tort suits, like automobile accidents. See Byron G. Stier, *Resolving the Class Action Crisis: Mass Tort Litigation as Network*, 2005 UTAH L. REV. 863, 932–33 (distinguishing the typical tort involving an automobile accident from mass tort cases).

16. See, e.g., *Arce v. Burrow*, 958 S.W.2d 239, 243 (Tex. App. 1997) (stating that the case involved a plant explosion killing 23 people and injuring hundreds), *aff'd in part, rev'd in part*, *Burrow v. Arce*, 997 S.W.2d 229 (Tex. 1999) (remanded to trial court for determination of the existence of damages).

17. The Supreme Court has decided ten products liability preemption cases since 1992: *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Warner-Lambert & Co. v. Kent*, 552 U.S. 440 (2008); *Bates v. Dow Agrosciences LLC.*, 544 U.S. 431 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

18. For a description of the various types of mass tort suits, see L. Elizabeth Chamblee, *Unsettling Efficiency: When Non-Class Aggregation of Mass Torts Creates Second-Class Settlements*, 65 LA. L. REV. 157, 164–70 (2004).

19. Cf. W. Kip Viscusi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1467–68 (“Application of broad liability rules and the application of 20-20 hindsight often places juries in the position of second guessing the FDA on the types of warnings that should be provided with prescription drug products and which products should be marketed.”).

20. See RICHARD A. NAGAREDA, *MASS TORTS IN A WORLD OF SETTLEMENT* 219–33 (2007) (describing how lawyers use the pathologies of settlement in class actions strategically, and how that influences the resulting settlements); Guy Halfteck, *Legislative Threats*, 61 STAN L. REV. 629, 643–45, nn.56–57 (2008) (describing the traditional view of litigation as regulation, which the author ultimately questions).

likely to come out were the case to proceed to trial.²¹ In that sense, the attorneys' determination of reasonableness should track those that would have been made by juries. But there are a host of other factors such as the cost of litigation facing each side, technical questions of procedure, and predictions about the extent of liability and how the remedy will be allocated among plaintiffs, all of which bear on the ultimate settlement of the matter.²²

Judges also can considerably influence whether a product liability suit succeeds or fails, or more significantly in the context of aggregated claims, whether it settles and on what terms.²³ Judges rule on outcome-determinative motions such as those for dismissal for failure to state a claim or summary judgment. These rulings allow them direct input into determining the standard of care for the defendant in a particular context. Judges also decide whether to certify a class, which greatly affects the potential liability threat faced by the defendant and thereby influences the likelihood that the defendant will settle.²⁴

Also, the choice between agencies and courts arises in the context where an agency has already acted, thereby setting some default standard of care. The question then is whether to allow courts to assess the reasonableness of industry conduct that has been approved by, or has complied with, the standards set by the relevant agency. When evaluating the institutional competence of the tort system, I therefore assume that the courts will have the information generated by the prior regulatory action.²⁵ Regulators, however, may or may not have information generated by tort suits depending on whether such suits have been preempted, or whether the cases have settled under agreements that restrict access to information. Aside from these assumptions, it is important to understand that

21. See NAGAREDA, *supra* note 20, at 14–15 (noting that for a mass tort to develop to a stage where defendants are apt to settle requires that plaintiffs' attorneys have a credible threat to prevail in individual cases).

22. See Roger C. Crampton, *Individualized Justice, Mass Torts, and "Settlement Class Actions": An Introduction*, 80 CORNELL L. REV. 811, 822 (1995).

23. See NAGAREDA, *supra* note 20, at 7 (stating that the prospect of settlement turns judges "from neutral umpires at trial to 'managerial' figures who oversee deals and administer their implementation over time").

24. See Robert G. Bone, *Securing the Normative Foundations of Litigation Reform*, 86 B.U. L. REV. 1155, 1169 (2006).

25. This may not be true if the information within the agency is deemed a trade secret or otherwise within an exception to the Freedom of Information Act. See Gardiner Harris, *Drug Agency May Reveal More Data on Actions*, N.Y. TIMES, June 2, 2009, at A10 (reporting on establishment of a task force to address FDA policy of withholding drug safety information that drug manufacturers claim to be trade secrets).

regulations always provide a floor for the standard of care. Allowing tort suits leaves the ultimate regulatory standard to the common law process only for conduct above the regulatory floor.²⁶

There are numerous potential benefits to authorizing agencies to preempt by regulation. As described below, they include: institutional advantages of agencies in setting an efficient level of care; reduction in uncertainty that could otherwise discourage production of useful products; national uniformity, which can reduce overall costs of production; prevention of states from cost exporting; and transparency and political accountability.

A. *Setting the Standard of Care*

Regardless of the precise criteria one advocates for setting the standard of care applicable to producers of goods and services, the incremental costs and benefits will have a bearing on the optimal level of care. Under either a negligence or regulatory standard that results in violators bearing significant costs, the standard of care provides a strong economic signal of the level of care for a producer. If that standard is set at a point other than where the marginal cost of care equals the marginal benefit from care—however society chooses to evaluate those costs and benefits—then producers will face a strong economic incentive to invest in an inefficient amount of care.²⁷ Under a strict liability system, the producer internalizes both the costs and benefits of care. Therefore, the incentive it faces to invest in care will depend on the marginal cost versus the liability that will be created by limiting care. As such, the manufacturer's level of diligence will depend on the regulator's or jury's assessment of the compensable costs of accidents.²⁸ There are reasons to expect that agencies will provide more accurate signals to manufacturers about their optimal level of care. Agency staff members come from professions that are often trained in matters relating to the industry they regulate.²⁹ Juries, however, are not only untrained but subject to biases that tend to overinflate the costs of accidents and understate the costs of care.³⁰

26. Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and Its Limits*, in *FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS* 309, 311 (Richard A. Epstein & Michael S. Greve, eds., 2007).

27. A negligence standard, however, will be fairly insensitive to the accuracy of the assessment of damages. See ROBERT COOTER & THOMAS ULEN, *LAW & ECONOMICS* 353–56 (5th ed. 2008); Josh Teitelbaum, *A Unilateral Accident Model under Ambiguity*, 36 J. LEG. STUD. 431, 459–60 (2007).

28. See COOTER & ULEN, *supra* note 27, at 338–41.

29. See B. GUY PETERS, *THE POLITICS OF BUREAUCRACY* 96 (4th ed. 1995).

30. See *infra* notes 35–39 and accompanying text.

Agency staff members have knowledge and experience that make them superior to juries in evaluating the harms likely to be caused by provision of a product or service and the costs of forcing entities to meet a particular level of care. Agencies employ professionals specialized in predicting the effects of products, or byproducts of their use, at various points along the chain of causation. These employees have no direct stake in the ultimate standard of care that is adopted by rule.³¹ Moreover, they are capable of learning about a problem and reaching fairly accurate conclusions about costs and benefits relatively quickly.³² The tort system, in contrast, uses an adversarial process that has been criticized for allowing hired guns to confuse even fairly accepted issues of scientific fact.³³ Moreover, the tort system often sets the standard of care by looking at how those other than the defendant have acted in similar situations, which sets up a feedback loop that can induce the establishment of non-optimal standards.³⁴

In addition, juries have been accused of caprice and bias in placing dollar values on life and health.³⁵ In part, this may stem

31. See Mark Seidenfeld, *Why Agencies Act: A Reassessment of the Ossification Critique of Judicial Review*, 70 OHIO ST. L.J. 251, 268–81 (2009) [hereinafter Seidenfeld, *Why Agencies Act*].

32. See Peter H. Schuck, *Some Reflections on the Future of Mass Torts*, 12 CONN. INS. L.J. 505, 511–12 (2006).

33. See, e.g., JOSEPH SANDERS, *BENEDICTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION* 110–15, 195–97 (1998); Susan Haack, *What's Wrong with Litigation-Driven Science? An Essay in Legal Epistemology*, 38 SETON HALL L. REV. 1053, 1054 (2008); cf. E. Donald Elliott, *Toward Incentive Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. REV. 487, 489 (1989) (describing how clinical ecologists' testimony about causation of harm from exposure to minute quantities of a wide range of chemicals has unduly influenced toxic tort litigation).

34. See James Gibson, *Doctrinal Feedback and (Un)Reasonable Care*, 94 VA. L. REV. 1641, 1653 (2008) (stating that “a legal standard that defers to custom can create systemic departures from efficient behavior and then allow those departures to infect custom”).

35. See Mark Geistfeld, *Constitutional Tort Reform*, 38 LOY. L.A. L. REV. 1093, 1106–07 (2005) (reporting that jury awards of pain and suffering are aptly criticized as “subjective, unpredictable and substantial”); Lars Noah, *Comfortably Numb: Medicalizing (and Mitigating) Pain-And-Suffering Damages*, 42 U. MICH. J. L. REFORM 431, 442–44 (2009). *But cf.* Deborah R. Hensler, *Jurors in the Material World: Putting Tort Verdicts in Their Social Context*, 13 ROGER WILLIAMS U. L. REV. 8, 27–28 (2008) (noting that jury awards for physical injuries in products liability cases are not particularly large compared to salaries of corporate executives). Without opining on the propriety of huge compensation packages for corporate executives, the victims of products liability most certainly would not have generated increases in social wealth anywhere near the dollar values reported in Professor Hensler's survey of jury awards in product liability cases.

from an offer-asking price conundrum.³⁶ The tort system generally seeks to compensate the victim to the extent that he is indifferent between receiving damages and not having been injured by the defendant's conduct.³⁷ This essentially requires that the plaintiff be awarded damages equal to the amount of money he would require to allow the defendant to injure him.³⁸ But this may be a far greater amount than the actual total wealth the individual would ever generate even if he was never injured. As such, it is as if each healthy individual has a potentially infinite reservoir of value greater than the earnings he will actually create by his labors. Tortious conduct depletes this reservoir and, accordingly, juries require tortfeasors to replenish it.³⁹ But the actual money that is awarded must come from somewhere. This can put a significant strain on society, particularly, on producers of products that create risks of harm and must generate dollars to pay claims. I do not mean to imply that agencies act in an ideal manner when putting an implicit value on safety when setting standards of care.⁴⁰ Analyses of the costs and benefits of regulation have revealed that there is a wide disparity between the implicit value of a life under different regulatory schemes and, under some schemes, these values may be as high as the jury awards that capture the attention of critics of the

36. The offer-asking price is "the amount one would be willing to pay for something given one's existing wealth versus the amount one would be willing to accept to give up something to another." Joseph William Singer, *Normative Methods for Lawyers*, 56 UCLA L. REV. 899, 918 (2009).

37. See Heidi M. Hurd, *Death to Rapists: A Comment on Kennedy v. Louisiana*, 6 OHIO ST. J. CRIM. L. 351, 362 (2008) (stating that in principle, tort law fixes damages at the point where the plaintiff would have been indifferent "between the harm done to her and a given cash payment").

38. See Jennifer Arlen, Note, *An Economic Analysis of Tort Damages for Wrongful Death*, 60 N.Y.U. L. REV. 1113, 1119–20, 1124 (1985) (noting the problems caused by the asking-offer price differential in wrongful death cases).

39. The reservoir idea is similar to the quantum theory concept of the electron which finds that a vacuum is comprised of an infinite number of electrons filling energy states up to a certain level that characterizes the vacuum. When a particle gets excited out of one of these base states, the result is the creation of an electron/positron pair. The theory works well, but essentially requires a renormalization of the energy in the universe to subtract off the energy of the infinite number of particles in the base states. See P.A.M. DIRAC, *THE PRINCIPLES OF QUANTUM MECHANICS* 273–75, 295–96 (4th ed. 1958). The jury when awarding damages essentially never fully subtracts off the virtually infinite wealth each individual enjoys simply by living in a healthy state.

40. See STEPHEN BREYER, *BREAKING THE VICIOUS CYCLE: TOWARD EFFECTIVE RISK REGULATION* 21 (1993) (noting that "agencies use different methods for estimating the effects of their regulations").

tort system.⁴¹ But, at least regulatory programs are not committed to a compensation principle that assumes a level of personal wealth that is inconsistent with the actual ability of individuals to generate wealth.

Another problem that plagues the tort system is the fact that once liability is imposed, the damage award often fails to take into account harms that would occur even if the defendant never put the product or service on the market. For example, suppose a plaintiff is suffering from shock and is prescribed a drug to maintain his blood pressure at a level that reduces his risk of dying from the shock. Suppose further that the manufacturer knows and does not reveal that some individuals overreact to the drug and risk vascular constriction that might threaten some of their extremities. It turns out that the plaintiff is one of those individuals, and the drug causes him to lose the last digit of one of his fingers. He sues, claiming that the drug company was negligent in failing to warn of the potential hazards of the drug. He may win his suit, in which case he would receive damages equal to the amount a jury determines sufficient to compensate him for the loss of his fingertip.⁴² It may well be, however, that without the drug, he would have died, but the tort system does not subtract from its damage award the value the drug provided by increasing the chance of his survival. In contrast, an agency evaluating the costs and benefits of the drug will explicitly consider the value of lives it is expected to save.⁴³

One might counter that the market implicitly takes the value of the drug into account. If there is no equivalent drug without the

41. *See id.* at 22 (reporting that the value that regulators implicitly attach to a statistical life vary from about \$100,000 to \$125 million). *But see* CASS R. SUNSTEIN, *THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION* 77 (2002) (reporting that agencies' explicit valuation of a life, used in CBA's required for major rules varies from \$1.5 to \$6.1 million). The difference between these figures may reflect that agency programs that save lives provide other benefits as well, so that a simple comparison of the cost of the program to lives saved may not represent an agency's valuation of a life saved.

42. Essentially, the problem is the converse of the controversy surrounding the "lost chance" tort doctrine. Under that doctrine, a tortfeasor pays the full cost of injury even though it only increased the probability that the injury would occur. *See* Todd S. Aagaard, Note, *Identifying And Valuing the Injury in Lost Chance Cases*, 96 MICH. L. REV. 1335, 1351 (1998). The problem I identify results from the tortfeasor's conduct being charged with all the harm it causes but not being credited with benefits it bestows.

43. *See* Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 77 (1995) (reporting that the FDA calculated benefits from drugs it evaluated by using a range between \$1.5 to \$3.0 million per life the drug was anticipated to save).

same potential side effects, and the tort system holds the manufacturer liable, then the manufacturer should be able to price the drug to cover the negative costs of the injuries it causes because of the great positive value it provides to its users. But markets do not work perfectly and consumers are not always rational, especially when it comes to actions to which they attribute subsequent harm.⁴⁴ First, consumers usually will not have sufficient information to determine the value of a product that helps prevent injuries or diseases. Second, as I just discussed, damage awards reflect an asking price that is above the price consumers are willing to offer for added safety and may reflect a premium for insurance that consumers do not wish to purchase.⁴⁵ Thus, profits from sales of a product or service may not cover tort liability even if its availability increases social wealth. Third, a manufacturer may decide not to continue producing a product even if it provides net benefits to society because consumers often overreact to fears of potential harm from a product, especially when that harm has been publicized due to a high profile tort suit.⁴⁶ This is of special concern when a tort claim is based on a manufacturer's failure to warn adequately about risks created by a product.⁴⁷ Jurors presented with the facts of a particular case are apt to focus on whether the warning was sufficient to discourage use by a person for whom risk from the product was great. Jurors are unlikely to consider situations not before them, such as when the warning might have discouraged use by a person who would have benefited from the product. Unlike juries, regulators know to

44. See, e.g., Ilana Ritov & Jonathon Baron, *Reluctance to Vaccinate: Omission Bias and Ambiguity*, 3 J. BEHAV. DECISION MAKING 263, 275 (1990) (reporting that parents say they would not vaccinate their children against an imminent epidemic because of a risk that the vaccine might kill their children, even if the risk of death from the vaccine is less than from the disease).

45. Thus, critics of products liability note that such liability essentially forces users of a product to pay for insurance that compensates for pain and suffering and other non-pecuniary harms that people rationally do not insure against. See Robert Cooter, *Towards a Market in Unmatured Tort Claims*, 75 VA. L. REV. 383, 391-92 (1989); George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1547, 1553 (1987).

46. Although peer-reviewed analyses of the morning sickness drug Bendectin found the drug to be effective and no evidence that the drug increases the risk of birth defects, its manufacturer took the drug off the market in response to the outcome of tort suits. See SANDERS, *supra* note 33, at 19-20, 61.

47. See W. KIP VISCUSI & WESLEY A. MAGAT, LEARNING ABOUT RISK: CONSUMER AND WORKER RESPONSES TO HAZARD INFORMATION 96 (1987); Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 ECONOMETRICA 263, 263-73 (1979) (discussing how consumers overweigh the risks of losses); W. Kip Viscusi & Richard J. Zeckhauser, *Hazard Communication: Warnings and Risk*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 106, 111 (1996).

assess all the costs of a warning, including the likelihood that warnings may discourage use that would provide net benefits.⁴⁸ Thus, regulators can modify the warning to minimize this problem. Fourth, for some products such as vaccines against easily transmitted diseases that do not work perfectly, there is an external public benefit provided by each individual who gets vaccinated. The more people who get vaccinated, the less likely everyone is to be exposed to the disease and therefore to contract the disease if the vaccine happens not to be effective for them. In that situation, the tort system and the market may drive the vaccine maker out of business even though the vaccine provides significant net benefits to society.

The over-deterrence that may be caused when tort actions are filed in response to alleged injury may be counter-balanced by the likelihood that in many situations in which producers may fail to take reasonable care, they will still escape suit. A person injured by a product may have to expend significant resources to learn that the producer failed to take adequate care or that use of the product likely caused him injury.⁴⁹ There are also costs to bringing suit even once the victim learns this information.⁵⁰ Such transaction costs pose less of a barrier if victims can band together to sue. Recent changes to federal law, however, may have significantly increased the difficulty of getting a national product liability class action certified.⁵¹ Moreover, for some mass tort claims, coordinat-

48. *See, e.g.*, Brief for the United States as Amici Curiae Supporting Defendant-Appellee and Cross-Appellant, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2001) (Nos. 02-55372, 02-55498, at 23–24) (making the FDA’s argument for pre-emption—that a stronger warning on the drug Zoloft would be non-optimal because it would unreasonably discourage use).

49. *See infra* note 50.

50. *See* Jeremy D. Fraiberg & Michael J. Trebilcock, *Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform*, 43 *MCGILL L.J.* 835, 840 (1998). For a detailed discussion of the impediments to litigation, see DON DEWEES, DAVID DUFF & MICHAEL TREBILCOCK, *EXPLORING THE DOMAIN OF ACCIDENT LAW: TAKING THE FACTS SERIOUSLY* (1996).

51. The Class Action Fairness Act (CAFA) generally allows removal to federal court of certain class claims with minimal diversity. *See* 28 U.S.C. § 1332(d)(2) (2006) (granting original jurisdiction to federal courts for certain class actions with minimal diversity and more than \$5 million in controversy). Any significant national class action will therefore be removable to federal court. CAFA, however, did not alter the preexisting choice of law regime, which leads to the potential that individual plaintiffs’ claims may be governed by the law in the state in which the injury or transaction occurred. This effectively means that the law will differ for plaintiffs from different states, which in turn may render the class action unmanageable. *See* Byron G. Stier, *Resolving the Class Action Crisis: Mass Tort Litigation as Network*, 2005 *UTAH L. REV.* 863, 883–89 (2005). For a discussion of the possible effects of CAFA on choice of law in class actions, see generally Samuel Issacharoff,

ing the trial of numerous independent cases may prove prohibitively burdensome.⁵²

If in fact the difficulties of bringing tort actions discourage them except when a producer engages in a blatant dereliction of the duty to exercise care, then there is little detriment to allowing tort suits as a backup to regulation. Torts suits will then only be brought in those cases where regulation proves to have grossly mis-specified the standard of care. This is precisely when such suits will have a salutary effect. It may be, however, that the ability of a lawyer to overcome the barriers to mass tort actions will depend not only on the egregiousness of the defendant's conduct, but also on such factors as the saliency of the injuries, the extent to which easily obtained data from the regulatory agency shows a causal connection between use of the product and injury—even if such use still does not explain most of the injuries—and the extent to which the producer has an interest in keeping aspects of its conduct secret. The problem with the under-deterrence argument is that once a lawyer can credibly threaten class certification or a multitude of independent suits in which the issue of liability poses identical factual issues, he will be better able to persuade the producer to settle, usually for more than the expected value that would result from going to trial.⁵³ A priori, it is not clear how strongly failure of regulation to prevent grossly inadequate care by a producer will correlate with a credible threat of a potentially ruinous tort suit. In short, whether allowing torts as a backup to regulation will beneficially influence the conduct of producers depends on the precise regulation at issue and the conduct it means to induce.

B. Certainty

Producers prefer certainty for at least two reasons: first, they are risk averse, and second, they seek to protect reliance interests. Regulations by themselves tend to serve both interests well. Once a regulation is adopted it remains the binding standard of conduct until it is repealed or amended by the agency or overridden by stat-

Settled Expectations in a World of Unsettled Law: Choice of Law After the Class Action Fairness Act, 106 COLUM. L. REV. 1839 (2006).

52. See Elizabeth Chamblee Burch, *Litigating Groups*, 61 ALA. L. REV. 1, 16 (2009) (noting the problems of “disunity” that plaintiffs face in organizing aggregate non-class action litigation).

53. The potential for plaintiffs' attorneys to extract greater value than the expected value from trial results from the different strategic interests of plaintiffs and defense lawyers with respect to the risk of going to trial. Chris Guthrie, *Framing Frivolous Litigation: A Psychological Theory*, 67 U. CHI. L. REV. 163, 169 (2000).

ute. For matters in which producers have significant reliance interests, it is likely to take several years for an agency to amend or repeal a regulation.⁵⁴ Agencies can react by amending rules more quickly, however, when post-adoption events clearly demonstrate that a regulation is counterproductive.⁵⁵ Sometimes regulations are far from pellucid and agencies give meaning to them by subsequent interpretation or application.⁵⁶ Interpretations issued outside of agency adjudications can be adopted without prior notice and procedure.⁵⁷ Once adopted, however, they only apply prospectively.⁵⁸ An agency can fill in the meaning of a regulation by applying it to a particular set of facts in an adjudication, but will be unable to impose liability or fines on a regulated entity unless that entity was on notice at least that the rule could reasonably be read to prohibit the conduct in which it engaged.⁵⁹ The worst case scenario for regulatory interference with reliance interests occurs when a producer invests significant resources in developing a product it thinks will meet regulatory standards, only to find after development that an agency is unwilling to approve the product.⁶⁰ This threatens significant loss of investment, but still leads to a fairly cer-

54. Amendment or repeal requires that the agency go through a full rulemaking proceeding, which for contested rules generally takes several years. See Cornelius M. Kerwin & Scott R. Furlong, *Time and Rulemaking: An Empirical Test of Theory*, 2 J. PUB. ADMIN. RES. & THEORY 113, 134 (1992) (reporting an average of 3 years from the time a rulemaking entered the Environmental Protection Agency's (EPA) regulatory development management system and time it was finally adopted).

55. See Michael Kolber, *Rulemaking without Rules: An Empirical Study of Direct Final Rulemaking*, 72 ALB. L. REV. 79, 82–83 (2009) (describing how the FDA has used “direct final rulemaking” to expedite the rulemaking process for some rules, but also how the agency has improperly attempted to get controversial rules approved without meaningful comment using this approach).

56. See, e.g., *Air Transp. Ass'n of Am. v. F.A.A.*, 291 F.3d 49, 53–54 (D.C. Cir. 2002) (clarifying that a regulation limiting maximum flight times for commercial airline crew members required airlines to use expected flight times based on actual conditions on the day of the flight rather than scheduled flight times). Agency interpretations of their own regulations enjoy great deference on judicial review. See *Auer v. Robbins*, 519 U.S. 452, 461 (1997); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945) (“[T]he administrative interpretation . . . [is] of controlling weight unless it is plainly erroneous or inconsistent with the regulation.”).

57. 5 U.S.C. § 553(b) (2006).

58. Such interpretations are rules under the APA, and hence apply prospectively. 5 U.S.C. § 551(4) (2006).

59. See *Epilepsy Found. of Ne. Ohio v. N.L.R.B.*, 268 F.3d 1095, 1102–03 (D.C. Cir. 2001).

60. Often the preemption question arises when an agency has to approve a product before it is sold, e.g., FDA approval of drugs. But even after an agency approves the product, the agency usually has authority to continue monitoring the

tain outcome after the agency decision: If the product is approved the producer can market it; if it is not approved, the producer cannot market it.

Tort suits, in contrast, create significant potential to interfere with reliance interests and to generate continuing uncertainty about the costs a producer will incur. The very nature of tort law requires suit after the injury has occurred. By necessity, it takes an ex post perspective on the conduct at issue when assessing whether it was reasonable.⁶¹ The availability of class actions and other mechanisms for consolidating claims allows tort suits to be settled en masse helping to create certainty of outcome after the alleged injury occurs.⁶² Hence, even tort law may allow for considerable future certainty. But it does so well after the producer has made significant investment in the product, and most importantly after the producer has already sold the product, thereby incurring potential liability. Tort law's potential disruption of reliance interests occurs even if tort law is merely a backup to regulation. Therefore, without preemption, tort law can threaten to destroy much of the certainty that regulation creates.

C. *Uniformity and State Cost Exporting*

Another concern of producers is the prospect of having to comply with a multitude of conflicting state standards imposed by the various state tort systems. Faced with conflicting standards of care, producers who wish to avoid liability have no choice but to differentiate their products to meet the standards of each jurisdiction or forbear from participating in some markets.⁶³

This concern about state standards that actually conflict—standards such that compliance with one means non-compliance with the other—does not arise in situations where the sole issue is how much care to take rather than the precise form in which care must

product and to order the producer to cease marketing it if the agency finds that the product fails to meet governing safety standards.

61. See Jeffrey J. Rachlinski, *Regulating in Foresight Versus Judging Liability in Hindsight: The Case of Tobacco*, 33 GA. L. REV. 813, 824 (1999).

62. See Samuel Issacharoff & Richard A. Nagareda, *Class Settlements Under Attack*, 156 U. PA. L. REV. 1649, 1651 (2008).

63. Producers can choose to market their product and pay damages for the violation of state tort standards. See Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1138 (2007). In many cases, however, this is not feasible because the cost of the product will not be sufficient to cover the liability plus the costs of resolving claims. See *supra* notes 35–39 and accompanying text.

be exercised.⁶⁴ Thus, the nature of the alleged violation of the duty of care greatly affects whether uniformity is an issue. In addition, the costs of producing products that vary state by state will differ depending on the product. For example, the cost of modifying the production lines for automobiles to meet standards of individual states would seem, at least on first reflection, to be much greater than the cost of labeling a drug to meet state by state differences regarding warnings of side effects or dangers.

Nonetheless, even state-by-state standards that simply hinge on the level of care create potential problems because manufacturers can avoid the costs of non-uniformity only by producing products that comply with the most stringent state standard. This essentially allows the tort system in a single state to set a national standard of care. Assuming that the standards set by the states vary around the actual optimal level of care, the fact that the most stringent standard will prevail effectively results in an overly strict standard of care. This tendency toward strict tort standards is exacerbated by the potential for juries to relate more to their “neighbor” plaintiffs rather than to out-of-state commercial entities that defend the injuring product.⁶⁵ Juries are unlikely to understand that imposing liability will raise the cost of the product to all who use it and, in extreme cases, might cause the producer to pull the product from the market altogether. Moreover, the fact that trial judges in many states are elected could further magnify the over-regulation tendency because judges may feel pressure to deliver verdicts in favor of local citizens.⁶⁶

64. If the issue is one of how stringent a standard is, then a manufacturer can meet all standards by meeting the most stringent one. Technically, the various standards do not conflict.

65. See Laura G. Dooley, *National Juries for National Cases: Preserving Citizen Participation in Large-Scale Litigation*, 83 N.Y.U. L. REV. 411, 437 (2008) (proposing a national jury system to overcome local nature of local jury values). *But cf.* Edward A. Purcell, Jr., *The Class Action Fairness Act in Perspective: The Old and The New in Federal Jurisdictional Reform*, 156 U. PA. L. REV. 1823, 1848 (2008) (“Except in the most obvious and egregious cases, charges of ‘bias’ and ‘local prejudice’ were exceptionally difficult—if not impossible—to prove.”).

66. See RICHARD NEELY, *THE PRODUCT LIABILITY MESS: HOW BUSINESS CAN BE RESCUED FROM THE POLITICS OF STATE COURTS* 62 (1988) (stating that where judges are elected, “it should be obvious that the in-state local plaintiff, his witnesses, and his friends, can all vote for the judge, while the out-of-state defendant can’t even be relied upon to send a campaign contribution”); Alexander Tabarrok & Eric Helland, *Court Politics: The Political Economy of Tort Awards*, 42 J.L. & ECON. 157, 158–59 (1999) (positing that voters will support judges who redistribute income to in-state plaintiffs from out-of-state defendants); *id.* at 186 (reporting strong empirical evidence that where judges are elected awards against out-of-state plaintiffs are

D. Transparency

The transparency of agency standard setting depends on whether the agency proceeds by rulemaking, adjudication or simply by ad hoc enforcement policy. Agency rulemaking is fairly transparent. An agency generally must use notice-and-comment rulemaking to adopt, amend or repeal a legislative rule.⁶⁷ Critics of administrative government have objected that the agency often is committed to the basic framework of a rule even before it publishes the Notice of Proposed Rulemaking (NOPR) that triggers the notice-and-comment process.⁶⁸ Current executive orders, however, require agencies to file regulatory plans that reveal intentions to adopt rules to address particular problems well in advance of the actual development of proposed rules.⁶⁹ Also, the structure of an agency rulemaking team helps ensure that groups with an interest in the subject of the rulemaking are informed about and provide input into the NOPR.⁷⁰ The transparency of the rulemaking process is further enhanced by judicially imposed requirements that an agency reveal in the NOPR any information on which it relies in developing the rulemaking proposal.⁷¹ Ultimately, judicial review requires the agency to explain how it reached its decision to adopt a rule given relevant statutory provisions and data.⁷²

Outside of the notice-and-comment rulemaking paradigm, transparency of agency standard setting declines, potentially precipitously. Standards that are announced in agency guidance docu-

much higher than those against in-state plaintiffs). It is informative that even Tabarrok and Helland fail to mention that the bias against out of state producers imposes costs on in state users of products. Cf. Saul Levmore, *Interstate Exploitation and Judicial Intervention*, 69 VA. L. REV. 563, 570–73 (1983) (distinguishing between state exploitation of other states, which create inefficiencies by exporting costs to other states, and state interferences with activities in other states, which may create inefficiencies, but do so at least partially at the expense of the adopting state).

67. 5 U.S.C. § 553 (2006).

68. See Stephanie Stern, *Cognitive Consistency: Theory Maintenance and Administrative Rulemaking*, 63 U. PITT. L. REV. 589, 600 (2002) (presenting evidence of agency “lock-in” to a rule once it is proposed).

69. Exec. Order. No. 12,866, § 4(c), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

70. See Brian Galle & Mark Seidenfeld, *Administrative Law’s Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 1956–57 (2008) [hereinafter Galle & Seidenfeld, *Administrative Law’s Federalism*].

71. See *Portland Cement Ass’n v. Ruckelshaus*, 486 F.2d 375, 392–93 (D.C. Cir. 1973); *Engine Mfrs. Ass’n v. EPA*, 20 F.3d 1177, 1181 (D.C. Cir. 1994); *Am. Med. Ass’n v. Reno*, 57 F.3d 1129, 1132–33 (D.C. Cir. 1995).

72. See Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 491–92 (1997) [hereinafter Seidenfeld, *Demystifying Deossification*].

ments must be published in the Federal Register if the agency is to rely on them,⁷³ which affords public notice before they are applied. Such standards are not rules with the force of law, however, so courts often find that these standards are not final agency action or are unripe for review.⁷⁴ Hence, standards often evade judicial review that would force the agency to reveal the information on which it relied in formulating them. Standards that are created via approval of specific products or enforcement actions are subject to judicial review but may be sufficiently obscure to elude public notice. Such proceedings are also frequently handled by informal procedures and therefore, unlike rulemaking, are less likely to be subject to scrutiny by staff members who bring varying professional perspectives.⁷⁵

To the extent enforcement affects regulatory standards, the information and criteria underlying agency policy may be far from clear. Agency personnel may not apply enforcement criteria consistently and the agency often does not reveal what drives decisions not to prosecute a violation of a regulation or statute unless the enforcement criteria are incorporated into a guidance document.⁷⁶ Nor must an agency explain its decision to decline prosecuting an individual violation because the Administrative Procedure Act (APA) exempts such decisions from judicial review.⁷⁷ Hence, enforcement policy is likely to be unknown and, even if known, not explained by the agency.

At first blush, the tort system might appear more transparent than agency regulation. Trials are open to the public and transcripts are generally public records. Evidence is admitted in open court so information from which liability stems is part of the open record. But few cases get to jury trial.⁷⁸ Attorneys settle cases on

73. See 5 U.S.C. § 552 (2006).

74. Stephen M. Johnson, *Good Guidance, Good Grief!*, 72 Mo. L. Rev. 695, 712–13 (2007).

75. Cf. Seidenfeld, *Why Agencies Act*, *supra* note 31, at 272, nn.69–70 (noting that agency enforcement and application of regulations is more readily subject to capture than rulemaking in part because of decreased monitoring of those activities by others in the agency).

76. An agency may incorporate criteria into a guidance document to inform its own staff of its enforcement policies. See Strauss, *Publication Rules*, *supra* note 12, at 804–05.

77. See *Heckler v. Chaney*, 470 U.S. 821, 837–38 (1985) (holding that decisions not to prosecute an alleged regulatory violation are excepted from judicial review by the APA because such decisions are committed to agency discretion by law).

78. John Fabian Witt, *Bureaucratic Legalism, American Style: Private Bureaucratic Legalism and the Governance of the Tort System*, 56 DEPAUL L. REV. 261, 267–68 (2007).

behalf of clients and part of getting the best settlement may include sealing or even destroying information.⁷⁹ Thus, the information needed to evaluate the efficacy of standard setting done via the tort system often is not public. Even for cases that go to trial, juries do not explain the reasoning underlying their verdicts. Hence, while the evidence admitted at trial may be available to the public, the evidence on which the jurors actually relied to reach their verdict remains uncertain.

E. Accountability

Although agency members are not directly elected, their relationship with the political branches provides significant democratic accountability.⁸⁰ The President has several mechanisms to assure that he retains significant influence over agency policy. First, and probably foremost, he appoints agency heads and their assistants.⁸¹ Second, for many agencies, the President has plenary power to remove political appointees.⁸² Third, agencies need the President as an ally if they are to succeed in the annual competition for appropriations for regulatory programs.⁸³ More formally, the President has issued several executive orders that have increased the authority

79. THOMAS O. MCGARITY & WENDY E. WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* 121 (2008) (reporting that defendants offer bonuses for settlements in which plaintiffs agree not to disclose documents that may be damaging to the defendants).

80. Although judges are elected in many states, those who are generally get elected by those in the region where they sit. This has the potential to create geographical bias in those judges who are elected.

81. U.S. CONST. art. II, § 2.

82. Although Congress has significant leeway to restrict the President's removal power, *see Morrison v. Olson*, 487 U.S. 654, 694–96 (1988), it may not be able to restrict, and to date has not restricted, the President's power to remove the heads of executive departments. *See Elena Kagan, Presidential Administration*, 114 HARV. L. REV. 2245, 2251 (2001) (distinguishing between Congress's intent with respect to Presidential control over independent and executive agencies).

83. *See* Thomas H. Hammond & Jack H. Knott, *Who Controls the Bureaucracy?: Presidential Power, Congressional Dominance, Legal Constraints, and Bureaucratic Autonomy in a Model of Multi-Institutional Policy-Making*, 12 J.L. ECON. & ORG. 119, 124 (1996) (reporting that many studies support the theory that the President plays "an agenda-setting role for congressional deliberations on agency appropriations"); Terry M. Moe, *Control and Feedback in Economic Regulation: The Case of the NLRB*, 79 AM. POL. SCI. REV. 1094, 1101 (1985) (discussing the president's influence over agencies through the use of such mechanisms as the appointment process and the agency budget).

of the White House to monitor agency policies to ensure that they are consistent with the administration's priorities.⁸⁴

Despite the increase in presidential clout,⁸⁵ Congress still retains significant means of influencing agency policy. For instance, the Senate must approve appointments of principal officers of the United States.⁸⁶ Congress also controls funding and can influence agencies directly by limiting the use of funds for programs it dislikes and indirectly by threatening to cut the overall budget of an agency.⁸⁷ Congress can also engage in oversight hearings that can embarrass an agency head and in the process sway public opinion against practices that Congress can spin as being inconsistent with basic public expectations about the agency's mandate.⁸⁸

The courts too influence the administrative state by requiring agencies to reveal the data underlying most of their regulatory actions, and to explain those actions.⁸⁹ Additionally, the reasoned decision-making requirement of the current standard for arbitrary

84. See Michael Hissam, *The Impact Of Executive Order 13,422 on Presidential Oversight of Agency Administration*, 76 GEO. WASH. L. REV. 1292, 1293–1300 (2008). President Obama recently reversed this trend, at least temporarily, by rescinding President George W. Bush's Executive Orders 13,258 and 13,422, returning the formal channels for White House monitoring of agency rulemaking to those in place under President Clinton. See Exec. Order No. 13,497, 74 Fed. Reg. 6113 (Jan 30, 2009).

85. See Kagan, *supra* note 82, at 2281–82 (detailing increased presidential influence on agency regulation in the Clinton White House); Yaniv Heled, *On Presidents, Agencies, and the Stem Cells Between Them: A Legal Analysis of President Bush's and the Federal Government's Policy on the Funding of Research Involving Human Embryonic Stem Cells*, 60 ADMIN. L. REV. 65 (2008) (describing President George W. Bush's promotion of his personal agenda regarding stem cell research).

86. U.S. CONST. art. II, § 2.

87. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1980 (noting Congress's influence over agencies that derives from its appropriations power).

88. See David W. Case, *The EPA's Environmental Stewardship Initiative: Attempting to Revitalize a Floundering Regulatory Reform Agenda*, 50 EMORY L.J. 1, 22–23 (2001) (describing how congressional hearings undermined the perceived legitimacy of Reagan's EPA and forced him to appoint William Ruckelshaus to head the agency); Geoffrey P. Miller, *From Compromise to Confrontation: Separation of Powers in the Reagan Era*, 57 GEO. WASH. L. REV. 401, 413–14 & n.79 (1989) (reporting on congressional hearings of Secretary of the Interior James Watt and EPA head Anne Gorsuch as attempts to get these agencies to take specific actions); David Johnston & Neil A. Lewis, *Senate Democrats Plan a Resolution on Gonzales*, N.Y. TIMES, May 18, 2007, at A16 (discussing need for Attorney General Gonzales to resign in light of information revealed and pressure put on Gonzales in Senate hearings about firing of United States Attorneys).

89. *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 49 (1983); Seidenfeld, *Demystifying Deossification*, *supra* note 72, at 498–99.

and capricious review pragmatically forces agencies to include as members of their rulemaking teams individuals from diverse professions who incorporate those perspectives into the regulatory process.⁹⁰

Although, in the federal system, courts are often viewed as the least democratically accountable branch of government,⁹¹ there are reasons to believe that they may provide some accountability for standards of care set by tort suits. Juries provide input from the ordinary person and can therefore ensure basic consistency with community norms. Being drawn directly from the populace, they also avoid undue interest group influence that can plague representative government and potentially, to a greater extent, administrative agencies. But juries are not chosen to be representative either of the polity as a whole or of groups with interests at stake in the battle to set regulatory standards. Also, most states use some electoral process for selection or retention of judges, who therefore provide some political accountability.⁹² Usually, however, they are elected by those in the region where they sit,⁹³ which can induce a parochial bias, especially when a case involves a local individual plaintiff injured by the product of a distant corporation. By contrast, agencies answer most directly to the President, who is accountable to the entire national polity.⁹⁴

90. Some of the analysis required by statute and executive order for agency rulemaking also demands that agencies include varying perspectives in the rulemaking process.

91. See Richard J. Pierce, Jr., *The Role of Constitutional and Political Theory in Administrative Law*, 64 TEX. L. REV. 469, 506 (1985) (discussing the compelling logic of describing the judiciary as the least politically accountable branch).

92. Herbert M. Kritzer, *Law Is the Mere Continuation of Politics by Different Means: American Judicial Selection in The Twenty-First Century*, 56 DEPAUL L. REV. 423, 431 (2007).

93. Mark C. Weber, *Complex Litigation and the State Courts: Constitutional and Practical Advantages of the State Forum Over the Federal Forum in Mass Tort Cases*, 21 HASTINGS CONST. L.Q. 215, 227 (1994) (noting that state judges are elected from their local districts, appellate judges and even sometimes supreme court justices are usually elected from regions).

94. See Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 95 (1985) (arguing that the relationship between agencies and the President along with the President's accountability to the national polity justifies delegating political decisions to agencies). See generally Peter L. Strauss, *Overseer, or "The Decider"?: The President in Administrative Law*, 75 GEO. WASH. L. REV. 696 (2007) (describing the debate about whether the President's authority allows him to substitute his decision for that of the agency to which Congress delegated authority). This does not mean that agencies are not capable of acting contrary to the preferences of the national polity, but it does mean that as a

The adversarial nature of the trial process also works to exclude the voice of many who have an interest in the regulatory standard established by the tort system. By pitting injured users of a product against the producer, the tort system fails to take into account others affected by the viability of the industry. These include, most notably, non-injured users as well as diverse groups such as employees and those who live near production facilities who may benefit from economic activity generated by production. In addition, the pragmatic financial need for plaintiffs' attorneys to aggregate mass tort suits, along with defendants' interest in resolving such suits once they mature sufficiently, creates a settlement system that favors lawyers over clients, and even some victims over others.⁹⁵

II. COMPARATIVE ADVANTAGES OF ALLOWING TORT SUITS

A. *Compensation for a Moral Wrong*

Although courts are not as knowledgeable as agencies about balancing costs and benefits—the grist for setting standards of care—tort claims have the advantage of providing compensation for victims of injuries caused by a product. The tort system, however, is not the only mechanism the state could use to provide compensation. For example, the state could provide a social insurance scheme to compensate victims, funded by a general tax. It could adopt New Zealand's system for accident compensation which couples an insurance scheme with contributions tied to the number and type of injuries a producer causes.⁹⁶ Such systems use a schedule of harms from injuries caused by covered conduct and, as such, may not accurately capture the costs and benefits of a particular course of conduct. More significantly, implementing such a system would require legislative action. These systems, however, do not placate the apparent desire of the public for a requirement that the state make a finding whether the causation of harm by a producer

matter of institutional structure, they are not beholden to a geographically distinct subset of the nation for their authority.

95. NAGAREDA, *supra* note 20, at 18–20.

96. See James C. Harris, Comment, *Why the September 11th Victim Compensation Fund Proves the Case for a New Zealand-Style Comprehensive Social Insurance Plan in the United States*, 100 NW. U. L. REV. 1367, 1373–76, 1389 n.161 (2006).

was wrong and, if so, to impose the costs created by that wrong on the producer.⁹⁷

B. Incentives for Producers to Determine the Optimal Level of Care

The tort system also creates an incentive for producers themselves to determine the appropriate level of care. The advantage of the system is its ability to induce producers to make the cost-benefit calculation, given that they will likely have better information than either regulators or the courts about the costs and benefits of the product. This is especially important because increased knowledge about product risks decreases costs of care. Hence, ex ante determinations of optimal care will be based on costs that are inflated above current costs of care, and the further out one moves from the date of approval, the less accurate the ex ante standard of care becomes.⁹⁸ As I already indicated, there are reasons to believe that the tort system imposes costs that are lower than the actual costs caused by use of products, and other reasons to believe that it imposes costs that are too high.⁹⁹ Even if the system is imperfect, however, it maintains an incentive for producers to continue learning about injuries caused by their product and how to decrease the costs of preventing those injuries—an incentive that would be eliminated were producers certain not to face liability for marketing in compliance with regulation.¹⁰⁰

By internalizing the cost of injuries to the producer, the tort system can make the producer a de facto insurer for these injuries: If the product remains viable, despite the prospect of tort damage awards, the producer can price the product to include the costs of

97. See Jules L. Coleman, *The Practice of Corrective Justice*, 37 ARIZ. L. REV. 15, 28–29 (1995); Benjamin C. Zipursky, *Rights, Wrongs, and Recourse in the Law of Torts*, 51 VAND. L. REV. 1, 56 (1998).

98. See Michael G. Faure, *Insurability of Damage Caused by Climate Change: A Commentary* 155 U. PA. L. REV. 1875, 1878 (2008) (noting that standards of care must be allowed to change to reflect new technology); Steven Shavell, *Liability and the Incentive to Obtain Information About Risk*, 21 J. LEGAL STUD. 259, 259–60 (1992) (contending that ex post liability for actions already taken give manufacturers an incentive to obtain information about product risks); cf. David Rosenberg, *Class Actions for Mass Torts: Doing Individual Justice by Collective Means*, 62 IND. L.J. 561, 575–79 (1987) (rebutting arguments that tort liability will deter investment in new technology).

99. See *supra* notes 35–39 and accompanying text. In addition to reasons why the tort system may impose liability that is greater or less than the actual cost of injuries, the system may impose costs in addition to direct liability to the extent it generates notoriety about a product that causes users to avoid buying the product.

100. See Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 166–67 (1995).

harm, spreading the cost among all users. In addition, through the doctrine of comparative fault, the tort system can reduce moral hazard problems.¹⁰¹

In some instances, however, the insurance scheme set up by the tort system may not be ideal. Most obviously, requiring the filing of a tort suit to get compensation is administratively expensive. In addition, the class of individuals who pay for the insurance may not be that which society would prefer as a matter of social justice. The insurance scheme spreads the cost among all product users, thereby alleviating the burden on the unlucky losers who are injured by the product. But the product users may already be the unlucky members of society who, through no fault of their own, are forced to use the potentially injurious product. In such a situation, it may be most fair to have the public bear the cost of injuries from product use. For example, consider expensive drugs used to keep those with a serious illness alive. The users of the drug are most likely already burdened by their illness, and the costs of insuring against a bad reaction to the drug would just be a further weight imposed on those unfortunate to be ill. Finally, the tort system may spread risks among product users who prefer not to pay for insurance for some injuries.¹⁰²

C. *Information Production and Monitoring*

Use of a product provides information about problems with the product that facilitate development of improvements or substitutes. Agency regulation is structured to provide incentives to develop information about product safety prior to the decision setting a safety standard or approving sale of the product. The threat of a tough standard or refusal to approve a product provides a significant incentive for producers to cooperate with regulators to provide information relevant to the initial regulatory decision. Once the agency makes its initial decision, however, a producer's incentive to cooperate is decreased. Agencies have limited resources and usu-

101. See COOTER & ULEN, *supra* note 27, at 345–46 (noting that under assumptions of perfect compensation and standards set at optimal levels, all forms of negligence result in incentives to both injurer and victim for efficient precaution); John A. E. Pottow, *Private Liability for Reckless Consumer Lending*, 1 U. ILL. L. REV. 405, 458–59 (2007) (addressing comparative fault in the context of contract law, but illustrating how comparative fault may reduce the risks of moral fault); see also Tom Baker, *On the Genealogy of Moral Hazard*, 75 TEX. L. REV. 237, 273 (1996).

102. For example, as previously noted, people do not purchase insurance for pain and suffering from injuries. See *supra* note 45.

ally a significant backlog of other matters needing attention.¹⁰³ Staff members garner recognition for getting standards adopted or drugs approved, not for revisiting actions already taken.¹⁰⁴ Hence, an agency has little incentive either at the institutional or individual level to revisit an issue it has already resolved.¹⁰⁵ As a corollary, an agency therefore has little interest in continuing to develop or monitor information about product safety once it has taken its initial regulatory action. The prospect of large awards can motivate plaintiffs and their attorneys to discover information about the risks of harm posed by a product that an agency might not have the ability or incentive to uncover.¹⁰⁶ Regulatory preemption, however, threatens to cut off discovery as an avenue for development of information that might bear on the proper standard of care.

D. Public Awareness of a Potential Problem with a Product

Tort suits for significant damages tend to generate greater publicity than all but the most salient regulatory actions. Media reports on large awards can heighten public awareness of the benefits and harms created by a product.¹⁰⁷ Public interest entrepreneurs can use the media reports to help organize members of the public to weigh in on whether a producer has acted improperly by continuing to market a product that threatens injury to users.¹⁰⁸ Even if the jury or judge is not representative of the public, the process of soliciting public reaction to tort suits and popular support for hold-

103. Thomas O. Sargentich, *The Emphasis on the Presidency in U.S. Public Law: An Essay Critiquing Presidential Administration*, 59 ADMIN. L. REV. 1, 34 (2007).

104. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 270 (stating that “individuals who promote a policy are evaluated not on whether the policy turns out to be wise but rather on whether the policy is adopted by the agency”).

105. See Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 698–700 (2007) (describing reasons why agencies may not be motivated to monitor risks created by products they regulate); *cf.* Marjorie A. Silver, *The Uses and Abuses of Informal Procedures in Federal Civil Rights Enforcement*, 55 GEO. WASH. L. REV. 482, 574–75 (1987) (noting that the limited resources of the EEOC and OCR, and their desire to eliminate backlogs, induce these agencies to inadequately monitor resolved cases).

106. See Samuel Issacharoff, *Group Litigation of Consumer Claims: Lessons from the U.S. Experience*, 34 TEX. INT’L L.J. 135, 141 (1999); Wagner, *supra* note 105, at 700–01.

107. See Robert J. MacCoun, *Media Reporting of Jury Verdicts: Is the Tail (of the Distribution) Wagging the Dog?*, 55 DEPAUL L. REV. 539, 551 (2006) (addressing both strengths and weaknesses of this view).

108. See generally Timothy D. Lytton, *Clergy Sexual Abuse Litigation: The Policymaking Role of Tort Law*, 39 CONN. L. REV. 809 (2007) (addressing the media’s effect on public discourse in relation to church sex abuse scandals).

ing a product to a higher standard of care can increase accountability of the tort system.

The decentralized nature of tort suits may also facilitate the development of a public consensus about the appropriate standard of care. Under current law, a product's safety is likely to be challenged in multiple suits rather than a single class action.¹⁰⁹ This allows repeated opportunities for development of relevant information and consideration by independent juries of issues, such as causation of injury and the blameworthiness of marketing the product, that inform the calculation of an optimal level of care. If an agency fails to generate accurate information or for some other reason gets the standard of care wrong, and tort suits are not available, then the standard will not get corrected unless the agency recognizes its error. By contrast, if a single court misses some information and sets the standard of care incorrectly, other cases are available to fill the information gap and correct the balancing of a product's costs and benefits. Thus, at least in theory, the tort system can facilitate a continuing deliberative public discourse that may ultimately generate some accepted understanding of benefits and injuries that flow from marketing the product, and some consensus about whether a producer has failed to take appropriate care.¹¹⁰

Unfortunately, heightened media attention on tort suits for large awards can also undermine the responsible setting of standards. The media has an incentive to sensationalize injuries. In addition, a plaintiffs' attorney in a product liability suit has an incentive to encourage this sensationalism because it creates a threat to the defendant, independent of the merits of the suit that might induce a settlement favorable to the plaintiffs. It also creates publicity for the attorney that might aid his career. Thus, there are strong incentives to create a distorted public portrayal of the effects of the product. Rather than deliberative public discourse, exaggerated media attention can erode trust in the information being presented which in turn undermines deliberative decision-making.¹¹¹

109. See *supra* note 51 and accompanying text.

110. Lytton, *supra* note 108, at 879.

111. See MacCoun, *supra* note 107, at 545–48, 551–62.

III.
INSTITUTIONAL COMPARISON OF WHO SHOULD
DECIDE WHETHER REGULATION PREEMPTS

My analysis thus far indicates that both regulatory preemption and availability of tort suits are potentially beneficial although each can also have negative consequences. Moreover, there is no set of factors that can be specified a priori which might indicate whether preemption or the availability of tort liability is likely to provide greater net social benefits in the context of injury from a particular product. Hence, the more meaningful question is: Who should decide for any given case whether preemption is warranted? The institutions that potentially can make this decision include Congress, agencies and courts. The mechanism for determining whether a particular suit is preempted follows from which institution has primary responsibility for the preemption determination.

A. *Congress*

Proponents of allocating to Congress primary responsibility for determining when federal regulation will preempt state law contend that preemption involves political choices and that Congress—being more deliberative, transparent, and accountable than administrative agencies and courts—is best at making those choices.¹¹² Elsewhere, Brian Galle and I have rebutted the orthodox assumption that Congress is superior with respect to these attributes, and concluded that agencies are better suited for deciding preemption issues.¹¹³ With respect to preemption of tort law, other attributes of Congress, courts and agencies reinforce that conclusion.

The complexity and particularity of the determinations that bear on the efficacy of preemption are beyond that to which Congress can pragmatically attend, especially on a regular basis.¹¹⁴ When Congress enacts a regulatory statute, it sometimes includes an explicit preemption or saving clause, but such clauses often ap-

112. See Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2111–15 (1990).

113. Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70.

114. See Lisa Schultz Bressman, *Chevron's Mistake*, 58 DUKE L.J. 549, 567 (2009); David Epstein & Sharyn O'Halloran, *Administrative Procedures, Information, and Agency Discretion*, 38 AM. J. POL. SCI. 697, 699 (1994). The limits on Congress's ability to attend to the necessary details of regulatory programs has long been a pragmatic justification for allowing Congress broad authority to delegate law-making functions to agencies. See Andrew J. Ziaja, *Hot Oil and Hot Air: The Development of the Nondelegation Doctrine Through the New Deal, a History, 1813–1944*, 35 HASTINGS CONST. L.Q. 921, 940 (2008).

ply to the entire regulatory scheme or, at best, to broad provisions within the scheme.¹¹⁵ These clauses do not include guidance about preemption that takes into account the conduct that plaintiffs allege to be tortious in a particular case.¹¹⁶ For example, a new antibiotic to treat drug-resistant bacteria might promise enormous benefits by significantly reducing the risk of contagion. These benefits inure to the public, not just the purchasers of the antibiotic, so the price of the drug does not reflect its marginal social benefit. At the same time, because such a drug may be rushed to market, it might pose a foreseeable and significant, albeit uncertain, risk of harm when approved. For such a product, preemption to encourage its development and production would appear warranted.¹¹⁷ For other drugs subject to the same approval regime, such as a new painkiller that provides moderate benefits to a small percentage of potential users but poses uncertain but potentially significant risks, preemption would be much more difficult to justify. Different products subject to a particular statutory provision may also raise different questions regarding either the benefits of non-uniformity that state tort systems might impose or the different levels of uncertainty for the risk of future harm. For example, the ability of automobiles to protect passengers in front-end collisions would seem to affect residents of different states similarly while the design of automobiles to increase traction on icy roads would be of more value in northern states than in southern ones. Preemption would be easier to justify with respect to the first safety concern than the second. To be fair, on occasion, Congress has responded to an impending threat to the public health or safety by providing guidance about potential tort liability for products developed to alleviate the threat.¹¹⁸ But in general, Congress lacks the time and

115. See e.g., Sharkey, *Products Liability Preemption*, *supra* note 3, at 461–62 (discussing the explicit preemption and savings clauses in the Motor Vehicle Safety Act of 1966).

116. See Sharkey, *Federalism Accountability*, *supra* note 2, at 2148 (saying Congress generally addresses preemption with “all-or-nothing” statutory provisions).

117. Such a drug would provide a public good, and therefore will be underproduced by the market unless subsidized by the government. MARK SEIDENFELD, *MICROECONOMIC PREDICATES TO LAW AND ECONOMICS* 65–66 (1996).

118. For example, in response to a pharmaceutical company’s unwillingness to produce vaccines against childhood diseases because of liability concerns, Congress enacted the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, 100 Stat. 3756 (codified as amended 42 U.S.C. §§ 300aa-1 to -34 (2006)). The goal of the Act was “to provide an expeditious method of compensating children who are injured because of vaccines and to make liability for vaccine manufacturers more predictable so that the supply of vaccines in the United States will be adequate.” Victor E. Schwartz & Liberty Mahshigian, *National Childhood Vaccine Injury*

incentive to focus on the differences in products at a level of detail that is needed to optimize the use of the tort system as a regulatory backdrop.

The breadth of matters Congress considers, coupled with the inertia built into the legislative process, decreases the attractiveness of Congress as the primary institution to set the bounds of regulatory preemption. These attributes preclude Congress from acting other than episodically,¹¹⁹ thus impeding its ability to react to new information about the need for tort liability. For many products, however, safety information bearing on the value of allowing tort suits is only developed or revealed after the product has reached the market.¹²⁰ If one had to wait for Congress to amend a regulatory statute to take such new information into account, the country likely would be stuck with Congress's initial determination regarding preemption, which could be far from efficient. In addition, post-marketing information can change the public's attitude about a particular product or the workings of an entire regulatory scheme. For example, the public's trust in both the medical profession—whose responsibilities include prescribing the most beneficial drugs on the market—and FDA regulators—whose job it is to keep drugs that are not safe and effective off the market—has declined markedly between the 1960s and 1990s.¹²¹ Yet Congress has not reacted by significantly amending preemption provisions that govern either medical devices or FDA approval of drugs.¹²²

Act of 1986: An Ad Hoc Remedy or a Window for the Future?, 48 OHIO ST. L.J. 387, 394 (1987).

119. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1980.

120. See Lyndon, *supra* note 100, at 148–50.

121. See Jonathan Todres, *Toward Healing and Restoration for All: Reframing Medical Malpractice Reform*, 39 CONN. L. REV. 667, 689 (2006); cf. Oliver Quick, *Outing Medical Errors: Questions of Trust and Responsibility*, 14 MED. L. REV. 22, 37–38 (2006) (characterizing changes in trust of the doctors as moving from “unconditional to conditional trust”).

122. With respect to medical devices, the Food, Drug, and Cosmetic Act (FDCA) includes both a clause seeming to permit state suits for liability despite compliance with an order approving a device, *see* 21 U.S.C. § 360h(d), and a clause preempting state health or effectiveness based requirements different from those imposed by the FDA, *see id.* § 360k. According to the United States Code Annotated, neither clause has been substantively amended since it was enacted as part of the Medical Device Act in 1976. With respect to approved drugs, the United States Code Annotated indicates that The FDCA has never contained any clause giving guidance on state law preemption or the availability of state tort suits for injuries caused by such drugs. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008) (noting that Congress could have, but did not, apply the preemption clause of the Medical Device Act to the entire FDCA).

My conclusion that in most instances Congress will not be well suited to determining whether a regulatory scheme should preempt tort law in the context of a particular case does not mean that Congress should never provide for preemption or, alternatively, for savings clauses allowing tort suits. Congress plays an important role in constraining agency action when the agency might otherwise pursue idiosyncratic preferences that deviate significantly from those of the polity generally.¹²³ In those instances, Congress can use the myriad means it has to influence the agency to “do the right thing.”¹²⁴ Ultimately, it may be necessary for Congress to override the agency by passing a statute explicitly mandating or prohibiting preemption. But my conclusion does imply that statutory preemption or savings clauses should be used sparingly by Congress—perhaps only when Congress believes that there are unusual circumstances indicating that the regulators cannot be trusted to decide the preemption issue to best serve the overall national interest.¹²⁵ Congress’s relatively weak competence to evaluate the wisdom of preemption in particular circumstances also suggests that courts should not read legislative intent to deny agency authority with respect to preemption of state tort law from anything less than clear statutory language.

B. Agencies

1. Agencies’ Superior Institutional Capacity to Evaluate the Need for the Availability of Tort Suits

The decision whether a particular regulatory action should preempt tort suits hinges on balancing the benefits of allowing tort suits against the detrimental impact such suits threaten. Agencies are uniquely suited among government institutions to perform such balancing. They develop knowledge about the cost structure and likely impact of potential liability on the industries that they

123. See Mark Seidenfeld, *Bending The Rules: Flexible Regulation and Constraints on Agency Discretion*, 51 ADMIN. L. REV. 429, 481 (1999).

124. See Jacob E. Gersen & Eric A. Posner, *Soft Law: Lessons from Congressional Practice*, 61 STAN. L. REV. 573, 606 (2008) (“Congress uses a range of instruments to influence administrative agencies, including restrictions on the appointment and removal of personnel, specification of substantive or procedural restrictions, appropriations, oversight hearings, and deadlines.”).

125. Such circumstances might result from an agency abdicating its regulatory responsibility, such as occurred in the EPA under President Reagan. See David W. Case, *The EPA’s Environmental Stewardship Initiative: Attempting to Revitalize a Floundering Regulatory Reform Agenda*, 50 EMORY L.J. 1, 22–23 (2001) (describing “the political embarrassment of mismanagement and scandal at the EPA under the watch of Reagan’s first EPA administrator, Anne Gorsuch”).

regulate.¹²⁶ Agencies that monitor product safety and approve products for market also often have the power to require producers to disclose potential injuries threatened by their products,¹²⁷ and may have independent knowledge about the likelihood of such injuries. Most significantly, during a rulemaking or approval process, an agency will directly face the uncertainties in the information available and will have to estimate the likely importance of such information in predicting product safety. Deliberating about the value of known information may provide the agency with some idea of the extent and importance of missing information, as well as whether experience with the product after it is marketed is likely to provide such information.

Preemption determinations may also involve a value judgment about whether and how to compensate those injured by a product. As noted above, agency rulemaking may be superior to the legislative process even with respect to deliberation, transparency and accountability. Agencies are subject to oversight by Congress and the President.¹²⁸ Simultaneously, unlike the legislature, agencies are not subject to vetogates or pragmatically limited to episodic behavior.¹²⁹ Moreover, unlike courts, agencies can be proactive and decide issues not yet presented by a dispute between particular parties. As such, agencies seem to be well suited to decide whether tort suits should be preempted.

126. Cf. Simonetti Samuels, *Interpreting Health Care Cost Containment Legislation: Good Samaritan Hospital v. Shalala and Relative Institutional Competence*, 4 SUP. CT. ECON. REV. 141, 142 (1995) (reporting how the Department of Health and Human Services developed knowledge of the health care industry as it gained experience setting limits on payments to Medicare providers).

127. Although agencies generally have such power, they may not have sufficient motivation to gather all the information they need to set an optimal standard. See Wagner, *supra* note 105, at 698–700 (describing reasons why agencies may fail to demand sufficient information on product risks from industry).

128. See generally Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 ADMIN. L. REV. 1, 1 (1994) (describing how Congress and the President compete to control agencies).

129. Vetogates are structural requirements in the legislative process that can prevent legislation from being passed even if it is popularly supported. They include the constitutional requirements of bicameralism and presentment, and congressionally adopted structures such as the committee system, which gives committee chairs significant power to kill legislation, and the filibuster in the Senate. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70 at 1962. The episodic behavior of Congress refers to the inertia that plagues the legislative process and the resulting phenomenon that Congress does not regularly update statutes to reflect new information or political preferences. See *id.* at 1967. Agencies' procedures for adopting regulations are more flexible, allowing them to amend regulations on a more regular basis. *Id.* at 1983.

2. Imperfections in the Administrative Process

The institutional superiority of agencies suggests that they should play a more central role in determining when their actions preempt tort law. But the administrative state suffers from its own imperfections. Most notably, an agency may act to further its own interests, which may deviate from those of the polity as a whole or from the balance of goals that Congress might have meant the agency to implement when it authorized agency action.¹³⁰

Folklore about the administrative state has led to the belief that agencies are motivated to maximize their power, measured either by their budget¹³¹ or the reach of their jurisdiction.¹³² Studies of agency motivation, however, demonstrate that this concept is not particularly coherent.¹³³ Agencies regulate through actions of their staff members and ultimately their agency head. Rarely is either interested in simply maximizing the agency budget or jurisdiction.¹³⁴

Agency staff members tend to see their role as performing the prescribed functions of their jobs which they view as allowing the

130. See Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1570–74 (1992) [hereinafter Seidenfeld, *A Civic Republican Justification*] (describing the potential for agencies to pursue idiosyncratic values).

131. WILLIAM A. NISKANEN, JR., *BUREAUCRACY AND REPRESENTATIVE GOVERNMENT* 114 (1971) (arguing that “the coterminous relation of a bureaucrat’s rewards and his position implies that a bureaucrat will maximize the total budget of his bureau”).

132. See Jonathan R. Macey, *Positive Political Theory and Federal Usurpation of the Regulation of Corporate Governance: The Coming Preemption of the Martin Act*, 80 NOTRE DAME L. REV. 951, 956 (2005) (positing that agencies care about their budget and jurisdictional turf); Mendelson, *supra* note 3, at 794–95 (asserting that agencies have incentives to maximize their jurisdiction to increase their ability to work out deals with interest groups).

133. Thus, one recent study undermined the notion that the agency can act with a single motivation because agency managers cannot easily get staff members to follow their bidding. JOHN BREHM & SCOTT GATES, *WORKING, SHIRKING, AND SABOTAGE: BUREAUCRATIC RESPONSE TO A DEMOCRATIC PUBLIC* 79, 101–08 (2000).

134. See Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 235 (labeling assumptions that agencies seek to maximize their jurisdictions as “unproven background assumptions”); Daryl J. Levinson, *Empire-Building Government in Constitutional Law*, 118 HARV. L. REV. 915, 932 (2005) (noting that “the relationship between a larger agency budget and higher salaries or cushier working conditions is empirically tenuous”); see also Seidenfeld, *Why Agencies Act*, *supra* note 31, at 268–86 (2009) (describing motives for action by agency staff and agency heads).

agency to achieve its mission.¹³⁵ Staff members, however, may harbor an idiosyncratic understanding of that mission. Agency staff members may be zealots for the stated regulatory protections of the programs within which they work.¹³⁶ If so, they may view tort suits favorably as a means of encouraging implementation of the agency mission regardless of the cost suits imposed on regulated entities. Some staff members, however, may see potential tort liability as going farther than the balance they deem appropriate between public protection and encouragement of beneficial production by the industry the agency regulates. These members would be predisposed to advocate preemption of tort claims stemming from products they regulate.

The motivation of an agency head will depend on his career goals.¹³⁷ The heads of regulatory agencies tend to come from political or professional backgrounds, rather than a career within the agency.¹³⁸ They also tend not to be interested simply in maximizing agency budgets, especially because their tenure is short and their ultimate future lies outside of their agency. Like staff, they too seek credit for getting things done at the agency. Agency heads, however, may be appointed because of their relationship with the current administration and their future careers may depend on the political support of those in the White House when their tenure ends.¹³⁹ Hence, they may be prone to an agenda that

135. See BREHM & GATES, *supra* note 133, at 79 (reporting that the two most popular aspects of public bureaucrats jobs were “a feeling of accomplishment,” and “chances. . .to accomplish something worthwhile”); cf. MARISSA MARTINO GOLDEN, *WHAT MOTIVATES BUREAUCRATS: POLITICS AND ADMINISTRATION DURING THE REAGAN YEARS 155–56* (2000) (reporting that upper level career civil servants are guided by “role perception” to provide analyses and information to allow their superiors to set agency policy).

136. That “single mission agencies” may have “dedicated but zealous” staff, which needs to be checked by political oversight outside the agency is a commonly cited excerpt from an administrative law opinion. *Sierra Club v. Costle*, 657 F.2d 298, 406 (D.C. Cir. 1981).

137. For an extended discussion of the motivations of agency staff members and heads, see Seidenfeld, *Why Agencies Act*, *supra* note 31, at 267–86.

138. *Id.*, at 282, n.101; see also JAMES Q. WILSON, *BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT 200–01* (1989) (careerist as opposed to political agency heads generally run agencies presented with the same sorts of decisions every day and not with policy choices).

139. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 282; see also *id.* at 284–84 (explaining that political agency heads may be loyal to their administration for social reasons as well).

the White House sees as politically expedient, which may deviate from what is best for the country.¹⁴⁰

As opposed to maximizing budgets or jurisdiction, it is more likely that both agency staff and heads prefer autonomy.¹⁴¹ Autonomy is created by an agency having a unique mission and therefore not having to compete with rivals to ensure its continued existence. Whether one is fanatical about protecting the putative beneficiaries of regulation or hell-bent on freeing industry from regulatory constraints, achievement of one's goals is easier without competition for resources and support of a constituency. It is possible that those in agencies may see tort suits as interfering with agency autonomy to the extent that the tort system is a regulatory rival that can increase the work load on an agency. This could occur if tort suits forced the agency to reconsider a prior regulatory decision when it is anxious to address the next problem or product.

Another concern raised by critics is capture of the agency by the regulated industry.¹⁴² Capture is not a precisely defined concept.¹⁴³ In the broadest sense it occurs when an agency acts on behalf of the entities it regulates rather than in the public interest.¹⁴⁴ But, the public interest usually requires a balance between zealous regulation and industry flexibility that permits production of beneficial goods and services at the lowest cost. Hence, it is not easy to determine when any agency decision reflects capture rather than a proper balance, especially when viewed by a group representing those potentially injured by a product. Moreover, an agency's political overseers may strike their own balance in favor of regulation. If the President and Congress favor a pro-industry outcome of a regulatory matter, an agency that implements their pref-

140. See John McKay, *Train Wreck at the Justice Department: An Eyewitness Account*, 31 SEATTLE U. L. REV. 265, 283–84 (2008) (describing Attorney General Gonzales' problematic and perhaps unlawful firing of United States Attorney David Iglesias seemingly to support the administration's political preferences); David Scheffer, *For Love of Country and International Criminal Law, Further Reflections*, 24 AM. U. INT'L L. REV. 665, 667–68 (2009) (describing how Justice Department lawyers who wrote memos justifying torture "did exactly what was required of them to fulfill the expedient objectives of their political masters").

141. See WILSON, *supra* note 138, at 180–82, 188–92 (1989).

142. See generally Thomas W. Merrill, *Capture Theory and the Courts: 1967–1984*, 72 CHI.-KENT L. REV. 1039 (1997) (describing the history of capture theory and its influence on judicial doctrines of administrative law).

143. See *id.* at 1059–62 (describing several different understandings of agency capture).

144. See Thomas W. Merrill, *Rethinking Article I, Section 1: From Nondelegation to Exclusive Delegation*, 104 COLUM. L. REV. 2097, 2143–45 (describing capture as a form of agency drift from the preferences of the polity).

erence for a regulatory scheme can be characterized as responsive to political influence rather than captured.¹⁴⁵

Nonetheless, regardless of whether through the influence of Congress or the President, or through incentives the regulated industry provides to agency staff members, agencies can be induced to further the interests of producers at the expense of the public.¹⁴⁶ Therefore, were courts to grant an agency primary responsibility to determine tort preemption, they would have to structure how the agency makes that determination to minimize the potential for capture.

3. Notice-and-Comment Procedures and Hard Look Review as Cures for Agency Imperfections

The two threats of the administrative state just described—officials' desire for autonomy to institute their conception of the regulatory scheme and industry capture—can be ameliorated to a great extent by requiring agencies to use notice-and-comment rulemaking to preempt tort law and by courts applying the exacting “hard look” standard of review to such preemptive rules.¹⁴⁷

However one defines capture, agency rulemaking is less likely to reflect an inappropriate balance of interests than agency enforcement or permitting actions.¹⁴⁸ Enforcement requires investigation in a particular instance to see if conduct violates rules or policies of the agency. As such, it necessarily involves “street level” officials who retain much discretion about whether to report a violation.¹⁴⁹ Hence, a regulated entity can provide “benefits”¹⁵⁰ to the

145. For example, the Interstate Commerce Commission (ICC) under President Reagan pursued a strong deregulatory agenda, which was the hallmark of Reagan's domestic policy against big government. But ICC actions were not so much a product of the agency being controlled by the trucking industry as it was the agency implementing the agenda of a free market-oriented President and, to a lesser extent, Congress. See Paul Stephen Dempsey, *The Interstate Commerce Commission—Disintegration of an American Legal Institution*, 34 AM. U. L. REV. 1, 49 (1984) (criticizing ICC deregulation of trucking and opining that “[t]he Commission has lost the autonomy that traditionally shielded its decisionmaking from the political winds that blow down Pennsylvania Avenue”).

146. Note, *The Mysteries of the Congressional Review Act*, 122 HARV. L. REV. 2162, 2178–79 (2009) (describing various posited mechanisms for agency capture and asserting that capture in the broad sense of an agency acting against the public interest does occur).

147. See *infra* notes 160–66 and accompanying text.

148. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 271–73 (2009).

149. See Keith Hawkins & John M. Thomas, *The Enforcement Process in Regulatory Bureaucracies*, in ENFORCING REGULATION 3, 9 (Keith Hawkins & John M. Thomas, eds., 1984) (describing how discretion of meat packing plant inspectors

official responsible for enforcement more easily and more secretly than it can to those responsible for rulemaking.¹⁵¹ The susceptibility of licensing to capture, which under the APA includes such actions as FDA approval to market a drug,¹⁵² falls somewhere in between that of enforcement and rulemaking.¹⁵³ Ostensibly, approval is a matter between the agency and the entity seeking approval, and public participation in a particular product approval may be limited by concerns for proprietary information and trade secrets.¹⁵⁴ Nonetheless, there may be some opportunity for public participation in setting standards for product approvals.¹⁵⁵ Public interest groups, however, will be limited in the extent they can introduce information into the record or challenge an agency decision to approve the marketing of a product. In addition, issuance

led to a norm of inspectors accepting gratuities from the plants they inspected); *id.* at 11 (stating that “field-level officials . . . have the power to commit the agency to the investigation and prosecution of specific violations”).

150. Benefits may be promises of future jobs or outright bribes, but may also be as simple as cooperating in providing information that allows an official expend less effort and time to perform his job. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 271–74 (discussing capture of staff involved in the rulemaking process).

151. For a recent example of apparent capture in the enforcement context, see Matthew L. Wald, *Inspectors Say FAA Ignored Southwest Violations*, N.Y. TIMES, Apr. 4, 2008, at C3 (reporting that a manager in an FAA (Federal Aviation Administration) regional office had allowed Southwest to continue flying planes that had not been inspected as required by FAA regulations).

152. The APA defines a “license” to include “the whole or part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission.” 5 U.S.C. § 551(8) (2006). Licensing is “adjudication” under the APA, 5 U.S.C. § 551(6)–(7) (2006), and hence the public may be limited in its ability to participate in the proceeding. See 5 U.S.C. § 555(b) (2006) (specifying that, unlike a party, an interested person may appear before an agency only “[s]o far as the orderly conduct of public business permits”).

153. As an example of what might be undue industry influence, the FDA has been criticized for pressuring drug reviewers to approve new drugs even when they had questions about the drugs’ safety or effectiveness. Christine D. Galbraith, *Dying To Know: A Demand For Genuine Public Access To Clinical Trial Results Data*, 78 MISS. L.J. 705, 769–70 (2009).

154. See James T. O’Reilly, *Knowledge Is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. CIN. L. REV. 1, 8 (1985) (reporting that from 1967 through the writing of the article, “the FDA uniformly has withheld, as confidential business information or trade secrets, business data it has received in the course of drug product approvals”).

155. See Lewis Rosman, *Public Participation in International Pesticide Regulation: When the Codex Commission Decides, Who Will Listen?*, 12 VA. ENVTL. L.J. 329, 355 (1993) (describing opportunities for participation and judicial challenges to EPA approval of pesticides).

of approvals may involve a single office in an agency,¹⁵⁶ which in turn may discourage deliberation between staff members with different professional backgrounds. Rulemaking, in contrast, allows all those with an interest in a rule to provide input into the ultimate decision in a transparent forum. Development and adoption of rules usually involves a team of agency officials from several offices within the agency.¹⁵⁷ It would be extremely difficult for an industry to provide incentives for all team members to unjustifiably support the industry's preferences.¹⁵⁸ If capture happens, it often occurs when the industry convinces Congress and the White House—the political overseers of the agency—to demand a pro-industry outcome.¹⁵⁹

The potential for an agency inappropriately to preempt tort law can be ameliorated by requiring agencies to proceed by notice-and-comment rulemaking subject to hard look review.¹⁶⁰ Rulemaking proceedings inform interest groups of the agency's plans before it formulates a final rule and allows these groups to alert Congress if they believe the proceedings are contrary to their interests. Use of rulemaking subject to exacting judicial review encourages the agency to collect input from its staff, usually comprised of individuals with varied professional backgrounds and different private con-

156. For example, at the FDA, new drugs are approved by "drug reviewers" in the agency's Center for Drug Evaluation and Research. Galbraith, *supra* note 153, at 769.

157. Mark Seidenfeld, *Cognitive Loafing, Social Conformity, and Judicial Review of Agency Rulemaking*, 87 CORNELL L. REV. 486, 527–28 (2002) [hereinafter Seidenfeld, *Cognitive Loafing*]; Thomas O. McGarity, *The Internal Structure of EPA Rulemaking*, 54 LAW & CONTEMP. PROBS. 57, 90 (1991).

158. The evidence that agencies as a body are improperly influenced by special interest groups is slim. See PAUL J. QUIRK, *INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES* 4–21 (1981); Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 52–56 (1998); Mark Kelman, *On Democracy-Bashing: A Skeptical Look at the Theoretical and "Empirical" Practice of the Public Choice Movement*, 74 VA. L. REV. 199, 238–68 (1988).

159. One example is the FCC giveaway of billions of dollars of electromagnetic spectrum to existing television stations, which was essentially mandated by Congress. See Thomas W. Hazlett, *Physical Scarcity, Rent Seeking, and The First Amendment*, 97 COLUM. L. REV. 905, 938–42 (1997) (describing how broadcasters influenced Congress to give away spectrum for HDTV licenses to existing television stations). See generally Ellen P. Goodman, *Digital Televisions and the Allure of Auctions: The Birth and Stillbirth of DTV Legislation*, 49 FED. COMM. L.J. 517 (1997) (giving a detailed account of congressional consideration of the auction of HDTV spectrum).

160. Seidenfeld, *Demystifying Deossification*, *supra* note 72, at 490–92 (describing "hard look" review).

tacts and constituents.¹⁶¹ Thus, interest groups can more effectively influence agency deliberation while the agency is formulating a proposed rule, rather than after a rule is proposed. Once the agency has formulated its position, it is less open to change. Nonetheless, even after an agency proposes a rule, interest groups can place comments in the record which often include data that can undermine the agency's explanation if it is later forced to defend its decision in court. Hence, subject to standing limitations, an interest group can use the data it submits to challenge an agency rule as arbitrary and capricious.

Hard look judicial review also provides a check against unjustified political influence. Courts require that agencies explain their actions in terms of factors "relevant" to their actions.¹⁶² Generally, such factors include those identified in the agency's authorizing statute,¹⁶³ and other fairly universally accepted values, such as the desire to avoid spending money unnecessarily. Thus, even when the political branches pressure an agency to preempt tort law, in at least some situations, the agency will simply not have sufficient data regarding the impact of future liability on a producer or its product to convince a reviewing court that preemption is warranted. Undoubtedly, mandated decision-making procedures and exacting judicial review on their own will not always prevent an agency from acting contrary to perceptions of the nation's interest. If Congress and the President support an agency's particular course of action, judicial review will not prevent the agency from ultimate implementation.¹⁶⁴ But even when Congress and the President strongly support a course of action, the public may be more hesitant about pursuing it, in which case procedures and review can slow the administrative process enough for politics to catch up with the agency

161. *Id.* at 493–94.

162. Jessica Mantel, *Procedural Safeguards For Agency Guidance: A Source Of Legitimacy For The Administrative State*, 61 ADMIN. L. REV. 343, 387 (2009); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1442 (1992).

163. See Richard J. Pierce & Sidney A. Shapiro, *Political and Judicial Review of Agency Action*, 59 TEX. L. REV. 1175, 1190–91 (1981) (noting that judges can pick and choose which of scores or even hundreds of statutory factors were relevant).

164. See Seidenfeld, *A Civic Republican Justification*, *supra* note 130, at 1547–48; see also William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere With Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393, 440 (2000) (finding that in almost every instance over a decade long period, agencies were able to reinstate the substance of rules remanded by the D.C. Circuit as arbitrary and capricious when the agency did not agree with the court's conclusion about the rule).

agenda.¹⁶⁵ In some cases this can facilitate political mobilization of less focused interest groups to protect the public interest.¹⁶⁶

4. Agencies' Potential Disdain for State Interests in Maintaining Tort Suits

Thus far, I have presented arguments for why notice-and-comment rulemaking along with hard look review can be expected to alleviate some of the pathologies of granting agencies wide discretion to set policy. Some scholars, however, cite evidence of an apparent trend among several agencies to support preemption generally and an accompanying willingness to shortchange state interests even in the rulemaking process.¹⁶⁷ In particular, these naysayers report that these agencies have virtually ignored their obligations under Executive Order 13,132¹⁶⁸ to consult with state and local government officials and prepare an analysis of significant impacts on these governmental entities.¹⁶⁹ In addition, scholars have reported that in several instances, agencies have abused the notice-and-comment process by sneaking preemption provisions into the preamble to rules thereby avoiding the notice-and-comment process altogether.¹⁷⁰ In other instances, agencies did accept comments on preemption, but entirely ignored them in their final determination to preempt state tort law.¹⁷¹ I believe that these scholars infer more about agency hostility to federalism than the

165. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 320 (describing how judicial review of the National Highway Traffic Safety Administration's (NHTSA) passive restraint rule allowed politics to catch up with the agency and derail its aggressive safety standard program).

166. See Mathew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 J.L. ECON. & ORG. 243, 257–58 (1987) (arguing that rulemaking procedures give Congress and the President early warning of agency moves potentially requiring oversight); Metzger, *supra* note 3, at 2087 (noting that “by forcing an agency to provide notice of actions it plans to take, procedural requirements empower congressional oversight and thus reinforce such political safeguards as Congress has to offer”).

167. See, e.g., Ronald K. Chen, *State Incarceration of Federal Prisoners After September 11: Whose Jail is it Anyway?*, 69 BROOK. L. REV. 1335, 1344–45 (2004); Thomas O. McGarity, *The Perils of Preemption*, 44 TRIAL 20, 20–24 (2008); Mendelson, *supra* note 3, at 783–86.

168. Exec. Order No. 13,132, 64 Fed. Reg. 43,257 (Aug. 10, 1999).

169. See Chen, *supra* note 167, at 1344–45; McGarity, *infra* note 174, at 24; Mendelson, *supra* note 3, at 783–86; see also Sharkey, *What Riegel Portends*, *supra* note 8, at 457 (taking the FDA to task for failing to prepare federalism impact statements, but adopting a more nuanced position on agency preemption generally).

170. See, e.g., Sharkey, *Federalism Accountability*, *supra* note 2, at 2131–34.

171. See, e.g., *id.* at 2137.

evidence supports. Rather than manifesting insensitivity to tort victims and federalism, recent agency decisions preempting tort suits reflect shortcomings in institutional incentives to consider such matters. Moreover, were judges to view the choice of preemption as a policy decision for which agencies have primary responsibility by way of the rulemaking process, judicial review would realign these institutional incentives so that administrative law would alleviate the supposedly antagonistic attitude of agencies towards tort suits.

To understand the significance of agency ignorance regarding Executive Order 13,132,¹⁷² one must recognize that this Order is one of many that purport to require consultation and analysis.¹⁷³ From an agency's perspective, these required analyses are "paperwork," rather than documents that inform their rulemaking decisions.¹⁷⁴ The requirement that agencies perform them is enforced by the Office of Management and Budget (OMB),¹⁷⁵ and is not backed up by judicial review.¹⁷⁶ From the White House's perspective these executive orders provide mechanisms for the President to force agencies to consider issues that the President deems important and generally to exert more influence on agency rulemaking.¹⁷⁷ Thus, that the Office of Information and Regulatory Affairs (OIRA)¹⁷⁸ did not rigorously police agency preparation of federalism impact analyses when the underlying rules were favored by the President says little about agency attitudes toward federalism.

172. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999).

173. See Mark Seidenfeld, *A Table of Requirements for Federal Administrative Rulemaking*, 27 FLA. ST. U. L. REV. 533, 536–37 (2000) (detailing all of the procedures with which an agency had to comply, in 2000, to adopt a legislative rule).

174. See THOMAS O. MCGARITY, *REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY* 43 (1991) (opining that the EPA did not devote much attention to an initial regulatory flexibility analysis in its lead phase down rule because it regarded the analysis "merely as a paperwork hurdle").

175. Exec. Order No. 13,132, 64 Fed. Reg. 43,258 (Aug. 10, 1999).

176. *Id.* at 43,259.

177. See Kagan, *supra* note 82, at 2288 (noting how President Clinton's executive order on regulatory review was worded to expand his ability to control agency rulemaking); Shapiro, *supra* note 128, at 8–10 (describing executive orders requiring regulatory impact analyses as one means for the President to engage in an oversight game with Congress).

178. OIRA is the group within OMB that is responsible for regulatory oversight. See Exec. Order. No. 12,866 § 6(b), 58 Fed. Reg. 51,735 (Sept. 30, 1993) (directing OIRA to "provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order").

Even when analyses are required by statute, agencies tend to avoid preparing meaningful statements, or even preparing statements at all. For example, the Regulatory Flexibility Act requires an agency to determine whether a rule will have a “significant economic impact on a substantial number of small entities,” and to prepare a Regulatory Flexibility Analysis (RFA) if it will.¹⁷⁹ The Act originally precluded judicial review of its requirements,¹⁸⁰ which led to complaints of lagging compliance, including agency failures to consult with small businesses about the effect of rules and failures to prepare RFAs when the impact would be significant.¹⁸¹ Congress has since amended the Act to allow judicial review of its requirements,¹⁸² and to make regulatory flexibility analyses prepared by agencies part of the rulemaking record.¹⁸³ This seems to have induced agencies to prepare RFAs, although it is not clear whether judicial review has prompted more consistent consideration of small business interests. Agencies are apt to continue to consider these analyses as “paperwork” unless courts consider the impact on small businesses a relevant factor in assessing whether a rule is arbitrary or capricious.

Given that Executive Order 13,132 is not judicially enforceable¹⁸⁴ and that the George W. Bush administration strongly pushed for preemption of state tort law, it is no surprise that agencies did not comply with the Order prior to issuing their stealth preemption statements. As such, if that executive order is to empower states in the regulatory process, at a minimum, Congress will have to make its requirements judicially enforceable. Such action, at least for now, would be unwarranted because one can give agencies better incentives to seriously consider state interests in allowing tort suits while still allowing more flexibility in the preemption decision. This can be done by requiring agencies to explicitly include their preemption determinations in rules. This, in turn, will trigger the reasoned decision-making requirements of arbitrary and capricious review under the APA.

179. 5 U.S.C. §§ 603, 604, 605(b) (2006).

180. Regulatory Flexibility Act, Pub. L. No. 96-354, § 3(a), 95 Stat. 1164, 1169–70 (1980).

181. See Jennifer McCoid, *EPA Rulemaking under the Regulatory Flexibility Act: The Need for Reform*, 23 B.C. ENVTL. AFF. L. REV. 203, 204, 231 (1995) (noting agencies’ propensity not to comply with the Act and suggesting judicial review as a cure).

182. Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. § 611(a)(1) (2006).

183. *Id.* § 611(b).

184. Exec. Order No. 13,132, 64 Fed. Reg. 43,259 (Aug. 10, 1999).

Abuse of the notice-and-comment process is somewhat more troubling because a state tort system does not necessarily involve any particular state regulatory office that can effectively represent a state's interests early in the rulemaking process. By the time a rule is proposed, an agency has usually invested significant time and effort in the matter and may remain wedded to the position it has taken. Therefore, the key for interest groups to influence a rulemaking is for them to get involved in pre-NOPR rule development, usually through interactions with agency staff members from the same profession or with similar views of the regulatory scheme.¹⁸⁵ If the subject of a rulemaking happens to fall within the ambit of a state regulatory office, staff members from that office will be aware of the pre-NOPR developments in the federal agency as state agency staff members will often have professional acquaintances on the federal agency staff,¹⁸⁶ and can get their viewpoints heard early in the process. Unfortunately, when the subject of preemption is tort law, there may be no state office to play the role of the informed and involved representative of the state's interest.¹⁸⁷ And although one might look to state attorneys general to represent state interests in the federal agency proceeding, these attorneys general do not have the focused mandate on particular regulatory matters to generate either the incentive or the agency contacts to keep abreast of rulemaking developments in the various industries regulated at the federal level.

185. See CORNELIUS M. KERWIN, *RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY* 79–80 (3d ed. 2003) (describing the importance of rule development before a rule is proposed); Scott R. Furlong, *Interest Group Influence on Rule Making*, 29 *ADMIN. & SOC'Y* 325, 334–35 (1997) (reporting that interest groups believe that informal contacts prior to a rule being proposed is one of the most effective ways to influence rulemaking).

186. See Mark Seidenfeld, *The Psychology of Accountability and Political Review of Agency Rules*, 51 *DUKE L.J.* 1059, 1078 (2001) (stating that “[o]ne suspects that agency staff also maintains contacts with representatives from affected interest groups and tries to keep such groups sufficiently placated to dissuade them from sounding the alarm to the [congressional] oversight committee”); James A. Thurber, *Dynamics of Policy Subsystems*, in *INTEREST GROUP POLITICS* 319, 325–26 (Allan J. Cigler & Burdett A. Loomis eds., 3d ed. 1991) (describing the role of participants in “policy subsystems,” including interest groups, agencies, policy specialists, and the media, among others); see also *id.* at 332 (noting that, even when policy subsystems are competitive, they often involve repeat players who “try to keep final decisions out of the view of the public”).

187. Cf. Sharkey, *Federalism Accountability*, *supra* note 2, at 2158–63 (discussing the problem of who represents the state regulatory interests in tort preemption questions); *id.* at 2160 (noting that few states have agencies focused on food and drug safety that could represent state interests in tort preemption issues before the FDA).

Perhaps the best representative of state interests in maintaining tort suits against firms in a federally regulated industry would be trial lawyers who represent potential victims, as they have a significant financial incentive in the continued availability of tort suits. Trial lawyers who sue firms in a particular industry will be aware of the developing federal regulations affecting that industry and are likely to have contacts on the staff of the federal agency. One might object that private plaintiffs' lawyers are not the state and cannot be trusted to represent the states' interests. The extent to which this is troubling may reflect one's attitude toward federalism. If one believes that preemption threatens "abstract federalism" interests—state sovereignty interests that can keep the federal government in check—then this objection has bite.¹⁸⁸ But if one believes in federalism for its instrumental potential—to create a system of government that in a particular context leads to better substantive outcomes—then it may be that those who have an interest in the substantive outcome are better suited to represent state interests before the federal agency than state officials.¹⁸⁹

The final concern with my proposal to have agencies preempt by legislative rule stems from the standing and ripeness restrictions courts have imposed in suits directly challenging agency preemption.¹⁹⁰ If courts do not allow those opposing preemption to seek judicial review, then reliance on judicial review's ability to force agencies to deliberate about preemption rings hollow. This concern warrants more extended treatment than I can give it in this

188. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1941–42, 1978–79 (distinguishing abstract from instrumental federalist interests and explaining why they do not put much weight on abstract federalism interests).

189. The response of the National Conference of State Legislatures (NCSL) to a proposed preemption provision in a NHTSA rulemaking is illustrative of the problems of having state officials represent state interests in rulemakings addressing preemption of tort law. NHTSA proposed a rule governing automobile roofs' resistance to being crushed in rollover accidents. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223 (proposed August 23, 2005). NCSL comments simply asserted that NHTSA was usurping state authority to set tort standards and argued that NHTSA did not have authority to preempt state law on its own. Comment, Federal Motor Vehicle Safety Standards; Roof Crush Resistance, Docket No. NHTSA 2005-21243 (filed Dec. 14, 2005). The comments did not address whether the NHTSA rule was justified by the need for uniformity, the uncertainty that the rule would reasonably protect against unforeseen types of injury in case of rollovers, or any other factor that bears on the wisdom of the preemption provision.

190. See *Time Warner Entm't Co. v. FCC*, 56 F.3d 151, 194–96 (D.C. Cir. 1995) (holding that a statement of FCC regarding preemption of inconsistent law not ripe for review because the FCC statement did not resolve whether a state regulation would be preempted in any particular factual setting).

Article, but let me suggest several reasons to believe that these issues may not be insurmountable for my approach.

Most significantly, until recently, the issue of preemption was treated as one of statutory interpretation, not agency policy.¹⁹¹ As such, agency statements about preemption represented, at best, the informed interpretations of the agency. Such interpretations warrant some deference from courts but are not pronouncements with independent force of law.¹⁹² To put this in more concrete terms, under current preemption doctrine, when a victim of an injury from a product sues in state court, there is no guaranty that that court will find the suit preempted by the statute just because the agency opined that it is.¹⁹³ Under the proposed approach, an agency could preempt only by issuing a legislative rule which by definition has independent force of law. Hence, a state court would be obligated to follow the determination of the agency so long as the case fell within the bounds of the preemption specified in the agency rule.

This goes a long way toward curing any uncertainties regarding standing and ripeness. For instance, if the agency rule preempted tort suits already filed in state court, any plaintiff in such a suit would be directly and immediately affected by the rule and could seek a direct review. Conversely, if the rule only preempted suits not yet filed, then plaintiffs who suffered injury and could show that they were preparing to file a suit in state court would probably be able to meet standing and ripeness requirements because they could show that they were precluded by the rule from conduct in which they would have engaged: filing the suit. Finally, even if plaintiffs could not directly seek review of a preemption rule, state attorneys general would most likely be able to do so.¹⁹⁴ Espe-

191. See Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 Nw. U. L. REV. 695, 697–98 (2008) (noting that recently agencies have asserted the authority to preempt state law without explicit statutory authority, which has changed preemption analysis from one of statutory interpretation to one of legitimacy).

192. See *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (denying *Chevron* deference to agency interpretative rule); *United States v. Mead Corp.*, 533 U.S. 218, 219 (2001) (stating that an interpretation gets *Chevron* deference only when “Congress would expect the agency to be able to speak with the force of law”).

193. Cf. *NRDC v. EPA*, 559 F.3d 561, 564–65 (D.C. Cir. 2009) (generally a preamble to a rule is not ripe for review because it does not constitute binding agency action).

194. The fact that state attorneys general may not be the best entities to represent states’ interests early in a federal rulemaking proceeding involving tort preemption, cf. *supra* notes 116–18, 186–87 and accompanying text, does not imply

cially in light of *Massachusetts v. EPA*'s "special solicitude" for allowing states to sue federal regulators to protect the interests of their citizens,¹⁹⁵ it is difficult to argue that a state official responsible for the enforcement of state legal standards would not have an interest in a rule that would prevent courts in her state from addressing the appropriate standard of care.

C. Courts

Courts can play several roles in tort preemption depending on which institution is primarily responsible for deciding when preemption is appropriate. If one sees Congress as the primary body responsible for preemption, the courts' role essentially consists of interpreting statutes to determine when they call for preemption.¹⁹⁶ If instead one views the judiciary as the body best suited to determine when tort preemption is warranted, courts would have to evaluate whether a particular suit interferes with the object of federal regulation to an extent that it is counterproductive.¹⁹⁷

Courts are not well suited, either theoretically or pragmatically, to evaluate whether allowing tort suits will pose sufficient hurdles to federal regulation to justify preemption. Such an evaluation will not follow from precedent, or some definitive legal text on which

that they would not be good representatives of the state's interests to challenge a preemption rule. By the time the challenge occurs, the agency will have issued a final rule. At that point, the attorney general will be aware of the preemption rule and the challenges raised before the agency about the propriety of preemption, and the state will not be shortchanged because the attorney general will have entered the fray late.

195. *Massachusetts v. EPA*, 549 U.S. 497, 520 (2007).

196. Under this view, preemption can occur because of actual conflict between state and federal law—when conduct necessary to comply with state law would violate federal law—and where a statute manifests intent to displace state law within an area. Displacement can occur either implicitly, for example when a court determines that Congress intended a statute to occupy the entire regulatory field, or explicitly, when the statutory text states that it preempts state law. See Merrill, *Preemption*, *supra* note 3, at 730–32 (distinguishing preemption by "displacement" from that by "trumping"). Strictly speaking, tort law simply mandates that a producer pay for the harm its product causes. In theory, therefore, state tort law that imposes liability for complying with federal regulations does not render compliance with both state law and federal regulation impossible. Pragmatically however, tort law that imposed such liability could dissuade producers from conduct that the federal government has determined to be beneficial.

197. See Sharkey, *What Riegel Portends*, *supra* note 8, at 438. Courts currently do this under the rubric that state law is an obstacle to the objectives of a federal regulatory scheme. See *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); see also Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 228–29 & n.14 (2000) (describing obstacle preemption as a version of conflict preemption and collecting case cites).

the court can rely. Instead, courts will have to make value judgments of the kind better left to the politically accountable branches. Moreover, any judicial evaluation will not depend on skills that judges hone, such as parsing statutes or evaluating evidence to determine whether an event occurred or not. Rather, they will depend on understanding the significance of data about costs to producers and benefits to society that might flow from allowing tort suits. Courts will have to resolve questions about how well markets are likely to work to ensure that beneficial products are not forced out and detrimental ones not allowed to succeed. This in turn will depend on an evaluation of the value the public places on avoiding risks both posed by the product and by its absence from the market. It also requires an understanding of how producers are likely to react to post-market uncertainty posed by potential tort suits, how much remains unknown about future risks from the product, and a host of other fairly complex questions that fall into the realm of policy analysis.¹⁹⁸ If one adopts my suggestion that agencies be primarily responsible for preemption determinations, one must reject both Congress and the courts as primary arbiters of preemption. That rejection, however, still leaves some important roles for Congress and the courts. Congress still retains its role of agency oversight. As with any other agency regulation, Congress can statutorily override agency preemption if it can muster the political will to do so.

As for courts, federal courts will be responsible for direct review of preemption rules.¹⁹⁹ Aggressive review of an agency's reasoning is an important constraint against the pathologies that might otherwise afflict agency policy making and an important incentive to encourage more deliberative decision-making.²⁰⁰ Judicial review can slow down politically driven decisions that reflect fleeting public preferences or imperfections that cause the politically accountable branches to drift from goals that best serve the

198. I concede that courts may have an advantage with respect to one determination—the abstract value of maintaining a federal system. But this value is not likely to be of great significance given the current state of the world in which states remain viable political competitors to the federal government, thereby providing some potential protection against the threat of a future tyrannical federal government. Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1971–72, 1978.

199. The APA provides for any person adversely affected by final agency action to seek judicial review. 5 U.S.C. § 704 (2006).

200. Seidenfeld, *Cognitive Loafing*, *supra* note 157, at 512–22; *see also* Buzbee, *supra* note 2, at 1576–77 (arguing that hard look review of agency preemption decisions will foster transparency, accountability and deliberation).

national polity.²⁰¹ Judicial review is also crucial for encouraging agencies to incorporate staff members with expertise in the tort system into their preemption decision-making process.

Of particular significance, judicial review can force agencies to confront not only whether to preempt, but also the bounds of that preemption. For example, cost advantages of uniformity, and the potential perversities of having to comply with the strictest state standard may justify preemption of torts based on defective product design. Presumably an agency would have to have additional reasons, such as a market imperfection necessitating a subsidy for the product, in order to justify a blanket preemption of torts relating to the product. Hence, in this example, review would encourage the agency to allow torts based on faulty manufacturing. More generally, judicial review will prompt agencies to limit preemption to precise situations where it would not eliminate a producer's incentives to continue improving the safety of their products and where elimination of tort suits would provide a demonstrable social benefit.

In addition, courts (or more broadly state tort systems) will provide an avenue for continued deliberation about an agency preemption decision. Even after regulating, agencies retain authority to continue monitoring and revising their rules.²⁰² Post-regulatory marketing and use may reveal the extent to which a product creates a public benefit or poses a threat of injury and may allow a producer to develop data about the costs of taking further care to avoid injuries. Although agencies can amend their preemption rules more easily than Congress can amend statutes,²⁰³ agencies, unfortunately, do not have much incentive to continue monitoring injuries from a product once it has adopted a preemption rule. Tort plaintiffs' lawyers, however, do. State courts thus can play a role in keep-

201. Seidenfeld, *Why Agencies Act*, *supra* note 31, at 320 (concluding that reversal of NHTSA's passive restraint rule in 1972 allowed interested parties and the public to organize to stop the agency from imposing this and other aggressive auto safety regulations).

202. Agency authority to issue rules includes the authority to amend them once issued. 5 U.S.C. § 551(5) (2006) (defining "rule making" to include the process for amending a rule). One impediment, however, to agency rule revision with respect to particular products may be an absence of agency authority to require manufacturers to provide data on the safety of products after they are approved. See Peter Chang, *Reauthorization of PDUFA: An Exercise in Post-Market Drug Safety Reform*, 36 J.L. MED. & ETHICS 196, 196 (concluding that the latest iteration of the Prescription Drug User Fee Act "augments a [previously] feeble post-marketing drug safety regime").

203. Recall that the ability to act on a more continuous basis was one of the advantages of granting primacy on preemption to agencies rather than Congress. See *supra* notes 119-22 and accompanying text.

ing plaintiffs' attorneys active in monitoring producers even after an agency adopts a preemption rule. The question is how the plaintiffs' bar can play that role if the agency has preempted tort suits. The answer is the flexibility state courts have in determining the scope of preemption rules.

Because agencies will be discouraged from adopting blanket preemption rules, a state court will have the opportunity to determine the bounds of preemption in many cases before it. For example, consider the National Highway Traffic Safety Administration (NHTSA) notice of proposed rulemaking on the ability of automobile roofs to withstand rollover collisions, which includes the following provision:

[T]he agency believes that either a broad State performance requirement for greater levels of roof crush resistance or a narrower requirement mandating that increased roof strength be achieved by a particular specified means, would frustrate the agency's objectives by upsetting the balance between efforts to increase roof strength and reduce rollover propensity. . . . [I]f the proposal were adopted as a final rule, it would preempt all conflicting State common law requirements, including rules of tort law.²⁰⁴

Assume that NHTSA adopts the rule. Suppose further that a plaintiff injured in a rollover collision in which the roof fails to protect him discovers that the automobile he was driving was three times more likely than the average car to rollover in a crash. The plaintiff then sues claiming that the car design was defective because of this tendency to rollover rather than any problem with the roof.

Presumably, the defendant will move for dismissal, and the trial court will have to decide whether this suit is preempted by NHTSA's rule. The trial court could delay the determination of preemption until discovery occurs, allowing the parties to develop information relevant to whether the injury could be attributed to something other than a faulty roof. In this way, suits that might generate information relevant to the agency's preemption decision will not be entirely barred by the preemption rule.²⁰⁵ Moreover,

204. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,245–46 (proposed Aug. 23, 2005).

205. Courts would have the best information if they could delay any preemption determination until after plaintiffs have discovered information the producer has amassed about a product that has already gone to market. There is a catch-22, however, to a court waiting until after discovery to decide a preemption motion. Allowing a case to proceed to the discovery phase will encourage producers to

this information can be shared with the agency either informally in communications with agency staff, or more formally by a petition asking the agency to amend its preemption rule.²⁰⁶ Finally, if an agency that has already adopted a preemption rule is truly unresponsive to persuasive arguments that determinations should be revisited, those seeking to allow suits could go to Congress or the White House to pressure the agency to reconsider its position.

CONCLUSION

In many contexts, there are benefits that derive from maintaining state tort suits as a backup to federal regulation of nationally marketed goods or services. In other contexts, however, there are benefits to prohibiting such tort actions. Thus, the more interesting question than whether regulation or torts are best at setting standards of care is: Who should decide whether the standard should be set by regulation or tort? With respect to that question, the institutional advantages of agencies suggests that they are best suited to exercise primary responsibility to answer the question of whether tort suits should be preempted in specific contexts.

In order for society to reap the rewards of agencies' institutional advantages, however, courts should require that agencies use notice-and-comment rulemaking subject to hard look judicial review when making preemption determinations. Congress and the state courts also retain roles in determining preemption. Congress remains an overseer of the agency and can reverse an agency regarding preemption. State courts still have to decide particular tort cases, and therefore must rule on the bounds of regulatory preemption. Because state courts may have more recent and complete information about product risks than the agency did when it issued its preemption rule, state judges should use their decisions about the bounds of preemption to update agencies about such risks.

settle on terms that allow them to keep trade secrets or embarrassing information secret. This in turn could keep hidden the very information the court hoped to obtain by delaying the preemption determination until after discovery. *See* McGARITY & WAGNER, *supra* note 79.

206. 5 U.S.C. § 553(e) (2006).

