

# Preemption Hard Look Review, Regulatory Interaction, and the Quest for Stewardship and Intergenerational Equity

William W. Buzbee\*

## *Abstract*

*Current debates over federalism, especially preemption, center on the merits of legal structures that rely on a sole or preemptive federal regulator versus strategies that retain roles for multiple regulatory actors, especially federal, state, and local actors sharing concurrent and interacting authority. Given that most regulatory regimes identify among their express purposes the preservation of resources, the environment, or health, which sort of regulatory regime—preemptive or concurrent and interactive—is most likely to further such stewardship, sustainability, and intergenerational equity goals? Such public-regarding goals confront political economic incentives and behavioral tendencies of political, legal, and business actors to seek immediate rewards and neglect longer-term perspectives and concerns. Preemption battles in political, regulatory, and judicial venues typically are a manifestation of this clash between longer-term protective goals and anti-regulatory preferences of industry and sometimes political and regulatory officials. In recent years, in a major change in prevailing federal governmental policy, many agencies and industries claimed that agency actions have broad preemptive impact on state and local regulatory powers and common law regimes, but these claims usually followed no advance opportunities for comment or open, reasoned agency decisionmaking.*

*This Article focuses upon a much neglected aspect of judicial review of preemption claims: How should courts review the factual and policy underpinnings of claims that federal regulatory actions should preempt? Through analysis of federalism and preemption jurisprudence, as well as central administrative law doctrine that rewards transparency, accountability, and constrained discretion, this Article argues that courts should explicitly embrace “preemption hard look review.” Courts should subject agency claims of preemptive power and effect to close analysis to see if such an outcome is well*

---

\* Professor of Law, Emory University School of Law; Director, Emory Environmental and Natural Resources Law Program; Director, Emory Center on Federalism and Intersystemic Governance; Member-scholar, The Center for Progressive Reform. This Article is an outgrowth of comments at a conference on Intergenerational Equity, sponsored by *The George Washington Law Review* on October 23–24, 2008. The author thanks his colleague Robert Schapiro for input into this and related publications and his colleagues affiliated with the Center for Progressive Reform for their participation in numerous discussions and papers that influenced this Article. The author also thanks research assistants Jeff Kerr, Adam Masarek, and Rob Ellis, fellow conference panelists Matthew Adler, Jamison Colburn, and Douglas Kysar, and student organizer and facilitator Jaclyn Nicole Lasaracina.

*justified by underlying facts and policy claims, but grant agencies greater policymaking latitude where they assert such power following transparent and participatory regulatory process resulting in well reasoned justifications. Explicit judicial embrace of preemption hard look review would constitute, at most, only a modest shift in preemption jurisprudence, but would further important federalism and administrative law values. By prodding agencies to make preemption claims in an open, transparent and participatory manner, such rigorous hard look review would also improve the odds that agency actions would be consistent with express public-regarding purposes in most laws, and thus would be likely to further stewardship, sustainability, and intergenerational equity goals.*

### *Table of Contents*

Introduction .....	1522
I. Stewardship, Intergenerational Equity, and Political Rejection of a Unitary Regulator .....	1530
A. Tendencies in Markets and Politics to Value Immediate Rewards .....	1531
B. The “One Versus the Many” in Protecting Distant Interests: The Long-Dominant Concurrent Regulation Norm .....	1541
II. The New Aggressive Face of Preemption .....	1547
III. The Doctrinal Case for Preemption Hard Look Review .....	1553
A. Distinguishing Law Interpretation from Factual and Policy Judgments in Agency Assertions of Preemptive Effect .....	1553
B. Precedents Regarding Review of the Factual and Policy Predicates for Agency Preemption Claims ...	1557
IV. Linking Preemption Hard Look Review, Interaction’s Benefits, and Stewardship Goals .....	1576
Conclusion .....	1580

### *Introduction*

If one assumes a goal of preserving a resource for future generations’ use, what sorts of institutional arrangements are likely to overcome political and market tendencies to value inordinately present or near-future rewards? The idea that actors in politics and markets should wisely use resources is widely shared in literature on sustainability, stewardship, and in this particular conference, intergenera-

tional equity.<sup>1</sup> Assuming a goal to regulate risk and protect the environment or health for future generations, this Article offers a preliminary comparative evaluation of regulatory strategies relying on a sole or preemptive regulator versus strategies that retain roles for multiple regulatory actors, particularly those with concurrent and interacting authority.<sup>2</sup> Especially with problems like climate change that are now the subject of fundamental regulatory architecture and institutional design choices, the question of unitary preemptive structures versus concurrent and interactive structures is a critical one.

After reviewing the many reasons actors in politics, law, and business will have proclivities to value the present over the future, this Article turns to analysis of how regulatory interaction has been the norm embraced in decades of law and regulation. The Article then reviews newly increased assertions of preemptive power and effect in areas of risk regulation by agencies and sometimes in legislation.<sup>3</sup>

---

<sup>1</sup> See, e.g., Michael Doran, *Intergenerational Equity in Fiscal Policy Reform*, 61 TAX L. REV. 241, 260–70 (2008); Douglas A. Kysar, *Discounting . . . on Stilts*, 74 U. CHI. L. REV. 119, 126–28 (2007) (critiquing embrace of cost-benefit analysis and discounting and discussing prevalence of view among scientists that concerted effort and change from current practices is necessary to preserve the earth); Charles Pouncy, *Economic Theory and the Road to Sustainable Development*, 2 INTERCULTURAL HUM. RTS. L. REV. 137 (2006); Cass R. Sunstein & Arden Rowell, *On Discounting Regulatory Benefits: Risk, Money, and Intergenerational Equity*, 74 U. CHI. L. REV. 171, 200–05 (2007) (reviewing scholarship of John Rawls, Robert Solow, and others advocating preservation of resources for future generations under concepts of justice and sustainability); James C. Wood, *Intergenerational Equity and Climate Change*, 8 GEO. INT'L ENVTL. L. REV. 293, 321–32 (1996).

<sup>2</sup> This paper takes as its starting point the widely shared view that some sensitivity to and concern for the well being of future generations is desirable. This can be rooted in a goal of stewardship of resources or perhaps concerns with intergenerational equity. It leaves to others at this conference exploration of when and to what extent current actors should consume resources versus preserve them for the future. See, e.g., Neil Buchanan, *What Do We Owe Future Generations?*, 77 GEO. WASH. L. REV. 101 (2009).

<sup>3</sup> See, e.g., William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1559–76 (2007) [hereinafter Buzbee, *Asymmetrical Regulation*]; William W. Buzbee, *Interaction's Promise: Preemption Policy Shifts, Risk Regulation, and Experimentalism Lessons*, 57 EMORY L.J. 145, 145–46 (2007); Robert L. Glicksman & Richard E. Levy, *A Collective Action Perspective on Ceiling Preemption by Federal Environmental Regulation: The Case of Global Climate Change*, 102 NW. U. L. REV. 579, 585–90 (2008) (using collective action theory to argue against the use of regulatory ceilings in legislation aimed at limiting greenhouse gases from stationary sources); David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 462–69, 495 (2008) (describing and critiquing legality and wisdom of FDA assertions of preemptive power under the Federal Food, Drug, and Cosmetic Act); Nina A. Mendelson, *The California Greenhouse Gas Waiver Decision and Agency Interpretation: A Response to Professors Galle and Seidenfeld*, 57 DUKE L.J. 2157, 2174 (2008) (arguing that court should review agency assertions of preemptive power with *Skidmore*—rather than *Chevron*—deference and that Congress and the Court may be better at making preemption decisions than agencies); Nina A. Mendel-

Many have looked at agency assertions of preemptive power and focused on the question of statutory authority, especially analyzing how much deference, if any, agencies should receive when they interpret their enabling legislation to justify a claim of preemptive power and impact.<sup>4</sup>

These recent analyses link to this Article's focus on the relative benefits of exclusive versus concurrent and interactive modes of regulation, but this essay turns to a far less analyzed facet of these debates over preemption claims. When an agency claims it has power to preempt, part of that claim necessarily concerns statutory power. But that is only part of the analysis. An agency also has to justify that choice with reference to real world claims about the effects of current arrangements and policy impacts of any proposed change.<sup>5</sup>

Where an agency's regulatory judgment turns on matters of policy judgment and fact claimed to justify displacement of states' political and legal powers, especially a high-stakes judgment reversing previous agency positions, a different judicial reviewing framework

---

son, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 706–25 (2008) [hereinafter Mendelson, *Presumption*] (arguing that courts should recognize a presumption against agency preemption since agencies lack the institutional competence and statutory guidance required to make informed choices on questions of state autonomy); Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 227–29 (2007) [hereinafter Sharkey, *Preemption by Preamble*] (discussing federal agencies' assertion of preemptive effect, often in regulatory preambles); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 521 (2008) [hereinafter Sharkey, *Products Liability Preemption*] (advocating an “agency reference model” as a middle way between the anti-preemption “presumption against preemption” and the pro-preemption method of providing *Chevron* deference to preemption decisions); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 102 NW. U. L. REV. 415, 416–27 (2008) [hereinafter Sharkey, *What Riegel Portends*] (articulating a framework for judging preemption claims in “implied conflict preemption” cases and arguing that courts should focus on whether an agency has considered the precise risks that state law would help to reduce).

<sup>4</sup> See, e.g., Brian Galle & Mark Seidenfeld, *Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 1935–41 (2008); Mendelson, *Presumption*, *supra* note 3, at 706–25; Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 759–79 (2008).

<sup>5</sup> Professor Merrill suggests that agency preemption claims involve (a) questions of federal statutory meaning; and (b) questions of state law's effects. Merrill, *supra* note 4, at 741–44. As explored further below, I agree with his analysis as far as it goes but suggest that there are broader empirical fact claims underlying many preemption assertions. Furthermore, as also explored below, I suggest that thinking about preemption involves questions not just about who has the power to make preemption decisions and under what standard of review, but also involves a judgment about *how* regulatory judgments are to be made and reexamined. Is the regulatory action one that should remain rigidly in place once set, or one that would benefit from interaction or at least diverse regulatory judgments about means and ends?

should be triggered.<sup>6</sup> This Article argues that policy and factual judgments underpinning preemption claims should be given a “hard look.” Indeed, when one looks at the rationales for more rigorous modes of judicial review, virtually all are triggered by these recent agency preemption claims. They usually involve a reversal of policy and run counter to the Supreme Court’s long-stated (but spottily observed) “presumption against preemption.” Such actions inherently impinge on and supplant an area of previous state regulatory turf, sometimes leaving injured individuals remediless. And the claims themselves hinge on contestable facts about harmful economic impacts or other inefficiencies of overlapping and interactive modes of regulation. Both due to the federalism setting of these impingements and the fundamentally empirical nature of these claims, they should not be accepted merely based on agency assertions of such effects. Agencies should offer opportunities for public input, provide supporting proof, and confront contrary data and arguments. This proposed rigorous review and burden of explanation would also further broader constitutionally rooted interests in retaining structures and procedures that check executive power and arbitrariness, and in not lightly displacing state legal systems.

Others have shown how case law leaves latitude for rigorous review, although the precedents do not speak in terms of “hard look.”<sup>7</sup> This Article provides additional doctrinal support and more directly explores the normative and political economic rationales justifying what I will refer to as “preemption hard look review.” As with other areas of hard look review, its requirements are in reality directed both to agencies and reviewing courts.<sup>8</sup> Agencies must show they have

---

<sup>6</sup> For recent articles seeing scrutiny of an agency’s factual and policy basis for a preemption claim as distinct from questions of statutory authority, and calling for rigorous review of such claims, see David J. Barron, *From Takeover to Merger: Reforming Administrative Law in an Age of Agency Politicization*, 76 GEO. WASH. L. REV. 1095, 1148 (2008) (calling for “expertise-forcing” modes of judicial review of agency claims of preemptive impact to deter excessive influence of political considerations); Galle & Seidenfeld, *supra* note 4, at 2013–15 (2008) (discussing benefits of hard look review in context of preemption assertions); Karen A. Jordan, *Agency Preemption and the Shimer Analysis: Unmasking Strategic Characterization by Agencies and Giving Effect to the Presumption Against Preemption*, 2008 WIS. L. REV. 69, 116–34 (2008) (focusing on FDA preemption claims and arguing latitude exists under Supreme Court cases involving the FDA and other agencies for courts to review agency preemption claims in a rigorous way akin to “hard look review”).

<sup>7</sup> See Jordan, *supra* note 6; see also *infra* Part III.B (setting forth the doctrinal arguments for preemption hard look review).

<sup>8</sup> Nat’l Lime Ass’n v. EPA, 627 F.2d 416, 451 & n.126 (D.C. Cir. 1980) (discussing the roots of hard look review and noting its shift from a description of agency obligations to a mode of judicial scrutiny).

taken a hard look at salient issues, and courts reviewing those judgments must take their own hard look at the agencies' decisions.<sup>9</sup>

As with all standards of review, the rigor or deference inherent in the proposed standard serves instrumental and normative ends. In this particular area, the applicable standard of review to be applied by courts and the process required of agencies are not mandated by statute, preordained by anything in the Constitution or the Administrative Procedure Act.<sup>10</sup> Furthermore, although an array of precedents reviewed here support application of preemption hard look review, no precedents at this point explicitly either mandate or preclude courts from engaging in preemption hard look review. But even if a case were viewed as establishing a prevailing standard of review, standard-of-review frameworks regularly adjust and evolve with experience and in light of competing policy claims.<sup>11</sup>

This Article's call for preemption hard look review links directly to its analysis of preemptive and interactive modes of regulation and their effects on stewardship and intergenerational equity goals. The same structural arrangements that tempt all to sacrifice the future for current consumption also influence executive agencies. Presidents may be the most directly accountable of actors in the three branches, or at least more accountable than courts, as the Supreme Court stated in support of its deferential *Chevron* framework.<sup>12</sup> And it is too simplistic to say that legislators, due to their standing for election, are

---

<sup>9</sup> *Id.*

<sup>10</sup> Administrative Procedure Act, 5 U.S.C. §§ 551–559 (2006).

<sup>11</sup> For example, the *Chevron* case, *Chevron U.S.A. v. Natural Resource Defense Council, Inc.*, 467 U.S. 837 (1984), created a prevailing framework that itself engendered debate in the courts and among scholars, leading to a seemingly endless stream of refinements and clarifications that typically are explicitly rooted in normative aims for the political branches and courts. See William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from Chevron to Hamdan*, 96 GEO. L.J. 1083, 1090 (2008) (arguing that since *Chevron*, the Supreme Court has applied not one single, consistent standard, but rather a “continuum of deference” in evaluating agency statutory interpretations, in which *Chevron* was applied in only eight percent of such cases, and has co-existed alongside deference regimes established by other cases (*italics omitted*)); Kristin E. Hickman & Matthew D. Krueger, *In Search of the Modern Skidmore Standard*, 107 COLUM. L. REV. 1235, 1237 (2007) (noting that *United States v. Mead* reasserted a form of deference comparable to that which was first established in *Skidmore v. Swift & Co.*); Eric R. Womack, *Into the Third Era of Administrative Law: An Empirical Study of the Supreme Court's Retreat from Chevron Principles in United States v. Mead*, 107 DICK. L. REV. 289, 290 (2002) (noting the “dramatic” shift in agency deference standards brought about by *United States v. Mead*); *infra*, notes 131–50 and accompanying text (reviewing scholarly debate over the applicability of *Chevron* deference to agency preemption claims).

<sup>12</sup> *Chevron*, 467 U.S. at 865–66 (emphasizing political accountability of the executive branch and lack of similar accountability of courts).

necessarily more accountable than agencies. As Professors Stewart, Mashaw, Schuck and, more recently, Galle and Seidenfeld argue, agencies' obligations to be transparent, seek input, explain decisions, compile a record, and justify actions before the courts all make agencies quite accountable in their own way.<sup>13</sup> But the executive branch at all levels of government is still susceptible to political and interest group entreaties for broadened federal preemption in exchange for immediate electoral or monetary benefit.<sup>14</sup> During a period of increasingly interventionist and politicized control of agencies by presidents,<sup>15</sup> entreaties to the President and other high officers outside of particular agencies heightens the risk of highly politicized but low-visibility presidential pressure.<sup>16</sup> Interest group and regulatory target entreaties for federal preemption are, by their nature, antiregulatory pleas.<sup>17</sup> Subjecting assertions of preemptive power and effect to judicial scrutiny and imposing a correlative burden of justification on executive agencies will reduce the likelihood of politicized agency

---

<sup>13</sup> See Galle & Seidenfeld, *supra* note 4, at 1954–60, 1979–83; Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 95–99 (1985) (countering argument that legislatures are necessarily more accountable than agencies by highlighting the visible and judicially accountable means by which agencies work); Peter H. Schuck, *Delegation and Democracy: Comments on David Schoenbrod*, 20 CARDOZO L. REV. 775, 776 (1999) (disagreeing with call for a revived nondelegation doctrine and arguing that agencies “instantiate the often competing values of democratic participation, political accountability, legal regularity, and administrative effectiveness”); Richard B. Stewart, *Beyond Delegation Doctrine*, 36 AM. U. L. REV. 323, 324 (1987) (arguing against reviving the nondelegation doctrine due both to its lack of “judicially manageable and defensible criteria to distinguish permissible from impermissible delegations” and to the belief that “unsound and less responsible government” would result from more detailed legislative enactments).

<sup>14</sup> See, e.g., MAJORITY STAFF OF H.R. COMM. ON OVERSIGHT & GOV'T REFORM, 110TH CONG., FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES i–ii (Comm. Print 2008) [hereinafter MAJORITY STAFF] (recounting clash between career FDA staff who opposed as unsound and inaccurate claims underlying newly pro-preemption views embraced by FDA during the Bush Administration, and political appointees who advocated stronger pro-preemption views in ways sought by regulated industry).

<sup>15</sup> See Barron, *supra* note 6, at 1096; Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 49–52 (2006); Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2246–50 (2001); Peter L. Strauss, *Overseer, or “The Decider”? The President in Administrative Law*, 75 GEO. WASH. L. REV. 696, 719 (2007).

<sup>16</sup> See Barron, *supra* note 6 (discussing politicization and centralization of presidential authority over agencies and discussing associated risks); Bressman & Vandenbergh, *supra* note 15 at 92–94 (discussing politicization of EPA and its implications).

<sup>17</sup> Ernest A. Young, *Federal Preemption and State Autonomy*, in *FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS* 249, 263 (Richard A. Epstein & Michael S. Greve eds., 2007).

decisionmaking and further accountability goals by channeling deliberation into quasi-democratic agency procedures.<sup>18</sup>

Hard look review serves as a powerful antidote to politicized agency decisionmaking because, by its nature, hard look review means that courts engage in intrusive review to ensure that executive agencies themselves have taken a hard look at their decision's implications and have a basis for their preemptive power claims. Furthermore, the prong of hard look review that looks for agency responses to criticisms and salient challenges would be suitable here, but in a slightly modified form. Drawing on analysis of nuances of language in foundational standard of review cases, and embracing the "metademocratic" ends served, this Article argues that the rigor of review should have an inverse relationship with the amount of political transparency, input, and responsiveness demonstrated by the agency asserting a preemptive impact.<sup>19</sup>

As discussed below, the Supreme Court's recent *Wyeth v. Levine*<sup>20</sup> decision took such an approach, declining to defer to the Food and Drug Administration's ("FDA's") pro-preemption views due to the lack of preceding process or in depth explanation. Much as the degree of deference afforded agency law interpretation hinges in part on the process preceding that interpretation, agency preemption claims lacking a transparent and open process and express revelation of preemptive intent should be reviewed with especial rigor. Preemption hard look review should be especially sensitive to agency consideration of states' sovereign interests and state views about potential preemption. Conversely, where an agency ultimately decides to take preemptive action following full, open, and responsive process, courts should afford that agency judgment greater latitude. After all, the choice to preempt is often rife with uncertainty and politically influenced judgments.

This approach would constitute a modest adjustment to hard look review for preemptive actions but is consistent with a growing doctri-

---

<sup>18</sup> See Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 5 (1998) (describing public interest theory assumption that public scrutiny correlates with public-regarding outcomes).

<sup>19</sup> Professor Schacter notes a pervasive judicial tendency to utilize reviewing frameworks to further various democratic values and goals. See Jane S. Schacter, *Metademocracy: The Changing Structure of Legitimacy in Statutory Interpretation*, 108 HARV. L. REV. 593, 595 (1995) (dubbing judicial statutory interpretation frameworks, which are often "self-consciously designed to produce 'democratizing' effects," as "metademocratic" because they are designed not only to resolve a particular case but also to advance a "larger democratic project").

<sup>20</sup> *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).



nal trend and several other scholars' embrace of a sliding scale of review that adjusts depending on the amount of process and transparency preceding the scrutinized judgment.<sup>21</sup> Such sliding scale review would create strong incentives for agencies to assert preemptive power not unilaterally, but rather through, at the very least, the interactions forced by notice and opportunity for stakeholder and public comment. Simple assertions of preemptive impact without any process or vetting of claims of harms of non-preemptive regimes would readily founder under the suggested form of hard look scrutiny.

Preemption hard look review in the risk-regulation context thus would both constitute and foster regulatory interaction, which in turn would help preserve resources and health. The rigor of the review would raise the bar for agency power assertions that would shift regulation from the norm of multiple, interacting regulators to a single actor with unilateral power. It would thus be likely to preserve concurrent power regimes. The mode of review would itself constitute an interactive regulatory one, with courts both forcing agencies to interact with stakeholders and states and also scrutinizing agencies' proffered justifications for their preemption power.

The very opening up of the decisionmaking power to public and judicial scrutiny, as well as greater internal agency deliberation over its claim, would serve as a counter to executive capitulation to demands for lax regulation for immediate industry or interest group benefit. Mere interaction cannot guarantee sensitivity to the interests of future generations. As with analyses undertaken pursuant to the National Environmental Policy Act,<sup>22</sup> the risk of empty words is real.<sup>23</sup> Nevertheless, the scrutiny that comes with such interaction and heightened burdens of justification would make resource and health preservation more likely than would ready acceptance of preemptive

---

21 See, e.g., Eskridge & Baer, *supra* note 11, at 1179–80; Galle & Seidenfeld, *supra* note 4, at 1997; Kagan, *supra* note 15, at 2380–82 (arguing courts should show greater deference to executive actions where the President has actually been involved but acknowledging contrary case law and arguing that a doctrinally sound variant of deference frameworks would show greater deference where executive branch actors “disclose publicly and in advance” their planned involvement in order to receive “judicial credit”); Ernest A. Young, *Executive Preemption*, 102 Nw. U. L. REV. 869, 899–900 (2008) (arguing that “the most authoritative agency actions” should be those that use participatory, deliberative procedures and that actions lacking such procedures should be found legally wanting because upholding them would “disembowel the notion of process federalism entirely”).

22 National Environmental Policy Act, 42 U.S.C. §§ 4321–4347 (2006).

23 See Joseph L. Sax, *The (Unhappy) Truth About NEPA*, 26 OKLA. L. REV. 239, 248 (1973).

power claims based merely on statutory-language analysis and power assertions by fiat.<sup>24</sup>

Part I discusses strong individual, political and economic incentives for people and institutions to value the present, disregarding more distant and less personal interests. It also explains that the prevalent choice of political institutions is to retain multiple regulators, including the common law, with each possessing independent authority to address risk. Part II reviews the shift in federal policy, which began around 2005, toward agencies more aggressively asserting that their actions preempt, and therefore displace, state regulatory and common law regimes. Part III assesses the doctrinal basis for judicial hard look review of agency claims of preemptive power and effect. It concludes that despite the lack of explicit embrace of preemption hard look review in case law, agency claims of preemptive power and effect satisfy all of the major criteria for subjecting agency action to hard look review. The recent *Wyeth v. Levine* decision's approach, while not using the phrase "hard look review," is especially consistent with the mode of review suggested here. Part IV analyzes preemption hard look review through an instrumental and normative lens, showing how such rigorous review would further quasi-democratic values, would allow the benefits of regulatory interaction, and ultimately would enhance the probability of public-regarding government actions in the interest of future generations.

### *I. Stewardship, Intergenerational Equity, and Political Rejection of a Unitary Regulator*

Efforts to protect the environment, health, and reduce risk, whether through environmental laws, workplace health and safety laws, regulation of product risks, or common law regimes, all confront strong individual and political economic tendencies to value inordinately the present over the future. In markets, politics, law, and legal implementation by agencies, a major challenge is to create institutional arrangements that will foster longer-term benefits and encourage stewardship of resources. Such stewardship would preserve resources for diverse short-term uses and the benefit of distant generations. With thorny regulatory challenges like climate change that involve massive risks that are dispersed over many nations and people,

---

<sup>24</sup> Cf. Jonathan R. Macey, *Promoting Public-Regarding Legislation Through Statutory Interpretation: An Interest Group Model*, 86 COLUM. L. REV. 223, 224–27, 264–66 (1986) (deriving theory that despite private bargains underlying much legislation, courts should enforce the publicly declared public-regarding purposes).

and will become manifest gradually over many years, fostering actors' attention and long-term perspective is an especially difficult challenge. This part examines tendencies to focus on immediate benefits, then turns to the choice of a single regulator versus a setting where more than one regulator shares responsibility. The long-enduring norm in risk, product, and environmental regulation has been rejection of unitary regulator schemes and embrace of concurrent, overlapping, and cooperative modes of regulation retaining roles for multiple actors.

*A. Tendencies in Markets and Politics to Value Immediate Rewards*

For privately owned property or businesses, a private actor has incentives to use its own resources wisely, which ideally leads to resource stewardship. However, if the property or business owner can export harms or risks to others without paying for them or being subjected to regulatory constraints, then such externalized costs will be overproduced.<sup>25</sup> Numerous other variables also undercut the ideal of coinciding private and public interests in resource use: risks and harms can arise from causes that cannot be traced, victims face many uncertainties in courts, victims confront high transaction costs in seeking regulatory relief or recompense, and agencies often underenforce regulatory regimes.<sup>26</sup> Furthermore, the more distant the harm or risk, the more the risk-creators will discount that risk and invest less today to avoid the risk.<sup>27</sup> Similarly, where that risk will be manifested many years down the road, especially in distant locations, such distant risks and harms will also be weighed less seriously by possible future victims.

Where a resource is shared, especially where it is a public good held in common, individual resource use decisions frequently confront the tragedy of the commons dynamic.<sup>28</sup> As long as resource extraction or use benefits inhere to an individual in an undivided way, and costs of that use or extraction are divided among many, all individuals will have rational incentives to continue using a resource even if the aggre-

---

<sup>25</sup> See EBAN S. GOODSTEIN, *ECONOMICS AND THE ENVIRONMENT* 32–33 (4th ed. 1995) (discussing the concept of negative externalities and how externalized harms will be overproduced).

<sup>26</sup> See ROBERT L. GLICKSMAN ET AL., *ENVIRONMENTAL PROTECTION: LAW AND POLICY* 11–15 (5th ed. 2007).

<sup>27</sup> Of course, how much one should or should not discount a risk or benefit is itself a subject of great interest. A recent University of Chicago conference focused exclusively on that question. See Symposium, *Intergenerational Equity and Discounting*, 74 U. CHI. L. REV. 1 (2007). Several conference articles are cited, *supra* note 1.

<sup>28</sup> See Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243, 1244 (1968).

gate impact is to despoil it. Cattle land will be grazed too intensively, fish stocks will be depleted, and greenhouse gases will be produced despite the collective harms they cause. As Garrett Hardin and others since have refined, the challenge is to devise countervailing structures fostering a more inclusive and sustainable perspective. But to get collective embrace of any solution—usually some variant on allocation of property rights, taxes, coercive mandates, or engendering of broader shared community norms and awareness—requires the very collective action that is lacking and creates the tragedy of the commons.<sup>29</sup>

The pathbreaking cognitive psychology work of Kahneman and Tversky, as well as subsequent related work by others in the field now broadly characterized as behavioral economics (or behavioral law and economics), similarly reveals how people tend to value the present inordinately and fail to think through the implications of more distant events, be they benefits or harms.<sup>30</sup> Status quo arrangements and recent information tend to be favored or weighed more heavily over what should be equally or more attractive alternative courses of action.<sup>31</sup> Thus, legal or regulatory interventions asking people to change their ordinary ways of acting and give up something they have, especially for more distant benefits or to avoid future risks (especially if borne by others), will tend to meet with resistance.<sup>32</sup>

Where the cause and effect linkages are not observable and intuitively obvious, especially where complex interactions and changes make the actual effects unknowable, then cognitive failures are especially likely. Professor Lazarus notes that climate change's many uncertainties and time and physical distances between pollution sources and harms create a "far more evil" "unavailability heuristic" than the usual "availability heuristic."<sup>33</sup> Attachment to the known status quo and difficulty in envisioning a distant, complicated future with harms that are hard to predict with precision is a recipe for inaction.<sup>34</sup> Asking individuals in their personal behavior, or actors in markets, polit-

---

<sup>29</sup> James E. Krier, *The Tragedy of the Commons, Part Two*, 15 HARV. J.L. & PUB. POL'Y 325, 335 (1992).

<sup>30</sup> See generally JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES (Daniel Kahneman et al. eds., 1982); Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCI. 1124 (1974).

<sup>31</sup> See Jeffrey J. Rachlinski, *The Psychology of Global Climate Change*, 2000 ILL. L. REV. 299, 307–11 (2000) (discussing "loss aversion" and "status quo bias").

<sup>32</sup> See *id.*

<sup>33</sup> Richard Lazarus, *Super Wicked Problems and Climate Change: Restraining the Present to Liberate the Future*, 94 CORNELL L. REV. (forthcoming 2009) (manuscript at 25).

<sup>34</sup> *Id.*

ics, or regulation, to forbear more immediate self-gratification for distant rewards, or even rewards to generations unborn, especially where linkages are not intuitively understood, is asking them to behave in ways counter to deeply engrained, psychologically rooted behavioral patterns.<sup>35</sup>

Business and economics literature, especially studies of corporate executives' incentives, shows that they behave similarly, likely due to a combination of economic incentives and cognitive shortcomings. Managers tend to seek positive business news for short business cycles to gain immediate profit and find favor in the market and with their boards.<sup>36</sup> A common criticism of business leadership and market players concerns failure to think longer-term.<sup>37</sup> Few companies benefit from forbearance, and more distant and possibly monetarily unrewarding consideration of future generations or environmental health will seldom yield commensurate market benefits.<sup>38</sup> A company's long-term economic health may itself be neglected due to managers' focus on short-term performance benchmarks. It is even less likely that corporate decisionmakers will weigh heavily risks or harms to others that are unlikely to be imposed on the corporation, or where those harms are many years into the future and uncertain.<sup>39</sup>

---

<sup>35</sup> Elinor Ostrom's work is perhaps the most optimistic counter to this summary of proclivities. She has shown how in smaller, usually more homogenous communities, resources can be preserved for collective good despite individual incentives. See ELINOR OSTROM, *GOVERNING THE COMMONS* 58–102 (1991).

<sup>36</sup> Ronald O. Cox, *Marketing Issues*, 43 J. MARKETING, Summer 1979, at 111 ("Company managements are under pressure to take the short-term gamble. . . . The need for good 'numbers' is powerful because increased sales and profits will help push the stock price up and keep top management fairly happy.").

<sup>37</sup> See Lisa M. Fairfax, *Achieving the Double Bottom Line: A Framework for Corporations Seeking to Deliver Profits and Public Services*, 9 STAN. J.L. BUS. & FIN. 199, 228 (2004) (observing how "capital markets may represent a powerful external force pressuring directors and officers to focus on profits," obliging them to focus on "issues of short-term profit and financial viability"); see also ASSOCIATION OF CHARTERED CERTIFIED ACCOUNTANTS, *CLIMBING OUT OF THE CREDIT CRUNCH* 4 (2008) (criticizing prevailing corporate governance strategies for failing to consider adequately "the best interests of long-term shareholders"); Cox, *supra* note 36, at 111; see generally LOUIS LOWENSTEIN, *WHAT'S WRONG WITH WALL STREET: SHORT-TERM GAIN AND THE ABSENTEE SHAREHOLDER* (1988) (questioning various aspects of financial markets' structures and practices).

<sup>38</sup> See Richard MacLean, *Avoiding "Chicken Little" Syndrome*, ENVTL. QUALITY MGMT., Fall 2008, at 101–05 (analyzing oil industry's lack of consideration of long-term environmental harm because of its inconsistency with opportunity for short-term economic gain).

<sup>39</sup> *Id.*; Andrew G. Oliver, *Can Sustainable Development and the Market Co-Exist?* 8 CORP. ENVTL. STRATEGY 24, 24–29 (2001) (arguing sustainable development must provide measurable short-term benefits to companies for them to embrace environmental conscientiousness).

As Professors Heinzerling, Ackerman, Wagner, and Kysar have shown, regulatory discounting in the setting of cost-benefit analysis can make quite substantial future benefits or harms fade into insignificance.<sup>40</sup> Different modes of regulatory analysis and discounting can lead to huge disparities in policy prescriptions.<sup>41</sup> In addition, a company that decides to be more protective of the environment, workers, or consumers than its competitors will often fear loss of competitiveness due to decreased profits and market value; some evidence, however, suggests that environmental performance and value can coincide.<sup>42</sup> Nevertheless, the socially sensitive corporation that invests in social welfare to its own detriment risks being weeded out by market forces.

The same holds true in examining political and legal actors.<sup>43</sup> For politicians sensitive to electoral cycles, the focus is often on short-term meeting of interest group demands in ways inuring to the politicians' credit.<sup>44</sup> Where a choice exists, policies that provide immediate monetary and employment benefits are likely to be far more politically rewarding than distant or speculative protection of resources like domestic wetlands or endangered species or of other nations that are especially vulnerable to climate change.<sup>45</sup>

---

<sup>40</sup> Lisa Heinzerling & Frank Ackerman, *Law and Economics for a Warming World*, 1 HARV. L. & POL'Y REV. 331, 349–53 (2007); Kysar, *supra* note 1, at 119; Wendy Wagner & Lynn Blais, *Children's Health and Environmental Exposure Risks: Information Gaps, Scientific Uncertainty, and Regulatory Reform*, 17 DUKE ENVTL. L. & POL'Y F. 249, 249–50 (2007).

<sup>41</sup> Daniel A. Farber, *Rethinking the Role of Cost-Benefit Analysis* 30 & nn.113–15 (U.C. Berkeley School of Law Public Law Research, Working Paper No. 1324388, 2009), available at <http://ssrn.com/abstract=1324388> (reviewing RICHARD L. REVESZ & MICHAEL A. LIVERMORE, *RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH* (2008), and citing articles from a 2007 *University of Chicago Law Review* symposium).

<sup>42</sup> At least one much-cited study indicates that environmental improvements and investments often accompany strong corporate performance, not poor market performance. Michael E. Porter & Claas van der Linde, *Green and Competitive: Ending the Stalemate*, HARV. BUS. REV., Sept.–Oct. 1995, at 120–21.

<sup>43</sup> Eric A. Posner, *Agencies Should Ignore Distant-Future Generations*, 74 U. CHI. L. REV. 139, 141 (2007) (asserting that “Congress and the president will support policies that benefit non-voting future generations only to the extent that they are supported by voting members of the current generation”).

<sup>44</sup> See William M. Landes & Richard A. Posner, *The Independent Judiciary in an Interest-Group Perspective*, 18 J.L. & ECON. 875, 877 (1975) (“[L]egislation is supplied to groups or coalitions that outbid rival seekers of favorable legislation. . . . Payment takes the form of campaign contributions, votes, implicit promises of future favors, and sometimes outright bribes.”); Saul Levmore, *Precommitment Politics*, 82 VA. L. REV. 567, 568–70 (1996).

<sup>45</sup> See William W. Buzbee, *Recognizing the Regulatory Commons: A Theory of Regulatory Gaps*, 89 IOWA L. REV. 1, 8–9 (2003) (identifying “regulatory commons dynamics” that arise from incentives for regulatory neglect where social ills such as climate change, urban sprawl, or

Similarly, politicians are unlikely to be rewarded for risk-reducing actions with benefits that are splintered among many or are in the distant future, especially if the risk is itself a low probability event.<sup>46</sup> Hence abundant political science and legal scholarship documents politicians favoring growth and employment over softer or more attenuated areas of concern.<sup>47</sup> This is especially true when one focuses on local governmental behavior, where jobs and economic vitality are often the key indicator of political success.<sup>48</sup> And if one adds in the importance of garnering campaign funding support, where wealthy interests and individuals wield more influence than not-for-profits or beneficiaries of risk-reducing or environment-preserving strategies, then political incentives are even more skewed to immediate, often monetary interests.<sup>49</sup> More than money and short-term rewards influence politicians, but most of these factors create incentives for politicians to neglect repercussions that are physically or temporally distant.

Regulators within agencies do not share legislators' and presidents' same nonstop incentives to raise money and seek electoral support; indeed, agency employees generally cannot engage in overtly partisan behavior,<sup>50</sup> although courts have long allowed informal agency engagement with regulatory stakeholders.<sup>51</sup> One of the central rationales for handing difficult regulatory tasks to agencies is precisely so experts not beholden to political pressures, but also not generalists like judges, can make sound judgments.<sup>52</sup>

---

aquaculture and fisheries risks lack a matching level of regulator who will be blamed or credited for a regulatory response, leading to ongoing social ills and lack of investment in necessary regulatory responses).

<sup>46</sup> Stefano Nesper, *Environmentalism and the Disaster Strategy*, 19 UCLA J. ENVTL. L. & POL'Y 211, 216 (2000) (suggesting that policymakers should resist pursuing action on future environmental problems because there is no way to ensure that "investments on a project to be realized in the distant future make economic sense").

<sup>47</sup> See, e.g., Vicki Been, "Exit" as a Constraint on Land Use Exactions: Rethinking the Unconstitutional Conditions Doctrine, 91 COLUM. L. REV. 473, 531-32 (1991); Jonathan R. Macey, *Transaction Costs and the Normative Elements of the Public Choice Model: An Application to Constitutional Theory*, 74 VA. L. REV. 471, 491 (1988) (discussing possibility of linking elected officials' compensation levels to their jurisdictions' output and noting that such a system would favor short-term growth over long-term investment).

<sup>48</sup> See Paul E. Peterson, CITY LIMITS 29-30 (1981).

<sup>49</sup> See Landes & Posner, *supra* note 44, at 877; Levmore, *supra* note 44, at 625.

<sup>50</sup> See Hatch Act, 5 U.S.C. § 7323 (2006).

<sup>51</sup> *Sierra Club v. Costle*, 657 F.2d 298, 400-01 (D.C. Cir. 1981) (upholding propriety of agency officials speaking extensively with rulemaking stakeholders during post-comment period and rejecting claims that such communications were illegal *ex parte* contacts).

<sup>52</sup> For the classic statement of this rationale, see James M. Landis, THE ADMINISTRATIVE PROCESS 7, 30-38, 46 (1938) (quoted in PETER L. STRAUSS ET AL., GELLHORN & BYSE'S ADMIN-

Agencies too, however, must stay in the good favor of executive branch leaders and legislators. If they do not, they can face budget cuts, legislative hostility, changes to their enabling legislation, and executive dismissal of agency leadership. Without adequate funds, agencies begin to be attacked from all sides as they cannot meet stakeholder requests for guidance, product approvals, or others' entreaties for enforcement against violators of the law. Agencies also are invariably subject to some criticism for lack of responsiveness given the elected branches' tendency to hand more tasks to agencies than they can fulfill.<sup>53</sup> Agency officials thus must be attentive to all constituencies, but they too face considerable pressures to focus upon immediate interests. A crisis often leads to legislation, but that by no means guarantees that the implemented reality will match the problem.

The focus on short-term rewards is magnified by the converse lack of interest in confessing error rooted both in psychological tendencies and institutional incentives.<sup>54</sup> No actor, whether an individual, a business, an elected official, or an agency official, will eagerly engage in self-criticism and reveal shortcomings.<sup>55</sup> Self-criticism is surely an individual and institutional virtue, but will seldom be politically or economically rewarding in the short term.<sup>56</sup> Especially in a world where negative news is seized upon by political, legal and regulatory opponents, and sometimes the press, and likely more remembered by everyone than news that all continues to be fine, admitting error and seeking change is a risky step to take.<sup>57</sup> Risk and criticism avoidance exacerbate harms associated with the focus on short-term benefits; with avoidance of criticism and rare confessions of error, corrections for longer term gain will often not occur.

---

ISTRATIVE LAW: CASES AND COMMENTS 27–31 (rev. 10th ed. 2003)) (“The administrative process is, in essence, our generation’s answer to the inadequacy of the judicial and the legislative processes.”).

<sup>53</sup> See generally John P. Dwyer, *The Pathology of Symbolic Legislation*, 17 *ECOLOGY L.Q.* 233 (1990).

<sup>54</sup> See generally SELF-CRITICISM AND SELF-ENHANCEMENT: THEORY, RESEARCH, AND CLINICAL IMPLICATIONS (Edward C. Chang ed., 2008) (book of essays reviewing scholarship and research on self-criticism, including several chapters emphasizing the psychological stress and hazards associated with self-criticism).

<sup>55</sup> See Thomas M. Brinthaup et al., *The Self-Talk Scale: Development, Factor Analysis, and Validation*, 91 *J. PERSONALITY ASSESSMENT* 82, 90 (discussing the likelihood that individuals will engage in “self-critical self-talk”).

<sup>56</sup> See Richard C. Sauer, *The Erosion of the Materiality Standard in the Enforcement of the Federal Securities Laws*, 62 *BUS. LAW.* 317, 339 (2007).

<sup>57</sup> See Katsuhiko Shimizu, *Imperfect Learning: What Does an Organization Learn from Its Mistake?*, 1999 *ACAD. MGMT. PROC.* 11, 11 (1999).



But this bleak perspective on individual, corporate, political, and legal incentives does not mean resources will invariably be destroyed or that all will capitulate to short-term business interests or expedient immediate political gain. Countervailing concerns and issues can gain salience, especially after crises or other high visibility events. In addition, some environmental and health risks provoke citizen fear more than one would rationally expect.<sup>58</sup> Politicians may be rewarded for meeting such citizen concerns, even if arguably overwrought. Furthermore, sometimes market and cultural shifts, such as recent market preferences for more “green” and sustainable business practices and products, may cause diverse actors to modify their behavior. Moreover, clout in politics and the law can arise even without monetary resources matching large businesses. For example, environmental not-for-profits can share expertise and perhaps deliver votes, much as groups like Public Citizen maintain their reputation, by remaining experts sought out for work before courts, agencies, and the legislature.<sup>59</sup>

In addition, those supplying legislation, regulation, or executive enforcement will sometimes be rewarded for responding to constituencies and interest groups pleading for long term fixes to challenges. For example, politicians sensitive to labor interests may push for occupational safety and health interests that are more durable, and other politicians may find reward in developing a reputation as a consumer or environmental advocate.<sup>60</sup> Still, the incentives for focusing on immediate and short-term needs and incentives are great and cut against longer-term stewardship and risk-reduction efforts by most actors, especially businesses focused on profits.

Unfortunately, even if individuals or others decide that they do want to address a risk, environmental harm, or some other social ill, they may confront another barrier. In a multilayered political and legal system like that in the United States, the existence of many potential political actors who can address a newly emergent risk or

---

<sup>58</sup> See generally CASS R. SUNSTEIN, *LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE* 35–63 (2005). This view is critiqued in Ann E. Carlson, *Heat Waves, Global Warming, and Mitigation*, 26 *UCLA J. ENVTL. L. & POL’Y* 169, 187–90 & nn.96–97 & 101 (2008).

<sup>59</sup> For a discussion of this influence despite political economic predictions, see Daniel A. Farber, *Politics and Procedure in Environmental Law*, 8 *J.L. ECON. & ORG.* 59, 70–73 (1992).

<sup>60</sup> In addition, legislators themselves have goals and preferences and distinctive political skills that shape their actions; they do not just respond to interest groups or short-term interests. See, e.g., RANDALL STRAHAN, *LEADING REPRESENTATIVES* 2 (2007); see generally DAVID R. MAYHEW, *AMERICA’S CONGRESS* (2000).

environmental concern can lead to “regulatory commons dynamics.”<sup>61</sup> Many potential regulators can lead to inaction and regulatory gaps.<sup>62</sup> Our federalist structures of government almost invariably mean federal, state and local actors all could take actions to address a social ill. Federal action can be confounded or upstaged by state action, and a state’s efforts always can be derailed or upstaged by other states’ innovations. With a plethora of agencies, especially at the federal level, few problems are clearly the province of only one agency or regulator. The same holds true at the legislative level, where a proliferation of committees with overlapping and sometimes competing areas of jurisdiction may lead to stasis. Opportunities for credit-claiming are uncertain if many regulators could act, or one regulator could undo or distort the efforts of another. The regulatory gaps that can result from these regulatory commons settings of shared potential jurisdiction thus result from both supply incentives of politicians and regulators and demand incentives of those interested in or affected by the social ill. Those seeking regulation are uncertain where to turn, and thus may divide their demands for action. Or they may free ride on others’ actions, but the splintered effects of a risk, the long odds that someone will be victim of a risk, and the individually small stakes most people have in an environmental or product risk will mean few actors will have rationale incentives to take the lead. Potential regulators’ control over regulatory outcomes and positive publicity is always uncertain when numerous other potential regulators may act.

Yet, while there may be regulatory gaps, there is also a great deal of risk, product, and environmental regulation. Where an actor becomes identified as a key political or regulatory player, then political and economic incentives and pressure for action may become concentrated.<sup>63</sup> Concomitantly, the regulator or politician may be able to claim credit and gain a subject area reputation, thus creating incen-

---

<sup>61</sup> This paragraph’s explication of “regulatory commons” dynamics was developed initially and in greater length in Buzbee, *supra* note 45.

<sup>62</sup> For other recent works applying the “regulatory commons” concept to illuminate poorly met social ills, see, e.g., Hope M. Babcock, *Grotius, Ocean Fish Ranching, and the Public Trust Doctrine: Ride ‘Em Charlie Tuna*, 26 STAN. ENVTL. L.J. 3 (2007) (fish ranching); Robin Kundis Craig, *Climate Change, Regulatory Fragmentation, and Water Triage*, 79 U. COLO. L. REV. 825 (2008) (water resource management); Carter H. Strickland, Jr., *Revitalizing the Presumption Against Preemption to Prevent Regulatory Gaps: Railroad Deregulation and Waste Transfer Stations*, 34 ECOLOGY L.Q. 1147 (2007) (railroad waste-transfer stations).

<sup>63</sup> William W. Buzbee, *The Regulatory Fragmentation Continuum, Westway, and the Challenges of Regional Growth*, 21 J.L. & POL. 323, 348–59 (2005) (distinguishing settings where multiple potential regulators can lead to gaps and inaction, on the one hand, or the involvement of numerous actors, on the other).

tives for action. Once many actors share jurisdiction over an area, regulatory fragmentation may not lead to inaction, but to many actors taking action.<sup>64</sup> Duplication and regulatory confusion can result.<sup>65</sup> However, a perhaps more common problem is sporadic political and legal attention when an issue is in the public eye, then periods of inattention and complacency, all fostered by the same temptation to seek more immediate rewards than tend to long term interests. Opponents of regulation will encourage inaction and slippage, even if a statute is itself unweakened. The regulatory commons incentives for inaction and inattention can then play out yet again at the implementation and enforcement stage as regulators with authority but limited resources decide what issues to attack. If many others share jurisdiction over an issue, the benefits and effectiveness of action are less certain.

Unlike regulatory mandates or reliance on potential regulatory intervention, common law actions do not suffer from regulatory commons dynamics and other political economic proclivities that threaten to defeat goals of stewardship, sustainability, and intergenerational equity. Concededly, common law tort claims can have a regulation-like effect by creating incentives to eliminate a risk, clean up a hazard, improve a product, or act with heightened care. This regulation-like effect of common law liability has been critical to the Supreme Court's occasionally expansive finding of preemption, especially in the recent *Riegel*<sup>66</sup> decision and its path-breaking but confusing and splintered *Cipollone*<sup>67</sup> case. However, as the Supreme Court itself also stated in the *Bates*<sup>68</sup> case, merely a couple of years before *Riegel*, incentives for action created by potential common law liability are not tantamount to the mandatory nature of formally issued regulatory requirements.<sup>69</sup> The *Wyeth* Court similarly noted that the FDA's long-held view until 2006 was that common law liabilities serve as a valuable adjunct to regulatory protections.<sup>70</sup> The Court also devoted an extensive footnote to studies indicating that the FDA's resources are often inade-

---

<sup>64</sup> *Id.* at 353–63 (distinguishing among settings along a continuum ranging from regulatory gaps to excessive regulation).

<sup>65</sup> J.B. Ruhl & James Salzman, *Mozart and the Red Queen: The Problem of Regulatory Accretion in the Administrative State*, 91 GEO. L.J. 757, 766–67 (2003).

<sup>66</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1007–11 (2008).

<sup>67</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 522 (1992) (Stevens, J.) (rejecting argument that preemption of state law is limited to “positive enactments by legislatures and agencies,” but stating that some common law claims can nevertheless survive).

<sup>68</sup> *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).

<sup>69</sup> *Id.* at 444–46, 450–51 (parsing statutory language to distinguish between “requirements” and “incentives” or “inducements”).

<sup>70</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1202–03 (2009).

quate to handle drug risks, as well as a recent congressional report documenting how career FDA officials opposed efforts to preempt common law, while political appointees ultimately sided with industry and asserted broadened preemptive effects of FDA actions.<sup>71</sup>

For purposes of understanding incentives for action, inaction, and the likelihood of concern for distant interests, a different point about common law regimes is relevant here. Regulatory gaps and inaction due to a multiplicity of potential regulators and other political economic incentives do not directly deter action under common law regimes.<sup>72</sup> By their very nature, clients and attorneys initiating and investigating common law tort or nuisance claims are motivated by individual monetary and sometimes retributive justice goals. Hence, in addition to the observations in *Bates* and *Wyeth* about how common law suits can help uncover information missed in the regulatory process or arising after regulators have finished their work,<sup>73</sup> common law incentives for action will remain as long as there are risks and injury.

From a defendant's perspective, the risk of facing many such suits when something goes wrong explains industry entreaties for regulation to preempt common law liabilities. Unlike regulators who for numerous reasons may fail to act to address a new concern, common law motivations for action are likely to be present if a harm is large enough to justify litigation costs and uncertainties. In short, common law litigation is vulnerable to neither regulatory commons dynamics nor regulatory failure risks. Paradoxically, the short-term and often monetary incentives of plaintiffs and their attorneys can serve to illuminate and create incentives for correction of longer term risks neglected due to short-term perspectives of risk producers and regulators.

The net effect of these various incentives of individual, business, legislative, and regulatory actors is that the immediate is more tended to in political and market realms, whereas more distant and probabilistic benefits or harms are downplayed. Distant generations' stakes will tend to be given little attention. Regulatory stasis and inattention are pervasive risks, especially where a social ill is newly emergent and

---

<sup>71</sup> *Id.* at 1202–03 & nn.11–12.

<sup>72</sup> *But see* Thomas O. McGarity, *The Regulation-Common Law Feedback Loop in Non-preemptive Regimes*, in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION* 237–41 (William W. Buzbee ed., 2009) [hereinafter *PREEMPTION CHOICE*] (discussing how common law actions can benefit from information adduced by regulatory schemes and vice versa).

<sup>73</sup> *See* McGarity, *supra* note 72, at 235–56; David C. Vladeck, *Preemption and Regulatory Failure Risks*, in *PREEMPTION CHOICE*, *supra* note 72, at 54, 57, 67, 71.

effective response strategies uncertain. And even if a regulatory scheme is enacted, over time “slippage” will occur, regulatory focus will be lost, implementation appropriations may dwindle, and with inattention rising, opponents of regulation will seek further weakening of the implemented law.<sup>74</sup> Resources will thus often not be utilized sustainably, and stewardship goals may be neglected.

Given these pervasive risks, as well as somewhat countervailing implications of multiple possible regulators, what are the implications of maintaining at least a few regulatory actors sharing turf versus sole occupation by a single regulator? This next subpart turns to that question, focusing on the long prevailing political choice to retain and often empower multiple layers of legal and regulatory actors.

*B. The “One Versus the Many” in Protecting Distant Interests: The Long-Dominant Concurrent Regulation Norm*

If a goal is to encourage public and private actors to take longer-term stewardship goals into account, a pervasive question concerns the relative benefits of entrusting regulatory goals to a single, usually federal, regulator, or instead allowing state or local actors, and state common law regimes, to continue operating concurrently with federal law in ways potentially affecting the same risk. An initial intuitive response that more regulators means more protection is not necessarily correct. As summarized above and explored in earlier scholarship, with a multiplicity of potential regulators or policymakers comes the risk of regulatory commons dynamics creating regulatory gaps and possibly later implementation and enforcement inertia resulting in slippage.<sup>75</sup> So entrusting possible responses to an emergent problem to a multiplicity of actors can paradoxically lead to underregulation. Whether underregulation results or abundant and possibly overlapping regulatory action arises will be subject-specific, as well as often dependent on the modality of agency actions.<sup>76</sup>

This risk of multiple actors with uncertain regulatory domains does not mean, however, that entrusting a social ill or stewardship goal solely to a single federal actor is therefore the best answer. As is often the case, comparative institutional analysis is necessary. Imper-

---

<sup>74</sup> Daniel A. Farber, *Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law*, 23 HARV. ENVTL. L. REV. 297, 301–11 (1999) (discussing types of regulatory slippage in the environmental law context).

<sup>75</sup> See *supra* notes 61–62, 74 and accompanying text (discussing regulatory commons dynamics and slippage).

<sup>76</sup> Buzbee, *supra* note 63, at 353–59.

fect alternatives must be compared, with attention to the risks and benefits each offers.<sup>77</sup> Here, the choice is not federal versus state, or federal versus state versus local, or even regulatory versus common law. The richer menu of choices must include not just the usual dualist focus on whether federal or state primacy would be better.<sup>78</sup> Instead, one must also consider the choice of retaining space for all actors, plus common law regimes, to retain their viability. In other words, in addition to considering the strengths of particular actors and also more general attributes of regulation and common law regimes, one must consider reliance on a unitary and completely preemptive actor, a partially preemptive actor, or a multiplicity of actors who almost unavoidably will engage with and learn from each other, as well as occasionally clash. If one assumes away human and institutional frailties, and indeed idealizes federal actors as disinterested and perfect, then of course handing power to federal actors is the answer. One could also idealize states, or perhaps agencies, assuming that they will with zeal and intelligence further the public interest. But one cannot assume perfection.

A considerable body of scholarship and existing law is rooted in the view that federal actors, while not perfect, are institutionally more likely than state and local actors to further protective risk reduction and environmental goals. Federal actors are viewed as less vulnerable to “race-to-the-bottom” competition in which state or local jurisdictions are tempted to sacrifice environmental or other risk goals for more immediate monetary and employment benefits.<sup>79</sup> A national actor is simply less vulnerable than state and local governments to industry threats to move or choose other jurisdictions. The growing

---

<sup>77</sup> See, e.g., NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* (1994) (setting forth view that all legal and policy questions need consideration of the comparative capabilities of different institutions); William W. Buzbee, *Sprawl's Dynamics: A Comparative Institutional Analysis Critique*, 35 WAKE FOREST L. REV. 509, 511–520 (2000) (explaining and critiquing comparative institutional analysis, with focus on applying its insights to understand urban sprawl dynamics); Merrill, *supra* note 4 (applying comparative institutional analysis frameworks to preemption debates).

<sup>78</sup> See generally ROBERT A. SCHAPIRO, *POLYPHONIC FEDERALISM: TOWARD THE PROTECTION OF FUNDAMENTAL RIGHTS* (2009) (criticizing dualist perspectives and exploring the benefits of “polyphony,” where numerous actors have a voice in generating legal responses).

<sup>79</sup> Richard L. Revesz, *Rehabilitating Interstate Competition: Rethinking the “Race-to-the-Bottom” Rationale for Federal Environmental Regulation*, 67 N.Y.U. L. REV. 1210 (1992) (explaining then disputing the race-to-the-bottom rationale for federal standard setting). Revesz questions whether race-to-the-bottom concerns justify federal regulation, while other scholars, notably Professor Kirsten Engel, have used both theory and empirical data to argue that race-to-the-bottom dynamics exist and justify federal intervention. Kirsten Engel, *State Environmental Standard-Setting: Is There a “Race” and Is It “to the Bottom”?*, 48 HASTINGS L.J. 271 (1997).

international movement of capital and production, however, means that the federal government itself can face similar temptation with the nation as the unit of competition. Relatedly, federal income tax revenues make the federal government relatively less dependent on property and other taxes than are state and local government, and federal political success is measured less directly by employment opportunities. In contrast, state and especially local governments face long-documented incentives to foster growth. Professor Peterson's work, for example, reveals that progressive redistributive policies are far more likely at the federal level, and are in fact more prevalent, than at the level of state and local law.<sup>80</sup>

Others' scholarship points to the greater professionalization and resources of federal legislators and agencies to suggest that they have greater capacity to handle risk and environmental challenges.<sup>81</sup> In addition, the fact that the federal government in many areas pushed workplace and environmental regulation in a progressive direction before most states also may have created "first mover" advantages, with federal actors gaining greater expertise and reputations that are not easily surpassed by other levels of government.<sup>82</sup> Other stakeholders, in turn, adjust their institutional focus to the regulatory leader. This turn to the regulatory leader in part explains the enduring dominance of federal environmental, risk and product regulation.

---

<sup>80</sup> See generally, PETERSON, *supra* note 48.

<sup>81</sup> See, e.g., William W. Buzbee, *Remembering Repose: Voluntary Contamination Cleanup Approvals, Incentives, and the Costs of Interminable Liability*, 80 MINN. L. REV. 35, 110–15 (1995) (exploring rationales for federal involvement in environmental clean up initiatives); Daniel C. Esty, *Revitalizing Environmental Federalism*, 95 MICH. L. REV. 570, 613–52 (1996) (exploring rationales against the current presumption in favor of decentralized environmental regulation); Peter P. Swire, *The Race to Laxity and the Race to Undesirability: Explaining Failures in Competition Among Jurisdictions in Environmental Law*, 14 YALE J. ON REG. 67, 99–105 (1996) (detailing public choice reasons why states will underprotect the environment).

<sup>82</sup> I have explored "first mover" advantages, but in the setting of advantages of regulatory interaction and sequential learning. See, e.g., William W. Buzbee, *Brownfields, Environmental Federalism, and Institutional Determinism*, 21 WM. & MARY ENVTL. L. & POL'Y REV. 1, 27–58 (1997) [hereinafter Buzbee, *Brownfields*]; William W. Buzbee, *Contextual Environmental Federalism*, 14 N.Y.U. ENVTL. L.J. 108 (2005) [hereinafter Buzbee, *Contextual Environmental Federalism*]; see also Richard L. Revesz, *Federalism and Environmental Regulation: A Public Choice Analysis*, 115 HARV. L. REV. 553 (2001) (acknowledging first-mover dynamics but also emphasizing areas of state innovation and leadership). I question several of Dean Revesz's historical claims in Buzbee, *Contextual Environmental Federalism*, *supra*, at 119–20, but states have undoubtedly sometimes taken the regulatory lead or at least advanced regulatory protections beyond a federal starting point, but this often is best seen as an interactive, iterative process. See Ann E. Carlson, *Iterative Federalism and Climate Change*, 103 NW. U. L. REV. (forthcoming 2009).

These pro-federal factors, however, do not add up to an inevitability of more progressive federal regulation and state laxity. In numerous areas, states have innovated and at times preceded federal law in addressing a social ill. In recent years, for example, states have been zealous investigators of financial wrongdoing<sup>83</sup> and also more active and innovative than the federal government in addressing climate change.<sup>84</sup>

But the federal versus state choice is, in a sense, the wrong question. Interaction and mutual learning has been the norm in most areas of federal risk, product and environmental regulation. As Professor Schapiro labels it, “polyphonic federalism” retaining multiple legal and political voices is both a prevalent choice and one that serves numerous salutary ends.<sup>85</sup> Federalism jurisprudence often neglects these benefits of polyphony, but in political and regulatory realms they are the norm. Federal actors have learned from state innovations. At other times, states have modeled law on federal law, but then improved on it. Most areas of social and environmental policy reveal federal leadership but then ongoing interaction and improvement that is fostered by the latitude left for political and legal contributions of state and local governments and courts.<sup>86</sup> This reality of regulatory interaction has been critical to regulatory progress. The interaction itself serves to allow room for pragmatic adjustment.<sup>87</sup>

---

<sup>83</sup> See generally Trevor W. Morrison, *The State Attorney General and Preemption*, in PRE-EMPTION CHOICE, *supra* note 73, at 81, 84–87. Professor Robert Ahdieh also explores state leadership and innovation in suggesting that regulation evolves in a “dialectical” fashion that is worthy of support. See Robert B. Ahdieh, *Dialectical Regulation*, 38 CONN. L. REV. 863 (2006).

<sup>84</sup> See David E. Adelman & Kirsten H. Engel, *Adaptive Federalism: The Case Against Reallocation Environmental Regulatory Authority*, 92 MINN. L. REV. 1796, 1843–49 (2008); Carlson, *supra* note 82.

<sup>85</sup> See generally SCHAPIRO, *supra* note 78. For a discussion of the benefits of polyphony in this context, see *id.* ch. 4.

<sup>86</sup> A growing body of scholarship observes this interactive and sequential learning. See, e.g., Adelman & Engel, *supra* note 84; Ahdieh, *supra* note 83; Buzbee, *Brownfields*, *supra* note 82; Buzbee, *Contextual Environmental Federalism*, *supra* note 82; Carlson, *supra* note 82.

<sup>87</sup> DANIEL FARBER, ECO-PRAGMATISM: MAKING SENSIBLE ENVIRONMENTAL DECISIONS IN AN UNCERTAIN WORLD 9–11 (1999) (exploring and lauding room for pragmatic adjustment in environmental law, including analysis of federalism structures and common law and statutory interaction). Carlson adds an additional point often neglected in federalism scholarship. Cooperative federalism schemes combined with savings clauses, regulatory floors, and special authorizations for California’s experimentation have not only revealed valuable innovations but also allowed testing of ideas that proved ineffective. See Carlson, *supra* note 82, at 1128–41. Allowing smaller scale experimentation and failure can be especially valuable in settings of novel sorts of regulation. See *id.*; see also Alice Kaswan, *A Cooperative Federalism Proposal for Climate Change Legislation: The Value of State Autonomy in a Federal System*, 85 DENV. U. L. REV. 791 (2008) (discussing benefits of state experimentation in context of climate-change regulation).



The structure of most federal environmental law, for example, does not eliminate state and local roles, but sets a regulatory “floor,” in the sense of a minimum required level of safety, risk, or environmental cleanliness.<sup>88</sup> Greater state laxity is prohibited. Still, state and local governments are pulled into federal law through cooperative federalism schemes that provide the option of delegating implementation and enforcement power to states, often also offering monetary inducements for such state involvement, and maintaining federal oversight of states assuming federal regulatory tasks. Even where states generally take over federal environmental programs, certain types of functions, especially gathering of national information and promulgation of uniform minimum standards of performance, remain federal roles. And federal enforcement typically remains a possibility even where a state has taken over a federal program.<sup>89</sup> Moreover, the norm of federal floors also allows states to enact their own bodies of related law that can address omitted risks or even be more protective than federal law. In the environmental area, parallel or overlapping laws are the norm.

Areas of risk regulation such as workplace safety, product approvals, and consumer protection less frequently use cooperative federalism structures, but have long accommodated the ongoing existence of federal and state regulators over many sorts of risk, and even more frequently have accepted the ongoing viability of common law tort and nuisance regimes.<sup>90</sup> This has created de facto federal floors, leaving state regulators or common law regimes able to find that a safer product or environment was possible and should be provided. Even if federal and state legal requirements are largely the same, the existence of parallel state law can empower state actors, such as a state attorney general, to police misbehavior ignored by federal regulators.<sup>91</sup> However, as a confusing series of Supreme Court

---

<sup>88</sup> See Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1557–59 (distinguishing between regulatory floors and ceilings).

<sup>89</sup> See, e.g., *Alaska Dep’t of Env’tl. Conservation v. EPA*, 540 U.S. 461, 468–74 (2004) (upholding federal authority under cooperative federalism structures of the Clean Air Act to block state issuance of an air pollution permit as contrary to federal law and, in so doing, describing basic workings of cooperative federalism structures).

<sup>90</sup> Appliance efficiency standards, for example, are presumptively federal, but states can petition for the right to require even more efficient machines. Ann E. Carlson, Commentary, *Energy Efficiency and Federalism*, 107 MICH. L. REV. FIRST IMPRESSIONS 63, 65 (2008), <http://www.michiganlawreview.org/firstimpressions/vol107/carlson.pdf>.

<sup>91</sup> In *Cuomo v. Clearing House Ass’n*, 129 S. Ct. 2710 (2009), the Supreme Court was confronted with such a scenario, where via regulation federal regulators claimed power to preempt both state visitorial authority over national banks and state authority to enforce other laws

cases also notes, clashing requirements can be preempted if they create a “conflict” with federal law. Sometimes common law relief can be tantamount to a “requirement” and will therefore be preempted just as a more straightforward form of state regulation, such as a state statute, would be.<sup>92</sup> Also confusing in preemption doctrine is when a federal action will be viewed as having struck a particular balance that under “obstacle preemption” theory precludes any different or additional legal contribution from state regulatory or common law.<sup>93</sup> The Supreme Court’s application of obstacle preemption doctrine has, like most of its preemption jurisprudence, been unpredictable, but obstacle preemption jurisprudence has perhaps the broadest preemptive potential since virtually any state or local regulation in an area will somehow make different choices and strike difference balances than under federal law.<sup>94</sup>

Long-prevailing regulatory arrangements hence actually embrace concurrent regulation, shared regulatory jurisdiction under federal law, and the ongoing existence of common law tort and nuisance regimes and their associated incentives to minimize risk. Despite the Supremacy Clause, the federal power to preempt state and local actors has seldom been exercised by the political branches beyond setting federal floors and creating cooperative federalism regimes.

The long-dominant norm in policy judgments of agencies and Congress has thus been to retain latitude for “the many” to play a role. Courts have at times found federal law to be preemptive, and agencies have on occasion pursued such a view, but this pattern has been the exception, not the rule. The dominant use of federal “floors”

---

against national banks. *Id.* at 2715. Due to close statutory parsing, precedents recognizing state enforcement power over banks, and recognition that federal law here, as in other areas, constituted a “mixed state/federal regime[ ],” the Court rejected the Office of the Comptroller of the Currency’s claim of preemptive power over enforcement as contrary to the statute and therefore unworthy of deference under *Chevron*. *Id.* at 2715–18.

<sup>92</sup> See, e.g., *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); see also *supra* notes 66–69 and accompanying text.

<sup>93</sup> In *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), for example, the Court found federal seatbelt and airbag regulation preemptive of any common law liability related to a manufacturer’s airbag choice, concluding that the particular regulation at issue struck a preemptive balance precluding any state tort award. See *id.* at 864–65.

<sup>94</sup> In assessing federalism and preemption choices in federal climate legislation, I explore in a forthcoming article reasons that obstacle preemption doctrine creates substantial risks that, in the absence of strong savings clause language, federal climate change legislation could be construed to have a broad preemptive impact. See William W. Buzbee, *State Greenhouse Gas Regulation, Federal Climate Legislation, and the Preemption Sword*, 1 SAN DIEGO J. OF CLIMATE CHANGE & ENERGY L. (forthcoming 2009).

and almost nonexistent express statutory preemption of common law has meant most bodies of law utilize multilayered law with multiple interacting actors interpreting and implementing the law, with latitude for diverse goals and use of diverse means to often shared ends.

Targets of regulation have nonetheless sought to defend themselves from added regulation and common law liability. They argue before courts that particular actions under federal law should preempt state law, especially common law. Courts have proved more receptive to such claims than have Congress and federal agencies, but they have done so in an array of cases that seldom allow one to predict outcomes in the next preemption case.<sup>95</sup>

A sea change in preemption law became apparent by 2006, when an array of agency declarations and a few legislative proposals sought to make federal actions more completely preemptive of any state role, whether in the form of regulation or common law regimes. Part II now turns to that development before exploring the doctrinal basis for and benefits of preemption hard look review.

## II. *The New Aggressive Face of Preemption*

Starting around 2005, the executive branch under President George W. Bush began to assert a more aggressively preemptive view of federal law, whether via agency action, in litigation, or in new legislation, as now well-documented in numerous articles.<sup>96</sup> A presidential memorandum issued early in President Obama's Administration indicates a general return to an executive branch presumption against preemption, as did President Obama's instructions to the Environmental Protection Agency ("EPA") to revisit its Bush Administration-era denial of authority for California to regulate greenhouse gas emissions from motor vehicles.<sup>97</sup> This Part summarizes the unusual aggressive

---

<sup>95</sup> Compare *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), with *Riegel*, 128 S. Ct. 999, *Bates*, 544 U.S. 431, and *Cipollone*, 505 U.S. 504.

<sup>96</sup> See, e.g., Buzbee, *Asymmetrical Regulation*, *supra* note 3; Kessler & Vladeck, *supra* note 3; Thomas O. McGarity, *The Perils of Preemption*, 44 TRIAL 20, 21–22 (2008); Catherine M. Sharkey, *What Riegel Portends*, *supra* note 3.

<sup>97</sup> On May 20, 2009, President Obama issued a Memorandum for the Heads of Executive Departments and Agencies with the subject line "Preemption." Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24,693, 24,693 (May 22, 2009). In it, he stated a strong anti-preemption norm and instructed executive departments and agencies not to claim preemptive power or impact through regulatory preambles, reaffirmed anti-preemption norms set forth in Executive Order 13,132, and ordered officials to review past regulatory actions asserting preemptive power or impact. *Id.* This Memorandum appears to signal that the Obama Administration will reject the strong pro-preemption views the Bush Administration asserted in litigation, in legislative advocacy, and via agency actions.

assertions of preemptive power and impact, mostly during the Bush Administration, then turns to the merits of preserving regulatory interaction and subjecting such agency preemption claims to preemption hard look review.

Probably the most significant policy change regarding preemptive impact of federal actions was asserted by the FDA during the Bush Administration years.<sup>98</sup> First in lower-court briefs, then in regulatory preambles accompanying explanations of other regulatory actions, and then with still greater detail in Supreme Court briefs, the FDA reversed its longstanding contrary view and embraced a position long sought by the pharmaceutical industry.<sup>99</sup> FDA approvals of drug labels and devices were now claimed to preempt state law on the same subjects, including possible torts claims litigated under state common law.<sup>100</sup> Rather than viewing federal actions as setting minimum requirements, the approvals and requirements were claimed to be a floor and a ceiling, leaving no room for juries to find that a federally approved label, product, or device was unduly dangerous.<sup>101</sup>

This argument met with some success before the Supreme Court in *Riegel v. Medtronic, Inc.*, which involved medical devices in a setting involving substantial pre- and post-approval device scrutiny, but without resolving the question of what deference, if any, to give agency assertions of preemptive impact.<sup>102</sup> The Court did find that the

---

Similarly, President Obama instructed EPA to reconsider its declination of California's petition for authority to regulate greenhouse gas emissions from automobiles. State of California Request for Waiver Under 42 U.S.C. [§] 7543(b), the Clean Air Act, 74 Fed. Reg. 4905 (Jan. 28, 2009). EPA subsequently reversed its position, granting California's petition. See Notice of Decision Granting a Waiver of Clean Air Act Preemption for California's 2009 and Subsequent Model Year Greenhouse Gas Emission Standards for New Motor Vehicles, 74 Fed. Reg. 32,744 (July 8, 2009); Press Release, Env'tl. Prot. Agency, EPA Grants Cal. GHG Waiver (June 30, 2009) (reporting EPA's waiver petition grant and reviewing the regulatory history of the petition), <http://www.epa.gov/newsroom/newsreleases.htm> (follow "By Date" hyperlink; then navigate to releases for June 30, 2009).

<sup>98</sup> Jordan, *supra* note 6, at 98–110; Kessler & Vladeck, *supra* note 3; Brian Wolfman, *Why Preemption Proponents Are Wrong*, 43 TRIAL 20, 27 (2008); Allison M. Zieve, *Rebutting the Implied-Preemption Defense*, 39 TRIAL 46 (2003).

<sup>99</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601); see also Jordan, *supra* note 6, at 98–110 (discussing FDA's shift toward a strongly pro-preemption position); Sharkey, *Products Liability Preemption*, *supra* note 3, at 511–13.

<sup>100</sup> Jordan, *supra* note 6, at 98–110; Sharkey, *Products Liability Preemption*, *supra* note 3, at 511–13. See also MAJORITY STAFF, *supra* note 14 (reviewing internal debate over changed FDA position and criticism of career staff that stronger preemption preferences of political appointees were unsound).

<sup>101</sup> See Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1552–54.

<sup>102</sup> *Id.* at 1006–11.

federal medical device approval and review scheme preempted state tort law, giving the statutory term “requirements” a broad read.<sup>103</sup>

The question of the preemptive impact of drug label approvals was addressed by the Supreme Court in *Wyeth v. Levine*.<sup>104</sup> The United States, during the Presidency of George W. Bush, submitted an amicus brief that urged the Court “to adopt the broad position that ‘FDA’s approval of a drug, including its labeling, generally preempts state law claims challenging the drug’s safety, efficacy, or labeling.’”<sup>105</sup> That view, in turn, was based in part on language in a regulatory preamble asserting broad preemptive impact.<sup>106</sup> In contrast to *Riegel*, and in analysis reminiscent of that in *Bates*, the Court found that the statute did not authorize the FDA to assert preemptive power.<sup>107</sup> The Court also held, as parsed in greater depth below, that the FDA’s preambular Federal Register claims of preemptive power were unsound and unworthy of judicial deference.<sup>108</sup> The Court noted the FDA’s previous longstanding view advocating the ongoing viability of common law liability claims and reviewed reasons preservation of both regulatory oversight and common law regimes can generate benefits.<sup>109</sup>

Similarly, the National Highway and Traffic Safety Administration (“NHTSA”) construed car roof crush standards to preempt the possibility of any tort conclusion that a car’s roof was unsafe.<sup>110</sup> NHTSA also asserted that its fuel efficiency standard-setting preempted state regulation of car green house gas emissions.<sup>111</sup> The Con-

---

<sup>103</sup> See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

<sup>104</sup> *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). This case was on appeal from *Levine v. Wyeth*, 944 A.2d 179, 194 (Vt. 2006), where the lower court concluded that the state law claim was not preempted by the FDA regulations.

<sup>105</sup> Sharkey, *Products Liability Preemption*, *supra* note 3, at 512 (quoting Brief for the United States as Amicus Curiae at 8, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249)).

<sup>106</sup> *Wyeth*, 129 S. Ct. at 1200.

<sup>107</sup> *Id.* at 1201–03.

<sup>108</sup> *Id.* at 1201.

<sup>109</sup> *Id.* at 1200–04.

<sup>110</sup> See Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1573 n.85; Sharkey, *Preemption by Preamble*, *supra* note 3, at 233–37.

<sup>111</sup> This position was asserted in NHTSA’s notice of proposed rulemaking for corporate average fuel economy (“CAFE”) standards for passenger cars and light trucks for model years 2011 through 2015. See Average Fuel Economy Standards, Passenger Cars, and Light Trucks: Model Years 2011–2015, 73 Fed. Reg. 24,352, 24,478–79 (May 2, 2008). This position was met with strong state disagreement. See Letter from Att’y Gen. of the States of Cal., Ariz., Conn., Del., Ill., Iowa, Me., Md., Mass., N.H., N.J., N.M., Or., R.I., and Vt., the Comm’r of the N.J. Dep’t of Env’tl. Prot., the Sec’y of the N.M. Env’t Dep’t, the Sec’y of the Commonwealth of Pa. Dep’t of Env’tl. Prot., the Att’y Gen. of D.C., and the Corp. Counsel of the City of N.Y., to Nicole R. Nason, Adm’r, Nat’l Highway Traffic Safety Admin., U.S. Dep’t of Transp. (July 1,

sumer Product Safety Commission likewise declared its mattress flammability standard preemptive of additional state regulation or “court created requirements.”<sup>112</sup>

The Department of Homeland Security proposed regulations regarding chemical facility safety, initially asserting that it preempted potential state and local regulation.<sup>113</sup> That choice was subject to substantial regulatory and legislative debate, with the agency ultimately backing off somewhat from its notice-stage declaration of broad preemptive impact.<sup>114</sup>

Relatedly, a substantial number of industry lobbyists in recent years have sought U.S. regulation of risks from an array of activities and products. These unusual entreaties for regulation have been linked to the hope that federal regulation would preempt additional state regulation and common law tort liabilities.<sup>115</sup> And in less-formal settings such as letter responses to requests for guidance, other agencies like the Occupational Safety and Health Administration (“OSHA”) have stated that respirators certified by another arm of the federal government, the National Institutes of Occupational Safety and Health (“NIOSH”), should preclude jury findings that a respirator is unsafe.<sup>116</sup> Documenting and analyzing the increasing prevalence

---

2008), available at [http://ag.ca.gov/globalwarming/pdf/comments\\_NHTSA\\_preemption.pdf](http://ag.ca.gov/globalwarming/pdf/comments_NHTSA_preemption.pdf) (criticizing NHTSA’s preemption policy).

<sup>112</sup> See Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1573 n.85, 1615; Sharkey, *Preemption by Preamble*, *supra* note 3, at 230–33.

<sup>113</sup> See Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1553–54, 1573–75 & n.87; Leticia M. Diaz, *Chemical Homeland Security, Fact or Fiction: Is the U.S. Ready for an Attack on Our Chemical Facilities? An Examination of State and Federal Laws Aimed at Immediate Remediation*, 56 CATH. U. L. REV. 1171, 1187–89 (2007); Galle & Seidenfeld, *supra* note 4, at 2013–15.

<sup>114</sup> Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1573–74.

<sup>115</sup> Eric Lipton & Gardiner Harris, *In Turnaround, Industries Seek U.S. Regulations*, N.Y. TIMES, Sept. 16, 2007, at A1.

<sup>116</sup> Letter from Thomas M. Stohler, Acting Assistant Sec’y of Labor for OSHA, to Daniel K. Shipp, President, Int’l Safety Equip. Ass’n (Jan. 9, 2009), available at [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=INTERPRETATIONS&p\\_id=27334](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=27334) (stating that “[t]o allow juries to enforce their own views of respirator design specifications and labeling for which NIOSH, as an expert agency, has already created standards and requirements, would directly conflict with OSHA’s mandate that employers only use respirators designed and manufactured in accordance with NIOSH requirements”). Similarly, the Mine Safety Health Administration (“MSHA”) recently stated the following about the effects of its own designations regarding manufactured refuges in mines: “MSHA weighed various trade-offs in setting requirements for approved refuge alternatives and components, such as those involved in arriving at space and volume requirements and strength requirements. Refuge alternatives and components cannot be altered once approved without seeking potentially time-consuming approval for modifications. Tort suits deeming approved designs insufficient could introduce state-by-state uncertainty to national manufacturers, thereby threatening the steady commercial supply of refuge alternatives and components and potentially leaving miners unprotected.” Refuge Al-

of such aggressive assertions of preemption, Professor McGarity labels these many pro-preemption claims “the preemption war.”<sup>117</sup>

Regulatory and legislative actions regarding climate change similarly revealed increasingly pro-preemption positions. Major federal legislation on climate change has yet to be enacted, but key industry players in recent years have indicated contingent support for such a law, provided it preempts state law.<sup>118</sup> Whether any forthcoming climate change law should use a unitary, preemptive architecture or embrace a “plural” architecture, or interactive regulation, or structures fostering dynamism, is the subject of ongoing policy and scholarly debate.<sup>119</sup>

Pursuant to the Clean Air Act,<sup>120</sup> California petitioned EPA for permission to require California vehicles to maintain low levels of greenhouse gas emissions<sup>121</sup>; numerous other states planned to impose similar restrictions.<sup>122</sup> California’s application was initially denied, however.<sup>123</sup> EPA’s Administrator first stated that the rejection was justified by concerns about a “patchwork” of regulatory measures,<sup>124</sup> but then in his more formal explanation several months later he rejected his staff’s recommendations and stated California had not met statutory criteria.<sup>125</sup> The effect was to make federal Clean Air Act automobile requirements the exclusive potential site of greenhouse gas regulation, declining to allow the diversity of California experi-

---

ternatives for Underground Coal Miners, 73 Fed. Reg. 80,656, 80,658 (Dec. 31, 2008). I thank Professors Nina Mendelson and William Funk for drawing these recent developments to my attention in an exchange among scholars affiliated with the Center for Progressive Reform.

<sup>117</sup> THOMAS O. MCGARITY, *THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES* ix–x (2008).

<sup>118</sup> Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1552–53; see Richard B. Stewart, *States and Cities as Actors in Global Climate Regulation: Unitary vs. Plural Architectures*, 50 ARIZ. L. REV. 681, 686 (2008).

<sup>119</sup> See David E. Adelman & Kirsten H. Engel, *Adaptive Federalism: The Case Against Reallocating Environmental Regulatory Authority*, 92 MINN. L. REV. 1796, 1798–99 (2008); Stewart, *supra* note 118, at 694–99. I offer recent analysis on this question in Buzbee, *supra* note 94.

<sup>120</sup> Clean Air Act, 42 U.S.C. §§ 7401–7671(q) (2006).

<sup>121</sup> CAL. HEALTH & SAFETY CODE § 38550 (West 2008).

<sup>122</sup> See *Green Mountain Chrysler Plymouth Dodge Jeep v. Crombie*, 508 F. Supp. 2d 295, 302 (D. Vt. 2000) (“[T]he Court and the parties have proceeded with this case on the assumption that EPA will grant California’s waiver application.”); John M. Broder & Felicity Barringer, *E.P.A. Says 17 States Can’t Set Emission Rules*, N.Y. TIMES, Dec. 20, 2007, at A1 (listing other states seeking to impose emissions limits). For the first time since the provision allowing waivers was added to the Clean Air Act, EPA rejected California’s petition. Broder & Barringer, *supra*.

<sup>123</sup> Broder & Barringer, *supra* note 122.

<sup>124</sup> *Id.*

<sup>125</sup> Statement of Stephen L. Johnson, Adm’r, U.S. Env’tl. Prot. Agency, Before the Committee on Environment & Public Works, U.S. Senate (Jan. 24, 2008), in 2008 WL 194332.

mentation, but without any similar federal regulation in place.<sup>126</sup> In effect, for this particular category of regulation of car emissions, EPA turned the Clean Air Act's partially preemptive regime that anticipated two types of cars—the national standard and California cars—into one where only the federal car could exist.<sup>127</sup> President Obama, in the early days of his administration, directed EPA, which by then was under new leadership, to revisit this action, making clear his hope that EPA would find a basis to reverse the decision.<sup>128</sup> EPA did so during the summer of 2009.<sup>129</sup>

Thus, between agency preambular assertions of preemptive impact, U.S. briefs and other less formal documents articulating this position, and recent legislative proposals and agency actions having the effect of preempting state diversity, a sea change occurred during the last few years of the Bush Administration.

In these many settings, several supporting rationales for preemption were often stated, in particular avoidance of duplicative regulation and “patchworks of requirements,” or perhaps concern with upsetting the regulatory balance struck by federal regulators. Despite the longstanding supposed “presumption against preemption,” arguments for not preempting state law were given little executive branch attention apart from fairly rote recitations of respect for state sovereignty under our Constitution.<sup>130</sup> Relatedly, until recently little attention was given by agencies or courts to the process through which agencies asserted preemptive impact and the standards by which they should be reviewed. Despite the recent apparent executive branch shift by the Obama Administration to a less pro-preemption view, preemption conflicts and claims will still arise.

The next Part turns to the doctrinal basis for subjecting agencies to preemption hard look review, then analyzes benefits of more inter-

---

<sup>126</sup> See Mark A. Linder, *Pollution v. Preemption: Vermont and the Fight for CO<sub>2</sub> Regulation*, 2 ENVTL. & ENERGY L. & POL'Y J. 357, 371 (criticizing Johnson's patchwork-prevention rationale as being flawed because “there can only be two standards: (1) those passed by Congress and (2) those implemented in California under authority of a section 209 waiver”).

<sup>127</sup> In a forthcoming article, Professor Jonathan Nash labels this situation “null preemption.” Jonathan R. Nash, *Null Preemption*, 85 Notre Dame L. Rev. (forthcoming 2010).

<sup>128</sup> State of California Request for Waiver Under 42 U.S.C. [§] 7543(b), the Clean Air Act, 74 Fed. Reg. 4905 (Jan. 28, 2009).

<sup>129</sup> See *supra* note 97.

<sup>130</sup> As discussed below, see *infra* notes 252–55 and accompanying text, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), has perhaps the most nuanced judicial language about why preemption of tort law should be avoided. *Wyeth* adopts similar logic. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1201–03 (2009).



active agency process and how it would be facilitated by rigorous preemption hard look review.

### III. *The Doctrinal Case for Preemption Hard Look Review*

Two fundamental questions persist about how courts should review agency assertions that their actions have a preemptive effect. The first, much debated, concerns whether agencies asserting preemptive effect should receive judicial deference regarding their statutory interpretations underlying their claimed preemptive power. The second, seldom addressed, concerns review of agency factual and policy claims regarding preemption. This Part starts with a discussion of these two distinct modes of review, especially developing the doctrinal case for preemption hard look review.

#### A. *Distinguishing Law Interpretation from Factual and Policy Judgments in Agency Assertions of Preemptive Effect*

The first mode of review question, at this point debated extensively by scholars, although not answered by the Supreme Court, is how courts should review agency legal interpretations that an agency uses to justify subsequent assertions of agency preemption power.<sup>131</sup> Should the usual *Chevron* deference apply, under which courts would defer to reasonable agency interpretations of statutory ambiguities or gaps? Due to questions about agency sensitivity to federalism values, as well as the rarity of broad, express legislative delegations of preemptive power to agencies, Professor Mendelson and others argue that the institutional assumptions underlying *Chevron* deference do not apply well to agency assertions of preemptive power.<sup>132</sup> Justice Stevens argues in his *Watters*<sup>133</sup> dissent, and Professor Young similarly argues in a recent work, that federalism concerns should trump the normal arguments for affording *Chevron* deference.<sup>134</sup> In the alternative, should courts utilize a standard that weighs explicitly and heavily the way an agency considered the preemption judgment, as *Skidmore* sliding scale deference would do?

---

<sup>131</sup> The Supreme Court stated that it “place[d] some weight” on a Department of Transportation interpretation, as set forth in an amicus brief, of a rule that it had promulgated. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000). For a lower court’s surveying of the legal landscape on this question, see *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), which concluded agency views about preemptive power and effect deserve “some degree of deference.” *Colacicco*, 521 F.3d at 275.

<sup>132</sup> See Mendelson, *Presumption*, *supra* note 3, at 698.

<sup>133</sup> *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1, 41 (2007) (Stevens, J., dissenting).

<sup>134</sup> *Id.*; Young, *supra* note 17, at 885–87.

At this point, *Skidmore* deference, or something like it, seems to be winning the votes of the legal academy and, somewhat elliptically, a majority of Supreme Court justices. Scholars such as professors Mendelson, Merrill, and Sharkey argue that *Skidmore*'s rewarding of thoroughness and consistency in interpretations is particularly important. Professor Young, however, dissents from this view, arguing that *Skidmore* deference is only slightly less deferential to agency views than is *Chevron* step two, and that courts should utilize a more rigorous, preemption-specific mode of review by building on the "presumption against preemption" as articulated in *Rice*.<sup>135</sup> Professor Young argues such an approach would be truer to the Constitution's structures and language, while also forcing Congress to make the preemption-empowering judgment with clarity, and putting agencies through additional preemption hurdles.<sup>136</sup>

Relatedly, Professor Clark articulates an argument rooted in the Constitution's language and structure to argue that the Constitution answers the question: agency declarations do not have the provenance to be considered "supreme" and therefore preemptive unless they have their roots in explicit legislative empowerment to act with such an effect.<sup>137</sup>

In addition, as Professor Funk has shown,<sup>138</sup> three dissenting Supreme Court Justices noted in *Watters*,<sup>139</sup> and a majority relied upon in the recent *Wyeth* decision,<sup>140</sup> Congress varies in its delegations of powers to agencies. Congress sometimes explicitly delegates power to agencies to declare an action preemptive, but at other times leaves that agency power unaddressed. Professor Funk suggests that these different sorts of delegations should be treated differently and that the authority to assert preemptive power and impact should not be as-

---

<sup>135</sup> See Hickman & Krueger, *supra* note 11, at 1259–90 (reviewing actual application of *Skidmore* and concluding that it is less deferential than *Chevron*, but nonetheless represents a highly deferential standard of judicial review); Young, *supra* note 21, at 890–91.

<sup>136</sup> See Young, *supra* note 21, at 871–81.

<sup>137</sup> Bradford R. Clark, *Process-Based Preemption*, in *PREEMPTION CHOICE*, *supra* note 72, at 192, 213.

<sup>138</sup> William Funk, *Preemption by Federal Agency Action*, in *PREEMPTION CHOICE*, *supra* note 72, at 214, 216–18.

<sup>139</sup> *Watters*, 550 U.S. at 38–39 & nn.21–23, 44 (Stevens, J., dissenting) (observing that "Congress knows how to authorize executive agencies to preempt state laws" and parsing how different statutes grant varying degrees of express agency power to make preemptive judgments, whereas other statutes merely grant rulemaking power). Chief Justice Roberts and Justice Scalia also joined Justice Stevens's dissent. *Id.* at 22.

<sup>140</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 & n.9 (2009).

sumed.<sup>141</sup> Professor Zellmer's work finds that courts frequently fail to give adequate weight to explicit savings clauses.<sup>142</sup> Moreover, most of these scholars argue that the sporadically stated and observed presumption against preemption should apply in the setting of agency claims of statutory power to preempt.<sup>143</sup>

The Supreme Court has issued numerous opinions making its own preemption judgments, but has yet to declare with clarity the standard of review or approach to be applied where the claim of preemption hinges not on preemptive impact of a federal law, regulation, or action (such as an approval or requirement), but on deference to an agency's claim about the preemptive effect of its own action.<sup>144</sup> The *Wyeth* Court offered the clearest explication but delimited its analytical frame to how it, in that case and under a statute lacking an explicit grant of preemptive power,<sup>145</sup> would not defer to an agency claim of preemptive power lacking any preceding participatory process. It merely noted agencies' "unique understanding" of statutes "they administer" before reviewing reasons it found FDA's views "entitled to no weight."<sup>146</sup>

---

<sup>141</sup> Funk, *supra* note 138, at 230–31.

<sup>142</sup> Sandi Zellmer, *When Congress Goes Unheard: Savings Clauses' Rocky Judicial Reception*, in PREEMPTION CHOICE, *supra* note 72, at 144–45.

<sup>143</sup> See Clark, *supra* note 137, at 213; Funk, *supra* note 138, at 230; Zellmer, *supra* note 142, at 165.

<sup>144</sup> The *Wyeth* Court explicitly noted the distinctly different posture of settings where "the Court has performed its own conflict determination, relying on the substance of state and federal law and not on agency proclamations of pre-emption," *Wyeth*, 129 S. Ct. at 1200–01, but the Court did not go on to articulate a generally applicable standard of review, *see id.* at 1199–204.

<sup>145</sup> See *id.* at 1195–96, where the Court traced the history of the FDA's power to regulate drug labels. The Court also noted that Congress repeatedly "took care to preserve state law," even as it amended the law regarding devices to be expressly preemptive. *Id.* at 1196.

<sup>146</sup> *Id.* at 1200–01. As discussed *infra* at notes 206–08 and accompanying text, the Court paraphrased but modified the *Skidmore* factors and cited *Skidmore* and *United States v. Mead*, 533 U.S. 218, 234–35 (2001), with a "cf." signal, finding the FDA change and explanation both contrary to the statute and unconvincing. See *Wyeth*, 129 S. Ct. at 1201–02. The Court never offered basic declarative language articulating how agency preemption claims should be reviewed and, especially, whether with full regulatory process and a statutory gap or ambiguity they would deserve the usual full extent of *Chevron* deference. See *id.* at 1199–1204. The Court reviewed the arguments against preemption under the particular facts and posture in *Wyeth* and concluded the FDA pro-preemption view was "entitled to no weight." *Id.* at 1204.

In the much-anticipated *Watters v. Wachovia Bank, N.A.* case, which concerned the preemptive power and effect of actions by the Office of the Comptroller of the Currency on a state's ability to act under its own registration and inspection requirements, the Court majority sidestepped a similar question. It found the federal statute acted to preempt state action directly. Justice Stevens's dissent, joined by Chief Justice Roberts and Justice Scalia, not only disagreed about the statutory issue, but also rejected *Chevron* deference, based on "a healthy respect for state sovereignty." *Watters*, 550 U.S. at 41 (Stevens, J., dissenting). He also noted that the Court

Until recently, few scholars and even fewer courts had considered how courts should review the policy and factual underpinnings of agency claims that preemptive impact is appropriate.<sup>147</sup> This is likely primarily due to the rarity of such assertions until recent years. Part of this assessment undoubtedly turns on interpretation of federal law, as well as interpretation of the state law or action that may create a conflict.<sup>148</sup> But agency claims of preemptive power and effect also virtually always contain an empirical footing with numerous factual and linked policy assumptions or findings: what about baseline conditions calls for preemptive action, and how do real world circumstances before and after an assertion of preemptive impact link to concerns made relevant by the underlying federal statute's criteria?<sup>149</sup> Agency preemption claims sometimes also contain assertions about benefits and harms of allowing multiple regulatory voices or displacing all but a single, federal regulatory actor.<sup>150</sup> If the claim is that state regulation or tort law will invariably create conflict and defeat statutory ends, is there a basis for this? Might state enforcement of parallel laws further federal ends rather than frustrate or conflict with them? Do targets of torts suits actually take occasional losses as tantamount to a requirement that creates insuperable conflict? Are there countervailing benefits of the interaction of common law and regulatory actors? When have common law claims revealed dangerous products that regulators missed? Or have common law suits lacked merit and earlier regulatory judgments been found sound? Some of these questions involve action-specific factual assessments, while others involve broader empirical claims about the benefits and harms of multiple sources of law versus a single, unitary source of preemptive law.

---

has "[n]ever before . . . endorsed administrative action whose sole purpose was to preempt state law rather than to implement a statutory command." *Id.* at 44. For discussion of *Watters*, see Funk, *supra* note 138, at 222–23. As noted above, Justice Stevens's dissenting opinion in *Watters*, like that for a majority in *Wyeth*, compared the different ways some statutes grant preemptive power to agencies while others do not, leading him to argue that courts should respect and enforce the distinctions among these different grants of authority.

*Watters*, 550 U.S. at 38–41 (Stevens, J., dissenting).

<sup>147</sup> The recent exceptions are Barron, *supra* note 6, at 1149; Galle & Seidenfeld, *supra* note 4, at 2011–17; Jordan, *supra* note 6, at 138–39.

<sup>148</sup> See Merrill, *supra* note 4, at 743 (observing that preemptive judgments invariably involve an assessment of state law, not just federal law).

<sup>149</sup> See *infra* notes 196–201, 252–255 and accompanying text (reviewing how the Supreme Court in *Bates* examined these questions in rejecting industry and government claims that state common law was preempted by federal pesticide law).

<sup>150</sup> See Broder & Barringer, *supra* note 122; cf. *Watters*, 550 U.S. at 41–43 (Stevens, J., dissenting) (analyzing the Office of the Comptroller of the Currency's preemptive judgment regarding regulatory oversight of operating subsidiaries).

Agencies largely failed to explore these questions in late Bush Administration agency assertions of preemptive power and effect. They also seldom sought public comment on whether to preempt.<sup>151</sup> Yet these are all fundamentally empirical, fact-dominated questions where neither agencies nor reviewing courts have all relevant information. The content of those factual and policy questions and claims necessarily must be shaped by what a federal statute deems relevant, but they remain contestable and provable. The question is how such claimed effects should be reviewed by courts and, relatedly, what kinds of procedures agencies should utilize if they wish to claim preemptive power and effect.

*B. Precedents Regarding Review of the Factual and Policy Predicates for Agency Preemption Claims*

Determining the standard of review for agency factual and policy determinations claimed to justify preemption relates both to doctrinal room left to articulate the standard of review and to normative goals in devising the standard. Although the Supreme Court has not explicitly spoken in terms of hard look review in the setting of agency preemption claims, preemption precedents and related administrative and constitutional law precedents support adoption of preemption hard look review. Explicitly embracing such a reviewing framework would constitute only a modest movement in existing doctrine, more clarification than change. Second, normative goals of encouraging agency transparency, accountability, and open process are furthered by hard look review. Such rigorous review, and the underlying regulatory process it would likely provoke, would also act to check preemption assertions. Ossification of regulation is often criticized,<sup>152</sup> but in an area where the Supreme Court has long stated a presumption disfavoring preemption, a procedural brake on preemption finds a doctrinal footing. Finally, the regulatory interactions fostered by such

---

<sup>151</sup> As is by now quite well established, the informal ways agencies and federal litigants late in the Bush Administration declared preemptive intent meant that the underlying statutory interpretation would, at most, receive sliding scale review under the *Skidmore* case. As explained in *Mead*, *Chevron* deference generally requires statutory indications that Congress intended the agency action to have the “force of law,” *Mead*, 533 U.S. at 229, and generally for *Chevron* deference the agency must offer its interpretation following notice and comment rulemaking or other formal process, *id.* at 229–31. Less formally issued interpretations, such as guidance documents, briefs, and other forms not preceded by participatory quasi-democratic process, at most get *Skidmore* deference in proportion to the “degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position.” See *Mead*, 533 U.S. at 228 (footnotes omitted).

<sup>152</sup> See, e.g., McGarity, *supra* note 72.

review would shine scrutiny on arguments for preemptive effect that, by their nature, will often be motivated by interest group entreaties for relief from state regulatory or common law.<sup>153</sup> Illuminating such entreaties and deliberation would enhance the likelihood of public-regarding behavior that would further the goals of intergenerational equity, stewardship and sustainability. In contrast, preemption claims emerging from no process, and subjected to little or no factual scrutiny, are far more likely to lack justification or merely reflect responsiveness to antiregulatory advocacy and short term political or economic interests.

No case analogous to *Chevron* clearly sets forth the standard of review to be applied to the factual and policy claims involved with an agency assertion of preemptive power and effect. A few cases review agency claims of preemptive effects and hence demonstrate some semblance of a standard of review, but several of those cases are decades old and hence do not review the sorts of agency and governmental assertions of preemptive power and effect evident in recent briefs and regulatory preambles. They also preceded both the Court's influential decisions about deference to agency law interpretations in *Chevron* and *Mead*<sup>154</sup> and its 1985 embrace of hard look review of high-stakes agency actions in *State Farm*.<sup>155</sup> When examined in conjunction with other settings where hard look review is applied, and in working through the underlying logic and normative underpinnings of these and other major standard of review decisions, preemption hard look review finds a strong doctrinal basis. The Supreme Court's recent *Wyeth* decision, while once again not using the phrase "hard look," utilizes a mode of review, including a factual and process focus, that is quite consistent with the preemption hard look review suggested here.

The basics of ordinary hard look review are well established and were first squarely embraced by the Supreme Court in *State Farm*. At its core, hard look review is a variant on the Administrative Procedure Act's "arbitrary and capricious" review, which in turn was first authoritatively construed in the *Overton Park* case.<sup>156</sup> Judicial analysis of an agency's action cannot stop with mere review to ensure an agency considered criteria mandated by law. Courts must review the agency's

---

<sup>153</sup> See Young, *supra* note 21, and accompanying text.

<sup>154</sup> United States v. Mead, 533 U.S. 218 (2001).

<sup>155</sup> Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 57 (1983).

<sup>156</sup> Citizens to Pres. Overton Park v. Volpe, 401 U.S. 402, 416-17 (1971).

action to be sure that “on the facts” the actual result is reasonable and not a “clear error of judgment.”<sup>157</sup>

The Supreme Court fleshed out the contours of “arbitrary and capricious” review of factual and policy conclusions and embraced hard look review in *State Farm*.<sup>158</sup> Lower courts during the 1970s had been developing the increasingly rigorous form of review referred to as “hard look review,” but the Supreme Court had not yet embraced it.<sup>159</sup> Lower courts tended to apply hard look review in settings of high stakes agency actions with a large economic impact or in settings where close agency scrutiny of facts was essential to fulfill a statutory mandate.<sup>160</sup>

The Supreme Court in *State Farm* was reviewing a deregulatory action of the Reagan Administration: the NHTSA eliminated the requirement that automobiles be equipped with airbags or seatbelts.<sup>161</sup> Debate over these requirements had involved, in the Court’s words, a “complex and convoluted history” that arose out of “the regulatory equivalent of war” against such requirements by the automobile industry.<sup>162</sup> The Court in *State Farm* embraced hard look review, both citing and adopting language relied on by lower courts applying hard look review.<sup>163</sup> It then painstakingly reviewed the agency’s record and logic.<sup>164</sup> Both were found lacking.<sup>165</sup> The core hard look requirements, as articulated in *State Farm*, are the following:

[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’ . . . Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an im-

---

<sup>157</sup> *Id.* at 416; see *State Farm*, 463 U.S. at 57.

<sup>158</sup> See *State Farm*, 463 U.S. at 43, 57.

<sup>159</sup> See, e.g., *Greater Boston Television Corp. v. FCC*, 444 F.2d 841 (D.C. Cir. 1970).

<sup>160</sup> See *infra* notes 213–18 and accompanying text (discussing this justification for hard look review). Much of this case law arises in cases stating that courts reviewing agency compliance with the National Environmental Policy Act’s environmental impact statement provisions needed to undertake their own hard look review of the agency’s work to ensure the agency itself undertook a hard look at environmental impacts. See, e.g., *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976).

<sup>161</sup> See *State Farm*, 463 U.S. at 34.

<sup>162</sup> *Id.* at 34, 49.

<sup>163</sup> Within the *State Farm* decision, see *id.* at 57, the Court approvingly cited the D.C. Circuit’s key case embracing and articulating hard look review, *Greater Boston Television Corp.*, 444 F.2d 841 (D.C. Cir. 1970).

<sup>164</sup> See *State Farm*, 463 U.S. at 36–57.

<sup>165</sup> *Id.* at 46.

portant aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.<sup>166</sup>

The Court in *State Farm* required additional reasoning and explanation because the agency's new policy was a change in agency position.<sup>167</sup> That it was a deregulatory action was of no consequence: "revocation" was a "reversal of the agency's former views" and hence required "a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance."<sup>168</sup> The Court emphasized that agencies still deserve some deference from courts but nevertheless declared that agencies must apply the "expertise" that justifies that deference: "Expert discretion is the lifeblood of the administrative process, but unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion."<sup>169</sup> The Court accordingly stated that "an agency must cogently explain why it has exercised its discretion in a given manner."<sup>170</sup>

*State Farm* has not achieved the citation prevalence of *Chevron*, but it is widely conceded in the courts and academe that questions of fact and law in high stakes decisions are now subject to hard look review.<sup>171</sup> Its reception has been mixed. Its admirers laud how it checks agency arbitrariness; others praise how the reality of rigorous judicial review empowers public-regarding agency officials to better ensure that agencies act with rigor and responsiveness.<sup>172</sup> Critics count *State Farm* as among the key cases leading to "ossification" of the regulatory process, giving regulatory opponents and sometimes hostile courts a means to second-guess almost any regulatory action.<sup>173</sup> Rigorous review and frequent judicial rejections of agency actions can

---

<sup>166</sup> *Id.* at 43.

<sup>167</sup> *See id.* at 57.

<sup>168</sup> *Id.* at 41–42.

<sup>169</sup> *Id.* at 48 (internal quotation marks omitted) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962)).

<sup>170</sup> *Id.* at 48.

<sup>171</sup> *See* Christopher H. Schroeder & Robert L. Glicksman, *Chevron, State Farm, and EPA in the Courts of Appeals During the 1990s*, 31 ENVTL. L. REP. 10371, 10394–96 (2001) (analyzing the prevalence and influence of *Chevron* and *State Farm* in the courts of appeals).

<sup>172</sup> *See* William F. Pedersen, Jr., *Formal Records and Informal Rulemaking*, 85 YALE L.J. 38, 59–60 (1975).

<sup>173</sup> *See, e.g.,* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1411–12 (1992).



lead agencies to overdo their regulatory explanations or avoid reviewable action altogether.<sup>174</sup> The net result can be better rules and sounder actions, but also fewer rules, delay, and possibly excessive regulatory process and explanation.<sup>175</sup> For reasons discussed below, these risks of hard look review are less likely to be present in the preemption hard look review setting.<sup>176</sup>

Preemption precedents have never directly or in declarative language addressed how courts should review agency factual and policy claims underlying assertions of preemptive impact, but a line of preemption precedents reveals a mode of analysis consistent with hard look review.

In 1961, in *United States v. Shimer*,<sup>177</sup> the Court confronted a case close, although not identical, to the setting under discussion: an agency had taken an action and had, in the Court's view, revealed its broad preemptive intent.<sup>178</sup> The Court declared that it had "no doubt that this regulatory scheme, complete as it is in every detail, was intended to provide the whole and exclusive source of protection of the Veterans' Administration . . . and was . . . meant to displace inconsistent state law."<sup>179</sup> The case gives no indication whether the Veterans' Administration ("VA") had declared the regulations' broad preemptive impact at the time they were issued,<sup>180</sup> but by the time of the *Shimer* litigation, the VA was arguing that they should preempt Pennsylvania state law. The *Shimer* Court discussed how to review an agency's claim that one of its actions had preemptive effect.<sup>181</sup>

The setting of that case, however, makes it of mixed applicability. VA regulations set forth a method by which mortgage shortfalls should be calculated and in so doing imposed various burdens on the

---

<sup>174</sup> See *id.* at 1412.

<sup>175</sup> As discussed below, hard look review of agency assertions of preemptive effect poses less of a risk of harmful ossification than agencies' scientific or technologically intensive regulatory actions.

<sup>176</sup> See *infra* notes 226–230 and accompanying text.

<sup>177</sup> *United States v. Shimer*, 367 U.S. 374 (1961).

<sup>178</sup> *Id.* at 381.

<sup>179</sup> *Id.*

<sup>180</sup> See generally *id.*

<sup>181</sup> See *id.* at 377. Professor Jordan sees this as the key doctrinal precedent and, like this Article, sees it as manifesting a form of review like modern hard look review. See *Jordan, supra* note 6, at 118–23. For reasons set forth in the text here and below, this Article views *Shimer* as less doctrinally relevant to, but still supportive of, this Article's thesis. This Article highlights recent cases supporting preemption hard look review and additional reasons why preemption hard look review is appropriate. Perhaps most import is the contemporary *Wyeth* case's substantial step in the direction of hard look review.

parties. The question was whether a different Pennsylvania statute applicable to mortgage default settings could continue to be applied.<sup>182</sup> The Court first determined that the underlying statute empowered the VA to “displace state law”<sup>183</sup> and then in considerable detail considered the rationale for displacing state law and the relative impacts of retaining and preempting state law. The Court ultimately concluded that the VA’s preemptive reading of the law should be upheld. The case, viewed through current preemption doctrine frameworks, appears to be a blend of implied field preemption in a setting where the existence of an actual conflict became apparent.

The *Shimer* case has only been cited a few times in the Court’s abundant preemption jurisprudence and similarly has been little used in briefs before the Court.<sup>184</sup> This record of doctrinal neglect is unsurprising. The case’s language reveals it to be primarily a pre-*Chevron* articulation of the usual grounds for judicial deference to agencies in an era when the Court often did not distinguish sharply between questions of law and fact. The *Shimer* Court stated:

[W]here Congress has committed to the head of a department certain duties requiring the exercise of judgment and discretion, his action thereon, whether it involve questions of law or fact, will not be reviewed by the courts unless he has exceeded his authority or this court should be of opinion that his action was clearly wrong.<sup>185</sup>

In framing its mode of review, the Court also mentioned the then-prevailing focus on an agency’s “more than ordinary knowledge” regarding the matters before it, then also cited scope-of-review precedents such as *SEC v. Chenery* and *NLRB v. Hearst*.<sup>186</sup> The Court did not discuss whether preemption judgments deserved any different

---

<sup>182</sup> *Shimer*, 367 U.S. at 376–77.

<sup>183</sup> *Id.* at 381–82.

<sup>184</sup> The Court’s strongest reliance on *Shimer* came in *Fidelity Federal Savings & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153–54 (1982), but there, too, the Court emphasized general language of deference to agency views and expertise. Perhaps significant to this Article’s argument, the Court in *de la Cuesta* did separately note the need for courts to review “whether [an agency administrator] has exceeded his statutory authority or acted arbitrarily.” *Id.* (citing *Shimer*, 367 U.S. at 381–82). The Court emphasized the agency’s intent and the effect of regulations, not the process or mode through which an agency indicated its views on preemptive impact. *Id.* (“Federal regulations have no less preemptive effect than federal statutes.”).

<sup>185</sup> *Shimer*, 367 U.S. at 381–82 (quoting *Bates & Guild Co. v. Payne*, 194 U.S. 106, 108–09 (1904)).

<sup>186</sup> See *SEC v. Chenery Corp.*, 332 U.S. 194 (1947); *NLRB v. Hearst Publ’ns*, 322 U.S. 111 (1944); see also *Shimer*, 367 U.S. at 382 (citing, *inter alia*, *Hearst*, 322 U.S. 111 and *Chenery*, 332 U.S. 194).

scrutiny, nor did the Court cite or discuss the already established “presumption against preemption.” Thus, as matter of doctrinal precedent, it is hard to see *Shimer* as shedding much light in the changed landscape applied to judicial review of agency action today.

As Professor Jordan correctly notes, however, the *Shimer* Court did undertake a close parsing of federal and state law, economic logic, and mortgage policies.<sup>187</sup> While lacking scrutiny of underlying process and especially agency responses to criticisms, as one regularly observes with modern hard look review, the Court probed deeply to confirm the soundness of the agency preemption choice. The review undertaken was rigorous and closer to hard look review than to a deferential rubber stamp.

One of the few Supreme Court cases citing *Shimer* was *de la Cuesta*, which similarly looked closely into the logic and agency analysis behind an agency’s preemption claim, there the Federal Home Loan Bank Board’s view that its regulations should preempt state law.<sup>188</sup> Much as the key Supreme Court hard look precedent, *State Farm*, is viewed as a hard look precedent in part due to the rigor of its review of agency factual and policy claims, *Shimer* and *de la Cuesta* likewise constitute supportive citations for hard look review.<sup>189</sup>

The most consistent overarching stated doctrinal presumption regarding preemption is the longstanding “presumption against preemption,” which, as is inherent in its terms, is a substantive canon disfavoring the result of preemption. It must be conceded that the Court’s application of it in recent years has been erratic.<sup>190</sup> Nevertheless, although erratically used, it remains the most consistently stated interpretive guide for how courts should review claims of preemptive effect. Like hard look review, it too serves an analytical function of requiring heightened political burdens of clarity and justification. First stated in 1933,<sup>191</sup> its most famous and cited exposition is in *Rice*: courts “start with the assumption that the historic police powers of the

---

<sup>187</sup> Jordan, *supra* note 6, at 118–24 (reviewing the *Shimer* Court’s rigorous analysis of the agency’s claim and likening it to the later-developed “hard look review”).

<sup>188</sup> *De la Cuesta*, 458 U.S. at 168–71.

<sup>189</sup> Neither *Shimer* nor *de la Cuesta* cited *State Farm*, which is the key Supreme Court embrace of hard look review, but they obviously could not have done so; that decision was not issued until 1983.

<sup>190</sup> See Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 971 (2002) (emphasizing contrast between the claimed “presumption against preemption” and the Supreme Court’s expanding pro-preemption jurisprudence); Christopher H. Schroeder, *Supreme Court Preemption Doctrine*, in PREEMPTION CHOICE, *supra* note 72, at 119, 122–24 (discussing the roots, variations, and occasional neglect of the presumption against preemption).

<sup>191</sup> See *Mintz v. Baldwin*, 289 U.S. 346, 350, 352 (1933).

States [a]re not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>192</sup> Later cases more fully flesh out the Court’s rationale for this presumption. As stated in *Medtronic v. Lohr*,<sup>193</sup> “because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action”; this is especially so where “Congress has ‘legislated . . . in a field which the States have traditionally occupied.’”<sup>194</sup>

Cases embracing the presumption against preemption look for a clear statement of preemptive legislative intent or a clear delegation to an agency of power to preempt, but they do not instruct agencies how, procedurally, they must assert preemptive effect. They similarly fail to instruct future courts on what methodology to use when reviewing agency claims of preemptive effect. By logical implication, however, the same anti-preemption rules of statutory construction should be expected of agencies asserting preemptive power and effect. Were a heightened burden not imposed on agencies, then the main law-creator, Congress, would face a more unfavorable reviewing climate than would agencies that act pursuant to enabling legislation. If preemption is ultimately a question of congressional intent, shaped against a constitutional norm of retained state concurrent power, then agencies too should have to overcome the presumption against preemption.

A Supreme Court majority, however, has so far sidestepped explicit embrace of preemption hard look review.<sup>195</sup> However, one finds a close variant on the rigorous review suggested here in the recent *Bates v. Dow Agrosciences*<sup>196</sup> and *Wyeth v. Levine* decisions, but a less clear analytical approach utilized in the intervening *Riegel* decision. The Court in *Bates* rejected industry arguments, joined by the United States in an amicus brief, that allowing common law actions for harms from pesticides constituted preempted state “requirements” under federal law.<sup>197</sup> The Court carefully distinguished “incentives” and “in-

---

<sup>192</sup> *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

<sup>193</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>194</sup> *Id.* at 485 (quoting *Rice*, 331 U.S. at 230); see Schoeder, *supra* note 190, at 123.

<sup>195</sup> See, e.g., *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000). In *Geier*, the majority relied on expertise-based rationales to justify giving an agency’s and Solicitor General’s preemption views “some weight.” *Id.* at 883–84. There, the Court also found the lack of advance agency vetting of such views through notice and comment process “not determinative,” *id.* at 884, while the dissenters disagreed with the Court’s finding of preemption and criticized agency views offered in “*ex post* administrative litigating position[s]” and without going through “notice-and-comment rulemaking,” *id.* at 910–12 (Stevens, J., dissenting).

<sup>196</sup> *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).

<sup>197</sup> See *id.* at 451–52.

ductions” arising out of the possibility of common law liability, from formal regulatory “requirements” that mandated specific conduct.<sup>198</sup> More significant to this Part’s focus on standard-of-review questions, the Court gave no indication of special weight or deference to the federal government’s pro-preemption advocacy, instead focusing on the statute’s language, emphasizing the long lineage of the “presumption against preemption,” and declining to find preemption absent “‘clear and manifest’” congressional intent.<sup>199</sup> Of especial importance to the argument for preemption hard look review, the *Bates* Court engaged in close and skeptical parsing of government and industry factual claims that conflicts necessitated preemption.<sup>200</sup> The Court examined the history of the interaction of tort litigation and pesticide regulation, the implications of decentralized elements in the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) regulation and the inevitable result of concurrent state and federal authority, the benefits of tort litigation to FIFRA goals, and finally noted that “[w]e have been pointed to no evidence” of “‘crazy quilt’” law or regulatory hardships.<sup>201</sup>

In the subsequent *Riegel* decision, however, the Court did find preemptive effect for federal law regulating medical devices with similar “requirements” language, but it shed little light on how courts should weigh federal agency and government views regarding preemption.<sup>202</sup> After considering the FDA’s and United States’ views, as expressed in regulations, interpretations of regulations, and in briefs, the Court ultimately concluded that such parsing of the underlying regulation “can add nothing to our analysis but confusion” and stated that “the regulation fail[ed] to alter [its] interpretation of the [statutory] text.”<sup>203</sup> The Court ultimately concluded that *Riegel*’s common law claims were preempted.<sup>204</sup> Because the case ultimately turned on

---

<sup>198</sup> *Id.* at 448–53. The Court majority conceded that under *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the term “requirements” can extend “beyond positive enactments, such as statutes and regulations, to embrace common-law duties.” *Bates*, 544 U.S. at 443. After scrutinizing federal pesticide law’s language and the reach of the common law liabilities asserted, the Court declined to find common law liabilities preempted by federal law. *See id.* at 452–54.

<sup>199</sup> *Id.* at 449 (citing and quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)).

<sup>200</sup> *Id.* at 449–52.

<sup>201</sup> *Id.*

<sup>202</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

<sup>203</sup> *Id.* at 1010–11. The Court construed “requirements” more expansively in *Riegel* than it had in *Bates*, justifying that result with close review of the comprehensive pre- and post-approval regulatory review of medical devices. *Id.* at 1006–07, 1011.

<sup>204</sup> *Id.* at 1011. The Court’s justification for finding common law action preempted was not,

clear statutory language and the onerous regulatory process for devices,<sup>205</sup> the Court did not need to look at evidence of conflict and policy implications of preemptive or non-preemptive regimes.

The *Wyeth* majority opinion provides the strongest support for preemption hard look review. It, like the other major preemption precedents, never offered direct declarative language about how future courts should review agency claims of preemptive impact, but came close. It stated the following: “The weight we accord the agency’s explanation of state law’s impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness.”<sup>206</sup> The Court then used a “cf.” signal before citing to *Mead* and *Skidmore*, cases generally cited for their articulation of how courts should review federal agency interpretations of federal law articulated in agency processes less formal than notice and comment rulemaking. The use of the “cf.” signal, which signifies authority “different from the main proposition but sufficiently analogous to lend support,”<sup>207</sup> makes sense for the following reasons.

The task before the Court and agency in the preemption setting is not just one of interpreting federal law, or deferring to an agency’s construction of federal law. A federal agency’s claimed preemptive power under judicial review actually involves three elements and one subpart: first, the construction of the federal statute to determine what should be preempted, with a subpart focus on what power to preempt has been conferred on the federal agency; second, the implications and meaning of the state law; and, third, the actual effects of leaving the federal and state laws and related actions coexisting, versus the effects of finding federal law preemptive.<sup>208</sup>

---

however, rooted just in statutory language: it also engaged in close examination of the extensive pre- and post-approval regulatory process for devices. *Id.* at 1006–07. This analysis was not of the federal statute itself, but of the overall regulatory scheme built up by the FDA. Of recent cases, *Riegel* is least analogous to hard look review precedents, but this portion of the Court’s decision shares attributes with hard look review. The Court was ensuring that regulatory procedures allowed questions of device safety to be scrutinized and vetted through an open regulatory process. *See id.*

<sup>205</sup> *See id.* at 1006–08.

<sup>206</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009).

<sup>207</sup> THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION R. 1.2(a), at 47 (Columbia Law Review Ass’n et al. eds., 18th ed. 2005).

<sup>208</sup> *Skidmore* and hard look review actually can be envisioned as having a field of overlapping content. *Skidmore* is mainly about statutory interpretation, while hard look review is mainly about factual and policy claims, but they overlap in their inquiry into the adequacy of an agency’s reasoning. *Skidmore* calls for analysis of the thoroughness of an agency’s analysis; hard look review similarly calls for an agency to look at underlying facts and address salient disputed points. *See infra* notes 217–25 (offering close analysis of hard look review based on the language

In calling for analysis of the “state law’s impact on the federal scheme,” the *Wyeth* Court was clearly not just construing statutory language, but was undertaking a fundamentally empirical, factual inquiry.<sup>209</sup> Upon closer examination, the Court’s inquiry has all of the trappings of hard look review’s close inquiry into factual and policy claims. It refers at several points to the “record” in the *Wyeth* case, and in parsing the earlier *Geier* case, emphasizes the record-based justification for that Court’s conclusion in favor of preemption.<sup>210</sup> It also looks at the FDA’s past and then-current views on the wisdom of FDA preemption of tort claims and discusses the benefits of retaining tort law incentives.<sup>211</sup> It also notes numerous studies, including one discussing internal FDA career staff views, finding that limited FDA resources and possible politicization rendered the FDA unlikely to so thoroughly prevent drug injury as to make tort law unnecessary.<sup>212</sup>

Thus, recent major Supreme Court preemption precedents adopt a level of policy and factual scrutiny consistent with hard look review, but never in explicit terms or with citations to foundational hard look review precedents.

If one looks more deeply at the underlying triggers for traditional hard look review, they too are present when agencies declare preemptive power and effect. The main triggering criterion is a “high-stakes” agency action with significant, important effects.<sup>213</sup> Judge Wald, speaking for the D.C. Circuit Court of Appeals, described hard look review as necessitated by the “sheer massiveness of impact” of modern regulations and the need to prompt agencies to provide “a more complete record and a more clearly articulated rationale to facilitate review for arbitrariness and caprice.”<sup>214</sup> When an agency declares that its action preempts state regulatory regimes across the country,

---

of *State Farm*). Others also note this overlap of *Skidmore* review and hard look review, although not in the setting of preemption claims. See Jim Rossi, *Respecting Deference: Conceptualizing Skidmore Within the Architecture of Chevron*, 42 WM. & MARY L. REV. 1105, 1142–46 (2001).

<sup>209</sup> See *Wyeth*, 129 S. Ct. at 1201.

<sup>210</sup> See *id.* at 1203 (citing to *Geier* and discussing that case’s “contemporaneous record, which revealed the factors the agency had weighed and the balance it had struck”); *id.* at 1203 & n.14 (disputing *Wyeth*’s claims about the use of the drug at issue and stating that *Wyeth*’s claim was “belied by the record”).

<sup>211</sup> See *id.* at 1200–03.

<sup>212</sup> *Id.* at 1202 (referring to the effects of tort suits in “uncover[ing] unknown drug hazards and provid[ing] incentives” for drug company diligence); *id.* at 1202 n.11 (citing and discussing numerous studies discussing the reality of an FDA lacking the resources to ensure post-approval safety of drugs).

<sup>213</sup> Section of Administrative Law and Regulatory Practice of the American Bar Association, *A Blackletter Statement of Federal Administrative Law*, 54 ADMIN. L. REV. 1, 42 (2002).

<sup>214</sup> *Nat’l Lime Ass’n v. EPA*, 627 F.2d 416, 451 n.26 (D.C. Cir. 1980).

thereby eliminating often parallel or concurrent areas of jurisdiction under states' police powers, the effect is massive. In one fell swoop, a federal agency can seek to displace or nullify the laws of fifty states, regardless of how closely federal and state laws actually match or conflict. And if the agency's preemption claim also involves displacing state common law regimes, it is even more centrally displacing a body of law that, by its nature, is the traditional domain of states.<sup>215</sup> Furthermore, because so few federal regulatory regimes establish their own compensatory schemes, an agency preemption declaration threatens to leave any injured person remediless, unable to secure compensation for injuries. The breadth of these impacts seems easily to satisfy the major-impact, "high-stakes" trigger for hard look review.

In addition, prior to the last few years of the Bush Administration, prevailing federal policy in litigation and within most agencies was to see parallel state laws and common law regimes as furthering federal ends.<sup>216</sup> Only actual conflicts, especially situations of compliance impossibility, typically led to agency assertions of preemptive impact. Even then, the conflicts tended to be in application of the law. Thus, these changed agency positions trigger the second prong of *State Farm's* rigorous review, which in turn is a variant on a well established administrative law meta-rule: agencies changing positions have to confront their past policies and justify the change before a court.<sup>217</sup> As the Court emphasized, agencies must utilize their "expertise" in reversing course.<sup>218</sup> Here, too, *Wyeth* shares attributes with *State Farm's*

---

<sup>215</sup> It is now well-established that federal common law is a rarity. See *Int'l Paper Co. v. Ouellette*, 479 U.S. 481 (1987) (declining to utilize federal common law to resolve interjurisdictional water pollution flows, and applying the source state's law as necessary to avoiding frustrating the policies and purposes of the federal Clean Water Act); *Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938) ("There is no federal general common law.").

<sup>216</sup> For discussion of recent changes in this policy, see Jordan, *supra* note 6, at 70–93; Kessler & Vladeck, *supra* note 3, at 462–64; Sharkey, *Preemption by Preamble*, *supra* note 3, at 229–42.

<sup>217</sup> See *Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983) ("‘An agency's view of what is in the public interest may change, either with or without a change in circumstances. But an agency changing its course must supply a reasoned analysis . . . .’" (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (1970) (footnote omitted))); *SEC v. Chenery Corp.*, 332 U.S. 194, 196–97 (1947) (declaring that the basis upon which an administrative action rests "must be set forth with such clarity as to be understandable" and that "[i]t will not do for a court to be compelled to guess at the theory underlying the agency's action; nor can a court be expected to chisel that which must be precise from what the agency has left vague and indecisive"). This element of hard look review also overlaps with *Skidmore* review. See *supra* note 208 and accompanying text (discussing relationship of *Skidmore* and hard look review).

<sup>218</sup> *State Farm*, 463 U.S. at 54; see *id.* at 43, 48.



hard look review. The *Wyeth* court emphasized the FDA's "dramatic change in position"<sup>219</sup> and the agency's special obligation to offer a contemporaneous "reasoned explanation" for the change.<sup>220</sup>

A perhaps somewhat neglected element of hard look review is of crucial importance here. Hard look review involves close scrutiny of agency factual and policy conclusions, but the precise language used by the Court in *State Farm* emphasizes the importance of agency engagement and responsiveness, and rejection of agency action that fails to grapple with criticisms and counter-arguments.<sup>221</sup> In the middle of its embrace of hard look review, the Court says courts must ensure that an agency under review does not fail "to consider an important aspect of the problem" or "offer[ ] an explanation for its decision that runs counter to the evidence before the agency, or [make a choice that] is so implausible that it could not be ascribed to a difference in view . . . ." <sup>222</sup>

These three elements of hard look review all, at their heart, are looking for evidence that an agency engaged the views of affected stakeholders, considered underlying data or facts in dispute, and addressed them in a reasonable way. This language is encouraging agency engagement, not agency avoidance of criticism or agency avoidance of deliberative process. It is certainly rejecting agency power assertions by mere fiat. As the Court's later discussion makes clear, if an agency meets the views of its critics, vets its action, and "cogently explain[s]" its choice, then courts can be better assured that agency expertise has been exercised.<sup>223</sup> According to the *State Farm* Court, where such engagement and deliberation have occurred, a posture of judicial deference should prevail: courts in that setting cannot assert their own judgments, or demand that the agency consider "every alternative device and thought conceivable by the mind of man."<sup>224</sup> Agencies simply cannot give no "consideration whatsoever" to contrary policy views.<sup>225</sup>

---

<sup>219</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1203 (2009).

<sup>220</sup> *Id.*

<sup>221</sup> See *State Farm*, 463 U.S. at 46–57. Professor Seidenfeld emphasizes this deliberation-inducing element of hard look review. See Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 491 (1997) (characterizing hard look review as fundamentally about scrutiny of an agency's "reasoning" and "deliberat[ion] about the issues raised by its decision").

<sup>222</sup> See *State Farm*, 463 U.S. at 43.

<sup>223</sup> *Id.* at 48.

<sup>224</sup> *Id.* at 51.

<sup>225</sup> *Id.*

The implication here is clear. The Court demands that in high-stakes regulatory actions agencies must demonstrate engagement of criticisms and the searching analysis called for by hard look review. This hard look review element also logically should be applied to agency claims of preemptive effects. It would be paradoxical and illogical if agencies could escape searching scrutiny by taking actions with major effect without providing notice or opportunity for challenge.

But a criticism of this embrace of preemption hard look review must be anticipated: if agency assertions of preemptive effect are to be subjected to hard look review, what of concerns that preemption hard look review will sweep too broadly, chilling public-regarding preemptive actions? Critics of hard look review often criticize how hard look review can delay and derail needed regulation.<sup>226</sup> Such an outcome is less likely in the preemption setting than one might at first expect. Courts and agencies already should, under the presumption against preemption, devote special attention to preserving latitude for state regulatory and common law. In most instances, the existence of state regulation and potential common law liabilities will serve to enhance protections. State and federal regulators will police a risk, and if federal regulators fail to address that risk, state regulators may do so.<sup>227</sup> And if citizens are injured despite federal and state regulations, common law regimes allow scrutiny into the risk source, especially possible undisclosed dangers and subsequent information that can reveal risks that regulators missed and producers failed to address.

Thus, in most risk regulation settings, an analytical anti-preemption hurdle will keep several legal regimes in place to discourage undue risk. In effect, an anti-preemption hurdle will not defeat regulation, but increase the likelihood that concurrent sources of regulatory protection will remain in place. This sort of interpretive regime furthers the Supreme Court's stated presumption in favor of preserving concurrent regulatory regimes: "federal rights should be regarded as supplementing state-created rights unless otherwise indicated."<sup>228</sup> Of course, preemption advocates prefer preemptive outcomes precisely to reduce regulatory and legal burdens. As a matter

---

<sup>226</sup> Thomas O. McGarity, *The Courts and Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV. 525, 532–36 (1997) (discussing how hard look review leads to "blunderbuss" industry attacks on regulation with delay as a major goal).

<sup>227</sup> See generally Trevor W. Morrison, *The State Attorney General and Preemption*, in PRE-EMPTION CHOICE, *supra* note 72, at 81 (discussing role of state attorneys general in investigating illegality overlooked by federal regulators).

<sup>228</sup> *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 646, 650–51 (1990) (concluding that state

of Supreme Court doctrine, however, the decided weight of preemption and administrative law precedents favors the presumption in favor of preserving “state-created rights.”

Still, that there are benefits of concurrent regulatory regimes does not directly address the risks of analytical hurdles to public-regarding federal preemptive action. After all, not all claims of preemptive effect are anti-regulatory in nature; preemption can further public-regarding ends. This raises the question of the effect and value of federal floors. If federal law sets a regulatory floor, in the sense of a mandate that no state can allow greater levels of risk, then the very nature of that judgment usually creates a direct conflict that must preempt contrary state law. Federal floors will often have a numerical element, setting an air pollution level or a maximum allowable toxin level; contrary state law must be preempted since a state cannot allow a more degraded environment or riskier product without directly flouting the federal requirement. Hard look scrutiny of federal floors imposed via regulation hence will involve the usual probing review of the level chosen, but the preemptive effect of that floor will not itself be subject to debate.<sup>229</sup> Preemption hard look review thus would generally enhance regulatory protections. It would not itself add to judicial scrutiny of regulatory judgments that, if upheld, would inherently have a preemptive effect.

It must be conceded, however, that where an agency is asserting preemptive effect due to goals of furthering economies of scale by eliminating varied state laws, or to preserve a balance of regulatory benefits and burdens under the logic often asserted in “obstacle” preemption settings, preemption hard look review would undoubtedly create an analytical hurdle.<sup>230</sup> But the process-inducing nature of hard

---

workers’ compensation law exclusivity provisions do not bar migrant workers from asserting claims under federal law protecting migrant and seasonal workers).

<sup>229</sup> If a federal agency were deciding among regulatory tools, and one choice involved floors, and the other some kind of market-based tool, such as taxes or subsidies, then an agency and reviewing courts might, in applying preemption hard look review, favor a non-preemptive means to the same regulatory end. Again, this might be a sound outcome. It is hard to see how asking an agency to justify the preemptive option over non-preemptive alternatives would chill public-regarding actions.

<sup>230</sup> For the classic statement of obstacle preemption doctrine, see *Hines v. Davidowitz*, 312 U.S. 52, 66–74 (1941) (invalidating a state regulation because the state “law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”). A more modern application was utilized to justify the preemptive outcome in *Geier v. American Honda Motor Co.*, 529 U.S. 861, 874–83 (2000), but *Wyeth* rejected obstacle preemption arguments, stating that “all evidence of Congress’ purposes is to the contrary.” *Wyeth v. Levine*, 129 S. Ct. 1187, 1199 (2009); see *id.* at 1199–1204.

look review would by no means preclude such preemptive action. Instead, it would merely reduce the risk of such power assertions without opportunities for input and judicial review.

Doctrinal support for preemption hard look review is also found in recent Supreme Court federalism precedents that erect presumptions against federal laws impinging on areas of traditional state regulation. These cases involve the far less-displacing setting of federal law that overlaps with areas of state regulation, but the Court has nevertheless interpreted federal law to avoid such overlap.<sup>231</sup> They constitute additional support for preemption hard look due to their shared project of protecting state domain. For example, in a major Clean Water Act<sup>232</sup> case, *Solid Waste Agency of Northern Cook County*,<sup>233</sup> the Court rejected federal assertion of power to protect isolated wetlands because, in the majority's view, federal law was impinging on state land-use regulation, an area of traditional state authority.

The Court's ruling in *Gonzales v. Oregon*<sup>234</sup> is similarly instructive. The Court rejected the U.S. Attorney General's assertion of power to criminalize physician-assisted suicide, as allowed under Oregon law in limited circumstances.<sup>235</sup> Due to the setting of that case and Court's mode of review, it provides strong support, by close analogy, for preemption hard look review. Much as agencies have been claiming preemptive effect in recent years with little or no advance process, the Attorney General in the *Oregon* case asserted his power through an interpretive rule lacking any formal or participatory pre-enactment process. He effectively banned such physician-assistance by saying it would constitute criminal conduct in violation of federal law. By this act, he in effect preempted and nullified Oregon's laws allowing such physician-assistance.<sup>236</sup>

The Court rejected on procedural, substantive, and federalism grounds the Attorney General's claim of power to override and effectively nullify Oregon's law. The Court elliptically acknowledged the preemption question at issue, relying on a preemption precedent<sup>237</sup>

---

<sup>231</sup> These pro-state substantive interpretive norms are not without risk, at times being used to subvert federal environmental protections by using federalism to trump other possible statutory interpretations.

<sup>232</sup> Clean Water Act, 33 U.S.C. §§ 1251–1376 (2006).

<sup>233</sup> *Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 174 (2001).

<sup>234</sup> *Gonzales v. Oregon*, 546 U.S. 243 (2006).

<sup>235</sup> *Id.* at 274–75.

<sup>236</sup> *See id.* at 249, 255–69.

<sup>237</sup> *See id.* at 263 (citing *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649–50 (1990), for the

and mentioning but concluding it did not need to rely on the presumption against preemption to decide the case.<sup>238</sup> Nevertheless, the case unquestionably involved preemption power, because the Attorney General was asserting federal power to override state law and “bar dispensing controlled substances for assisted suicide” specifically permitted by state law.<sup>239</sup>

The Court’s mode of analysis is consistent with this Article’s call for judicial review frameworks that create incentives for agencies to assert preemptive power and effect only after they have engaged in an open and deliberative process. The *Oregon* Court did not defer under the *Chevron* framework, noting that the mere presence of undefined or ambiguous terms is not itself sufficient to justify *Chevron* deference.<sup>240</sup> Instead, it closely analyzed the allocations of power to several federal actors, the retention of state regulatory authority over doctors, and even the roles of state licensing authorities.<sup>241</sup> It distinguished between the Attorney General’s ability to decide “‘compliance’ with the law” and the power to “decide what the law says.”<sup>242</sup> Furthermore, it compared the procedures required of the Attorney General under his clearly granted areas of authority and the complete lack of process used by the Attorney General in declaring criminal the physician conduct specifically allowed by state law.<sup>243</sup> The Court noted that the Controlled Substances Act “gives the Attorney General limited powers, to be exercised in specific ways.”<sup>244</sup> To allow such action via an interpretive rule would be “anomalous” since it would allow the “power to criminalize” with less analysis and process than required by statute for less significant assertions of power.<sup>245</sup> The Court expressed concern with such “unrestrained” power.<sup>246</sup> In addition, it held against the agency the lack of any consultation with any outside experts who might have enabled the agency to exercise “reasoned judgment.”<sup>247</sup> As developed at greater length in Part IV, this strain in

---

proposition that a grant of authority to an agency to set standards “did not include the authority to decide the pre-emptive scope of the federal statute because ‘no such delegation regarding the statute’s enforcement provisions is evident in the statute’” (brackets omitted)).

<sup>238</sup> *Id.* at 274.

<sup>239</sup> *Id.* at 275.

<sup>240</sup> *See id.* at 258.

<sup>241</sup> *Id.* at 258–75.

<sup>242</sup> *Id.* at 264.

<sup>243</sup> *See id.* at 260.

<sup>244</sup> *Id.* at 259.

<sup>245</sup> *See id.* at 262.

<sup>246</sup> *Id.*

<sup>247</sup> *Id.* at 269.

*Gonzales v. Oregon* is consistent with a growing trend in the law to reward agency deliberative process and withhold or lessen deference for actions asserted by fiat.

Lastly, subjecting agency assertions of preemptive power and effect to hard look review is supported by an interpretive presumption against leaving injured people without a remedy. Congress tends to preserve or create a remedy for those who are injured. For example, the rare federal regulatory regimes that explicitly result in complete preemption typically include their own substitute compensatory regimes.<sup>248</sup> Similarly, most bodies of risk regulation contain explicit savings clauses that preserve common law.<sup>249</sup> In contrast, recent agency assertions of preemptive effect have often had as their explicit purpose eliminating the possibility of common law damages actions.<sup>250</sup> Although scholars have argued that a right to a remedy should be presumed or protected, such a right is not now explicitly part of our current constitutional fabric.<sup>251</sup> Two of the major recent preemption cases, however, come close. They do not call a remedy a right, but disfavor statutory interpretations that would leave those injured without a remedy.

For example, in the *Bates* case, the Court articulated a variant on a typical “clear statement” rule to preserve tort remedies absent clear legislative intent to preclude such claims. It stated, “[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.”<sup>252</sup> The Court also noted unsuccessful efforts to enact tort reform legislation and the benefits of the common law in creating “incentive[s]” for manufacturers to use “utmost care.”<sup>253</sup> The Court in *Bates* was prima-

---

<sup>248</sup> See Buzbee, *Asymmetrical Regulation*, *supra* note 3, at 1561 & n.36 (discussing and citing such laws).

<sup>249</sup> This does not mean that courts pay them much heed. See generally Zellmer, *supra* note 142.

<sup>250</sup> See *supra* Part II.

<sup>251</sup> Professor Goldberg has made the case for seeing tort law rights to redress as being at least arguably supported by constitutional provisions and values. See John C.P. Goldberg, *The Constitutional Status of Tort Law: Due Process and the Right to a Law for the Redress of Wrongs*, 115 YALE L.J. 524 (2005). Goldberg anticipates the assertion of tort reform goals by agencies, see *id.* at 624, and advocates that courts ought not lightly leave tort plaintiffs without any remedy, but send the signal that “Congress and federal agencies . . . are obligated to consider the effects of their enactments on potential tort claimants.” *Id.*; see also Richard E. Levy & Robert L. Glicksman, *Access to Courts and Remedial Preemption in Collective Action Perspective*, 59 CASE W. L. REV. (forthcoming 2009) (exploring arguments against preemption due to the resulting elimination of remedies for injured parties).

<sup>252</sup> *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449–50 (2005).

<sup>253</sup> *Id.* at 450.

rily discussing an interpretive assumption to be applied in construing statutes, but the same concerns should drive rigorous review of the claimed needs for preemptive action by agencies.<sup>254</sup> *Bates* itself provides support for such scrutiny of claimed arguments in favor of preemption. As noted earlier, the Court delved into the underlying evidence supporting the industry's and the United States' argument that preemption was needed.<sup>255</sup> The *Bates* Court's approach—both utilizing an anti-preemptive presumption preserving common law remedies and also looking for evidence to back up claims that preemption is necessary—together constitute a close variant on the preemption hard look review that this Article suggests is appropriate.

*Wyeth* similarly utilizes an interpretive presumption against reading a statute to authorize preemption that would eliminate citizen rights to a compensatory remedy. It states that “[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision.”<sup>256</sup> The Court weighed as “powerful evidence” congressional “silence on the issue, coupled with [Congress’s] certain awareness of the prevalence of state tort litigation.”<sup>257</sup> It later noted the complementary risk-reducing function of tort litigation, especially longstanding FDA support for retaining both FDA regulatory scrutiny and state law protections.<sup>258</sup> It also noted empirical studies questioning the capacity of the FDA to fulfill its protective roles without the adjunct support provided by state common law regimes.<sup>259</sup>

Putting these various doctrinal strands together, it becomes clear that subjecting agency assertions of preemptive power and effect to hard look review has a sound basis in the case law and also furthers

---

<sup>254</sup> A similar presumption in favor of preserving state domain and longstanding duties defined principally by state law is evident in *United States v. Bestfoods*, 524 U.S. 51, 61–62 (1998) (declining to construe the Comprehensive Environmental Response, Compensation, and Liability Act as overriding “deeply ‘ingrained’” assumptions about a parent corporation’s liability for its subsidiary’s acts; due to its “venerable common-law backdrop, the congressional silence is audible”).

<sup>255</sup> As discussed at greater length at *supra* notes 196–201 and accompanying text, the *Bates* Court concluded that Dow and the United States had “greatly overstate[d] the degree of uniformity and centralization that characterizes FIFRA” and had similarly “exaggerate[d] the disruptive effects of using common-law suits to enforce the prohibition on misbranding.” *Bates*, 544 U.S. at 450. The Court stated that it “ha[d] been pointed to no evidence that such tort suits led to a ‘crazy-quilt’ of FIFRA standards or otherwise created any real hardship for manufacturers or for EPA.” *Id.* at 451–52.

<sup>256</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009).

<sup>257</sup> *Id.*

<sup>258</sup> *See id.* at 1202.

<sup>259</sup> *See id.* at 1202 & n.11.

the normative underpinnings of preemption precedents, well established administrative law doctrine, and broader federalism jurisprudence.<sup>260</sup>

*IV. Linking Preemption Hard Look Review, Interaction's Benefits, and Stewardship Goals*

It is difficult to prove that agency deliberation and transparency will improve the quality of agency action or prevent agency capitulation to anti-regulatory arguments. Agencies can at times just go through the motions and, with the benefit of judicial deference, get away with imprudent action not in the public interest. However, if one has to choose a regulatory process option that is conducive to public-regarding action, it is hard to fashion an argument in favor of agency actions lacking any preceding transparency and process.

Consider the process choice in light of Mancur Olson's insights about how collective action dynamics favor small organized interests over broader public interests that may be greater in the aggregate. Olson's framework indicates that open and deliberative process is much more likely to generate public-regarding outcomes.<sup>261</sup> In the setting of risk, product, or environmental regulation, targets of regulation will tend to be favored in markets and legal venues due to their resources, the high stakes they have in any regulatory action, and their small numbers. Beneficiaries of regulation will always be organizationally disadvantaged due to their dispersed interests and large numbers, but their greatest strength will tend to be in their collective political clout, in arguments rooted in protective legislative policy, and perhaps information they can share.<sup>262</sup>

With open and transparent agency process, coupled with the rigors of preemption hard look review, agencies cannot just give in to the arguments of industry. Instead, they will need to balance and respond to all arguments and tailor their analysis to statutory criteria, most of which will have a declared public-regarding purpose. The process and rigors of hard look review guarantee little in the way of particular results, but agencies cannot sweep under the rug and ignore issues and

---

<sup>260</sup> Thus, the conclusion reached is similar to that recently noted by Professor Gillian Metzger, who observes that administrative law doctrines in recent years provide protections previously provided by federalism doctrine. See Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 DUKE L.J. 2023, 2025–28 (2008).

<sup>261</sup> See generally MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* (1965).

<sup>262</sup> See Farber, *supra* note 59, at 70–72, 78 (discussing successes of environmental groups as rooted in their policy expertise and influence with voters despite industry's other advantages).



arguments presented to them. In contrast, with no advance process and little or highly deferential judicial review, agencies would never be forced to discuss or defend the choices they make, which in turn would likely lead to more poorly reasoned and articulated regulatory decisions.<sup>263</sup> However, with advance public notice, open deliberation, and a burden of justification before the courts, agencies should be far more likely to weigh the interests of beneficiaries, be they current participants in the regulatory process or future generations whose interests may be made relevant by statute.

This argument in favor of open and deliberative agency process and rigorous judicial review of preemptive agency factual and policy judgments is also rooted in the likelihood of better results. Preemptive action can have its place, especially with design mandates or to create benefits of economies of scale.<sup>264</sup> More interactive, multi-actor regulatory strategies, however, greatly reduce several pervasive sources of regulatory risk and also improve the odds of superior regulatory outcomes.

First, if all regulatory power is handed to one actor, all is dependent on the initial regulatory judgment being right. If it falls short, or is imprudent at the moment of creation, the absence of other actors or regulatory venues to reconsider that judgment can freeze the law. Not only will no better approach be tested or revealed, but incentives to critique the status quo will exist only if that single actor is amenable to persuasion. When one factors in reluctance to engage in self-criticism,<sup>265</sup> giving sole regulatory turf to one actor is risky.

A second benefit of regulatory structures that retain concurrent and overlapping actors and turfs is unavoidable opportunities for mutual learning and adjustment. Politicians and regulators seeking recognition and perhaps advantage for their jurisdiction will have incentives and opportunities to improve on others' regulatory efforts. Citizens and other stakeholders unhappy with a regulator's actions can point to others' better efforts to advocate change. And in settings such as climate change policy, where basic regulatory design choices and future repercussions of accumulating greenhouse gases remain uncertain, allowing multiple actors to retain roles reduces the risk of a

---

<sup>263</sup> Galle and Seidenfeld develop similar arguments in favor of rigorous judicial review. See Galle & Seidenfeld, *supra* note 4, at 2011–12.

<sup>264</sup> See William W. Buzbee, *Federal Floors, Ceilings, and the Benefits of Federalism's Institutional Diversity*, in *PREEMPTION CHOICE*, *supra* note 72, at 98, 114–15.

<sup>265</sup> See *supra* notes 54–57 and accompanying text.

single actor monopolizing the regulatory field without opportunities for dynamic learning.<sup>266</sup>

The idea that open, deliberative, interactive and transparent legal and political process fosters better decisionmaking pervades our legal system. A core argument for federalist systems is to preserve states as laboratories of democracy.<sup>267</sup> Environmental laws themselves use many cooperative and interactive structures that are open and provide room for pragmatic adjustment.<sup>268</sup> The prevailing political choice to preserve common law regimes in tandem with regulatory schemes provides latitude for interactive learning and regulatory “feedback,” with regulators learning from common law litigation and vice versa.<sup>269</sup> The federal Freedom of Information Act (“FOIA”)<sup>270</sup> is justified on the similar assumption that open government is better government. In the words of Judge Patricia Wald, “too much secrecy breeds irresponsibility.”<sup>271</sup> The public trust doctrine protects public, shared environmental resources not through an absolute bar on changed uses but with a requirement that resource-use changes be made through open legislative action rather than unilateral executive action.<sup>272</sup> The assumption is that open legislative process will act as a brake on opportunistic executive action for short-term individual gain.<sup>273</sup>

---

<sup>266</sup> The most persistent advocate for such ongoing adjustment and learning by monitoring is Charles Sabel, who has developed his ideas in previous work and in a lengthy article with Michael Dorf. See, e.g., Michael C. Dorf & Charles F. Sabel, *A Constitution of Democratic Experimentalism*, 98 COLUM. L. REV. 267 (1998). For citation to this and other works exploring the benefits of “learning by monitoring” and benchmarking of best practices, see Buzbee, *supra* note 264, at 108–09 & n.25.

<sup>267</sup> See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

<sup>268</sup> See FARBER, *supra* note 87, at 180–87 (noting the dynamic nature of environmental law and discussing benefits of decentralization and experimentation but also noting general failure to track actual accomplishments).

<sup>269</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187, 1202–03 (2009); McGarity, *supra* note 72, at 235–36.

<sup>270</sup> Freedom of Information Act, 5 U.S.C. § 552 (2006).

<sup>271</sup> Patricia M. Wald, *The Freedom of Information Act: A Short Case Study in the Perils and Paybacks of Legislating Democratic Values*, 33 EMORY L.J. 649, 654 (1984); see also STRAUSS ET AL., *supra* note 52, at 736–37 (discussing Judge Wald’s view and quoting then-Professor Scalia’s far less favorable view of FOIA as “do-it-yourself oversight” (citation omitted)).

<sup>272</sup> See *Paepke v. Pub. Bldg. Comm’n*, 263 N.E.2d 11 (Ill. 1970) (identifying a park as a public trust resource but allowing open legislative action to modify its use for educational purposes); GLICKSMAN ET AL., *supra* note 26, at 45–49 (discussing the contours of the public trust doctrine).

<sup>273</sup> For one of the most influential works regarding this strain of public trust doctrine, see Joseph L. Sax, *The Public Trust Doctrine in Natural Resources Law: Effective Judicial Intervention*, 68 MICH. L. REV. 471 (1970).

A growing strain in Supreme Court jurisprudence similarly reflects the belief that open and deliberative regulatory process should be rewarded when judicially reviewed. Several important recent cases calibrate the amount of deference to the amount of agency deliberative process preceding the challenged action. With less or absent process, the level of deference drops. This strain is important to the argument for preemption hard look review due to how it supports more rigorous review of agency actions taken without preceding open and deliberative process. The Court in *Gonzales v. Oregon* stated that the “deference [t]here [wa]s tempered by the . . . apparent absence of any consultation with anyone outside the Department of Justice who might aid in a reasoned judgment.”<sup>274</sup> Similarly, in the *Brand X* case,<sup>275</sup> picking up on the heart of Court’s revision of *Chevron* deference in *Mead*,<sup>276</sup> the Court buttressed its conclusion that the Federal Communications Commission deserved deference due to how it offered its disputed law interpretation in “the exercise of [its] authority” to promulgate rules.<sup>277</sup> This was the key modification of *Chevron* made by *Mead*: deference to agency actions (there, law-interpretation) is not contingent merely on linguistic ambiguity, but rather on Congress’s delegation of power to an agency to promulgate regulations with the “force of law” and agency use of notice and comment procedures or other “relatively formal” process in generating such law interpretations.<sup>278</sup> Deference is linked to these “relatively formal” procedural prerequisites because they “tend[ ] to foster the fairness and deliberation that should underlie a pronouncement of such force.”<sup>279</sup>

Similarly, in another recent case involving a regulation under the Fair Labor Standards Act,<sup>280</sup> the Court even more explicitly pegged the degree of deference to the amount of process undertaken by the agency: the Court will assume Congress intends judicial deference to an agency’s determinations “where the agency focuses fully and directly upon the issue, where the agency uses full notice-and-comment

---

<sup>274</sup> *Gonzales v. Oregon*, 546 U.S. 243, 269 (2006).

<sup>275</sup> *Nat’l Cable & Telecomm. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967 (2005).

<sup>276</sup> *United States v. Mead Corp.*, 533 U.S. 218 (2001).

<sup>277</sup> *Brand X*, 545 U.S. at 980–81.

<sup>278</sup> *Mead*, 533 U.S. at 226–27, 230.

<sup>279</sup> *Id.* at 230 (emphasis added). Several scholars note this growing trend. See, e.g., Eskridge & Baer, *supra* note 11, at 1180–81 (2008) (arguing that the “reason for deference is greatest when the agency process *looks* legislative . . . , where affected interests provide relevant information that the agency must consider”); cf. FARBER, *supra* note 87, at 190 (arguing for lowered rigor of review when agency has process in place to assess policy in light of results).

<sup>280</sup> Fair Labor Standards Act, 29 U.S.C. §§ 201–219 (2006).

procedures to promulgate a rule,” and in other respects comports with the underlying statute.<sup>281</sup>

In addition, as noted above, the *Wyeth* case likewise calibrated its degree of deference to the agency deliberative process preceding assertions of preemptive impact. The FDA preemption claim in *Wyeth*, which was first asserted in a regulatory preamble subject to no opportunities for notice and comment, then amplified in court briefs, was held “entitled to no weight.”<sup>282</sup> The same result followed similar reasoning in *Gonzales v. Oregon*.<sup>283</sup>

Judicial review is itself a form of deliberative, interactive process. When courts scrutinize executive action to ensure it is well-justified, the very nature of judicial inquiry and litigant input is itself open, deliberative, and interactive. Excessive deference can undermine that checking and deliberative role.<sup>284</sup> Excessive rigor in review can inappropriately displace inherently political judgments best left to the political branches, but, as argued above, in the setting of preemption hard look review those risks are less prevalent. More importantly, calibrating the rigor of judicial review to reward open and responsive agency process would provide incentives for agencies to utilize quasi-democratic regulatory process. Because most laws have at least a claimed public-regarding rationale, often targeted at protecting resources, health, the environment, or future generations, forcing agencies to explain publicly how their action comports with public-regarding goals and confront citizen comments enhances the likelihood agencies will act in furtherance of a statute’s stated goals.

### Conclusion

In law, politics, and markets, incentives to act for short-term, selfish benefits are always great. Those tendencies can be alleviated, although never eliminated, by requiring political actors, especially agencies, to act in open, transparent and deliberative ways. A chief means to this end has long been hard look review of high-stakes regulatory actions. Recent aggressive assertions by agencies of preemptive power and effect, however, have been made with little or no advance

---

<sup>281</sup> *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2350–51 (2007) (citing *Mead*, 533 U.S. at 232–33). For an article linking *Long Island Care*, *Mead*, and *Brand X*, and suggesting that courts are using administrative law doctrines to further federalism goals, see Metzger, *supra* note 260, at 2058 (2008).

<sup>282</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1204 (2009).

<sup>283</sup> See *supra* notes 234–47 and accompanying text.

<sup>284</sup> See Jonathan T. Molot, *The Judicial Perspective in the Administrative State: Reconciling Modern Doctrines of Deference with the Judiciary’s Structural Role*, 53 STAN. L. REV. 1, 5 (2000).

consultation, process, or opportunity for public input. To illuminate a little-examined strain in preemption scholarship, this Article explores doctrinal arguments and other rationales for subjecting the factual and policy judgments underlying agency preemptive power claims to hard look review. The Supreme Court has never explicitly called for such review, but several recent preemption decisions and numerous strains of related administrative law, statutory interpretation, and federalism doctrine add up to a strong argument for preemption hard look review. Furthermore, the open and deliberative procedures rewarded by hard look review, and manifested in preemption hard look review itself, are likely to encourage agencies not to act for short-term gain or to capitulate to entreaties for anti-regulatory ends, but to act in furtherance of the public interest.