STANDING TO CHALLENGE REGULATORY FAILURE IN THE AGE OF PREEMPTION

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INTRODUCTION

Suppose you rent a mobile home as your primary residence. After living in your rented mobile home for a few years, you discover that the model you live in results in dangerously high levels of formaldehyde exposure among residents. You speak to a

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lawyer, and she tells you that you cannot sue the manufacturer of the mobile home for damages, because your claim would be preempted by the federal Manufactured Home Construction and Safety Standards.[1] You decide that if you cannot get damages, you would like to ensure that the regulations are stringent enough to provide the protection from harm you require to live in a mobile home, by suing for injunctive relief against the Department of Housing and Urban Development (HUD). Your lawyer tells you that you will not have standing to bring the suit, because there is no guarantee that updated standards will reduce your risks of harm, and because the risks to your health are insufficiently concrete and particularized.[2] You are stuck.

The mobile home renter's predicament illustrates the way in which federal preemption of state tort law combines with Article III standing requirements to prevent citizens from using the judicial system to influence the regulatory environment in which they reside. This Note proposes a framework that would allow citizens in this type of predicament[3] to bring litigation under section 706(2) of the Administrative Procedure Act (APA)[4] to

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[1] *See, e.g.*, *In re* FEMA Trailer Formaldehyde Prods. Liab. Litig., 620 F. Supp. 2d 755 (E.D. La. 2009) (finding that plaintiff's products liability claims were preempted by HUD's Manufactured Home Construction and Safety Standards).

[2] *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 561–62 (1992).

[3] I am not suggesting that the Manufactured Home Construction and Safety Standards, 24 C.F.R. § 3280 (2008), are an example of a regulatory failure. The hypothetical is merely for the purpose of illustration.

[4] Section 706 of the APA provides:

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be—
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> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
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> (B) contrary to constitutional right, power, privilege, or immunity;
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> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
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> (D) without observance of procedure required by law;
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> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
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> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

5 U.S.C. § 706(2) (2006).

force agency action, by recognizing a legally cognizable injury in cases of "preemptive regulatory failure."[5]

Federal preemption of state tort law enhances the dangers of regulatory failure by sapping the power of state courts and legislatures to protect their citizens.[6] It thereby compounds the costs of regulatory failure. Under current law, preemption is a one-way street: if a tort defendant succeeds in asserting preemption as a defense, similar future claims will be dismissed.[7] Without congressional intervention, the regulatory agency gains an irrevocable monopoly over the maintenance of acceptable standards of safety.[8] Doctrinally, preemption of state tort law represents a congressional decision (as interpreted by the courts) to transfer the enforcement of acceptable standards of care from state courts to an administrative agency.[9] Entrusting standards of care to administrative agencies can have a variety of desirable effects, such as channeling decision-making authority to experts,[10] use of deliberative process to create regulatory standards (notice and comment rulemaking),[11] the ability to assess costs and benefits in

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[5] For these purposes, a "preemptive regulatory failure" occurs when an agency fails to follow congressional instruction in updating or maintaining a set of regulations that preempt state law, depriving citizens of a remedy they held before preemption. *See infra* Part II.A.

[6] *See infra* Part I.B.

[7] *See* Elizabeth J. Cabraser, *When Worlds Collide: The Supreme Court Confronts Federal Agencies with Federalism in* Wyeth v. Levine, 84 TUL. L. REV. 1275, 1280–81 (2010) ("When state law tort claims are preempted, injured patients' damages suits are dismissed with prejudice, leaving them without any source of compensation for the medical expenses, lost wages, personal injuries, and emotional distress they and their families suffer when medical products fail.").

[8] William W. Buzbee, *Preemption Hard Look Review, Regulatory Interaction, and the Quest for Stewardship and Intergenerational Equity*, 77 GEO. WASH. L. REV. 1521, 1568 (2009) ("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. 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.").

[9] *See* FMC Corp. v. Holliday, 498 U.S. 52, 56 (1990) ("In determining whether federal law pre-empts a state statute, we look to congressional intent.").

[10] Andrew Jackson Heimert, *Keeping Pigs Out of Parlors: Using Nuisance Law to Affect the Location of Pollution*, 27 ENVTL. L. 403, 443 (1997).

[11] *See* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 238 (2007) (describing how the FDA drug approval process justifies preemption of state tort

a comprehensive manner,[12] and the creation of uniform nationwide standards that facilitate economies of scale.[13] However, this transfer of authority is only legitimate if the agency is faithful to its organic statute in promulgating rules.[14] When an agency fails to adhere to the principles expressed in its organic statute, preemption can ossify the standard of care at a suboptimal level, creating a regulatory failure that endangers citizens while preventing them from seeking relief through the courts.[15]

To compensate citizens for the loss of tort remedies, federal preemption ought to be understood to give rise to a duty that the regulatory agency owes to citizens to maintain adequate standards of protection. The statute authorizing the agency to promulgate regulations would provide the substance of that duty. In this paper, I contend that courts should recognize the violation of this duty as a legally cognizable injury, constituting injury in fact for the purposes of the Article III standing analysis. This legally cognizable injury should arise among citizens who (1) fall within the statute's zone of interests,[16] (2) experience a particularly acute risk of material injury, (3) as a result of an agency regulatory failure in administering that statute, and (4) whose tort claims are preempted by that statute or its regulations. For these purposes, I measure regulatory failure by whether agency practice violates

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law).

[12] *See* Don Bradford Hardin, Jr., Comment, *Why Cost-Benefit Analysis? A Question (and Some Answers) About the Legal Academy*, 59 ALA. L. REV. 1135, 1145 (2008).

[13] Susan Bartlett Foote, *Beyond the Politics of Federalism: An Alternative Model*, 1 YALE J. ON REG. 217, 220 (1984).

[14] Agencies derive their preemptive authority from congressional grants of statutory authority. If an agency is not faithful to its organic statute, then preemption of state law would be *ultra vires*. *See* New York v. FERC, 535 U.S. 1, 18 (2002) ("[A]n agency literally has no power to act, let alone preempt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it.") (quoting Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986)).

[15] *See* Jim Rossi & Thomas Hutton, *Federal Preemption and Clean Energy Floors*, 91 N.C. L. REV. 1283, 1352 (2013) (distinguishing between "floor preemption," which presents a low risk of ossification, and "unitary preemption," which presents a higher risk of ossification).

[16] The zone of interests is a measure of whether a statute was designed to protect the interest that the claimant seeks to vindicate. *See* Ass'n of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 153 (1970). The concept illustrates the Administrative Procedure Act's grant of standing to persons "aggrieved by agency action within the meaning of a relevant statute." *Id.*; *see also* 5 U.S.C. § 702 (2006).

relevant statutory language in the organic statute.[17]

To make this case, I proceed as follows: Part I demonstrates how the issues presented by federal preemption of state tort law and the ossification of the rulemaking process can combine to entrench dangerously inadequate regulatory regimes at the federal level. In Part II, I first define regulatory failure for the purposes of this Note, and identify examples of the sorts of statutes where these regulatory failures might present themselves. Next, I outline why the principles of federalism and democratic accountability warrant judicial recognition of procedural standing for citizens to combat regulatory failure, in a limited set of circumstances. Part III illustrates how a citizen seeking to challenge agency inaction using this method would obtain Article III standing.

I. WHEN PREEMPTION MET REGULATORY FAILURE

A. *The Problem of Regulatory Lock-in*

One of the benefits of the common law has historically been its ability to adapt to new realities, with doctrinal change approximating the changing economics and morals of America. For example, the theories of market share liability[18] and comparative negligence,[19] the application of *res ipsa loquitur* to medical malpractice,[20] the rejection of the privity of contract requirement for products liability,[21] and many other doctrinal developments represented judicial adaptations precipitated by technological and societal developments. The common law's flexibility allows new rules to be proposed cheaply and reformulated iteratively over time.[22] This iterative process

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17 In the literature, other definitions of regulatory failure abound. *See, e.g.*, Lloyd N. Cutler & David R. Johnson, *Regulation and the Political Process*, 84 YALE L.J. 1395, 1399 (1975) (anti-democratic regulation); Robert L. Glickman & Stephen B. Chapman, *Regulatory Reform and (Breach of) The Contract with America: Improving Environmental Policy or Destroying Environmental Protection?*, 5 KAN. J.L. & PUB. POL'Y 9, 10 (inefficient regulation); David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 118 (2005) (mass harms caused by products or processes with regulatory approval); Matthew D. Zinn, *Policing Environmental Regulatory Enforcement: Cooperation, Capture, and Citizen Suits*, 21 STAN. ENVTL. L.J. 81, 109 (2002) (capture).

18 *See* Sindell v. Abbott Labs., 607 P.2d 924, 937 (Cal. 1980).

19 *See* Li v. Yellow Cab Co., 532 P.2d 1226 (Cal. 1975).

20 *See* Ybarra v. Spangard, 154 P.2d 687 (Cal. 1944).

21 *See* MacPherson v. Buick Motor Co., 217 N.Y. 382 (1916).

22 *See generally* David L. Shapiro, *Courts, Legislatures, and Paternalism*,

historically allowed tort law to play a major role in the regulation of business, and the protection of workers and consumers, through judicial innovation.[23]

Over time, however, the demands of an increasingly nationalized economy began to drive common law courts out of the business of regulation, to be replaced by federal administrative agencies.[24] While not as nimble as common law courts, administrative agencies could accrue vast informational advantages in the form of institutional expertise,[25] and ensure uniform regulation nationwide by preempting state law, thereby upholding minimum standards of care to protect citizens and allowing corporations to develop massive economies of scale.[26]

As the administrative state has matured, it has expanded, placing increased regulatory burdens on the bureaucracy.[27] The federal apparatus regulates more fields than ever before, but it has also been unable to regulate quickly enough to keep pace with the challenges Congress has delegated to it.[28] Agencies often take years to promulgate regulations after the passage of major legislation and then fail to revisit these regulations, even if the

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74 VA. L. REV. 519, 554–55 (explaining the process by which judges can change the law over time).

[23] *See, e.g.*, OLIVER WENDELL HOLMES, JR., THE COMMON LAW 15–16 (Dover Publications, Inc. 1991) (1881) (describing the emergence of the doctrine of respondeat superior).

[24] *See* JAMES M. LANDIS, THE ADMINISTRATIVE PROCESS 10–16, 46–50 (1938) (explaining how the defenders of the administrative state argue that agencies are necessary to manage a nationalized economy).

[25] *See* Phillip G. Oldham, Comment, *Regulatory Consent Decrees: An Argument for Deference to Agency Interpretations*, 62 U. CHI. L. REV. 393, 415–18 (1995) (arguing that agencies are warranted expansive deference due to their various institutional advantages).

[26] *See* Susan Bartlett Foote, *Administrative Preemption: An Experiment in Regulatory Federalism*, 70 VA. L. REV. 1429, 1462 ("If many states have differing design standards, national marketing becomes constrained and economies of scale become impossible. At stage one, then, the national interest in interstate commerce justifies federal preemption.").

[27] *See* Gary Lawson, *The Rise and Rise of the Administrative State*, 107 HARV. L. REV. 1231, 1236 (1994) ("There is now virtually no significant aspect of life that is not in some way regulated by the federal government.").

[28] *See* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1394 (1992) (describing how EPA's RCRA rulemaking "has become so ossified that it cannot keep up with" changes in scientific techniques); Cary Coglianese, *The Rhetoric and Reality of Regulatory Reform*, 25 YALE J. ON REG. 85, 87 (2008) (describing how EO 13,422 slows down an "already overburdened administrative process").

organic statute demands that they do so.[29] As a result, the administrative state fails to satisfy its mandate fully, in large part because it is not nimble enough to keep pace with the rapidly evolving problems presented by the modern world.

The problem of regulatory lethargy at the federal level might not be so serious if state regulatory statutes and state tort law could fill the gaps created by the demands of a changing economy. However, the recent trend toward preemption of state law compounds the difficulties presented by regulatory sclerosis.[30] If an agency promulgates regulations that preempt state law and require periodic reassessment, neglect or delay at the federal level will entrench bad or outdated policy nationwide, leaving congressional intervention as the only hope of respite.

B. *Preemption Makes the Threat of Regulatory Failure More Severe*

Due to ossification of the rulemaking process, the rate of change for heavily regulated areas of federal law may fall below the optimal rate for social welfare.[31] As I will demonstrate in this section, the rate of doctrinal change in administrative regulatory regimes will likely fall below the rate warranted by the pace of economic and societal change, whereas state tort law will likely keep better pace.

Examples of state tort law evolving to match contemporary economics and morality abound throughout legal history. From the death of the "unholy trinity" of defenses to workplace injury,[32] to

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[29] McGarity, *supra* note 28, at 1436 ("Given all of the barriers to writing a rule in the first place, few agencies are anxious to revisit the process in light of changed conditions or new information.").

[30] *See generally* David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 130–32 (2005) (describing how the preemption of tort law allows the costs of regulatory failures to fall directly upon injured persons).

[31] *See* McGarity, *supra* note 28, at 1386 ("[T]he rulemaking process has become increasingly rigid and burdensome."). For example, while the Occupational Safety and Health Administration (OSHA) produced its first occupational health standard for asbestos in six months in 1972, more recent OSHA health standards have taken more than five years to produce. *Id.* at 1387–88.

[32] *See* John Fabian Witt, *The Transformation of Work and the Law of Workplace Accidents, 1842–1910*, 107 YALE L.J. 1467, 1467 (1998) (describing the common law rules of fellow servant, assumption of risk, and contributory negligence as the "unholy trinity" of defenses to workplace injury, which perished in the early twentieth century).

the emergence of legal recognition for emotional harms,[33] to the relaxation of contributory negligence doctrine,[34] tort law has evolved roughly in tandem with the modern economy. This flexibility may be attributable to the fact that courts see the same kinds of harms over the course of many years, and are therefore able to determine whether the common law is providing adequate protections, and to experiment with changes in the doctrine at low cost.[35]

While the cost of lower court experimentation with new doctrine before federal preemption is mainly limited to the cost of appeals, the cost of experimentation after preemption is much higher. After common law has been completely preempted and replaced by a federal regulatory scheme, standards of care can be changed only by congressional action or agency action,[36] such as issuing new guidance, notice and comment rulemaking, or adjudication. While issuing new guidance is a relatively low cost approach, it is also limited in the degree of change it can effect.[37] Notice and comment regulation is very costly to undertake,[38] involving in-depth study,[39] rigorous public engagement,[40] the

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[33] *See generally* Martha Chamallas & Linda K. Kerber, *Women, Mothers, and the Law of Fright: A History*, 88 MICH. L. REV. 814 (1990) (documenting the emergence of recognition in tort for fright-based injuries).

[34] *See* Li v. Yellow Cab Co., 532 P.2d 1226 (Ca. 1975) (rejecting strict contributory negligence doctrine, and adopting comparative negligence).

[35] *See, e.g.*, Michael D. Weiss & Mark W. Bennett, *New Federalism and State Court Activism*, 24 MEM. ST. U. L. REV. 229, 234 (1994) ("State courts are ideal laboratories for the development of new legal theories because of the distinctiveness of individual states. Each state court can create a different law governing a single subject, creating individualized rules for that state. By comparing the results from other states' experiments, each court can fine tune and optimize its own law.").

[36] William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1554 (2007) ("[C]eiling preemptions . . . preclude more protective state regulations or common law protections. Diversity of regulatory approaches becomes impossible, as only one standard matters—the federal one.").

[37] *See, e.g.*, Appalachian Power Co. v. EPA, 208 F.3d 1015, 1024 (D.C. Cir. 2000) ("It is well-established that an agency may not escape the notice and comment requirements . . . by labeling a major substantive legal addition to a rule a mere interpretation.").

[38] *See, e.g.*, McGarity, *supra* note 28, at 1387 (describing how the cost of supporting documents for the mere preamble to an environmental standard has run into the millions of dollars).

[39] *See id.* at 1405–06 (describing the requirement to prepare Regulatory Impact Analyses).

[40] *See id.* at 1385 ("[I]nformal rulemaking is still an exceedingly effective

obligation to respond to comments,[41] and (typically) expensive litigation.[42] While formal adjudication can proceed more quickly than notice and comment rulemaking in some cases, the agency's decision-making is limited by both the narrower, fact-bound scope of the adjudication, and lack of access to potentially interested parties who are not implicated in the proceeding.[43] The cost of congressional action is even higher,[44] and such action is rare given the legislative inertia that plagues Congress.[45]

When an agency finally does engage in regulatory reform, it is more likely that it will have been prompted by the regulated industry than by a response to unacceptably high levels of citizen injury.[46] The reasons for this are threefold. First, the regulated industry is better positioned to put pressure on relevant political and bureaucratic actors (public choice advantage).[47] Second, agency bureaucrats are more aware of the challenges faced by the regulated industry due to the need to coordinate closely with industry in designing, implementing, and enforcing regulations (informational advantage).[48] Third, the regulated industry is more

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tool for eliciting public participation in administrative policymaking.").

41 *See id.* at 1412 (describing the obligation to respond to public comments).

42 *See* Cary Coglianese, *Litigating Within Relationships: Disputes and Disturbance in the Regulatory Process*, 30 LAW & SOC'Y REV. 735, 742 (1996) ("13 of the 28 significant and major hazardous waste rules EPA issued ended up getting challenged in court.").

43 *See* Scott A. Zebrak, *The Future of NLRB Rulemaking: Analyzing the Mixed Signals Sent by the Implementation of the Health Care Bargaining Unit Rule and by the Proposed* Beck *Union Dues Regulation*, 8 ADMIN. L.J. AM. U. 125, 128 (1994) ("[D]espite its risks, rulemaking offers an administrative agency the valuable benefits of more clearly articulated standards and a fairer and more effective administration.").

44 *See* Brian Galle & Mark Seidenfeld, *Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 2009 (2008) (describing Congress's inability to adjust legislative schemes due to legislative inertia).

45 *Id.* ("[G]iven the inertia involved in Congress's law making process, it is unlikely that Congress will return the volley.").

46 *See generally* Sidney A. Shapiro, *The Complexity of Regulatory Capture*, 17 ROGER WILLIAMS U. L. REV. 221, 234–41 (2012) (explaining how regulatory capture can occur even when regulators have public interest-based motives).

47 *See, e.g.*, Richard L. Hasen, *Lobbying, Rent-Seeking, and the Constitution*, 64 STAN. L. REV 191, 196 (2012) ("The reason for the skewing [toward industry] is that those with resources and with narrow (as opposed to diffuse) interests in particular legislation can more easily overcome collective action problems and engage in political activity such as hiring lobbyists.").

48 Wesley A. Magat & Christopher H. Schroeder, *Administrative Process Reform in a Discretionary Age: The Role of Social Consequences*, 1984 DUKE L.J. 301, 338 (1984) ("Furthermore, because under most regulatory processes the

likely to have standing to challenge agency actions than harmed individuals, whose injuries may be widely shared, due to the bias of the traditional standing analysis in favor of particularized injuries (standing advantage).[49]

Article III standing doctrine is designed to grant standing to claimants that have distinctive injuries, while denying standing to those that have injuries indistinguishable from the population at large.[50] Since industrial actors are regulated directly, and regulatory beneficiaries reap relatively uniform benefits from third-party regulation, it is far more likely that an industrial actor's complaint with respect to a regulation will suffice for standing than will a regulatory beneficiary's complaint. The Supreme Court has held that "when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish."[51]

While the public choice advantage and the informational advantage are not judicially remediable, the standing advantage could be remedied if courts recognize the denial of a rulemaking petition to correct an agency's preemptive regulatory failure as a legally cognizable injury. Courts should recognize the enhanced duties to protect that arise post-preemption, by finding the injury in fact requirement satisfied when a plaintiff, who falls within the zone of interests for the statute that the agency has failed to administer properly, brings a challenge to a petition denial under section 706(2) of the APA.

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agency must rely in the first instance on the regulated industry for accurate information, industry groups will continue to enjoy the advantage of their superior familiarity with the relevant data and their ability to disclose information in potentially favorable formats.").

[49] *See* Cass Sunstein, *Standing and the Privatization of Public Law*, 88 COLUM. L. REV. 1432, 1433 (1988) ("The principal problem with [a private law conception of standing is that]

. . . interests of regulated industries could be protected through the courts, whereas the interests of regulatory beneficiaries were to be vindicated through politics or not at all."). Sunstein also points out that when regulated entities have easier access to court than regulatory beneficiaries, it creates "a perverse set of incentives on administrative actors by inclining them against regulatory implementation when it is legally required," because making regulations more protective will result in burdensome litigation, while refusing to revisit regulations will not. *Id.* at 1463.

[50] *See infra* Part III.

[51] Lujan v. Defenders of Wildlife, 504 U.S. 555, 562 (1992); *see also* Summers v. Earth Island Inst., 555 U.S. 488, 493–94 (2009) (quoting *Lujan*, 504 U.S. at 562).

II. PROCEDURAL STANDING TO COMBAT REGULATORY FAILURE

A. *Defining Regulatory Failure for Purposes of Procedural Standing*

In the secondary literature, definitions of regulatory failure include anti-democratic regulation,[52] inefficient regulation,[53] causation of mass harms by products or processes that have regulatory approval,[54] regulatory capture,[55] procedural failures,[56] and failure to respond to changes in the regulated field.[57] For the purposes of this Note, the only relevant form of regulatory failure is when an agency fails to follow congressional instructions in producing and maintaining the regulations for a particular statute. For example, failure to respond to changes in the regulated field would be permissible under certain statutes, where Congress did not provide instruction on how to ensure that the statute's regulations remain up to date. On the other hand, when a statute prescribes a process for updating its regulations, and the agency fails to follow that process, the agency may work a procedural injury upon citizens who fall within the protective ambit of the statute.

Because agency decisions on whether to revisit regulations are generally committed to discretion,[58] the most likely way for a court to find a preemptive regulatory failure would be when an agency is required to periodically revisit or reevaluate its regulations. Note, however, that even without a mandatory revisitation requirement, once an agency "has responded to a

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[52] Lloyd N. Cutler & David R. Johnson, *Regulation and the Political Process*, 84 YALE L.J. 1395, 1399 (1975) ("Regulatory 'failure,' then, as we would define it, occurs when an agency has not done what elected officials would have done had they exercised the power conferred on them by virtue of their ultimate political responsibility.").

[53] Robert L. Glickman, *supra* note 17, at 10 (defining "regulatory failure" as characterizing situations where the costs of regulation outweigh its benefits).

[54] *See* David C. Vladeck, *supra* note 17, at 118 ("the MDA was enacted in response to a massive regulatory failure brought to light by tort litigation").

[55] Matthew D. Zinn, *supra* note 17, at 109 (discussing regulatory capture).

[56] *See* Sidney A. Shapiro & Rena Steinzor, *Capture, Accountability, and Regulatory Metrics*, 86 TEX. L. REV. 1741, 1746–47 (2008) (discussing the use of procedural accountability to combat regulatory failure).

[57] See the discussion that follows in this Part for a full explanation of "failure to respond to changes in the regulated field."

[58] *See* Massachusetts v. EPA, 549 U.S. 497, 527 (2007) ("[A]n agency has broad discretion to choose how best to marshal its limited resources and personnel to carry out its delegated responsibilities.").

petition for rulemaking, its reasons for action or inaction must conform to the authorizing statute."[59] In other words, an agency's denial of a rulemaking petition could be based on an impermissible rationale. However, statutory revisitation or reevaluation requirements provide the surest legal hook for a court to find that an agency's regulatory failure was legally impermissible.

Revisitation requirements of this kind appear in the Consumer Product Safety Improvement Act of 2008.[60] The Danny Keysar Child Product Safety Notification Act, which governs "standards and consumer registration of durable nursery products",[61] commands the Consumer Products Safety Commission to set standards that "reduce the risk of injury associated with [durable infant or toddler products],"[62] and to "periodically review and revise the rules set forth under this section to ensure that such rules provide the highest level of safety for such products that is feasible."[63] Additionally, a provision governing mandatory toy safety standards provides an identical revisitation requirement.[64] If the Commission were to fail to revisit these regulations in a manner that made it possible to "ensure . . . the highest level of safety . . . that is feasible,"[65] a court would be justified in finding that the agency had presumptively failed to meet its statutory revisitation requirement.[66]

More concrete revisitation requirements can be found in numerous other statutes, including the FDA Food Safety Modernization Act, which requires the Secretary of Health and Human Services to "determine the most significant foodborne contaminants" every two years, and to revise FDA regulations

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[59] *Id.* at 533.

[60] Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016 (2008).

[61] 15 U.S.C. § 2056a (2011).

[62] *Id.* at § 2056a(b)(1).

[63] *Id.* at § 2056a(b)(2).

[64] *Id.* at § 2056b(c).

[65] *See id.* at § 2056a(b)(2).

[66] The CPSC's regulations occasionally have preemptive effect. In *Moe v. MTD Prods., Inc.*, 73 F.3d 719 (8th Cir. 1995), plaintiff's failure to warn claim was preempted by CPSC regulations that covered the warning of the lawnmower that injured him. Similarly, in *Frazier v. Heckingers*, 96 F. Supp. 2d 486 (E.D. Pa. 2000), safety standards authorized by the Consumer Products Safety Act preempted plaintiff's state law damages claim for negligence, strict liability, and breach of warranty related to a lawnmower injury. *See also* Cortez v. MTD Products, 927 F. Supp. 386 (N.D. Ca. 1996).

accordingly;[67] and the Housing and Community Development Act, which requires the Department of Housing and Urban Development (HUD) to consider revisions to the "Federal manufactured home construction and safety standards" every two years.[68] Both the food safety standards[69] and the manufactured home standards have been found to have preemptive effect in the past.[70]

B. *Principles of Federalism and Democratic Accountability Favor Judicial Review in Cases of Preemptive Regulatory Failure*

The standard objection to allowing standing in cases where regulatory beneficiaries seek to reinforce the protection provided by government regulation of third parties is that such claims are not suitable for judicial disposition, but rather should be reserved to the political branches.[71] In such cases, any harm to the regulatory beneficiaries is directly attributable to a third party, and only indirectly to the government's failure to regulate that third party, weakening the chain of causation between the agency action (or inaction) and the plaintiff's injury.[72] In *Allen v. Wright*, the Supreme Court warned that allowing standing in cases where the chain of causation between the government action and the

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[67] FDA Food Safety Modernization Act, 21 U.S.C. § 2201 et seq. (2011).

[68] *See* 42 U.S.C. § 5403(a)(4)(A) (2000).

[69] Note that the Food Safety Modernization Act was passed too recently to have generated any relevant case law. However, the FDA's food labeling regime preempts state law, suggesting that new FDA food regulations may be given preemptive effect. *See, e.g.*, Turek v. General Mills, Inc., 662 F.3d 423 (7th Cir. 2011) (holding that FDA food labeling requirements preempted plaintiff's state tort law claims); Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp., 626 F. Supp. 278 (D. Mass. 1986) (holding that the FDA's food labeling regime preempts the field of state food labeling law).

[70] *See, e.g.*, Hill v. John Foster Homes, Inc., No. 3:10–CV–209, 2010 WL 2696655 (E.D. Va. 2010) (finding that plaintiff's negligence claims were preempted by HUD's Manufactured Home Construction and Safety Standards); *In re* FEMA Trailer Formaldehyde Prods. Liab. Litig., 620 F. Supp. 2d 755 (E.D. La. 2009) (finding that plaintiff's products liability claims were preempted by HUD's Manufactured Home Construction and Safety Standards).

[71] *See* Sunstein, *supra* note 49, at 1459–60.

[72] *See, e.g.*, Lujan v. Defenders of Wildlife, 504 U.S. 555, 562 (1992) ("When, however, as in this case, a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else,* much more is needed. In that circumstance, causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party to the government action or inaction—and perhaps on the response of others as well.") (emphasis in original).

plaintiff's injury was weak would cast "the federal courts as virtually continuing monitors of the wisdom and soundness of Executive action."[73] Justice O'Connor, writing for the Court, emphasized that "such a role is appropriate for the Congress acting through its committees and the 'power of the purse;' it is not the role of the judiciary, absent actual present or immediately threatened injury resulting from unlawful governmental action."[74] Moreover, O'Connor argued, recognizing standing in the circumstances would "run afoul" of the constitutional principle that it is the duty of the Executive Branch and not the Judicial Branch to "take care the Laws be faithfully executed."[75] In Justice O'Connor's view, it would be judicial overreach to allow litigants to vindicate their interest in protective regulations against federal agencies in federal court.

Justice O'Connor's concern that federal courts might overreach is misdirected in this case; rather, denying standing to litigants seeking to ensure that agencies follow statutes that preempt state law permits overreach by the Executive Branch. Federal agencies derive their authority to issue regulations preempting state law from Congress.[76] It is but a small step to note that an agency cannot validly preempt state law if it fails to follow congressional instructions in the process of administering its regulations.[77] In other words, an executive agency acting alone cannot preempt state law; rather, it requires either implicit or explicit congressional imprimatur.[78] When the validity of a regulation is challenged at the outset, federal courts have no qualms about exercising the judicial power in order to afford

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[73] Allen v. Wright, 468 U.S. 737, 760 (1984).

[74] *Id.*

[75] U.S. CONST. art. II, § 3.

[76] *See* Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 604–05 (1991) (noting that because preemption is derived from the Supremacy Clause of the Constitution, U.S. CONST., art. VI, cl. 2, preemption is based on congressional intent).

[77] *See, e.g.*, Am. Optometric Ass'n v. FTC, 626 F.2d 896, 916–17 (D.C. Cir. 1980) (remanding for reconsideration Antitrust regulations that would have preempted state law). Indeed, "an agency literally has no power to act, let alone preempt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it." New York v. FERC, 535 U.S. 1, 18 (2002).

[78] *Wis. Pub. Intervenor*, 501 U.S. at 605 ("Absent explicit pre-emptive language, Congress' intent to supersede state law in a given area may nonetheless be implicit if a scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it . . . .").

review. Because preemption of state tort law works an ongoing burden on citizens by removing their common law remedies, federal courts retain good reason to continue to monitor agency compliance with congressional instruction, even after the implementing regulations go into effect. Providing judicial review is essential in this instance, because Congress has already proffered its answer to the problem of agency inaction by instructing the agency on how to update and maintain its regulations. If agency compliance with these congressional instructions is non-justiciable, then there is no check on the ability of the Executive Branch to preempt state law without congressional imprimatur. Although this might not give rise to a specific constitutional infraction,[79] it certainly gives rise to serious federalism and separation of powers concerns that often find expression in the Tenth Amendment, which reserves to the States powers not delegated to the federal government by the Constitution.[80]

The Supreme Court has held that "[t]he individual, in a proper case, can assert injury from governmental action taken in excess of the authority that federalism defines."[81] Moreover, the Court has recognized that citizens have "a direct interest in objecting to laws that upset the constitutional balance between the National Government and the States when the enforcement of those laws causes injury that is concrete, particular, and redressable."[82] In the case of preemptive regulatory failures, it is not the operation of the law itself that causes injury to the at-risk citizen whose tort claims are preempted. Rather, it is the agency's failure to follow congressional instructions that causes the injury. The Court should make an exception to its normal practice of enforcing a high bar for injury in fact when a third party is most directly responsible, because in this instance, the government has stepped in to block the citizen from accessing normal methods of redressing injury (lawsuits in state or federal court against the third party). The

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[79] An argument could be made that either states or citizens would have a right of action under APA § 706(2)(B) to challenge an agency's violation of the Tenth Amendment, in this instance, but that goes beyond the scope of this article. Section 706(2)(B), a rarely used provision of the APA, requires a federal court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . contrary to constitutional right, power, privilege, or immunity . . . ." 5 U.S.C. § 706(2)(B) (2006).

[80] U.S. CONST. amend. X.

[81] Bond v. United States, 131 S. Ct. 2355, 2363–64 (2011).

[82] *Id.* at 2364.

government's regulatory failure is therefore a principal cause of the increased risk of injury the citizen suffers, and the government is the only actor that the citizen can hold accountable in court.

Only when "there is a real need to exercise the power of judicial review in order to protect the interests of the complaining party"[83] can a federal court "oversee legislative or executive action."[84] Here, there is a "real need" to exercise review in order to avoid, in the words of Justice Scalia, "significantly alter[ing] the allocation of power . . . away from a democratic form of government."[85] Accordingly, the government's failure to follow the correct procedures in administering the statute should be recognized as a procedural injury,[86] caused by regulatory failure, and remediable via an injunction ordering the government to grant the citizen's rulemaking petition. I assume that for purposes of obtaining standing to challenge regulatory failure, a plaintiff would need to file a rulemaking petition, pursuant to section 553(e) of the APA[87] or the relevant section of the statute at issue, and then challenge the denial of that rulemaking petition, rather than simply seeking to prompt an agency to action without first submitting a petition.[88]

Recognizing this procedural injury will not dramatically expand access to the courts to initiate agency action. This is a narrow exception, and, moreover, a high bar in its own right. The plaintiff has to make four specific showings: (1) that she is within the organic statute's zone of interests; (2) that she is experiencing a high risk of injury; (3) that this elevated risk is attributable to an agency regulatory failure; and (4) that her only recourse is to seek an injunction, because any claim she would have had in state court would be preempted, if and when she is harmed. Only a very particular subset of potential litigants, making claims in a

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[83] Summers v. Earth Island Inst., 555 U.S. 488, 493 (2009) (quoting Schlesinger v. Reservists Comm. to Stop the War, 418 U.S. 208, 221 (1974)).

[84] *Id.*

[85] *Id.* (quoting United States v. Richardson, 418 U.S. 166, 188 (1974)).

[86] *See infra* notes 90–95 and accompanying text for a discussion of procedural injuries.

[87] 5 U.S.C. § 553(e) (2006) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.").

[88] This assumption has two advantages: first, giving the agency the opportunity to respond to a rulemaking petition may prompt action in its own right, or prompt the agency to explain the basis for its inaction; second, the agency's denial of a rulemaking serves as final agency action, which is necessary to obtain review under the APA. 5 U.S.C. § 704 (2006).

particularly narrow subset of circumstances, will have standing under this rubric.

III. OBTAINING PROCEDURAL STANDING TO CHALLENGE REGULATORY FAILURE IN PRACTICE

Lujan v. Defenders of Wildlife[89] sets out the basic test under Article III for a plaintiff to obtain standing in a federal suit. The plaintiff must demonstrate "injury in fact," "a causal connection between the injury and the conduct complained of," and "that the injury will be redressed by a favorable decision."[90] Injury in fact is defined as "a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical."[91] When "the plaintiff is himself an object of the [agency] action,"[92] as is the case in enforcement proceedings, this test is fairly easily met, as the plaintiff's interests are directly affected. However, when the plaintiff is indirectly harmed by rulemaking or agency inaction, "it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury."[93] Furthermore, "[p]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief if unaccompanied by any continuing, present adverse effects."[94]

The Supreme Court has carved out an exception to its redressability and imminence requirements in certain cases, to recognize procedural injuries. A claimant suffers a procedural injury "when an agency fails to follow a legally required procedure, such as the preparation of an [Environmental Impact Statement], and this failure increases the risk of future harm to some party."[95] A plaintiff who has a right to a certain procedure, such as the completion of an EIS,[96] and is denied that procedure,

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89 Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992).

90 *Id.* at 560–61.

91 *Id.* at 560 (citations omitted) (internal quotation marks omitted).

92 *Id.* at 561.

93 *Id.* at 562.

94 *Id.* at 564 (quoting Los Angeles v. Lyons, 461 U.S. 95, 102 (1983)) (internal punctuation marks omitted).

95 Christopher T. Burt, *Procedural Injury Standing After Lujan v. Defenders of Wildlife*, 62 U. Chi. L. Rev. 275, 276 (1995).

96 *See, e.g.*, Nat'l Parks Conservation Ass'n v. Manson, 414 F.3d 1, 5 (D.C. Cir. 2005).

normally finds it nearly "impossible for him to prove that a favorable action by the court . . . will prevent the . . . harm that he fears."[97] Accordingly, the Supreme Court, in footnote 7 of *Lujan v. Defenders of Wildlife*, recognized that "procedural rights are special: The person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy."[98] However, a mere violation of a procedural right does not suffice for standing, unless the plaintiff can also show harm to a "concrete interest that is affected by the deprivation" of her procedural right.[99] When "the same actor [is] responsible for the procedural defect and the injurious final agency action," the plaintiff does not need to show that "(1) the agency action would have been different but for the procedural violation, and (2) that court-ordered compliance with the procedure would alter the final result."[100]

A. *Injury in Fact*

To satisfy the injury in fact prong of the standing analysis, a plaintiff must show "a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical."[101] In procedural standing cases, the imminence requirement is relaxed.[102] To receive Article III standing, a plaintiff need not have already been actually injured in the past; rather, the plaintiff must suffer a "sufficient likelihood" of injury.[103] The plaintiff must be precise in defining her injury, in order to avail herself of procedural standing. She must plead both a procedural injury—in this case, the agency's inaction and subsequent denial of her rulemaking petition—and a connected injury to a concrete interest, such as an increased risk of harm.

Elevated risk has satisfied the injury in fact requirement in many cases. In *Clinton v. City of New York*, the likelihood of

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97 Burt, *supra* note 91, at 276.

98 *Lujan*, 504 U.S. at 572 n.7.

99 Summers v. Earth Island Inst., 555 U.S. 488, 496 (2009).

100 *Nat'l Parks Conservation Ass'n*, 414 F.3d at 5.

101 *Lujan*, 504 U.S. at 561 (citations omitted) (internal quotation marks omitted).

102 Sierra Club v. Salazar, 894 F. Supp. 2d 97, 108 (D.C. Cir. 2012) ("Due to the nature of the injury in a procedural rights case, the courts relax—while not wholly eliminating—the issues of imminence and redressability, but not the issues of injury in fact or causation.").

103 Clinton v. City of New York, 524 U.S. 417, 432 (1998).

future economic injuries was held sufficient to create injury in fact, in a situation where the President's line item veto threatened the economic interests of the plaintiffs.[104] In *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, the Court held that the elevated risk caused by illegal discharges of pollutants could reasonably curtail residents' use of a waterway, as a response to the unreasonably high risk.[105] The *Laidlaw* facts closely resemble the set of facts likely to exist in a suit to force rulemaking to remedy a preemptive regulatory failure, in that the agency's failure to constrain the behavior of regulated actors not only creates an environment of elevated risk for the plaintiffs, but also might cause them to curtail their activities, resulting in concrete and non-speculative injuries.[106] Furthermore, like the risk created by the illegal discharge of pollutants, the harm resulting from a preemptive regulatory failure will affect both the entire statutory zone of interests, and a subclass of citizens that suffer concrete harm as a result of the regulatory failure. It is this subclass of citizens who can satisfy the Article III requirements.

B. *Causation*

A plaintiff seeking to remedy a preemptive regulatory failure must demonstrate a causal connection between the agency's inaction and the elevated risk she experiences. In general, the causation inquiry turns on the level of generality of the injury.[107] The more generally stated the injury, the easier the showing of causation will be.[108] However, injuries must be pled at a sufficient level of specificity in order to qualify for injury in fact, rather than be dismissed as generalized grievances.[109] To satisfy the causation

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[104] *Id.* at 418 (holding that a company suffered an injury in fact when the President cancelled a tax benefit for which the company was likely to be eligible, although the company had not yet completed the transaction that would make it eligible for the tax benefit).

[105] Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 184–85 (2000).

[106] *Id.* at 184 ("[W]e see nothing 'improbable' about the proposition that a company's continuous and pervasive illegal discharges of pollutants into a river would cause nearby residents to curtail their recreational use of that waterway and would subject them to other economic and aesthetic harms.").

[107] Sunstein, *supra* note 49, at 1465.

[108] *Id.*

[109] *See* United States v. Richardson, 418 U.S. 166, 176–77 (1974) ("[The Government's refusal to disclose] detailed information on CIA expenditures . . . . is surely the kind of a generalized grievance described in both *Frothingham* and *Flast* since the impact on him is plainly undifferentiated and common to all

requirement, "[a] substantial probability" that the agency's inaction "created a demonstrable risk, or caused a demonstrable increase in an existing risk, of injury to the particularized interests of [the plaintiff] will suffice."[110] Although the plaintiff need not prove with 100 percent certainty that she would not be experiencing harm if the agency had followed its congressional mandate, she must *demonstrate* increased risk, which entails the presentation of specific allegations tending to show the agency is responsible.[111] It would be judicial overreach, as Justice O'Connor suggested,[112] were standing obtainable without a demonstrated connection between the agency's behavior and the plaintiff's plight.

C. *Redressability*

As discussed above, courts relax the redressability requirement in procedural standing cases.[113] Rather than requiring a showing that legal relief will directly ameliorate harms to the plaintiff's concrete interests, courts have held that "it suffices that the agency's decision *could be influenced*" by vindication of the plaintiff's procedural right.[114] So long as the plaintiff has persuasively connected the agency's flawed decision-making to a concrete interest, a finding of redressability should follow naturally, since an injunction requiring changes in the agency's decision-making process will affect the concrete interest in the same way that its flawed decision-making did.

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members of the public.") (internal quotation marks omitted).

[110] Nat'l Parks Conservation Ass'n v. Manson, 414 F.3d 1, 6 (D.C. Cir. 2005) (holding that "the Assistant Secretary's failure to conduct a reasoned determination regarding the proposed plant's impact on air quality" in Yellowstone National Park sufficed for injury, even though a reasoned determination would not necessarily result in denial of the permit the plant required).

[111] *See* Florida Audubon Soc. v. Bentsen, 94 F.3d 658, 666 (D.C. Cir. 1996) ("As we are reviewing a motion for summary judgment, we require specific facts, not 'mere allegations,' to substantiate each leap necessary for standing.") (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992)).

[112] *See supra* notes 71–81 and accompanying text.

[113] Sierra Club v. Salazar, 894 F. Supp. 2d 97, 108 (D.C. Cir. 2012) ("Due to the nature of the injury in a procedural rights case, the courts relax—while not wholly eliminating—the issues of imminence and redressability, but not the issues of injury in fact or causation.").

[114] Citizens for Better Forestry v. U.S. Dep't of Agric., 341 F.3d 961, 975 (9th Cir. 2003).

In *FEC v. Akins*,[115] a case in which plaintiffs sought review of a Federal Election Commission (FEC) decision not to treat the American Israel Public Affairs Committee as a "political committee" under the Federal Election Campaign Act, the Supreme Court found the redressability requirement satisfied "even though the agency (like a new jury after a mistrial) might later, in the exercise of its lawful discretion, reach the same result for a different reason."[116] According to James Pfander, "the Court define[s] success . . . in terms of altering the internal agency processes in ways that might produce a different regulatory outcome down the road."[117]

A court should find redressability satisfied for the purposes of challenging a preemptive regulatory failure when it finds (1) that a plaintiff seeking injunctive relief from the agency is subject to ongoing, elevated risk of injury, or a present injury that is likely to continue; and (2) that a more protective regulatory scheme will reduce the likelihood of future injury to the plaintiff by causing regulated actors to modify their risky activities.[118] The Court has made clear that mere "psychic satisfaction" at forcing the defendant to change behavior is insufficient for redressability.[119]

It must be left to the courts to decide how significant the likely reduction in risk to the plaintiff that would follow from a favorable disposition must be in order to meet the redressability requirement. However, it cannot be denied that when a plaintiff is in line to be repeatedly exposed to a harmful or hazardous material, for example, a reduction in the permissible level of exposure may significantly reduce the plaintiff's morbidity. This observation implies that certain kinds of air-borne, water-borne, and food-borne harms are particularly amenable to being redressed in this manner, since they are encountered continually. Admittedly, rarely encountered risks[120] may be so remote that a reduction in

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115 FEC v. Akins, 524 U.S. 11 (1998).

116 *Id.* at 25.

117 James E. Pfander, *Triangulating Standing*, 53 ST. LOUIS U. L.J. 829, 836 (2009).

118 A plaintiff must prove, even if he has been injured in the past, that he is at elevated risk of future injury. *See* City of Los Angeles v. Lyons, 461 U.S. 95, 106–07 (1983) (holding that a plaintiff who had been illegally choked by police in the past did not have standing to sue the city for equitable relief unless he could show "a real and immediate threat" that Los Angeles police officers would again "illegally choke him into unconsciousness . . . .").

119 Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 107 (1998).

120 *See, e.g.*, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) (products

their incidence would not redress a plaintiff's harm. That said, so long as a plaintiff satisfies the injury in fact requirement by tying her procedural injury to an increased risk of harm to a concrete interest, an injunction ordering the agency to initiate rulemaking should satisfy redressability.

D. *Distinguishing* Heckler v. Chaney

Demonstrating Article III standing is not the only obstacle to challenging regulatory failures. *Heckler v. Chaney*[121] stands for the proposition that agency decisions not to enforce in a particular instance are not judicially reviewable, due to the APA's preclusion of such review when agency action (or inaction) is "precluded by statute, or committed to agency discretion by law."[122] Specifically, section 701(a)(2) of the APA applies where Congress "has not affirmatively precluded review," but a "court would have no meaningful standard against which to judge the agency's exercise of discretion."[123] The *Chaney* Court held that "agency decisions to refuse enforcement" were unsuitable for judicial review because such decisions "[involve] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise."[124] However, *Chaney* left a window to reviewability slightly ajar: "the decision [not to enforce] is only presumptively unreviewable; the presumption may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers."[125]

Although *Chaney's* anti-reviewability presumption for decisions not to enforce may present some hurdles to challenging regulatory failures, courts have typically distinguished between non-enforcement decisions and denials of rulemaking petitions. As the Supreme Court explained in *Massachusetts v. EPA*:

> [i]n contrast to nonenforcement decisions, agency refusals to initiate rulemaking are less frequent, more apt to involve legal as opposed to factual analysis, and subject to special formalities, including a public explanation. . . . Refusals to promulgate rules are thus susceptible to judicial review though

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liability suit arising out of explosion of balloon catheter barred by preemption).

121 Heckler v. Chaney, 470 U.S. 821 (1985).

122 5 U.S.C. § 701.

123 470 U.S. at 830.

124 *Id.* at 831.

125 *Id.* at 832-33.

such review is extremely limited and highly deferential.[126]

As in the nonenforcement decision context, review of denials of rulemaking petitions is limited to cases where a court would have a "meaningful standard against which to judge the agency's exercise of discretion."[127] However, the organic statute may be able to provide such meaningful standards.[128]

Therefore, in cases where federal preemption of state law is based on regulations,[129] rather than adjudication,[130] review can be had when the organic statute provides a clear legal standard on which to base judicial review, and when the agency has fallen short of that legal standard in its failure to revisit past rules, or in its denial of petitions for rulemaking relevant to the rules in question. So long as the challenge to a preemptive regulatory failure is not solely based on an agency's enforcement decisions, but rather on its failure to follow congressional instruction with respect to its rulemaking obligations, then *Heckler v. Cheney* will be successfully distinguished, and the agency's inaction can be challenged by an affected party.

Tort preemption due to regulations, rather than enforcement decisions, is most likely to occur in the context of environmental, health, and safety standards. Regulations that contain such standards are self-executing in the sense that they operate to give license to certain kinds of regulated behavior without reference to the exercise of agency discretion.[131] Furthermore, these standards reflect the administrative state's predominant method of replacing the common law, in that they require regulated actors to follow their mandates in lieu of following common law liability regimes.[132] It follows that an agency's duties to protect citizens whose tort claims are preempted are vested in these types of standards.

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126 Massachusetts v. EPA, 549 U.S. 497, 527–28 (2007) (citation omitted).

127 470 U.S. at 830.

128 *See supra* notes 60–70 and accompanying text.

129 5 U.S.C. § 551(5).

130 5 U.S.C. § 551(7).

131 *See generally* Federal Motor Vehicle Safety Standards, 49 C.F.R. pt. 571 (2008).

132 *See* Patrick O. Gudridge, *The Persistence of Classical Style*, 131 U. PA. L. REV. 663, 687 (1983). Gudridge identifies two ways in which administrative law replaces common law: first, "another legal resource . . . explicitly replaces common law as the governing source of law;" and second, "the common law process now borrows its ideas from, for example, constitutional law or statutory policy." *Id.*

CONCLUSION

Recognizing this framework for challenging agency derelictions of the duty to regulate would give the public another tool to prevent regulatory failures from holding regulation hostage to a sclerotic administrative state. Furthermore, it would recognize that citizens who have ceded their right to sue for damages to administrative agencies have a cognizable interest in ensuring that those agencies are vigilant in maintaining an acceptable standard of care (as measured by the relevant statute). By ensuring that federal agencies whose regulations preempt state law do not shirk their congressionally mandated responsibilities, granting standing in this instance would ensure that the "allocation of power" in our system of administrative government does not drift "away from a democratic form of government."[133] In sum, recognizing standing for this type of injury would create a much needed safety valve, to be opened only when preemption and regulatory failure combine to entrench dangerously inadequate standards of care.

[133] Summers v. Earth Island Inst., 555 U.S. 488, 493 (2009) (quoting United States v. Richardson, 418 U.S. 166, 188 (1974)).