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Regulation of Emerging Risks

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Why has the EPA not regulated fracking? Why has the FDA not regulated e-cigarettes? Why has NHTSA not regulated autonomous vehicles? This Article argues that administrative agencies predictably fail to regulate emerging risks when the political environment for regulation is favorable. The cause is a combination of administrative law and interest group politics. Agencies must satisfy high initial informational thresholds to regulate, so they postpone rulemaking in the face of uncertainty about the effects of new technologies. But while regulators passively acquire more information, fledgling industries consolidate and become politically entrenched. By the time agencies can justify regulation, the newly entrenched industries have the political capital to thwart them.

This Article offers a prophylactic against this predictable regulatory failure. It defends an experimentalist model of regulation, in which agencies are empowered to impose moratoria on risky emerging technologies while regulators organize experiments to learn about the risks they pose and the means to mitigate them. The agency-coordinated experiments would expedite the promulgation of empirically informed rules. The moratoria would extend the political window for regulatory action and protect the public in the interim. The Article applies this experimentalist model to the regulation of fracking, e-cigarettes, and autonomous vehicles. It also identifies legal strategies for implementing experimental regulation under existing law. It challenges the conventional wisdom that agencies should postpone regulation until they can confidently predict the effects of new risky technologies.

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INTRODUCTION

Emerging risks differ from other risks that the state regulates in two ways. The first is epistemic: the information necessary to answer potentially dispositive questions about how the risk should be regulated will not be available when regulators first become aware of the technology. For example, regulators do not currently know whether fracking contaminates groundwater, whether e-cigarettes help smokers quit, or what effects autonomous vehicles will have on the rate of collisions.[1] But effective regulation of each of these risks requires answers to these basic questions.

The second is political: emerging risks create a brief window during which a wide range of regulatory interventions are politically viable. But that window can quickly elapse as interest groups and social norms become entrenched. Before fracking became intertwined in our economy and e-cigarettes became widely used, there was no powerful, organized interest group coalition opposing regulation. Now, even if evidence accumulates that suggests restrictions are justified, restrictive regulation may no longer be possible. The window for a safe transition to autonomous vehicles may also close suddenly if a high-profile collision turns public opinion against the technology.

There is a mismatch between existing administrative law and these features of emerging risks. The conventional rulemaking process requires agencies to satisfy high, early informational hurdles that they would struggle to meet when regulating emerging risks. A regulatory agency must generally give notice of a proposed rule, provide an opportunity for comments on the proposed rule, and respond to those comments.[2] It must also conduct a cost-benefit analysis of the rule.[3] After an agency promulgates the rule, the rule will be subject to judicial

1. For a review of the evidence on each of these issues, *see infra* Part IV.

2. *See* 5 U.S.C. § 553(b)–(c) (2012) ("[N]otice of proposed rule making shall be published in the Federal Register . . . After notice . . . the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.").

3. Exec. Order No. 13,563 § 1(b), 3 C.F.R. § 215 (2012) ("[E]ach agency must . . . propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs . . . .").

review, and the agency will be expected to justify its substantive decisions during the rulemaking process.[4]

Each of these hurdles can be insurmountable obstacles to regulating emerging risks. An agency may lack sufficient information to respond to skeptical comments from regulated parties. It could offer only speculative predictions about a rule's costs and benefits. It would create a rulemaking record vulnerable to judicial challenge. Consequently, agencies often postpone regulating emerging risks. But while agencies wait to acquire more information, interest groups organize and social norms crystallize. When agencies are prepared to regulate, the political window for optimal regulation may have elapsed.

This Article proposes that regulatory agencies should be granted a new set of powers to regulate emerging risks. Specifically, agencies should be empowered to (1) organize experiments with new risky technologies; and (2) impose moratoria or other limits on the use of those technologies outside of the experimental conditions. Agencies would be able to initiate these powers without having to satisfy the procedural requirements of the conventional rulemaking process, and some of their decisions would be protected from judicial review. But the powers would be temporary and limited in scope. Once the experiments conclude, agencies would need to proceed to rulemaking or end the moratoria.

The new powers would enable early, effective regulation of emerging risks. The experiment power would allow agencies to rapidly acquire reliable information about the risk and how to regulate it. The moratorium power would protect against interference with experimental conditions and prevent the political window for regulatory action from elapsing while the experiments were ongoing. The time and scope limits would protect against agencies using these powers as a *de facto* regulatory tool.

This Article defends the utility of these specific legal reforms. But they are intended to illuminate a new way of thinking about how public policy should respond to emerging risks. The Article contrasts this new model with the three main alternative models for regulating emerging risks: (1) the Precautionary model[5]—banning new risky

4. *See* 5 U.S.C. § 706(2) (2012) (providing that courts shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "unsupported by substantial evidence").

5. *See generally, e.g.*, FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (2004); DOUGLAS A. KYSAR, REGULATING FROM NOWHERE: ENVIRONMENTAL LAW AND THE SEARCH FOR OBJECTIVITY (2010).

technologies until they are proven safe; (2) the Common Law model[6]—allowing market innovation until regulation is proven cost-benefit justified; and (3) the Laboratory of Democracy model[7]—relying on state and local governments to test out regulatory solutions and choosing the best.[8]

Each of these models has its disadvantages. The Precautionary model does not provide a determinate answer when a new technology both creates new risks and mitigates existing risks, unless the state simply bans all potentially risky technologies regardless of their benefits and forgoes socially useful innovation. The Common Law model allows for market innovation, but also permits interest groups to entrench themselves and impede even cost-benefit justified regulation. The Laboratory of Democracy model can start a race to the bottom, in which the regulatory regime that most favors firms' interests wins out.

Critically, none of these models provide a mechanism for what the regulation of emerging risks needs most: rigorously controlled experiments that produce useful knowledge about which regulatory response is best. This Article defends an Experimentalist model for regulating emerging risks, building on recent scholarship arguing for a greater use of randomized experiments in regulation.[9] The Experimentalist model aims to maximize the potential for regulatory learning, while preserving regulatory options.

This new model should not apply to all areas of risk regulation. For many risks, from asbestos to climate change, the relevant science is settled, so there is little marginal value to publicly organized experiments. For other risks, especially catastrophic risks, randomized experiments might not be feasible or ethical. Some risks are latent for decades, so controlled experiments would take too long for any concurrent moratoria to be meaningfully temporary. Likewise, when science learns of a new risk from old technologies—for example, when we learn that plastics are leaching endocrine disruptors[10]—imposing a

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6. *See generally, e.g.*, Henry N. Butler, *A Defense of Common Law Environmentalism: The Discovery of Better Environmental Policy*, 58 CASE W. RES. L. REV. 705 (2008); Roger Meiners & Bruce Yandle, *Common Law and the Conceit of Modern Environmental Policy*, 7 GEO. MASON L. REV. 923 (1999).

7. *See generally, e.g.*, Michael C. Dorf & Charles F. Sabel, *A Constitution of Democratic Experimentalism*, 98 COLUM. L. REV. 267 (1998).

8. *See infra* Part II.

9. *See, e.g.*, Michael Abramowicz, Ian Ayres & Yair Listokin, *Randomizing Law*, 159 U. PA. L. REV. 929, 931–33 (2011); Zachary J. Gubler, *Experimental Rules*, 55 B.C. L. REV. 129, 129–30 (2014).

10. *See, e.g.*, UNITED NATIONS ENV'T. PROGRAMME & WORLD HEALTH ORG., STATE OF THE SCIENCE OF ENDOCRINE DISRUPTING CHEMICALS – 2012, iii (Åke Bergman et. al. eds., 2013),

moratorium would be difficult because the relevant interest groups might have already mobilized. Most importantly, although experiments would help resolve questions of fact, they provide no help with questions of value that regulators inevitably confront. Few experts dispute that obesity has become a significant public health problem.[11] But the regulatory choices—and the questions of moral and political philosophy that underlie them—remain labyrinthine.

Experiments and moratoria can be useful for a heterogeneous set of sources of emerging risks: consumer products, industrial processes, and the byproducts of research in science and engineering. To this Article's list of fracking, e-cigarettes, and autonomous vehicles, one might add genetically modified organisms,[12] nanotechnology,[13] or other emerging risks. But the most important risks to regulate may be those that have yet to emerge. So while the Article proposes solutions to three current issues in risk regulation, the point of the examples is to give some empirical plausibility to the claim that agencies ought to have the experiment and moratorium powers available to address emerging risks in the future.

Fully institutionalizing an Experimentalist model of regulation would require a new statute authorizing the experiment and moratorium powers. That one statute could be leveraged to solve a broad set of recurring problems in health, safety, and environmental regulation. As long as a new, risky technology fits within the substantive areas of risk that an agency was statutorily authorized to regulate, the experiment and moratorium powers could be used to regulate the risk. But because the prospect of adopting any new regulatory statute in the current political environment is minimal,[14] the Article concludes with second-best strategies for partially implementing the Experimentalist model under existing law.

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http://www.who.int/iris/bitstream/10665/78101/1/9789241505031_eng.pdf [http://perma.cc/AK7L-BTPJ].

11. *E.g.*, Barbara L. Atwell, *Obesity, Public Health, and the Food Supply*, 4 IND. HEALTH L. REV. 3, 3 (2007) ("It is undisputed that obesity is one of the major public health concerns of our day.").

12. *See, e.g.*, Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 403–06 (2002) (advocating a more precautionary approach for regulation of genetically modified foods).

13. *See, e.g.*, Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323, 1325–26 (2008) (discussing nanotechnology and its current regulation, and suggesting improvements in its regulatory scheme).

14. *See, e.g.*, Jody Freeman & David B. Spence, *Old Statutes, New Problems*, 163 U. PA. L. REV. 1, 5 (2014) (observing that "Congress has not passed a major environmental statute in nearly a quarter-century, nor has it produced more than incremental reforms to federal energy legislation during that time, despite dramatic technological, economic, and social changes in these fields that would seem to demand a legislative response.").

The Article proceeds in five parts. Part I describes the mismatch between existing administrative law and the features of emerging risks. Part II critiques the alternative models that scholars have proposed for regulating emerging risks. Part III presents the Experimentalist model and defends granting agencies experiment and moratorium powers. Part IV applies that model to the regulation of fracking, e-cigarettes, and autonomous vehicles. Part V proposes second-best strategies for partially implementing experiment and moratorium powers under existing law.

I. MISMATCH BETWEEN EXISTING LAW AND EMERGING RISKS

Administrative law conditions an agency's rulemaking power on the agency satisfying a series of informational hurdles. The most important of these are (1) notice and comment rulemaking; (2) cost-benefit analysis; and (3) judicial review. Scholars have long contested the utility of these hurdles for most rules.[15] I take no position on these larger debates; I address only the desirability of these information hurdles for rules designed to regulate emerging risks.

I defend three claims about existing law and its effects on emerging risks. First, for many emerging risks, there will be a gap between the information an agency will have about the risk and its possible means of mitigation, and the information the agency needs to satisfy these information hurdles. Second, as a result of this gap, agencies will often postpone regulation of emerging risks as they wait to acquire more information. Third, while agencies wait, the political environment for regulation may change, and the rule that an agency later determines to be justified may no longer be politically viable.

I cannot prove any of these claims in the abstract. The only way to offer evidence for these claims is with specific examples. Part IV demonstrates each of these claims—the gap between the information the agency has and the information it would need to regulate, the postponement of regulation, and the change in political economy during that postponement—for both fracking and e-cigarettes. It also offers suggestive evidence that these claims might be true for autonomous vehicles as well. My hope is that these empirical examples will convince the reader that the more general claims are likely to be true.

This Part analyzes in more detail the informational hurdles that existing law requires and the mismatch they create for emerging risks. It then explains why the political economy for regulation might change as an agency waits to acquire information to meet those hurdles.

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15. *See infra* notes 19–22, 24, 26–34, 36–42 and accompanying text.

A. Existing Law

The law governing administrative rulemaking comes from four sources: the Administrative Procedure Act ("APA"),[16] organic statutes, judicial doctrines, and executive orders. These sources of law have largely congealed into a standardized procedure for agency rulemaking. First, an agency provides notice of a proposed rule and facilitates public comment on the rule. Second, the agency conducts an analysis of a rule's costs and benefits. Third, the final rule is subject to judicial review.

1. Notice and Comment Rulemaking

Under the APA, rulemaking starts when an agency publishes a Notice of Proposed Rulemaking in the Federal Register, which must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[17] The agency must then provide "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," and, after considering those public comments, the agency must "incorporate in the rules adopted a concise general statement of their basis and purpose."[18] The agency must also keep a public record of the rulemaking process, which includes "copies or an index of written factual material, studies, and reports relied on or seriously consulted by agency personnel in formulating the proposed" rule.[19]

Although these procedural requirements may sound modest, in practice they place substantial informational demands on agencies. Through judicial interpretation, "the APA requirement that agencies must attach a 'concise general statement of basis and purpose' to final rules . . . has blossomed into a requirement that agencies provide a 'reasoned explanation' for rules and that they rationally respond to outside comments passing a 'threshold requirement of materiality.' "[20] Therefore, agencies must offer reasons for their own decisions in

16. 5 U.S.C. §§ 500–596 (2012).

17. 5 U.S.C. § 553(b)(3) (2012).

18. 5 U.S.C. § 553(c).

19. Section of Administrative Law and Regulatory Practice, American Bar Association, Special Feature, *A Blackletter Statement of Federal Administrative Law*, 54 ADMIN. L. REV. 1, 34 (2002). *But see id.* at 35 ("The obligation to disclose written factual material, studies, and reports relied on or seriously consulted by agency personnel is limited to materials whose disclosure would be required under the Freedom of Information Act.").

20. Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1400 (1992) (quoting Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 394 (D.C. Cir. 1973)).

rulemaking and reasons in response to comments from private parties that will satisfy reviewing courts.

Firms that seek to avoid regulation can strategically use the informational demands of notice and comment rulemaking to delay or prevent new rules. For example, they can deliberately flood the agency with comments, knowing that the agency will be held accountable for responding to them during judicial review.[21] Agencies are therefore faced with the choice of expending precious resources to respond in detail, ignoring the comments and risking judicial invalidation of the rule, or forgoing regulation altogether. Because agencies often elect to forgo regulation, some scholars have argued that the rulemaking process has ossified.[22]

Regardless of whether the rulemaking process has become too demanding in general, the notice and comment requirements are crippling when agencies seek to regulate emerging risks. In this context, agencies often lack the facts to offer a reasoned justification for their rules, and they are often unable to rebut regulated parties' comments raising doubts about the proposed rule in light of factual uncertainties. Consequently, agencies face strong pressure to forgo regulation of emerging risks.

2. Cost-Benefit Analysis

A series of executive orders, uninterrupted since the Reagan administration, require agencies to conduct a cost-benefit analysis of certain proposed rules.[23] Some regulatory statutes impose a cost-benefit

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21. *See* Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L.J. 1321, 1329–34 (2010) (explaining how a commitment to open government in the administrative system allows regulated firms to use the informational requirements of the rulemaking process strategically).

22. *See* McGarity, *supra* note 20, at 1426 ("As long as . . . agency decisionmakers believe that they must expend additional resources in anticipation of overly intrusive judicial review, they will be reluctant to undertake new rulemaking initiatives, to experiment with more flexible regulatory techniques, and to revisit old rulemaking efforts."). Scholars dispute whether the empirical evidence supports the claim that the rulemaking process has ossified. *See* Jason Webb Yackee & Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed, 1950–1990*, 80 GEO. WASH. L. REV. 1414, 1445–64 (2012) (examining success rates of proposed rules at the Department of the Interior to argue that evidence of ossification as a serious problem appears weak). *But see* Richard J. Pierce, Jr., *Rulemaking Ossification Is Real: A Response to* Testing the Ossification Thesis, 80 GEO. WASH. L. REV. 1493, 1495–1503 (2012) (analyzing *Testing the Ossification Thesis* to point out deficiencies in the study and suggesting improvements to better understand the breadth of ossification issues).

23. For the current Executive Order, see Exec. Order No. 13,563 § 1(b), 3 C.F.R. § 215 (2012) ("[E]ach agency must . . . propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs . . . .").

mandate as well.[24] The centralized Office of Information and Regulatory Affairs ("OIRA"), which reviews significant regulatory actions,[25] has institutionalized the practice of cost-benefit analysis and expanded its use across the administrative state.[26]

Cost-benefit analysis provides a decision-making procedure for regulation: acquire information about the relevant risk and the effects of potential rules to regulate it and select a rule for which the expected benefits exceed the expected costs.[27] Its proponents claim that it can counteract cognitive bias in regulatory decision-making,[28] solve regulatory principal-agent problems,[29] and police regulatory capture.[30] It has also been the target of persistent criticisms.[31]

One frequent criticism of cost-benefit analysis is that it requires exhaustive, specific information for its calculations to be meaningful and, in practice, that information is often unclear, incomplete, or unavailable.[32] I take no position on the general question of whether the informational demands of cost-benefit analysis are so frequently disproportionate to what is available that regulators should abandon

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24. For a discussion of the relationship between statutory cost-benefit mandates and the practice of cost-benefit analysis, see CASS R. SUNSTEIN, THE COST-BENEFIT STATE 12–15 (2003).

25. A regulatory action is "significant" if it will "[h]ave an annual effect on the economy of $100 million or more" or if it satisfies at least one of four other criteria. Exec. Order No. 12,866 § 3(f), 3 C.F.R. § 638 (1994).

26. For more on OIRA, see generally Cass R. Sunstein, *The Office of Information and Regulatory Affairs: Myths and Realities*, 126 HARV. L. REV. 1838 (2013); and Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260 (2006).

27. Some defenders of cost-benefit analysis defend it as an optimization tool. *See, e.g.*, Steve P. Calandrillo, *Responsible Regulation: A Sensible Cost-Benefit, Risk Versus Risk Approach to Federal Health and Safety Regulation*, 81 B.U. L. REV. 957, 991 (2001) (arguing in favor of a marginal-cost–marginal-benefit analysis). But in practice agencies using cost-benefit analysis more often choose a rule for which the expected benefits range exceeds the expected costs range. For examples, see generally Cass R. Sunstein, *The Real World of Cost-Benefit Analysis: Thirty-Six Questions (And Almost As Many Answers)*, 114 COLUM. L. REV. 167 (2014).

28. Cass R. Sunstein, *Cognition and Cost-Benefit Analysis*, 29 J. LEGAL STUD. 1059, 1059 (2000) ("[Cost-benefit analysis] is most plausibly justified on cognitive grounds—as a way of counteracting predictable problems in individual and social cognition.").

29. *See* Eric A. Posner, *Controlling Agencies with Cost-Benefit Analysis: A Positive Political Theory Perspective*, 68 U. CHI. L. REV. 1137, 1197 (2001) ("Many of the philosophical difficulties with cost-benefit analysis disappear when a principal-agent perspective is taken.").

30. *See, e.g.*, Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1370 (2013) (defending cost-benefit analysis's role in regulatory review on the ground that it has "the potential to reduce agency capture").

31. For leading criticisms of cost-benefit analysis, see generally ACKERMAN & HEINZERLING, *supra* note 5; KYSAR, *supra* note 5.

32. *See, e.g.*, David M. Driesen, *Cost-Benefit Analysis and the Precautionary Principle: Can They Be Reconciled?*, 2013 MICH. ST. L. REV. 771, 777–78 (2013); Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7, 12–13 (1998); Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1723 (2004).

the methodology altogether. Cost-benefit analysis may very well be better, for most areas of risk regulation, than alternative decision procedures.[33]

But cost-benefit analysis is particularly unsuited to the regulation of emerging risks. Even defenders of cost-benefit analysis have conceded that information deficits can diminish its utility.[34] Any cost or benefit predictions that an agency could offer in the analysis of a proposed rule to regulate an emerging risk would be speculative at best. The cost and benefit ranges produced by the analysis would provide little guidance for the choices that an agency would need to make in deciding which, if any, rule to promulgate. OIRA would be rightly skeptical of the agency's figures, and the rule might not survive its review. Therefore, agencies may avoid an unproductive and unsuccessful cost-benefit analysis by deciding not to regulate at all.

3. Judicial Review

The APA permits courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ."[35] Some scholars argue that judicial review of agency action ensures statutory compliance,[36] allows monitoring of agencies,[37] prevents

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33. As one defense of cost-benefit analysis puts it, "[A]t least it is quite plausible to think that [cost-benefit analysis], suitably modified to function as a practical decision-making tool, is welfare-maximizing, as compared to currently available competitor procedures . . . across a wide range of governmental choice situations." MATTHEW D. ADLER & ERIC A. POSNER, NEW FOUNDATIONS OF COST-BENEFIT ANALYSIS 62 (2006).

34. *See, e.g.*, Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165, 175 (1999) ("[Cost-benefit analysis] is frequently hampered by a lack of data . . . ."); *see generally* Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation*, *in* NEW PERSPECTIVES ON REGULATION 114 (David Moss & John Cisternino eds., 2009) ("Proponents of a new regulation inevitably argue that its benefits are substantial, while opponents inevitably argue that the costs are too high. The difficulty is that the evidence needed to assess such claims is almost always unavailable."); Cass R. Sunstein, *Empirically Informed Regulation*, 78 U. CHI. L. REV. 1349 (2011) (acknowledging the importance of improving the informational inputs into cost-benefit analysis).

35. 5 U.S.C. § 706(2) (2012).

36. Cass R. Sunstein, *On the Cost and Benefits of Aggressive Judicial Review of Agency Action*, 1989 DUKE L.J. 522, 522 (1989) ("The most obvious goal . . . of judicial review is to increase the incidence of legality. Under this view, judicial review of administrative action is necessary above all to ensure that regulatory agencies comply with congressional commands.").

37. *See, e.g.*, Lisa Schultz Bressman, *Procedures as Politics in Administrative Law*, 107 COLUM. L. REV. 1749, 1776 (2007) ("[T]he Court has shaped administrative law in a manner that enables Congress—beyond the bare provisions of the APA and other statutes—to monitor agency action.").

agency capture,[38] or provides quality control for agency decision-making.[39]

In academia, however, judicial review of agency action has as many critics as supporters.[40] One line of criticism states that judicial ideology influences outcomes in cases reviewing agency action.[41] Another claims that judicial review is neither sufficiently nor consistently deferential to agencies.[42] Either way, risk-averse agencies have a strong incentive to only promulgate rules and risk judicial invalidation when they can exhaustively document their justifications.

By now, the refrain should be clear: the hurdle judicial review creates for regulation generally is particularly acute for the regulation of emerging risks because of the information gap. Judicial review reinforces the dual requirements of notice and comment and cost-benefit analysis that agencies regulating emerging risks struggle to meet, and it adds a further incentive to exhaustively document information that an agency might lack. When agencies predict that they will not satisfy these informational hurdles, they may postpone regulating emerging risks until they acquire sufficient information.

B. Entrenchment

Postponing regulation in the face of limited information has its benefits. A rule based on more thorough information is not simply a rule that can survive the rulemaking process; if the informational hurdles have any value, they should also produce a more optimal rule. But the costs of postponing the regulation of emerging risks often outweigh its benefits. Agencies are partially constrained by politics, and the political economy of a regulation may change over time.

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38. *See, e.g.*, Jonathan R. Macey, *Separated Powers and Positive Political Theory: The Tug of War over Administrative Agencies*, 80 GEO. L.J. 671, 675 (1992) ("In order to prevent agency capture by special interest groups, the judiciary should subject agency action to rationality review and rigorous means-ends analysis.").

39. *See, e.g.*, McGarity, *supra* note 20, at 1452 ("[J]udicial review can perform a necessary 'quality control' function.").

40. *See, e.g.*, Nicholas Bagley, *The Puzzling Presumption of Reviewability*, 127 HARV. L. REV. 1285, 1289 (2014) (claiming that judicial review of agency action "has come under searing criticism for undermining effective governance").

41. *See, e.g.*, Cass R. Sunstein & Thomas J. Miles, *Depoliticizing Administrative Law*, 58 DUKE L.J. 2193, 2209 (2009) ("[J]udicial review of administrative action shows a strong effect from the political inclinations of federal judges . . . [even though] . . . existing administrative law principles are best understood as a self-conscious effort to prevent this state of affairs.").

42. *See, e.g.*, McGarity, *supra* note 20, at 1419 ("Because the agencies perceive that the reviewing courts are inconsistent in the degree to which they are deferential, they are constrained to prepare for the worst-case scenario on judicial review. This can be extremely resource-intensive and time-consuming.").

Changes in law can create path dependence: large, unanticipated future effects from seemingly small initial changes.[43] Sometimes a change in law will entrench the ability of political forces to resist future status quo changes.[44] Scholars have long noted that the adoption of a constitutional provision or the enactment of a statute can lead to entrenchment and prevent amendment or repeal.[45] Inaction, just as much as action, can also lead to entrenchment. A failure to pass legislation or regulation during a critical political window can entrench a lightly regulated status quo.[46]

Failing to regulate emerging risks at an early stage can cause two types of entrenchment: interest group entrenchment and social norm entrenchment. Preventing interest group entrenchment often justifies early regulation of emerging risks. Preventing social norm entrenchment is more normatively problematic, but it still may justify early regulation in a limited set of cases.

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43. For a rigorous analysis of the multiple meanings of "path dependence" as applied to law, see Oona A. Hathaway, *Path Dependence in the Law: The Course and Pattern of Legal Change in a Common Law System*, 86 IOWA L. REV. 601, 606–23 (2001).

44. For a similar analysis using the phrase "lock-in" instead of entrenchment, see generally Clayton P. Gillette, *Lock-In Effects in Law and Norms*, 78 B.U. L. REV. 813 (1998).

45. *See, e.g.*, Michael J. Klarman, *Majoritarian Judicial Review: The Entrenchment Problem*, 85 GEO. L.J. 491, 502–09 (1997) (defining "legislative" and "cross-temporal" entrenchment). Private law can be a source of entrenchment as well; Daryl J. Levinson & Benjamin I. Sachs, *Political Entrenchment and Public Law*, 124 YALE L.J. 400, 454–56 (2015) (arguing that informal entrenchment may result from measures that strengthen allies, weaken opponents, change composition of a political community, or change decisionmaking processes); John O. McGinnis & Michael B. Rappaport, *Symmetric Entrenchment: A Constitutional and Normative Theory*, 89 VA. L. REV. 385, 388–89 (2003) (arguing that formal constitutional and legislative entrenchment in the United States is generally forbidden and undesirable); Eric A. Posner & Adrian Vermeule, Essay, *Legislative Entrenchment: A Reappraisal*, 111 YALE L.J. 1665, 1666 (2002) (arguing that a constitutional rule barring formal entrenchment should be eliminated); John C. Roberts & Erwin Chemerinsky, *Entrenchment of Ordinary Legislation: A Reply to Professors Posner and Vermeule*, 91 CAL. L. REV. 1773, 1775 (2003) (using the death penalty and abortion to explain the concept of entrenchment); *see generally* Christopher Serkin, *Public Entrenchment through Private Law: Binding Local Governments*, 78 U. CHI. L. REV. 879 (2011).

46. The entrenchment problem and the importance of the pre-entrenchment political window have been acknowledged in the emerging technologies literature. *See, e.g.*, Albert C. Lin, *Revamping Our Approach to Emerging Technologies*, 76 BROOK. L. REV. 1309, 1309 (2011) ("[N]ew technologies also raise the specter of adverse health effects, environmental degradation and disaster, and even dehumanization, should those technologies go awry. . . . Addressing these problems becomes especially difficult when technological systems become entrenched."); Thomas O. McGarity & Karl O. Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 478–79 (1983) ("Experience with other potentially dangerous technologies, however, repeatedly has demonstrated the value of assessing the risks to man and the environment before the technologies attain widespread use.").

1. Interest Group Entrenchment

Interest group influence pervades risk regulation. Interest group theory predicts that, in legislative and regulatory processes, the interests of small, concentrated groups will prevail over the interests of a diffuse public.[47] Concentrated interest groups are better able to solve collective action problems than larger groups because each individual member of those groups has a higher per capita stake in the group effort and the group can more easily police free riding.[48] When interest groups become repeat players, they augment these advantages by acquiring strategic knowledge and the will to sacrifice short-term losses for long-term goals.[49]

Many of the statutes and rules that regulate risks to health, safety, and the environment confer benefits on a diffuse public—including future generations, foreigners, and nonhuman animals—and costs on concentrated, repeat-player interest groups, especially risk-creating firms and their trade associations. For these reasons, the political viability of risk regulation statutes or rules can depend considerably on the interest group power of such regulated firms.[50]

Emerging risks can bring with them a brief political window in which concentrated interest groups may not have yet entrenched themselves. This can happen for several reasons. The firms may be start-ups lacking any lobbying relationships. Even if some firms in the industry have retained lobbyists, the firms may have not yet organized together into a trade association that can police free riding. Even if a trade association has been organized, it might not have developed relationships with powerful officials or gained the requisite experience for repeat-player advantages.

Interest groups can become entrenched while agencies wait to acquire information before regulating. The firms that would be

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47. *E.g.*, MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION 144 (20th prtg. 2002). For a critique of these arguments, see generally DANIEL A. FARBER & PHILLIP P. FRICKEY, LAW AND PUBLIC CHOICE: A CRITICAL INTRODUCTION (1991).

48. *See* OLSON, *supra* note 47, at 44.

49. *See generally* Marc Galanter, *Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change*, 9 LAW & SOC'Y REV. 95 (1974) (arguing that organized and influential groups have adapted to benefit from pre-existing rules).

50. *See, e.g.*, Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 128 (1998) ("[L]arge regulated parties enjoy much greater presence in agency decisionmaking processes than do public interest groups and other outside parties."); Mark Seidenfeld, *Bending the Rules: Flexible Regulation and Constraints on Agency Discretion*, 51 ADMIN. L. REV. 429, 464 (1999) ("[W]ithin niches of an agency's policy domain, firms in regulated industries and interest groups with strong central staffs still occupy a favored position in regulatory and political structures that allows them an advantage in influencing agency decisions.").

regulated may grow, and the industry may organize. In some cases, the industry may expand employment, which gives a wider swath of the public a stake in the continuation of the risky technology. If agencies subsequently discover a strong case for aggressive regulation, newly entrenched risk-creating firms may be able to block forthcoming statutes or rules.[51] For this reason, industry has a strong incentive to delay regulation, and existing administrative law gives them tools to pressure agencies to do so.

2. Social Norm Entrenchment

Social norm entrenchment is subtler. It occurs when some new risky technology gains sufficient widespread public acceptance that new regulation or legislation restricting it would fail even without interest group influence.[52] Imagine, for example, that mobile phones really did significantly increase the risk of cancer.[53] In the early 1990s, only a small percentage of the population of the United States used mobile phones,[54] so it likely would have been politically possible to restrict them. If new evidence accumulated suggesting that mobile phones caused cancer today, it is not inconceivable that *some* regulation would still be politically viable. Perhaps the spread of texting has made voice calls less necessary or perhaps Bluetooth devices could be mandated. But there is no doubt that the widespread use of mobile phones would make regulation more difficult to achieve. Entrenched

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51. Eugene Volokh calls this a "political power slippery slope." Eugene Volokh, *The Mechanisms of the Slippery Slope*, 116 HARV. L. REV. 1026, 1114 (2003). He explains: "Decision A may thus change the balance of political power by empowering an interest group that might use this power to promote B; getting to A first and then to B would thus be politically easier than getting to B directly (though of course still not certain)." *Id.* at 1115. Note that in all of Volokh's examples, he is concerned with government action, rather than a decision not to regulate. But there is no obvious reason why, for some of his examples, a similar argument could not be made for the latter.

52. For similar arguments, see Gillette, *supra* note 44, at 832–41, analyzing the lock-in effects of norms, and Volokh, *supra* note 51, 1077–105, analyzing "attitude-altering slippery slopes."

53. According to the National Institutes of Health, "[T]o date there is no evidence from studies of cells, animals, or humans that radiofrequency energy can cause cancer." *Cell Phones and Cancer Risk*, NAT'L CANCER INST., NAT'L INST. OF HEALTH (June 24, 2013), http://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/cell-phones-fact-sheet [http://perma.cc/HM2M-4M7K]

54. According to one wireless industry survey, there were an estimated 5,283,055 wireless subscribers in 1990, 7,557,148 in 1991, and 11,032,753 in 1992. *See CTIA's Annual Survey Says US Wireless Providers Handled 3.2 Trillion Megabytes of Data Traffic in 2013 for a 120 Percent Increase over 2012*, CTIA (June 17, 2014), http://www.ctia.org/resource-library/press-releases/archive/ctia-annual-survey-2013 [perma.cc/P4D5-6F6Y]; *Background on CTIA's Wireless Industry Survey*, CTIA, http://www.ctia.org/docs/default-source/Facts-Stats/ctia_survey_ye_2014_graphics.pdf?sfvrsn=2 (last visited Oct. 19, 2015) [http://perma.cc/F8QG-AX54].

telecommunications firms might lobby against regulation, or dispute whatever scientific evidence supported the cancer link, as the tobacco firms did for decades. But there would likely be public opposition even in the absence of industry lobbying—that is social norm entrenchment.[55]

The case for taking early action to prevent interest group entrenchment is straightforward. If interest group power will constrain a democratically legitimate and justified regulatory solution in the future, it is likely worth such early action to preserve that option.[56] The normative case for preventing social norm entrenchment is more complicated. Even if a regulation is otherwise justified, the fact that a democratic majority opposes it is at least plausibly a reason to reject it. Any argument about limiting the ability of future popular majorities to govern their own fate is problematic. At a minimum, whether it is legitimate for the state to act so as to influence majority opinion is an open normative question. As one constitutional law scholar has argued, "Actions that are later in time presumably more accurately track the current desires of those who will actually be affected by those actions and who, therefore, have the stronger claim to legitimate input into the decisionmaking process."[57]

There are, however, at least three plausible scenarios in which social norm entrenchment might reflect something other than genuine disagreement about values. If any of these arguments apply for a particular emerging risk, agencies might be justified in using the moratorium power to prevent social norms surrounding that risk from becoming entrenched.

First, consider the unusual case of *reverse* social norm entrenchment—the possibility that some event will cause the public to oppose the introduction of an emerging technology for which the benefits outweigh the risks. For example, consider the early days of

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55. Volokh argues that the public can be misled by the "is-ought fallacy":

> [People] erroneously assume [ ] that just because the law allows some government action . . . actions of that sort must be proper. If this error is common, then one might generally worry that the government's implementing decision A will indeed lead people to fallaciously assume that A is right, which will then make it easier to implement B.

Volokh, *supra* note 51, at 1079. This Article's argument is the mirror image of Volokh's: the public will assume that just become some risky activity is legal and widely practiced, it must be innocuous.

56. Volokh defends this type of reasoning by taking the perspective of a voter rather than a society: "This approach might at first seem improperly paternalistic or anti-majoritarian, but it simply reflects political reality. . . . So if we do think that implementing A would lead others to support B while we ourselves would continue to oppose B, that's a reason for us to oppose A." *Id.* at 1104.

57. Louis Michael Seidman, *Ambivalence and Accountability*, 61 S. CAL. L. REV. 1571, 1592 (1988).

passenger air travel, in which the public was fearful about the new technology.[58] It is conceivable that some early crash might have created popular momentum favoring restriction of the technology, even though its benefits outweighed its risks, possibly at that time and most certainly in the future.

Cognitive science has demonstrated that we process information using the availability heuristic—"estimating the probability of an event on the basis of how easily instances of it can be brought to mind."[59] We also will estimate the probability of a risk to be higher if the risk is particularly salient or vivid.[60] When many individuals in a group overestimate the likelihood of a risk because of the availability heuristic, these "individual uses of the availability heuristic increase the public availability of data pointing to a particular interpretation or conclusion, and this increase in availability then triggers reinforcing individual responses," resulting in an availability cascade.[61] Availability cascades may have, for example, caused the disproportionate public reaction to vivid, high profile examples of health, safety, and environmental harm like the outrage over the Love Canal toxic waste site, the Alar pesticide scare, and airplane crashes.[62]

A moratorium or other early limitations on an emerging technology could prevent an early, vivid, but unrepresentative manifestation of its risk that could lead to an availability cascade and overly restrictive permanent regulation. Market incentives may not be sufficient because, even if the median risk-creating firm in an industry is sufficiently cautious to avoid an early incident, the least cautious firm can still create a problem for the whole industry. This unconventional sort of market failure justifies action against reverse social norm entrenchment.

Second, scholars have long recognized that many risky activities have a social meaning.[63] Our perceptions of risk and our beliefs about how to regulate them are influenced by "cultural cognition," defined as

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58. Elaine Iljon Foreman et al., *Flight or Fright? Psychological Approaches to the Treatment of Fear of Flying, in* AVIATION MENTAL HEALTH: PSYCHOLOGICAL IMPLICATIONS FOR AIR TRAVEL 70 (Tony Hubbard & Robert Bor eds., 2006).

59. Timur Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 706 (1999).

60. *See id.* at 707.

61. *Id.* at 712.

62. *See id.* at 691–703. Kuran and Sunstein's examples are drawn from AARON B. WILDAVSKY, BUT IS IT TRUE? A CITIZEN'S GUIDE TO ENVIRONMENTAL HEALTH AND SAFETY ISSUES (1995).

63. Lawrence Lessig, *The Regulation of Social Meaning*, 62 U. CHI. L. REV. 943, 963–71 (1995) (describing the social meaning of wearing motorcycle helmets in the Soviet Union, wearing helmets in hockey, and dueling).

"the psychological disposition of persons to conform their factual beliefs about the instrumental efficacy (or perversity) of law to their cultural evaluations of the activities subject to regulation."[64] Risk perceptions of guns, smoking, nuclear power, and climate change all exhibit the effects of cultural cognition.[65] If, for example, one identifies with hierarchical or individualistic cultural groups, one is likely to be skeptical about climate change.[66] Alternatively, if one identifies with egalitarian or communitarian cultural groups, one is more apt to believe that nuclear power poses significant risks.[67]

Cultural cognition might raise a special problem for perceptions of emerging risks. One recent study examined the effects of cultural cognition on the perception of nanotechnology's risks and benefits.[68] In the study, one group of participants was "told nothing about nanotechnology other than it is a scientific process for producing and manipulating very small particles."[69] When participants in that group were asked whether the benefits of nanotechnology were greater than its risks, there was no divergence in answer based on cultural worldview.[70] Another group was given a two-paragraph explanation of nanotechnology's risks and benefits.[71] In that informed group, the respondents displayed widely different perceptions of risk depending on their cultural worldview: 86% of hierarchical individualists said the benefits were greater than its risks, but only 23% of egalitarian or communitarians said so.[72]

If the results of the nanotechnology study are generalizable, it suggests that being exposed to information about an emerging risk might alter opinions about the risks and benefits of that technology through the process of cultural cognition. It is possible that risky technologies might have a "cultural cognition window." At the beginning of the window, the risky activity might have no particular social meaning. But as certain social groups begin to participate in the activity or as it becomes otherwise associated with a specific cultural identity, perceptions about the risk and views about whether and how

64. Dan M. Kahan & Donald Braman, *Cultural Cognition and Public Policy*, 24 YALE L. & POL'Y REV. 149, 151–52 (2006).

65. *See* Dan M. Kahan, *The Cognitively Illiberal State*, 60 STAN. L. REV. 115, 134–42 (2007).

66. *Id.* at 140–41.

67. *See id.* at 139–40.

68. *See generally* Dan M. Kahan et al., *Cultural cognition of the risks and benefits of nanotechnology*, 4 NATURE NANOTECH. 87 (2009).

69. *Id.* at 87.

70. *Id.* at 87–88.

71. *Id.* at 87.

72. *Id.* at 88.

it ought to be regulated calcify. This polarization leads to political obstacles to justified regulation—social norm entrenchment. A moratorium, by preventing any social group from participating in a new risky activity, delays the process by which the technology would acquire a cultural meaning and reduces the possibility that future debates about how to regulate it became entangled in cultural cognition.

Third, future majorities might oppose regulation temporarily because of cognitive dissonance—the psychological process that causes us to discount new evidence that would show our earlier choices to have been mistaken.[73] Consider again the case of mobile phones and cancer. Mobile phones have become so interwoven into our lives that cognitive dissonance might be a powerful force resisting new regulation, should evidence accumulate that they are sufficiently carcinogenic to be banned. A moratorium on mobile phones—or at least on mobile phones that are held close to the brain—might have allowed us to precommit ourselves against the predictable effects of cognitive dissonance.[74] The argument would be especially strong if the social norm entrenchment was temporary—that is, if cognitive dissonance merely *delayed* our acceptance of the evidence justifying the ban.

These examples suggest that preventing social norm entrenchment will be justified in some limited cases when the change in social norms will predictably impair future decisionmaking. Preventing interest group entrenchment is justified in a wider set of cases. Existing administrative law creates the risk of entrenchment and thereby often prevents effective regulation of emerging risks.

II. ALTERNATIVE MODELS FOR REGULATING EMERGING RISKS

Scholars have offered three alternative models for regulating under conditions of factual uncertainty, which I call the Precautionary, Common Law, and Laboratory of Democracy models. These models were not specifically designed for the problem of emerging risks. They are, undoubtedly, motivated by deeper ideological commitments about

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73. *See, e.g.*, Frank B. Cross, *The Public Role in Risk Control*, 24 ENVTL. L. 887, 914 (1994) ("Another form of cognitive dissonance also biases public risk perceptions. People are closely wedded to their current set of beliefs and relatively unwilling to change their beliefs, regardless of the strength of contrary evidence. Pre-existing opinions, even those arbitrarily held, overwhelm even reliable contradictory evidence . . . .").

74. In addition to the general objection to any precommitment argument that the future agent will have a more legitimate claim to decide for itself, there is the additional objection that groups, which will not all agree with the precommitment, are relevantly different than individuals, who at least have some claim to be acting for their future selves. For an objection along those lines, see Jon Elster, *Don't Burn Your Bridge Before You Come to It: Some Ambiguities and Complexities of Precommitment*, 81 TEX. L. REV. 1751, 1757–61 (2003).

the proper role of the administrative state. But because each of these models responds to the problem of factual uncertainty, they have come to frame the scholarly debate about how to regulate emerging risks. I argue that the Precautionary, Common Law, and Laboratory of Democracy models ultimately offer unsatisfactory solutions to the problem of regulating emerging risks. Identifying the strengths and weaknesses of these models will clarify the need for the Experimentalist model that Part III introduces.

A. Precautionary

The manifesto of the Precautionary model is the Precautionary Principle. It states, in one famous formulation, that, "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[75] How the Precautionary Principle should be operationalized is not immediately obvious, in part because its advocates support it for various reasons.[76]

Some defenders of the Precautionary model appeal directly to deontological moral intuitions, relying on a distinction between doing and allowing harm or otherwise emphasizing the collective moral agency of the community.[77] Others offer the related but distinct argument that regulating through cost-benefit analysis requires "putting a price on human life," which they contend is intrinsically wrong.[78] Even if human death and suffering could be quantified, some argue, it is immoral to weigh those costs against economic benefits.[79]

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75. *The Wingspread Consensus Statement on the Precautionary Principle*, SCIENCE & ENVTL. HEALTH NETWORK (Jan. 1998), http://www.sehn.org/wing.html [http://perma.cc/R36P-HR6C]. Another leading statement is the Rio Declaration, which states: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, U.N. DOC. A/CONF.151/26/Rev.1 (Vol. I), annex I (Aug. 12, 1992), http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm [http://perma.cc/GKF3-3V32].

76. *See* John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVT'L. L. & POL'Y REV. 13, 17 (identifying as a principal criticism of the Precautionary Principle that "[t]here are many versions of it and none gives explicit direction for individual cases," but contending that "it is perfectly possible to make sense out of the numerous formulations of the [P]recautionary [P]rinciple by breaking it down into elements and charting the variation within those elements").

77. *E.g.*, KYSAR, *supra* note 5, at 46–67.

78. *See, e.g.*, ACKERMAN & HEINZERLING, *supra* note 5, at 8 ("[H]uman life, health, and nature cannot be described meaningfully in monetary terms; they are priceless."); Steven Kelman, *Cost-Benefit Analysis: An Ethical Critique*, REG. AM. ENTERPRISE INST. J. ON GOV'T & SOC'Y, Jan.–Feb. 1981 at 33, 38 ("[S]ome things . . . are priceless . . . such as life or health.").

79. *E.g.*, ACKERMAN & HEINZERLING, *supra* note 5, at 61–90.

In addition to the moral case for the Precautionary model, some scholars argue that there are empirical reasons to take a precautionary approach. They point to the complexity of natural systems and the inherent uncertainty of scientific predictions about how the natural environment will respond to changes.[80] Some risks, they contend, involve the possibility of irreversible damage.[81] Other risks are catastrophic, on such a scale that any non-precautionary approach would be disastrous.[82]

With the diversity of arguments supporting the Precautionary model, it is unsurprising that there is no consensus on how to operationalize it. What action does the Precautionary Principle require when a technology, like nuclear power, both causes and mitigates risks to the environment or when a new technology, like genetically modified foods, has the potential to both benefit and harm human health? Critics of the Precautionary Principle argue that the Principle is indeterminate in these risk-risk tradeoff scenarios, in which regulators cannot simply choose the course of action that avoids all health or environmental costs.[83]

Some precautionary thinkers have responded that risk-risk tradeoffs are rare—most regulatory decisions involve a tradeoff between economic costs and risks to health, safety, or the environment.[84] Regardless of whether that claim is true in general, it is false for the emerging risks considered here. Fracking creates multiple environmental risks, but, by shifting energy production from coal to natural gas, it reduces the climate risks of carbon emissions.[85] E-cigarettes might be a net positive for public health, if—and this is a big if—they help smokers quit and do not addict nonsmokers. Autonomous vehicles have the potential to cut traffic fatalities down to a fraction of current numbers.[86] At least for these emerging risks, the argument that some versions of the Precautionary Principle are indeterminate in risk-risk situations cannot be dismissed.

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80. *E.g.*, KYSAR, *supra* note 5, at 71–90.

81. *See, e.g.*, *id.* at 90–98 (arguing that cost-benefit analysis in environmental contexts often cannot and should not provide a quantitative estimate of consequences).

82. *E.g.*, *id.*

83. *See, e.g.*, CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE 26–34 (2005) (arguing that the precautionary principle is paralyzing if taken at face value); Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 859–60 (arguing that even actions aimed at reducing harm carry some risk of causing harm) (1996).

84. *See* Steffen Foss Hansen & Joel A. Tickner, *Putting Risk-Risk Tradeoffs in Perspective: A Response to Graham and Wiener*, 11 J. RISK RES. 475, 476 (2008) (discussing the examples of mercury in fish and tropospheric ozone).

85. *See infra* Part IV.

86. *See id.*

Of course, the state could ban all new and potentially risky technologies, but this radical version drains some of the intuitive appeal of the Precautionary Principle.[87] What intuitive appeal it retains might be influenced by loss aversion.[88] A society that faithfully implemented that kind of Precautionary Principle might be a society without antibiotics, air travel, or mobile phones.[89] The pervasiveness of scientific uncertainty, especially with respect to emerging risks, can cut both ways. Foreclosing all innovation precludes the possibility of learning that some risks might be more innocuous than they initially appeared.

Even for regulatory decisions that do not involve risk-risk tradeoffs, it is difficult to defend total insensitivity to disproportionate economic costs or benefits. Some have argued that economic costs translate into health costs because "wealth leads to health,"[90] but one need not accept that view to agree that economic costs can cause significant suffering, especially when the distributional effect falls on the least well-off. These and other conceptual difficulties with simple interpretations of the Precautionary Principle have led to proposals for its refinement, some of which are compatible with considering economic costs and benefits.[91]

Despite the Precautionary model's shortcomings, precautionary thinking does offer important insights for regulating emerging risks. In particular, its caution about scientific uncertainty raises doubt about the advisability of early cost-benefit analyses and counsels in favor of early research into risky emerging technologies. Although risks to health, safety, or the environment are rarely literally irreversible, it is critical to consider the difficulty of reversing such regulation after entrenchment has occurred.

The Experimentalist model offers a distinct alternative to some implementations of the Precautionary model, but it could also be

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87. For a summary of other responses to the risk-risk tradeoff objection to the Precautionary Principle, see Noah M. Sachs, *Rescuing the Strong Precautionary Principle from Its Critics*, 2011 U. ILL. L. REV. 1285, 1316–17 (2011).

88. SUNSTEIN, *supra* note 83, at 35–63.

89. For a similar argument, see *id.* at 25.

90. For a qualified defense of that view, see generally, Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533 (1996).

91. *See, e.g.*, Stephen Charest, *Bayesian Approaches to the Precautionary Principle*, 12 DUKE ENVTL. L. & POL'Y F. 265, 272–277 (2002) (advocating a Bayesian approach to risk analysis); Daniel A. Farber, *Uncertainty*, 99 GEO. L.J. 901, 936–44 (2011) (weighing scientific and economic uncertainties for the example of climate change mitigation); Mark Geistfeld, *Implementing the Precautionary Principle*, 31 ENVTL. L. REP. 11326, 11328–32 (2001) (suggesting that the precautionary principle and cost-benefit analysis are not incompatible).

considered a more nuanced way of implementing the precautionary vision for the regulation of emerging risks.[92]

B. Common Law

The Precautionary model's mirror image is the Common Law model. In its purest form, the Common Law model would leave those injured by a new risky technology to their common law remedies. The more commonly defended form of the Common Law model is a temporary one, in which the market is allowed to innovate with new risky technologies until agencies develop information that indicates that regulation is warranted. But if firms are able to thwart regulation, the temporary Common Law model can collapse into the permanent Common Law model.

Some scholars have defended the permanent Common Law model for risk regulation.[93] The absence of regulation would allow for unlimited market innovation, but it would come at a crippling cost to those on whom the risk would fall. Common Law enthusiasts argue that the ex post penalties of tort law can provide some ex ante deterrence and protection from risk, but there are several well-established limitations on this deterrent effect.

First, because of causation, standing, evidential, and incentive problems, tort law is generally ineffective at reducing certain types of environmental or health risks. These include risks dispersed across a broad public,[94] risks that are caused by diffuse sources,[95] and risks that

92. For a distinct, but related, argument about how to reconcile cost-benefit analysis with the Precautionary Principle, see generally Driesen, *supra* note 32.

93. *See, e.g.*, Butler, *supra* note 6 (arguing that "common law rules should be the presumptively optimal method of controlling local environmental harms"); Meiners & Yandle, *supra* note 6 (arguing that "the common law, aided by state-level controls, could have done much of the job needed to protect the environment").

94. *See* Christopher H. Schroeder, *Lost in the Translation: What Environmental Regulation Does that Tort Cannot Duplicate*, 41 WASHBURN L.J. 583, 601 (2002) (explaining that in cases "where harm falls broadly on a large group and any individual harm does not rise above a threshold necessary to constitute an actionable injury . . . the sources of the harm may be causing harm that in the aggregate justifies intervention, but no one will be able to litigate.").

95. *See id.* (explaining that cases involving "concentrated effects from diffuse origins, present different doctrinal problems, especially ones having to do with the cause-in-fact requirement" and noting that joint and several liability is not always an answer because "the range of cases to which joint and several liability applies is under continual pressure from defendants claiming it to be unfair."). Schroeder emphasizes the special problem of tort claims that combine dispersed harms and diffuse origins. *See id.* at 601–02. For a similar argument, see Adam D.K. Abelkop, *Tort Law as an Environmental Policy Instrument*, 92 OR. L. REV. 381, 385 (surveying the limits of tort law regulation of environmental risks and concluding that "in most circumstances, tort law will not function efficiently and effectively as a lone policy instrument; but nonetheless, it serves important functions as a complement to regulatory rules.").

are latent for decades,[96] let alone risks to future generations, nonhuman animals, or the natural environment.

Second, emerging risks are especially ill-suited to tort law because tort claims are generally limited to injuries that were or should have been foreseeable to defendants.[97] The potential injuries that emerging risks might cause are, by definition, clouded by scientific uncertainty, so tortfeasors will have at least a potentially successful defense in arguing they were unforeseeable.

Third, tort defendants in emerging risk cases may be judgment-proof.[98] Firms innovating with new risky technologies are more likely to be start-ups than established incumbents. If the risky technology turns out to cause significant injuries, the market for the firm's product may evaporate and the firm may be bankrupt by the time that all injured plaintiffs are able to sue.

Fourth, relatedly, the solvency of defendants in the tort system relies on insurance coverage, and insurers are unlikely to cover emerging risks.[99] Insurers will only cover risks that they can classify with some confidence.[100] The claims that will be paid out for emerging risks will depend on factual predictions about the likelihood and magnitude of injuries that would be unknown at the time of underwriting. In addition, if the firms innovating with new risky technologies are small start-ups, they will likely be unable to self-insure.

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96. *See* Albert C. Lin, *Beyond Tort: Compensating Victims of Environmental Toxic Injury*, 78 S. CAL. L. REV. 1439, 1446 (2005) (explaining that, with latent harms, the "passage of time not only complicates proof, but also increases the risk that a defendant will no longer be financially viable, assuming that the defendant can even be identified. Compounding plaintiffs' difficulties, statutes of limitations may bar suit . . . .").

97. *See* David G. Owen, *Bending Nature, Bending Law*, 62 FLA. L. REV. 569, 588–605 (2010) (explaining that, despite some doctrinal innovations in the 1960s and 1970s, the foreseeability requirement continues to limit tort liability for injuries caused by what were emerging risks at the time of the tortious act).

98. *See, e.g.*, Maksim Rakhlin, *Regulating Nanotechnology: A Private-Public Insurance Solution*, 2008 DUKE L. & TECH. REV. 2 (2008) (discussing the judgment-proof problem in the context of nanotechnology risks and noting that many nanotechnology companies are start-ups).

99. For an example in the context of nanotechnology, see *id.* at 32 ("[S]parse exposure and toxicology research, a lack of nano-related accident history, and the breadth of nanotechnology applications leave insurers without reasonable means to classify the risk posed by nanomaterials.").

100. *See, e.g.*, Kenneth S. Abraham, *Environmental Liability and the Limits of Insurance*, 88 COLUM. L. REV. 942, 946–47 (1988) ("When faced with excessive uncertainty regarding . . . probabilities, an insurer . . . cannot estimate its probable success in diversifying risk through pooling, and . . . cannot determine the correct price to charge for its risk-bearing services.").

These theoretical limitations on the ability of tort law to regulate risks are predictable.[101] In the case of environmental risks, there is "[e]mpirical evidence suggest[ing] that environmental torts suits currently send a weak deterrent signal."[102]

The more sophisticated defense of the Common Law model argues not that the state should abandon public regulation altogether, but that it should wait until market innovation has produced enough information that the state can regulate effectively.[103] The temporary Common Law model is the tacit position of those who support the status quo, in which agencies wait to acquire information about emerging risks before regulating.

All of the criticisms of the permanent Common Law model apply to the temporary Common Law model until the eventual regulation can happen. But there are two additional problems with the temporary Common Law model. Its passive mechanism for acquiring information diminishes the quality of regulation and its waiting period allows regulatory entrenchment.

Market innovation may not produce information useful for regulation for three reasons. First, much of the information relevant to regulation—what pollutants are being emitted, what carcinogens are in the byproducts, who might be exposed, what symptoms are being observed—may be held by risk-creating firms or entities.[104] Second, because risk-creating firms have an interest in influencing public perceptions about the risks of their activities, they have the incentive to conceal unfavorable information about those risks, selectively reveal more favorable information, or at least prolong uncertainty to the extent it serves their regulatory interests. Third, even if market innovation does reveal some information about the risk, the uncontrolled market action lacks even the most rudimentary controls

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101. The tort system may still serve an important purpose for risk regulation: providing information that agencies can use in public law regulation. *See* Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 695 (2007) ("[T]he tort system can be more effective than the regulatory system in accessing the various types of information needed to inform regulatory decisions.").

102. Troyen A. Brennan, *Environmental Torts*, 46 VAND. L. REV. 1, 6 (1993).

103. To be clear, my claim is not that scholars have defended the temporary Common Law model. I contend that it is the implication of supporting a Cost-Benefit model that allows agencies to wait to regulate until they have received sufficient information to conduct a meaningful analysis. Jonathan Adler comes closest to explicitly embracing that position. *See* Jonathan H. Adler, *More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 205 (2000) (arguing for shifting the burden to the state to provide sufficient evidence of harm before regulating).

104. For examples and a more detailed theoretical account of why firms have little incentive to make public information that could be relevant to regulation public, see Wagner, *supra* note 32, at 1625–59.

of experimentation, so inferring causal effects may be exceedingly difficult.

The net effect of relying on interested, uncoordinated outside parties to voluntarily produce information for regulation is that agencies may be late to act when emerging risks justify aggressive regulation and will be less informed when they do act. Moreover, even if market innovation does provide some information about the costs and benefits of a risky technology, it may not provide information about the potential means to mitigate the risk. Because regulatory agencies take a passive role in the Common Law model, they will be less prepared to evaluate competing strategies for regulation when they acquire sufficient information about the risk to regulate.

Finally and most importantly, the Common Law model may lead to entrenchment. Firms opposed to regulation may grow and organize into effective interest groups that can thwart regulation. Social norms can develop during the period of market innovation that later impede effective decisionmaking. Of course, to some proponents of the Common Law model, entrenchment is a feature, not a flaw. But, if and when regulation is justified, entrenchment can turn the temporary Common Law model into a permanent Common Law regime and prevent effective regulation.

C. Laboratory of Democracy

Justice Brandeis wrote that "[i]t is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[105] The Laboratory of Democracy model thereby serves as the legal baseline for regulating emerging risks in the United States because, in the absence of federal legislation preempting state laws, the states are free to innovate with different regulatory regimes.[106] Unlike market innovation, which can at best only produce information about the costs and benefits of a risky technology, policy innovation can provide information about regulatory options as well.[107] In the context of emerging risks, the hope is that

105. *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

106. *But see* William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1560 (2007) ("In our post-New Deal era, most areas of law traditionally dominated by state and local choice include at least limited federal involvement.").

107. *See, e.g.*, Dorf & Sabel, *supra* note 7, at 287 ("The private sector institutions of learning by monitoring suggest a public sector model of problem solving adapted to a polity . . . . The model requires linked systems of local and inter-local or federal pooling of information . . . so that actors scrutinize their initial understandings of problems and feasible solutions."); *see also* Yair Listokin,

states will simultaneously test out the plausible regulatory alternatives, and federal regulators can then select the approach with the best benefit-cost ratio.[108]

The Laboratory of Democracy model has considerable appeal. Although the federal government can experiment with multiple regulatory alternatives, one might think the states are more likely to exhaust the plausible regulatory options because each state "experiment" will be designed by a different decision-maker.[109] Because the states are ideologically heterogeneous, there might be political will for certain policy innovations in some states that is lacking at the federal level. The optimal regulatory regime may vary from state to state because local conditions differ, and state governments and their electorates will be more familiar with those idiosyncratic conditions.[110]

There is, however, a counterintuitive strain in the federalism literature which argues that states innovate at a less-than-socially-efficient level.[111] The argument is that state and local innovation face a collective action problem. Because politicians in one jurisdiction can free ride on the experience of other jurisdictions, they have little individual incentive to innovate.[112] While these arguments may be plausible a priori, at least the brief histories of the three emerging risks analyzed below demonstrate that state and local governments sometimes do innovate, even if not at the socially efficient level.[113]

Learning Through Policy Variation, 118 YALE L.J. 480, 514 (2008) ("Other jurisdictions can costlessly observe the outcomes of these high-variance/high-expected-value policies and adopt the policies if they are successful while avoiding their negative effects if they are failures.").

108. *See* Listokin, *supra* note 107, at 483 ("If the policy succeeds, then policymakers will have achieved an ideal outcome and will no longer need to search for alternatives."). *But see* Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342, 380 (2004) ("The most sophisticated articulations of the governance model, however, understand competition and diversity not as a temporary strategy before choosing the superior solution . . . but rather as a means for continuous change and improvement.").

109. *See, e.g.*, Listokin, *supra* note 107, at 513 ("[L]ocalities will naturally experiment because different populations will have different policy goals. In other words, different jurisdictions will pursue new policies because the new policies have higher expected value for that particular jurisdiction than do existing policies . . . .").

110. *See, e.g.*, Dorf & Sabel, *supra* note 7, at 317 ("[C]itizen users have unique knowledge of those particulars of their own, local circumstances that must be taken into account[;] . . . those exposed to potential side effects are likely to have the sharpest eye for threats to their well-being.").

111. The origin of these arguments is Susan Rose-Ackerman, *Risk Taking and Reelection: Does Federalism Promote Innovation?*, 9 J. LEGAL STUD. 593 (1980). *See also* Brian Galle & Joseph Leahy, *Laboratories of Democracy? Policy Innovation in Decentralized Governments*, 58 EMORY L.J. 1333, 1334 (2009) (reviewing responses to Rose-Ackerman's claims and concluding that "there are no demonstrably overwhelming replies").

112. Rose-Ackerman, *supra* note 111, at 594.

113. For more on state responses to fracking, e-cigarettes, and autonomous vehicles, see *infra* Part IV.

The stronger criticism of the Laboratory of Democracy model is that when states do innovate, those innovations will not be reliable experiments. The worst-case scenario for state innovation is the so-called "race to the bottom."[114] The premise behind the race-to-the-bottom argument, as applied to risk regulation, is that risky activities are mobile.[115] Consequently, in the absence of any federal preemptive legislation, risk-creating firms will seek to move operations to the state or locality that will provide them with the least restrictive regulatory regime. The firms may be able to acquire this regime through sheer interest group power, such as by making campaign contributions to legislators. State and local legislators might also believe that attracting the risky activity is in their constituents' interests, if moving operations to the state will increase tax revenue or provide employment opportunities.[116] What makes this process a "race" is that firms can pit states or localities against one another competitively and move to the jurisdiction with the most attractive bid. The firms might not even need to direct the bidding war themselves; states will anticipate the race to the bottom and strategize accordingly.[117]

One possible result of a race to the bottom is a Common Law regime of the worst kind: the risky activity will migrate to a jurisdiction with a weak, nonexistent, or captured regulatory infrastructure. This jurisdiction may have a weak tax base, suffer from high unemployment, or be ideologically opposed to aggressive risk regulation. If these conditions are present, the regulatory regime imposed by that state or

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114. The literature is voluminous and contentious. The recent debate started with 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). For leading critiques, see generally Kirsten H. Engel, *State Environmental Standard-Setting: Is There A "Race" and Is It "To the Bottom"?*, 48 HASTINGS L.J. 271 (1997); Daniel C. Esty, *Revitalizing Environmental Federalism*, 95 MICH. L. REV. 570 (1996). For a reply, see generally Richard L. Revesz, *The Race to the Bottom and Federal Environmental Regulation: A Response to Critics*, 82 MINN. L. REV. 535 (1997).

115. *See, e.g.*, Richard B. Stewart, *Pyramids of Sacrifice? Problems of Federalism in Mandating State Implementation of National Environmental Policy*, 86 YALE L.J. 1196, 1212 (1977) ("Given the mobility of industry and commerce, any individual state or community may rationally decline unilaterally to adopt high environmental standards that entail substantial costs for industry . . . for fear that the resulting environmental gains will be more than offset by movement of capital to other areas with lower standards.").

116. *See* Esty, *supra* note 114, at 603–04 ("Regulators and the politicians who appoint them perceive that by cutting environmental standards and stealing a march on other jurisdictions in the competition for new investment, jobs, and industrial activity, they will increase their constituents' welfare by more than the utility losses inflicted by whatever environmental degradation occurs.").

117. *See id.* at 604 ("The knowledge that one's competitors intend to lower or already have lowered environmental standards induces parties to act preemptively or responsively and to lower their own standards, triggering a downward regulatory spiral and nonoptimal results.").

locality might be less like an experiment to determine the optimal policy and more like a front for the interests of the risk-creating firms.[118] Of course, if initial expectations of some risk turn out to be too high or expectations of the associated benefits are too low, the jurisdiction at the bottom may have chosen the optimal policy. The right conclusion to draw from the race-to-the-bottom argument is that we have no reason to *assume* that the policy adopted by the state that wins the race-to-the-bottom is the optimal one.

But even if a race to the bottom does not take place and states and localities innovate policy by choice rather than pressure from firms, the Laboratory of Democracy model has a more basic flaw: decentralized innovation is not an "experiment" in a rigorous sense.[119] As one scholar put it, " 'Innovation' might have been a better word choice for Justice Brandeis than 'experimentation,' saving us all a lot of bother."[120]

The information federal regulators can glean from these innovations will be far less informative than what they can achieve through deliberate regulatory experiments. As with market innovation, the regulatory innovations that the Laboratory of Democracy model makes possible will not be randomized or even subject to weaker controls, so regulators hoping to learn from them will face difficulties in disentangling causation.[121] Selection effects may cloud the results because which jurisdictions choose which regulatory interventions may be correlated with other facts about those jurisdictions that could be relevant to the health or environmental outcomes observed.

The Laboratory of Democracy model also allows for interest group and social norm entrenchment, at least in jurisdictions that do not rapidly adopt precautionary regulation. Mobile risk-creating firms are on the fortunate side of a power asymmetry: they only need to prevail in one jurisdiction to continue their operations and build up a

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118. *But see generally* Richard L. Revesz, *Federalism and Environmental Regulation: A Public Choice Analysis*, 115 HARV. L. REV. 553 (2001) (arguing that it is not clear whether the interest group power of regulated firms would be worse at the federal or state level).

119. In theory, a centralized federal government could conduct experiments by randomly assigning certain policies to certain states or localities, but this type of experiment would deprive sub-federal polities of what supposedly makes federalism attractive: the ability to choose. *See* Edward L. Rubin & Malcolm Feeley, *Federalism: Some Notes on a National Neurosis*, 41 UCLA L. REV. 903, 925 (1994) ("To experiment with different approaches for achieving a single, agreed-upon goal, one sub-unit must be assigned an option that initially seems less desirable . . . . Allowed to choose their own strategies, as they are in a decentralized system, no sub-units would choose these unappealing options . . . .").

120. Barry Friedman, *Valuing Federalism*, 82 MINN. L. REV. 317, 399 (1997).

121. *See infra* Section III.B (explaining randomization).

power base before expanding to other locales, but must lose in all jurisdictions in order to be restrained.

For these reasons, at best, the state and local policy innovations that the Laboratory of Democracy model permits are inferior to deliberate federal regulatory experiments. At worst, when a vicious race to the bottom occurs, the Laboratory of Democracy model collapses into the Common Law model and exhibits all of its problems.

III. AN EXPERIMENTALIST MODEL

Part II lodged two criticisms at the existing models for regulating emerging risks. First, they do not generate the information needed for regulation rapidly and reliably. Second, they make future regulation more difficult, either by cutting off innovation (the Precautionary model) or allowing entrenchment (the Common Law and Laboratory of Democracy models).

This Part proposes an Experimentalist model for regulating emerging risks that addresses both of these problems. Its answer to the information generation problem is to empower regulatory agencies to organize randomized experiments with new risky technologies. Its answer to the entrenchment problem is to empower agencies to impose moratoria or other limits on the risky technologies outside of the experimental conditions. The effect would be to expedite the acquisition of reliable information while preserving all regulatory options.

An agency would respond to emerging risks in four steps. First, the agency would initiate its new powers by demonstrating that a technological development plausibly created a significant risk to health, safety, or the environment. Second, the agency would, in consultation with affected parties, decide on conditions for randomized experiments with the new risky activity and possible means to regulate it. Third, the agency would, if necessary, impose moratoria or other temporary limits on the risky technology outside of the experiment to protect the experiment's controls, protect the public in the interim, and prevent entrenchment. Fourth, the agency's actions would be subject to judicial review to ensure that the risk was plausible and significant and that the experiments and moratoria were appropriately limited in time and scope.

A. Plausibility Standard

The philosophy of the Experimentalist model of regulation is to vary the power an agency is granted with the information it has available. It would not alter existing administrative law requiring that

rules must survive notice and comment rulemaking, cost-benefit analysis, and thorough judicial review to be permanent. But an agency would be granted power to implement a moratorium if it could demonstrate that an emerging technology *plausibly* created a significant risk to health, safety, or the environment.

The aim of the plausibility standard is to allow agencies to act notwithstanding scientific uncertainty. A risk is plausible if the theory suggesting the potential harm is consistent with existing scientific evidence.[122] The available evidence need not establish the likelihood of the risk. The plausibility standard would not require that an agency provide even one study showing evidence of the risk. Yet not all perceived risks would pass the standard.

Consider, for example, fluoridation of the public water supply. Extensive research establishes that drinking water with small quantities of sodium fluoride added reduces tooth decay by about 25% over a lifetime.[123] According to the CDC, "[t]he weight of the peer-reviewed scientific evidence does not support an association between water fluoridation and any adverse health effect or systemic disorder . . . ."[124] At least in some communities, however, the public continues to fear that fluoridation poses serious health risks. For example, in 2013, the electorate of Portland, Oregon voted, by a 60 percent to 40 percent margin, to oppose fluoridation of the public water supply, continuing the city's longstanding ban on the practice.[125]

A purported risk from fluoridation, because it is inconsistent with existing scientific evidence, would fail a plausibility test. Part IV will argue that the risk that fracking could contaminate groundwater, the risk that e-cigarettes could increase tobacco consumption, and the risk that autonomous vehicles could increase traffic fatalities would all pass the plausibility test. The plausibility standard undoubtedly leads to borderline cases, but the basic concept—that agencies should be able

122. *Cf.* Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007) ("Asking for plausible grounds to infer [a factual conclusion] does not impose a probability requirement[;] . . . it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [that factual conclusion].").

123. CTR. FOR DISEASE CONTROL & PREVENTION, CMTY. WATER FLUORIDATION: FLUORIDATION BASICS (July 28, 2015), http://www.cdc.gov/fluoridation/basics/index.htm [http://perma.cc/MV77-KXGN].

124. CTR. FOR DISEASE CONTROL & PREVENTION, CMTY. WATER FLUORIDATION: HEALTH EFFECTS AND ENVIRONMENTAL IMPACT (July 10, 2013), http://www.cdc.gov/fluoridation/safety/health_effects.htm [http://perma.cc/GVW3-HGQV].

125. *See* Ryan Kost, *Portland Fluoride: For the Fourth Time Since 1956, Portland Voters Reject Fluoridation*, OREGONIAN, May 21, 2013, http://www.oregonlive.com/portland/index.ssf/2013/05/portland_fluoride_for_the_four.html [http://perma.cc/RTH6-4MXB].

to act with evidence of only a potential risk—is critical to effective regulation of emerging risks.

B. Experiment Power

The word "experiment" is sometimes used expansively in political debates about emerging technologies. But, as Part II argued, these phrases are misleading. Market activity is not the deliberate product of a neutral experimenter aiming to learn about a new technology. It is the spontaneous, decentralized activity of firms seeking to profit from bringing a new technology to market. Experimental conditions are designed, or at least *should be* designed, to achieve accurate results, whereas it would be absurd to suggest that firms should be neutral about what benefits and risks their new technological innovations bring. Similarly, although individual state or local governments may conduct experiments with new regulatory policies, the entire set of such policies as a whole is not centrally organized or subject to experimental controls.[126] This lack of organization creates the possibility of selection effects and cautions against treating the results of state and local policy innovations as the results of scientific experiments. The Experimentalist model is different: agencies would be empowered to conduct non-metaphorical experiments.

One benefit of focusing agencies on acquiring information before they propose a rule is to increase the likelihood that regulators will approach an issue with an open mind. Because agencies will not yet have psychologically committed to a particular regulatory solution, their information acquisition may be less influenced by confirmation bias.[127] This is not to say that agencies will be completely neutral about future regulation. That they have initiated the new powers presumes that these agencies consider the risk to be plausible. But focusing regulators on acquiring information, rather than defending a proposed

126. For a discussion of how the federal government can use its subdivisions and regional offices to direct and coordinate local-level experimentation with different regulatory approaches, see David Owen, *Regional Federal Administration*, 63 UCLA L. REV. 58, 116–20 (2016). For the observation that the federal government is well-positioned to use federal law to encourage state-based experimentation when states are not experimenting at optimal levels, see Abbe Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 YALE L.J. 534, 566–68 (2011).

127. The law and behavioral economics literature sometimes analyzes confirmation bias with the related, more general concept of self-serving biases, which cause us to interpret information so as to promote our self-interest. *See, e.g.*, Russell B. Korobkin & Thomas S. Ulen, *Law and Behavioral Science: Removing the Rationality Assumption from Law and Economics*, 88 CAL. L. REV. 1051, 1093 (2000) (describing what the authors call "the 'confirmatory' or 'self-serving' bias," which they define as "the term to describe the observation that actors often interpret information in ways that serve their interests or preconceived notions").

rule, might make them more open to revising their prior actions than they are in maintaining the status quo.

1. Benefits of Randomization

The main benefit of experiments is that they would produce better information through randomization.[128] Randomized experiments are "[t]he gold standard for estimating the causal impact of a regulation."[129] In a randomized experiment, subjects are deliberately assigned to treatment or control groups randomly.[130] If the experiment is of a sufficient size, the law of large numbers ensures that the treatment will be the best causal explanation for any observed differences in outcome between the two groups.[131]

In the context of a regulatory experiment, randomization requires that whether a participant is exposed to a risky technology (the treatment group) or not (the control group) be intentionally randomized. Regulators could choose multiple treatment groups in which different means of mitigating the risk are tested. The results of a multi-treatment experiment would give regulators a menu of different regulatory options to consider when they move to a cost-benefit analysis for permanent regulation.[132]

Risk-creating firms would have an incentive to suggest potential means for efficiently mitigating a risk if they predicted complying with the rule mandating those means would be less costly than a rule that the agency might otherwise promulgate. An agency would not be legally required to test out firm-proposed ideas, but would have an incentive to do so because although the conditions of the experiment itself would not be subject to judicial review, whatever permanent rule the agency ultimately promulgated would be. A regulated firm could use an

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128. Abramowicz et al., *supra* note 9, at 939–46.

129. Greenstone, *supra* note 34, at 116.

130. Indeed, "[r]andom selection thus is not haphazard selection or selection by convenience—it follows very specific rules and, in the vast majority of studies, will occur only if the researcher intentionally chooses to invoke it." Lee Epstein & Gary King, *The Rules of Inference*, 69 U. CHI. L. REV. 1, 108–09 (2002).

131. Abramowicz et al., *supra* note 9, at 934–37.

132. Notwithstanding the benefits of randomized regulatory experiments, regulatory agencies rarely use them. *See id.* at 931 (noting only a "handful of exceptions" to the lack of randomized regulatory experiments). One notable exception is the FDA, which relies heavily on randomized clinical trials for its regulation of pharmaceuticals. *See* Jennifer J. Kulynych, *Will FDA Relinquish the "Gold Standard" for New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 FOOD & DRUG L.J. 127, 131 (1999) (briefly explaining the history of the FDA's preference for randomized clinical trials and explaining that a "properly conducted [randomized clinical trial] permits an accurate, objective, and scientific assessment of whether a treatment works—and if so, how effective it is").

agency's failure to test out the firm's proposed risk-mitigating measure to challenge the analysis underlying the permanent rule.

2. Practical Challenges to Randomized Experiments

There are real challenges in implementing randomized experiments in natural environments, even when the experimental subjects are cooperating. These challenges include: attrition[133]—subjects might quit the experiment; crossover[134]—subjects might switch from one group to another; and spillover[135]—subjects in one group might be affected by treatments applied to another group. But all of these challenges can be overcome. Attrition can be managed through a large sample size and by randomly pre-pairing each subject with subjects from other groups, so that the pair as a whole can be cut out of the experiment if one member quits.[136] Crossover and spillover effects can be more difficult to police, but carefully monitoring the experiment while it is ongoing and limiting the risky technology outside of the experiment with the moratorium power will help.

Another worry is that, in some instances, a treatment may affect individual subjects differently enough that information about population effects is not useful for future rulemaking. Some have argued, for example, that, as genomics research leads to more personalized medicine, the FDA's insistence on randomized trials designed to observe net effects on a large population has become misguided.[137] One can imagine analogues of this argument in other risk regulation contexts in which exposure to a risk has heterogeneous effects. But this is really an argument against drawing all-or-nothing policy conclusions from randomized experiments rather than an argument against conducting them. In fact, regulated firms can and should use evidence from randomized experiments to argue that, even if some risk should be banned for the overall population, it should be permitted for some narrow subpopulation or under some specialized conditions where the experiment suggests atypical results.[138]

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133. Abramowicz et al., *supra* note 9, at 957–59.

134. *Id.* at 959–60.

135. *Id.* at 960.

136. *Id.* at 958–59.

137. *See* PETER W. HUBER, THE CURE IN THE CODE 103–12 (2013) (criticizing "The Fading Myth of the FDA's 'Gold Standard' ").

138. Firms do so after FDA clinical trials, although in some cases this can create the problem of "data dredging"—scouring statistical data for some subgroup that could technically be argued to have a benefit, even if that benefit is just an artifact of the data. *See generally* Anup Malani et al., *Accounting for Heterogeneous Treatment Effects in the FDA Approval Process*, 67 FOOD & DRUG L.J. 23 (2012) (explaining and proposing a solution to the data dredging problem).

A more powerful objection to this way of implementing regulatory experiments is that scientific practice generally counsels against relying too much on the results of one experiment, even if it is a randomized one. Yet allowing time for replication would undermine many of the benefits of temporary regulation. There is an inevitable tradeoff between allowing time for experiment replication and quickly implementing the regulation that early experimental results support.[139] One carefully controlled, large group size, federal regulatory experiment will likely be more useful than uncontrolled market innovation or state and local policy innovation. Moreover, although the length of experiments and moratoria would be subject to judicial review, courts would not be precluded from allowing an agency to conduct an additional experiment or extend a moratorium if early results proved inconclusive.

3. Ethical Challenges to Randomized Experiments

Some randomized regulatory experiments have been criticized on ethical grounds. For example, consider randomized experiments on the effectiveness of social welfare programs.[140] Assigning someone to a control group means denying someone a benefit, which is effectively making that individual worse off so that society might gain policy knowledge. To some extent, this worry is a product of framing effects. It appears less objectionable to conduct a random experiment with a previously unavailable social benefit than to experiment with a benefit to which some individuals are entitled under existing law. But in either case, the experimenter has a partial response. If the benefit does not achieve the desired result, no harm is done. If the benefit does achieve the result, the prospects of the benefit program persisting over the long run improve, thereby serving the long-term interests of the individuals from whom the benefit is temporarily withheld. This is, however, only a partial response. There is still a potential short-term harm done to the subjects denied a benefit, and that must be factored into the overall normative evaluation of whether the experiment is worthwhile.

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139. *Cf.* Matthew C. Stephenson, *Information Acquisition and Institutional Design*, 124 HARV. L. REV. 1422, 1437 (2011) ("The agent's marginal research benefit from investing an additional unit of effort in research is simply the difference between the research payoff and the default payoff. Thus, the strength of the agent's research incentive is a decreasing function of her default payoff and an increasing function of her research payoff.").

140. This is not a hypothetical scenario. Abramowicz and collaborators explain that most randomized policy "experiments have been in the area of social services, testing whether expenditures on entitlements succeed in achieving social goals, such as reducing poverty." Abramowicz et al., *supra* note 9, at 932; *see also id.* at 932–33 (listing examples).

In clinical trials, the answer is informed consent: patients will generally only enter experiments with new drugs if their medical condition is dire enough to take the risk. But even in clinical trials, the tradeoff re-emerges as the experimenters begin to observe differences between the control group and the treatment group and do not immediately relay that knowledge to the subjects. So in clinical trials, as in social benefit experiments, it is often imperative to end experiments early when enough evidence has accumulated that the interests of the subjects in the less fortunate group outweigh the marginal benefits of increased confidence in the results.[141]

These considerations—short-term harm, informed consent, and early termination—should be incorporated into regulatory experiments. Regulators should acknowledge that subjects in an experiment will be exposed to a risk over the short-term and consider whether the experiment is still warranted or whether the technology simply ought to be banned outright. Whether those risks can be voluntarily accepted through informed consent will often be critical to the decision. Regulators will sometimes face a difficult tradeoff between ending an experiment early and entering into rulemaking with less confidence versus letting the experiment continue and maintaining risk exposure or limits on a seemingly innocuous technology. But those decisions are difficult only because randomized experiments can produce socially useful knowledge.

C. Moratorium Power

A moratorium on a new risky technology would serve two aims: protecting the reliability of experimental conditions and preventing entrenchment. For many emerging risks, an agency might be able to achieve these goals with restrictions short of a total moratorium on the technology outside of the experimental conditions. All things being equal, agencies should choose the least restrictive means consistent with those goals.[142] Yet total moratoria will sometimes be necessary and can be justified.

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141. *See* Abramowicz et al., *supra* note 9, at 973 ("[I]t is standard protocol to shut down medical trials early if it becomes clear that either the control or treatment therapy is superior.").

142. This prescription does not entail that the decision about means should be subject to judicial review. Determining what the least restrictive means to protect experiments and prevent entrenchment are may require a judgment call in the face of scientific uncertainty.

1. Protecting Experimental Conditions

For a randomized experiment to work, a sufficient number of the initial subjects need to remain in their assigned treatment or control group until the end of the experiment.[143] For at least some types of risks, permitting the risky technology outside of the experiment will increase the chance of interference with the experiment. There could be crossover effects because subjects in the control group participated in the risky activity outside of the experiment or subjects in a risk-mitigation treatment group participated in the risky activity without the benefit of the risk-mitigating measure. Imagine a pharmaceutical trial in which a subject in a control group consumes a drug with similar properties outside of the experiment. There could also be spillover effects because subjects in a control group were exposed to the risky technology because of its presence outside of the experimental conditions. Imposing a moratorium on the technology outside of the experiment is the simplest way to solve these problems.

2. Preventing Entrenchment

The moratorium power would allow agencies to preserve a broad set of regulatory options.[144] The most straightforward justification for preserving options is to prevent interest groups from blocking them. If a regulation is otherwise justified, the political reality that well-financed, well-organized firms possess interest group power is not a good reason to oppose the regulation. Rather, it is a good reason to prevent that political reality from developing in the first instance.

Two important predictors of interest group power are wealth and organization. A moratorium can temporarily prevent risk-creating firms from acquiring both. The moratorium limits the growth and profits of risk-creating firms. This can be a direct effect of restricting the risky technology to sites or subjects randomly selected to participate in the experiment. It can also be an indirect result of the signal that the moratorium sends to investors: regulators are serious about reducing

143. *See* Abramowicz et al., *supra* note 9, at 957 (explaining that attrition is a problem in part because it reduces sample size).

144. The basic idea that risk regulation policy should be concerned with preserving future options is familiar, but scholars have not generally emphasized preserving *political* options. *See, e.g.*, Cass R. Sunstein, *Irreversible and Catastrophic*, 91 CORNELL L. REV. 841, 896 (2006) (concluding that real option theory suggests that "those who make environmental policy, should find it worthwhile to invest resources to preserve flexibility for the future"). *See generally* Michael A. Livermore, *Patience Is An Economic Virtue: Real Options, Natural Resources, and Offshore Oil*, 84 U. COLO. L. REV. 581 (2013) (applying real-option theory to nonrenewable resource extraction).

this risk and, depending on the results of the experiment, the risky technology might be limited, or even prohibited, permanently.

Investors might still decide to bet on the risk-creating firms nonetheless, because they expect that the experimental results will be favorable for the firms and lead to less restrictive regulation. In that case, the firms might still be able to grow during the course of the experiment. But that is not a bad outcome. To the extent that investors base their decisions on private information that the relevant risk is not as bad as feared or can be inexpensively mitigated, they are relying on information that indicates that stricter regulation might not be justified and that interest group entrenchment will not be problematic. The critical point is that, because of the moratorium, investors will be betting on facts about the risk and its potential for cost-effective mitigation, rather than on the risk-creating firm's likelihood of evading justified regulation through interest group power.

A moratorium will also limit risk-creating firms' ability to organize for similar reasons. A fledgling industry with small start-ups facing regulatory uncertainty will less rapidly form a trade association with sophisticated lobbyists. To the extent that the experiment tests out risk-mitigating measures that might benefit some firms more than others, the experiment and moratorium period might even pit some of the risk-creating firms against each other.

In the narrower set of cases where there is a justification for preventing social norm entrenchment, a moratorium could also achieve that aim. By restricting the use of the new technology to experimental conditions, social norms might not crystallize around its use. How that dynamic would work would depend on the specific social facts surrounding the particular technology. Part IV explores this possibility for the particular technologies it analyzes in greater detail.

3. Moratoria and Capture

One might object to granting agencies a moratorium power on the basis that the power itself could become a tool of interest groups. Interest group theory predicts that incumbent firms in an industry will seek to capture regulatory agencies to impose barriers to entry into their market.[145] It is conceivable that, in a captured agency, the moratorium power could be used to impose temporary restrictions on a new technology as a means to stifle potential competition to the incumbent firms.

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145. *See, e.g.*, George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 5 (1971).

The problem with this objection is that incumbent firms have a countervailing incentive to oppose regulation that would limit the future size of their market, particularly if they could consolidate the expanded market by acquiring new entrants. Consider e-cigarettes: the major tobacco firms could have responded to the rise of start-ups selling e-cigarettes by seeking regulation to ban the technology. For a brief political moment, that might have been possible. But the tobacco firms eventually realized that e-cigarettes could expand their customer base and either started their own lines of e-cigarettes or acquired the new entrants.[146] Banning e-cigarettes would have foreclosed what the tobacco firms came to view as a profit opportunity. Of course, this market consolidation occurred in a world without a moratorium power. One cannot know how it would have played out in a counterfactual world in which agencies had such power available. But the same economic incentive favoring expanding markets would hold.

The moratorium power's capacity to prevent interest group entrenchment is strongest when an agency can act while there is neither a united industry coalition opposing regulation nor one aiming to capture an agency to impose regulation. That moment is possible when agencies first become aware of an emerging risk, or so Part IV will argue.

4. Alternatives to Moratoria

Agencies could also choose to impose other limits on the risky technology short of a moratorium. If it did not interfere with experimental conditions, they could permit firms to continue working with the risky technology within certain limits of time, space, or intensity or while employing a particular risk-mitigating measure. With some risks, an agency might simply forbid sale or marketing of the risky product to consumers, or to some especially vulnerable subset of consumers. Agencies could also make permission to continue working with the risky technology contingent on the firm allowing more intrusive observation, so that use of the technology would be easy to halt if the experimental results suggested the risk warranted it. The optimal set of limitations will vary by risk. Restrictions short of a total moratorium might, in some cases, protect the experiment and prevent entrenchment.

146. For more on the consolidation of the e-cigarette market, see *infra* Section IV.B.

D. Circumscribed Judicial Review

There are good reasons not to shield *all* agency decisions with experiment and moratorium powers from judicial review. Most of the traditional arguments for judicial review of agency action—statutory compliance, congressional monitoring, the threat of capture, and quality control—would still apply.[147] In addition, the new powers would give regulatory agencies more authority to impose burdens on risk-creating firms than they currently possess. The special features of emerging risks—the factual uncertainty they present and the short political window for action they allow—justify those new powers. But agencies may be tempted to use them as an end run around the sluggish rulemaking process.[148] Protecting the powers from judicial review would exacerbate the temptation to use them as a de facto regulatory tool.

But some agency decisions in implementing experiments and moratoria do merit protection. With emerging risks, agencies will lack rigorous evidence establishing the likelihood or magnitude of harm that the source of risk could create. Agencies will sometimes also need to test multiple means of mitigating those risks. An agency's decision about which means to test will involve considerable discretion, and, given the lack of basic information about the risk, will be difficult to justify conclusively. Judicial review of these issues—facts about the risk and choices about which regulatory means to test—would constrain the flexibility that the new powers were intended to provide.

1. Judicial Review of the Experiment and Moratorium Powers

Judicial review of agency experiments and moratoria should be limited to the perimeter: decisions about when a moratorium should start, when it should end, and what its scope should be—that is, what risks are covered—while it is ongoing. Details internal to how the experiments should be conducted and the ideal content of the moratorium should be shielded.

The plausibility standard should be subject to judicial review. It is intended to screen out theories of risk inconsistent with the best

147. *See supra* Section I.A.3.

148. An early empirical study "speculated . . . that reviewing courts' imposition of adjudicatory-type procedural and evidentiary burdens on rulemaking during [the period of the study] may have had the perverse effect of discouraging its use." Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984, 1057 (1990). If this speculation is correct, providing agencies with new powers more flexible than rulemaking might tempt agencies to substitute use of those powers for rulemaking.

available scientific evidence. The plausibility standard has the effect of a weak regulatory priority-setting device:[149] if an agency seeks to initiate an experiment and a moratorium for a risk that does not plausibly create a significant harm to health, safety, or the environment, it will be a red flag that the agency's priorities were misplaced. It might even be evidence of agency capture. The courts should not be setting agencies' priorities for them. But the minimum threshold of the plausibility standard can serve as a check on egregiously misplaced priorities.

Federal courts are, of course, familiar with making plausibility determinations from their experience with motions to dismiss.[150] Once the agency satisfied the plausibility standard, it need not provide any more evidence of the risk being regulated until it ultimately promulgated a rule to regulate it.

Judicial review should also ensure that an agency's experiment and moratorium are limited in time and scope. How long a moratorium should last could be a difficult question, and courts should give some deference to agency judgments. But agencies must be subject to judicial review on their decisions about the length of moratoria to prevent them from using moratoria as de facto regulation. Agencies' good faith experimental goals should be the decisive factor in setting the length of a moratorium.

The scope of the risk should also receive judicial scrutiny. A risk like "e-cigarettes" is neatly defined. A risk like "biotechnology" would be too amorphous. A risk like "nanotechnology" would present a more complicated question. One can define "nanotechnology" as any technology at nanoscale.[151] But that definition is broad enough to encompass technologies for a myriad of industrial and consumer uses that could create a broad range of safety risks.[152] Courts should probably permit experiments and moratoria for nanotechnology, but the closeness of this issue suggests that some line-drawing problems will be inevitable.

As with any area of repeated judicial review, courts can self-calibrate through the development of precedent. Issues such as what makes a risk "plausible," how long a moratorium should last, and what

149. *See* John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277, 311–13 (1992) (proposing a "de minimis risk" standard as a tool for agency priority-setting in toxic risk regulation).

150. FED. R. CIV. P. 12(b)(6). The leading cases on the 12(b)(6) plausibility standard are *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007); and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

151. For a similar definition, see Mandel, *supra* note 13, at 1328 (defining nanotechnology as pertaining to "a variety of activities that involve manipulating matter at an atomic scale").

152. *Id.* at 1340–45.

kind of definition should limit the scope of a "risk"—or at least what range of discretion agencies should have over those questions—will gradually resolve themselves through precedent.

2. Judicial Review of Subsequent Rules

The division between issues subject to and protected from judicial review discussed above applies only to agency action during and about the experiments and moratoria. At the end of the experimental period, if the agency sought to promulgate a permanent rule, it would need to proceed through a conventional rulemaking. That rulemaking would then be subject to judicial review, just like any other agency action.

Agencies should have discretion to retain the moratoria or other limits *during* the rulemaking that follows an experiment. If agencies lacked that discretion, then each time an agency adopted a strict moratorium and experiments demonstrated that the risk justified a permanent ban, the agency would be compelled to relax the restrictions as it crafted the permanent rule, immediately after acquiring evidence that the restrictions were justified.

Administrative law has confronted a similar problem before. Until 1993, courts that held rules to be "arbitrary and capricious" would generally vacate the rules when they remanded them to the agencies.[153] But in *Allied-Signal v. NRC*, the D.C. Circuit recognized that "the consequences of vacating may be quite disruptive" and remanded a rule without vacatur.[154] Likewise, the consequences of lifting a moratorium during a rulemaking designed to convert that moratorium into a permanent rule justify giving agencies a brief extension so that they have time to carry a proposed rule through the rulemaking process.

The shadow of a judicial challenge to a post-experiment rulemaking would create incentives for agencies and regulated firms during the experiment.[155] The results of the regulatory experiment would effectively create presumptions for the subsequent rulemaking. If the expected risk were not observed, agencies would be hard pressed to justify continued regulation. If a particular means to mitigate the risk worked, the agency would likely conduct a cost-benefit analysis for

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153. Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 75 (1995).

154. Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n, 988 F.2d 146, 151 (D.C. Cir. 1993).

155. The metaphor of parties' bargaining in the "shadow of the law" as result of judicially created incentives started with Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L. J. 950, 997 (1979).

adopting it. Failure to do so would leave the agency especially vulnerable to judicial challenge from firms who would have preferred some other means of mitigating the risk.

The net effect of circumscribed judicial review for the experiment moratorium—and conventional judicial review for whatever rule the agency adopts following it—would be to give agencies broad discretion to experiment with different regulatory options, but compel them to make the resulting regulation empirically informed.

IV. APPLICATIONS

This Part applies the Experimentalist model to the regulation of three emerging risks: fracking, e-cigarettes, and autonomous vehicles. With fracking and e-cigarettes, regulators still lack answers to basic questions that would be critical to sensible regulation. While the information deficit surrounding autonomous vehicles cannot be reduced to a set of specific questions, there is still massive uncertainty about the effects these vehicles would have on safety and thus a strong case for controlled testing.

Each of these emerging risks also raises an entrenchment problem. Unfortunately, for both fracking and e-cigarettes, interest groups may already be entrenched, but there was some point in the past decade in which that entrenchment could have been halted. For e-cigarettes, we may have missed the window for preventing social norm entrenchment as well. With autonomous vehicles, the main worry is reverse social norm entrenchment, and that window may soon elapse. But even if our ability to prevent entrenchment of these particular risks has declined, the plausibility of having done so at some point suggests the importance of moratoria for future emerging risks.

A. Fracking

In the past several years, the deployment of new techniques to extract previously unreachable oil and gas has transformed the energy sector. The United States has passed Russia as the world's largest producer of natural gas, and is also predicted to pass Saudi Arabia as the largest producer of oil by the end of the decade.[156] The leading cause of the boom is hydraulic fracturing, or fracking—creating fractures in

156. Thomas W. Merrill & David M. Schizer, *The Shale Oil and Gas Revolution, Hydraulic Fracturing, and Water Contamination: A Regulatory Strategy*, 98 MINN. L. REV. 145, 147 (2013).

layers of shale and tight rock with pressurized liquid to release oil and gas.[157]

Fracking has been in commercial use since 1949, but it was only in the 2000s that the practice became widespread.[158] The recent rise of fracking is in part due to another technique, horizontal drilling, in which vertical drills are extended sideways once they reach the desired layer, so as to maximize contact with the rock containing oil or gas.[159] These techniques have been enormously profitable for the gas and oil industries, but they have also raised questions about risks to health, safety, and the environment.

1. Risks and Benefits

Some of the risks fracking creates are familiar from other industrial activities. Fracking operations emit conventional air pollutants: methane, volatile organic compounds, and so-called naturally occurring radioactive materials.[160] Fracking also consumes massive quantities of water.[161] When fracking wastewater is disposed of, the force can induce earthquakes; the earthquake risk is not new to fracking, but it has nonetheless received significant recent attention.[162]

One risk fracking might create that is genuinely new—and possibly merits new regulation—is the risk of groundwater contamination.[163] The main potential contaminant is the fracking fluid itself; there are several plausible ways in which the chemicals in fracking fluid could get into groundwater.[164] It is also possible that fracking could contaminate the groundwater in other ways by releasing methane, by disturbing sludge already present in wells, or through the disposal of fracking waste.[165] Only a small number of limited studies have attempted to assess the risks of fracking fluid contaminating

157. For a concise but detailed explanation of how fracking works, see Hannah Wiseman, *Untested Waters: The Rise of Hydraulic Fracturing in Oil and Gas Production and the Need to Revisit Regulation*, 20 FORDHAM ENVTL. L. REV. 115, 117–21 (2009).

158. For an account of the history, see *id.* at 121–27.

159. Merrill & Schizer, *supra* note 156, at 153–54; *see also* Wiseman, *supra* note157, at 120 (explaining how horizontal drilling fits into fracking).

160. Merrill & Schizer, *supra* note 156, at 172–75.

161. *See id.* at 177–79 ("EPA estimates that fracturing will consume as much water as 5 million people if 35,000 wells are fractured each year.").

162. *See id.* at 179–80 (detailing earthquake risks in different stages of fracturing and state regulatory response).

163. *Id.* at 180.

164. *Id.* at 180–81.

165. *Id.* at 192–96.

groundwater.[166] A recent review of the evidence concluded that "[t]he magnitude of all these risks is uncertain and highly contested."[167]

The EPA conducted an investigation of fracking's effects on groundwater contamination in Pavillion, Wyoming and released a draft report in 2011, which concluded that "the explanation best fitting the data for the deep monitoring wells is that constituents associated with hydraulic fracturing have been released into the [local] drinking water aquifer at depths above the current production zone."[168] But, after intense criticism of the draft report, the EPA turned over the investigation to the Wyoming state government, and the research was funded in part by Encana Oil and Gas, the firm responsible for the fracking operation that may have contaminated the water.[169] The final report, released in 2015, concluded that "it is unlikely that hydraulic fracturing fluids have risen to shallower depths intercepted by water-supply wells," although it noted the possibility that preexisting gas wells could have served as a conduit for some contamination.[170]

According to its proponents, the economic benefits of fracking and the associated oil and gas boom have been dramatic. IHS, a leading energy analysis firm funded by the industry, has estimated that unconventional oil and gas operations contributed $283 billion to the gross domestic product and employed 2.1 million workers in 2012.[171] Fracking also reduces energy prices for US consumers. IHS has predicted that "[b]etween 2012 and 2015, the gain in average annual disposable household income [will be] $926 per year as a result of the lower natural gas prices brought about by" unconventional natural

166. *See id.* at 187–91 (detailing six studies); *see also* Garth T. Llewellyn, *Evaluating a Groundwater Supply Contamination Incident Attributed to Marcellus Shale Gas Development*, 112 PROC. NAT'L ACAD. SCI. U.S. 6325 (2015).

167. *Id.* at 187.

168. *Draft Investigation of Ground Water Contamination near Pavillion, Wyoming*, EPA, 33 (2011), http://www2.epa.gov/sites/production/files/documents/EPA_ReportOnPavillion_Dec-8-2011.pdf [http://perma.cc/G6KJ-TUJD].

169. Abraham Lustgarten, *EPA's Abandoned Wyoming Fracking Study One Retreat of Many*, PROPUBLICA (July 3, 2013, 11:58 PM), http://www.propublica.org/article/epas-abandoned-wyoming-fracking-study-one-retreat-of-many [http://perma.cc/25PC-4STP].

170. WYO. DEP'T OF ENVTL. QUALITY, PAVILLION, WYOMING AREA DOMESTIC WATER WELLS DRAFT FINAL REPORT AND PALATABILITY STUDY 107 (2015), http://deq.wyoming.gov/media/attachments/Water%20Quality/Pavillion%20Investigation/Draft%20Report/01_Pavillion%20WY%20Area%20Domestic%20Water%20Wells%20Draft%20Final%20Report.pdf [http://perma.cc/MS66-VPSM].

171. *America's New Energy Future: The Unconventional Oil and Gas Revolution and the US Economy, Volume 3: A Manufacturing Renaissance*, IHS 41 (2013), http://www.energyxxi.org/sites/default/files/pdf/Americas_New_Energy_Future_Phase3.pdf [http://perma.cc/YV6T-A8M5]. Merrill and Schizer take IHS data at face value. Merrill & Schizer, *supra* note 156, at 148 n.3.

gas.[172] Finally, the increase in production is also changing the balance of trade.[173] The US Energy Information Administration (EIA) predicts that, due in part to continued growth in shale gas production resulting from "the dual application of horizontal drilling and hydraulic fracturing," the United States will become a net exporter of natural gas in 2017.[174]

Some critics have questioned how long the boom in unconventional oil and gas will last, even if regulation does not limit it.[175] In parts of Wyoming, the early natural gas boom has already faded, and "getting drilling companies who claim to be on the verge of collapse to take responsibility for wells they still technically own has proved difficult."[176] An assessment of the costs and benefits of fracking should include the economic and social costs of a potential bust as much as the benefits of the current boom.[177]

The most important effect of fracking is its impact on climate change. Natural gas is less carbon-intensive than coal. Natural gas emits 117 lbs. of CO_2 per million Btu of energy while coal emits between 214 and 229 lbs.[178] Therefore, replacing coal-fired power with gas-fired power will result in lower carbon emissions.[179] Those reductions already

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172. *The Economic and Employment Contributions of Shale Gas in the United States*, IHS 26 (2011), http://energyindepth.org/wp-content/uploads/2011/12/Shale-Gas-Economic-Impact-Dec-2011_EMB1.pdf [http://perma.cc/X6HF-SYEK].

173. I do not mean to imply that a more favorable balance of trade for the United States is obviously desirable. If one evaluates domestic risk regulation policy from a cosmopolitan perspective, it might not be.

174. *Annual Energy Outlook 2015*, U.S. ENERGY INFO. ADMIN. E-11 (Apr. 2015), http://www.eia.gov/forecasts/aeo/pdf/0383(2015).pdf [http://perma.cc/6W9N-763R].

175. *See, e.g.*, Asjylyn Loder, *U.S. Shale-Oil Boom May Not Last as Fracking Wells Lack Staying Power*, BLOOMBERG BUSINESSWEEK (Oct. 10, 2013), http://www.businessweek.com/articles/2013-10-10/u-dot-s-dot-shale-oil-boom-may-not-last-as-fracking-wells-lack-staying-power [http://perma.cc/574Q-DJUY].

176. Dan Frosch, *Wyoming May Act to Plug Abandoned Wells as Natural Gas Boom Ends*, N.Y. TIMES (Dec. 25, 2013), http://www.nytimes.com/2013/12/25/us/state-may-act-to-plug-abandoned-wyoming-wells-as-natural-gas-boom-ends.html?_r=0 [http://perma.cc/95RF-8JBE].

177. For an assessment of the economic and social costs of fracking, see, for example, Susan Christopherson & Ned Rightor, *The Boom-Bust Cycle of Shale Gas Extraction Economies*, CARDI REP. (Cornell Univ. Cmty. & Reg'l Dev. Inst., Ithica, N.Y.), Sep. 2011, at 4, 4–6, http://assembly.state.ny.us/member_files/125/20110915/index.pdf, [http://perma.cc/KNK3-2G8K]; Jaffrey Jacquet, *Energy Boomtowns & Natural Gas: Implications for Marcellus Shale Local Governments & Rural Communities*, 13–23, 24 (Ne. Reg'l Ctr. for Rural Dev., Paper No. 43, 2009).

178. U.S. ENERGY INFO. ADMIN., HOW MUCH CARBON DIOXIDE IS PRODUCED WHEN DIFFERENT FUELS ARE BURNED?, http://www.eia.gov/tools/faqs/faq.cfm?id=73&t=11 (last updated June 18, 2015) [http://perma.cc/ZLS6-E4GF].

179. Some authorities contest the claim that fracking will necessarily result in climate benefits, given certain unknowns about the risk of methane leakage during the process of gathering natural gas from production sites. One peer-reviewed study found higher rates of methane emissions at fracking sites compared to conventional natural gas wells, largely attributed to "venting of methane at the time that wells are completed." Robert W. Howarth, *A Bridge to*

have begun over the past few years. According to the most recent data from the EIA, "[t]he natural gas share of electricity generation grew from approximately 11% in 1990 . . . to 26% in 2014," which "has contributed to the decline in carbon intensity of the energy mix since 2008."[180]

Some environmental policy experts view the transition from coal to natural gas caused by fracking as a salutary development. In 2011, a panel chaired by Ernest Moniz—then the U.S. Secretary of Energy—issued a report stating that "a combination of demand reduction and displacement of coal-fired power by gas-fired generation is the lowest-cost way to reduce CO_2 emissions by up to 50%."[181] The report concedes that "[f]or more stringent CO_2 emissions reductions, further de-carbonization of the energy sector will be required," but concludes that "natural gas provides a cost-effective bridge to such a low-carbon future."[182]

Some environmentalists nonetheless oppose fracking. For example, Bill McKibben, a leader in the environmental movement, admits that "if we could convert our coal-fired power plants to natural gas . . . carbon emissions would drop."[183] But he worries that natural gas will "crowd out truly low-carbon sources of power: abundant and cheap natural gas would make it that much harder to get sun and wind (or, if it's your cup of hot water, nuclear power) up and running on a large scale."[184] One could add to McKibben's economic argument the possibility of interest group entrenchment. Once the nation becomes so heavily invested in natural gas, energy firms might be able to thwart regulation that would require a transition to renewable energy.

Nowhere: Methane Emissions and the Greenhouse Gas Footprint of Natural Gas, 2 ENERGY SCI. & ENG'G 47, 49 (2014). *But see* A.R. Brandt et al., *Methane Leaks from North American Natural Gas Systems*, 343 SCIENCE 733, 733 (2014) ("[A]ssessments using 100-year impact indicators show system-wide leakage is unlikely to be large enough to negate climate benefits of coal-to-[natural gas] substitution.").

180. U.S. ENERGY INFO. ADMIN., U.S. ENERGY-RELATED CARBON DIOXIDE EMISSIONS, 2014 (Nov. 23, 2015), https://www.eia.gov/environment/emissions/carbon [http://perma.cc/T36H-WT8Z].

181. ERNEST MONIZ ET AL., THE FUTURE OF NATURAL GAS: AN INTERDISCIPLINARY MIT STUDY 2 (2011), http://mitei.mit.edu/system/files/NaturalGas_Report.pdf [http://perma.cc/GY4N-JQ8A].

182. *Id.* (emphasis omitted).

183. Bill McKibben, *Why Not Frack?*, N.Y. REV. BOOKS (Mar. 8, 2012), http://www.nybooks.com/articles/archives/2012/mar/08/why-not-frack/ [http://perma.cc/9ZPB-AC6Q].

184. *Id.* The International Energy Agency has echoed this concern. *See* INTERNATIONAL ENERGY AGENCY, GOLDEN RULES FOR A GOLDEN AGE OF GAS 80 (Nov. 12, 2012), http://www.worldenergyoutlook.org/media/weowebsite/2012/goldenrules/weo2012_goldenrulesreport.pdf [http://perma.cc/5MXJ-4RQS] ("Depending on the type of policies in place, an abundance of natural gas might diminish the resolve of governments to support low and zero-carbon sources of energy.")

But until renewable energy becomes more efficient and a political consensus is formed around aggressive climate regulation, the comparative improvement that natural gas offers over coal may be the bridge, as Moniz argues. It is at least reasonable to believe that, if fracking can be done in a way that does not create other countervailing health or environmental risks, its climate and economic benefits might justify its costs. The problem now is that we do not know enough about these potentially countervailing risks.

2. Existing Regulation

Interest group entrenchment has influenced the lax federal regulation of fracking, though some federal environmental statutes do apply to the practice. For example, the New Source Performance Standards contained in the Clean Air Act ("CAA"),[185] which controls certain types of emissions, apply to fracking operations. The EPA has promulgated a regulation putting those requirements into effect for new oil and gas operations in 2012.[186]

But fracking is mostly exempt from federal environmental statutes.[187] In some statutes, fracking is exempted simply because all oil and gas operations are exempted.[188] The most critical exemptions for fracking in federal environmental statutes, however, were added in the Energy Policy Act of 2005.[189] That legislation amended the Safe Water Drinking Act ("SWDA") to exclude fracking from permitting requirements designed to protect the water in injection wells, unless the fracking uses diesel fuel.[190] It also amended the Clean Water Act ("CWA")—which, it is important to note, mostly regulates surface water rather than groundwater—to expand the exemption for stormwater

185. *See* 42 U.S.C. § 7411(b)(1)(B) (2012).

186. Oil and Natural Gas Sector: New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants Reviews, 77 Fed. Reg. 49,490 (Aug. 16, 2012) (to be codified at 40 C.F.R. pts. 60, 63).

187. *See* Merrill & Schizer, *supra* note 156, at 200 ("Given the traditional primacy of states in oil and gas regulation, federal law has little to say about fracturing. Indeed, key environmental statutes exempt the practice."). For a more detailed summary of the relevant federal law, see generally ADAM VANN ET AL., CONG. RESEARCH SERV., R43152, HYDRAULIC FRACTURING: SELECTED LEGAL ISSUES (2013), http://www.fas.org/sgp/crs/misc/R43152.pdf [http://perma.cc/HA4E-8HXU].

188. *See, e.g.*, 42 U.S.C. § 6921(b)(2)(A) (2012) (exemption in the Resource Conservation and Recovery Act); 42 U.S.C. § 9601(14) (2012) (exemption in the Comprehensive Environmental Response, Compensation, and Liability Act).

189. Pub. L. No. 109-58, 119 Stat. 594 (2005).

190. *See* 42 U.S.C. § 300h(d)(1)(B)(ii) (2012) (excluding "the underground injection of fluids or propping agents (other than diesel fuels) pursuant to hydraulic fracturing operations related to oil, gas, or geothermal production activities" from the definition of "[u]nderground injection").

runoff from oil and gas operations, including fracking, provided the stormwater did not come into contact with the wastewater.[191] Wastewater remains regulated with a permitting regime under the CWA.[192]

Only recently have federal regulators begun to tackle the groundwater contamination issue. In 2009, in a report attached to an appropriations bill, Congress "urge[d] EPA to review the risks that hydraulic fracturing poses to drinking water supplies, using the best available science, as well as independent sources of information."[193] In the aftermath of the Pavillion study, the EPA undertook a more comprehensive study of the groundwater contamination risk.[194] It issued a draft assessment in 2015, in which the EPA concludes that "there are above and below ground mechanisms by which hydraulic fracturing activities have the potential to impact drinking water resources."[195] The assessment "did not find evidence that these mechanisms have led to widespread, systemic impacts on drinking water resources in the United States," but did find "specific instances where one or more mechanisms led to impacts on drinking water resources, including contamination of drinking water wells."[196] The number of instances "was small compared to the number of hydraulically fractured wells," but that may have been a result of the limited availability of data.[197]

Federal regulation may also soon require that firms disclose the chemicals they use in fracking. In 2015, the Department of the Interior published a final rule that would require oil and gas companies to "public[ly] disclos[e] the chemicals used in hydraulic fracturing" on

191. *See* 33 U.S.C. § 1342(l)(2) (2012) ("The Administrator shall not require a permit under this section . . . for discharges of stormwater runoff from mining operations or oil and gas exploration . . . which . . . do not come into contact with[ ] any overburden, raw material, intermediate products, finished product, byproduct, or waste products located on the site of such operations.").

192. For a brief discussion of this issue, see Hannah J. Wiseman, *Risk and Response in Fracking Policy*, 84 U. COLO. L. REV. 729, 774 (2013).

193. H.R. REP. No. 111-180, at 100 (2009).

194. *See generally EPA's Study of Hydraulic Fracturing for Oil and Gas and Its Potential Impact on Drinking Water Resources*, ENVTL. PROT. AGENCY, http://www2.epa.gov/hfstudy (last visited Oct. 16, 2015) [http://perma.cc/R4B8-BHCJ].

195. ENVTL. PROT. AGENCY, ASSESSMENT OF THE POTENTIAL IMPACTS OF HYDRAULIC FRACTURING FOR OIL AND GAS ON DRINKING WATER RESOURCES (2015), http://www.epa.gov/sites/production/files/2015-06/documents/hf_es_erd_jun2015.pdf [http://perma.cc/2LU6-HBDU].

196. *Id.*

197. *Id.*

federal and tribal lands.[198] However, industry groups challenged the regulations in court, and in September 2015 a Wyoming federal judge granted a preliminary injunction barring enforcement of the rule pending the outcome of the case.[199] In discussing the agency's likelihood of success on the merits, the court stressed the absence of "a single confirmed case of the hydraulic fracturing process contaminating groundwater."[200] The court agreed that the agency "need not wait for 'a catastrophe' to take action," but ruled that "there must be substantial evidence to support the existence of a risk" for the agency's action to satisfy the APA's arbitrary and capricious requirement.[201]

Further, the Toxic Substances Control Act ("TSCA") generally requires firms to maintain a record of certain chemicals used in manufacturing or processing.[202] In 2014, the EPA published advanced notice of a proposed rule that would "develop an approach to obtain information on chemical substances and mixtures used in hydraulic fracturing."[203]

In the absence of tighter federal regulation, fracking has become a test case for the Laboratory of Democracy model. In some ways, the light federal regulation of fracking is consistent with the historical distribution of policy authority in our federal system. The "regulation of oil and natural gas exploration and production in the United States has always been primarily a state matter."[204] Likewise, "regulation of groundwater contamination has traditionally been left to the states."[205]

State responses have varied from strongly precautionary to effectively Common Law. A complete survey of existing state and local regulations would require a separate article.[206] But it is worth noting the diversity of such policies. Vermont has enacted a permanent statutory ban, which flatly states: "No person may engage in hydraulic

198. Oil and Gas; Hydraulic Fracturing on Federal and Indian Lands, 80 Fed. Reg. 16,128, 16,128 (March 26, 2015) (to be codified at 43 C.F.R. pt. 3160).

199. Wyoming v. U.S. Dep't of the Interior, No. 15-CV-043, 2015 WL 5845145 (D. Wyo. Sep. 30, 2015) (granting preliminary injunction).

200. *Id.*

201. *Id.*

202. 15 U.S.C. § 2607(a) (2012).

203. Hydraulic Fracturing Chemicals and Mixtures, 79 Fed. Reg. 28,664 (proposed May 19, 2014) (to be codified at 40 C.F.R. ch. I).

204. David B. Spence, *Federalism, Regulatory Lags, and the Political Economy of Energy Production*, 161 U. PA. L. REV. 431, 447 (2013).

205. *Id.* at 490.

206. For a good summary of existing state regulations, with an emphasis on enforcement patterns, see generally Hannah Wiseman, *Fracking Regulation Applied*, 22 DUKE ENVTL. L. & POL'Y F. 361 (2012).

fracturing in the State."[207] New York has enacted a ban through the state's Department of Environmental Conservation, which denies all applications for fracking permits.[208] In Pennsylvania, fracking is permitted, but the state's Department of Environmental Protection regulates it.[209] In many states, though, the primary regulator is the state oil and gas commission.[210]

3. Prescriptions

Fracking is—or was—a strong candidate for an experiment and a federal moratorium. It presents both the need for regulatory learning and an entrenchment risk. But because the EPA lacks information that would be relevant for a rulemaking, the federal government has conducted only a study reliant on voluntary cooperation and has allowed interest groups to become entrenched.

A key factual question regulators need to answer is whether fracking contaminates groundwater. If the risk is established, regulators then need to answer whether regulations can mitigate the risk. To the extent that information about this risk exists, the firms conducting the fracking likely possess it. They have little incentive to be fully forthcoming with this information because it could lead to increased public opposition, tighter regulation, or tort suits. It is conceivable that residents who live adjacent to fracking operations have some evidence of the risk to groundwater, but this evidence will be scattered and anecdotal.

To imagine how an experiment and a moratorium for fracking might have worked best, one would need to travel back to the early 2000's, not long after it first became clear that horizontal drilling and the new, slickwater fracking technique applied to shales were economically viable.[211] At that point, there would have been a plausible case that fracking created a significant risk to health and the environment, but not enough information to start a conventional rulemaking or conduct a meaningful cost-benefit analysis. This would have been the prime moment for intervention.

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207. VT. STAT. ANN. tit. 29, § 571 (West 2015).

208. NEW YORK DEPARTMENT OF ENVIRONMENTAL CONSERVATION, FINAL SUPPLEMENTAL GENERIC ENVIRONMENTAL IMPACT STATEMENT ON THE OIL, GAS, AND SOLUTION MINING REGULATORY PROGRAM (2015), http://www.dec.ny.gov/docs/materials_minerals_pdf/findingstatehvhf62015.pdf, [http://perma.cc/3ZWH-6UFN].

209. Spence, *supra* note 204, at 455.

210. *See, e.g.*, 16 TEX. ADMIN. CODE § 3.30 (2015) (assigning regulation to the Railroad Commission, which is the main oil and gas regulator in the state).

211. *See* Merrill & Schizer, *supra* note 156, at 154 ("In 2000, shale supplied negligible amounts of oil and only 2% of domestically produced natural gas in the U.S.").

A randomized experiment, coupled with a moratorium on fracking outside of the experimental conditions, could have been possible. The EPA could have set up a lottery, and firms interested in conducting fracking operations could have entered each site at which they proposed to drill. The firms also could have suggested possible risk-mitigating measures to test. The EPA would have then used the lottery to randomly assign each site into multiple groups: a control group, an unrestricted group, and possibly other groups designed to test promising risk-mitigating measures. Sites assigned to the control group could not commence operations, but would nonetheless be monitored to establish baseline conditions. Sites in the unrestricted group could begin fracking. Sites in the risk-mitigation groups would begin fracking within the risk-mitigation conditions.

One advantage of a randomized experiment is that the evidence that it would produce would not be susceptible to the type of site-specific criticisms that can cloud the results of localized groundwater contamination studies. For example, one fracking proponent has argued that "it can be difficult to determine the cause of particular incidents of alleged groundwater contamination . . . [because] (1) often there are multiple potential causes of contamination and (2) a lack of baseline water quality data may make it difficult to know when the contamination first appeared."[212] On this reasoning, industry groups have requested baseline testing at fracking sites.[213] It is easy to see why industry would want the tests: they could yield possible explanations for subsequent evidence of contamination other than fracking operations. The benefit of a large, randomized experiment is that, if the groundwater near the sites at which fracking is allowed (the treatment group) is observed to be contaminated at a significantly higher rate than it is at sites at which it is prohibited (the control group), there would be strong evidence that other theories of contamination do not explain the results.

The main challenge in organizing an experiment like this would be getting a large sample: firms would need to submit enough sites into the lottery for the groups to be large enough to measure effects.[214] But firms' incentives would be well aligned with the agency's on this issue because the more sites the firms entered, the greater the chance that

212. Keith B. Hall, *Hydraulic Fracturing and the Baseline Testing of Groundwater*, 48 U. RICH. L. REV. 857, 868 (2014).

213. *Id.* at 873.

214. *See* Abramowicz et al., *supra* note 9, at 974 ("There is no magic number for all experiments; a small number of observations may be enough if the measured effect of the intervention is anticipated to be large, but a large number may be needed for small anticipated measured effects.").

the firms would actually get to start operations. Another potential worry is that the lottery will give some lucky firms a sufficiently large competitive advantage that the firm may come to dominate the market. If some firms are able to grow quickly, they could increase the risk of entrenchment. But a large-n sample should make any one firm's dominance unlikely.

The EPA would also need to carefully monitor that firms complied with the risk-mitigating measures to police crossover[215] and that they did not conduct fracking outside of the experimental conditions to police spillover.[216] If the experiment worked, the agency should acquire good evidence on whether groundwater contamination is likely and whether it can be mitigated. The agency also might monitor ambient environmental conditions in the areas surrounding the sites and pick up on any changes, which could provide evidence of unanticipated risks.[217] The EPA could then proceed to rulemaking with less risk of regulatory error.

It is difficult to imagine a similar regulatory experiment today. The practical obstacles to shutting down some percentage of the numerous fracking operations underway might make it infeasible. But the main reason such an experiment would not be viable is interest group entrenchment.

The recent fracking boom had its origins in "a number of independent gas producers," who "started fiddling around with the idea that you could combine horizontal drilling with hydraulic fracturing."[218] The "breakthrough" came in 1998, when "an independent gas producer named George Mitchell, working in the Barnett Shale field near Fort Worth, Texas, figured out the right combination of horizontal drilling, pressure, and proppants to get the gas flowing out of shale."[219] The best window for aggressively regulating fracking was then—when its only proponents were independent gas producers like Mitchell.

But Mitchell's "success was observed by other producers, and they quickly emulated his methods."[220] The structure of the industry has changed radically. Today, "[l]arge production companies are

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215. *See id.* at 959–60 (explaining other ways to address crossover, but conceding that they are "imperfect").

216. *See id.* at 960 (proposing randomizing by geographical area to address spillover, but also noting that doing so might create a small sample size).

217. For an explanation of the challenges of effective ambient environmental monitoring, see Eric Biber, *The Problem of Environmental Monitoring*, 83 U. COLO. L. REV. 1, 22–34 (2011).

218. Thomas W. Merrill, *Four Questions About Fracking*, 63 CASE W. RES. L. REV. 971, 972 (2013).

219. *Id.* at 973.

220. *Id.*

gradually replacing the small and independent firms that pioneered this practice."[221] Fracking interests have increasing influence in state legislatures and Washington. According to a report by Common Cause, an activist group that tracks money in politics, oil and gas firms involved in fracking spent $110.2 million on lobbying in 2010, up from $29.1 million in 2001.[222]

Perhaps more importantly, local economies have come to rely on fracking. In the Bakken Shale in North Dakota and Montana, the Marcellus Shale in Pennsylvania and surrounding parts of Appalachia, and multiple shale plays in Texas and elsewhere, fracking has brought employment, tax revenue, and new infrastructure—along with health, safety, and environmental risks.[223] It is the perfect storm of interest group entrenchment: a wealthy but concentrated and organized industry that has created economic dependence in certain state and local economies.

There also may be a type of social norm entrenchment taking place as well. Cultural cognition may be influencing perceptions about the risks fracking creates. Support for and opposition to fracking correlates strongly with self-identifying as conservative or liberal respectively.[224] Critically, individuals who report greater familiarity with fracking are significantly more likely to express strong support or strong opposition to the practice.[225] It is possible that, since fracking resembles a lot of other industrial processes that create environmental risks, these cultural cognition effects were inevitable, but it is difficult to know how public opinion might have developed during a regulatory experiment. If these cultural divisions calcify, public opinion might not

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221. Merrill & Schizer, *supra* note 156, at 249.

222. James Browning & Melanie McElroy, *Deep Drilling, Deep Pockets In Congress & Michigan*, COMMON CAUSE 4 (2011), http://www.commoncause.org/research-reports/National_111011_Report_Michigan_Deep_Drilling_Deep_Pockets.pdf [http://perma.cc/TP6T-9SLA].

223. Media coverage has been extensive. For one account of the Bakken Shale, see Chip Brown, *North Dakota Went Boom*, N.Y. TIMES MAG. (Jan. 31, 2013) http://www.nytimes.com/2013/02/03/magazine/north-dakota-went-boom.html?_r=0 [http://perma.cc/LF4N-J5TX]; for an account on the Marcellus Shale, see Eliza Griswold, *The Fracturing of Pennsylvania*, N.Y. TIMES MAG. (Nov. 17, 2011) http://www.nytimes.com/2011/11/20/magazine/fracking-amwell-township.html [http://perma.cc/C5CG-F3Y6]. But see Daniel Raimi & Richard G. Newell, *Oil and Gas Revenue Allocation to Local Governments in Eight States*, DUKE U. ENERGY INITIATIVE (Duke Univ., Durham, N.C.), Oct. 2014, at 4, https://energy.duke.edu/sites/default/files/attachments/Oil%20Gas%20Revenue%20Allocation%20to%20Local%20Government%20FINAL.pdf, [http://perma.cc/8BSD-NJDP] ("[S]ome local governments [have] faced fiscal challenges associated with industry-driven growth in population and heavy vehicle traffic.").

224. CHRIS CLARKE, HILARY BOUDET, & DYLAN BUGDEN, FRACKING IN THE AMERICAN MIND: AMERICANS' VIEWS ON NATURAL GAS DRILLING USING HYDRAULIC FRACTURING 13 (2012), http://climatechangecommunication.org/sites/default/files/reports/Fracking_In_the_American_Mind_2012.pdf [http://perma.cc/W7BQ-KYJ9].

225. *Id.* at 14.

be receptive to new evidence about whether fracking risks justify regulation.

There may still be a window for regulatory action, however. If the groundwater contamination risks prove to be substantial, and they can be vividly demonstrated, public opinion might turn against fracking, even in areas where it has come to dominate the local economy. The risks might also turn out to be insignificant or susceptible to mitigation with inexpensive measures. The fracking boom could end just as rapidly as it began, if some future emerging technology undercuts its economic rationale. But if the risks do turn out to justify regulation, the window for regulatory action may have elapsed, in part due to the structure of administrative law.

B. E-Cigarettes

E-cigarettes are battery-controlled devices that vaporize a liquid solution containing nicotine to produce a sensation that mimics tobacco smoking. According to the industry, e-cigarettes provide "enjoyment without the stigma."[226] But according to the activist group Americans for Nonsmokers' Rights, the message the public should be sent is that "Electronic Cigarettes are NOT a safe alternative!"[227] In a proposed rule published in April 2014, the FDA stated flatly: "We do not currently have sufficient data about these products to determine what effects e-cigarettes have on the public health."[228]

What we do know is that use of e-cigarettes is rising rapidly. As of 2013, the most recent year for which data from a peer-reviewed study is available, 8.5% of surveyed US adults reported having used e-cigarettes at least once, increasing from 3.3% in 2010.[229] According to the CDC's National Health Interview Survey, which in 2014 included questions about e-cigarette use for the first time, 12.6% of surveyed US adults reported ever having tried an e-cigarette.[230] According to the

226. *E-Cig FAQs*, SMOKE-FREE ALT. TRADE ASS'N, http://sfata.org/resources/e-cig-faqs/ (last visited Oct. 18, 2015) [http://perma.cc/U4LB-VQVA].

227. *Electronic Cigarettes*, AMS. FOR NONSMOKERS' RIGHTS, http://www.no-smoke.org/learnmore.php?id=645 (last visited Oct. 18, 2015) [http://perma.cc/7UC4-RLDK].

228. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142, 23,144 (proposed April 25, 2014) (to be codified at 21 C.F.R. pts. 1100, 1140, & 1143) [hereinafter Proposed E-Cigarette Rule].

229. Brian A. King et al., *Trends in Awareness and Use of Electronic Cigarettes Among US Adults, 2010–2013*, 17 NICOTINE & TOBACCO RES. 219, 221 (2015).

230. CHARLOTTE A. SCHOENBORN & RENEE M. GINDI, CTRS. FOR DISEASE CONTROL & PREVENTION, ELECTRONIC CIGARETTE USE AMONG ADULTS: UNITED STATES, 2014, at 1 (2015), http://www.cdc.gov/nchs/data/databriefs/db217.pdf [http:// perma.cc/ER6X-JCAB].

CDC's National Youth Tobacco Survey, as of 2014, 13.4% of high school students surveyed reported using e-cigarettes in the past 30 days, up from 1.5% in 2011.[231] Even 3.9% of middle school students surveyed reported e-cigarette usage in the past 30 days,[232] up from 0.6% in 2011.[233]

1. Risks and Benefits

Tobacco smoking causes more than 480,000 deaths in the United States each year, which makes it the nation's leading cause of preventable deaths.[234] As of 2014, 16.8% of the adult population smoked.[235] The persistence of tobacco smoking in spite of widespread awareness of its lethality motivates both the case for and against e-cigarettes.

Proponents generally make two arguments. First, "switching to vaping e-cigarettes instead of smoking combustible cigarettes means users can avoid the myriad of toxins and other carcinogens created by tobacco combustion."[236] Second, "[e]-cigarettes have the potential to be more effective at moving smokers away from traditional cigarettes than traditional nicotine reduction devices."[237] Proponents point to the United Kingdom's Royal College of Physicians, which in June 2014 reiterated its position that, based on the available evidence, "e-

231. René A. Arrazola et al., TOBACCO USE AMONG MIDDLE AND HIGH SCHOOL STUDENTS — UNITED STATES, 2011–2014, CTRS. FOR DISEASE CONTROL & PREVENTION (2015), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a3.htm [http:// perma.cc/D26W-JS85].

232. *Id.*

233. CTRS. FOR DISEASE CONTROL & PREVENTION, NOTES FROM THE FIELD: ELECTRONIC CIGARETTE USE AMONG MIDDLE AND HIGH SCHOOL STUDENTS—UNITED STATES, 2011–2012 (2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm [http://perma.cc/R4BH-YMAJ].

234. CTRS. FOR DISEASE CONTROL AND PREVENTION, CURRENT CIGARETTE SMOKING AMONG ADULTS IN THE UNITED STATES (2015), http://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm [http://perma.cc/UL6K-BR4U].

235. *Id.*

236. Nick Dantonio, *Vape Away: Why A Minimalist Regulatory Structure Is The Best Option for FDA E-Cigarette Regulation*, 48 U. RICH. L. REV. 1319, 1350 (2014); *see also* John Tierney, *A Tool to Quit Smoking Has Some Unlikely Critics*, N.Y. TIMES (Nov. 7, 2011), http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokers-quit-but-they-have-some-unlikely-critics.html?_r=0 [http://perma.cc/2EX8-DC3A] (approvingly quoting an e-cigarette proponent for the view that "[i]t's time to abandon the myth that tobacco is devoid of benefits, and to focus on how we can help smokers continue to derive those benefits with a safer delivery system").

237. Dantonio, *supra* note 236, at 1351; *see also* Tierney, *supra* note 236 (arguing that evidence suggests that e-cigarettes will help smokers quit).

cigarettes could lead to significant falls in the prevalence of smoking in the UK."[238]

Opponents argue that e-cigarettes will "induce nicotine addiction" in non-smokers and "possibly serv[e] as a gateway product for subsequent cigarette use."[239] In particular, they contend that consumers might be misled because e-cigarette firms have (at least until recently, as we will see below) made unsupported claims about e-cigarettes' safety or effectiveness at helping smokers smoke less.[240] Opponents have also claimed that industry has deliberately targeted youth by marketing e-cigarettes with chocolate, vanilla, and fruit flavorings,[241] which are banned in conventional cigarettes.[242] There are potential secondary risks as well. The FDA has claimed that trace amounts of toxic chemicals have been found in e-cigarette cartridges.[243] The CDC has reported that there has been a rise in calls to poison control centers about e-cigarette poisoning, 51.1% of which involved children under age five,[244] raising fears that e-cigarettes create a risk of acute toxicity.

Because e-cigarettes have been in wide use for only a few years, there is little empirical research that might help assess the competing claims about the causal relationship between e-cigarette use and tobacco smoking. When the FDA published its proposed rule on e-cigarettes, the agency stated that "[a]lthough e-cigarettes may have short-term smoking reduction benefits, FDA cautions that long-term studies are not available to conclude that e-cigarettes are a proven cessation product."[245] The FDA also stated that it could not "establish what effects e-cigarettes have in users who might have otherwise quit, but instead engage in dual use of e-cigarettes and another tobacco product."[246]

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238. *RCP Statement on E-Cigarettes*, ROYAL COLL. OF PHYSICIANS (June 25, 2014), https://www.rcplondon.ac.uk/press-releases/rcp-statement-e-cigarettes [https://perma.cc/59ZK-GWNX].

239. Jordan Paradise, *No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes*, 13 YALE J. HEALTH POL'Y, L. & ETHICS 326, 335 (2013).

240. *Id.* at 355–56.

241. *Id.* at 358.

242. 21 U.S.C. § 387g(a)(1)(A) (2012).

243. This is consistent with the FDA's claim, mentioned above, that "[w]e do not currently have sufficient data about these products to determine what effects e-cigarettes have on the public health." *Proposed E-Cigarette Rule*, *supra* note 228, at 23,144, 23,157.

244. *New CDC Study Finds Dramatic Increase in E-Cigarette-Related Calls to Poison Centers*, CTRS. FOR DISEASE CONTROL AND PREVENTION (April 3, 2014), http://www.cdc.gov/media/releases/2014/p0403-e-cigarette-poison.html [http://perma.cc/63E8-TG2G].

245. *Proposed E-Cigarette Rule*, *supra* note 228, at 23,152.

246. *Id.*

The FDA's summary of the evidence reveals that almost no randomized studies have been published. One exception is a high-profile randomized control study from New Zealand published in *The Lancet* in 2013.[247] In the study, 657 adult smokers who wanted to quit were randomly assigned to e-cigarette, nicotine patch, or placebo e-cigarette groups, and the experimenters sought to measure what percentage of each group was abstinent from smoking six months later.[248] While abstinence was slightly higher in the e-cigarette group, at 7.3%, than in the patches group, at 5.8%, or the placebo group, 4.1%, those numbers were much lower than anticipated. As a result, the experimenters conceded they "had insufficient statistical power to conclude superiority of nicotine e-cigarettes to patches or to placebo e-cigarettes."[249] The New Zealand study does not provide strong evidence for either side of the e-cigarette debate, but it does demonstrate both the theoretical possibility—and some of the practical difficulties—of conducting randomized studies on the effects of e-cigarettes.

2. Existing Regulation

Federal statutes treat drugs and tobacco products differently, so the set of regulatory options for controlling e-cigarettes depends on its categorization. The FDA has broad authority under the Food, Drug, and Cosmetic Act ("FDCA")[250] to regulate drugs to ensure that they are "safe and effective."[251] The FDCA generally requires that any new drug receive the FDA's premarket approval and also empowers the agency to withdraw approval if it learns that the drug is unsafe or ineffective.[252] In 1996, the FDA asserted that nicotine was a "drug" within the meaning of the FDCA and promulgated a series of regulations intended to reduce tobacco use among minors.[253] In 2000, in *FDA v. Brown & Williamson Tobacco Co.*, the Supreme Court held, "based on the FDCA's overall regulatory scheme and . . . subsequent tobacco legislation, that Congress has directly spoken to the question at issue and precluded the FDA from regulating tobacco products."[254]

247. Christopher Bullen et al., *Electronic Cigarettes for Smoking Cessation: A Randomised Controlled Trial*, 382 LANCET 1629, 1629 (2013).

248. *Id.* at 1630.

249. *Id.* at 1633.

250. 21 U.S.C. §§ 301–399f (2012).

251. *Id.* § 393(b)(2).

252. *Id.* § 355(d)–(e).

253. FDA v. Brown & Williamson Tobacco Co., 529 U.S. 120, 125 (2000).

254. *Id.* at 160–61.

Nine years later, Congress responded to *Brown & Williamson* by enacting the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"),[255] which amended the FDCA to authorize the FDA to regulate tobacco.[256] The TCA explicitly required that the FDA reintroduce the rules it promulgated in 1996 that the Court struck down in *Brown & Williamson*.[257]

The TCA includes two new provisions that are potentially relevant for e-cigarettes. One provision requires premarket review for any "new tobacco product," which is defined as a tobacco product "that was not commercially marketed in the United States as of February 15, 2007."[258] Another provision requires that any "modified risk tobacco product,"—which is defined as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products"—will only be approved for market when the agency issues an order permitting it.[259] An order will be issued only if the agency determines that the new product would "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," and "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."[260]

The FDA's initial attempt to regulate e-cigarettes did not use these new authorities under the TCA. Instead, in 2009, the FDA ordered that a shipment of e-cigarettes from the firm Sottera, which markets its e-cigarettes under the label NJOY, be denied entry into the United States on the legal theory that the e-cigarettes were unapproved drug-device combinations under the FDCA.[261] Sottera sued, and, in *Sottera, Inc. v. FDA*, the D.C. Circuit rejected the FDA's theory on the ground that Sottera had not made any therapeutic claims in advertising the products.[262] The FDA decided not to appeal and stated in a letter that it would instead regulate e-cigarettes under the TCA.[263]

In April 2014, the FDA published a proposed rule, which would deem e-cigarettes to be a "tobacco product" so it could regulate them

255. Tobacco Regulation, Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

256. 21 U.S.C. § 387a (2012).

257. *Id.* § 387a-1(a)(2).

258. *Id.* § 387j(a).

259. *Id.* § 387k(a)–(b).

260. *Id.* § 387k(g)(1)(A)–(B).

261. Sottera, Inc. v. FDA, 627 F.3d 891, 893 (D.C. Cir. 2010).

262. *Id.* at 898.

263. Lawrence R. Deyton & Janet Woodcock, *Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products*, FDA (Apr. 25, 2011), http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm [http://perma.cc/28CX-AYJT].

under the TCA.[264] The proposed rule states that e-cigarettes likely "would be considered new tobacco products and would be required to obtain an order from FDA prior to marketing."[265] It also anticipates that firms would no longer make any claims that e-cigarettes are "light," "low," or "mild" in light of the modified risk provision.[266]

In the absence of federal regulation, state laws and local ordinances have been enacted. According to a list maintained by Americans for Nonsmokers' Rights, eight states have explicitly prohibited e-cigarettes in all workplaces, restaurants, and bars.[267] Utah, for example, includes e-cigarettes in its ban on smoking in public places other than retail shops that sell e-cigarettes.[268] Sixteen other states have at least some regulation of e-cigarettes.[269] Presently, 475 municipalities have banned e-cigarettes in at least one of workplaces, restaurants, or bars.[270]

3. Prescriptions

The New Zealand study demonstrates that the effects of e-cigarettes on smoking are amenable to testing. To avoid ethical issues, regulators could study pre-existing smokers, both those who, like the participants in the New Zealand study, want to quit,[271] and also those who intend to keep smoking. The experiment should include a control group that has no access to e-cigarettes, a treatment group that does have access, and a placebo group. It would be helpful to measure both the effect on quit rates and on the frequency with which participants smoked conventional cigarettes.

This type of experiment would have several challenges. Because smoking is a stigmatized behavior, individual self-reports are not

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264. *See Proposed E-Cigarette Rule*, *supra* note 228, at 23,143 (clarifying that the FDA has the authority to issue regulations to bring other tobacco products not explicitly mentioned in the statute under the law so long as those products meet the statutory definition of tobacco product, and e-cigarettes meet that definition).

265. *Id.* at 23,174.

266. *See id.* at 23,149 (including one of the health benefits of this rule as the "[e]limination of 'light,' 'low,' and 'mild' descriptors and other unproven modified risk claims").

267. *States and Municipalities with Laws Regulating Use of Electronic Cigarettes*, AM. NONSMOKERS' RIGHTS FOUND. 1, http://www.no-smoke.org/pdf/ecigslaws.pdf (last updated Jan. 1, 2016) [http://perma.cc/3H4D-H82A] [hereinafter *U.S. State and Local Laws*].

268. *See* UTAH CODE ANN. § 26-38-2.6 (West 2012) (listing exceptions to the general ban on use of e-cigarettes in places of public access).

269. *See U.S. State and Local Laws*, *supra* note 267, at 1–3 (listing different states' approaches to e-cigarette regulation).

270. *See id.* at 3–8 (listing different localities' approaches to e-cigarette regulation).

271. *See* Bullen et al., *supra* note 247, at 1630 (stating that participants had said they "wanted to quit smoking").

always reliable. Because it is a repetitive behavior, memories may not be reliable even if reports are sincere. There is a strong possibility of attrition. In the New Zealand study, the researchers observed a strong dropout rate among the group that was randomly assigned nicotine patches; the study speculated that some of these group members, who joined the study in the hope of access to free e-cigarettes, grew uninterested after they learned they had been assigned not to receive them.[272] Consistent with that theory, in the absence of a tight moratorium, there may be crossover risk from control group members who use e-cigarettes outside of the experimental conditions.

There are also practical and ethical limitations to what could be learned from experiments. It would be useful to learn if non-smokers, some of whom were randomly assigned to receive free e-cigarettes, were more likely to start smoking conventional cigarettes. But it would be impossible to justify the health harm to participants, even if they gave informed consent. Randomized experiments with e-cigarettes obviously cannot include minors, but how tightly e-cigarettes should be controlled may ultimately hinge on how minors are affected. There also would not be sufficient time in the experiment to observe the long-term health effects of e-cigarette use itself, which could be just as important as e-cigarettes' causal effects on conventional smoking.

Even with these challenges and limitations, the case for randomized experiments with e-cigarettes is strong. If e-cigarettes really do help smokers quit, they should probably be commercially available, and should definitely be available by prescription to current smokers. If e-cigarettes lead to greater smoking, there is a plausible argument for banning them outright, if the black market can be effectively suppressed, or at least imposing more coercive restrictions.

The open question is whether regulations more restrictive than the FDA's proposed rule remains politically feasible. The political economy of e-cigarette regulation has rapidly changed in the past few years, leading to interest group entrenchment. An article published in 2013 stated that "[t]he industry [wa]s dominated by small, independent companies, with the exception of blu eCigs, which was acquired in April 2012 by Lorillard Tobacco Company for $135 million."[273] Now, the other major tobacco firms have followed Lorillard. In 2014, Altria acquired e-cigarette maker Green Smoke.[274] Reynolds American, which was

272. *Id.* at 1635 ("Some of the participants might have agreed to take part in the study to try e-cigarettes, and then lost interest when randomised to patches.").

273. Paradise, *supra* note 239, at 355.

274. Mike Esterl, *Altria Expands in E-Cigarettes With Green Smoke*, WALL ST. J. (Feb. 3, 2014, 6:11 PM), http://online.wsj.com/news/articles/ SB10001424052702304626804579360552508696542[http://perma.cc/M7KL-YJ6Q].

created by a merger of R.J. Reynolds and Brown & Williamson, planned to introduce its own line of e-cigarettes, called Vuse.[275] Interestingly, later in 2014, Lorillard acquired Reynolds American, and in a sign of how important the e-cigarettes market is expected to become, agreed to sell blu to another major tobacco firm, Imperial Tobacco, to improve the chances of the merger surviving antitrust review.[276] In 2015, Japan Tobacco acquired the e-cigarette company Logic Technology Development.[277]

For a brief period, it was conceivable that the major tobacco firms would view e-cigarettes as a threat, creating the possibility of a Baptist-and-Bootlegger coalition between public health advocates and tobacco firms for tighter e-cigarette regulation.[278] But now that the major tobacco firms have consolidated their position in the e-cigarette market, one of the most powerful industries in Washington can oppose tighter regulation of e-cigarettes.

Social norm entrenchment is happening as well. Some public health scholars contend that tobacco use has declined in part because it has been successfully stigmatized. For example, a recent article in the *New England Journal of Medicine* explained that "[a]s information about the hazards of sidestream smoke was publicized in the 1980s and 1990s, the imperative to protect 'innocent bystanders' moved to the center of tobacco-control efforts, and public smoking bans pushed smokers into the shadows. The once-widespread habit . . . became highly stigmatized."[279] Now, "[m]arketing campaigns for e-cigarettes threaten to reverse the successful, decades-long public health campaign to denormalize smoking."[280] The renormalization may already be

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275. *Id.*

276. *See* Mike Esterl & Peter Evans, *Reynolds American to Buy Lorillard for $25 Billion*, WALL ST. J. (July 15, 2014 8:01 PM), http://online.wsj.com/articles/reynolds-american-to-buy-lorillard-for-27-4-billion-1405422823 [http://perma.cc/SJS9-667H].

277. Tripp Mickle, *Japan Tobacco to Acquire U.S. Electronic Cigarette Company Logic Technology Development*, WALL ST. J. (Apr. 30, 2015, 11:25 PM), http://www.wsj.com/articles/japan-tobacco-to-acquire-u-s-electronic-cigarette-company-logic-technology-development-1430423065 [http://perma.cc/Y84C-BP7T].

278. For the origin of this metaphor, see Bruce Yandle, *Bootleggers and Baptists—The Education of a Regulatory Economist*, REGULATION: AM. ENTERPRISE INST. J. ON GOV'T & SOC'Y, May–June 1983, at 12, 13–14.

279. Amy L. Fairchild et al., *The Renormalization of Smoking? E-Cigarettes and the Tobacco "Endgame,"* 370 NEW ENG. J. MED. 293, 293 (2014).

280. *Id.* To be clear, Fairchild and her colleagues are open to the possibility that e-cigarettes can be a net positive for public health; in fact, they contend that "an unwillingness to consider e-cigarette use until all risks or uncertainties are eliminated is dangerously close to dogmatism." *Id.* at 295. But they note that "strict denormalization strategies may be incompatible with e-cigarette use." *Id.*

underway—in 2013, the *New York Times* declared in a headline: "Smoking Is Back, Without the Stigma."[281]

The status of the stigma is important for public health outcomes because it might affect how many non-smokers start using e-cigarettes, and possibly start smoking conventional cigarettes. But what makes it relevant for entrenchment is that the electorate might be more reluctant to support restrictive regulation on e-cigarettes if they do not perceive e-cigarette use as stigmatized. The normative case for imposing a moratorium solely to halt social norm entrenchment is always uneasy. One person's social norm entrenchment can be another's democratic deliberation. Yet there are three plausible justifications in the case of e-cigarettes.

First, if firms are misleading consumers about the health effects of e-cigarettes, that might justify discounting the value of decisions based on that misleading information. After the *Sottera* decision, some e-cigarette firms have been attempting to avoid making therapeutic claims. For example, on its website, the Smoke-Free Alternatives Trade Association, an e-cigarette trade association, claims: "While electronic cigarettes are not smoking cessation tools nor are they marketed that way, there may be anecdotal evidence that some people have reduced or eliminated use of traditional cigarettes."[282] But there is evidence that, in the words of one comment that the FDA received on the proposed rule from public health scholars, "e-cigarette companies have explicitly and implicitly made therapeutic claims about their products in their online marketing and promotional materials" in the past.[283] So even if firms are no longer making these claims, the lingering effects of earlier therapeutic claims in advertising may be contributing to the de-stigmatization. But, of course, this issue is impossible to resolve now because the evidence on the therapeutic claims is mixed.

Second, cognitive dissonance might delay future acceptance of evidence demonstrating worse than anticipated health risks from e-cigarettes. There is evidence that smokers' beliefs exhibit the effects of cognitive dissonance, but that these beliefs fade when smokers quit.[284]

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281. Steven Kurutz, *Confounding a Smoking Ban, and Bouncers*, N.Y. TIMES (Aug. 8, 2013), http://www.nytimes.com/2013/08/08/fashion/smoking-is-back-without-the-stigma.html [http://perma.cc/2CFS-LNDZ].

282. *E-Cig FAQs*, *supra* note 226.

283. RACHEL GRANA ET AL., COMMENT SUBMITTED REGARDING FOOD AND DRUG ADMINISTRATION ACTIONS RELATED TO NICOTINE REPLACEMENT THERAPIES AND SMOKING-CESSATION PRODUCTS (2013), http://www.tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-comment-ecig-cessation-1jx-835b-n9ph.pdf [http://perma.cc/EX5J-63GP].

284. Omid Fotuhi et al., *Patterns of Cognitive Dissonance-Reducing Beliefs Among Smokers: a Longitudinal Analysis from the International Tobacco Control (ITC) Four Country Survey*, 22 TOBACCO CONTROL 52, 52 (2013).

The combination of potentially misleading advertising early on, lax regulation, and widespread use leading to de-stigmatization, could bolster the effect of cognitive dissonance.

Third, there is a related possibility that cultural cognition could influence assessment of future health and safety evidence about e-cigarettes, as it influenced the reception of evidence about the health risks of conventional cigarettes. A former Surgeon General stated that "'the diffusion of new knowledge . . . was impeded by the entrenched norm of smoking, a widespread practice fueled by the persistent and pervasive marketing of cigarettes.'"[285] The public "did ultimately come to believe the empirical information . . . only after a shift in social meaning . . . made acceptance of that information compatible with a diverse array of cultural outlooks."[286] To the extent that similar perceptions develop for e-cigarettes, cultural cognition, rather than pure normative disagreement, might motivate opposition to regulation.

C. Autonomous Vehicles

As of December 2015, Google reports that its autonomous cars had travelled over 1.3 million miles autonomously on public roadways.[287] In 2014, Rio Tinto claimed that fully autonomous trucks had logged 2.3 million kilometers at its mines in Australia.[288] In 2012, Volvo demonstrated the feasibility of linking cars in a computer-controlled "road train" so that they drive along a highway in tandem.[289] Daimler has demonstrated that its autonomous Mercedes can navigate traffic on the autobahn.[290] In 2016, the Department of Transportation announced a ten-year, $4 billion proposal to fund pilot programs for autonomous vehicles, an acknowledgement that "partially and fully automated vehicles are nearing the point at which widespread

285. Kahan, *supra* note 65, at 137–38 (quoting CTRS. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., REDUCING TOBACCO USE: A REPORT OF THE SURGEON GENERAL 40 (2000)).

286. *Id.* at 138.

287. *See Google Self-Driving Car Project Monthly Report*, GOOGLE 1 (2015), https://static.googleusercontent.com/media/www.google.com/en//selfdrivingcar/files/reports/report-1215.pdf [http://perma.cc/29U5-MCVA] (specifying that since 2009, the project's cars have driven 1,372,111 miles in autonomous mode).

288. *See* David Stringer, *How Robots, Drones Are Transforming Mining and Mine Safety*, INS. J. (Apr. 4, 2014), http://www.insurancejournal.com/news/national/2014/04/04/325475.htm [http://perma.cc/B95A-GUJT].

289. *Volvo's Self-Drive "Convoy" Hits the Spanish Motorway*, BBC NEWS (May 29, 2012, 6:08 AM), http://www.bbc.com/news/technology-18248841 [http://perma.cc/4JJ9-2WWM].

290. *See* Joseph B. White, *Mercedes Makes Driverless Ride*, WALL ST. J. (Sept. 10, 2013), http://online.wsj.com/news/articles/SB10001424127887324549004579065541926070378 [http://perma.cc/A2XU-RVKT].

deployment is feasible."[291] The prospects of autonomous vehicles are no longer science fiction and deserve serious scholarly and regulatory attention.

The history of the current generation of research into autonomous vehicles started with a government agency. In 2004, the US military's in-house think tank, the Defense Advanced Research Projects Agency ("DARPA"), organized a competition, the DARPA Grand Challenge, in which teams were to race autonomous vehicles over a 142-mile route across the Mojave Desert to win a $1 million prize.[292] In the first DARPA Grand Challenge, no vehicle travelled more than 7.5 miles, but by 2005 teams were successfully completing similar courses, and by 2007 they were completing courses with traffic and obstacles.[293] In the past several years, development has shifted to the private sector. Google's project may be the most advanced and high profile, but many of the major automakers now claim to be researching semi- or fully autonomous vehicles.

1. Risks and Benefits

To understand the risks and benefits of autonomous vehicles, it is important to distinguish among different degrees of automation. The National Highway Traffic Safety Administration ("NHTSA") divides autonomous vehicles into four levels, the most important and advanced of which are Levels 3 and 4.[294] Level 3 is "Limited Self-Driving Automation," which "enable[s] the driver to cede full control of all safety-critical functions under certain traffic or environmental conditions" and "rel[ies] heavily on the vehicle to monitor for changes in those conditions requiring transition back to driver control."[295] Level 4 is "Full Self-Driving Automation."[296]

Lower level technologies can bring significant safety benefits, and NHTSA is starting to require some of them in new models.[297] But

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291. Bill Vlasic, *U.S. Proposes Spending $4 Billion on Self-Driving Cars*, N.Y. TIMES (Jan. 14, 2016), http://www.nytimes.com/2016/01/15/business/us-proposes-spending-4-billion-on-self-driving-cars.html [http://perma.cc/T8DH-X6VC].

292. *The DARPA Grand Challenge: Ten Years Later*, DEFENSE ADVANCED RES. PROJECTS AGENCY (March 13, 2014), http://www.darpa.mil/news-events/2014-03-13 [http://perma.cc/4L4H-2CA2].

293. *See id.*

294. NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., PRELIMINARY STATEMENT OF POLICY CONCERNING AUTOMATED VEHICLES 4–5 (2013), http://www.nhtsa.gov/staticfiles/rulemaking/pdf/Automated_Vehicles_Policy.pdf [http://perma.cc/Y46T-68P2].

295. *Id.* at 5.

296. *Id.*

297. *See id.*

the effects of Level 4 autonomous vehicles could transform society. Much of the discussion of the costs and benefits of autonomous vehicles has, therefore, focused on a world in which Level 4 technologies are widely available. The most recent estimates suggest that an estimated 32,675 Americans died in auto collisions in 2014.[298] Many of those crashes are due to driver error. In 2008, NHTSA issued a report to Congress on the causes of motor vehicle collisions.[299] The report itself does not explicitly state what percentage of total collisions are attributable to driver error, but the data the report presents has been used to calculate the widely repeated claim that driver error accounts for approximately 93% of collisions.[300] For that reason alone, the benefits of autonomous vehicles—at least with Level 4 technology—could be staggering.

There are other significant benefits other than the body count. Reducing collisions would save resources spent on auto repair, policing, and adjudication, and because collisions would be less frequent, cars might be designed lighter, reducing manufacturing costs and saving fuel.[301] Level 4 autonomous vehicles could also advance civil rights by providing mobility to the elderly and the disabled.[302] A change in patterns of car ownership would trigger many of these economic benefits.[303] We take it for granted now that, outside of a few very dense cities, individuals who can afford to do so will own cars and drive them when needed, but otherwise leave them parked for most of the day.[304] With fully autonomous vehicles, individuals might be able to sign up for

298. NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., EARLY ESTIMATE OF MOTOR VEHICLE TRAFFIC FATALITIES IN 2014 1 (2015), http://www-nrd.nhtsa.dot.gov/Pubs/812160.pdf [http://perma.cc/6KRN-E7DW].

299. *See generally* NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., NATIONAL MOTOR VEHICLE CRASH CAUSATION SURVEY (2008), http://www-nrd.nhtsa.dot.gov/Pubs/811059.pdf [http://perma.cc/Z4G4-Z25L].

300. *See* Bryant Walker Smith, *Human Error As A Cause of Vehicle Crashes*, CTR. FOR INTERNET & SOC'Y (Dec. 18, 2003, 3:15 PM), http://cyberlaw.stanford.edu/blog/2013/12/human-error-cause-vehicle-crashes [http://perma.cc/ZDN2-3RY7].

301. For a similar analysis from an industry expert who has consulted with Google's self-driving car project, see Brad Templeton, *New Design Factors for Robot Cars*, TEMPLETONS http://www.templetons.com/brad/robocars/design-change.html (last visited Oct. 18, 2015) [http://perma.cc/L55L-3RK5].

302. *See, e.g.*, Sven A. Beiker, *Legal Aspects of Autonomous Driving*, 52 SANTA CLARA L. REV. 1145, 1151–52 (2012) ("[A]utonomous driving technology can help elderly or disabled citizens keep an active lifestyle such as running daily errands and maintaining their social relationships.").

303. *See* Templeton, *supra* note 301 (discussing the potential rise of car clubs and rentals, which could trigger economic benefits).

304. *See* KPMG, SELF-DRIVING CARS: ARE WE READY? 30 (2013), https://www.kpmg.com/US/en/IssuesAndInsights/ArticlesPublications/Documents/self-driving-cars-are-we-ready.pdf [https://perma.cc/AFN3-RK6U] (discussing focus group responses to the question of whether consumers would be willing to abandon individual ownership).

a service that sends whatever car is available to them on demand. Think of today's ridesharing services like Uber and Lyft, but without human drivers. In this way, individuals may no longer be responsible for purchasing and maintaining privately owned cars, and cars would no longer sit idle in driveways or parking garages. They might be used much more efficiently, reducing congestion and the total number of vehicles on the road, diminishing the need for highways as the distance between cars necessary for safety (and thus the total space needed for the same volume of cars) decreases, and freeing up valuable land currently devoted to parking.[305]

Level 4 autonomous vehicles would bring risks as well. Because they will make riding by car less expensive, they might have the effect of increasing the amount of total miles traveled.[306] That could raise fuel consumption, although that effect might be counterbalanced by ridesharing services owning more electric vehicles, with a smaller set of gasoline-powered vehicles reserved for infrequent, long trips outside of an electric vehicle's range. The reduced cost of travel might also change land use patterns by encouraging suburban sprawl.[307]

Some scholars have worried that the ease of tracking autonomous vehicles might reduce privacy.[308] Others speculate that autonomous vehicles will be hacked by criminals or terrorists.[309] But the most significant negative effect is orthogonal to risk regulation: the potential for massive, sudden unemployment, concentrated among unskilled workers and workers with non-transferable skills.[310] A world without a need for taxi, bus, and truck drivers, and less of a need for workers in the auto manufacturing, auto parts, auto repair, and auto insurance industries might be a world with an unemployment problem that might compare to the unemployment effects of de-industrialization.

The pervasive uncertainty surrounding how society will adjust to fully autonomous vehicles makes speculative any suggestions about what regulatory regime should govern their use in the long term. But

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305. *See* Bryant Walker Smith, *Managing Autonomous Transportation Demand*, 52 SANTA CLARA L. REV. 1401, 1412–13 (2012).

306. *See id.* at 1417–18.

307. *See id.*

308. *See generally* Dorothy J. Glancy, *Privacy in Autonomous Vehicles*, 52 SANTA CLARA L. REV. 1171 (2012) (discussing privacy concerns).

309. *See* Frank Douma & Sarah Aue Palodichuk, *Criminal Liability Issues Created by Driverless Cars*, 52 SANTA CLARA L. REV. 1157, 1164–68 (2012).

310. For an analysis of the potential employment effects of autonomous vehicles in the context of the broader effects of automation on the workforce, see generally ERIK BRYNJOLFSSON & ANDREW MCAFEE, THE SECOND MACHINE AGE: WORK, PROGRESS, AND PROSPERITY IN A TIME OF BRILLIANT TECHNOLOGIES (2014).

despite the significant risks and costs, it is difficult to dispute that, if autonomous vehicles can prevent most of the tens of thousands of deaths and hundreds of thousands of injuries vehicle collisions cause, they should be encouraged. The best policy for smoothing the transition to autonomous vehicles might require regulation.

2. Existing Regulation

The 1966 National Traffic and Motor Vehicle Safety Act grants NHTSA broad authority to "prescribe motor vehicle safety standards."[311] In a law review article published in 2012, four NHTSA-affiliated lawyers outlined how NHTSA might implement that authority, stating that the agency could "establish safety standards applicable to vehicles that are originally manufactured with autonomous capabilities and to aftermarket equipment that could be added to vehicles . . . to convert them into autonomous vehicles."[312]

So far, however, NHTSA's role in autonomous vehicle policy has been limited to research and voluntary guidelines.[313] In 2013, NHTSA issued a preliminary statement of policy, which stated that the agency "believe[s] that states are well suited to address issues such as licensing, driver training, and conditions for operation related to specific types of vehicles."[314] The statement explains that, "[w]hile NHTSA's authority, expertise, and mandate is to establish uniform, national standards needed for vehicle safety, the agency recognizes that premature regulation can run the risk of putting the brakes on the evolution toward increasingly better vehicle safety technologies."[315] But NHTSA nonetheless recommended guidelines for state regulation, discouraging states from permitting autonomous vehicles on the road for purposes other than testing, and suggesting how testing might be regulated for safety.[316]

In 2016, however, NHTSA released an update to their preliminary statement of policy. Recognizing that "partially and fully automated vehicles are nearing the point at which widespread deployment is feasible," the statement commits NHTSA to releasing

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311. 49 U.S.C. § 30111 (2012).

312. Stephen P. Wood et al., *The Potential Regulatory Challenges of Increasingly Autonomous Motor Vehicles*, 52 SANTA CLARA L. REV. 1423, 1439 (2012). Their argument relies on the statutory definition provisions in 49 U.S.C. § 30102 (2012).

313. For a description of its current research plans, see NAT'L HIGHWAY TRAFFIC SAFETY ADMIN, *supra* note 294, at 5–9.

314. *Id.* at 10.

315. *Id.*

316. *See id.* at 11–14.

best-practice guidance for the safe operation of Level 4 autonomous vehicles within six months.[317]

Five states have enacted statutes to govern autonomous vehicles[318]—California,[319] Florida,[320] Nevada,[321] Michigan,[322] and Tennessee.[323] So has the District of Columbia.[324] California[325] and Nevada[326] have promulgated regulations to implement the new statutes. California has set up a permitting system to control testing of autonomous vehicles.[327] Nevada has provided for a special license.[328]

Both states rely on the continuing presence of human operators. California requires that a human driver be "seated in the vehicle's driver seat and either: monitoring its operations and able to take over physical control of the vehicle; or, in physical control of the vehicle."[329] Nevada requires that at least two humans ride in any autonomous vehicle on public roadways, "one of whom is the operator and must at all times be seated in a position which allows the person to take complete control of the vehicle, including, without limitation, control of the steering, throttle and brakes."[330] So even if firms are testing Level 4 technology, California and Nevada expect that a human driver will act as if the vehicle had only Level 3 technology.

In the absence of federal legislation or regulation, the legal status of autonomous vehicles in other states is not obvious. In 2014, one scholar undertook a survey of every state's vehicle code[331] and

317. *See* NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., DOT/NHTSA POLICY STATEMENT CONCERNING "AUTOMATED VEHICLES": 2016 UPDATE TO "PRELIMINARY STATEMENT OF POLICY CONCERNING AUTOMATED VEHICLES," 1 (2016), http://www.nhtsa.gov/staticfiles/rulemaking/pdf/Autonomous-Vehicles-Policy-Update-2016.pdf [http://perma.cc/4JWW-4LHM].

318. For a compilation of relevant state bills, statutes, and regulations, see Gabriel Weiner & Bryant Walker Smith, *Automated Driving: Legislative and Regulatory Action*, CTR. FOR INTERNET & SOC'Y: WIKI, http://cyberlaw.stanford.edu/wiki/index.php/Automated_Driving:_Legislative_and_Regulatory_Action [http://perma.cc/2VLF-8MKH] (last visited Oct. 18, 2015).

319. *See* CAL. VEH. CODE § 38750 (West 2015).

320. *See* FLA. STAT. ANN. § 316.85 (West 2012).

321. *See* NEV. REV. STAT. ANN. § 482a (West 2015).

322. *See, e.g.*, MICH. COMP. LAWS ANN. § 257.244 (West 2014).

323. *See* TENN. CODE ANN. §55-8-202 (2015).

324. *See* D.C. CODE § 50-2352 (2007).

325. *See, e.g.*, CAL. CODE REGS. tit. 13, § 227.22 (2015).

326. *See* NEV. ADMIN. CODE § 482A (2013).

327. *See* CAL. CODE REGS. tit. 13, § 227.26 (2015).

328. *See* NEV. ADMIN. CODE § 482A.110 (2013).

329. CAL. CODE REGS. tit. 13, § 227.34 (2015).

330. NEV. ADMIN. CODE § 482A.130 (2013).

331. *See* Bryant Walker Smith, *Automated Vehicles Are Probably Legal in the United States*, 1 TEX. A&M L. REV. 411, 463–500 (2014).

concluded that "[c]urrent law probably does not prohibit automated vehicles."[332]

3. Prescriptions

Autonomous vehicles differ from fracking and e-cigarettes in that there is no isolatable factual question that regulators need to answer quickly. A randomized experiment may not be necessary. Instead, regulators need to monitor the development of autonomous vehicles to ensure that the state will pick up on any of the speculative risks like hacking or, more importantly, any risks that are unforeseen, so that rapid intervention is possible.

But there is a strong case for controlling the testing of autonomous vehicles on reverse entrenchment grounds. One potential obstacle to public acceptance is that early, high profile collisions will turn public sentiment against the new technology and lead to legislation that impedes its development. One leading automotive technology researcher has stated that "[i]t is unclear how courts, regulators, and the public will react to accidents involving robotic cars. Overreaction is a clear danger, even if could it be shown that a transition to autonomous vehicles leads to far fewer traffic-related deaths over all."[333] This type of worry is familiar from the history of emerging technologies. As one historian puts it, "we have seen examples in which a single incident gone awry undermined years of careful planning and building of regulatory systems."[334]

With autonomous vehicles, one potential risk is that firms will market cars with level 3 technologies, which will have the perverse effect of increasing collisions. This theory of risk is based on the premise that, once human drivers come to rely on partial automation, their driving skills may atrophy, or they may just become dangerously inattentive, so that they will not be prepared to take over in the event of an emergency. For this reason, both NHTSA and private firms have emphasized the importance of human-machine interface research.[335] These concerns resemble familiar worries in aviation safety. For example, France's civil aviation safety investigation authority determined that analogous human-machine interaction problems

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333. Beiker, *supra* note 302, at 1152.

334. Gary E. Marchant et al., *What Does the History of Technology Regulation Teach Us About Nano Oversight?*, 37 J.L. MED. & ETHICS 724, 725; *see also* Beiker, *supra* note 302, at 1152 (listing as examples the Three Mile Island nuclear disaster, genetically modified "Starlink" corn, and the death of Jesse Gelsinger, a participant in an early gene therapy clinical trial).

335. *See* Wood et al., *supra* note 312, at 1472-76; Beiker, *supra* note 302, at 1154.

contributed to the crash of Air France Flight 447 over the Atlantic Ocean in 2009.[336]

Federal regulation could significantly reduce the risk of reverse entrenchment by controlling experimentation and ensuring that all firms take sufficient care to avoid collisions that could impede public acceptance. Note that, even if the median firm takes due care, the whole industry could be set back by a collision caused by just one negligent outlier firm.

The best regulatory strategy to ease the transition to autonomous vehicles may be to prohibit firms from testing vehicles with Level 3 technologies on public roads. The political complication with this strategy is that it appears that Google and the major automakers have diverged on whether Level 3 technologies should be used. Until May 2014, Google had been testing autonomous vehicles with Level 3 technologies. As *The New York Times* reported, "[t]here were no crashes. But Google engineers realized that asking a human passenger—who could be reading or daydreaming or even sleeping—to take over in an emergency won't work."[337] The Google researchers "'saw stuff that made [them] a little nervous.'"[338] So Google is now testing fully autonomous, Level 4 vehicles limited to 25 miles per hour.[339]

But most of the major automakers, perhaps because their brands are bound up with the appeal of the driving experience or perhaps because they anticipate that fully autonomous vehicles will bring the end of individual car ownership, "favor an incremental approach to self-driving cars, in which features such as lane centering and parking assistance are gradually integrated into vehicles."[340]

So the automakers may resist mandating Level 4 technologies. But the interests of Google and any other firm that takes its Level-4-or-bust approach may be roughly aligned with the interests of federal regulators over the medium term. These firms might actually support federal regulation if it would reduce the risk of reverse entrenchment

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336. *See generally* BUREAU D'ENQUÊTES ET D'ANALYSES POUR LA SÉCURITÉ DE L'AVIATIONCIVILE, FINAL REPORT ON THE ACCIDENT ON 1ST JUNE 2009 TO THE AIRBUS A330-203 REGISTERED F-GZCP OPERATED BY AIR FRANCE FLIGHT AF 447 RIO DE JANEIRO-PARIS 2009 (2012), http://www.bea.aero/docspa/2009/f-cp090601.en/pdf/f-cp090601.en.pdf [http://perma.cc/ D9LD-UZXB] (reporting the details and theory behind flight AF447's crash over the Atlantic in 2009).

337. *See* John Markoff, *Google's Next Phase in Driverless Cars: No Brakes or Steering Wheel*, N.Y. TIMES (May 28, 2014), http://www.nytimes.com/2014/05/28/technology/googles-next-phase-in-driverless-cars-no-brakes-or-steering-wheel.html?_r=0 [http://perma.cc/GPE4-C7RF].

338. *Id.*

339. *See id.*

340. Alexei Oreskovic & Ben Klayman, *Google, Detroit Diverge on Road Map for Self-Driving Cars*, REUTERS (June 30, 2014), http://www.reuters.com/article/2014/06/30/us-google-detroit-insight-idUSKBN0F50C320140630 [http://perma.cc/6NG2-LY8T].

or at least give them a competitive advantage over the automakers. So far, however, NHTSA has not shown interest in this type of approach. In its initial policy statement, NHTSA "strongly recommend[ed] that states require that a properly licensed driver be seated in the driver's seat and ready to take control of the vehicle while the vehicle is operating in self-driving mode on public roads."[341]

Which side has more influence is unclear. By market capitalization and lobbying expenditures,[342] Google is far more powerful than a typical innovator start-up, but its potential adversaries—the major automakers—are some of the most powerful firms in the nation. So the political opportunity autonomous vehicles presents is not as straightforward as it would be for the typical emerging risk. But the benefits of controlled testing—and a moratorium to protect against collisions outside of the tests—might justify regulatory intervention.

V. SECOND BEST STRATEGIES UNDER EXISTING LAW

The robust Experimentalist model of regulation this Article defends would require a statute. Given how infrequently Congress has enacted new statutes in recent years, one should be skeptical about any proposal that requires statutory reform. This Part considers how agencies might be able to implement experiments and moratoria under existing law. It is important to note at the outset that there is no general statutory barrier to conducting regulatory experiments. Agencies have issued rules that function as experiments under existing statutes,[343] and the absence of more experimental rules need not be explained by a lack of statutory authority. It may be that regulated firms do not want to bet on rules that might generate evidence of their own disutility.[344]

Even randomized experiments are possible under existing law. Hard look review should not pose a problem because "an agency should be able to justify employing a randomized experiment on the ground that this approach could provide information relevant to the administrative process."[345] But this is only true if an agency goes through the "ordinary notice-and-comment process"[346]—the process

341. NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., *supra* note 294, at 12.

342. *See, e.g.*, Tom Hamburger & Matea Gold, *Google, Once Disdainful of Lobbying, Now a Master of Washington Influence*, WASH. POST (Apr. 12, 2014), http://www.washingtonpost.com/politics/how-google-is-transforming-power-and-politicsgoogle-once-disdainful-of-lobbying-now-a-master-of-washington-influence/2014/04/12/51648b92-b4d3-11e3-8cb6284052554d74_story.html.

343. For examples, see Gubler, *supra* note 9, at 149–54.

344. *See id.* at 156.

345. Abramowicz et al., *supra* note 9, at 981.

346. *Id.* at 980.

that, along with cost-benefit analysis and judicial review, stymies early attempts to regulate emerging risks. This Article has argued that agencies need to be able to start experiments on emerging risks before they have sufficient information to survive a conventional rulemaking, and they need to be able to use experimental results to generate rules before entrenchment has precluded regulatory options.

This Part analyzes two strategies to permit agencies to conduct experiments and impose moratoria on emerging risks without going through the conventional rulemaking process. First, agencies could bypass notice-and-comment rulemaking by adopting interim final rules. Second, they could expedite the rulemaking process by working towards a negotiated regulation with interested parties.

Each of these approaches is a second best strategy. The legal provisions on which they rely were not designed for the purpose of allowing a flexible response to emerging risks. For many emerging risks, these strategies would not be legal or practical. But in some cases, they might provide agencies useful workarounds to the brittle rulemaking process that might otherwise impede sensible regulation.

A. Interim Final Rules

Interim final rules "are rules adopted by federal agencies that become effective without prior notice and public comment and that invite post-effective public comment."[347] Agencies possess the power to promulgate interim final rules because of a statutory exception in the APA, which provides that an agency need not follow notice and comment procedures "when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."[348]

The process of using an interim final rule works as follows. First, an agency makes a legal determination that it has good cause to deviate from conventional notice-and-comment rulemaking procedures.[349] The agency can then promulgate its interim final rule immediately. Next, an agency decides to accept comments on the rule after it has gone into effect.[350] Agencies are not legally obligated to solicit post-effective comments, but it is a sound strategy because "[t]he fact that the agency solicited and considered the post-effective comments in good faith might

347. Michael Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 ADMIN. L. REV. 703, 704 (1999).

348. 5 U.S.C. § 553(b)(B) (2012).

349. *See* Asimow, *supra* note 347, at 710 (describing the occasions for adopting interim-final rules without public participation).

350. *See id.* at 711 (noting that "[s]olicitation of post-effective comments" is voluntary).

persuade a court that the agency's initial good cause claim was justified."[351] After an agency receives the post-effective comments on the interim rule, it can, following conventional rulemaking procedures, proceed to adopt a final rule.[352]

Interim final rules are not unheard of in practice. In fact, empirical evidence suggests that "interim final rulemaking ha[s] been increasing over time."[353] Agencies are also more likely to use interim final rules when the stakes are high.[354] According to the Government Accountability Office (GAO), between 2003 and 2010, agencies used interim final rules for 15% of major rules[355]—a category that includes all rules that are likely to result in effects of $100 million or more per year.[356] By contrast, agencies only used interim final rules for 4% of nonmajor rules.[357]

The appeal of interim final rules for regulating emerging risks is considerable. When an agency confronts an emerging risk, it could use an interim final rule to impose a moratorium or other limits on the risky technology. It could then organize experiments with the risky technology without allowing entrenchment to occur. When the experiments were completed, the agency could use the conventional rulemaking process to arrive at a final rule, making sure to consider post-effective comments from outside parties to increase its chances of surviving judicial review.

The main obstacle to agencies using interim final rules to regulate emerging risks is satisfying the good cause exception. Unfortunately, "[n]umerous judicial decisions, well supported by the legislative history, establish that the APA's good cause provision is narrowly construed."[358] Although an interim final rule is more likely to be upheld if the agency makes it effective only for a temporary period,[359]

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351. *Id.*

352. *See id.* at 722–23 (discussing the adoption of what the author calls a "final-final rule," a process that includes "modifying and finalizing an interim-final rule").

353. Anne Joseph O'Connell, *Political Cycles of Rulemaking: An Empirical Portrait of the Modern Administrative State*, 94 VA. L. REV. 889, 930 (2008). For empirical evidence indicating that direct and interim final rulemaking have increased since the 1980s, see *id.* at 931.

354. For a discussion of recent trends in the use of notice and comment rulemaking and its substitutes, see Daniel A. Farber & Anne Joseph O'Connell, *The Lost World of Administrative Law*, 92 TEX. L. REV. 1137, 1160–67 (2014).

355. U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-21, FEDERAL RULEMAKING: AGENCIES COULD TAKE ADDITIONAL STEPS TO RESPOND TO PUBLIC COMMENTS 41 (2012), http://www.gao.gov/assets/660/651052.pdf [http://perma.cc/E9ZB-VCJF].

356. *See* 5 U.S.C. § 804(2) (2012) (defining a "major rule").

357. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 355, at 41.

358. Asimow, *supra* note 347, at 719.

359. *See id.* at 724 (indicating that courts are more likely to uphold interim final rules when the rules are limited and have a brief duration).

the D.C. Circuit has held that "the limited nature of the rule cannot in itself justify a failure to follow notice and comment procedures."[360]

For emerging risks, whether the good cause exception applies would depend on the facts of the particular case. This whole area of doctrine is "exceedingly factbound."[361] In general, the courts have demanded that agencies seeking to invoke the exception demonstrate exigent circumstances.[362] It is possible that "[a] public health or safety emergency or an environmental crisis . . . potentially qualifies."[363] But the cases in which such an emergency has been held to justify the good cause exception—a spate of helicopter accidents, a threat of extinction during an ongoing hunting season, and the allocation of landing slots at Reagan National Airport—reflect a genuine urgency that the development of a new risky technology may not create.[364] The most high-profile recent case about the good cause exception, *Jifry v. FAA*,[365] involved the Federal Aviation Administration's decision to forgo notice-and-comment rulemaking for a rule allowing the agency to revoke the pilot certificates of non-resident aliens automatically upon receiving notification that the pilot posed a security risk[366]—a risk arguably more urgent than the risks addressed here.

One further complication is that, for many emerging risks, the need for quick restrictions is not potential harm from the technology itself, but the threat of entrenchment foreclosing regulatory options. It is difficult to imagine an agency arguing for a good cause exception to the notice and comment provisions on the ground that the agency's regulatory options might elapse because of changes in interest group power or social norms, at least given the strong judicial practice of institutional formalism.[367]

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360. Tenn. Gas Pipeline Co. v. FERC, 969 F.2d 1141, 1145 (D.C. Cir. 1992) (quoting Council of S. Mountains, Inc. v. Donovan, 653 F.2d 573, 582 (D.C. Cir. 1981)).

361. Adrian Vermeule, *Our Schmittian Administrative Law*, 122 HARV. L. REV. 1095, 1123 (2009).

362. *See* Asimow, *supra* note 347, at 720 (providing examples of circumstances that would implicate the good cause exception, including impracticability, public health and safety, or situations "contrary to the public interest").

363. *Id.*

364. *See id.* n.64 (listing cases regarding the good cause exception).

365. 370 F.3d 1174 (D.C. Cir. 2004).

366. *See id.* at 1179 (showing that the good cause exception can apply in this situation, in which "delay could result in serious harm" and pose a threat to TSA and FAA security).

367. *See generally* Richard H. Pildes, *Institutional Formalism and Realism in Constitutional and Public Law*, 2013 SUP. CT. REV. 1 (2013) (showing that under the institutional formalism model, courts generalize the functions of government entities and fail to take into account how the institutions work). Pildes argues, however, that judicial review of agency action under the hard look doctrine is an exception in that courts are willing to engage in a " 'realist' political-economy analysis of agency functioning." *Id.* at 22.

But when an emerging risk itself poses a risk of urgent harm to health, safety, or the environment and the moratorium would prevent that harm, it might be possible for agencies to prevail under the good cause exception. It is conceivable that such a rationale could have persuaded a court at the moment a new risky product like e-cigarettes was introduced. If fracking had had the attention of regulators before it became commercially viable, there too it is conceivable that an agency could have persuasively cited a potential risk to health or the environment. But both of these examples would more likely have come out the other way. The doctrine is too factbound to generate strong predictions, and agencies have not even attempted to use interim final rules to regulate emerging risks.

If an agency could prevail under the good cause exception, however, an interim final rule would improve on the conventional rulemaking process. If one agency successfully adopted an interim final rule to temporarily limit a new risky technology, it might establish a beachhead precedent for the regulation of emerging risks.

B. Negotiated Regulation

Negotiated regulation allows agencies to expedite rulemaking by dealing directly with the parties it was designed to benefit. It is "a consensus-based process, usually convened by an agency, through which stakeholders negotiate the substance of a rule."[368] Although agencies have engaged in negotiated rulemakings since at least the early 1980s,[369] the current practice was codified in 1990 through the Negotiated Rulemaking Act (NRA).[370]

The basic procedure is as follows. First, the agency "determine[s] that a negotiated rule making is in the public interest and [announces] the formation of a negotiating committee in the Federal Register so that members of the public may apply to participate."[371] Once convened, the "negotiating committee seeks to produce a consensus rule that will either be proposed intact by the agency in [a notice of proposed rulemaking] or form the basis of the proposed rule."[372]

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368. Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 34 (1997).

369. *See id.* at 34–35 (describing Philip Harter's work in 1982 to developed negotiated rulemaking). For an early defense of the practice, see generally Philip J. Harter, *Negotiating Regulations: A Cure for Malaise*, 71 GEO. L.J. 1 (1982).

370. 5 U.S.C. §§ 561–70 (2012). For the history of the act, see Freeman, *supra* note 368, at 36–37.

371. Freeman, *supra* note 368, at 37.

372. *Id.*

Rules promulgated through negotiated regulation "are still subject to notice and comment" even if the parties in the committee arrive at a consensus.[373] In addition, NRA provides that "[a] rule which is the product of negotiated rulemaking and is subject to judicial review shall not be accorded any greater deference by a court than a rule which is the product of other rulemaking procedures."[374]

Proponents of negotiated rulemaking argue that the process "improves rule quality, reduces transaction costs and increases legitimacy."[375] Opponents charge that it concentrates too much power in private parties and allows them to steer regulation away from the public interest.[376] They emphasize empirical evidence that negotiated rulemaking does not save time[377] and does not reduce litigation.[378]

These debates, however, are fought at the level of the practice of negotiated regulation as a whole. The empirical results that raise doubt about the efficiency gains of negotiated regulation reflect aggregate numbers. For any particular regulatory problem, negotiated rulemaking may still be sound policy.

One advantage of negotiated regulation that is relevant for emerging risks is its potential for agencies and interested parties to learn more from each other than they would under conventional rulemaking procedures. Participants in negotiated regulations frequently report that they learned from the process, particularly about the scientific and technical aspects of a proposed rule.[379]

The regulation of autonomous vehicles is a prime candidate for negotiated rulemaking. NHTSA, by its own statements and actions, is not prepared or sufficiently informed to enter the conventional notice-and-comment rulemaking process. But, as Part IV argued, there is a strong case for early regulation to forestall reverse social norm entrenchment. Fortuitously, the set of firms developing autonomous

373. *Id.*

374. 5 U.S.C. § 570.

375. Jody Freeman & Laura I. Langbein, *Regulatory Negotiation and the Legitimacy Benefit*, 9 N.Y.U. ENVTL. L.J. 60, 60 (2000).

376. *See generally* William Funk, *Bargaining Toward the New Millennium: Regulatory Negotiation and the Subversion of the Public Interest*, 46 DUKE L.J. 1351 (1997) (asserting that private parties that negotiate rules bargain to achieve their own interests, making it the parties' rule, not the public's). For a skeptical take on negotiated regulation as part of a broader critique of the developments in administrative law that have enhanced the power of private parties, see generally Susan Rose-Ackerman, *American Administrative Law Under Siege: Is Germany a Model?*, 107 HARV. L. REV. 1279 (1994).

377. *See* Cary Coglianese, *Assessing Consensus: The Promise and Performance of Negotiated Rulemaking*, 46 DUKE L.J. 1255, 1278–86 (1997) (calculating the length of a rulemaking).

378. *See id.* at 1286–309 (examining legal challenges to negotiated rules).

379. *See* Freeman & Langbein, *supra* note 375, at 88 (describing the learning outcomes of regulatory negotiation).

vehicles is small, and they are all sophisticated repeat players in the regulatory process. There is also a broad consensus about the ultimate goal of regulation: to smooth the transition to a world with dramatically fewer traffic fatalities.

The challenge, of course, is that at the present moment, Google and the automakers differ on how that transition should best be achieved. But it is possible that, with NHTSA convening, a negotiated rulemaking might lead the parties to converge on a consensus set of rules for regulating autonomous vehicles. Short of granting NHTSA the powers defended here, negotiated regulation may be the most promising option.

Other emerging risks might resemble autonomous vehicles in their suitability for negotiated regulation, especially if the parties to the rulemaking could be expected to arrive at a consensus. Nanotechnology might be one such risk. But, for most emerging risks, the politics of regulation are too contentious for negotiated rulemaking to provide a solution. For regulating those risks, agencies need the experiment and moratorium powers they currently lack.

CONCLUSION

For most of modern history, medicine was a net negative for human health. If one contracted an illness during the era of bloodletting, the wisest response may have been to avoid medical care altogether. Science knew so little about disease and how to treat it that existing treatments did more harm than good. But in the twenty-first century, although evidence-based medicine is still a work in progress and some ineffective and many not-cost-justified practices persist, basic medical science has advanced far enough that one should not think twice about seeking medical treatment.

There may be a similar story to tell about regulation. Scientific understanding of health and environmental risks has developed dramatically over the past several decades, so regulators are more likely to know what evidence is reliable, what theories are plausible, and what further tests ought to be done. It may be that, in a world in which the risk of regulatory error was high, waiting to let risks develop before acting—or cutting them off permanently at the start—was good policy. But now that we know more about how to regulate, maybe we should be more willing to experiment with regulation on the next risk.