

THE GEORGE WASHINGTON LAW REVIEW



ANNUAL REVIEW OF ADMINISTRATIVE LAW

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FOREWORD

Presidential Brokering in the Regulatory State

*Jennifer Nou**

ABSTRACT

Presidents seeking to make regulatory policy face formidable hurdles—most recently, heightened litigation risk, reduced judicial deference, and political polarization. In response, they have increasingly relied upon the Executive Office of the President (“EOP”) to manage these challenges. This Foreword spotlights the practice of presidential brokering, a structured process often led by White House policy councils such as the Domestic Policy Council and National Economic Council. Brokering involves the delegated authority to generate and test regulatory options through moderated deliberation with the rulemaking agency and other components of the EOP, ultimately shaping select rules to align with the highest presidential priorities.

This Foreword provides an institutional account of presidential brokering—distinguishing it from more commonly studied mechanisms of administrative oversight, such as regulatory review and executive orders. Through historical and contemporary examples, it illustrates how brokering promotes agency responsiveness through a form of procedural legitimacy and

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enhances rulemaking quality by leveraging diverse perspectives within the EOP. Despite its benefits, however, presidential brokering also presents transparency concerns and imposes significant decision-making costs.

The Foreword thus proposes several reforms. For presidents, they include the continued issuance of publicly available domestic policy directives as well as measures to facilitate more effective regulatory prioritization. Congress, for its part, could enhance its oversight by leveraging statutory offices within the EOP. Finally, courts should revisit the functional premises of the major questions doctrine and continue to reinforce the incentives for honest brokering through independent evaluation of a rule's legal and policy justifications.

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INTRODUCTION

Presidents seeking to make policy through the administrative state—whether regulatory or deregulatory—face daunting challenges. Regulations that seemed settled have now been reopened for litigation.¹ Once in court, agencies no longer receive judicial deference on questions of statutory interpretation.² Their efforts to explain decisions

¹ See, e.g., *Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 603 U.S. 799, 806 (2024).

² See *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024).

will be flyspecked.³ Ambitious regulatory efforts will be greeted with skepticism.⁴ Meanwhile, the political landscape remains polarized, requiring great skill to navigate the noise. All of this exists in a world of novel regulatory problems and technological uncertainty.

No wonder presidents have decided not to go it alone. For decades now, they have been building out their own bureaucracy within the Executive Office of the President (“EOP”) as a means of centralizing authority.⁵ A cursory glance at the law reviews might lead one to think that the sole manifestation of this phenomenon was the review process led by the Office of Information and Regulatory Affairs (“OIRA”), which resides in the EOP’s Office of Management and Budget (“OMB”).⁶ By executive order, agencies must submit “significant” regulatory actions to OIRA to ensure that they align with presidential priorities and cost-benefit principles.⁷ Dozens of articles by legal scholars on presidential oversight foreground OIRA’s review process—its mechanics,⁸ criteria,⁹ legality,¹⁰ and prudence.¹¹ Many social scientists too—particularly those writing in an empirical vein—focus on OIRA as the “point of the president’s spear” when it comes to administrative control.¹²

³ See, e.g., *Ohio v. EPA*, 603 U.S. 279, 294–98 (2024); *id.* at 309–19 (Barrett, J., dissenting) (arguing the majority applied stricter standards of review than in previous cases).

⁴ See *Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab.*, 595 U.S. 109, 113 (2022); *West Virginia v. EPA*, 597 U.S. 697, 706 (2022); *Biden v. Nebraska*, 600 U.S. 477, 483 (2023).

⁵ See JOHN HART, *THE PRESIDENTIAL BRANCH* 3–12 (Christopher J. Kelaher ed., 2d ed. 1995); Terry M. Moe, *The Politicized Presidency*, in *THE NEW DIRECTION IN AMERICAN POLITICS* 235, 244 (John E. Chubb & Paul E. Peterson eds., 1985) (“Because the president can count on unequaled responsiveness from his own people, increases in White House organizational competence—for example, through greater size, division of labor, specialization, hierarchic coordination, formal linkages with outside organizations and constituencies—appear to him to have direct, undiluted payoffs for the pursuit of presidential interests.”).

⁶ See Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 65 (2006) (“Scholars concentrate primarily on OIRA and less on other White House offices.”).

⁷ Exec. Order No. 12,866, 3 C.F.R. 638, 642–43 (1994), *reprinted as amended* in 5 U.S.C. § 601 note (2018).

⁸ See, e.g., Cass R. Sunstein, Commentary, *The Office of Information and Regulatory Affairs: Myths and Realities*, 126 HARV. L. REV. 1838, 1844–63 (2013).

⁹ See, e.g., Eric A. Posner, *Controlling Agencies with Cost-Benefit Analysis: A Positive Political Theory Perspective*, 68 U. CHI. L. REV. 1137, 1144–47 (2001) (discussing the role of cost-benefit analysis in agency decision-making); Jason Scott Johnston, *A Game Theoretic Analysis of Alternative Institutions for Regulatory Cost-Benefit Analysis*, 150 U. PA. L. REV. 1343, 1401–04 (2002).

¹⁰ See, e.g., Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2319–31 (2001); Lisa Heinzerling, *Statutory Interpretation in the Era of OIRA*, 33 FORDHAM URB. L.J. 1097, 1097 (2006).

¹¹ See, e.g., Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1300–04 (2006); Richard L. Revesz, *The Evolution of Regulatory Review*, 77 ADMIN. L. REV. 131, 132–34 (2025) [hereinafter Revesz, *Regulatory Review*].

¹² Alex Acs & Charles M. Cameron, *Does White House Regulatory Review Produce a Chilling Effect and “OIRA Avoidance” in the Agencies?*, 43 PRESIDENTIAL STUD. Q. 443, 444 (2013).

Although OIRA is undoubtedly important, this lopsided attention to one corner of the EOP has obscured other centralized actors within it, such as the White House policy councils. Unlike administration- and issue-specific “czars,”¹³ White House policy councils like the National Economic Council (“NEC”) and the Domestic Policy Council (“DPC”) are increasingly institutionalized features of the administrative state that merit greater scholarly scrutiny.¹⁴ Both DPC and NEC have persisted across presidencies from both parties since the Clinton Administration, with precursors dating back to President Nixon.¹⁵ Although both are technically “councils” comprising cabinet officers and other units within the EOP, in practice, senior White House officials and their staffs lead and drive their day-to-day work.¹⁶

For some of the most high-profile matters, agencies do not simply send draft rules for presidential consideration through OIRA.¹⁷ To the contrary, the President has called upon DPC and NEC to help develop

(“OIRA is the point of the president’s spear in his battle to control the content of federal regulations.”); *see also, e.g.*, Alex Acs, *Policing the Administrative State*, 80 J. POL. 1225, 1226 (2018) (“[T]he conventional wisdom [is] that OIRA has been an effective ‘cop’ of the administrative state.”); Annie Benn, *Presidential Partisanship and Regulatory Review*, 53 PRESIDENTIAL STUD. Q. 316, 318 (2023) (“[T]hrough the review process, OIRA shapes the regulations that emerge from the agencies.”); Simon F. Haeder & Susan Webb Yackee, *Presidentially Directed Policy Change: The Office of Information and Regulatory Affairs as Partisan or Moderator?*, 28 J. PUB. ADMIN. RSCH. & THEORY 475, 475 (2018) (“Presidents rarely intercede personally; instead, they rely on [OIRA] . . . to represent presidential interests during regulatory policymaking.”); Alexander Bolton, Rachel Augustine Potter & Sharece Thrower, *Organizational Capacity, Regulatory Review, and the Limits of Political Control*, 32 J.L. ECON. & ORG. 242, 242–43 (2016) (describing OIRA as one of “the political control apparatus[es] of the administrative state”).

¹³ Aaron J. Saiger, *Obama’s “Czars” for Domestic Policy and the Law of the White House Staff*, 79 FORDHAM L. REV. 2577, 2578 (2011).

¹⁴ *See* SHIRLEY ANNE WARSHAW, *THE DOMESTIC PRESIDENCY* 5 (1997) (defining an “institutional unit” within the EOP as one that “recur[s] from administration to administration, ha[s] a continual presence within White House decision making, involve[s] a staff with certain hierarchical qualities and bureaucratic functions, and whose primary responsibility [i]s consistently focused on domestic policy”); TEVI TROY, *HOW PRESIDENTS USE WHITE HOUSE POLICY COUNCILS TO MANAGE ADMINISTRATION PRIORITIES* 4–5, 8–15 (2024) (describing how “the last half century has seen the occasional creation, and even more infrequent dissolution, of White House policy councils,” though “for the most part they endure”).

¹⁵ *See infra* Section I.A.

¹⁶ *See* BRADLEY H. PATTERSON JR., *THE WHITE HOUSE STAFF* 77 (2000) (observing that it is “the top staffs of the councils—senior White House officers—who supply the leadership, scope out the questions, draft the papers, and call the meetings”).

¹⁷ *See* Bressman & Vandenbergh, *supra* note 6, at 49 (“Although OIRA exerts influence on many day-to-day issues, other White House offices often wield more influence on high-profile or high-stakes matters.”); Cary Coglianese & Daniel E. Walters, *Agenda-Setting in the Regulatory State: Theory and Evidence*, 68 ADMIN. L. REV. 93, 109 (2016) (“Some participants stressed that the White House will have much greater influence over a small number of rules that administration officials consider to be the most significant ones.”).

and drive rules *ex ante*—that is, well before they are submitted for review. Consider some examples:

- During his campaign, President Clinton promised to “end welfare as we know it.”¹⁸ In August 1996, he signed into law the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (“PRWORA”),¹⁹ which imposed stricter time limits and work requirements on welfare recipients.²⁰ Clinton subsequently gave DPC the “lead role” in welfare-reform implementation, including a rulemaking effort tightening the child disability standard for supplemental security income.²¹
- During the Obama Administration, White House policy councils sometimes started “a process to consider or promote rulemaking and to help coordinate discussions long before OIRA review” began.²² For example, President Obama had a series of “We Can’t Wait” rulemaking initiatives,²³ one of which included a Department of Health and Human Services (“HHS”) rule requiring all Head Start grantees failing to meet rigorous quality benchmarks to compete for continued federal funding.²⁴
- During the first Trump Administration, Trump’s DPC Director Joe Grogan “had little patience for agencies that fail[ed] to follow through on Trump’s deregulatory measures.”²⁵ Grogan worked alongside NEC to help advance an HHS rule aimed at broadening healthcare options for small businesses.²⁶

¹⁸ Jasmin Sethi, *Lessons for Social Scientists and Politicians: An Analysis of Welfare Reform*, 17 GEO. J. ON POVERTY L. & POL’Y 5, 16, 26 (2010) (quoting Bill Clinton, Governor, Ark., Acceptance Speech at 1992 Democratic National Convention, at 56:20 (July 16, 1992), <https://www.c-span.org/program/historic-convention-speeches/governor-bill-clinton-acceptance-speech-at-1992-democratic-national-convention/146779> [https://perma.cc/SWB9-5TK6]).

¹⁹ Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, 110 Stat. 2105.

²⁰ See *id.* sec. 103, § 407, 110 Stat. at 2129–34 (codified as amended at 42 U.S.C. § 607).

²¹ Letter from Carol H. Rasco, Assistant to the President for Domestic Pol’y, to Leon Panetta, White House Chief of Staff, & Erskine Bowles, White House Deputy Chief of Staff for Operations (Nov. 25, 1996) (on file with author).

²² Sunstein, *supra* note 8, at 1849.

²³ *Id.* at 1849 n.47.

²⁴ See Press Release, Off. of the Press Sec’y, The White House, We Can’t Wait: President Obama Takes Action to Improve Quality and Promote Accountability in Head Start Programs (Nov. 8, 2011), <https://obamawhitehouse.archives.gov/the-press-office/2011/11/08/we-cant-wait-president-obama-takes-action-improve-quality-and-promote-ac> [https://perma.cc/369B-YWKY].

²⁵ Elaina Plott Calabro & Peter Nicholas, *How a Forgotten White House Team Gained Power in the Trump Era*, ATLANTIC (June 27, 2019), <https://www.theatlantic.com/politics/archive/2019/06/trump-domestic-policy-council/592516/> [https://perma.cc/H64F-9KJG].

²⁶ See *id.*

The rule introduced a mechanism whereby employers could provide tax-exempt funds, known as health-reimbursement arrangements, enabling employees to purchase insurance on the individual market rather than relying on traditional company plans.²⁷

In this manner, presidents have turned to White House policy councils to advance their highest regulatory and deregulatory priorities. More recently, the second Trump Administration has explicitly called upon independent regulatory agency chairs to “regularly consult with and coordinate policies and priorities with” DPC and NEC, alongside OMB.²⁸

The importance of this subset of rules—those that have been instigated and actively shaped by White House policy councils—has been heightened by the emergence of the major questions doctrine. Formulations vary, but the basic idea of the doctrine is that courts will “expect Congress to speak clearly” when it assigns agencies matters of “economic” or “political” significance.²⁹ Regulations subject to the major questions doctrine in recent years have been central to presidential regulatory agendas,³⁰ including a COVID-19 vaccination and testing mandate for workers at large employers³¹ and a rule addressing carbon dioxide emissions from existing natural-gas- and coal-fired power plants.³² Despite being issued by the Department of Labor and Environmental Protection Agency, respectively, these regulations involved the active participation of the White House.³³

One of the functional premises of the major questions doctrine—particularly when justified as a canon of avoidance—is that Congress possesses superior deliberative lawmaking procedures.³⁴ In this view,

²⁷ See *id.*

²⁸ Exec. Order No. 14,215, 90 Fed. Reg. 10,447, 10,448 (Feb. 18, 2025).

²⁹ *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (“We expect Congress to speak clearly if it wishes to assign to an agency decisions of vast ‘economic and political significance.’” (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000))).

³⁰ See Jodi L. Short & Jed H. Shugerman, *Major Questions About Presidentialism: Untangling the “Chain of Dependence” Across Administrative Law*, 65 B.C. L. REV. 511, 514 (2024) (“The doomed [major questions doctrine] policies were promulgated by agencies linked to presidents with formal supervisory power who directed, actively supported, and took public responsibility for those agencies’ key policy decisions.”).

³¹ See *Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab.*, 595 U.S. 109, 115, 117 (2022).

³² See *West Virginia v. EPA*, 597 U.S. 697, 711–15, 724 (2022).

³³ See Jody Freeman, *The Environmental Protection Agency’s Role in U.S. Climate Policy—A Fifty Year Appraisal*, 31 DUKE ENV’T L. & POL’Y F. 1, 61 (2020) (describing how White House officials “Podesta, McDonough, and Deese” provided “crucial support for McCarthy and her agency as EPA delivered major climate rules,” including the Clean Power Plan); Short & Shugerman, *supra* note 30, at 540–48 (discussing presidential involvement in the Clean Power Plan and the Occupational Safety and Health Administration’s emergency temporary workplace-safety standard).

³⁴ See *Nat’l Fed’n of Indep. Bus.*, 595 U.S. at 124 (Gorsuch, J., concurring) (“[T]he major questions doctrine is closely related to what is sometimes called the nondelegation doctrine.”);

bicameralism and presentment result in policy choices that are well debated and more democratically legitimate than those made by the President. To evaluate this claim of comparative competence, however, it is critical to appreciate the increasingly institutionalized structures and processes within the presidency to formulate what are likely to be designated as “politically” significant major rules.

This Foreword refers to such dynamics as *presidential brokering*, seeks to explain why this distinct method of agency influence has developed, and normatively evaluates the practice. In the rulemaking context, presidential brokering consists of the delegated authority to generate regulatory options from different perspectives throughout the executive branch; to test the arguments through actively moderated deliberation; and then to elevate decisions up the presidential hierarchy as necessary. When it comes to domestic regulatory policy,³⁵ these delegations often, though not always,³⁶ run to DPC and NEC. Brokering, in turn, can vary in its level of formality. The most formal version involves the use of standardized decision-making memoranda and works through a hierarchy of committees, from lower-level interagency policy committees to those at the level of deputies and then principals. The more informal—and far more common—version uses working groups consisting of personnel from agencies and various units of the EOP, led and managed by White House policy-council staff.

After persisting for years through norms and internal documents,³⁷ the brokering process was publicly memorialized for the first time by the Biden Administration in a formal directive identifying DPC as the “principal forum” for advising and assisting the President in domestic policy development.³⁸ Mirroring counterparts in the national security

Blake Emerson, *Administrative Answers to Major Questions: On the Democratic Legitimacy of Agency Statutory Interpretation*, 102 MINN. L. REV. 2019, 2048 (2018) (“Interpreted in its best light, the [major questions] doctrine aims to protect and to strengthen the connection between the people and governmental action by presuming that a popular and deliberative process settles major questions of policy.”); *Gundy v. United States*, 588 U.S. 128, 154 (2019) (Gorsuch, J., dissenting) (“Article I’s detailed processes for new laws were also designed to promote deliberation.”).

³⁵ The category of domestic policy may best be thought of as the “residual” of other more defined arenas such as national security or economic policy. Karen M. Hult & Charles E. Walcott, *Domestic Policy Development in the White House*, in GOVERNING AT HOME 84, 84 (Michael Nelson & Russell L. Riley eds., 2011). Representative issues include those relating to the environment, health, food, labor, and crime. *See id.* at 92–101. But, of course, the borders between domestic, economic, and national security can be porous, sometimes resulting in intra-White House turf wars. *See id.*

³⁶ President Obama, for example, turned to the Office of Science and Technology Policy (“OSTP”) and the Council on Environmental Quality (“CEQ”) to coordinate national ocean policy. *See* Exec. Order No. 13,547, 3 C.F.R. 227, 229 (2011). Specifically, OSTP and CEQ were to lead a National Ocean Council charged with promoting “stewardship of the ocean, our coasts, and the Great Lakes” to be “healthy[,] . . . resilient, safe[,] and productive.” *Id.* at 227.

³⁷ *See infra* notes 214–28 and accompanying text.

³⁸ Memorandum from President Joseph R. Biden to Cabinet Sec’y’s et al. (May 6, 2021) [hereinafter Domestic Policy Presidential Directive], <https://bidenwhitehouse.archives.gov/>

realm,³⁹ the document's stated purpose was to ensure that domestic policy implemented by agencies was "developed and coordinated through a systematic, evidence-driven process" designed to "ensure that all major priorities are addressed, the views of all relevant agencies are considered, [and] appropriate options are analyzed."⁴⁰ In other words, the directive called for DPC to lead a process that incorporated the views of a range of intra-executive branch actors in order to identify policy options and priorities.

Importantly, that process involves not only the rulemaking agency but also a number of structurally distinct entities within the EOP, such as OMB, the Council of Economic Advisors ("CEA"), and the Office of Science and Technology Policy ("OSTP").⁴¹ These entities have generally been established by statute rather than executive action, are charged with congressionally mandated duties and responsibilities, feature heads that require Senate confirmation, and contain career staff that persist through administrations.⁴² As a result, these statutory units are more structurally independent, as compared with the White House, from the personal interests of the President.⁴³ By and large, Congress created them to serve the office of the President, rather than its occupant.⁴⁴ They were designed, in other words, to provide for what Congress, at the time of their creation, perceived as the longer-run interests of the presidency.

This is not to say, of course, that the practice of presidential brokering is always followed. The previous Trump Administration, for example, featured many counterexamples⁴⁵ despite concerted efforts to reestablish the process,⁴⁶ which may help explain why its deregulatory agenda suffered so many losses in court.⁴⁷ Indeed, there are strong

briefing-room/presidential-actions/2021/05/06/domestic-policy-presidential-directive-1-dppd-1/
[<https://perma.cc/TN5U-FDVC>].

³⁹ See, e.g., Memorandum from President George H.W. Bush to Vice President Dan Quayle et al. (Jan. 30, 1989), <https://bush41library.tamu.edu/files/nsd/nsd1.pdf> [<https://perma.cc/H9LQ-RLRY>].

⁴⁰ Domestic Policy Presidential Directive, *supra* note 38.

⁴¹ See *id.*; see also *infra* Section I.B.

⁴² See *infra* Section I.B.

⁴³ See *infra* notes 122–23 and accompanying text.

⁴⁴ See Daphna Renan, *The President's Two Bodies*, 120 COLUM. L. REV. 1119, 1151–52, 1211 (2020).

⁴⁵ See Karen M. Hult, *Assessing the Trump White House*, 51 PRESIDENTIAL STUD. Q. 35, 44 (2021) ("To the extent a standard model for guiding presidential decision making has existed in past presidencies, it appeared to be conspicuously absent under Donald Trump." (citation omitted)).

⁴⁶ See *infra* notes 223–26 and accompanying text.

⁴⁷ By one measure, agencies during the Trump Administration had a seventy-eight percent loss rate in litigation—losing 192 out of 246 challenges to the agencies' efforts to implement policy. *Roundup: Trump-Era Agency Policy in the Courts*, INST. FOR POL'Y INTEGRITY (Apr. 25, 2022), <https://policyintegrity.org/trump-court-roundup> [<https://perma.cc/W7C4-93JE>].

indications that the practice is not being followed in Trump's second term as well,⁴⁸ but much remains to be seen, especially with a Chief of Staff who professes to prize decision-making discipline.⁴⁹ In the meantime, this Foreword highlights some of the consequences for presidents departing from these established practices. It also considers some exogenous reforms that could help encourage brokering despite an individual president's instincts to the contrary.

Appreciating the dynamics of presidential brokering can also enrich empirical work on administrative control. Some of the literature, for example, posits that presidents use OIRA-coordinated review as a means of partisan control.⁵⁰ Puzzlingly, however, some scholars find that "ideological misalignment between the president and promulgating agencies does not affect review outcomes."⁵¹ Perhaps one partial explanation has been the role of policy councils in influencing administrative agencies *ex ante*—that is, before the rules are submitted for review. If DPC or NEC has achieved a great deal of alignment before the review process begins, then some of the findings to date may be less surprising or at least in need of further refinement. Other empirical efforts focus solely on the "unilateral" issuance of executive orders as evidence of presidential control.⁵² Brokering, however, occurs independently of those orders, thus potentially understating the true magnitude of presidential influence. Finally, although the policymaking process has been studied in depth for legislative proposals⁵³ and executive orders,⁵⁴ focusing specifically on rulemaking is valuable because of the unique challenges of that process as well as the implications for OIRA and judicial review.

⁴⁸ See, e.g., Jonathan Swan & Maggie Haberman, *Inside Trump's Hastily Written Proposal to 'Own' Gaza*, N.Y. TIMES (Feb. 5, 2025), <https://www.nytimes.com/2025/02/05/us/politics/trump-gaza-takeover.html> [<https://perma.cc/HNP7-NXJJ>] ("Inside the U.S. government, there had been no meetings with the State Department or Pentagon, as would normally occur for any serious foreign policy proposal, let alone one of such magnitude. There had been no working groups. The Defense Department had produced no estimates of the troop numbers required, or cost estimates, or even an outline of how it might work.").

⁴⁹ See Rachael Bade, Kara Tabor, Renee Klahr & Krystal Campos, *'The Oracle,' 'the Ice Maiden' and the New Discipline of Trump's White House*, POLITICO (Mar. 22, 2025, 2:00 PM), <https://www.politico.com/news/magazine/2025/03/22/trump-white-house-james-blair-economy-judges-00242434> [<https://perma.cc/37GB-C9QA>].

⁵⁰ See, e.g., sources cited *supra* note 12.

⁵¹ Benn, *supra* note 12, at 316; see also Haeder & Yackee, *supra* note 12, at 484 (finding that ideological extremity in promulgating agencies does not affect review outcomes).

⁵² See, e.g., Kenneth R. Mayer & Kevin Price, *Unilateral Presidential Powers: Significant Executive Orders, 1949–99*, 32 PRESIDENTIAL STUD. Q. 367, 368–70 (2002).

⁵³ See, e.g., ANDREW RUDALEVIGE, *MANAGING THE PRESIDENT'S PROGRAM* (Ira Katznelson et al. eds., 2002).

⁵⁴ See, e.g., ANDREW RUDALEVIGE, *BY EXECUTIVE ORDER* (2021).

Part I begins by placing White House policy councils within the larger institutional context of the EOP. This historical background highlights the structural differences between the White House and other components of the EOP designed by Congress to serve the office of the presidency rather than the individuals within it. This framing seeks to explain why presidents have turned to policy councils rather than alternatives such as OIRA to help advance their highest priority rules. Because such councils are led by White House advisors that do not require Senate confirmation, possess no programmatic duties beyond serving the President, and lack career staff, they are more likely to be responsive to the President's political agenda. Of course, in reality, individual personalities and reputations are relevant as well, but focusing primarily on these structural characteristics can help generate testable hypotheses about how the presidency operates as an institution. More broadly, the discussion seeks to help open the black box of the presidency,⁵⁵ akin to analogous efforts to explore the internal dynamics of traditional administrative agencies.⁵⁶

Against this backdrop, Part II then turns to the development of brokering to implement the President's agenda, given the limits of other better-studied mechanisms of agency control. Strategic appointments suffer from familiar principal-agent problems due to the need for Senate confirmation, narrow statutory missions, and the potential for capture by career staff.⁵⁷ Removals of recalcitrant personnel, in turn, can be politically

⁵⁵ There is a great deal of insightful work on the institutional presidency in political science, but much of it requires updating. See, e.g., PERI E. ARNOLD, *MAKING THE MANAGERIAL PRESIDENCY* (2d ed., rev. 1998); JOHN P. BURKE, *THE INSTITUTIONAL PRESIDENCY* (Michael Nelson ed., 2d ed. 2000); MATTHEW J. DICKINSON, *BITTER HARVEST* (1996); HART, *supra* note 5; STEPHEN HESS & JAMES P. PFIFFNER, *ORGANIZING THE PRESIDENCY* (4th ed. 2020); JOHN H. KESSEL, *THE DOMESTIC PRESIDENCY* (Katharine G. Tsoulcas ed., 1975); WARSHAW, *supra* note 14; GOVERNING AT HOME, *supra* note 35. The legal literature is comparatively sparser, though similar themes can be found in work sensitive to the institutional aspects of the presidency. See, e.g., ADAM B. COX & CRISTINA M. RODRÍGUEZ, *THE PRESIDENT AND IMMIGRATION LAW* (2020); Catherine Crump, *Reforming Policing from the White House: The Challenges of Implementing Police Reform Through Executive Order*, in *RESEARCH HANDBOOK ON PENAL POLICY* (Alessandro Corda ed., forthcoming 2025) (on file with author); Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1197–1203 (2012) (recognizing that regulatory coordination can also occur through “White House policy offices, councils, and special advisors” and considering some of the tradeoffs with OIRA, which the authors argue is more “reactive” in nature and focused on “economic efficiency”).

⁵⁶ See, e.g., Rachel E. Barkow, Foreword, *Overseeing Agency Enforcement*, 84 GEO. WASH. L. REV. 1129, 1137 (2016); Elizabeth Magill & Adrian Vermeule, *Allocating Power Within Agencies*, 120 YALE L.J. 1032, 1035 (2011) (analyzing power allocation within agencies); Gillian E. Metzger & Kevin M. Stack, *Internal Administrative Law*, 115 MICH. L. REV. 1239, 1248 (2017) (discussing internal operations of agencies); Jon D. Michaels, *Of Constitutional Custodians and Regulatory Rivals: An Account of the Old and New Separation of Powers*, 91 N.Y.U. L. REV. 227, 229 (2016) (discussing divisions of authority within administrations).

⁵⁷ See *infra* notes 170–77 and accompanying text.

costly.⁵⁸ Executive orders, for their part, are not self-executing; indeed, empirical research reveals that agency compliance with them is uneven.⁵⁹ Finally, OIRA-coordinated regulatory review is more reactive than proactive. Generally speaking, the process does not begin until the agency has already completed substantial drafting of the rule.⁶⁰ Presidents have thus developed policy councils to spur agency rulemakings through the brokering process.⁶¹ This Part will illustrate some of these dynamics with an extended case study involving a welfare-reform-related rulemaking during the Clinton Administration.

Part III then turns to a more normative evaluation of presidential brokering by White House policy councils in the rulemaking context. It concludes that the phenomenon has both strengths and weaknesses. One salutary aspect for those who believe presidential oversight provides a measure of accountability is that presidential brokering likely increases agency responsiveness as compared with ad hoc “jawboning.”⁶² This is especially likely when the process is perceived as “honest”—that is, reflecting a sincere effort to identify options from multiple vantage points in ways that build trust and legitimize intra-executive branch decision-making.⁶³ Brokering also improves the quality and effectiveness of regulatory policymaking by drawing upon the expertise of not only the rulemaking agency but also the statutory components of the EOP. Many of these components, such as the CEA, are headed by subject-matter experts drawn from academia or elsewhere who are themselves aided by experienced career staff. Relatedly, presidential brokering also serves a debiasing function. By exposing the political instincts of the White House to competing perspectives, the deliberative process can reduce the White House’s proclivities toward groupthink and other familiar cognitive biases. In this manner, presidential brokering

⁵⁸ See *infra* notes 174–75 and accompanying text.

⁵⁹ See *infra* notes 183–94 and accompanying text.

⁶⁰ See *infra* notes 207–13 and accompanying text.

⁶¹ See Sunstein, *supra* note 8, at 1849–50 (“While OIRA has written formal ‘prompt letters,’ designed to promote agency action, such ‘prompting’ is far more likely to occur informally and from other offices, which have a particular responsibility to explore desirable policy initiatives.” (footnote omitted)); CHRISTOPHER P. LIDDELL, *YEAR ZERO* 142 (Guian A. McKee & Marc J. Selverstone eds., 2024) (describing “policy councils” as “the integrating force in the White House” with “elaborate structures and procedures for integrating the diverse units in the organization”).

⁶² See, e.g., Paul R. Verkuil, *Jawboning Administrative Agencies: Ex Parte Contacts by the White House*, 80 COLUM. L. REV. 943, 943 (1980) (describing discussions that “pit[] White House advisors . . . against agency officials” as “a variation . . . of presidential ‘jawboning’”); Richard J. Pierce, Jr., *Saving the Unitary Executive from Those Who Would Distort and Abuse It: A Review of The Unitary Executive by Steven G. Calabresi and Christopher S. Yoo*, 12 U. PA. J. CONST. L. 593, 600 (2010) (book review) (discussing “[l]argely invisible ad hoc White House jawboning”).

⁶³ See *infra* notes 216–18 and accompanying text.

can further administrative law values such as political accountability and effectiveness.⁶⁴

On the other side of the ledger, however, are a number of features that weaken these values. Perhaps most importantly, these presidential brokering dynamics are largely shielded from public and congressional scrutiny. This lack of transparency stymies monitoring and increases the risk of capture. In addition, the potential for principal-agent problems between the President and the policy councils persists. Policy councils are often staffed by individuals who have worked for interest groups, which may exert outside influence as a result. Second, the broad scope of policy-council responsibilities necessarily results in information asymmetries that cannot be completely redressed through elevation. Finally, presidential brokering also raises concerns about the efficiency of the process. The decision costs of the practice are extremely high. These decision costs, in turn, are exacerbated by the overlapping jurisdictions between DPC and NEC, as well as other components of the EOP.⁶⁵

Part III accordingly offers some suggestions for reform. They include the continued issuance of publicly available domestic policy directives to facilitate transparency and management, as well as measures to facilitate more effective regulatory prioritization, public participation, and coordination with OIRA. Exogenous actors such as Congress and the courts could also bolster the incentives for honest brokering: Congress could leverage statutory offices within the EOP to provide fire-alarm oversight.⁶⁶ Courts, in turn, could revisit some of the functional premises of the major questions doctrine and continue to reinforce the incentives of honest brokering through independent evaluation of a rule's legal and policy justifications.⁶⁷

I. PRESIDENTIAL BUREAUCRACY

Astute observers of the Oval Office have long recognized that presidents have centralized power by drawing authority closer to them through the institutions of the presidency.⁶⁸ Since 1939, those institutions have resided within the EOP.⁶⁹ From its origins, the EOP has exhibited important internal structural variations, emerging from contestations between the President and Congress over the structure of the presidency. These design choices have resulted in various units within the White

⁶⁴ See *infra* Section III.A.1.

⁶⁵ See *infra* Section III.A.2.

⁶⁶ See *infra* Section III.B.2.

⁶⁷ See *infra* Section III.B.3.

⁶⁸ See sources cited *supra* note 55.

⁶⁹ See ARNOLD, *supra* note 55, at 114.

House Office that are less insulated from the President relative to other EOP entities such as OMB and OIRA. Centralization, in this manner, is a matter of degree.⁷⁰ This Part surveys the main structural cleavages for those actors within the EOP most frequently involved in regulatory policymaking and the diverging organizational incentives that result.

A. White House Policy Councils

The origins of the EOP can be traced to President Franklin Roosevelt's New Deal aspirations, which put unprecedented pressures on the presidency. "Overlap and redundancy ran through" the jurisdictions of the new agencies he had helped to create.⁷¹ Conditions were thus ripe for the management ideas of public administration scholars like Louis Brownlow and the so-called "Brownlow Committee."⁷² The Committee was charged with devising recommendations regarding the "managerial and administrative relationship of the President to all the farflung . . . agencies."⁷³ One of the Brownlow Committee's most durable recommendations was the creation of the EOP.⁷⁴ The EOP's task would be to aid the President in quickly obtaining information from agencies and to "guide him in making his responsible decisions."⁷⁵ This dedicated institution would provide the Chief Executive with both the staff and resources to discharge his constitutional duties.⁷⁶

President Roosevelt swiftly put the Committee's ideas into action by issuing an executive order pursuant to reorganization plans approved by Congress.⁷⁷ The order provided, among other things, for the creation

⁷⁰ See, e.g., RUDALEVIGE, *supra* note 54, at 216–17 (adopting the "usual distinction between the 'bureaucracy' and the 'White House'" but recognizing that "internal divergences" are also important "as the size of the EOP grows and fragmentation rises"); Peter L. Strauss, Foreword, *Overseer, or "The Decider"? The President in Administrative Law*, 75 GEO. WASH. L. REV. 696, 753–54 (2007) ("We can also have no illusions that the decision will be made by 'the' President . . . It will, rather, be made within an apparatus of a few thousand White House employees . . ."); Bressman & Vandenberg, *supra* note 6, at 65–67 (exploring whether "non-OIRA White House offices wield more influence in a given case or across the board"); Sunstein, *supra* note 8, at 1840 (noting that "while the President is ultimately in charge, the White House itself is a 'they,' not an 'it'"); Anya Bernstein & Cristina Rodríguez, *The Diffuse Executive*, 92 FORDHAM L. REV. 363, 367 (2023) ("[E]ven centralized power over agency action can come not from the President individually but from the complex EOP bureaucracy.").

⁷¹ ARNOLD, *supra* note 55, at 89.

⁷² See *id.* at 91, 95.

⁷³ *Id.* at 93 (alteration in original) (quoting Memorandum from Louis Brownlow to President Franklin Roosevelt (Feb. 1936), in LOUIS BROWNLOW, *A PASSION FOR ANONYMITY* 333, 334 (1958)).

⁷⁴ See *id.* at 104, 114.

⁷⁵ See Michael Nelson, *Domestic Policy, Domestic Policy Advisers, and the American Presidency*, in GOVERNING AT HOME, *supra* note 35, at 1, 2.

⁷⁶ See *id.*

⁷⁷ See Exec. Order No. 8248, 3 C.F.R. 217 (1939); Reorganization Plan No. I, 3 C.F.R. 248 (1939), *reprinted as amended* in 5 U.S.C. app. at 609 (2018); Reorganization Plan No. II, 3 C.F.R. 254 (1939), *reprinted as amended* in 5 U.S.C. app. at 616 (2018).

of a new White House Office within the EOP.⁷⁸ The office would comprise six assistants who would “work directly and anonymously” to get “information when needed by the President in making decisions” and ensuring those decisions were “promptly communicated to those who are involved.”⁷⁹ These assistants would be handpicked by the President, their effectiveness a function of their work behind the scenes.⁸⁰ In this manner, a core function of the White House staff would be to gain the information necessary to facilitate presidential decision-making.

With six new presidential assistants, the White House full-time staff during the Roosevelt Administration would now number about forty-three.⁸¹ In subsequent administrations, this number would skyrocket from about fifty-eight in 1944 to 560 in 1974,⁸² eventually settling into numbers closer to 400 in subsequent years.⁸³ One explanation for this growth has been the increasing need for interagency management given the decline of the cabinet as a “coordinating mechanism.”⁸⁴ Cabinet meetings would ultimately prove inefficient and frustrating to many presidents due to the slow pace of policy development within agencies, the perceived lack of creativity, and the necessarily narrow perspectives that jurisdictionally bound agencies could offer.⁸⁵

To aid in this management task, President Nixon was the first to create a White House-centered unit squarely focused on domestic policy within the EOP.⁸⁶ This decision was reached upon the recommendation

⁷⁸ See Exec. Order No. 8248, 3 C.F.R. at 217.

⁷⁹ Summary of the Report of the Committee on Administrative Management, 5 PUB. PAPERS 674, 677 (Jan. 12, 1937).

⁸⁰ See THE PRESIDENT'S COMM. ON ADMIN. MGMT., REPORT OF THE PRESIDENT'S COMMITTEE: ADMINISTRATIVE MANAGEMENT IN THE GOVERNMENT OF THE UNITED STATES 19 (1937) [hereinafter BROWNLOW REPORT] (“Their effectiveness in assisting the President will, we think, be directly proportional to their ability to discharge their functions with restraint. They would remain in the background, issue no orders, make no decisions, emit no public statements.”).

⁸¹ HART, *supra* note 5, at 112.

⁸² *Id.*

⁸³ See Nelson, *supra* note 75, at 2; Charles E. Walcott & Karen M. Hult, *White House Staff Size: Explanations and Implications*, 29 PRESIDENTIAL STUD. Q. 638, 643 (1999).

⁸⁴ HART, *supra* note 5, at 125 (“Many attempts to explain the development of the White House staff emphasize its role as a coordinator of executive branch activity, a role assumed as a direct result of the weakness of the Cabinet as a coordinating mechanism.”); see also CONG. RSCH. SERV., RL30673, THE PRESIDENT'S CABINET: EVOLUTION, ALTERNATIVES, AND PROPOSALS FOR CHANGE 9 (2000) (“In the 20th century, the Cabinet has experienced a not-so-gradual decline in its political and administrative relevance to the President.”).

⁸⁵ See CONG. RSCH. SERV., *supra* note 84, at 10–13; Lester M. Salamon, *The Presidency and Domestic Policy Formulation*, in THE ILLUSION OF PRESIDENTIAL GOVERNMENT 177, 181 (Hugh Heclo & Lester M. Salamon eds., 1981).

⁸⁶ See Nelson, *supra* note 75, at 4 (“Starting with Nixon, every president has centered domestic policymaking not in the cabinet departments or in Johnson-style outside task forces, but rather in one or more White House staff units.”); Raymond J. Waldmann, *The Domestic Council: Innovation in Presidential Government*, 36 PUB. ADMIN. REV. 260, 261 (1976) (noting that “the Nixon

of Nixon's own Advisory Council on Executive Management headed by Roy Ash.⁸⁷ In 1970, after receiving approval for his reorganization plan, Nixon issued Executive Order 11,541.⁸⁸ That order formalized the Domestic Council, which was charged with gathering information for "defining national domestic goals," developing "alternative proposals for reaching those goals," and providing "policy advice to the President on domestic issues."⁸⁹ The Domestic Council was to be headed by an executive director with the formal title of Special Presidential Assistant for Domestic Policy.⁹⁰ The cabinet-level Domestic Council was composed of the President, Vice President, Attorney General, and a subset of the cabinet, but it would be driven and staffed by the White House.⁹¹

Every President since has followed Nixon's cue to centralize domestic policymaking, albeit with different naming conventions.⁹² Even those who professed a desire to return to a cabinet-led approach eventually returned the locus of policymaking back to the White House.⁹³ One particularly noteworthy development came with President Clinton, who decided to place White House staff directly onto the freshly renamed

Administration [was] the first to institutionalize and define the relationships" within the White House for policy planning).

⁸⁷ See Edwin L. Harper, *Domestic Policy Making in the Nixon Administration: An Evolving Process*, 26 PRESIDENTIAL STUD. Q. 41, 44 (1996). The Ash Council had been charged with studying ways to improve management in the executive branch. See *id.*

⁸⁸ Exec. Order No. 11,541, 3 C.F.R. 141 (1971); see Reorganization Plan No. 2 of 1970, 3 C.F.R. 197 (1971), reprinted as amended in 5 U.S.C. app. at 720 (2018).

⁸⁹ Exec. Order No. 11,541, 3 C.F.R. at 141.

⁹⁰ See Salamon, *supra* note 85, at 182.

⁹¹ See Reorganization Plan No. 2 of 1970, 3 C.F.R. at 198. Domestic Council members included the President; Vice President; Attorney General; Secretary of Agriculture; Secretary of Commerce; Secretary of Health, Education, and Welfare; Secretary of Housing and Urban Development; Secretary of the Interior; Secretary of Labor; Secretary of Transportation; and Secretary of the Treasury. *Id.* The Reorganization Plan also contained catchall language providing that the Domestic Council could also include "such other officers of the Executive Branch as the President may from time to time direct." *Id.*

⁹² President Jimmy Carter, for example, ran on a promise to "devolve domestic policymaking" from the White House back to the cabinet, leading him to abolish the Domestic Council and rename it the Domestic Policy Staff ("DPS") to emphasize that the role would be to staff the cabinet rather than serve as a thought leader. Nelson, *supra* note 75, at 13. However, Carter's disillusionment with his cabinet heads—resulting in his asking for the resignation of his entire cabinet and accepting five midway through his presidency—led to a resurgence of staffing in DPS toward the end of his Administration. See Robert A. Strong, *Recapturing Leadership: The Carter Administration and the Crisis of Confidence*, 16 PRESIDENTIAL STUD. Q. 636, 647 (1986). As a result, Carter's "initial plans and intentions were diluted or abandoned," and Nixon's Domestic Council essentially survived reorganization and emerged with a new name but basically the same functions. See Nelson, *supra* note 75, at 13–14. The institutionalization of centralized policymaking continued.

⁹³ See, e.g., WARSHAW, *supra* note 14, at 125, 135 (detailing the Reagan Administration's original goal of "keeping the cabinet officers within the presidential orbit" through the creation of cabinet councils, which were later "redesigned" to "gain control of the policy apparatus within the White House" and "reduce[] the access points for the cabinet into the White House and to the president").

DPC, making it even clearer that domestic policy would be centrally managed.⁹⁴ As in previous iterations, its role would be not only to formulate policy but also to work on its implementation, whether through legislative proposals, executive orders, public speeches, or administrative actions such as rules or grants.⁹⁵ Under Clinton, the number of DPC staff grew to about thirty.⁹⁶ In addition, Clinton created NEC to similarly concentrate economic policymaking in the White House.⁹⁷ NEC under Clinton also had about thirty staff members.⁹⁸ Given the intersection of domestic policy and economic issues, NEC often works closely with DPC and can sometimes have overlapping portfolios as a result.⁹⁹

DPC and NEC also work with a number of other actors in the White House to advance policy. Presidents sometimes create more ephemeral policy councils, often only lasting a year or two. President Nixon, for example, created a Council for Urban Affairs that only lasted from 1969 to 1970.¹⁰⁰ Presidents also sometimes establish single policy “czars” to coordinate specific issues. Take, for example, President George W. Bush’s Director of the Office of Faith-Based and Community Initiatives,¹⁰¹ or President Obama’s Director of the Office of Health Reform,¹⁰² mainly charged with implementation of the Affordable Care Act.¹⁰³ These roles, however, are often repealed relatively quickly or simply eliminated in subsequent administrations.¹⁰⁴

On legal matters, DPC and NEC also work closely with the White House Counsel, who generally serves as the President’s in-house lawyer.¹⁰⁵ The role of the White House Counsel historically grew out

⁹⁴ See *id.* at 161 (“[President] Clinton became the first president to significantly change the composition of the cabinet council by adding a host of White House staff to the membership in 1993.”).

⁹⁵ See GEORGE E. SHAMBAUGH IV & PAUL J. WEINSTEIN JR., *THE ART OF POLICYMAKING* 59 (3d ed. 2024) (noting that policy implementation can occur through “presidential directive[,] . . . legislation, regulatory change, or simply the use of the presidential bully pulpit”).

⁹⁶ See *id.* at 31–32 (reporting that DPC “grew to around 30 staffers under President Clinton”).

⁹⁷ See Exec. Order No. 12,835, 3 C.F.R. 586 (1994).

⁹⁸ See SHAMBAUGH & WEINSTEIN, *supra* note 95, at 30 (“Under Clinton, the [NEC] staff size was roughly thirty individuals . . .”).

⁹⁹ See HART, *supra* note 5, at 66–67; SHAMBAUGH & WEINSTEIN, *supra* note 95, at 32 (discussing how during Clinton’s second term, DPC “gained control over several issues given to the NEC”).

¹⁰⁰ See Exec. Order No. 11,452, 3 C.F.R. 102 (1970). For a catalog of these entities over time, see HAROLD C. RELYEA, CONG. RSCH. SERV., 98-606 GOV, *THE EXECUTIVE OFFICE OF THE PRESIDENT: AN HISTORICAL OVERVIEW* 25–28 (2008).

¹⁰¹ See Exec. Order No. 13,199, 3 C.F.R. 752 (2002).

¹⁰² See Exec. Order No. 13,507, 3 C.F.R. 233 (2010).

¹⁰³ Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended in scattered sections of 25 U.S.C., 26 U.S.C., 29 U.S.C., 42 U.S.C.); See Exec. Order No. 13,507, 3 C.F.R. at 233.

¹⁰⁴ See, e.g., Exec. Order No. 13,569, 3 C.F.R. 232 (2012) (revoking Executive Order 13,507).

¹⁰⁵ See PATTERSON, *supra* note 16, at 96–97, 112; cf. Crump, *supra* note 55 (manuscript at 14–15) (discussing the ways in which DPC and the White House Counsel’s Office can conflict and engage in turf battles).

of the sense that the President's existing sources of legal advice at the Department of Justice ("DOJ") were untimely and ultimately too divorced from the President's immediate needs.¹⁰⁶ The Roosevelt Administration initially created an Assistant Solicitor General position within DOJ to focus on presidential legal advice—a position that would be renamed the Office of Legal Counsel ("OLC") two decades later.¹⁰⁷ Over the years, however, OLC would develop norms and practices that resulted in the office adopting a "best view" of the law independent of the desires of the President.¹⁰⁸ As a result, presidents have increasingly come to rely on White House Counsels for legal advice on signature regulatory agenda items.¹⁰⁹

B. *The Impersonal Presidency*

White House policy councils also work with a number of other structurally distinct entities within the EOP. If the role of the White House Office was to pursue the President's personal interests at the top of the hierarchy,¹¹⁰ the Brownlow Committee also recognized the need for a more enduring and impersonal arm of the presidency.¹¹¹ This part of the EOP would pertain to the office of the President rather than its transient occupant.¹¹² Core to the Brownlow vision was a revitalized Bureau of the Budget housed in the EOP that would focus on managerial and budgetary needs.¹¹³ Congress had initially created the Bureau within the Department of Treasury in 1921 to compile, review, and send agency budgetary requests to Congress.¹¹⁴ Its "impartial" and "expert" ethos, however, would clash decades later with a President resolute on a New Deal that required large expenditures and deficits.¹¹⁵ To accomplish these aims, President Roosevelt, with the Brownlow Committee's

¹⁰⁶ See *id.* at 97 (describing the "view from the White House" of DOJ as "too remote" and "twenty blocks away").

¹⁰⁷ See Daphna Renan, *The Law Presidents Make*, 103 VA. L. REV. 805, 819 & n.44 (2017).

¹⁰⁸ *Id.* at 830.

¹⁰⁹ See SHAMBAUGH & WEINSTEIN, *supra* note 95, at 49–50 (discussing the ways in which the White House Counsel is "significantly involved in the policymaking process" and "will use its authority as the president's legal adviser to influence policy proposals" as "its authority continue[s] to grow as presidents rely on the office for more and more legal services" in the face of "narrower interpretations" offered by DOJ).

¹¹⁰ See HART, *supra* note 5, at 50 ("[A]s the Executive Office has developed, so the White House Office has become the directing force and the most powerful division within the EOP").

¹¹¹ See BROWNLOW REPORT, *supra* note 80, at 63.

¹¹² See Renan, *supra* note 44, at 1137–38.

¹¹³ See Exec. Order No. 8248, 3 C.F.R. 217, 218 (1940). These other entities included the Liaison Office for Personnel Management, the Office of Government Reports, and "in the event of a national emergency, or threat of a national emergency, such office for emergency management as the President shall determine." *Id.* at 218–19.

¹¹⁴ See Budget and Accounting Act of 1921, Pub. L. No. 67-13, §§ 207–217, 42 Stat. 20, 22–23.

¹¹⁵ See Moe, *supra* note 5, at 247–48.

support, sought to bring the Bureau more directly under his control within the EOP.¹¹⁶

Given its budgetary levers and infrastructure for coordinating agency proposals, the Bureau of the Budget often participated in domestic policy decisions—with its directors becoming “more overtly involved” during the Kennedy Administration.¹¹⁷ Perhaps as a result, in 1970, President Nixon sought to subject the Bureau to even greater control through the placement of more political appointees at the top, renaming the Bureau the “Office of Management and Budget.”¹¹⁸ At the same time, however, Nixon pointedly did not place the OMB Director on his newly formed White House–based Domestic Council.¹¹⁹ This “demot[ion]”¹²⁰ was apparently motivated by Nixon’s desire to avoid bogging down policy development with OMB’s perceived “single-minded” focus on budgetary concerns.¹²¹ In other words, the Nixon Administration distinguished between the White House and structurally distinct entities such as OMB.

Indeed, the impersonal units of the presidency often share several characteristics insulating them from the President as compared with the White House. To be clear, this is not to question whether the individuals within, especially the political appointees, aspire to serve the President loyally. Rather, these are descriptive observations about the structural design of the presidency that can influence the institutional incentives within it. These impersonal units within the EOP have generally been established by statute rather than executive action,¹²² are charged with

¹¹⁶ See *id.* at 248–49. Accordingly, the Bureau of the Budget sought an enlarged career staff that grew almost overnight from about forty members to more than 500 in number. See *id.* at 249.

¹¹⁷ HART, *supra* note 5, at 86.

¹¹⁸ See Reorganization Plan No. 2 of 1970, 3 C.F.R. 197 (1971), *reprinted as amended in* 5 U.S.C. app. at 720 (2018); ARNOLD, *supra* note 55, at 283.

¹¹⁹ See ARNOLD, *supra* note 55, at 285.

¹²⁰ *Id.* at 285.

¹²¹ Salamon, *supra* note 85, at 183.

¹²² See HART, *supra* note 5, at 39–40. As a historical matter, divisions of the EOP could also be created through a hybrid model. See *id.* at 40. Under this approach, presidents submitted reorganization plans to Congress under a broad grant of reorganization authority. See *id.* Congress often paired these grants with conditions and a limited time period for submission. See *id.* Once submitted, reorganization plans would usually go into effect after sixty days unless defeated by a legislative veto. See *id.* Congress could disapprove the plan through a joint resolution of two houses or a resolution by a single house. See *id.* This scheme gave Congress power to impose conditions on the presidency along with the ultimate power to veto the reorganization. See *id.* at 40–41. On the other hand, the President gained a way to bypass the difficult legislative process. See *id.* at 41. The reorganization plans, after all, did not have to be affirmatively approved by Congress. See *id.* The onus, rather, was on Congress to marshal the resources and opposition to block a plan if it so desired. See *id.* This entire scheme, however, came to a halt when the Supreme Court declared the legislative veto unconstitutional in 1983. See *Immigr. & Naturalization Serv. v. Chadha*, 462 U.S. 919, 959 (1983). The following year, Congress required bicameral approval of presidential reorganization plans within ninety days to go into effect. See HART, *supra* note 5, at 41. Because Presidents no longer

statutory duties and responsibilities, feature heads that require Senate confirmation, and contain career staff that persist through administrations.¹²³ Once established by statute, later presidents cannot unilaterally abolish such units. President Clinton, for example, sought to eliminate the statutory Council on Environmental Quality (“CEQ”), further discussed below, in favor of a new office that he claimed would elevate environmental issues in the policy process.¹²⁴ Clinton’s efforts, however, were stymied by the House of Representatives and major environmental groups concerned about losing a statutory body in the EOP.¹²⁵

Moreover, the statutory duties of these units require resources that constrain their ability to pursue purely presidential interests. OIRA, for instance, is statutorily required by the Paperwork Reduction Act¹²⁶ to review information collections¹²⁷—a task that demonstrably detracts from its regulatory review responsibilities.¹²⁸ In addition, the heads of these units are often subject to Senate confirmation,¹²⁹ which can result in delays, vacancies, and nominees that may not otherwise have been the President’s first choice. Finally, tenure-protected career staff can also serve as a form of resistance to the President’s desires, whether due to bureaucratic capture, mission zeal, or good-faith disagreements about how best to accomplish the President’s desires.¹³⁰ In this manner, the impersonal arm of the presidency is structured with more independent institutional incentives relative to those within the White House Office.

had an incentive to seek reorganization authority—it was easier to pursue the traditional legislative process, which lacked the same deadline—this method came to an end in 1984 after the last reorganization statute expired. *See id.* Many units within the modern EOP were established under this method, including the current OMB—the successor to the Bureau of the Budget. *See* 3 C.F.R. 197. Because reorganization plans did not have to be actively approved by Congress and important details were often left to executive orders, on balance, this analysis will largely credit presidents with these innovations.

¹²³ *See, e.g.*, 31 U.S.C. §§ 501–503; Reorganization Plan No. 2 of 1970, 3 C.F.R. at 197. It should be noted that these features often appear together in the impersonal presidency but are not all necessary and admit of some variation. For example, the OIRA Administrator was not subjected to Senate confirmation until 1986. *See* 44 U.S.C. § 3503 (1982), *amended by* Paperwork Reduction Reauthorization Act of 1986, Pub. L. No. 99-500, § 813, 100 Stat. 1783-335, 1783-336 (codified as amended at 44 U.S.C. § 3503).

¹²⁴ *See* HART, *supra* note 5, at 93.

¹²⁵ *See id.*

¹²⁶ 44 U.S.C. §§ 3501–3521.

¹²⁷ *See id.* § 3504.

¹²⁸ *See* Bolton et al., *supra* note 12, at 242 (arguing that the “low organizational capacity [of OIRA] inhibits the president’s ability to expedite priority rules”).

¹²⁹ *See, e.g.*, 31 U.S.C. § 502(a).

¹³⁰ *See* Rebecca Ingber, *Bureaucratic Resistance and the National Security State*, 104 IOWA L. REV. 139, 163–65 (2018); Heidi Kitrosser, *Accountability in the Deep State*, 65 UCLA L. REV. 1532, 1544 (2018); Jon D. Michaels, *The American Deep State*, 93 NOTRE DAME L. REV. 1653, 1663–65 (2018); Jennifer Nou, *Civil Servant Disobedience*, 94 CHI.-KENT L. REV. 349, 381 (2019).

The first entity created by statute within the EOP since its establishment was CEA.¹³¹ CEA was conceived by the Employment Act of 1946¹³² to assist and advise the President in the preparation of economic reports, to collect and transmit relevant economic data, and to provide the President with economic advice, among other duties.¹³³ More generally, Congress was concerned about the “increasingly dominant role of the president in economic policy,” and the council—with its structurally independent features—“was an attempt to curb and counterbalance presidential power.”¹³⁴ To this end, Congress also mandated a number of statutory qualifications for council members who were to have “training, experience, and attainments” demonstrating that they were “exceptionally qualified to analyze and interpret economic developments.”¹³⁵ As a result, the role of CEA has often been understood as one of providing more “detached, objective, . . . and nonpolitical” advice, bolstered by the fact that CEA is often headed by an academic economist.¹³⁶

Similarly, Congress has also sought to ensure the existence of a statutory office within the EOP charged with providing scientific advice to the President. After the demise of various presidentially established science advisory bodies, Congress passed and President Ford signed a bill in 1976 establishing OSTP within the EOP.¹³⁷ OSTP is charged with providing scientific advice to the President.¹³⁸ In addition, OSTP

¹³¹ See HART, *supra* note 5, at 39.

¹³² Employment Act of 1946, Pub. L. No. 79-304, 60 Stat. 23 (codified as amended at 15 U.S.C. §§ 1021–1025).

¹³³ See *id.* § 4, 60 Stat. at 24–25 (codified as amended at 15 U.S.C. § 1023); HART, *supra* note 5, at 51.

¹³⁴ HART, *supra* note 5, at 40. The National Security Council, established in 1947, was similarly seen as a “congressional vote of no confidence in presidential management of national security during the war years,” *id.*, though its head has not been subject to Senate confirmation, see 50 U.S.C. § 3021, presumably given the President’s inherent Article II powers.

¹³⁵ Employment Act § 4, 60 Stat. at 24 (codified as amended at 15 U.S.C. § 1023) (“The Council shall be composed of three members . . . each of whom shall be a person who, as a result of his training, experience, and attainments, is exceptionally qualified to analyze and interpret economic developments, to appraise programs and activities of the Government in the light of the policy declared in section 2, and to formulate and recommend national economic policy to promote employment, production, and purchasing power under free competitive enterprise.”).

¹³⁶ See HART, *supra* note 5, at 51–52 (“The requirement that members of the CEA be distinguished professional economists implied, to some observers at least, that the council was meant to dispense advice to the president in a thoroughly detached, objective, scientific, and nonpolitical manner.”); see also Rick Dearborn, *White House Office* (“CEA acts as the White House’s internal research arm for economic analysis.”), in MANDATE FOR LEADERSHIP 23, 39 (Paul Dans & Steven Groves eds., 2023).

¹³⁷ See Presidential Science and Technology Advisory Organization Act of 1976, Pub. L. No. 94-282, 90 Stat. 463 (codified as amended at 42 U.S.C. §§ 6611–6618).

¹³⁸ See 42 U.S.C. § 6613. Congress established OSTP as an office within the EOP to, among other things, “serve as a source of scientific and technological analysis and judgment for the

can serve as a “sounding board and conduit of information” for other agency personnel regarding science policy, as well as assist with resolving interagency conflicts.¹³⁹

Congress has also established more policy-specific units within the EOP. Take, for example, CEQ, created by the National Environmental Policy Act of 1969 (“NEPA”).¹⁴⁰ The Act charges CEQ with offering recommendations to the President on improving environmental policy as well as drafting congressional reports on the subject.¹⁴¹ In addition, CEQ is responsible for implementing NEPA and, in this role, provides oversight on the preparation of environmental impact statements.¹⁴² Similar bodies established by statute that persist today include units devoted to drug policy,¹⁴³ intellectual property enforcement,¹⁴⁴ space policy,¹⁴⁵ homeland security,¹⁴⁶ cyber security,¹⁴⁷ and pandemic preparedness.¹⁴⁸

* * *

The EOP, in this manner, contains a White House Office with policy councils that serve the interests of the sitting President at the top of the hierarchy. Units within it have generally been established by executive order, have no statutory or programmatic responsibilities beyond serving the President, are not subject to Senate confirmation, and have no career staff. By contrast, the impersonal presidency has generally been created through traditional legislation resulting in statutory duties, has leaders subject to Senate confirmation, and contains career staff. In this manner, there is a spectrum of structural independence from the

President with respect to major policies, plans, and programs of the Federal Government.” *Id.* § 6614(a).

¹³⁹ JOHN F. SARGENT JR. & DANA A. SHEA, CONG. RSCH. SERV., RL34736, THE PRESIDENT’S OFFICE OF SCIENCE AND TECHNOLOGY POLICY (OSTP): ISSUES FOR CONGRESS 3–4 (2014) (discussing OSTP’s role).

¹⁴⁰ National Environmental Policy Act of 1969, Pub. L. No. 91-190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. §§ 4321–4347).

¹⁴¹ *See id.* § 204, 83 Stat. at 855 (codified at 42 U.S.C. § 4344).

¹⁴² *See id.* § 102(B)–(C), 83 Stat. at 853 (codified as amended at 42 U.S.C. § 4332(B)–(C)).

¹⁴³ *See* 21 U.S.C. § 1702 (“There is established in the Executive Office of the President an Office of National Drug Control Policy . . .”). This Office, however, has historically seen large reductions in staffing since its creation, likely attributable in part to the perception that its success and tools have been limited. *See* HART, *supra* note 5, at 94.

¹⁴⁴ *See* 15 U.S.C. § 8111 (“The President shall appoint, by and with the advice and consent of the Senate, an Intellectual Property Enforcement Coordinator . . .”).

¹⁴⁵ *See* 51 U.S.C. § 2011 note (“[T]here is established in the Executive Office of the President the National Space Council, which shall be chaired by the Vice President.”).

¹⁴⁶ *See* 6 U.S.C. § 491 (“There is established within the Executive Office of the President a council to be known as the ‘Homeland Security Council’ . . .”).

¹⁴⁷ *See id.* § 1500 (“There is established, within the Executive Office of the President, the Office of the National Cyber Director . . .”).

¹⁴⁸ *See* 42 U.S.C. § 300hh-3 (“There is established in the Executive Office of the President an Office of Pandemic Preparedness and Response Policy . . .”).

President to the broader executive branch—from the personally loyal White House to the statutory components of the EOP, to executive agencies, and then to more independent agencies.¹⁴⁹

II. PRESIDENTIAL BROKERING

Armed with the apparatus of the EOP, presidents must decide how to utilize it most effectively to accomplish their political agendas. The first Section of this Part examines how such agendas are formed, particularly with respect to rules, and how presidents have used the EOP to further those agendas. It then briefly evaluates some prominent mechanisms for presidential control over agency rulemaking—strategic appointments, executive orders, and regulatory review—and explains why each is limited in its ability to help presidents accomplish their highest regulatory priorities. The next Section then identifies a distinct mechanism, presidential brokering, and explores why it has developed and how it operates as a strategy of agency influence.

A. *The Incomplete Toolkit*

Presidents come into power having made many promises.¹⁵⁰ Before his first term, for example, President Trump pledged to radically reform immigration policy¹⁵¹—a priority he has renewed for his second tour in office.¹⁵² President George W. Bush campaigned on reforming education and prescription drug programs,¹⁵³ whereas President Bill Clinton specifically committed to “present a plan” in his first year “to provide affordable, quality health care for all.”¹⁵⁴ These campaign promises often form the most important elements of the President’s agenda, especially in the early years.¹⁵⁵ According to Clinton’s former DPC Director Bruce

¹⁴⁹ See generally Kirti Datla & Richard L. Revesz, *Deconstructing Independent Agencies (and Executive Agencies)*, 98 CORNELL L. REV. 769, 770–824 (2013) (discussing the commonalities and distinguishing factors of “executive” and “independent” agencies).

¹⁵⁰ See Andrew E. Busch, *Domestic Policy from Campaigning to Governing* (“Domestic policy advisers from the Nixon administration to the George W. Bush administration agree that campaign promises—at least on major issues that receive significant attention—set public expectations for the president and must be kept.”), in *GOVERNING AT HOME*, *supra* note 35, at 24, 27.

¹⁵¹ See TABITHA BONILLA, *THE IMPORTANCE OF CAMPAIGN PROMISES* 3 (2022).

¹⁵² See Drishti Pillai & Samantha Artiga, *Expected Immigration Policies Under a Second Trump Administration and Their Health and Economic Implications*, KFF (Nov. 21, 2024), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/expected-immigration-policies-under-a-second-trump-administration-and-their-health-and-economic-implications/> [<https://perma.cc/3UR9-W7K4>] (“Immigration was a central campaign issue during the 2024 Presidential election with President-elect Trump vowing to take strict action to restrict both lawful and unlawful immigration into the U.S.”).

¹⁵³ See Busch, *supra* note 150, at 29.

¹⁵⁴ BONILLA, *supra* note 151, at 6.

¹⁵⁵ See Hult & Walcott, *supra* note 35, at 85.

Reed, “We treated the campaign promises as gospel [when establishing policy priorities]. That was the only scripture to guide us.”¹⁵⁶ Because White House policy councils are most likely “to share the president’s intense concern” about fulfilling these commitments, they became the “trusted keeper[s] of the flame.”¹⁵⁷

Although the early days of an administration are often preoccupied with campaign promises, presidential priorities evolve and shift.¹⁵⁸ By many accounts, presidents seek to advance their most ambitious undertakings in the first year because they anticipate reductions in political support.¹⁵⁹ Since presidents can usually expect a loss of party seats during midterm elections, they often move early to strike while the iron is hot.¹⁶⁰ By contrast, electoral considerations complicate the second and fourth years.¹⁶¹ In addition, presidents are keenly attuned to public opinion.¹⁶² As a general matter, they can expect an overall erosion in public approval ratings throughout their term, further augmenting the incentive to act quickly.¹⁶³ For these reasons, the President only has limited “policy windows”—that is, opportunities for effective interventions.¹⁶⁴

Given these constraints, rules are attractive to presidents as policymaking instruments because they have binding effects on classes of individuals.¹⁶⁵ Like statutes, rules can bring about highly consequential policy changes as compared to adjudication or enforcement.¹⁶⁶ Rules, however, also demand a great deal of resources to draft alongside their preambles and required analyses. Indeed, some research suggests that

¹⁵⁶ Busch, *supra* note 150, at 27 (quoting JOHN P. BURKE, *PRESIDENTIAL TRANSITIONS* 207–08 (2000)).

¹⁵⁷ Nelson, *supra* note 75, at 7.

¹⁵⁸ See Busch, *supra* note 150, at 27, 29.

¹⁵⁹ See PAUL C. LIGHT, *THE PRESIDENT’S AGENDA* 41–42 (3d ed. 1999) (“Presidents and staffs . . . understand that the essential resource, capital, evaporates over time, [such] that the first year offers the greatest opportunity for establishing the domestic program.”).

¹⁶⁰ See *id.* at 36 (observing that “[a]t least for the past fifty years, all Presidents, whether Democratic or Republican, have faced a drop in House party seats at the midterm election”).

¹⁶¹ See *id.* at 40.

¹⁶² See Jon C. Rogowski, *Public Opinion and Presidents’ Unilateral Policy Agendas*, 67 AM. J. POL. SCI. 1134, 1134–35 (2023).

¹⁶³ See LIGHT, *supra* note 159, at 36 (“Today the President can expect a near-linear drop in his approval rating in the first three years of office, with a slight rebound at the end of the term.”).

¹⁶⁴ JOHN W. KINGDON, *AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES* 166 (2d ed., Pearson New International ed. 2013).

¹⁶⁵ See M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383, 1386 (2004) (“Many agencies have the authority to promulgate legislative rules, which are akin to statutes in that they prospectively set forth a general substantive standard of conduct for a class of private actors.”).

¹⁶⁶ See *id.* at 1394 (“[A] legislative rule . . . , if valid, operates like a statute.”).

rulemakings can take an average of two years or more to complete.¹⁶⁷ These tradeoffs mean that presidents must weigh the benefits and costs of rulemaking when forming their agendas. Although the number of rules on the presidential agenda may be relatively “small” as compared with the thousands of rules issued by agencies each year,¹⁶⁸ they are likely among the “most significant” along many dimensions.¹⁶⁹

Rules, however, can only be issued by agencies with the statutory authority to promulgate them. Thus, the President must rely on tools of administrative control when seeking to pursue this policymaking strategy. Yet some of the most prominently studied tools are limited in their ability to advance the President’s priorities. First, presidents can “politicize” the bureaucracy through strategic appointments on the basis of preference alignment or ideology.¹⁷⁰ The reality, however, is much messier. Presidents and their appointees suffer from familiar principal-agent problems, which are exacerbated by similar issues between agency heads and their career staff.¹⁷¹ There is, for example, the prospect of bureaucratic capture by external special interests, exacerbated by the notorious “revolving door.”¹⁷² Moreover, agency heads may focus only

¹⁶⁷ See MICHAEL TANGLIS, PUB. CITIZEN, UNSAFE DELAYS: AN EMPIRICAL ANALYSIS SHOWS THAT FEDERAL RULEMAKINGS TO PROTECT THE PUBLIC ARE TAKING LONGER THAN EVER 27 (Taylor Lincoln et al. eds., 2016), <https://www.citizen.org/wp-content/uploads/unsafe-delays-report.pdf> [<https://perma.cc/TTW2-A9YE>] (finding that “the length of completed rulemakings inched up to 2.7 years in 2016”); Anne Joseph O’Connell, *Political Cycles of Rulemaking: An Empirical Portrait of the Modern Administrative State*, 94 VA. L. REV. 889, 959 (2008) (reporting that “[a]ll agencies but the HHS completed rulemakings started by a [Notice of Proposed Rulemaking] in less than two years, on average”).

¹⁶⁸ See MARK FEBRIZIO, FEDERAL AGENCIES ARE PUBLISHING FEWER BUT LARGER REGULATIONS 2 (2021), <https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs4751/files/2022-06/gw-reg-studies-fewer-yet-larger-regulations-mfebrizio.pdf> [<https://perma.cc/Y7DH-N8CJ>] (showing that agencies produce thousands of rules each year, though the numbers are declining in the aggregate).

¹⁶⁹ Coglianese & Walters, *supra* note 17, at 109 (reporting that participants in an expert discussion “stressed that the White House will have much greater influence over a small number of rules that administration officials consider to be the most significant ones”).

¹⁷⁰ See DAVID E. LEWIS, THE POLITICS OF PRESIDENTIAL APPOINTMENTS 202–05 (2008) [hereinafter LEWIS, PRESIDENTIAL APPOINTMENTS]; David E. Lewis, *Presidential Appointments and Personnel*, 14 ANN. REV. POL. SCI. 47, 49–50 (2011).

¹⁷¹ See Jody Freeman & David B. Spence, *Old Statutes, New Problems*, 163 U. PA. L. REV. 1, 64 (2014). Much empirical evidence supports the notion that the preferences of career civil servants within an agency diverge from those of political appointees. See, e.g., Joshua D. Clinton, Anthony Bertelli, Christian R. Grose, David E. Lewis & David C. Nixon, *Separated Powers in the United States: The Ideology of Agencies, Presidents, and Congress*, 56 AM. J. POL. SCI. 341, 345–46 (2012).

¹⁷² See PAUL J. QUIRK, INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES 4, 187–88 (1981). According to this argument, regulated industries have the resources, incentives, and information necessary to influence agency career staff or political appointees. See *id.* at 23–24. Similarly, public interest groups are also influential given their ability to marshal publicity and political pressure. See Michael E. Levine & Jennifer L. Forrence, *Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis*, 6 J.L. ECON. & ORG. 167, 169 (1990).

on their narrow statutory missions rather than adopt the more general perspective of the President.¹⁷³

Such misalignment could be of little concern if presidents simply removed recalcitrant appointees.¹⁷⁴ Such removals, however, can exact high political costs, especially when they defy norms or conventions about the removed party's perceived need for independence.¹⁷⁵ Relatedly, the requirement of Senate confirmation for top agency leadership imposes significant delays, often resulting in vacancies.¹⁷⁶ Although presidents have sometimes offset this problem through the appointment of acting administrators—nonconfirmed temporary leaders—such “actings” are often limited in their ability to effect change.¹⁷⁷ For these reasons, presidents cannot rely on agency personnel alone to accomplish their highest regulatory priorities.

Second, if political appointees cannot generate the desired results, then perhaps issuing executive orders or other presidential directives could do the trick. Indeed, then-Professor Elena Kagan's account of the proactive nature of presidential administration focused on such directives,¹⁷⁸ as have contemporary social scientists studying what they call “unilateral” executive action.¹⁷⁹ In Kagan's estimation, executive orders are powerful instruments of bureaucratic control because they are framed in legal terms and can invoke the President's directive authority.¹⁸⁰ Such orders can serve to “lock in” a policy even if the agency

¹⁷³ See Freeman & Spence, *supra* note 171, at 64.

¹⁷⁴ Although Congress can subject such removals to for-cause requirements, the Supreme Court has made such efforts more constitutionally suspect. See *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 204–05 (2020); *Collins v. Yellen*, 594 U.S. 220, 250–51 (2021).

¹⁷⁵ See Pierce, *supra* note 62, at 607 (describing numerous examples of when “legal obstacles to the use of the President's removal power [we]re insignificant in their effects” while the “political obstacles [we]re often formidable”).

¹⁷⁶ See Anne Joseph O'Connell, *Shortening Agency and Judicial Vacancies Through Filibuster Reform? An Examination of Confirmation Rates and Delays from 1981 to 2014*, 64 DUKE L.J. 1645, 1647 (2015). Recent empirical work suggests that such delays are only increasing in length, both due to limited Senate floor time and competing priorities in the White House. See *id.* (noting that between fifteen and twenty percent of senior agency positions are vacant at any point in time).

¹⁷⁷ See Anne Joseph O'Connell, *Actings*, 120 COLUM. L. REV. 613, 617, 699–700 (2020) (“[A]cting leaders typically govern more as caretakers than change agents.”).

¹⁷⁸ See Kagan, *supra* note 10, at 2285, 2290–99 (describing directives as the “most important” presidential “technique[]” of administrative control and discussing such directives). Interestingly, Elena Kagan herself was the Deputy Assistant to the President for Domestic Policy and Deputy Director of DPC, but one possible, purely speculative, reason she did not expand in great detail about its innerworkings and practices was because DPC had just been established in its current form by President Clinton and yet to be fully institutionalized.

¹⁷⁹ See, e.g., Kenneth Lowande & Jon C. Rogowski, *Presidential Unilateral Power*, 24 ANN. REV. POL. SCI. 21, 23–24 (2021).

¹⁸⁰ See Kagan, *supra* note 10, at 2298–99.

may have been resisting it.¹⁸¹ They also increase the costs of noncompliance by agency officials by “spotlight[ing]” the results and putting the agency publicly on the hook for them.¹⁸²

Presidential directives, however, are not self-executing. They require a great deal of sustained leadership and coordination to implement, especially with rules; put differently, “the exercise of formal directive authority cannot, by itself, overcome the management and coordination dilemmas inherent in the administrative process.”¹⁸³ In addition, agencies are also subject to congressional oversight, which can stymie implementation.¹⁸⁴ For example, although President Obama issued an executive order to fulfill a campaign promise to close the Guantanamo Bay detention camp,¹⁸⁵ Congress refused to appropriate the funds necessary for the closure.¹⁸⁶

In fact, a growing body of research suggests that executive orders often result in limited agency responsiveness on the ground.¹⁸⁷ One empirical study, for example, finds that when an order names an agency and explicitly requests the promulgation of a rule, the probability of response is about sixty-seven percent.¹⁸⁸ In other words, more than thirty percent of orders directing a discrete agency to promulgate a rulemaking do not yield the result sought. Meanwhile, if the executive order fails to name a specific agency but still calls for the promulgation of a rule, the probability of response drops to about thirty-five percent.¹⁸⁹ It drops even further to about an 8.5% probability if the agency is named but the promulgation of a rule is not specifically requested.¹⁹⁰ Agencies that are more structurally insulated from the President appear to be even less responsive, especially if they have had only limited involvement in the drafting of the executive order itself.¹⁹¹ Relatedly, Andrew Rudalevige’s rich archival-based work details how a substantial number of executive

¹⁸¹ See David J. Barron, Foreword, *From Takeover to Merger: Reforming Administrative Law in an Age of Agency Politicization*, 76 GEO. WASH. L. REV. 1095, 1116 (2008) (describing how executive orders “locked an agency into a path that it had not yet finally settled upon”).

¹⁸² Kagan, *supra* note 10, at 2299.

¹⁸³ Jennifer L. Selin, Cody A. Drolc, Jordan Butcher, Nicholas L. Brothers & Hanna K. Brant, *Under Pressure: Centralizing Regulation in Response to Presidential Priorities*, 52 PRESIDENTIAL STUD. Q. 340, 343 (2022).

¹⁸⁴ See Joshua B. Kennedy, “‘Do This! Do That!’ And Nothing Will Happen”: *Executive Orders and Bureaucratic Responsiveness*, 43 AM. POL. RSCH. 59, 65 (2015).

¹⁸⁵ See Exec. Order No. 13,492, 3 C.F.R. 203 (2010).

¹⁸⁶ See Kennedy, *supra* note 184, at 65.

¹⁸⁷ See, e.g., Alex Acs, *Presidential Directives in a Resistant Bureaucracy*, 41 J. PUB. POL’Y 776, 779–80 (2021); Kennedy, *supra* note 184, at 65; Joshua B. Kennedy & Andrew Rudalevige, *Implementing Executive Orders in the Administrative State*, 55 PRESIDENTIAL STUD. Q. 72, 78 (2025).

¹⁸⁸ Kennedy, *supra* note 184, at 72.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ See Kennedy & Rudalevige, *supra* note 187, at 79–80.

orders are primarily drafted by agencies themselves, suggesting that such orders may serve other functions distinct from presidential control.¹⁹² Yet another body of work suggests that presidential directives often serve more as glorified press releases¹⁹³ or vehicles to signal competence to voters, rather than efforts to actually change agency policy on the ground.¹⁹⁴

Perhaps as a result, a bipartisan consensus of presidents has also imposed a regime of ex post review on agency rules. This third strategy essentially allows presidents to evaluate and surgically influence draft rules before they are issued.¹⁹⁵ Although President Nixon was arguably one of the first to do so,¹⁹⁶ President Reagan exerted more supervisory control “self-consciously and openly”¹⁹⁷ when he issued Executive Order 12,291 in 1981.¹⁹⁸ Among other things, the order required executive agencies to submit draft proposed and final rules along with cost-benefit analyses to OMB,¹⁹⁹ a role delegated soon thereafter to the then newly established OIRA.²⁰⁰

Although Executive Order 12,291 persisted through George H.W. Bush’s Administration, President Clinton issued Executive Order 12,866 in 1993, which continues to govern the process today.²⁰¹ Unlike the previous regime that reviewed all regulations, agencies now only have to submit those rules that are the most “significant.”²⁰² The effort

¹⁹² See Rudalevige, *supra* note 54, at 99–101.

¹⁹³ See, e.g., KENNETH LOWANDE, FALSE FRONT 1 (2024) (“When presidents sign orders, they put on a show.”).

¹⁹⁴ See Justin Fox & Matthew C. Stephenson, *Judicial Review as a Response to Political Posturing*, 105 AM. POL. SCI. REV. 397–98 (2011).

¹⁹⁵ See STEVEN P. CROLEY, REGULATION AND PUBLIC INTERESTS 97 (2007) (noting that “whereas the president lacks the ability to veto selective pieces of legislation, he enjoys a ‘line-item veto,’ so to speak, of agencies’ regulatory initiatives”).

¹⁹⁶ See Jim Tozzi, *OIRA’s Formative Years: The Historical Record of Centralized Regulatory Review Preceding OIRA’s Founding*, 63 ADMIN. L. REV. 37, 44–45 (2011). Specifically, Nixon’s “quality of life reviews” focused on draft rules “pertaining to environmental quality, consumer protection, and occupational and public health and safety.” Memorandum from George P. Shultz, Dir., Off. of Mgmt. & Budget, to the Heads of Dep’ts & Agencies (Oct. 5, 1971), <https://thehre.com/ombpapers/QualityofLife1.htm> [<https://perma.cc/82TJ-88ZE>]; see also Tozzi, *supra*, at 46; Andrew Rudalevige, *Beyond Structure and Process: The Early Institutionalization of Regulatory Review*, 30 J. POL’Y HIST. 577, 582 (2018).

¹⁹⁷ Kagan, *supra* note 10, at 2277.

¹⁹⁸ Exec. Order No. 12,291, 3 C.F.R. 127 (1982).

¹⁹⁹ *Id.* at 128–30.

²⁰⁰ *Id.* at 131. Created under the Paperwork Reduction Act of 1980, OIRA is located within the EOP and more specifically, OMB. Paperwork Reduction Act of 1980, Pub. L. No. 96-511, § 3503, 94 Stat. 2812, 2814–15 (codified as amended at 44 U.S.C. § 3503); see also U.S. GEN. ACCT. OFF., GAO-03-929, RULEMAKING: OMB’S ROLE IN REVIEWS OF AGENCIES’ DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS 17–18 (2003).

²⁰¹ Exec. Order No. 12,866, 3 C.F.R. 638 (1994), *reprinted as amended in* 5 U.S.C. § 601 note (2018); see also Exec. Order No. 14,094, 3 C.F.R. 369 (2024) (reaffirming Executive Order 12,866).

²⁰² Exec. Order No. 12,866, 3 C.F.R. at 645.

was an attempt to make the process more selective “so as to focus resources on the most important” rules.²⁰³ This criterion for review has always explicitly included the potential for a rule to bear on presidential priorities.²⁰⁴ At the same time, one standard of the review itself is to ensure the rule’s alignment with those priorities.²⁰⁵ President Trump has recently extended this review process to independent regulatory agencies as well.²⁰⁶

The reactive nature of review, however, severely limits its utility for pursuing the President’s affirmative regulatory agenda.²⁰⁷ The OIRA process generally does not begin until after the agency has submitted its draft rule.²⁰⁸ OIRA sometimes receives draft rules from agencies “informally”—that is, before they are formally submitted—but this informal review still usually only begins after the agency has already done a substantial amount of work.²⁰⁹ At that point, most of the core policy choices will have already been drafted into the rule and accompanying analyses. Asking agencies to change course at that point would result in much wasted time and effort along with further delay. To be sure, OIRA is uniquely situated to pursue a number of crosscutting managerial goals with respect to the rulemaking process.²¹⁰ And OIRA administrators have also occasionally issued “prompt letters” to agencies suggesting the development of rules in particular areas.²¹¹ Administrator John Graham, for example, encouraged the Occupational Safety and Health Administration to prioritize the promotion of automatic external heart defibrillators.²¹² By most accounts, however, such letters have rarely spurred new agency rulemaking efforts on their own.²¹³

²⁰³ Kagan, *supra* note 10, at 2287; *see also* Sally Katzen, *OIRA at Thirty: Reflections and Recommendations*, 63 ADMIN. L. REV. 103, 105 (2011) (describing the various impacts of Executive Order 12,866 on OIRA review).

²⁰⁴ *See* Exec. Order No. 12,866, 3 C.F.R. at 645.

²⁰⁵ *See id.* at 640.

²⁰⁶ Exec. Order No. 14,215, 90 Fed. Reg. 10,447, 10,448 (Feb. 18, 2025).

²⁰⁷ *See* Curtis W. Copeland, *The Role of the Office of Information and Regulatory Affairs in Federal Rulemaking*, 33 FORDHAM URB. L.J. 1257, 1288 (2006) (“OIRA has traditionally been a reactive force in the rulemaking process, commenting on draft proposed and final rules that are generated by the agencies.”); Kagan, *supra* note 10, at 2285 (describing regulatory review as the “least significant” instrument of presidential administrative control during the Clinton Administration).

²⁰⁸ *See* Copeland, *supra* note 207, at 1273–74.

²⁰⁹ *See id.* at 1278–81.

²¹⁰ *See* Revesz, *Regulatory Review*, *supra* note 11, at 134.

²¹¹ *See* Copeland, *supra* note 207, at 1288–89.

²¹² *See id.*

²¹³ *See id.* at 1288 (“Several . . . agencies took action in response to the letters, but few new rulemakings have directly resulted from them.”).

B. *Brokering*

Given the shortcomings of the strategies above, presidents have sought other mechanisms to accomplish their regulatory priorities. Specifically, they have developed the institution of policy councils and the practice of brokering to spur agency rulemaking on priority timelines. Presidential brokering is a structured set of deliberative White House–led interactions between components of the EOP and the rulemaking agency to formulate policy. The practice, as defined here, consists of delegated authority to identify an array of regulatory options from different intra-executive branch perspectives; to test arguments through moderated deliberation; and to elevate decisions up the presidential hierarchy when consensus is not otherwise achieved.

The process has evolved over the years, but a “once-lively” debate has been replaced by a broad “consensus” model that is now “wide[ly] accept[ed]” by many presidents from both parties.²¹⁴ This growing, though not always linear, trend can be attributed to multiple channels, including veterans of previous administrations engaging in repeated government service and an emerging bipartisan consensus among external transition advisors and academics.²¹⁵ Central to this model is the perceived need for what has become known as the “honest” broker.²¹⁶ An honest broker seeks the best outcome for the President and therefore presents options from multiple EOP vantage points beyond the White House in ways that build trust in the process.²¹⁷ The honest broker does not advocate for a particular point of view but rather seeks to synthesize and fairly include those of others.²¹⁸

Historically, this decision-making approach had its roots in the Eisenhower Administration, which had a chief of staff and a staff secretariat to manage the process.²¹⁹ Although subsequent presidents adopted

²¹⁴ Charles E. Walcott & Karen M. Hult, *White House Structure and Decision Making: Elaborating the Standard Model*, 35 *PRESIDENTIAL STUD. Q.* 303, 303 (2005); see also LIDDELL, *supra* note 61, at 115–19; Daphna Renan, *Presidential Norms and Article II*, 131 *HARV. L. REV.* 2187, 2223–24 (2018).

²¹⁵ See, e.g., Walcott & Hult, *supra* note 214, at 311 (seeking to “refute[] the old saw that the White House has no institutional memory”); LIDDELL, *supra* note 61, at 136 (“[I]n practice in recent White Houses, most of the actual structure looks very similar to previous ones, mainly because a lack of conscious design causes the president and White House staff to simply copy what has come before.”); TROY, *supra* note 14, at 3–4 (“This policy process has a long and storied White House history, one that, for the most part, continues from administration to administration, regardless of partisan affiliation.”).

²¹⁶ See JOHN P. BURKE, *HONEST BROKER?* 1–4 (2009).

²¹⁷ See LIDDELL, *supra* note 61, at 118 (“Honest brokers are to arrange different options, and do so out of a genuine desire to seek the best result, in a way that builds trust in the person and the system.”).

²¹⁸ See *id.*

²¹⁹ See Walcott & Hult, *supra* note 214, at 304.

a more “spokes of the wheel” model involving multiple coequal staffers reporting to the President, President Nixon returned to Eisenhower’s hierarchical model, now delegating a brokering role to his newly created Domestic Council.²²⁰ In the words of his Chief of Staff Alexander Haig, Nixon wanted multiple perspectives presented “not waffled, not mushed into consensus-type recommendations but rather in sharp, clear, conceptually pure, philosophically pure options.”²²¹ His Domestic Council Director, John Ehrlichman, and his staff accordingly brokered Nixon’s signature programs in welfare reform, labor disputes, urban growth, health, and revenue sharing, among others.²²²

Since then, administrations from both parties have largely adhered to this increasingly “standard” approach through the use of policy councils.²²³ Some exhibit variations early in their terms but invariably return to the model.²²⁴ Even the first Trump Administration, which famously bucked many norms, saw Chief of Staff John Kelly seeking to reimpose discipline through the brokering process after a chaotic first year.²²⁵ That process would “integrate the input of Cabinet agencies and policy councils and present the president with various options, as well as with the advantages and drawbacks of each one.”²²⁶ It would represent “a reversion to the habits of previous administrations” to “ensure competing views are completely and straightforwardly presented to the president.”²²⁷ More recently, the Heritage Foundation’s Project 2025 also recommended a return to the brokering model in a second Trump term,²²⁸ but only time will tell whether its prescription will be followed.

President Biden, as mentioned earlier, embraced the model explicitly in the domestic policy context. Although previous administrations largely relied on internal memos²²⁹ and norms²³⁰ to reinforce the importance of brokering, the Biden Administration was the first to publicly memorialize important aspects of the process in a formal

²²⁰ *Id.* at 305–06.

²²¹ KAREN M. HULT & CHARLES E. WALCOTT, *EMPOWERING THE WHITE HOUSE* 20 (2004).

²²² *See* RICHARD P. NATHAN, *THE ADMINISTRATIVE PRESIDENCY* 36 (1983).

²²³ *See* Walcott & Hult, *supra* note 214, at 309–11.

²²⁴ *See id.*; *supra* note 92 and accompanying text.

²²⁵ *See* Hult, *supra* note 45, at 40, 44.

²²⁶ Eliana Johnson & Nancy Cook, *Kelly Moves to Control the Information Trump Sees*, *POLITICO* (Aug. 24, 2017, 5:11 AM), <https://www.politico.com/story/2017/08/24/john-kelly-trump-control-241967> [<https://perma.cc/SAF3-4GZL>].

²²⁷ *Id.*

²²⁸ *See* Dearborn, *supra* note 136, at 36 (recommending that the second Trump White House have a process to “ensure that all relevant offices are included; that competing or conflicting opinions are thoroughly discussed and evaluated; and, when there is disagreement among White House senior staff or among Cabinet members, a well-structured question is presented to the President for an intermediate or final decision”).

²²⁹ *See* Johnson & Cook, *supra* note 226.

²³⁰ *See* Renan, *supra* note 214, at 2228, 2236–37.

domestic policy directive.²³¹ First, the directive specified a model involving an increasingly hierarchical set of committees.²³² This general model, sometimes referred to as the “Principals Committee” process, was originally adopted in the context of the White House National Security Council.²³³ As specified in Biden’s domestic policy directive, the main day-to-day work of the process would occur through interagency policy committees, which would meet on a “regular basis” to generate policy options.²³⁴ This committee would “be composed of representatives from all relevant agencies . . . with significant management and policymaking responsibilities.”²³⁵

When issues would require resolution amidst disagreements, matters would then be elevated to a Deputies Committee, the “senior sub-Cabinet forum.”²³⁶ As the name suggests, this level would involve more senior, deputy-secretary-level staff from agencies, the White House, and other components of the EOP.²³⁷ Many key decisions are often made in these meetings “because the deputies generally have the necessary time that their principals often lack to ensure quality control and the seniority to work through disputes to the extent possible.”²³⁸ In Biden’s model, the committee would be chaired by the White House Deputy Assistant to the President for Domestic Policy.²³⁹ Through a brokering process, this committee would whittle down open issues by reaching consensus on some issues and then elevate any remaining disputes to the last committee in the hierarchy—the Principals Committee, which is a cabinet-level senior forum.²⁴⁰ Under Biden, the White House DPC Director would chair this committee, which would generally be composed of agency heads, including those within the EOP.²⁴¹ It is at this stage that final options would be developed for the President’s consideration, if appropriate.²⁴²

²³¹ Domestic Policy Presidential Directive, *supra* note 38.

²³² *See id.*

²³³ LIDDELL, *supra* note 61, at 116; *see also* JOHN W. ROLLINS, CONG. RSCH. SERV., R44828, THE NATIONAL SECURITY COUNCIL: BACKGROUND AND ISSUES FOR CONGRESS 8 (2022). It is almost certainly not a coincidence that the DPC Director at the time of this directive’s issuance was Susan Rice, the former head of the National Security Council. *See* Zolan Kanno-Youngs & Eileen Sullivan, *Susan Rice to Step Down as Biden’s Domestic Policy Adviser*, N.Y. TIMES (Apr. 24, 2023), <https://www.nytimes.com/2023/04/24/us/politics/susan-rice-biden.html> [<https://perma.cc/PA2Y-T2S8>].

²³⁴ Domestic Policy Presidential Directive, *supra* note 38.

²³⁵ *Id.*

²³⁶ *See id.*

²³⁷ *See* LIDDELL, *supra* note 61, at 116.

²³⁸ *Id.* at 116–17.

²³⁹ *See* Domestic Policy Presidential Directive, *supra* note 38.

²⁴⁰ *See id.*

²⁴¹ *See id.*

²⁴² *See* LIDDELL, *supra* note 61, at 117 (noting that “[i]t is at this level that the true final options are developed for presidential decisions”).

While this structured, formal process is used for many important priorities, it is frequently supplemented by more informal working groups and task forces drawing upon the same logic: White House policy council staff help to generate regulatory options from different perspectives throughout the executive branch, test arguments through moderated deliberation, and elevate decisions as necessary.²⁴³ In Bradley Patterson's words,

The picture [of formal councils] is more fakery than fact. The formal assemblages, chaired by the president, rarely assemble. Principals meet as teams, often without the president; deputies get together frequently; working groups abound. It's the top staffs of the councils—senior White House officers—who supply the leadership, scope out the questions, draft the papers, and call the meetings. Even the final sessions of cabinet folks and White House staffers in the Oval Office are not the grinding of formal “council” machinery but informal decisionmaking clusters.²⁴⁴

In this manner, the presidential brokering process varies in terms of its level of formality and scope.

Whether informal or formal in nature, White House policy councils can influence the brokering process in many ways, including through control over agenda setting, participant selection, framing, and discretion over when to elevate a decision and to whom. Policy councils accordingly exercise levers of power hidden to the agencies.²⁴⁵ As famously recognized by Peter Bachrach and Morton Baratz, this subterranean form of agency influence is no less real or effective than its more observable facets.²⁴⁶ Although such decisions may be guided by the ideal of honest brokering, policy councils like any other bureaucratic actor

²⁴³ See *id.* at 113 (opining that a presidential decision-making framework “should allow for a level of less structured process [as well], because uncontrollable external events and changing presidential directives drive so much activity”).

²⁴⁴ PATTERSON, *supra* note 16, at 77.

²⁴⁵ Note that some of the descriptive claims are presented here to draw a contrast to a rich portrait of presidential policymaking recently offered by Anya Bernstein and Cristina Rodríguez based on agency-centered interviews. See Anya Bernstein & Cristina Rodríguez, *The Accountable Bureaucrat*, 132 YALE L.J. 1600, 1606–08, 1617–28 (2022). Although they too emphasize the deliberative nature of the policymaking process, *id.* at 1638–50, their account presents officials that “continually present ideas to be reviewed, vetted, and tested by other actors” and “routinely lead to the reconsideration of views,” *id.* at 1607–08. Policymaking, from this perspective, has a decidedly languid feel amidst what they characterize as a “web” of “multifarious” and “reticulated” norms of engagement. *Id.* at 1638–39. Perhaps due to their reliance on the agency's perspective, however, this characterization arguably does not sufficiently account for the ways in which the presidency structures and drives these deliberations.

²⁴⁶ See Peter Bachrach & Morton S. Baratz, *Two Faces of Power*, 56 AM. POL. SCI. REV. 947, 949 (1962).

must “satisfice”—that is, make decisions that are good enough amid often severe resource constraints.²⁴⁷ Policy councils are also motivated to serve the President’s political agenda while facing acute time pressures. As a result, they are likely to manage and structure deliberations in ways that serve the President’s substantive and procedural interests.

To illustrate some of these dynamics in action, recall the rulemaking mentioned above involving President Clinton’s promise to “end welfare as we know it.”²⁴⁸ In August 1996, Clinton signed into law PRWORA, which generally imposed stricter time limits and work requirements on welfare recipients.²⁴⁹ The text and legislative history of the statute made clear that Congress called for a more stringent standard for children’s disability benefits.²⁵⁰ The question for the Administration was how much stricter. The answer required a rulemaking from the Social Security Administration (“SSA”) under extreme time pressure: The statute required action within ninety days, and in the meantime, new social security claims could not be processed.²⁵¹ President Clinton delegated the “lead role” in brokering this rulemaking to DPC.²⁵²

The first critical task for DPC was to ensure that the rule became and remained a priority, both in terms of SSA’s regulatory agenda as well as within the EOP itself. To this end, Clinton’s DPC Director Carol Rasco circulated a top-ten list of “Hot” items that included both things that “must get done immediately” and “‘big’ issues.”²⁵³ Second on the list was SSA’s child disability benefits rule.²⁵⁴ To further drive the point home, Rasco sent an internal memo to cabinet secretaries and select EOP units making clear that “[t]he successful implementation of the

²⁴⁷ See HERBERT A. SIMON, *ADMINISTRATIVE BEHAVIOR* 118 (4th ed. 1997).

²⁴⁸ Sethi, *supra* note 18, at 16.

²⁴⁹ Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, sec. 103, § 407, 110 Stat. 2105, 2129–34 (codified as amended at 42 U.S.C. § 607).

²⁵⁰ See *id.* sec. 211(a), 110 Stat. at 2188–89 (codified as amended at 42 U.S.C. § 1382c); H.R. REP. NO. 104-651, at 1387 (1996) (“The committee intends that only needy children with severe disabilities be eligible for [supplemental security income] and that the Listings and other disability determination regulations as modified by these provisions properly reflect the severity of disability contemplated by the statutory definition.”). Before the Act’s enactment, a child was considered disabled if the child had an impairment of “comparable severity” to that of an adult in order to receive means-tested cash benefits. See 42 U.S.C. § 1382c(a)(3)(A) (1994). The new welfare law now provided that a child was disabled if the child had an impairment that resulted in “marked and severe functional limitations” that could “be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.” Personal Responsibility and Work Opportunity Reconciliation Act sec. 211(a), 110 Stat. at 2188 (codified as amended at 42 U.S.C. § 1382c).

²⁵¹ See Memorandum from Brian Coyne, Chief of Staff, Soc. Sec. Admin., to Diana Fortuna, Assoc. Dir., Domestic Pol’y Council 2 (Sept. 12, 1996) (on file with author).

²⁵² Memorandum from Carol H. Rasco to Leon Panetta & Erskine Bowles, *supra* note 21.

²⁵³ Memorandum from Jeremy D. Benami, Deputy Domestic Pol’y Adviser, Domestic Pol’y Council, to Diana M. Fortuna, Assoc. Dir., Domestic Pol’y Council (Oct. 22, 1996) (on file with author).

²⁵⁴ See *id.*

welfare reform bill is one of the President's highest priorities for the second term."²⁵⁵ She set an ambitious biweekly meeting schedule to ensure that progress would be made.²⁵⁶ Outside of these meetings, DPC staff also generally kept in regular contact with political appointees within the agency to prod and keep abreast of their activities.²⁵⁷ In this manner, White House policy councils played a critical agenda-setting role.

Policy-council staff also have the discretion to decide who gets to be involved in the policy process and when. This decision necessarily dictates which perspectives are represented and incorporated into the outcome. According to meeting manifests drafted by DPC staff, many of the discussions regarding welfare reform included the Chief of Staff, OMB, NEC, and the offices of the First Lady, Vice President, Legislative Affairs, and White House Counsel.²⁵⁸ At other points in the process, Rasco decided that the statutory Office of National Drug Control Policy ("ONDCP") should also be included in the meetings given that "substance abuse is a much bigger factor in welfare reform than many want to admit."²⁵⁹ CEA also played an important role in welfare-reform implementation more generally.²⁶⁰ In this manner, DPC convened many components of the EOP beyond those in the White House.

In addition to deciding who gets to participate, policy councils also have the ability to frame the decisions at hand. Framing implicates the ways in which a problem or choice is presented, which can in turn influence the perception and ultimately the preferences of those deliberating

²⁵⁵ Memorandum from Carol H. Rasco, Assistant to the President for Domestic Pol'y, to Cabinet Sec'y's (Nov. 13, 1996) (on file with author).

²⁵⁶ See *id.*; Draft Memorandum from Carol Rasco, Assistant to the President for Domestic Pol'y, & Bruce Reed, Director, Domestic Pol'y Council, to the President of the United States (Sept. 2, 1996) (on file with author); Annotated Memorandum from Carol H. Rasco, Assistant to the President for Domestic Pol'y, & Frank Raines, Director, Off. of Mgmt. & Budget, to the President of the United States (Oct. 2, 1996) (on file with author).

²⁵⁷ See Memorandum from Carol H. Rasco, Assistant to the President for Domestic Pol'y, to Thomas O'Donnell & Elizabeth E. Drye (Nov. 13, 1996) (on file with author). This practice was also used during the Reagan Administration. See Roger B. Porter & Mark Goldberg, Interview, *Roger B. Porter on How the White House Works*, BROOKINGS REV., Fall 1985, at 37, 39. According to Roger Porter, the Director for Reagan's Office of Policy Development, "We are in constant contact with departments and agencies and periodically will ask them—say, every three months or every six months—to provide us with a list of issues that they anticipate will require attention in the next three to six months." *Id.*

²⁵⁸ See, e.g., Letter from Jeremy D. Benami, Deputy Domestic Pol'y Adviser, Domestic Pol'y Council, to Claudia M. Rayford-Williams (Nov. 26, 1996) (on file with author).

²⁵⁹ Memorandum from Carol H. Rasco to Thomas O'Donnell & Elizabeth E. Drye, *supra* note 257.

²⁶⁰ See Eric Swank, *Clinton's Domestic Policy Makers: Big Business, Think Tanks, and Welfare Reform*, 2 J. POVERTY 55, 63 (1998) (noting that CEA was one of Clinton's important advisers regarding welfare reform based on "governmental flow charts and 'inside' reports that identified Clinton's closest domestic advisors").

over a matter.²⁶¹ Practically speaking, presidential brokers usually hold the pen on decision memos, framing the relevant issues and deciding how to incorporate feedback and comments from other executive branch actors. One regulatory context in which framing is especially salient, for example, is in debates regarding environmental regulatory tools.²⁶² When tools are market based, such as those calling for tradeable pollution permits, they often “emphasize the role of private actors” rather than government.²⁶³ This framing “separate[s] pollution from the underlying benefit of the activity that results in pollution generation” and, as a result, can increase support for such schemes.²⁶⁴

Returning to the welfare reform example, DPC played a critical framing role during the Clinton Administration. SSA had presented the relevant policy choices in terms of procedural fairness and had generated some options for consideration accordingly.²⁶⁵ One option, for example, relied on a “functional equivalence” test to determine by a standard format if a child’s disability rose to the level of one of the medical conditions on SSA’s listings.²⁶⁶ SSA believed this option would “better focus adjudicators on functional equals, clarify the process,” and allow “adjudicators to explain their decision in a standard format.”²⁶⁷ In a memo to the President coauthored with OMB, however, DPC framed the issue differently: The choice instead was a tradeoff between monetary cost savings and children now ineligible for disability benefits.²⁶⁸

DPC, however, disagreed with OMB on the right course of action. Although the memo laid out five analytically distinct options,²⁶⁹ OMB advocated for an approach less stringent than the understanding at the time of statutory enactment. The initial baseline at enactment would have rendered 190,000 children ineligible with cost savings of \$8.4 billion over six years.²⁷⁰ By contrast, OMB favored a rulemaking that would “limit the impact of tightened eligibility requirements on children with multiple physical impairments” and also “require [SSA] adjudicators to complete a standard form that will promote greater

²⁶¹ See Amos Tversky & Daniel Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 *SCIENCE* 453, 453 (1981) (explaining framing effects and implications for rational choice theory).

²⁶² See Jonathan Remy Nash, *Framing Effects and Regulatory Choice*, 82 *NOTRE DAME L. REV.* 313, 315 (2006).

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ See Memorandum from Brian Coyne to Diana Fortuna, *supra* note 251.

²⁶⁶ *Id.* at 2.

²⁶⁷ *Id.* at 3.

²⁶⁸ See Memorandum from Franklin D. Raines, Director, Off. of Mgmt. & Budget, & Carol H. Rasco, Assistant to the President for Domestic Pol’y, to the President of the United States 1 (Nov. 15, 1996) (on file with author).

²⁶⁹ See *id.* at 5–7.

²⁷⁰ *Id.* at 5.

uniformity”—options which had also been suggested and supported by SSA.²⁷¹ This OMB-favored option would result in 145,000 children losing benefits and would cost an additional \$2.4 billion.²⁷² DPC, however, wanted to go further to ease the standard for benefits. It recommended an approach that would provide “additional recognition of children with chronic or episodic illnesses” with an additional “assessment of children on the borderline.”²⁷³ This option would only result in 100,000 ineligible children but would cost \$4.2 billion more relative to the baseline.²⁷⁴ In this manner, DPC brokered a process resulting in the identification of multiple regulatory options framed in the manner it preferred.

White House policy councils also help drive the brokering process to reach legal conclusions, which can then determine which policy options are on or off the table. For this task, they usually work closely with the Office of White House Counsel alongside a “diffuse” number of other executive branch lawyers, including those from DOJ and agency general counsels’ offices.²⁷⁵ These deliberative efforts often enable presidents to pursue their policy priorities on the strongest legal footing.²⁷⁶ During its initial presentation of regulatory options, for example, SSA opined that

the most likely meaning based on SSA’s discussions with congressional staff as the bills were being drafted, and the one that is best supported by the conference agreement, is that a child’s impairment(s) will be disabling if it “meets,” “medically equals,” or “functionally equals” the severity of an impairment in our listings.²⁷⁷

After intra-executive branch debates, however, DPC reported to President Clinton that SSA had more legal flexibility to define childhood disability than expected, even though “Congress would undoubtedly view this [stance] as subverting their intent.”²⁷⁸ SSA was able to interpret child “impairment” in a way that struck “the right balance” between competing policy priorities, including those of the President.²⁷⁹ In this manner, DPC was deliberating with SSA and other EOP components

²⁷¹ *Id.* at 6–7.

²⁷² *Id.*

²⁷³ *Id.* at 6.

²⁷⁴ *Id.*

²⁷⁵ Daphna Renan, *supra* note 107, at 835 (detailing “diffuse” executive branch lawyers “talking shop” about legal and policy questions).

²⁷⁶ *See id.*

²⁷⁷ Memorandum from Brian Coyne to Diana Fortuna, *supra* note 251, at 2.

²⁷⁸ Annotated Memorandum from Carol H. Rasco & Frank Raines to the President of the United States, *supra* note 256, at 4.

²⁷⁹ *Id.*

about the scope of SSA's legal authority, while recognizing SSA's primary role in determining that scope.

Finally, in addition to helping determine the relevant legal issues, brokering also includes the ability to influence when and to whom to elevate an issue for a final decision.²⁸⁰ Elevation is often necessary when the members of a working group cannot agree on an issue or when that issue is so central to a president's agenda that it requires sign-off from someone at the highest levels of the EOP hierarchy.²⁸¹ Given the importance of welfare reform to the presidential agenda, DPC initially sought to elevate the decision to President Clinton himself, but it remains unclear from publicly available documents whether he personally weighed in.²⁸² Indeed, sometimes the threat of elevation alone can help those involved in brokering to reach a mutually satisfactory compromise.²⁸³ After further meetings and deliberation between the EOP and SSA, the approach eventually adopted was a hybrid of the OMB- and DPC-favored options as reflected in SSA's interim final rulemaking.²⁸⁴

In this manner, presidents can foster greater responsiveness from agencies through brokering led by White House policy councils. According to former Clinton DPC Director Bruce Reed, "We always describe it as an honest broker, but it isn't exactly that It's to force the government to deal with what the president wants to do, rather than force the president to do what the government wants to do."²⁸⁵ Brokering, in other words, can help the President influence the substance and timing of an agency's rulemaking agenda. Beyond legislatively or judicially mandated rules, agencies have substantial discretion over which rules to prioritize.²⁸⁶ Although the degree to which the White House succeeds

²⁸⁰ See Sunstein, *supra* note 8, at 1856–57 (describing how an "issue may be 'elevated,' which means that it has to be resolved at a higher level").

²⁸¹ See *id.* at 1857.

²⁸² See Memorandum from Franklin D. Raines & Carol H. Rasco to the President, *supra* note 268. Although this memo sought decisions from President Clinton, the record is unclear on whether he signed off on a particular approach; this particular memo, despite bearing signatures from Raines and Rasco, does not indicate any decisions. See *id.*

²⁸³ See William F. West, *The Institutionalization of Regulatory Review: Organizational Stability and Responsive Competence at OIRA*, 35 PRESIDENTIAL STUD. Q. 76, 86 (2005).

²⁸⁴ See Supplemental Security Income; Determining Disability for a Child Under Age 18, 62 Fed. Reg. 6408, 6411–18 (interim final rule Feb. 11, 1997) (to be codified at 20 C.F.R. pts. 404, 416).

²⁸⁵ *Developing Domestic Policy*, C-SPAN, at 1:25:06 (June 12, 2009), <https://www.c-span.org/program/public-affairs-event/developing-domestic-policy/207492> [<https://perma.cc/3EYV-SLQQ>].

²⁸⁶ See William F. West & Connor Raso, *Who Shapes the Rulemaking Agenda? Implications for Bureaucratic Responsiveness and Bureaucratic Control*, 23 J. PUB. ADMIN. RSCH. & THEORY 495, 504 (2013) (reporting that sixty percent of the rules and 52.5% of the significant rules in their sample were "agency initiatives"—that is, "at [the] agencies' discretion"); Coglianese & Walters, *supra* note 17, at 101 ("[A]round thirty-seven percent of all agency rules are legally required—that

in changing agency priorities remains an ongoing empirical debate,²⁸⁷ the available evidence is consistent with the observation that the White House is effective at shifting agency regulatory agendas, at least for a “small number of rules that administration officials consider to be the most significant ones.”²⁸⁸ Put differently, policy councils appear to successfully get agencies to prioritize the President’s highest priority rules.

Presidential brokering helps in this endeavor through multiple channels. First, the process usually involves high-level political appointees within the agencies.²⁸⁹ These political appointees help to drive agency priorities.²⁹⁰ Second, the costly nature of the brokering process also requires more resources from other actors such as career staff and policy analysts within the agency. Presidential brokering thus helps to shift agency agendas through the internal reallocation of agency resources. Finally, the deliberative nature of presidential brokering likely increases the internal legitimacy of the decisions reached. Through a process of mutual reason giving, rulemaking agencies who may otherwise bristle at presidential involvement are more likely to perceive the resulting decision as worthy of respect.²⁹¹

is, they are initiated in response to either legislative mandates . . . or court orders imposed on agencies without a clear underlying statutory source . . .”).

²⁸⁷ See Coglianese & Walters, *supra* note 17, at 109–10 (concluding that “it seems at a minimum premature at this time to conclude definitively that the presidency does not exert significant influence over agency agenda-setting”).

²⁸⁸ *Id.* (reporting that participants in an expert discussion “stressed that the White House will have much greater influence over a small number of rules that administration officials consider to be the most significant ones”). One interview-based study of political appointees at EPA, for example, found that more than sixty-one percent of respondents perceive that “White House involvement sometimes or often induced the agency to change its regulatory priorities.” See Bressman & Vandenbergh, *supra* note 6, at 77. In other words, more than a majority of respondents perceived that the White House succeeded in shifting the regulatory agenda, at least at one of the highest profile regulatory agencies. On the other hand, empirical work based on surveys from listed contacts in rules found that the White House had limited influence, though it is unclear the extent to which such contacts had visibility into discussions with the White House. See West & Raso, *supra* note 286, at 510–11 (“[R]ulemaking staff may not always be aware of communications between the White House and agency executives.”). Regardless, this study found that seven percent of the rules in its sample had been instigated as a result of presidential influence. *Id.* at 504.

²⁸⁹ See Selin et al., *supra* note 183, at 340 (“[E]xecutive agencies respond to presidential policy preferences by centralizing policymaking to the top of an agency’s hierarchy, placing regulation in the hands of political appointees.”); Bernstein & Rodríguez, *supra* note 245, at 1607–08, 1626 (reporting that “conversations with higher-placed appointees with larger policy purviews within their agencies” are a means for the President to communicate diffuse priorities).

²⁹⁰ See Selin et al., *supra* note 183, at 347 (“When the upper echelons of an agency’s hierarchy are involved in policy, an agency’s leadership can exert more control over the regulatory process.”).

²⁹¹ See Bernard Manin, *On Legitimacy and Political Deliberation*, 15 POL. THEORY 338, 352 (1987) (discussing how political decisions can be legitimized by more deliberative environments).

Beyond agency agenda setting, policy councils will also remain heavily involved after the agency submits the rule to OIRA for the regulatory review process.²⁹² Once OIRA receives the rule, OIRA will circulate it widely to other agencies as well as to other units of the EOP.²⁹³ This review process allows a broader group to review the entire draft rule rather than just the core policy choices.²⁹⁴ At this stage, however, large-scale changes are more difficult for rules that have been brokered in advance. Many of the actors reviewing the rule have already sunk substantial decision-making costs with “psychological commitments” to particular courses of action.²⁹⁵ According to former OIRA Administrator John Graham, revisiting central policy choices in draft rules “make[s] waves and bruise[s] egos, which means that they will be resisted, sometimes fiercely and effectively.”²⁹⁶ As a result, the review process is likely to proceed more quickly; empirical work suggests that this is indeed the case for the highest priority rules subject to brokering, at least when there is a confirmed OIRA Administrator.²⁹⁷

III. IMPLICATIONS

This Part now turns to a normative assessment of presidential brokering. The first Section evaluates some of the strengths and weaknesses of the practice in terms of fostering accountable, effective, and efficient regulatory policymaking. The second Section then considers potential reforms from the perspective of the President, Congress, and the courts. Among other things, it argues that the executive branch is best situated to enforce the ideal of honest brokering through OIRA but that Congress and the courts can reinforce exogenous incentives as well.

²⁹² See Sunstein, *supra* note 8, at 1854–55. Because the draft rule is likely to be deemed “significant” under the relevant executive orders as pertaining to presidential priorities, the agency is then likely to submit it to OIRA. See Exec. Order No. 12,866, 3 C.F.R. 638 (1994), *reprinted as amended* in 5 U.S.C. § 601 note (2018).

²⁹³ See Sunstein, *supra* note 8, at 1854.

²⁹⁴ See *id.* at 1854–55.

²⁹⁵ CURTIS W. COPELAND, CONG. RSCH. SERV., R40713, THE UNIFIED AGENDA: IMPLICATIONS FOR RULEMAKING TRANSPARENCY AND PARTICIPATION 5 (2009).

²⁹⁶ *Id.* (quoting John D. Graham, Adm’r, Off. of Info. & Regul. Affs., Remarks Prepared for Delivery to the National Economists Club (Mar. 7, 2002), <https://georgewbush-whitehouse.archives.gov/omb/legislative/testimony/graham030702.html> [<https://perma.cc/U3HX-S2XX>]).

²⁹⁷ See Bolton et al., *supra* note 12, at 249. It is also possible that this result stems from increased “informal” review of the rule as well, though the study’s authors take this possibility into account. See *id.* at 265. Informal review simply means that agencies share preliminary drafts of rules or cost-benefit analyses informally with OIRA in order to receive early input and feedback. See *id.* at 245 n.3. According to a 2001 annual OIRA congressional report, “This practice is useful for agencies since they have the opportunity to educate OIRA desk officers in a more patient way, before the formal 90-day review clock at OMB begins to tick.” OFF. OF INFO. & REGUL. AFFS., OFF. OF MGMT. & BUDGET, MAKING SENSE OF REGULATION: 2001 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 43 (2001).

A. *Evaluating Brokering*

1. *Strengths*

Insofar as presidential oversight provides a measure of accountability,²⁹⁸ one beneficial aspect of brokering is that it increases agency responsiveness in the ways described above. Debates over the legality of such agency influence by the President are long running, with competing claims of constitutional and statutory interpretation as to whether the President can displace the discretion afforded to agency heads by statute and, if so, when statutes should be read as congressional blessings to do so.²⁹⁹ While these debates will not be resolved here, brokering adds yet another reason to think that the line between presidential command and persuasion—which is thin in practice—is even thinner when a process exists to afford a sense of procedural legitimacy to the outcome reached.³⁰⁰ In other words, the White House can influence regulatory outcomes through means beyond simple direction or cajoling backed by the threat of removal.

Presidents, however, require more than agency responsiveness to promulgate regulations capable of withstanding legal challenge. They also need information.³⁰¹ And rulemaking, as discussed, imposes especially high demands.³⁰² Brokering improves the quality and effectiveness of regulatory policy by drawing upon the expertise of not only the rulemaking agency but also the EOP. Many components, such as CEA, are headed by subject-matter experts drawn from academia or elsewhere; these components are also served by experienced career staff with expertise as well as experience working with the relevant agencies.³⁰³ OMB too has a wealth of substantive and managerial experience, not only within OIRA, but also within its resource management

²⁹⁸ See Bernstein & Rodríguez, *supra* note 245, at 1605 (“Agency action is often regarded by judges and commentators as accountable only insofar as it can be directly controlled by the elected President.”).

²⁹⁹ See Kagan, *supra* note 10, at 2317; Kevin M. Stack, *The President’s Statutory Powers to Administer the Laws*, 106 COLUM. L. REV. 263, 264–67 (2006) (rejecting implicit presidential directive authority over agencies); Strauss, *supra* note 70, at 696–705 (arguing that presidential authority consists of oversight over agencies rather than directive authority).

³⁰⁰ See Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 25 (1995) (“[B]ecause of the general understanding that the President is in charge of the executive branch, agency heads will generally follow the President on matters of importance. Most likely, they will acquiesce in the President’s preference, even when that preference runs contrary to their own. In practice, then, the distinction between presidential influence and command might be thin indeed.”).

³⁰¹ See RUDALEVIGE, *supra* note 53, at 28–29, 35–36 (explaining centralization as a function of the “primacy of information” to the President and the President’s centralized need for “technical expertise”).

³⁰² See *supra* notes 167–77 and accompanying text.

³⁰³ See *supra* notes 134–36 and accompanying text.

offices.³⁰⁴ In addition, White House policy councils supplement their own expertise by hiring detailees: temporary employees drawn from administrative agencies.³⁰⁵

Beyond strengthening expertise, however, the President also needs a means of mitigating the cognitive biases that can influence expert judgment.³⁰⁶ The President, in other words, also requires a means of debiasing.³⁰⁷ This need is particularly acute for the White House: Its members are more likely than other units of the EOP to be subject to “groupthink,” the tendency of groups to breed conformity of thought.³⁰⁸ This phenomenon is most likely to arise in highly cohesive organizations operating under conditions of high stress.³⁰⁹ Many DPC and NEC staff begin their jobs early in an administration having just helped wage a campaign to win the presidency³¹⁰—dynamics which are especially prone to breeding a “hard-hearted” attitude toward outgroups.³¹¹ This group identity and coldness toward outsiders frequently privileges loyalty and morale above critical thinking.³¹²

Presidents are also called upon weekly, if not daily, to react to new political circumstances and exogenous events.³¹³ Such conditions of high stress and fast thinking further exacerbate now well-known behavioral

³⁰⁴ See Eloise Pasachoff, *The President's Budget as a Source of Agency Policy Control*, 125 YALE L.J. 2182, 2199–2201 (2016).

³⁰⁵ 3 U.S.C. § 112 (“The head of any department, agency, or independent establishment of the executive branch of the Government may detail, from time to time, employees of such department, agency, or establishment to the White House Office, the Executive Residence at the White House, the Office of the Vice President, the Domestic Policy Staff, and the Office of Administration.”); HART, *supra* note 5, at 43–44 (discussing the practice in which “EOP personnel were ‘detailed’ to the presidential staff from the departments and agencies”).

³⁰⁶ Cf. Itiel E. Dror, Bridget M. McCormack & Jules Epstein, *Cognitive Bias and Its Impact on Expert Witnesses and the Court*, JUDGES’ J., Fall 2015, at 8, 8 (surveying how “expert evidence may be influenced by contextual information and cognitive bias”).

³⁰⁷ See generally Christine Jolls & Cass R. Sunstein, *Debiasing Through Law*, 35 J. LEGAL STUD. 199 (2006) (detailing legal mechanisms to achieve debiasing).

³⁰⁸ See Irving L. Janis, *Groupthink*, PSYCH. TODAY, Nov. 1971, at 43, 44.

³⁰⁹ See *id.* at 43–44.

³¹⁰ See PATTERSON, *supra* note 16, at 77 (“Some of the domestic policy chiefs have come straight from the presidential campaign staff . . .”); see also, e.g., Kierra Frazier, *Trump Picks Former Gingrich Aide to Lead Domestic Policy Council*, POLITICO: INSIDE CONG. LIVE (Nov. 26, 2024, 9:02 PM), <https://www.politico.com/live-updates/2024/11/26/congress/trumps-domestic-agenda-00191823> [<https://perma.cc/T8KR-6U48>] (“President-elect Donald Trump has chosen his campaign speechwriter to lead his Domestic Policy Council.”).

³¹¹ Janis, *supra* note 308, at 43.

³¹² See *id.*

³¹³ See Paul C. Light, *Domestic Policy Making*, 30 PRESIDENTIAL STUD. Q. 109, 111 (2000) (arguing that domestic policy not only reflects the “president’s priorities” but also “works its will on presidents and the presidency[,] . . . shap[ing] the office even as the office seeks to shape it, whether by placing new issues on the agenda or bringing new participants to the fore, by creating short-term crises or breaking down existing coalitions”).

quirks, such as judgment errors through the use of simple heuristics,³¹⁴ status quo biases,³¹⁵ and other cognitive shortcuts.³¹⁶ While the temptation to make decisions “in house”—that is, without the involvement of agencies or the broader EOP—is strong, presidents have learned the hard way that their instincts must be tempered and tested by competing perspectives.³¹⁷ In the words of Egil Krogh, Nixon’s Domestic Council Assistant Director,

when the president is spoken to individually there’s risk, or when he sets up a unit on his own and tells them they can’t talk to anybody else—“You come up with it and go forward”—there’s risk. You need to have a system in place where you can bring to bear all the different points of view Otherwise, [the president is] out and he’s exposed and he can get into a terrible amount of trouble.³¹⁸

As a result, presidents and their advisers have come to appreciate Herbert Simon’s central insight that institutions can be designed to overcome human cognitive limitations.³¹⁹

By designing a process that encourages debate between the rulemaking agency and structurally distinct EOP units with jurisdictional overlap, such as NEC and CEA,³²⁰ the President is able to invite opposing perspectives and thus test the premises underlying regulatory options. The same is true for the White House Counsel and more insulated OMB General Counsel’s Office for legal arguments—or DPC and other policy-specific statutory units within the EOP, such as ONDCP. Presidents, in this manner, have discovered the value of agents that can provide opposing perspectives from an outsider’s point of view. Exposure to these conflicts can reduce the effects of many behavioral limitations, such as those arising from anchoring, confirmation, and hindsight biases.³²¹

³¹⁴ See Jolls & Sunstein, *supra* note 307, at 203–04.

³¹⁵ See *id.* at 205 (describing prospect theory, in which perspectives are biased toward an “initial reference point”).

³¹⁶ See *id.* at 204–06 (discussing hindsight bias, optimism bias, endowment effects, and framing effects).

³¹⁷ See ROGER B. PORTER, *PRESIDENTIAL DECISION MAKING* 241–42 (1980).

³¹⁸ Panel Discussion with James M. Cannon III, Bertram Carp, Egil Krogh, Roger Porter, Charles Walcott & Karen Hult, *in* *GOVERNING AT HOME*, *supra* note 35, at 108, 119.

³¹⁹ See SIMON, *supra* note 247, at 110–17.

³²⁰ See HART, *supra* note 5, at 50 (observing that the EOP “necessarily overlaps, second-guesses, and often conflicts with the work done in the departments and agencies”).

³²¹ See Jolls & Sunstein, *supra* note 307, at 204–06, 210.

2. Weaknesses

On the other side of the ledger, however, are a number of features that weaken core administrative law values. Perhaps most important, many of these dynamics are largely shielded from both public and congressional scrutiny, thus undermining accountability. In addition to the breadth of the deliberative process privilege under the Freedom of Information Act (“FOIA”),³²² the Supreme Court has also interpreted the statute so as not to cover the “Office of the President” and “the President’s immediate personal staff.”³²³ The D.C. Circuit, for its part, has further clarified that if the sole role of an entity within the EOP is to “advise and assist the President,” it is not covered.³²⁴ Under these principles, White House policy councils like DPC and NEC are generally not subject to FOIA.³²⁵

The records of such policy councils are also covered by the Presidential Records Act,³²⁶ which shields them from the public for at least five years after the conclusion of the presidency.³²⁷ Presidents have also historically claimed absolute immunity from congressional investigations for their “immediate advisors” who lack “statutory authority and instead act solely to advise and assist the President.”³²⁸ What limited precedent exists, however, suggests that courts will not accept such arguments absent illegitimate congressional purposes and national security concerns;³²⁹ nevertheless, the practice of invoking immunity can deter congressional oversight given the inevitable delays.

³²² 5 U.S.C. § 552.

³²³ *Kissinger v. Reps. Comm. for Freedom of the Press*, 445 U.S. 136, 156 (1980) (quoting H.R. REP. NO. 93-1380, at 15 (1974) (Conf. Rep.)).

³²⁴ *Meyer v. Bush*, 981 F.2d 1288, 1298 (D.C. Cir. 1993).

³²⁵ See David Cohen, Note, *FOIA in the Executive Office of the President*, 21 N.Y.U. J. LEGIS. & PUB. POL’Y 203, 226 & nn.158–59 (2018).

³²⁶ 44 U.S.C. §§ 2201–2209.

³²⁷ See *id.* §§ 2201, 2204. A number of exceptions, however, could potentially allow presidents to restrict public access for up to twelve years. See *id.* §§ 2201(2), 2204(a), 2204(b)(2)(A); NAT’L ARCHIVES & RECS. ADMIN., GUIDANCE ON PRESIDENTIAL RECORDS 2, <https://www.archives.gov/files/presidential-records-guidance.pdf> [<https://perma.cc/D88Q-MHDD>] (interpreting the Presidential Records Act to cover the “Office of Policy Development,” a precursor to DPC, and the “National Economic Council”).

³²⁸ TODD GARVEY, CONG. RSCH. SERV., LSB10301, LEGISLATIVE PURPOSE AND ADVISER IMMUNITY IN CONGRESSIONAL INVESTIGATIONS 5 (2019); see also PATTERSON, *supra* note 16, at 5 (observing a “strong tradition, rather strictly adhered to, that no persons serving in the White House are to appear before congressional committees and testify about their actions: nor do they, except in connection with criminal investigations . . . or allegations of wrongdoing that would create great political embarrassment for the White House if they refused to appear”).

³²⁹ See, e.g., Comm. on the Judiciary v. Miers, 558 F. Supp. 2d 53, 105 (D.D.C. 2008) (suggesting that qualified immunity may exist in some situations “involving national security or foreign affairs” or in situations “where Congress is not utilizing its investigatory authority for a legitimate purpose”).

Second, the sheer scale of policy-council responsibilities results in a large workload as well as information asymmetries that cannot be completely redressed through elevation. Presidents have often delegated broad portfolios to the policy councils.³³⁰ President Biden's recent domestic policy directive, for example, called for DPC to

lead interagency policy processes on a wide range of issues, including but not limited to those related to health care and public health; substance use disorders; racial equity and justice; gender equity and justice; criminal justice reform; native affairs; disability policy; LGBTQ+ policy; immigration; veterans; education; faith-based and community initiatives; gun policy and community safety; poverty reduction; domestic human trafficking; youth policy; disadvantaged and marginalized communities; labor and workforce development; the caregiving economy; agriculture; food security and nutrition; rural, suburban, and urban affairs; housing; strengthening American democracy; national service; the United States Postal Service; and the census.³³¹

These broad portfolios require substantial resources and make policy councils more difficult to monitor.

As for effectiveness, policy-council staff who lack previous government experience often face a steep learning curve regarding how to work productively with agencies.³³² These challenges are exacerbated by relatively high rates of turnover and the lack of career staff.³³³ Relatedly, presidential brokering in its current form also raises concerns about the efficiency of the process. Simply stated, the decision costs of the practice are extremely high.³³⁴ Convening committees and working groups requires time and resources, as does drafting informational or decision memoranda, preparing for deliberations, and elevating decisions. These decision costs, in turn, can also be exacerbated by the overlapping jurisdictions between DPC and NEC, as well as other components of the EOP.³³⁵

B. Reforms

In light of the normative concerns identified above, this Section considers some reforms to improve the practice of presidential

³³⁰ See, e.g., Domestic Policy Presidential Directive, *supra* note 38.

³³¹ *Id.*

³³² See Crump, *supra* note 55 (manuscript at 2) (describing “rapid turnover” at the Biden DPC).

³³³ See LEWIS, PRESIDENTIAL APPOINTMENTS, *supra* note 170, at 145, 184, 211.

³³⁴ See *supra* note 247 and accompanying text.

³³⁵ See *supra* notes 99–100 and accompanying text.

brokering from the perspective of presidents seeking to drive their regulatory agendas. It will then inquire into the ways in which Congress and the courts can better incentivize honest brokering within the executive branch.

1. President

To enhance accountability, presidents should continue to publicly promulgate domestic policy directives outlining the organization of DPC and NEC and their decision-making processes. Presidents have long issued such directives in the national security context, often on day one.³³⁶ A directive in the domestic policy context would likely increase confidence in government decision-making as well as provide much needed transparency. Should such directives omit important components of the EOP, for example, or otherwise not reflect the norms of honest brokering, they could be subject to public criticism. By emphasizing the importance of honest brokering, formal directives could help reinforce internal norms of fair process and the inclusion of relevant perspectives.³³⁷

Documents such as these can also help socialize White House staff and other political appointees—some of whom may be new to government—into the brokering process. Making these operating procedures public would also help sustain more consistency across administrations.³³⁸ These directives should additionally be supplemented by trainings provided by a statutory component of the EOP with institutional memory, such as OMB.³³⁹ On the whole, these directives would increase the accountability of the process as well as reduce decision costs by serving as a means of intra-executive branch coordination.

In addition, presidents could also consider issuing a directive specific to agency rulemaking—analogue to executive orders governing regulatory review. Such a directive would be an opportunity to articulate best practices to govern the relationship between regulatory policy development and review. Presidential brokering, as discussed, helps to inform and debias regulatory policymaking through a process often led by White House policy councils to advance the President's priorities

³³⁶ See PHILLIP J. COOPER, *BY ORDER OF THE PRESIDENT* 225 (2d ed. 2014) (observing that “one of the first orders of business in almost all administrations is to organize the [National Security Council]” and “define the administration’s preferred processes for developing” national security directives).

³³⁷ See, e.g., Domestic Policy Presidential Directive, *supra* note 38 (emphasizing the need for “coordinat[ion] through a systematic, evidence-driven process that will ensure that all major priorities are addressed, [and] the views of all relevant agencies are considered”).

³³⁸ See Walcott & Hult, *supra* note 214, at 310–11 (detailing issues in attempting to radically modify the EOP).

³³⁹ See PATTERSON, *supra* note 16, at 232–34 (emphasizing the need for training of new appointees).

and timing.³⁴⁰ Many of these goals are shared and also well-served by the OIRA-coordinated review process once the agency has drafted the rule.³⁴¹ The two processes, however, differ in ways that can result in organizational inefficiencies. Perhaps most importantly, while the policy-council-led process privileges presidential interests, regulatory review also considers whether the benefits of a rule justify its costs.³⁴²

Because it is easier to change course earlier in the policy development process rather than after the agency has drafted the rule and submitted it for review, the brokering process would benefit from some earlier attention to a rule's anticipated costs and benefits.³⁴³ Although the policy options may be too general to allow for detailed analyses, there is still value in seeking out preliminary information to help inform deliberations, as in the Clinton welfare-reform rulemaking discussed above.³⁴⁴ Memorializing those considerations for the policy process as it pertains to rulemaking could help facilitate the review that occurs later.

In addition, this directive could encourage early consultation with OIRA to ensure that the appropriate agencies are included in the policymaking process. The OIRA-coordinated review process, unlike the preceding policy process, usually features an OIRA career desk officer who helps determine in the first instance which agencies and units of EOP should get a draft of a rule.³⁴⁵ Sometimes, such career staff, by virtue of their longer experience in government or previous reviews, may identify equities in a particular agency that the initial policy coordination process may not have considered. For example, say DPC had brokered a high-profile FDA rulemaking regarding electronic cigarettes; those efforts may not have appreciated the implications of the rule on smoking cessation programs developed by the Department of Veterans

³⁴⁰ See *supra* Section III.A.1.

³⁴¹ See Sunstein, *supra* note 8, at 1838 ("One of OIRA's chief functions is to collect widely dispersed information—information that is held by those within the Executive Office of the President, relevant agencies and departments, state and local governments, and the public as a whole."); see also Revesz, *Regulatory Review*, *supra* note 11, at 134 ("OIRA's review . . . can . . . be[] harnessed to issue regulations more expeditiously, address biases of benefit-cost analysis, and promote the priorities of the sitting President.").

³⁴² See Exec. Order No. 12,866, 3 C.F.R. 638, 639 (1994), *reprinted as amended in* 5 U.S.C. § 601 note (2018) ("Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider."); *supra* notes 207–13 and accompanying text.

³⁴³ See CASS R. SUNSTEIN, *THE COST-BENEFIT REVOLUTION* 94–95 (2018).

³⁴⁴ See *supra* notes 248–84 and accompanying text.

³⁴⁵ See Sunstein, *supra* note 8, at 1854 ("Very soon after submission, the relevant OIRA desk officer—as noted, a member of the career staff—will generally circulate the rule to a wide range of offices and departments, both within the Executive Office of the President and outside of it."). Of course, the desk officer will usually honor all requests from political appointees to see a rule, but that initial circulation list is an exercise in discretion. See *id.* at 1855.

Affairs (“VA”) until the OIRA-coordinated review process. It would have been much more efficient, however, if DPC had included the VA in the policy process and benefited from their perspective from the start. Involving OIRA, at the very least as an observer, during the brokering process could also facilitate a more efficient review down the road.

Beyond the issuance of a domestic policy directive, the brokering process could also be improved by greater attention to and discipline with respect to regulatory prioritization. Because of the costly nature of brokering, presidents should deploy the strategy only for the rulemaking efforts in which it would produce the most procedural benefits. Those rules that are the most important to the President should be brokered by White House policy councils, while the remainder would still be subject to more limited oversight through the OIRA-coordinated review process.³⁴⁶ Although formal planning mechanisms for prioritization theoretically already exist, they are not effectively deployed in practice.³⁴⁷ By executive order, for example, the Vice President is called upon to convene an annual meeting of White House advisers and agency heads to set regulatory priorities for the year ahead,³⁴⁸ but it is unclear how often these meetings occur, if at all. In addition, agencies are required to publish their short- and long-term rulemaking plans in the Unified Agenda,³⁴⁹ but the document is usually incomplete, either for strategic or resource-related reasons.³⁵⁰ According to one former OIRA Administrator, however, the Unified Agenda “process itself has become more of a paper exercise than an analytical tool.”³⁵¹

³⁴⁶ For example, the OIRA review process only covers “significant” rules, which was an effort to make the process “more selective” as to which rules would undergo review. Katzen, *supra* note 203, at 105.

³⁴⁷ See Freeman & Rossi, *supra* note 55, at 1179 (“This planning process affords OIRA several opportunities to identify regulations that might implicate the jurisdiction or interests of other agencies, and to intervene to help ensure that such actions are consistent and coordinated. It is not clear, however, whether in practice OIRA spends significant resources on such tasks.”).

³⁴⁸ See Exec. Order No. 12,866, 3 C.F.R. 638, 642 (1994), *reprinted as amended in* 5 U.S.C. § 601 note (2018) (“Early in each year’s planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.”).

³⁴⁹ See Jennifer Nou & Edward H. Stiglitz, *Strategic Rulemaking Disclosure*, 89 S. CAL. L. REV. 733, 748–50 (2016). By statute and executive order, agencies are required to publish semiannual regulatory agendas. See *id.* Their entries usually include the agency’s name, a short description of the rule, the rule’s title, and the estimated rulemaking schedule. OIRA then circulates the Unified Agenda for intra-executive branch review, during which DPC and other EOP entities can comment and share concerns on the substance and timing of the rules. See *id.*

³⁵⁰ See *id.* at 765 (“[A]gencies substantially underreport their rulemaking activit[ies] . . .”); Coglianese & Walters, *supra* note 17, at 108 (“[I]t is clear that the *Unified Agenda* is itself not the locus of the most important decisionmaking within agencies and reflects only a partial snapshot of the totality of agencies’ ‘real’ regulatory agenda-setting.”).

³⁵¹ See Katzen, *supra* note 203, at 111.

Perhaps a more realistic approach is for presidents to task their chiefs of staff or other high-level managers with running a disciplined prioritization process during the transition period and at regular intervals afterward.³⁵² Although preparations for the State of the Union Address are a natural focusing event,³⁵³ special attention should be paid to this exercise of disciplined prioritization in the early months of the administration, given that it can take years to successfully promulgate a final rule.³⁵⁴ Such an effort should seek to identify only a very limited number of regulatory priorities per agency to allow for robust brokering and implementation.³⁵⁵ These efforts could complement more informal efforts to monitor agencies' regulatory agendas to identify opportunities that could further presidential goals. According to Roger Porter, one of Reagan's domestic policy advisors, the White House often develops these "early warning system[s]" with staff who "are in constant contact with departments and agencies."³⁵⁶ With this information in hand, the Chief of Staff could then continue to set priorities by "taking stock of the President's campaign promises[and] identifying current and prospective opportunities" through further discussions involving the OIRA Administrator, policy councils, and heads of agencies.³⁵⁷

Although some have proposed cost-benefit analysis as a method to inform priority setting,³⁵⁸ as a descriptive matter, presidents take into account a host of other considerations, including political ones.³⁵⁹ Given this broader set of considerations from the President's perspective, the process would also benefit from centralized input by important interest groups and constituencies.³⁶⁰ The most natural institutional home for such a task would likely be the White House Office of Public Liaison.³⁶¹

³⁵² See Dearborn, *supra* note 136, at 24 (describing the role of the Chief of Staff as fulfilling the need to "implement the President's agenda by setting priorities" for the White House Office); LIDDELL, *supra* note 61, at 190–91 (arguing that proposed regulations should be drafted during "Year Zero").

³⁵³ See Dearborn, *supra* note 136, at 30.

³⁵⁴ See TANGLIS, *supra* note 167, at 27.

³⁵⁵ See LIDDELL, *supra* note 61, at 190–91 (proposing that such efforts be limited to "three meaningful" priorities per agency to ensure execution and effective implementation).

³⁵⁶ Porter & Goldberg, *supra* note 257, at 39.

³⁵⁷ Dearborn, *supra* note 136, at 24.

³⁵⁸ See CASS R. SUNSTEIN, *THE COST-BENEFIT STATE* 139–40 (2002) (defending cost-benefit analysis as "an approach that attempts to assess the magnitude of problems and to ensure sensible priority setting").

³⁵⁹ See Stuart Shapiro, *Unequal Partners: Cost-Benefit Analysis and Executive Review of Regulations*, 35 ENV'T L. REP. 10,433, 10,442 (2005).

³⁶⁰ See LIGHT, *supra* note 159, at 136–39 (arguing that "three basic cost criteria act to screen policy alternatives: political, economic, and technical").

³⁶¹ See Joseph A. Pika, *The White House Office of Public Liaison*, 39 PRESIDENTIAL STUD. Q. 549, 550 (2009). This Office has sometimes been renamed and reorganized in different administrations. The Biden Administration, for example, renamed it the Office of Public Engagement.

That Office was originally created during the Nixon Administration “to formalize a set of staff responsibilities for working with interest groups that had been unsystematically scattered among staff members during [previous] presidencies.”³⁶² Although different presidents have used the Office in different ways, the Office could serve a more focused function by helping to identify public regulatory priorities through meetings, proactive outreach, and information gleaned from rulemaking petitions.³⁶³

Once these limited regulatory priorities have been identified, they should then be delegated to White House policy councils like DPC to help develop those policies through the brokering process. This effort should strongly limit the ability of individual DPC or NEC staff to advance their own rulemaking priorities without clear sign-off from the Chief or another high-level White House official. Setting these limits would reduce the likelihood that various EOP offices send agencies conflicting signals about priority rulemaking efforts.³⁶⁴ OIRA should also continue to play an important role in helping to ensure that presidential priority rulemakings are expedited during the review process.³⁶⁵

Finally, there is also an important part for the Chief of Staff to play in resolving the potential for jurisdictional overlap between DPC and NEC, as well as other components of the EOP. In the Reagan Administration, for example, the Chief of Staff “assign[ed] issues” when there was a “question in some people’s minds about whether an issue is primarily economic or primarily domestic or primarily foreign policy.”³⁶⁶ Although such overlap can sometimes be productive,³⁶⁷ turf battles are especially costly in the context of agency rulemaking given the sheer amount of time and resources at stake.

See *Office of Public Engagement*, THE WHITE HOUSE, <https://bidenwhitehouse.archives.gov/ope/> [<https://perma.cc/3GQE-LKTH>].

³⁶² Pika, *supra* note 361, at 550.

³⁶³ This proposal would be analogous to proposals to task OIRA with initiating rules based on rulemaking petitions, a proposal which may be limited due to OIRA’s institutional characteristics and role in regulatory review. See Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1382–83 (2013) (“OIRA can use information generated by private actors to identify areas where action is needed but where agencies have failed to move forward.”).

³⁶⁴ See Bressman & Vandenberg, *supra* note 6, at 68 (reporting that “[a]s many as nineteen White House offices were involved in EPA rule-making,” offices that “often were not on the same page”).

³⁶⁵ See Revesz, *Regulatory Review*, *supra* note 11, at 103.

³⁶⁶ Porter & Goldberg, *supra* note 257, at 38.

³⁶⁷ See Freeman & Rossi, *supra* note 55, at 1139 (“[O]verlapping delegations can produce positive goods by generating productive interagency competition and prompting agencies to produce ‘policy-relevant information.’” (footnote omitted)).

2. Congress

The account of presidential brokering offered here has emphasized the structures and processes within the presidency to help implement the President's highest regulatory priorities. Those structures include EOP units created by executive order as well as those established and designed by Congress to foster what it perceives as the longer-term interests of the office.³⁶⁸ Congress could potentially improve the presidential brokering process, however, by continuing to consider what kinds of information could benefit from relative insulation within the EOP and creating institutional homes for them. Recall that CEA was an effort by Congress to provide the President with relatively "detached, objective, scientific, and nonpolitical" economic advice in the wake of the economic turmoil introduced by the Great Depression and World War II.³⁶⁹ Since then, as mentioned above, Congress has also created a number of substantive units within the EOP that focus on issues such as drug policy, intellectual property enforcement, space, homeland security, cyber security, and pandemic preparedness.³⁷⁰ Given the important policy choices ahead regarding artificial intelligence, Congress might similarly consider seeking a means to build expertise within the EOP and provide advice to the President accordingly.³⁷¹

At the same time, Congress should continue to repeal or transfer units out of the EOP that are outdated or have proven ineffective over time. Indeed, Congress has a long history of doing so and has revisited dozens of units since the original establishment of the EOP.³⁷² For example, it established the National Council on the Arts in 1964 to assist the President with regard to the "growth and development" of arts and cultural resources, but later transferred this unit out of the EOP.³⁷³ In 1975, Congress also transferred out programs of the Office of Economic Opportunity that it had originally established within the EOP to provide education and training opportunities.³⁷⁴ The need for Congress to continue revisiting EOP units is especially important because each new component increases the coordination costs of the brokering process.

³⁶⁸ See *supra* text accompanying notes 41–44.

³⁶⁹ HART, *supra* note 5, at 52. As a result, Congress designed it to be headed by three presidentially appointed and Senate-confirmed members with statutory qualification requirements: They were to be "exceptionally qualified" by virtue of their "training, experience and attainments," which has traditionally meant that CEA members are drawn from academia. *Id.* at 51.

³⁷⁰ See *supra* notes 143–48 and accompanying text.

³⁷¹ See Diana Gehlhaus, *The Race for Data and AI Expertise in Government*, FED. NEWS NETWORK (Dec. 13, 2024, 10:28 AM), <https://federalnewsnetwork.com/commentary/2024/12/the-race-for-data-and-ai-expertise-in-government/> [<https://perma.cc/QHQ9-7DG8>] (discussing the need for greater artificial intelligence expertise in government).

³⁷² See RELYEA, *supra* note 100, at 25–28 (collecting examples).

³⁷³ *Id.* at 12.

³⁷⁴ See *id.* at 14.

Regardless of whether Congress establishes a unit within the EOP, however, the President still has “considerable freedom to use the component parts of the EOP in the manner he chooses, irrespective of the reason they were ordained in the first place, especially if he wants to ignore them.”³⁷⁵ In other words, presidents can always refuse to consider the advice of offices even if Congress places them within the EOP. OSTP, for example, saw its status “deteriorate[] rapidly” during the Nixon Administration, which displayed an “antipathy . . . toward scientists who were” viewed as “symbolic of the academic and intellectual community’s hostility toward” the Administration.³⁷⁶ As a result, OSTP saw its responsibilities diminished and was shut out of important meetings.³⁷⁷

Similarly, President Carter’s domestic policy staff purportedly “tried as much as possible to freeze OMB out of the process” regarding welfare-reform implementation efforts because they “knew [OMB was] going to oppose the plan.”³⁷⁸ Apparently, OMB was “concerned over its costs,” so DPC “wouldn’t always invite them to meetings.”³⁷⁹ President Reagan moved the statutory CEQ out to Jackson Place rather than keeping them in the Old or New Executive Office Buildings, which house most EOP staff.³⁸⁰ President Trump, during his first term, “all but ignored OSTP during his first [six] months in office, . . . excluding it from even a cursory role in formulating science-related policies and spending plans.”³⁸¹

The ideal of honest brokering, however, demands that these diverse perspectives are given an opportunity to be a part of the deliberations when relevant, even if the views are not ultimately adopted. In other words, the norm encourages conflicting perspectives to be presented and thoroughly debated. It is these opposing sources of information within the presidency that contribute to the expertise and debiasing of the political proclivities of the White House. The statutory offices established by Congress should thus be allowed to participate in the brokering process when their views are relevant, even if their particular concerns do not end up winning the day.

³⁷⁵ HART, *supra* note 5, at 49.

³⁷⁶ *Id.* at 98.

³⁷⁷ *See id.*

³⁷⁸ DANIEL E. PONDER, GOOD ADVICE 116 (2000).

³⁷⁹ *Id.*

³⁸⁰ *See* HART, *supra* note 5, at 92–93.

³⁸¹ Jeffrey Mervis, *Trump’s White House Science Office Still Small and Waiting for Leadership*, SCIENCE (July 11, 2017), <https://www.science.org/content/article/trump-s-white-house-science-office-still-small-and-waiting-leadership> [<https://perma.cc/LL9W-9DR8>] (“President Donald Trump has all but ignored OSTP during his first 6 months in office, keeping it small and excluding it from even a cursory role in formulating science-related policies and spending plans.”).

The OIRA-coordinated review process reinforces this ideal.³⁸² Once a rule is submitted to OIRA, the established practice is that all units within the EOP and other executive branch agencies presumptively get to have their say on it.³⁸³ Although views offered by these statutorily created EOP units may not prevail, they are at least aired for the rulemaking agency and other reviewers during the process. When these units submit comments, they can raise the decision costs by calling for responses and elevating issues when unsatisfactorily resolved.³⁸⁴ In this manner, OIRA-led review can serve as a means for Congress to ensure that the views of statutory EOP entities receive consideration during the rulemaking process. This conceptualization of OIRA-coordinated review may help explain congressional acquiescence to the review process as well as the protracted fight and eventual victory by Congress to subject the OIRA head to Senate confirmation.³⁸⁵

When a White House policy council cuts certain units out of the preceding policymaking process, however, that does not mean that these congressionally established components are without recourse. To use Margo Schlanger's terminology, these components resemble "[o]ffices of [g]oodness," which possess tools to exert influence even without formal authority.³⁸⁶ They are internal units within an agency, the EOP, whose role in the presidential policy process is advisory in nature and which are infused with values that can be orthogonal to the President's personal interests.³⁸⁷ Their placement within the EOP often gives them access to information that would be more difficult to access if housed in an external agency. Reagan's tactics notwithstanding,³⁸⁸ the individuals within these units are usually physically proximate to other members of the EOP, which includes them in informal networks that can yield intelligence as to when their views have been excluded. As a result, these statutory units can raise "fire alarms" with the public or congressional committees when their perspectives are cut out of the process.³⁸⁹ Even when presidents appoint sympathetic heads of these EOP components, these units also contain career staff who can similarly raise alarms.³⁹⁰

³⁸² See *supra* notes 207–13 and accompanying text.

³⁸³ See Sunstein, *supra* note 8, at 1840 (describing OIRA's role as an "information aggregator" across EOP entities and executive branch agencies).

³⁸⁴ See *id.* at 1854–59 (discussing OIRA's "internal process").

³⁸⁵ See Paperwork Reduction Reauthorization Act of 1986, Pub. L. No. 99-500, § 813, 100 Stat. 1783-335, 1783-336 (codified as amended at 44 U.S.C. § 3503).

³⁸⁶ Margo Schlanger, *Offices of Goodness: Influence Without Authority in Federal Agencies*, 36 CARDOZO L. REV. 53, 55, 60–61 (2014) (defining "[o]ffices of [g]oodness" as "advisory rather than operational," "value-infused," and "internal and dependent on their agency").

³⁸⁷ See *id.* at 60–61.

³⁸⁸ See *supra* text accompanying note 380.

³⁸⁹ Mathew D. McCubbins & Thomas Schwartz, *Congressional Oversight Overlooked: Police Patrols Versus Fire Alarms*, 28 AM. J. POL. SCI. 165, 166 (1984).

³⁹⁰ See, e.g., Kitrosser, *supra* note 130, at 1537; Nou, *supra* note 130, at 357.

Congress could bolster these fire alarms by imposing greater transparency requirements on presidential brokering. For example, Congress could enact a general requirement that agencies docket written comments from various components of the EOP or do so on a statute-specific basis.³⁹¹ Congress could also go further and require agencies to explain how they changed their rules in response to those comments and why.³⁹² The potential chilling effects of these measures on the robust deliberations that lie at the heart of presidential brokering, however, ultimately render them undesirable.

Alternatively, Congress could pursue other transparency-enhancing measures that better preserve the candor necessary for the deliberative process. For example, as it did for OIRA, Congress could threaten to defund the White House to pressure the White House into disclosing meetings with outside visitors.³⁹³ Such measures could, at a minimum, help to prevent regulatory capture as well as the appearance of it. Presidents currently disclose outside meetings with the White House inconsistently.³⁹⁴ When such meetings are disclosed, these visitor logs have been subject to criticism regarding their utility.³⁹⁵ Finally, congressional staff could also establish regular contacts with statutory units to stay apprised of the extent of these units' involvement—or lack thereof—in presidential decision-making and hold public hearings accordingly.³⁹⁶

3. Courts

Turning from Congress to the courts, the practice of brokering for the President's highest-priority rules bears on a number of doctrines functionally premised on the superior policymaking capacity of Congress as compared with the executive branch. The emergence of the

³⁹¹ See Nina A. Mendelson, *Disclosing "Political" Oversight of Agency Decision Making*, 108 MICH. L. REV. 1127, 1164 (2010) (suggesting these reforms in the context of a broader argument for disclosure of presidential oversight).

³⁹² See *id.*

³⁹³ See HAROLD C. RELYEA, CONG. RSCH. SERV., RL30590, PAPERWORK REDUCTION ACT REAUTHORIZATION AND GOVERNMENT INFORMATION MANAGEMENT ISSUES 12–15 (2007); Exec. Order No. 12,866, 3 C.F.R. 638, 648 (1994), *reprinted as amended in* 5 U.S.C. § 601 note (2018).

³⁹⁴ See Josh Dawsey & Nolan D. McCaskill, *White House Says It Won't Make Visitor Logs Public*, POLITICO (Apr. 14, 2017, 5:14 PM), <https://www.politico.com/story/2017/04/white-house-says-it-wont-make-visitor-logs-public-237235> [<https://perma.cc/B5C8-XH9C>].

³⁹⁵ See, e.g., Fred Schulte & Viveca Novak, *White House Visitor Logs Riddled with Holes*, CTR. FOR PUB. INTEGRITY (Apr. 13, 2011), <http://www.publicintegrity.org/2011/04/13/4115/white-house-visitor-logs-riddled-holes> [<https://perma.cc/T4N8-55LV>].

³⁹⁶ See, e.g., *Committee Holds Hearing on Political Influence on Government Climate Change Scientists*, HOUSE OF REPRESENTATIVES COMM. ON OVERSIGHT AND GOV'T REFORM DEMOCRATS (Jan. 30, 2007, 12:56 PM), <https://oversightdemocrats.house.gov/legislation/hearings/committee-holds-hearing-on-political-influence-on-government-climate-change> [<https://perma.cc/87TK-XGD5>].

major questions doctrine, for example, has called for judges to apply a heightened degree of scrutiny to what are most likely to be presidentially brokered rules.³⁹⁷ Under this doctrine, the Supreme Court requires a clear statement from Congress authorizing an agency action of “economic and political significance.”³⁹⁸ In recent cases, however, the Supreme Court has emphasized the political over the economic dimensions of agency action.³⁹⁹ As described by Justice Gorsuch, politically significant rules are those that implicate an “earnest and profound debate across the country,” including debates in state legislatures and Congress⁴⁰⁰—circumstances in which White House policy councils are most likely to become involved.

For those rules, judges apply what amounts to a substantive presumption that Congress did not delegate the requisite authority to the executive branch.⁴⁰¹ In Chief Justice Roberts’s words, courts are to “presume that ‘Congress intends to make major policy decisions itself, not leave those decisions to agencies.’”⁴⁰² As a result, the presidential brokering process must yield an especially compelling legal showing that the agency has the statutory authority to promulgate the rule at hand. The Court’s justifications for this doctrine have shifted over time, but one prominent rationale offered by Justice Gorsuch arises in part from the need for judges to engage in constitutional avoidance.⁴⁰³ Under this rationale, statutory grants of agency power to decide “major questions” are more likely to run afoul of nondelegation concerns; thus, judges should strive to interpret such statutes so as not to grant what amounts to legislative power absent a clear indication from Congress.

On Gorsuch’s account, the Constitution designed a lawmaking process—bicameralism and presentment—“requiring a broad consensus to pass legislation . . . to ensure that any new laws would enjoy wide social acceptance[and] profit from input by an array of different

³⁹⁷ See Short & Shugerman, *supra* note 30, at 514 (“The doomed [major questions doctrine] policies were promulgated by agencies linked to presidents with formal supervisory power who directed, actively supported, and took public responsibility for those agencies’ key policy decisions.”).

³⁹⁸ *West Virginia v. EPA*, 597 U.S. 697, 716 (2022) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)).

³⁹⁹ See Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009, 1051–56 (2023).

⁴⁰⁰ *West Virginia v. EPA*, 597 U.S. at 743 (Gorsuch, J., concurring) (quoting *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006)).

⁴⁰¹ See *id.* at 723 (majority opinion).

⁴⁰² *Id.* (quoting *U.S. Telecom Ass’n v. FCC*, 855 F.3d 381, 419 (D.C. Cir. 2017) (Kavanaugh, J., dissenting)).

⁴⁰³ See *Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab.*, 595 U.S. 109, 124 (2022) (Gorsuch, J., concurring) (arguing that “the major questions doctrine is closely related to what is sometimes called the nondelegation doctrine”); *West Virginia v. EPA*, 597 U.S. at 737 (Gorsuch, J., concurring) (“In Article I, ‘the People’ vested ‘[a]ll’ federal ‘legislative Powers . . . in a Congress.’” (alterations in original) (first quoting U.S. CONST. pmbl.; and then quoting *id.* art. I, § 1)).

perspectives during their consideration.”⁴⁰⁴ In other words, Gorsuch praised the ability of the legislative process to foster wide support, garner democratic legitimacy, and incorporate diverse perspectives. The Court, however, rarely acknowledges the role of the President in cases involving major questions⁴⁰⁵—let alone the ways in which presidential brokering serves many of the same goals that Gorsuch identifies with congressional policymaking.⁴⁰⁶

Presidential brokering, for example, exhibits public support and features of democratic legitimacy. As Justice Breyer’s dissent in *FDA v. Brown & Williamson Tobacco Corp.*⁴⁰⁷ put it,

Presidents, just like Members of Congress, are elected by the public. Indeed, the President and Vice President are the *only* public officials whom the entire Nation elects. I do not believe that an administrative agency decision of this magnitude—one that is important, conspicuous, and controversial—can escape the kind of public scrutiny that is essential in any democracy. And such a review will take place whether it is the Congress or the Executive Branch that makes the relevant decision.⁴⁰⁸

In other words, if one purpose of the major questions doctrine is to ensure politically accountable policy decisions, then the President too is an important source that the Court has yet to acknowledge in this context.

Next, presidential brokering, like the lawmaking process in Congress, also seeks to “profit from input by an array of different perspectives.”⁴⁰⁹ Although these perspectives are not the same as those that arise from bicameralism, they are arguably superior along some dimensions, including fostering greater expertise. Brokering, as discussed, is a procedural mechanism for surfacing and incorporating diverse, expert views from the rulemaking agency and different components within the EOP.⁴¹⁰ By contrast, when Congress considers a bill that implicates overlapping committees, a referring parliamentarian grants jurisdiction over that bill to one of the committees,⁴¹¹ with limited coordination or

⁴⁰⁴ *West Virginia v. EPA*, 597 U.S. at 738 (Gorsuch, J., concurring).

⁴⁰⁵ See Short & Shugerman, *supra* note 30, at 569 (“Many of the core [major questions doctrine] cases do not even mention the President.”).

⁴⁰⁶ See *West Virginia v. EPA*, 597 U.S. at 738 (Gorsuch, J., concurring) (“[T]he framers deliberately sought to make lawmaking difficult by insisting that two houses of Congress must agree to any new law and the President must concur or a legislative supermajority must override his veto.”).

⁴⁰⁷ 529 U.S. 120 (2000).

⁴⁰⁸ *Id.* at 190–91 (Breyer, J., dissenting).

⁴⁰⁹ *West Virginia v. EPA*, 597 U.S. at 738 (Gorsuch, J., concurring).

⁴¹⁰ See *supra* Section II.B.

⁴¹¹ See DAVID C. KING, *TURF WARS* 37–39 (1997) (“Precedent-setting referral decisions are made by the House and Senate parliamentarians routinely . . .”).

consultation thereafter.⁴¹² Congress's permanent bureaucracy can provide more policy support, but the main institutions for doing so, such as the Congressional Research Service and Government Accountability Office, are not subject-matter specific in the same way as some of the statutory components of the EOP.⁴¹³

As such, the rise of presidential brokering arguably helps to ameliorate the major questions doctrine's functional concerns with political accountability and deliberative expertise-based policymaking.⁴¹⁴ These considerations may not sway more formalist defenders of the doctrine such as Justices Gorsuch and Thomas.⁴¹⁵ Nevertheless, the future of the major questions doctrine remains in doubt after the Court's recent decision in *Loper Bright Enterprises v. Raimondo*,⁴¹⁶ overturning *Chevron*'s⁴¹⁷ call for judges to grant deference to reasonable agency interpretations of ambiguous statutes.⁴¹⁸ *Chevron* itself celebrated the President's influence on agencies as a legitimizing source of political accountability.⁴¹⁹ Critics, however, argued that *Chevron* encouraged interpretive "aggressiveness on a large scale," including from the "White House," which often went unchecked by judges.⁴²⁰

⁴¹² See *id.* at 139 (describing "Congress's scattered approach to policymaking" as "often unfocused and uncoordinated"). King observes, however, that coordination may be improving through sequential referrals. See *id.* at 144.

⁴¹³ See Jesse M. Cross & Abbe R. Gluck, *The Congressional Bureaucracy*, 168 U. PA. L. REV. 1541, 1624 (2020) (noting that the Congressional Research Service and Government Accountability Office "provide the most direct substantive policy support . . . [and] may produce policy reports that Congress can use as it wishes").

⁴¹⁴ See Short & Shugerman, *supra* note 30, at 590 ("The democratic deficit argument falls flat, however, when the agency has acted at the direction of the President.").

⁴¹⁵ See, e.g., *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 487 (2001) (Thomas, J., concurring) ("I believe that there are cases in which the principle is intelligible and yet the significance of the delegated decision is simply too great for the decision to be called anything other than 'legislative.'").

⁴¹⁶ 603 U.S. 369 (2024).

⁴¹⁷ *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984), *overruled by Loper Bright*, 603 U.S. 369.

⁴¹⁸ See *id.* at 865–66. The *Chevron* two-part test called for the judge, first, to ask "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If Congress's intent is "clear," then that intention governs; but if the statute is ambiguous or silent, then judges next ask whether the agency's interpretation is reasonable or "permissible" and, if so, defer accordingly. *Id.* at 842–43.

⁴¹⁹ See *id.* at 865–66 ("While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices—resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.").

⁴²⁰ See Brett M. Kavanaugh, *Keynote Address: Two Challenges for the Judge as Umpire: Statutory Ambiguity and Constitutional Exceptions*, 92 NOTRE DAME L. REV. 1907, 1911 (2017) ("[T]he *Chevron* doctrine encourages agency aggressiveness on a large scale. Under the guise of

Loper Bright, by contrast, calls for judges to exercise “independent judgment”⁴²¹ using the “traditional tools of statutory construction.”⁴²² One such tool is the continued granting of *Skidmore*⁴²³ weight to agency interpretations according to their “power to persuade.”⁴²⁴ Under this canon, interpretations are more likely to be persuasive the more “thorough[],” “valid[],” and “consisten[t]” they are, along with any other persuasive factors.⁴²⁵ In addition, *Loper Bright* endorsed the idea that Congress can constitutionally delegate interpretive authority to an agency.⁴²⁶ According to the *Loper Bright* Court, Congress can “authorize[]” agencies to “exercise a degree of discretion” by granting rulemaking authority to fill gaps⁴²⁷ or to regulate pursuant to a term that “leaves agencies with flexibility.”⁴²⁸

By identifying other indicia of congressional intent to delegate beyond “express” or clear delegations, *Loper Bright* could be read as softening the major questions doctrine’s professed search for clarity, perhaps in favor of a return to an older version that relied more heavily on the ordinary tools of construction rather than operating as a substantive presumption.⁴²⁹ Under this approach, a rule’s political and economic significance could simply be understood as important “contextual” factors in determining whether there has been an implicit delegation to the agency, as Justice Barrett has argued in a recent concurring opinion.⁴³⁰ As Thomas Merrill notes, the major questions doctrine is also inconsistent with *Loper Bright*’s approach to interpreting the Administrative Procedure Act (“APA”),⁴³¹ which looked to case law preceding the statute’s enactment to shed light on its meaning.⁴³² Simply put, the “major questions doctrine has no analog in pre-APA decisional

ambiguity, agencies can stretch the meaning of statutes enacted by Congress to accommodate their preferred policy outcomes. I saw this first-hand when I worked in the White House . . .”).

⁴²¹ *Loper Bright*, 603 U.S. at 394 (“The [Administrative Procedure Act], in short, incorporates the traditional understanding of the judicial function, under which courts must exercise independent judgment in determining the meaning of statutory provisions.”).

⁴²² *Id.* at 401 (“The very point of the traditional tools of statutory construction . . . is to resolve statutory ambiguities.”).

⁴²³ *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

⁴²⁴ *Id.* at 140; see also Thomas W. Merrill, *The Demise of Deference—and the Rise of Delegation to Interpret?*, 138 HARV. L. REV. 227, 228–29, 253 (2024) (remarking that “*Loper Bright* makes clear that independent judgment includes three substantive canons of interpretation that apply when a court is reviewing an agency interpretation,” including *Skidmore* weight).

⁴²⁵ Merrill, *supra* note 423, at 253 (quoting *Skidmore*, 323 U.S. at 140).

⁴²⁶ See *Loper Bright*, 603 U.S. at 394–95.

⁴²⁷ *Id.* at 394.

⁴²⁸ *Id.* at 395 (quoting *Michigan v. EPA*, 576 U.S. 743, 752 (2015)).

⁴²⁹ See Merrill, *supra* note 423, at 270–71 (noting that “it is conceivable that the *Loper Bright* regime could, in time, supersede the major questions doctrine”).

⁴³⁰ See *Biden v. Nebraska*, 600 U.S. 477, 514–15 (2023) (Barrett, J., concurring).

⁴³¹ 5 U.S.C. §§ 551–559, 701–706.

⁴³² See Merrill, *supra* note 423, at 240.

law, which would suggest . . . that the major questions doctrine violates the APA.”⁴³³ For all these reasons—doctrinal and functional—the major questions doctrine should abandon its substantive presumption and instead merge into *Loper Bright*’s call for judges to engage in independent statutory interpretation.

In addition, even when judges have determined the scope of an implicit delegation, *Loper Bright* makes clear that judges still have a role to play in ensuring that the agency has engaged in “reasoned decisionmaking.”⁴³⁴ In other words, as under *Chevron*, judges must still undertake an inquiry into whether the agency’s decision is adequately supported. Judicial application of *Loper Bright* thereby increases the motivation for executive branch lawyers to deliberate over the “best” reading of the statute and to ensure that the discretion exercised remains reasonable.⁴³⁵ Relative to the *Chevron* regime, it is now more risky for White House lawyers to simply pick between a range of interpretive possibilities without deliberating with agency general counsels and other EOP lawyers in search of a defensible “point estimate.”⁴³⁶ Purely presidential interests are thus more likely to be tempered by the views of a broader array of lawyers within the executive branch amid the need to now provide a stronger justification for them.

Similar incentives also exist for policy decisions that fall within the bounds of a statute thanks to the development of “hard look” review under the APA’s arbitrariness standard.⁴³⁷ Under this approach, agencies are required to show that they have “examine[d] the relevant data and [then] articulate a satisfactory explanation for [their] action[s].”⁴³⁸ These explanations must demonstrate “rational connection[s] between the facts found and the choice[s] made.”⁴³⁹ This obligation has been supplemented by other doctrines providing that a court will only uphold an agency’s decision on the grounds that an agency originally acted on, as opposed to those grounds introduced as post hoc litigating positions.⁴⁴⁰ As a result, these prospects similarly help to bolster the White House’s incentives to debias and test the basis for its policy choice through honest brokering.

Should arbitrariness review more directly enforce the ideal of honest brokering by taking notice of deficiencies in the brokering

⁴³³ *Id.* (footnote omitted).

⁴³⁴ *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)).

⁴³⁵ *See id.* at 400 (“It therefore makes no sense to speak of a ‘permissible’ interpretation that is not the one the court, after applying all relevant interpretive tools, concludes is best.”).

⁴³⁶ E. Donald Elliott, *Chevron Matters: How the Chevron Doctrine Redefined the Roles of Congress, Courts and Agencies in Environmental Law*, 16 VILL. ENV’T L.J. 1, 11 (2005).

⁴³⁷ *See* 5 U.S.C. § 706(2)(A).

⁴³⁸ *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

⁴³⁹ *Id.* (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

⁴⁴⁰ *See SEC v. Chenery Corp.*, 318 U.S. 80, 87–88 (1943).

process? Under this potential approach, evidence that a policy council had not engaged in honest brokering might help inform the court's evaluation of the agency's policy rationale. If that process excluded agencies or EOP components with relevant expertise, for example, the resulting agency rule may not be deemed per se arbitrary, but that evidence may nevertheless inform the court's independent evaluation of the policy justification. A version of this approach was arguably on display during lower courts' consideration of President Trump's first-term executive order that imposed a ninety-day entry ban on nationals of seven majority-Muslim countries.⁴⁴¹

One of the initial complaints in the litigation alleged that the executive order "did not arise out of the usual process of consulting with the relevant cabinet-level officials and agencies" but was instead "primarily drafted by a small team of Presidential aides, overseen by chief White House strategist Stephen K. Bannon."⁴⁴² The district court accordingly found that the order "did not involve traditional interagency review by relevant departments and agencies."⁴⁴³ Upon appeal in a related action, the Ninth Circuit also emphasized the lack of an "interagency" process in concluding that the President did not make a required legal finding.⁴⁴⁴ Analogously, one could argue that courts should take notice of the lack of brokering as context through which to evaluate an agency's justification under arbitrariness review.

There are multiple problems, however, with this approach in the rulemaking context. The first is that deficiencies in the brokering process will rarely come to light to inform judicial review. As discussed earlier, the process is highly opaque due in part to the limited coverage of FOIA and its exemptions.⁴⁴⁵ Moreover, White House communications with agencies generally need not be disclosed in rulemaking records.⁴⁴⁶ Although such information may become available to the public through leaks and other channels, it will not reliably be available for courts to evaluate. Second, this doctrinal innovation would also be in some tension with *Vermont Yankee Nuclear Power Corp. v. Natural Resources*

⁴⁴¹ See, e.g., *Int'l Refugee Assistance Project v. Trump*, 241 F. Supp. 3d 539, 545 (D. Md. 2017), *aff'd in part, vacated in part*, 857 F.3d 554 (4th Cir. 2017), *vacated*, 583 U.S. 912 (2017); see also Exec. Order No. 13,769, 3 C.F.R. 272 (2018).

⁴⁴² Complaint for Declaratory and Injunctive Relief at 15, *Int'l Refugee Assistance Project*, 241 F. Supp. 3d 539 (No. 17-cv-00361).

⁴⁴³ *Int'l Refugee Assistance Project*, 241 F. Supp. 3d at 545.

⁴⁴⁴ *Hawaii v. Trump*, 859 F.3d 741, 756 (9th Cir. 2017) (per curiam), *vacated*, 583 U.S. 941 (2017); see also Renan, *supra* note 214, at 2259 (characterizing this approach as an indirect approach to enforcing deliberative norms).

⁴⁴⁵ See *supra* notes 322–25 and accompanying text.

⁴⁴⁶ See *Sierra Club v. Costle*, 657 F.2d 298, 408–09 (D.C. Cir. 1981) (holding that ex parte communications with the President or presidential staff during informal rulemaking is permissible and need only be docketed if the agency relies on factual support provided during such communications).

Defense Council, Inc.,⁴⁴⁷ which forbids courts from requiring more process from agencies than that demanded by statute.⁴⁴⁸ If courts were to key arbitrariness determinations to the quality of the deliberations that a rulemaking agency had with the White House, then courts risk running afoul of this prohibition.

For these reasons, courts should continue to engage in substantive evaluation of agencies' legal and policy justifications to indirectly encourage the norm of honest brokering. Although Congress and the courts have an important role to play in providing exogenous incentives, the direct enforcement of the ideal by White House policy councils may best be left to the executive branch—specifically, more independent actors like OIRA whose role during regulatory review has been to facilitate the inclusion of intra-executive branch viewpoints that may have otherwise been excluded during the preceding policy process.

CONCLUSION

This Foreword has sought to understand how the President organizes the presidency to advance domestic regulatory policy. In doing so, it has foregrounded a set of centralized bodies beyond OIRA. One of its contributions has been to shed light on structural variations within the EOP, why they matter, and how they likely affect the President's decision to delegate the authority to coordinate policy. Appreciating these institutional differences can enrich both positive and normative debates about centralization in the rulemaking context.

Many research questions, of course, remain: What explains structural variations not only between various parts of the EOP, but also over time? Do they reflect partisan dynamics between the President and Congress, or can they be better explained by information-based theories? How many rules are involved in the presidential brokering process and in what ways are they treated differently during the review process? Which units within the EOP are more influential than others at both stages?

On the heels of another recent presidential transition, this Foreword has argued that more attention is owed to the design, structure, and internal processes of the presidency as a core part of the administrative state. Such matters should be front and center of any administration eager to wrest control over domestic regulatory policy as well as for those eager to provide more checks on the White House. Presidential power, in this view, lies not only in the interstices between the President and administrative agencies but also between the President and the presidency.

⁴⁴⁷ 435 U.S. 519 (1978).

⁴⁴⁸ See *id.* at 524–25.

Administrative Law as a Choice of Business Strategy: Comparing the Industries Who Have Routinely Sued Their Regulators with the Industries Who Rarely Have

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ABSTRACT

For some large and powerful industries, it has long been normal and even routine for businesses to sue their federal regulator. For other large and powerful industries, it has been rare for the last twenty-five to forty years or more. This variation is enormous yet almost entirely unknown to the literature on administrative law.

This Article documents and analyzes this variation in one type of federal regulation: public health and safety. For every major federal health-and-safety regulator, I search dockets to identify every judicial challenge to the agency's actions brought by the agency's principal regulated industry—whether by individual companies therein or by trade associations—during the period from 2013 to 2021 and, for several of the agency-industry pairings, for additional time periods extending as far back as the 1980s and as recent as 2024. The pairings covered are the following: the Food Safety and Inspection Service at the U.S. Department of Agriculture and meat and poultry processors; the Food and Drug Administration and drugmakers; the National Highway Traffic Safety Administration and automakers; the Federal Aviation Administration and airlines; the Consumer Product Safety Commission and children's product companies; the Nuclear Regulatory Commission and nuclear plant operators; the Occupational Safety and Health Administration and employers generally; the Mine Safety and Health Administration and coal mines; the Environmental

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Protection Agency and power companies; the Federal Motor Carrier Safety Administration and for-hire trucking companies; and the Centers for Medicare and Medicaid Services and hospitals and nursing homes. For each pairing, I use the data on judicial challenges as the starting point for a qualitative discussion of how big or small a role litigation plays in agency-industry interaction.

I find that industry judicial challenges tend to be few and marginal when two conditions are met. The first condition is that companies in the industry have a thick relationship with the regulator—that is, each company knows the regulator will be making repeat decisions impacting its business into the indefinite future, so each company has a stake in winning the agency’s trust and goodwill. The second condition is that, with regard to the agency action at issue, industry economic interests are aligned with the mission of the regulator. This is especially the case for agency action that has the official purpose of protecting the health and safety of the industry’s own consumers, as opposed to protecting industry workers or victims of externalities of industry conduct. In protection of consumer health and safety, the industry and the regulator are more likely to view each other as on the “same team,” and industry tends to (1) see the regulator as a source of credible guarantees that help attract business, (2) fear the “bad look” with consumers that conflict with the regulator could cause, and (3) seek influence and leverage over the agency by less open and adversary means than litigation.

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INTRODUCTION

In the field of administrative law, scholars tend to focus, first and foremost, on judicial review of agency action. In that sense, the

field's dominant thinking is simpatico with the "adversarial legalism" that Robert Kagan identified as "the American way of law"—a lawyer-dominated style of interaction between government and private actors, of which litigation challenging agency action is the archetype.¹ Those studying administrative law typically examine judicial review by analyzing the reasoning and outcomes of the cases that reach the courts. But remarkably little attention is paid to the question of whether and how disputes between private actors and agencies make their way to court in the first place.

This Article takes up that question with regard to federal regulatory agencies and regulated businesses. For some large and powerful industries, it has long been normal, and even routine, for businesses to sue their regulator. But for other large and powerful industries, it has been rare for the last twenty-five to forty years or more.

This variation is enormous, yet in the academic literature it is almost unknown—let alone explained. There are, of course, many studies that consider variation among agencies by analyzing published judicial opinions, often comparing litigation win rates across agencies.² Although those studies are important for understanding *courts'* decision-making about matters that parties choose to litigate to judgment, they do not directly address the question of which parties go to court and reach that point. Indeed, studies of published opinions *cannot* speak much to that question, because many cases that are brought against agencies end up settling and never become published opinions.³

There are just a few pioneering studies of whether and when businesses bring judicial challenges against agencies to begin with. Their authors, seeking to learn what cannot be known from published opinions, rely on sources like court docket filings, surveys, and interviews. Although each of these studies does much to illuminate the agency and industry that it analyzes, all except two of these studies are confined to one agency and one industry, and they do not employ comparative analysis to document or account for variation across industries.⁴

¹ ROBERT A. KAGAN, *ADVERSARIAL LEGALISM: THE AMERICAN WAY OF LAW* 218–19 (2d ed. 2019).

² For a review of agency win-rate studies, see Bethany A. Davis Noll, "Tired of Winning": *Judicial Review of Regulatory Policy in the Trump Era*, 73 *ADMIN. L. REV.* 353, 377–79 (2021).

³ That settlements are common in suits to review agency action is noted in some of the few studies that have focused on decisions whether to sue. PATRICK SCHMIDT, *LAWYERS AND REGULATION* 101–02 (2005) (discussing rulemaking litigation at the Environmental Protection Agency ("EPA") and the Occupational Safety and Health Administration ("OSHA")).

⁴ See Cary Coglianese, *Litigating Within Relationships: Disputes and Disturbance in the Regulatory Process*, 30 *LAW & SOC'Y REV.* 735, 741 (1996) (EPA rulemakings under the Resource Conservation and Recovery Act in 1988–1990, based on D.C. Circuit filings, comments to EPA, and interviews); Isaac Unah, *Explaining Corporate Litigation Activity in an Integrated Framework on Interest Mobilization*, 5 *BUS. & POL.* 65, 69 (2003) (denials of import relief petitions by the International Trade Commission and Department of Commerce, based on surveys of companies

The two exceptions are both recent. One is an article by Libby Dimenstein, Donald L.R. Goodson, and Tyler Szeto, assembling important data on the rates at which major rules of eighteen agencies were challenged over the period of 1996–2021. But the authors discuss these rates only as a brief part of a larger (and impressive) study focused mainly on other, more downstream aspects of rulemaking litigation.⁵

The other exception is David Zaring’s article about how banking regulation stands apart from adversarial legalism and employs a model of public-private collaboration resonant with defense contracting and public utility law.⁶ There, Zaring contrasts the rarity of suits against banking regulators with the frequency of those against the Environmental Protection Agency (“EPA”).⁷ Zaring’s proof of concept that federal regulatory agencies need not fit the adversarial-legalist paradigm has inspired me to look across the firmament of federal regulators to see which of them do and do not fit the paradigm—and to see what we might learn from an even more expansive set of comparisons.

To systematically document variation in court challenges to federal regulators across industries,⁸ this Article draws upon a dataset that I built

who faced denials in 1990–1995); SCHMIDT, *supra* note 3, at 96–136, 173, 182, 223–28 (OSHA rulemakings and enforcement proceedings, based on surveys, interviews, and OSHA rulemaking dockets from the 1990s); Scott Graves, *Congress, Litigants, and Judicial Review of Bureaucracy: A Competing Risks Model of Administrative Case Terminations* 13 (Conf. on Empirical Legal Stud., Univ. of Tex., 2006), papers.ssrn.com/sol3/papers.cfm?abstract_id=913840 [<https://perma.cc/C9CE-XVU4>] (focusing on Consumer Product Safety Commission (“CPSC”) enforcement proceedings in 1973–1984, based on agency reports); Wendy Wagner, *Revisiting the Impact of Judicial Review on Agency Rulemakings: An Empirical Investigation*, 53 WM. & MARY L. REV. 1717, 1735–38 (2012) (EPA rulemakings on hazardous air pollutants in 1994–2009, based on EPA dockets and filings and judicial opinions); Jerry L. Mashaw & David L. Harfst, *From Command and Control to Collaboration and Deference: The Transformation of Auto Safety Regulation*, 34 YALE J. ON REGUL. 167, 243–44 (2017) (National Highway Traffic Safety Administration (“NHTSA”) rulemaking and recalls from the 1980s to 2015, based on agency documents, judicial opinions, and industry sources).

⁵ Libby Dimenstein, Donald L.R. Goodson & Tyler Szeto, *Major Rules in the Courts: An Empirical Study of Challenges to Federal Agencies’ Major Rules*, 13 TEX. A&M L. REV. (forthcoming 2025) (manuscript at 20–21), <https://ssrn.com/abstract=4819477> [<https://perma.cc/BL86-VAVF>].

⁶ David Zaring, *The Corporatist Foundations of Financial Regulation*, 108 IOWA L. REV. 1303, 1322–26, 1354–60 (2023).

⁷ *Id.* at 1327.

⁸ By focusing on affirmative suits that businesses bring against their regulators, I am capturing only one of the two forms that judicial review can take, the other being enforcement suits brought by the government against a defendant who may argue as a defense that agency action on which the enforcement suit is premised (e.g., a regulation) is unlawful. *See* 5 U.S.C. § 703. The advantage of studying affirmative suits is that the mere filing of such a suit is per se evidence that a member of the industry is willing to seek judicial review, whereas the mere filing of an enforcement suit against a defendant is *not necessarily* evidence that the defendant will seek meaningful judicial review of some agency action on which the suit is premised. To know whether the latter is happening, one must ensure the docket is updated, obtain the merits stage underlying filings, and examine them. Given the large number of agencies concerned, this can be cost prohibitive. Moreover, affirmative suits are probably the more important form of judicial review in aggregate,

with a team of research assistants. In deciding what agencies the dataset should cover, I considered (1) for every “Department,” each component of the Department that was one step down its organizational hierarchy,⁹ and (2) every other non-Department agency in the federal government. From this initial set of agencies, I selected, for data gathering, every agency that had a primary mission of regulating business and that either (1) had at least 1,000 employees or (2) promulgated at least five major nontransfer regulations during the period covering the second Obama Administration and first Trump Administration.¹⁰ For each agency thus

because they extend to types of action that by nature could never be reviewed in an enforcement proceeding (e.g., denial of a benefit or license) and are attractive to industry because they allow for judicial review without the risk of immediate liability in the event of defeat.

⁹ For example, in the case of the Department of Labor (“DOL”), this would mean agencies like OSHA and the Mine Safety and Health Administration (“MSHA”), while in the Department of Health and Human Services (“HHS”), it would mean agencies like the Centers for Medicare and Medicaid Services (“CMS”) and the Food and Drug Administration (“FDA”).

¹⁰ The dataset used in this Article is NICHOLAS R. PARRILLO, DATASET (2025), <https://doi.org/10.7910/DVN/MK6RNZ>. For a full explanation of the data-gathering methods, see Methodological Appendix, in DATASET, *supra*, File 0. In selecting the agencies to cover, I began with two partly overlapping groups. The first was Rory Van Loo’s list of the nineteen federal business regulators with significant monitoring and enforcement capacity. See Rory Van Loo, *Regulatory Monitors: Policing Firms in the Compliance Era*, 119 COLUM. L. REV. 369, 382–83 (2019) (defining large business regulators as agencies that “focus on enforcing laws against businesses” and who had at least 1,000 employees as of 2016). The second consisted of any regulators who promulgated at least five nontransfer major rules in fiscal years 2013 through 2021 in the reports of the Office of Management and Budget (“OMB”). See *OIRA Reports to Congress*, WHITE HOUSE: OFF. MGMT. & BUDGET, <https://bidenwhitehouse.archives.gov/omb/information-regulatory-affairs/reports/> [<https://perma.cc/JR3D-HZTS>]. For independent agencies, for which OMB does not distinguish between transfer and nontransfer rules, I simply included any independent agency with five or more major rules during the period. Twenty-five agencies met this five-rule criterion; however, I excluded five of these because I thought *regulating business* was clearly not their primary mission. (These were Citizenship and Immigration Services at the Department of Homeland Security (“DHS”), Customs and Border Protection at DHS, the Federal Acquisition Regulatory Council, the Internal Revenue Service, and the Small Business Administration.) Twenty-eight agencies either (1) were on Van Loo’s list or (2) met the five-rule criterion after my exclusions. They are listed below with their parent departments, if any, plus the relevant criterion they met in parentheses (“1” for Van Loo’s list, “2” for the five-rule criterion):

- *In public health and safety*: CMS within HHS (2); EPA (1, 2); Federal Aviation Administration (“FAA”) within Department of Transportation (“DOT”) (1); FDA within HHS (1, 2); Federal Motor Carrier Safety Administration (“FMCSA”) within DOT (1, 2); Food Safety and Inspection Service (“FSIS”) within U.S. Department of Agriculture (“USDA”) (1); MSHA within DOL (1); NHTSA within DOT (2); Nuclear Regulatory Commission (“NRC”) (1, 2); OSHA within DOL (1, 2).
- *In labor*: Equal Employment Opportunity Commission (1); Employee Benefits and Services Administration within DOL (2); National Labor Relations Board (1); Wage and Hour Division within DOL (2).
- *In finance*: Consumer Financial Protection Bureau (1, 2); Commodity Futures Trading Commission (2); Federal Housing Finance Agency (2); Federal Reserve (1, 2); Federal Deposit Insurance Corporation (1, 2); National Credit Union

selected, my research team and I conducted an exhaustive search of the Bloomberg Law dockets database¹¹ to create a list of all U.S. district court civil actions and all U.S. circuit court petitions for review challenging the agency's actions—whether against the agency or its top official by title or name or against the agency's parent department or its top official by title or name—that were brought by any organization¹² during the *core study period* of January 20, 2013 through January 20, 2021.¹³ For all suits in each list, I identified every suit in which at least one challenger was a business or association of businesses—a group of suits I call *industry challenges*.¹⁴ Research assistants then examined the complaint or petition for review (“PFR”) in each of those industry challenges to identify the agency action being challenged. This provided

Administration (1); Office of the Comptroller of the Currency (1, 2); Securities and Exchange Commission (1, 2).

- *In other areas:* Agricultural Marketing Service within USDA (2); Federal Energy Regulatory Commission within Department of Energy (1); Federal Communications Commission (1, 2); Federal Trade Commission (1); Fish and Wildlife Service within the Department of the Interior (2); Office of Energy Efficiency and Renewable Energy within Department of Energy (2).

Although the CPSC does not meet either criterion, I added it to the study because my overall analysis moved in the direction of consumer safety, and I therefore felt I had to see whether the analysis worked for CPSC. For a tabular summary of which agencies met which criteria and were ultimately included or not, see generally DATASET, *supra*, File 00.

¹¹ The Bloomberg Law dockets database comprehensively scrapes docket sheets from PACER. See *Litigation Overview—Using Bloomberg Law Dockets*, BLOOMBERG L.: PRAC. GUIDANCE, <https://www.bloomberglaw.com/document/X9HLF7600000000> [<https://perma.cc/AB5H-S4LJ>]. Note that the SCALES Project at Northwestern aspires to make all federal court docket materials freely available, but currently it only covers one year's worth of records. See generally David L. Schwartz et al., *The SCALES Project: Making Federal Court Records Free*, 119 NW. U. L. REV. 23 (2024), <https://scholarlycommons.law.northwestern.edu/nulr/vol119/iss1/3/> [<https://perma.cc/KSC8-URQB>].

¹² This would include any business, trade association, nongovernmental organization (“NGO”), or nonfederal government entity.

¹³ The main challenges of creating these lists are that (1) neither PACER nor Bloomberg Law has any convenient and reliable way of identifying suits against federal agencies and (2) challengers to federal agency action have numerous options for how to choose and name a defendant or respondent, including the name or acronym of the agency, the title of the top official, the personal name of the top official, etc. Thus, for each agency, we conducted an exhaustive search based on a long list of all plausible defendant or respondent names that might be used, either for the agency or for its parent department. For example, a search for FDA required searching for several terms—the institutional name, the agency-head title, and the personal names of all the period's successive agency heads—for both FDA itself and for its parent department HHS, as well as all likely abbreviations and variations of all these terms. (Additionally, we sifted through the thousands of suits that named only the “United States” as defendant and found that these almost never concerned the sorts of challenges to rules and adjudications that are the bread and butter of administrative law—e.g., they concern the Federal Tort Claims Act, tax disputes, or federal interests in real estate. See Methodological Appendix, *supra* note 10, at 7-10.)

¹⁴ By *business*, I mean any entity whose mission is to provide goods or services in exchange for payments, which would include not only for-profit businesses but also nonprofit service providers like nonprofit hospitals. See generally *id.*

us with a list of several thousand industry lawsuits, each with the corresponding agency action that the suit challenged.

Because trying to analyze all these industry challenges to all these agencies would be too much for one article, this Article focuses on (1) the subgroup of covered agencies that regulate public health and safety¹⁵ and, (2) for each of those agencies, the industry most prominently regulated by the agency.¹⁶ This yields twelve industry-agency pairings.¹⁷ For each of these pairings, this Article reports on industry challenges during the core study period—extended for the low-litigation agencies into the first three years of the Biden Administration, to January 20, 2024—and is supplemented by research into the prevalence of challenges extending back as far as the 1980s based on additional Bloomberg Law dockets database searches,¹⁸ secondary literature, the trade press, and interviews with experienced practitioners.

The main finding of this Article is that there appears to be a pattern in how industries vary in whether they challenge their public-health-and-safety regulators, with some good reason to think the pattern reveals causation. Industry challenges tend to be few and marginal when two conditions are both met. *First*, companies in the industry each have a thick relationship to the regulator—that is, each company knows the regulator will be repeatedly making discretionary decisions substantially impacting its business into the indefinite future, so each company has a big stake in winning and maintaining the agency’s trust

¹⁵ I think it is reasonable to focus on public health and safety as distinct from other, primarily economic, forms of regulation, as companies seem to view judicial challenges about health-and-safety regulation and economic regulation differently, as reflected in interviews with practitioners who deal with different agencies across the two types. Interview with Anonymous Interviewee #11, counsel to a trade association (Oct. 3, 2024) (noting that for a company, “the fear of the publicity and the [adverse] commercial impact of litigation [against the economic regulator] is much less than it is with” litigating against the health-and-safety regulator; “safety is . . . sort of primal”; economic regulation is “just dollars and cents”; “I think [safety is] a whole different category, unique”; “you’re not going to have testimony of mothers of dead children in [economic regulation] proceedings or litigation, simple as that”); Interview with Anonymous Interviewee #12, trade association official (Oct. 3, 2024) (“economic regulation “doesn’t hold a candle to safety”; in economic regulation, the “reputational risk there is much lower” for a company).

¹⁶ For CMS, an agency with especially broad jurisdiction, I covered two industries: hospitals and nursing homes. For another such agency, EPA, I focused on electricity generators but also briefly discuss EPA’s other most important regulated industries. *See infra* Section II.B.

¹⁷ The twelve pairings, with agencies’ parent departments (if any) in parentheses, are the following: FSIS (USDA) and meat and poultry processors; FDA (HHS) and drugmakers; NHTSA (DOT) and automakers; FAA (DOT) and airlines; CPSC and children’s product companies; NRC and nuclear plant operators; MSHA (DOL) and coal mines; OSHA (DOL) and employers generally, reflecting OSHA’s broad jurisdiction; EPA and electricity generators; FMCSA (DOT) and for-hire trucking companies; CMS (HHS) and hospitals; and CMS (HHS) and nursing homes.

¹⁸ These additional searches sometimes used more targeted methods than for the core study period, as explained for each individual search throughout the Article.

and goodwill. *Second*, industry economic interests are aligned with the mission of the regulator with regard to the agency action at issue, which is especially the case for agency action that has the official purpose of protecting the health or safety of *the industry's own consumers*, as opposed to protecting industry workers or victims of externalities of industry conduct. Summing the two conditions, it seems that industries are much less likely to reach public impasses with an intimately related regulator who is officially seeking to protect the health and safety of the very customers the industry wishes to attract.

Although the first condition seems like it could logically be a deterrent to litigation, an idea supported by other studies,¹⁹ Cary Coglianese's classic work on EPA in the 1980s demonstrates the possibility of industry litigation against an agency despite a thick relationship.²⁰ It is therefore appropriate for us also to consider a causal role for the second condition—interest alignment—especially as manifested in an agency mission to protect the health and safety of the industry's customers. The literature on corporate behavior has noted that businesses have stronger built-in incentives to prevent harm to their own consumers than harm to other parties,²¹ and some scholarship has cited that difference as a factor in industry-regulator alignment and regulatory success,²² though, to my knowledge, its potential effect on judicial review has not yet been considered.²³

¹⁹ See, e.g., DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 656–62 (2010) (discussing drugmakers' investment in their relations to FDA as a deterrent to judicial challenges); Roy Gava, *Challenging the Regulators: Enforcement and Appeals in Financial Regulation*, 16 REGUL. & GOVERNANCE 1265, 1278 (2022) (finding that companies are less likely to sue European financial regulators with whom they share strong relationships); Zaring, *supra* note 6, at 1330 (invoking relationships as a reason U.S. banks do not sue their regulators).

²⁰ Coglianese, *supra* note 4.

²¹ See, e.g., Cécile Carpentier & Jean-Marc Suret, *Stock Market and Deterrence Effect: A Mid-Run Analysis of Major Environmental and Non-Environmental Accidents*, 71 J. ENV'T ECON. & MGMT. 1, 3, 5–6, 15–17 (2015) (finding that front-page corporate disasters cause long-term diminishment of stock prices in the case of airline crashes but generally not in the case of other disasters, such as those involving environmental harm, industrial facilities, or freight trains); BRENT FISSE & JOHN BRAITHWAITE, THE IMPACT OF PUBLICITY ON CORPORATE OFFENDERS 240 (1983) (suggesting that bad publicity is most likely to change corporate behavior “when it challenges the integrity of a [corporation's] product,” as distinct from challenging “sales tactics” or “damage done to the environment”); Neil Gunningham, Robert A. Kagan & Dorothy Thornton, *Social License and Environmental Protection: Why Businesses Go Beyond Compliance*, 29 LAW & SOC. INQUIRY 307, 334–35 (2004) (“[M]ore typically, when the harm is associated with the only production process and not the product produced, social license demands are less effectively enforced through economic mechanisms.”).

²² See, e.g., Kieran Walshe, *Regulating U.S. Nursing Homes: Are We Learning from Experience?* 20 HEALTH AFFS. 128, 139–40 (2001).

²³ Zaring's important analysis of banking regulation—including the absence of industry challenges—emphasizes the collaboration between industry and regulators to promote the provision of banking services to the public by analogy to, among other things, the provision of

There are several mechanisms by which a regulator's customer-protective mission could result in sparseness of industry judicial challenges. First, at a micro level, a business might fear that conflict with a perceived consumer protector could generate bad publicity for its products, suggest those products are dangerous to consumers, and reduce demand for them. Second, at a macro level, companies may discern that a regulator can provide consumers with credible assurances of the safety of the industry's products generally, so it serves industry's interest to bolster public confidence in the regulator—not undermine or override it—and to emphasize industry acceptance of regulation as a guarantee of product safety. Third, the agency, if aware of the first and second dynamics, may try using those dynamics as leverage against companies, such as by threatening industry with bad publicity. Fourth, the industry may decide the first three factors render judicial challenges unattractive and may therefore invest more heavily in means of influencing the agency that are less adversarial and less likely to result in public perception that industry is resisting regulation. For example, industry may lobby congressional overseers to pressure the agency to accede to industry wishes—an approach that lessens litigation and, if successful, lessens industry's *need* for litigation. Fifth, if the agency itself views the industry as having an interest in not injuring or sickening customers, the agency may therefore trust and defer to the industry on health-and-safety matters, forbearing from forcing companies to depart from the course they think best: Agency forbearance means industry has no reason to sue.

Depending on which of the five mechanisms predominate, interest alignment could be more on the industry's terms or on the agency's terms. If the first, second, and third mechanisms predominate, the story is one of agency leverage over industry. If the fourth and fifth predominate, it is a story of industry control over the agency—what some call “capture.”²⁴ Any or all of the five mechanisms could be operating at one time, and their relative prevalence may often be uncertain and contested. But however prevalent each of them may be in any given situation, my main point is that *all five* mechanisms point in the same direction of *less judicial review*—of industry and agency working out their joint course of action without judges exercising power or providing input. Additionally, as I argue below, for every agency-industry pairing that sees few industry judicial challenges, agency forbearance

utility services. Zaring, *supra* note 6, at 1309–10, 1354–60. This certainly sounds in interest alignment generally but not specifically in protection of consumers against harm—and not in health-and-safety regulation. *Id.*

²⁴ On the complications of “capture” as a concept, see Daniel Carpenter, *Detecting and Measuring Capture*, in PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 57 (Daniel Carpenter & David A. Moss eds., 2014).

alone—although sometimes a medium or large factor—is never a sufficient explanation for litigation’s absence.²⁵ Every little-challenged agency has at times acted in ways that press hard upon industry yet elicit no judicial challenge.²⁶ When there are few challenges, it is never a pure story of agency forbearance or industry capture—and sometimes very far from it.²⁷

To show how the two conditions (relationship thickness and interest alignment) appear to shape the role of judicial review across industries, I divide the twelve industry-agency pairings identified above into three groups for analysis. For each pairing in each group, I describe the levels and types of industry challenges, the presence or absence of thick relationships, and the degree of interest alignment in each.

Part I focuses on six “low-challenge” pairings: meat and poultry processors and the Food Safety and Inspection Service (“FSIS”) at the U.S. Department of Agriculture (“USDA”); drugmakers and the Food and Drug Administration (“FDA”); automakers and the National Highway Traffic Safety Administration (“NHTSA”); airlines and the Federal Aviation Administration (“FAA”); children’s product companies and the Consumer Product Safety Commission (“CPSC”); and nuclear plant operators and the Nuclear Regulatory Commission (“NRC”). For each of these six pairings, I show that industry suits against the regulator’s restrictive actions on health and safety are few and marginal and have been for the last twenty-five to forty years or more. In particular, this means that trade associations²⁸ and large companies challenge regulator actions little

²⁵ See *infra* Part I.

²⁶ See *infra* notes 172–85, 260–62, 351–59, 449–70, 553–63, 665–96 and accompanying text.

²⁷ *Id.*

²⁸ Challenges by trade associations are an important gauge of the industry’s overall willingness to confront the regulator. Interviewees across several industries noted that a trade association’s decision to sue involves a collective vote (of the membership or of a subset like the board or a committee), or that the decision to sue reflects some degree of industry consensus. See, e.g., Interview with Jolyda Swaim, Principal, Olsson Frank Weeda (Aug. 15, 2024) (meat and poultry processing); Interview with Anonymous Interviewee #1, Former general counsel of a large drug manufacturer (Aug. 23, 2024) (drugmakers); Interview with Anonymous Interviewee #3, Partner in a law firm aviation regulatory practice (Aug. 12, 2024) (airlines); Interview with Anonymous Interviewee #7, Partner in a law firm representing Clean Air Act-regulated businesses (Oct. 14 & 18, 2024) (electric generators). That said, in the social science on trade associations—which has said nothing about them as litigants—there is evidence that their decision-making in general tends to be dominated by their largest members, at least informally. See, e.g., Michael L. Barnett, *One Voice, But Whose Voice? Exploring What Drives Trade Association Activity*, 52 Bus. & Soc’y 213, 227–29 (2012). But that effect can be offset by the formation of small-company-specific associations, *id.* at 230, e.g., the Association of American Meat Processors, Regional Airline Association, or Owner-Operator Independent Drivers Association.

Note that suing through a trade association can mitigate concerns that individual companies have about damaging their relationships with the agency. Interview with Anonymous Interviewee #7, *supra*. But that advantage is limited if the government questions the association’s standing, which means the association must produce sworn statements identifying one or a few members

or none, and litigation tends to be brought, if at all, by companies that are few, small, scattered, and suing on narrow issues.²⁹

I also show for each pairing that both conditions are met. Regulated companies have a thick relationship with the regulator, to which the dearth of challenges may be partly attributed.³⁰ Regulated companies also have economic interests aligned with the mission of the regulator, usually arising because the regulator's mission is to protect the health and safety of the industry's customers.³¹ This is the case for the first five of the six pairings in Part I. However, note that for the sixth pairing (nuclear plant operators and NRC), the alignment of interests between industry and regulator has a different origin: the public's unique terror of nuclear accidents.³² This means the *political* viability of nuclear

harm by the agency action. Interview with Anonymous Interviewee #1, *supra*; Interview with Anonymous Interviewee #6, Partner in a large law firm with extensive experience representing mining companies in interactions with MSHA (Sept. 23, 2024).

²⁹ All my analysis of individual-company challenges in this Article uses parent companies as the unit of measure. I used different approaches for different industries to determine whether each named challenger company had a parent:

- The search for parents was incidental to research on individual cases for pairings with very few individual-company suits (meat processors and FSIS; automakers and NHTSA; and children's product companies and CPSC).
- For pairings with more individual-company suits, research assistants conducted a systematic search and either examined challengers' corporate disclosure statements required by the Federal Rules of Civil Procedure (coal mines and MSHA; generators and EPA; nursing homes and CMS) or matched challenger names to industry lists of parent companies, conducting follow-up research where no match was found (drugmakers and FDA, airlines and FAA).
- No searches were conducted for employers and OSHA or for-hire truckers and FMCSA because industry's high litigiousness against those agencies was already evident from trade association challenges.
- No search was necessary for nuclear plant operators, who never sued the NRC individually, or for hospitals, who never sued CMS on patient-safety issues in the sample we took.

³⁰ Although CPSC has a thicker relationship with the children's product industry than it has with any other industry, the children's product industry's relationship with CPSC is thinner than in the other pairings in Part I. Yet what the children's product industry lacks on the relationship dimension is made up for on the interest-alignment dimension—that is, the industry is especially sensitive to consumer safety concerns. *See infra* Section I.E.

³¹ In some cases, like airlines, it seems industry challenges on health and safety have been low throughout the history of the industry and agency. For others, challenges were previously more common but became marginal due to historical changes either in consumer preferences for health and safety or in the perceptions that boundedly rational companies have of such consumer preferences. For example, drugmakers initially resisted strong FDA regulation in the 1960s and 1970s but adapted to take advantage of FDA safety-and-efficacy assurances by the 1980s, *see infra* Section I.B.; automakers were initially convinced that “safety doesn't sell” and resisted adding safety features but then had a change of heart circa 1990 and entered a far more cooperative pattern of interaction with NHTSA, *see infra* Section I.C.; and meat and poultry processors initially resisted USDA's shift to pathogen regulation in 1994 but shifted by the early 2000s, *see infra* Section I.A.

³² *See infra* Section I.F.

power depends on its safety reputation in a way that is not true for other industries, including those that emit other kinds of pollution than radiation. Additionally, it should be noted that the industries in Part I *do* sometimes challenge their regulator on actions that are not about health and safety (e.g., which of two drugmakers has the right to market a concededly safe drug or which of two airlines has the right to an airport slot), or actions that protect the health and safety of people other than industry's customers (e.g., whether automakers must improve fuel economy to help the environment), or actions that industry says are *insufficiently* protective of health and safety (e.g., a brand name drugmaker claiming FDA should reject a rival generic drug as unsafe). The fact that companies *do* sue their regulators on such matters suggests that relationship thickness is not sufficient as an explanation and that interest alignment has causal bite.

Part II focuses on four "high-challenge" industry-agency pairings: employers generally and the Occupational Safety and Health Administration ("OSHA");³³ coal mines and the Mine Safety and Health Administration ("MSHA"); electricity generators and the EPA; and for-hire trucking companies and the Federal Motor Carrier Safety Administration ("FMCSA"). For each of these four pairings, I show that industry lawsuits against agencies' health-and-safety restrictions are mainstream, in that trade associations and individual companies, including larger ones, sue frequently, often on broad issues.³⁴

I also show for each pairing that the interest-alignment condition is absent, and sometimes the thick-relationship condition is absent, as well. As to the absence of interest alignment: (1) MSHA and OSHA's missions are to protect industry employees, the cost of whose injuries are mostly not internalized by regulated employers, due to gaps in workers' compensation systems and the limitations of labor markets in delivering wage premiums for dangerous work; (2) EPA's mission is to protect victims of the externalities of industry behavior, who have no transactional connection at all to the regulated companies; and (3) FMCSA's mission is a combination of the mission types just described—that is, to protect industry employees (truck drivers) and externality victims (third parties in truck crashes). None of these regulators protect industry customers. As to relationship thickness, these four industry-agency

³³ Obviously "employers generally" are not an "industry" in the usual specific sense. But that is precisely the point: OSHA's exceptionally broad jurisdiction prevents it from having thick relationships. *See infra* notes 715–16 and accompanying text.

³⁴ For-hire trucking is somewhat more complicated. Small companies have a bigger share of for-hire trucking than of any other industry discussed in this Article, and small trucking companies, compared to large ones, have thinner relationships and less-aligned interests with FMCSA, making them more adverse to the agency. However, small companies lack resources to sue individually. Thus, our best gauge for overall industry litigiousness against FMCSA is small-company-specific trade associations, which do indeed sue FMCSA frequently. *See infra* Section II.C.

pairings exhibit variation. For two of the pairings (employers generally and OSHA and for-hire trucking companies and FMCSA), the relationship is relatively thin, in that the agency does not have frequent high-stakes interactions with the companies or high leverage over them.³⁵ The high levels of challenges against FMCSA and OSHA therefore might be causally linked *either* to the thinness of relationships *or* to nonalignment of interests—or both. Importantly, however, MSHA has a very thick relationship with coal mining companies, and EPA has a fairly thick relationship with electricity generators, yet both industries still sue.³⁶ This reinforces what Coglianese found previously regarding EPA with respect to a different industry: Thick relationships are not necessarily sufficient to block litigation.³⁷ This in turn supports the idea that interest alignment among the industries in Part I makes a difference in the frequency of industry-agency litigation.³⁸

Part III provides a short preliminary look at the Centers for Medicare and Medicaid Services (“CMS”) in conjunction with two major

³⁵ See *infra* Sections II.A., .C.

³⁶ See *infra* Sections II.A–.B.

³⁷ See Coglianese, *supra* note 4, at 762–63.

³⁸ OSHA and FMCSA meet neither condition and see high challenges. See *infra* Sections II.A., .C. MSHA and EPA meet only the thick-relationship condition and see high challenges. See *infra* Sections II.A–.B. One might fairly wonder about the opposite case, where companies meet only the interest-alignment condition. Would they see high or low challenges? I have some uncertainty about this. Among the six low-challenge pairings that make up Part I, the industries all meet the industry-alignment condition, and they generally meet the thick-relationship condition as well, though children’s product companies (vis-à-vis CPSC) are weaker on that condition, so perhaps their low-challenge status suggests interest alignment is sufficient to discourage litigation even when the relationship is only moderate.

As an alternative theory of the pattern of interindustry variation, one might posit that the dearth of suits in Part I is because the agencies therein are scientific or technical, such that industry does not believe judges will be willing to interfere, so industry does not sue. This theory is untenable, as the agencies in Part II are plenty technical, including EPA, which is one of the most sued agencies despite being extremely scientific. See *infra* notes 265–74. A more plausible alternative theory is that the harms that agencies in Part I are seeking to prevent have obvious causal chains. Thus, industry anticipates that judges will be squeamish about overriding health-and-safety strictures because if harm then occurs, the judges will have obvious blood on their hands. That is, a judge may be willing to override an air pollution regulation that could have prevented heart attacks or strokes—in a way that does not allow us to discern *which individuals’* life chances were affected—but may be skittish about overriding an airplane regulation in a way that might cause a crash. The theory may have some explanatory power, but I think not that much. Several of the harms at which Part II agencies aim are acute with obvious causation yet still draw industry lawsuits, as with MSHA actions on coal mine evacuation routes, ventilation to counter explosive gas or low oxygen, and breathable air in emergencies, see *infra* notes 765, 767, 772 and accompanying text; OSHA actions on electrocutions, chemical-plant process safety management, construction site falls, and work in confined spaces, see *infra* note 755 and accompanying text; and FMCSA actions on truck drivers who are sleep-deprived or intoxicated, see *infra* notes 932–37, 942 and accompanying text. Conversely, causal chains are not always certain for Part I agency actions on matters like the safety of meat or drugs.

healthcare industries dependent on Medicare and Medicaid: hospitals and nursing homes. This Article discusses CMS only briefly because it is contestable whether the agency is really a business regulator or a benefit program administrator. Insofar as we try to apply the interest-alignment theory posited above, hospitals appear consistent with it, in that patients may be understood as a hospital's "customers," and hospitals sue CMS little to none regarding CMS patient safety regulations, even as they *do* sue CMS frequently on reimbursement matters not directly related to patient safety. As for nursing homes, whose "customers" are their residents, the industry's litigiousness about resident safety regulation is, perhaps surprisingly, at least somewhat greater than that of the industries in Part I. The reason for nursing homes' at-least-moderate divergence from a theory of interest alignment and customer protection appears to be that there is very imperfect alignment between nursing homes' economic interests and CMS's safety mission: The choices that residents or their families make among facilities are driven by location more than quality; residents and their families are poorly positioned to judge quality of care, and CMS's safety ratings may fail to capture it; once residents are in a facility, they cannot switch to another without risking trauma; and low Medicaid rates do not provide much space for quality improvement.

Having summarized the Article, let me add a few words about its mode of argument. Gauging the level of judicial challenges by an industry to an agency in a way that can be compared with other industry-agency pairings is a task that involves numbers but cannot, at this early stage of understanding, be entirely quantitative. Counting lawsuits is valuable—and this Article does a good deal of counting—but one must also take account of how powerful or marginal the challenging companies are within the industry, how significant the challenged agency actions are, what actions the agency takes that industry does *not* challenge, and how significant those unchallenged actions are. These questions are amenable to quantitative analysis only in part, and, at this stage, I think they are not amenable to any common quantitative metric that would allow one-dimensional interindustry comparison. One might posit that we could, for each agency, count the actions the agency took within some category and calculate the proportion that were challenged. In fact, I will do that for certain categories of action by some of the agencies. But I will not attempt it comprehensively, because such a technique would not be meaningful for many important categories of action across many of the agencies, or at least not meaningful in ways that are uniform and comparable across agencies. For example, you can count the number of times MSHA has cited coal mines for safety violations and see what proportion of citations were challenged, but you cannot do a parallel analysis of how often CPSC forces recalls of children's products and see what proportion of recalls were challenged,

because companies virtually never hold out against CPSC pressure for “voluntary” recalls in such a way that produces the forced recall that is the predicate for judicial review. To take another example, electricity generators frequently challenge EPA rules, while drugmakers almost never challenge FDA rules. But simply comparing suit counts or challenge rates across the two agencies misses what is really going on—that is, FDA makes relatively few rules to begin with, because FDA has so much leverage over the drugmakers by virtue of its drug approval power that drugmakers will do what the agency “suggests” even without a rule. The point is that calculating parallel numeric metrics for how much different industries challenge their respective agencies would require so many context-specific caveats as to be more confusing than helpful.

Because of all this, my accounts of the various industry-agency pairings and my comparisons between them are essentially qualitative, albeit with numbers embedded at various points in each description. My hope is that the qualitative account I provide for each pairing gives a holistic and intuitive sense of judicial challenges’ importance or unimportance therein, though at a cost to objectivity and parsimony. Given this qualitative approach, the Article is not scientific in the sense of formulating a hypothesis and quantitatively testing it. But prior to devising formal hypotheses comes observation. That is what this Article is—my best initial interpretation of vast and largely unexplored phenomena, one that hopefully provides a provisional map for others who might convert some of the ideas here into things that are more scientifically testable and then confirm, refine, disprove, or replace them accordingly.

Yet, although the real foundation for my claims consists of the several qualitative discussions that compose the bulk of the Article, I will close this Introduction with tabular summaries of the various pairings. Though crude, these tables make a *prima facie* case for the pattern of interindustry variation described above and may provide a guide for the reader.

Table 1 provides the number of trade-association suits and individual-company suits against restrictive agency actions on public health and safety within each pairing for the core study period—January 20, 2013, through January 20, 2021—plus information on how dominant or marginal the challenging companies were.³⁹ Of the six pairings that I consider “low-challenge” and group into Part I, four had no suits by associations or individual companies (meat processors and FSIS; automakers and NHTSA; airlines and FAA; and children’s products and CPSC), while FDA saw no association suits and a set of

³⁹ The rankings of companies for different industries use different metrics—net sales for meat processors, firm value for drugmakers and electric utilities, revenue for airlines, production for coal companies, number of beds for nursing home chains—depending on what published rankings were available.

individual-company suits that were almost entirely scattered among smaller firms, and NRC saw one association suit on a minor issue and no individual-company suits. Meanwhile, of the four pairings that I consider “high-challenge” and group into Part II, three saw dramatically more prevalent industry challenges—either mainly in association suits (employers and OSHA), mainly in individual-company suits (coal mines and MSHA), or both (generators and EPA). The fourth pairing in Part II, between the for-hire trucking industry and FMCSA, saw challenges that were perhaps not as dramatic as the other Part II pairings, though trucking’s four association suits easily exceed any Part I pairing.

TABLE 1. INDUSTRY SUITS AGAINST AGENCIES' RESTRICTIVE ACTIONS ON PUBLIC HEALTH AND SAFETY IN CORE STUDY PERIOD (JAN. 20, 2013 TO JAN. 20, 2021)

Industry and Agency	Suits by Trade Associations	Suits by Individual Companies
<i>Meat Processors & FSIS (USDA)</i>	no suits	no suits
<i>Drugmakers & FDA</i>	no suits	• of largest 200 companies (totaling 81% of global value), suits by Ranbaxy/Sun (#64) and Mallinckrodt (#174) on core safety issues and by Teva (#29) and Ipsen (#95) on choice of pathway • of largest 201–1,000, suits by 8 companies • outside largest 1,000, suits by 5 companies
<i>Automakers & NHTSA</i>	no suits on car safety (excludes fuel economy)	no suits on car safety (excludes fuel economy)
<i>Airlines & FAA</i>	no suits	no suits
<i>Children's Product Companies & CPSC</i>	no suits	no suits
<i>Nuclear Plant Operators & NRC</i>	1 suit by Nuclear Energy Institute, on minor issue	no suits
<i>Coal Mines & MSHA</i>	2 suits by National Mining Association	of largest 15 companies (totaling over 78% of U.S. production), suits by 8 (including 3 of top 4)
<i>Employers (Generally) & OSHA</i>	25+ suits by 30+ associations	~100 suits, mostly by small companies, with 2 by Walmart (#1 U.S. employer)
<i>Electricity Generators & EPA</i>	22 suits by Utility Air Regulatory Group	• of largest 20 investor-owned utilities (over 80% of U.S. market cap), suits by 9 (including 3 of top 6) • of the 4 publicly traded independent power producers, suits by 3
<i>For-Hire Trucking Companies & FMCSA</i>	4 suits by associations, mostly representing small companies	17 suits, by companies of varying size (industry very deconcentrated)
<i>Hospitals & CMS</i>	no suits on patient safety (based on sample and interviews, not full count)	no suits on patient safety (based on sample and interviews, not full count)
<i>Nursing Homes & CMS</i>	1 suit by American Health Care Association	• of largest 10 chains (11% of U.S. beds), suits by at least 3 chains (including top 2) • at least 20 other suits

Table 2 adds to the *prima facie* case by presenting the data I have gathered for the low-challenge pairings and some of the high-challenge pairings for time spans beyond the 2013–2021 core study period, including earlier in time from the 1980s or 1990s up to January 20, 2013,⁴⁰ and later in time from January 20, 2021 to January 20, 2024, with the exact time spans varying among the pairings depending on the availability and cost of data.⁴¹ For the six pairings in Part I, expanding the temporal scope to the thirty-five-year period of 1989–2024, or something near it, adds very few association suits: three by meat processors against

⁴⁰ The coverage of the Bloomberg Law dockets database for all U.S. district courts goes back to 1989, while for U.S. courts of appeals it goes back at least to 1989 with a few small gaps. See Methodological Appendix, *supra* note 10, at 2 n.3.

⁴¹ For the industries that have rarely sued—that is, the six that have ended up in Part I—I began by finding what seemed to be sparse litigation in 2013–2021 and then investigated whether that sparseness was longer-lasting than those eight years. To do that, I extended the exhaustive Bloomberg search forward in time to January 20, 2024, for all six pairings. As to the pre-2013 years, I took different approaches with different agencies depending on research costs. For NHTSA, there are unusually detailed published accounts by insiders and scholars confirming the absence of suits since the 1980s, so I report that. For CPSC and the NRC, I extended the exhaustive Bloomberg search back to the start of Bloomberg’s coverage in 1989, which was workable because each of those agencies is freestanding and not part of a larger department. For FSIS, FDA, and the FAA, extending the Bloomberg search backward before 2013 was more challenging, because each of those agencies is a component of a larger department whose name (or the title or personal name of the department’s head) may be the only defendant or respondent named in a suit that is really against the component. A Bloomberg search encompassing the department will produce numerous suits, some against the department’s component of interest and many other suits against the department’s other components. Discerning which are which requires reading underlying filings, which is costly, and especially so if suits against the other components are numerous or if the search goes into the pre-2010 period when underlying filings are often missing from the database. Therefore, I extended the exhaustive Bloomberg search backward in time to 2009 for FSIS (sifting through all suits against its parent USDA) and for the FAA (sifting through all suits against its parent DOT), but not for FDA since the suits against its parent (HHS) are so numerous as to make the cost prohibitive. That said, scholarship by FDA insiders indicates that one major type of agency action—denials of new drug approvals—has not been challenged since 1979, so I report that fact, as well as a targeted Bloomberg search for suits by the main drugmaker trade associations back to 1989. As for the FAA, I extended the Bloomberg search from 2009 back to 1989 using narrowed search terms, searching for the FAA only and not including its parent DOT. I did the same for FSIS, searching for FSIS only and not USDA, though for FSIS I went back only to 1994, which is when modern, microbe-focused meat regulation began. These more targeted approaches for the FAA and FSIS can miss suits, though other sources indicate they are likely very few:

- FSIS was the subject of a 2005 law review article by leading industry attorneys documenting the (very few) suits against the agency. See Dennis R. Johnson & Jolyda O. Swaim, *The Food Safety and Inspection Service’s Lack of Statutory Authority to Suspend Inspection for Failure to Comply with HACCP Regulations*, 1 J. Food L. & Pol’y 337 (2005).
- For the FAA, I was able to conduct a partial check of my component-specific Bloomberg results against a list of one major subset of judicial challenges to the FAA that the agency itself happens to publish on its website, and it turned up only one missed suit (not a significant one) in an eighteen-year period. See *infra* notes 395–96.

FSIS but none since 2000 except by a small-company association in 2005; one suit by airlines against FAA; and zero in the other four pairings. This contrasts with pairings from Part II, where the expansion of the timeframe confirms that association suits have been mainstream in the relationship between coal mines and MSHA, in which the top association challenged eleven different rules or policies between 1989 and 2013, and in the relationship between the for-hire trucking industry and FMCSA, in which associations challenged six actions from the agency's founding in 2000 through 2012. As for individual-company challenges, the expanded timeframe for the Part I pairings mostly yields only small-company suits and sparse ones at that. The only challenges by larger companies are two suits against FSIS across thirty years, by House of Raeford in 2001 and by Tyson in 2008 (the latter defending an *extra-safety* marketing claim that Tyson's product went above and beyond legal requirements); one against NHTSA across forty years, by Chrysler; one against FAA across thirty-five years, by several major airlines concerning only a narrow set of flights; two suits against CPSC across thirty-five years, which notably aimed to keep secret either the content of the agency proceeding or the company's very identity; and no suits against NRC across thirty-five years. My expanded searches on FDA, which were more targeted, similarly yielded little: one suit, by Ipsen, the ninety-fifth-largest drugmaker, plus suits by a few tiny companies, as well as the fact that no drugmaker of any size has challenged the denial of a new drug approval since 1979.

TABLE 2. INDUSTRY SUITS AGAINST AGENCIES' RESTRICTIVE ACTIONS ON PUBLIC HEALTH AND SAFETY DURING VARIOUS TIME SPANS OUTSIDE THE CORE STUDY PERIOD (UP TO JAN. 20, 2024)

Industry and Agency	Suits by Trade Associations	Suits by Individual Companies
<i>Meat Processors & FSIS (USDA)</i>	<u>1994–2013</u> : 2 suits by leading associations (in 1994 and 2000) and 1 suit by small-processor association (in 2005) <u>2021–2024</u> : no suits	<u>1994–2013</u> : • of largest 125 companies by net sales, 1 suit by Raeford (#21) in 2001 on safety enforcement; and 1 suit by Tyson (#1) in 2008, defending a prosafety marketing claim • outside largest 125, suits by 4 companies, none after 2004 <u>2021–2024</u> : no suits
<i>Drugmakers & FDA</i>	<u>1989–2013</u> : targeted search for PhRMA (including under its prior name) and for all major generic associations detects no suits <u>2021–2024</u> : no suits	<u>1979–2024</u> : no suits by a sponsor to a denial of a new-drug approval <u>2021–2024</u> : • of largest 200 companies (totaling 81% of global value), 1 suit by Ipsen (#95) on choice of pathway • of largest 201–1,000 companies, no suits • outside largest 1,000 companies, suits by 3 companies
<i>Automakers & NHTSA</i>	<u>1984–2013</u> : no suits on car safety (excludes fuel economy) <u>2021–2024</u> : same	<u>1984–2013</u> : 1 suit by Chrysler <u>2021–2024</u> : no suits on car safety (excludes fuel economy)
<i>Airlines & FAA</i>	<u>1989–2013</u> : 1 suit by major associations in 2001 <u>2021–2024</u> : no suits	<u>1989–2013</u> : • among major airlines (totaling over 90% of U.S. revenue), 1 suit by several majors in 2008 on narrow set of flights (ultralong haul) • among nonmajor airlines, 7 suits <u>2021–2024</u> : no suits
<i>Children's Product Companies & CPSC</i>	<u>1989–2013</u> : no suits <u>2021–2024</u> : no suits	<u>1989–2013</u> : 2 suits by large companies (both seeking secrecy) and 1 suit by small company <u>2021–2024</u> : 2 suits by midsize companies, 1 by small company
<i>Nuclear Plant Operators & NRC</i>	<u>1989–2013</u> : no suits <u>2021–2024</u> : no suits	<u>1989–2013</u> : no suits <u>2021–2024</u> : no suits
<i>Coal Mines & MSHA</i>	<u>1989–2013</u> : 11 suits by National Mining Association or predecessor	[no additional search performed]
<i>For-Hire Trucking Companies & FMCSA</i>	<u>2000–2013</u> : 6 suits by small-company associations <u>2021–2024</u> : no suits	<u>2021–2024</u> : 6 suits, by companies of varying size (industry very deconcentrated)

I. INDUSTRIES THAT HAVE RARELY CHALLENGED HEALTH AND SAFETY RESTRICTIONS

A. *Meat and Poultry Processors and USDA's FSIS*

The first of our six industry-agency pairings involving a low level of judicial challenges is the one between meat and poultry processors and FSIS within USDA. This pairing fits our pattern in that sparse challenges are coupled with (1) a thick relationship between companies and the regulator and (2) relative alignment of industry economic interests with the regulatory mission, which is to protect the safety of the industry's own customers, whose perceptions regarding product safety the industry cares about.

Meat and poultry processors—that is, businesses who slaughter animals and process their carcasses to sell for human consumption—have long had a close regulatory relationship with USDA.⁴² The regulatory regime began with the 1907 meat legislation inspired by Upton Sinclair's *The Jungle* and was extended to poultry in legislation of 1957.⁴³ From its inception in each category, federal scrutiny has been remarkably close.⁴⁴ In slaughter operations, *every single animal* must be inspected by a USDA official before and after it is killed, and in postslaughter processing operations (culminating in shipment to distributors or retailers), a USDA official must visit *every facility every day*,⁴⁵ during which visits the official will “monitor operations, check sanitary conditions, examine ingredient levels and packaging, review records, verify [anticontamination] processes, and conduct statistical sampling

⁴² Twenty-one of the states have no state government inspection programs for these businesses, making USDA the only regulator therein. This group includes big states like California, Florida, and New York, which have had no state inspection programs since the 1970s. *States With and Without Inspection Programs*, FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/inspection/state-inspection-programs/states-and-without-inspection-programs> [https://perma.cc/N3MX-NF5U]. Even in the other twenty-nine states, which do have state inspection programs, those programs must be at least equivalent to the federal one, and they are confined to facilities that are small and whose product is sold entirely within their state, leaving all other facilities to USDA. *State Inspection Programs*, FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/inspection/state-inspection-programs> [https://perma.cc/4GTC-BNFT]. The only exception is if the state is in a Cooperative Interstate Shipment Program, which only ten states are, the largest being Ohio. *Cooperative Interstate Shipping Program*, FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/inspection/state-inspection-programs/cooperative-interstate-shipping-program> [https://perma.cc/WX2X-92BT].

⁴³ Johnson & Swaim, *supra* note 41, at 340–41.

⁴⁴ *Id.* at 340–44.

⁴⁵ JOEL L. GREENE, CONG. RSCH. SERV., RL32922, MEAT AND POULTRY INSPECTION: BACKGROUND AND SELECTED ISSUES 3 (2010); Interview with Shawn Stevens, Partner, Food Industry Counsel (Aug. 13, 2024). Slaughter and processing may occur in one facility or in separate facilities, perhaps owned by different businesses. Interview with Shawn Stevens, *supra*.

and testing of products.”⁴⁶ Many of the judgments officials must make are “subjective.”⁴⁷

USDA can maintain this level of scrutiny because it has an extraordinarily high ratio of inspectors to regulated facilities. FSIS, the USDA component that has been responsible for meat and poultry safety since its establishment in 1981, has long possessed a field service of between 8,000 to 9,000 to inspect around 6,000 facilities.⁴⁸ This ratio, of more than one officer per facility, is more than twenty times the ratio in the food-safety operation at FDA, which is responsible for the safety of all food besides meat and poultry and is spread very thin.⁴⁹

“In no other industry [besides meat and poultry] are regulators required to be continuously present in order for the regulated facility to operate.”⁵⁰ Interviewee Shawn Stevens, a founding partner of the country’s only boutique law firm exclusively dedicated to the food industry, gave me this description of how meat and poultry processors view FSIS: “Imagine the sheriff, in . . . his or her uniform, walking through your house, all the time, right? Or [always sitting] in the back seat of the car while you’re driving, and if you speed, they just hand you a ticket, over your shoulder.”⁵¹

The close relationship between meat and poultry processors and USDA involves vanishingly few industry judicial challenges. During the core study period of 2013–2021, meat and poultry processors and their associations brought no suits against FSIS or against USDA on FSIS matters.⁵² To check if that period was an anomaly, I extended my exhaustive Bloomberg dockets search forward in time to January 20, 2024. Additionally, I expanded the same search backward in time to January 20, 2009. In this expanded fifteen-year window of 2009 through 2024, I found two suits against FSIS or against USDA on FSIS matters by processors, but neither suit was about consumer health or safety.⁵³ One was brought in 2012 by a small processor trying to get FSIS to allow

⁴⁶ GREENE, *supra* note 45, at 3.

⁴⁷ Interview with Shawn Stevens, *supra* note 45.

⁴⁸ RENEE JOHNSON, CONG. RSCH. SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 12–13 (2016).

⁴⁹ *See id.* at 4, 11–12; *see also* Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 100–04 (2000) (similar point); Interview with Jolyda Swaim, *supra* note 28 (noting inspection is much less frequent for FDA than FSIS).

⁵⁰ MILBANK MEM’L FUND, CONFLICT AND VIOLENCE IN THE FOOD SAFETY WORKPLACE: A REPORT ON MEETINGS CONVENED BY THE MILBANK MEMORIAL FUND AT THE REQUEST OF THE U.S. DEPARTMENT OF AGRICULTURE IN FULFILLMENT OF A COOPERATIVE AGREEMENT OF SEPTEMBER 2000 (2001), <https://www.milbank.org/wp-content/uploads/2016/06/Conflict-and-Violence-in-the-Food-Safety-Workplace.pdf> [<https://perma.cc/KF9C-CXV8>].

⁵¹ *See* Interview with Shawn Stevens, *supra* note 45.

⁵² DATASET, *supra* note 10, Files 1–2.

⁵³ *Id.* Files 3–6.

slaughter of horses for meat.⁵⁴ A second was brought in 2021 by three small processors challenging a mask mandate for processor employees that FSIS had imposed to protect its own onsite inspectors from contracting COVID-19,⁵⁵ in which the lead plaintiff said, “I think it’s really important to point out to people that this is not about food safety.”⁵⁶

The absence of judicial challenges is driven not only by the closeness of the relationship but also by the agency mission’s consumer-protective nature. To better understand that interplay, it is necessary to consider some historical context. Despite the long and storied past of USDA meat and poultry regulation, stretching back to the days of Upton Sinclair, the present-day regime is really the product of a transformation centered in the mid-1990s that affected regulator goals, consumer expectations, and industry’s evolving understanding of those expectations.

From its dawn in 1907 through most of the twentieth century, federal inspection focused on visible disease in slaughtered animals or visible spoilage in food; it did not consider contamination by microbes that could invisibly make consumers sick, i.e., pathogens.⁵⁷ Yet over the latter half of the 1900s, the meat and poultry industries changed in ways that worsened the prevalence and danger of pathogens affecting consumers. The raising and slaughtering of animals became far more concentrated and systematized, meaning that animals were transported over longer distances and were in close contact with each other in larger numbers; the widening use of antibiotics led to antibiotic resistance; and the rise of supermarkets and restaurants increased the probability of outbreaks from a common source.⁵⁸ The 1980s saw the emergence of newly identified pathogens like *Listeria* and *Campylobacter*, plus new strains of

⁵⁴ Complaint for Declaratory and Injunctive Relief at 1, *Valley Meat Co. v. Vilsack*, No. 12-cv-01083 (D.D.C. Oct. 19, 2012). The suit was joined by certain stockgrower trade associations—but not processors. See Motion to Intervene, *Valley Meat Co.*, No. 12-cv-01083 (Feb. 21, 2013).

⁵⁵ Complaint for Declaratory and Injunctive Relief at 3–4, *Nolechek’s Meats, Inc. v. Vilsack*, No. 21-cv-762 (W.D. Wis. Dec. 2, 2021). On the small size of Nolechek, see *Nolechek’s Meats, A Small, Family-Run Business in Wisconsin, Is Fighting Back Against the Biden Administration’s Use of the USDA to Implement Its Partisan Public Health Agenda*, LIBERTY JUST. CTR., <https://libertyjusticecenter.org/cases/nolecheks-meats-v-usda-and-fsis/> [<https://perma.cc/J9P8-5HVE>]. On the small size of the other two plaintiffs, Golden City Meats and We’re the Wurst, see *Meat, Poultry, and Egg Product Inspection Directory*, FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory> [<https://perma.cc/QHA6-J26P>].

⁵⁶ Brittany Slaughter, *Thorp Business Sues USDA Over Mask Rule*, WQOW (Dec. 20, 2021), https://www.wqow.com/news/wisconsin/thorp-business-sues-usda-over-mask-rule/article_c604998d-974c-5597-91c7-bc2be0f2688a.html [<https://perma.cc/4EYU-NT9B>].

⁵⁷ GREENE, *supra* note 45, at 5; MARION NESTLE, *SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM* 52, 54, 66 (2003).

⁵⁸ NESTLE, *supra* note 57, at 43–49.

known pathogens like *Salmonella*.⁵⁹ Perhaps most importantly, *E. Coli*—which in its generic form is familiar and harmless—was found to have an extremely dangerous strain (O157:H7) that led to its first outbreak in 1982.⁶⁰ In light of all this, the National Academy of Sciences in 1985 recommended that FSIS shift focus to microbial contamination.⁶¹ Initially this proposal went unheeded, but in winter of 1992–1993, *E. Coli* O157:H7 in hamburgers at Jack in the Box restaurants killed four small children,⁶² and the same microbe killed other children in other locales into the following year.⁶³

In 1994, FSIS responded with two revolutionary changes.⁶⁴ First, it declared *E. Coli* O157:H7 in raw ground beef to be an “adulterant” whose mere presence would bar the product from commerce.⁶⁵ This was the first time USDA had treated a meat pathogen as an adulterant,⁶⁶ making it “perhaps the single most important change in USDA history.”⁶⁷ Second, FSIS began a rulemaking to require all meat and poultry processors to adopt the food industry’s gold standard for microbial-contamination prevention systems, known as Hazard Analysis Critical Control Points (“HACCP”).⁶⁸ Two years later in 1996, when the regulation mandating HACCP was promulgated, it was known as the “Mega-Reg.”⁶⁹ One of its several features was that certain pathogens that were *not* declared adulterants, such as *Salmonella*, would be subject to “pathogen standards” whereby each facility had to keep their presence below a certain level or face consequences.⁷⁰

Given that the modern history of FSIS really begins in 1994, this Article supplements the data on industry judicial challenges in 2009–2024 with additional research on such challenges for the earlier period of 1994–2009 to provide a sense of the full arc of that history. The idea of using Bloomberg docket searches for the period from 1994 to 2009 was unpromising, because (1) FSIS is a component of USDA, and challengers to FSIS actions may reference only USDA as a defendant or respondent,

⁵⁹ See *id.* at 40.

⁶⁰ *Id.* at 40–42.

⁶¹ *Id.* at 70; Johnson & Swaim, *supra* note 41, at 349.

⁶² NESTLE, *supra* note 57, at 73; see also Johnson & Swaim, *supra* note 41, at 352.

⁶³ See *STOP, CPSI Protest Meat Industry E. Coli Lawsuit*, FOOD CHEM. NEWS, Nov. 7, 1994.

⁶⁴ See NESTLE, *supra* note 57, at 81–82.

⁶⁵ *Id.*

⁶⁶ Tex. Food Indus. Ass’n v. Espy, 870 F. Supp. 143, 145 & n.1 (W.D. Tex. 1994).

⁶⁷ NICOLS FOX, SPOILED: THE DANGEROUS TRUTH ABOUT A FOOD CHAIN GONE HAYWIRE 256 (1997). On the legal status of “adulterant,” see U.S. GOV’T ACCOUNTABILITY OFF., GAO-18-272, FOOD SAFETY: USDA SHOULD TAKE FURTHER ACTION TO REDUCE PATHOGENS IN MEAT AND POULTRY PRODUCTS 10 (2018).

⁶⁸ See NESTLE, *supra* note 57, at 67–68; Johnson & Swaim, *supra* note 41, at 350, 352–54, 354 n.99.

⁶⁹ Johnson & Swaim, *supra* note 41, at 337–38, 353–54, 354 n.99.

⁷⁰ See U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 67, at 9–10.

with the result that any search will turn up numerous challenges to USDA that may have nothing to do with FSIS, and (2) Bloomberg contains fewer and fewer underlying filings as one goes back toward the early 2000s such that it would be difficult to determine whether these USDA-only suits concerned FSIS or not. Therefore, I conducted two alternative searches for the period of 1994–2009 that were likely to catch any major litigation. First, I searched the Bloomberg dockets database for all suits naming, as defendant or respondent, FSIS—whether by name, by acronym, or by its top officials’ title (the Under Secretary for Food Safety or the FSIS Administrator) or personal name.⁷¹ Second, I searched the Westlaw database of federal judicial opinions for any opinion that included FSIS’s full name or acronym anywhere in the opinion.⁷² I also reviewed treatises and law review literature.

What I found is that, starting from when FSIS transformed the regulatory regime in 1994, meat and poultry processors did bring a few challenges over a period of about ten years, but these challenges were always limited, were decidedly mixed in whether they improved industry’s position as a matter of law and customer relations, and ultimately died out in the mid-2000s, leading to the no-challenge equilibrium that has been stable up to 2024. Here, I recount the limited and mixed-result challenges that occurred from 1994 to the mid-2000s⁷³ with attention to

⁷¹ DATASET, *supra* note 10, Files 7–8.

⁷² This was a search of Westlaw ALLFEDS database within the date range with the following search terms: “Food Safety and Inspection Service” OR “Food Safety & Inspection Service” OR “Food Safety Inspection Service” OR FSIS.

⁷³ My account covers all suits turned up by these searches that were by a processor or association of processors against FSIS (or against USDA on an FSIS matter) except the following:

- One challenge involving a minor bespoke issue: Original Honey Baked Ham Co. of Ga., Inc. v. Glickman, 172 F.3d 885, 886–87 (D.C. Cir. 1999) (deciding challenge to USDA’s decision that a retailer’s use of temporary shopping mall kiosks to sell its product subjects it to inspection requirements that would otherwise be inapplicable);
- Challenges by companies who are not processors (e.g., stockgrowers or exporters), including companies that were previously in processing but were no longer in processing at the time of suit: *E.g.*, Complaint at 4–7, Heine v. Vilsack, No. 12-cv-01992 (E.D. Cal. Dec. 6, 2012);
- Challenges brought only for damages: *E.g.*, Complaint at 1, OMC LLC v. United States, No. 21-cv-02183 (D. Minn. Oct. 5, 2021); Goetz & Sons W. Meat LLC v. United States, No. C07-00986, 2008 WL 449654, at *2 (W.D. Wash. Feb. 19, 2008); and
- Challenges by processors on issues other than product safety: FPL Food LLC v. USDA, 671 F. Supp. 2d 1339, 1344–45 (S.D. Ga. 2009) (challenging USDA finding that inspector did not harass processor’s employees and seeking declaration that inspector’s continued harassment would violate their civil rights while also bringing damages claims and state law claims); Columbia Farms, Inc. v. Glickman, No. 6:98-cv-03318 (D.S.C. Nov. 10, 1998); North Am. Casing Ass’n v. USDA, No. 1:96-cv-2349 (D.D.C. Oct. 9, 1996). The Bloomberg docket for *Columbia Farms* has no documents, but the press reported the challenge was about the inspectors refusing

the risks the lawsuits entailed for processors' stakes in their relationships with FSIS and to their reputations with their own customers. I will then discuss, in light of those risks, some ways of understanding the no-challenge pattern that took hold afterward and persists today.

The first challenge in this chronology was to the very act that kicked off the revolution in 1994: FSIS's designation of *E. Coli* O157:H7 as a banned adulterant. The processors' leading trade association, American Meat Institute ("AMI"), sued alongside several other trade associations in a federal district court in Texas, seeking a preliminary injunction.⁷⁴ As one journalist recounted, FSIS had anticipated such a lawsuit but "had gambled that," in light of recent tragic events, "the weight of public opinion now favored food safety."⁷⁵ When AMI hosted a conference in Chicago on the day after filing suit, its officials "were surprised when . . . they were met by protestors" outraged by the litigation.⁷⁶ The protest included a press conference by two mothers of small children recently killed by the exact bacterial strain at issue.⁷⁷ Addressing AMI and its president, one of the mothers said, "AMI, Mr. Boyle, how dare you oppose microbial testing that if used could have prevented [my 6-year-old son] Alex's death?"⁷⁸ A few weeks later, the district judge denied the preliminary injunction.⁷⁹ Within a week, AMI and its allied associations dropped the suit, even as they issued a statement that they "continue[d] to believe" that FSIS's approach was "wrong."⁸⁰ As one journalist said, the industry "would back off publicly. There wasn't a lot of good press to be gained by fighting food safety in the open. The industry would confine its considerable influence to getting the best deal it could from the upcoming HACCP regulations."⁸¹

to stay in the plant because "something in the air was causing them respiratory distress, headaches, burning eyes, and blurred vision" but without a suggestion that "the food [is] contaminated." *Judge Puts Chicken Processor Back in Business*, ASSOCIATED PRESS, Nov. 18, 1998. The Bloomberg Docket for *North American Casings* has no documents, but the press reported the challenge was about a labeling issue unrelated to safety. *FSIS Proposes Rule to Label Sausage Casings Differently from Sausage Contents*, FOOD LABELING NEWS, July 31, 1997.

⁷⁴ Texas Food Indus. Ass'n v. Espy, 870 F. Supp. 143, 144-45 (W.D. Tex. 1994).

⁷⁵ Fox, *supra* note 67, at 255, 257.

⁷⁶ *Id.* Fox says the protest was three days after the filing, but it was actually one day, as the suit was filed on Tuesday, November 1, 1994, Espy, 870 F. Supp. at 145, and the protest was on Wednesday, November 2, Steven Pratt, *Some Unsavory Questions for Meat Industry Group*, CHI. TRIB., Nov. 3, 1994, at B1.

⁷⁷ Pratt, *supra* note 76.

⁷⁸ STOP, CSPI Protest Meat Industry *E. Coli* Lawsuit, *supra* note 63.

⁷⁹ Espy, 870 F. Supp. at 143, 149.

⁸⁰ *E. Coli Sampling Lawsuit Dropped by Industry Groups*, FOOD CHEM. NEWS, Dec. 26, 1994 (referring to announcement previously reported on December 19).

⁸¹ Fox, *supra* note 67, at 258.

The HACCP “Mega-Reg” was ultimately promulgated in 1996 after a set of complex and opaque machinations in which industry players were at times divided and shifting, and members of the new Republican Congress were enlisted to try to derail the rulemaking but ultimately backed off in the face of its perceived popularity.⁸² Industry brought no pre-enforcement suits to challenge the Mega-Reg.⁸³

To understand the industry judicial challenges that then occurred from 1996 to the mid-2000s, it is important to begin by considering how FSIS conducted enforcement of HACCP and related policies. By a series of statutes dating from 1907 through the 1960s, FSIS clearly had the power, when a plant was producing under insanitary conditions, to *suspend inspection* of the plant—that is, to stop its inspectors from going to the plant to do their inspection jobs.⁸⁴ Because the meat and poultry inspection acts⁸⁵ prohibit uninspected products from entering commerce,⁸⁶ suspension means the processor “is effectively expelled from the marketplace” while the suspension lasts, which “can be financially ruinous, especially for smaller firms.”⁸⁷

FSIS in the 1990s claimed that it could use this old and fearsome power to enforce the new regime. At a substantive level, FSIS’s 1999 Rules of Practice interpreted the USDA’s enabling legislation—over the objections of industry commenters—to mean that suspension could be used to sanction violations involving the new HACCP requirements and pathogen standards.⁸⁸ The Rules threatened suspension for any processor who failed to adopt an adequate HACCP plan, failed to follow its HACCP plan, or failed to meet pathogen performance standards for a pathogen like *Salmonella*.⁸⁹ At a procedural level, FSIS initially claimed in 1996, before HACCP was even promulgated, that it generally could

⁸² NESTLE, *supra* note 57, at 90–97.

⁸³ The only judicial challenge to HACCP was by FSIS inspectors themselves who disliked the change it made in their duties. See Johnson & Swaim, *supra* note 41, at 351–52, 355.

⁸⁴ See *id.* at 341–44; NESTLE, *supra* note 57, at 338.

⁸⁵ Federal Meat Inspection Act, 21 U.S.C. §§ 601–695; Poultry Products Inspection Act, 21 U.S.C. §§ 451–473.

⁸⁶ See Johnson & Swaim, *supra* note 41, at 341–43.

⁸⁷ *Munsell v. USDA*, 509 F.3d 572, 576 (D.C. Cir. 2007); see also Johnson & Swaim, *supra* note 41, at 338; U.S. Gov’t ACCOUNTABILITY OFF., *supra* note 67, at 27. A plant might shift to state inspection to keep operating and producing saleable product, but this is only possible in the subset of states that have their own inspection systems. Even then, the plant’s product would be limited to sale within the state (unless it is in one of the few states with a cooperative interstate agreement), not to mention the transaction costs of making the shift. See *supra* note 42.

⁸⁸ Rules of Practice, 64 Fed. Reg. 66,541, 66,546 (Nov. 29, 1999) (to be codified at 9 C.F.R. pt. 500).

⁸⁹ *Id.*; 9 C.F.R. §§ 500.3(a)(2), 500.4(a), 500.4(e). Suspension is distinct from withdrawal, which entails ceasing inspection (and shutting down the plant) either permanently or for a definite period of time. This requires a formal hearing beforehand and is relatively rare. Rules of Practice, 64 Fed. Reg. at 66,546; 9 C.F.R. § 500.6; see also Johnson & Swaim, *supra* note 41, at 356, 359–60.

suspend inspection at a processor without any prior notice. When the agency that year actually did this to a processor, a company named Velasam Veal owned by one individual, to sanction an old-fashioned type of violation unrelated to HACCP (undisclosed use of sulfites that can mask spoilage), the processor went to a U.S. district judge who granted a preliminary injunction against the suspension on the ground that, unless public health or safety required otherwise, FSIS could not suspend inspection without first giving the processor notice and a chance to achieve compliance.⁹⁰ Fifteen days after obtaining the injunction, Velasam—which had suffered a month-long closure and lost many of its customers forever⁹¹—entered a consent decree under which it dropped the suit and agreed to begin following, within a month, “strict procedures” for detecting sulfites on pain of being shut down.⁹² In its 1999 Rules of Practice, FSIS made a limited concession in light of the district court’s ruling, asserting the power to impose a no-warning suspension only in certain extreme cases, like if a processor had no HACCP plan at all.⁹³ But the prior warning that FSIS promised to provide for the mine run of suspensions, like for inadequacy of a HACCP system, allowed only for an opportunity to achieve compliance with agency demands,⁹⁴ and FSIS asserted power to impose suspension in the event of the processor’s failure to do so. Although the processor might then contest the suspension through internal FSIS appeals or a USDA administrative law judge (“ALJ”) hearing,⁹⁵ the agency claimed it could keep the suspension in place while those proceedings unfolded and, further, that the processor could not seek judicial review until the proceedings were completed.⁹⁶ This approach threatened to diminish or negate the usefulness of all these stages of review for the processor, who might be driven

⁹⁰ Johnson & Swaim, *supra* note 41, at 362–63; see also *Court Orders FSIS to Reinstate Inspection at California Plant*, FOOD CHEM. NEWS, July 29, 1996. On Velasam’s ownership, see *Meat Recall Ordered*, PRESS DEMOCRAT, Jan. 26, 1996, at B2. Velasam was not among the nation’s top 125 processors by net sales in 1996. See *Top 125 Meat & Poultry Processors*, NAT’L PROVISIONER, May 1996, at 26–37.

⁹¹ Johnson & Swaim, *supra* note 41, at 363 n.166, 372.

⁹² *Velasam Veal Agrees to HACCP, Sulfite Testing in Consent Order with USDA*, FOOD CHEM. NEWS, Aug. 19, 1996 (citing the consent order dated August 6, 1996).

⁹³ Rules of Practice, 64 Fed. Reg. at 66,546. On the link between Velasam and the Rules of Practice, see Johnson & Swaim, *supra* note 41, at 363.

⁹⁴ Rules of Practice, 64 Fed. Reg. at 66,546. Note how the administrative law judge hearing is structured as something entirely separate that happens once a suspension is in place and *not* in abeyance. *Id.*

⁹⁵ *Id.*

⁹⁶ See *infra* note 138. For the key provision, see 7 U.S.C. § 6912(e) (requiring any person bringing suit against USDA or its officers to first “exhaust all administrative appeal procedures established by” the agency). The D.C. Circuit would later say this bar applies to enforcement decisions but not challenges to regulatory policies. *Munsell v. USDA*, 509 F.3d 572, 579 (D.C. Cir. 2007).

out of business while waiting to learn if their objections to the suspension were vindicated.⁹⁷

Strikingly, the legality of most of these controversial assertions of substantive and procedural powers has been left hanging from the 1990s to the present without the industry or the agency forcing a judicial resolution. The case that went furthest toward providing resolution—which was not terribly far—arose in late 1999. The case, *Supreme Beef Processors, Inc. v. USDA*,⁹⁸ concerned the Mega-Reg’s pathogen performance standard for *Salmonella*, under which a processor whose product exceeded certain levels of that pathogen was subject to suspension.⁹⁹ Industry commenters had argued against this provision of the Mega-Reg during the rulemaking,¹⁰⁰ but, as with the rest of the Mega-Reg, nobody in industry had sued to challenge it facially. Yet when FSIS in November 1999 moved to suspend the small Dallas processor Supreme Beef¹⁰¹ for failing the standard, the company went to a U.S. district court on November 30 and obtained a temporary restraining order (“TRO”) that day.¹⁰² A preliminary injunction followed on December 20.¹⁰³ The court granted summary judgment on May 25, 2000, on the ground that a processor’s failure to meet the pathogen performance standard for *Salmonella*—which FSIS had never declared a banned adulterant—could not be the *sole basis* for FSIS’s exercise of its authority to suspend inspection for insanitary conditions, because it was possible that *Salmonella* entered the plant in the supplies it received, such that plant conditions were not responsible for the pathogen’s presence.¹⁰⁴

Yet even as the district court shielded Supreme Beef from suspension and ruled in its favor on the merits, the agency took other actions that drove the company out of business. From the time of the *Salmonella* test failures that triggered the attempted suspension, FSIS conducted *daily* testing of Supreme Beef’s product for another pathogen (*E. Coli* O157:H7) on the ground that the agency now “lacked confidence” in

⁹⁷ See Johnson & Swaim, *supra* note 41, at 372 (noting that “under the Rules of Practice FSIS can suspend inspection without any external review outside the agency,” which would include review by Article III courts and adjudicators housed in USDA’s Office of Administrative Law Judges); see also *infra* notes 178–79 and accompanying text.

⁹⁸ 113 F. Supp. 2d 1048 (N.D. Tex. 2000), *aff’d*, 275 F.3d 432 (5th Cir. 2001).

⁹⁹ *Id.* at 1052.

¹⁰⁰ NESTLE, *supra* note 57, at 95.

¹⁰¹ Steven Spiritas, President of Supreme Beef, referred to the company as “our small business.” *Id.* at 105. In 1999, Supreme was not among the nation’s top 160 processors by net sales. See *Top 200: The 1999 Ranking of Leading Processors*, NAT’L PROVISIONER, May 1999, at 28–41.

¹⁰² Temporary Restraining Order and Notice of Hearing at 1, *Supreme Beef I*, 113 F. Supp. 2d 1048 (No. 99-cv-02713).

¹⁰³ Preliminary Injunction at 1, *Supreme Beef I*, 113 F. Supp. 2d 1048 (No. 99-cv-02713).

¹⁰⁴ *Supreme Beef I*, 113 F. Supp. 2d at 1052–54.

the company's safety generally.¹⁰⁵ Daily testing was an unprecedented step; it effectively forced the company to hold back all product from shipping for the five to seven days necessary to obtain test results, expending much of the product's shelf life.¹⁰⁶ This could make it "difficult for the company to retain customers."¹⁰⁷ In September 2000, the company declared bankruptcy and later ended up in liquidation.¹⁰⁸ The trade press reported that "some industry sources . . . alleged" that "FSIS used the daily tests to try to drive the company out of business."¹⁰⁹

Although trade associations had never brought pre-enforcement challenges to the Mega-Reg, one of them did seek to intervene in support of Supreme Beef after the company's initial success in obtaining the preliminary injunction on December 20, 1999. This was the California-based National Meat Association ("NMA"), which had changed its name in 1995 from the Western States Meat Association ("WSMA").¹¹⁰ The NMA had a particular connection with Supreme Beef, as Supreme Beef's president Steven Spiritas had been president and chair of WSMA from 1993 to 1994.¹¹¹ NMA's motion to intervene on Supreme Beef's side in January 2000 was denied by the district court, but it was later granted by the Fifth Circuit after the agency had appealed its district court loss and the company had gone bankrupt.¹¹²

The Fifth Circuit affirmed in December 2001, handing a victory to NMA, albeit a limited one.¹¹³ On the one hand, there was now a precedential holding that failing the *Salmonella* pathogen performance standards could not be the *sole basis* for suspending inspection—a view

¹⁰⁵ Allison Beers & Jay Fletcher, *Supreme Beef to Shut Down, File for Bankruptcy*, FOOD CHEM. NEWS, Oct. 2, 2000.

¹⁰⁶ Johnson and Swaim attribute Supreme Beef's bankruptcy primarily to the daily testing. Johnson & Swaim, *supra* note 41, at 366 n.180, 372 n.217. They add that Supreme Beef also lost government contracts. *Id.* at 366 n.180. Nestle emphasizes that Supreme was subjected to daily testing and that USDA canceled its contract with a school lunch program. NESTLE, *supra* note 57, at 105.

¹⁰⁷ Beers & Fletcher, *supra* note 105.

¹⁰⁸ See *Supreme Beef Processors, Inc. v. USDA (Supreme Beef II)*, 275 F.3d 432, 436 (5th Cir. 2001).

¹⁰⁹ Beers & Fletcher, *supra* note 105.

¹¹⁰ History, MEAT INST., <https://www.meatinstitute.org/History> [<https://perma.cc/9WVY-QFK9>].

¹¹¹ Bruce Ingersoll, *Texas Processing Plant Tests USDA's New Meat-Safety Program*, WALL ST. J. (Dec. 6, 1999), <https://www.wsj.com/articles/SB944436094481450424> [<https://perma.cc/BCV9-7FCJ>] (noting Spiritas is a past NMA president and chair); *Western Meat Association Elects Officers, Directors*, SUPERMARKET NEWS (Apr. 18, 1994), <https://www.supermarketnews.com/meat/western-meat-association-elects-officers-directors> [<https://perma.cc/XF4Y-X6FB>] (reporting Spiritas's successor as president of WSMA for the 1994–1995 season).

¹¹² *Supreme Beef II*, 275 F.3d at 437. The original motion to intervene is docket entry 30 in the district court case. See Motion by Movant National Meat for Leave to Intervene as Plaintiff, *Supreme Beef I*, 113 F. Supp. 2d 1048 (N.D. Tex. 2000) (No. 99-cv-02713). Note that four other trade associations were amici. See Nestle, *supra* note 57, at 104. However, AMI was not one of these. See *Supreme Beef II*, 275 F.3d at 434.

¹¹³ See *Supreme Beef II*, 275 F.3d at 434.

to which USDA, with Republican appointees now in charge, acquiesced nationwide.¹¹⁴ But on the other hand: (1) the principle that FSIS could not shut down plants *solely* for *Salmonella* levels still permitted the agency to use such levels as *one factor* in enforcement,¹¹⁵ including as a basis for intensifying scrutiny of plants, which FSIS promised it would, and did, do;¹¹⁶ (2) the question whether FSIS could shut down plants for HACCP violations remained unresolved;¹¹⁷ (3) the question whether suspended processors had to exhaust FSIS internal appeals or a USDA ALJ hearing before going to court remained unresolved;¹¹⁸ and (4) FSIS had demonstrated its ability to bankrupt a company *even while a court was protecting the company from suspension*.

It should also be noted that this limited court victory resulted in bad publicity before consumer audiences, not only for Supreme Beef—which attracted “a great deal of criticism in the press”¹¹⁹—but also for NMA. A few weeks after the Fifth Circuit ruling, the CBS Evening News ran a report about the case, which Dan Rather introduced as showing “why you may have grounds for concern” about eating ground beef.¹²⁰ The report by Wyatt Andrews opened with an interview with a food safety advocate who said, “The courts have given the ground beef industry permission to sell filthy meat to the American public.”¹²¹ It then cut to an interview with the NMA spokesman:

¹¹⁴ NESTLE, *supra* note 57, at 106–07.

¹¹⁵ See GREENE, *supra* note 45, at 6.

¹¹⁶ On FSIS’s initial plan for continued testing for *Salmonella* and inspection scrutiny, see NESTLE, *supra* note 57, at 106–07. Starting in 2015, every plant that did not meet a pathogen standard had to get a public health risk evaluation. U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 67, at 28; see also Interview with Shawn Stevens, *supra* note 45 (noting that the triggered assessment can involve experts coming in for a week). But this assessment does not necessarily lead to shut-down; plants can repeatedly fail to meet the *Salmonella* standard and not be shut down. U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 67, at 28 n.50. A former FSIS career official reflected on the loss in *Supreme Beef II* by saying the agency “would test product for *Salmonella* and interpret a positive test result as a ‘license to hunt’ for yet to be identified regulatory noncompliance.” Michael Fisher, *FSIS and a Fundamental Truth*, FOOD SAFETY NEWS (Nov. 14, 2022), <http://foodsafetynews.com/2022/11/fsis-and-a-fundamental-truth/> [<https://perma.cc/97YX-QMB4>].

¹¹⁷ Johnson & Swaim, *supra* note 41, at 364 (explaining the suit “did not challenge FSIS’s asserted authority to suspend for HACCP or [sanitation standard operating procedure] non-compliance”).

¹¹⁸ *Id.* at 365 n.175. The district court had ruled favorably for Supreme Beef on the exhaustion question, *id.*; however, the Fifth Circuit avoided the issue, never addressing the exhaustion of agency procedures in its opinion, see *Supreme Beef II*, 275 F.3d at 434–43. Given Supreme Beef’s bankruptcy and exit from the processing business, the government’s brief focused its availability-of-review argument on mootness and did not address exhaustion. See Brief for Appellant at 25–28, *Supreme Beef II*, 275 F.3d 432 (No. 00-11008).

¹¹⁹ Beers & Fletcher, *supra* note 105.

¹²⁰ *Evening News with Dan Rather: Is U.S. Meat Safe?* (CBS News television broadcast Jan. 28, 2002) (transcript on file with *The George Washington Law Review*).

¹²¹ *Id.*

JEREMY RUSSELL, NATIONAL MEAT ASSOCIATION:

When you close down a grinder for an action they cannot control, something—a problem they did not create, it's essentially unfair. There's nothing they can do to fix the problem.

ANDREWS: Excuse me, can't they just buy cleaner meat?

RUSSELL: Well, that would be a goal, but there's only so clean that you can make the meat.

The segment then immediately contradicted the NMA spokesman by cutting to an interview with a grinder who said it would cut off a supplier who didn't pass *Salmonella* tests. Andrews then said "the grinding business has good actors and bad actors. And right now, says USDA inspector Steve Cockerham, the courts have given the bad actors a green light."¹²²

NMA's involvement in Supreme Beef's suit appears to have been the peak of the meat and poultry industry's use of the courts to challenge FSIS regulation over the last thirty years. That industry challenges dwindled to near zero soon thereafter might be attributed to a combination of multiple historical shifts. Obviously, FSIS backed off direct enforcement of the *Salmonella* standards, relieving pressure on processors. On the other side, it appears the industry was growing more sensitive to consumer preferences for microbial safety. This may be partly because the Centers for Disease Control and Prevention was building PulseNet, a national surveillance system for pathogens using DNA signatures that made it more feasible to identify which companies were the sources of outbreaks. PulseNet began in 1996 and expanded to include all fifty states by 2001.¹²³ Looking back on his experience representing meat companies at that time, interviewee Stevens said, "That's when the lights went on. . . . Suddenly you can see everything, right? That's kind of what happened, [in the] early 2000s, with PulseNet."¹²⁴ Simultaneously the number of meat and poultry recalls skyrocketed from about twenty-five per year in 1996–1997 to 125 in 2002.¹²⁵ Retailers of meat and poultry in the late 1990s and early 2000s increasingly demanded less-tainted product out of reputational concern: The 2002 CBS News Report cited above said the grinder who cut off substandard suppliers did so because its fast food chain buyers demanded it.¹²⁶ Earlier, Burger King in 1997 had bought full-page advertisements in major

¹²² *Id.*

¹²³ See 20 Years of PulseNet USA: 1996–2016 (illustration), in CDC Stacks Historic Archive, CTRS. FOR DISEASE CONTROL & PREVENTION (May 9, 2016).

¹²⁴ Interview with Shawn Stevens, *supra* note 45.

¹²⁵ Acton Gorton & Matthew J. Stasiewicz, *Twenty-Two Years of U.S. Meat and Poultry Product Recalls: Implications for Food Safety and Food Waste*, 80 J. FOOD PROT. 674, 677 tbl.1 (2017).

¹²⁶ EVENING NEWS WITH DAN RATHER: *Is U.S. Meat Safe?*, *supra* note 120.

newspapers trumpeting that it would not use beef from Hudson Foods, a processor that had a recent outbreak of *E. Coli* O157:H7.¹²⁷

Industry challenges to FSIS that followed *Supreme Beef* faced intra-industry skepticism and were few. The first was by House of Raeford, the twenty-first-largest processor nationwide in 2002, owning poultry plants in multiple states.¹²⁸ After its Louisiana plant was suspended repeatedly, the company sued in district court in December 2001 to challenge FSIS's "pattern and practice of issuing suspensions of inspections without any prior hearing."¹²⁹ A magistrate judge later said, in a report adopted by the district judge, that it was unclear whether Raeford was challenging individual FSIS enforcement decisions or instead the Rules of Practice facially: if the former, the suit was barred by Raeford's obligation to exhaust USDA's internal appeals process, but if the latter, the company could sue now.¹³⁰ Accordingly, the judge denied the government's motion to dismiss in order to sort out exactly what Raeford was challenging.¹³¹ The suit later settled.¹³² Raeford's suit never garnered any support from trade associations or other parties as intervenors or amici. Raeford's fellow processors appear to have been annoyed with its adversary tactics generally. For instance, the year before Raeford sued, the company had resisted an FSIS request to recall products from another of its plants that tested positive for *Listeria*. The trade press reported that, in contrast to *Supreme Beef*, "there was no move by trade associations or other meat companies to rally to Raeford's side. Indeed, the company was simultaneously criticized and mocked for behaving in a manner that many considered to be foolish" by "hand[ing] legislative ammunition to USDA" and "rekindl[ing] public concern that meat companies put profits ahead of public safety."¹³³

The second post-*Supreme Beef* suit was by Nebraska Beef, a one-plant company that was "mid-sized" compared with other Nebraska

¹²⁷ NESTLE, *supra* note 57, at 100.

¹²⁸ *Front Runners: Top 150*, NAT'L PROVISIONER, May 2003, at 14.

¹²⁹ Complaint for Declaratory and Injunctive Relief at 9, *House of Raeford Farms of La., LLC v. Veneman*, No. 01-cv-02682 (W.D. La. Dec 26, 2001).

¹³⁰ Report & Recommendation at 7–10, *House of Raeford Farms*, No. 01-cv-02682 (Oct. 7, 2002), *adopted by*, Order Denying Motion to Dismiss, *House of Raeford Farms*, No. 01-cv-02682 (Feb. 10, 2003).

¹³¹ See Order Denying Motion to Dismiss, *supra* note 130. Although the complaint asked for preliminary relief, Complaint for Declaratory and Injunctive Relief, *supra* note 129, at 16, no disposal of that motion appears on the docket sheet. See Court Docket, *House of Raeford Farms*, No. 01-cv-02682 (filed Dec. 12, 2001).

¹³² See Stipulation of Voluntary Dismissal at 1, *House of Raeford Farms*, No. 01-cv-02682 (Dec. 5, 2003).

¹³³ Allison Beers, *Meat Company Refuses to Recall Product Despite Positive Micro Tests*, FOOD CHEM. NEWS, Oct. 16, 2000.

processors and was not in the top 150 processors nationwide.¹³⁴ After two suspensions, FSIS sought to close the plant a third time in January 2003, for “repeated failure to correct and implement changes to its HACCP plan.”¹³⁵ Nebraska Beef went to a U.S. district court and sought a TRO preventing suspension.¹³⁶ The suit initially looked as if it might lead to disposal of the two issues left unresolved in the *Supreme Beef* litigation. First, Nebraska Beef raised “the potentially explosive issue” of “whether USDA has the authority under the meat inspection act to require that plants have a HACCP plan” at all.¹³⁷ Second, FSIS argued that the processor could not go to court at all before completing internal agency appeals or an ALJ hearing, during either of which the agency would continue the suspension.¹³⁸ Yet, interestingly, the players quickly stepped back from the brink of resolving these issues. The judge granted a TRO on January 14, but on January 24, FSIS and Nebraska Beef entered a two-year consent agreement by which the processor had to “[h]ire an independent third party to assess the plant’s food safety systems repeatedly, in specified time frames.”¹³⁹ FSIS could impose immediate suspension “if the company fail[ed] to meet any critical limit of a critical control point, or [did not] take corrective and preventive action for direct product contamination or adulteration,” but disposition of any other alleged violations of the agreement would allow the company an ALJ hearing before any suspension began.¹⁴⁰ The trade press said the settlement spotlighted several looming questions: “Can USDA close a plant because it fails to follow its HACCP plan? Or does it need evidence of direct product contamination or adulteration to do so? And will this settlement embolden other plants to challenge closures?”¹⁴¹

¹³⁴ Mark Thiessen, *Nebraska Beef Plant Stays Open as USDA Settlement Reached*, ASSOCIATED PRESS, Jan. 24, 2003. Nebraska Beef was not in the top 150 processors nationwide at the time of its suit. See *Front Runners: Top 150*, *supra* note 128, at 10–28.

¹³⁵ Carole Sugarman, *Federal Judge Prevents USDA from Closing Nebraska Beef Plant*, FOOD CHEM. NEWS, Jan. 27, 2003.

¹³⁶ *Id.*; Plaintiff’s Complaint, Application for Temporary Restraining Order, Preliminary Injunction, & Permanent Injunction at 1–2, *Nebraska Beef, Ltd. v. USDA*, No. 03-cv-00016 (D. Neb. Jan. 14, 2003).

¹³⁷ Sugarman, *supra* note 135.

¹³⁸ *Id.* (“Further, USDA argued, Nebraska Beef failed to exhaust its administrative remedies as mandated by the suit. Nebraska Beef is entitled to appeal the suspension in abeyance to a superior agency authority, but it failed to do so, USDA wrote. As for the company’s contention that USDA did not allow it an opportunity for a formal hearing, the department argued that it was not entitled to a hearing prior to the suspension. An expedited hearing comes after a suspension, according to USDA, ‘because the agency must act quickly to prevent adulterated meat from entering interstate commerce and threatening public health and safety.’”).

¹³⁹ David Accord & Carole Sugarman, *USDA Details Decision to Settle Nebraska Beef Case*, FOOD CHEM. NEWS, Feb. 3, 2003.

¹⁴⁰ *Id.*; see also *id.* (“The settlement does not, however, preclude Nebraska Beef from going back to federal court to appeal an unfavorable decision.”).

¹⁴¹ *Id.*

Interestingly, the big trade associations supported the mutual avoidance of judicial resolution and denied that the settlement would encourage more processors to use the courts to resist suspensions. The “general counsel for the American Meat Institute . . . said that he doesn’t believe there’s a winner or loser in the case. Nor does he believe the settlement will set a precedent, or lead to a ‘flurry’ of plants suing the government for being shut down.”¹⁴² And the director of NMA—who had “participated in negotiations between the company and USDA”—stated, “in my view, resolving these issues through a negotiated agreement is far and away the best solution for the future of both the inspection program and the industry.”¹⁴³

The trade association leaders’ prediction that the floodgates of litigation would not open proved correct. To be sure, Nebraska Beef itself did sue again, later in 2003, claiming that FSIS was violating the settlement agreement because of inspector bias.¹⁴⁴ But the suit ultimately settled,¹⁴⁵ with the company lawyer soon afterward saying its “relationship with regulators has changed,” as evidenced by its cooperation in a big recall.¹⁴⁶ Throughout its dispute, Nebraska Beef had no support from trade associations or other processors as intervenors or amici. More broadly, industry had brought no other suits as of mid-2005.

A striking discussion of the rarity of industry challenges appeared in a law review article published in fall 2005 by attorneys at Olsson, Frank, and Weeda,¹⁴⁷ a top agriculture law firm in Washington, D.C.,¹⁴⁸

¹⁴² *Id.*

¹⁴³ *Id.* An official at Consumer Federation of America expressed concern that the agreement “indicates that USDA, or its lawyers, may not believe in its heart of hearts that it actually has the authority to enforce HACCP and the [anti-contamination practices] unless they have direct product adulteration.” *Id.*

¹⁴⁴ See Complaint & Request for Trial by Jury at 3–9, *Nebraska Beef, Ltd. v. USDA*, No. 03-cv-00174 (D. Neb. May 2, 2003). The company also renewed its sweeping challenge to HACCP and the suspension procedures, adding constitutional challenges. *Id.* at 10–11. The litigation continued for years and mostly focused on issues outside the heartland of administrative law, like whether the company could sue the inspectors for damages under *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*, 403 U.S. 388 (1971), reaching the appellate courts only on those issues. See *Nebraska Beef, Ltd. v. Greening*, 398 F.3d 1080, 1080 (8th Cir. 2005). The district judge twice rejected USDA motions to dismiss based on exhaustion. See Memorandum & Order at 5, *Nebraska Beef*, No. 03-cv-00174 (Mar. 18, 2004); Memorandum & Order at 5, *Nebraska Beef*, 03-cv-00174 (Aug. 15, 2007), 2007 WL 2344819. But the exhaustion question was never appealed.

¹⁴⁵ See Memorandum & Order at 1, *Nebraska Beef*, No. 03-cv-00174 (Aug. 15, 2007), 2007 WL 2344819, at *1; Order of Dismissal, *Nebraska Beef*, No. 03-cv-00174 (May 16, 2008).

¹⁴⁶ Annys Shin & Ylan Q. Mui, *Whole Foods Recalls Beef Processed at Plant Long at Odds with USDA*, WASH. POST (Aug. 10, 2008), <https://www.washingtonpost.com/archive/national/2008/08/10/whole-foods-recalls-beef-processed-at-plant-long-at-odds-with-usda/894f65a4-3da9-412f-a9c0-73bd115599ad/> [<https://perma.cc/VD39-8S5T>].

¹⁴⁷ Johnson & Swaim, *supra* note 41, at 337 n.*.

¹⁴⁸ Jonathan Ellis, *Herseth Sandlin Considers Lobbying*, ARGUS LEADER, Feb. 18, 2011 (calling Olsson Frank Weeda “the nation’s premier agriculture firm”).

which had represented NMA in the *Supreme Beef* litigation.¹⁴⁹ In the article, the attorneys presented a copiously documented argument that FSIS lacked statutory authority to suspend inspection for HACCP violations, and they criticized FSIS's more general assertion of unilateral authority to suspend prior to any judicial review.¹⁵⁰ The Olsson attorneys then confronted the looming question: "If the thesis of this article is correct—that FSIS lacks the statutory authority to suspend inspection for most violations of the Mega-Reg," there had nonetheless "been hundreds of enforcement actions threatening and/or imposing suspension," so "the question becomes *why has there been virtually no lawsuits?*"¹⁵¹ "The answer," said the authors, "may rest in several practical issues which make litigation a less attractive course of action."¹⁵² The first issue, they noted, was that FSIS had adopted a prior-warning system whereby it gave processors the opportunity to meet agency demands before it imposed suspension; this tended to head off litigation. The second, third, and fourth issues involved the processors' stakes in consumer perceptions and in their long-term relationships with their regulator:

Second, many of the companies who have been involved in enforcement actions have a brand name which they wish to protect—a challenge to FSIS when the agency is alleging non-compliance with food safety regulations could damage a company's brand name. Third, the establishment may recognize it is placing itself at a competitive disadvantage by resorting to litigation. Fourth, even if a company is successful in litigation, it must not be forgotten that FSIS will continue inspecting the establishment when the case is over. The agency retains sufficient authority to increase the intensity of inspection and increase product testing for adulterants which will make operating under inspection more difficult.¹⁵³

This tendency not to challenge has only grown more pervasive. From mid-2005 to the end of the decade, there were only two suits, neither of which reflected concerted industry resistance to safety regulation—if anything, one reflected industry's adoption of safety as a marketing tool.

The first of these suits had to do with the complaint sometimes heard from small downstream processors that FSIS would punish them for the presence of microbes in their beef when its contamination was really the fault of their suppliers, large upstream processors with whom

¹⁴⁹ *Supreme Beef II*, 275 F.3d 432, 434 (5th Cir. 2001).

¹⁵⁰ Johnson & Swaim, *supra* note 41, at 368–73.

¹⁵¹ *Id.* at 360 (emphasis added).

¹⁵² *Id.*

¹⁵³ *Id.* at 360–61.

FSIS was supposedly too friendly. The American Association of Meat Processors (“AAMP”), which represents small processors, lent its name in August 2005 to a suit on this issue.¹⁵⁴ However, AAMP did not initiate the litigation and may not have committed resources to it.¹⁵⁵ Further, AAMP’s claim—which simply repeated one already made by the small processor who initiated the suit before AAMP became involved¹⁵⁶—was peculiar: It challenged FSIS enforcement, but only “as applied” in the particular scenario where a small processor received tainted product from a large one. Moreover, it sought to enjoin FSIS in that scenario to hold recipient processors blameless and instead trace back contamination to large processors.¹⁵⁷ This was an unusual sort of challenge that the D.C. Circuit on appeal found “hard to fathom” and rejected as unripe, because the challengers were mounting it prior to any actual enforcement proceeding.¹⁵⁸

The second suit against the agency in this earlier period, brought by the industry giant Tyson Foods in 2008,¹⁵⁹ ironically confirmed how far the industry had come since the 1990s in embracing safety as part of its marketing. When Tyson injected its chickens with antibiotics prior to hatching and then labeled the product as “raised” without antibiotics,¹⁶⁰ its competitors got FSIS to rescind its initial approval of the label.¹⁶¹ Tyson then sued FSIS to challenge the rescission, with the competitors moving to intervene on FSIS’s side.¹⁶² Tyson dropped the suit after nine days¹⁶³ once FSIS agreed to give the company an extra three weeks to

¹⁵⁴ First Amended Complaint & Demand for Jury Trial at 1, *Munsell v. USDA*, 435 F. Supp. 2d 149 (D.D.C. 2006) (No. 04-cv-01745) (filed Aug. 22, 2005).

¹⁵⁵ The owner of one very small processor initiated the suit ten months earlier, claiming that he was the victim of unfair enforcement of safety regulations. See [Original] Complaint & Demand for Jury Trial at 21, *Munsell*, 435 F. Supp. 2d 149 (No. 04-cv-01745) (filed Oct. 13, 2004). The processor, Montana Quality Food Processing, was not among the nation’s top 125 processors by net sales in *The Provisioner*. See *The National Provisioner* 125, NAT’L PROVISIONER, May 2004, at 24–42. At the time AAMP joined the suit, Munsell and his company were already being represented by a nonprofit whistleblower organization. See [Original] Complaint & Demand for Jury Trial, *supra*.

¹⁵⁶ Compare [Original] Complaint & Demand for Jury Trial, *supra* note 155, at 18–19 with First Amended Complaint & Demand for Jury Trial, *supra* note 154, at 21–22.

¹⁵⁷ See First Amended Complaint & Demand for Jury Trial, *supra* note 154, at 19–22.

¹⁵⁸ See *Munsell v. USDA*, 509 F.3d 572, 584–87 (D.C. Cir. 2007). The district court had dismissed the complaint on the ground that plaintiffs failed to exhaust administrative remedies. See *Munsell*, 435 F. Supp. 2d at 153.

¹⁵⁹ Tyson was the nation’s largest processor by net sales in *The National Provisioner’s Top 100*. See *Top 100: Ahead of the Pack*, NAT’L PROVISIONER, May 2008, at 38.

¹⁶⁰ Complaint at 3, *Tyson Foods, Inc. v. USDA*, No. 08-cv-01000 (D.D.C. June 11, 2008).

¹⁶¹ Randall K. Miller, *Chicken “Raised Without Antibiotics”: The Latest Lanham Act Deception Case to Bring Down a National Advertising Campaign*, 28 Advert. Compliance Serv. (JLCom Publ’g Co.) 17, 19 (July 21, 2008).

¹⁶² See Emergency Motion to Intervene at 1, *Tyson Foods*, No. 08-cv-01000 (June 13, 2008).

¹⁶³ Notice of Voluntary Dismissal at 1, *Tyson Foods*, No. 08-cv-01000 (June 20, 2008).

change its labels.¹⁶⁴ In contrast to the litigation of 1994, when industry was directly resisting increased safety measures, major companies were now using litigation to jockey for competitive advantage in making *pro-safety* claims that were over and above the requirements of the law.

Now that we have a sense of the limited industry challenges that occurred from 1994 through the mid-2000s, combined with the subsequent absence of challenges up to 2024, we can consider in more depth the factors that have likely contributed to making challenges so rare: the agency's forbearance, or what critics would call its weakness; processors' stake in ensuring their close relationship to the agency is relatively positive; and processors' alignment with the agency, based on their stake in consumer perceptions of safety.

First, agency forbearance (or if you prefer, weakness) plays some role, perhaps a large one. FSIS has refused requests from nongovernmental organizations ("NGOs") to declare certain pathogens, such as the more dangerous strains of *Salmonella*, to be banned adulterants.¹⁶⁵ It has left in place performance standards for some pathogens that critics, such as the Government Accountability Office, consider lax—and for some pathogens it has adopted no performance standards at all.¹⁶⁶ And where pathogen standards do exist, FSIS has always acquiesced to the Fifth Circuit's ruling in *Supreme Beef Processors, Inc. v. USDA*¹⁶⁷ that failing such a standard cannot be the sole basis for suspending inspection—an approach that may have caused a rise in *Salmonella* in chicken in the early 2000s.¹⁶⁸ In these contexts where FSIS does not press the industry, the agency's approach is perhaps being shaped by various nonlitigation means of industry influence over FSIS, which the meat and poultry processors are skillful at using. To name a few, the processors can share data that is useful for program implementation with the agency;¹⁶⁹ they can offer jobs to former FSIS officials;¹⁷⁰ and they can leverage their strong connections on Capitol Hill.¹⁷¹

¹⁶⁴ [Proposed] Joint Stipulation & Order, *Tyson Foods*, No. 08-cv-01000 (June 12, 2008).

¹⁶⁵ Lydia Zuraw, *FSIS Denies CSPI Petition to Declare Antibiotic-Resistant Salmonella an Adulterant*, FOOD SAFETY NEWS (Aug. 1, 2014), <https://www.foodsafetynews.com/2014/08/fsis-denies-cspi-petition-to-declare-antibiotic-resistant-salmonella-adulterant/> [https://perma.cc/6Y-HK-ZHE2]; see also *Salmonella Framework for Raw Poultry Products*, 90 Fed. Reg. 17,344 (Apr. 25, 2025) (withdrawing proposal to declare *Salmonella* an adulterant in certain poultry products).

¹⁶⁶ See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 67, at 13–16.

¹⁶⁷ 275 F.3d 432 (5th Cir. 2001).

¹⁶⁸ See Michael S. Williams, Eric D. Ebel, Gurinder Saini & Epiphany Nyirabahizi, *Changes in Salmonella Contamination in Meat and Poultry Since the Introduction of the Pathogen Reduction and Hazard Analysis and Critical Control Point Rule*, 83 J. FOOD PROT. 1707, 1715–16 (2020).

¹⁶⁹ See Interview with Jolyda Swaim, *supra* note 28.

¹⁷⁰ E.g., *JBS Taps Almanza to Lead Its Food Safety Program Worldwide*, FOOD SAFETY NEWS (Aug. 4, 2017), <https://www.foodsafetynews.com/2017/8/jbs-taps-almanza-to-lead-its-food-safety-program-worldwide/> [https://perma.cc/S3ZP-8A94].

¹⁷¹ NESTLE, *supra* note 57, at 62; see also *supra* notes 81–82 and accompanying text.

But I do not think FSIS forbearance (or weakness) is a complete explanation for the absence of industry challenges, because FSIS has taken significant actions that constrain industry. To give one key example, the agency in 2011–2012 banned six additional strains of *E. Coli* as adulterants,¹⁷² even as the executive vice president of AMI stated publicly, “I can’t find a scientific way to rationalize the path USDA is taking,” adding, “this policy is simply without a sound foundation.”¹⁷³ Such remarks sound like the basis for a judicial challenge under the arbitrary and capricious standard of the Administrative Procedure Act (“APA”),¹⁷⁴ yet nobody in the industry sued. More generally, FSIS has for many years, across the roughly 6,000 plants it inspects, engaged in regular and active use of suspensions when enforcing safety requirements—including HACCP requirements, notwithstanding the legal doubts cited earlier. In fiscal year 2016, suspensions for violations implicating consumer safety numbered eighty-two, of which thirty were for HACCP violations.¹⁷⁵ In fiscal year 2019, such suspensions numbered eighty, of which thirty were for HACCP.¹⁷⁶ To be sure, most suspensions are eventually held in

¹⁷² Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products, 76 Fed. Reg. 58,157, 58,160 (Sept. 20, 2011) (to be codified at 9 C.F.R. pts. 416–17, 430); Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products, 77 Fed. Reg. 31,975, 31,975 (May 31, 2012) (to be codified at 9 C.F.R. pts. 416–17, 430).

¹⁷³ James H. Hodges, *Wrestling with the Science of STEC*, FOOD SAFETY NEWS (Feb. 15, 2012), <https://www.foodsafetynews.com/2012/02/wrestling-with-the-science-of-stec/> [<https://perma.cc/UP5E-HQDK>].

¹⁷⁴ 5 U.S.C. §§ 551–559; see also *id.* § 706(2)(A) (arbitrary and capricious standard of review).

¹⁷⁵ See FOOD SAFETY & INSPECTION SERV., U.S. DEP’T OF AGRIC., QUARTERLY ENFORCEMENT REPORT OCTOBER 1, 2015 THROUGH DECEMBER 31, 2015, at 5–32 (2016), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/QUER-Q1-FY2016.pdf [<https://perma.cc/H2BG-73V4>] (compiled with deduplication); FOOD SAFETY & INSPECTION SERV., U.S. DEP’T OF AGRIC., QUARTERLY ENFORCEMENT REPORT JANUARY 1, 2016 THROUGH MARCH 31, 2016, at 5–28 (2016), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/QUER-Q2-FY2016-Tables.pdf [<https://perma.cc/TQH2-USLT>] (compiled with deduplication); FOOD SAFETY & INSPECTION SERV., U.S. DEP’T AGRIC., QUARTERLY ENFORCEMENT REPORT APRIL 1, 2016 THROUGH JUNE 30, 2016, at 5–27 (2016), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/QUER-Q3-FY2016-Tables.pdf [<https://perma.cc/K8WF-QNJ6>] (compiled with deduplication); FOOD SAFETY & INSPECTION SERV., U.S. DEP’T OF AGRIC., QUARTERLY ENFORCEMENT REPORT JULY 1, 2016 THROUGH SEPTEMBER 30, 2016, at 5–30 (2016), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/QUER-Q4-FY2016-Tables-R.pdf [<https://perma.cc/QQ96-6SV4>] (compiled with deduplication). The counts are for suspensions for violations of HACCP, of Sanitation Standard Operation Procedures (which are aimed at preventing contamination), or of more general Sanitation Performance Standards. For details, see DATASET, *supra* note 10, File 61.

¹⁷⁶ See FOOD SAFETY & INSPECTION SERV., U.S. DEP’T AGRIC., QUARTERLY ENFORCEMENT REPORT OCTOBER 1, 2018 THROUGH DECEMBER 31, 2018, at 6–26 (2019), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/QUER-Q1-FY2019-Tables.pdf [<https://perma.cc/62SU-WN52>] (compiled with deduplication); FOOD SAFETY & INSPECTION SERV., U.S. DEP’T AGRIC., QUARTERLY ENFORCEMENT REPORT JANUARY 1, 2019 THROUGH MARCH 31, 2019, at 6–23 (2019), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/quer-q2-fy2019-tables.pdf [<https://perma.cc/F687-4UVC>] (compiled with deduplication); FOOD SAFETY & INSPECTION SERV., U.S. DEP’T AGRIC.,

abeyance, but even those suspensions typically go into force for a few days before the abeyance begins, thereby imposing costs on the processor.¹⁷⁷ Plus, FSIS's willingness to hold a suspension in abeyance is generally conditioned on the processor's coming into compliance with FSIS demands¹⁷⁸—and suspension is an effective threat, because without abeyance it can lead to bankruptcy.¹⁷⁹ Moreover, these statistics do not include the much larger number of early stage warnings backed by the threat of suspension that induce processors to come into compliance¹⁸⁰

QUARTERLY ENFORCEMENT REPORT APRIL 1, 2019 THROUGH JUNE 30, 2019, at 5–23 (2019), https://www.fsis.usda.gov/sites/default/files/media_file/2020-11/qer-q3-fy2019-tables.pdf [<https://perma.cc/C9XK-648G>] (compiled with deduplication); FOOD SAFETY & INSPECTION SERV., U.S. DEP'T AGRIC., QUARTERLY ENFORCEMENT REPORT JULY 1, 2019 THROUGH SEPTEMBER 30, 2019, at 5–23 (2019) https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/qer-q4-fy2019.pdf [<https://perma.cc/V6G4-PDBM>] (compiled with deduplication). For details, see DATASET, *supra* note 10, File 62.

¹⁷⁷ Abeyance is expressly contemplated in Rule of Practice § 500.5(e). 9 C.F.R. § 500.5(e). In fiscal year 2016, seventy-two of the eighty-two suspensions were ultimately held in abeyance, though the average number of business days of shutdown prior to holding in abeyance was nine for large plants, nine for small plants, and nine for very small plants. *See* sources cited in *supra* note 175. In fiscal year 2019, sixty-five of the eighty suspensions were ultimately held in abeyance, though the average number of business days of shutdown prior to holding in abeyance was two for large plants, five for small plants, and eight for very small plants. *See* sources cited in *supra* note 176.

¹⁷⁸ Andrew Lorenz, *How to React to USDA Enforcement Actions*, NAT'L PROVISIONER, May 2020, at 25 (“Appealing [a notice of suspension] is even harder, because every minute it takes you to put your evidence together for the appeal is time you are not operating. What I typically recommend is that you answer the findings so you can run [i.e., stay open] and then appeal so [the suspension] is struck from the record. When doing this, I also write to the suspending authority and tell them I intend to appeal, but I’m going to do what they want so I can run.”).

¹⁷⁹ Michael Fisher, *FSIS and the Era of Enforcement*, FOOD SAFETY NEWS (Nov. 21, 2022), <https://www.foodsafetynews.com/2022/11/fsis-and-the-era-of-enforcement/> [<https://perma.cc/UA7W-Y3CC>] (“Any appeal of alleged noncompliance must pass up the FSIS chain of command until granted. . . . Moving an appeal through the FSIS chain of command can take months. Most establishments give up long before that. . . . An establishment may request a formal proceeding before an Administrative Law Judge (ALJ) if FSIS implements a suspension not held in abeyance. . . . If the ALJ rules in favor of FSIS, the establishment can appeal to the [USDA Office of General Counsel] Judicial Officer. If the Judicial Officer rules for FSIS, the establishment can seek judicial review in federal District Court. The FSIS requirement to provide procedural due process has been satisfied. In the meantime, the suspension remains in place. . . . FSIS offers a free choice in which only one choice is offered (i.e., do it my way) because the alternative (i.e., bankruptcy) is highly undesirable. The FSIS bureaucracy does not obstruct the pathway to due process; however, it does put in place a detour of such magnitude that few establishments have sufficient political clout or pockets deep enough to navigate the detour. Those who choose to travel the detour . . . risk finding themselves a party to bankruptcy. Such is the administrative power of FSIS.”). The author here, Dr. Michael Fisher, is a former FSIS career official. *Dr. Michael Fisher*, FOOD SAFETY NEWS, <https://www.foodsafetynews.com/author/mfisher/> [<https://perma.cc/QX6Q-VHBH>].

¹⁸⁰ For an official list of the number of these warnings, see *Quarterly Enforcement Reports*, FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/inspection/regulatory-enforcement/quarterly-enforcement-reports> [<https://perma.cc/H67D-Q74V>]. On this warning system, see Shawn K. Stevens, *Managing Your Next Food Safety Assessment*, NAT'L PROVISIONER (Mar. 4, 2014), www.provisioneronline.com/articles/100193-managing-your-next-food-safety-assessment [<https://perma.cc/6ZB5-GG52>] (“If FSIS determines that there is a problem or observes something it does not

or to conduct a recall.¹⁸¹ Additionally, the policies enforced through these suspensions and warnings have grown more elaborate and specific over time. Whereas the HACCP regulation was very basic when first adopted in 1996, FSIS issued guidelines in 2015 for how processors must provide validation studies for their HACCP plans, and inspectors have since been demanding that companies point to validation studies to show that their processes at each critical point are acceptable for preventing contamination.¹⁸² FSIS has issued, for *Salmonella*, revised and more stringent performance standards for different products in 2011 and 2016 and, for *Campylobacter*, entirely new performance standards for different products in 2011 and 2016.¹⁸³ And while FSIS will not suspend a plant solely for failing these standards, it does use such failures as a factor in evaluating a company's "process control" and has "found that using pathogen reduction performance standards in this way is effective in encouraging improved establishment control of pathogens."¹⁸⁴ A related FSIS innovation, starting in the 2000s, was to publish data revealing how individual companies were doing on the pathogen standards; this made the data available to purchasers like downstream

like, FSIS will in many cases issue[] a[] Notice of Intended Enforcement (NOIE) threatening to shut the company down. Although FSIS may hold the threatened suspension 'in abeyance,' it will not lift the NOIE until any problems have been remedied to the satisfaction of [the] agency."); Johnson & Swaim, *supra* note 41, at 360 ("In most occasions, the establishment will take action to allay any concerns the agency might have and continue operations. In some cases, due to an inadequate response or repeated positive laboratory findings, an actual suspension may result, requiring additional actions on the part of the establishment to respond to agency concerns."); MICHAEL T. ROBERTS, *FOOD LAW IN THE UNITED STATES* 137 (2016) ("Th[e] leverage [arising from powers like suspension] provides a good deal of power to USDA [meat] inspectors"); *see id.* at 139 (same for poultry).

¹⁸¹ FSIS does not have statutory authority to order a recall directly. *See* Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 *FOOD & DRUG L.J.* 565, 581 (2003). But it can use threats of actions like suspension to pressure a processor to do a recall. *See* Anita Bernstein, *Voluntary Recalls*, 2013 *U. CHI. LEGAL F.* 359, 388 (2013); Interview with Shawn Stevens, *supra* note 45. FSIS requests for recalls are generally never refused except sometimes by small unsophisticated companies. Interview with Jolyda Swaim, *supra* note 28. There were 1,515 FSIS-supervised recalls in the period from 1994 to 2015. *See* Gorton & Stasiewicz, *supra* note 125, at 677 tbl.1.

¹⁸² HACCP Systems Validation, 80 *Fed. Reg.* 27,557 (May 14, 2015) (to be codified at 9 C.F.R. pt. 417); Interview with Jolyda Swaim, *supra* note 28.

¹⁸³ *See* New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments, 76 *Fed. Reg.* 15,282 (Mar. 21, 2011); New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures, 81 *Fed. Reg.* 7285 (Feb. 11, 2016).

¹⁸⁴ New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments; New Compliance Guides, 75 *Fed. Reg.* 27,288, 27,294 (May 14, 2010).

processors, distributors, and retailers, and it may well be one cause of major reductions in *Salmonella*.¹⁸⁵

If forbearance or weakness is not a complete explanation, we may also look to another factor discouraging judicial challenges: each processor's stake in its long-term relationship with FSIS. As documented above, the agency monitors each processor closely and can exercise leverage with the threat of suspension. This means processors have reason to build up goodwill and trust with FSIS and not get crosswise with the agency. Interviewee Stevens, reflecting on many instances of representing processors in matters that theoretically could be litigated but were not, cited the example of one processor who disagreed with certain agency findings of violations and went down a confrontational path of building up documentation to show the findings were wrong. As a result, the "tension rose," the inspectors reciprocated by exercising their discretion to cite relatively technical violations they might otherwise overlook, and the company ultimately decided that "[t]his isn't sustainable, we just need to back off." "When the companies concede," Stevens explained, "the regulatory pressure or aggression decreases." He later added that "[o]ver the years, usually, if there's a dispute between a company and the regulators, it's more likely we're going to create additional problems and challenges for the company if we aggressively lock horns with the regulators."¹⁸⁶ A trade press essay by an attorney at Olsson, Frank, and Weeda warns that if a processor appeals an FSIS decision, "the threat of retaliation is real" and that "appealing too many agency decisions, particularly when they are on shaky grounds, could undermine the establishment's credibility and can cause the agency to question the company's commitment to meeting regulatory requirements."¹⁸⁷

Yet another factor likely playing a role, as documented throughout this discussion, is processors' economic interest in their reputations for safety with consumers or with large purchasers, like supermarkets and restaurants, who transact directly with consumers—an interest that aligns the industry with FSIS's mission. Interviewee Jolyda Swaim, a partner at Olsson with a specialty in dealing with FSIS, discussed how processors' engagement with FSIS is generally by means other than judicial challenges to the agency. When asked why, she replied: "The big thing is the perception by the consumers. I mean that—that's huge. Because how can you say, 'No, we don't want to reduce *Salmonella*'?"

¹⁸⁵ See Michael S. Williams, Eric D. Ebel, Neal J. Golden, Gurinder Saini, Epiphany Nyirabizi & Nelson Clinch, *Assessing the Effectiveness of Performance Standards for Salmonella Contamination of Chicken Parts*, 378 INT'L J. FOOD MICROBIOLOGY, June 2022, at 2, 10; Williams et al., *supra* note 168, at 1712, 1714–15 (2020); GREENE, *supra* note 45, at 7–8.

¹⁸⁶ Interview with Shawn Stevens, *supra* note 45.

¹⁸⁷ Brett Schwemer, *Should Your Establishment Appeal a FSIS Decision?*, NAT'L PROVISIONER (Apr. 5, 2017), <https://www.provisioneronline.com/articles/104634-should-your-establishment-appeal-a-fsis-decision> [<https://perma.cc/H2KQ-BBQA>].

The consumer-perception risks that companies face, added Swaim, have only grown larger in recent years with the rise of social media.¹⁸⁸ Relatedly, interviewee Stevens explained how processors have increasingly embraced food safety over the last several years, such that “it would likely be contrary to a company’s brand if it were to publicly challenge the regulators on a food safety issue.”¹⁸⁹ All this is consistent with a recent literature review on food safety regulation, including FSIS, by the agricultural economics professor John Bovay, which finds that companies “have strong private incentives to provide safe food, largely related to reputation, especially the negative demand effects seen in response to food-safety problems.”¹⁹⁰ A public adversary stance toward the safety regulator would go against this incentive.

B. *Drugmakers and FDA*

The second of our six industry-agency pairings involving a low level of judicial challenges is the one between drug manufacturers and FDA. I argue this pairing fits the pattern of sparseness in challenges, thickness of the company-regulator relationship, and relative interest alignment between companies and the regulator, once again manifested in the agency’s mission to protect the safety of the industry’s customers.¹⁹¹

FDA regulation of drugmakers grew by leaps and bounds over the course of the twentieth century. Its central feature has been the agency’s “gatekeeping” power. In 1938, Congress required the manufacturer of every new drug to submit it to FDA before marketing, and, if the agency found the drug unsafe within sixty days, it could not enter commerce.¹⁹² In 1962, Congress greatly increased the agency’s power by prohibiting any new drug from entering the market until FDA approved it—with no deadline by which the agency had to decide—and by reformulating FDA review to include not only the agency’s judgment of whether the new drug was safe, but also whether it was effective.¹⁹³ Under the

¹⁸⁸ Interview with Jolyda Swaim, *supra* note 28.

¹⁸⁹ Interview with Shawn Stevens, *supra* note 45.

¹⁹⁰ John Bovay, *Food Safety, Reputation, and Regulation*, 45 *APPLIED ECON. PERSPS. & POL’Y* 684, 684 (2022). For specific reference to FSIS, see *id.* at 690–91. Interestingly, “the threat of legal liability does not seem to function as a major deterrent.” *Id.* at 692; see also Fortin, *supra* note 181, at 574–78 (explaining that “the vast majority of foodborne illnesses do not result in lawsuits” because causation for many foodborne illnesses is hard to establish, especially for longer latency periods, which limits the role of tort law).

¹⁹¹ I do not cover other products regulated by FDA, such as biologics, medical devices, tobacco products, dietary supplements, homeopathic products, animal drugs, or food; nor do I cover pharmacies, including compounding pharmacies.

¹⁹² See DANIEL CARPENTER, *REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA* 102–16, 254 (2010).

¹⁹³ See *id.* at 256–80. Indeed, effectiveness review had naturally arisen from safety review even before 1962, since every drug has side effects and the question of safety depends on whether these are offset by the drug’s therapeutic benefits. See *id.* at 118–97.

1962 act, drug companies were at the mercy of FDA for permission to sell their new drugs, and they adapted and fundamentally transformed themselves so their products could pass the expensive scientific tests that the agency required.¹⁹⁴ The process for seeking premarket approval for a new drug has grown into a years-long negotiation in which FDA reviewers make demands and the manufacturer seeks to persuade and satisfy the reviewers with more data.¹⁹⁵ A premarket approval process is also required for generic drugs, though since the Hatch-Waxman Act of 1984¹⁹⁶ this typically has been far less elaborate than for new drugs, as generics need only show equivalence to an already approved drug, not safety and effectiveness in the first instance.¹⁹⁷ Additionally, the Hatch-Waxman Act and other statutes enacted in the last several decades have empowered FDA, apart from its safety-and-effectiveness judgments, to adjudicate manufacturers' rights to various marketing advantages over their competitors, especially "exclusivity" periods, patent extensions, and other monopolies. These rights may be vested in manufacturers as rewards for creating a new chemical entity ("NCE"), for being the first-in-time generic to successfully challenge a new drug patent, for the rarity of a disease that an approved drug treats, and so forth.¹⁹⁸ And beyond its mission of deciding which companies can enter the market and sell what drugs, FDA also has enforcement power to ensure that the manufacturing and marketing of approved drugs conform to law. Thus, FDA has a core mission to protect consumer health and safety by ensuring that drugs reaching consumers are safe and effective, but it also has secondary missions involving rival marketing rights like exclusivity periods over approved drugs.

To gauge the level and nature of industry judicial challenges to FDA, I propose thinking in terms of two categories of industry lawsuits: (1) those that do not challenge FDA's core power to keep unsafe or ineffective drugs from the consuming public and (2) those that do. The first type of suit mostly focuses on FDA's non-health-and-safety role as a director of traffic among companies jostling over their rival marketing rights, which depend not upon safety and efficacy but instead upon

¹⁹⁴ See *id.* at 373, 512–18, 635–41.

¹⁹⁵ See *id.* at 492–505.

¹⁹⁶ Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

¹⁹⁷ Garth Boehm, Lixin Yao, Liang Han & Qiang Zheng, *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013).

¹⁹⁸ See Emily Michiko Morris, Patent Exclusivity Versus Regulatory Exclusivity Under the Hatch-Waxman Act 24 (Robert H. McKinney Sch. L., Legal Studies Research Paper No. 2012-30, 2012), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2185180 [<https://perma.cc/3BYP-P8J2>].

things like NCE status, first-in-time generic status, disease rarity, etc.¹⁹⁹ In this first type of suit, the challenger may include or even focus on a safety claim in stating that its *competitors'* products are *unsafe*, such that FDA should keep them off the market. But even then, such suits merely accuse FDA of *not being protective enough*.²⁰⁰ Such suits do not try to keep the agency from closing the gate of commerce, nor do they contemplate selling to consumers over FDA's safety-based veto. By contrast, the second category of suit—claiming that FDA is being *too protective*—threatens FDA's primacy as protector against unsafe drugs.

While the first type of lawsuit is somewhat mainstream for the drug industry, the second is marginal. In reaching this conclusion, I began with the core study period of 2013–2021 and then extended my exhaustive Bloomberg dockets search forward to January 20, 2024, looking for all drugmaker suits against FDA—or against HHS on FDA matters—during the eleven-year window of 2013–2024. To gauge the size and prominence of the companies suing, I have relied upon *The Pharma 1000*, a ranking of the largest 1,000 drug companies by value that was published in 2020 by the healthcare-focused investment bank Torrey Partners.²⁰¹ Although limited to one snapshot in time, the list has the advantage of including non-U.S. companies and privately held companies.²⁰²

There were thirty-nine suits in the first category of suits from 2013 to 2024, brought by three trade associations and thirty-six companies.²⁰³ The trade associations' involvement consisted of a single suit to challenge the 2020 initiative by HHS and FDA to authorize importation of certain drugs from Canada.²⁰⁴ The associations who sued, including the principal association of the large brand-name manufacturers, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), were bringing a *proregulation* challenge, accusing FDA of not being cautious enough about the safety of imported drugs.²⁰⁵ As to the other thirty-eight suits (all brought by individual companies), let me start by noting that none were pre-enforcement challenges to general FDA rules

¹⁹⁹ E.g., Complaint for Declaratory and Injunctive Relief at 1, Amneal Pharms. LLC v. FDA, 285 F. Supp. 3d 328 (D.D.C. 2018) (No. 17-cv-00180).

²⁰⁰ There are several suits like these involving determinations that generics are equivalent to the challenger's brand name drug, discussed in Christopher J. Kochevar, *Reforming Judicial Review of Bioequivalence Determinations*, 87 N.Y.U. L. REV. 2040, 2051–64 (2012).

²⁰¹ Note that Torrey Partners was acquired by Stifel Financial Corporation in 2022. Press Release, Stifel Financial Corp., Stifel to Acquire Torrey Partners (Dec. 22, 2022), https://www.stifel.com/docs/pdf/pressreleases/2022/Stifel_Acquires_Torrey.pdf [<https://perma.cc/Q5HR-SR4F>].

²⁰² See generally TORREY PARTNERS, *THE PHARMA 1000: TOP GLOBAL PHARMACEUTICAL COMPANY REPORT* (2020).

²⁰³ DATASET, *supra* note 10, File 14, Rows 34–72.

²⁰⁴ Complaint at 2, Pharm. Rsch. & Mfrs. of Am. v. HHS, 656 F. Supp. 3d 137 (D.D.C. 2023) (No. 20-cv-03402).

²⁰⁵ *Id.* at 2–3.

or policies; in each, there was just one company making the challenge, or very occasionally two or three, and the suit was focused on an adjudication affecting the company. Challenges to general policies, if they occurred at all, were channeled through those policies' applications in a given adjudication.²⁰⁶ Of Torrey's top fifty drugmakers, eight were among the challengers: Sandoz, which at the time of suit was the large generic division of Novartis (#6 of the top fifty), Amgen (#7), Astra-Zeneca (#8), Boehringer (#12), Takeda (#16), Teva (#29, suing twice), Eisai (#41), and Otsuka (#48). If we expand our view to Torrey's top 200, estimated to cover eighty-one percent of the industry's global value in 2020,²⁰⁷ the number of challengers grows to fourteen with the addition of Mylan (#53), Octapharma (#61), Ferring (#63), Jazz (#111), Endo (#122), and Lupin (#139, suing twice). Of the twenty-two other companies that brought suit in this category, nine ranked in Torrey's 201–1,000 range, bringing the total challengers in the top 1,000 to twenty-three, leaving thirteen challengers outside the top 1,000.²⁰⁸

Litigation in the second category in 2013–2024 was not mainstream at all. There were thirty-one suits brought by twenty companies. None of these suits involved trade associations, and there were no pre-enforcement challenges to rules or policies. All suits involved an individual company—or in one case, two—challenging an adjudication.²⁰⁹ And compared to the first-category challengers, these second-category challengers tended to be much smaller companies. The only second-category challenger among Torrey's top fifty was Teva (#29). Expanding our view to Torrey's top 200, the count grows to four with the addition of Ranbaxy, a subsidiary of Sun Pharma (#64); Ipsen (#95, suing twice on the same matter); and Mallinckrodt (#174).²¹⁰ Moreover, the suits brought by these four companies sometimes did not go *that far* in challenging FDA's consumer-protective power. Teva and Ipsen's suits were disagreements with FDA over which regulatory pathway their products should take through the agency (drugs versus biologics), not the ultimate question of whether the products were to be approved under whatever pathway was correct.²¹¹ Mallinckrodt's suit

²⁰⁶ DATASET, *supra* note 10, File 14, Rows 34–61, 63–72; *see also id.* cols. AE, AJ (description of and notes on the challenged agency action).

²⁰⁷ I calculated this by summing the values of the top 200, *see* TORREYA PARTNERS, *supra* note 202, at 56–63, and dividing by the estimated value of the industry, *see id.* at 8.

²⁰⁸ *See id.* at 56–95. *See supra* note 206 for data on the challengers.

²⁰⁹ DATASET, *supra* note 10, File 14, Rows 2–32.

²¹⁰ *See* TORREYA PARTNERS, *supra* note 202, at 56–63. At the time of suit on November 14, 2014, Ranbaxy's parent was Daiichi Sankyo (#24), but Ranbaxy's acquisition by Sun Pharma had already been contracted and announced in April 2014 and was completed in April 2015. *See* DAIICHI SANKYO GROUP, VALUE REPORT 2014, at 8 (2014).

²¹¹ *See* Complaint at 2, Teva Pharms. U.S.A., Inc. v. FDA, No. 20-cv-00808 (D.D.C. Mar. 24, 2020); Complaint at 1–2, Ipsen Biopharms., Inc. v. Becerra, No. 22-cv-00860 (D.D.C. Mar. 30, 2022); Complaint at 1–2, Ipsen Biopharms., Inc. v. Azar, No. 20-cv-02437 (D.D.C. Aug. 31, 2020).

came closer to the core of consumer protection. Its generic drug had previously enjoyed a high rating for therapeutic equivalence to the brand name drug, but FDA downgraded the rating in light of new evidence suggesting lesser effectiveness.²¹² The company asked the court to force FDA to conduct a hearing and provide better reasons before downgrading, but it lost.²¹³ Ranbaxy's suit came nearest to the core of consumer protection. FDA had brought enforcement proceedings against the "troubled" company for unsafe manufacturing, banned its India-based factories from supplying the U.S. market, and helped the Justice Department extract a criminal guilty plea and half-billion-dollar fine.²¹⁴ The company's own lawsuit against FDA was an attempt to stop the agency from rescinding a previous generic drug approval due to Ranbaxy's compliance problems.²¹⁵ The company lost and dropped its appeal.²¹⁶ Overall, of the sixteen other companies who brought second-category suits, eight ranked in Torrey's 201–1,000 range for a total of twelve second-category challengers in the top 1,000, leaving eight outside the top 1,000.²¹⁷

²¹² See *Mallinckrodt Inc. v. FDA*, No. 14-3607, 2015 WL 13091366, at *1–3 (D. Md. July 29, 2015).

²¹³ See *id.* *Mallinckrodt* appealed to the Fourth Circuit, which has held the case in abeyance for eight years pending further FDA proceedings. See Court Docket, *SpecGX LLC v. FDA*, No. 15-01933 (4th Cir. Aug. 18, 2015). Therapeutic equivalence ratings matter because they may allow a generic to be substituted for a brand name without patient or physician consent. Bruce S. Manheim, *A Primer: Recent Developments and Strategies in Petitions and Lawsuits Challenging FDA Approval of Generic Drug Products Under the Administrative Procedure Act*, in *FOOD AND DRUG LITIGATION STRATEGIES: LEADING LAWYERS ON BUILDING STRONG DEFENSES AND ADAPTING TO EVOLVING FDA REGULATIONS* 4 (2013).

²¹⁴ Sushmi Dey, *A Look at Ranbaxy's Chequered Legacy*, *BUS. STANDARD* (Apr. 8, 2014), https://www.business-standard.com/article/companies/a-look-at-ranbaxy-s-chequered-legacy-114040700254_1.html [<https://perma.cc/B94D-RFQ9>].

²¹⁵ *Ranbaxy Lab's, Ltd. and Ranbaxy, Inc.'s Complaint for Declaratory and Injunctive Relief* at 2, *Ranbaxy Lab's, Ltd. v. Burwell*, 82 F. Supp. 3d 159 (D.D.C. 2015) (No. 14-cv-01923).

²¹⁶ See *Ranbaxy Lab's*, 82 F. Supp. 3d at 198–99; *Sun Drops Suit Against US FDA*, *NEW INDIAN EXPRESS* (Oct. 10, 2015, 12:41 AM), <https://www.newindianexpress.com/business/2015/Oct/10/sun-drops-suit-against-us-fda-827286.html> [<https://perma.cc/YXJ3-KHQP>].

²¹⁷ See *TORREYA PARTNERS*, *supra* note 202, at 56–95. Companies suing in Torrey's ranks 201 to 1000 were as follows in descending order by rank, each with a parenthetical giving its rank and the FDA action(s) each was challenging: Complaint at 2, *Perrigo Isr. Pharms. Ltd. v. FDA*, No. 14-cv-00475 (D.D.C. Mar. 21, 2014) (#224, FDA failure to add an approved therapeutic equivalence for challenger's generic drug to the Orange Book that authorizes substitution for the brand name); Final Brief for Respondents at 3, *Breckenridge Pharm. Inc. v. FDA*, 754 F. App'x 1 (D.C. Cir. 2018) (Nos. 18-1112, 18-1120, 18-1130) (Paddock Laboratories, a subsidiary of Perrigo, #224, FDA withdrawal of approval of a generic Abbreviated New Drug Application); Complaint for Declaratory and Injunctive Relief at 2, *Genus Med. Tech. LLC v. FDA*, 427 F. Supp. 3d 74 (D.D.C. 2019) (No. 19-cv-544) (#228, FDA choice of regulatory pathway as between drug and device); Complaint for Declaratory and Injunctive Relief at 3, *Pacira Pharms., Inc. v. FDA*, No. 15-cv-07055 (S.D.N.Y. Sept. 8, 2015) (#297, FDA threat to enforce against off-label promotion); Petition for Review at 1–2, *Breckenridge Pharm., Inc. v. FDA*, 754 F. App'x 1 (D.C. Cir. 2018) (No. 18-1112) (Breckenridge, a subsidiary of Towa, #394, FDA withdrawal of approval of a generic Abbreviated

Although even small numbers of suits by small companies could theoretically have a substantial impact on an agency's regulatory scheme, it seems the effect of drugmaker suits against FDA has been limited. Analyzing the recent history of FDA drug review through 2023, Daniel Aaron finds that, although diverse forces beyond the judiciary have rendered such review less stringent in the last few decades, the courts have been "generally unwilling to disturb premarket review of drugs."²¹⁸ The one exception to this conclusion that Aaron notes is FDA's restriction of manufacturers' promotion of off-label uses of their drugs.²¹⁹ Off-label promotion's relevance to safety and efficacy may not be readily apparent, given that it is lawful and very common for doctors to prescribe drugs for off-label uses. The concern is that a company, left to its own devices, might seek approval for some narrow, easy-to-justify use while intending to market the drug far more broadly.²²⁰ On this issue, the key anti-FDA precedent has not been an industry suit against FDA but instead a criminal prosecution of a drug company sales consultant for promoting off-label use of a drug, which the Second Circuit overturned on First Amendment grounds in 2012.²²¹ This precedent inspired affirmative suits against FDA by a couple of companies. First, in 2015, Amarin, a "small" one-drug manufacturer ranked #496 by Torreya,²²² sued FDA and convinced the U.S. district court to adopt a relatively broad reading of the First Amendment theory from the prior Second Circuit case, thereby obtaining a preliminary injunction.²²³ FDA then settled the case in a way that avoided creating precedent but allowed Amarin to do

New Drug Application); Complaint for Declaratory and Injunctive Relief at 1, *Athenex, Inc. v. Azar*, 397 F. Supp. 3d 56 (D.D.C. 2019) (No. 19-cv-00603) (#491, FDA removal of challenger's bulk substance from clinical need list); Complaint at 2, 6, *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (No. 15-cv-03588) (#496, FDA threat to enforce against off-label promotion); Complaint for Declaratory and Injunctive Relief at 1, *REGENXBIO Inc. v. FDA*, No. 19-cv-03373 (D.D.C. Nov. 7, 2019) (#618, FDA clinical hold on investigational new drug); Petition for Review, *Breckenridge Pharm., Inc. v. FDA*, 754 F. App'x 1 (D.C. Cir. 2018) (No. 18-1130) (see *infra* on challenger Lannett Company); Complaint for Declaratory and Injunctive Relief at 1, *Lannett Co. v. FDA*, No. 16-cv-01350 (D.D.C. June 28, 2016) (see *infra* on Lannett); Petition for Review, *Lannett Co. v. FDA*, No. 16-1211 (D.C. Cir. June 28, 2016) (#649, two suits on FDA withdrawal of approvals of generic Abbreviated New Drug Applications, one suit on FDA rescission of a prior approval).

²¹⁸ See Daniel G. Aaron, *The Fall of FDA Review*, 22 YALE J. HEALTH POL'Y, L. & ETHICS 95, 125 (2023).

²¹⁹ *Id.* at 125 n.188, 135–38.

²²⁰ See Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2377–78 (2018).

²²¹ *United States v. Caronia*, 703 F.3d 149, 157, 168–69 (2d Cir. 2012).

²²² See TORREYA PARTNERS, *supra* note 202, at 75. On the company's "small" single-drug status, see Katie Thomas, *F.D.A. Deal Allows Amarin to Promote Drug for Off-Label Use*, N.Y. TIMES (Mar. 8, 2016), <https://www.nytimes.com/2016/03/09/business/fda-deal-allows-amarin-to-promote-drug-for-off-label-use.html> [<https://perma.cc/VHN5-LJCY>].

²²³ See *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 237 (S.D.N.Y. 2015). For a discussion of the case, see Kapczynski, *supra* note 220, at 2377–78.

certain off-label marketing.²²⁴ Second, later in 2015, Pacira, a company ranked #297 and drawing nearly all its revenue from one drug,²²⁵ brought a similar suit and obtained a settlement clarifying that the label for its drug did allow certain claims the company wanted to make.²²⁶ Notably, Amarin and Pacira both had the support of PhRMA as an amicus, there being only one other industry suit resisting FDA gate closing in which PhRMA took the challenger's side from 1989 to 2024.²²⁷ Besides Amarin and Pacira's cases, studies covering FDA policy on off-label promotion through 2023 cite no further cases along these lines,²²⁸ nor did I find any. The suits do not appear to have driven decisive changes in FDA policy; new guidance drafted in 2017 and finalized in 2018 offered incremental and suggestive changes at most, with practitioners concluding in 2019 that off-label promotion was still "a particularly dangerous minefield for drug manufacturers" and that avoiding off-label promotion was still "likely the most prudent course of action for most" such companies.²²⁹ FDA in 2021 completed a rulemaking on intended use that a leading practitioner said would chill protected speech,²³⁰ yet no one brought a pre-enforcement challenge to it.²³¹

Drugmakers' reluctance to sue to overcome FDA safety-and-effectiveness constraints appears to go far back—to the 1980s at the latest. The brand-name manufacturers' association PhRMA has not been

²²⁴ See Thomas, *supra* note 222.

²²⁵ TORREYA PARTNERS, *supra* note 202, at 67; Brendan Pierson, *Pacira, FDA Reach Agreement on Pain Drug Marketing Restrictions*, REUTERS (Dec. 15, 2015, 12:05 AM), <https://www.reuters.com/article/business/healthcare-pharmaceuticals/pacira-fda-reach-agreement-on-pain-drug-marketing-restrictions-idUSKBN0TY0E7/> [<https://perma.cc/DY34-SGKL>].

²²⁶ See Complaint for Declaratory and Injunctive Relief at 1, 4–5, 56, *Pacira Pharms., Inc. v. FDA*, No. 15-cv-07055 (S.D.N.Y. Sept. 8, 2015); Pierson, *supra* note 225.

²²⁷ Brief of Amicus Curiae Pharmaceutical Research & Manufacturers of America in Support of Plaintiffs' Motion for Preliminary Injunction, *Pacira Pharms.*, No. 15-cv-07055 (Nov. 16, 2015); Brief of Amicus Curiae Pharmaceutical Research & Manufacturers of America in Support of Plaintiffs' Motion for Preliminary Injunction, *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (No. 15-cv-03588). On the one other suit, see *infra* note 233.

²²⁸ Aaron, *supra* note 218, at 135–38; Coleen Klasmeier, *FDA, Medical Communications, and Intended Use—A New Challenge to First and Fifth Amendment Constraints on Government Power*, 78 FOOD & DRUG L.J. 263, 303–08 (2023); David A. Simon, *Off-Label Speech*, 72 EMORY L.J. 549, 572–74, 574 n.143 (2023).

²²⁹ Rodney K. Adams & Leslie Crudele, *The Eroding Off-Label Drug Use Promotion Prohibition*, 12 J. HEALTH & LIFE SCI. L. 1, 16–21 (2019).

²³⁰ Klasmeier, *supra* note 228, at 313.

²³¹ Apart from off-label promotion, it seems that judicial challenges by (generally small) drugmakers to FDA health-and-safety constraints since 2013 have had a significant impact in only one other area: Genus (#228 in the Torreya 1000) obtained a ruling in 2021 that prompted FDA to generally back off regulating certain medical devices under the more stringent regime for drugs—but that impact proved short-lived because in 2022 Congress restored FDA's original approach. Anjali Deshmukh, *The End of FDA Exceptionalism? Dissecting Deference to the FDA in Drug Disputes*, 46 CARDOZO L. REV. 767, 810–11 (2025).

a plaintiff or petitioner in *any* suit against FDA—or against HHS on an FDA matter—since the start of the coverage of the Bloomberg dockets database in 1989, with the exception of the proregulation challenge it brought to the Canadian import program in 2020.²³² Even as an amicus, PhRMA has taken sides against FDA in industry challenges in only three cases—two in 2015 and one in 1999—all concerning off-label promotion.²³³ As to the several major generic drugmaker associations who have changed names and merged over time, none have been plaintiff or petitioner in a suit against FDA or HHS on FDA matters, except two that did not seek to overcome safety-and-effectiveness constraints.²³⁴ Nor were there any industry challenges seeking to overcome safety-and-effectiveness constraints in which a major generic association took sides against FDA as an amicus.²³⁵

This many-decade pattern for trade associations seems also to hold for individual companies in their role as new drug sponsors seeking approval. Challenges to the denial of premarket approval of a new drug application have apparently been rare to nonexistent for about forty-five years. In a classic 1996 article, former FDA chief counsel Richard Merrill said “that a [new] drug sponsor must satisfy [FDA’s standards for clinical studies] or it will never see its drug approved. The disincentives to challenging FDA’s views are formidable; sponsors almost

²³² I conducted a Bloomberg dockets search for PhRMA’s full name and its previous name, Pharmaceutical Manufacturers Association, as plaintiff in district courts or petitioner in courts of appeals going back to 1989, obtaining thirty-five results for district courts and three for circuit courts. I presumed that if a suit were challenging both HHS and any *non*-FDA component of HHS, it was not a challenge to FDA action. Apart from the Canadian import suit, the only suit that looked as if it might be against FDA was *PhRMA v. Shalala*, No. 96-cv-01630 (D.C. Cir. July 12, 1996), but other documentation indicates this case concerned the 340B drug pricing program, not an FDA matter. See Combined Brief in Support of Defendants’ Motion to Dismiss or, in the Alternative, Motion for Summary Judgment & Brief in Opposition to Plaintiff’s Motion for Summary Judgment at 2–3, *Astrazeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021) (No. 21-cv-00027).

²³³ I conducted a Bloomberg dockets search for PhRMA analogous to that *supra* note 232, but as amicus, unconfined by court. For the 2015 cases in which PhRMA was amicus, see *supra* note 227. For the 1999 case, see Brief of Pharmaceutical Research & Manufacturers of America as Amicus Curiae in Support of Appellee, *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 1999) (No. 99-5304).

²³⁴ I conducted a Bloomberg dockets search for all the major generic association names—Association for Accessible Medicines, Generic Pharmaceutical Association, Generic Pharmaceutical Industry Association, National Pharmaceutical Alliance, and National Association of Pharmaceutical Manufacturers—as plaintiff in district courts or petitioner in courts of appeals going back to 1989, obtaining eleven results for district courts and no results for circuit courts. The two suits against FDA were *Mylan Laboratories, Inc. v. Thompson*, 332 F. Supp. 2d 106 (D.D.C. 2004), and *National Pharmaceutical Alliance v. Henney*, 47 F. Supp. 2d 37 (D.D.C. 1999).

²³⁵ I conducted a Bloomberg dockets search for all the major generic association names analogous to that *supra* note 234, but as amicus, unconfined by court. Such an association was amicus against FDA in several cases about matters like exclusivity not implicating safety and effectiveness. See, e.g., *Mylan Pharms., Inc. v. FDA*, 454 F.3d 270 (4th Cir. 2006).

invariably engage the agency on its own terms.”²³⁶ He added: “It is clear that the formal statutory procedures for challenging the judgment of FDA reviewers by requesting a formal hearing and then seeking judicial review play no role in the process.”²³⁷ The rarity of these challenges is noted in the most recent edition of Merrill’s casebook, co-authored with former FDA Chief Counsel Peter Barton Hutt, the longtime dean of the pharmaceutical bar,²³⁸ and Lewis Grossman, in 2013:

An FDA decision to *approve* a [new] drug has seldom been contested in court. . . . Perhaps surprisingly, court challenges to decisions refusing approval have been equally rare. No sponsor has successfully sought reversal of an FDA refusal to approve its drug. The lesson has not been lost on applicants, who understand that the only way to secure approval of [a New Drug Application] is to satisfy the agency.”²³⁹

The casebook has no citation to any such challenge after the one that Edison Pharmaceutical Company lost in 1979.²⁴⁰ My search of the period from January 20, 2013, through January 20, 2024, turns up no serious challenge to a denial of a new drug approval, no matter the size of the company.²⁴¹

²³⁶ Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1780–81 (1996).

²³⁷ *Id.* at 1781 n.87.

²³⁸ See Peter Barton Hutt, COVINGTON & BURLING, <https://www.cov.com/en/professionals/h/peter-hutt> [<https://perma.cc/XYB4-8HFC>] (“Peter was Chief Counsel for the Food and Drug Administration . . . [and] the Legal Times also referred to him as ‘the dean of the food-and-drug bar.’”).

²³⁹ PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW* 738–39 (4th ed. 2013).

²⁴⁰ *Id.* at 740 (discussing *Edison Pharm. Co., Inc. v. FDA*, 600 F.2d 831 (D.C. Cir. 1979)).

²⁴¹ I say “no serious challenge” because one company did challenge such a denial, but its new drug application appears to have been not a commercial endeavor so much as a political protest against FDA’s approach to opioids. The sponsor, Pharmaceutical Manufacturing Research Services (“PMRS”), had only thirty employees and was owned by its founder and president, Edwin Thompson. *About Us*, PMRS, <https://www.pmrinc.com/about-us/> [<https://perma.cc/TJK8-6KXT>]. The company was not really a drug developer but a contract manufacturer. Catherine Dunn, *Drug Firm’s Founder Critic of FDA Science; Objects to Use of Most Opioids for Chronic Pain*, PHILA. INQUIRER, Feb. 23, 2019, at A1 (“Pharma firms outsource aspects of researching and making drugs, and that’s where the firm Thompson founded comes into play. PMRS provides manufacturing services for four FDA-approved drugs and ‘numerous developmental and investigational drugs,’ according to court filings.”). Thompson “has waged a crusade on the [FDA]” regarding its approach to approving opioids, criticizing the agency at public advisory committee meetings and on *60 Minutes*. See *id.* When FDA rejected PMRS’s application for “a litany of deficiencies” and denied the company a hearing, the company sued to demand a hearing, and expert observers commented that “it seem[ed] from the Complaint that PMRS may [have been] using this litigation as a bully pulpit to protest FDA’s framework for evaluating purported abuse-deterrent opioids,” raising “the question of whether the entire NDA was submitted simply to contest FDA’s approach to abuse-deterrent and chronic use opioid approval.” See Sara W. Koblitz & Kurt R. Karst, *It’s a*

The absence of sponsor challenges to denials of premarket approval for new drug applications is striking in part because of the substantial number of such denials over the last several years—denials that in principle could have led to lawsuits but did not. To appreciate this, we first need to understand some nuances in FDA procedure. The relevant legislation contemplates that a rejection of a drug approval application will occur in an agency hearing, after which the sponsor can seek judicial review;²⁴² this is what happened in Edison Pharmaceutical’s case back in the 1970s.²⁴³ But as Merrill said, by 1996, the procedures for a “formal hearing” actually “play no role.”²⁴⁴ Since the 1970s, FDA has been able to reject an application without a hearing if the sponsor has not provided enough evidence to warrant one—essentially, it can decide by summary judgment.²⁴⁵ Further, as a practical matter, it has long been common for FDA not even to issue a summary judgment but instead to send the sponsor a letter—known since the 1960s as a “not approvable letter” and since 2008 as a “complete response letter” (“CRL”)—stating that FDA will not approve the application in its current form, upon which the sponsor normally “either abandons the application or later corrects the deficiencies” that the letter concluded were fatal.²⁴⁶ When experts count up FDA “rejections” of new drugs, they use CRLs as their unit of measure.²⁴⁷ Similarly, the “not approvable” letters that served the same

Trap—Or Is It? PMRS’ Abuse-Deterrent Opioid NDA, HYMAN, PHELPS & McNAMARA PC: FDA L. BLOG (Sept. 17, 2018), <https://www.thefdalawblog.com/2018/09/its-a-trap-or-is-it-pmrs-abuse-deterrent-opioid-nda/> [<https://perma.cc/Y57Q-7KGY>]. They added:

Given that PMRS does not appear to hold any approved drug applications, it is possible that this NDA was submitted to make a point—and to provide PMRS with standing to sue FDA for its review practices with respect to opioids. If so, it is a creative—albeit expensive—strategy.

Id. Ultimately, PMRS sued FDA again over the denial and lost both in district court and on appeal. *See Pharm. Mfg. Rsch. Servs., Inc. v. FDA*, 957 F.3d 254, 256, 267 (D.C. Cir. 2020). Also, after the extended period ending January 20, 2024, FDA’s denial of a request for a hearing on a Supplemental New Drug Application was challenged by Vanda, a very small company outside the Torrey’s top 1,000, and the D.C. Circuit ultimately set aside FDA’s refusal to hold a hearing as inconsistent with the record. *Vanda Pharms., Inc. v. FDA*, No. 24-1049 (D.C. Cir. Aug. 15, 2025); TORREYA PARTNERS, *supra* note 202, at 56–95.

²⁴² 21 U.S.C. § 355(d)–(e), (h).

²⁴³ *See Edison*, 600 F.2d at 841–43. One of Edison’s arguments was that the hearing excluded too much evidence, but there is no doubt there *was* a hearing. *See id.*

²⁴⁴ Merrill, *supra* note 236, at 1781 n.87.

²⁴⁵ CARPENTER, *supra* note 192, at 355–57 (discussing recognition of the summary judgment process in the 1970s).

²⁴⁶ *Id.* at 478–79, 493–94, 673 & n.56.

²⁴⁷ *See* Melanie Senior, *Fresh from the Biotech Pipeline: Record-Breaking FDA Approvals*, 42 NATURE: BIOTECHNOLOGY 355, 360 (2024).

function as CRLs during the period of 1962–2008 were cast by the FDA Commissioner as the means by which the agency “rejected” drugs.²⁴⁸

With this background, consider the number of rejections of new drugs in recent years. CRLs over the period from 2008 to 2023 numbered 123, averaging more than eight per year.²⁴⁹ The fates of huge investments depend on these decisions: The cost of developing a new drug is well over \$1 billion on average if one includes the cost of failed trials.²⁵⁰ And yet not one of these rejections elicited a serious judicial challenge by the sponsor.²⁵¹ To be sure, the proportion of new drugs reaching the end of FDA’s process that are thus rejected is relatively low—about ten percent to thirty percent in recent years²⁵²—but most new drugs never reach the end because sponsors abandon them earlier in the process, often in response to FDA signals that approval will be unlikely.²⁵³ The point is that, when about 120 drugs reached what is practically the process’s end and were rejected, all these sponsors opted either to give up or to try harder to meet FDA’s demands—not to sue.

²⁴⁸ See David A. Kessler, *Remarks by the Commissioner of Food and Drugs*, 51 FOOD & DRUG L.J. 207, 214 (1996). For background on CRLs and their predecessor genre of “not approvable” letters, see CARPENTER, *supra* note 192, at 673 & n.56.

²⁴⁹ There were forty-eight CRLs for new drugs—counting only the first letter for each new drug and excluding letters on supplemental applications—from August 11, 2008, through June 27, 2013. Peter Lurie, Harinder S. Chahal, Daniel W. Sigelman, Sylvie Stacy, Joshua Sclar & Barbara Ddamulira, *Comparison of Content of FDA Letters Not Approving Applications for New Drugs and Associated Public Announcements from Sponsors: Cross Sectional Study*, 350 BRIT. MED. J. 1, 2–3 (2015). I found the number of CRLs for new drugs from June 27, 2013, through December 31, 2023, by using the Complete Response Letters database compiled by Pink Sheet. *US FDA Performance Tracker*, PINK SHEET: CITELINE REGUL., <https://insights.citeline.com/pink-sheet/regulatory-trackers/us-fda-performance-tracker/complete-response-letters/> [https://perma.cc/DB5Q-N99X]. I began with all entries during the time period marked with an asterisk (*), which covers “New molecular or biologic entities.” Among the asterisk entries, I counted only those that referred to a new drug application (“NDA”), not those that referred to a biologics license application (“BLA”) or supplemental NDA (“SDNA”). There were seventy-five. Note that the count conducted by Lurie et al., *supra*, is complete because it was obtained from FDA internal files, whereas my count using Pink Sheet may be less than complete, because a CRL is confidential unless the recipient reports it. See 21 C.F.R. § 314.430.

²⁵⁰ Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009–2018*, 323 J. AM. MED. ASS’N 844, 844 (2020).

²⁵¹ On PMRS’s application and challenge, which appear not to have been a commercial endeavor, see *supra* note 241.

²⁵² See Bridget Silverman, *US FDA’s Use of CRLs Hit a High Note in 2022: One-Third of Novel Agent Decisions Were Not Approvals*, PINK SHEET: CITELINE REGUL. (Jan. 9, 2023), <https://insights.citeline.com/PS147548/US-FDAs-Use-Of-CRLs-Hit-A-High-Note-In-2022-One-Third-Of-Novel-Agent-Decisions-Were-Not-Approvals/> [https://perma.cc/5R7Y-9QLP]; BIOTECH. INDUS. ORG., CLINICAL DEVELOPMENT SUCCESS RATES AND CONTRIBUTING FACTORS 2011–2020, at 6 (2021).

²⁵³ On the dropout rate, see BIOTECH. INDUS. ORG., *supra* note 252. On the signals that lead to abandonment, see CARPENTER, *supra* note 192, at 478–79, 493–94, 516, 520, 545, 581–84, 660–62.

Turning from denials of new drugs to denials of generics, which occur if the drug is not shown to be equivalent to the brand name, sponsor judicial challenges appear to be nearly as rare despite a high volume of decisions. In recent years, the number of CRLs on generics has often been well over a thousand per year.²⁵⁴ Yet my search of the eleven-year period from 2013 to 2024 yielded only one challenge to a generic rejection, in 2020, by the small generic manufacturer Nostrum Pharmaceuticals.²⁵⁵ FDA defended itself on the ground that a CRL is not a final agency action reviewable in court; that is, the sponsor must get to the stage of agency summary judgment or an agency hearing before suing.²⁵⁶ The D.C. Circuit agreed with FDA in a 2022 opinion, citing no prior circuit cases that had decided the issue.²⁵⁷ What is remarkable about the case is not so much the outcome as the fact that a CRL's finality for judicial review was a question of first impression in the D.C. Circuit in the year 2022, fourteen years after FDA began using CRLs as the routine instrument for rejecting drug applications and half a century after it began using "not approvable" letters—which apparently produced no case law on finality, or at least none that the D.C. Circuit cited in *Nostrum*.

Drugmaker reluctance to sue FDA has been a matter of insider comment for decades. James G. Dickinson, who ran a leading trade publication on FDA starting in the 1970s, published an article in 1993 bemoaning the agency's overreach with the frustrated headline, "Will Anybody Sue the FDA?"²⁵⁸ In a 2001 oral history, mega-investor Thomas Perkins reflected on his tenure as chair of Genentech from 1976 to 1990 and on how Kirk Raab, a top executive there from 1985 to 1995, had twice talked him out of trying to sue FDA: "In both cases, I learned [from Raab], you don't sue the FDA"; Raab "perceived that that's not the way you play the game. You just cooperate, and love 'em, and eventually it will work out."²⁵⁹

²⁵⁴ E.g., 2021 FDA OFF. GENERIC DRUGS ANN. REP. 1 (noting FDA Office of Generic Drugs ("OGD") issued 1,787 CRLs in 2021); 2018 FDA OFF. GENERIC DRUGS ANN. REP. 3 (noting FDA OGD issued 2,648 CRLs in 2018); 2015 FDA OFF. GENERIC DRUGS ANN. REP. 10 (noting FDA OGD issued 1,278 CRLs in 2015).

²⁵⁵ Petition for Review, *Nostrum Pharms., LLC v. FDA*, 35 F.4th 820 (D.C. Cir. 2022) (No. 20-01525). The closest results otherwise were four challenges to withdrawals or rescissions of prior approvals of generic Abbreviated New Drug Applications, brought by Paddock, Breckinridge, as co-plaintiff with Nexgen, and Lannett, bringing two challenges. See *supra* note 217. Nostrum was not included in Torreya's top 1,000. See TORREYA PARTNERS, *supra* note 202, at 56–95.

²⁵⁶ *Nostrum Pharms., LLC v. FDA*, 35 F.4th 820, 825 (D.C. Cir. 2022).

²⁵⁷ *Id.* at 822–27.

²⁵⁸ James G. Dickinson, *Will Anybody Sue FDA?*, 28 MED. MKTG. & MEDIA 100 (1993).

²⁵⁹ CARPENTER, *supra* note 192, at 659 (quoting Interview by Glenn E. Bugos with Thomas J. Perkins, Founder & Chairman, Kleiner Perkins, in Berkeley, Cal. at U.C. Berkeley Reg'l Oral Hist. Off. (Oct. 14, Oct. 31 & Nov. 14, 2001) (on file with The Bancroft Library, U.C. Berkeley as Thomas J. Perkins, *Kleiner Perkins, Venture Capital, and the Chairmanship of Genentech*,

Why do drugmakers bring so few court challenges to FDA's restrictions on them, especially when it comes to safety and efficacy? One contributing factor, presumably, is agency forbearance. The last few decades have seen Congress and FDA somewhat lessen premarket review requirements for new drugs and create easier pathways for subsets of them.²⁶⁰ The pharmaceutical lobby's influence in Congress is deep.²⁶¹ Nonetheless, the forbearance explanation has limits. As noted above, most new drugs never even reach the final stage, often because sponsors realize FDA will not approve them: In the period of 2011–2020, new drugs that *completed* the “large, expensive” Phase III trials still had a forty-two percent chance of not advancing to an actual application, and even then approval was not a certainty.²⁶² Further, the rising forbearance of the last few decades does not explain why trade association and sponsor challenges have been low even farther back, since the 1980s.

Another possible explanation is that the judiciary finds FDA science-based decision-making too complex and opaque to review, so companies usually predict they will lose and therefore do not bother suing. This would be consistent with industry's tendency, documented above, to sue more on questions about rival marketing rights like exclusivity periods than on questions about safety and efficacy, as the latter involve more science.²⁶³ Still, this explanation alone seems insufficient. Although courts often say they defer to agencies' scientific decisions, one leading study found that such judicial language has long since “become meaningless boilerplate that obscures what courts are really doing: hard-look review.”²⁶⁴ The courts not uncommonly take a “hard look” at decisions of agencies in areas like environmental protection

1976–1995, U.C. LIBRS.: ONLINE ARCHIVE CAL. (2002), https://oac.cdlib.org/view?docId=kt1p3010dc&brand=oac4&doc.view=entire_text [<https://perma.cc/3QDE-DT4C>]).

²⁶⁰ For a critical review of these developments, see Aaron, *supra* note 218, at 121–41.

²⁶¹ CARPENTER, *supra* note 192, at 638.

²⁶² BIOTECH. INDUS. ORG., *supra* note 252, at 6.

²⁶³ This point arose in an interview I conducted with William Schultz, who was FDA Deputy Commissioner and HHS General Counsel. Schultz explained:

Another area is generic drugs. There's been a lot of litigation not over whether the drug is safe and effective, but over what we call Hatch-Waxman issues . . . issues about exclusivity, patent extensions, orphan drug exclusivity, all those kinds of issues . . . where there's a ton of money at stake, and there is a great incentive to litigate, and historically there's been a lot of litigation.

Interview with William Schultz, Former Gen. Couns., HHS (Aug. 14, 2024). I later asked: “Are the Hatch-Waxman and orphan drug and patent extension type suits—would it be right to say that those usually don't involve scientific questions?” Schultz replied: “Yes, those don't,” although “there are some suits that are brought that raise issues that are on the edge of the scientific questions.” *Id.*

²⁶⁴ Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 764 (2011). Note that Hammond's study is not focused on FDA. See *id.* at 724–39.

that involve quite complex science;²⁶⁵ aggressive judicial review of EPA decision-making under the arbitrary and capricious standard has persisted from the 1970s to the present.²⁶⁶ And the courts have not expressly articulated a higher level of deference for scientific decisions of FDA than of other science-oriented agencies.²⁶⁷ Nor is FDA decision-making some fortress of esoteric truth. Judgments of policy and value are obviously occurring in the agency's application of the vague statutory standards of safety and efficacy.²⁶⁸ The longtime author of a leading treatise on FDA has said, "based on my observations during more than three decades working with the FDA review process, advocacy is a very important factor in drug approval—perhaps even more important than the sufficiency of data in support of clinical testing end points."²⁶⁹ Recent years have seen, if anything, some diminishment in FDA's scientific reputation before the courts, where the agency may be sued by parties *other than* regulated drugmakers.²⁷⁰ The Supreme Court itself openly doubted FDA's scientific expertise in a 2009 opinion.²⁷¹ It has been possible for a company to beat the agency on a classic arbitrary and capricious theory per *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*,²⁷² as Bayer did in 2013 when it obtained a TRO against FDA approval of a competing generic animal drug,²⁷³ after which the case settled.²⁷⁴ Yet none of these developments have opened the floodgates of industry suits against FDA.

A fuller explanation of drugmakers' reluctance to sue likely rests on two other factors: the companies' stake in their bilateral relationships to FDA and their need for FDA-fostered credibility with the consuming public. As to relationships with FDA, most new drugs are made by

²⁶⁵ See, e.g., Daniel Kim, Robert L. Glicksman & Keziah Groth-Tuft, *Judicial Review of Scientific Uncertainty in Climate Change Lawsuits: Deferential and Nondeferential Evaluation of Agency Factual and Policy Determinations*, 46 HARV. ENV'T L. REV. 367 (2022).

²⁶⁶ See, e.g., *Ohio v. EPA*, 603 U.S. 279, 290 (2024); see also R. SHEP MELNICK, REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT 24–26 (1983) (discussing the development of air pollution regulations in the 1970s).

²⁶⁷ A study of agency science with substantial attention to judicial review, focusing on FDA and on environmental agencies, mentions no such distinction. See Pasky Pascual, Wendy Wagner & Elizabeth Fisher, *Making Method Visible: Improving the Quality of Science-Based Regulation*, 2 MICH. J. ENV'T & ADMIN. L. 429 (2013).

²⁶⁸ On value-laden discretion and politics in FDA drug approval decisions, see CARPENTER, *supra* note 192, at 260–63, 354–55, 474–76, 512–18, 524, 732–33, 737–38, 743.

²⁶⁹ James T. O'Reilly, *Drug Review "Behind the Curtain": A Response to Professor Struve*, 93 CORNELL L. REV. 1075, 1084 n.58 (2008).

²⁷⁰ See CARPENTER, *supra* note 192, at 747–48.

²⁷¹ See *Wyeth v. Levine*, 555 U.S. 555, 578 n.11 (2009).

²⁷² 463 U.S. 29 (1983).

²⁷³ *Bayer Healthcare, LLC v. FDA*, 942 F. Supp. 2d 17, 24, 27 (D.D.C. 2013); see also Manheim, *supra* note 213 at 20–21.

²⁷⁴ See Notice of Dismissal, *Bayer Healthcare*, 942 F. Supp. 2d 17 (No. 13-cv-00487).

companies that are repeat players with the agency, continually at its mercy to obtain approvals for new products or for new uses of old products.²⁷⁵ “Firms’ reputations [with FDA] matter in part because a resource-constrained and uncertain regulator is compelled to rely partially upon trust [in regulated companies].”²⁷⁶ A company that loses FDA’s trust may find it harder to get favorable and timely decisions in future interactions when it needs them—an outcome that one may interpret as a legitimate agency reaction to uncertainty about the company or as illegitimate agency retaliation. In either case, there is a disincentive to sue the agency, as Carpenter explained in 2010:

[Drugmakers] can in principle contest the agency’s actions legally. They can, in concept, call the agency’s bluff in response to its threats. Yet the deterrence power of the Administration . . . operates to stop most such challenges before they begin. Company officials seem continually haunted by the possibility that their argumentative and legal challenges will bring reprisal in the form of aggressive enforcement action, adverse publicity, arbitrary delays in current product submissions, or negative decisions on future submissions. Whether or not these fears are well-founded and rational is a separate question; such tremblings have been widely shared and expressed in the past half-century.²⁷⁷

While Carpenter himself is carefully agnostic about whether FDA really does “retaliate,” his point is that widespread industry *perception* of this phenomenon shapes industry behavior.²⁷⁸

Carpenter published his analysis in 2010, and the importance of the drugmaker-FDA relationship and the specter of retaliation have been invoked as reasons for industry not to sue both before and since. In 1993, Dickinson, in explaining why no drugmakers were suing FDA for its legally doubtful regulation of off-label promotion, said that “companies that have all of their future livelihood locked away in FDA’s drug-review back rooms universally elect not to be the agency’s ‘equal and opposite force’ when it comes to non-statutory restrictions on marketing activities.”²⁷⁹ When Perkins in 2001 said, “you don’t sue the FDA,” he explained that “[t]hey’ll crucify you for ever after.”²⁸⁰ When I spoke in 2024 with Anonymous Interviewee #1, the former general counsel of a large drug manufacturer, the interviewee said that large

²⁷⁵ See CARPENTER, *supra* note 192, at 638.

²⁷⁶ *Id.* at 663.

²⁷⁷ *Id.* at 659.

²⁷⁸ See *id.* at 660 n.38.

²⁷⁹ Dickinson, *supra* note 258, at 100.

²⁸⁰ CARPENTER, *supra* note 192, at 659 & n.37 (quoting Interview by Glenn E. Bugos with Thomas J. Perkins, *supra* note 259).

“repeat player” companies would almost never challenge an FDA adjudicatory decision, especially a scientific one such as a denial of approval, in part because it was so important to maintain a “positive relationship” with the agency reviewers; drugmakers were afraid of FDA “reprisals,” albeit in the interviewee’s view “overly so.”²⁸¹ The interviewee added that such companies might consider supporting a challenge to a regulation brought by a trade association, which would give them some “anonymity” and “protection.” But the trade association would then face the “challenge” of getting individual member companies to submit sworn statements to support the association’s standing to sue, and the member companies would face a “collective action” problem, each wishing to avoid a scenario in which it was the one company revealing itself, because FDA might then attribute the suit to the company.²⁸²

Relationship-based concerns appear to be consistent with industry’s greater willingness to challenge decisions on rival marketing rights, like exclusivity periods, than on safety and effectiveness. The FDA officials who make decisions about matters like exclusivity are separate from the ones who make decisions about safety and effectiveness.²⁸³ Accordingly, a company could weigh the litigation-versus-relationship risks for one set of officials independently of how it weighs them for the other set.

Another and perhaps even stronger likely reason for drugmakers’ not-openly adversarial stance toward FDA—especially the larger companies who tend to be the least litigious on safety and efficacy—is that FDA’s power and credibility have long been foundational to the lucrative demand for drugs that the industry enjoys among consumers, doctors, and insurers. Unlike *search goods* that consumers can evaluate before purchase or *experience goods* that consumers can evaluate after purchase and use, drugs are *credence goods*—that is, consumers cannot evaluate them even after use, because the consumer’s sickness might improve regardless of the drug, or due to a placebo effect.²⁸⁴ An individual doctor drawing solely on her patients’ experiences faces a similar information problem.²⁸⁵ The accurate way to tell the effectiveness of a drug is through large-scale scientific studies that isolate causation. The large-scale study entry barrier that FDA has imposed on the drug market since 1962 has made it possible for drugmakers to recoup the enormous research and development costs necessary to make truly

²⁸¹ Interview with Anonymous Interviewee #1, *supra* note 28.

²⁸² *Id.*

²⁸³ *Id.*

²⁸⁴ See Daniel Carpenter, *Confidence Games: How Does Regulation Constitute Markets?*, in *GOVERNMENT AND MARKETS: TOWARD A NEW THEORY OF REGULATION* 164, 173–78 (Edward J. Bal-leisen & David A. Moss eds., 2010).

²⁸⁵ See Benjamin Berger, Amitabh Chandra & Craig Garthwaite, *Regulatory Approval and Expanded Market Size 1* (Nat’l Bureau of Econ. Rsch., Working Paper No. 28,889, June 2021), <http://www.nber.org/papers/w28889> [<https://perma.cc/PKE4-GHGB>].

effective drugs—without the risk of being crowded out by cheap, ineffective drugs trading on consumer misperception and with the result that drugs have become an extremely attractive product whose high price consumers, insurers, and doctors think is worth paying.²⁸⁶ As FDA established the system for new drugs in the 1960s and afterward, the premarket approval requirements leading to governmental guarantees of safety and efficacy “generated a far broader and deeper demand for pharmaceutical goods,”²⁸⁷ including a significant rise in the volume and predictability of sales.²⁸⁸ Although initially there was “broad and active company-sponsored litigation against FDA” in the 1960s and 1970s, the companies by the 1980s “adapted to the rule of the [FDA] over their marketplace.”²⁸⁹ Under this regime, “[c]onsumers’ trust in the safety and efficacy of drugs means more money for drug companies. It increases the value consumers ascribe to new drugs”²⁹⁰ This argument is supported by an econometric study finding that when a drug has been approved by FDA for one use but can lawfully be prescribed for another, FDA’s subsequent approval for the other use increases market share for that use beyond what market-based learning would have done.²⁹¹

The value of FDA’s guarantee extends from new drugs to generics. Amid the rise of generic sales in the 1980s, FDA corruption scandals for a time “severely” shook “the public’s faith in generic drugs”; a poll in 1989 found that fifty-one percent of respondents “feared that generics were not manufactured to the same standards as brand medications.”²⁹² The subsequent tightening of FDA regulation has increased confidence in these products. A survey in 2014 of persons with diseases treatable by generic drugs that had recently obtained FDA approvals despite controversy found that eighty-nine percent of respondents “w[ere] very or somewhat comfortable that the FDA’s approval process ensured generic drug safety and effectiveness.”²⁹³

Anonymous Interviewee #1, the former general counsel of a large drug manufacturer, explained that if we focus on the real world in which companies do not challenge FDA refusals to approve drugs, individual

²⁸⁶ Carpenter, *supra* note 284, at 178–81. On historical shifts in the relative roles of doctors, insurers, and consumers, see Lewis A. Grossman, *FDA and the Rise of the Empowered Consumer*, 66 ADMIN. L. REV. 627, 657–65 (2014).

²⁸⁷ Carpenter, *supra* note 284, at 181.

²⁸⁸ *Id.* at 183.

²⁸⁹ CARPENTER, *supra* note 192, at 373.

²⁹⁰ Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMMS. & TECH. L. REV. 1, 17 (2007).

²⁹¹ Berger et al., *supra* note 285, at 4.

²⁹² Boehm et al., *supra* note 197, at 299.

²⁹³ Aaron S. Kesselheim, Joshua J. Gagne, Jessica M. Franklin, Wesley Eddings, Lisa A. Fulchino & Eric G. Campbell, *Do Patients Trust the FDA?: A Survey Assessing How Patients View the Generic Drug Approval Process*, 26 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 694, 695–96 (2017).

patients receiving prescriptions are unlikely to know anything about the companies who obtained the approvals for the drugs they take.²⁹⁴ But the interviewee added hypothetically that if a disappointed sponsor were to obtain a judicial order that FDA approve a drug, the agency could publicly broadcast its reasons for disagreeing with the judicially forced approval.²⁹⁵ The sponsor's competitors would then use those reasons against the sponsor—as would attorneys for tort plaintiffs, who could force the sponsor to admit to a jury that it used the courts to force FDA to approve its drug. The interviewee explained that these negative outcomes were reasons why companies did not sue to force approvals in the first place.²⁹⁶ The hypothetical is compelling, I think, because it is premised on FDA's superior credibility.

C. Automakers and NHTSA

The third of our six industry-agency pairings, between automakers and NHTSA within the Department of Transportation ("DOT"), has seen very few industry judicial challenges on safety in the last forty years. Roughly consistent with the other pairings thus far, industry's nonlitigious approach is linked with a fairly close industry-agency relationship and especially with agency-industry alignment on handling customer safety. Although that alignment was largely absent during the agency's early development in the 1960s and 1970s, the alignment emerged and strengthened in the late 1980s and early 1990s and has resulted in agency deference to industry on some issues and industry reluctance to cross the agency on others.

NHTSA has three main powers. First, it can use rulemaking to set Motor Vehicle Safety Standards, mandating levels of safety that motor vehicles and related equipment must achieve.²⁹⁷ Second, it can order recalls—that is, require any automaker to remedy, at no cost to the consumer, any safety-related defect in any of its cars.²⁹⁸ Third, the agency can use rulemaking to impose Corporate Average Fuel Economy standards on each automaker's fleet of cars.²⁹⁹ The first two powers aim at car safety, including consumer safety, while the third aims at entirely different goals, those being national energy independence, environmental protection, and perhaps consumer economic protection—but not consumer safety.

²⁹⁴ Interview with Anonymous Interviewee #1, *supra* note 28.

²⁹⁵ *Id.*

²⁹⁶ *Id.* On tort liability for unsafe drugs, to which FDA approval is *not* a definitive defense, see Bernstein, *supra* note 181, at 377; CARPENTER, *supra* note 192, at 747.

²⁹⁷ See 49 C.F.R. § 1.95; 49 U.S.C. § 30111.

²⁹⁸ 49 U.S.C. § 30120.

²⁹⁹ *Id.* § 32902.

On its car safety powers, NHTSA has long faced virtually no industry judicial challenges. In researching this point, I began with the core study period of 2013–2021 and extended my exhaustive Bloomberg dockets search forward to January 20, 2024, looking for all suits by automakers or their associations against NHTSA or against DOT on NHTSA matters during the eleven-year window of 2013–2024. There were none, except on fuel economy issues.³⁰⁰

The absence of automaker litigation against NHTSA on car safety observed from 2013 to 2024 was consistent with the norm going back to the mid-1980s, as revealed by the work of analysts and advocates in the auto-safety realm who have closely scrutinized the agency's activity throughout the period. Automakers can challenge Safety Standards, and they did so vigorously in the 1970s and up to 1984, but then not at all after that, through 2024.³⁰¹ An automaker can also challenge a recall order, either by suing directly to have the order invalidated or by refusing to follow the order, thereby inducing the government to sue to enforce it and occasioning judicial review of the order's legality.³⁰² Automakers did force such litigation repeatedly in the 1970s and up to 1983,³⁰³ but since then it appears they have forced litigation only once. Chrysler refused an order in 1996 upon which NHTSA sued and lost, though it should be noted the order was premised on noncompliance per se with a Safety Standard, not a safety-related defect with documented malfunctions or accidents.³⁰⁴ None of the major industry trade

³⁰⁰ For all suits against NHTSA in this period by any businesses or associations thereof, see DATASET, *supra* note 10, File 15, Row 11, which contains no automaker suits; *id.* File 16, Rows 72–80, which contains suits by National Coalition for Advanced Transportation on fuel economy; *id.* File 17, Row 20, which contains no automaker suits; and *id.* File 18, Rows 29–35, which contains suits by Tesla on fuel economy.

³⁰¹ For a list of all suits on NHTSA Safety Standards that went to judgment from 1966 to 2013, see *Justice Denied: Rules Delayed on Auto Safety and Mental Health: Hearing Before the Subcomm. on Oversight, Fed. Rts. & Agency Action of the S. Comm. on the Judiciary*, 113th Cong. 18 tbl.1 (2013) (statement of Cary Coglianese, Professor, University of Pennsylvania). For discussion of the suits, see Mashaw & Harfst, *supra* note 4, at 178 n.21, 243–44. On the suit that was brought in 1984, see *infra* notes 316–22 and accompanying text.

³⁰² Kevin M. McDonald, *Judicial Review of NHTSA-Ordered Recalls*, 47 WAYNE L. REV. 1301, 1321–22 (2001). There is an incentive for the target to sue, because if it disobeys and is sued, it can be forced to notify customers of the potential defect pending suit and is subject to penalties if it loses. *Id.*

³⁰³ See *id.* at 1330–32 (discussing the General Motors (“GM”) “X-Cars” suit that began in 1983). For the preceding suits going back through the 1970s, see *id.* at 1322–30. When Ralph Nader in 2014 said that NHTSA “has not ordered a manufacturer to recall its defective vehicles for 35 years,” Ralph Nader, *Ralph Nader: Safety in Name Only at NHTSA*, USA TODAY (Sept. 17, 2014, 7:22 PM), <https://www.usatoday.com/story/opinion/2014/09/17/ralph-nader-safety-nhtsa-investigation-regulation-congress-gm-stalled-column/15801047/> [<https://perma.cc/K8C2-W4HC>], he was likely referring to the 1980 model year of the GM X-Cars on which the government sued GM in 1983.

³⁰⁴ *United States v. Chrysler Corp.*, 158 F.3d 1350, 1351–52 (D.C. Cir. 1998); McDonald, *supra* note 302, at 1332–33. For the original complaint, see Complaint for Declaratory and Injunctive

associations took sides against the agency as amici in any cases on car safety covered by the Bloomberg database (1989–2024), except in the 1996 Chrysler case.³⁰⁵ (The automakers’ forty-one-year streak of not challenging Safety Standards and their twenty-nine-year streak of not challenging on safety matters at all were broken in January 2025, after the end of the extended study period, when the principal trade association sued to challenge a Safety Standard on automatic emergency braking.³⁰⁶ This Article discusses that suit at the very end of this Section, including how I think it fits into this Article’s underlying theory.)

To understand why automakers challenged NHTSA in court up to the mid-1980s but so rarely afterward, some background on the history of this regulatory field is necessary. When an agency has the mission of protecting the safety of the industry’s own customers, that mission tends to bring industry and agency into alignment, but only if the industry believes customers want safety and will pay for it. The auto industry has perceived a customer preference for safety since about the late 1980s

Relief and for Civil Penalties, *United States v. Chrysler Corp.*, 16 F. Supp. 2d 25 (D.D.C. 1998) (No. 96-01236). For confirmation that there was no other recall litigation from the mid-1980s to the present, consider that as of 2011, “[a]ccording to NHTSA officials, the agency has not ordered any vehicle recalls since prior to 2000, and since the agency was established [in 1970], it has ordered seven recalls for motor vehicles or equipment.” U.S. GOV’T ACCOUNTABILITY OFF., GAO-11-603, AUTO SAFETY: NHTSA HAS OPTIONS TO IMPROVE THE SAFETY DEFECT RECALL PROCESS 8 (2011). These seven recalls appear to correspond to the ten cases listed by McDonald, *see* McDonald, *supra* note 302, at 1322–33 (running from the 1970s through the X-Cars case brought in 1983, plus the Chrysler case brought in 1996), minus the cases numbered 7 (lacking a final order), 8 (concerning only penalties), and 9 (lacking a final order). This lack of recall litigation has also been confirmed in various articles and presentations. *See* Eric Pearson, *Chrysler Reaches 11th Hour Agreement with Federal Officials to Recall Jeep SUVs Linked to Fire Deaths*, HEYGOOD, ORR & PEARSON (June 19, 2013), <https://www.hop-law.com/chrysler-reaches-11th-hour-agreement-with-federal-officials-to-recall-jeep-suvs-linked-to-fire-deaths/> [<https://perma.cc/LV8C-XMJ6>] (stating that if Chrysler in 2013 had not agreed to a voluntary recall, “[t]he company would have become the first car manufacturer to refuse a NHTSA recall order since 1996, when Chrysler had refused another recall”); Allan J. Kam, Former Senior Enf’t Att’y, NHTSA, NHTSA Safety Defect Investigations, Presentation at ALTA 2001 Annual Convention, Product Liability Section 8 (July 17, 2001) (on file with Highway Traffic Safety Associates), <https://www.htsassociates.com/nhtsa-safety-defect-investigations> [<https://perma.cc/3JCD-QEUV>] (stating, as of mid-2001, that “there has been no further litigation contesting the agency’s determination that a [sic] safety-related defects exists” since the GM X-Cars case of 1983–1988); *see also* Mashaw & Harfst, *supra* note 4, at 249–50 (noting that the GM X-Cars case in 1988 and the Chrysler case in 1998 were NHTSA’s only losses in recall matters from 1986 to 2015).

³⁰⁵ I conducted in November 2024 a search of Bloomberg dockets, unrestricted by date or court, for amicus field containing the following current and former trade association names: “*Automobile Importers of America*” OR “*Association of International Automobile Manufacturers*” OR “*Association of Global Automakers*” OR “*Auto Alliance*” OR “*Alliance of Automobile Manufacturers*” OR “*Automobile Manufacturers Association*” OR “*Motor Vehicle Manufacturers Association*” OR “*Alliance for Automotive Innovation*.” There was one suit on fuel economy, which was *Natural Resources Defense Council v. NHTSA*. *See* Court Docket, *Nat. Res. Def. Council v. NHTSA*, No. 22-01080 (D.C. Cir. May 11, 2022).

³⁰⁶ Petition for Review, *All. for Auto. Innovation v. DOT*, No. 25-1026 (D.C. Cir. Jan. 17, 2025).

and early 1990s, but the industry generally did not perceive such a preference in the decades before then. For example, during the 1950s, Ford tried a safety-based marketing campaign and got lackluster results, with “many in the industry conclud[ing] that ‘safety does not sell.’”³⁰⁷ Indeed, when Congress in 1966 passed the landmark legislation that first empowered DOT to regulate auto safety and led to the creation of NHTSA, the main purpose was for the agency to impose Safety Standards that would force the industry to invent new technologies to make cars safer, precisely because the industry had no business reason to do such things.³⁰⁸

Under these conditions, NHTSA’s initial Safety Standards of the late 1960s and 1970s, which were often technology-forcing and lifesaving, ran into strong resistance from the industry. Ford’s president Lee Iacocca said outright in 1972 that “safety doesn’t sell.”³⁰⁹ That year, Ford, Chrysler, American Motors, the foreign-automakers association, and others—though not General Motors—won a lawsuit against one of NHTSA’s most important Safety Standards: the one requiring cars to have “passive restraints” that would leave car occupants no choice but to be protected, such as automatic seatbelts and airbags, of which the latter were potentially most effective but also more expensive and as yet unproven.³¹⁰ The Sixth Circuit struck down much of the rule, leaving in place only the “ignition interlock” that prevented a car from starting unless the driver buckled the seatbelt.³¹¹ When the interlock went forward in 1974, it led—in a graphic demonstration of how poorly safety could “sell”—to mass consumer fury, driving an angry Congress to ban the interlock and certain other safety measures in a way that sent the agency’s rulemaking officials into a long-term defensive crouch, especially when combined with their continuing losses in industry court challenges to Safety Standards.³¹² Meanwhile, Congress in that same 1974 legislation gave NHTSA clear power to investigate defects and order

³⁰⁷ MARTIN ALBAUM, *SAFETY SELLS: MARKET FORCES AND REGULATION IN THE DEVELOPMENT OF AIRBAGS* 8 (2005), https://www.iihs.org/media/186adabe-9ef4-479c-ad37-36b9f0e7fca1/Ka0wWQ/Albaum_Safety_Sells.pdf [<https://perma.cc/4TUR-NSGC>].

³⁰⁸ Mashaw & Harfst, *supra* note 4, at 255–56.

³⁰⁹ Paul C. Judge, *Selling Autos by Selling Safety*, N.Y. TIMES, Jan. 26, 1990, at D3.

³¹⁰ *Chrysler Corp. v. DOT*, 472 F.2d 659, 660, 664, 666 (6th Cir. 1972). On the unproven nature of airbags as of 1979, see ALBAUM, *supra* note 307, at 96–97.

³¹¹ See *Chrysler Corp.*, 472 F.2d at 674–75; Mashaw & Harfst, *supra* note 4, at 180–81.

³¹² Mashaw & Harfst, *supra* note 4, at 179–81, 258. In another matter, Ford sued alone in 1973 but lost. *Ford Motor Co. v. NHTSA*, 473 F.2d 1241, 1244 (6th Cir. 1973). However, NHTSA suffered other defeats at the hands of tire manufacturers and retreaders, truck manufacturers, and supply companies. See *Justice Denied: Rules Delayed on Auto Safety and Mental Health: Hearing Before the Subcomm. on Oversight, Fed. Rts. & Agency Action of the S. Comm. on the Judiciary*, *supra* note 301, at 18 tbl.1. Note that in *Pacific Legal Foundation v. DOT*, 593 F.2d 1338 (D.C. Cir. 1979), Ford intervened, but it was on the agency’s side, U.S. GOV’T ACCOUNTABILITY OFF., CED-79-93, *PASSIVE RESTRAINTS FOR AUTOMOBILE OCCUPANTS—A CLOSER LOOK* 10 (1979), <https://www.gao.gov/products/ced-79-93> [<https://perma.cc/8B8Y-T45G>].

recalls,³¹³ which were less threatening than Safety Standards to automaker autonomy, were congenial to consumers because they looked like free extended warranties, and were less foreign to reviewing courts because they were conceptually similar to tort litigation.³¹⁴ By the late 1970s, recalls were becoming NHTSA's main activity, with the number of cars annually recalled sometimes exceeding the number of cars sold.³¹⁵

From the crisis of 1974 through the 1980s, NHTSA's Safety Standard program went forward with regard to passive restraints, but in a slow and complicated way, and the program never advanced with regard to any major features besides passive restraints.³¹⁶ Industry resistance, judicial and congressional skepticism, and consumer indifference were reinforced after 1980 by the Reagan White House's deregulatory attitude.³¹⁷ NHTSA under Carter adopted a passive restraints rule in 1977, but the industry was in uniform opposition (except for the luxury manufacturer Mercedes) when Reagan's appointee entered in 1981, and he rescinded the rule only to have insurers sue and block the rescission.³¹⁸ DOT Secretary Elizabeth Dole in 1984 responded to the court decision with a new compromise rule whereby automakers could choose among types of passive restraints—automatic seatbelts or the more expensive and potentially more effective airbag—on a phase-in schedule up to 1989, plus a “trapdoor” provision for terminating the entire rule if enough states enacted laws requiring seatbelt use by 1989—which, it turned out, the states did not.³¹⁹ Notably, the rule provided extra credit toward the phase-in requirements when automakers chose airbags, and the agency increased that extra credit through its petition process shortly after 1984.³²⁰ One trade association brought suit to stop Dole's 1984 rule but later dropped the challenge.³²¹

That abortive suit turned out to be the last automaker challenge to a NHTSA Safety Standard for forty years, as the late 1980s and early 1990s witnessed the formation of a new regime for how automakers,

³¹³ McDonald, *supra* note 302, at 1311–13. Recalls had been an afterthought in the original 1966 legislation. Mashaw & Harfst, *supra* note 4, at 177.

³¹⁴ JERRY L. MASHAW & DAVID L. HARFST, *THE STRUGGLE FOR AUTO SAFETY* 147–71 (1990).

³¹⁵ *Id.* at 164.

³¹⁶ Mashaw & Harfst, *supra* note 4, at 182 n.37, 188, 233.

³¹⁷ *Id.* at 193–94, 197, 253–54.

³¹⁸ On the automakers' positions, see ALBAUM, *supra* note 307, at 100–01, 106, 111, 116, 187.

³¹⁹ *Id.* at 130–37, 143.

³²⁰ *Id.* at 134, 138–40.

³²¹ *Id.* at 135 (on the suit being dropped); Henry Gilgoff, *Safety First*, *NEWSDAY*, Sept. 24, 1984, at A3 (“The Automobile Importers of America Inc., a trade group, filed suit, too, arguing that the rule was too restrictive in parts and vague in others.”); *Dole Orders Crash-Protection Gear*, *CINCINNATI ENQUIRER*, July 12, 1984, at A8 (“The Automobile Importers of America, Inc., which represents all but three foreign automakers selling cars in America, immediately asked the U.S. 9th Circuit Court of Appeals in San Francisco to review the regulation. . . . [S]ome of its members have opposed the cost and timing of previous crash-protection proposals.”).

customers, and the agency related to each other. In the words of Jerry Mashaw and David Harfst, this era saw “the emergence . . . of something resembling a market for motor vehicle safety.”³²² This car-safety market emerged partly because NHTSA helped create it.³²³ The agency did so in three ways.

First, the agency’s open-ended encouragement of the largely untried airbag fostered competitive dynamics that allowed that technology to become a winner in the consumer marketplace and gain the allegiance of the industry.³²⁴ The years following the 1984 rule were fraught with uncertainty on several questions, including whether the “trapdoor” would open and negate the entire passive-restraint requirement, whether companies complying with the rule’s phase-in would have more business success offering airbags as compared with cheaper automatic seatbelts, and, if so, on what timeline.³²⁵ Some companies bet on airbags: Mercedes was poised to lead with its luxury cars;³²⁶ Ford convinced NHTSA to offer extra credit for the airbags it was installing in some models;³²⁷ and Chrysler, now headed by Iacocca, “stole a march on Ford” in 1988 by becoming the first U.S. automaker to adopt airbags as standard equipment, buying full-page newspaper ads featuring its formerly anti-airbag chairman with the caption, “Who says you can’t teach an old dog new tricks?”³²⁸ Meanwhile, General Motors and several Japanese manufacturers bet against airbags—and lost.³²⁹ With a subset of manufacturers putting airbags into wide practice for the first time, the devices began saving actual lives and attracting dramatically positive media attention.³³⁰ When two Chrysler LeBarons collided head-on in 1990, both drivers walked away, saved by airbags, and Chrysler publicized the crash in a “massive television campaign.”³³¹ Another Chrysler ad that year showed an actual driver crashing a Plymouth into a brick wall and walking away thanks to the airbag, with the voiceover: “If you’re looking at a Japanese car, see if it’s got an airbag. Then ask yourself if you can live without one.”³³² Surveys documented a pro-airbag

³²² Mashaw & Harfst, *supra* note 4, at 175.

³²³ *Id.* at 261 (“[W]e must remember that the market for safety in motor vehicles did not emerge independently of regulation.”).

³²⁴ *Id.* at 257 & n.348; ALBAUM, *supra* note 307, at 187.

³²⁵ ALBAUM, *supra* note 307, at 135–41.

³²⁶ *Id.* at 100, 141.

³²⁷ *Id.* at 138–40.

³²⁸ *Id.* at 143.

³²⁹ *Id.* at 99, 101–02, 147.

³³⁰ *Id.* at 147.

³³¹ *Id.*

³³² Roger Richman, *Chrysler Airbad Commercial*, YOUTUBE (Aug. 14, 2015), <https://www.youtube.com/watch?v=oNfEW4trd50> [https://perma.cc/9FE5-KGZH]; Daniel Bukszpán, *A Brief History of the Car Crash Commercial*, CAMPAIGN (July 27, 2015), <https://www.campaignlive.com/article/brief-history-car-crash-commercial/1357636> [https://perma.cc/J4BG-5GN6].

shift in consumer sentiment compared to the 1980s.³³³ The *New York Times* observed in 1990, “After years of insisting that safety features do not sell cars, auto makers have noticed that many prospective buyers think differently. Suddenly, many car ads talk of little else.”³³⁴ For the 1990 model year, “General Motors and the Japanese manufacturers were at a disadvantage because of their late start—they had to cope not only with the design changes needed to install airbags but also with a shortage of facilities for manufacturing them” amid all the new demand.³³⁵ When NHTSA promulgated a rule in 1991 requiring passive restraints for the massively expanding market in minivans and sport utility vehicles (“SUVs”), nobody sued.³³⁶ “Safety could sell.”³³⁷

The second way NHTSA helped create a market for auto safety was by establishing its New Car Assessment Program (“NCAP”) in 1978, which crash tested cars and published the results, allowing consumers to compare the safety of different models with each other.³³⁸ The agency has made NCAP more elaborate and user-friendly over time, by adopting a “five-star” rating system in 1994, for example.³³⁹ NHTSA was joined in this space by the Insurance Institute for Highway Safety (“IIHS”), a well-funded creature of the insurance companies that began publishing its own crash test ratings in 1995.³⁴⁰ The econometric literature finds that crash test ratings affect sales to consumers and elicit manufacturer improvements in safety.³⁴¹

Third, NHTSA’s recall program, which has affected a staggering proportion of cars nationwide since the 1970s, “may well have contributed importantly to the development of the vehicle safety market.”³⁴² Recalls force manufacturers to engage consumers on safety and to try to differentiate their recall experience from those of their competitors; more generally, recalls keep “vehicle safety in the public eye.”³⁴³

Whereas NHTSA rulemaking outside the realm of passive restraints was frozen by judicial and political resistance from 1974 into the 1990s, the years since 2000 have seen the agency return to promulgating

³³³ ALBAUM, *supra* note 307, at 141, 147–48, 155, 159.

³³⁴ Judge, *supra* note 309, at D1.

³³⁵ ALBAUM, *supra* note 307, at 147. On slow adoption by Japanese automakers, see Judge, *supra* note 309, at D3.

³³⁶ ALBAUM, *supra* note 307, at 150, 181. Indeed, the airbag was so successful that Congress in late 1991 preempted NHTSA by simply mandating airbags via statute. *Id.* at 151.

³³⁷ Mashaw & Harfst, *supra* note 4, at 257.

³³⁸ *Id.* at 259.

³³⁹ See Max Gates, *NHTSA Revises Crash Reporting Data: 5-Star System Is Consumer Friendly*, AUTO. NEWS, Jan. 10, 1994, at 20.

³⁴⁰ See Damien Sheehan-Connor, *Reducing Informational Asymmetry Impacts Choices and Improves Safety: An Evaluation of Automobile Crash Tests*, 89 J. RISK & INS. 697, 700 (2022).

³⁴¹ *Id.* at 698–99 (reviewing literature and introducing own study to same effect).

³⁴² Mashaw & Harfst, *supra* note 4, at 261–62.

³⁴³ *Id.* at 262.

Safety Standards, but with a new interpretation of its mandate “as one of technology diffusion rather than technology forcing.”³⁴⁴ This new interpretation rests on the premise that safety sells and that industry realizes it does. Essentially, NHTSA recognizes that industry’s safety research capacity is massively greater than its own, allows industry to take the lead in originating safety innovations and scaling them up to a large portion of the fleet, and tasks itself with ensuring diffusion of those innovations to the entirety of the fleet on a faster and more universal basis than the market by itself would achieve, especially as to lower-priced models.³⁴⁵ NHTSA also plays a role in fostering innovation to begin with by periodically grading harder in the NCAP program; in this way, informational safety ratings serve as a kind of substitute for coercive rulemaking.³⁴⁶

With this background, we can now consider why industry has sued so little since the 1980s. We must bifurcate the answer, as it appears to be different for Safety Standards compared with recalls.

For Safety Standards, the answer is clearly agency forbearance: Industry has refrained from challenges because NHTSA has been highly deferential to industry decision-making. “The Agency’s strategic shift from technology forcing to diffusion nudging paid off handsomely in avoiding legal challenge or embarrassment.”³⁴⁷ Anonymous Interviewee #2, a former senior NHTSA official, explained that if comparative safety ratings are published on, say, roof crush standards that shape consumer preferences and drive industry adoption of new safety features,

then NHTSA can come along and say, “oh, we should have a vehicle safety standard for roof structural safety,” and the industry has already gone a significant way [toward it], which actually makes rulemaking easier, but frequently also makes the rulemaking less technology-forcing than what we see in the [non-consumer-safety] fuel economy and greenhouse-gas side. There’s much less incentive to sue if you’re already essentially either complying or compliance is marginally tougher.³⁴⁸

One may think this approach wise and appropriate or weak and disappointing. Some argue that NHTSA has moved too far away from technology forcing.³⁴⁹ After all, the 1984 passive-restraints rule would appear to be evidence that technology forcing can succeed: Consumers

³⁴⁴ *Id.* at 254.

³⁴⁵ *Id.* at 216–31, 258.

³⁴⁶ *Id.* at 259. On upward revisions of NCAP, see Joseph Gavin, *Crash Test Dummies: What Drives Automobile Safety in the United States?*, 25 *LOY. CONSUMER L. REV.* 86, 91, 106 (2012).

³⁴⁷ Mashaw & Harfst, *supra* note 4, at 243.

³⁴⁸ Interview with Anonymous Interviewee #2, former senior NHTSA official (Aug. 23, 2024).

³⁴⁹ Mashaw & Harfst, *supra* note 4, at 273–77.

would never have realized the attractiveness of the airbag had not the government pressed some manufacturers to start offering it.³⁵⁰ Then again, the 1980s were a different technological era, which did not yet have the rapid and highly complex digital developments that may merit a more experimental, less command-and-control approach today. In any event, whether NHTSA's forbearance is good or bad, it seems to be the overwhelming causal explanation for the dearth of litigation on rulemaking.

However, for recalls, I do not think agency forbearance is a sufficient explanation for the absence of litigation. Yes, recalls are less threatening to industry's autonomy than technology-forcing rules would be. But recalls are common enough and costly enough that one might think automakers would find it worth challenging them at a higher rate than they have.³⁵¹ Focusing narrowly on what NHTSA calls "influenced" recalls, or recalls undertaken by a manufacturer after an agency investigation,³⁵² the period of 1997–2023 saw 3,137 recalls affecting 437 million vehicles—similar to the number of new cars sold during that period.³⁵³ There appears not to be official data on the average cost to the manufacturer of a recall: *Forbes* put it at \$500 per vehicle over the period of 2013–2022, which is much higher than the \$100 per vehicle that NHTSA was said to have estimated in 2009,³⁵⁴ even adjusted for inflation—though this 2009 estimate was said to be "rather conservative[]." ³⁵⁵ Applying a split-the-difference estimate of \$300 to NHTSA's annual "influenced" recalls in 2013–2022 and discounting each year by the agency's reported completion rate, we get a cost of \$4.6 billion per year industry wide. This seems like a conservative estimate, considering a report that General Motors alone spent \$2.8 billion on repairs across several recalls in 2016, a particularly bad year.³⁵⁶ Applying the \$300 estimated cost to the total vehicles affected by influenced recalls in 2013–2022, discounted by completion rates (152 million) and divided by the number of influenced

³⁵⁰ *Id.* at 261.

³⁵¹ Indeed, automakers have only challenged recalls once, in 1996, across the forty-year period of 1983–2024. *See supra* note 304.

³⁵² Mashaw & Harfst, *supra* note 4, at 245 n.301.

³⁵³ 2023 NHTSA ANN. REP.: SAFETY RECALLS (2024), https://www.nhtsa.gov/sites/nhtsa.gov/files/2024-03/NHTSA-2023-Annual-Recalls-Report_0.pdf [<https://perma.cc/6GND-K3DM>] (data from 2003–2023); 2017 NHTSA RECALL ANN. REP. (2018), <https://www.nhtsa.gov/document/2017-recall-annual-report> [<https://perma.cc/98WK-2YR5>] (data from 1997–2017).

³⁵⁴ Steve Tengler, *Auto Recalls Way Down in 2023 and Mercedes Knows Why*, FORBES (June 28, 2023, 4:00 AM) <https://www.forbes.com/sites/stevetengler/2023/06/28/auto-recalls-way-down-in-2023-and-mercedes-knows-why/> [<https://perma.cc/MRT5-RLDJ>]; Kevin M. McDonald, *Do Auto Recalls Benefit the Public?*, 32 REGULATION 12, 13 (2009).

³⁵⁵ McDonald, *supra* note 354, at 13.

³⁵⁶ Chris Isidore, *GM's Total Recall Cost: \$4.1 Billion*, CNN (Feb. 4, 2015, 1:07 PM), <https://money.cnn.com/2015/02/04/news/companies/gm-earnings-recall-costs/> [<https://perma.cc/X4BH-YY36>].

recalls in that period (858), we get \$53 million per recall. As that is merely the average, it seems that *some* recalls would be, as the saying goes, “cases worth litigating.” Yet none were. To be sure, the legal standard for recalls that the judiciary established in the 1970s is favorable to the agency,³⁵⁷ but after the latest recall case was decided in 1998, an article by industry counsel said it “remains to be seen” whether further litigation would answer the question of whether “the definition of ‘safety-related defect’ [was] too broad, such that recalls are conducted (voluntarily or involuntarily) to include vehicles and parts that otherwise present no risk to safety.”³⁵⁸ The cases invoked as evidence of the pro-industry standard were decided in the 1970s, whereas the last two cases litigated by industry, decided in 1988 and 1998, were both industry wins.³⁵⁹ Considering the sums of money repeatedly at stake, year in and year out, we may wonder why no company has been entrepreneurial enough to press questions like these.

It is plausible that the reasons are similar to those for meat processors and drugmakers: maintaining the regulated company’s relationship to the agency and preserving the confidence of the company’s customers. First consider each automaker’s relationship to NHTSA’s recall operation. Unlike USDA or FDA, the agency does not have the power to shut down the manufacturer or to decide whether its products can enter the market to begin with.³⁶⁰ But because the number of automakers is small and recalls are so frequent, the recall process is very much a repeated game, and each recall entails a negotiation over its scope and terms.³⁶¹ “The entire recall apparatus has evolved into a kind of in terrorem confessional society. The earlier the confession, the better.”³⁶² And the game is informationally intimate. Automakers “are required to supply NHTSA with a constant stream of data that might suggest the existence of a defect,” including “quarterly Early Warning Reports . . . covering information on incidents involving death or injury, aggregate data on property damage claims, consumer complaints, warranty claims, and

³⁵⁷ Kam, *supra* note 304, at 8 (referencing *United States v. Gen. Motors Corp. (“Wheels”)*, 518 F.2d 420 (D.C. Cir. 1975) and *United States v. Gen. Motors Corp. (“Pitman Arms”)*, 561 F.2d 293 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 1055 (1977)) (“[M]anufacturers have been unwilling, when push comes to shove, to contest a NHTSA safety-defect determination made in light of the *Wheels* and *Pitman Arms* precedents.”); Mashaw & Harfst, *supra* note 4, at 179–80, 249. But note both these works *also* invoke consumer relations as a factor deterring litigation. *Id.* at 249–51 (citing Kam, *supra* note 304).

³⁵⁸ McDonald, *supra* note 302, at 1337.

³⁵⁹ See *United States v. Chrysler Corp.*, 158 F.3d 1350 (D.C. Cir. 1998); *United States v. Gen. Motors Corp.*, 841 F.2d 400 (D.C. Cir. 1988).

³⁶⁰ Letter of Interpretation from Stephen P. Wood, Acting Chief Counsel, NHTSA, to Douglas Shoner (Oct. 5, 1989), <https://www.nhtsa.gov/interpretations/2067y> [<https://perma.cc/S4P3-MPLV>].

³⁶¹ Mashaw & Harfst, *supra* note 4, at 248 (“NHTSA generally negotiates the scope of a recall without the need for a formal administrative order.”).

³⁶² *Id.* at 246.

field reports on their investigation of specific incidents.”³⁶³ NHTSA in the recall context has “extraordinary information power,” which is “a big, big lever.”³⁶⁴ Furthermore, via consent decrees, NHTSA has increasingly inserted itself into some automakers’ internal managerial decision-making—“a seat at the internal management table . . . that [the agency] has never been able to achieve through standard setting.”³⁶⁵

Second, consider each automaker’s need to preserve its brand before a consuming public that will pay for safety. If this is a factor deterring litigation, it would be consistent with the virtual disappearance of recall litigation during the 1980s when the market for safety was coming into being. In 2001, Allan Kam, a longtime NHTSA enforcement attorney who had recently retired, gave a speech that considered why automakers so rarely litigated recalls.³⁶⁶ He described the agency-friendly legal standard for recalls, argued that manufacturers were reluctant to sue in light of it, and then gamed out the very public and adversarial administrative process that occurs if negotiation over a recall breaks down and the manufacturers and company head toward litigating the matter, concluding:

In today’s media-hyped environment, no manufacturer wants to undergo such an ordeal. The continuing adverse publicity would be devastating. Challenging the agency’s recall order in court would bring more adverse media attention. General Motors’ experience with the *X-Cars* litigation [in 1983–1988] could be described as winning the battle and losing [sic] the war, as the publicity negatively impacted sales of the vehicles at issue. There is no market share to be gained in fighting NHTSA.³⁶⁷

Having discussed the factors that may have caused the near-total lack of automaker judicial challenges from the mid-1980s to the present, I will close with a word about a recent suit that was brought in January 2025, after the end of my extended study period. The automakers’ principal trade association brought the suit to challenge NHTSA’s 2024 Safety Standard requiring automatic emergency braking (“AEB”) in cars by 2029.³⁶⁸ The dispute appears to reflect a Biden-era departure

³⁶³ *Id.* at 247.

³⁶⁴ Interview with Anonymous Interviewee #2, *supra* note 348.

³⁶⁵ Mashaw & Harfst, *supra* note 4, at 250.

³⁶⁶ See generally Kam, *supra* note 304.

³⁶⁷ *Id.* at 13. In their argument that “just about everything in the legal environment and beyond worked to nurture recalls,” Mashaw and Harfst included the point that “[n]egative publicity and reputational damage further upped the ante” in preventing litigation. Mashaw & Harfst, *supra* note 4, at 251.

³⁶⁸ Petition for Review, *All. for Auto. Innovation v. DOT*, No. 25-1026 (D.C. Cir. Jan. 17, 2025); Federal Motor Vehicle Safety Standards; Automatic Emergency Braking Systems for Light Vehicles, 89 Fed. Reg. 93,199 (Nov. 26, 2024).

from the agency's decades-long deference to industry on Safety Standards, as the challengers say the Standard is "practically impossible with available technology."³⁶⁹ But the departure may be temporary, as the agency quickly delayed the Standard in the wake of the suit and of President Trump's inauguration and is still reviewing the Standard as of summer 2025.³⁷⁰ Further, I do not think industry's willingness to challenge the AEB initiative negates the claim I made earlier that automakers are averse to the optics of public opposition to agency action that protects their own consumers. On the contrary, the lawsuit is, to a large degree, the exception that proves the rule. Anonymous Interviewee #2 explained that whereas Safety Standards have "pretty much always been focused on vehicle occupants," the 2024 AEB Standard embodies how "for the first time, NHTSA is paying attention to benefits to pedestrians and cyclists" as their deaths have been recently rising.³⁷¹ Although the AEB Standard is not exclusively focused on pedestrian and cyclist protection, such protection is a central feature of the rule—one that is "new" and "something that we haven't seen auto manufacturers voluntarily offering."³⁷² Sixty-six percent of the lives projected to be saved by the Standard belong to pedestrians.³⁷³ In contrast to the agency's history of vehicle-occupant protection that largely overlaps protection of consumers and their families, the AEB Standard's pedestrian-and-cyclist aspect addresses "a classic externality."³⁷⁴ Therefore, the litigation is to a large degree about something other than *consumer* safety.

D. Airlines and the FAA

Our fourth industry-agency pairing in which industry judicial challenges stay at a low level is between airlines and the FAA. As with the other pairings considered so far, airlines have an intimate relationship with the FAA and a major interest in the success of the FAA's mission

³⁶⁹ Press Release, All. For Auto. Innovation, Automakers Seek Repeal of Biden Department of Transportation's Flawed Automatic Emergency Braking Rule (Jan. 17, 2025), <https://www.auto-innovate.org/posts/press-release/automakers-seek-repeal-of-biden-dot-flawed-aeb-rule> [https://perma.cc/C3NH-SULZ].

³⁷⁰ See Federal Motor Vehicle Safety Standards; Automatic Emergency Braking Systems for Light Vehicles, 90 Fed. Reg. 8179 (Jan. 27, 2025) (to be codified at 39 C.F.R. pt. 571) (delaying the effective date of the final rule until March 20, 2025); Status Report, All. for Auto. Innovation v. DOT, No. 25-1026 (D.C. Cir. July 3, 2025) (noting the agency "is continuing to review the rule").

³⁷¹ Interview with Anonymous Interviewee #2, *supra* note 348.

³⁷² *Id.*

³⁷³ OFF. OF REGUL. ANALYSIS AND EVALUATION, NHTSA, FINAL REGULATORY IMPACT ANALYSIS: FEDERAL MOTOR VEHICLE SAFETY STANDARD NO. 127; LIGHT VEHICLE AUTOMATIC EMERGENCY BRAKING (AEB); AEB TEST DEVICES 11 tbl.2 (2024) (breaking down fatalities prevented into "Lead Vehicle AEB" and "PAEB," i.e., pedestrian AEB).

³⁷⁴ Interview with Anonymous Interviewee #2, *supra* note 348.

to keep air travel safe for the consuming public, aligning their incentives with those of the agency.³⁷⁵

The FAA administers an elaborate system of safety regulation. No business can operate as an air carrier without a certification from the FAA, which the agency grants only if it determines the business is capable of operating in accordance with applicable regulations.³⁷⁶ The regulations are numerous, complicated, and subject to ongoing technical adjustments. “Every year the FAA issues hundreds of rules, many related to this topic [of air safety].”³⁷⁷ Some rules apply to the entire industry (e.g., the deicing rule of 1992), though rules of such sweep are exceptional.³⁷⁸ More common are the more narrowly applicable technical rules known as “airworthiness directives” (“ADs”), by which carriers are required “to fix potentially dangerous defects” in the types of planes they operate.³⁷⁹ On top of the general rules and the ADs, each carrier is subject to a detailed set of directives for *just how* it is to comply with the applicable rules. These directives, known as “operating specifications” (“OpSpecs”), are individually tailored to the carrier, the types of planes it flies, and the airports it serves.³⁸⁰ OpSpecs are binding.³⁸¹ Unlike the general rules and ADs, which are normally adopted through a generalized notice-and-comment rulemaking process,³⁸² an OpSpec for an individual carrier is served personally on that carrier, who then normally has thirty days to comment on it.³⁸³

³⁷⁵ Throughout, this Section cites the lists of U.S. airlines appearing in the annual reports of the Air Transport Association (“ATA”) from 1989 to 2008. The full list of reports is available at *Past A4A Annual Reports (1937–2011)*, AIRLINES FOR AM. (Mar. 1, 2011), <https://www.airlines.org/dataset/past-a4a-annual-reports-1937-2011/> [<https://perma.cc/XU8U-8BDR>].

³⁷⁶ Rebecca MacPherson, *The FAA’s Certification and Regulatory Scheme for U.S. and Foreign Air Carriers*, in AVIATION REGULATION IN THE UNITED STATES 285, 287 (David Heffernan & Brent Connor eds., 2014) (citing to and explaining 14 C.F.R. pt. 119).

³⁷⁷ ROGER W. COBB & DAVID M. PRIMO, *THE PLANE TRUTH: AIRLINE CRASHES, THE MEDIA, AND TRANSPORTATION POLICY* 48 (2003).

³⁷⁸ *Id.* On deicing, see John H. Cushman Jr., *U.S. Imposes New De-Icing Rules to Lower Risk of Plane Accidents*, N.Y. TIMES, Sept. 26, 1992, at 5; see also MacPherson, *supra* note 376, at 293 (similarly noting that wide-sweep rules are rare but giving examples).

³⁷⁹ COBB & PRIMO, *supra* note 377, at 48. The burden of repair is on the carrier who operates the plane, not the manufacturer who built it. MacPherson, *supra* note 376, at 292. Note also that FAA rules require carriers to perform maintenance on aircraft. *Id.*

³⁸⁰ MacPherson, *supra* note 376, at 287–88, 290 (citing 14 C.F.R. pts. 119, 129).

³⁸¹ See *id.* at 290. No licensed air carrier may operate an aircraft “in violation of an air carrier operating certificate, operating certificate, or appropriate operations specifications issued under this part.” 14 C.F.R. § 119.5(l).

³⁸² On ADs, see *Types of Airworthiness Directives*, FED. AVIATION ADMIN., https://www.faa.gov/aircraft/air_cert/continued_operation/ad/type_pub [<https://perma.cc/6HMH-Y6KB>].

³⁸³ MacPherson, *supra* note 376, at 290–91. At times, OpSpecs may be less tailored to individual carriers and more standardized and generic across carriers, raising the question of whether they ought to have gone through generalized notice-and-comment. *Id.* at 291.

The FAA seeks to ensure compliance with general rules, ADs, and OpSpecs through a system of surveillance and enforcement. The agency employs on the order of 4,000 aviation safety inspectors working in the “Flight Standards” area overseeing the airlines.³⁸⁴ Whereas “[m]ost regulatory agencies organize by broad functional areas . . . and also by geography” so that “any one inspector normally deals with multiple corporations on a daily basis[,]” the “majority of FAA airline inspectors are assigned to a specific Certificate Management Office [(“CMO”)], and deal with exactly one airline, full time, and for many years at a stretch (e.g., the ‘Southwest CMO’ deals only with Southwest, and is responsible for Southwest Airlines’ operations everywhere).”³⁸⁵ FAA personnel monitor airlines through physical inspections of equipment, audits of airline procedures, review of company records, and receipt of information from company employees through various voluntary disclosure systems, whereby an airline avoids penalties if it voluntarily discloses its violations and redresses them.³⁸⁶

As for enforcement when airlines commit violations, the FAA has the fearsome power to revoke an airline’s certificate and put it out of business, plus the lesser powers to suspend the certificate or to modify what business the certificate allows the airline to do.³⁸⁷ The agency can force the airline to act in certain ways as a condition for lifting a suspension or modification.³⁸⁸ Relatedly, the FAA can, by threatening to take any of these actions, induce an airline to agree “voluntarily” to pause or limit its business.³⁸⁹ All such stops to business, mandatory or nominally voluntary, are known colloquially as “grounding” the airline.³⁹⁰ However, because grounding an air carrier is such an extreme measure and harms innocent parties by stranding or delaying passengers, the FAA tends to enforce against airlines through the softer alternative

³⁸⁴ OFF. OF INSPECTOR GEN., DEP’T OF TRANSP., AV2021034, FAA CAN INCREASE ITS INSPECTOR STAFFING MODEL’S EFFECTIVENESS BY IMPLEMENTING SYSTEM IMPROVEMENTS AND MAXIMIZING ITS CAPABILITIES 3 & tbl.1 (2021).

³⁸⁵ EDWARD W. STIMPSON, J. RANDOLPH BABBITT, WILLIAM O. MCCABE, MALCOLM K. SPARROW & CARL W. VOGT, *MANAGING RISKS IN CIVIL AVIATION: A REVIEW OF THE FAA’S APPROACH TO SAFETY* 36 (2008); *see also* Interview with Anonymous Interviewee #3, *supra* note 28 (confirming this is still the case).

³⁸⁶ Gerald F. Murphy & Jonathan T. Linde, *FAA’s Role, History, and Statutory Authority*, in *AVIATION REGULATION IN THE UNITED STATES*, *supra* note 376, at 263; Interview with Anonymous Interviewee #3, *supra* note 28 (noting the rising importance of the review of records).

³⁸⁷ James Aloysius Barry, *FAA Legal Enforcement Actions*, in *AVIATION REGULATION IN THE UNITED STATES*, *supra* note 376, at 405–06.

³⁸⁸ *Id.* “The most stringent [measure for FAA to use] is to ground an airline until the particular problem has been addressed.” COBB & PRIMO, *supra* note 377, at 18.

³⁸⁹ *See infra* notes 459–63 and accompanying text.

³⁹⁰ *See infra* notes 464–70 and accompanying text.

mechanism of monetary civil-penalty adjudications,³⁹¹ which are subject to certain caps above which the agency must go to court to seek penalties.³⁹²

We can now consider industry judicial challenges to FAA actions. Let me first explain the three parameters that governed my search for such suits.

First, as to the time period and the agencies searched for, I began with an exhaustive Bloomberg dockets search for all suits against the FAA or against DOT on FAA matters for the core study period of 2013–2021, extended forward in time by three years up to January 20, 2024, and backward in time by four years to January 20, 2009.³⁹³ Besides this exhaustive search of the period from 2009 to 2024, I further extended the search backward in time to the start of the Bloomberg database's coverage—January 1, 1989. For the period of 1989–2009, I searched only for suits against FAA defendants or respondents, not more generally against DOT defendants or respondents,³⁹⁴ because searching for DOT generally would turn up numerous suits that might have nothing to do with the FAA, and it would often be hard to discern whether each suit involved the FAA or not, given that Bloomberg contains fewer and fewer underlying filings as one goes earlier in time. I think my search of 1989–2009 likely turned up the large majority of industry judicial challenges to the FAA for that period, because when I conducted a partial check of my results against a list of one major subset of judicial challenges to the FAA that the agency itself happens to publish on its website (suits reviewing civil penalty adjudications going back to 1991),³⁹⁵ it turned up only one suit over the eighteen-year period

³⁹¹ Barry, *supra* note 387, at 416–17.

³⁹² *Id.* at 413–14.

³⁹³ For all suits by businesses or associations thereof against the FAA or against DOT on FAA matters, see, for years 2013–2021, DATASET, *supra* note 10, File 15, Rows 3–10; *id.* File 16, Rows 4–70. For years 2021–2024, see *id.* File 17, Rows 7–12, as well as *id.* File 18, Rows 2–15. For the period of 2009–2013, I checked for suits against the FAA specifically as part of a longer-term search, on which see *infra* note 394, and I also searched for any suits against DOT on FAA matters in 2009–2013 that failed to name the FAA as defendant or respondent, on which see DATASET, *supra* note 10, Files 19–20.

³⁹⁴ DATASET, *supra* note 10, Files 21–22 (covering FAA specifically for the period 1989–2013).

³⁹⁵ See *Civil Penalty Appeals*, FED. AVIATION ADMIN., https://www.faa.gov/about/office_org/headquarters_offices/agc/practice_areas/adjudication/civil_penalty [<https://perma.cc/GZS8-BJX7>]; *Cases Appealed to the Federal Court*, FED. AVIATION ADMIN., https://www.faa.gov/about/office_org/headquarters_offices/agc/practice_areas/adjudication/civil_penalty/CaseFile/CasesAppToFed/ [<https://perma.cc/Z8X5-9AVP>]. I checked all entries in which the challenger's name could conceivably have referred to an air carrier, then excluded any who were under Part 135 or were not on the list of scheduled airlines in the ATA annual report for the year of the challenge. I also excluded cargo carriers, such as Ryan International.

that was not already in my results.³⁹⁶ Additionally, because the National Transportation Safety Board (“NTSB”) hears interagency appeals from the FAA on certain matters,³⁹⁷ I also conducted a Bloomberg docket search for all suits against the NTSB, either by its full name or acronym, as defendant or respondent for 1989 through January 20, 2024; this ended up adding nothing to my preexisting results.³⁹⁸

Second, as to the challenger businesses that I included in my results, I focused on mainstream passenger air carriers, broadly defined in two slightly different ways depending on data availability: (1) for 2019–2024, all “Part 121” passenger carriers and (2) for 1989–2018, all passenger carriers classified by DOT as first tier (major), second tier (national), or third tier (regional).³⁹⁹ This focus easily covers all familiar airlines, given the longstanding high concentration of the industry. In 2024, the major carriers alone—all of whom are within the Part 121⁴⁰⁰ category—had a collective market share of domestic revenue passenger-miles exceeding ninety-two percent, and their collective share in 1988 likewise exceeded ninety-two percent.⁴⁰¹ To elaborate on these various classifications, Part 121 is the section of the Code of Federal Regulations title on aeronautics that governs the larger scheduled air carriers, as opposed to Part 135,⁴⁰² which governs carriers whose scheduled service is confined to small planes—normally no more than ten

³⁹⁶ The court ruled for the FAA without opinion in this suit, which a regional airline brought in 2000, naming DOT but not the FAA. *See* Court Docket, *Falcon Air Express, Inc. v. DOT*, 248 F.3d 1178 (11th Cir. 2001) (No. 00-10778) (unpublished table decision). Falcon is listed as a regional airline in 2001 ATA ANN. REP. 23. The dispute was over a narrow enforcement issue. *See* *Falcon Air Express, Inc.*, FAA Order No. 99-13, 1999 WL 1279831, at 1 (Dec. 22, 1999).

³⁹⁷ Barry, *supra* note 387, at 409–11, 415.

³⁹⁸ I searched for “*National Transportation Safety Board*” OR *NTSB* as respondent in the courts of appeals and as defendant in the district courts for the timeframe January 1, 1989, through January 20, 2024. All results these searches turned up also included the FAA, in which case they would be picked up in my FAA search, or did not involve carrier challengers that were within the parameters of my search. DATASET, *supra* note 10, Files 23–24.

³⁹⁹ Note the “regional” category is sometimes divided by DOT into large and medium. Note also that I excluded airlines outside scheduled passenger service, such as cargo airlines. This applies to a suit by Ryan International, an airline listed as national in 2000 ATA ANN. REP. 23, but focused on cargo service and nonscheduled charter service, *see* Ryan Airlines, LINKEDIN, <https://www.linkedin.com/company/ryan-international-airlines> [https://perma.cc/5VD3-S6H7]. Ryan’s suit was about a cargo flight. *See* Court Docket, *Ryan Int’l Airlines v. Tran*, No. 00-cv-01091 (D. Kan. Mar. 3, 2000); *Ryan Int’l Airlines, Inc.*, FAA Order No. 2000-2, 2000 WL 298577, at 2 n.4, (Feb. 3, 2000).

⁴⁰⁰ 14 C.F.R. pt. 121.

⁴⁰¹ For 2024, compare JONNATHAN HANDSHOE & WILSON KO, CFRA, *INDUSTRY SURVEYS: PASSENGER AIRLINES 14* (Raymond Jarvis et al. eds., 2024), with COMPETITION & POL’Y ANALYSIS DIV., U.S. DEP’T OF TRANSP., *AIRLINE Q. FIN. REV. FIRST QUARTER 2024: MAJORS 40* (2024). For 1988, compare Stephen R. Klein, *Airlines*, STANDARD & POOR’S *INDUSTRY SURVEYS: AIRLINES*, May 6, 1999, at 7 (giving 1988 data), with 1988 ATA ANN. REP. 15.

⁴⁰² 14 C.F.R. pt. 135.

seats each and never more than thirty seats.⁴⁰³ For the most recent suits, we determined Part 121 or 135 status by looking at docket filings, supplemented by the FAA's lists of carriers under each Part as of 2024.⁴⁰⁴ Because turnover among companies becomes substantial as one goes farther back in time—and because there is not published historical data on which airlines have held Part 121 status—we also looked to the most readily available historical compilation of airlines by size, that is, the DOT's annual classification of airlines among three tiers: first, *major* airlines, with annual revenue over \$1 billion; second, *national* airlines, with revenue over \$100 million; and third, *regional* airlines, with revenue under \$100 million (and no lower bound based on revenue).⁴⁰⁵ Annual DOT three-tier classifications are readily available in the Air Transport Association (“ATA”) annual reports for 1989–2008 and in the DOT “Yellow Book” for 2002–2018.⁴⁰⁶

Third, as to the subject matters of the suits, I included any industry suits that challenged safety-based constraints or safety-based sanctions against airlines. Thus, I excluded the few suits in which an airline was challenging the FAA for not being cautious enough about safety.⁴⁰⁷ And I excluded the many suits in which an airline challenged the FAA

⁴⁰³ The exact distinction between the Parts is complex and contested, and it has recently shifted due to a “loophole.” See Letter from Greg Regan, President, Transp. Trades Dep’t, AFL-CIO, to David H. Boulter, Acting Assoc. Adm’r, Aviation Safety, FAA, on Regulatory Definitions of On-Demand Operation, Supplemental Operation, and Scheduled Operation (Oct. 13, 2023), https://downloads.regulations.gov/FAA-2023-1857-55741/attachment_1.pdf [<https://perma.cc/XS9B-V6QB>]; Alexander T. Marriott, *FAA Policy Changes to Parts 135 and 380 Operations*, BAKER DONELSON (Oct. 17, 2024), <https://www.bakerdonelson.com/faa-policy-changes-to-parts-135-and-380-operations> [<https://perma.cc/9SRE-9WAA>].

⁴⁰⁴ For certificated air carriers (Part 121), see *Certificated Air Carriers List*, U.S. DEP’T OF TRANSP. (Aug. 12, 2024), <https://www.transportation.gov/policy/aviation-policy/certificated-air-carriers-list> [<https://perma.cc/DJF8-NAXU>]. For commuter air carriers (Part 135), see *Commuter Air Carriers List*, U.S. DEP’T OF TRANSP. (July 3, 2024), <https://www.transportation.gov/policy/aviation-policy/commuter-air-carriers-list> [<https://perma.cc/6B6R-KPTQ>].

⁴⁰⁵ For the dividing lines among the tiers currently, see *Airline Quarterly Financial Review*, U.S. DEP’T OF TRANSP. (June 3, 2025), <https://www.transportation.gov/policy/aviation-policy/airline-quarterly-financial-review> [<https://perma.cc/CW5G-VWY3>]. The dividing lines were the same in 1989. See 1989 ATA ANN. REP. 15.

⁴⁰⁶ See, e.g., *Air Carrier Financial Statistics (Yellow Book)*, BUREAU OF TRANSP. STAT. (Dec. 10, 2020), <https://www.bts.gov/browse-statistical-products-and-data/bts-publications/air-carrier-financial-statistics-yellow-book> [<https://perma.cc/6WJA-3KZL>]. This data, which includes regional airlines, is “no longer being updated.” *Id.* But the majors-and-nationals data has updates up to the present. See, e.g., *Airline Quarterly Financial Review*, *supra* note 405.

⁴⁰⁷ Hawaiian Airlines repeatedly sued to challenge an FAA determination that a crane near one of its runways was not a hazard and did not have to be moved. See *Petition for Review of an Agency, Board, Commission, or Officer at 10–12, Hawaiian Airlines, Inc. v. FAA*, No. 17-1199 (D.C. Cir. Aug. 30, 2017). For the other suits, see *Petition for Review of an Agency, Board, Commission, or Officer, Hawaiian Airlines, Inc. v. FAA*, No. 12-1424 (D.C. Cir. Oct. 22, 2012) and *Petition for Review of an Agency, Board, Commission, or Officer, Hawaiian Airlines, Inc. v. FAA*, No. 12-1332 (D.C. Cir. July 31, 2012).

on economic decisions—most commonly how to allocate airport slots among airlines or how to regulate economic interactions between an airport and its carriers.⁴⁰⁸

Within these three parameters, our results show that challenges by airlines and their associations to safety-based constraints or safety-based sanctions by the FAA have been rare throughout the period of 1989–2024. There is only one safety issue—crew rest to prevent fatigue—that has seen anything like concerted airline industry resistance to the FAA through the courts during the whole thirty-five-year period, and even that resistance was fragmentary and peripheral, with the core struggle ultimately reaching resolution without judicial involvement. The story of crew rest begins with the agency’s longstanding statutory authority to make “regulations in the interest of safety for the maximum hours or periods of service of aircrew.”⁴⁰⁹ The FAA promulgated rules on the subject in 1985.⁴¹⁰ In 1995, the agency began a process to adopt new rules to require more rest, but industry questioned the approach, and

⁴⁰⁸ On allocation of slots at airports, see MacPherson, *supra* note 376, at 294–95. The airport slot disputes that perhaps come closest to safety are ones involving whether certain slots should continue to exist at all—distinct from the question of how a set number of slots should be allocated. But even a dispute like this will be argued in terms of a tradeoff between lowering entry barriers and reducing delay, which assumes that an airport with more slots will inevitably cause planes to take off more slowly at whatever pace is needed for safety. See *Spirit Airlines, Inc. v. DOT*, 997 F.3d 1247, 1251 (D.C. Cir. 2021); Petition for Review, *Spirit Airlines*, 997 F.3d 1247 (No. 19-1248). For other nonsafety challenges by industry from 2013 to 2024, see the following:

- *Cases on airport slot allocation*: Petition for Review, *ABC Aerolineas, S.A. de C.V. v. DOT*, No. 17-1115 (D.C. Cir. Apr. 10, 2017); Petition for Review, *ABC Aerolineas, S.A. de C.V. v. DOT*, No. 17-1056 (D.C. Cir. Feb. 13, 2017); Petition for Review, *Southwest Airlines Co. v. DOT*, No. 15-1276 (D.C. Cir. Aug. 13, 2015); *Delta Air Lines, Inc. v. DOT*, No. 15-1055 (D.C. Cir. Mar. 13, 2015); *Southwest Airlines Co. v. DOT*, No. 15-1036 (D.C. Cir. Mar. 23, 2015).
- *Other cases*: Petition for Review at 5, *Air Transp. Ass’n of Am., Inc. v. FAA*, No. 18-1157 (D.C. Cir. June 5, 2018) (airport choice on uses of federal funding); Petition for Review at 1–3, *Kuwait Airways Corp. v. DOT*, No. 15-1429 (D.C. Cir. Nov. 24, 2015) (discrimination against passengers); *Airlines for Am. v. FAA*, No. 13-1140 (D.C. Cir. Apr. 19, 2013) (FAA plan for across-the-board furloughs of air traffic controllers without regard to varying impacts at different airports in terms of delay).

For nonsafety industry challenges from 1989 to 2013, see DATASET, *supra* note 10, File 22, Rows 55, 91–93, 96–99, 103 (airport slot allocation); Rows 101, 451, 514, 526, 537–39, 707 (other airport-airline economic interactions); and Rows 301–08, 325–32, 359–66, 485–92 (fees on foreign carriers). There were three suits in 1989–2013 for which we did not obtain filings but that appear from the identities of the parties to concern airport-airline economic interactions. *Id.* File 22, Rows 703, 719; *id.* File 21, Row 373. There was also one Federal Tort Claims Act lawsuit. *Id.* File 21, Row 104.

⁴⁰⁹ *Air Transp. Ass’n of Am., Inc. v. FAA*, 291 F.3d 49, 51 (D.C. Cir. 2002) (quoting 49 U.S.C. § 44701(a)(4)).

⁴¹⁰ *Id.* (citing Flight Time Limitations and Rest Requirements, 50 Fed. Reg. 29,306 (July 18, 1985)).

the matter eventually ended up in stalemate.⁴¹¹ Then a flight crashed partly due to pilot fatigue in 1999,⁴¹² and *60 Minutes* ran a segment on the problem in 2000.⁴¹³ Between fall 2000 and spring 2001, prompted by one of the pilot unions, the FAA issued a letter and then a notice interpreting the work limits in the 1985 regulations—which the airlines had long understood to depend on *scheduled* flight times⁴¹⁴—to depend instead on *actual* flight times, including delays.⁴¹⁵ The two principal trade groups—large airlines’ ATA and small airlines’ Regional Airline Association (“RAA”)—sued to challenge the interpretation in 2001, while pilot unions intervened to defend it.⁴¹⁶ ATA and RAA obtained a stay but then lost on the merits in 2002.⁴¹⁷ This dispute over how to treat delays was only a skirmish in a much broader conflict about reforming crew-rest regulations more generally: One ATA lawyer characterized the suit as involving a “narrow set of operations that get flummoxed because of weather or mechanical delays,”⁴¹⁸ and the trade press reported that, after the FAA’s victory, a “larger impasse remains” about crew-rest rules overall.⁴¹⁹ An additional skirmish occurred a few years later regarding how to handle crew rest for the “handful” of U.S. airline flights that fell into the emerging “ultra-long” category of sixteen hours or longer,⁴²⁰ covering, for example, the U.S. East Coast to Asia but *not*

⁴¹¹ Various sources provide retrospectives on the stalemate. *See, e.g.*, Linda Werfelman, *Regulating Rest*, AEROSAFETY WORLD, Feb. 2012, at 16 (“[A] previous rulemaking [around 1995] had collapsed, largely because of airline opposition to the projected costs, as well as what the industry said was insufficient supporting data.”); *Regulators Rebuff Airlines’ Petition to Suspend Enforcement Policy*, AIR SAFETY WK., July 16, 2001 (referring to the idea of “a broader overhaul of the flight time/duty time rules, where an impasse has prevailed for years”); *Allied Pilots Association Reports That Federal Aviation Administration Addresses Pilot Fatigue, Closes Loophole on Unlimited Duty*, PR NEWswire, Nov. 29, 2000 (noting that a proposed rule “was issued during 1995 but was stalled in part by the Air Transport Association . . . due to economic concerns”).

⁴¹² COBB & PRIMO, *supra* note 377, at 51, 53.

⁴¹³ *60 Minutes: Sleepless in the Cockpit* (CBS television broadcast Oct. 15, 2000) (transcript on file with *The George Washington Law Review*).

⁴¹⁴ Martha Brannigan, *Airlines Are Urging FAA to Withdraw Pilot-Rest Rules*, WALL ST. J., Dec. 19, 2000, at B21 (explaining that whereas FAA said “airlines must determine crews’ eligibility to continue flying based on the actual conditions of the flight, such as weather, ground delays, and other variables[,] [t]he industry instead has relied on scheduled flight times to calculate if pilots are permitted to fly”).

⁴¹⁵ *Air Transp. Ass’n of Am.*, 291 F.3d at 52–53 (citing Notice, 66 Fed. Reg. 27,548 (May 17, 2001)). Delays were more frequent by 2000 than when the initial interpretation took hold in the 1980s. *See* Matthew L. Wald, *Airlines and Federal Regulators at Odds*, N.Y. TIMES, Jan. 24, 2001, at A17.

⁴¹⁶ *Air Transp. Ass’n of Am.*, 291 F.3d at 51, 53.

⁴¹⁷ *Id.* at 53, 58.

⁴¹⁸ Jim Morris, *FAA to Defend Crew-Rest Rule*, DALL. MORNING NEWS, Jan. 18, 2002, at 2D.

⁴¹⁹ *Court Upholds Government Clarification of Crew Rest Regulation*, AIR SAFETY WK., June 10, 2002.

⁴²⁰ For the “handful” language and explanation of “ultra-long” flights, see MacPherson, *supra* note 376, at 291. The author was an FAA Assistant Chief Counsel at the time of the dispute. *Id.* at

the U.S. West Coast to Asia.⁴²¹ In 2006, the FAA and Delta, with regard to Delta's ultralong route to India, agreed to crew-rest OpSpecs that pilot unions strongly favored.⁴²² The FAA later used the Delta approach as the model for standardized OpSpecs for each of several major U.S. airlines on their respective ultralong routes.⁴²³ Several of those majors then sued the FAA in 2008 on the ground that the policy should have gone through notice-and-comment rulemaking, while Delta intervened in the FAA's favor.⁴²⁴ The FAA then retreated, dropping the OpSpecs on ultralong flights in early 2009.⁴²⁵ The far more general issue of crew-rest regulation was ultimately resolved without judicial involvement: A Colgan Air crash in early 2009 turned out to result partly from pilot fatigue;⁴²⁶ Congress in summer 2010 passed legislation by unanimous consent in the Senate and voice vote in the House⁴²⁷ requiring the FAA to adopt *some* new rule addressing pilot fatigue without remotely specifying what the rule should be;⁴²⁸ and the FAA announced the new rule in late 2011.⁴²⁹ The rule involved various compromises but was, on balance, a win for more crew rest⁴³⁰—the largest pilots' union endorsed it instantly⁴³¹ while ATA said it was "reviewing" the rule and gave no further press comment⁴³²—but industry did not sue.

285. Journalists chronicled the recent emergence of such flights. See David Learmount, *Pushing the Limit*, FLIGHT INT'L, June 14, 2005, at 66–68 (noting novelty generally); Andy Pasztor, *Continental, American Balk at New Rest Rules for International-Flight Crews*, WALL ST. J. (Mar. 20, 2007, 12:01 AM), <https://www.wsj.com/articles/SB117436206075342463> [<https://perma.cc/DJ3D-Q4GZ>] (noting that Continental has been flying Newark to Hong Kong since 2001 and American has been flying Chicago to New Delhi since 2005).

⁴²¹ See Pasztor, *supra* note 420 (noting that "nonstop flights [of] 16 hours or more" are "typically [those] connecting U.S. East Coast or Midwestern cities with destinations in India and China").

⁴²² For retrospective discussion of these developments, see *FAA Drops Rest Strategy for Long Haul Flying*, AVIATION TODAY'S DAILY BRIEF, Mar. 17, 2009.

⁴²³ *Id.*

⁴²⁴ Petition for Review by American Airlines, Inc., Atlas Air, Inc., Continental Airlines, Inc., Evergreen International Airlines, Inc., Jetblue Airways Corporation, United Air Lines, Inc., and US Airways, Inc. at 2, *Am. Airlines, Inc. v. FAA*, No. 08-1397 (D.C. Cir. Dec. 24, 2008).

⁴²⁵ *FAA Drops Rest Strategy for Long Haul Flying*, *supra* note 422.

⁴²⁶ Natalie N. DuBose, *Flightcrew Member Duty and Rest Requirements: Does the Proposed Legislation Put to Rest the Concern Over Pilot Fatigue?*, 76 J. AIR L. & COM. 253, 258–59 (2011).

⁴²⁷ See 156 CONG. REC. 14,715–21, 14,785–87 (2010).

⁴²⁸ Airline Safety and Federal Aviation Administration Extension Act of 2010, Pub. L. No. 111-216, § 212(a), 124 Stat. 2348 (2010).

⁴²⁹ Flightcrew Member Duty and Rest Requirements, 77 Fed. Reg. 330 (Jan. 4, 2012) (to be codified at 14 C.F.R. pts. 117, 119, 121).

⁴³⁰ See Andy Pasztor, *FAA Mandates Longer Rest Periods for Pilots*, WALL ST. J. (Dec. 21, 2011, 10:05 PM), <https://www.wsj.com/articles/SB10001424052970204464404577112510252482088> [<https://perma.cc/PFX7-GNUF>].

⁴³¹ See *id.*

⁴³² Joan Lowy, *FAA Issues Rules to Prevent Tired Airline Pilots*, ASSOCIATED PRESS, Dec. 21, 2011.

Apart from the two judicial skirmishes initiated by the trade associations and the major airlines amid the crew-rest stalemate, airline industry judicial challenges to FAA safety actions from 1989 to 2024 have been utterly marginal. There have been no other suits by trade associations, nor by any of the first-tier (major) airlines whose market share has long been around ninety percent or more.⁴³³ And the period has seen only four suits—all solo—by second-tier (national) airlines, a category numbering at least twenty-five airlines in each of the years that saw a suit.⁴³⁴ The first of these suits was in 1994, when the “niche” Central American resort carrier Sun Country,⁴³⁵ one of twenty-six nationals at the time,⁴³⁶ sued to challenge an FAA rule mandating rest for flight attendants only to have the court rule for the FAA without a published opinion.⁴³⁷ The other three suits by national airlines were all narrowly focused on individual civil-penalty enforcement proceedings, with none resulting in court wins for industry. These were by Trans States,⁴³⁸ GoJet, a sister subsidiary of Trans States,⁴³⁹ and Pinnacle.⁴⁴⁰ There were also three suits by third-tier (regional) airlines, all narrowly focused on individual enforcement actions, with none resulting in court wins for industry.⁴⁴¹

⁴³³ On the majors’ market share, *see supra* note 401 and accompanying text. These claims do not apply to nonsafety matters, on which there have been several suits by associations and majors. *See supra* note 408 and accompanying text.

⁴³⁴ *See* 2005 ATA ANN. REP. 2 (thirty-three national airlines); 1994 ATA ANN. REP. 19 (twenty-five national airlines); *Air Carrier Financial Statistics (Yellow Book)*, *supra* note 406 (December 2012 data; thirty-seven national airlines). Some of the nationals may be all-cargo airlines.

⁴³⁵ Amy O’Connor, *Commuter Lines Gain, Int’l Air Carriers Lose*, CRAIN’S CHI. BUS., Feb. 20, 1995.

⁴³⁶ 1994 ATA ANN. REP., *supra* note 434, at 19.

⁴³⁷ *Sun Country Airlines, Inc. v. FAA*, 56 F.3d 1531 (D.C. Cir. 1995) (unpublished table decision). ATA got involved in the case, but only six months after it was filed and only for the “limited purpose” of responding to the FAA’s motion for clarification of the court’s stay of the rule pending litigation. *See* the titles of the entries for the Motion of Feb. 21, 1995, and the Per Curiam Order of Feb. 27, 1995, in Court Docket, *Sun Country Airlines*, 56 F.3d 1531 (No. 94-1611).

⁴³⁸ *See Trans States Airlines, Inc. v. FAA*, 439 F.3d 863, 864 (8th Cir. 2006); *see also* Court Docket, *Trans States Airlines*, 439 F.3d 863 (No. 05-1963).

⁴³⁹ *See GoJet Airlines, LLC v. FAA*, 743 F.3d 1168, 1170 (8th Cir. 2014); *see also* Petition for Review at 5, *GoJet Airlines*, 743 F.3d 1168 (No. 12-2719). On sister subsidiary status, *see* Corporate Disclosure Statement, *GoJet Airlines*, 743 F.3d 1168 (No. 12-2719) (filed Aug. 28, 2012).

⁴⁴⁰ *See* Petition for Review at 1, *Pinnacle Airlines, Inc. v. FAA*, No. 12-3876 (6th Cir. July 18, 2012). Pinnacle voluntarily dismissed the case on February 28, 2013. *See* Motion to Voluntarily Dismiss with Prejudice, *Pinnacle*, No. 12-3876 (Feb. 28, 2013).

⁴⁴¹ These cases were the following:

- *Falcon Air Express, Inc. v. DOT*, 248 F.3d 1178 (11th Cir. 2001); *see also supra* note 396.
- *Casino Airlines, Inc. v. NTSB*, 439 F.3d 715 (D.C. Cir. 2006); *see also* Court Docket, *Casino Airlines*, 439 F.3d 715 (Nov. 9, 2004) (No. 04-1381).
- *Cape Smythe Air Serv., Inc. v. FAA*, No. 01-1049, 2001 WL 674609 (D.C. Cir. May 10, 2001) (dismissing as moot). On the substance of the suit, *see generally* Petition for Review, *Cape Smythe Air Serv.*, No. 01-1049 (Feb. 1, 2001).

Part of the reason that airlines sue the FAA so rarely on safety is agency forbearance. When Congress created the FAA in the 1950s, it gave the agency a “dual mandate” to ensure safety but also promote the airline industry; although Congress in 1996 officially shifted that mandate to safety alone, the FAA has been subject to frequent accusations of undue industry influence both before and since.⁴⁴² In the realm of rulemaking, the FAA’s sometime reputation for laxity derives partly from the role of the NTSB, which issues authoritative reports on the causes of plane crashes and recommends new safety rules but has no power or responsibility for actually adopting or implementing such rules.⁴⁴³ That falls to the FAA, which is more mindful of costs and more subject to industry cross pressures, historically eschewing around one-fifth of the NTSB’s recommendations while often taking years to implement the four-fifths that it does accept, such that the NTSB serves as an ever-present yardstick of cautionary measures that the FAA might be imposing but is not.⁴⁴⁴ The stalemate over crew-rest rules that ran from 1995 to 2011 is an obvious case in point. Meanwhile, in the realm of enforcement, the FAA possesses the enormous power to ground any plane or airline, but the disruptive effect of such stoppages for both airlines and passengers means that the FAA wields the power sparingly, instead using a civil-penalty power that is modest compared with many airlines’ revenues.⁴⁴⁵ Additionally, the structure of the FAA’s inspection apparatus, in which a corps of inspectors is assigned full-time and long-term to each of the larger airlines, has “the potential to increase [the] risk” of “regulatory capture.”⁴⁴⁶ For example, there was a wave of scandal that broke in 2008 about the FAA CMO for Southwest allowing the airline to fly planes that were in violation of safety strictures,⁴⁴⁷ then another wave of scandal about excessive FAA laxity toward that same airline that broke in 2022.⁴⁴⁸

Yet forbearance does not entirely explain the sparseness of litigation. First of all, the longstanding accusations that the FAA fails to hold airlines accountable for safety must be weighed against the striking fact that passenger fatalities for Part 121 air carriers have become amazingly rare—a better outcome than in almost any area of federal

⁴⁴² COBB & PRIMO, *supra* note 377, at 16–19.

⁴⁴³ *See id.* at 19–20.

⁴⁴⁴ *Id.* at 20–21, 49–52, 149, 152.

⁴⁴⁵ *Id.* at 19.

⁴⁴⁶ STIMPSON ET AL., *supra* note 385, at 36.

⁴⁴⁷ *Id.* at 14–15.

⁴⁴⁸ Michael Laris, *FAA Acknowledges Mismanagement in Safety Oversight of Southwest Airlines*, WASH. POST (July 28, 2022), <https://www.washingtonpost.com/transportation/2022/07/28/faa-southwest-airlines-oversight/> [https://perma.cc/EU65-5VRY].

health-and-safety regulation.⁴⁴⁹ Consistent with the notion that FAA regulation is meaningful, the agency has at times used its rulemaking power in consequential ways, as when in the 1990s it issued a series of airworthiness directives on aging aircraft.⁴⁵⁰ One economic analysis describes these ADs as an “unprecedented and aggressive regulation initiative” that “required heavy modification” of planes at certain milestones of age and usage, entailing “expensive maintenance that included replacement of certain airframe structures.”⁴⁵¹ The cost was enough to put financially weaker major airlines and startups at a competitive disadvantage.⁴⁵² Yet no airline sued.⁴⁵³ Similarly, the crew-rest rule of 2011, though long in coming, was ultimately a fairly clear win for pilot unions—but again industry did not sue.⁴⁵⁴ Consider also the FAA’s use of OpSpecs. The theory for why these do not have to go through generalized notice and comment is that each OpSpec is tailored to each individual airline and merely implements some preexisting rule that did go through notice and comment.⁴⁵⁵ But a former FAA lawyer writes that “[o]ccasionally, the FAA has sought to impose OpSpecs without a regulatory or statutory basis,” yet nonetheless “carriers have generally complied with the OpSpec” when it “has been based on a clear safety risk,” refraining from suing even when they could.⁴⁵⁶ Finally, consider FAA groundings. They are exceptional, and their occurrence is

449 See *U.S. Air Carrier Safety Data*, BUREAU OF TRANSP. STAT., <https://www.bts.gov/content/us-air-carrier-safety-data> [<https://perma.cc/BGF7-8J3K>] (giving an average of one fatality per year from 2010 to 2022). When a collision with a U.S. army helicopter brought down an American Eagle flight on January 29, 2025, it was the first fatal crash of a Part 121 air carrier since Colgan Air in 2009. See Max Roser, *US Airlines Have Transported Passengers for More Than Two Light-Years Since the Last Plane Crash*, OUR WORLD IN DATA (Dec. 1, 2024), <https://ourworldindata.org/us-airline-travel> [<https://perma.cc/M35C-958C>]; *Accidents Involving Passenger Fatalities: U.S. Airlines (Part 121) 1982–Present*, NAT’L TRANSP. SAFETY BD., <https://www.nts.gov/safety/data/Pages/paxfatal.aspx> [<https://perma.cc/WJY4-VD8E>]; *Families Mourn 67 Killed in Army Helicopter Collision with American Eagle Jet*, NBC NEWS (Jan. 31, 2025, 4:27 PM) <https://www.nbcnews.com/news/us-news/live-blog/dc-plane-crash-live-updates-rcna190079> [<https://perma.cc/3H35-B8QM>]. For more on the astonishing levels of air safety reached in developed nations in recent decades, see Arnold Barnett & Jan Reig Torra, *Airline Safety: Still Getting Better?*, 119 J. AIR TRANSP. MGMT. 1, 1 (2024), and Arnold Barnett, *Aviation Safety: A Whole New World?*, 54 TRANSP. SCI. 84, 84, 94 (2020).

450 Alfredo Lagos, Vahid Motevalli, Majid Motevalli & Nobuyo Sakata, *Review and Analysis of the Effects of Major Aviation Accidents in the United States on Safety Policy, Regulation, and Technology*, 45 J. TRANSP. RSCH. F. 137, 146–47 (2006). Congress did mandate regulation of “aging aircraft” but did little to specify what the FAA should do. See Pub. L. No. 103-272, § 44717(a), 108 Stat. 1199 (1994) (codified at 49 U.S.C. § 44717(a)).

451 ELDAD BEN-YOSEF, *THE EVOLUTION OF THE US AIRLINE INDUSTRY* 188 (2005).

452 *Id.* at 194–95.

453 See DATASET, *supra* note 10, Files 21–22.

454 *Id.* Files 19–22.

455 See *supra* notes 380–83 and accompanying text.

456 MacPherson, *supra* note 376, at 291. The one exception she notes is the 2008 suit over ultralong-route crew rest, when the airlines did not think the regulation had a good safety basis. *Id.*

sometimes a delayed FAA response to public pressure, but they *do* happen, and they happen without prompting judicial challenges even though judicial review is in principle available. Grounding can be imposed on an entire airline—something the FAA did to three second-tier airlines in the 1990s, including KIWI in 1994, then “one of the nation’s most successful new airlines,” as well as ValuJet in 1996.⁴⁵⁷ Before the May 1996 crash that precipitated the grounding, ValuJet had enjoyed the single-highest profit margin in the entire industry, was the fastest-growing airline in history, and was a darling of both Wall Street and the Clinton Administration.⁴⁵⁸ The ValuJet grounding, five weeks after the crash, was nominally “voluntary,” “[b]ut it was clearly forced by the FAA” via threats of a coercive order.⁴⁵⁹ Even as ValuJet agreed to the FAA’s demands, the company publicly called the grounding “grossly unfair” and claimed it had “been denied the opportunity to respond to the FAA’s concerns”⁴⁶⁰—classic grounds for a judicial challenge if ValuJet had held out, yet it did not. The FAA allowed ValuJet to resume flying only after three months and on a much reduced basis;⁴⁶¹ eight months after that, the airline’s business was half its precrash size,⁴⁶² and it soon disappeared in a merger through which the founder and chairman ceased to head the company.⁴⁶³ Besides ValuJet and the other nationals, the FAA has also imposed airline-wide groundings on at least four

⁴⁵⁷ Bill Adair & Susan Clary, *FAA Clips the Wings of KIWI Airlines*, ST. PETERSBURG TIMES, Dec. 16, 1994, at 14A (explaining the status and grounding of KIWI International Airlines). KIWI was classed as regional in ATA’s 1994 to 1995 reports but as national in ATA’s 1996 to 1998 reports. See 1994 ATA ANN. REP., *supra* note 434, at 19; 1995 ATA ANN. REP. 10; 1996 ATA ANN. REP. 19; 1997 ATA ANN. REP. 19; 1998 ATA ANN. REP. 19. On ValuJet’s grounding, see *infra* notes 459–63 and accompanying text. For the third national airline that was grounded, see *MarkAir Grounded by FAA Over Concern About Maintenance*, WALL ST. J., Aug. 3, 1995, at C10. On Mark’s status, see 1995 ATA ANN. REP., *supra*, at 19.

⁴⁵⁸ On ValuJet’s pregrounding status, see COBB & PRIMO, *supra* note 377, at 80–81.

⁴⁵⁹ Asra Q. Nomani & Martha Brannigan, *ValuJet Ceases Operations Indefinitely*, WALL ST. J., June 18, 1996, at A3.

⁴⁶⁰ *Id.*

⁴⁶¹ COBB & PRIMO, *supra* note 377, at 94 (“On September 26, a little more than three months after ValuJet had been grounded . . . the DOT gave ValuJet permission to resume flying on a limited basis.”).

⁴⁶² Russ Bynum, *ValuJet Flying a Year Later, But Not As High As Before*, ASSOCIATED PRESS, May 4, 1997 (“ValuJet flies just 25 planes to 22 cities, compared with 51 planes to 31 cities before the crash.”).

⁴⁶³ Carol Woodford, *ValuJet to Buy Airtran, Drop Its Name*, ASSOCIATED PRESS, July 10, 1997 (“The companies didn’t immediately say what role ValuJet Chairman Lewis Jordan will play. Jordan, who gave up daily control of the airline when [D. Joseph] Corr took over [as president and chief executive] in November [1996]”); Scott Thurston, *It’s Official: ValuJet Now AirTran with Completion of Airline Merger*, ATLANTA CONST., Nov. 18, 1997, at C2 (“ValuJet’s two primary founders, Robert Priddy and Lewis Jordan, are on the AirTran Holdings’ board of directors, but have no executive role.”).

regional carriers.⁴⁶⁴ Groundings can also be imposed on types of planes, which has impacted major airlines, as with the FAA's grounding of all DC-10s in 1979 (135 planes nationwide, for thirty-seven days);⁴⁶⁵ all older models of the Boeing 737 in 1998 (179 planes, until wiring was checked and repaired);⁴⁶⁶ all MD-80 aircraft owned by American Airlines in 2008 (over 350 planes, about half of American's fleet, for four days);⁴⁶⁷ all 787 Dreamliners owned by United in 2013 (six planes, for three months);⁴⁶⁸ and all 737 MAX aircraft, first in 2019 in response to two crashes abroad (seventy-two planes, for twenty months)⁴⁶⁹ and then in 2024 in response to the Alaska Airlines door blowout (171 planes, for eighteen days).⁴⁷⁰ None of these groundings elicited a judicial challenge.

Part of the reason why airlines do not sue even when pressed by the FAA is likely that they care about their relationship to the agency. Every airline requires a certificate from the FAA in order to do business at all, receives from the FAA a tailored and evolving set of OpSpecs specifically directing how it is to conduct its business, and, in the case of larger airlines, has a full-time corps of inspectors focused exclusively on its own operations.⁴⁷¹ All this makes for a close relation-

⁴⁶⁴ *FAA Grounds Hawaii Carrier Mokulele Airlines Because of Lack of Training*, ASSOCIATED PRESS, Oct. 22, 2008; *Pro Air, Its Planes Grounded by FAA, Files for Chapter 11*, WALL ST. J., Sept. 21, 2000; *FAA Grounds Nevada Carrier*, ASSOCIATED PRESS, Apr. 13, 1997 (discussing Great American Airways); *FAA Grounds Express One International*, AIRCLAIMS, June 8, 1995 (noting the airline transported both cargo and passengers).

⁴⁶⁵ Ernest Holsendolph, *U.S. Grounds DC-10's After Check Shows 'Grave' Deficiencies*, N.Y. TIMES, May 30, 1979, at A1; Chris Loh, *The DC-10 1979 Grounding—What Happened?*, SIMPLE FLYING (June 7, 2020), <https://simpleflying.com/dc-10-1979-grounding/> [https://perma.cc/6VUG-BMU7].

⁴⁶⁶ Glen Johnson, *FAA Grounds Older Boeing 737s After Finding Wire Wear*, ASSOCIATED PRESS, May 11, 1998.

⁴⁶⁷ STIMPSON ET AL., *supra* note 385, at 15–16 (noting grounding was voluntary but “faced with the prospect of imminent enforcement action by the FAA”).

⁴⁶⁸ Ashley Halsey III, *FAA Grounds All Six Boeing Dreamliners in United's Fleet*, WASH. POST, Jan. 17, 2013, at A14; Dominic Rushe, *Boeing 787 Dreamliner Cleared to Fly by US Aviation Authorities*, GUARDIAN (Apr. 19, 2013), <https://www.theguardian.com/business/2013/apr/19/boeing-787-dreamliner-cleared-fly-faa> [https://perma.cc/96EB-EDEU].

⁴⁶⁹ *FAA Updates on Boeing 737 MAX*, FED. AVIATION ADMIN. (Apr. 8, 2021), <https://www.faa.gov/newsroom/faa-updates-boeing-737-max-0> [https://perma.cc/3MH3-Y7TU]; Leslie Josephs, *After Two Fatal Boeing Plane Crashes, the World Turned on the US*, NBC NEWS (Mar. 17, 2019, 9:57 AM), <https://www.cnbc.com/2019/03/17/two-boeing-737-fatal-plane-crashes-the-world-turns-on-the-faa.html> [https://perma.cc/7YS7-77GP].

⁴⁷⁰ *Updates on Boeing 737-9 MAX Aircraft*, FED. AVIATION ADMIN. (Dec. 5, 2024), <https://www.faa.gov/newsroom/updates-boeing-737-9-max-aircraft> [https://perma.cc/9YS6-KSFV]; David Koenig, *FAA Approves Inspection Process That Could Clear the Way for Grounded Boeing Planes to Fly Again*, AP NEWS (Jan. 24, 2024, 8:25 PM), <https://apnews.com/article/boeing-ceo-congress-senate-hearing-calhoun-cantwell-f83248428fc32b968a5b9192b79d88ff> [https://perma.cc/2LJY-CPMM].

⁴⁷¹ *General Information*, FED. AVIATION ADMIN., https://www.faa.gov/licenses_certificates/airline_certification/135_certification/general_info [https://perma.cc/GPU3-4PZQ].

ship where mutual trust is valuable to both sides. The agency has the ability to intensify inspection and make the carrier's business far more difficult if it loses that trust. Even before the FAA grounded ValuJet in 1996, the crash prompted the agency to ramp up inspections in a way that took up so much of ValuJet's time that the airline had to halve its flight schedule.⁴⁷² When asked about the rarity of airline lawsuits against the FAA, Anonymous Interviewee #3, a partner in a law firm aviation regulatory practice, first responded that a Part 121 carrier has "a continuing oversight relationship with the FAA."⁴⁷³ As the interviewee explained, the agency and the airline "don't necessarily—very much like a marriage—necessarily always agree on everything; there are occasional spats and disagreements; but there always is that relationship," and therefore "there is a real reluctance to get engaged in lawsuits and to try to resolve things through the courts."⁴⁷⁴ "It's a continuing relationship that I tell clients that is equivalent, in many respects, to a long-term and stable marriage."⁴⁷⁵

Another factor that would appear to greatly discourage airline judicial challenges is the airlines' need to convince customers that their service is safe. This goes to the peculiar customer psychology of aviation safety. Regardless of how unlikely a danger may be, a person tends to dread the danger more if, conditional on the danger's occurrence, the person will have little control over the danger's consequence and will likely die as a result of it.⁴⁷⁶ Consistent with this, research indicates that airplane crashes have the highest "dread score" of any familiar risk—far higher than car crashes, even though car crash deaths are exponentially more likely.⁴⁷⁷ Perhaps relatedly, the ratio between the media coverage that plane crashes attract and the number of deaths they cause has long been vastly greater than for other modes of transport.⁴⁷⁸ This dread must be assiduously countered if customers are going to buy airline tickets. Indeed, according to a study of U.S. airlines in the period of 1937–2000, the rate of plane crash fatalities per passenger boarding, controlling for air fares, has a significant negative impact on industry-wide demand for air travel.⁴⁷⁹ Thus, airlines have a strong economic interest

⁴⁷² Bynum, *supra* note 462 ("After the crash, daily federal inspections forced ValuJet to cut its number of daily flights in half.").

⁴⁷³ Interview with Anonymous Interviewee #3, *supra* note 28.

⁴⁷⁴ *Id.*

⁴⁷⁵ *Id.*

⁴⁷⁶ Ian Savage, *Competition on the Basis of Safety?*, in *PRICING BEHAVIOR AND NON-PRICE CHARACTERISTICS IN THE AIRLINE INDUSTRY* 297, 310–11 (James Peoples ed., 2012).

⁴⁷⁷ Savage, *supra* note 476, at 310–11; COBB & PRIMO, *supra* note 377, at 1.

⁴⁷⁸ COBB & PRIMO, *supra* note 377, at 1.

⁴⁷⁹ Haoming Liu & Jinli Zeng, *Airline Passenger Fatality and the Demand for Air Travel*, 39 *APPLIED ECON.* 1773, 1778–79, 1779 tbl.2 (2007) (excluding the year 2001 when the September 11 attacks occurred).

in maintaining a consumer perception that air travel generally is safe. To be sure, each individual airline has an incentive to free ride off the safety efforts of its competitors. But the FAA is a powerful solution to that collective action problem. With the agency in place, airlines do not have to “monitor other airlines to ensure that they are not spending less on safety and endangering the reputation of the entire industry.”⁴⁸⁰ Plus, the FAA “centraliz[es] the production of safety standards so that each airline does not have to rely on an internal safety department.”⁴⁸¹ Hence, “[m]ost airlines cooperate with the FAA because they find that regulation is in their interest.”⁴⁸² Any remaining incentive to defect is blunted because consumers, even if they cannot make fine distinctions among airlines’ levels of safety, could likely identify an airline falling below some minimum.⁴⁸³ Indeed, the historical pattern has been that an individual airline suffers enduringly in the capital markets from a front-page crash of one of its planes in a way that no other type of business suffers when it causes any other kind of front-page disaster—like an oil spill, factory explosion, or freight train crash.⁴⁸⁴ Accordingly, the literature has long suggested that airlines internalize much of the cost of plane crashes and therefore tend to align with the FAA.⁴⁸⁵

It goes against all this for airlines to take an adversarial stance toward the FAA on safety matters, such as by suing to challenge FAA safety actions. As one scholar argues, financially weak airlines in the 1990s, dependent on older aircraft, may well have been correct that

⁴⁸⁰ Patrick Soren Roberts, *Crisis as Opportunity: Innovation in Federal Homeland Security Agencies, 1946–2004*, at 218 (Jan. 2006) (Ph.D. dissertation, University of Virginia) (ProQuest).

⁴⁸¹ *Id.*

⁴⁸² *Id.*

⁴⁸³ Savage, *supra* note 476, at 311.

⁴⁸⁴ Consider a study of stock market reactions to the 161 nonintentional “major accidents” involving publicly traded companies reported on the front page of the *New York Times* from 1959 to 2010. Carpentier & Suret, *supra* note 21, at 3, 5–6, 15–17 tbl.A1 (consisting mainly of environmental accidents, fires and blasts, plane crashes, and train crashes, of which nearly all were freight trains). The authors find that if we look beyond the immediate reaction to longer-lasting effects (at the eight-month mark after the accident), plane crashes are in a class by themselves, inducing “a large negative return and significant average compounded abnormal returns, reaching -17% with some estimation models,” whereas the other accidents induce no significant abnormal returns, except in instances that prompted “strong government intervention.” *Id.* at 14. The authors note that the market’s extremely negative long-term reaction to front-page plane crashes, independent of any government intervention, may result from “a reputational effect at the consumer level.” *Id.* at 10. This makes sense given that the other types of accidents in the study generally were not of the type that would harm the firm’s own customers. For the other types of accidents, which would generally harm company workers or third-party strangers, see *id.* at 15–17; see also Jerry C. Ho, Mei Qiu & Xiaojun Tang, *Do Airlines Always Suffer from Crashes?*, 118 *ECON. LETTERS* 113, 115 & figs.1 & 2 (2013) (finding large negative stock market reaction to U.S. plane crashes over 100 fatalities at twenty-five-day mark in period of 1950–2009). On airlines’ investments in countering the reputational effects of a crash, see COBB & PRIMO, *supra* note 377, at 32, 67.

⁴⁸⁵ See COBB & PRIMO, *supra* note 377, at 32, 40, 44; STIMPSON ET AL., *supra* note 385, at 36.

the FAA's—and the public's—apprehension about such aircraft was inaccurately high and that the retrofits demanded by the FAA's ADs were not cost beneficial.⁴⁸⁶ However, “it was a losing battle for [those airlines] to challenge the public perception[,] . . . [because] by identifying themselves publicly as ‘old aircraft operators,’ these airlines could differentiate themselves right out of the market. They had no other choice but to remain silent.”⁴⁸⁷

E. Children's Product Companies and CPSC

The fifth agency-industry pairing in which industry judicial challenges are relatively marginal is the one between children's product companies and CPSC. For this pairing, regulated businesses' relationship to the regulator is significant, though thinner than for the USDA, FDA, NHTSA, and FAA. But the businesses' stake in consumer perception of their products' safety—and consequently their degree of alignment with the regulator's mission—appears to be as great or greater.

The term “children's product” is defined by CPSC's enabling legislation as any “consumer product designed or intended primarily for children 12 years of age or younger.”⁴⁸⁸ This includes any “durable infant or toddler product,” defined as one for use “by children under the age of 5 years” and expressly encompassing cribs, high chairs, bath seats, play yards, strollers, and more.⁴⁸⁹ My analysis focuses on manufacturers and importers of children's products. Although distributors and retailers are also within CPSC jurisdiction, manufacturers and importers have long been the main focus of the agency's enforcement activities.⁴⁹⁰ I refer to these manufacturers and importers collectively as “children's product companies.”

My analysis pairs CPSC with children's product companies because, although the agency officially has vast jurisdiction over consumer

⁴⁸⁶ BEN-YOSEF, *supra* note 451, at 194–95.

⁴⁸⁷ *Id.*

⁴⁸⁸ 15 U.S.C. § 2052(a)(2).

⁴⁸⁹ *Id.* § 2056a(f).

⁴⁹⁰ See ERIC A. RUBEL, MICHELLE F. GILLICE, S. MICHAEL GENTINE, JESSICA L. WANG & KELSIE SICINSKI, CPSC DESK REFERENCE: SECTION 15 OF THE CONSUMER PRODUCT SAFETY ACT 9 (2024), <https://www.arnoldporter.com/en/perspectives/advisories/2024/02/cpsc-notification-requirements> [<https://perma.cc/TG2B-ZPZ9>] (discussing recalls); see also Kelsie Sicinski & Michelle F. Gillice, *Forget Me Not: CPSC Reminds Retailers of Their Reporting Obligations Under Section 15(b) of the CPSA with Civil Penalty Against BJ's Wholesale Club* (Oct. 30, 2023), <https://www.arnoldporter.com/en/perspectives/blogs/consumer-products-and-retail-navigator/2023/10/cpsc-reminds-retailers-of-their-reporting-obligations> [<https://perma.cc/3SJ3-LRWZ>] (discussing civil penalties for late reporting).

products,⁴⁹¹ its resources are very limited,⁴⁹² which has forced it to be highly selective. In fact, CPSC “has historically been a leader in protecting children,”⁴⁹³ focusing its regulatory scheme more on children’s products than anything else. The agency was created by the Consumer Product Safety Act of 1972 (“CPSA”),⁴⁹⁴ and of the sixty-six safety standards currently in force under CPSA for product categories, more than half—thirty-six—focus on children’s products, while the rest are relatively scattered.⁴⁹⁵ Most of these children’s product safety standards were adopted in response to the Consumer Product Safety Improvement Act of 2008 (“CPSIA”),⁴⁹⁶ which directed the agency to promulgate at least four mandatory rules per year until its rules covered “all” categories of durable infant or toddler products.⁴⁹⁷ The CPSIA also singled out children’s products for a uniquely stringent requirement of premarket testing for conformity with CPSC safety regulations to be performed by third-party laboratories whose accreditation is recognized by the agency.⁴⁹⁸

In regulating children’s products, CPSC has several powers. First, it conducts rulemaking in the form of the safety standards for product categories noted above.⁴⁹⁹ Second, it enforces these standards in multiple ways. One way is by overseeing the system of accredited third-party laboratories who test children’s products for safety standard conformity as a prerequisite for marketing.⁵⁰⁰ Another form of enforcement is product recalls, whereby a company must notify consumers of a problem in a product and, depending on the recall’s particular terms, may provide

⁴⁹¹ See Richard J. Hunter, Jr. & Melissa A. Montuori, *The Hand That Truly Rocks the Cradle: A Reprise of Infant Crib Safety, Lawsuits and Regulation From 2007–2012*, 25 LOY. CONSUMER L. REV. 229, 230–33 (2013) (noting vast jurisdiction with discrete exceptions for things regulated by other agencies, such as food and drugs).

⁴⁹² U.S. GOV’T ACCOUNTABILITY OFF., GAO-21-56, CONSUMER PRODUCT SAFETY COMMISSION: ACTIONS NEEDED TO IMPROVE PROCESSES FOR ADDRESSING PRODUCT DEFECT CASES 1 (Nov. 2020) (“Despite its broad jurisdiction, CPSC is a relatively small agency with just over 500 full-time equivalent employees as of September 2020.”).

⁴⁹³ Todd C. Frankel, *After Hundreds of Crashes, This Britax Jogging Stroller Faced Recall. Then Trump Appointees Stepped In*, WASH. POST (Apr. 2, 2019), https://www.washingtonpost.com/business/economy/after-hundreds-of-crashes-this-britax-jogging-stroller-faced-recall-then-trump-appointees-stepped-in/2019/04/02/faf23c20-4c06-11e9-b79a-961983b7e0cd_story.html [https://perma.cc/XU8Q-HX94].

⁴⁹⁴ 15 U.S.C. §§ 2051–2089; see also Hunter & Montuori, *supra* note 491, at 230 (describing the passage of the CPSA).

⁴⁹⁵ See 16 C.F.R. pts. 1201–1461.

⁴⁹⁶ Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016.

⁴⁹⁷ See *id.* § 104(b)(2) (codified at 15 U.S.C. § 2056a(b)(2)); see also 15 U.S.C. § 2056b (providing for mandatory rulemaking for toys).

⁴⁹⁸ 15 U.S.C. § 2063(a).

⁴⁹⁹ See *supra* note 495 and accompanying text.

⁵⁰⁰ Lesley K. McAllister, *Harnessing Private Regulation*, 3 MICH. J. ENV’T & ADMIN. L. 291, 338–45 (2014).

some degree of refund, replacement, or repair at its own expense.⁵⁰¹ Recalls may be required for a product's violation of a safety standard⁵⁰² or more generally for any "defect which . . . creates a substantial risk of injury to the public."⁵⁰³ CPSC can force a recall, but this requires a trial-like agency adjudication; nearly all recalls are in fact negotiated by companies with CPSC prior to any such adjudication, either on the company's initiative or in response to an agency "request."⁵⁰⁴ Third, CPSC provides information to the public in various ways. One form is guidance for consumers that addresses types of products without naming individual companies or their particular products.⁵⁰⁵ Another is a public database of complaints from outside parties about the safety of products of named companies.⁵⁰⁶ Yet another consists of "unilateral press releases" by CPSC, which may name a company's product as unsafe.⁵⁰⁷ Public disclosures are constrained in certain ways. If a database posting is "materially inaccurate," CPSC must delete or correct it.⁵⁰⁸ Before issuing a unilateral press release, the agency must allow the company fifteen days to comment before disclosure and must "take reasonable steps to assure" that the information "is accurate, and that such disclosure is fair in the circumstances and reasonably related to effectuating the purposes of" the CPSA.⁵⁰⁹

Children's product companies make little use of judicial challenges against CPSC. Although the core study period for this Article is January 20, 2013, through January 20, 2021, the nature of CPSC allows us easily to gather data on a longer time span. Because CPSC is a free-standing agency, a relatively low-cost Bloomberg dockets search of the defendant and respondent fields for CPSC's name and acronym and the names of its successive chairs will very likely catch all challenges to the agency. A search for CPSC defendants or respondents over the thirty-five-year period from 1989 through January 20, 2024, yields seven children's product company suits against the agency's actions.⁵¹⁰

⁵⁰¹ See 15 U.S.C. § 2064(b)–(c).

⁵⁰² CPSC can send "notices of violations" to companies if it thinks their products violate safety standards, and these notices can lead to recalls. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 492, at 16–18.

⁵⁰³ 15 U.S.C. § 2064(a)(2); U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 492, at 7.

⁵⁰⁴ RUBEL ET AL., *supra* note 490, at 11–16.

⁵⁰⁵ E.g., *Remember CPSC's "Dos and Don'ts" for Baby Sleep Spaces*, CONSUMER PROD. SAFETY COMM'N, <https://www.cpsc.gov/SafeSleep> [<https://perma.cc/24Y3-XEC5>].

⁵⁰⁶ SAFERPRODUCTS, <https://www.saferproducts.gov> [<https://perma.cc/DJ74-4L84>].

⁵⁰⁷ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 492, at 11.

⁵⁰⁸ See 15 U.S.C. § 2055a(c)(4)(A).

⁵⁰⁹ 15 U.S.C. § 2055(b)(1). On application of this provision to unilateral press releases, see RUBEL ET AL., *supra* note 490, at 12.

⁵¹⁰ See DATASET, *supra* note 10, File 25, Rows 5–8; *id.* File 26, Rows 4–6; see also *id.* File 25, Row 4 (outside of the study period). Two items are excluded from my report of the results:

The first thing to note is that no children's product trade associations were among the challengers.⁵¹¹ The two principal trade associations for children's products have long been the Juvenile Products Manufacturers Association ("JPMA") and the Toy Association (formerly the Toy Manufacturers of America).⁵¹² Neither was a challenger for the entire period of 1989–2024,⁵¹³ nor was either association an amicus in any litigation involving CPSC during that period.⁵¹⁴ It appears the most recent

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- First, these results exclude a challenge brought by upstream non-consumer-facing chemical manufacturers to a rule banning the use of certain phthalates in toys that, by the time of the rule, were no longer actually used in toys. *See* Amended Petition for Review at 1–2, *Texas Ass'n of Mfrs. v. CPSC*, 989 F.3d 368 (5th Cir. 2021) (No. 17-60836); Statement, Toy Ass'n, *The Toy Association Statement on Phthalates* (Oct. 2024), <https://www.toyassociation.org/PressRoom2/IndustryStatements/statement-on-phthalates.aspx> [<https://perma.cc/QB8L-4NOB>] ("[T]he rule has had very little impact on the toy industry because the restricted materials are not used in toys."). The chemical industry may have been litigating to avoid a rule that could set a precedent for other uses of phthalates.
 - Second, these results exclude challenges by industries making products that are not marketed to children or to children's caregivers qua caregivers, but are prone to harm children incidentally—such as window coverings that can cause strangulation. *See, e.g.*, *Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1279 (D.C. Cir. 2023). My rationale for this exclusion is that an industry like window coverings does not expect its potential customers to be attuned to child strangulation (and therefore to CPSC) to nearly the same degree that, say, an airline expects its potential customers to be attuned to plane crashes (and therefore to the FAA). A borderline category is high-powered magnets, which are officially marketed as hobby or novelty items for adults but are in fact attractive to children and may unfortunately be purchased for children, who may then swallow the magnets. Todd C. Frankel, *Number of Children Swallowing Dangerous Magnets Surges as Industry Largely Polices Itself*, WASH. POST (Dec. 25, 2019), https://www.washingtonpost.com/business/economy/number-of-children-swallowing-dangerous-magnets-surges-as-industry-largely-polices-itself/2019/12/25/77327812-2295-11ea-86f3-3b5019d451db_story.html [<https://perma.cc/33QW-4FYY>] (noting that high-powered magnets were "not covered by the [CPSC] toy safety standard because they were not meant for children"). Some adult hobby magnet companies have litigated extensively against CPSC. For an example of this litigation, see RUBEL ET AL., *supra* note 490, at 14–15.

⁵¹¹ DATASET, *supra* note 10, File 25, Rows 5–8; *id.* File 26, Rows 4–6. Trade associations were involved in ERGO Baby's Fourth Circuit appeal to keep its judicial challenge sealed and its name under a pseudonym, but all these associations were of industries other than children's products (except the National Association of Manufacturers, which covers everything). *See Doe v. Pub. Citizen*, 749 F.3d 246, 246, 252 (4th Cir. 2014). The sealing and pseudonymity issues pertained only to the judicial case itself and were not challenges to CPSC action. *See id.* at 256 (noting CPSC withdrew its appeal).

⁵¹² *See* Deborah White & Kathleen McGuigan, *Business Groups Call USTR Tariffs Process 'Flawed,'* RETAIL LITIG. CTR. (Aug. 9, 2021), <https://www.rila.org/retail-litigation-center/business-groups-ustr-tariffs-process-flawed> [<https://perma.cc/69XW-3P2D>] (describing the JPMA and Toy Association's leadership in the children's products industry).

⁵¹³ *See* DATASET, *supra* note 10, Files 25–26.

⁵¹⁴ A Bloomberg docket search of U.S. district courts and U.S. circuit courts for "*Juvenile Product Manufacturers Association*" OR "*Toy Association*" OR "*Toy Manufacturers*" in the party field, with no other restrictions, yields nine results, none involving CPSC.

judicial challenge to CPSC by either the JPMA or Toy Association was brought in 1988 against CPSC's interpretation of its prohibition against small parts in toys to cover not only plastic parts but also fabric ones.⁵¹⁵

The seven suits over the thirty-five year period were each brought by one individual company, and these suits collectively suggest that openly challenging CPSC in court is very far from the industry mainstream.⁵¹⁶ To be sure, the statuses of the challenging companies are somewhat difficult to discern, because all of them were closely held and public sources offer only fragmentary information about them. But there is enough to get a reasonable sense.

This section begins with the five companies out of seven who challenged CPSC rulemakings or enforcement actions aiming to preserve safety. One of these, Hollander Home Fashions, sued in 1992 to challenge a CPSC rule banning certain infant cushions—and lost.⁵¹⁷ Hollander was a large company with annual sales over \$100 million that year, but it was a general bedding manufacturer and was not specialized in children's products.⁵¹⁸ This presumably diminished its connection to CPSC and the significance of safety to its business. The four remaining companies were specialized in children's products. Two were clearly small and were each challenging a CPSC action that would ban the company's only product. X-tra Art was a “small” company founded in about 1985 to sell shaving cream mixed with food coloring as fingerpaint; it sued in 1991 to try to stop CPSC from treating its product as prohibited on the ground it was “highly flammable,” ultimately losing.⁵¹⁹ Finnbin began as a startup in 2016 to sell Finnish-style “baby boxes” for infant sleep;⁵²⁰ it brought and lost a challenge to CPSC's 2022 rule banning

⁵¹⁵ The case is *Jerri's Ceramic Arts, Inc. v. CPSC*, 874 F.2d 205, 206 (4th Cir. 1989), which challenged the interpretation of the “Small Parts Rule,” 16 C.F.R. §§ 1501.1–.5 (1988), that CPSC issued in 1988. The associations were intervenors for the challenger. *Jerri's Ceramic Arts*, 874 F.2d at 205.

⁵¹⁶ DATASET, *supra* note 10, File 25, Rows 5–8; *id.* File 26, Rows 4–6.

⁵¹⁷ *Hollander Home Fashions Corp. v. CPSC*, No. 92-1346, 1993 WL 118186 (D.C. Cir. Mar. 4, 1993). For the subject matter of the suit and the agency's victory, see 1994 CONSUMER PROD. SAFETY COMM'N ANN. REP. app. G, <https://www.cpsc.gov/content/1994-annual-report> [<https://perma.cc/F4HM-NZ9E>], under the subheading “Other Cases Against the Commission.”

⁵¹⁸ See Sharyn K. Bernard, *Hollander Acquires Countess York Assets*, HFD—WKLY. HOME FURNISHINGS NEWSPAPER, Mar. 30, 1992.

⁵¹⁹ See *X-tra Art v. CPSC*, 969 F.2d 793, 795–96 (9th Cir. 1992). For the docket, see Court Docket, *X-tra Art, Inc. v. CPSC*, No. 91-cv-1336, 1991 WL 405183 (N.D. Cal. June 12, 1991).

⁵²⁰ On the company, see Carolyn Webber Adler, *Marketplace: Finnbin Baby Boxes Bring Finnish Tradition to Park City*, PARK REC. (July 16, 2018), <https://www.parkrecord.com/2018/07/16/marketplace-finnbin-baby-boxes-bring-finnish-tradition-to-park-city> [<https://perma.cc/V33A-K8YG>]. On its 2016 founding, see *Finnbin Baby Box*, F6S, <https://www.f6s.com/company/finnbin-babybox#about> [<https://perma.cc/G9EB-HUK5>]. Finnbin was not even “the most common name in baby boxes” during the few years when they were sold in the United States. See Jennifer Doering & Rebecca Sinicki, *Rise and Fall of the Baby Box in the United States*, 53 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 3, 3 (2024).

all infant sleep products that, like its boxes, lacked “a firm stand and an elevated sleeping surface.”⁵²¹ This leaves the two challengers who were nearest to the industry mainstream, Leachco and Keezio. Leachco made infant loungers; when CPSC requested a recall after two infants died, the company refused, arguing that the product did not cause the deaths.⁵²² This prompted CPSC to initiate an agency adjudication in 2022 to force a recall, after which Leachco went to court—represented pro bono by the Pacific Legal Foundation—with a collateral attack on the constitutionality of the agency’s structure.⁵²³ Meanwhile, Keezio, under the brand name Hiccapop, made, among other things, aftermarket mattresses for play yards; the company challenged a 2022 CPSC rule imposing a thickness limit on such mattresses that would render some of the company’s inventory unlawful to sell, especially because the agency refused to wait for a private standard-setting organization to weigh in.⁵²⁴ To try to gauge the relative sizes of Leachco and Keezio, we can look to the ninety-eight manufacturer members of JPMA,⁵²⁵ for several of whom we were able to obtain annual revenue or employment data from S&P’s Capital-IQ database. Leachco’s complaint said it had about forty full-time employees,⁵²⁶ which would rank it about twenty-sixth among the fifty-four JPMA manufacturer members for which we found employment data.⁵²⁷ Thus, Leachco was not tiny, but it was far smaller than industry leaders like Goodbaby (6,329 employees), Dorel Juvenile (2,700 employees), Graco (1,420 employees), or Fisher-Price

⁵²¹ *Finnbin, LLC v. CPSC*, 45 F.4th 127, 132 (D.C. Cir. 2022) (citing 16 C.F.R. pt. 1218). For the docket, see Court Docket, *Finnbin*, 45 F.4th 127 (No. 21-01180).

⁵²² *Leachco, Inc. v. CPSC*, 103 F.4th 748, 751, 765 (10th Cir. 2024), *aff’g* No. 22-cv-00232, 2022 WL 17327494 (E.D. Okla. Nov. 29, 2022); Verified Complaint for Injunctive & Declaratory Relief at 9, *Leachco*, 2022 WL 17327494 (No. 22-cv-00232).

⁵²³ *Leachco*, 103 F.4th at 751, 765; Verified Complaint for Injunctive & Declaratory Relief, *supra* note 522, at 9. The district court denied Leachco’s request for a preliminary injunction. *Leachco*, 2022 WL 17327494, at *1. On the pro bono nature of PLF’s representation, see Petition for a Writ of Certiorari at 3, *Leachco, Inc. v. CPSC*, 145 S. Ct. 1047 (2025) (No. 24-156) (“Unlike most companies, who would have been forced to accede to the Commission’s unjustified recall demands, Leachco has so far survived the Commission’s war of attrition, but only because Leachco found pro bono legal representation.”).

⁵²⁴ Petitioner Keezio Group LLC’s Opening Brief at 2, 26–27, 32, *Keezio Grp. LLC v. CPSC*, No. 22-1057 (D.C. Cir. Mar. 15, 2023) (filed July 11, 2022), 2023 WL 2604238. Keezio dropped its challenge once the organization weighed in. See Letter Filed by Keezio Group LLC, *Keezio Grp.*, No. 22-1057 (filed Nov. 30, 2022); Stipulation of Voluntary Dismissal, *Keezio Grp.*, No. 22-1057 (filed Mar. 15, 2023).

⁵²⁵ DATASET, *supra* note 10, File 63. If sister subsidiary companies are counted as one company, the number of JPMA members is ninety instead of ninety-eight. *Id.* The rankings of JPMA members below (1) rely upon data for member companies, not their parent companies, if any, and (2) for any set of sister subsidiaries, exclude all but the largest subsidiary. Had the rankings included parents or sister subsidiaries, Leachco and Keezio would look even smaller by comparison.

⁵²⁶ Verified Complaint for Injunctive & Declaratory Relief, *supra* note 522, at 4.

⁵²⁷ DATASET, *supra* note 10, File 63 (tab titled “Ranked by Employees”).

(830 employees).⁵²⁸ As to Keezio, the company's complaint said it made \$13 million in the preceding year from aftermarket mattresses alone,⁵²⁹ which were only one of its product lines.⁵³⁰ Just \$13 million in revenue would rank Keezio about twenty-third among the forty-three JPMA manufacturer members for which we found revenue data,⁵³¹ but its ranking with all its product lines would of course be higher—and we do not know how much higher. Still, it does not appear that Keezio ranks with leaders like Goodbaby (over \$1 billion annual revenue), Dorel Juvenile (over \$579 million annual revenue), Graco (over \$469 million annual revenue), or Fisher-Price (about \$228 million annual revenue).⁵³²

Besides these five suits challenging CPSC safety rulemaking or enforcement, the other two suits occurring during the period from 1989 to 2024 were brought by fairly well-known companies. However, their aim, ironically, was to keep their adversity with the agency *out* of the public eye. One was Daisy Manufacturing, a century-old air rifle maker which sued CPSC in 1996 to stop the agency from complying with a Freedom of Information Act⁵³³ request from ABC News for records of the agency's investigation of the company; Daisy lost.⁵³⁴ The other was ERGO Baby Carrier, a JPMA member currently listed as having nearly \$24 million annual revenue and eighty-four employees,⁵³⁵ which sued in 2011 to stop CPSC from posting a complaint from a local government agency linking an ERGO Baby product with an infant death in its Saferproducts.gov database.⁵³⁶ Notably, ERGO Baby won on the merits but sought to keep the litigation under seal and to mask itself with the pseudonym "Company Doe"; it succeeded in maintaining this secrecy through its district court merits victory only to be unmasked when consumer NGOs intervened, brought an appeal opposing the grant of secrecy, and won.⁵³⁷

⁵²⁸ *Id.* File 63, Rows 2–5.

⁵²⁹ Petitioner Keezio Group LLC's Opening Brief, *supra* note 524, at 70 (Declaration of L. Jason Clute).

⁵³⁰ *Id.* at 69.

⁵³¹ DATASET, *supra* note 10, File 63 (tab titled "Ranked by Revenue").

⁵³² *Id.* File 63, Rows 2–4, 7. These figures do not include revenue for sister subsidiaries of these companies.

⁵³³ 5 U.S.C. § 552.

⁵³⁴ *Daisy Mfg. Co. v. CPSC*, No. 96-cv-5152, 1997 WL 578960, at *1 (W.D. Ark. Feb. 5, 1997), *aff'd*, 133 F.3d 1081 (8th Cir. 1998).

⁵³⁵ See DATASET, *supra* note 10, File 63, Row 75 (tab titled "JPMA Mfrg Members Cap-IQ Data").

⁵³⁶ Complaint at 5, *Doe v. Tenenbaum*, 900 F. Supp. 2d 572 (D. Md. 2012) (No. 11-cv-02958), *vacated in part and rev'd in part on other grounds sub nom. Doe v. Pub. Citizen*, 749 F.3d 246 (4th Cir. 2014).

⁵³⁷ See *Doe*, 749 F.3d at 254–56, 275. After the close of the search period on January 20, 2024, one other suit was brought by a children's product company, Dreamland Baby, challenging the CPSC's issuance of public guidance on safety problems regarding the company's product category

It becomes clearer how far these seven challenges were outside the mainstream when considering the volume of underlying CPSC activity. Over the thirty-five-year period, the only rulemakings on children's products to elicit judicial challenges were the rules on infant cushions (by the large but not child-focused Hollander in 1992), sleep products (by the small Finnbinn in 2021), and crib mattresses (by the apparently mid-sized Keezio in 2022).⁵³⁸ In comparison, there are a total of thirty-six children's product rules that are currently in force, thirty-five of which were adopted since the enactment of the CPSIA in 2008.⁵³⁹ A challenge rate of three out of thirty-six is not terribly high, especially considering that because of the preclusion clause in the enabling legislation, a CPSC rule on infant or toddler products or toys can *only* be challenged within sixty days of its promulgation and never thereafter—not even by a company targeted in an enforcement proceeding.⁵⁴⁰ Over the same thirty-five-year period, only one children's product recall matter resulted in a judicial challenge (Leachco's),⁵⁴¹ compared with the 2,400 recalls in the CPSC recall database during that same period under the category "Babies and Kids."⁵⁴² The common pattern for these recalls is that CPSC "requests" a recall, the company and agency negotiate the terms, and the two announce the recall as being "voluntary" on the company's part.⁵⁴³ It is possible for the agency to force a recall by way of a trial-like agency adjudication, but the agency has initiated such adjudications against children's product companies only rarely: four times from 1998 to 2024.⁵⁴⁴ Finally, the entire thirty-five-year period saw only

(weighted sleep products), though not naming the company or its products. Complaint for Declaratory and Injunctive Relief at 28, 31–39, *Dreamland Baby Co. v. CPSC*, No. 24-cv-03277 (D.D.C. Nov. 19, 2024). *Dreamland Baby* is represented by the New Civil Liberties Alliance. *Id.* at 43. It has between eleven and fifty employees. *See* *Dreamland Baby Co.*, LINKEDIN, <https://www.linkedin.com/company/dreamland-baby> [https://perma.cc/ERT6-B98M].

⁵³⁸ *See supra* notes 517, 520–21, 524 and accompanying text.

⁵³⁹ The thirty-five children's product standards adopted since 2008 are 16 C.F.R. §§ 1215–1239, 1241, 1250–1253, 1272, 1307–1310. One was adopted earlier. *Id.* § 1213.

⁵⁴⁰ *See* 15 U.S.C. § 2060(g). CPSIA added this provision to the CPSA in 2008. *See* Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 236(a), 122 Stat. 3075.

⁵⁴¹ *See* DATASET, *supra* note 10, File 25, Row 5; *supra* notes 522–23 and accompanying text.

⁵⁴² DATASET, *supra* note 10, File 64. This data is based on a search of CPSC's online recall database, with category "Babies and Kids" over the period January 1, 1989, to January 20, 2024. *See Recalls and Product Safety Warnings*, CONSUMER PROD. SAFETY COMM'N, <https://www.cpsc.gov/Recalls> [https://perma.cc/T96W-EGA2].

⁵⁴³ The process generally involves either (1) a "preliminary determination" by the agency that there is a hazard, after which the company normally agrees to a recall, or (2) the company's agreement at the outset to conduct a "Fast Track Recall" to avoid an agency preliminary determination of a hazard, which can hurt the company in future tort litigation. RUBEL ET AL., *supra* note 490, at 11–16.

⁵⁴⁴ Besides Leachco in 2022, the companies were Daisy Manufacturing in 2001 (air rifles), Baby Matters in 2012 (Nap Nanny infant recliner), and Britax in 2018 (jogging stroller). *See id.* at 13 & n.110

two challenges to CPSC informational disclosures—Daisy and ERGO Baby—in comparison with the posting of thousands of complaints about product safety on Saferproducts.gov since its 2008 inception.⁵⁴⁵

Why have industry judicial challenges been so marginal? One important reason is agency forbearance, especially when it comes to rulemaking. The CPSIA instructs CPSC to adopt safety standards for all categories of durable infant or toddler products, but it constrains these rulemakings by reference to “voluntary consumer product safety standards,”⁵⁴⁶ which are formulated and adopted by private standard-setting organizations like ASTM International, whose process involves substantial industry participation and has been criticized as unduly industry dominated.⁵⁴⁷ The CPSIA says that, regarding infant or toddler products, CPSC must promulgate rules that “are substantially the same as such voluntary standards” unless the agency “determines that more stringent standards would further reduce the risk of injury.”⁵⁴⁸ That is, going beyond ASTM standards requires a special agency determination. In practice, it is common that a CPSC rule for a product category copies the ASTM standard, though there are some categories for which CPSC has adopted a rule that is more stringent.⁵⁴⁹ Among the rules that went beyond ASTM are the two that have recently drawn challenges. The rule Finnbin challenged had “leapfrogged an ongoing ASTM effort

⁵⁴⁵ There were over 3,400 complaints in the product category “baby” and over 2,900 in the product category “Toys & Children.” See DATASET, *supra* note 10, File 66, Rows 2–3483, 53,756–56,734 (containing download of search results from SAFERPRODUCTS.GOV, *supra* note 506, ordered by product category). Theoretically, companies might be bringing some untold number of challenges to the posting of safety complaints and succeeding in keeping the cases completely secret, as ERGO Baby tried but ultimately failed to do in its case. See *supra* note 537 and accompanying text. But this seems unlikely, because even in ERGO Baby’s case, the furthest any court went in favor of secrecy was the district judge in releasing the merits opinion, including CPSC’s status as defendant, while referring to the company by a pseudonym and redacting much material—and even that limited amount of concealment was torn away by the circuit court. *Id.* In any event, sealed cases, if they exist, would not provide usable precedent for future litigation.

⁵⁴⁶ 15 U.S.C. § 2056a(b)(1)(A).

⁵⁴⁷ E.g., Frankel, *supra* note 510 (tracing industry involvement with ASTM and quoting former CPSC chair Elliott Kaye saying “[i]t makes our jobs harder to have to defer by law to an extremely inefficient and industry-focused process”). Note that CPSC itself is involved in ASTM’s standard-setting process. See U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 492, at 20–21.

⁵⁴⁸ 15 U.S.C. § 2056a(b)(1)(B). Note also the central role of the ASTM voluntary standard when it comes to toys. See *id.* § 2056b(a), (g). For consumer products beyond the children’s realm, the agency is not allowed to undertake rulemaking at all unless it makes a finding that the existence of a voluntary standard is inadequate. U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 492, at 7 n.11, 20.

⁵⁴⁹ For examples of more stringent rules, see 2011 CONSUMER PROD. SAFETY COMM’N ANN. REP. 13, which discusses the 2010 standard for cribs and the 2011 standard for toddler beds; similarly, see 2012 CONSUMER PROD. SAFETY COMM’N ANN. REP. 13, for a discussion of the 2012 standard for portable bed rails. Also see 2012 CONSUMER PROD. SAFETY COMM’N ANN. REP. 14 for an example of CPSC rules copying ASTM standards.

to create a voluntary standard for infant flat sleep products,”⁵⁵⁰ while the rule Keezio challenged had been promulgated before ASTM had weighed in on the products at issue.⁵⁵¹ One reason CPSC rules elicit few challenges is that they often do not depart from ASTM in this way. Beyond rulemaking, agency forbearance may also help explain the dearth of litigation in areas like recalls. The high process cost that CPSC must bear to force a recall through trial-like adjudication incentivizes the agency to accept negotiated recall plans,⁵⁵² presumably on more company-friendly terms than if forcing recalls were easier.

That said, agency forbearance is not a sufficient explanation for the low level of judicial challenges. CPSC does not always do what industry wants, and when it defies industry, it does not always face judicial challenge. This is evident if we take a bird’s-eye view of recall activity: It is hard to believe that *none* of the nearly 2,400 children’s product recalls since 1989 except Leachco’s were “worth litigating” in the narrow sense that savings of direct compliance costs, discounted by the probability of losing in court, would exceed direct litigation costs.⁵⁵³ Perhaps the best example of CPSC going against industry preferences and facing no judicial challenge was the leading role the agency played in stamping out drop-side cribs, which were increasingly blamed for causing infant deaths in the mid-2000s.⁵⁵⁴ This type of crib had been “quite popular from the 1980s through the early 2000s, at one point constituting roughly 50 percent of the market by some estimates, although that dropped off to 18 percent by 2009.”⁵⁵⁵ The decline up to 2009 resulted partly from recalls that CPSC administered in large numbers beginning in 2007; in the four-year period of 2007–2010, the agency “issued 46 recalls of more than 11 million cribs,”⁵⁵⁶ including several million drop-side types.⁵⁵⁷ In late December 2010, CPSC promulgated a

⁵⁵⁰ *Finnbin, LLC v. CPSC*, 45 F.4th 127, 132 (D.C. Cir. 2022).

⁵⁵¹ Petitioner Keezio Group LLC’s Opening Brief, *supra* note 524, at 35–36.

⁵⁵² U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 492, at 16.

⁵⁵³ See *supra* note 542 and accompanying text.

⁵⁵⁴ See, e.g., *Infant Entrapment and Suffocation Prompts Stork Craft to Recall More Than 2.1 Million Drop-Side Cribs*, CONSUMER PROD. SAFETY COMM’N (Nov. 23, 2009), <https://www.cpsc.gov/Recalls/2009/infant-entrapment-and-suffocation-prompts-stork-craft-to-recall-more-than-21-million> [<https://perma.cc/TL8R-VBU5>]; *About 1 Million Simplicity Cribs Recalled Due To Failures Resulting in Infant Deaths*, CONSUMER PROD. SAFETY COMM’N (Sept. 21, 2007), <https://www.cpsc.gov/Recalls/2007/about-1-million-simplicity-cribs-recalled-due-to-failures-resulting-in-infant-deaths> [<https://perma.cc/4N53-XPKT>].

⁵⁵⁵ Peter H. Schwartz, *Child Safety, Absolute Risk, and the Prevention Paradox*, 42 HASTINGS CTR. REP., July–Aug. 2012, at 20, 21 (citing Personal Communication from Michael Dwyer, Exec. Dir., JPMA (Sept. 26, 2011)).

⁵⁵⁶ Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs; Final Rule, 75 Fed. Reg. 81,766, 81,767 (Dec. 28, 2010) (to be codified at 16 C.F.R. pts. 1219–1220, 1500).

⁵⁵⁷ See, e.g., sources cited *supra* note 554. For background on the decline, including the simultaneous role of tort suits that mostly ended in settlements not in the public record, see Hunter & Montuori, *supra* note 491, at 237–46.

rule on cribs—which it designated as “major”⁵⁵⁸ under the Congressional Review Act⁵⁵⁹—that went beyond ASTM and imposed an outright ban on drop-side cribs,⁵⁶⁰ as well as an unprecedented requirement that places of public accommodation, such as child care facilities, replace all such cribs by 2012.⁵⁶¹ Interviewee Rick Locker, a law firm partner who is independent general counsel to many children’s product manufacturer associations, recalled that, at the time of the ban, the industry’s view was: “We don’t think there’s anything wrong with drop side cribs. We think [the drop-side design] provides function and value to consumers. But the government wants us to do it [i.e., stop selling them]. We’re not going to fight it.” He added, “Would [the disappearance of drop-side cribs] have happened but for the agency’s decision to get involved in how the product was designed? The answer is no, it would not have happened.”⁵⁶² Throughout this chain of events—in which CPSC’s work was the but-for cause of eliminating a once-dominant type of a ubiquitous product—there were no judicial challenges to what CPSC was doing, on either the recalls or the rule.⁵⁶³

Given that agency forbearance is not a complete explanation, another possible factor is the regulated companies’ stake in their relationship to CPSC. This factor likely plays some role, though a more limited one than at the USDA, FDA, NHTSA, and FAA. “Despite its broad jurisdiction, CPSC is a relatively small agency with just over 500 full-time equivalent employees,”⁵⁶⁴ less than any of these other agencies. CPSC’s supervision of the premarket third-party lab testing system for the rule conformity of children’s products does not entail the same leverage over regulated parties that one finds in, say, FDA’s power to make direct and highly discretionary decisions about premarket approval. And CPSC does not remotely have the resources for continuous monitoring of regulated parties that, say, FSIS has. Still, CPSC does have a substantial surveillance system, consisting not only of the premarket lab tests but also of the statutory obligation of manufacturers and importers—as

⁵⁵⁸ *Consumer Product Safety Commission: Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs; Final Rule*, U.S. GOV’T ACCOUNTABILITY OFF. (Jan. 20, 2011), <https://www.gao.gov/fedrules/165077> [<https://perma.cc/R3AQ-T57H>].

⁵⁵⁹ Congressional Review Act, Pub. L. No. 104-121, 110 Stat. 868 (1996).

⁵⁶⁰ For the rule, see *Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs; Final Rule*, 75 Fed. Reg. at 81,766. On going beyond ASTM, see 2011 CONSUMER PROD. SAFETY COMM’N ANN. REP. 13. For confirmation this was a ban, see Press Release, Off. of Rep. Jan Schakowsky, Schakowsky, CPSC Announce New Federal Rules to End Dangerous Drop-Side Cribs (Dec. 15, 2010), <https://schakowsky.house.gov/media/press-releases/schakowsky-cpsc-announce-new-federal-rules-end-dangerous-drop-side-cribs> [<https://perma.cc/Z55P-J4CZ>].

⁵⁶¹ Hunter & Montuori, *supra* note 491, at 236.

⁵⁶² Interview with Rick Locker, law firm partner and independent general counsel to many children’s product manufacturer associations (Sept. 6, 2024).

⁵⁶³ DATASET, *supra* note 10, Files 25–26.

⁵⁶⁴ U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 492, at 1.

well as distributors and retailers—to report product defects,⁵⁶⁵ lest they become liable for civil penalties that have, in recent times, led to settlements with individual companies that average several million dollars each.⁵⁶⁶ And at least for larger players, hazard investigations and negotiations of recalls can be repeat games in which a company's reputation for compliance vis-à-vis CPSC can matter. According to one law firm alert in 2024, amid the aggressive posture taken by CPSC during the Biden Administration, “companies are increasingly inclined to take such voluntary actions [i.e., agree to agency requests for recalls] to avoid further scrutiny from the CPSC and other regulators—even when a voluntary recall may not be warranted” on the legal merits.⁵⁶⁷

Given the substantial but not intimate relationship of companies to CPSC, there is probably more explanatory punch in another factor: companies' concern about consumer perceptions of their products' safety. Children's product companies seem to believe that “safety sells.” The phrase has been appearing in CPSC-company discourse about children's products since the early 1990s.⁵⁶⁸

To appreciate how companies' aversion to publicly associating their brands with safety problems can discourage suing the agency, let us begin with the difficulties a company faces in litigating a challenge to an agency disclosure per se. As noted earlier, legislation prohibits CPSC from disclosing safety problems associated with a named company or named product in formats like CPSC's public database or unilateral press releases if the information does not meet certain standards of accuracy.⁵⁶⁹ A company can enforce these statutory standards against CPSC by suing to halt disclosure, but such a suit will itself normally be

⁵⁶⁵ 15 U.S.C. § 2064(b); RUBEL ET AL., *supra* note 490, at 9.

⁵⁶⁶ RUBEL ET AL., *supra* note 490, at 20.

⁵⁶⁷ Erik K. Swanholt, Nathan A. Beaver, Nicholas R. Johnson, Kristin McGaver Sikora & Mikaela R. Mitcham, *2024 CPSC and FDA Enforcement Trends*, FOLEY LARDNER (Aug. 29, 2024) <https://www.foley.com/insights/publications/2024/08/2024-cpsc-fda-enforcement-trends/> [<https://perma.cc/PZ8Q-LJ9C>].

⁵⁶⁸ See, e.g., Jacqueline Jones-Smith, Chairman, CPSC, Remarks Before the International Consumer Product Health and Safety Organization 6 (Mar. 3, 1994), https://www.cpsc.gov/s3fs-public/pdfs/foia_consumerhealth.pdf [<https://perma.cc/S6HJ-6E7J>] (“Two years ago, I began several CPSC ‘Safety Sells’ initiatives with an emphasis on the toy and juvenile products industries—industries that cater to the most vulnerable segment of our population. In partnership with such companies as Hasbro, Fisher-Price, Toys R Us, and Mattel, CPSC provides child-safety information to consumers in a variety of ways.”); see also, e.g., Press Release, CPSC, CPSC to Sponsor “Safety Sells” Conference March 28th, (Mar. 3, 1995), <https://www.cpsc.gov/Newsroom/News-Releases/1995/CPSC-To-Sponsor-Safety-Sells-Conference-March-28th> [<https://perma.cc/H3R7-3EG4>] (“The one-day conference, called ‘Safety Sells,’ will feature corporate executives from major companies who will highlight product safety as an emerging business trend. Ann Brown, CPSC chairman, will host the event. . . . The lineup of featured speakers includes Michael Goldstein, CEO of Toys ‘R’ Us; Alan Hassenfeld, chairman and CEO of Hasbro Inc;” and others.).

⁵⁶⁹ See *supra* notes 506–09 and accompanying text.

public. As one law firm has noted with regard to suits to block unilateral press releases, “the litigation itself inevitably requires the disclosure of the very information the company is trying to prevent—any victory for the company would be a pyrrhic one at best.”⁵⁷⁰

The only way for a company to dodge this problem is to keep secret the judicial challenge itself, but the track record on accomplishing that is not encouraging for industry. Recall ERGO Baby. It sued to block the posting of an infant-death report about its product in a public database, predicting the posting would “destroy [its] brand goodwill and commercial reputation.”⁵⁷¹ The company won a ruling that the report was materially inaccurate and thus could not lawfully be posted, plus a ruling that the company could remain pseudonymous and keep most of the lawsuit under seal.⁵⁷² When consumer groups challenged the pseudonymity-and-sealing ruling, ERGO Baby fought them up to the appellate level, trying to keep secret a lawsuit *in which it had won a merits victory that nobody was challenging*. The Fourth Circuit ruled against ERGO Baby in a decidedly bad-for-industry holding that the public’s right of access to court records outweighed the company’s concern about public embarrassment.⁵⁷³ There have been no other public judicial challenges to CPSC informational disclosures about specific companies since ERGO Baby’s loss in 2014.⁵⁷⁴

While the litigation just described was about CPSC disclosure per se, the threat of such disclosure can play a big role in other types of CPSC activity beyond purely informational matters, including the adjudication and negotiation of recalls. Although it is rare for CPSC to actually issue unilateral press releases,⁵⁷⁵ agency staff may use the possibility of a release “to persuade a company to conduct a ‘voluntary’ recall.”⁵⁷⁶ Indeed, one Commissioner has said the threat of such releases can “create leverage in corrective action plan negotiations” for a recall.⁵⁷⁷

When I asked interviewee Rick Locker (who is independent general counsel to many children’s product manufacturer associations) why

⁵⁷⁰ *Consumer Product Safety Act, Section 6(b): Myth Versus Fact*, MINTZ (Jan. 20, 2020), <https://www.mintz.com/sites/default/files/media/documents/2020-01-20/Section%206b%20Myth%20v%20Fact%20Sheet%20%2800089014%29.pdf> [<https://perma.cc/3LXS-BS8Z>].

⁵⁷¹ Complaint, *supra* note 536, at 2.

⁵⁷² *Doe v. Tenenbaum*, 900 F. Supp. 2d 572, 583–612 (D. Md. 2012), *rev’d in part sub nom. Doe v. Pub. Citizen*, 749 F.3d 246 (4th Cir. 2014).

⁵⁷³ *Doe*, 749 F.3d at 265–75.

⁵⁷⁴ To be sure, there is Dreamland Baby’s challenge, filed after the close of the search period and discussed *supra* note 537, but that suit’s target is guidance to the public about the danger of a general product type, not a named product or company. See Complaint for Declaratory and Injunctive Relief, *supra* note 537, at 2. Theoretically there could have been other suits that were kept entirely under seal, but that seems unlikely for the reasons discussed *supra* note 545.

⁵⁷⁵ See U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 492, at 11.

⁵⁷⁶ RUBEL ET AL., *supra* note 490, at 11–12.

⁵⁷⁷ See U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 492, at 11 (paraphrasing the commissioner).

a children's product company might not sue CPSC on a matter in which the company could win on the merits, the first factor he brought up was that "in the children's product space, there's the public perception—even if you're correct legally and the correct due process has not been followed [by the agency]—that the industry is not focused on safety and is litigating with the regulator that enforces safety requirements. And that public perception is always a concern."⁵⁷⁸

The story of Fisher-Price and its once-popular inclined sleeper, the "Rock 'n Play," illustrates how rapidly and decisively the prospect of publicity can push a brand-name company to conduct a major recall. CPSC began confidentially investigating the Rock 'n Play in early 2018 for possibly causing infant deaths.⁵⁷⁹ In April 2018, Fisher-Price provided data to the agency and pushed back against the idea that the product was defective.⁵⁸⁰ CPSC then asked a university orthopedist for a study of the product.⁵⁸¹ When CPSC later received preliminary study findings that the product was unsafe, combined with additional death reports, it suddenly told Fisher-Price on April 1, 2019 that it planned to issue a public warning about the product.⁵⁸² Fisher-Price reacted speedily. Three days later, on April 4, the company told CPSC that it wished to conduct a fast-track recall,⁵⁸³ which it announced on April 12, covering 4.7 million units.⁵⁸⁴

These events suggest that the prospect of CPSC publicity can strongly motivate a company to conduct a recall. Admittedly, the episode is complicated by the fact that while the agency was obtaining the preliminary study findings and additional death reports leading up to April 1, its staffers also "inadvertently" disclosed nonpublic data about the Rock 'n Play's dangers to *Consumer Reports*, which then refused CPSC's request to destroy the data and instead asked Fisher-Price for comment about the data on April 1.⁵⁸⁵ Thus, CPSC and Fisher-Price's respective decisions to go public and to recall the product may have been motivated in part by a desire to "get ahead of" an explosive story that they knew was going to be published by *Consumer Reports*. Without the inadvertent disclosure to *Consumer Reports*, one might imagine

⁵⁷⁸ Interview with Rick Locker, *supra* note 562.

⁵⁷⁹ STAFF OF H. COMM. ON OVERSIGHT & REFORM, 117TH CONG., INFANT DEATHS IN INCLINED SLEEPERS: FISHER-PRICE'S ROCK 'N PLAY REVEALS DANGEROUS FLAWS IN U.S. PRODUCT SAFETY 21–22 (Comm. Print 2021).

⁵⁸⁰ *Id.* at 24.

⁵⁸¹ *Id.* at 25–26.

⁵⁸² *Id.* at 27–28.

⁵⁸³ *Id.* at 28.

⁵⁸⁴ *Fisher-Price Recalls Rock 'n Play Sleepers Due to Reports of Death*, U.S. CONSUMER PROD. SAFETY COMM'N (Apr. 12, 2019), <https://www.cpsc.gov/Recalls/2019/Fisher-Price-Recalls-Rock-n-Play-Sleepers-Due-to-Reports-of-Deaths> [<https://perma.cc/KN2C-YPJ9>].

⁵⁸⁵ STAFF OF H.R. COMM. ON OVERSIGHT & REFORM, 117TH CONG., *supra* note 579, at 28.

that CPSC might not have moved as decisively toward giving a public warning or, if it had, Fisher-Price might have tried suing—under seal—to stop the public warning. But then again, ERGO Baby’s previous failure would have given serious pause to Fisher-Price, and the company’s actual behavior still suggests in a broad sense that publicity can greatly influence the behavior of children’s product companies.

Of course, sensitivity to agency publicity may vary among companies, and it may be weaker for companies not as well-known as Fisher-Price. CPSC specialists at Arnold and Porter note that cases where adverse CPSC publicity fails to motivate a recall are “particularly those involving smaller, less-conspicuous companies or non-U.S. manufacturers selling products on third-party internet platforms.”⁵⁸⁶ But although these small companies may have less reputational reason to refrain from suing, they also have fewer resources to bring suit, which prevents them from becoming a force for litigation. Furthermore, CPSC does have some leverage over smaller manufacturers and importers, because it can influence large retailers to stop carrying those companies’ products if it considers them unsafe: CPSC “staff has on occasion, over the manufacturer’s objection, notified retailers of an alleged product hazard and requested that [the retailers] stop selling the product.”⁵⁸⁷ There are clear examples of retailers following the agency’s views. One involved Leachco’s infant lounger, the Podster. “Because of the Commission’s allegations [that the product is unsafe], large retailers like Amazon, Buy Buy Baby, and Bed, Bath, and Beyond no longer carry the Podster.”⁵⁸⁸ Interviewee Locker said:

[Y]ou can count the number of retailers . . . on one hand that account for probably, almost in any industry, eighty, eighty-five percent of the market. And so if you have a regulator who tells one of those retailers, “If I were you, I wouldn’t sell this product,” or tells the consumer, “don’t buy this product,” and

⁵⁸⁶ RUBEL ET AL., *supra* note 490, at 12.

⁵⁸⁷ *Id.*

⁵⁸⁸ Verified Complaint for Injunctive & Declaratory Relief, *supra* note 522, at 5. For CPSC’s initial warning against the Podster, see *CPSC Warns Consumers: Stop Using the Leachco Podster, Podster Plush, Bummie and Podster Playtime Infant Loungers Due to Suffocation Hazard; Two Infant Deaths Investigated*, CONSUMER PROD. SAFETY COMM’N (Jan. 20, 2022), <https://www.cpsc.gov/Warnings/2022/CPSC-Warns-Consumers-Stop-Using-the-Leachco-Podster-Podster-Plush-Bummie-and-Podster-Playtime-Infant-Loungers-Due-to-Suffocation-Hazard-Two-Infant-Deaths-Investigated> [<https://perma.cc/VXK5-5H2Z>]. For another example, see Joe Hernandez, *Amazon, Target and Other Retailers Pull Weighted Infant Sleepwear Over Safety Fears*, NPR (May 7, 2024, 2:07 PM), <https://www.npr.org/2024/05/02/1248194639/weighted-infant-sleepwear-amazon-target-safety> [<https://perma.cc/5XCR-WPWQ>].

they do so before any sort of due process, you basically can put companies out of business.⁵⁸⁹

Most businesses looking at the economic damage Leachco has sustained, said Locker, would say to themselves, when contemplating suit against CPSC, “I might win the battle but lose the war end in the end, if my business is damaged.”⁵⁹⁰ Indeed, a larger company also making infant loungers, Boppy, agreed to a recall of 3.3 million units about a year before Leachco’s refusal to agree became public.⁵⁹¹

F. Nuclear Plant Operators and NRC

The sixth industry-agency pairing this Article addresses is nuclear plant operators and the NRC. Like the previous five pairings, this pairing has seen a history of very few industry judicial challenges, coupled with a thick company-regulator relationship and alignment of industry

⁵⁸⁹ Interview with Rick Locker, *supra* note 562.

⁵⁹⁰ *Id.*

⁵⁹¹ Rachel Rabkin Peachman, *Millions of Boppy Loungers Recalled After Products Linked to Infant Deaths*, CONSUMER REPS. (Sept. 23, 2021), <https://www.consumerreports.org/baby-product-recalls/boppy-loungers-recalled-linked-to-infant-deaths-a9736180995/> [https://perma.cc/XZV4-AYKM]. To be sure, if we look beyond companies that focus on manufacturing or importing children’s products, things are different. Factors like the company’s relationship to CPSC and the company’s sensitivity to consumer perceptions of safety tend to weaken, so judicial challenges become more likely. This is the case with Amazon. Although Amazon has long been recognized as a distributor and retailer—and sometimes importer—of products it sells directly, CPSC has recently sought to designate the company as a distributor with regard to its “Fulfilled by Amazon” business. RUBEL ET AL., *supra* note 490, at 12–13. And CPSC has signaled interest in imposing more responsibility on Amazon in this distributor capacity—including responsibility for recalls—than the agency has historically tended to impose on distributors as compared with manufacturers or importers. *Id.* (noting this shift at CPSC); Amazon.com, Inc., CPSC Docket No. 21-2, at 18–19 (CPSC July 29, 2024) (seeking to make Amazon conduct recalls in its capacity as distributor). Amazon has sued. *See generally* Complaint for Declaratory and Injunctive Relief, Amazon.com, Inc. v. CPSC, No. 25-cv-00853 (D. Md. Mar. 14, 2025).

In proportion to its size, Amazon has historically had a thin relationship with CPSC in terms of being a legally responsible party for recalls, and Amazon appears to be less sensitive to consumer safety perceptions than are companies specializing in children’s products, given Amazon’s vast diversification beyond that category—and beyond the whole universe of safety-sensitive categories. Consider the CPSC database of recalls for the period during which responsible importers, manufacturers, and distributors are listed for most recalls (April 1, 2015, through November 21, 2024), for which I downloaded all results in an Excel file that I searched for company names. With regard to *all* products (not just children’s), Amazon has been listed as importer for five recalls, in three of which another company was also listed as responsible, DATASET, *supra* note 10, File 65, Rows 603, 802, 923, 1158, 1523 (tab titled “Imprs-Mfgs-Dists”), and as distributor for four recalls, always with another company also listed as responsible, *id.* File 65, Rows 192, 881, 1822, 1889. By contrast, Fisher-Price has been listed as importer for six recalls, never with another company listed as responsible, *id.* File 65, Rows 604, 1508, 1568, 1616, 1939, 2397, and distributor for four, never with another company listed as also responsible, *id.* File 65, Rows 34, 59, 203, 361. That is, Amazon saw fewer recalls than Fisher-Price despite being 200 times larger than Fisher-Price in terms of revenue.

interests with the regulator's safety mission. But the mechanism for that alignment is different than in the other five pairings. Instead of consumer protection, nuclear plant operators are aligned with the NRC's mission due to the public's unique terror of nuclear accidents, which renders nuclear power's political survival dependent on credible regulation in a way that has no parallel among American industries.

First, a word about the nature and significance of the industry that the NRC regulates. The original owner-operators of nuclear plants—electric utilities—initiated construction of many such plants in the 1960s and 1970s, which continued to reach completion and start operations through the 1980s.⁵⁹² Nuclear power's share of the production of U.S. electricity rose fairly steadily from just over two percent in 1971 to nearly twenty percent in 1988.⁵⁹³ It did not rise much further.⁵⁹⁴ By the late 1970s, orders had overshot demand, inflation made it harder for utilities to raise money, and antinuclear sentiment gathered force.⁵⁹⁵ That sentiment was intensified by the partial meltdown of one of the reactors at Three Mile Island ("TMI") in 1979, which caused over 140,000 people to evacuate the area,⁵⁹⁶ although it ultimately had no detectable health effects.⁵⁹⁷ After TMI, orders for many plants were canceled, and new orders for plants ceased entirely.⁵⁹⁸ New orders have resumed only recently, starting in the 2010s, and in a minor and halting way.⁵⁹⁹ Though not growing, nuclear power's share of U.S. electricity has remained steady in the range of eighteen percent to twenty-one percent from 1990 through 2023.⁶⁰⁰ Although the reactor fleet was originally operated entirely by utilities which also distributed electricity to homes and businesses, since the 1990s, about half the plants have been gradually sold

⁵⁹² *Nuclear Reactors in United States of America*, WORLD NUCLEAR ASS'N: REACTOR DATABASE, <https://world-nuclear.org/nuclear-reactor-database/summary/United%20States%20Of%20America> [<https://perma.cc/538M-J8DE>].

⁵⁹³ *U.S. Nuclear Generating Statistics*, NUCLEAR ENERGY INST., <https://www.nei.org/resources/statistics/us-nuclear-generating-statistics> [<https://perma.cc/WV3K-QWNU>].

⁵⁹⁴ *Id.*

⁵⁹⁵ BONNIE A. OSIF, ANTHONY J. BARATTA & THOMAS W. CONKLING, *TMI 25 YEARS LATER: THE THREE MILE ISLAND NUCLEAR POWER PLANT ACCIDENT AND ITS IMPACT* 85 (2004).

⁵⁹⁶ Robert A. Stallings, *Evacuation Behavior at Three Mile Island*, 2 INT'L J. MASS EMERGENCIES & DISASTERS 11, 12–13 (1984).

⁵⁹⁷ *Backgrounder on the Three Mile Island Accident*, U.S. NUCLEAR REGUL. COMM'N, <https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/3mile-isle.html> [<https://perma.cc/F4DK-BA3F>]; see also Padmaparna Ghosh, *Nuclear Power 101*, NAT. RES. DEF. COUNCIL (Jan. 5, 2022), <https://www.nrdc.org/stories/nuclear-power-101> [<https://perma.cc/96EV-R547>] ("[S]ome epidemiological studies have found inconclusive evidence that the radiation influenced cancer risk.").

⁵⁹⁸ OSIF ET AL., *supra* note 595, at 85–86.

⁵⁹⁹ See, e.g., Zach Bright, *What Vogtle's Stumbling Finish Means for U.S. Nuclear Energy*, E&E NEWS (July 31, 2023, 8:45 AM), <https://www.eenews.net/articles/what-vogtles-stumbling-finish-means-for-u-s-nuclear-energy/> [<https://perma.cc/6978-8UHL>].

⁶⁰⁰ *U.S. Nuclear Generating Statistics*, *supra* note 593.

to independent power producers (“IPPs”) who operate the plants and sell the power onto the grid to be distributed by others.⁶⁰¹ Throughout the industry’s history, 135 reactors have been built.⁶⁰² Ninety-four of these reactors across fifty-four plants are currently online,⁶⁰³ and they are operated by a mix of about twenty-five utilities and IPPs.⁶⁰⁴

All this nuclear electricity has been produced without the dangers of fossil fuels, such as greenhouse gases and deadly pollutants like particulate matter. The substitution of nuclear for fossil-fuel generation over the period of 1971–2009 is estimated to have prevented 580,000 deaths nationwide.⁶⁰⁵

The mission of the NRC since its founding in 1974 has been to guard against the principal threat to public health that does arise from nuclear power: the risk of emitting radiation due to an accident in plant operation or from the inadequate storage of waste such as spent fuel.⁶⁰⁶ No plant can operate without an NRC license, which bindingly specifies how the plant is to be designed and operated.⁶⁰⁷ The specifications about operations include “licensing basis” materials that can run to thousands of pages, tailored to the plant, and from which any departure is a violation.⁶⁰⁸ Although recent decades have seen few license applications

⁶⁰¹ On the liberalization of electricity markets and the rise of IPPs generally, see Emily Hammond & David B. Spence, *The Regulatory Contract in the Marketplace*, 69 VAND. L. REV. 141, 151–52 (2016). On the first sales of nuclear plants to merchant generators, see THOMAS R. WELLOCK, *SAFE ENOUGH? A HISTORY OF NUCLEAR POWER AND ACCIDENT RISK* 132 (2021). For the proportion of reactors now operated by utilities as compared with IPPs, compare the list of reactors and their owners and operators, *List of Power Reactor Units*, U.S. NUCLEAR REGUL. COMM’N (Feb. 21, 2025), <https://www.nrc.gov/reactors/operating/list-power-reactor-units.html> [<https://perma.cc/7UTF-2NPM>], with the list of utility operating companies and parents, *EEI U.S. Member Company Service Territories*, EDISON ELEC. INST. (Aug. 2024), <https://www.eei.org/-/media/Project/EEI/Documents/About/EEI-Member-Map.pdf> [<https://perma.cc/2VGX-TCBT>].

⁶⁰² *Nuclear Power in the USA*, WORLD NUCLEAR ASS’N: COUNTRY PROFILES (June 6, 2025), <https://world-nuclear.org/information-library/country-profiles/countries-t-z/usa-nuclear-power> [<https://perma.cc/BS8F-C94L>].

⁶⁰³ *Id.*

⁶⁰⁴ See *List of Power Reactor Units*, *supra* note 601 (column titled “Owner/Operator”). I counted companies with the same parent name—e.g., the various Exelon subsidiaries—as one company.

⁶⁰⁵ Pushker A. Kharecha & James E. Hansen, *Prevented Mortality and Greenhouse Gas Emissions from Historical and Projected Nuclear Power*, 47 ENV’T SCI. & TECH. 4889, 4891 & fig.2 (2013).

⁶⁰⁶ See *About NRC*, U.S. NUCLEAR REGUL. COMM’N (Feb. 4, 2025), <https://www.nrc.gov/about-nrc.html> [<https://perma.cc/UD9S-W47L>]. Note that the NRC is a successor agency to the Atomic Energy Commission. *History*, U.S. NUCLEAR REGUL. COMM’N (Feb. 20, 2025), <https://www.nrc.gov/about-nrc/history.html> [<https://perma.cc/XM9Z-DEZ6>].

⁶⁰⁷ *Oversight Program*, U.S. NUCLEAR REGUL. COMM’N (May 20, 2024), <https://www.nrc.gov/reactors/operator-licensing/oversight-programs.html> [<https://perma.cc/B6UW-8GC8>].

⁶⁰⁸ WELLOCK, *supra* note 601, at 138; BRIAN W. SMITH, U.S. NUCLEAR REGUL. COMM’N, *FROM 40 TO 60 TO 80 YEARS—WHAT IS NEXT FOR LICENSE RENEWAL IN THE USA?* 2–3 <https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML22286A004> [<https://perma.cc/9QCV-DQ5S>];

for new plants, there have been numerous applications for renewals, with many plants now operating on a twenty-year renewal of their original forty-year license and with several receiving a second twenty-year renewal.⁶⁰⁹ Nor is renewal the NRC's only opportunity to formulate new specifications. The NRC has the power to amend, or "backfit," any license during its term.⁶¹⁰ On top of that, the agency can promulgate generic rules applying to all plants.⁶¹¹ License requirements and generic rules are enforced by NRC inspectors who are on-site in every plant full-time.⁶¹² The agency has power to shut down any plant that is not operating safely, meaning the plant cannot restart until it meets conditions set by the agency.⁶¹³ The agency can also impose money penalties.⁶¹⁴

Nuclear plant operators and their associations have brought vanishingly few judicial challenges to the NRC on health or safety.⁶¹⁵ Although the core study period for this Article is January 20, 2013, through January 20, 2021, the nature of the NRC means we can easily gather data on a longer time period. Like CPSC, the NRC is a free-standing agency, so a relatively low-cost Bloomberg dockets search of the defendant and respondent fields for the NRC's name and acronym and the names of its successive chairs will very likely catch all challenges to the agency, in contrast to agencies like FSIS that are part of a larger department. A search for NRC defendants or respondents over the thirty-five-year period from 1989 through January 20, 2024, yields many suits to which nuclear plant operators or their associations were parties.⁶¹⁶ However, these operators and associations overwhelmingly played the role of intervenors in favor of the NRC.⁶¹⁷ There was neither litigation in which any nuclear plant operator was a petitioner or plaintiff against the NRC, nor, it seems, litigation where any operator was an intervenor against the NRC,⁶¹⁸ except one dispute in 1993

Interview with Anonymous Interviewee #4, In-house counsel to a nuclear plant operator (Sept. 18, 2024).

⁶⁰⁹ WELLOCK, *supra* note 601, at 133, 144, 201; Smith, *supra* note 608, at 4.

⁶¹⁰ Emily Hammond, *Nuclear Power, Risk, and Retroactivity*, 48 VAND. J. TRANSNAT'L L. 1059, 1068–71 (2015); WELLOCK, *supra* note 601, at 128, 136.

⁶¹¹ See Hammond & Spence, *supra* note 601, at 175.

⁶¹² See WELLOCK, *supra* note 601, at 139, 200; 10 C.F.R. § 50.70.

⁶¹³ E.g., WELLOCK, *supra* note 601, at 200 (discussing the NRC's conditions for restarting the Davis-Besse nuclear plant owned by FirstEnergy Nuclear Operating Company).

⁶¹⁴ *Id.* at 197.

⁶¹⁵ It is more common, if still unusual, for other nuclear-industry companies besides plant operators to challenge the NRC, particularly fuel producers. See, e.g., *Honeywell Int'l, Inc. v. NRC*, 628 F.3d 568 (D.C. Cir. 2010).

⁶¹⁶ See DATASET, *supra* note 10, File 28 (covering PFRs in the courts of appeals); *id.* File 27 (covering civil actions in district courts).

⁶¹⁷ *Id.* Files 27–28.

⁶¹⁸ There were six suits, confined to the period of 1989–1993, in which nuclear plant operators were intervenors without information as to which side they were taking and for which Bloomberg

did not have underlying filings that might give the answer. *DATASET*, *supra* note 10, File 28, Rows 194, 197, 199, 201, 207–08. Given the overwhelming tendency of operator-intervenors to be on the NRC’s side, that was likely the case with these six suits, as well. There were three other suits in which one of the challengers might appear to have been a plant operator but was not, *see DATASET*, *supra* note 10, File 28, Rows 182–83, 161, 42. For further discussion of these three disputes, see below:

- Cajun Electric Power Cooperative was a minority owner of River Bend nuclear plant, in which Gulf States Utilities (“GSU”) was majority owner. Entergy Corp., Annual Report (Form 10-K) 35 (Feb. 29, 1996) (“GSU and Cajun, respectively, own 70% and 30% undivided interests in River Bend . . .”). Cajun accused GSU of fraud and other wrongdoing in this joint ownership. *Id.* GSU sought to merge with Entergy and applied to the NRC for two amendments to the River Bend license, the first for the NRC’s consent to the merger and the second to change the licensed operator “from GSU to Entergy Operations.” *Id.* The NRC issued the amendments, and Cajun challenged them via two PFRs in the D.C. Circuit. *Id.*; *Cajun Elec. Power Coop., Inc. v. NRC*, No. 94-1113 (D.C. Cir. Feb. 14, 1994) (challenging, alongside certain local electricity providers as copetitioners, Notice of Amendment, 58 Fed. Reg. 36,435 (July 7, 1993) (Amendment No. 69)); *Cajun Elec. Power Coop. v. NRC*, No. 94-1114 (D.C. Cir. Feb. 14, 1994) (challenging Notice of Amendment, 58 Fed. Reg. 36,436 (July 7, 1993) (Amendment No. 70)). GSU and Entergy were intervenors in both suits, obviously in favor of the NRC amendments that had been granted to GSU, though this alignment is not made explicit in the docket sheets. *See* Court Docket, *Cajun Elec.*, No. 94-1113 (May 4, 1994); Court Docket, *Cajun Elec.*, No. 94-1114 (May 4, 1994). For our purposes, the key point is that the challenger Cajun was never the “operator” of the plant: GSU was.
- Several government-owned electricity providers, as well as their collective trade association, sued the NRC in 1998, but they appear to have been minority owners of nuclear plants—not operators of them—and were challenging an NRC policy statement reserving the agency’s right to hold them jointly and severally liable for operating and decommissioning funds in the event that majority owners became insolvent. *See* Docket Information, *Am. Pub. Power Ass’n v. NRC*, No. 98-1219, 1998 WL 633796 (D.C. Cir. Aug. 3, 1998) (PFR filed Apr. 21, 1998). The challenged action was the Final Policy Statement on the Restructuring and Economic Deregulation of the Electric Utility Industry, 62 Fed. Reg. 44,071, 44,076–77 (Aug. 19, 1997) (to be codified at 10 C.F.R. pt. 50) (“Many of the NRC’s power reactor licensees own their plants jointly with other, unrelated organizations. Although some co-owners may only be authorized to have an ownership interest in the nuclear facility and its nuclear material, and not to operate it, the NRC views all co-owners as co-licensees who are responsible for complying with the terms of their licenses. The NRC is concerned about the effects on the availability of operating and decommissioning funds, and about the division of responsibility for operating and decommissioning funds, when co-owners file for bankruptcy or otherwise encounter financial difficulty. The NRC recognizes that co-owners and co-licensees generally divide costs and output from their facilities using a contractually defined, pro rata share standard. The NRC . . . reserves the right, in highly unusual situations . . . to consider imposing joint and several liability on co-owners of more than *de minimis* shares when one or more co-owners have defaulted.” (citation and footnote omitted)). For the agency’s description of the suit, see JOHN F. CORDES, JR., NUCLEAR REGUL. COMM’N, SECY-98-143, LITIGATION REPORT (1998), <https://www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-143/1998-143scy.pdf> [<https://perma.cc/J7YX-ZNZZ>] (stating that the petitioners in *Am. Pub. Power Ass’n*, No. 98-1219, attack the

concerning the NRC's non-health-and-safety antitrust functions.⁶¹⁹ And there were only two suits involving any association of operators in any role adverse to the NRC. Both involved the operators' principal trade association, Nuclear Energy Institute ("NEI"), which was formed in 1994 by a merger of predecessor associations.⁶²⁰ NEI was petitioner in a 2019 suit regarding very low-level waste ("VLLW")⁶²¹ and was amicus against the NRC in two related 2010–2011 suits to stop NRC delay in deciding whether to approve Yucca Mountain as a waste repository.⁶²² None of these suits reflect major industry resistance to NRC safety regulation. The VLLW suit was minor. The question was whether an NRC letter had altered the agency's stance on whether state governments could decide the requirements for how operators may undertake intra-state disposal of the least dangerous forms of radioactive waste.⁶²³ The D.C. Circuit, in ruling against NEI, did not issue a published opinion,⁶²⁴ and a search of the Factiva database—with its wealth of trade-press material on the regulation of energy, including nuclear energy—for the full names of the NRC and NEI for the period from the letter's issuance to one month after the court's decision yields no headlines on the letter or the lawsuit.⁶²⁵ As for the Yucca Mountain suits, NEI faced an unusual situation in which NRC staff and four of its five commissioners were

policy statement "insofar as it suggested that the NRC in some future circumstances might impose joint and several liability for nuclear plant costs on minority owners").

- The suit *Vermont v. NRC*, No. 15-1279, 2016 U.S. App. LEXIS 2201 (D.C. Cir. Feb. 8, 2016), may look like an operator challenge because the petitioners included Vermont Yankee Nuclear Power Corporation and Green Mountain Power Corporation, but the plant at issue was no longer owned by either company; its "owner/operator" was instead Entergy, which intervened on the NRC's side. Petition for Review at 2, *Vermont*, No. 15-1279, 2016 U.S. App. LEXIS 2201 (filed Aug. 13, 2015).

⁶¹⁹ *City of Cleveland, Ohio v. NRC*, 68 F.3d 1361, 1366 (D.C. Cir. 1995) (covering case Nos. 92-1532, 93-1665, 93-1672, 93-1673).

⁶²⁰ *Trade Associations: Nuclear Energy Institute*, STANDARDSPORTAL.ORG, https://www.standardsportal.org/usa_en/trade_associations/nei.aspx [<https://perma.cc/78YM-MYFZ>].

⁶²¹ Petition for Review at 2, *NEI v. NRC*, 857 F. App'x 2 (D.C. Cir. 2021) (No. 19-1240).

⁶²² Brief of Amicus Curiae Nuclear Energy Institute in Support of the Petitioners, *In re Aiken Cnty.*, 645 F.3d 428 (D.C. Cir. 2011) (No. 10-1069); Brief of Amicus Curiae Nuclear Energy Institute, Inc. in Support of Petitioners at 9–11, *In re Aiken Cnty.*, 725 F.3d 255 (D.C. Cir. 2013) (No. 11-1271).

⁶²³ Petitioner Nuclear Energy Institute's Opening Brief at 1–3, 6, *NEI*, 857 F. App'x 2 (No. 19-1240).

⁶²⁴ *NEI*, 857 F. App'x 2 (mem.).

⁶²⁵ Factiva search for "*Nuclear Regulatory Commission*" and "*Nuclear Energy Institute*" in date range September 16, 2019, through June 4, 2021. There were two headlines about the larger issue of NRC policy regarding VLLW disposal, but they concerned a proceeding separate from the lawsuit over the letter—that is, an NRC proposal to deregulate VLLW treatment via interpretive rule, which NEI joined environmental groups in opposing; neither story mentioned the lawsuit or the letter. See Suzanne Yohannan, *Nuclear Energy Industry Raises Broad Concerns Over NRC Waste Plan*, INSIDE EPA, Oct. 30, 2020; Suzanne Yohannan, *After Major Pushback, NRC Drops Plan to Ease Nuclear Waste Disposal*, INSIDE EPA, Dec. 18, 2020.

at odds with the Commission's maverick Chairman Gregory Jaczko—a protégé of anti-Yucca Nevada Senator Harry Reid—who effectively stopped the review that NEI, agency staff, and the four other commissioners all wanted to go forward.⁶²⁶ Here, NEI was, if anything, aligned with the NRC as an institutional whole.⁶²⁷

It appears the dearth of operator suits against the NRC extends back in time roughly, though not exactly, to TMI in 1979. If we search the Westlaw database of judicial opinions from TMI in 1979 through 1988—which could admittedly miss suits—we find two operator challenges involving nuclear health and safety.⁶²⁸ One, by Connecticut Light and Power and other utilities in 1981, was a challenge against an important NRC regulation on protection against plant fires that could lead to disasters.⁶²⁹ The D.C. Circuit in 1982 upheld the regulation while emphasizing that it provided a generous exemption procedure for individual plants,⁶³⁰ and the agency did indeed end up granting a number of exemptions to every plant.⁶³¹ The other suit was far narrower: In 1984, Duke Power challenged a decision about the appropriate location of

⁶²⁶ The first suit named the NRC as one of the respondents, but it was really against the Department of Energy for seeking to withdraw its application to the NRC for approval of the Yucca Mountain site. *Aiken Cnty.*, 645 F.3d at 433; *see also* Petition for Review at 1, *Aiken Cnty.*, 645 F.3d 428 (No. 10-1069) (filed Mar. 26, 2010). The second suit was squarely against the NRC for failing to act on the Department's application, *see Aiken Cnty.*, 725 F.3d at 256; Petition for Writ of Mandamus at 2–3, *Aiken Cnty.*, 725 F.3d 255 (No. 11-1271) (filed July 29, 2011), though that failure was really the work of Chair Jaczko in opposition to the NRC's other commissioners and its staff, *see Aiken Cnty.*, 725 F.3d at 267–68 (Randolph, J., concurring); Darius Dixon, *Jaczko Announces NRC Resignation*, POLITICO (May 21, 2012, 4:25 PM), <https://www.politico.com/story/2012/05/jaczko-announces-resignation-from-nrc-076568> [<https://perma.cc/G3KV-2KJB>] (referring to Jaczko as “a Harry Reid protégé”). Jaczko resigned during the litigation. Dixon, *supra*.

⁶²⁷ Interview with Anonymous Interviewee #4, *supra* note 608 (“Nobody in the NRC was going to be offended if the industry sued them on [the NRC's failure to review the Yucca Mountain application], because [NRC personnel] wanted, they actually secretly wanted that to happen [i.e., for the review to continue]. They wanted the court to come in and say, ‘no, you have to resume this review.’”).

⁶²⁸ The search was for “*Nuclear Regulatory Com!*” OR NRC in the title. It turned up one operator challenge regarding the scope of the NRC's authority to mitigate the impact of transmission line siting on general environmental matters under NEPA—a matter unrelated to radiation's health-and-safety effects. *See* *Detroit Edison Co. v. NRC*, 630 F.2d 450, 451 (6th Cir. 1980). The search also turned up some operator challenges to the NRC that were not about health, safety, or environment at all. Four concerned fees: *Fla. Power & Light Co. v. United States*, 846 F.2d 765, 766–67 (D.C. Cir. 1988); *Commonwealth Edison Co. v. NRC*, 830 F.2d 610, 611 (7th Cir. 1987); *New Eng. Power Co. v. NRC*, 683 F.2d 12, 12–13 (1st Cir. 1982); *Miss. Power & Light Co. v. NRC*, 601 F.2d 223, 225 (5th Cir. 1979). One concerned antitrust issues: *Ala. Power Co. v. NRC*, 692 F.2d 1362, 1363–64 (11th Cir. 1982); *see also* *Duke Power Co. v. NRC*, 670 F.2d 1234 (D.C. Cir. 1981) (unpublished table decision) (dismissing case without opinion).

⁶²⁹ *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 527 (D.C. Cir. 1982).

⁶³⁰ *Id.* at 537.

⁶³¹ Interview with Daniel Stenger, Partner, Hogan Lovells (Sept. 25, 2024).

one plant's emergency operations facility.⁶³² Thus, it seems the 1981 fire-protection suit was the last major industry judicial challenge to the NRC. Consistent with this, in my interview with Hogan Lovells partner Daniel Stenger, who has specialized in nuclear regulation full-time since the early 1980s, Stenger said the 1981 suit was the "last time" industry had sued the NRC on a "substantive safety regulation," and he mentioned no other industry judicial challenges in our seventy-five-minute discussion of operator-NRC legal relations.⁶³³

One might think that operators refrain from challenges because the judiciary has historically articulated a deferential approach to NRC expertise,⁶³⁴ but although this deference plays some role, it is not at all a sufficient explanation. As discussed earlier in the section on FDA, courts are entirely capable of giving a "hard look" to complex scientific agency decision-making, as they have historically done with EPA.⁶³⁵ As to the NRC particularly, one study notes that, despite the judicial rhetoric of "super deference," "there are occasional examples of much harder-look review," such as a 2012 D.C. Circuit ruling in favor of states' and environmentalists' challenge to an NRC waste rule.⁶³⁶ The last major industry challenge to the NRC, the 1981 fire-protection regulation suit, was no resounding victory for agency expertise: The D.C. Circuit sternly criticized the agency's process and reasoning, warned that it was upholding the rule only "reluctant[ly]," and signaled that the NRC should grant exemptions generously,⁶³⁷ which the agency then did.⁶³⁸ Moreover, to the extent the judiciary has articulated a deferential standard for the NRC, this may be as much an effect as a cause of the scarcity of operator challenges. Among potential challengers to agency action, industry tends to have the most resources and the highest level of sophistication—especially in a complex area like nuclear plant operation in which the operators by the nature of their business know more than anyone else.⁶³⁹ When industry sues little, the development of case-law on matters like deference is left to suits by less sophisticated and less resourced parties like NGOs, state and local governments, and

⁶³² *Duke Power Co. v. NRC*, 770 F.2d 386, 388 (4th Cir. 1985).

⁶³³ Interview with Daniel Stenger, *supra* note 631.

⁶³⁴ On the articulation of deference, see Ryan Lighty & Scott Clausen, *After Chevron: NRC Is Shielded From Loper Bright's Effects*, LAW360 (Aug. 5, 2024, 3:53 PM) <https://www.law360.com/articles/1865185/after-chevron-nrc-is-shielded-from-loper-bright-s-effects> [<https://perma.cc/F2VT-4F5J>]. Anonymous Interviewee #4, in-house counsel at a nuclear plant operator, cited judicial deference in explaining the paucity of industry challenges, but only as one of several causal factors. Interview with Anonymous Interviewee #4, *supra* note 608.

⁶³⁵ See *supra* note 264 and accompanying text.

⁶³⁶ Hammond, *supra* note 610, at 1080 (citing *New York v. NRC*, 681 F.3d 471, 481–83 (D.C. Cir. 2012)).

⁶³⁷ *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 528, 532, 535–37 (D.C. Cir. 1982).

⁶³⁸ See Interview with Daniel Stenger, *supra* note 631.

⁶³⁹ See Hammond, *supra* note 610, at 1080.

unions.⁶⁴⁰ In a recent article by a leading practitioner on the judiciary's historic articulation of a high level of deference to the NRC,⁶⁴¹ seven of the eight relevant cases cited were not brought by industry at all,⁶⁴² and the eighth was brought in 1977 by fuel producers with operators only as amici.⁶⁴³ The rhetoric of NRC caselaw might be different if industry were to bring the kind of full-court press that it historically brought against EPA.⁶⁴⁴

A further and necessary explanation for the dearth of operator challenges to the NRC is that operators' interests are fairly aligned with the NRC's antiradiation mission—far more aligned than are, say, fossil fuel generators' interests with EPA's antipollution mission. This is because of nuclear power's peculiar politics arising from the voting public's extraordinary dread of nuclear accidents, intensified by TMI in 1979.⁶⁴⁵ This is a different mechanism of industry-regulator alignment than the customer-protection story that we observed in the five industry-agency pairings in Sections A through E above, but it is a mechanism of alignment nonetheless.

Nuclear power faces a uniquely hard-to-negotiate political environment because of the voting public's extraordinary demand for protection against nuclear accidents as compared with other risks.⁶⁴⁶ People tend to want stricter regulation of risks that are, in psychological terms, more dreadful and less familiar, of which a nuclear accident is perhaps the ultimate example.⁶⁴⁷ “[High-d]read risks are . . . particularly susceptible to ‘punctuating events,’ that is, spectacular, high-profile, low-probability events that are processed by the brain as representative of the risks posed by a technology generally[,]” with TMI being a major instance, as well as the meltdowns of Chernobyl in 1986 and Fukushima in 2011.⁶⁴⁸ “Support for nuclear power [in the United States] . . . plunged after accidents like [TMI], Chernobyl, and Fukushima.”⁶⁴⁹ As discussed above,

⁶⁴⁰ Such parties are common among challengers to the NRC. See DATASET, *supra* note 10, File 28.

⁶⁴¹ Lightly & Clausen, *supra* note 634.

⁶⁴² See *id.* The cases, some of which were against the NRC's predecessor agency, with challenger type in parentheses, are *Power Reactor Dev. Co. v. Int'l Union of Elec., Radio & Mach. Workers, AFL-CIO*, 367 U.S. 396 (1961) (labor union); *Pub. Citizen v. NRC*, 573 F.3d 916 (9th Cir. 2009) (states and NGOs); *Nuclear Info. Res. Serv. v. NRC*, 969 F.2d 1169 (D.C. Cir. 1992) (NGOs); *Massachusetts v. NRC*, 924 F.2d 311, 315 (D.C. Cir. 1991) (states, localities, and NGOs); *Cnty. of Rockland v. NRC*, 709 F.2d 766 (2d Cir. 1983) (locality and NGOs); *Illinois v. NRC*, 591 F.2d 12 (7th Cir. 1979); *Siegel v. Atomic Energy Comm'n*, 400 F.2d 778 (D.C. Cir. 1968) (pro se individual).

⁶⁴³ *Westinghouse Elec. Corp. v. NRC*, 598 F.2d 759, 765 (3d Cir. 1979).

⁶⁴⁴ See MELNICK, *supra* note 266, at 20–21 tbl.I-I.

⁶⁴⁵ See OSIF ET AL., *supra* note 595, at 80.

⁶⁴⁶ See Hammond & Spence, *supra* note 601, at 178–84.

⁶⁴⁷ *Id.* at 181–83.

⁶⁴⁸ *Id.* at 183; WELLOCK, *supra* note 601, at 204, 219.

⁶⁴⁹ WELLOCK, *supra* note 601, at 219.

TMI perpetuated a multidecade drought of orders for new reactors.⁶⁵⁰ Although new orders had begun again by the time of Fukushima, that accident resulted in several U.S. companies canceling them,⁶⁵¹ not to mention prompting the German government to draw down its nuclear reliance from twenty-five percent to zero over the next twelve years.⁶⁵² In the words of Anonymous Interviewee #4, in-house counsel at a U.S. nuclear plant operator, “I can’t think of another industry [besides nuclear power] in which one big screwup is gonna shut the entire industry down, permanently, forever.”⁶⁵³

Public dread of nuclear accidents, intensified by the rare actual meltdown, has led, politically, to a situation where “the nuclear licensing scheme is one of the strictest in the United States, in terms of both the substantive requirements for adequate protection and the procedural requirements associated with obtaining licenses.”⁶⁵⁴ Other risks are neither subject to this psychology to the same degree nor to the consequent regulatory stringency: This is especially clear when it comes to harmful pollution from other electricity-generating fuels.⁶⁵⁵ The strictness of the regulatory scheme has forced nuclear plant operators to internalize the potential costs of radiation emissions to a far greater degree than fossil fuel generators have been forced to internalize the costs of the pollution they produce.⁶⁵⁶ This internalization consists of the investments that nuclear operators must make as a matter of compliance in things like “a highly trained workforce, backfits, upgrades, insurance payments, fuel management, and final waste disposal.”⁶⁵⁷ Lest this notion of internalization seem naive, I should note it is consistent with U.S. nuclear plants’ real-world safety record. They have produced about twenty percent of the nation’s electricity since 1990,⁶⁵⁸ and yet the operators’ entire history has seen no radiation accident with detectable health effects,⁶⁵⁹ in contrast to the hundreds of thousands of Americans who have died from fossil fuel pollutants like particulate matter.⁶⁶⁰

If acceptance of stringent NRC regulation is the price that nuclear plant operators must pay to avoid potentially fatal political opposition,

⁶⁵⁰ OSIF ET AL., *supra* note 595, at 85.

⁶⁵¹ See WELLOCK, *supra* note 601, at 214–15.

⁶⁵² *Nuclear Power in Germany*, WORLD NUCLEAR ASS’N: COUNTRY PROFILES (July 8, 2024), <https://world-nuclear.org/information-library/country-profiles/countries-g-n/germany> [<https://perma.cc/WEA9-XXLT>].

⁶⁵³ Interview with Anonymous Interviewee #4, *supra* note 608.

⁶⁵⁴ Hammond & Spence, *supra* note 601, at 182 (footnote omitted).

⁶⁵⁵ *Id.* at 184 (“[B]ecause nuclear power has unique risk perception attributes, it bears costs that other fuel sources do not bear.”).

⁶⁵⁶ *Id.* at 174, 177, 184, 190, 201.

⁶⁵⁷ *Id.* at 190.

⁶⁵⁸ *U.S. Nuclear Generating Statistics*, *supra* note 593.

⁶⁵⁹ See *supra* note 597 and accompanying text.

⁶⁶⁰ See Kharecha & Hansen, *supra* note 605, at 4891.

they understandably wish to get what they have bargained for in terms of the credible assurance of safety that NRC regulation provides to the voting public—a valuable benefit to the industry that suing the regulator would undermine. Anonymous Interviewee #4 cited this as a factor discouraging industry judicial challenges:

The industry gets a lot of political pressure which ebbs and flows over the years, depending on where the public is on nuclear. . . . But the industry often says, “Well, you can trust us because we have an independent, tough regulator that very closely watches what we’re doing, and they’re very vigorous and strong in how they regulate us. And so, that’s why you shouldn’t get all upset or worried about nuclear safety.”⁶⁶¹

This does not work if the industry is publicly getting judges to override the regulator. Noting that the political environment has now turned relatively favorable for nuclear power, Anonymous Interviewee #4 later said:

If [my] company were asking me, “Should we sue the NRC?” I couldn’t help but say, “Well, do you want the optics of a lawsuit against the NRC? The politics of this field right now are pretty good. Do you want to be in the position of . . . challenging the NRC, or looking like the bad guy? I mean, that’s not a good look.”⁶⁶²

Interviewee Daniel Stenger, the Hogan partner specializing in nuclear regulation, brought up a similar point in explaining the absence of litigation: “[P]sychologically, philosophically, . . . participants in the industry don’t want to be viewed as opposing health and safety regulation. So there’s kind of a bias against using judicial review as a normal part of the process.”⁶⁶³

Although the NRC has faced criticism over the years for going too soft on industry⁶⁶⁴—which might tempt us to think the real reason operators do not sue is that the NRC always lets them do as they please—one can find several striking instances where the NRC has pressed industry yet faced no lawsuits; agency forbearance is nowhere near a complete explanation of litigation’s absence.

Perhaps the best example is the NRC’s Systematic Assessment of Licensee Performance (“SALP”), which was the plant inspection and enforcement program the agency had in place from 1980, shortly

⁶⁶¹ Interview with Anonymous Interviewee #4, *supra* note 608.

⁶⁶² *Id.*

⁶⁶³ Interview with Daniel Stenger, *supra* note 631.

⁶⁶⁴ *E.g.*, WELLOCK, *supra* note 601, at 135, 198 (discussing a 1997 GAO report and NRC inspector general report circa 2002); Ghosh, *supra* note 597.

after TMI, until its replacement in 1998–2000.⁶⁶⁵ Under SALP, periodic inspections resulted in each plant receiving a rating; lower ratings meant greater inspector scrutiny and, if ratings were bad enough, inclusion on the dreaded “watch list.”⁶⁶⁶ This generally meant the agency would order—or successfully pressure—the plant to shut down until it corrected its problems.⁶⁶⁷ Over SALP’s nearly two decades, “more than three dozen nuclear reactors had to remain shut down for over a year while an army of workers corrected enough safety problems to permit the reactors to be safely restarted.”⁶⁶⁸ These included the shutdown of Maine Yankee in 1996, which never reopened because “abandonment was less costly than NRC-required upgrades,”⁶⁶⁹ plus the shutdown of all three reactors at Millstone in Waterford, Connecticut that same year—two of which the NRC kept closed for over two years and one of which closed forever.⁶⁷⁰ More generally, “joining the watchlist” was “a black eye that got upper management fired, sent utility stock prices tumbling, and required millions on maintenance and operational improvements.”⁶⁷¹ “By the early 1990s, the industry had turned decisively against the SALP”⁶⁷² In 1994, NEI hired a consulting firm that surveyed nuclear plant staff about the program.⁶⁷³ The consultant submitted a report in which “[i]ndustry respondents believed the NRC’s SALP rating system and dreaded ‘watch list’ of problem plants were arbitrary, secretive, and subject to the whims of NRC managers.”⁶⁷⁴ The consultant further argued that watch-listed companies were incurring shutdowns and enormous losses with “no safety benefit.”⁶⁷⁵ Such claims of irrationality and arbitrariness are classic bases for judicial challenges to agency action under the APA,⁶⁷⁶ yet neither NEI nor any plants sued on any SALP activities.⁶⁷⁷

⁶⁶⁵ On SALP adoption in 1980, see U.S. GOV’T ACCOUNTABILITY OFF., GAO-85-5, BETTER INSPECTION MANAGEMENT WOULD IMPROVE OVERSIGHT OF OPERATING NUCLEAR PLANTS 3 (1985). On the replacement of SALP with ROP in 1998–2000, see David Lochbaum, *Reactor Oversight Process*, EQUATION (Sept. 27, 2016, 6:00 AM), <https://blog.ucsusa.org/dlochbaum/reactor-oversight-process/> [<https://perma.cc/N9R7-FDJH>], and WELLOCK, *supra* note 601, at 141.

⁶⁶⁶ WELLOCK, *supra* note 601, at 123.

⁶⁶⁷ Interview with Daniel Stenger, *supra* note 631 (noting that the NRC follows a nominally voluntary shutdown with a public confirmatory letter that details corrections the operator will undertake).

⁶⁶⁸ Lochbaum, *supra* note 665.

⁶⁶⁹ WELLOCK, *supra* note 601, at 136–37.

⁶⁷⁰ *Id.* at 135–36.

⁶⁷¹ *Id.* at 124.

⁶⁷² *Id.*

⁶⁷³ *Id.* at 134.

⁶⁷⁴ *Id.*

⁶⁷⁵ *Id.*

⁶⁷⁶ See 5 U.S.C. § 706.

⁶⁷⁷ DATASET, *supra* note 10, Files 27–28.

The ultimate resolution of this struggle was entirely nonjudicial. In 1998, Senators led by Pete Domenici and including Harry Reid allied with the industry and used threats of budget cuts to force the NRC to scrap SALP and replace it with a new approach that continues to this day: the Reactor Oversight Process (“ROP”).⁶⁷⁸ ROP was similar to SALP in principle—it entailed inspections, ratings, and intensifying inspections in the event of bad ratings, all backed by the threat of shutdown—but it was practically different in that (1) inspections and ratings were far more frequent and covered more parameters, providing more detailed and timely assessments for each plant that allowed problems to be addressed before they grew big,⁶⁷⁹ and (2) ratings and attention were dependent on risk assessment.⁶⁸⁰ Industry helped develop this approach and has strongly supported it,⁶⁸¹ no doubt partly because it has made shutdowns much rarer.⁶⁸²

One might interpret this episode as congressional overseers forcing a regulator to let the industry put profit above safety. However, there are two responses to this. First, for this Article’s purposes, the main point is that industry helped achieve regulatory transformation after years of struggle *while never trying to use judicial review*, despite openings to do so that seem clear from a strictly doctrinal perspective. Second, there is a strong case that ROP has improved safety. The new approach “won the approval of some industry critics,”⁶⁸³ including David Lochbaum, a onetime nuclear industry engineer turned whistleblower who worked for the Union of Concerned Scientists (“UCS”) from 1996 to 2009 and was director of its Nuclear Safety Project from 2010 to 2018.⁶⁸⁴ Lochbaum wrote in 2016 that ROP, although “by no means perfect,” was “far superior” to SALP, and he suggested shutdowns became rarer because ROP set clearer expectations for plants and induced them to fix problems earlier.⁶⁸⁵

SALP is hardly the only example of nuclear plant operators being pressed but not suing. Having long focused on reactor design, the NRC in the late 1980s proposed its first big rule on maintenance, eliciting opposition from industry—which vowed to seek redress from Congress if the final rule tracked the proposal—and from the agency’s own advisory committee.⁶⁸⁶ Even as the trade press predicted that no mandatory rule

⁶⁷⁸ WELLOCK, *supra* note 601, at 129–31, 139–43.

⁶⁷⁹ Lochbaum, *supra* note 665.

⁶⁸⁰ WELLOCK, *supra* note 601, at 124, 142.

⁶⁸¹ *See id.*

⁶⁸² *See* Lochbaum, *supra* note 665 (noting there were only two shutdowns exceeding one year during ROP’s first sixteen years).

⁶⁸³ WELLOCK, *supra* note 601, at 143. *But see id.* at 190 (citing criticism by an advocate at Public Citizen).

⁶⁸⁴ David Lochbaum, NUCLEAR REGUL. COMM’N <https://www.nrc.gov/docs/ML2109/ML21091A271.pdf> [<https://perma.cc/7QDH-4SBZ>].

⁶⁸⁵ Lochbaum, *supra* note 665.

⁶⁸⁶ WELLOCK, *supra* note 601, at 110.

at all would be adopted, in 1991 the “commission passed the rule anyway. In a stunning vote, three commissioners set aside industry pressure as well as staff and [advisory committee] advice.”⁶⁸⁷ A trade association president wrote to the Chairman that the industry was “surprised” and “disappointed.”⁶⁸⁸ UCS’s Lochbaum said decades later that the 1991 rule was “the best thing the NRC has done during my nearly 40-year career in the nuclear power industry.”⁶⁸⁹ There was no industry judicial challenge, and within a few years operators discovered they liked the rule’s approach.⁶⁹⁰ To give some more recent examples, the NRC in the early 2010s had been deep into a “highly touted” and industry-supported rulemaking to revise procedures for dealing with a key type of accident, loss of coolant.⁶⁹¹ This revision promised to be the agency’s “most ambitious” use of risk assessment ever, but after the Fukushima accident, the NRC withdrew the proposal.⁶⁹² UCS cheered, while NEI’s Director of Risk Assessment said industry was “extremely disappointed,” noting that “[i]t seems crazy to . . . come that close to the finish line and then just boot it off into oblivion.”⁶⁹³ But nobody sued.⁶⁹⁴ In 2022, the NRC reversed two license renewals that it had granted less than three years earlier, in a move that a dissenting commissioner called “arbitrary” and that pronuclear advocates said “bowed to pressure from environmental advocates.”⁶⁹⁵ Interviewee Stenger said that from a legal perspective,

That was a decision where I was scratching my head going, “Why isn’t the industry taking the NRC to court on this?” . . . I think there would have been a strong case that the NRC was acting arbitrarily and capriciously, or at least something that would be worth going to court over.⁶⁹⁶

There is an additional likely reason why nuclear plant operators refrain from suing on these and virtually all other NRC matters: Besides

⁶⁸⁷ *Id.* at 111.

⁶⁸⁸ *Id.* at 111 & n.36 (quoting Letter from Byron Lee, President, Nuclear Mgmt. & Res. Council, to Ivan Selin, Chairman, NRC (Aug. 16, 1991), <https://www.nrc.gov/docs/ML2008/ML20082N118.pdf> [<https://perma.cc/TG2Q-8S3C>]).

⁶⁸⁹ Dave Lochbaum, *NRC’s Nuclear Maintenance Rule*, EQUATION (Sept. 20, 2016, 6:00 AM), <https://blog.ucsusa.org/dlochbaum/nrcs-nuclear-maintenance-rule/> [<https://perma.cc/QQ5W-T793>].

⁶⁹⁰ See WELLOCK, *supra* note 601, at 112–13.

⁶⁹¹ *Id.* at 216.

⁶⁹² *Id.*

⁶⁹³ *Id.* (second alteration in original) (quoting Biff Bradley). On Bradley’s post at NEI, see Letter from Biff Bradley, Dir. Risk Assessment, Nuclear Energy Inst., to Cindy Bladey, Chief, Rules, Announcements & Directives Branch, NRC (Jan. 25, 2012), <https://www.nrc.gov/docs/ML1202/ML12027A142.pdf> [<https://perma.cc/GQ2J-ZR5Z>].

⁶⁹⁴ DATASET, *supra* note 10, Files 27–28.

⁶⁹⁵ Adam Stein & Rani Franovich, *NRC Revises Previously Issued Subsequent License Renewal for Existing Nuclear Power Plants*, BREAKTHROUGH INST. (Feb. 25, 2022), <https://thebreakthrough.org/blog/blog-nrc-revises-previously-issued-subsequent-license-renewal-for-existing-nuclear-power-plants> [<https://perma.cc/M3TB-L3DE>].

⁶⁹⁶ Interview with Daniel Stenger, *supra* note 631.

the NRC's value to the industry in protecting against a risky political environment, each operator also has a stake in its individual relationship to the NRC given the agency's high stakes decision-making power. Recall that the NRC (1) has power to grant, revoke, and modify the operator's license and licensing basis material; (2) keeps inspectors in each plant full-time; (3) can ramp up inspections if anything seems amiss; and (4) can shut down the plant entirely.⁶⁹⁷ As explained by Anonymous Interviewee #4, "all operators in the industry highly value a positive relationship with the regulator," and "when you put litigation into that, it really skews how that relationship works or doesn't work."⁶⁹⁸ The interviewee added that "having that positive relationship actually maintains . . . what we . . . like to call 'regulatory margin,'" that is, the agency's willingness to act cooperatively and not punitively with the operator if the latter discovers and discloses a possible compliance problem and is working to fix it.⁶⁹⁹ Interviewee Stenger similarly noted that the agency's "total control over the licensing" of plants, including the power to suspend licenses, "greatly influences any decision by the licensee on whether they want to take on the regulator through the judicial review process."⁷⁰⁰ This broad type of concern is longstanding. During the SALP era, plant staffers responded to the NEI-sponsored survey of 1994 by saying that "they dared not object to inspection violations 'because of an intense and widespread fear of retribution by the NRC.'"⁷⁰¹

Before closing, there is one final complication to this analysis. We have so far assumed that nuclear plant operators behave like normal firms in the sense they want to avoid the loss of their assets, as would occur if a reactor melts down, and that they seek to foster a political environment favorable to the flourishing and expansion of their investments. For the independent power producers that have increasingly acquired nuclear plants from the 1990s to the present, this assumption is unproblematic.⁷⁰² But what about the electric utilities that originally owned and operated all the plants and still hold about half of them? Recent scholarship has cautioned against understanding an electric utility as a normal firm that maximizes value for shareholders, given that a utility has a captive pool of ratepayers and that its prices are

⁶⁹⁷ *Oversight Program*, *supra* note 607.

⁶⁹⁸ Interview with Anonymous Interviewee #4, *supra* note 608.

⁶⁹⁹ *Id.*

⁷⁰⁰ Interview with Daniel Stenger, *supra* note 631.

⁷⁰¹ WELLOCK, *supra* note 601, at 134 (quoting 1994 survey report).

⁷⁰² See *id.* at 144 (paraphrasing and quoting Email from Scott Morris, NRC Official, to author (Apr. 16, 2020)) (noting that after liberalization of electricity markets and the rise of independent power producers, "[m]arket forces made licensees 'terrified' of low marks from the NRC," causing them to go "to great lengths to stay in the good green column of ROP performance metrics"). On the nuclear safety record of independent power producers, which is equal or superior to that of their rate-regulated peers, see Catherine Hausman, *Corporate Incentives and Nuclear Safety*, 6 AM. ECON. J.: ECON. POL'Y 178, 180 (2014).

set by the public utility commission (“PUC”) of the state in which it operates.⁷⁰³ This means the company can obtain rate increases through a political PUC process that insulates managers from the consequences of their economic decisions—and conversely, the PUC will tend to negate unusually high profits by imposing rate cuts.⁷⁰⁴ I would argue this understanding of utilities is consistent with the idea that such firms are sensitive to the public’s fear of nuclear power and thus to the usefulness of the NRC in mitigating that fear. This is because PUCs are political bodies, embedded in their state political systems and attuned to their state electorates,⁷⁰⁵ and state politics can reflect popular fears of nuclear accidents. A recent study finds that, for the period of 1970–1995, state PUCs tended to allow lower rates for nuclear utilities when antinuclear protests occurred in geographic proximity to their plants,⁷⁰⁶ apparently because such protests can “damage the firm’s standing in the eyes of the [PUC].”⁷⁰⁷ Although PUCs have been notorious for an ossified approach that encourages the utility industry to keep using fossil fuels,⁷⁰⁸ they have not been reliable in allowing full cost recovery for nuclear plant investments.⁷⁰⁹ In the case of TMI—a meltdown that had no detectable health effects—the politics proved so adverse to the operating utility’s multistate parent company General Public Utilities that the Pennsylvania PUC removed the damaged reactor from the company’s rate base⁷¹⁰ and held out against sought-after rate increases during the two years after the accident.⁷¹¹ The company “lurched from one financial crisis to another” in an era when utility bankruptcies were unheard of,⁷¹² with its stock at one point losing seventy-six percent of its pre-accident value.⁷¹³

⁷⁰³ See Anel Kovvali & Joshua C. Macey, *The Corporate Governance of Public Utilities*, 40 YALE J. ON REGUL. 569, 582–83, 585 (2023).

⁷⁰⁴ See *id.* at 583–85.

⁷⁰⁵ On state-level PUCs’ politics and utilities’ sensitivity to their politics, see, for example, Douglas J. Howe, *Governance Models of Public Utility Commissions in the United States*, 20 COMPETITION & REGUL. NETWORK INDUS. 229 (2019), and Paul L. Joskow, Nancy L. Rose & Catherine D. Wolfram, *Political Constraints on Executive Compensation: Evidence from the Electric Utility Industry*, 27 RAND J. ECON. 165 (1996).

⁷⁰⁶ Adam R. Fremeth, Guy L.F. Holburn & Alessandro Piazza, *Activist Protest Spillovers into the Regulatory Domain: Theory and Evidence from the U.S. Nuclear Power Generation Industry*, 33 ORG. SCI. 1163, 1164, 1171–72 (2022).

⁷⁰⁷ *Id.* at 1164.

⁷⁰⁸ Kovvali & Macey, *supra* note 703, at 594–96.

⁷⁰⁹ Hammond & Spence, *supra* note 601, at 185.

⁷¹⁰ William Glasgall, *TMI Firm Fears a Financial Meltdown*, PITT. POST-GAZETTE, Sept. 27, 1979, at 2.

⁷¹¹ John R. Emshwiller, *GPU Again Faces a Threat of Insolvency as It Awaits Moves by Banks, Regulators*, WALL ST. J., Mar. 26, 1981, at 13.

⁷¹² *Id.*

⁷¹³ See Thomas J. Laslavic, *A Market Shock: The Effect of the Nuclear Accident at Three Mile Island Upon the Prices of Electric Utility Securities 32–37 tbl.1* (June 4, 1981) (M.S. thesis, Massachusetts Institute of Technology) (on file with the Massachusetts Institute of Technology).

II. INDUSTRIES THAT HAVE ROUTINELY CHALLENGED HEALTH AND SAFETY RESTRICTIONS

A. *Coal Mines and MSHA; Employers Generally and OSHA*

As an initial foray into areas where industry judicial challenges are routine, this Section jointly addresses two industry-agency pairings in which the agency's mission is to protect the health and safety of workers. The first pairing is coal mine operators and MSHA. The second is employers generally and OSHA.⁷¹⁴ Obviously "employers generally" are not an industry in the same sense that all the other industries in this Article are. But that is part of the point: Because OSHA is the safety regulator for the vast residual category of all employers not regulated by other agencies,⁷¹⁵ its jurisdiction is broader and more diffuse than of all the other agencies in this Article, which means it has relatively thin relationships with its regulated businesses—even the comparatively dangerous ones on whom OSHA concentrates more, such as construction companies.⁷¹⁶ The thinness of OSHA's relationships will be a theme in this Section's analysis.

For the purposes of this Article, the key commonality of these two pairings is that industry judicial challenges are routine and mainstream against the health-and-safety efforts of both agencies, in contrast to all the industry-agency pairings in Part I. Because OSHA generally has thin relationships to the businesses it regulates—it does not monitor them frequently, has no power to shut them down, and does not have preapproval power over what they do—one might initially identify such thinness as a potential cause of industry willingness to challenge. If OSHA lacks the kind of omnipresence and leverage that motivates companies in other regulatory areas to cultivate agency goodwill, that seems like an explanation of why industry has so little hesitation about suing OSHA. In fact, it is not so simple. Yes, the thinness of employers' relationship to OSHA likely plays a role in explaining judicial challenges, but it is not enough. We know this because MSHA *does* have a thick, high-leverage relationship toward the coal mines it regulates, yet the mines *still* take MSHA to court routinely. There must be a further explanatory factor. A strong candidate, I think, is that the material interests of the regulated businesses—coal mines and other employers

⁷¹⁴ State governments can administer their own occupational safety and health plans in place of OSHA's if their plans are at least as effective as the federal one and obtain OSHA's approval. See Occupational Safety and Health Act of 1970 § 18, 29 U.S.C. § 667. Currently twenty-two states have plans covering private sector workers. *State Plans*, OCCUPATIONAL SAFETY & HEALTH ADMIN., <https://www.osha.gov/stateplans> [<https://perma.cc/XTT5-AS5F>].

⁷¹⁵ See OCCUPATIONAL SAFETY & HEALTH ADMIN., FIELD OPERATIONS MANUAL, ch. 17, at 1 (2025), <https://www.osha.gov/fom/chapter-17> [<https://perma.cc/9K5A-Q8XC>].

⁷¹⁶ See *infra* notes 732–39 and accompanying text.

more generally—are much less aligned with the respective missions of MSHA and OSHA than was the case with all the agency-industry pairings in Part I. In particular, coal mines and other employers tend not to have as much of an economic incentive to protect the health and safety of their employees as the industries in Part I have to assure their customer audience of the safety of their products and services.

To start the analysis, first consider MSHA and OSHA's respective powers and industry relationships. To first address similarities, both agencies are responsible for regulating the health and safety of employees. "Safety" generally refers to acute injuries like falls, amputations, explosions, or cave-ins, while "health" generally refers to diseases that may result from long-term exposures with latency periods, such as cancer or black lung.⁷¹⁷ Both agencies promulgate regulations forcing employers to take measures to improve health and safety.⁷¹⁸ Both agencies inspect workplaces for compliance with those regulations, impose sanctions for violations, and go before their respective independent review commissions for adjudication of disputes over those sanction decisions.⁷¹⁹

But there the resemblance ends. MSHA is dedicated with high intensity to a single occupation—mining and especially coal mining⁷²⁰—which historically has been the nation's most dangerous job.⁷²¹ MSHA has formidable powers and resources in proportion to the mines it regulates, reflecting the extraordinary commitment to coal

⁷¹⁷ On this dichotomy, see David C. Vladeck, *The Failed Promise of Workplace Health Regulation*, 111 W. VA. L. REV. 15, 17–19 (2008).

⁷¹⁸ See 29 C.F.R. ch. 17 (2024) (labor); 30 C.F.R. ch. 1 (2024) (mineral resources).

⁷¹⁹ See OCCUPATIONAL SAFETY & HEALTH ADMIN., OSHA-3000-12R, EMPLOYER RIGHTS AND RESPONSIBILITIES FOLLOWING A FEDERAL OSHA INSPECTION 1, 9 (2024), <https://www.osha.gov/sites/default/files/publications/osha3000.pdf> [<https://perma.cc/25CP-YKCA>]; U.S. DEP'T OF LAB., A GUIDE TO MINERS' RIGHTS AND RESPONSIBILITIES UNDER THE FEDERAL MINE SAFETY AND HEALTH ACT OF 1977 17, 22–23 (2017), <https://arlweb.msha.gov/S&HINFO/minersrights/MinersRights.pdf> [<https://perma.cc/RJS8-BMA6>].

⁷²⁰ Besides coal mining, MSHA also regulates mining of metals (such as copper, iron ore, gold, silver, and uranium) and nonmetals (such as sand and gravel). See 30 U.S.C. § 803; 30 C.F.R. ch. 1. These other types of mines do not have coal mining's extraordinary historical death count and receive a much lower number of inspection hours per mine. *MSHA at a Glance*, MINE SAFETY & HEALTH ADMIN., <https://www.msha.gov/msha-glance> [<https://perma.cc/CN8Q-NT2C>]. This Article does not focus on them. See Interview with Anonymous Interviewee #6, *supra* note 28 (noting that MSHA's historical emphasis has been on coal mines and that more of the inspection service focuses on such mines, providing more intense oversight and leading to more industry-regulator tension).

⁷²¹ Michael S. Lewis-Beck & John R. Alford, *Can Government Regulate Safety? The Coal Mine Example*, 74 AM. POL. SCI. REV. 745, 746 (1980). Coal mining has become far less dangerous during the modern era of federal regulation. See Gautam Gowrisankaran, Charles He, Eric A. Lutz & Jefferey L. Burgess, Productivity, Safety, and Regulation in Underground Coal Mining: Evidence from Disasters and Fatalities 10 fig.3 (Nat'l Bureau of Econ. Rsch., Working Paper No. 21,129, 2018).

miner protection that Congress made in the Coal Act of 1969.⁷²² In contrast, the Occupational Safety and Health Act of 1970,⁷²³ the legislation that created OSHA, reflects an aspiration toward worker safety on a vastly greater scale: all workers in all industries.⁷²⁴ This aspiration could never achieve anything like MSHA's efficacy absent a truly enormous commitment of power and resources to OSHA, which has never been forthcoming in the agency's enabling legislation or its appropriations. These differences are manifested in three main ways.

First, MSHA has far more inspectors per protected worker than OSHA, and it inspects far more intensively. The ratio between protected workers and agency inspectors at OSHA has long been about 200 times greater at OSHA than at MSHA.⁷²⁵ At a statutory minimum, each year MSHA inspects every surface coal mine twice and every underground coal mine four times.⁷²⁶ The agency often inspects underground coal mines more frequently, depending on risk factors like methane emissions.⁷²⁷ In the period from 2000 to 2014, inspections of each underground coal mine averaged more than twenty-four per year,⁷²⁸ and the figures were similar from 1983 to 1997.⁷²⁹ It is usual for each individual inspection to take several weeks: The average inspection length

⁷²² 30 U.S.C. §§ 801–966. On the 1969 act and its far more limited predecessors, see Lewis-Beck & Alford, *supra* note 721, at 751–52. Implementation of the Coal Act was originally vested in the Department of Interior but was shifted to the Department of Labor and particularly MSHA in 1977 under the Federal Mine Safety and Health Act. See *Legislative History of U.S. Mine Safety and Health*, MINE HEALTH & SAFETY ADMIN., <https://www.msha.gov/about/about/history> [<https://perma.cc/78MQ-5L3P>]; Federal Mine Safety & Health Act of 1977, Pub. L. No. 95-164, 91 Stat. 1290 (codified at 30 U.S.C. §§ 801–966).

⁷²³ 29 U.S.C. §§ 651–678.

⁷²⁴ See *id.* §§ 651(b), 652(5)–(6), 653(a), 654.

⁷²⁵ Karen L. Johnston, *The Federal Mine Safety and Health Act of 1977: Is It Suffering from a Mid-Life Crisis?*, 78 DENVER U. L. REV. 441, 450 (2001) (noting as of 2001 that MSHA had 920 inspectors for 357,000 miners, a ratio of one to 388, while OSHA had 1,240 inspectors for 111 million workers, a ratio of one to 89,516). Ratios since 2001 have not changed much. See MINE SAFETY & HEALTH ADMIN., FY 2023 CONGRESSIONAL BUDGET JUSTIFICATION 20 (2022), <https://www.dol.gov/sites/dolgov/files/general/budget/2023/CBJ-2023-V2-13.pdf> [<https://perma.cc/8828-ZEVU>] (noting as of 2022 about 1,200 FTEs for MSHA enforcement); OFF. OF INSPECTOR GEN., U.S. DEP'T OF LAB., U.S. DEPARTMENT OF LABOR'S TOP MANAGEMENT AND PERFORMANCE CHALLENGES 10, 12–13 (2024), https://www.oig.dol.gov/public/DOL-OIG%202024%20Top%20Management%20and%20Performance%20Challenges_Final.pdf [<https://perma.cc/5EJW-L6XT>] (noting as of 2024 there are 320,000 protected miners and that OSHA has 846 inspectors—or 1,850 when including state inspectors—compared to 130 million protected workers).

⁷²⁶ 30 U.S.C. § 813(a); Johnston, *supra* note 725, at 443.

⁷²⁷ Thomas J. Kniesner & John D. Leeth, *Data Mining Mining Data: MSHA Enforcement Efforts, Underground Coal Mine Safety, and New Health Policy Implications*, 29 J. RISK & UNCERTAINTY 83, 96 (2004).

⁷²⁸ Gowrisankaran et al., *supra* note 721, at 23 (noting 6.1 inspections on average per quarter).

⁷²⁹ Kniesner & Leeth, *supra* note 727, at 96 (noting four to five inspections per quarter per coal mine in 1983–1997).

from 2000 to 2014 was nearly 279 hours.⁷³⁰ As noted by Anonymous Interviewee #5, a partner in a large law firm that represents the mining industry, there is an inspector in the mine for almost the whole year.⁷³¹ Meanwhile OSHA, possessing less than one percent of this inspector-per-worker capacity, has no statutory minimums for inspections,⁷³² and the agency “visits many worksites only once during a ten-year period.”⁷³³ Although OSHA concentrates disproportionately on sectors that are relatively dangerous, especially construction and manufacturing,⁷³⁴ those sectors are much larger than mining,⁷³⁵ and OSHA’s limited resources only go so far and do not achieve anything like MSHA’s intensity.⁷³⁶ OSHA devotes almost half its inspections to construction,⁷³⁷ yet in 2015 a federal OSHA inspector or state occupational safety and health inspector visited fewer than ten percent of construction establishments in forty-six states and fewer than six percent of construction establishments in forty-one states.⁷³⁸ “Most companies interact with OSHA enforcement irregularly,” and “[e]ven in larger companies,” whose large numbers of facilities mean they see OSHA more, “individual factories or offices may avoid inspection for years if there are no injuries or complaints.”⁷³⁹

Second, MSHA can—and regularly does—unilaterally shut down an employer’s business, while OSHA cannot do anything of the kind. If a coal mine fails to remedy a violation within the time designated by the agency, MSHA issues a “withdrawal” order removing all workers from the affected part of the mine, thereby halting operations.⁷⁴⁰

⁷³⁰ Gowrisankaran et al., *supra* note 721, at 23.

⁷³¹ Interview with Anonymous Interviewee #5, Partner in a large law firm that represents the mining industry (Sept. 13, 2024).

⁷³² See Johnston, *supra* note 725, at 448.

⁷³³ *Id.* at 457 (quoting HERITAGE FOUNDATION, A BUDGET FOR AMERICA 245 (Angela M. Antonelli et al. eds., 2001)).

⁷³⁴ See, e.g., CTR. FOR CONSTR. RSCH. & TRAINING, THE CONSTRUCTION CHART BOOK § 52 (6th ed. 2018).

⁷³⁵ Although the 2024 Inspector General’s report states that there are about 320,000 miners in 2024, there used to be more. OFF. OF INSPECTOR GEN., U.S. DEP’T OF LAB., *supra* note 725, at 10; Johnston, *supra* note 725, at 450 (counting 357,000 miners in 2000).

⁷³⁶ Kniesner & Leeth, *supra* note 727, at 84 (contrasting MSHA inspections with “the relatively infrequent OSHA inspections in construction or manufacturing”); see also OCCUPATIONAL SAFETY & HEALTH ADMIN., CPL 02-00-155, INSPECTION SCHEDULING FOR CONSTRUCTION § VII.B (2013) (“[R]esources limit OSHA programmed inspections to approximately 5% of construction projects (excluding single-family housing) started each year . . .”).

⁷³⁷ CTR. FOR CONSTR. RSCH. & TRAINING, *supra* note 734, § 52 (noting forty-six percent of OSHA inspections in 2015 were in construction). This is the most recent year for which such fine-grained construction inspection data seems to be available.

⁷³⁸ Numbers were only slightly higher a few years earlier. Compare *id.*, with CTR. FOR CONSTR. RSCH. & TRAINING, THE CONSTRUCTION CHART BOOK § 51 fig.51c (5th ed. 2013).

⁷³⁹ SCHMIDT, *supra* note 3, at 156.

⁷⁴⁰ See Johnston, *supra* note 725, at 445 (citing 30 U.S.C. § 814(b)).

A study of the period from 1983 to 1997 finds that MSHA issued over 2,000 withdrawal orders per year and that twenty-five percent of them lasted six days or more, with five percent lasting 112 days or more.⁷⁴¹ Anonymous Interviewee #5 confirmed that withdrawal orders remain common today.⁷⁴² The prospect of lengthy withdrawal orders gives mines “strong incentives” to stay in compliance, in contrast to the “quite small” incentives arising from MSHA’s monetary penalties, whose economic damage is comparatively low.⁷⁴³ Notably, a MSHA withdrawal order remains in effect during any challenge the operator makes via the intra-agency adjudicatory process or in court⁷⁴⁴ unless an ALJ stays the withdrawal, which is “unusual.”⁷⁴⁵ OSHA has no such unilateral shut-down power.⁷⁴⁶ It can bring a lawsuit to seek an injunction to shut down an imminent danger, but this has no effect unless a judge agrees, and in fact OSHA rarely brings such suits.⁷⁴⁷ OSHA can order an employer to abate a violation, but such an order is generally stayed while the employer goes through intra-agency adjudication and judicial review.⁷⁴⁸ Otherwise, OSHA’s main weapon is its monetary penalties, which are famously low.⁷⁴⁹

Third, coal mines cannot undertake certain key operations without first obtaining MSHA’s permission, while employers do not need OSHA’s prior permission for anything. Before opening or expanding a coal mine, an operator must obtain MSHA’s approval for its plans for ventilation and roof control.⁷⁵⁰ Also, more generally, when an operator wants to use a technique that is not recognized by an existing safety standard, it must submit a “petition for modification” and obtain MSHA’s approval first; such petitions are frequent partly because safety standards sometimes have not been updated to account for new

⁷⁴¹ Kniesner & Leeth, *supra* note 727, at 95, 105 app. A.

⁷⁴² See Interview with Anonymous Interviewee #5, *supra* note 731 (estimating that an average coal mine sees about one withdrawal order per year).

⁷⁴³ Kniesner & Leeth, *supra* note 727, at 95–96.

⁷⁴⁴ Johnston, *supra* note 725, at 443; Interview with Anonymous Interviewee #6, *supra* note 28.

⁷⁴⁵ Interview with Anonymous Interviewee #5, *supra* note 731.

⁷⁴⁶ Johnston, *supra* note 725, at 448 (“The OSH Act provides no withdrawal order authority without first obtaining an order from a federal court, and then only in the case of an imminent danger.”); Kniesner & Leeth, *supra* note 727, at 97 (“In contrast [to MSHA], OSHA . . . has no power to shut down a firm’s operations for serious hazards or for failure to correct a previously identified problem.”).

⁷⁴⁷ Arthur G. Sapper, *Litigation by Ambush: The Struggle to Obtain Fair Notice of OSHA Allegations*, 20 GEO. J.L. & PUB. POL’Y 713, 724 (2022).

⁷⁴⁸ Johnston, *supra* note 725, at 449; Interview with Anonymous Interviewee #5, *supra* note 731.

⁷⁴⁹ See Jonathan D. Karmel, *What Can We Do?*, 3 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. 107, 117 (2016); see also *infra* note 779.

⁷⁵⁰ Interview with Anonymous Interviewee #5, *supra* note 731.

technologies that have entered widespread use, such as electronic surveying equipment.⁷⁵¹ Anonymous Interviewee #5 noted that MSHA's preapproval powers give the agency "quite a bit of leverage" and that agency delays in deciding time-sensitive petitions for modification can "turn people's hair grey."⁷⁵²

Although MSHA and OSHA differ greatly in their capacities and powers, the two agencies have *both* routinely been objects of industry judicial challenges throughout their respective histories. With regard to OSHA, this point is well-known in the literature. The agency has a "notorious reputation for . . . litigious rulemaking,"⁷⁵³ and "nearly every health standard and most safety standards are challenged" in the courts.⁷⁵⁴ The Article's core study period of 2013–2021, for which I conducted an exhaustive search of the Bloomberg dockets database for all industry suits against OSHA or against DOL on OSHA matters was no exception. Pre-enforcement challenges were brought against seven OSHA rules or general policies, each by one or more trade associations—representing at least one, but often several, industries for each rule, reflecting OSHA's pan-industry jurisdiction: three associations challenged a rule on electric protective equipment in 2014; two associations, a rule on confined spaces in construction in 2015; five associations, a policy on process safety management in chemical manufacturing in 2015; ten associations, a rule on tracking injuries in 2016; at least thirty associations, a crystalline silica exposure rule in 2016; one association, a rule on fall protection in 2016; and five associations, a rule on beryllium exposure in 2017.⁷⁵⁵ As to individual enforcement and adjudicatory proceedings, there were about 100 judicial challenges, each generally by one company that is usually not well-known,⁷⁵⁶ although Walmart—the nation's largest employer by far—sued twice to challenge two different enforcement citations.⁷⁵⁷

Industry judicial challenges are likewise familiar when it comes to coal mines and MSHA. First consider pre-enforcement challenges to rules and other general policies. In the core study period, for which I conducted

⁷⁵¹ *Id.*

⁷⁵² *Id.*

⁷⁵³ SCHMIDT, *supra* note 3, at 54.

⁷⁵⁴ Wendy Wagner, William West, Thomas McGarity & Lisa Peters, *Deliberative Rulemaking: An Empirical Study of Participation in Three Agency Programs*, 73 ADMIN. L. REV. 609, 650 (2021).

⁷⁵⁵ DATASET, *supra* note 10, File 29, Rows 168, 170; *id.* File 31, Rows 2–68. These challenges were sometimes joined by a few individual companies, though usually not well-known ones.

⁷⁵⁶ DATASET, *supra* note 10, File 31, Rows 69–185.

⁷⁵⁷ See Alexander E.M. Hess, *The 10 Largest Employers in America*, USA TODAY (Aug. 22, 2013, 7:48 AM), <https://www.usatoday.com/story/money/business/2013/08/22/ten-largest-employers/2680249/> [<https://perma.cc/N9RE-7MSJ>]; Wal-Mart Stores E., LP v. Acosta, 919 F.3d 1073 (8th Cir. 2019); Wal-Mart Distrib. Ctr. #6016 v. Occupational Safety & Health Rev. Comm'n, 819 F.3d 200 (5th Cir. 2016).

an exhaustive search of the Bloomberg dockets database for all industry suits against MSHA or against DOL on MSHA matters, industry brought challenges against two MSHA rules imposing safety restrictions on coal mine operators.⁷⁵⁸ Each challenge was brought by multiple trade associations with both cases including the National Mining Association (“NMA”), which is the mining industry’s principal group.⁷⁵⁹ These suits respectively challenged rules on sanctions against mines with “pattern[s] of violations” in 2013⁷⁶⁰ and on coal dust in 2014.⁷⁶¹ (Several associations, including the NMA, brought another challenge after the core study period in mid-2024, against a new rule protecting against silica dust in coal and other mines.⁷⁶²) This kind of litigation has been a longstanding pattern. A Bloomberg dockets search for challenges by the NMA or its predecessor association over the twenty-four-year period from 1989 to 2013 yields fourteen suits that challenge eleven distinct MSHA rules or other general policies on coal mine health and safety, averaging about one suit every two years.⁷⁶³ Specifically, the NMA or its predecessor sued to challenge MSHA rules or other general policies on lung disease diagnosis reporting in 1991–1992,⁷⁶⁴ mine ventilation in 1992,⁷⁶⁵ the effect of blasting and drills

⁷⁵⁸ DATASET, *supra* note 10, File 32, Rows 5–7.

⁷⁵⁹ See *id.*; *About NMA*, NAT’L MINING ASS’N, <https://nma.org/about-nma-2/> [<https://perma.cc/SSUW-Q2AJ>].

⁷⁶⁰ Pattern of Violations, 78 Fed. Reg. 5056 (Jan. 23, 2013) (to be codified at 30 C.F.R. pt. 104); Complaint at 2, *Ohio Coal Ass’n v. Sec’y of Lab.*, No. 14-cv-02646 (S.D. Ohio Dec. 16, 2014) (challenging 78 Fed. Reg. 5056); Petition for Review at 2, *Nat’l Mining Ass’n v. MSHA*, 763 F.3d 627 (6th Cir. 2014) (No. 13-3324) (same).

⁷⁶¹ Lowering Miners’ Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors, 79 Fed. Reg. 24,814 (May 1, 2014) (to be codified at 30 C.F.R. pts. 70–72, 75, 90); *Nat’l Mining Ass’n v. Sec’y of Lab.*, 812 F.3d 843, 848, 884 (11th Cir. 2016) (denying petitions for review of 79 Fed. Reg. 24,814 for case numbers 14-12163 and 14-11942); see also Court Docket, *Murray Energy Corp.*, 812 F.3d 843 (No. 14-12163) (filed May 15, 2014) (challenging 79 Fed. Reg. 24,814); Petition for Review at 1, *Nat’l Mining Ass’n*, 812 F.3d 843 (No. 14-11942) (filed May 1, 2014) (same).

⁷⁶² Petition for Review at 1, *Nat’l Stone, Sand & Gravel Ass’n v. MSHA*, No. 24-2661 (8th Cir. Aug. 16, 2024) (challenging Lowering Miners’ Exposure to Respirable Crystalline Silica and Improving Respiratory Protection, 89 Fed. Reg. 28,218 (Apr. 18, 2024)).

⁷⁶³ DATASET, *supra* note 10, File 32, Rows 3–32 cols. S, T, U. The predecessor was American Mining Congress, which merged with other associations to form NMA in 1995. 2 *Mining Trade Groups Merge into 381-Member Body*, DESERET NEWS (Feb. 21, 1995), <https://www.deseret.com/1995/2/21/19160683/2-mining-trade-groups-merge-into-381-member-body/> [<https://perma.cc/5Q84-HGA7>]. My counts cover rules and policies applicable specifically to coal mines or to all types of mines including coal. The counts exclude rules and policies applicable only to metal or nonmetal mines, on which NMA also brought many challenges.

⁷⁶⁴ *Am. Mining Cong. v. MSHA*, 995 F.2d 1106, 1107 (D.C. Cir. 1993) (three consolidated suits to challenge three successive program policy letters).

⁷⁶⁵ *Nat’l Mining Ass’n v. Tattersall*, No. 92-1289 (D.C. Cir. filed July 9, 1992) (challenging Safety Standards for Underground Coal Mine Ventilation, 57 Fed. Reg. 20,868 (May 15, 1992) (to be codified at 30 C.F.R. pts. 70, 75)); *Nat’l Mining Ass’n v. MSHA*, No. 92-1288 (D.C. Cir. filed July 8, 1992) (same).

on mine air quality in 1994,⁷⁶⁶ further policy changes regarding mine ventilation in 1996,⁷⁶⁷ safe use of diesel-powered equipment in 1996,⁷⁶⁸ testing methods for coal dust in 1998,⁷⁶⁹ noise exposure in 1999,⁷⁷⁰ communication of hazards to workers in 2001,⁷⁷¹ emergency evacuations and breathable air in 2007 with separate suits against a rule and a policy,⁷⁷² and digging beyond roof-controlled areas in 2008.⁷⁷³ Contrast this with the six industries in Part I, in which, during the period of 1989–2024, trade association suits against health-and-safety restrictions numbered zero against FDA, NHTSA, and CPSC; three against the USDA and FSIS (zero after 2005); one against the FAA; and one against the NRC.⁷⁷⁴ Coal trade association challenges to mine safety regulations were familiar well before 1989, dating back almost to the advent of the modern regulatory scheme in 1969.⁷⁷⁵

⁷⁶⁶ See Court Docket, *Am. Mining Cong. v. MSHA*, No. 94-1320 (D.C. Cir. Apr. 15, 1994) (challenging Air Quality: Health Standards for Abrasive Blasting and Drill Dust Control, 59 Fed. Reg. 8318 (Feb. 18, 1994) (to be codified at 30 C.F.R. pts. 56–58, 70, 72)).

⁷⁶⁷ See Court Docket, *Nat'l Mining Ass'n v. MSHA*, 116 F.3d 520 (D.C. Cir. 1997) (No. 96-1150) (challenging Safety Standards for Underground Coal Mine Ventilation, 61 Fed. Reg. 9764 (Mar. 11, 1996) (to be codified at 30 C.F.R. pt. 75)). The 1992 challenges, *supra* note 765, were held in abeyance and were then consolidated with the 1996 challenge to the revised regulations. See *Nat'l Mining Ass'n*, 116 F.3d at 525.

⁷⁶⁸ See Court Docket, *Nat'l Mining Ass'n v. MSHA*, No. 96-1489 (D.C. Cir. Dec. 23, 1996) (challenging Approval, Exhaust Gas Monitoring and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines, 61 Fed. Reg. 55,412 (Oct. 25, 1996) (to be codified at 30 C.F.R. pts. 7, 31–32, 36, 70, 75)).

⁷⁶⁹ *Nat'l Mining Ass'n v. Sec'y of Lab.*, 153 F.3d 1264, 1266 (11th Cir. 1998) (challenging Mine Shift Atmospheric Conditions; Respirable Dust Sample, 63 Fed. Reg. 5664 (Feb. 3, 1998)).

⁷⁷⁰ See Court Docket, *Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, No. 99-1445 (D.C. Cir. Nov. 10, 1999) (challenging Health Standards for Occupational Noise Exposure, 64 Fed. Reg. 49,548 (Sept. 13, 1999) (to be codified at 30 C.F.R. pts. 56–57, 62, 70–71)); see also *Federal Briefs: Soot Study Underway; Mining Noise*, COAL WK., Nov. 15, 1999 (“The [NMA] has asked a federal appeals court in Washington, D.C. to review MSHA [sic] new rule for occupational noise exposure in coal mines.” (emphasis added)).

⁷⁷¹ See Court Docket, *Nat'l Mining Ass'n v. MSHA*, No. 01-1056 (D.C. Cir. Feb. 5, 2001) (challenging Hazard Communication (HazCom), 65 Fed. Reg. 59,048 (Oct. 3, 2000) (to be codified at 30 C.F.R. pts. 42, 47, 56, 57, 77)).

⁷⁷² For the challenge to the rule, see *National Mining Association v. MSHA*, 512 F.3d 696, 698 (D.C. Cir. 2008) (No. 07-1026) (challenging Emergency Mine Evacuation, 71 Fed. Reg. 71,430 (Dec. 8, 2006) (to be codified at 30 C.F.R. pts. 3, 48, 50, 75)). For the challenge to the policy, see Court Docket, *Nat'l Mining Ass'n v. MSHA*, No. 07-1068 (D.C. Cir. Mar. 20, 2007) (challenging MINE SAFETY & HEALTH ADMIN., PIB P07-03, BREATHABLE AIR QUESTIONS AND ANSWERS (2007)).

⁷⁷³ *Nat'l Mining Ass'n v. Sec'y of Lab.*, 589 F.3d 1368, 1269–70 (11th Cir. 2009) (challenging Procedure Instruction Letter No. I08-V-03, promulgated by MSHA).

⁷⁷⁴ See *supra* notes 74, 112, 154, 416, 621 and accompanying text. Note that the search only goes back to 1994 for USDA and FSIS. See *supra* note 71 and accompanying text.

⁷⁷⁵ A casual search of published judicial opinions—which of course can omit many suits—finds such challenges going back to the 1970s against MSHA and its predecessor agency. See, e.g., *Nat'l Indep. Coal Operators' Ass'n v. Kleppe*, 423 U.S. 388 (1976); *Am. Mining Cong. v. Marshall*, 671 F.2d 1251 (10th Cir. 1982); *Bituminous Coal Operators' Ass'n v. Marshall*, 82 F.R.D. 350 (D.D.C. 1979); *Bituminous Coal Operators' Ass'n v. Hathaway*, 406 F. Supp. 371 (W.D. Va. 1975), *aff'd*, 547

Consider also challenges to individual MSHA enforcement actions by individual companies. These are likewise mainstream in the coal mining industry. During the core study period, coal companies brought forty-five suits challenging MSHA health-and-safety enforcement actions—significantly more than in any of the six pairings in Part I.⁷⁷⁶ Furthermore, coal differs strikingly from those six industries in that suing is normal for large dominant companies. During the core study period, the largest fifteen U.S. coal producers each year accounted for between seventy-eight percent and eighty-six percent of total national coal production.⁷⁷⁷ Judicial challengers to MSHA included eight companies who were in the top fifteen at the time each sued, including Peabody, ranked first at the time of its two suits; Alpha Natural Resources, ranked fourth at the time of its six suits; Murray Energy, ranked fourth at the time of its six suits; Alliance Resource Partners, ranked seventh or eighth at the time of its three suits; and CONSOL Energy, ranked eighth or ninth at the time of its four suits.⁷⁷⁸

Why has industry been so willing for so long to bring judicial challenges against OSHA and MSHA's health-and-safety actions compared with the six agencies discussed in Part I? The case of OSHA may suggest that the thinness of company-agency relations could be an explanation for litigiousness,⁷⁷⁹ but that idea clearly does not work for MSHA,

F.2d 240 (4th Cir. 1977); Nat'l Indep. Coal Operators' Ass'n v. Brennan, 372 F. Supp. 16 (D.D.C. 1974).

⁷⁷⁶ DATASET, *supra* note 10, File 30, Rows 2–46.

⁷⁷⁷ These calculations are based on the U.S. Energy Information Administration's Annual Coal Reports. See *Annual Coal Report*, U.S. ENERGY INFO. ADMIN., <https://www.eia.gov/coal/annual/> [<https://perma.cc/AHZ3-UF33>] (see table 10 in each report, with previous years' reports available via a dropdown list titled "Previous Years").

⁷⁷⁸ These counts attribute suits by a subsidiary to the parent, DATASET, *supra* note 10, File 30, Rows 2–46, consistent with how suits are treated throughout this Article.

⁷⁷⁹ It should be noted that, for the purpose of defining "repeat" violations, for which civil penalties can be up to ten times more than that of regular civil penalties, see Memorandum from Erin Gilmore, Acting Dir., Directorate of Enf't Programs to OSHA Reg'l Adm'rs (Jan. 7, 2025), <https://www.osha.gov/memos/2025-01-07/2025-annual-adjustments-osha-civil-penalties> [<https://perma.cc/R92P-2252>], OSHA in 2010 extended its lookback period from three years to five; since around the same time, the agency has gone further in attributing violations at a parent company's disparate facilities or subsidiaries to the parent, Jason E. Markel, *OSHA Repeat Violations and Affiliated or Subsidiary Companies: The 'Single Employer' Test*, HODGSON RUSS (June 7, 2013), <https://www.hodgsonruss.com/newsroom/publications/OSHARepeatViolations> [<https://perma.cc/5EJ7-PXCW>]. These shifts could cause companies to think about their interactions with OSHA more in terms of repeat play, thereby "thickening" the company-agency relationship. Yet industry counsel perceives these shifts as *encouraging* industry judicial challenges to nip initial citations in the bud so they do not become predicates for later findings of repeat violations. Melissa A. Bailey, *Are OSHA's Enforcement Policies Making It More Difficult to Settle Cases? Considerations for Employers*, OGLETREE DEAKINS (Oct. 23, 2023), <https://ogletree.com/insights-resources/blog-posts/are-oshas-enforcement-policies-making-it-more-difficult-to-settle-cases-considerations-for-employers> [<https://perma.cc/P2TJ-8SXF>]; Interview with Eric Conn, Founding Partner, Conn Maciel Carey (Nov. 21, 2024). This is the opposite of the response one would expect based on the sources

which maintains a thick, high-leverage relationship to the coal mines—replete with pervasive inspections and formidable powers of shutdown and preapproval—even as the coal mines still routinely sue the agency. Anonymous Interviewee #5, a partner in a large law firm that represents the mining industry, said every coal mine operator has to manage its operation “looking over [its] shoulder” to see what MSHA is doing, treating the agency’s supervision as a “fact of life”—“they’re there”—and yet the interviewee found it rare for anyone to refrain from suing because they feared it would upset MSHA; only “inexperienced” people would think such a thing.⁷⁸⁰ The mining industry simply recognizes litigation as part of the process.⁷⁸¹

Although the thickness or thinness of the industry-agency relationship is insufficient to explain why challenges are far more pervasive against MSHA than against all the agencies in Part I, a more promising explanation centers on the relative degree of interest alignment between industry and agency. Employers tend to have less of an economic stake in protecting worker safety than in assuring customers of product safety. This weaker alignment of interests may combine with the thinness of the relationship to explain the frequency of challenges against OSHA, while weaker alignment may operate by itself as a sufficient cause of the frequency of challenges against MSHA.

At first glance, it might seem that employers, whether coal mine operators or any other type, *would* have a decisive economic stake in the health and safety of their workplaces, because (1) state laws on workers’ compensation make employers strictly liable for on-the-job harms, plus some level of replacement wages for time that injured workers are

regarding the various industries in Part I, which generally couched a thick repeat-play relationship as a factor *discouraging* industry suits. The reason for these different responses may be that OSHA’s rising emphasis on repeat violations is centered on its power to impose civil penalties, which are not high enough to intimidate companies into seeking agency goodwill in the way that the prospect of, say, shutdown orders or licensing decisions affect the companies discussed in Part I. See Karmel, *supra* note 749, at 117 (discussing OSHA’s low penalties). The penalties seem especially limited when viewed in proportion to the relatively large companies on whom OSHA’s multifacility, multisubsidiary approach would tend to operate. See *Top Enforcement Cases in History Based on Total Issued Penalty*, OCCUPATIONAL HEALTH & SAFETY ADMIN., <https://www.osha.gov/enforcement/top-cases> [<https://perma.cc/9ZJ5-B8GF>] (indicating that from 1970 through 2024—OSHA’s entire fifty-four-year history—only twenty-four cases ever involved a total issued penalty over \$3 million, with no penalties over \$3 million after 2010); *Enforcement Cases with Initial Penalties of \$40,000 or Above*, OCCUPATIONAL HEALTH & SAFETY ADMIN., <https://www.osha.gov/enforcement/toppenalties> [<https://perma.cc/SSF5-WF4Q>] (sort “Issuance Date” ascending from oldest to most recent) (indicating that in the ten-year period of 2015–2024, there have been only thirty-seven initial penalties over \$1 million and none over \$3 million).

⁷⁸⁰ Interview with Anonymous Interviewee #5, *supra* note 731.

⁷⁸¹ *Id.*

off-the-job,⁷⁸² and (2) workers demand wage premiums in exchange for dangerous work, such that an employer who reduces harms or appears to do so can retain workers at lower wages and thereby save money.⁷⁸³ Yet both these potential factors have more limited impact than at first glance.

As to the first factor, workers' compensation does not ensure that most harm to workers is internalized by employers. For one thing, employers generally do not pay the costs of harm directly; instead they buy insurance to cover those costs, and each employer faces the consequences of its own *individual* level of workplace safety only insofar as insurance premiums are experience-rated, which typically is not the case at all for small companies and only partly the case for all other companies except very large ones.⁷⁸⁴ To the extent that worker harms do affect employers' profits through experience rating, that is likely to happen only for injuries and hardly at all for diseases; for the latter, obstacles such as latency periods and causal uncertainties mean that the overwhelming majority of disease-based harms receive no compensation.⁷⁸⁵ And even injuries seem to be quite far from getting full compensation—for example, benefits cover less than half of direct medical costs.⁷⁸⁶ This undercompensation arises from several factors. For one thing, the original design of the state laws was not to make workers whole but to prevent outright destitution,⁷⁸⁷ and although state legislatures increased benefit levels in the 1970s,⁷⁸⁸ scholarship in the 1990s found little evidence that employers responded to such increases by reducing injuries.⁷⁸⁹ Factors driving this ongoing undercompensation

⁷⁸² Thomas J. Kniesner & John D. Leeth, *Regulating Occupational and Product Risks*, in *HANDBOOK OF THE ECONOMICS OF RISK AND UNCERTAINTY* 493, 494, 533 (Mark J. Machina & W. Kip Viscusi eds., 2014).

⁷⁸³ *Id.* at 496, 536–37.

⁷⁸⁴ GREGORY A. HUBER, *THE CRAFT OF BUREAUCRATIC NEUTRALITY: INTERESTS AND INFLUENCE IN GOVERNMENTAL REGULATION OF OCCUPATIONAL SAFETY* 94 (2007); Kniesner & Leeth, *supra* note 782, at 558.

⁷⁸⁵ See J. Paul Leigh & John A. Robbins, *Occupational Disease and Workers' Compensation: Coverage, Costs, and Consequences*, 82 *MILBANK Q.* 689, 709 (2004) (estimating nationally for 1985 and 1999 that workers' compensation “misses from 91.1 percent to 99.9 percent of deaths [from disease] and from 80.0 percent to 93.8 percent of medical costs [from disease]”); see also J. Paul Leigh & James P. Marcin, *Workers' Compensation Benefits and Shifting Costs for Occupational Injury and Illness*, 54 *J. OCCUPATIONAL & ENV'T MED.* 445, 445 (2012) (finding that, on the basis of data covering most states in 2007, “[m]ore than 97% of death cases are injuries” rather than diseases). On latency, causation issues, and other obstacles to disease compensation, see HUBER, *supra* note 784, at 93.

⁷⁸⁶ See Leigh & Marcin, *supra* note 785, at 449 tbl.4 (estimating that workers' compensation benefits paid for 44.5% of medical costs based on data for most U.S. states in 2007).

⁷⁸⁷ Sidney A. Shapiro, *The Necessity of OSHA*, 8 *KAN. J.L. & PUB. POL'Y* 22, 28–29 (1998).

⁷⁸⁸ PRICE V. FISHBACK & SHAWN EVERETT KANTOR, *A PRELUDE TO THE WELFARE STATE: THE ORIGINS OF WORKERS' COMPENSATION* 201 (2000).

⁷⁸⁹ L.I. Boden, *Workers' Compensation in the United States: High Costs, Low Benefits*, 16 *ANN. REV. PUB. HEALTH* 189, 193–200 (1995).

include employer strategies for discouraging workers from making claims⁷⁹⁰ and for using corporate subsidiaries—who may end up judgment-proof—to cabin and avoid liability for more dangerous work.⁷⁹¹ In any event, state legislatures' trend toward increases ceased and reversed by the 2000s.⁷⁹² Finally, internalization of harm by employers is limited by public subsidies for those harms, such as the exemption of workers' compensation from income and payroll taxes.⁷⁹³

As to the second factor, wage premiums for danger—and wage cuts for reducing danger—are quite limited in giving employers a material incentive to improve workplace health and safety. First off, wage premiums are unlikely for diseases, because workers often have insufficient information about disease, due to factors like causal uncertainty and latency periods, similar to what happens with workers' compensation.⁷⁹⁴ Even if one shifts focus from diseases to injuries, many injuries are low-probability events that workers may not evaluate accurately.⁷⁹⁵ Even if workers know about injury risk, that only goes so far. If already in a job, they may lack bargaining power because of the costs of switching jobs, such as geographic considerations.⁷⁹⁶ And although a worker not already in a job can bargain for a premium without such switching costs, this means such a premium will reflect the preferences not of the average worker but of the marginal worker, who may demand less, especially if the job's dangers become more evident with experience.⁷⁹⁷ At an empirical level, studies of wage premiums for danger have encountered great difficulty in measuring such premiums or even establishing that they exist in the first place.⁷⁹⁸ One especially sophisticated recent study, using a quasi-experimental design to gauge how randomized OSHA inspections affected 65,000 manufacturing plants from 1987 to 1997, finds that (1) plants responded to inspections by investing more in safety and thereby reducing fatal injuries by forty-five percent and (2) the increase in safety allowed those plants to reduce

⁷⁹⁰ Alison Morantz, Julia Bodson, Sarah Michael Levine & Marcus Vilhelm Palsson, *Economic Incentives in Workers' Compensation: A Holistic, International Perspective*, 69 *RUTGERS U. L. REV.* 1015, 1055–57 (2017).

⁷⁹¹ HUBER, *supra* note 784, at 93 n.69.

⁷⁹² Michael Grabell & Howard Berkes, *The Demolition of Workers' Comp*, *PROPUBICA* (Mar. 4, 2015), <https://www.propublica.org/article/the-demolition-of-workers-compensation> [<https://perma.cc/W443-6MCA>].

⁷⁹³ HUBER, *supra* note 784, at 90; FISHBACK & KANTOR, *supra* note 788, at 202.

⁷⁹⁴ Leigh & Robbins, *supra* note 785, at 715; HUBER, *supra* note 784, at 91, 93.

⁷⁹⁵ HUBER, *supra* note 784, at 91.

⁷⁹⁶ *Id.* at 90–91.

⁷⁹⁷ *Id.*

⁷⁹⁸ See Kurt Lavetti, *Compensating Wage Differentials in Labor Markets: Empirical Challenges and Applications*, 37 *J. ECON. PERSPS.* 189, 190–91 (2023); Leigh & Robbins, *supra* note 785, at 715. One problem is that many dangerous industries with high wages were rent-extracting ones such that wages could be explained as rent sharing. Leigh & Robbins, *supra* note 785, at 715.

wages, but (3) the wage reduction was only about one-third of the loss in productivity that plants suffered from the safety investments.⁷⁹⁹ Thus, danger-based wage premiums existed, but they were so small that avoiding them by improving safety was net-negative for employers' material interests.⁸⁰⁰

Even if employers internalized a larger share of worker harm, there is the further point that a difference likely exists in the importance of optics between employer-worker relations and seller-customer relations. People generally invest more in choosing among jobs than in choosing among consumer products, which means consumers are more likely to act on mere casual impressions—like from the news—than workers are. Companies might rationally expect news about industry-regulator conflict to influence consumer beliefs more easily than worker beliefs; companies would therefore hold back challenges against consumer protectors more than against worker protectors.⁸⁰¹

Consistent with all this, the possibility that employer suits against OSHA or MSHA will cause worker audiences to view those employers individually or their industry overall as less safe does not operate as a strong barrier to bringing such challenges. This is in contrast to the industries in Part I, where companies are especially intent on guarding their own reputations, and their industry's overall reputation, for customer safety. In Patrick Schmidt's monograph on OSHA, he found that public conflict with the agency could potentially detract from a company's reputation with the public or with its labor union, but "[w]hether [company] reputations are at stake depends on very specific factors, including the type of industry, the size of the firm, the reason for OSHA's visit, and the company's history of labor relations."⁸⁰² In fact, Schmidt's 1998 survey of 177 industry-side OSHA lawyers found that of seven issues that might be important to employers in attorney-client discussions of OSHA enforcement matters, "[p]reserving [the employer's] relationship with union or public" ranked last.⁸⁰³ More recently, one of my interviewees, Eric Conn, the founding partner of a leading industry-side occupational safety and health law firm, explained that individual employers prefer that their involvement in OSHA rulemakings or in suits challenging OSHA rules be channeled through trade associations or other mechanisms of anonymization because they wish to avoid being perceived as

⁷⁹⁹ Jonathan M. Lee & Laura O. Taylor, *Randomized Safety Inspections and Risk Exposure on the Job: Quasi-Experimental Estimates of the Value of a Statistical Life*, 11 AM. ECON. J.: ECON. POL'Y 350, 363, 368 & n.26 (2019). For a literature review confirming the relative sophistication of this study, see Lavetti, *supra* note 798, at 206–07.

⁸⁰⁰ See Lee & Taylor, *supra* note 799, at 368 & n.26 (noting that total factor productivity losses outweighed labor cost savings).

⁸⁰¹ I am grateful to Christine Jolls and Zachary Liscow for conversations on this point.

⁸⁰² SCHMIDT, *supra* note 3, at 170; see also *id.* at 63, 100.

⁸⁰³ *Id.* at 171, 172 tbl.5.6. For the survey question, see *id.* at 234.

antisafety by “their employees, their union, [or] a possible union”; there is a concern, “even if you’re not currently organized, that if [you] are viewed as antisafety, organizing might be coming soon.”⁸⁰⁴ This is consistent with the fact, noted above, that so much of the high volume of industry litigation against OSHA happens through trade groups. Thus, employers making litigation decisions do take account of worker audiences. Yet this apparently comes with important limitations. First, the worker-audience concern motivates employers to channel their challenges through the anonymizing mechanism of a trade association—not to refrain from challenging altogether, in contrast to drugmakers facing FDA, airlines facing the FAA, or other pairings from Part I, where the companies have a decisive economic stake in their industry’s *collective* reputation for customer safety, and associations almost never sue.⁸⁰⁵ Second, although employer concern about worker audiences may well alter employer behavior when the employer is unionized or could face unionization, such concern may not be impactful otherwise. A recent study finds that while employers improve compliance when OSHA engages in “public shaming” of a nearby same-sector employer for major violations,⁸⁰⁶ this effect disappears entirely if one focuses only on right-to-work states or only on counties whose union presence is below the sample median.⁸⁰⁷

As with OSHA, so with MSHA: Worker perceptions are not a strong barrier to coal mines suing the safety regulator. It does not appear that danger-based wage premiums in coal mining are nearly large enough that avoiding them through safety improvements would offset the cost of such improvements any more than is the case in manufacturing. A study of underground coal mines during the period from 2000 to 2014 finds that employers improve safety in response to certain exogenous events but that the productivity losses from these improvements are more than 2.5 times greater than the value of statistical lives

⁸⁰⁴ Interview with Eric Conn, *supra* note 779.

⁸⁰⁵ On the paucity of trade association suits in Part I, see *supra* note 774.

⁸⁰⁶ Matthew S. Johnson, *Regulation by Shaming: Deterrence Effects of Publicizing Violations of Workplace Safety and Health Laws*, 110 AM. ECON. REV. 1866, 1884–89 (2020) (focusing on federal-OSHA-inspected states from 2009 to 2013).

⁸⁰⁷ *Id.* at 1895–99. The author argues that in the compulsory-representation states and above-median-unionization counties where the effect does occur, employers observing the public shaming of a nearby peer are acting out of fear that the shaming will prompt their own workers to demand higher wages and better conditions or unionize. *Id.* But the author overlooks another potential reason for the effect that may explain much of it: The employer may fear that its own workers, after observing the public shaming of a nearby peer employer, will submit complaints to OSHA that will prompt OSHA to inspect the employer. This complaint-based theory is consistent with the effect’s confinement to more worker-activist locales. On how worker complaints can prompt OSHA inspections, see *id.* at 1876.

and injuries saved according to conventional measures,⁸⁰⁸ which are themselves based largely on wage-premium studies.⁸⁰⁹

When speaking with Anonymous Interviewee #6, a partner in a large law firm with extensive experience representing mining companies in interactions with MSHA, I brought up the question of why mining companies sue MSHA so much more than meat processors sue the USDA or than drugmakers sue FDA, and the interviewee replied:

If you're dealing with FDA or you're dealing with USDA, it's not just about the employer and employee. There is a fairly substantial consumer-related aspect to that dynamic, right? And so I think the consequences of pushing back against the regulator, where third parties—and not just individual one-off third parties but a substantial consumer base—[are] affected by those decisions, I think companies just make fundamentally different decisions.⁸¹⁰

Later, when asked about mine operators' decision-making on whether to sue MSHA, the interviewee elaborated that because

it's a closed universe, for reasons I said earlier—it's not really about people outside the mine site or customers or consumers, it's just about that relationship between employer and employee within the working in-house system—I think using legal process to raise disputes—it's just not as difficult a decision to make.⁸¹¹

B. *Electric Generators and EPA*

The next industry-agency pairing is electricity generators and the EPA, another pairing where industry judicial challenges against the agency's health-and-safety initiatives are routine and mainstream. As with coal mines and MSHA, the electric generation industry's frequent litigation against the EPA is not easily explained by a thin-relationship theory. But a key factor that *does* distinguish the EPA in this context from the agencies in Part I is the relative lack of alignment between agency

⁸⁰⁸ Gowrisankaran et al., *supra* note 721, at 7, 35. For a similar result, see Ling Li, *Workplace Safety and Worker Productivity: Evidence from the Miner Act*, 75 INDUS. & LAB. RELS. REV. 117 (2022).

⁸⁰⁹ W. Kip Viscusi & Joseph E. Aldy, *The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World*, 27 J. RISK & UNCERTAINTY 5, 6 (2003). This study is relied upon in Gowrisankaran et al., *supra* note 721, at 34.

⁸¹⁰ Interview with Anonymous Interviewee #6, *supra* note 28.

⁸¹¹ *Id.* Note that coal mine operator internalization of workplace health harms is further diminished because Congress's black-lung benefit program has collectivized employer liability for black lung costs while barring other liability and offering partial taxpayer funding of the benefits. See Vladeck, *supra* note 717, at 40–42.

mission and industry interests. The EPA's mission in this context is to protect people harmed by air pollution arising from electric generation—that is, to protect victims of externalities of industry conduct.⁸¹² Whereas companies in Part I had a major economic stake in the health and safety of customers who buy their products, and companies in Section II.A had a far lesser economic stake in the health and safety of employees who work for them, electric generators have *no* transactional connection at all with pollution victims qua pollution victims.

First, some background is needed on the definition and nature of the industry. Electric generators are entities who convert energy sources, such as coal, natural gas, uranium, hydropower, wind, solar, and others, into electricity for sale.⁸¹³ Up to the end of the twentieth century, entities who generated electricity were, as a rule, also responsible for its transmission and distribution to homes and businesses—that is, they were *utilities*.⁸¹⁴ Most of them were *investor-owned* utilities (“IOU”), which delivered over ninety percent of electricity nationwide early in the twentieth century and about seventy-five percent near century's end, with the remainder delivered by government-owned or cooperative utilities.⁸¹⁵ Since the late 1990s, electricity markets in most of the country have gone through a process of restructuring whereby generation has become decoupled from transmission and distribution.⁸¹⁶ In a restructured market, an entity that owns generation capacity but not the adjoining transmission or distribution lines can produce electricity and sell it onto the grid; such an entity is known as an IPP or merchant generator.⁸¹⁷ Meanwhile, utilities who own the lines have increasingly given up control of them to “system operators” whose job is to maintain a fair competitive playing field among multiple generators selling electricity onto the lines.⁸¹⁸ These generators can include (1) IPPs who do not own the adjoining lines and (2) IOUs who do own the adjoining lines but do not control them. As of 2021, government-owned or cooperative utilities generated approximately twenty percent of electricity,

⁸¹² See *Air Enforcement*, ENV'T PROT. AGENCY (Mar. 10, 2025), <https://www.epa.gov/enforcement/air-enforcement> [https://perma.cc/6J2C-LS9K].

⁸¹³ *Electricity Explained: Electricity in the United States*, U.S. ENERGY INFO. ADMIN. (Mar. 26, 2024), <https://www.eia.gov/energyexplained/electricity/electricity-in-the-us.php> [https://perma.cc/ZNQ8-YZVW].

⁸¹⁴ JEFF HEIN, W. AREA POWER ADMIN., *SHINING LIGHT ON THE UTILITY INDUSTRY'S EARLIEST FOUNDINGS* 4–7 (2003).

⁸¹⁵ Scott E. Masten, *Public Utility Ownership in 19th-Century America: The “Aberrant” Case of Water*, 27 J.L. ECON. & ORG. 604, 605 & n.1 (2011).

⁸¹⁶ JEFF LIEN, ECON. ANALYSIS GRP., U.S. DEP'T OF JUST., EAG 08-4, *ELECTRICITY RESTRUCTURING: WHAT HAS WORKED, WHAT HAS NOT, AND WHAT IS NEXT* 6 (2008).

⁸¹⁷ *Independent Power Producer*, WESTLAW PRACTICAL LAW GLOSSARY (2025); see also *supra* note 601 and accompanying text (discussing IPPs in the context of nuclear power).

⁸¹⁸ See *Electric Power Markets*, FED. ENERGY REGUL. COMM'N (Mar. 27, 2025), <https://www.ferc.gov/electric-power-markets> [https://perma.cc/7ACL-4QUW].

IOUs generated approximately thirty-four percent, and IPPs generated approximately forty-five percent.⁸¹⁹

Importantly, however, it is common for a holding company that has long owned one or more IOUs to additionally acquire one or more IPPs—that is, to own generation facilities without acquiring the lines adjoining them. Thus, much of “independent” generation is actually owned by holding companies whose names are familiar from the age of prerestructuring utilities—Duke, Dominion, American Electric Power (“AEP”), and so forth—and who are considered “IOUs” by virtue of still having IOU subsidiaries.⁸²⁰ This is significant because IOUs have long been, and still are, rate-regulated by state PUCs for delivery of electricity along their distribution lines, and holding companies that own both IOUs and IPPs can sometimes—somewhat strangely—obtain rate recovery even for their “independent” generation assets.⁸²¹ That said, there are IPPs that are not affiliated with any IOUs and are thus not subject to any state PUC regulation. There seems to be no published calculation of their proportion of nationwide generation, but it is presumably much lower than the forty-five percent cited above. Indeed, the nonutility generation “landscape” was recently said to be dominated by “large diversified utilities” that own both IOUs and IPPs, as well as two non-IOU merchant generators, NRG Energy and Vistra.⁸²² This Section focuses on (1) IOU holding companies that are publicly traded, which is nearly all of them, numbering between forty and fifty during the core study period of 2013–2021,⁸²³ and (2) the only large,

⁸¹⁹ Calculations based on EDISON ELEC. INST., SOURCES OF ELECTRIC GENERATION (2021), <https://www.eei.org/-/media/Project/EEI/Documents/Resources-and-Media/Sources-of-Electric-Generation.pdf> [<https://perma.cc/6AZA-R5PA>].

⁸²⁰ Email from Joshua Macey, Assoc. Professor, Yale L. Sch., to author (Sept. 30, 2024, 4:57 PM) (on file with author). I am grateful to Macey for permission to cite this communication.

⁸²¹ *Id.*

⁸²² See Lucas Bifera, *With Growing Share of Power Assets, Private Equity Thrust into Regulatory Arena*, SNL CAN. ENERGY WK., July 16, 2018.

⁸²³ To identify IOUs for each year and their respective market capitalizations and rankings, see Edison Electric Institute’s annual financial reports, which each have the title “[year] Financial Review: Annual Report of the U.S. Investor-Owned Electric Utility Industry.” All are available at *Issues & Policy: Tax, Finance & Accounting*, EDISON ELEC. INST., <https://www.eei.org/en/issues-and-policy/finance-and-tax> [<https://perma.cc/66UA-SSGG>], under the heading “Financial Review.” Each report contains a table, toward the beginning or end, titled “Market Capitalization at December 31, [year]” and dated New Year’s Eve of the year in the report title. *E.g.*, EDISON ELEC. INST., 2020 FINANCIAL REVIEW 7 (2021) [hereinafter EEI 2020 FINANCIAL REVIEW]. As can be seen from the IOUs listed near the end of each report, the publicly traded IOUs listed in the market capitalization table account for about eighty-five percent to ninety percent of the IOUs operating in the country. *See, e.g., id.* at 7, 80.

This Article treats IOUs as operating on an incentive to minimize the costs of EPA regulation. To be sure, IOUs are not normal firms, as state PUC rate regulation shields them from losses through rate increases and recaptures supranormal profits through rate cuts. Kovvali & Macey, *supra* note 703, at 583–84, 587. But one can think of IOU decisions about challenging EPA as

publicly traded non-IOU IPPs during the period, which were Dynegy; NRG Energy; Calpine, which went private in 2017; and Texas Competitive Electric Holdings, which changed its name to Vistra in 2016 and acquired Dynegy in 2017.⁸²⁴

Some background on the EPA is also needed. The agency administers a raft of major statutes governing all sorts of environmental threats, but its most impactful task is to regulate air pollution: The Clean Air Act (“CAA”)⁸²⁵ surpasses all other federal regulatory statutes in terms of its economic costs and public health benefits, which arise from preventing human diseases to which air pollution contributes.⁸²⁶ The CAA regulates pollution arising from numerous sources, from oil-and-gas operations to cars and trucks to incinerators and boilers, but none is more consequential than electricity generation.⁸²⁷ “The utility sector is by far the largest polluter [of air] in the economy, accounting for one-third of air pollution damages.”⁸²⁸

being made jointly by the actual utility company and the state PUC, *both* of whom usually wish to maximize post-EPA-regulation surplus, which they view as a common “pie” that they can divide between the shareholder profits and consumer rate cuts that they respectively want. *See* Inara Scott, *Teaching an Old Dog New Tricks: Adapting Public Utility Commissions to Meet Twenty-First Century Climate Challenges*, 38 HARV. ENV'T L. REV. 371, 396, 400 (2014) (finding that state PUCs generally pursue short-term consumer interests in lower rates far more than the redress of environmental externalities).

⁸²⁴ *See Vistra Energy; Parent Company for TXU Energy and Luminant Announces Corporate Rebranding as Vistra Energy*, ENERGY WKLY. NEWS, Nov. 18, 2016 (noting TCEH's renaming as Vistra); Lucas Bifera, *Dynegy-Vistra Merger Spawns New Power Juggernaut*, SNL ENERGY FIN. DAILY, Oct. 31, 2017 (noting that the upcoming merger of Vistra and Dynegy will create the largest IPP with generating capacity at forty gigawatts (“GW”); that its “only true unregulated [i.e., non-rate-regulated] public peer” is NRG Energy at thirty-one GW; that Calpine has a twenty-six GW capacity but is going private; and that Vistra and NRG will now “constitute the universe of public equities for pure-play independent power producers”); *see also* Bifera, *supra* note 822 (identifying Vistra and NRG as defining the IPP market alongside diversified IOUs in mid-2018); Jeffrey Ryser, *Renewables ‘Disrupting’ Merchant Power Sector—S&P Ratings*, SNL ENERGY M&A REV., Jan. 1, 2021 (referring to NRG and Vistra as “the two major IPPs” as of early 2021). Note that Constellation Energy is now a very large IPP but was not formed until 2022 by a spinoff from IOU holding company Exelon and thus did not exist during the core study period of 2013–2021. Andrew Maykuth, *Peco Parent Exelon Completes Spinoff of Its Power Generation Business*, PHILA. INQUIRER (Feb. 2, 2022), <https://www.inquirer.com/business/exelon-peco-constellation-spinoff-nuclear-zero-carbon-energy-20220202.html> [<https://perma.cc/AKM4-PCW5>].

⁸²⁵ 42 U.S.C. §§ 7401–7671q.

⁸²⁶ OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, 2017 REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REPORT ACT 10 (2017) (“Across the Federal government, the rules with the highest estimated benefits as well as the highest estimated costs come from the [EPA] and in particular its Office of Air and Radiation”).

⁸²⁷ *See Summary of the Clean Air Act*, ENV'T PROT. AGENCY (July 14, 2025), <https://www.epa.gov/laws-regulations/summary-clean-air-act> [<https://perma.cc/7G2X-HEMG>].

⁸²⁸ Nicholas Z. Muller, Robert Mendelsohn & William Nordhaus, *Environmental Accounting for Pollution in the United States Economy*, 101 AM. ECON. REV. 1649, 1651 (2011).

The CAA's regulatory scheme is notoriously complex, but a quick sketch will suffice for our purposes. The EPA promulgates rules known as National Ambient Air Quality Standards ("NAAQS") that set goals for limiting certain identified "criteria" pollutants, including sulfur dioxide, nitrogen oxides, particulate matter, and ozone.⁸²⁹ State governments then devise State Implementation Plans ("SIP"), which impose specific constraints on individual pollution sources, including generators.⁸³⁰ The EPA has power to approve or reject each state's SIPs, which it can do wholly or in part, substituting federal requirements to fill gaps left by its rejection decisions.⁸³¹ Besides the NAAQS, the EPA also has rulemaking power to implement programs for New Source Review,⁸³² for the limitation of hazardous air pollutants ("HAP") that often come from generators,⁸³³ and for a host of other problems, including, since the landmark Supreme Court decision *Massachusetts v. EPA*,⁸³⁴ greenhouse gas ("GHG") emissions causing climate change, of which generators are, again, a top source.⁸³⁵ A running theme across many of the EPA's programs is that, similar to the NAAQS, the agency makes rules while state authorities cash them out in application to specific sources, especially through the formulation of permits.⁸³⁶ Although the EPA itself is not the permitting authority, it makes rules and guidance to govern permit issuance, can reject state permit decisions in some circumstances,⁸³⁷ and will normally be consulted by the state on permitting decisions that may be controversial.⁸³⁸ In the end, an elaborate scheme of reporting, monitoring, and compliance orders ensures compliance with the various rules and permits, which the EPA can enforce by bringing lawsuits.⁸³⁹

Resisting the EPA's health-and-environmental efforts through litigation is mainstream and routine in the electric generation industry. In this Article's core study period of 2013–2021, for which I conducted an exhaustive search of the Bloomberg dockets database for industry suits against EPA, generators brought a barrage of judicial challenges

⁸²⁹ See F. William Brownell, *Clean Air Act*, in ENVIRONMENTAL LAW HANDBOOK 263, 264–66 (Thomas F.P. Sullivan ed., 24th ed. 2019); *Summary of the Clean Air Act*, *supra* note 827.

⁸³⁰ Brownell, *supra* note 829, at 266.

⁸³¹ See *id.* at 266–68 ("Until a SIP is approved by EPA, it is enforceable only as a matter of state law.").

⁸³² *Id.* at 279–81. These include standards that sources like generators must meet when they are newly built or majorly modified. *Id.*

⁸³³ *Id.* at 282, 294–95, 301–04.

⁸³⁴ 549 U.S. 497 (2007).

⁸³⁵ See Brownell, *supra* note 829, at 263, 279–322; *Electric Utilities*, AM. LUNG ASS'N. (Nov. 13, 2024), <https://www.lung.org/clean-air/outdoors/what-makes-air-unhealthy/electric-utilities> [<https://perma.cc/W5R4-VXTA>].

⁸³⁶ Brownell, *supra* note 829, at 322–31.

⁸³⁷ *Id.* at 324–39.

⁸³⁸ Interview with Anonymous Interviewee #7, *supra* note 28.

⁸³⁹ Brownell, *supra* note 829, at 331–32.

to EPA's CAA actions imposing public health and environmental-protection constraints.⁸⁴⁰ This was especially true during the second Obama Administration when the agency acted concertedly on GHG regulation and many other matters.⁸⁴¹ First consider pre-enforcement challenges to rules by trade associations. Although neither Edison Electric Institute ("EEI"), the IOUs' principal association, nor the IPPs' Electric Power Supply Association brought pre-enforcement challenges,⁸⁴² another entity was extremely active: Utility Air Regulatory Group ("UARG"), an association purpose-built for the unusually specific mission of influencing and challenging the EPA's CAA actions.⁸⁴³ Formed in the 1970s with a broad utility membership⁸⁴⁴ during a time when utilities were uniformly resistant to air pollution regulation, UARG later saw some utilities exit the association over the years as they became more aligned with the EPA.⁸⁴⁵ For example, northeastern utilities quit in the late 1990s as it became evident that their midwestern and southern peers were advantaged by lax regulation of pollutants that blew toward the northeast.⁸⁴⁶ As of the 2010s, UARG's membership was secret, but when someone leaked a roster from 2017, it showed a clearly formidable group of companies encompassing seventeen of the forty-four publicly traded IOUs and four of the largest six by market capitalization: Duke (#2), Southern (#3), Dominion (#4), and AEP (#6), plus two of the four major publicly traded IPPs, Dynegy and Vistra, the latter through its big

⁸⁴⁰ See DATASET, *supra* note 10, Files 33–36.

⁸⁴¹ This Article's counts of lawsuits exclude the many instances in which generators with less-polluting fuel portfolios sued EPA during the first Trump Administration to halt the rollback of regulations that they saw as beneficial to their competitive position. See, e.g., Petition for Review at 1, *Am. Lung Ass'n v. EPA*, 985 F.3d 914 (D.C. Cir. 2021) (No. 19-1188) (filed Sept. 6, 2019) (challenging repeal of the Clean Power Plan, 84 Fed. Reg. 32,520 (July 8, 2019)). These counts also exclude challenges to actions under the CAA's Renewable Fuel Standards Program, which is not a genuine environmental program—it is criticized by environmentalists as net harmful—but is a pork barrel project for corn farmers. See Jason Hill, *The Sobering Truth About Corn Ethanol*, 119 *PROC. NAT'L ACAD. SCI.*, Mar. 15, 2022, at 1–2.

⁸⁴² DATASET, *supra* note 10, Files 33–34. None of the industry challenges to EPA's CAA actions in the district courts during the core study period were by electric generators. *Id.* File 33, Rows 5–17. All generator challenges in the upcoming discussion were PFRs in the courts of appeals.

⁸⁴³ See *Revised New Source Performance Standards for Fossil-Fuel Fired Electric Utility Steam Generating Units: Hearing Before the EPA 1* (1978) (statement of George C. Freeman, Jr., Utility Air Regulatory Group) https://iif.library.cmu.edu/file/Heinz_box00096_fld00035_bdl0010_doc0001/Heinz_box00096_fld00035_bdl0010_doc0001.pdf [<https://perma.cc/AT7W-NLNR>].

⁸⁴⁴ *Id.*

⁸⁴⁵ See Alex Farrell, *The Political Economy of Interstate Public Policy: Power-Sector Restructuring and Transboundary Air Pollution*, in *IMPROVING REGULATION: CASES IN ENVIRONMENT, HEALTH, AND SAFETY* 115, 131–32 (Paul S. Fischbeck & R. Scott Farrow eds., 2001); *Utility Industry Pollution Group Loses Members*, CLEAN AIR NETWORK ONLINE TODAY, Mar. 5, 1997.

⁸⁴⁶ See sources cited *supra* note 845.

subsidiary Luminant.⁸⁴⁷ This membership was oriented toward the more carbon- and coal-intensive generators, who tended to be most adverse to the Obama EPA.⁸⁴⁸ In the period from 2013 to 2017 alone, UARG brought twenty-two lawsuits against the EPA—each challenging a distinct EPA rule, including the GHG regulations on new and existing plants, NAAQS on ozone and particulate matter, the cross-state ozone rule, a half-dozen rules on hazardous air pollutants, multiple SIP actions, a rule on new source review, and more.⁸⁴⁹

Besides UARG's campaign, major generators were aggressive in challenging EPA individually. During the period from 2013 to 2021, between forty and fifty publicly traded IOUs existed at any given time,⁸⁵⁰ of which the twenty largest accounted for about eighty percent to eighty-seven percent of total market capitalization of publicly traded IOUs nationwide.⁸⁵¹ Nine IOUs brought judicial challenges to EPA CAA rules in their own name or that of a subsidiary in a year when they ranked in the top twenty IOUs, including Duke, ranked first and second at the time of its two suits;⁸⁵² Southern, ranked third and fourth at the time of its seven suits;⁸⁵³ AEP, ranked sixth at the time of its two

⁸⁴⁷ For the list of the leaked members, see Util. Air Regul. Grp., Workshop Materials 6 (June 20, 2017) (unpublished materials) (on file with Politico), <https://static.politico.com/59/f4/19e386684cde98d283683e8bbb54/utility-air-regulatory-group.pdf> [<https://perma.cc/8DXB-UMK4>]. The nearest-in-time ranked list of IOUs is for December 31, 2016. EDISON ELEC. INST., 2016 FINANCIAL REVIEW 75 (2017) [hereinafter EEI 2016 FINANCIAL REVIEW]. On Vistra as Luminant's parent, see *Vistra Energy; Parent Company for TXU Energy and Luminant Announces Corporate Rebranding as Vistra Energy*, *supra* note 824. On Vistra's and Dynegy's statuses, see *supra* note 824 and accompanying text.

⁸⁴⁸ On UARG and coal, see Zack Colman & Alex Guillén, *Documents Detail Multimillion-Dollar Ties Involving EPA Official, Secretive Industry Group*, POLITICO (Feb. 20, 2019, 7:09 PM), <https://www.politico.com/story/2019/02/20/epa-air-pollution-regulations-wehrum-1191258> [<https://perma.cc/8UAV-EZXX>]. On the split among generators based on carbon with regard to EPA GHG regulation, see Irja Vormedal & Jonas Meckling, *How Foes Become Allies: The Shifting Role of Business in Climate Politics*, 57 POL'Y SCIS. 101, 114–15 (2024), and CHRISTIAN DOWNIE, BUSINESS BATTLES IN THE US ENERGY SECTOR: LESSONS FOR A CLEAN ENERGY TRANSITION 86 (2019).

⁸⁴⁹ See DATASET, *supra* note 10, File 36.

⁸⁵⁰ See *supra* note 823 and accompanying text.

⁸⁵¹ Calculations based on EDISON ELEC. INST., 2013 FINANCIAL REVIEW 66 (2014) [hereinafter EEI 2013 FINANCIAL REVIEW] (eighty percent); EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75 (eighty-one percent); and EEI 2020 FINANCIAL REVIEW, *supra* note 823, at 7 (eighty-seven percent).

⁸⁵² DATASET, *supra* note 10, File 35, Rows 52, 273; EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75; EEI 2013 FINANCIAL REVIEW, *supra* note 851, at 66.

⁸⁵³ DATASET, *supra* note 10, File 35, Rows 42, 53, 77, 89, 116, 134, 213; EDISON ELEC. INST., 2015 FINANCIAL REVIEW 69 (2016) [hereinafter EEI 2015 FINANCIAL REVIEW]; EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75; EDISON ELEC. INST., 2017 FINANCIAL REVIEW 68 (2018) [hereinafter EEI 2017 FINANCIAL REVIEW].

suits;⁸⁵⁴ PPL, ranked ninth and twelfth at the time of its two suits;⁸⁵⁵ and Xcel, ranked tenth and thirteenth at the time of its two suits.⁸⁵⁶ Altogether, twelve IOUs were either in the top twenty when they sued⁸⁵⁷ or were in the top twenty when their UARG membership was leaked⁸⁵⁸ or both.⁸⁵⁹ As for publicly traded IPPs, three of the four sued, each challenging multiple rules: Vistra (through Luminant),⁸⁶⁰ NRG Energy,⁸⁶¹ and Dynegy.⁸⁶²

Generators' litigiousness against the EPA during Obama's second term was in keeping with most of the industry's history since the EPA was founded in 1970. Electric utilities, in the words of Anonymous Interviewee #7, a partner in a large law firm representing CAA-regulated businesses, "have a long storied history of suing the agency."⁸⁶³ In the twenty-four years preceding this Article's core study period—1989 through 2012—UARG brought sixty-four lawsuits against the EPA.⁸⁶⁴ In the same twenty-four-year period, EEI brought fifty-six suits against

⁸⁵⁴ DATASET, *supra* note 10, File 35, Rows 52, 260, 273 (latter two are the same matter); EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75; EEI 2013 FINANCIAL REVIEW, *supra* note 851, at 66.

⁸⁵⁵ DATASET, *supra* note 10, File 35, Rows 29, 80; EEI 2015 FINANCIAL REVIEW, *supra* note 853, at 69; EEI 2017 FINANCIAL REVIEW, *supra* note 853, at 68.

⁸⁵⁶ DATASET, *supra* note 10, File 35, Rows 238, 296; EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75; EEI 2017 FINANCIAL REVIEW, *supra* note 853, at 68. The four others were FirstEnergy (#14 and #17), Wisconsin Electric Power ("WEC") (#20), Entergy (#18), and Ameren (#19 and #21). DATASET, *supra* note 10, File 35, Rows 30, 52, 75, 162, 210, 219, 224, 273, 277, 286, 297, 307; EEI 2013 FINANCIAL REVIEW, *supra* note 851, at 66; EEI 2017 FINANCIAL REVIEW, *supra* note 853, at 68; EEI 2015 FINANCIAL REVIEW, *supra* note 853, at 69; EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75.

⁸⁵⁷ Xcel and Entergy. *See* sources cited *supra* note 856.

⁸⁵⁸ Dominion, DTE Energy, and Eversource. *See* Util. Air Regul. Grp., *supra* note 847, at 6; EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75. On how certain generators publicly supported GHG regulations of existing plants without dissociating themselves from UARG, *see* DOWNIE, *supra* note 848, at 90.

⁸⁵⁹ Duke, Southern, AEP, PPL, FirstEnergy, WEC, and Ameren. *See* Util. Air Regul. Grp., *supra* note 847, at 6; EEI 2016 FINANCIAL REVIEW, *supra* note 847, at 75; *supra* notes 852–56 and accompanying text.

⁸⁶⁰ DATASET, *supra* note 10, File 35, Rows 54, 281, 299; *see also id.* File 35, Rows 117, 212, 241 (listing the Luminant challenges before the parent company changed its name from Texas Competitive Electric Holdings).

⁸⁶¹ *Id.* File 35, Rows 24, 235.

⁸⁶² *Id.* File 35, Row 52; *see also id.* File 35, Row 239 (noting that challenger Coletto Creek Power was acquired by Dynegy during its lawsuit).

⁸⁶³ Interview with Anonymous Interviewee #7, *supra* note 28.

⁸⁶⁴ UARG and EPA Bloomberg Docket Search (dated Jan. 27, 2025), BLOOMBERG L., <https://www.bloomberglaw.com/product/blaw/search/results/5bd85fe525a2bbfe66c5c69371f20009> [<https://perma.cc/HA7F-9KK5>] (go to Bloomberg Law's search bar; then change the selection from "All Content" to "Court Dockets"; then click "Select Sources" and filter "Parties" to include "Utility Air Regulatory Group" as type "Petitioner" and "Environmental Protection Agency" as type "Respondent"; then choose filter "Federal Court Dockets," click "Supreme, Appellate & District Courts," and choose "U.S. Courts of Appeals"; then click "Search"). All challenges were in 2001–2013. *Id.*

the agency.⁸⁶⁵ The literature on the EPA in the 1970s easily turns up leading cases arising from electric utility challenges.⁸⁶⁶ If anything, the 2010s were a shift toward *less* uniform antiregulatory litigiousness in that a growing subset of generators—the ones with fuel portfolios less affected by restrictions at issue in that period—were supporting tougher EPA action (which was to their competitive advantage) and in some cases suing Trump’s EPA for being too lax.⁸⁶⁷ This industry split presumably explains why EEI pulled back on suing, leaving the arena to UARG.⁸⁶⁸

Why have electric generators long been willing to challenge the EPA’s efforts to regulate them? In light of the many sources indicating that businesses in Part I were unwilling to challenge partly because they felt a need to preserve their relationship with the agency, one possibility is that electric generators do not have a big stake in their relationship to the EPA and thus feel there is nothing to lose by suing. As support for this idea, it is perhaps relevant that so much of the EPA’s CAA activity consists of rulemaking, as opposed to the kind of adjudications—especially permit decisions, which are left to state agencies—that make for a thick, high-leverage relationship between agency and business, as with, say, FDA and each drugmaker.⁸⁶⁹

Although generator-EPA relations do seem to be thinner than drugmaker-FDA relations, we should not go too far in discounting relationships in the EPA context. They appear to be much higher stakes than, say, employers’ relationships with OSHA. Although directives issued by the EPA’s Office of Air and Radiation, including those subject to the suits catalogued above, are typically characterized as “rules” in a legal sense, they vary tremendously in their level of specificity. Some, like the NAAQS, are sweeping and general, but many others are implementational rules that can be quite granular—for example, a “rule” that partially rejects a SIP and substitutes the EPA’s own federal emission requirements for certain named power plants.⁸⁷⁰ The closer EPA directives get to minutiae, as they often do, the more they have predictable bespoke effects on individual companies, especially if those

⁸⁶⁵ Docket Search Results with Edison Electric Institute as Petitioner and Environmental Protection Agency as Respondent, BLOOMBERG L., <https://www.bloomberglaw.com/product/blaw/search/results/2ede2741addebed2ecda70ab7f9e0030> [<https://perma.cc/4HGJ-DZ49>] (repeat the same steps described *supra* note 864 but filter “Parties” to include “Edison Electric Institute” as type “Petitioner”).

⁸⁶⁶ MELNICK, *supra* note 266, at 20–21 tbl.I-I (citing seven published opinions from 1973–1979).

⁸⁶⁷ On the subset of clean generators supporting CPP, see Vormedal & Meckling, *supra* note 848, at 114–15. An example is Petition for Review, *supra* note 841, at 1, where Consolidated Edison, Inc. challenged the repeal of the Clean Power Plan.

⁸⁶⁸ On EEI’s pullback, compare *supra* text accompanying note 842 (2013–2021), with text accompanying note 865 (1989–2012).

⁸⁶⁹ See generally Brownell, *supra* note 829; *supra* Section I.B.

⁸⁷⁰ Approval and Promulgation of Implementation Plans, 81 Fed. Reg. 296, 346–47 (Jan. 5, 2016) (to be codified at 40 C.F.R. pt. 52).

companies are (1) relatively few and large, as IOUs and major IPPs are, and (2) variable in the characteristics that make them more or less vulnerable to regulation, as electric generators are, due to factors like the various designs of their plants, including what fuels they are built to use. In writing a directive, the EPA may be choosing among alternatives that have very different effects on different companies, such as deciding which of several pollution-control technologies to mandate when some technologies will fit more cheaply with some companies' plants, while others will with different companies' plants.⁸⁷¹ Much of lawyers' advocacy on behalf of clients in EPA rulemaking involves accepting a regulation's overall structure while seeking incremental changes "that would lessen the pain": "[A]long with every regulatory proposal, there may be scads of details that—depending upon how they are drafted—could result in greatly varying degrees of burdens for [one's] clients."⁸⁷² Anonymous Interviewee #7 insisted that individualized company effects still mattered even though the EPA's CAA work product is so heavily weighted toward directives that are labeled "rules."⁸⁷³ Consider these comments, which the interviewee cast as applicable to a range of CAA-regulated entities, expressly including electric utilities:

INTERVIEWEE: If [EPA regulation writers] want to damage a company, they can find out the pain points for that company, which, by the way, are usually laid out pretty clearly in whatever rulemaking comments that the agency has [received]. And they just, you know, push those buttons . . . They'll go through the reg, and they'll say, "Oh, it would really hurt [this one company] if we, you know, if we change this provision and that provision."

AUTHOR: Even though superficially it's a general rule, they know how the rule is gonna differentially impact different companies?

INTERVIEWEE: Precisely. And they know either generally from industry knowledge, or, like I said, it's probably pretty ascertainable by the reg writers from the comments that the [company] filed.⁸⁷⁴

A further reason generator-EPA relationships can matter is that many EPA rules are subject to frequent—and essentially endless—reopenings and reformulations due to statutorily mandated periodic reviews, agency judicial defeats, and political party turnover.⁸⁷⁵ One advice book for EPA practitioners emphasizes that many rulemaking processes are

⁸⁷¹ See RICHARD G. STOLL, *EFFECTIVE EPA ADVOCACY* 87 (2d ed. 2014).

⁸⁷² *Id.* at 77.

⁸⁷³ Interview with Anonymous Interviewee #7, *supra* note 28.

⁸⁷⁴ *Id.*

⁸⁷⁵ STOLL, *supra* note 871, at 128–29.

“never-ending” and “can often drag on for decades.”⁸⁷⁶ This, too, raises the stakes of a company’s long-term relations to the EPA.

Despite the value that many generators likely see in their relationship to EPA’s air pollution regulators, they still sue in a way that none of the companies in Part I do. Likely relevant is a key distinguishing factor between EPA regulation of generators and the schemes in Part I: the absence of alignment between industry interests and agency mission. The EPA is protecting victims of the externalities of generators’ activity, whereas the agencies in Part I are generally protecting regulated companies’ own customers.⁸⁷⁷ There may be some detriment to their popular image that generators suffer from resisting the EPA’s public health initiatives, but fundamentally, the generators do not have any sort of valuable transactional connection with pollution victims qua pollution victims. This holds for every type of generator. First, it holds for IPPs, who sell electricity at wholesale and do not reach retail customers.⁸⁷⁸ Second, it holds for IOUs insofar as they are operating generators not connected to transmission or distribution lines that they own, in which case IOUs similarly are not reaching retail customers.⁸⁷⁹ Third, it even holds for IOUs when they are both generating power and delivering that power over lines they own to their own retail customers, because the public health harms of air pollution are geographically widespread and range well beyond the service territory of a utility, leaving the danger unlinked to the product. This is true of the criteria pollutants associated with electric generators⁸⁸⁰ and often of the hazardous air pollutants

⁸⁷⁶ *Id.* at 128.

⁸⁷⁷ See *Air Enforcement*, *supra* note 812; see also *supra* Part I.

⁸⁷⁸ See *supra* notes 601, 816–19 and accompanying text.

⁸⁷⁹ See *supra* notes 820–21 and accompanying text.

⁸⁸⁰ As to criteria air pollutants, the proportion of early deaths in the continental United States caused by ozone and fine particulate matter arising from *out-of-state* electric power generation has been estimated at seventy-six percent in 2005, seventy-three percent in 2011, and sixty-five percent in 2018. Irene C. Dedoussi, Sebastian D. Eastham, Erwan Monier & Steven R.H. Barrett, *Premature Mortality Related to United States Cross-State Air Pollution*, 578 NATURE 261 (2020); *id.* Extended Data Fig. 2 (appended following p.265). For an earlier and similar estimate regarding the geographic origins of particulate matter, though not confined to generation, see ENV’T PROT. AGENCY, EPA 454-R-04-002, THE PARTICLE POLLUTION REPORT 8 & fig.5 (2004). It is estimated that, in any given state, sixty-five percent to eighty-five percent of nitrogen oxides and sulfur dioxide that originate from coal-fired plants is from *out-of-state* plants. John M. Morehouse & Edward Rubin, Downwind and Out: The Strategic Dispersion of Power Plants and Their Pollution 16–18 (Apr. 23, 2021) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3915247 [<https://perma.cc/T3UZ-VR3P>]; see also Ann E. Carlson, *The Clean Air Act’s Blind Spot: Microclimates and Hotspot Pollution*, 65 UCLA L. REV. 1036, 1056 (2018) (stating that near-source exposure is important for particulate matter and nitrogen dioxide while suggesting that “the largest culprit” for near-source effects is cars and trucks, not mentioning power plants); *id.* at 1059 (“There is a surprising dearth of data about near-site exposure to emissions of NAAQS pollutants from stationary sources like power plants . . .”); *id.* at 1062–63 (noting that fine particulate matter can be concentrated near roadways but is also a regional pollutant whose sources

associated with such generators.⁸⁸¹ And it is strikingly true of GHGs, which “uniformly mix in the atmosphere, and so the nature, magnitude, and location of damages [from the resulting changes in the climate] are independent of the location of emissions.”⁸⁸²

are often unclear); *id.* at 1063 (referring to nitrogen dioxide as “more uniformly a traffic-related pollutant” than fine particulate matter); *id.* at 1076 (stating that sulfur dioxide does “not create near-source problems”). Indeed, the sites of major sources of NAAQS pollutants or of HAPs, very much including power plants, are chosen strategically so that the pollutants will be more likely to blow out of state. James E. Monogan III, David M. Konisky & Neal D. Woods, *Gone with the Wind: Federalism and the Strategic Location of Air Polluters*, 61 AM. J. POL. SCI. 257, 257 (2017).

⁸⁸¹ Most prominent in the HAP discourse has been mercury, which harms humans by contaminating seafood they consume. See *Mercury in Food*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/environmental-contaminants-food/mercury-food> [<https://perma.cc/J687-W7QK>]. The spread of mercury is partly local but also has a major global component. See Jozef M. Pacyna et al., *Current and Future Levels of Mercury Atmospheric Pollution on a Global Scale*, 16 ATMOSPHERIC CHEMISTRY & PHYSICS 12,495, 12,496, 12,505 (2016). The geography of mercury emissions’ local effects is not straightforward. A study of fish within ten kilometers of coal-fired power plants finds they have *less* mercury in their tissue than fish more than thirty kilometers away. Dana K. Sackett, D. Derek Aday, James A. Rice, W. Gregory Cope & David Buchwalter, *Does Proximity to Coal-Fired Power Plants Influence Fish Tissue Mercury?*, 19 ECOTOXICOLOGY 1601, 1601 (2010). When EPA justified its Mercury and Air Toxics Standards rule, it found health benefits from reducing mercury were mostly too difficult to quantify and instead based its cost-benefit analysis (“CBA”) mainly on incidental reductions the rule would cause for particulate matter. ENV’T PROT. AGENCY, EPA-452/R-11-011, REGULATORY IMPACT ANALYSIS FOR THE FINAL MERCURY AND AIR TOXICS STANDARDS §§ ES.1, 4.8.5.6 (2011), <https://www3.epa.gov/ttnecas1/regdata/RIAs/matsriafinal.pdf> [<https://perma.cc/L4D4-S88F>].

⁸⁸² Robert N. Stavins, *The Problem of the Commons: Still Unsettled After 100 Years*, 101 AM. ECON. REV. 81, 98 (2011). One study argues with regard to three Obama-era CAA rules aiming to mitigate pollution arising mainly from coal—on mercury, cross-state pollution, and GHGs—that each rule passes a CBA at not only the national level but also the regional level. David E. Adelman & David B. Spence, *Ideology vs. Interest Group Politics in U.S. Energy Policy*, 95 N.C. L. REV. 339, 391–401 (2017). The study does not undermine the idea that IOUs are likely to view EPA CAA rulemaking as protecting externality victims rather than their own ratepayers. First, because the study aims to answer critiques of the EPA leveled by managers of regionally organized power markets and grid-stability entities, it defines “regions” according to those contexts, i.e., as very large areas, each encompassing about four to eight states, *id.* at 369, such that each region often covers the service territories of several utilities. Second, the claim about intraregion CBA comes with several qualifications, including that the Southeast “is arguably an exception” with regard to the mercury rule, *id.* at 394; that “the benefits [of the cross-state rule] are not equally shared across different regions of the country” and that the rule’s costs may be “unevenly spread,” *id.* at 396–97; that the unevenness in the cross-state rule’s costs and benefits is not so much nonexistent as deserved in light of the distribution of past externalities, *id.* at 397; that EPA’s analysis for the GHG rule is cruder and lumpier than even a “regional” analysis, *id.* at 398; and that the study’s own analysis of the GHG rule—going beyond EPA’s—reaches “mixed” results in finding that there are “clear interstate and regional disparities” in costs and benefits for each of several regions, *id.* at 398–99, which may be “distributed unevenly,” *id.* at 400. Relatedly, the study “stops short of state-by-state comparisons” and notes that states in “coal-producing regions may be exempted” from any claim that CBA for each state will be positive, as “job losses” in a coal state “might outweigh the benefits of emissions reductions.” *Id.* at 401 & n.299. Third, the idea that EPA rules like these pass a region-specific CBA, even if correct, is not widely known or accepted in the discourse. The Obama EPA’s own analyses “center[ed]” on national effects while “obfuscat[ing]” regional effects.

The remainder of this Section pulls the camera back to consider industries' willingness to challenge the EPA across a wider range of the agency's activities. Although CAA regulation of electric generators is arguably the most impactful thing the EPA does, the agency also regulates many other industries—typically with the aim of protecting externality victims—and these other industries often tend to litigate against externality regulation, similarly to what we observe in the case of the generators. The two most prominent industries that the EPA regulates under the CAA besides generators are oil-and-gas companies and automakers.⁸⁸³ During this Article's core study period of 2013–2021, the principal oil-and-gas trade association, American Petroleum Institute, brought sixteen suits challenging as many distinct EPA rules.⁸⁸⁴ The automakers' principal trade association brought only one suit in the same period,⁸⁸⁵ although this relatively accommodating stance toward environmental regulation is a recent phenomenon.⁸⁸⁶ Top automaker associations brought twenty-six suits against the agency in the period from 1989 to 2011.⁸⁸⁷

EPA's other major enabling acts are the Resource Conservation and Recovery Act ("RCRA"),⁸⁸⁸ Clean Water Act ("CWA"),⁸⁸⁹ and Toxic Substances Control Act ("TSCA").⁸⁹⁰ As to RCRA, regulated waste

Id. at 376, 392. Indeed, the data necessary for region-specific CBA was "buried" by EPA in ways that the authors overcame only with "time and persistence." *Id.* at 392 n.271.

⁸⁸³ See Greg Dotson & Dustin J. Maghamfar, *The Clean Air Act Amendments of 2022: Clean Air, Climate Change, and the Inflation Reduction Act*, 53 ENV'T L. REP. 10,017, 10,017, 10,021, 10,032 (2023).

⁸⁸⁴ DATASET, *supra* note 10, File 35, Rows 62, 63, 104, 153, 163, 179, 185, 190, 199, 313, 320, 323, 330, 338, 353, 360.

⁸⁸⁵ *All. of Auto. Mfrs. v. EPA*, No. 17-1086 (D.C. Cir. filed Mar. 13, 2017).

⁸⁸⁶ On the shift in automaker strategy on issues like fuel economy, see Vormedal & Meckling, *supra* note 848, at 113, 117–18.

⁸⁸⁷ See Search Return of Lawsuits Brought by Automobile Trade Organizations Against the EPA from 1989 to 2011, BLOOMBERG LAW, <https://www.bloomberglaw.com/product/blaw/search/results/57ce203259c4345532656d782f2641fb> [<https://perma.cc/5LYN-V69V>] (go to Bloomberg Law's search bar; then change the selection from "All Content" to "Court Dockets"; then click "Select Sources" and filter "Parties" to include names of automobile trade organizations listed *supra* note 305 as type "Petitioner" and "Environmental Protection Agency" as type "Respondent"; then click "Search"; then "Sort" the list by "Date" and scroll to the period from 1989 to 2011). Fuel economy standards might be viewed as a type of consumer protection—albeit one of the economic variety, as the standards reduce consumer costs but do not protect the *consumer's* health or safety and may even reduce crashworthiness—but it has been doubtful whether consumers actually recognize the net savings they can anticipate from fuel economy, and the automakers have not perceived consumers as recognizing those savings. See NAT'L RSCH. COUNCIL, COST, EFFECTIVENESS, AND DEPLOYMENT OF FUEL ECONOMY TECHNOLOGIES FOR LIGHT-DUTY VEHICLES 315 (2015).

⁸⁸⁸ Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901–6987.

⁸⁸⁹ Clean Water Act, 33 U.S.C. §§ 1251–1389.

⁸⁹⁰ Toxic Substances Control Act, 15 U.S.C. §§ 2601–2629. This Article does not address the Safe Drinking Water Act, 42 U.S.C. § 300f, because water utilities regulated thereunder are

producers have long been major challengers. The core study period saw the principal trade associations of more than a dozen waste-producing industries sue.⁸⁹¹ A classic study used RCRA rulemakings in 1988 through 1990 to demonstrate that entities can litigate against agencies even as they maintain an ongoing relationship.⁸⁹² As with generators under the CAA, industry litigiousness against the EPA under RCRA demands an explanation apart from the thinness of the relationship, and the statute's protective focus on externality victims rather than customers⁸⁹³ could serve that purpose. As to the CWA, industry is likewise active. During the core study period, the EPA's rulemaking to assert broader jurisdiction over wetlands elicited scores of lawsuits from an extraordinary range of industries through their respective associations.⁸⁹⁴ Finally, as to TSCA, there had long been few challenges, because the EPA was not very active in administering the statute, though a search of the period from 2021 to 2024 shows that industry has become active as implementation of major amendments from 2016 has come to fruition.⁸⁹⁵ The case of TSCA is complicated because the harms arising from regulated chemicals can be environmental externalities, workplace hazards, or consumer hazards, so TSCA is partly a *consumer* health-and-safety statute.⁸⁹⁶ But TSCA's connection to consumers is more attenuated than is the case for the regulatory statutes in Part I,⁸⁹⁷ because normally the regulated chemicals are, at most, used *in the process of making* consumer

overwhelmingly government owned, so they are not an industry by my definition, *see* FOOD & WATER WATCH, THE STATE OF PUBLIC WATER IN THE UNITED STATES 2 (2016) (noting that eighty-seven percent of the U.S. population received water from government entities as of 2014).

⁸⁹¹ DATASET, *supra* note 10, File 34, Rows 504, 508, 511, 513–15.

⁸⁹² *See* Coglianese, *supra* note 4, at 736–37, 762–63. For confirmation that the challenging companies included regulated waste producers and their associations as opposed to waste management companies whose incentive would be to favor regulation, *see* Cary Coglianese, *Challenging the Rules: Litigation and Bargaining in the Administrative Process* 233–35 (1994) (Ph.D. dissertation, University of Michigan) (on file with the University of Michigan).

⁸⁹³ *See Resource Conservation and Recovery Act (RCRA) Overview*, ENV'T PROT. AGENCY (Sept. 11, 2024), <https://www.epa.gov/rcra/resource-conservation-and-recovery-act-rcra-overview> [<https://perma.cc/Y67Q-9587>].

⁸⁹⁴ Most of the rows in the following ranges are challenges to this CWA rule: DATASET, *supra* note 10, File 34, Rows 530–575; *id.* File 33, Rows 59–95.

⁸⁹⁵ DATASET, *supra* note 10, Files 37, 37A; *id.* File 33 (no industry TSCA challenges in district courts); *id.* File 34, Rows 526–529; *see* Richard A. Denison, *A Primer on the New Toxic Substances Control Act (TSCA) and What Led to It*, ENV'T DEF. FUND: EDF HEALTH, Apr. 2017, at 1–2, 4–7, <https://www.edf.org/sites/default/files/denison-primer-on-lautenberg-act.pdf> [<https://perma.cc/KU2G-XU6E>].

⁸⁹⁶ *See* Denison, *supra* note 895, at 2–3.

⁸⁹⁷ In the industry challenge that was widely viewed as crippling TSCA during the era before its 2016 amendment, *see* *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1201 (5th Cir. 1991), the rule at issue was a ban on asbestos that EPA had framed mainly in terms of workplace risks and not more broadly, *id.* at 207–08; *see* Rachel Rothschild, *Unreasonable Risk: The Failure to Ban Asbestos and the Future of Toxic Substances Regulation*, 47 HARV. ENV'T L. REV. 529, 570 (2023).

products—they are not the products themselves.⁸⁹⁸ Relatedly, my search for suits in 2013 through 2021, which I extended through December 31, 2024 to cover more of the recent wave of TSCA suits, finds that industry challenges were generally brought by makers of regulated chemicals upstream in supply chains or their associations,⁸⁹⁹ not by downstream makers of actual consumer products.⁹⁰⁰ Consistent with this, interviewee

⁸⁹⁸ Interview with James W. Conrad Jr., Conrad Law & Policy Counsel (Aug. 30, 2024) (“[I]t’s unusual that a TSCA-regulated chemical would be sold directly to consumers, because in most cases it would end up being covered by some other, food-and-drug regulation, or it would be a pesticide” regulated by EPA under separate legislation.).

⁸⁹⁹ DATASET, *supra* note 10, Files 37, 37A; *id.* File 33 (no industry TSCA challenges in district courts); *id.* File 34, Rows 526–29. Note that the searches producing Files 37 and 37A (covering the period 2021–2024) were confined to suits including the term “toxic substances control act” in the docket sheet or in underlying documents available on Bloomberg.

⁹⁰⁰ There were three exceptions to the upstream nature of the challengers, but I think none reflected the kind of deep industry-agency confrontation that we often see elsewhere at EPA:

- First, several associations of consumer-facing companies—but no individual companies—brought an initial suit and later related suits to get EPA to delay implementation of a ban on the chemical PIP 3:1 that was being used in many consumer products, such as electronics; the ban was unusual because it extended to downstream sellers of the products who normally were not regulated by TSCA, and a representative of the National Association of Manufacturers spoke supportively of “transition[ing] out the chemicals of concern” while explaining that the associations wanted the transition to have “timelines that can work.” David LaRoss, *Manufacturers Seek PBT Rules ‘Pause’ Due to Implementation Concerns*, INSIDE TSCA (Mar. 5, 2021), <https://insideepa.com/tsca-news/manufacturers-seek-pbt-rules-pause-due-implementation-concerns> [https://perma.cc/2JPY-HKKZ]; Petition for Review at 1, *Air-Conditioning, Heating, & Refrigeration Inst. v. EPA*, No. 21-1082 (D.C. Cir. Mar. 4, 2021). EPA rapidly acknowledged the reasonableness of the associations’ concerns, promised to hold off enforcement and consider revising the rule, and said it had not been the agency’s “intent . . . to have such a broad disruptive impact.” Maria Hegstad, *EPA Vows ‘No Action’ for Violating One PBT’s Limits, Eyes Program Fixes*, INSIDE TSCA (Mar. 8, 2021), <https://www.proquest.com/docview/2501453678/F320104B5C67456EPQ/> [https://perma.cc/V2UD-V8LP]. EPA ultimately revised the rule, strengthening it in certain ways while relaxing constraints on distribution of products already made with the chemical. Maria Hegstad, *Industry Sees ‘Some Relief’ in TSCA PBT Rule Despite Tightened Limits*, INSIDE TSCA (Nov. 15, 2024), <https://insideepa.com/tsca-news/industry-sees-some-relief-tsca-pbt-rule-despite-tightened-limits> [https://perma.cc/9UPP-5BZW]. The associations then dropped their challenge. Consent Motion for Voluntary Dismissal of Petitions for Review, *Air-Conditioning, Heating, & Refrigeration Inst.*, No. 21-1082 (Dec. 13, 2024).
- Second, two individual businesses challenged EPA’s rule on methylene chloride, joined by the American Chemistry Council, which represents the entire chemical manufacturing supply chain. See Petition for Review at 1, *E. Fork Enters., Inc. v. EPA*, No. 24-60227 (5th Cir. May 10, 2024). The chemical has various workplace and industrial uses but also consumer ones, especially in paint stripper. See Joe Schwarcz, *Methylene Chloride Can Strip Paint But Can Also Strip Years Off Your Life*, MCGILL OFF. FOR SCI. & SOC’Y (May 15, 2024), <https://www.mcgill.ca/oss/article/medical-general-science/methylene-chloride-can-strip-paint-can-also-strip-years-your-life>

James W. Conrad Jr., longtime counsel to the chemical manufacturing industry and former chair of the ABA's administrative law section, told me, with regard to TSCA:

There are the downstream [companies], the Proctor and Gamble and so on. And those companies—those downstream companies—tend to be very averse to litigating things with EPA, because these are the companies that, you know, everybody trusts to put their products on their shelf and put them on their counters and on their babies and everything, so . . . if there's a chemical that works great and EPA comes up with some unjustified restriction, if [the downstream companies] can't talk EPA out of it, in many cases they just say, "well, just shows you how stupid the government is," and they go off and do something else. If it's more upstream—if it's Dupont or Dow or somebody, and you're making some commodity chemical in vast quantities that's used as a feedstock to make other things, or . . . it's going to be an additive to industrial lubricants and things that are not on anybody's radar screen unless you're in that industry—there's a lot more willingness to litigate stuff [with EPA], because whatever reporting there is about it is not likely to find its way to the popular media and to consumers.⁹⁰¹

Thus, proximity to consumer audiences appears to help shape industry litigation decisions.

C. *For-Hire Trucking Companies and FMCSA*

Our last agency-industry pairing in which industry judicial challenges are prevalent is that between for-hire trucking companies and the DOT's FMCSA, which is responsible for the safety of trucking operations.⁹⁰² For-hire trucking is unlike all the other industries analyzed

[<https://perma.cc/E7H3-R6EE>]. Both businesses appear small. One challenger, Epic Paint, has a website and appears to be a retailer with just one store, *see* Epic Paint Co., <https://epicpaint.net/> [<https://perma.cc/CC74-BARX>], while the other challenger, East Fork Enterprises, seems to have no web presence.

- Third, a one-showroom door-and-window seller with "a few" employees challenged an EPA enforcement proceeding for alleged violations of TSCA's requirement that firms doing renovations obtain certification and conduct notifications regarding hazards of lead-based paint. Verified Complaint for Injunctive & Declaratory Relief at 4, 8, *Ro Cher Enters., Inc. v. EPA*, No. 23-cv-16056 (N.D. Ill. Nov. 16, 2023).

⁹⁰¹ Interview with James W. Conrad, *supra* note 897.

⁹⁰² *About Us*, FED. MOTOR CARRIER SAFETY ADMIN. (Dec. 12, 2013), <https://www.fmcsa.dot.gov/mission/about-us> [<https://perma.cc/V47F-H38K>]. The safety of truck *design* is regulated by NHTSA. *See National Highway Traffic Safety Administration*, U.S. DEP'T OF TRANSP. (May 2, 2018), <https://www.transportation.gov/briefing-room/safetyfirst/national-highway-traffic-safety-administration> [<https://perma.cc/MV43-2PRE>].

in this Article so far because it is exceptionally dominated by small companies (outside the peculiar area of parcel delivery).⁹⁰³ Although small companies generally lack the resources to mount many individual lawsuits, small-company-specific trade associations, which represent a majority of the industry or something near it, have brought repeated and important challenges to major FMCSA initiatives. Small for-hire trucking companies' willingness to sue FMCSA could potentially be arising from either or both of two factors: the companies' lack of a strong relationship to the agency and the lack of a close alignment between companies' economic interests and the agency's mission. In contrast to coal mines' very thick relationship to MSHA or electric generators' moderately thick relationship to EPA, small for-hire trucking companies have a relatively thin relationship to FMCSA. And in contrast to the industries in Part I that align with their regulators' consumer-protective mission, the small-company for-hire trucking industry is weakly aligned with FMCSA in *both* of the ways that MSHA, OSHA and EPA are weakly aligned with their respective industries. First, the trucking regulator has a mission to protect employees of trucking companies, as with MSHA and OSHA.⁹⁰⁴ And second, it has a mission to protect third-party roadway travelers who might get into crashes with trucks, that is, externality victims, as with EPA.⁹⁰⁵ There are mechanisms by which harms to third-party travelers may be internalized by trucking companies, but these are limited, especially when it comes to small firms.

To be clear about the definition of the industry under study, *for-hire* trucking companies are roadway carriers who offer to shippers interstate transportation of goods.⁹⁰⁶ This category excludes companies that are mainly in nontransportation lines of business and own trucks to ship the company's *own* goods, known as *private fleets*, as is often the case with large retailers—for example, Walmart owns thousands of trucks to move goods from its distribution centers to its retail outlets, though it contracts with for-hire carriers to bring goods to those centers.⁹⁰⁷

In its treatment of for-hire trucking, this Article generally excludes parcel delivery, in which each shipper is sending only a small package. The parcel business requires the setup of distribution centers, plus the buildup of a large customer base to accumulate enough small items to

⁹⁰³ See *infra* notes 909–17 and accompanying text.

⁹⁰⁴ See *Federal Motor Carrier Safety Administration*, U.S. DEP'T OF TRANSP. (May 2, 2018), <https://www.transportation.gov/briefing-room/safetyfirst/federal-motor-carrier-safety-administration> [<https://perma.cc/9EGK-GLTG>].

⁹⁰⁵ See *Our Mission*, FED. MOTOR CARRIER SAFETY ADMIN. (Dec. 13, 2013), <https://www.fmcsa.dot.gov/mission> [<https://perma.cc/5KAR-44T4>].

⁹⁰⁶ Steve Viscelli, *The Trouble with Trucking: How Low Road Strategies Work in the Transportation Industry*, in *CREATING GOOD JOBS* 281, 282 (Paul Osterman ed., 2019).

⁹⁰⁷ *Id.* at 281, 303.

fill trucks, so the business is dominated by huge companies—UPS and FedEx—in a way that is totally unlike the rest of for-hire trucking.⁹⁰⁸

Apart from parcel delivery, for-hire trucking—the road transport of *commercial-sized* shipments—is remarkable for its dependence on small businesses. Compared to the capital investments necessary in nearly all the other industries in this Article, a truck is cheap and a company can do business with just one, so barriers to entry are low.⁹⁰⁹ If we look at FMCSA’s annual snapshot of U.S.-domiciled for-hire freight trucking companies for December 2017, a point in time near the middle of this Article’s core study period, we find that such companies numbered over 700,000 and that, excluding drivers for the parcel giants UPS and FedEx,⁹¹⁰ forty percent of their drivers worked for companies with ten drivers or fewer and sixty-two percent worked for companies with 100 drivers or fewer.⁹¹¹ The smallest businesses are the hundreds of thousands of “owner-operators,” each consisting of one driver owning one truck, while small companies with two or more trucks are known as “small truck fleets.”⁹¹² Some drivers are employed by larger companies, but even the largest ones are not big enough to dominate the industry. The largest nonparcel for-hire carrier is J.B. Hunt Transport,⁹¹³

⁹⁰⁸ On parcel delivery’s distinctness, see STEPHEN V. BURKS, MICHAEL BELZER, QUON KWAN, STEPHANIE PRATT & SANDRA SHACKELFORD, *TRANSP. RSCH. BD., TRUCKING 101: AN INDUSTRY PRIMER* 7, 13, 22 (2010); see also Viscelli, *supra* note 906, at 283.

⁹⁰⁹ See Viscelli, *supra* note 906, at 300.

⁹¹⁰ DATASET, *supra* note 10, File 70, Rows 1–20. To estimate the number of drivers for UPS and FedEx, I started with the company snapshots for United Parcel Service, Inc. and Federal Express Corporation drawn from the DOT Company Snapshot tool on January 5, 2025. See *Company Snapshot*, DEP’T OF TRANSP., <https://safer.fmcsa.dot.gov/CompanySnapshot.aspx> [<https://perma.cc/5JR9-AKTN>] (click search field “Name”; then enter either “United Parcel Service, Inc.” or “Federal Express Corporation” into the “Enter Value” bar; then click “Search”). I then discounted the totals by the ratio between the total numbers of drivers in (1) my industry-wide search for December 2017 and (2) a version of that same search that I ran for December 2024.

⁹¹¹ DATASET, *supra* note 10, File 70, Rows 1–20. I based calculations on the results of a search of the FMCSA’s custom reports tool, *Custom Reports*, FED. MOTOR CARRIER SAFETY ADMIN., <https://ai.fmcsa.dot.gov/registrationstatistics/CustomReports> [<https://perma.cc/U6CJ-YEFC>], with all search parameters set to “All” except for the following: “Count” (set to “# of drivers”), “Domicile Country” (set to “United States”), “Operation Class” (set to “For Hire” only, as opposed to “Private”), and “Carrier Type” (set to “Freight,” as opposed to more specialized types).

⁹¹² For the definition of owner-operator, see Kristen Monaco & Brydey Redmon, *Does Contracting with Owner Operators Lead to Worse Safety Outcomes for US Motor Carriers? Evidence from the Motor Carrier Management Information System*, 45 ACCIDENT ANALYSIS & PREVENTION 654, 656 (2012). The Owner-Operator Independent Drivers Association says it represents both owner-operators and owners and operators of “small truck fleets.” See, e.g., *About Us*, OWNER-OPERATOR INDEP. DRIVERS ASS’N, <https://www.ooida.com/who-we-are/about-ooida/> [<https://perma.cc/58HH-CQL8>].

⁹¹³ WILSON KO, CFRA, *INDUSTRY SURVEYS: GROUND TRANSPORTATION* 21, 30 (Raymond Jarvis et al. eds., 2024).

which employs 0.6% of all drivers in that category.⁹¹⁴ By comparison, Delta Airlines employs more than ten percent of U.S. airline pilots.⁹¹⁵ Of course, the many small companies in for-hire trucking often do not have the administrative capacity to obtain business from shippers on their own. They frequently get business through brokers—some of whom are very large—or by working as independent contractors, sometimes for other for-hire companies, often by arrangements that involve a lease of the truck.⁹¹⁶ When I spoke with Anonymous Interviewee #8, a partner in a large law firm specializing in regulation of transportation, including FMCSA matters, I asked about the role of “small carriers” in the for-hire market. The interviewee replied, “in aggregate, they dominate the market,” aided by brokers and various independent contracting arrangements.⁹¹⁷

The operations of for-hire truckers, small and large, are regulated by the FMCSA. As I elaborate later,⁹¹⁸ the agency seeks to ensure safety through a host of means. Substantively, the FMCSA requires that drivers have state commercial drivers’ licenses, periodic health certifications, and be drug-tested; that drivers limit their hours of service to prevent fatigue and are scrutinized for traffic violations; that vehicles be maintained properly, including annual inspections by third parties; and that drivers and vehicles be scrutinized for accidents.⁹¹⁹

The for-hire trucking industry has been relatively active in bringing judicial challenges to FMCSA safety constraints, with associations of small companies taking the lead. All these association challenges have targeted rules or other general policies or, if nominally aimed at an individual matter, have sought to challenge the general approach taken therein. I conducted an exhaustive Bloomberg dockets search for

⁹¹⁴ *Compare Company Snapshot*, *supra* note 910 (showing 24,043 drivers for “J B Hunt Transport” on January 5, 2025), with *DATASET*, *supra* note 10, File 70, Cell E9.

⁹¹⁵ *Compare* Delta Air Lines, Inc., Annual Report (Form 10-K) 9 (Feb. 12, 2024) (showing Delta employed 16,960 pilots during fiscal year 2023), with *Occupational Outlook Handbook: Airline and Commercial Pilots*, U.S. BUREAU OF LAB. STATS., <https://www.bls.gov/ooh/transportation-and-material-moving/airline-and-commercial-pilots.htm> [<https://perma.cc/2T9N-29HD>] (showing 152,800 total airline pilot jobs during calendar year 2023).

⁹¹⁶ On independent contracting and leasing, see BURKS ET AL., *supra* note 908, at 9–11; Viscelli, *supra* note 906, at 294, 297. On brokers, see Interview with Anonymous Interviewee #8, Partner in a large law firm specializing in regulation of transportation including FMCSA matters (Sept. 25, 2024). The largest for-hire carriers vary in whether they rely mainly on drivers who are employees or on drivers who are contractors. Monaco & Redmon, *supra* note 912, at 655.

⁹¹⁷ Interview with Anonymous Interviewee #8, *supra* note 916.

⁹¹⁸ See *infra* text accompanying notes 919, 948–65, 977–79.

⁹¹⁹ See FED. MOTOR CARRIER SAFETY ADMIN., SAFETY MEASUREMENT SYSTEM (SMS) METHODOLOGY § 2.1 (2024); *The Safety Measurement System (SMS)*, FED. MOTOR CARRIER SAFETY ADMIN., <https://csa.fmcsa.dot.gov/about/Measure> [<https://perma.cc/T658-E5MB>]. Anonymous Interviewee #8 noted the annual third-party inspection requirement. Interview with Anonymous Interviewee #8, *supra* note 916.

all suits against the FMCSA or against DOT on FMCSA matters for the core study period of 2013–2021, extended forward in time by three years up to January 20, 2024. I also conducted a more targeted search of the period from FMCSA’s establishment in 2000 up to January 20, 2013—but only for suits naming the FMCSA as defendant or respondent, not DOT, as searching for DOT would turn up suits that might have nothing to do with the FMCSA, often with no way of telling if they were, given the dearth of underlying filings. This two-tiered search of the twenty-four-year period from 2000 to 2024 yielded ten suits by associations against ten distinct FMCSA actions—nearly one every two years.⁹²⁰ The most frequent challenger was the Owner-Operator Independent Drivers Association (“OOIDA”), which represents both owner-operators—that is, one-person-one-truck companies—and slightly larger companies with “small truck fleets,” as well as individual drivers.⁹²¹ OOIDA has over 150,000 members and provides a range of services to truckers, including compliance management.⁹²² Sociologist Steve Viscelli, author of a recent and outstanding ethnography of trucking, finds that small truckers are vulnerable to all sorts of economic exploitation by larger entities with whom they contract—and that OOIDA is the only institution providing those drivers accurate advice to protect themselves, although the group insists on being a small-business association, not a union, and refuses to call for independent-contractor work stoppages.⁹²³ Anonymous Interviewee #8 called OOIDA a “major player” in trucking regulation.⁹²⁴ Besides OOIDA, other associational challengers included the Small Business in Transportation Coalition (“SBTC”), with over 15,000 members,⁹²⁵ sometimes coordinating with OOIDA,⁹²⁶ and the National Association of Small Trucking Companies (“NASTC”), with 8,000 members.⁹²⁷

⁹²⁰ DATASET, *supra* note 10, File 38, Rows 9, 12, 15, 22, 39; *id.* File 39 (no association suits); *id.* File 40, Rows 35, 40, 44, 51, 65.

⁹²¹ See sources cited *supra* note 920; *About Us*, *supra* note 912.

⁹²² *About Us*, *supra* note 912.

⁹²³ STEVE VISCELLI, *THE BIG RIG: TRUCKING AND THE DECLINE OF THE AMERICAN DREAM* 189, 192 (2016).

⁹²⁴ Interview with Anonymous Interviewee #8, *supra* note 916.

⁹²⁵ *SBTC Appeals Unreasonable Delay of Publication of ELD Exemption Application to Secretary of Transportation*, PRWEB (Oct. 21, 2019, 2:45 PM), <https://www.prweb.com/releases/sbtc-appeals-unreasonable-delay-of-publication-of-eld-exemption-application-to-secretary-of-transportation-863763954.html> [<https://perma.cc/WS6T-YZYC>].

⁹²⁶ John Gallagher, *ArcBest: Broker Costs Increase to \$500,000/Year If Owner-Operators Have Their Way*, FREIGHTWAVES (Sept. 21, 2020), <https://www.freightwaves.com/news/arcbest-broker-costs-increase-to-500000-year-if-owner-operators-have-their-way> [<https://perma.cc/58CD-E8RF>] (referring to a joint “OOIDA/SBTC petition” to FMCSA).

⁹²⁷ *Highway to Headache: Federal Regulations on the Small Trucking Industry: Hearing Before the H. Comm. on Small Bus.*, 115th Cong. 36 (2018) (statement of Marty DiGiacomo, Owner, True

The challenges came in a few subject matter clusters. The largest cluster concerned rules imposing hours-of-service (“HOS”) limits on truckers to prevent fatigue, plus related rules seeking to replace truckers’ traditional handwritten logbooks with electronic logging devices (“ELD”) that automatically record engine driving times and thus sharpen enforcement of the HOS.⁹²⁸ Truckers, whether employees or independent contractors, are typically paid by the mile, have little control over the time-wasting delays of shippers or customers at stops, and face extreme pressure to falsify their hours so as to drive more.⁹²⁹ Viscelli wrote in 2016 that “it is common knowledge that HOS rules are routinely broken by most drivers on a daily basis,” typically reporting that they work sixty-five or seventy hours per week when actually it is ninety or 100.⁹³⁰ This practice is one that employers and contracting companies largely allow because it is in their interest, and it is one that ELDs can reduce but not eliminate, because the devices only record driving, not labor at stops.⁹³¹ OOIDA sued to challenge FMCSA’s tighter HOS rules in 2006⁹³² and rules mandating ELDs in 2010.⁹³³ The American Trucking Associations—which includes the largest for-hire companies, private-fleet companies, and parcel giants and typically does not sue—challenged a yet-tighter set of HOS rules in 2012, and OOIDA supported the challenge as intervenor.⁹³⁴ OOIDA then challenged guidance purporting to expand enforcement against fatigue in 2012,⁹³⁵ as well as the agency’s second try at an ELD mandate in 2015.⁹³⁶ SBTC sued in 2020 to force the agency to process its proposal that smaller trucking companies be exempt from ELDs.⁹³⁷ Besides the cluster of HOS and ELD suits, there were also suits brought by the NASTC against a major FMCSA initiative to reformulate and publish carrier safety ratings in 2010,⁹³⁸ then again

Blue Transportation) (“NASTC represents more than 8,000 small motor carriers . . . [with] the average size [of members’ fleets] being 16 power units.”).

⁹²⁸ *Id.* at 31, 36.

⁹²⁹ VISCELLI, *supra* note 923, at 86–92.

⁹³⁰ *Id.*

⁹³¹ *Id.*

⁹³² OOIDA v. FMCSA, 494 F.3d 188 (D.C. Cir. 2007) (No. 06-1035) (filed Jan. 23, 2006).

⁹³³ Petition for Review at 1, OOIDA v. FMCSA, 656 F.3d 580 (7th Cir. 2011) (No. 10-2340) (filed June 3, 2010).

⁹³⁴ Petition for Review at 1–2, Am. Trucking Ass’n v. FMCSA, 724 F.3d 243 (D.C. Cir. 2013) (No. 12-1092) (filed Feb. 14, 2012).

⁹³⁵ Petition for Review at 1–2, OOIDA v. Ferro, 554 F. App’x 1 (D.C. Cir. 2014) (unpublished table decision) (No. 12-1483) (filed Dec. 21, 2012).

⁹³⁶ OOIDA v. DOT, 840 F.3d 879, 883 (7th Cir. 2016) (No. 15-3756) (filed Dec. 11, 2015).

⁹³⁷ Complaint & Request for a Temporary Restraining Order (TRO) at 3, SBTC v. DOT, No. 20-cv-00883 (D.D.C. Apr. 1, 2020). An earlier version of the same suit was *Small Business in Transportation Coalition v. DOT*, No. 19-cv-1311 (D.D.C. May 6, 2019).

⁹³⁸ Petition for Review at 1–2, NASTC v. FMCSA, No. 10-1402 (D.C. Cir. Nov. 29, 2010). For background on this and the next suit, see *Alliance for Safe, Efficient, and Competitive Truck Transportation v. FMCSA*, 755 F.3d 946, 947–49 (D.C. Cir. 2014).

in 2012 to a purported effort to alter the rating system.⁹³⁹ Additionally, OOIDA sued in 2013 to force the FMCSA to purge its database of safety violations dismissed by state courts⁹⁴⁰ and in 2016 to halt a supposed addition of mandatory sleep-apnea testing to trucker medical certifications.⁹⁴¹ OOIDA's litigation against regulation apparently goes back to the 1990s, when it challenged drug-testing policies by FMCSA's predecessor.⁹⁴²

Small-company trade associations' in-court resistance to FMCSA safety actions⁹⁴³ appears to be related to the fact that small trucking companies are generally less compliant with FMCSA safety rules than large companies are. This divergence in compliance is a "relatively consistent finding" of a large academic literature, as stated in a recent review essay by Jason Miller, a management professor specializing in the business and regulation of trucking.⁹⁴⁴ Miller explains that the literature has identified two reasons for the divergence, which are not mutually exclusive, and he further finds empirically that the two are operating simultaneously.⁹⁴⁵ First, large companies have more resources to devote to compliance.⁹⁴⁶ Second, large companies have stronger incentives to comply, because (1) their size exposes them to more regulatory monitoring and (2) they "have more brand equity (e.g., reputation) at risk if they are noncompliant with safety rules," as shippers and brokers may view violations as raising the risk of commercial disruption or tort

⁹³⁹ *All. for Safe, Efficient, & Competitive Truck Transp.*, 755 F.3d at 948–49 (No. 12-1305) (filed July 16, 2012).

⁹⁴⁰ Petition for Review at 1, *Weaver v. FMCSA*, 743 F.3d 142 (D.C. Cir. 2014) (No. 13-1172) (filed May 10, 2013). OOIDA was co-petitioner. *Id.*

⁹⁴¹ *OOIDA v. DOT*, 878 F.3d 1099 (8th Cir. 2018); Petitioners' Opening Brief at 1, *OOIDA*, 878 F.3d 1099 (No. 16-4159) (filed Jan. 23, 2017).

⁹⁴² *OOIDA v. Pena*, 862 F. Supp. 470, 473 (D.D.C. 1993). Besides the associational challenges to rules and general policies just discussed, the period from 2013 to 2024 saw a couple dozen suits by individual carriers to FMCSA enforcement actions, often other-than-satisfactory safety ratings or orders to shut down. DATASET, *supra* note 10, File 38. Considering the many thousands of FMCSA enforcement proceedings, which themselves touch only a small fraction of the huge trucking population, *see infra* notes 955–62 and accompanying text, these do not seem very significant. The challengers appear from FMCSA's database to be mostly smaller companies, consistent with the observation that large companies find FMCSA compliance relatively easy while if small companies do not, they usually lack the resources to challenge any resulting enforcement. Interview with Anonymous Interviewee #8, *supra* note 916.

⁹⁴³ It should be noted that OOIDA has challenged other FMCSA actions for being insufficiently safe, often when more safety regulation means barriers to entry. *E.g.*, *Advocs. for Highway & Auto Safety v. FMCSA*, 429 F.3d 1136, 1143–45 (D.C. Cir. 2005) (noting that OOIDA was among challengers to driver training requirements found to be overly lax); *OOIDA v. DOT*, 724 F.3d 230, 232 (D.C. Cir. 2013) (No. 12-1264) (filed June 18, 2012) (challenging exemption of foreign drivers from regulation).

⁹⁴⁴ Jason Miller, *Why Are Larger Motor Carriers More Compliant with Safety Regulations?*, 59 *TRANSP. J.* 28, 29 (2020).

⁹⁴⁵ *Id.*

⁹⁴⁶ *Id.*

liability.⁹⁴⁷ The corollary is that small companies have less money to spare on compliance and weaker incentives to comply.

This last point—that smaller companies have weaker incentives for compliance—can be framed in the terms employed to analyze all the agency-industry pairings in this Article so far. First, small for-hire companies are subjected less frequently to FMCSA monitoring, which goes to the point that they have a thin relationship to the agency. Second, the mechanisms that might cause trucking companies to internalize the externality of harm to third-party accident victims are weaker in the case of small companies, leaving those companies less aligned with the FMCSA's safety mission. This Article discusses these points in turn.

First, as to company relationships with the FMCSA, the agency's relationship with all companies, large and small, is generally thinner than in all the pairings in Part I, except perhaps CPSC and children's product companies. The FMCSA does not have much of a frontline inspector service; instead it relies overwhelmingly upon information from state and local officers or private parties: reports of traffic violations, reports of crashes, complaints from individuals, or inspections performed—usually by state transportation officers—at places like weigh stations at state borders, which are often partly or entirely randomized.⁹⁴⁸ This monitoring is intermittent and nothing like real time. FMCSA data indicates that in 2018 through 2022 there were roughly 2.5 million to 3.5 million inspections per year, of which about a third were full inspections while another third focused only on the driver and another third only on the vehicle exterior.⁹⁴⁹ Meanwhile, there were roughly 4.5 million to 5.5 million FMCSA-regulated trucks and 3.6 million to 4.2 million

⁹⁴⁷ *Id.* at 38; Deborah Whistler, *Research Evaluates CSA's Operational Impacts*, FLEETOWNER (Dec. 13, 2012), <https://www.fleetowner.com/safety/article/21684348/research-evaluates-csas-operational-impacts> [<https://perma.cc/2GDZ-D4FT>].

⁹⁴⁸ On the relative numbers of inspectors and inspections at federal and state levels, see FED. MOTOR CARRIER SAFETY ADMIN., 2023 POCKET GUIDE TO LARGE TRUCK AND BUS STATISTICS 17 tbls. 2-1 & 2-2 (2023). On the various information sources, see U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-433T, MOTOR CARRIER SAFETY: IMPROVEMENTS TO DATA-DRIVEN OVERSIGHT COULD BETTER TARGET HIGH RISK CARRIERS 1 (2015) [hereinafter GAO TESTIMONY] (referring to crash reports and inspections); U.S. GOV'T ACCOUNTABILITY OFF., GAO-14-114, FEDERAL MOTOR CARRIER SAFETY: MODIFYING THE COMPLIANCE, SAFETY, ACCOUNTABILITY PROGRAM WOULD IMPROVE THE ABILITY TO IDENTIFY HIGH RISK CARRIERS 11–12 (2014) [hereinafter GAO (2014)] (referring to carrier safety scores, complaints, and crashes); Interview with Anonymous Interviewee #8, *supra* note 916 (referring to state-border weigh stations and more generally to any incidents that would prompt interactions with police; noting inspections may be random or based on carrier safety scores the agency uses internally for prioritization); VISCELLI, *supra* note 923, at 88 (“Enforcement of HOS is handled by state DOT officials at truck scales and roadside checkpoints and by police.”).

⁹⁴⁹ FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 20 tbl.2-5. The Pocket Guide is an imperfect source because it does not differentiate between for-hire and private fleets, but it seems to be the best available for FMCSA activity statistics.

FMCSA-regulated drivers,⁹⁵⁰ suggesting one could expect an inspection of a given driver or truck about once every two years on average—far more frequent monitoring than OSHA, but far less than FSIS, FAA, or NRC.⁹⁵¹ These occasional inspections serve a narrow ad hoc compliance purpose in themselves, as the inspector, usually a state officer, can order that a compliance problem, most commonly a vehicle maintenance issue, be fixed before business can resume; this happens in roughly twenty percent of inspections.⁹⁵² Considering that the information the FMCSA receives is so intermittent, the agency seeks to identify carriers for which intervention at the company level might be salutary in preventing serious future problems, but the agency is resource-constrained in doing so, as it has only about 1,000 employees⁹⁵³ to police the huge truck and driver populations cited above (which are grouped into about 580,000 to 800,000 companies at any given time).⁹⁵⁴ When reports flow in suggesting problems with companies, the agency autogenerates warning letters to them, typically numbering between 20,000 to 25,000 per year.⁹⁵⁵ Warning letters per se do not require a response.⁹⁵⁶ But they form part of a system whereby the agency gives escalating scrutiny to carriers about which it receives further concerning information, the key step being an audit in which the agency visits the carrier's office or requires it to submit records so the agency can scrutinize company management with regard to the problems at issue.⁹⁵⁷ Audits number about 12,000 per year⁹⁵⁸—around one percent of all carriers.⁹⁵⁹ If the audit indicates problems, FMCSA can (1) give the carrier an other-than-satisfactory safety rating, which can have bad business consequences, discussed below,⁹⁶⁰ (2) impose monetary penalties, which are very low, or (3) if problems

⁹⁵⁰ FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 10 tbl.1-8. I refer to “CDL Drivers,” not “Total Drivers.”

⁹⁵¹ See *supra* Sections I.A, I.D, I.F, II.A.

⁹⁵² FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 19 tbl.2-4.

⁹⁵³ GAO (2014), *supra* note 948, at 5.

⁹⁵⁴ FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 13 tbl.1-11.

⁹⁵⁵ GAO (2014), *supra* note 948, at 11 tbl.2 (24,126 in the year 2012); FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 27 tbl.3-3 (covering years 2018 to 2022).

⁹⁵⁶ FED. MOTOR CARRIER SAFETY ADMIN, FMC-CSA-14-003, I GOT A WARNING LETTER—WHAT DO I DO? (2014), https://csa.fmcsa.dot.gov/documents/Warning_Letter_Factsheet_GRS_K_Final_508.pdf [<https://perma.cc/2NNP-BHOK>].

⁹⁵⁷ See Mariah Barr, *3 Types of FMCSA Safety Investigations & How to Prepare for Them*, FOLEY (Mar. 5, 2025), <https://www.foleyservices.com/articles/three-types-of-fmcsa-safety-investigations-how-to-prepare-for-them> [<https://perma.cc/QJ7A-6LL9>]; GAO (2014), *supra* note 948, at 11 tbl.2; see also Interview with Anonymous Interviewee #8, *supra* note 916 (discussing a system whereby the agency uses incoming information to prioritize among possible audit targets).

⁹⁵⁸ FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 27 tbl.3-3 (using the term “Investigations”).

⁹⁵⁹ See *id.* at 27 tbls. 3-3 & 3-4.

⁹⁶⁰ See *infra* notes 977–78 and accompanying text.

are especially serious or not fixed within allotted time, or if penalties go unpaid, shut down the company.⁹⁶¹ As of 2022, about 11,000 carriers had an other-than-satisfactory safety rating status, but more than ninety percent of carriers had no rating at all because they had not been recently audited.⁹⁶² As for licensing authority, the FMCSA has something like it, though nothing approaching the fearsome authority that FDA has over drugmakers:⁹⁶³ Every new trucking company faces a document-based audit within eighteen months of entry, which about ten percent do not pass.⁹⁶⁴ But it is not clear how intensive this new-entrant audit program really is, as it appears not to catch a substantial but hard-to-discern number of “chameleon” companies that go out of business amid safety violations and then return under the guise of different names.⁹⁶⁵

While the relationship between FMCSA and trucking companies generally is thinner than in all the pairings in Part I (except perhaps CPSC), the FMCSA-carrier relationship is even thinner for smaller companies. Although large carriers are inspected somewhat less frequently than small carriers on a *per-truck* basis,⁹⁶⁶ they are inspected more frequently on a *per-company* basis.⁹⁶⁷ This means that because every inspected truck is a window into the management of its owner-company, large companies’ management is visible to the FMCSA on much closer to a real-time basis, far more than is that of small companies.

Besides having thin relationships with the FMCSA, small trucking companies also experience much of the harm from safety problems as an externality. To be sure, a small company that has a truck in a crash stands to lose the truck as an asset temporarily or, depending on insurance, permanently; in the case of an owner-operator, the risk extends

⁹⁶¹ On these different options, see GAO (2014), *supra* note 948, at 10–12. Monetary penalties averaged less than \$7,000 per enforcement case in 2018–2022. See FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 30 tbl.3-8 (see the row for “Carrier”). There seem not to be published numbers on shutdowns. One possible proxy is “unsatisfactory” ratings that result in shutdown if not remedied promptly; these numbered 882 as of 2022, which is little more than one out of a thousand trucking companies. See FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 27 tbl.3-4.

⁹⁶² FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 27 tbl.3-4. On the rarity of carriers having any rating at all, see John Gallagher, *Feds Told to Start Rating ‘Unrated’ Trucking Companies for Safety*, FREIGHTWAVES (Dec. 1, 2023), <https://www.freightwaves.com/news/feds-told-to-start-rating-unrated-trucking-companies-for-safety> [<https://perma.cc/W28S-VFA3>].

⁹⁶³ See *supra* notes 242–48 and accompanying text.

⁹⁶⁴ FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 29 tbl.3-7. The audit is document based and is not based on actual trucks or drivers. Interview with Anonymous Interviewee #8, *supra* note 916.

⁹⁶⁵ GAO TESTIMONY, *supra* note 948, at 6–7.

⁹⁶⁶ GAO (2014), *supra* note 948, at 74 tbl.14.

⁹⁶⁷ Companies with over 100 power units make up 0.68% of FMCSA-regulated carriers, see FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 13 tbl.1-11, but they account for 26% of inspections, see *id.* at 21 tbl.2-7. But companies over 100 power units see only 3% of audits, presumably because they are more compliant. See *id.* at 28 tbl.3-6. For calculations, see DATASET, *supra* note 10, File 69.

to the company principal's life and body. But for companies other than owner-operators, the risk to the driver—an employee—is internalized only through workers' compensation, which has all the limitations discussed in Section II.A. More to the point, trucking is rife with safety-profit tradeoffs, as illustrated by the pressure many truckers feel to work ninety-hour weeks, and the whole idea of regulation is that allowing a business to decide the safety-profit tradeoff on its own is sub-optimal because the unregulated business decisionmaker, in trading off profit against risk to their own assets or own safety, is not incentivized to take account of how the tradeoff affects others. More than eighty percent of people killed in large-truck crashes in recent years were not occupants of the truck: They were third parties.⁹⁶⁸

Of course, tort liability may force internalization of these third-party harms—recent years have seen “nuclear” jury verdicts in truck-crash cases⁹⁶⁹—but this is probably more applicable to large companies than to small companies. According to Anonymous Interviewee #8,

a lot of those safety interventions that end up getting required by FMCSA are the sorts of things that large carriers might be implementing anyway because it helps them in their accident [i.e., tort] litigation, based on . . . whatever the standard of care might be and how they can prove that they're operating safely.⁹⁷⁰

Unlike tort litigation, FMCSA regulation “is not the thing that's moving the needle, at least for large carriers.”⁹⁷¹ It would seem the corollary is that small companies are not as likely to respond to the prospect of tort liability with safety measures, both because they lack resources, as Miller argues,⁹⁷² and because of the judgment-proof problem: Their low assets limit their downside. Relatedly, it should be noted that the minimum liability insurance required for a trucking company remains where it was set in 1985, at \$750,000 per crash.⁹⁷³ A study of the year 1994 estimated that general freight motor carriers were internalizing only about forty-one percent of crash costs.⁹⁷⁴ And the minimum has

⁹⁶⁸ See FED. MOTOR CARRIER SAFETY ADMIN., *supra* note 948, at 38 tbls. 4-9 & 4-10. I made this calculation by adding all persons other than occupants of “large truck”; note that “light truck” refers to SUVs and the like and that these data include private fleets. See *id.* at 43 tbl.4-17.

⁹⁶⁹ Cassandra R. Cole & Chad Marzen, *Nuclear Verdicts, Tort Liability, and Legislative Responses*, J. INS. REGUL., May 2023, at 1, 3 fig.1.

⁹⁷⁰ Interview with Anonymous Interviewee #8, *supra* note 916.

⁹⁷¹ *Id.*

⁹⁷² See Miller, *supra* note 944, at 29–30.

⁹⁷³ FED. MOTOR CARRIER SAFETY ADMIN., MOTOR CARRIER FINANCIAL RESPONSIBILITY: REPORT TO CONGRESS 4 tbl.1 (2018). The states generally do not require more. *Id.* at v–viii.

⁹⁷⁴ See David J. Forkenbrock, *External Costs of Intercity Truck Freight Transportation*, 33 TRANSP. RSCH. PT. A 505, 512 (1999).

never since been raised for inflation, despite some lawmakers' efforts to do so.⁹⁷⁵ Data on the proportion of judgments that exceed the limit in recent years are sparse, but the number may be substantial.⁹⁷⁶ In any event, underinsurance may discourage injured parties from seeking a judgment to begin with.

Finally, it is doubtful whether shippers' or brokers' concerns about safety would force much internalization when it comes to small trucking companies. To be sure, shippers could face tort liability for negligent selection of a carrier, and they might view safety problems as raising the risk of operational disruption. Indeed, the imposition of a "safety rating" other than *satisfactory* is conventionally viewed as making it harder to attract and keep customers.⁹⁷⁷ But that stigma happens only after an audit and only to one percent or two percent of companies.⁹⁷⁸ A potentially more far-reaching program, launched nationwide by the FMCSA in 2010 and known as Compliance, Safety, and Accountability ("CSA"), constructed a Safety Measurement System ("SMS") that assigned percentile rankings to a large proportion of all companies based on their compliance and violation records—published rankings that the agency also used internally to target its enforcement resources.⁹⁷⁹ According to a survey in 2012 by the American Transportation Research Institute, shippers were unlikely to drop a known carrier due to a CSA score, though many said the score would affect their choice among new carriers—but even then, only half said "poor" CSA scores would be a deal-breaker.⁹⁸⁰ There seems to be no study of actual shipper behavior on this. Even if shippers do care about carrier safety, it is not clear they have good means to discern it; crashes are low-probability events, and in 2014 GAO criticized the CSA scores as resting on too little data to serve as the basis for predictions about crashes.⁹⁸¹ Further, in 2015 Congress forced the FMCSA to start keeping the CSA scores confidential, which they have remained; the raw data underlying them is still public, though

⁹⁷⁵ Lucija Muehlenbachs, Stefan Staubli & Ziyang Chu, *The Accident Externality from Trucking*, 4 n.7, 30 (Nat'l Bureau of Econ. Rsch., Working Paper No. 23,791, 2017), <https://www.nber.org/papers/w23791> [<https://perma.cc/KA64-YRBT>].

⁹⁷⁶ On data problems and various estimates, see FED. MOTOR CARRIER SAFETY ADMIN., EXAMINING THE APPROPRIATENESS OF THE CURRENT FINANCIAL RESPONSIBILITY AND SECURITY REQUIREMENTS FOR MOTOR CARRIERS, BROKERS, AND FREIGHT FORWARDERS: REPORT TO CONGRESS 10–13 (2022).

⁹⁷⁷ Barr, *supra* note 957.

⁹⁷⁸ See *supra* notes 957–62 and accompanying text.

⁹⁷⁹ GAO (2014), *supra* note 948, at 1–2, 5–6, 13–14.

⁹⁸⁰ MICAH D. LUECK & REBECCA M. BREWSTER, COMPLIANCE, SAFETY, ACCOUNTABILITY: EVALUATING A NEW SAFETY MEASUREMENT SYSTEM AND ITS IMPLICATIONS 41, 43 (2012).

⁹⁸¹ GAO (2014), *supra* note 948, at 15–16; see also GAO TESTIMONY, *supra* note 948, at 3–4. Further, seventy-two percent of carriers had no SMS score in 2015. GAO TESTIMONY, *supra* note 948, at 5.

it is not as easy to interpret.⁹⁸² Additionally, it is not clear how shippers trade off the benefits of carrier safety against the costs that will, after all, be passed on to them. When the American Trucking Associations and OOIDA challenged the tightening of HOS rules in 2012, the National Industrial Transportation League (“NITL”), the trade association of industrial shippers, joined them, noting that “costs incurred by the truckers are included in the freight rates paid by NITL members.”⁹⁸³ Even if some shippers are willing to pay for safety, other shippers may not be, and small trucking companies looking to avoid safety costs may find that non-safety-conscious shippers are a sufficient customer base.

III. A PRELIMINARY LOOK AT HOSPITALS, NURSING HOMES, AND CMS

In closing, this Article offers a preliminary discussion of the level of judicial challenges by certain healthcare providers to CMS. This Article has not focused centrally on Medicare and Medicaid because they do not fit entirely comfortably into the category that defines the project, that is, government regulation of private industry. For one thing, the industries in Parts I and II are virtually all for-profit enterprises (the one partial exception being the minority of electric generators owned by governments or cooperatives), whereas for-profit status is less pervasive in healthcare: seventy-two percent of nursing homes and thirty-six percent of hospitals.⁹⁸⁴ More fundamentally, Medicare and Medicaid at their establishment in 1965 were not intended to regulate the healthcare industry.⁹⁸⁵ They were spending programs that made payments to healthcare providers incidentally for the purpose of giving benefits to patients.⁹⁸⁶ But the programs have gradually become such a large portion of federal spending that Congress and HHS have asserted tighter control over

⁹⁸² Miller, *supra* note 944, at 59. On the continued confidentiality of CSA scores as compared with safety ratings, see Kathy Close, *What Is a Compliance, Safety, and Accountability (CSA) BASIC Score?* (Aug. 1, 2024), <https://eld.kellerencompass.com/resources/blog/2020-blogs/what-is-a-csa-basic-score> [<https://perma.cc/3ANN-35Q6>].

⁹⁸³ Motion for Leave to Intervene of the National Industrial Transport League at 2, *Am. Trucking Ass'ns v. FMCSA*, 724 F.3d 243 (D.C. Cir. 2013) (No. 12-1092) (filed Mar. 15, 2012).

⁹⁸⁴ W. PETE WELCH, LANLAN XU, NANCY DE LEW & BENJAMIN D. SOMMERS, ASPE OFF. OF HEALTH POL'Y, U.S. DEP'T OF HEALTH & HUM. SERVS., HP-2023-14, OWNERSHIP OF HOSPITALS 1 (2023), <https://aspe.hhs.gov/reports/hospital-ownership> [<https://perma.cc/8JXM-V8NZ>]; W. PETE WELCH, IARA OLIVEIRA, MARTIN BLANCO & BENJAMIN D. SOMMERS, APSE OFF. OF HEALTH POL'Y, U.S. DEP'T OF HEALTH & HUM. SERVS., OWNERSHIP OF SKILLED NURSING FACILITIES 1 (2022), <https://aspe.hhs.gov/reports/ownership-skilled-nursing-facilities> [<https://perma.cc/RLG8-6PEQ>].

⁹⁸⁵ See *History*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 10, 2024, 6:04 PM), <https://www.cms.gov/about-cms/who-we-are/history> [<https://perma.cc/SHG5-WK4Z>]. Medicare and Medicaid were established as part of the Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. ch. 7).

⁹⁸⁶ *History*, *supra* note 985.

what the providers can be paid for.⁹⁸⁷ And while providers' participation remains formally voluntary, many providers have become so dependent on the programs that the government has just as much leverage over them as over companies in statutory schemes that are formally mandatory, with the ultimate sanction—exclusion from the programs—sufficient to put many providers out of business.⁹⁸⁸ Furthermore, the congressional mandate for how HHS must deal with providers has expanded beyond merely deciding which healthcare services are worth taxpayer money. The mandate has become something closer to regulation per se, with providers cast as potential doers-of-harm who must be constrained by rules and surveillance.⁹⁸⁹ This is especially true for legislation protecting nursing home residents enacted in the 1980s,⁹⁹⁰ as well as the patient safety legislation for hospitals enacted in the 2000s.⁹⁹¹

On balance, CMS is close enough to a business regulator that its experience with industry judicial challenges on health-and-safety matters deserves some attention here. This last Part offers preliminary findings on two of the largest categories of institutional providers: hospitals and nursing homes.

In a nutshell, hospitals seem to fit closely with the broader theory posited by this Article, while nursing homes fit at least somewhat less easily, which calls for some explanation. As to hospitals, they appear to challenge CMS on patient-safety matters little to none, which is all the more striking because they *do* challenge CMS very frequently on reimbursement matters with no direct connection to patient safety.⁹⁹² This seems

⁹⁸⁷ See generally Isaac Buck, *The Battle for Medicare*, 16 ST. LOUIS U.J. HEALTH L. & POL'Y 147 (2023) (examining Medicare as a regulatory regime).

⁹⁸⁸ On how Medicare, in particular, has become federal regulation of healthcare, see *id.* at 147, 158–59, 162.

⁹⁸⁹ See *id.* at 162.

⁹⁹⁰ See Joseph L. Bianculli, *Nursing Facility Enforcement Before the Department of Health and Human Service Appeals Board*, 13 LIBERTY U. L. REV. 223, 230 (2019).

⁹⁹¹ E.g., Barry Furrow, *The Confused and Bewildered Hospital: Adverse Event Discovery, Pay-for-Performance, and Big Data Tools as Halfway Technologies*, 46 AM. J.L. & MED. 219, 223 (2020); David M. Studdert & Michelle M. Mello, *In From the Cold? Law's Evolving Role in Patient Safety*, 68 DEPAUL L. REV. 421, 424 (2019).

⁹⁹² For the core study period of 2013–2021, a Bloomberg dockets search of district courts for suits against HHS or any of its components, including CMS, yielded 996 suits that concerned CMS brought by businesses, including nonprofit service providers, or associations of businesses. DATASET, *supra* note 10, File 10, Rows 476–1471. Discerning whether a suit involves CMS action *on patient safety* requires reviewing the complaint in more detail. To this end, I took a fifteen percent random sample of the 996 suits (amounting to 150). *Id.* File 10A (using the Excel “Hide” function to hide all nonsampled rows while not hiding the 150 sampled rows). A law student research assistant who had read academic literature on patient-safety regulation reviewed the complaints in the 150 suits and determined whether each either did not involve patient safety or might involve patient safety. The student ultimately found that fifteen complaints might involve patient safety and the other 135 did not. These 150 cases included ninety cases in which the challengers were hospitals and sixty in which the challengers were nonhospital entities. Possible patient-safety cases as identified by the student

consistent with the idea that CMS, when administering patient-safety legislation, is protecting the “customers” of the hospitals, because even if the patients are not always spending their own money, they have a role in choosing which hospital gets the government’s money. As to nursing homes, they do not engage in much of the association-based, industry-wide efforts to challenge health-or-safety constraints that we observe with coal mines, electric generators, or small trucking companies.⁹⁹³ Yet they bring challenges to a greater degree than do the industries in Part I.⁹⁹⁴ This result seems in tension with the fact that CMS’s actions aim to protect the very residents whom nursing homes seek to serve, retain, and attract—residents who are like customers, even when they are directing Medicaid’s money instead of spending their own.

During the core study period of 2013–2021, there was exactly one suit by an association of nursing homes: The American Health Care Association (“AHCA”), nursing homes’ principal trade group, brought the suit in 2016 to challenge a significant rule preventing nursing homes from contracting with residents for mandatory arbitration of tort claims.⁹⁹⁵ One might quibble that this rule was not *quite* about health and safety but was more in the nature of economic regulation. But there can be no quibbling about a 2024 AHCA lawsuit, after the core study

were all among the sixty nonhospital cases; none were among the hospital cases. *Id.* File 10A. Consistent with this, I found in conducting interviews that practitioners experienced with hospitals and CMS could not recall any instance where a hospital had sued CMS on a patient-safety matter. *See* Interview with Anonymous Interviewee #9, Senior in-house counsel to a major medical center (Aug. 27, 2024); Interview with Anonymous Interviewee #10, Partner in a large law firm with specialization in healthcare law (Sept. 16, 2024). A striking example of hospitals’ apparent tendency not to sue on patient safety is the 2021 HHS mandate that all staff of Medicare- and Medicaid-participating facilities be vaccinated against COVID-19. *See* Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (to be codified at 42 C.F.R. pts. 416, 418, 441, 460, 482–486, 491, 494). Of the thousands of hospitals nationwide, none challenged the mandate except the small number of hospitals that happened to be owned by state governments, such that their litigation decisions were controlled by state attorneys general. Justice Kavanaugh emphasized this point at oral argument, noting that states owned “a very small percentage” of all hospitals and that there were otherwise no “hospitals” challenging the mandate. Transcript of Oral Argument at 69–70, *Biden v. Missouri*, 595 U.S. 87 (2022) (No. 21A240). Note that certain industry suits on Medicaid should have been grouped with the industry CMS suits but were not; however, none of these suits involved actions on patient safety. *See* DATASET, *supra* note 10, File 10, Rows 281–301.

⁹⁹³ *See infra* notes 995–1008 and accompanying text.

⁹⁹⁴ *See infra* notes 995–1008 and accompanying text.

⁹⁹⁵ Complaint for Declaratory and Injunction Relief at 2, *Am. Health Care Ass’n v. Burwell*, 217 F. Supp. 3d 921 (N.D. Miss. 2016) (No. 16-cv-00233) (filed Oct. 17, 2016). For the absence of any other suit by any association of nursing homes in the core study period, *see* DATASET, *supra* note 10, File 10B, Rows 476–500, which covers all suits in district courts by associations of businesses involving CMS, with ACHA’s suit in row 495, and *id.* File 11, Rows 17–37, which covers all PFRs in the courts of appeals by businesses or associations of businesses involving CMS, with no nursing-home association suits. Note that certain industry suits on Medicaid should have been grouped with the industry CMS suits in File 10, but were not, *see id.* File 10, Rows 281–301; however, none of these suits involved actions on patient safety, *see id.*

period, challenging one of the most important nursing home regulations on resident safety ever promulgated: the rule imposing minimum staffing levels, which are widely viewed as essential to preventing bad care.⁹⁹⁶ A search for AHCA challenges going back to 1989 yields one other suit, in 1999, against a shift in CMS civil penalty enforcement covering resident-safety matters from a per-day basis to a per-instance basis.⁹⁹⁷ So nursing homes have brought more trade association challenges than have drugmakers, automakers, airlines, children's product companies, or nuclear plants since the 1980s, or meat processors since the 1990s.⁹⁹⁸ Still, AHCA's suits do not reflect the kind of enduring full-court press conducted by coal mines with MSHA, generators with EPA, small truckers with FMCSA, or various industries with OSHA.⁹⁹⁹

Besides AHCA's challenges, the period from 2013 through 2021 saw challenges by individual nursing homes. To put these in context, note that the country has about 15,000 nursing homes, of which about 5,000 are freestanding and the other 10,000 owned by chains of varying sizes.¹⁰⁰⁰ The largest chain has 237 facilities, which translates to 1.6% of the nation's facilities and 1.7% of its beds, while the ten largest chains have 10.7% of the beds,¹⁰⁰¹ making nursing care far less concentrated than most industries in this Article, such as coal mining, where the top ten companies produce about seventy percent of coal,¹⁰⁰² or investor-owned utilities, where the top ten account for about sixty percent of total market capitalization.¹⁰⁰³ During the core study period, a preliminary search shows that individual nursing homes brought at least twenty-three suits challenging CMS resident-safety actions.¹⁰⁰⁴ Two of these were chal-

⁹⁹⁶ *Am. Health Care Ass'n v. Kennedy*, No. 24-cv-00114, 2025 WL 1032692, at *1 (N.D. Tex. Apr. 7, 2025) (filed May 23, 2024) (challenging Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40,876 (May 10, 2024) (to be codified at 42 C.F.R. pts. 438, 442, 483)), *appeal docketed*, No. 25-10700 (5th Cir. June 6, 2025). On the importance of staffing, see ABT ASSOCS., *NURSING HOME STAFFING STUDY COMPREHENSIVE REPORT 1-3* (2023), <https://www.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf> [<https://perma.cc/6R55-PGEJ>].

⁹⁹⁷ Complaint for Declaratory and Injunctive Relief at 1-2, *Am. Health Care Ass'n v. Shalala*, No. 99-cv-01207 (D.D.C. May 18, 1999).

⁹⁹⁸ See *supra* note 774.

⁹⁹⁹ See *supra* Sections II.A-C.

¹⁰⁰⁰ See WELCH ET AL., *OWNERSHIP OF SKILLED NURSING FACILITIES*, *supra* note 984, at 5 tbl.2.

¹⁰⁰¹ *Id.* (showing data on the top ten nursing home chains in 2022, including first-place Genesis with 1.7% of all beds); see Charlene Harrington, Brian Olney, Helen Carrillo & Taewoon Kang, *Nurse Staffing and Deficiencies in the Largest For-Profit Nursing Home Chains and Chains Owned by Private Equity Companies*, 47 HEALTH SERVS. RSCH. 106, 112 (2012) (reporting similar proportion for the top ten chains in 2008).

¹⁰⁰² See U.S. ENERGY INFO. ADMIN., *ANNUAL COAL REPORT 2023*, at 15 tbl.10 (2024).

¹⁰⁰³ See the sources cited in *supra* note 823 and accompanying text, such as EEI 2020 FINANCIAL REVIEW, *supra* note 823, at 7.

¹⁰⁰⁴ My team conducted a search of DATASET, *supra* note 10, File 10, Rows 476-1471. These rows cover all suits by businesses or associations of businesses involving CMS in district courts in

lenges to rules—the first duplicative with AHCA’s challenge to the 2016 arbitration clause ban, brought by 100 facilities, all from three chains,¹⁰⁰⁵ and the second to a rule on inspection procedures, brought by forty-one facilities, of which thirty were from two chains.¹⁰⁰⁶ A third challenge was to CMS deficiency findings and a “safety rating,” brought by nine facilities in one chain.¹⁰⁰⁷ Additionally, there were at least twenty challenges to CMS enforcement actions on resident safety, each by a single facility, though some of these were subsidiaries of the largest chains: Genesis, ranked first, owning 237 facilities; Ensign, ranked second, owning 234 facilities, and who brought two of the suits; and Consulate, ranked sixth, owning 128 facilities.¹⁰⁰⁸ Although large companies like these represent only a small portion of the industry (because nursing care is so deconcentrated), these data do suggest—along with the other suits by midsize chains—that suing the safety regulator is more mainstream among individual nursing home companies than in any of the industries in Part I.

Why do nursing homes exhibit at least some departure from the non-litigious pattern of other industries whose regulator protects customer health and safety? Likely one important factor is that, as healthcare scholar Kieran Walshe argued in 2001, there is not much “alignment” between HHS’s safety objectives and nursing homes’ market incentives due to the peculiarities of the nursing-care market.¹⁰⁰⁹ “While nursing

the period of 2013–2021. The search was for the word *nursing*, which might appear in challenger names or descriptions of challenged agency actions. After substantive examination of the rows containing the word, the search identified four suits by nursing homes against CMS patient-safety actions. *See id.* File 10, Rows 531, 637, 857, 1387. It also identified the already noted AHCA suit in Row 1058. *Id.* Follow-up on one of these suits turned up a fifth suit, in Row 580. *Id.* My team also conducted a more intensive examination on all suits by businesses or associations of businesses involving CMS in courts of appeals from 2013 to 2021. DATASET, *supra* note 10, File 11, Rows 17–40. This identified eighteen suits by nursing homes against CMS patient-safety actions, those being in rows 17–18, 20–25, 27, and 29–37. *Id.*

¹⁰⁰⁵ *See* Complaint at 1–2, Northport Health Servs. of Ark., LLC v. HHS, 438 F. Supp. 3d 956 (W.D. Ark. 2020) (No. 19-cv-05168) (filed Sept. 4, 2019). For plaintiffs’ affiliations, *see* DATASET, *supra* note 10, File 10 (tab titled “Row 637 Plaintiffs”). In this and the following citations, we determined the chain affiliation of plaintiff facilities by entering their names in the CMS nursing home database. *See Skilled Nursing Facility Enrollments*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 2022), <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/skilled-nursing-facility-enrollments/data/september-2022> [<https://perma.cc/6ZPX-5UNM>].

¹⁰⁰⁶ *See* Complaint at 2, Avon Nursing and Rehab. v. Azar, 410 F. Supp. 3d 648 (S.D.N.Y. 2019) (No. 18-cv-02390) (filed Mar. 16, 2018). For plaintiffs’ affiliations, *see* DATASET, *supra* note 10, File 10 (tab titled “Row 857 Plaintiffs”). Affiliations were identified through the CMS database, *Skilled Nursing Facility Enrollment*, *supra* note 1005.

¹⁰⁰⁷ *See* Complaint for Preliminary and Permanent Injunction and Declaratory Judgment at 7–8, Generations at Elmwood Park, Inc. v. Ezike, No. 20-cv-00533 (N.D. Ill. Jan. 23, 2020). For plaintiffs’ affiliations, *see* DATASET, *supra* note 10, File 10 (tab titled “Row 580 Plaintiffs”). Affiliations were identified through the CMS database, *Skilled Nursing Facility Enrollments*, *supra* note 1005.

¹⁰⁰⁸ DATASET, *supra* note 10, File 11, Rows 21–23, 27.

¹⁰⁰⁹ Walshe, *supra* note 22, at 139.

home regulation attempts to promote high quality of care,” Walshe says, “the market does not seem to reward nursing homes that provide such care.”¹⁰¹⁰ Walshe based this claim on several points, each of which has had continued force since the time he wrote. For one thing, an elderly person’s choice between nursing homes—which may, depending on the person’s capacities, really be made by the person’s relatives—is driven by a facility’s physical proximity to those relatives, which weakens competition among facilities on matters like quality of care.¹⁰¹¹ More empirical evidence has confirmed this point.¹⁰¹² Additionally, prospective residents and their relatives do not have good information about quality of care.¹⁰¹³ CMS has sought to mitigate this problem with the formulation and publication of nursing home quality ratings, but it is very questionable whether these can actually be trusted to capture quality and provide quality-improvement incentives to facilities.¹⁰¹⁴ Furthermore, noted Walshe, residents who have moved into a facility cannot easily switch to another, which blunts provider incentives for quality even more.¹⁰¹⁵ Empirical research has continued to document the high risk of “transfer trauma” when residents move.¹⁰¹⁶ Finally, Walshe said that Medicaid rates may simply be too low to give many nursing homes much opportunity for quality improvement.¹⁰¹⁷ Recent empirical work finds “that raising Medicaid rates is about 7.1 times as effective in increasing the quality of care than encouraging local competition.”¹⁰¹⁸

¹⁰¹⁰ *Id.*

¹⁰¹¹ *Id.*

¹⁰¹² See, e.g., Irena Pesis-Katz, Charles E. Phelps, Helena Temkin-Greener, William D. Spector, Peter Veazie & Dana B. Mukamel, *Making Difficult Decisions: The Role of Quality of Care in Choosing a Nursing Home*, 103 AM. J. PUB. HEALTH e31, e35 (2013) (finding that “distance was the strongest predictor of nursing home choice” in 2001, prior to introduction of agency ratings).

¹⁰¹³ Walshe, *supra* note 22, at 139.

¹⁰¹⁴ A literature review in 2021 found a “modest but meaningful response by both consumers and providers” to the ratings, but with “evidence that some improvement in scores does not reflect true quality improvement.” R. Tamara Konetzka, Kevin Yan & Rachel M. Werner, *Two Decades of Nursing Home Compare: What Have We Learned?*, 78 MED. CARE RSCH. & REV. 295, 295 (2021). A forthcoming paper finds the ratings are grossly inaccurate when judged against a new measure of short-term resident mortality. See Andrew Olenski & Szymon Sacher, *Estimating Nursing Home Quality with Selection*, REV. ECON. & STATS. (forthcoming) (manuscript at 1), https://direct.mit.edu/rest/article/doi/10.1162/rest_a_01449/120874/Estimating-Nursing-Home-Quality-with-Selection [<https://perma.cc/3JQ3-FSMP>].

¹⁰¹⁵ Walshe, *supra* note 22, at 139.

¹⁰¹⁶ See, e.g., Ana Montoya, Pil Park, Julie Bynum & Chiang-Hua Chang, *Transfer Trauma Among Nursing Home Residents: Development of a Composite Measure*, GERONTOLOGIST (July 1, 2023), <https://academic.oup.com/gerontologist/article/64/2/gnad085/7216820> [<https://perma.cc/3Y6H-5MV9>].

¹⁰¹⁷ Walshe, *supra* note 22, at 139–40.

¹⁰¹⁸ Martin B. Hackmann, *Incentivizing Better Quality of Care: The Role of Medicaid and Competition in the Nursing Home Industry*, 109 AM. ECON. REV. 1684, 1714 (2019).

All this is broadly consistent with the idea that hospitals' interests are better aligned with CMS's patient-safety goals, which resonates with the fact that hospitals challenge CMS little to none on such matters.¹⁰¹⁹ In particular, because hospital stays are comparatively short, choice among hospitals is not as dominated by narrow geographic proximity as is choice among nursing homes.¹⁰²⁰ And because hospitals receive more of their compensation from the more generous Medicare program than do nursing homes, they have more resources to devote to quality.¹⁰²¹ The conventional wisdom has long been that hospitals are leaders in the patient-safety movement and that nursing homes have lagged behind.¹⁰²² Thus, although nursing home industry litigation against CMS presents an interesting departure from the more traditional regulatory programs analyzed in Part I, it may still be consistent with an interest-alignment theory of industry judicial challenges.

CONCLUSION

This Article has sought to document variation across industries in their use of courts to challenge health-and-safety restrictions by their federal regulators. In tracing the apparent significance of thick relationships and of interest alignment in driving industry use of lawsuits, this study offers some building blocks for a fuller account of the economic and political role of judicial review in American society—one that recognizes adversarial legalism while seeing it as one among multiple possibilities.

¹⁰¹⁹ See *supra* note 992 and accompanying text.

¹⁰²⁰ Nursing home markets are often defined as “coincident with the boundaries of the county in which [a facility] is located” but may often actually be even smaller. Jack Zwanziger, Dana B. Mukamel & Indridi Indridason, *Use of Resident-Origin Data to Define Nursing Home Market Boundaries*, 39 INQUIRY 56, 56 (2002). Hospital markets are probably best defined at something like the level of a Hospital Referral Region, which is much larger than a county. Austin S. Kilaru, Douglas J. Wiebe, David N. Karp, Jennifer Love, Michael J. Kallan & Brendan G. Carr, *Do Hospital Service Areas and Hospital Referral Regions Define Discrete Health Care Populations?*, 53 MED. CARE 510, 510, 512–14 (2015).

¹⁰²¹ Zachary Levinson, Scott Hulver, Jamie Godwin & Tricia Neuman, *Key Facts About Hospitals*, KFF (Feb. 19, 2025), <https://www.kff.org/health-costs/key-facts-about-hospitals/> [https://perma.cc/UJP9-NV5Y] (noting that in 2023 Medicare accounted for twenty-five percent of hospital spending and Medicaid accounted for nineteen percent); Priya Chidambaram, Alice Burns, Tricia Neuman & Robin Rudowitz, *5 Key Facts About Nursing Facilities and Medicaid*, KFF (May 28, 2025), <https://www.kff.org/medicaid/5-key-facts-about-nursing-facilities-and-medicaid/> [https://perma.cc/AEH8-DHRX] (noting that in 2024 Medicaid was the primary payer for sixty-three percent of nursing home residents and Medicare for thirteen percent); Walshe, *supra* note 22, at 139–40.

¹⁰²² Kali S. Thomas, Kathryn Hyer, Nicholas G. Castle, Laurence G. Branch, Ross Andel & Robert Weech-Maldonado, *Patient Safety Culture and the Association with Safe Resident Care in Nursing Homes*, 52 GERONTOLOGIST 802, 802–03 (2012).

The Necessary and Proper Clause and the Law of Administration

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ABSTRACT

The Necessary and Proper Clause authorizes Congress to establish and shape the administrative state. But the Necessary and Proper Clause is rarely cited in the relevant Supreme Court opinions or litigant briefs. This is a mistake. In several of the Court's recent prominent cases, the Necessary and Proper Clause's meaning and effect could have been dispositive. This Article makes that case. It demonstrates that there are plausible arguments against the Supreme Court's removal and Seventh Amendment jurisprudence as they relate to public administration, though this Article takes no strong position on those arguments. The Court recently and correctly held, on the other hand, that the Consumer Financial Protection Bureau's funding structure does not violate the Appropriations Clause. But even if Article II's Vesting Clause, the Seventh Amendment, and the Appropriations Clause do not get in the way of Congress's relevant statutes, it does not follow that those statutes are constitutional under the Necessary and Proper Clause. This Article does not seek to resolve definitively how the Court's recent cases should have come out under the Necessary and Proper Clause, but rather seeks to center the Necessary and Proper Clause as an important source of authority—and limits—on Congress's power to structure administration. It further offers a framework in which the Court's emphasis on history and tradition might be both relevant and more disciplined.

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INTRODUCTION

The source of Congress's power to structure administration is the Necessary and Proper Clause. It provides, after the enumeration of other powers in Article I, Section 8, that "Congress shall have Power . . . To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof."¹ The Appointments Clause provides that the President shall appoint persons to offices "which shall be established by Law,"² and the Opinions Clause provides that the President may demand opinions from the principal officers of the "executive Departments,"³ implying that Congress has the power to establish administrative departments. No clause other than the Necessary and Proper Clause could plausibly do the work of authorizing Congress to establish these offices and departments.

The Necessary and Proper Clause is a grant of extraordinary discretion. Pursuant to it, Congress can decide to establish a single-headed agency or a multimember one,⁴ to impose bipartisanship requirements on the principal officers,⁵ to establish the tenure of office before another appointment is necessary,⁶ and more. Yet the Necessary and Proper Clause may also create at least some internal limits on Congress's discretion relevant to the law of administration. Although scholars have

¹ U.S. CONST. art. I, § 8, cl. 18.

² *Id.* art. II, § 2, cl. 2.

³ *Id.* art. II, § 2, cl. 1.

⁴ *See, e.g.*, 6 U.S.C. §§ 111–112 (establishing the single-headed Department of Homeland Security); 15 U.S.C. § 41 (establishing the multimember Federal Trade Commission).

⁵ *See, e.g.*, 15 U.S.C. § 41 (requiring that no more than three of the five Commissioners of the Federal Trade Commission "be members of the same political party").

⁶ *See, e.g., id.* (establishing staggered terms of seven years for Commissioners).

focused on the great breadth of discretion the Necessary and Proper Clause affords Congress in this regard,⁷ few have focused on the obverse side of the Clause: its potential internal limits on Congress's discretion.

Moreover, despite being the source of and possible limit to Congress's power to structure administration, the Necessary and Proper Clause is rarely cited in the relevant Supreme Court opinions or litigant briefs. And yet the Clause might have been relevant, if not necessarily dispositive, in several prominent cases involving administration that the Court has recently decided. For example, there are serious arguments against the Court's removal and Seventh Amendment jurisprudence. The Court has held in the former line of cases that the President's "executive Power"⁸ and duty to see that the laws be faithfully executed⁹ imply an unrestricted power to remove at least principal officers.¹⁰ In the latter line of cases, it has held that the "right of trial by jury" in "Suits at common law"¹¹ requires that administrative prosecutions seeking monetary penalties for violations of regulatory statutes must be determined by juries and therefore also Article III courts.¹² Assuming the Court was wrong about its interpretation of the President's law-execution powers in the former and the scope of the jury trial right in the latter, it does not follow that Congress has power under the Necessary and Proper Clause to impose removal restrictions on principal officers or to impose monetary penalties on private citizens without a real court or jury.

Similarly, the Court recently held that the Appropriations Clause, which requires that money be drawn from the Treasury only "in Consequence of Appropriations made by Law,"¹³ does not prohibit indefinite funding from the Federal Reserve System for a regulatory agency.¹⁴ Here too, it does not follow that merely because Congress has not violated the Appropriations Clause then it has the power under the Necessary and Proper Clause to structure the agency in that way.

This Article's aim is not to resolve these questions definitively but to center the Necessary and Proper Clause as relevant to any analysis of modern administrative structure. The Necessary and Proper Clause is almost entirely invoked to emphasize how much power and discretion

⁷ See *infra* notes 20–21.

⁸ U.S. CONST. art. II, § 1 ("The executive Power shall be vested in a President of the United States of America.").

⁹ *Id.* art. II, § 3 ("[H]e shall take Care that the Laws be faithfully executed . . .").

¹⁰ *Seila L. LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 213–14, 217 (2020). The Court still maintains, for now, that Congress can create for-cause removal restrictions for officers exercising "quasi" legislative and "quasi" judicial power. See *Humphrey's Ex'r v. United States*, 295 U.S. 602, 610–11 (1935).

¹¹ U.S. CONST. amend. VII.

¹² *SEC v. Jarkesy*, 603 U.S. 109, 140 (2024).

¹³ U.S. CONST. art. I, § 9, cl. 7.

¹⁴ *Consumer Fin. Prot. Bureau v. Cmty. Fin. Servs. Ass'n of Am.*, 601 U.S. 416, 435 (2024).

it gives to Congress to structure administration;¹⁵ that is a given. But scholars and judges have not paid enough attention to the other side of the Necessary and Proper Clause: the way it also establishes and reaffirms limits on Congress's power. As shall become clear, the framework for analysis under the Necessary and Proper Clause might also discipline the Court's renewed attention to history and tradition.¹⁶

A preliminary observation is in order. That the Constitution enumerates legislative powers and thereby limits the scope of the national government's powers is the conventional story told about America's Constitution.¹⁷ It is not obviously the correct story. The delegates to the Constitutional Convention rejected a proposal to enumerate power; they approved instead a resolution granting Congress power to legislate on all subjects over which the separate states were incompetent.¹⁸ Yet the Committee of Detail tasked with drafting the proposed Constitution proceeded to enumerate power.¹⁹ Some scholars have suggested that the best reading of the Constitution in light of the Convention's proceedings is that Congress may enact any legislation necessary and proper to effectuate the purposes of the Union.²⁰ A few scholars have suggested that it is possible the Framers enumerated power despite the instructions because they sought to limit the power of the Executive.²¹

¹⁵ See, e.g., *Seila L.*, 591 U.S. at 266 (Kagan, J., concurring in the judgment in part and dissenting in part).

¹⁶ The Article tentatively concludes on the merits of the respective cases that the Necessary and Proper Clause does in fact limit Congress's ability to create for-cause removal protections at least for principal officers; that it likely limits Congress's ability to impose monetary penalties on private citizens for violations of administrative statutes without a court or jury; and that it probably does not prevent Congress from creating insulated funding structures. These conclusions, again, are tentative, perhaps with the exception of those relative to the removal power that the Author has examined recently in more detail. See *infra* note 144.

¹⁷ See, e.g., Kurt T. Lash, *The Sum of All Delegated Power: A Response to Richard Primus*, *The Limits of Enumeration*, 124 YALE L.J.F. 180, 207 (2014).

¹⁸ 2 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, at 17 (Max Farrand ed., 1911).

¹⁹ See MICHAEL W. MCCONNELL, *THE PRESIDENT WHO WOULD NOT BE KING* 67 (2020).

²⁰ See Andrew Coan & David S. Schwartz, *The Original Meaning of Enumerated Powers*, 109 IOWA L. REV. 971, 1033 (2024); John Mikhail, *The Original Federalist Theory of Implied Powers*, 46 HARV. J.L. & PUB. POL'Y 57, 58–59 (2023); William Michael Treanor, *The Case of the Dishonest Scrivener: Gouverneur Morris and the Creation of the Federalist Constitution*, 120 MICH. L. REV. 1, 49–59 (2021); Jonathan Gienapp, *The Myth of the Constitutional Given: Enumeration and National Power at the Founding*, 69 AM. U. L. REV. F. 183, 198–201 (2020); David S. Schwartz, *A Question Perpetually Arising: Implied Powers, Capable Federalism, and the Limits of Enumerationism*, 59 ARIZ. L. REV. 573, 595 (2017) [hereinafter Schwartz, *Implied Powers*]; John Mikhail, *The Constitution and the Philosophy of Language: Entailment, Implicature, and Implied Powers*, 101 VA. L. REV. 1063, 1069 (2015); John Mikhail, *The Necessary and Proper Clauses*, 102 GEO. L.J. 1045, 1047 (2014) [hereinafter Mikhail, *Necessary and Proper*]. Most of these scholars owe a great debt to William Crosskey. See 1 WILLIAM WINSLOW CROSSKEY, *POLITICS AND THE CONSTITUTION IN THE HISTORY OF THE UNITED STATES* 365–401 (1953) (making this argument about the scope of national powers).

²¹ This insight also began with Crosskey. 1 CROSSKEY, *supra* note 20, at 428–29; see also MCCONNELL, *supra* note 19, at 68 (adopting the argument and attributing it to Crosskey).

The effect, however, could have been both to ensure that the President would not exercise a suite of historically royal prerogative powers and to limit the national government's powers to certain enumerated objects.

This is not the place to adjudicate these debates.²² They are, however, relevant to the question of Congress's power to structure administration. If the enumeration of powers was not intended to limit the scope of the national government to enumerated functions, then it is highly unlikely that the Necessary and Proper Clause, through which Congress is understood to have the power to structure administration, would impose any kind of limit on what Congress could accomplish. For present purposes, this Article shall assume the conventional story. The remainder of the argument proceeds as follows. Part I excavates the original meaning of the Necessary and Proper Clause and addresses some revisionist arguments. Part II applies the framework to the Supreme Court's recent removal, Seventh Amendment, and appropriations jurisprudence.

I. THE NECESSARY AND PROPER CLAUSE

Under the Articles of Confederation, Congress could only exercise powers "expressly delegated" by the states.²³ The objective of the Necessary and Proper Clause was to eliminate that restriction and, more affirmatively, to put Congress's authority to exercise incidental powers beyond doubt.²⁴ But the Necessary and Proper Clause does not authorize Congress to exercise great and important powers that one would have expected the Constitution to enumerate specifically if the Framers intended and the ratifying public thought that Congress would have the power in question. If the Constitution had not granted Congress the power to tax, it would be difficult to conclude that Congress could nevertheless exercise such an important power by implication.

Early on, Congress used this clause to establish the form of oath its members would take,²⁵ provide that census takers shall record the

²² The Author does so in a forthcoming work. ILAN WURMAN, *THE CONSTITUTION OF 1789: A NEW INTRODUCTION* (forthcoming July 2026).

²³ ARTICLES OF CONFEDERATION of 1781, art. II.

²⁴ See *infra* note 68 and accompanying text.

²⁵ DAVID P. CURRIE, *THE CONSTITUTION IN CONGRESS 14* (1997). Currie further explains that Congress supplied the oaths for state officers, and there is some question as to whether it had authority to do so. *Id.* Article VI, Clause 3 of the Constitution provides that state legislators, as well as state executive and judicial officers, "shall be bound by Oath or Affirmation, to support this Constitution." U.S. CONST. art. VI, cl. 3. But the Necessary and Proper Clause granted Congress power for carrying into execution its powers or those the Constitution vests in the government of the United States or in any department or officer thereof. U.S. CONST. art. I, § 8, cl. 18. Many at the Founding believed the Necessary and Proper Clause simply stated what would follow from necessary implication in its absence. See CURRIE, *supra*, at 14. In other words, even without the Clause

sex and age of those counted,²⁶ erect the first executive departments,²⁷ divide the army into units and provide salaries and pensions,²⁸ make it a crime to bribe federal judges or commit perjury or interfere with the delivery of the mails,²⁹ purchase a building to house the U.S. Mint,³⁰ and authorize a national flag, presumably necessary and proper for executing various martial powers.³¹ The Founders included a Necessary and Proper Clause because it would have been impossible to list in the Constitution all the minor, detail-oriented powers such as these that Congress might exercise.³² Had they done so, the Constitution would have had the “prolixity of a legal code.”³³ But only such detail-oriented powers could be left to implication; great and important ones could not. This Part makes that case, focusing first on the great debate in 1791 over Congress’s power to establish a national bank, then turning to other legal materials and evidence of public understanding, and concluding with some early discussions of the potential great powers of eminent domain and abrogating sovereign immunity.

A. *The Bank Debate*

One place to start the analysis is the 1791 debate in Congress and in the President’s cabinet over whether Congress had the power under the Necessary and Proper Clause to incorporate a national bank. The leading players in the debate agreed on the principle in question, although they disagreed on its lower-order application to the bank.

Representative James Madison, the architect of the constitutional argument against incorporating a national bank, argued that the Necessary and Proper Clause was a grant of implied powers only. In his speech in the House of Representatives, Madison asserted the following interpretive principle: “In admitting or rejecting a constructive authority, not only the degree of its incidentality to an express authority is to [be] regarded, but the degree of its importance also; since on this will depend

there would still have been implied powers. Thus, one can understand Congress to have the implied power directly under Article VI to implement the oath for state officers. *See id.* at 14–15.

²⁶ *See* CURRIE, *supra* note 25, at 19.

²⁷ *Id.* at 36–47.

²⁸ *Id.* at 82.

²⁹ *Id.* at 96–97 (offenses against courts); *id.* at 150 (postal crimes).

³⁰ *Id.* at 153 n.160.

³¹ *Id.* at 205 n.243. Though Congress, as Currie notes, may have believed it had inherent power to make a flag for the nation even in the absence of the Necessary and Proper Clause; the Continental Congress had provided for a flag in 1777. *Id.* at 204.

³² *See* THE FEDERALIST No. 44, at 284–85 (James Madison) (Clinton Rossiter ed., 1961).

³³ *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 407 (1819).

the probability or improbability of its being left to construction.”³⁴ On the merits, Madison argued, “It cannot be denied that the power proposed to be exercised is an important power[because] . . . the bill creates an artificial person, previously not existing in law.”³⁵ Madison explained,

It confers important civil rights and attributes, which could not otherwise be claimed. It is, though not precisely similar, at least equivalent, to the naturalization of an alien, by which certain new civil characters are acquired by him. Would Congress have had the power to naturalize, if it had not been expressly given?³⁶

Madison here argued that incorporation of a bank is an important power, similar to the naturalization power, and one would not lightly presume that Congress had the latter power without express authorization. Later in his speech, he added, “Had the power of making treaties, for example, been omitted, however necessary it might have been, the defect could only have been lamented, or supplied by an amendment of the Constitution.”³⁷ Important powers are generally not left to implication.

Madison believed that the power to incorporate a bank was important because it involved “the power to make by-laws,” which was “a sort of Legislative power” and “unquestionably an act of a high and important nature.”³⁸ The proposed bill “g[ave] a power to purchase and hold lands,” which even Congress could not do within a state “without the consent of its Legislature.”³⁹ And the bill “involve[d] a monopoly, which affects the equal rights of every citizen.”⁴⁰ Madison concluded,

From this view of the power of incorporation exercised in the bill, it could never be deemed an accessory or subaltern power, to be deduced by implication, as a means of executing another power; it was in its nature a distinct, an independent and substantive prerogative, which not being enumerated in the Constitution, could never have been meant to be included in it, and not being included, could never be rightfully exercised.⁴¹

Attorney General Edmund Randolph similarly opposed the bank in two written opinions to President Washington. Randolph’s first opinion is a bit opaque but can be read to support Madison. Randolph described the attributes of the corporation and wrote, “their importance

³⁴ 2 ANNALS OF CONG. 1896 (1791).

³⁵ *Id.* at 1899.

³⁶ *Id.* at 1899–1900.

³⁷ *Id.* at 1900–01.

³⁸ *Id.* at 1900.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

strikes the eye.”⁴² He went on to write, “Governments, having no written Constitution, may perhaps claim a latitude of power, not always easy to be determined. Those, which have written Constitutions, are circumscribed by a just interpretation of the words contained in them”⁴³ He gestured to the doctrine of implied powers when he quoted the Necessary and Proper Clause and observed, “To be necessary is to be incidental, or . . . the natural means of executing a power.”⁴⁴ In his second paper he elaborated that powers “are either incidental[] or substantive, that is independent powers,” the latter of which are “capable of being used[] independently of what is called the principal power.”⁴⁵ Randolph’s differentiation between incidental and substantive powers suggests that he agreed that it would be improper to interpret the words of a written Constitution to authorize important powers by implication.

Secretary of State Thomas Jefferson also agreed that the Necessary and Proper Clause authorized Congress to legislate regarding “means” but not “end[s].”⁴⁶ In his opinion for President Washington, he used those terms in pointing out that the very power under discussion was rejected by the Constitutional Convention: “It is known that the very power now proposed *as a means* was rejected as *an end* by the Convention which formed the Constitution.”⁴⁷ Jefferson’s argument about the Convention proceedings was of dubious validity; the power might have been rejected because the Convention believed it to be incidental and, as Hamilton responded, the meaning of a legal instrument is to be gathered from the instrument itself.⁴⁸ For present purposes, though, Jefferson agreed that the Necessary and Proper Clause granted incidental powers only; his concern was to avoid interpreting the Clause

⁴² Memorandum from Edmund Randolph, Att’y Gen. of the United States, to George Washington, President of the United States (Feb. 12, 1791), <https://founders.archives.gov/documents/Washington/05-07-02-0200-0002> [<https://perma.cc/8NX4-W26M>].

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ See Memorandum from Edmund Randolph, Att’y Gen. of the United States, to George Washington, President of the United States (Feb. 12, 1791), <https://founders.archives.gov/documents/Washington/05-07-02-0200-0003> [<https://perma.cc/5VNN-X8JH>].

⁴⁶ Thomas Jefferson, Opinion on the Constitutionality of a National Bank (Feb. 15, 1791), in 6 THE WORKS OF THOMAS JEFFERSON 197, 200 (Paul Leicester Ford ed., 1904) (emphasis omitted).

⁴⁷ See *id.*

⁴⁸ As Hamilton responded,

whatever may have been the intention of the framers of a constitution or of a law, that intention is to be sought for in the instrument itself, according to the usual and established rules of construction. Nothing is more common than for laws to *express* and *effect* more or less than was intended. If, then, a power to erect a corporation in any case be deducible, by fair inference, from the whole or any part of the numerous provisions of the Constitution of the United States, arguments drawn from extrinsic circumstances, regarding the intention of the Convention, must be rejected.

Alexander Hamilton, Opinion as to the Constitutionality of the Bank of the United States (Feb. 23, 1791), in 3 THE WORKS OF ALEXANDER HAMILTON 445, 463 (Henry Cabot Lodge ed., 1904).

in a way that swallowed the enumeration of powers. The alternative construction, he argued, “would swallow up all the delegated powers, and reduce the whole to one power.”⁴⁹

Secretary of Treasury Alexander Hamilton led the defense of the bank bill and did not disagree on the applicable principles. He began with the proposition that the Necessary and Proper Clause explicitly granted Congress implied powers. “It is conceded that implied powers are to be considered as delegated equally with express ones,” he wrote in his opinion for President Washington.⁵⁰ And the power to erect a corporation was “incident to” Congress’s various regulatory power.⁵¹ The dispute was one of application: “An incorporation seems to have been regarded as some *great independent substantive thing*; as a political end of peculiar magnitude and moment; whereas it is truly to be considered as a *quality, capacity, or means* to an end.”⁵² Corporations are never constructed for the sake of their own existences; they are always constructed for some other purpose.

Thus “the importance of the power of incorporation has been exaggerated,” Hamilton emphasized,⁵³ before proceeding to argue that a national bank would be useful, expedient, and convenient for laying and collecting taxes, borrowing money, regulating trade, and raising and supporting armies.⁵⁴ The contrary argument, he concluded, “is founded upon an exaggerated and erroneous conception of the nature of the power” in question.⁵⁵ “[V]iewed in a just light, [incorporating a national bank] is a means, which ought to have been left to *implication*, rather than an *end*, which ought to have been expressly granted.”⁵⁶ Hamilton summarized, “the power to erect corporations is not to be considered as an independent or substantive power, but as an incidental and auxiliary one, and was therefore more properly left to implication, than expressly granted.”⁵⁷ Congress enacted the bank legislation and President Washington signed it.⁵⁸

When Chief Justice Marshall upheld the constitutionality of the Second Bank of the United States almost three decades later in the 1819 case *McCulloch v. Maryland*,⁵⁹ he was treading old ground. Marshall went on to explain why a clause authorizing implied pow-

⁴⁹ See Jefferson, *supra* note 46, at 201.

⁵⁰ See Hamilton, *supra* note 48, at 450 (emphasis omitted).

⁵¹ *Id.*

⁵² *Id.* at 451.

⁵³ *Id.*

⁵⁴ *Id.* at 473–86.

⁵⁵ *Id.* at 465.

⁵⁶ *Id.*

⁵⁷ *Id.* at 472 (emphasis omitted).

⁵⁸ See Act of Feb. 25, 1791, 1 Stat. 191.

⁵⁹ 17 U.S. (4 Wheat.) 316 (1819).

ers was critical to the Constitution's success. The Framers surely could not have drafted "an accurate detail of all the subdivisions of which its great powers will admit, and of all the means by which they may be carried into execution."⁶⁰ If they had done so, Marshall wrote, the Constitution "would partake of the prolixity of a legal code."⁶¹ The Constitution's nature required "that only its great outlines should be marked, its important objects designated, and the minor ingredients which compose those objects be deduced from the nature of the objects themselves."⁶² Given this feature, Marshall said that in considering Congress's implied powers "we must never forget, that it is *a constitution* we are expounding."⁶³

Marshall then turned to the bank itself. Marshall observed that the enumeration of powers in Article I, Section 8 included "the great powers to lay and collect taxes; to borrow money; to regulate commerce; to declare and conduct a war; and to raise and support armies and navies."⁶⁴ The Constitution, however, "does not profess to enumerate the means by which the powers it confers may be executed; nor does it prohibit the creation of a corporation, if the existence of such a being be essential to the beneficial exercise of those powers."⁶⁵ The power to create a corporation, Marshall wrote, "is not, like the power of making war, or levying taxes, or of regulating commerce, a great substantive and independent power, which cannot be implied as incidental to other powers, or used as a means of executing them."⁶⁶ A corporation "is never the end for which other powers are exercised, but a means by which other objects are accomplished."⁶⁷

B. *Other Evidence*

The distinction between incidental and important powers also featured in salient legal sources and discussions before and after the bank debate. This Section considers these legal sources and discussions, examining first the public understanding around the time of ratification and then legal materials that support this distinction.

⁶⁰ *Id.* at 407.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at 408–09.

⁶⁶ *Id.* at 411.

⁶⁷ *Id.*

1. *Public Understanding*

Madison explained in *Federalist No. 44* that the Necessary and Proper Clause was inserted precisely to avoid the problems under the Articles of Confederation with its provision disabling the Confederation Congress from exercising “any power not *expressly* delegated” by the states.⁶⁸ If the new Constitution had contained a like provision, it would “disarm the government of all real authority whatever.”⁶⁹ “It would be easy to show,” Madison explained, “that no important power delegated by the Articles of Confederation has been or can be executed by Congress, without recurring more or less to the doctrine of *construction* or *implication*.”⁷⁰

Hence, Madison acknowledged that the Necessary and Proper Clause granted only implied powers. Had the Constitutional Convention attempted to enumerate all such implied powers, “the attempt would have involved a complete digest of laws on every subject to which the Constitution relates.”⁷¹ And if the Convention had taken the approach of not including the Necessary and Proper Clause at all, Congress would still have had implied powers because “[n]o axiom is more clearly established in law, or in reason, than that wherever the end is required, the means are authorized.”⁷²

James Wilson agreed. He stated in the Pennsylvania Ratifying Convention that the Necessary and Proper Clause granted “nothing more than what was necessary to render effectual the particular powers that are granted.”⁷³ In responding to various Antifederalist attacks on the Necessary and Proper Clause, he emphasized in relation to Article I, Section 8,

I leave it to every gentleman to say whether the powers are not as accurately and minutely defined, as can be well done on the same subject, in the same language. . . . [E]ven the concluding clause, with which so much fault has been found, gives no more or other powers; nor does it, in any degree, go beyond the particular enumeration; for, when it is said that Congress shall have power to make all laws which shall be necessary and proper, those words are limited and defined by the following, “for carrying into execution the foregoing powers.” It is saying

⁶⁸ THE FEDERALIST NO. 44, *supra* note 32, at 284 (James Madison).

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.* at 284–85.

⁷² *Id.* at 285.

⁷³ James Wilson, Address in the Pennsylvania Convention to Ratify the Constitution (Dec. 4, 1787), in 2 THE DEBATES IN THE SEVERAL STATE CONVENTIONS, ON THE ADOPTION OF THE FEDERAL CONSTITUTION 453, 481 (Jonathan Elliot ed., Washington, Taylor & Maury 1836).

no more than that the powers we have already particularly given, shall be effectually carried into execution.⁷⁴

In his Lectures on Law, he reiterated, “The powers of congress are, indeed, enumerated; but it was intended that those powers, thus enumerated, should be effectual, and not nugatory.”⁷⁵

Additionally, on the whole, the Antifederalist writers did not think that the Necessary and Proper Clause on its own could work much mischief; the risk depended instead on the scope of the specific enumerated grants of power in combination with the apparent breadth and flexibility of the Necessary and Proper Clause. Centinel acknowledged that the Clause only authorized laws “necessary and proper for carrying into execution any of the powers vested in them.”⁷⁶ The Federal Farmer agreed.⁷⁷ Brutus argued that the Necessary and Proper Clause and Article VI’s Supremacy Clause would give the national government “absolute and uncontrollable power, legislative, executive and judicial, *with respect to every object to which it extends*.”⁷⁸ That is a truism; the question is the scope of those referenced objects.

Brutus argued that the Necessary and Proper Clause in combination with the Preamble created the inference “that the legislature will have an authority to make all laws which they shall judge necessary for the common safety, and to promote the general welfare.”⁷⁹ Brutus also interpreted the first grant of power in Article I, Section 8 as a power “to provide for the common defence, and promote the general welfare,” rather than as a power to tax for such purposes or to appropriate funds; he worried about that power combined with the Necessary and Proper Clause.⁸⁰ A Countryman similarly stated the Necessary and Proper Clause “gives [Congress] power to do any thing at all, if they

⁷⁴ *Id.* at 468 (quoting U.S. CONST. art. I, § 8, cl. 18). Of course, Wilson elided the remainder of the Necessary and Proper Clause, which also granted Congress the power to carry into execution any of the “other Powers vested by th[e] Constitution in the Government of the United States, or in any Department or Officer thereof.” See U.S. CONST. art. I, § 8, cl. 18. But there is no reason to think Wilson was dissimulating. The latter parts of the Necessary and Proper Clause are not inconsistent with enumerationism, as they cover enumerated powers of the coordinate branches. See *id.*

⁷⁵ James Wilson, Assoc. Just. of the United States Sup. Ct., Of the Constitutions of the United States and of Pennsylvania—of the Legislative Department, Lectures at the College of Philadelphia, in 2 THE WORKS OF THE HONOURABLE JAMES WILSON, L.L.D. 181 (Bird Wilson ed., Philadelphia, Lorenzo Press 1804).

⁷⁶ Letter from Centinel to the People of Pennsylvania (Nov. 30, 1787), in 2 THE COMPLETE ANTI-FEDERALIST 166, 168 (Herbert J. Storing ed., 1981).

⁷⁷ Letter from the Federal Farmer (Oct. 12, 1787), in 2 THE COMPLETE ANTI-FEDERALIST, *supra* note 76, at 245, 247.

⁷⁸ Letter from Brutus to the Citizens of the State of New York (Oct. 18, 1787), in 2 THE COMPLETE ANTI-FEDERALIST, *supra* note 76, at 363, 365 (emphasis added).

⁷⁹ Letter from Brutus to the People of the State of New York (Dec. 13, 1787), in 2 THE COMPLETE ANTI-FEDERALIST, *supra* note 76, at 388, 389.

⁸⁰ *Id.*

only please to say, it is for the common welfare.”⁸¹ Revisionist scholars have pointed to a handful of other Antifederalist writers who made this interpretation of the so-called “general welfare clause.”⁸²

What is remarkable is how few—if any—Antifederalists worried about the Necessary and Proper Clause in isolation.⁸³ The merits of their claims about the meaning of the first clause in Article I, Section 8 must be deferred. The present point is that not even the Antifederalists disputed that Congress’s laws under the Necessary and Proper Clause required a connection to some other vested power or that it extended only to implied or incidental powers.⁸⁴ The doctrine of implication could be abused, and that appears to have been the Antifederalist concern. But that the Necessary and Proper Clause was a grant of implied powers does not seem to have been doubted.

2. *Legal Materials*

Perhaps the Antifederalists understood along with the proponents of ratification that implied powers were a well-established feature of many areas of law. As four modern scholars have argued, the Necessary and Proper Clause in some form captures the earlier doctrine of implied powers.⁸⁵ The Clause “has a rich history, with numerous antecedents that would have been readily knowable (and were almost certainly known) by informed eighteenth-century drafters and ratifiers,” they write.⁸⁶ The Necessary and Proper Clause’s origins “are found in principles of agency law, administrative law, and corporate law that infused Founding-era constitutionalism.”⁸⁷ Many Founding-era and pre-Founding-era legal instruments involving a principal-agent relationship included “necessary and proper clauses” or their equivalents as a means

⁸¹ Letter from A Countryman (Jan. 17, 1788), in 6 THE COMPLETE ANTI-FEDERALIST, *supra* note 76, at 86, 86. The author also expressed concern that the second part of the Necessary and Proper Clause might imply there was some undifferentiated power vested in the “government of the United States.” *See id.* The author did not, however, suggest that the Necessary and Proper Clause itself granted such powers. *See id.* (“By the last of these clauses, it would appear, that there are some powers vested in this government, besides what are mentioned in it, since it speaks of the foregoing, and all other powers . . .”).

⁸² *See* Coan & Schwartz, *supra* note 20, at 1012–13, 1013 n.164 (citing Richard Henry Lee, Patrick Henry, and George Mason).

⁸³ Hence, David Schwartz relies on “The General Welfare and Necessary and Proper Clauses” together, and his nonenumerationist reading of the Constitution hinges mostly on the former. Schwartz, *Implied Powers*, *supra* note 20, at 595–600.

⁸⁴ Thus, An Old Whig explained that by virtue of the Clause, Congress would not be limited to powers expressly granted, which no one denied; that was the point. Letter from An Old Whig (Oct. 1787–Feb. 1788), in 3 THE COMPLETE ANTI-FEDERALIST, *supra* note 76, at 22, 24–25.

⁸⁵ *See* GARY LAWSON, GEOFFREY P. MILLER, ROBERT G. NATELSON & GUY I. SEIDMAN, THE ORIGINS OF THE NECESSARY AND PROPER CLAUSE 1–14 (2010).

⁸⁶ *Id.* at 4–5.

⁸⁷ *Id.* at 5.

of giving “fiduciary agents incidental powers beyond those expressly described in the instruments.”⁸⁸ Similar clauses also appeared in corporate charters “to ensure that an organization with limited powers and purposes would not be frustrated in the essential conduct of its governmentally authorized activities but would still be confined to its assigned functions.”⁸⁹

The reader may consult the work of these scholars for a more detailed treatment; a few examples will suffice here. Blackstone wrote in his *Commentaries* in the context of a land grant that “[a] subject’s grant shall be construed to include many things, besides what are expressed, if necessary for the operation of the grant.”⁹⁰ Sir Edward Coke’s influential *Institutes of the Laws of England* from a century earlier referenced incidental powers several times. In the context of one statute, for example, Coke wrote that although the Act was “general, . . . all necessary incidents are to be supplied.”⁹¹ Elsewhere he wrote, “they that have [jurisdiction] of any thing are to have [jurisdiction] also of all Incidents and Dependants thereupon, for an Incident is a thing necessarily depending upon another.”⁹²

The central insight is that grants of implied or incidental powers did not authorize important or extraordinary actions. Coke wrote that an “incident” was “a thing appertaining to or following another, as a more worthy or principal.”⁹³ Giles Jacob’s *New Law-Dictionary*, which was the most prominent law dictionary in America at the Founding,⁹⁴ similarly explained that an “incident” was “a thing necessarily depending upon, appertaining to, or following another that is more worthy or principal.”⁹⁵

⁸⁸ *Id.* at 6.

⁸⁹ *Id.* at 7.

⁹⁰ 2 WILLIAM BLACKSTONE, COMMENTARIES *347.

⁹¹ EDWARD COKE, THE FIRST PART OF THE INSTITUTES OF THE LAWS OF ENGLAND § 454 (London, William Rawlins et al., 9th ed. 1684).

⁹² *Id.* § 366.

⁹³ *Id.* § 227.

⁹⁴ GILES JACOB, A NEW LAW-DICTIONARY (J. Morgan ed., London, W. Strahan & W. Woodfall, 10th ed. 1782) [hereinafter JACOB 1782]. He wrote the first edition of the law dictionary in 1729 with several editions, including the one in 1782. GILES JACOB, A NEW LAW-DICTIONARY (London, E. and R. Nutt & R. Gosling, 1st ed. 1729). The law dictionary was the “fourth most popular of all law books available” in colonial Virginia. GARY L. McDOWELL, THE LANGUAGE OF LAW AND THE FOUNDATIONS OF AMERICAN CONSTITUTIONALISM 172 (2010). It appears to have been the “most widely used English law dictionary” of the period. Leonard W. Levy, *Origins of the Fifth Amendment and Its Critics*, 19 CARDOZO L. REV. 821, 854 (1997); see also WILLIAM HAMILTON BRYSON, CENSUS OF LAW BOOKS IN COLONIAL VIRGINIA, at xvi–xvii (1978) (relating colonial Virginia’s most popular books and the number of copies sold). The dictionary has been found in the libraries of Francis Dana, John Mercer, Robert Treat Paine, St. George Tucker, Theophilus Parsons, and John Adams, among other luminaries. HERBERT A. JOHNSON, IMPORTED EIGHTEENTH-CENTURY LAW TREATISES IN AMERICAN LIBRARIES 1700–1799, at 33 (1978).

⁹⁵ JACOB 1782, *supra* note 94 (under entry for “incident”).

Another example is found in the English case *Howard v. Baillie*⁹⁶ from 1796, a few years after the Founding. The executrix of an estate authorized two others “to act for her in collecting and getting in the estate of the deceased, and paying his debts.”⁹⁷ The question was whether that authorization included the power to make the executrix personally liable for a debt on condition that the creditor wait twenty months for payment.⁹⁸ Although this may seem like an important power by modern lights, Lord Chief Justice Kenyon explained that such a procedure was not unusual in the administration of estates.⁹⁹ The critical point is that the Lord Chief Justice recognized that the grant of a general, principal power to pay the debts “necessarily includes . . . all the means necessary to be used, in order to attain the accomplishment of the object of the principal power”—that is, “subordinate powers, though not expressly given, . . . must be understood to be included in this power to pay debts.”¹⁰⁰ This implies that subordinate powers can be left to implication, but principal powers cannot.

John Mikhail cites to a pair of 1774 English cases authored by Chief Justice Mansfield for his argument that “sweeping clauses” were intended to provide for omitted powers,¹⁰¹ but these cases, too, support the proposition that such powers could not have been important ones. In one of these cases, Mansfield explained that by “sweeping clauses, conveyancers often take in every thing relative to what had been before recited, and which it was possible they might have omitted to enumerate precisely.”¹⁰² That clause ended in a semicolon, after which Mansfield added, “but they never mean to pass any thing new.”¹⁰³ The entire case concerned the meaning of a sweeping clause in a land grant in which the grantor minutely described two pieces of land and then ended “with all my other estates in the kingdom of Ireland.”¹⁰⁴ The estates were of considerable value. Lord Mansfield asked, “Now is it credible this would

⁹⁶ (1796) 126 Eng. Rep. 737; 2 H. Bl. 618.

⁹⁷ *Id.* at 737, 2 H. Bl. at 618.

⁹⁸ *Id.* at 739, 2 H. Bl. at 622.

⁹⁹ *Id.* at 739–40, 2 H. Bl. at 622 (finding that the executrix’s liability was in substance comparable to “a mere agreement to forbear”).

¹⁰⁰ *Id.* at 738, 2 H. Bl. at 620.

¹⁰¹ Mikhail, *Necessary and Proper*, *supra* note 20, at 1121–22.

¹⁰² *Lessee of Moor v. Moor* (1774) 98 Eng. Rep. 714, 714; Lofft 398, 398.

¹⁰³ *Id.* at 714, Lofft at 399. There is a parenthetical in the report. The entire passage reads, “by which kind of sweeping clauses, conveyancers often take in every thing relative to what had been before recited, and which it was possible they might have omitted to enumerate precisely; (and besides it helps forwards a line,) but they never mean to pass any thing new.” *Id.* at 714, Lofft at 399.

¹⁰⁴ *Id.* at 714, Lofft at 398.

have passed by so few general words, when such an immense detail was made of the others?”¹⁰⁵

These sources all tend to show that implied powers, authorizations, and grants were accepted in several areas of law. Such grants were in service of specified objects, and the incidental powers were therefore subordinate to, incidental to, or less important than those objects. Otherwise, the Necessary and Proper Clause would supersede the specification and make the specification nugatory. That is consistent with the many other examples of the phrase “necessary and proper” prior to the Constitution.¹⁰⁶ The evidence from the bank debate, ratification, and preratification legal sources all point to the distinction between great powers and incidental ones.¹⁰⁷

¹⁰⁵ *Id.* at 714, Lofft at 399. Lord Mansfield concluded that “probably the word said had been left out” and it was intended to read “all my other said estates,” which would limit the clause to previously described land. *Id.* at 714–15, Lofft at 400.

¹⁰⁶ Mikhail, *Necessary and Proper*, *supra* note 20, at 1114–21. Professor Mikhail correctly argues that the phrase “signal[ed] little more than an informal and flexible standard for exercising appropriate discretion in various contexts.” *Id.* at 1121. Examples include the Bank of New York, which authorized leadership to petition the legislature for protective legislation “as they shall judge *necessary and proper* for the Security of the Stockholders,” and the State of Pennsylvania’s appointment of legal representatives “to do every thing *necessary and proper* for the vindication and defence of the claim” at issue. *Id.* at 1117–18 (first quoting Alexander Hamilton, Constitution of the Bank of New York (Feb.–Mar. 1784), <https://founders.archives.gov/documents/Hamilton/01-03-02-0332> [<https://perma.cc/5XPX-HJ7W>]; and then quoting 22 JOURNALS OF THE CONTINENTAL CONGRESS 347 (Gaillard Hunt ed., 1914)). What seems evident is that such clauses were always used in service of some other specified objective of importance. The question is in service of what objectives does Congress have its residual powers. The Necessary and Proper Clause answers the question: for carrying into execution power that the Constitution has already vested in the government of the United States or in one of its departments or officers.

¹⁰⁷ The distinction between great and incidental powers is similar, though not quite identical, to the distinction between “proper” and “improper” powers. See Gary Lawson & Patricia B. Granger, *The “Proper” Scope of Federal Power: A Jurisdictional Interpretation of the Sweeping Clause*, 43 DUKE L.J. 267, 289–90 (1993). Lawson and Granger uncover numerous statements in which it was presumed that laws that would violate the kinds of rights that would eventually be enumerated in the Bill of Rights would not have been “proper.” *Id.* at 267–74. It is difficult to know what would be “proper” and not “proper,” however, even with their understanding that proper means “peculiar to” a particular institution—namely the national government or whichever department Congress is empowering. *Id.* at 291. The distinction between great and incidental powers has more intuitive appeal and is supported by much evidence, including as unearthed by Lawson’s coauthored book discussed above. See *supra* notes 85–89 and accompanying text. See generally LAWSON ET AL., *supra* note 85 (exploring the “agency law, administrative law, and corporate law” roots of the Necessary and Proper Clause). Lawson and Granger also convincingly show that it was presumed that the judiciary would be able to police the bounds of “propriety.” *Id.* at 276–85.

To the extent one fears that the judiciary deciding on what is too great for Congress to do without express authorization leaves too much room for judicial policymaking, the evidence decisively shows that it was expected the courts would assume this role. See *id.* What the remainder of this Article aims to show is that the judicial role can be cabined through proper intratextual and historical analyses. Thus, it is hoped to avoid and perhaps solve in part John Manning’s concern that “both the Rehnquist and Roberts Courts have held that a law is not ‘proper’ if it cannot satisfy

C. *Examples of Great Powers*

This Section examines two likely examples of powers at the Founding that were thought to be too great and important to be left to implication: abrogating sovereign immunity and eminent domain. These examples are useful for two purposes. First, they constitute further confirmation that the Necessary and Proper Clause did not authorize the exercise of any great and important power. Second, they demonstrate the kind of evidence needed to make a reasonably firm conclusion that a particular power would have been understood as a great and important one. That will be helpful for the analysis of the administrative law subjects discussed in Part II.

1. *Sovereign Immunity*

It is often asserted that the Supreme Court's sovereign immunity jurisprudence, which maintains that Congress cannot abrogate a state's sovereign immunity through its Article I powers,¹⁰⁸ is entirely made up.¹⁰⁹ That is because the Eleventh Amendment provides only that the judicial power shall not extend to diversity suits against states.¹¹⁰ But many of the cases in which the Supreme Court has disabled Congress from abrogating a state's sovereign immunity involve federal question jurisdiction where citizens sue their own state.¹¹¹ The Court has often asserted, however, that sovereign immunity emanates from the Eleventh Amendment or that the Eleventh Amendment is simply illustrative of more fundamental postulates.¹¹²

By its plain text, however, the Eleventh Amendment is irrelevant to sovereign immunity in cases not involving diversity jurisdiction. But it does not follow that the Supreme Court's results are incorrect. As other scholars have pointed out, the real question is whether Congress

the Court's own conception of freestanding, and thus indefinite, principles of federalism and separation of powers," see John F. Manning, *Foreword: The Means of Constitutional Power*, 128 HARV. L. REV. 1, 6 (2014), while acknowledging that there are in fact limits to Congress's power under the Necessary and Proper Clause.

¹⁰⁸ See, e.g., *Seminole Tribe v. Florida*, 517 U.S. 44, 72–73, 76 (1996) (holding that Article I does not give Congress the power to abrogate state sovereign immunity in federal court); *Alden v. Maine*, 527 U.S. 706, 754 (1999) (same for state courts).

¹⁰⁹ See, e.g., ERIC J. SEGALL, *ORIGINALISM AS FAITH* 133 (2018); Erwin Chemerinsky, *Against Sovereign Immunity*, 53 STAN. L. REV. 1201, 1204–10 (2001); David P. Currie, *Response, Ex Parte Young After Seminole Tribe*, 72 N.Y.U. L. REV. 547, 547 (1997) (noting that almost no law professors think the Court's sovereign immunity cases are correct).

¹¹⁰ U.S. CONST. amend. XI ("The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.").

¹¹¹ See, e.g., *Alden*, 527 U.S. at 711–12.

¹¹² See *Seminole Tribe*, 517 U.S. at 68; *Alden*, 527 U.S. at 728–29.

has power to abrogate sovereign immunity in the first place.¹¹³ The only plausible explicit textual hook in the original Constitution was Article III's grant of diversity jurisdiction, which gave federal courts jurisdiction over suits involving "States."¹¹⁴ Following the ratification of the Eleventh Amendment, however, Article III could no longer be read to abrogate sovereign immunity.

Without Article III, nothing else in the Constitution expressly grants Congress power to abrogate a state's sovereign immunity. It could only have that power by virtue of the Necessary and Proper Clause. The question then becomes whether sovereign immunity was understood to be such an important prerogative that abrogating it would have been understood to be a great and important power. The very reaction to the Supreme Court's early decision in *Chisholm v. Georgia*¹¹⁵ authorizing suits against states,¹¹⁶ which led to the Eleventh Amendment, is an indication that the ratifying public would not have understood the Constitution to have abrogated—or to have authorized Congress to abrogate—sovereign immunity without stating so explicitly.¹¹⁷

The Court and scholars have canvassed much of the historical evidence for its conclusion that many in the Founding generation believed that states retained their sovereign immunity and that the Constitution itself, at least, did not abrogate it.¹¹⁸ And the Eleventh Amendment creates an intratextual inference against finding the power to abrogate sovereign immunity by implication. When significant evidence demonstrates that a particular power was understood to be important, supported by intratextual evidence that makes it unlikely such a power would have been left to implication, one can more confidently conclude that it is unlikely that Congress has that power under the Necessary and Proper Clause.

¹¹³ See Bradford R. Clark, *The Eleventh Amendment and the Nature of the Union*, 123 HARV. L. REV. 1817, 1822 (2010); William Baude, *Sovereign Immunity and the Constitutional Text*, 103 VA. L. REV. 1, 14–15 (2017).

¹¹⁴ U.S. CONST. art. III, § 2; see also Clark, *supra* note 113, at 1862–70 (discussing the significant attention that Federalists and Antifederalists gave to Article III's diversity suit provisions, as such provisions could be read to authorize lawsuits against states).

¹¹⁵ 2 U.S. (2 Dall.) 419 (1793).

¹¹⁶ *Id.* at 425.

¹¹⁷ See Clark, *supra* note 113, at 1886–87 (describing the "swift and almost uniformly hostile" reaction to *Chisholm*). Of course, the Supreme Court's opinion in *Chisholm* is some evidence of the opposite proposition.

¹¹⁸ *Id.* at 1862–70 (canvassing evidence and concluding "[i]n the debates over state-citizen diversity jurisdiction, the Founders generally seem to have assumed that the states would retain their preexisting immunity unless they expressly surrendered it in the Constitution"); Hans v. Louisiana, 134 U.S. 1, 12–21 (1890) (overviewing similar evidence).

2. Eminent Domain

Another example is the power of eminent domain. The Supreme Court held in *Kohl v. United States*¹¹⁹ that Congress has the power of eminent domain in furtherance of its enumerated powers,¹²⁰ which is what the modern doctrine maintains.¹²¹ Professor William Baude has demonstrated, however, that the historical understanding was different:

Eminent domain could not be inferred from Congress's enumerated powers or the Necessary and Proper Clause because it was a great power, too important to be left to implication. . . . [T]his understanding was reflected in uniform, widespread practice. While there certainly were expressions of the contrary view, especially several decades after the Founding, those views were not actually reflected in any judicial holding or federal practice until the Civil War.¹²²

According to Baude's work, Congress would have needed the states to exercise their power of eminent domain and then transfer the land to the federal government.¹²³ There is some intratextual evidence of this point: The Constitution provides that Congress may exercise "exclusive Legislation in all Cases whatsoever . . . over all Places purchased by the Consent of the Legislature of the State in which the Same shall be, for Erection of Forts, Magazines, Arsenals, dock-Yards, and other needful Buildings."¹²⁴ A natural reading of the clause is that it requires state consent to acquire the land, although it is not the only possible reading.¹²⁵ But it at a minimum "suggest[s] that the constitutional design anticipated state involvement in federal land acquisitions and building projects."¹²⁶

This intratextual evidence is supported by early historical practice and discussions in which "a federal takings power was explicitly denied."¹²⁷ As Baude summarizes, until 1864, "when the government needed land for federal projects, it did not take it," but rather "relied on the state's condemnation authority—either by having the state condemn the land and then transfer it to the federal government, or by having federal agents proceed as plaintiffs under state condemnation law."¹²⁸ Although the mere absence of congressional exercises of power does not prove

¹¹⁹ 91 U.S. 367 (1876).

¹²⁰ *Id.* at 371–72.

¹²¹ *See, e.g., PennEast Pipeline Co. v. New Jersey*, 594 U.S. 482, 508 (2021).

¹²² William Baude, *Rethinking the Federal Eminent Domain Power*, 122 YALE L.J. 1738, 1742 (2013).

¹²³ *Id.* at 1762.

¹²⁴ U.S. CONST. art. I, § 8, cl. 17.

¹²⁵ *See* Baude, *supra* note 122, at 1759–61.

¹²⁶ *Id.* at 1760.

¹²⁷ *Id.* at 1761.

¹²⁸ *Id.* at 1762.

the power does not exist, Congress's approach to eminent domain "was not simply the oversight of an earlier time, but rather the result of a well-functioning" and thought-out "regime of cooperative federalism."¹²⁹ Once again, the historical evidence of a specific understanding, supported by intratextual evidence, suggests that Congress lacks the relevant power under the Necessary and Proper Clause.

II. THE COURT AND THE ADMINISTRATION

If the previous analysis is correct, the Necessary and Proper Clause empowers Congress to establish an administrative state but also limits how it can do so. As a more trivial but not unimportant matter, any law must help carry into execution the President's executive power, whatever that is; it cannot hinder, diminish, or expand the President's powers. More significantly for present purposes is the restriction on Congress's exercise by implication of any great and important powers. Precisely how one determines what is great and important is the most understudied of the questions here addressed. It is hoped that the examples discussed in this Part—removal, juries, and appropriations—might help future litigants and scholars conduct such an analysis.

A. Removal

The Supreme Court's removal jurisprudence is well known and will only be briefly summarized. In *Myers v. United States*,¹³⁰ the Court held that any officer appointed "by and with . . . advice and consent"—all principal officers and all inferior officers whose appointments Congress has not vested in the head of a department—is removable by the President.¹³¹ Congress cannot give the U.S. Senate a check on removal, even though the Senate must advise and consent to appointments.¹³² That left open the question of whether Congress can leave the removal power in the President but restrict it through for-cause removal protections for the officer. In *Humphrey's Executor v. United States*,¹³³ the Court upheld such for-cause protections on the ground that the officers in question, Commissioners of the Federal Trade Commission, exercised only quasi-legislative and quasi-judicial power and exercised "no part of the executive power vested by the Constitution in the President."¹³⁴

¹²⁹ *Id.*

¹³⁰ 272 U.S. 52 (1926).

¹³¹ *Id.* at 176.

¹³² *See id.* at 119; U.S. CONST. art. II, § 2, cl. 2 (providing that the Senate must generally advise and consent to appointments).

¹³³ 295 U.S. 602 (1935).

¹³⁴ *Id.* at 628.

That reasoning was erroneous.¹³⁵ If the power in question was legislative, it had to be exercised by Congress;¹³⁶ if judicial, it had to be exercised by a court.¹³⁷ And if the power was executive, then it had to be exercised according to the strictures of Article II. The Court thus should have had to decide the meaning of “[t]he executive Power” in the President¹³⁸ and the meaning of the Take Care Clause.¹³⁹ Most recently, in limiting the reach of the *Humphrey*’s decision without quite overturning it, the Supreme Court held in *Seila Law LLC v. Consumer Financial Protection Bureau*¹⁴⁰ that Congress cannot insulate a single-director agency with for-cause removal protections.¹⁴¹

Significantly, neither the unanimous Court in *Humphrey*’s nor the majority in *Seila Law* even addressed the Necessary and Proper Clause. Yet, as this Part shall now make clear, it is highly likely that the Necessary and Proper Clause is dispositive to the inquiry. A rule that the President has a power to remove can follow relatively clearly from the meaning and history of “[t]he executive Power,”¹⁴² but the Necessary and Proper Clause provides even stronger support for such a rule. More difficult is the question of whether Congress can impose for-cause protections. There is nothing obvious about the text or early history that would preclude Congress from doing so. An analysis of the Necessary and Proper Clause, however, suggests two important limits on any such attempts by Congress. First, if for-cause removals are judicially reviewable, then that would transfer the “take Care” duty¹⁴³ to the courts—a relatively clear violation of the Constitution’s distribution of responsibilities. Second, for-cause protections effectively create property interests in holding federal office. The creation of such property interests is likely a great and important power that would not have been left to implication. The remainder of this Section seeks to make that case.

¹³⁵ As Justice Kagan wrote in dissent in *Seila Law LLC v. Consumer Financial Protection Bureau*, “The majority is quite right that today we view *all* the activities of administrative agencies as exercises of ‘the “executive Power.”’” 591 U.S. 197, 278 n.7 (2020) (Kagan, J., concurring in the judgment in part and dissenting in part) (quoting *City of Arlington v. FCC*, 569 U.S. 290, 304 n.4 (2013)).

¹³⁶ U.S. CONST. art. I, § 1 (“All legislative Powers herein granted shall be vested in a Congress of the United States”); *id.* art. I, § 7 (requiring majority votes of both houses of Congress and a presidential signature or overridden veto for a bill to become a law).

¹³⁷ *Id.* art. III, § 1 (“The judicial Power of the United States, shall be vested in one supreme Court, and . . . inferior Courts . . .”).

¹³⁸ *Id.* art. II, § 1 (“The executive Power shall be vested in a President of the United States of America.”).

¹³⁹ See *id.* art. II, § 3 (“[The President] shall take Care that the Laws be faithfully executed . . .”).

¹⁴⁰ 591 U.S. 197 (2020).

¹⁴¹ *Id.* at 204.

¹⁴² U.S. CONST. art. II, § 1.

¹⁴³ *Id.* art. II, § 3.

1. *The Executive Power Clause*

The Author has recently argued at some length that a presidential removal power follows from a series of propositions.¹⁴⁴ First, the President's executive power can be loosely translated as the power to oversee the execution of law by others.¹⁴⁵ The British monarch could not personally execute the laws, and there is little reason to think the American President had that power in absence of congressional legislation.¹⁴⁶ Second, as a consequence, the power to oversee execution included the power to appoint officers to assist in the execution of the laws.¹⁴⁷ The power to remove followed from the power to appoint: It was a firmly established common law maxim that "[h]e who appoints may remove."¹⁴⁸ The power of appointment included the power to remove if for no other reason than the appointer could appoint a new officer to the position.

This maxim explains why the Constitutional Convention did not mention the removal power, which some prominent scholars have argued is otherwise inexplicable.¹⁴⁹ The Convention had no opportunity to discuss removal because until September 4, the draft Constitution had provided that the Senate would appoint ambassadors and judges and the President would appoint all other officers.¹⁵⁰ As a result, the Senate and the President would be able to remove those respective officers simply by making new appointments. It was not until the Committee on Postponed Matters assigned all appointments to the President and shared that power with the Senate that the question arose as to who would have the removal power—the President alone or the President and Senate together.¹⁵¹

The Necessary and Proper Clause and the Take Care Clause help answer this question. Representative James Madison, participating in the great 1789 debate over the removal of the principal officers of the first three cabinet departments, agreed that "the power to annul an appointment is, in the nature of things, incidental to the power

¹⁴⁴ See generally Ilan Wurman, *The Original Presidency: A Conception of Administrative Control*, 16 J. LEGAL ANALYSIS 26 (2024) (arguing that the President's power to remove principal officers stems from the Opinions Clause).

¹⁴⁵ See *id.* at 30–31.

¹⁴⁶ See *id.* at 30–34.

¹⁴⁷ See *id.* at 34–35.

¹⁴⁸ *Id.* at 36 (quoting Thomas Jefferson, Notes Concerning the Right of Removal from Office (1780), in 4 THE PAPERS OF THOMAS JEFFERSON 281 (Julian P. Boyd ed., 1951)).

¹⁴⁹ McCONNELL, *supra* note 19, at 162 ("The Committee of Detail and the Convention addressed and allocated every other significant royal prerogative, but not the Removal Power. Yet it is hard to see how it could have been neglected; it is crucial to the structure of the executive branch.").

¹⁵⁰ 2 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, *supra* note 18, at 183, 185.

¹⁵¹ See *id.* at 495; Wurman, *supra* note 144, at 37.

which makes the appointment”; if that were all the Constitution had said on the matter, he would have agreed that the President and Senate together must remove.¹⁵² But Madison gestured to the Executive Power Clause, arguing that the appointment component of the executive power is shared with the Senate, an “exception” to the general vesting of this power in the President.¹⁵³ Furthermore, the Take Care Clause implies the President has the power “necessary to accomplish” that duty.¹⁵⁴ Madison effectively argued that a back-end senatorial veto on the removal decision would unconstitutionally transfer the take care duty from the President to the Senate.¹⁵⁵

The Necessary and Proper Clause then demonstrates why the third dominant position in the debates in 1789, that Congress had discretion whether to vest the removal power with the President alone or with the President and Senate together,¹⁵⁶ was inconsistent with the Constitution. This is also the position to which most modern scholars adhere.¹⁵⁷ But to vest removal in the Senate and President together would run into the same problem as maintaining that as the default rule—the take care duty would be transferred to the Senate. Moreover, Madison explained, if Congress had discretion to grant a back-end check to the Senate, it is unclear why it could not grant the same back-end check to the House, or Congress as a whole, or even to anyone else.¹⁵⁸ This analysis suggests that although Congress has power under the Necessary and Proper Clause to establish offices, qualifications, duties, and tenure, all of which carry into execution the President’s power to oversee law execution, it does not have the power to transfer to some other entity the take care duty.

2. *For-Cause Restrictions*

None of the above answers the question of whether Congress can structure the removal power in such a way that Congress does not retain a role for any part of itself but nevertheless limits the President’s ability to remove. Two views appear to have been widely shared during the Founding period through the Civil War, with one predominating before the Jacksonian period and the other predominating after. One view

¹⁵² Wurman, *supra* note 144, at 37 (quoting 1 ANNALS OF CONG. 496 (1789) (Joseph Gales ed., 1834)).

¹⁵³ 1 ANNALS OF CONG. 496.

¹⁵⁴ *Id.*

¹⁵⁵ See Wurman, *supra* note 144, at 37.

¹⁵⁶ See, e.g., 1 ANNALS OF CONG. 492 (“As the officer is the mere creature of the Legislature, we may form it under such regulations as we please . . .”).

¹⁵⁷ See, e.g., PETER M. SHANE, DEMOCRACY’S CHIEF EXECUTIVE 114–17 (2022).

¹⁵⁸ 1 ANNALS OF CONG. 495–96.

maintained that the President could remove for any reason.¹⁵⁹ The other maintained that although the President had the constitutional power to remove for any reason, that power could be abused if done for the purpose of inducing a subordinate officer in whom Congress has granted discretion to execute the laws in a particular way.¹⁶⁰ That both views predominated and imply that for-cause removal restrictions would be unconstitutional and that such restrictions for principal officers did not appear until several decades later¹⁶¹ are some evidence against the constitutionality of for-cause restrictions.

But it is not dispositive. Particularly if the second view prevailed, for-cause restrictions could be seen to help carry into execution the President's law-execution power and take care duty. That is because the President would not otherwise have a constitutional right to direct the officer; the President can always make demands of the principal officers, but the Opinions Clause suggests that the only obligation on the part of the latter to obey is with respect to giving the President information.¹⁶² So long as a removal restriction still permits the President to remove an officer whom the President believes is failing to execute the law faithfully, that would seem to be consistent with the Vesting Clause, the Take Care Clause, and the Opinions Clause.

In other words, for-cause restrictions would still "carry into execution" the President's powers, depending on one's view of the meaning of "the executive power." But the Necessary and Proper Clause might still come into play another way. For-cause removal restrictions could still be problematic under the Necessary and Proper Clause for two additional reasons. The first, more trivial reason is that they would recreate the problem of a senatorial veto.¹⁶³ At least if Congress makes presidential removals of officers who hold offices with for-cause protections judicially reviewable, that would seem to transfer the take care duty to the courts. That would be equally impermissible as the Senate retaining a check. To be sure, it is possible to conceive of removal protections that do not involve the judiciary. For example, if for-cause restrictions are interpreted as merely requiring a process to terminate an officer for a particular cause, as opposed to merely removing the officer for policy differences, then they can be understood as due process protections for

¹⁵⁹ This was obviously the Jacksonian view. See Wurman, *supra* note 144, at 44–45.

¹⁶⁰ For evidence of this view, see *id.* at 39–46.

¹⁶¹ See Aaron L. Nielson & Christopher J. Walker, *Congress's Anti-Removal Power*, 76 VAND. L. REV. 1, 34 (2023) (describing the adoption in 1864 of a reason-giving requirement for dismissal of the Comptroller of the Currency).

¹⁶² *Id.* at 46–47; U.S. CONST. art. II, § 2, cl. 1 ("The President . . . may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices . . .").

¹⁶³ See *supra* notes 155–58 and accompanying text.

the reputation of the officer.¹⁶⁴ The President can still remove the officer, but if it is not for a stated cause, then Congress could conceivably carry forward an impeachment if Congress believed there was a pattern of undermining the discretion of officers in whom Congress has vested such discretion. And if the President does remove for cause, then the officer receives some measure of due process. In either case, the President can still remove, and no provision of the Constitution has been violated.

3. *Offices as Property*

The second, possibly more consequential reason that for-cause protections may be problematic under the Necessary and Proper Clause is that they effectively create property interests in holding federal office. A statutory provision granting an officeholder the right to hold the office without a statutory term after which the office expires and with for-cause protections would be tantamount to granting lifetime tenure during good behavior. The Constitution only contemplates such tenure for judges.¹⁶⁵ And it prohibits both the state and federal governments from granting titles of nobility.¹⁶⁶ These create at least intratextual inferences that the granting of lifetime tenure to an executive officeholder would be a great and important power that would not have been left to implication. Lifetime tenure was an important enough matter with respect to judges that the Constitution addressed it explicitly.¹⁶⁷ And titles of nobility were sufficiently serious that the granting of them was prohibited to both levels of government. It would be surprising to say the least if Congress would nevertheless have discretion by implication to grant lifetime tenure, which is at least analogous to a title of nobility; the nobility and officeholding were intertwined throughout much of English history.¹⁶⁸ Certainly it is unclear why it would be less important than the granting of such a title. If hereditary officeholding would be a kind of title of nobility, a grant of lifetime tenure could easily be considered along similar lines.

¹⁶⁴ That is how the Supreme Court first interpreted such provisions. *See* *Shurtleff v. United States*, 189 U.S. 311, 317–18 (1903).

¹⁶⁵ U.S. CONST. art. III, § 1.

¹⁶⁶ *Id.* art. I, § 9, cl. 8; *id.* art. I, § 10, cl. 1.

¹⁶⁷ To be sure, the specification in Article III was intended to disable congressional discretion, and so it could be thought that Congress had discretion to nevertheless grant lifetime tenure to executive officeholders. But at the Founding, at least, the grant in Article III was understood more often in accord with the *expressio unius* canon: The specification of lifetime tenure in one instance precludes lifetime tenure in other instances. For example, summarizing the recent Decision of 1789, Representative Benson argued that the tenure of offices was “well fixed now”—namely, “The judges hold theirs during good behaviour, as established by the Constitution; all others, during pleasure.” 1 ANNALS OF CONG. 614 (1789) (Joseph Gales ed., 1834).

¹⁶⁸ *See* 2 WILLIAM STUBBS, THE CONSTITUTIONAL HISTORY OF ENGLAND 178 (1875).

There are other historical reasons to suspect that granting property interests in federal office would have been considered a great and important power that would not have been left to implication. The Founding generation was greatly concerned with the ability of rulers to create webs of influence through officeholding. The Declaration of Independence alleged that the King had “erected a Multitude of new Offices, and sent hither Swarms of Officers to harrass our People, and eat out their Substance.”¹⁶⁹ Royal governors did the same; offices were the greatest source of patronage and influence. “With the unforeseen and prodigious multiplication of offices, places, favors, and perquisites,” Gordon Wood has written, it appeared by the eighteenth century that the Crown “had been given nothing less than the power to structure the society as it saw fit.”¹⁷⁰ And in the colonies, eighteenth-century royal governors “continually sought to use their authority as the source of honor and privilege in the community to build webs of influence.”¹⁷¹ As a result, “Americans in 1776 were resolved to destroy the capacity of their rulers ever again to put together such structures of domination,” and they took this power away from the governors acting alone.¹⁷² In most of the revolutionary constitutions, “the appointing power was lodged in the legislatures, either exclusively, or concurrently with the governor.”¹⁷³ That does not conclusively demonstrate that tenure protections would have been impermissible. But if the problem was webs of influence and privilege, a lifetime post would be an attractive tool in an executive’s arsenal.

Montesquieu was also hugely influential at the Founding,¹⁷⁴ and his writing suggests that property in offices was incompatible with republicanism. To be sure, he described the removal power as indispensable to a despotism because commands had to be followed strictly and quickly.¹⁷⁵

¹⁶⁹ THE DECLARATION OF INDEPENDENCE para. 12 (U.S. 1776).

¹⁷⁰ GORDON S. WOOD, *THE CREATION OF THE AMERICAN REPUBLIC 1776–1787*, at 145 (1998 ed. 1998).

¹⁷¹ *Id.*

¹⁷² *Id.* at 148.

¹⁷³ *Id.*

¹⁷⁴ BERNARD BAILYN, *THE IDEOLOGICAL ORIGINS OF THE AMERICAN REVOLUTION* 27–30 (enlarged ed. 1992); FORREST McDONALD, *NOVUS ORDO SECLORUM* 80–85, 233–35 (1985); see also Jack N. Rakove, *Fidelity Through History (Or to It)*, 65 *FORDHAM L. REV.* 1587, 1598 (1997) (“There is no question that politically articulate eighteenth-century Americans—and certainly members of the political elite—were eclectically conversant with the works of luminaries like Hobbes, Locke, Montesquieu, Hume, and Blackstone.”).

¹⁷⁵ MONTESQUIEU, *THE SPIRIT OF THE LAWS* 70 (Anne M. Cohler et al. eds. & trans., Cambridge Univ. Press 1989) (1748). Contrary to what Professor Jed Shugerman has written, however, Montesquieu did not describe removal as despotic. See Jed Handelsman Shugerman, *Venality: A Strangely Practical History of Unremovable Offices and Limited Executive Power*, 100 *NOTRE DAME L. REV.* 213, 220 (2024). He merely described it as necessary that offices “should not be sold in despotic states, where the prince must place or displace subjects in an instant.” MONTESQUIEU, *supra*, at 70.

But treating offices as property—and allowing the buying and selling of offices—was appropriate for a monarchy “because it provides for performing as a family vocation what one would not want to undertake for virtue, and because it destines each to his duty and renders the orders of the state more permanent.”¹⁷⁶ Montesquieu made clear, however, that he was not referring to republics, for which Plato had rejected the buying and selling of offices because that practice would be like making someone on a ship “a pilot or a sailor for his silver.”¹⁷⁷ Montesquieu’s dictum, connecting property rights in offices to monarchy and suggesting they would be inappropriate in republics, is further evidence that the Framing generation is unlikely to have allowed Congress to create such property rights by implication.

Another, perhaps more relevant set of historical evidence comes from the recent work of Jane Manners and Lev Menand.¹⁷⁸ Their work demonstrates that property rights in offices were common in England prior to the eighteenth century, and Parliament sought to restrict the practice over the course of the eighteenth century as the political system became more republican.¹⁷⁹ Parliament established shorter tenures through legislation providing that several offices would be for fixed terms of years.¹⁸⁰ These offices were still property for the duration of their statutory terms, so Parliament sought to make them even more accountable by allowing removal for specified causes.¹⁸¹ These reforms, in other words, diminished property rights in officeholding in England in service of republican principles.¹⁸²

It follows that the granting of lifetime tenure would be incompatible with republican principles of accountability.¹⁸³ And if granting lifetime tenure during good behavior would be incompatible, then it is hard to distinguish a seven-year term during good behavior, which was at issue in *Humphrey’s Executor* and is more typical.¹⁸⁴ After all, if Congress can create tenure protections for a term of seven years or even ten years,¹⁸⁵ then it is unclear why it could not create such protec-

¹⁷⁶ MONTESQUIEU, *supra* note 175, at 70.

¹⁷⁷ *Id.*

¹⁷⁸ See generally Jane Manners & Lev Menand, *The Three Permissions: Presidential Removal and the Statutory Limits of Agency Independence*, 121 COLUM. L. REV. 1 (2021) (documenting the history of “inefficiency, neglect of duty, and malfeasance in office” removal provisions and arguing that such provisions are removal permissions rather than removal protections).

¹⁷⁹ See *id.* at 18–20, 29, 33–34.

¹⁸⁰ See *id.* at 18–19.

¹⁸¹ See *id.* at 31–34.

¹⁸² Wurman, *supra* note 144, at 38; see also Manners & Menand, *supra* note 178, at 28.

¹⁸³ See Manners & Menand, *supra* note 178, at 21.

¹⁸⁴ *Humphrey’s Ex’r v. United States*, 295 U.S. 602, 618 (1935).

¹⁸⁵ See 28 U.S.C. § 532 note (Confirmation and Compensation of Director; Term of Service) (providing that the Director of the Federal Bureau of Investigation may not serve more than a single ten-year term).

tions for a term of thirty years or even ninety-nine years. The inability to draw such a line is another argument against the enterprise altogether.

There are not many American cases on the question, but those that exist suggest the American revolutionary generation rejected the idea of property rights in office. As the Supreme Court said in *Ex parte Hennen*,¹⁸⁶ “The tenure in [English] cases depends, in a great measure, upon ancient usage. But with us, there is no ancient usage which can apply to and govern the tenure of offices created by our Constitution and laws.”¹⁸⁷ The Supreme Court would eventually say that “[t]he decisions are numerous to the effect that public offices are mere agencies or trusts, and not property as such.”¹⁸⁸ Other scholars, even those favorable to removal restrictions, agree that property in office was “roundly rejected” by the Founding generation.¹⁸⁹

To summarize, if Americans rejected property interests in federal office, which many seem to think, then it would seem to be a great and important power to grant lifetime tenure with good behavior to executive officers. And if that is a great and important power, it is likely that so too would be granting any property interest for a shorter term of years. The above discussion is not meant to resolve this issue definitively. But it does suggest that the key to unlocking the Constitution’s meaning as it relates to the Supreme Court’s most important removal power cases—from *Humphrey’s Executor* to *Seila Law*—is the Necessary and Proper Clause.

B. Juries

One prominent feature of the administrative state is the prevalence of administrative adjudications, the results of which appellate courts tend to review with highly deferential standards at least as to factfinding.¹⁹⁰ That has raised the question of whether in certain adjudications an Article III factfinder, or even a jury, is necessary. The Supreme Court recently supplied something of an answer in *SEC v. Jarkesy*,¹⁹¹ which involved a civil prosecution for fraud under various securities statutes that the agency brought before its own in-house tribunals.¹⁹² The

¹⁸⁶ 38 U.S. (13 Pet.) 230 (1839).

¹⁸⁷ *Id.* at 260.

¹⁸⁸ *Taylor v. Beckham*, 178 U.S. 548, 577 (1900).

¹⁸⁹ *Manners & Menand*, *supra* note 178, at 20. *But see* Shugerman, *supra* note 175, at 216 n.6 (“[B]eyond the Revolution and the Founding, the concept of offices as property continued into the First Congress and early republican America . . .”).

¹⁹⁰ *See* *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 497 (1951); *Crowell v. Benson*, 285 U.S. 22, 46 (1932). Courts used to defer on questions of law but apparently no longer will. *See* *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024).

¹⁹¹ 603 U.S. 109 (2024).

¹⁹² *Id.* at 115.

Court deployed a two-step analysis. First, if the remedy is analogous to one that would have been heard at common law, then a jury is typically required under the Seventh Amendment.¹⁹³ Second, the first rule does not apply to cases involving “public rights” in which no Article III court is required at all.¹⁹⁴ As a logical matter, the Court’s decision leaves something to be desired. It would seem to make more sense to reverse the order of the inquiries: First, is this a case that requires an Article III court? Second, if so, does it require a jury? Even if a case does not require a jury, that does not quite answer the question of what is a “private right” that an Article III court must adjudicate. In other words, it would seem that all cases that require juries require Article III courts,¹⁹⁵ but not all cases that require Article III courts require juries.

Whatever the merits of the decision, plausible arguments exist that an adjudication of that kind does not violate the Seventh Amendment or the Fifth Amendment.¹⁹⁶ And plausible arguments also exist that at least under the public rights doctrine as it historically developed, Congress can effectively choose what cases to bring in Article III courts.¹⁹⁷ But even if all that is true—even if the adjudication does not strictly speaking violate Article III or the Fifth and Seventh Amendments—it does not follow that Congress has power under the Necessary and Proper Clause to institute executive branch tribunals that take away core liberties or property.

This Section illustrates how such an analysis might operate under the Necessary and Proper Clause. In capsule form, the prerogative powers of the monarch in Great Britain included the power to erect courts, which were understood to be a component of the executive part of government.¹⁹⁸ That power, along with almost all the other royal prerogatives, were assigned in the Constitution instead to Congress.¹⁹⁹ That assignment was a central feature of the Framers’ design: Assigning such powers to Congress is why they felt confident in creating a

¹⁹³ See *id.* at 122–23; U.S. CONST. amend. VII (“In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved . . .”).

¹⁹⁴ *Jarkesy*, 603 U.S. at 127.

¹⁹⁵ The modern doctrine has some counterexamples, but the constitutionality of those examples has never been settled. See *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 64 (1989) (holding that a jury trial is required for fraudulent conveyance claims but not addressing the Article III question, thereby allowing the non-Article III Bankruptcy Court to empanel juries). *But see Stern v. Marshall*, 564 U.S. 462, 503 (2011) (holding that certain cases assigned to bankruptcy judges must be adjudicated in Article III courts).

¹⁹⁶ U.S. CONST. amend. V (“No person shall . . . be deprived of life, liberty, or property, without due process of law . . .”). Justice Gorsuch in his concurrence in *Jarkesy* argued that the in-house adjudication also violates this amendment. *Jarkesy*, 603 U.S. at 141 (Gorsuch, J., concurring).

¹⁹⁷ See *Jarkesy*, 603 U.S. at 174–78 (Sotomayor, J., dissenting).

¹⁹⁸ See *infra* note 235 and accompanying text.

¹⁹⁹ See *infra* notes 238–39 and accompanying text.

unitary executive.²⁰⁰ But the specification in Article I provides only that Congress may erect tribunals inferior to the Supreme Court—that is, within Article III.²⁰¹ It does not specify that Congress may erect executive branch courts to divest someone of liberty or property rights. The historical opposition to such courts in the revolutionary era further suggests that the power to erect them would have been a great and important power that would not have been left to implication.²⁰²

The rest of this Section summarizes the existing debates regarding jury trials and whether they are required by Article III, the Fifth Amendment, or the Seventh Amendment. It then makes the case that the Necessary and Proper Clause may play a role in the analysis.

1. *Article III and Amendments V and VII*

This Article takes no position on whether the in-house adjudication in *Jarkesy* violated the Seventh Amendment or the Fifth Amendment as an original matter; this Section shall explain why plausible arguments exist that neither was violated. Nor does the Article take a position on the Article III question, although it will explain why Article III was likely violated—which in turn might affect the Seventh Amendment question—under a proper and narrow understanding of the public rights doctrine. But that doctrine has expanded beyond its logical and structural limits, and if that expansion is accepted, then the doctrine could plausibly stand for the proposition that Congress can reassign certain cases involving liberty and property away from the Article III courts.

Beginning with the Seventh Amendment, that provision declares that “[i]n Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved.”²⁰³ The Supreme Court has interpreted the Amendment to apply to statutory causes of action analogous to those that would have been heard by common law courts.²⁰⁴ On the other hand, it has upheld statutes in which statutory causes of action arguably analogous to those at common law are assigned to executive agencies to adjudicate.²⁰⁵ There are two ways one could make sense of this distinction. The Supreme Court

²⁰⁰ See *infra* notes 230–33 and accompanying text.

²⁰¹ See *infra* notes 238–39 and accompanying text.

²⁰² See *infra* notes 240–41 and accompanying text.

²⁰³ U.S. CONST. amend. VII.

²⁰⁴ See *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 42 (1989) (“[T]he Seventh Amendment . . . applies to actions brought to enforce statutory rights that are analogous to common-law causes of action ordinarily decided in English law courts in the late 18th century, as opposed to those customarily heard by courts of equity or admiralty.”).

²⁰⁵ See, e.g., *Atlas Roofing Co. v. Occupational Safety & Health Rev. Comm’n*, 430 U.S. 442, 446, 449–50 (1977) (upholding the administrative adjudication of civil penalties for safety and health violations).

has tended to hold that the latter cases involved “public rights,”²⁰⁶ but as explained presently, that goes more to the question of whether an Article III court is required.²⁰⁷ The other way to maintain the distinction is to say that the jury trial right only applies to “suits” and that an executive branch adjudication is not such a “suit.” This approach, which the dissenters would have taken in *Jarkesy*, puts the Article III question logically prior to the Seventh Amendment issue.²⁰⁸

As a textual matter, the dissent’s argument is plausible. For example, as the dissent pointed out,²⁰⁹ Chief Justice Marshall described a suit as “the prosecution of some demand in a Court of justice”²¹⁰ and a “proceeding in a court of justice.”²¹¹ “The modes of proceeding may be various,” he noted, “but if a right is litigated between parties in a court of justice, the proceeding by which the decision of the court is sought, is a suit.”²¹² These definitions are, however, question-begging because an administrative court may or may not be considered a “court of justice.” These definitions simply do not answer the question. But it is certainly plausible to think that the jury trial right only attaches in a “suit,” and there is no suit if the case is not in a judicial as opposed to administrative court.

Justice Gorsuch, in concurrence, suggested that the Fifth Amendment also requires a real court and jury to determine whether *Jarkesy* violated the laws and the relevant penalties should be imposed.²¹³ Justice Gorsuch argued that “[a]s originally understood, this provision prohibited the government from ‘depriv[ing] a person of those rights without affording him the benefit of (at least) those customary procedures to which freemen were entitled by the old law of England.’”²¹⁴ That is certainly one possible interpretation of the amendment.²¹⁵ But it is also possible to conceive of due process in a narrower sense: Whatever legal process exists must be established by the legislative power in advance; it

²⁰⁶ See, e.g., *Granfinanciera*, 492 U.S. at 53.

²⁰⁷ See *supra* notes 193–95 and accompanying text.

²⁰⁸ *SEC v. Jarkesy*, 603 U.S. 109, 171 (2024) (Sotomayor, J., dissenting).

²⁰⁹ *Id.*

²¹⁰ *Cohens v. Virginia*, 19 U.S. (6 Wheat.) 264, 407 (1821).

²¹¹ *Weston v. City Council of Charleston*, 27 U.S. (2 Pet.) 449, 464 (1829).

²¹² *Id.*

²¹³ *Jarkesy*, 603 U.S. at 149–50 (Gorsuch, J., concurring).

²¹⁴ *Id.* (second alteration in original) (quoting *Sessions v. Dimaya*, 584 U.S. 148, 176 (2018) (Gorsuch, J., concurring in part and concurring in the judgment)).

²¹⁵ See also *Murray’s Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 277 (1855) (“We must examine the constitution itself, to see whether this process be in conflict with any of its provisions. If not found to be so, we must look to those settled usages and modes of proceeding existing in the common and statute [sic] law of England, before the emigration of our ancestors, and which are shown not to have been unsuited to their civil and political condition by having been acted on by them after the settlement of this country.”).

is not left to the courts, the king, or any other executive officer to make up novel processes.²¹⁶

As for Article III, it is difficult to see why *Jarkesy*'s case should not have been heard in a federal court. Article III provides that the judicial power of the United States, which is vested in the supreme and inferior courts, "shall extend to all Cases, in Law and Equity, arising under . . . the Laws of the United States."²¹⁷ *Jarkesy*'s case arose under the securities laws, which are "Laws of the United States."²¹⁸ To be sure, there are some cases that arise under the laws of the United States that historically could be adjudicated outside Article III courts. Tort claims against federal government officers are an example,²¹⁹ as are social security hearings.²²⁰ The narrow explanation for this "public rights" exception to Article III is sovereign immunity. In those examples, the plaintiff was seeking a money judgment from the government, which falls within the core of sovereign immunity.²²¹ The government's greater power to refuse consent to suit surely includes the lesser power to consent to suit in the Court of Claims or within the Social Security Administration's own tribunals.²²² The sovereign immunity rationale would not apply to a case such as *Jarkesy*'s in which the government was seeking to punish a private individual.²²³

Nevertheless, there are broader definitions of public rights that complicate the story. Public rights were also those that existed in the state of nature but which were shared in common, such as the right to use highways or navigable waters and the right to access natural resources.²²⁴ Under this broader definition, it is easy enough to conceive of a common market as a public right. That might explain why

²¹⁶ "Not only the substantial part, or judicial decisions, of the law, but also the formal part, or method of proceeding, cannot be altered but by parliament," Blackstone wrote. 1 BLACKSTONE, *supra* note 90, at *138. To be sure, in America there is a written Constitution superintending the legislative power. But that only means Congress cannot abolish processes established in the Constitution, such as the right to confrontation, the right to assistance of counsel, and so on. Under Blackstone's narrower conception, Congress might still be free to establish other process so long as it abides by the specific procedural amendments.

²¹⁷ U.S. CONST. art. III, § 2, cl. 1.

²¹⁸ *Jarkesy*, 603 U.S. at 115–16.

²¹⁹ See Floyd D. Shimomura, *The History of Claims Against the United States: The Evolution from a Legislative Toward a Judicial Model of Payment*, 45 LA. L. REV. 625, 637–53 (1985).

²²⁰ See, e.g., *Mathews v. Eldridge*, 424 U.S. 319, 323–35 (1976).

²²¹ See Ilan Wurman, *Nonexclusive Functions and Separation of Powers Law*, 107 MINN. L. REV. 735, 766 (2022).

²²² *Id.*; see also Caleb Nelson, *Adjudication in the Political Branches*, 107 COLUM. L. REV. 559, 582 (2007) ("[A]ccording to the traditional view, claims against the public treasury 'do not require judicial determination.'" (quoting *Ex parte Bakelite Corp.*, 279 U.S. 438, 451 (1929))).

²²³ *Jarkesy*, 603 U.S. at 115.

²²⁴ See, e.g., Ilan Wurman, *Reconstructing Reconstruction-Era Rights*, 109 VA. L. REV. 885, 921 (2023) (demonstrating that "[i]n the antebellum era, natural resources, including fisheries, were public rights").

licensing regimes may be public rights,²²⁵ but it would not explain why civil monetary penalties should be so considered. Still, the Supreme Court has sometimes treated civil monetary penalties as public rights cases when such penalties arise from an otherwise public right, such as foreign immigration.²²⁶ Thus, although some scholars have argued that such “mixed” cases are still private rights cases,²²⁷ one could just as easily say that such cases are better characterized as involving public rights. For present purposes, the point is only that although this Author is relatively certain that such cases belong in Article III courts, there are plausible arguments to the contrary.

2. *Text and History*

Even assuming the assignment of *Jarkesy*’s case to an administrative tribunal would not violate Article III, the Seventh Amendment, or the Fifth Amendment, it does not follow that such an assignment would be constitutional under the Necessary and Proper Clause. The argument would be that the power to deprive someone of liberty and property, as *Jarkesy* was deprived,²²⁸ is a great and important power that likely would not have been left to implication. There are both intratextual and historical reasons to think that is the case.

The intratextual argument depends on understanding some history, in particular the reason why the Framers enumerated powers and assigned most of them to Congress. It is not commonly known that the Committee of Detail appears to have enumerated Congress’s powers despite the Convention’s instruction not to do so, at least in part because the Committee sought to assign historically royal powers to Congress.²²⁹ The only way to do so would be to enumerate them. All the powers that Blackstone described as part of the royal prerogative are assigned somewhere in the Constitution or prohibited to the state or national governments.²³⁰ Most of them were assigned to Congress.²³¹

This assignment of powers was critical to the Framers’ strategy over executive power. In the Convention, there was a vigorous dispute over whether to have a single or plural executive. James Madison proposed to “fix the extent of the Executive authority” — to settle on the executive’s

²²⁵ See John Harrison, *Public Rights, Private Privileges, and Article III*, 54 GA. L. REV. 143, 196–99 (2019).

²²⁶ See *Oceanic Steam Navigation Co. v. Stranahan*, 214 U.S. 320, 329–30, 339–40 (1909).

²²⁷ Caleb Nelson, *Vested Rights, “Franchises,” and the Separation of Powers*, 169 U. PA. L. REV. 1429, 1437–38 (2021).

²²⁸ He was fined \$300,000 and prohibited from participating in the securities industry in the future. *Jarkesy*, 603 U.S. at 119.

²²⁹ See McCONNELL, *supra* note 19, at 67–68.

²³⁰ See 1 CROSSKEY, *supra* note 20, at 411–12.

²³¹ See *id.*; *supra* note 21 and accompanying text.

powers—before “determining how far” such powers “might be safely entrusted to a single officer.”²³² He moved and the Convention subsequently agreed that the executive have “power to carry into effect[] the national laws[]” and “to appoint to offices in cases not otherwise provided for.”²³³ When the Committee of Detail drafted the Constitution, they naturally added the power to direct the armed forces and some powers related to law execution, such as the pardon power and the right to demand opinions from principal officers.²³⁴ But what to do with all the other royal prerogatives? The Convention had decided on a unitary executive, but only because they had agreed that the extent of executive authority related only to law execution. The only way to effectuate that decision was to enumerate Congress’s power and to assign to Congress most of the royal prerogatives.

One of those powers was the power to erect courts. As Blackstone had written,

The original power of judicature, by the fundamental principles of society, is lodged in the society at large: but as it would be impracticable to render complete justice to every individual, by the people in their collective capacity, therefore every nation has committed that power to certain select magistrates, who with more ease and expedition can hear and determine complaints; and in England this authority has immemorially been exercised by the king or his substitutes.

He therefore has alone the right of erecting courts of judicature: for, though the constitution of the kingdom hath entrusted him with the whole executive power of the laws, it is impossible, as well as improper, that he should personally carry into execution this great and extensive trust: it is consequently necessary, that courts should be erected, to assist him in executing this power; and equally necessary, that, if erected, they should be erected by his authority. And hence it is, that all jurisdictions of courts are either mediately or immediately derived from the crown, their proceedings run generally in the king’s name, they pass under his seal, and are executed by his officers.²³⁵

²³² 1 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, *supra* note 18, at 66–67.

²³³ *Id.* at 67.

²³⁴ U.S. CONST. art. II, § 2, cls. 1–2; 2 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, *supra* note 18, at 185.

²³⁵ 1 BLACKSTONE, *supra* note 90, at *257 (paragraph break added).

There is little question that this prerogative is a great and important one. It is part of the king's capacity as "the fountain of justice and general conservator of the peace of the kingdom."²³⁶ It is the power that allows the government to imprison, to execute, and to deprive the citizen of vested rights. It is such an important power that various protections exist for the citizen even within the courts, such as the right to trial by jury.²³⁷

In the U.S. Constitution, this power is assigned to Congress. The Constitution establishes one supreme court and "such inferior Courts as the Congress may from time to time ordain and establish."²³⁸ This authority is then reiterated in Article I: "The Congress shall have Power . . . To constitute Tribunals inferior to the supreme Court."²³⁹ And within those courts, the parties are entitled to certain protections, such as those provided by the Fifth and Seventh Amendments.

All of this raises the question: If the power to erect courts was such an awesome power, so significant that Congress's authority was twice specified expressly, can the Necessary and Proper Clause possibly be interpreted to allow Congress to erect *other* courts within the executive branch, not "inferior" to the supreme court, and to which the Constitution's other protections do not apply? To ask the question is almost to answer it. It is highly improbable that such a power would have been left to implication after expressly specifying the power to erect tribunals inferior to the Supreme Court.

An intratextual analysis is a concrete way to establish the probability or improbability of certain powers being left to implication. Historical evidence can then buttress or militate against any such conclusion. Justice Gorsuch's concurrence in *Jarkesy* supplies significant historical support for the conclusion that creating juryless tribunals within the executive department was a central complaint of the American colonists, making it unlikely they would have left such a power to implication.²⁴⁰ The Continental Congress and the Declaration of Independence inveighed against such practices.²⁴¹ Those are reasonably concrete historical circumstances that make the grant of such a power by implication highly unlikely. To these examples Justice Gorsuch might have added the "Intolerable Acts," all of which led to the Boston Tea Party and from thence directly to the Revolution and two of which

²³⁶ *Id.*

²³⁷ U.S. CONST. amend. VII.

²³⁸ *Id.* art. III, § 1.

²³⁹ *Id.* art. I, § 8, cl. 9.

²⁴⁰ See *SEC v. Jarkesy*, 603 U.S. 109, 147–50 (2024) (Gorsuch, J., concurring).

²⁴¹ 1 JOURNALS OF THE CONTINENTAL CONGRESS 1774–1789, at 68–69 (Worthington Chauncey Ford ed., 1904); THE DECLARATION OF INDEPENDENCE paras. 11, 20 (U.S. 1776).

undermined the right to trial by jury and impartial courts.²⁴² This is not the place to rehearse this history in all its details. The history is highlighted to make the case that when concrete historical circumstances align with strong intratextual evidence, the argument against finding a power by implication is strong.

C. Appropriations

The final example is the funding structure of the Consumer Financial Protection Bureau (“CFPB”), which the Court upheld in *Consumer Financial Protection Bureau v. Community Financial Services Ass’n of America* (“CFPB”).²⁴³ Congress had provided that a proportion of Federal Reserve funds were to finance the functions and operations of the CFPB indefinitely.²⁴⁴ Unlike the usual appropriations process through which Congress decides on a regular basis how much to appropriate for an agency and can thereby hold the agency accountable, the statute in question provided that the CFPB was to decide itself how much money was reasonably necessary to carry out its functions.²⁴⁵ Congress did impose a cap, but it was relatively high—namely, twelve percent of the total Federal Reserve expenditures in 2009 adjusted for inflation.²⁴⁶

The case was entirely litigated under the Appropriations Clause of Article I, Section 9: “No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law”²⁴⁷ Not a single one of the parties’ briefs mentioned the Necessary and Proper Clause; and as a consequence, neither did any of the Supreme Court’s opinions.²⁴⁸ Yet properly understood, the Appropriations Clause has nothing to do with the case. When the Federal Reserve collects funds, those funds are part of the Treasury of the United States for constitutional purposes.²⁴⁹ Those funds are held in banks, just as the rest of the funds of the U.S. government are held in banks.²⁵⁰ And Congress established by law that

²⁴² For these and other acts that the colonists thought dangerous to the right to trial by jury, see SOURCES OF OUR LIBERTIES: DOCUMENTARY ORIGINS OF INDIVIDUAL LIBERTIES IN THE UNITED STATES CONSTITUTION AND BILL OF RIGHTS 281–83 (Richard L. Perry ed., rev. ed. 1978); AKHIL REED AMAR, THE WORDS THAT MADE US: AMERICA’S CONSTITUTIONAL CONVERSATION, 1760–1840, at 53–54, 62–63, 69, 83–84 (2021).

²⁴³ 601 U.S. 416, 421 (2024).

²⁴⁴ *Id.* at 422–23.

²⁴⁵ *See id.*

²⁴⁶ *See id.* at 421–23; 12 U.S.C. § 5497(a)(1)–(2).

²⁴⁷ U.S. CONST. art. I, § 9, cl. 7.

²⁴⁸ *See, e.g., CFPB*, 416 U.S. at 421 (considering only the “narrow question whether this funding mechanism complies with the Appropriations Clause”).

²⁴⁹ *Id.* at 425.

²⁵⁰ *See Cash and Debt Forecasting*, U.S. DEP’T OF THE TREASURY, <https://home.treasury.gov/policy-issues/financial-markets-financial-institutions-and-fiscal-service/cash-and-debt-forecasting> [https://perma.cc/2WT9-6DUY].

a specified portion of those funds shall go to finance the activities of this government agency.²⁵¹ Congress has quite literally complied with the terms of the Appropriations Clause, as the Supreme Court correctly concluded.²⁵²

It does not follow, however, that this unique funding structure would be constitutional under the Necessary and Proper Clause. This Article's tentative conclusion is that this funding structure can in fact be sustained after an implied powers analysis. But it is at least a closer question than that arising under the Appropriations Clause, and the history described by the dissenting Justices and by the Fifth Circuit becomes much more relevant under an analysis of the Necessary and Proper Clause.

1. *Early Examples of Necessary and Proper Laws*

As an initial matter, the Appropriations Clause is a limitation on power. It does not empower Congress to make appropriations.²⁵³ Neither does this case fall, strictly speaking, under a power to spend for the general welfare.²⁵⁴ Even if that clause authorizes spending, which is dubious from a textual perspective,²⁵⁵ it has long been understood to authorize spending on projects relatively well distributed throughout the nation—hence “general” welfare— or on the American people directly. Classic examples of spending for the general welfare include Henry Clay's “American system” of internal improvements,²⁵⁶ of which one modern manifestation is distributing funds to states for highway improvements;²⁵⁷ social security and other welfare payments directly to the American people;²⁵⁸ and spending on disaster relief.²⁵⁹ Even if the clause as interpreted today can be understood to authorize spending

²⁵¹ 12 U.S.C. § 5497(a)(1)–(2).

²⁵² *CFPB*, 601 U.S. at 435.

²⁵³ See U.S. CONST. art. I, § 9, cl. 7.

²⁵⁴ *Id.* art. I, § 8, cl. 1 (“The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States.”).

²⁵⁵ The clause most naturally reads as a power to lay taxes for certain purposes. That reading is confirmed by the final clause about uniformity, which modifies the entire preceding clause, but which only makes sense in the context of taxes. There is significant historical evidence for a taxing-only reading, but a complete analysis must await another day.

²⁵⁶ See 8 REG. DEB. 256–96 (1832).

²⁵⁷ See, e.g., *South Dakota v. Dole*, 483 U.S. 203, 207–09 (1987) (discussing Congress's distribution of highway funds in pursuit of the general welfare).

²⁵⁸ See, e.g., *Helvering v. Davis*, 301 U.S. 619, 641–45 (1937) (upholding the constitutionality of the Social Security Act).

²⁵⁹ See, e.g., *Disaster Assistance and the Supremacy Clause*, 5 Op. O.L.C. 198, 199 (1981) (“We harbor no doubt that it is within the constitutional competence of the Congress, by law, to make the funds, equipment, expertise, and personnel of the United States available to supplement the

on government agencies, for decades after the Founding many prominent figures presumed that the clause only empowered Congress to raise taxes.²⁶⁰ It was not until 1936 that the Supreme Court held that the clause also authorized spending beyond the specific enumeration of powers.²⁶¹

Yet appropriations occurred routinely, without any debate, for the entire history of the American Republic. The obvious reason is that such spending derives from the Necessary and Proper Clause.²⁶² The raising of money includes a series of great and important powers. The power to tax—which is “the power to destroy”²⁶³—is a great and important power that cannot be left to implication. That is why it is specifically enumerated. So is the power to borrow money,²⁶⁴ to sell public lands,²⁶⁵ to pillage,²⁶⁶ or to coin money.²⁶⁷ Once the necessary funds are available, however, and the objects of the national government enumerated, it would be incidental for Congress to spend the money that the national government has collected on the enumerated objects. It would make little sense to empower Congress to establish post offices and roads if it could not pay for a building or for mail carriers.

The best textual reading of the Constitution is that ordinary government appropriations derive from the Necessary and Proper Clause. The Clause therefore may limit this power just as it limits Congress more generally. Unlike in the examples of removal and juries, there is no intratextual evidence suggesting that the CFPB’s funding structure might be unconstitutional. If anything, the intratextual evidence suggests the opposite because the Constitution recognizes that Congress can enact appropriations valid for long periods of time.²⁶⁸

efforts of the several states in providing disaster assistance to save lives and protect property and the public health and safety.”).

²⁶⁰ See, e.g., THE FEDERALIST NO. 41, *supra* note 32, at 262–63 (James Madison); Jefferson, *supra* note 46, at 198–200.

²⁶¹ See *United States v. Butler*, 297 U.S. 1, 65–67 (1936) (holding that Congress can spend for the general welfare beyond the enumerated powers).

²⁶² Chad Squitieri recently elaborated on the argument that Congress’s power to appropriate funds comes from this clause. See generally Chad Squitieri, *The Appropriate Appropriations Inquiry*, 74 FLA. L. REV. F. 1 (2023) (arguing that Congress has appropriations powers only to the extent that such powers are necessary and proper to carry out its enumerated powers).

²⁶³ *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 431 (1819).

²⁶⁴ U.S. CONST. art. I, § 8, cl. 2 (“The Congress shall have Power . . . To borrow Money on the credit of the United States.”).

²⁶⁵ *Id.* art. IV, § 3, cl. 2 (“The Congress shall have Power to dispose of and make all needful Rules and Regulations respecting the Territory or other Property belonging to the United States . . .”).

²⁶⁶ *Id.* art. I, § 8, cl. 11 (“The Congress shall have Power . . . To declare War . . .”).

²⁶⁷ *Id.* art. I, § 8, cl. 5 (“The Congress shall have Power . . . To coin Money[and] regulate the Value thereof . . .”).

²⁶⁸ *Id.* art. I, § 8, cl. 12 (“The Congress shall have Power . . . To raise and support Armies, but no Appropriation of Money to that Use shall be for a longer Term than two Years.”).

Some scholars, led by Professor Christine Chabot, have argued that early historical examples of funding structures further support the CFPB's structure.²⁶⁹ Certainly such examples fall quite comfortably under the Necessary and Proper Clause. Congress in the Federalist era, rather than making specific appropriations, tended to make lump-sum appropriations for agencies—a practice that even the Jeffersonians eventually conceded was necessary.²⁷⁰ Some might think that such lump-sum appropriations violate the nondelegation doctrine,²⁷¹ but if appropriations are by definition “incidental” and not so important that they must be expressly enumerated, then it follows they are less significant for nondelegation purposes.²⁷²

Other examples include a success fee model whereby customs collectors, U.S. attorneys, and other officers would be funded for successful actions—for example, successful convictions.²⁷³ There was also a fee-for-service model whereby regulated entities or customers of the agency would pay for services.²⁷⁴ Hence ship captains would have to pay entry fees to the collectors.²⁷⁵ And the new patent board financed its activities entirely through the payment of fees by patentees.²⁷⁶ The Post Office funded much of its activities through postage.²⁷⁷ Both models fit comfortably under the Necessary and Proper Clause. A fee-for-success model encourages vigorous and faithful execution of the laws, which would then be necessary and proper for carrying into execution the President's powers and duties.²⁷⁸ Service fees are necessary and proper for carrying into execution Congress's own powers because surely Congress can require that the beneficiaries of its programs bear the costs of

²⁶⁹ See generally Christine Kexel Chabot, *The Founders' Purse*, 110 VA. L. REV. 1027 (2024) (presenting historical evidence to counter the claim that the Constitution places “duration, generality, and source” limits on Congress's appropriations powers).

²⁷⁰ See ABRAHAM D. SOFAER, WAR, FOREIGN AFFAIRS AND CONSTITUTIONAL POWER 170–71 (1976).

²⁷¹ See *Cnty. Fin. Servs. Ass'n of Am. v. Consumer Fin. Prot. Bureau*, 51 F.4th 616, 633 (5th Cir. 2022), *rev'd and remanded*, 601 U.S. 416 (2024) (noting that the plaintiffs made that argument but waived it by waiting too long to raise it).

²⁷² Cf. *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42–43 (1825) (noting that Congress cannot delegate authority over “important subjects”). This argument provides further support for Professor Michael Rappaport's conclusion that the nondelegation doctrine does not apply to appropriations. Michael B. Rappaport, *The Selective Nondelegation Doctrine and the Line Item Veto: A New Approach to the Nondelegation Doctrine and Its Implications for Clinton v. City of New York*, 76 TUL. L. REV. 265, 320–45 (2001).

²⁷³ See Chabot, *supra* note 269, at 1093–99.

²⁷⁴ See *id.* at 1088–90.

²⁷⁵ See Act of July 31, 1789, ch. 5, § 3, 1 Stat. 29, 36.

²⁷⁶ See Chabot, *supra* note 269, at 1099–1100; Patent Act of 1790, ch. 7, § 7, 1 Stat. 109, 112.

²⁷⁷ See Act of Feb. 20, 1792, ch. 7, § 9, 1 Stat. 232, 235.

²⁷⁸ See Zachary S. Price, *Enforcement Discretion and Executive Duty*, 67 VAND. L. REV. 671, 720 (2014) (noting that fee-based arrangements for prosecutors “encouraged maximum enforcement (at least of provable cases) rather than discretionary nonenforcement”).

them. Moreover, such fees would not be paid out of the Treasury, and so technically speaking they do not constitute appropriations. There is nothing particularly surprising about these examples.

Professor Chabot also points to the Sinking Fund Commission.²⁷⁹ Congress appropriated funds to the Commission to take certain actions with respect to the public debt with the ultimate goal of winding down the public debt.²⁸⁰ The Commission's actions could generate interest and add funds to the Treasury.²⁸¹ Congress authorized the Commission to use that interest to further pay down debt.²⁸² Allowing an agency to use interest generated on its activities to further its own activities, especially when those activities have a specific endpoint—the paying down of the debt²⁸³—seems necessary, proper, and incidental to Congress's power to pay the debts.

2. *History and the Power of the Purse*

The CFPB's funding structure did not, however, closely follow those earlier examples. No success fees encourage the CFPB to execute the laws vigorously and faithfully. The CFPB has no customers to pay for the services it provides. Nor does the CFPB itself generate any interest, nor does its regulatory program have any specific endpoint. The CFPB is instead funded indefinitely through another government agency and decides for itself how much funding it requires up to a cap.²⁸⁴ This structure was, therefore, novel. But as Justice Kagan once wrote, the Necessary and Proper Clause is not “a Rinse and Repeat Clause.”²⁸⁵ The question is whether funding the agency through this structure is a great and important power that cannot be left to implication.

Unlike in the cases of juries or offices as property, there is little specific historical evidence that would speak to this situation. And in the absence of intratextual evidence supporting the inference of a great and important power, the historical evidence would presumably have to be even more compelling than that provided in the prior two contexts.

Additionally, much of the historical evidence that does exist and that the dissent in *CFPB* highlighted suggests that the central concern

²⁷⁹ Chabot, *supra* note 269, at 1080–88.

²⁸⁰ *Id.* at 1080–82.

²⁸¹ *See id.*

²⁸² Act of Aug. 12, 1790, ch. 47, § 4, 1 Stat. 186, 187.

²⁸³ Professor Chabot, however, takes the broader view that the Sinking Fund Commission's role involved open market purchases and not necessarily outright redemption of debt. *See* Chabot, *supra* note 269, at 1082–86. She notes that the first two sinking fund acts contained no end dates. *Id.* at 1083–84. In any event, as noted below, it is unlikely that the CFPB funding structure is unconstitutional even if one does not look to the Sinking Fund Commission example.

²⁸⁴ *See supra* notes 243–46 and accompanying text.

²⁸⁵ *Seila L. LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 291 (2020) (Kagan, J., concurring in the judgment in part and dissenting in part).

was the ability of the Crown to raise money independently of Parliament. The problem of illegal ship money and forced loans, central to the leadup to the civil war of the mid-seventeenth century, was that the King sought to raise money on his own to finance his own policies.²⁸⁶ Thus, the Bill of Rights of 1689 declared that the “levying” of “Money for or to the Use of the Crowne by pretence of Prerogative without Grant of Parlyament for longer time or in other manner then the same is or shall be granted is Illegal.”²⁸⁷ The Appropriations Clause even originated in a draft dealing with both the raising and the spending of revenues.²⁸⁸ The two were tied together. Congress would only appropriate money that it had raised.

Having said that, the CFPB’s structure is not entirely unproblematic.²⁸⁹ Parliament did not want the King raising money to spend on his own purposes.²⁹⁰ A delegation from Parliament to the King to do that very thing would seem equally problematic, particularly if the King would have to assent to any future legislation to revoke that delegated authority. And there is at least a plausible account of the CFPB statute that allows it effectively to raise its own revenues. Namely, another independent agency—the Federal Reserve—raises money through the purchase and sale of securities and the fees it charges to depository institutions.²⁹¹ The latter agency’s source, if properly cabined by statute, is consistent with many early statutes.²⁹² But the former agency’s source of funds is effectively a grant of power to one part of the executive branch to raise money for another part of the executive branch. That is not quite like the Sinking Fund Commission, which used any profit to further wind down the public debt to zero, at which point the Commission’s work would be done.²⁹³ Nevertheless, the presence of a statutory cap greatly diminishes the strength of this argument.

To summarize, unlike early statutes, this funding scheme does not tie fees for the agency’s services, nor does it carry into execution the duty of faithful execution. And it may ensure additional independence

²⁸⁶ See *CFPB*, 601 U.S. 416, 454–56 (2024) (Alito, J., dissenting) (going over relevant historical episodes).

²⁸⁷ Bill of Rights, 1 W. & M. c. 2 (1689).

²⁸⁸ “All bills for raising or appropriating money . . . shall originate in the House of Representatives, and shall not be altered or amended by the Senate. No money shall be drawn from the public Treasury, but in pursuance of appropriations that shall originate in the House of Representatives.” 2 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, *supra* note 18, at 178.

²⁸⁹ For a recent paper suggesting that the CFPB statute was unconstitutional based on a combination of the Necessary and Proper Clause and the Commerce Clause, though not addressing the great powers argument, see generally Chad Squitieri, “Appropriate” Appropriations Challenges After Community Financial, 2024 CATO SUP. CT. REV. 73.

²⁹⁰ See *supra* notes 285–86 and accompanying text.

²⁹¹ See 12 U.S.C. §§ 243, 355.

²⁹² See *supra* notes 274–76 and accompanying text.

²⁹³ See *supra* notes 279–83 and accompanying text.

from Congress, but that is certainly not necessary for carrying into execution either Congress's powers or the President's powers. Nevertheless, courts grant Congress wide leeway in deciding what is necessary or convenient for executing the various powers assigned in the Constitution.²⁹⁴ Any law would still, however, have to be merely incidental and not a great and important power. The CFPB's funding scheme likely meets this criterion, but its novelty opens the door to claims that Congress has effectively exercised a great and important power. Such claims would likely require much more analysis and historical research to be convincing. But at least they would reflect the correct frame of analysis.

CONCLUSION

The Necessary and Proper Clause allows Congress to establish administrative agencies but also limits how it can do so. It authorizes Congress to exercise incidental powers necessary and proper for carrying into execution its own powers or those of the President; but Congress cannot thereby exercise any great or important power that one would not expect to have been left to implication. The Necessary and Proper Clause is therefore relevant to the Supreme Court's recent and contested separation of powers decisions relating to public administration, from its removal cases to those involving the Seventh Amendment and appropriations. And yet that clause has rarely been cited in the relevant cases and briefs. What is more, the Necessary and Proper Clause has the potential to discipline the Court's use of history and tradition. The several discussed examples, from sovereign immunity and eminent domain to removal and jury trials, involve intratextual evidence and specific and concrete historical understandings. Any invocation of an "implied powers" limit on congressional action could, and should, rely on both kinds of evidence.

²⁹⁴ See *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 421 (1819).

ESSAY

How Long Is Long Enough? Judicial Review of Agency Comment Periods

*Rachel Layne**

ABSTRACT

Federal agencies are granted discretion to shape their rulemaking procedures within the confines of the Administrative Procedure Act ("APA"). Although this flexibility is typically beneficial, it creates openings for agencies to use inadequate procedures that do not meaningfully engage the public, a fundamental purpose of the quasi-legislative rulemaking process. During the Biden Administration, the U.S. Securities and Exchange Commission ("SEC") proposed an unprecedented volume of major rules with short comment periods, raising questions about agency discretion to set comment periods and the scope of judicial review when a comment period is allegedly insufficient.

*This Note surveys approaches to judicial review of comment periods. First, it analyzes the restrictions on review of comment periods imposed by the Supreme Court's landmark decision *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, which limited courts' ability to impose additional rulemaking procedures beyond those mandated by the APA. Next, it assesses the standard of review and tests that courts use to review comment periods, including by examining a recent Sixth Circuit decision regarding comment period length of an SEC rule. Finally, it proposes factors for courts to consider when an agency is engaging in a flurry of rulemaking, including (1) interrelated rule proposals, (2) the significance of the rule, and (3) previous agency rulemaking activity.*

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INTRODUCTION

The Administrative Procedure Act (“APA”)¹ governs the federal administrative process.² Congress passed the APA in 1946 to establish procedural requirements for federal government agencies to follow when promulgating rules and adjudicating disputes.³ The APA provides transparency, uniformity, and notice requirements for administrative

¹ 5 U.S.C. §§ 551–559, 701–706.

² ROBERT L. GLICKSMAN & RICHARD E. LEVY, ADMINISTRATIVE LAW 53 (3d ed. 2020).

³ Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended at 5 U.S.C. §§ 551–559, 701–706); GLICKSMAN & LEVY, *supra* note 2, at 53–55.

lawmaking.⁴ It has been described as a “framework” statute because it “sets out structural guidelines for governance and procedural guideposts” for agencies to follow.⁵ However, the statute’s minimal requirements for notice-and-comment rulemaking—the process agencies use to create binding regulations by soliciting public input⁶—give agencies discretion to adapt the required procedures as needed to achieve their goals.⁷ When allegations arise that an agency used inadequate procedures, regulated parties can challenge the procedures in court.⁸

During the Biden Administration, the U.S. Securities and Exchange Commission (“SEC”) proposed a large volume of economically significant rules with short comment periods.⁹ The financial industry argued that this increase in the volume and pace of rulemaking diminished its ability to research, analyze, and sufficiently comment on proposed rules, undermining the notice-and-comment process’s fundamental purpose of soliciting meaningful public feedback.¹⁰ Two lawsuits challenging an SEC rule alleged that the rule’s short comment period violated the APA by failing to meet the minimum standards established by the statute.¹¹ Although the Fifth Circuit did not address the issue,¹² both district

⁴ William N. Eskridge Jr. & John Ferejohn, *The APA as a Super-Statute: Deep Compromise and Judicial Review of Notice-and-Comment Rulemaking*, 98 NOTRE DAME L. REV. 1893, 1923–27 (2023).

⁵ *Id.* at 1926; *see also* Antonin Scalia, Vermont Yankee: *The APA, the D.C. Circuit, and the Supreme Court*, 1978 SUP. CT. REV. 345, 363 (“[T]he Supreme Court regarded the APA as a sort of superstatute, or subconstitution, in the field of administrative process: a basic framework that was not lightly to be supplanted or embellished”); Kathryn E. Kovacs, *Superstatute Theory and Administrative Common Law*, 90 IND. L.J. 1207, 1223–37 (2015) (characterizing the APA as a “superstatute”).

⁶ *See* GLICKSMAN & LEVY, *supra* note 2, at 417–22.

⁷ *See* CHARLES H. KOCH, JR. & RICHARD MURPHY, ADMINISTRATIVE LAW AND PRACTICE § 4:30, Westlaw (database updated Mar. 2024).

⁸ *See* 5 U.S.C. § 702 (“A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.”).

⁹ *See* Stefania Palma, *Finance Hits Back Against US Regulator’s Rulemaking Spree*, FIN. TIMES (Sept. 11, 2023), <https://www.ft.com/content/3d12a3c7-32af-4164-ae6a-6526000c7336> [<https://perma.cc/3UXE-MRT5>]. A comment period is the opportunity that an agency engaged in notice-and-comment rulemaking must provide to the public to submit written feedback on the agency’s proposed rule. *See* GLICKSMAN & LEVY, *supra* note 2, at 56–60.

¹⁰ *See* Kenneth E. Bentsen, Jr., *The Unprecedented Speed and Volume of SEC Rulemaking*, SIFMA (Sept. 21, 2023), <https://www.sifma.org/resources/news/the-unprecedented-speed-and-volume-of-sec-rulemaking/> [<https://perma.cc/B7N3-65XA>]; Jennifer J. Schulp & Nicholas Anthony, *The SEC Short-Changes Public Comment*, CATO INST.: CATO AT LIBERTY (Jan. 14, 2022, 9:39 AM), <https://www.cato.org/blog/sec-short-changes-public-comment> [<https://perma.cc/93FK-4GBX>].

¹¹ *See* Nat’l Ass’n of Mfrs. v. SEC, 644 F. Supp. 3d 342, 346 (W.D. Tex. 2022), *rev’d on other grounds*, 105 F.4th 802 (5th Cir. 2024); Chamber of Com. of the U.S. v. SEC, 670 F. Supp. 3d 537, 550 (M.D. Tenn. 2023), *aff’d*, 115 F.4th 740 (6th Cir. 2024).

¹² *See* Nat’l Ass’n of Mfrs., 105 F.4th at 810 n.4.

courts and the Sixth Circuit examined the rule's comment period, each with varying approaches and results.¹³

This Note surveys the varying approaches to judicial review of comment periods and examines whether and how review of comment periods should occur.¹⁴ It argues that judicial review of comment periods is permissible,¹⁵ and at times favorable, particularly when agencies attempt to enact sweeping regulatory overhauls.¹⁶

Agencies act in a quasi-legislative manner by creating regulatory regimes that shape the behavior and activities of the public.¹⁷ In the U.S. democratic system, this large grant of power obligates agencies to meaningfully engage the public.¹⁸ During the Biden Administration, the SEC diminished the significance of public feedback in the rulemaking process when it proposed a high volume of complex rules with short comment periods.¹⁹ When an agency proposes rules in this manner and faces subsequent challenges to such rules, the reviewing court should give special consideration to these circumstances.

Part I explains why public comment matters in the context of agency rulemaking and examines the SEC's rulemaking activity during the Biden Administration.²⁰ Part II addresses the threshold question of whether the Supreme Court's *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*²¹ decision permits courts to

¹³ See *infra* Sections I.A, II.C.

¹⁴ See *infra* Part II.

¹⁵ See *infra* Section II.A.

¹⁶ See *infra* Part III.

¹⁷ GLICKSMAN & LEVY, *supra* note 2, at 110–11.

¹⁸ SEC Commissioner Hester Peirce has reflected this sentiment on various occasions. See, e.g., Hester M. Peirce, *Rat Farms and Rule Comments—Statement on Comment Period Lengths*, SEC (Dec. 10, 2021), <https://www.sec.gov/news/statement/peirce-rat-farms-and-rule-comments-121021> [<https://perma.cc/B3H5-9J9R>] (“The notice and comment process is intended to be a dialogue. The regulatory conversation flows only when the Commission affords the commenting public sufficient time both to review and analyze proposals thoroughly and to formulate fully articulated opinions and suggestions.”); Hester M. Peirce, *Rip Current Rulemakings: Statement on the Regulatory Flexibility Agenda*, SEC (June 22, 2022) [hereinafter *Rip Current Rulemakings*], <https://www.sec.gov/newsroom/speeches-statements/peirce-statement-regulatory-flexibility-agenda-062222> [<https://perma.cc/ACS3-HXE6>] (“We can avoid creating regulatory rip currents by recalibrating our agenda to focus on issues core to the protection of investors and operation of our markets and by slowing down the pace to ensure that we and the public can think about what we are doing.”); Hester M. Peirce, Comm’r, Sec. & Exch. Comm’n, *At the SEC: Nothing but Crickets Remarks at SEC Speaks* (Apr. 2, 2024) [hereinafter *Crickets*], <https://www.sec.gov/news/speech/peirce-remarks-sec-speaks-040224> [<https://perma.cc/46K6-C5PH>] (“The Commission should think about each rule proposal as an opportunity to foster a public discussion with the goal of developing the best solution to a carefully identified problem . . .”).

¹⁹ See *Rip Current Rulemakings*, *supra* note 18 (“We have abandoned our careful and considered approach to altering regulation in favor of effecting hasty and sweeping change.”).

²⁰ This Note uses the SEC as a case study to explore agency comment periods, but it does not comment on the merits of the SEC's proposals.

²¹ 435 U.S. 519 (1978).

review comment periods. It also surveys the standard of review and tests that courts use when reviewing comment periods. Part III proposes three factors that a court should consider when reviewing a comment period set by an agency engaged in a flurry of rulemaking:²² (1) whether the rule is closely related to other rules being proposed, (2) the relative significance of the rule, and (3) the volume of recent rulemaking compared to previous agency rulemaking activity.

I. THE SIGNIFICANCE OF PUBLIC COMMENT

A. *The APA's Public Comment Requirement*

Congress tasks federal agencies with executing legislative policy choices through regulation.²³ Agencies fulfill this task in part by rulemaking, in which agencies promulgate rules that carry the force of law and regulate conduct.²⁴ The APA governs the federal rulemaking process.²⁵ APA section 553 is the core provision for notice-and-comment rulemaking, a commonly used form of rulemaking that is binding but does not require formal, trial-like procedures.²⁶ The basic procedures required by section 553 are notice, an opportunity for public comment, and a concise statement of the agency's basis and purpose for the rule.²⁷

Notably, section 553(c) does not specify the length of the comment period, only requiring "an opportunity to participate in the rule making through submission of written data, views, or arguments"²⁸ Because agencies are not bound to a minimum comment period, they are expected to allow a "reasonable" time for comment, with "'reasonableness' judged in relation to the particular facts of each rulemaking."²⁹ Generally, more complex rules will require longer comment periods.³⁰

²² No numeric threshold constitutes a flurry of rules. This term intends to refer to situations in which an agency significantly increases its pace of rulemaking compared to its historic rulemaking activity and in a manner that is likely to elicit criticism from public commenters.

²³ See GLICKSMAN & LEVY, *supra* note 2, at 5.

²⁴ *Id.* at 361.

²⁵ *Id.* at 53.

²⁶ *Id.* at 417–23.

²⁷ *Id.* Section 553(b) requires agencies to publish notice of the rulemaking in the *Federal Register* with information about the "time, place, and nature of public rule making proceedings; . . . the legal authority under which the rule is proposed; and . . . a description of the" proposed rule's substance. 5 U.S.C. § 553(b). Section 553(c) requires agencies to provide an opportunity for public comment and "incorporate in the rules adopted a concise general statement of their basis and purpose." *Id.* § 553(c). Section 553(d) requires the publication of a final rule no fewer than thirty days before it goes into effect. *Id.* § 553(d).

²⁸ 5 U.S.C. § 553(c).

²⁹ JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 307 (6th ed. 2018).

³⁰ KOCH & MURPHY, *supra* note 7, § 4:33.

Although agencies have discretion over comment period length,³¹ the executive branch has provided some guidance.³² The Clinton and Obama Administrations issued executive orders that specified sixty days as the typical minimum comment period necessary to “afford the public a meaningful opportunity to comment” on proposed rules,³³ although this is not a legal requirement.³⁴ In addition, the Administrative Conference of the United States (“ACUS”)³⁵ advised in 1994 that Congress amend the APA to require a thirty-day mandatory minimum comment period with a good cause exception for shorter periods.³⁶ The thirty-day standard is not codified, but the Supreme Court has recognized it as a baseline minimum comment period.³⁷ Separately, many federal agencies require at least thirty- or sixty-day comment periods while recognizing that more time is often necessary for technical and complex rules.³⁸

Although thirty to sixty days is the norm, the APA’s statutory silence on comment period length gives agencies discretion to adjust comment periods depending on the complexity of a rule and the

³¹ The lack of a mandatory comment period length in section 553 characterizes this discretion. *See* 5 U.S.C. § 553(c).

³² *See, e.g.*, Exec. Order No. 12,866 § 6(a), 3 C.F.R. 638, 644–45 (1994); Exec. Order No. 13,563 § 2, 3 C.F.R. 215, 216 (2012); Exec. Order No. 14,094 § 2, 3 C.F.R. 369, 369–70 (2024).

³³ Exec. Order No. 12,866 § 6(a), 3 C.F.R. at 644; Exec. Order No. 13,563 § 2, 3 C.F.R. at 216. Additionally, the Biden Administration issued an executive order requiring that “opportunities for public participation . . . be designed to promote equitable and meaningful participation by a range of interested or affected parties, including underserved communities.” Exec. Order No. 14,094 § 2(a), 3 C.F.R. at 369–70.

³⁴ *Centro Legal de la Raza v. Exec. Off. for Immigr. Rev.*, 524 F. Supp. 3d 919, 936 (N.D. Cal. 2021).

³⁵ ACUS is an independent agency charged with recommending improvements to the efficiency and fairness of the rulemaking process. *See About ACUS*, ADMIN. CONF. OF THE U.S., <https://www.acus.gov/about-acus> [<https://perma.cc/Y7L3-Z22U>].

³⁶ Adoption of Recommendations and Statement Regarding Administrative Practice and Procedure, 59 Fed. Reg. 4669, 4672–74 (Feb. 1, 1994). ACUS did not define “good cause” in this context, but the APA contains a “good cause” exception that permits an agency to bypass notice-and-comment rulemaking when it finds “that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B).

³⁷ *See Azar v. Allina Health Servs.*, 587 U.S. 566, 570 (2019) (describing “the APA minimum [comment period] of 30 days”).

³⁸ *See, e.g., Rulemaking Process*, FED. COMM’NS COMM’N, <https://www.fcc.gov/about-fcc/rulemaking-process> [<https://perma.cc/6KXL-4CR6>] (describing thirty days as the minimum comment period but allowing for “much longer periods” for “highly technical and complex matters” or “shorter periods where there is a need to act quickly”); *Rulemaking Process*, U.S. DEP’T OF TRANSP. (Mar. 25, 2025), <https://www.transportation.gov/regulations/rulemaking-process> [<https://perma.cc/39ZR-7XLC>] (providing for sixty days “[g]enerally” but providing “much longer periods” if necessary or “shorter periods where we can provide justification for them”); *A Guide to the Rulemaking Process*, OFF. OF THE FED. REG., <https://uploads.federalregister.gov/uploads/2013/09/The-Rulemaking-Process.pdf> [<https://perma.cc/Z3EN-ENFC>] (stating that thirty to sixty days is typical but “180 days or more” may be provided for “complex rulemakings” and shorter periods may be permissible “when that can be justified”).

agency's timeframe to act.³⁹ The APA's legislative history states that the APA's procedures are minimum requirements and that "[m]atters of great import . . . should naturally be accorded more elaborate public procedures."⁴⁰ The length of a comment period can affect the level of transparency and public involvement in the rulemaking process.⁴¹

B. *Why Comment Periods Matter*

Courts have stated that the purpose of notice-and-comment procedures is to provide for "meaningful" public participation in the rulemaking process.⁴² The APA's requirement that agencies publish rules for public comment intends to benefit both the agencies promulgating rules and regulated entities.⁴³ On one hand, agencies benefit because they receive feedback from diverse parties that will be affected by the proposed rule.⁴⁴ Public comments can help the agency understand public opinion, potential compliance challenges, and whether or how to revise the rule before final publication.⁴⁵ On the other hand, regulated entities and members of the public benefit from the notice-and-comment process because it allows them to voice suggestions and concerns about a proposed rule before it is enacted, with the hope that the agency will modify the rule.⁴⁶ In addition, comments enter the administrative record, which serves as a court's focal point for review in the event of a future legal challenge.⁴⁷ Although more participation does not necessarily equate to better rulemaking—special interests may be overrepresented and increased participation can slow the process⁴⁸—public input is typically considered beneficial.⁴⁹

Meaningful public participation requires a sufficiently long comment period because many notices of proposed rulemaking contain

³⁹ See STEVEN J. BALLA, PUBLIC COMMENTING ON FEDERAL AGENCY REGULATIONS: RESEARCH ON CURRENT PRACTICES AND RECOMMENDATIONS TO THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES 3–4 (Mar. 15, 2011), <https://www.acus.gov/sites/default/files/COR-Balla-Report-Circulated.pdf> [<https://perma.cc/V825-DWLY>].

⁴⁰ H.R. REP. NO. 79-1980, at 259 (1946).

⁴¹ See BALLA, *supra* note 39, at 3.

⁴² See, e.g., *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1404 (9th Cir. 1995); *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011); *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009).

⁴³ See Eskridge & Ferejohn, *supra* note 4, at 1922.

⁴⁴ See *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005); *Prometheus Radio Project*, 652 F.3d at 449.

⁴⁵ See KOCH & MURPHY, *supra* note 7, § 4:33 (explaining that agency staff aim to create "the best possible rule" by obtaining the best information and a variety of perspectives).

⁴⁶ See *id.* (explaining that interested parties participate in the rulemaking process to "provide the agency decisionmakers with information and assure that they consider it").

⁴⁷ See GLICKSMAN & LEVY, *supra* note 2, at 195–99.

⁴⁸ See KOCH & MURPHY, *supra* note 7, § 4:33.

⁴⁹ See *id.* ("In general anything that expands participation is valued.").

highly sophisticated information, which frequently demands significant time and effort from stakeholders to prepare informed comments.⁵⁰ A comment period that is too short, therefore, may compromise public participation and limit the quality of public feedback that an agency receives.⁵¹ It also may preclude an agency from considering potential unintended consequences of the rule that the public may have raised had it been given more time to analyze the proposal.⁵² If an agency proposes several significant rules with short comment periods, smaller entities and individuals without the resources to submit comments and share their views are likely to be disproportionately impacted.⁵³

Additionally, an insufficient comment period may create the perception that an agency has already decided the final form of the rule, making the comment process a formality with little actual impact.⁵⁴ This behavior goes against the spirit of the APA's notice-and-comment procedures and the broader notion that government should be both participatory and collaborative.⁵⁵ Now more than ever, as the Supreme Court has pared back agency power,⁵⁶ agencies should provide comment periods that are proportional to a rule's complexity and their cumulative rulemaking activity to minimize further political and legal scrutiny.

C. *The SEC's Rise in Rulemaking Activity and Short Comment Periods*

The SEC is the federal agency responsible for enforcing the federal securities laws.⁵⁷ Its regulatory remit derives from a series of statutes⁵⁸

⁵⁰ See BALLA, *supra* note 39, at 3.

⁵¹ See *Crickets*, *supra* note 18.

⁵² See Schulp & Anthony, *supra* note 10.

⁵³ See *id.*; *Rip Current Rulemakings*, *supra* note 18 (“I also have concerns that the volume of comment requests will give even greater weight to the views of bigger players and mute the voices of retail investors, smaller advisers, broker-dealers, mutual funds, and companies, which lack the resources necessary to give each of these proposals the attention they deserve.”).

⁵⁴ See Letter from Alt. Credit Council et al. to Gary Gensler, Chair, SEC 6, 14 (Apr. 5, 2022) [hereinafter *Joint Comment Letter*], https://www.sifma.org/wp-content/uploads/2022/02/SEC_Joint-Trades_Comment-Period-Letter_4-5-2022.pdf [https://perma.cc/C4AS-6D2C] (joint comment letter from twenty-five industry associations to the SEC).

⁵⁵ See Memorandum on Transparency and Open Government, 2009 DAILY COMP. PRES. DOC. 10 (Jan. 21, 2009) (memorandum from President Obama on the importance of government transparency).

⁵⁶ See, e.g., *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024) (overruling *Chevron* deference); *SEC v. Jarkesy*, 603 U.S. 109, 120–21 (2024) (limiting the scope of agency in-house adjudicatory proceedings for claims with roots in common law).

⁵⁷ *Mission*, SEC (Aug. 9, 2023), <https://www.sec.gov/about/mission> [https://perma.cc/EP5L-Z9G4].

⁵⁸ See *The Laws that Govern the Securities Industry*, INVESTOR.GOV, <https://www.investor.gov/introduction-investing/investing-basics/role-sec/laws-govern-securities-industry> [https://perma.cc/9ZNU-UYSS].

that give the SEC “broad regulatory authority over significant parts of the securities industry.”⁵⁹ During the first half of the Biden Administration, the SEC dramatically increased the pace and volume of rulemaking activity compared to previous administrations.⁶⁰ The SEC proposed fifty-two new rules during Chair Gary Gensler’s first two and a half years in office, many more than Obama Administration Chair Mary Jo White and Trump Administration Chair Jay Clayton, who proposed twenty-eight and thirty-five rules, respectively.⁶¹ The average comment period of proposed rules under Gensler’s first three years was forty-seven days—measured from the date of publication in the *Federal Register*—which is nearly twenty percent fewer days than previous chairs’ durations.⁶²

The quick pace and high volume of the SEC’s rulemaking is not inherently problematic. But as the new rulemaking trends became apparent, financial industry groups began to argue that shorter comment periods diminished their ability to provide meaningful comments and could result in economic harm.⁶³ These industry groups raised the concern that the sheer volume and complexity of rule proposals over a short time span prevented them from adequately analyzing how the proposals would impact their businesses, retail investors, and the economy.⁶⁴ These arguments were coming from large, well-resourced industry groups—like the Securities Industry and Financial Markets Association (“SIFMA”)—that typically have the means to provide extensive comments in response to agency rulemakings.⁶⁵ Their concern indicates that

⁵⁹ EVA SU, CONG. RSCH. SERV., IF11714, INTRODUCTION TO FINANCIAL SERVICES: THE SECURITIES AND EXCHANGE COMMISSION (SEC) (2023).

⁶⁰ See Bentsen, *supra* note 10.

⁶¹ See *SEC Rulemaking Tracker*, SIFMA (Jan. 20, 2025), <https://www.sifma.org/resources/general/sec-rulemaking-tracker/> [<https://perma.cc/NZ3Y-AT9N>] (choose “SEC Rulemaking Tracker (xls)” from the main page; then open the downloaded spreadsheet; then click the tab titled “7. Proposals Comparison”). The first Obama Administration Chair Mary Schapiro issued and finalized more rules than Gensler in roughly three years—sixty-six proposed and final rules in total—but her tenure occurred during the tumultuous 2007–2008 financial crisis, the resulting Great Recession, and the passage of statutorily mandated financial reforms. See *SEC Overreach: Examining the Need for Reform: Hearing Before the Subcomm. on Cap. Mkts. of the H. Comm. on Fin. Servs.*, 118th Cong. 66–68 (2024) [hereinafter *SEC Overreach Hearing*] (statement of John A. Gulliver, Executive Director, Committee on Capital Markets Regulation).

⁶² See *SEC Rulemaking Tracker*, *supra* note 61 (click the tab titled “6. Comment Period Comparison”).

⁶³ See Eric J. Pan, *The SEC’s Multi-Rule Pileup*, INV. CO. INST. (Oct. 3, 2023), <https://www.ici.org/viewpoints/23-view-sec-multi-rule> [<https://perma.cc/UZ34-JVLL>].

⁶⁴ See *id.*; Kirsten Wegner, *When a Regulatory Last Resort Becomes the Only Resort for Market Participants*, TRADERS MAG. (Sept. 26, 2023), <https://www.tradersmagazine.com/am/when-a-regulatory-last-resort-becomes-the-only-resort-for-market-participants/> [<https://perma.cc/BG8T-JE8S>].

⁶⁵ See, e.g., *Joint Comment Letter*, *supra* note 54; see also *About*, SIFMA <https://www.sifma.org/about/> [<https://perma.cc/4G5Y-ESG6>] (“SIFMA’s broker-dealer members comprise nearly 90% of U.S. market share by revenues and 80% of financial advisors managing \$13 trillion of client assets.”).

individual companies and other less resourced commenters likely faced an even tighter strain to provide comments.⁶⁶

The financial industry also argued that the SEC's rulemaking practices could lead to conflicting and poorly drafted rules.⁶⁷ This argument stemmed from the belief that the SEC was not considering the complicated, interrelated nature of their multiple significant rule proposals, each with a different comment period that often did not overlap with the others.⁶⁸ As a result, commenters could not assess proposals in parallel to understand their aggregate impact.⁶⁹ Some industry participants argued that the SEC was prioritizing its policy agenda over adopting well-reasoned rules because the agency was significantly underestimating the implementation and compliance costs for new rules.⁷⁰ Separately, the SEC's rulemaking activity led the financial industry to bring lawsuits arguing that the SEC promulgated the rules in violation of the APA or in excess of the agency's statutory authority,⁷¹ exposing the SEC to increased litigation risk.⁷²

In response to these concerns, Congress urged the SEC to heed caution in its pace of rulemaking.⁷³ A bipartisan group from the House of Representatives warned Chair Gensler that the "abbreviated [comment] period" the SEC had allotted for a significant proposed rule "[would] likely hinder engagement from Congress, investors, and other market

⁶⁶ See *Crickets*, *supra* note 18 (discussing how small- and medium-sized advisers expressed to Commissioner Peirce that "dealing with existing rules and implementing new ones precludes spending the time to read, let alone comment on, proposed rules").

⁶⁷ See *id.*; COMM. ON CAP. MKTS. REGUL., THE UNPRECEDENTED PACE OF SEC PROPOSED AND FINAL RULEMAKINGS CONTINUES 3 (2023), <https://capmktsreg.org/wp-content/uploads/2024/03/CCMR-Statement-on-SEC-Agenda-Mapping-08.31.2023.pdf> [<https://perma.cc/W8YN-VH7Y>].

⁶⁸ Kenneth E. Bentsen, Jr., *America's Capital Markets Are Too Important to Be Put at Risk*, SIFMA (Nov. 3, 2023), <https://www.sifma.org/resources/news/americas-capital-markets-are-too-important-to-be-put-at-risk/> [<https://perma.cc/96VM-CVZN>].

⁶⁹ See Pan, *supra* note 63.

⁷⁰ See *id.*; Wegner, *supra* note 64 (describing comment letters as a "facade" in the SEC's current rulemaking environment).

⁷¹ See Michelle Price & Carolina Mandl, *Wall Street Heads to Court to Fend Off Biden's Regulators*, REUTERS (Nov. 21, 2023, 6:41 AM), <https://www.reuters.com/markets/us/wall-street-heads-court-fend-off-bidens-regulators-2023-11-21> [<https://perma.cc/XB86-4E5J>]; Bob Pisani, *Gensler Is Testifying Before Congress and Facing Increasing Lawsuits over His Many Rule Changes*, CNBC (Sept. 27, 2023, 10:10 AM), <https://www.cnbc.com/2023/09/27/sec-chair-gensler-facing-increasing-lawsuits-over-his-rule-changes.html> [<https://perma.cc/9BMX-TU9Y>].

⁷² See OFF. OF INSPECTOR GEN., SEC, THE INSPECTOR GENERAL'S STATEMENT ON THE SEC'S MANAGEMENT AND PERFORMANCE CHALLENGES 3 (2022).

⁷³ See, e.g., Matthew Goldstein, *Senate Republicans Grill S.E.C. Chair on Pace of Rule Making*, N.Y. TIMES (Sept. 12, 2023), <https://www.nytimes.com/2023/09/12/business/sec-gary-gensler-senate-hearing.html> [<https://perma.cc/QZ7V-BLK5>]; *Examining the SEC's Agenda: Unintended Consequences for U.S. Capital Markets and Investors: Hearing Before the Subcomm. on Cap. Mkts. of the H. Comm. on Fin. Servs.*, 118th Cong. 2 (2023) (statement of Rep. Ann Wagner, Chairwoman, Subcomm. on Cap. Mkts.); *SEC Overreach Hearing*, *supra* note 61, at 34 (statement of Rep. Mike Lawler, Member, Subcomm. on Cap. Mkts.).

participants.”⁷⁴ A dozen Democratic senators reportedly sent a letter to Chair Gensler privately urging the SEC to provide sufficient comment periods so that “there is adequate time to evaluate each individual rule as well as how those rules interact with existing and other proposed rules.”⁷⁵ In May 2024, a member of the House Financial Services Committee introduced legislation that would set mandatory minimum comment periods of sixty days for all SEC rulemakings.⁷⁶ Separately, the SEC’s Office of Inspector General, an independent office that audits the SEC’s operations, reported that SEC staff members “raised concerns about increased risks and difficulties managing resources.”⁷⁷ The concerns stemmed from the surge in rulemaking, an increase in attrition, less feedback from the public because of shortened comment periods, less time for research and analysis, and increased litigation risk.⁷⁸

II. CURRENT APPROACHES TO REVIEW OF COMMENT PERIODS

The SEC’s rulemaking activity raises questions about how a court should review an allegedly deficient comment period. In answering this question, it is necessary to consider whether a court can review a comment period, the level of deference it should grant the agency if it does so, and the test it should employ.

A. *Threshold Question: Is Review Permissible Under Vermont Yankee?*

The Supreme Court’s 1978 *Vermont Yankee* decision significantly constrained courts’ ability to impose procedural requirements above the minimum notice-and-comment procedures required by section 553 of the APA.⁷⁹ Little scholarly work addresses whether review of comment periods is permissible under *Vermont Yankee*, but some argue that a judicially imposed minimum comment period violates the decision by imposing additional procedures beyond the APA’s requirements.⁸⁰

⁷⁴ Letter from Bill Foster et al., Reps., United States House of Reps., to Gary Gensler, Chair, SEC 2 (Apr. 13, 2022), <https://www.sec.gov/comments/s7-03-22/s70322-20127548-288697.pdf> [<https://perma.cc/MX3Y-SW5Z>].

⁷⁵ Declan Harty, *Senate Dems Press SEC Chair to Slow Wall Street Rules*, POLITICO (Oct. 20, 2022, 4:12 PM), <https://www.politico.com/news/2022/10/20/senate-democrats-gensler-public-comments-sec-00062732> [<https://perma.cc/R52B-DQ3P>].

⁷⁶ H.R. 8255, 118th Cong. (2024).

⁷⁷ OFF. OF INSPECTOR GEN., *supra* note 72, at 3.

⁷⁸ *Id.*

⁷⁹ See GLICKSMAN & LEVY, *supra* note 2, at 424–25.

⁸⁰ See, e.g., Kadie Martin, Comment, *So Much to Comment on, So Little Time: Notice-and-Comment Requirements in Agency Informal Rulemaking Under the Administrative Procedure Act*, 61 B.C. L. REV. (E. SUPP.) II.-132, II.-151–52 (2020).

Although *Vermont Yankee* limited judicial imposition of additional procedures, it did not prohibit courts from interpreting the APA.⁸¹ Judicial review of comment periods is permissible because it is an interpretation of the APA that falls within the widely accepted category of judge-made “administrative common law.”⁸²

1. *Vermont Yankee’s Constraints on Procedure*

Prior to *Vermont Yankee*, several courts, including most prominently the U.S. Court of Appeals for the D.C. Circuit, imposed additional procedures for notice-and-comment rulemaking that were not mandated by the APA or other statutes.⁸³ Courts imposed these requirements—for example, cross-examination or highly detailed notices of proposed rulemaking—in response to perceived inadequacies in the APA’s notice-and-comment requirements and fears that agencies were serving the interests of industry groups.⁸⁴

In *Vermont Yankee*, the Supreme Court significantly constrained the ability of courts to impose procedures beyond the minimum requirements of section 553.⁸⁵ The question in the case was whether the Atomic Energy Commission (“AEC”), a federal agency, used adequate notice-and-comment procedures in its promulgation of a rule regulating the environmental impacts of nuclear power plants.⁸⁶ The D.C. Circuit held that despite meeting the section 553 notice-and-comment requirements, the AEC employed inadequate rulemaking procedures because it had relied on insufficient evidence to justify its decisions and develop the factual record, which could have been remedied through cross-examination and discovery.⁸⁷

The Supreme Court reversed the D.C. Circuit and said it “had seriously misread or misapplied” the APA.⁸⁸ The Court held that section 553 establishes the “maximum procedural requirements” for notice-and-comment rulemaking and that reviewing courts have no authority

⁸¹ See Kenneth Culp Davis, *Administrative Common Law and the Vermont Yankee Opinion*, 1980 UTAH L. REV. 3, 12; Emily S. Bremer, *The Undemocratic Roots of Agency Rulemaking*, 108 CORNELL L. REV. 69, 83 (2022); Gillian E. Metzger, *Embracing Administrative Common Law*, 80 GEO. WASH. L. REV. 1293, 1305 (2012).

⁸² See Davis, *supra* note 81, at 7.

⁸³ GLICKSMAN & LEVY, *supra* note 2, at 424–25; see also Scalia, *supra* note 5, at 348–52 (discussing the cases that imposed these heightened procedures).

⁸⁴ See Jack M. Beermann & Gary Lawson, *Reprocessing Vermont Yankee*, 75 GEO. WASH. L. REV. 856, 857 (2007).

⁸⁵ See *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 525 (1978).

⁸⁶ See *id.* at 539.

⁸⁷ See *id.* at 535, 541; Scalia, *supra* note 5, at 353–54.

⁸⁸ *Vt. Yankee*, 435 U.S. at 525.

to require additional procedures beyond those mandated in the APA.⁸⁹ It maintained that “[a]bsent constitutional constraints or extremely compelling circumstances,”⁹⁰ agencies “should be free to fashion their own rules of procedure.”⁹¹ The Court concluded that the APA’s legislative history and the *Attorney General’s Manual on the Administrative Procedure Act*⁹²—viewed as a contemporaneous interpretation of the APA—both confirm that agencies and not courts can decide whether to impose additional procedures.⁹³ It warned that permitting courts to impose additional procedures would lead to unpredictable judicial review because a court would subjectively determine whether the agency employed procedures to reach “the ‘best’ or ‘correct’ result.”⁹⁴ As a consequence, agencies would always adopt full adjudicatory procedures to avoid reversal, frustrating the APA’s purpose and depriving agencies of the benefits of notice-and-comment rulemaking, such as efficiency.⁹⁵

Vermont Yankee set a boundary on the scope of section 553 but said little about how courts should interpret the notice-and-comment rulemaking requirements contained within the statute.⁹⁶ Scholars have debated the extent to which *Vermont Yankee* has limited courts’ ability to interpret the meaning of section 553 given the statute’s minimal language.⁹⁷ One approach argues that *Vermont Yankee* can be read (1) broadly, requiring strict adherence to the language of the requirements set out in section 553 according to the plain meaning of the text; (2) narrowly, to strike down only the specific additional procedures required by the D.C. Circuit in the case; or (3) “naturally,” so as to require all procedural requirements to be “firmly grounded in some

⁸⁹ *Id.* at 524.

⁹⁰ *Id.* at 543.

⁹¹ *Id.* (quoting *FCC v. Schreiber*, 381 U.S. 279, 290 (1965)).

⁹² U.S. DEP’T OF JUST., ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT (1947).

⁹³ *Vt. Yankee*, 435 U.S. at 545–46.

⁹⁴ *Id.* at 546.

⁹⁵ *See id.* at 547.

⁹⁶ *See* Kristin E. Hickman & Mark R. Thomson, *Textualism and the Administrative Procedure Act*, 98 NOTRE DAME L. REV. 2071, 2091–94 (2023) (“[A]lthough *Vermont Yankee* and its progeny establish a textual line that courts may not cross, the Supreme Court also left the lower courts with a fair amount of latitude in construing the APA’s text.”); *see also* Peter L. Strauss, Dedication, *Changing Times: The APA at Fifty*, 63 U. CHI. L. REV. 1389, 1412 (1996) (“Emphatic as the *Vermont Yankee* Court was about the impropriety of judicial improvisation of procedures outside the Act, it did not speak to evolving interpretation within it . . .”).

⁹⁷ *See, e.g.,* Beermann & Lawson, *supra* note 84, 871–72 (arguing that courts should read *Vermont Yankee* narrowly such that it permits them to review agency procedures); Ronald M. Levin, *The Evolving APA and the Originalist Challenge*, 97 CHI.-KENT L. REV. 7, 19–20 (2022) (discussing the perceived misalignment between the legal principles outlined in *Vermont Yankee* and the way in which it has been applied by lower courts over the years).

source of positive statutory, regulatory, or constitutional law.”⁹⁸ In reality, however, the Supreme Court has read *Vermont Yankee* in none of these ways, instead invoking the case only when the Court disagrees with a procedural requirement.⁹⁹

2. *Administrative Common Law*

The extensive judicial innovation in administrative law that has occurred since *Vermont Yankee* contradicts a broad reading of the decision.¹⁰⁰ Since the APA’s enactment in 1946, the administrative state has grown dramatically and so have challenges to agency action.¹⁰¹ As a result, courts have grappled with the minimalist text of section 553 by extrapolating several requirements for notice-and-comment rulemaking.¹⁰² This is an example of what has come to be known as “administrative common law.”¹⁰³ Other prominent examples include requiring agencies to disclose the technical studies and data they rely on when proposing a rule,¹⁰⁴ address the “significant” comments they receive,¹⁰⁵ and ensure that a final rule is a “logical outgrowth” of a proposed rule.¹⁰⁶ Some scholars argue that administrative common law is both necessary and compatible with the APA’s text, structure, and legislative history.¹⁰⁷ Others contend that judicial interpretation of section 553 contradicts Congress’s intent that agencies maintain discretion over rulemaking procedures.¹⁰⁸ In practice,

⁹⁸ See Beermann & Lawson, *supra* note 84, at 860.

⁹⁹ See Levin, *supra* note 97, at 21–22.

¹⁰⁰ See Metzger, *supra* note 81, at 1305.

¹⁰¹ See Eskridge & Ferejohn, *supra* note 4, at 1928–29.

¹⁰² See *id.* at 1929; Levin, *supra* note 97, at 12.

¹⁰³ Bremer, *supra* note 81, at 81–86.

¹⁰⁴ See, e.g., *Portland Cement Ass’n v. Ruckelshaus*, 486 F.2d 375, 394, 402 (D.C. Cir. 1973); *Conn. Light & Power Co. v. Nuclear Regul. Comm’n*, 673 F.2d 525, 530–31 (D.C. Cir. 1982); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008). In *American Radio Relay League v. FCC*, then-Judge Kavanaugh wrote that the requirement that agencies disclose technical studies they rely on “cannot be squared with the text of § 553 of the APA” and that its “lack of roots in the statutory text creates a serious jurisprudential problem because the Supreme Court later rejected this kind of freeform interpretation of the APA [in *Vermont Yankee*].” *Id.* at 246 (Kavanaugh, J., concurring).

¹⁰⁵ See, e.g., *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 96 (2015).

¹⁰⁶ See, e.g., *Nat’l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986); *Am. Fed’n of Lab. & Cong. of Indus. Orgs. v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985).

¹⁰⁷ See, e.g., Metzger, *supra* note 81, at 1320–21; Bremer, *supra* note 81, at 132 (“The text [of section 553] invites, even demands, post-enactment liquidation of its meaning.”); Eskridge & Ferejohn, *supra* note 4, at 1929–33; Davis, *supra* note 81, at 12.

¹⁰⁸ See Kovacs, *supra* note 5, at 217; see also John F. Duffy, *Administrative Common Law in Judicial Review*, 77 TEX. L. REV. 113, 118 (1998) (“For many other standard administrative law doctrines, however, the textual home in statutory law either is nonexistent or has never been identified.”).

the Supreme Court's acceptance of administrative common law¹⁰⁹ supports a narrow reading of *Vermont Yankee*.

3. *Judicial Review of Comment Periods Is Permissible Under Vermont Yankee*

In several cases since *Vermont Yankee*, courts have reviewed the length of agency comment periods and set baseline standards for comment period length.¹¹⁰ In setting these baseline standards, courts have interpreted section 553's requirement that agencies "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments."¹¹¹ Courts have primarily taken two approaches: (1) recognizing a minimum APA comment period of thirty days, or (2) evaluating whether an agency has provided a "meaningful opportunity" to comment.¹¹² The first approach turns the widely used thirty-day norm into a rule of administrative common law. The second approach creates a flexible standard that requires a more fact-intensive analysis. Courts engaging in each approach have done so without mention of *Vermont Yankee*,¹¹³ perhaps indicating that they felt they were acting within the textual boundaries of section 553.

In a recent challenge to an SEC rule, a district court concluded that it could not evaluate the rule's comment period under the second approach because of *Vermont Yankee*.¹¹⁴ The court recognized the thirty-day minimum comment period endorsed by the Supreme Court but said it would "not introduce its own policy preferences about what is a 'meaningful opportunity'" because doing so would involve imposing additional procedures prohibited by *Vermont Yankee*.¹¹⁵ This analysis misconstrues the scope of *Vermont Yankee* by accepting one approach to interpretation of comment periods but rejecting another approach that is equally valid under *Vermont Yankee* and within the accepted realm of administrative common law. The court could have concluded that a thirty-day comment period was sufficient under the circumstances but should not have shied away from evaluating whether the SEC's comment period gave the public a meaningful opportunity to comment.

¹⁰⁹ See, e.g., *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (endorsing the "logical outgrowth" test); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (explaining that agencies "must consider and respond to significant comments" even though such actions are not explicitly required by the APA's text).

¹¹⁰ See *infra* Section II.C.

¹¹¹ 5 U.S.C. § 553(c); see *infra* Section II.C.

¹¹² See *infra* Section II.C.

¹¹³ See discussion *infra* Section II.C.

¹¹⁴ See *Nat'l Ass'n of Mfrs. v. SEC*, 644 F. Supp. 3d 342, 354 (W.D. Tex. 2022).

¹¹⁵ See *id.*

B. Standard of Review

The standard of review a court uses to review agency action affects the level of deference given to the agency decision.¹¹⁶ Courts typically review comment period lengths as a discretionary decision¹¹⁷ and therefore use the arbitrary and capricious standard provided by APA section 706, the statute's scope of review provision.¹¹⁸ A court could also use de novo review and give the agency no deference.¹¹⁹ A uniform approach for reviewing comment periods would provide the most clarity, but both of these approaches are suitable.

1. Arbitrary and Capricious

The arbitrary and capricious standard is used to review agency factual findings and discretionary decisions.¹²⁰ The standard is deferential but requires agencies to provide a reasoned explanation for their decisions.¹²¹ A court reviewing under this standard may not “substitute its judgment for that of the agency” but “must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.”¹²² The Supreme Court articulated a test for whether an agency has acted arbitrarily in its 1983 *Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Insurance Co.*¹²³ decision. Under the *State Farm* test, courts typically find that an agency has acted arbitrarily if it “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”¹²⁴

Most courts consider the length of a comment period a discretionary decision for agencies and therefore review comment period length using the arbitrary and capricious standard.¹²⁵ For example, in *California*

¹¹⁶ GLICKSMAN & LEVY, *supra* note 2, at 61–65.

¹¹⁷ See *infra* notes 126–33 and accompanying text.

¹¹⁸ Section 706(2)(A) permits a court to “hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

¹¹⁹ See *infra* Section II.B.2.

¹²⁰ JARED P. COLE, CONG. RSCH. SERV., R44699, AN INTRODUCTION TO JUDICIAL REVIEW OF FEDERAL AGENCY ACTION 18 (2016).

¹²¹ See GLICKSMAN & LEVY, *supra* note 2, at 65.

¹²² *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

¹²³ 463 U.S. 29 (1983).

¹²⁴ *Id.* at 43.

¹²⁵ See *infra* notes 126–33 and accompanying text.

ex rel. Becerra v. U.S. Department of the Interior,¹²⁶ a district court held that the Department of the Interior (“DOI”) repealed a rule arbitrarily and capriciously because DOI failed to consider an important aspect of the problem when it did not provide a meaningful opportunity to comment, precluding DOI from receiving substantive comments about whether the rule should be repealed.¹²⁷ In *North Carolina Growers’ Ass’n v. United Farm Workers*,¹²⁸ the Fourth Circuit similarly held that the Department of Labor acted arbitrarily and capriciously by “ignor[ing] important aspects of the problem” when it failed to provide a meaningful opportunity for comment.¹²⁹

The D.C. Circuit and Third Circuit have applied the arbitrary and capricious standard by asking generally whether an agency acted reasonably. In *National Lifeline Ass’n v. FCC*,¹³⁰ the D.C. Circuit found a rule arbitrary and capricious because the Federal Communications Commission (“FCC”) used a single, short comment period after promising it would provide an additional, longer comment period, lulling commenters into thinking they did not need to submit comments during the initial comment period.¹³¹ Similarly, in *Prometheus Radio Project v. FCC*,¹³² the Third Circuit found an FCC rule arbitrary and capricious because the FCC provided too short a comment period and had already circulated the draft final rule internally while the comment period was open, suggesting the agency was not planning to use the feedback.¹³³ These two cases demonstrate that, although generally deferential, the arbitrary and capricious standard will strike down agency actions that lack good-faith, reasoned decision-making.

2. *De Novo Review*

Although most courts have used the arbitrary and capricious standard to review agency comment periods, a court could also review comment periods *de novo* under APA section 706(2)(D), which requires a court to set aside agency action that is “without observance of procedure required by law.”¹³⁴ Some courts use a *de novo* standard to evaluate compliance with section 553, granting an agency no

¹²⁶ 381 F. Supp. 3d 1153 (N.D. Cal. 2019).

¹²⁷ *See id.* at 1177–78.

¹²⁸ 702 F.3d 755 (4th Cir. 2012).

¹²⁹ *See id.* at 770 (quoting *Ohio River Valley Env’t Coal., Inc. v. Kempthorne*, 473 F.3d 94, 103 (4th Cir. 2006)). The Fourth Circuit described the arbitrary and capricious standard for procedural rules as “narrow” and “strict.” *See id.* at 764.

¹³⁰ 921 F.3d 1102 (D.C. Cir. 2019).

¹³¹ *See id.* at 1117–18.

¹³² 652 F.3d 431 (3d Cir. 2011).

¹³³ *See id.* at 453.

¹³⁴ 5 U.S.C. § 706(2)(D).

deference.¹³⁵ For example, the D.C. Circuit announced a *de novo* standard for reviewing an agency's invocation of the good cause exception, which exempts an agency from using notice-and-comment procedures to promulgate a rule.¹³⁶ The argument for *de novo* review of procedural compliance is that agencies have "no interpretive authority over the APA" and therefore should not determine whether their procedures meet the statutory requirements laid out in section 553.¹³⁷ No court has explicitly announced a *de novo* standard for review of comment periods, but some courts have reviewed comment periods without granting an agency any deference.¹³⁸ Although the arbitrary and capricious standard is more deferential, a court reviewing *de novo* should still consider whether an agency acted reasonably under the circumstances when it applies the substantive test of whether the agency meaningfully engaged the public.

C. *Tests for Review and a Recent SEC Example*

As discussed above, courts typically review comment periods using two approaches: Some courts use a specific length of time as a minimum acceptable standard.¹³⁹ Other courts ask whether there was a meaningful opportunity to comment.¹⁴⁰ Although developing a baseline length can provide clarity to the agency and public, courts should focus their analysis on whether there was a meaningful opportunity to comment to holistically evaluate whether the public comment period achieved its purpose.

1. *Specific Durations*

Some courts have endorsed minimum-baseline comment period lengths as permissible under the APA.¹⁴¹ These pronouncements are useful but generally insufficient on their own because analyzing a comment period requires evaluating the specific rulemaking circumstances.

¹³⁵ COLE, *supra* note 120, at 16.

¹³⁶ See *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014); see also Kyle Schneider, Note, *Judicial Review of Good Cause Determinations Under the Administrative Procedure Act*, 73 STAN. L. REV. 237, 255–56 (2021) (discussing courts' use of *de novo* review when agencies claim their actions are based upon "good cause"). An agency can bypass notice-and-comment rulemaking for "good cause" when it finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B).

¹³⁷ *Sorenson*, 755 F.3d at 706; see Schneider, *supra* note 136, at 256.

¹³⁸ See, e.g., *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009); *Pangea Legal Servs. v. U.S. Dep't of Homeland Sec.*, 501 F. Supp. 3d 792, 818–22 (N.D. Cal. 2020).

¹³⁹ See *infra* Section II.C.1.

¹⁴⁰ See *infra* Section II.C.2.

¹⁴¹ See *infra* notes 142–45 and accompanying text.

In *Petry v. Block*,¹⁴² the D.C. Circuit stated that thirty days is not “talismanic” but looked to the ACUS policy recommendations to conclude that a “barebones” comment period would be at least thirty days.¹⁴³ In 2019, the D.C. Circuit more explicitly endorsed the thirty-day standard when it held that thirty days is “generally the shortest time period sufficient for interested persons to meaningfully review a proposed rule and provide informed comment.”¹⁴⁴ Most significantly, the Supreme Court in 2019 characterized the APA as having a minimum comment period of thirty days.¹⁴⁵

2. *Meaningful Opportunity to Comment*

Other courts ask whether the public has had a meaningful opportunity to comment when evaluating a comment period.¹⁴⁶ This is a fact-specific inquiry that requires a court to assess the reasons that the agency used a certain comment period length and whether the public was genuinely deprived of submitting good-faith comments.¹⁴⁷ For example, in *North Carolina Growers’ Ass’n v. United Farm Workers*, the Fourth Circuit held that a ten-day comment period for a Department of Labor rule failed to comply with section 553 because its “exceedingly short duration” did not provide a meaningful opportunity to comment.¹⁴⁸ In *California ex rel. Becerra v. U.S. Department of the Interior*, the court compared the length of comment period for a proposed rule repeal—thirty days—to the comment period when the rule was initially proposed—120 days.¹⁴⁹ The court found that the agency failed to provide a meaningful opportunity to comment because of the shortened comment period for the rule repeal combined with the agency’s failure to fully consider the comments it received.¹⁵⁰

In *Prometheus Radio Project v. FCC*, the Third Circuit found that the FCC’s use of a twenty-eight-day comment period—compared to its standard practice of ninety days—was insufficient because it was significantly shorter than usual and because the rule at issue was of “great public concern.”¹⁵¹ In addition to the insufficiently long comment

¹⁴² 737 F.2d 1193 (D.C. Cir. 1984).

¹⁴³ See *id.* at 1201–02.

¹⁴⁴ See Nat’l Lifeline Ass’n v. FCC, 921 F.3d 1102, 1117 (D.C. Cir. 2019). The Fifth Circuit also has endorsed the thirty-day minimum requirement. See *Chem. Mfrs. Ass’n v. EPA*, 899 F.2d 344, 347 (5th Cir. 1990).

¹⁴⁵ *Azar v. Allina Health Servs.*, 587 U.S. 566, 570 (2019).

¹⁴⁶ See, e.g., *Rural Cellular Ass’n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009).

¹⁴⁷ See *infra* notes 148–50 and accompanying text.

¹⁴⁸ *N.C. Growers’ Ass’n v. United Farm Workers*, 702 F.3d 755, 770 (4th Cir. 2012).

¹⁴⁹ *California ex rel. Becerra v. U.S. Dep’t of the Interior*, 381 F. Supp. 3d 1153, 1177 (N.D. Cal. 2019).

¹⁵⁰ *Id.* at 1177–78.

¹⁵¹ *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011).

period, the court concluded that the FCC failed to meet its “obligation to remain ‘open-minded’ about the issues raised” in public comments because the FCC had circulated a draft of the final rule during the comment period.¹⁵²

The test of whether an agency provided a meaningful opportunity to comment gives courts the flexibility to evaluate agency decision-making in a context-specific manner that accounts for the circumstances of rulemaking. Agencies act on a range of timelines—sometimes quickly to address an emergency or over a long period to promulgate a highly complex and technical rule—and courts should be able to account for these differences. Importantly, the meaningful opportunity test asks whether the public was able to provide thoughtful comments for the agency to consider, which addresses the APA’s core aim to promote public participation and transparency in the rulemaking process.

3. A Recent SEC Example Represents Diverging Approaches

A decision by the Sixth Circuit in September 2024 demonstrates the diverging approaches to evaluating comment periods. In *Chamber of Commerce of the United States v. SEC*,¹⁵³ the Sixth Circuit affirmed a district court’s decision to uphold a 2022 SEC rule that repealed a 2020 rule on proxy-advice regulations.¹⁵⁴ The Sixth Circuit held, among other things, that the SEC had provided a sufficient comment period.¹⁵⁵ Judge Bush dissented, finding the rescission procedurally invalid, in part because the comment period was insufficient.¹⁵⁶ The Chamber of Commerce argued that the thirty-day comment period for the 2022 rule failed to observe procedure required by law because (1) it fell over the Thanksgiving and Christmas holidays, (2) “the original rule had a 60-day [comment] period that yielded far more comments” than the 2022 rule, (3) “the SEC’s stated ordinary practice . . . calls for significant rule changes to have at least a 60-day [comment] period,” and (4) several commenters had requested an extension of the comment period.¹⁵⁷

The district court found “the SEC’s decision to rely on such a short comment period, over the objections of interested parties and in apparent departure from much of the agency’s usual practice, to be somewhat troubling.”¹⁵⁸ Despite these concerns, the court found that the Chamber of Commerce had “done very little to establish that the 30-day period

¹⁵² See *id.* (quoting *Rural Cellular Ass’n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009)).

¹⁵³ 115 F.4th 740 (6th Cir. 2024).

¹⁵⁴ *Id.* at 755–58.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 763–64 (Bush, J., dissenting).

¹⁵⁷ *Chamber of Com. of the U.S. v. SEC*, 670 F. Supp. 3d 537, 552 (M.D. Tenn. 2023), *aff’d*, 115 F.4th 740.

¹⁵⁸ *Id.* at 552–53.

was actually inadequate.”¹⁵⁹ After reviewing the record, the district court concluded that there had been a robust public debate in the promulgation of the 2020 proxy rule, so the arguments that commenters would want to submit “had already been assembled” once the SEC proposed repealing the rule.¹⁶⁰ The court declared the rule procedurally valid, stating that the thirty-day comment period was “within the bounds of what was legally permissible,” even if it was “unnecessarily short or even frustratingly short.”¹⁶¹

The Sixth Circuit largely affirmed the district court and emphasized some additional points.¹⁶² The majority reasoned that finding the comment period insufficient would amount to holding the SEC to an “erroneously heightened procedural standard.”¹⁶³ The court concluded that the APA requires a “meaningful opportunity to comment” but concluded that thirty days is largely accepted as the *de facto* norm absent “extenuating circumstances.”¹⁶⁴ Further, the majority found that the case law cited by the Chamber of Commerce was distinguishable because the comment periods in those cases had content restrictions, unlike the rule repeal at issue.¹⁶⁵ Finally, the court rejected the argument that failure to extend the comment period was procedural error because the plaintiffs did not “identify any novel substantive arguments they would have made or specific data they would have presented had the comment window been extended.”¹⁶⁶

Judge Bush dissented, finding sixty days, not thirty, to be an established norm for comment periods and no justifiable reason for the SEC to refuse to extend the comment period without exigent circumstances.¹⁶⁷ He also cited factors to consider when evaluating the length of a comment period, including the complexity of the rule, its impact, public interest in the proposal, and whether exigent conditions justify a shorter comment period.¹⁶⁸ Judge Bush suggested that the SEC’s refusal to extend the comment period for the rule repeal to sixty days—the comment period when the rule was initially proposed—indicated that the SEC had already made up its mind and was discounting any public

¹⁵⁹ *Id.* at 553.

¹⁶⁰ *See id.*

¹⁶¹ *Id.* at 553–54 (“A 30-day period may have been unnecessarily short or even frustratingly short, but that does not mean that it was impermissibly short. The evidence in the record suggests that 30 days was a sufficient period of time for commenters to formulate and provide their views on the proposal, which is what the APA requires.”).

¹⁶² *See infra* notes 163–66 and accompanying text.

¹⁶³ *Chamber of Com. of the U.S. v. SEC*, 115 F.4th 740, 755 (6th Cir. 2024).

¹⁶⁴ *Id.* at 755–56.

¹⁶⁵ *Id.* at 756–57.

¹⁶⁶ *Id.* at 758.

¹⁶⁷ *See id.* at 763–64 (Bush, J., dissenting).

¹⁶⁸ *Id.* at 763.

feedback.¹⁶⁹ He also explained that there was not harmless error in a shorter comment period because the record indicated that several commenters wanted an extension so they could submit more data concerning the economic impact of repealing the rule.¹⁷⁰

Key points of contention between the majority and dissent were (1) whether the established norm for a comment period is thirty or sixty days, and (2) whether the SEC should have provided at least the same comment period for the rule repeal as the initial rule proposal.¹⁷¹ The majority and dissent also disagreed whether the plaintiffs were harmed by the SEC's refusal to extend the comment period.¹⁷²

The majority's conclusion that the SEC need not extend the comment period beyond thirty days does not fully address whether there was a meaningful opportunity to comment and applies an overly deferential standard of review.¹⁷³ Whether the norm for comment periods is thirty or sixty days is a disputed factual question that cannot be easily discerned because there is no codified minimum duration.¹⁷⁴ Rather, a court should focus on whether the agency provided a meaningful opportunity to comment by assessing if commenters raised concerns about their ability to comment within the established period and whether the agency had a legitimate reason or explanation for refusing to grant a comment period extension. In *Chamber of Commerce of the U.S. v. SEC*, the majority did not assess whether the SEC used reasoned decision-making when it refused to extend a comment period despite there being no apparent exigent circumstances that prevented the SEC from granting the extension.¹⁷⁵ Judge Bush's dissent more appropriately assessed whether the comment period was adequate based on the circumstances.¹⁷⁶

III. PROPOSED FACTORS FOR HIGH-VOLUME RULEMAKING

A significant increase in rulemaking that results in several major rule proposals with short comment periods warrants additional scrutiny because this rulemaking activity increases the burden on the public to analyze and provide input on significant regulatory changes. In these circumstances, courts should assess whether there was a meaningful opportunity to comment by considering additional factors that may

¹⁶⁹ *Id.* at 764.

¹⁷⁰ *Id.* at 764–65.

¹⁷¹ *See id.* at 758–65.

¹⁷² *Id.* at 764–65.

¹⁷³ *See id.* at 755–56 (majority opinion).

¹⁷⁴ *See supra* Sections I.A, II.C.1.

¹⁷⁵ *See* *Chamber of Com. of the U.S. v. SEC*, 115 F.4th at 764 (Bush, J., dissenting).

¹⁷⁶ *See id.*

account for the aggregate impact of several rules being proposed at once, rather than considering a single comment period in isolation.

A. *Interrelated Nature of Rules*

When a plaintiff alleges that an agency has failed to provide a meaningful opportunity to comment, a court should consider whether the rule in question has been proposed simultaneously with other related rules. During the Biden Administration, the financial industry complained that the SEC promulgated several interrelated rules in a short period.¹⁷⁷ Situations such as this may warrant a longer comment period than if a rule were proposed in isolation because it may require consideration of how the rules could impact one another.¹⁷⁸

Some district courts have assessed the interrelated nature of rules in analyzing comment periods.¹⁷⁹ During the final months of the first Trump Administration, the U.S. Department of Justice (“DOJ”) and the Executive Office for Immigration Review—a subagency of DOJ—promulgated a final rule that made significant changes to the U.S. immigration system.¹⁸⁰ These changes included shortening the briefing schedule for the Board of Immigration Appeals (“BIA”), limiting the grounds for the BIA to remand cases to immigration judges, and restricting the ability for the BIA and immigration judges to reopen or reconsider cases *sua sponte*.¹⁸¹ The proposed rule had a thirty-day comment period and the comment period was not extended despite requests from several commenters.¹⁸² Nonprofit legal groups sought to enjoin the rule in two separate cases, arguing that it was procedurally defective under section 553 because of an insufficient comment period.¹⁸³ In their briefs, the plaintiffs argued that their ability to submit timely and meaningful comments was severely burdened by the “staggered” rulemaking process of DOJ and the Department of Homeland Security (“DHS”) because the agencies had proposed several other

¹⁷⁷ See *supra* Section I.C.

¹⁷⁸ See, e.g., *Rip Current Rulemakings*, *supra* note 18 (“We can avoid creating regulatory rip currents by recalibrating our agenda to focus on issues core to the protection of investors and operation of our markets and by slowing down the pace to ensure that we and the public can think about what we are doing.”).

¹⁷⁹ See, e.g., *Centro Legal de la Raza v. Exec. Off. for Immigr. Rev.*, 524 F. Supp. 3d 919, 955–56 (N.D. Cal. 2021); *Cath. Legal Immigr. Network, Inc. v. Exec. Off. for Immigr. Rev.*, No. 21-00094, 2021 WL 3609986, at *3 (D.D.C. Apr. 4, 2021).

¹⁸⁰ See Appellate Procedures and Decisional Finality in Immigration Proceedings; Administrative Closure, 85 Fed. Reg. 81,588, 81,651–56 (Dec. 16, 2020) (codified at 8 C.F.R. pts. 1003, 1240 (2024)).

¹⁸¹ See *id.*

¹⁸² See *Centro Legal de la Raza*, 524 F. Supp. 3d at 935.

¹⁸³ See *id.* at 953–54; *Cath. Legal Immigr. Network*, 2021 WL 3609986, at *2–3.

rules related to the immigration process.¹⁸⁴ The district courts deciding the cases both granted preliminary injunctions and found the rule likely violated section 553 of the APA.¹⁸⁵

In one of the cases, *Centro Legal de la Raza v. Executive Office for Immigration Review*,¹⁸⁶ the district court stated that the “staggered nature of [the] rulemaking in conjunction with other related rules resulted in an arbitrary and capricious failure to consider the combined impact of numerous intersecting policy changes.”¹⁸⁷ The court noted that thirty days is already a short comment period for a substantial rulemaking, which was further exacerbated by the combined timing with other proposed immigration rules.¹⁸⁸ As a result of the staggered but short comment periods, commenters were unable to consider how the other rules “intersected and impacted” the rule at issue.¹⁸⁹ The court concluded that the numerous intertwined rules promulgated at different times deprived the public of a meaningful opportunity to comment.¹⁹⁰

In the other case, *Catholic Legal Immigration Network, Inc. v. Executive Office for Immigration Review*,¹⁹¹ the court similarly reasoned that when an agency “engages in a slew of interrelated rulemaking activity,” a thirty-day comment period “is likely insufficient to provide a meaningful opportunity to comment on a highly technical and complex regulation.”¹⁹² Although the cases were not appealed because the Trump Administration left office,¹⁹³ the cases stand as relevant examples because a main factor in the courts’ analyses of the comment period length was the effect of interrelated rulemakings and commenters’ ability to consider how the rules impacted one another.¹⁹⁴

In another case relating to the first Trump Administration’s immigration rulemaking, a district court enjoined a rule issued by DHS that would have narrowed asylum eligibility on the grounds that it likely

¹⁸⁴ See Plaintiffs’ Notice of Motion and Motion for a Preliminary Injunction at 3, *Centro Legal de la Raza*, 524 F. Supp. 3d 919 (No. 21-cv-00463); Complaint for Declaratory and Injunctive Relief at 95, *Cath. Legal Immigr. Network*, 2021 WL 3609986 (No. 21-cv-00094).

¹⁸⁵ See *Centro Legal de la Raza*, 524 F. Supp. 3d at 954–55; *Cath. Legal Immigr. Network*, 2021 WL 3609986, at *2.

¹⁸⁶ 524 F. Supp. 3d 919 (N.D. Cal. 2021).

¹⁸⁷ *Id.* at 955.

¹⁸⁸ See *id.* at 955, 958.

¹⁸⁹ *Id.* at 958.

¹⁹⁰ See *id.* at 962.

¹⁹¹ No. 21-cv-00094, 2021 WL 3609986 (D.D.C. Apr. 4, 2021).

¹⁹² *Id.* at *3.

¹⁹³ See Priscilla Alvarez, *Federal Judge Blocks Last-Minute Trump Rule Limiting Asylum Claims*, CNN (Feb. 16, 2021, 5:37 PM), <https://www.cnn.com/2021/02/16/politics/immigration-asylum-trump-rule/index.html> [<https://perma.cc/2ELA-MD2H>] (explaining that the Biden Administration would be unlikely to defend a similar Trump-era asylum rule because of Biden’s commitment to restoring asylum at the southern border).

¹⁹⁴ See *Centro Legal de la Raza*, 524 F. Supp. 3d at 958.

violated section 553 of the APA.¹⁹⁵ The court analyzed the plaintiff's claims that the rule was procedurally defective under the APA although the case was ultimately decided on substantive grounds.¹⁹⁶ The court found that the thirty-day comment period for such a substantial rule—both in terms of the changes proposed and the subject matter—was already short.¹⁹⁷ The court noted that there were several other interrelated asylum-related rules promulgated by DHS around the same time that received sixty-day comment periods.¹⁹⁸ And the court said that although a “staggered” rulemaking process is “not dispositive on its own,” the “overall context” in which the rule was promulgated, given the already short comment period, made it an important factor in considering whether the comment period was sufficient.¹⁹⁹

With respect to the SEC's recent rulemaking activity or other future agency rulemaking that demonstrates this pattern, a court could evaluate the interrelated nature of the rules proposed when analyzing a comment period. For example, if a proposed rule impacted a certain segment of the financial markets, the court could assess whether there were other related rules likely to impact the same segment of the markets. A court could evaluate whether one rule interacts with another to determine if commenters would benefit from analyzing the rules together or separately. Looking at the interrelated nature of the rules could help the court understand the cumulative impact of the proposals and whether a longer or overlapping comment period would be beneficial.²⁰⁰ Like in *Centro Legal de la Raza*, a court could find a rule arbitrary and capricious because the SEC failed to consider an important aspect of the problem—in other words, a court could find the SEC did not consider the need for a longer comment period given the volume of rulemaking.²⁰¹

¹⁹⁵ *Pangea Legal Servs. v. U.S. Dep't of Homeland Sec.*, 501 F. Supp. 3d 792, 829 (N.D. Cal. 2020).

¹⁹⁶ *See id.* at 818–22, 829.

¹⁹⁷ *Id.*

¹⁹⁸ *Id.* at 820.

¹⁹⁹ *See id.* at 821.

²⁰⁰ The financial industry publicly made the case that having more time to analyze how rules interacted with one another would be beneficial. *See, e.g.,* Pan, *supra* note 63; Bentsen, *supra* note 68.

²⁰¹ In a case pending at the Fifth Circuit as of April 2025, a group of trade associations are challenging two SEC rules as arbitrary and capricious for being highly interconnected but contradictory. Although not related to comment periods, the case may illustrate whether courts are willing to consider interrelated rules substantively arbitrary and capricious. *See* Opening Brief for Petitioners at 1–5, Nat'l Ass'n of Priv. Fund Managers v. SEC, No. 23-60626 (5th Cir. Mar. 5, 2024).

B. Significance of the Rule

A court should look at the significance of a proposed rule, both economically and substantively, to determine whether a longer comment period is warranted. Rule proposals are often highly complex and technical, and this complexity is likely to be compounded for a proposed rule that is economically significant or would make sweeping regulatory reforms.²⁰² In the context of an agency promulgating a high volume of rules, significant rules are likely to need even longer comment periods because commenters may wish to provide input on multiple significant proposals and will need time to analyze and respond to them.²⁰³

Courts have looked at the significance of a rule in determining the sufficiency of a comment period.²⁰⁴ In one of the aforementioned cases concerning the Trump Administration's immigration rules, the court noted that the rule was considered by the Executive Office of Immigration Review to be a "significant regulatory action" that was drafted in accordance with the principles of Executive Orders 12,866 and 13,563, the Clinton and Obama executive orders recommending minimum comment periods of sixty days.²⁰⁵ The comment period for the rule, however, was only thirty days.²⁰⁶

In *National Lifeline Ass'n*, the D.C. Circuit stated that thirty days is typically the minimum comment period necessary when "substantial rule changes are proposed."²⁰⁷ Likewise, in *Prometheus Radio Project*, the Third Circuit considered that a rulemaking of "great public concern" should have a longer comment period to permit commenters to submit their views.²⁰⁸ By focusing on whether the rule changes are "substantial," a court can place into context the overall significance of a rule, including its impacts on the economy and current regulatory scheme. Evaluating the significance of the rule may also help a court determine whether the agency has engaged in reasoned decision-making given the facts of the situation and the agency's choice.

In the case of the SEC, a reviewing court could look at whether the challenged rule is considered a significant rule compared to the SEC's

²⁰² See LUBBERS, *supra* note 29, at 307–08.

²⁰³ See Wegner, *supra* note 64.

²⁰⁴ See, e.g., *Centro Legal de la Raza v. Exec. Off. for Immigr. Rev.*, 524 F. Supp. 3d 919, 955–56 (N.D. Cal. 2021); *Chamber of Com. of the U.S. v. SEC*, 115 F.4th 740, 763 (6th Cir. 2024) (Bush, J., dissenting).

²⁰⁵ *Centro Legal de la Raza*, 524 F. Supp. 3d at 955–56 (quoting Appellate Procedures and Decisional Finality in Immigration Proceedings; Administrative Closure, 85 Fed. Reg. 81,588, 81,643 (Dec. 16, 2020) (codified at 8 C.F.R. pts. 1003, 1240 (2024))); see *supra* notes 32–33 and accompanying text.

²⁰⁶ See *Centro Legal de la Raza*, 524 F. Supp. 3d at 955.

²⁰⁷ *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1118 (D.C. Cir. 2019).

²⁰⁸ *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011).

rulemaking agenda.²⁰⁹ Some SEC rules target a narrower segment of the financial markets and may be significant for a smaller group of regulated entities but not the entire financial industry. On the other hand, many of the rules under Chair Gensler's tenure brought sweeping changes to the regulatory system and affected most segments of U.S. capital markets.²¹⁰ Rules that apply more broadly, propose sweeping changes, or have a large economic impact should have longer comment periods to allow commenters to digest the changes. These proposals also tend to be the most complex and require more resources for commenters to analyze and provide feedback.

C. *Comparison to Previous Agency Action*

A court should compare an agency's current rulemaking behavior—specifically the number of rules it proposed and the comment periods provided for those rules—to the agency's previous rulemaking behavior. This would demonstrate whether the agency has changed its pace of rulemaking activity in an unprecedented manner. It is important to compare the period of alleged increased activity with the agency's previous activity because the increase in rulemaking activity is a comparative, not absolute, metric. This approach would ground the court's analysis in quantitative data, which could help aid comparisons and prevent arbitrariness.

With respect to the SEC, a court could look at the number of rules promulgated by previous SEC chairs over the last few administrations and the corresponding comment periods.²¹¹ Then, the court could determine if the SEC's increase in rulemaking is justified under the circumstances or if the rules should have longer comment periods. Although this is not a perfect metric, it can help diagnose whether a single lawsuit indicates a broader trend of diminished public engagement by an agency.

By analyzing the interrelated nature of rules, the relative importance of a rule, and the agency's rulemaking compared to previous time periods, a court can undertake an informed analysis of whether a rule's

²⁰⁹ The SEC publicly posts its rulemaking agenda. *Rulemaking Activity*, SEC, <https://www.sec.gov/rules/rulemaking-activity> [<https://perma.cc/7K8P-2QKQ>].

²¹⁰ Brooke Masters, *Gary Gensler Unleashes Biggest SEC Regulatory Blitz Since Financial Crisis*, FIN. TIMES (Aug. 31, 2023), <https://www.ft.com/content/413408f9-8c57-4420-ae44-19ccd06df0d0> [<https://perma.cc/W44C-G3YG>]; see, e.g., Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure, 88 Fed. Reg. 51,896 (Aug. 4, 2023) (codified at 17 C.F.R. pts. 229, 232, 239, 240, 249 (2024)); The Enhancement and Standardization of Climate-Related Disclosures for Investors, 89 Fed. Reg. 21,668 (Mar. 28, 2024) (to be codified at 17 C.F.R. pts. 210, 229, 230, 232, 239, 249).

²¹¹ SIFMA, a financial industry association, tracked these metrics during the Biden Administration. See SIFMA, *supra* note 61.

comment period deprives the public of a meaningful opportunity to comment.

CONCLUSION

The APA's notice-and-comment rulemaking requirements are designed to ensure that agencies exercising their quasi-legislative rulemaking functions meaningfully engage the public to encourage participatory democracy and create an open and transparent rulemaking process. Judicial review of comment periods is permissible under *Vermont Yankee* and sometimes favorable to ensure an agency provides a meaningful opportunity to comment. The Biden Administration SEC's rulemaking activity demonstrates the challenges to public engagement that can occur when an agency proposes many significant rules with short comment periods. In future cases, courts should consider the interrelated nature of rules, the significance of a rule, and an agency's overall rulemaking activity when determining if there has been a meaningful opportunity to comment.

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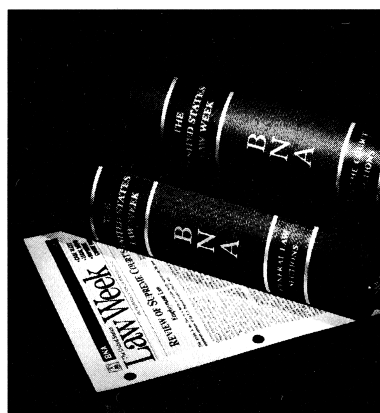
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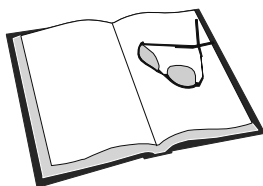
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