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]

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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

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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

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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 database[11] 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 organization[12] 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

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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/X9HLF760000000 [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 safety[15] 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

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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]

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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

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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 associations[28] and large companies challenge regulator actions little

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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

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harmed 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

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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

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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
Meat Processors & FSIS (USDA)	no suits	no suits
Drugmakers & FDA	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
Automakers & NHTSA	no suits on car safety (excludes fuel economy)	no suits on car safety (excludes fuel economy)
Airlines & FAA	no suits	no suits
Children's Product Companies & CPSC	no suits	no suits
Nuclear Plant Operators & NRC	1 suit by Nuclear Energy Institute, on minor issue	no suits
Coal Mines & MSHA	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)
Employers (Generally) & OSHA	25+ suits by 30+ associations	~100 suits, mostly by small companies, with 2 by Walmart (#1 U.S. employer)
Electricity Generators & EPA	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
For-Hire Trucking Companies & FMCSA	4 suits by associations, mostly representing small companies	17 suits, by companies of varying size (industry very deconcentrated)
Hospitals & CMS	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)
Nursing Homes & CMS	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

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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
Meat Processors & FSIS (USDA)	1994–2013: 2 suits by leading associations (in 1994 and 2000) and 1 suit by small-processor association (in 2005) 2021–2024: no suits	1994–2013: • 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 2021–2024: no suits
Drugmakers & FDA	1989–2013: targeted search for PhRMA (including under its prior name) and for all major generic associations detects no suits 2021–2024: no suits	1979–2024: no suits by a sponsor to a denial of a new-drug approval 2021–2024: • 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
Automakers & NHTSA	1984–2013: no suits on car safety (excludes fuel economy) 2021–2024: same	1984–2013: 1 suit by Chrysler 2021–2024: no suits on car safety (excludes fuel economy)
Airlines & FAA	1989–2013: 1 suit by major associations in 2001 2021–2024: no suits	1989–2013: • 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 2021–2024: no suits
Children's Product Companies & CPSC	1989–2013: no suits 2021–2024: no suits	1989–2013: 2 suits by large companies (both seeking secrecy) and 1 suit by small company 2021–2024: 2 suits by midsize companies, 1 by small company
Nuclear Plant Operators & NRC	1989–2013: no suits 2021–2024: no suits	1989–2013: no suits 2021–2024: no suits
Coal Mines & MSHA	1989–2013: 11 suits by National Mining Association or predecessor	[no additional search performed]
For-Hire Trucking Companies & FMCSA	2000–2013: 6 suits by small-company associations 2021–2024: no suits	2021–2024: 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

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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

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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

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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 Nolecheck, see *Nolecheck'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,

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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-2000s[73] with attention to

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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]

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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 Casing* 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 acts[85] 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

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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 forever[91]—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

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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 Beef[101] 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

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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

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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:

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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 shutdown; 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-fundmental-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

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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

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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]

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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]

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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

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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 involved[156]—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 days[163] once FSIS agreed to give the company an extra three weeks to

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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]

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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 & Epiphanie 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

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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/QER-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/QER-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/QER-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/QER-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/QER-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/qer-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 demands[178]—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 compliance[180]

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*'?"

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185 *See* Michael S. Williams, Eric D. Ebel, Neal J. Golden, Gurinder Saini, Epiphanie Nyirabahizi & 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 1984[196] 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

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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 Torreya 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

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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 Torreya was acquired by Stifel Financial Corporation in 2022. Press Release, Stifel Financial Corp., Stifel to Acquire Torreya Partners (Dec. 22, 2022), https://www.stifel.com/docs/pdf/pressreleases/2022/Stifel_Acquires_Torreya.pdf [https://perma.cc/Q5HR-SR4F].

202 *See generally* Torreya 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 Torreya'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), AstraZeneca (#8), Boehringer (#12), Takeda (#16), Teva (#29, suing twice), Easai (#41), and Otsuka (#48). If we expand our view to Torreya'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 Torreya'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 Torreya's top fifty was Teva (#29). Expanding our view to Torreya'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

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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 Torreya'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]

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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'ys, Ltd. and Ranbaxy, Inc.'s Complaint for Declaratory and Injunctive Relief at 2, Ranbaxy Lab'ys, Ltd. v. Burwell, 82 F. Supp. 3d 159 (D.D.C. 2015) (No. 14-cv-01923).

216 *See Ranbaxy Lab'ys*, 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 Torreya 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

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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

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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

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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]

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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.pmrsinc.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

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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 Torreya 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 years[252]—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.

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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]

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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

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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

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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

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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

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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. Balleisen & 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

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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.

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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

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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

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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

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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,

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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 Bukszpan, *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

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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 2O.

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

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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

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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

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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 loosing [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

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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

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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.autosinnovate.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]

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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 dockets 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 121[400] 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

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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

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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 times[414]—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*

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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 House[427] 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 rest[430]—the largest pilots' union endorsed it instantly[431] while ATA said it was "reviewing" the rule and gave no further press comment[432]—but industry did not sue.

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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]

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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

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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.ntsb.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

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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-

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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

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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

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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

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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

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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 standard[502] 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]

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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

- 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-phtalates.aspx [https://perma.cc/QB8L-4NQB] ("[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

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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

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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 Act[533] 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]

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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 Mfgr 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 Finnbin 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

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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 Act[559]—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

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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

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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

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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

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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, Bummzie 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-Bummzie-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

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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-Mfgrs-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

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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

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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 intrastate 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

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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

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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

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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,

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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,

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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 environmental 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 industry[664]—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

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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]

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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

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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

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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

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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 base[710] 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]

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703 *See* Aneil 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

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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 mining[720]—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

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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

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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]

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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 court[744] unless an ALJ stays the withdrawal, which is "unusual."[745] OSHA has no such unilateral shutdown 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

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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

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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 2013[760] 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

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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/5SUW-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]

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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,

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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-UFX3] (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

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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

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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 claims[790] 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

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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*, PROPUBLICA (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

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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

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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,

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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,

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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]

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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

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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 membership[844] 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. SCIS., 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://iiif.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

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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 sued[857] or were in the top twenty when their UARG membership was leaked[858] 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

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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 Coleto 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

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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

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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 generators[880] and often of the hazardous air pollutants

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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]

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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

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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 customers[893] 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

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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 Gambles 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

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[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

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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]

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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

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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]

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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 2006[932] 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

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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'ns 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 courts[940] 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 actions[943] 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

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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

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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 employees[953] 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 year[958]—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

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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-BHQK].

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

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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 suboptimal 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 cases[969]—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

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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

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975 Lucija Muehlenbachs, Stefan Staubli & Ziyan 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

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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

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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

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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-

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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 nonlitigious 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

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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).