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At Least As Effective: OSHA, the State Plans, and Divergent Worker Protections from COVID-19

Caroline Grueskin *

Abstract:

The federal Occupational Safety and Health Administration (OSHA) sets nationwide standards for workplace health and safety. But private sector workers in twenty-one states and Puerto Rico rely on a state agency (State Plan) for their enforcement. Those State Plans must remain “at least as effective” as OSHA. Are they? Despite their key role in protecting workers in many states, few legal scholars have tried to answer that question. It takes on renewed significance due to the worker health crisis caused by the COVID-19 pandemic.

This Article develops a framework for understanding and evaluating the federal-state system of worker protection and OSHA’s responsibility to monitor State Plans for continued effectiveness. It argues that during the COVID-19 pandemic, the system failed to provide the uniform baseline of protection that Congress sought to achieve when it created OSHA. Rather, a new empirical analysis derived from FOIA requests demonstrates that workers received different levels of protection based on where they lived. Some states exceeded the federal baseline, while others fell far below it. This Article proposes reforms to strengthen and unify the nationwide system of workplace health and safety enforcement before the next emergency.

* J.D. 2022, Yale Law School; B.A. 2014, Stanford University. A version of this Article was awarded Yale Law School’s Judge Ralph K. Winter, Jr. Prize for the best student paper written in Law and Economics during the 2021-2022 term.

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INTRODUCTION

As COVID-19 first spread throughout the United States, doctors and nurses, meatpackers and grocery clerks, bus drivers and delivery workers continued working in person, at considerable risk of illness or death. While most Americans sheltered in place, taking care to avoid contact with others, these workers risked exposure to an unknown virus every day. Their workplaces became the scenes of viral outbreaks, and it was widely reported that some employers failed to take the necessary steps to stop the disease.¹ In meatpacking plants, for example, frigid conditions, shoulder-to-shoulder workstations, and inadequate personal protective equipment combined to put workers at particular risk.² Yet data assembled by the federal Occupational Safety and Health Administration (OSHA) suggest meatpacking plants were no anomaly; workplace outbreaks were common in a wide range of establishments, such as health care facilities, restaurants, retail stores, and nursing homes.³

Faced with unhealthy conditions, thousands of workers sought help from OSHA and its state-level counterparts (State Plans). This Article presents the first comprehensive look at how the federalist worker protection system fared during the COVID-19 pandemic.⁴ This Article also aims to provide a framework for

1 See, e.g., Jazmine Hughes, *As Meatpacking Plans Look to Reopen, Some Families Are Wary*, N.Y. TIMES (May 27, 2020), <https://www.nytimes.com/interactive/2020/05/27/magazine/coronavirus-nebraska-unemployment-jobs.html> [<https://perma.cc/AYR5-YL7E>].

2 Jonathan Steinberg et al., *COVID-19 Outbreak Among Employees at a Meat Processing Facility—South Dakota, March–April 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 5 (2020); Beth L. Rubenstein et al., *Factors that Might Affect SARS-CoV-2 Transmission Among Foreign-Born and U.S.-Born Poultry Facility Workers—Maryland, May 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1906, 1906 (2020); Polly Mosendz, Peter Waldman & Lydia Mulvany, *U.S. Meat Plants Are Deadly as Ever, with No Incentive to Change*, BLOOMBERG BUSINESSWEEK (June 18, 2020), <https://www.bloomberg.com/news/features/2020-06-18/how-meat-plants-were-allowed-to-become-coronavirus-hot-spots> [<https://perma.cc/NGZ7-KW3U>]. A recent Congressional report found that in numerous factories, nearly half of the workers became infected in a single outbreak. MAJ. STAFF OF H. SUBCOMM. ON THE CORONAVIRUS CRISIS, 117TH CONG., REP. ON CORONAVIRUS INFECTIONS AND DEATHS AMONG MEATPACKING WORKERS AT TOP FIVE COMPANIES WERE NEARLY THREE TIMES HIGHER THAN PREVIOUS ESTIMATES 7 (Comm. Print 2021) [hereinafter *House Meatpacking Report*] (finding at least 59,000 meatpacking workers were infected with SARS-CoV-2 and 269 people died across the five largest meatpacking conglomerates in the first year of the pandemic). A National Academy of Sciences report estimated 6 to 8 percent of all coronavirus cases in the five months of the pandemic traced back to the meatpacking facilities. Charles Taylor, Christopher Boulos & Douglas Almond, *Livestock Plants and COVID-19 Transmission*, 117 PROC. NAT’L ACAD. SCI. 31706 (Dec. 15, 2020).

3 OSHA Vaccine ETS, 86 Fed. Reg. 61,402, 61,411-15 (Nov. 5, 2021).

4 The most similar studies are the following: The Department of Labor’s Inspector General released an audit of federal and state enforcement related to COVID-19 reviewing data from Feb. 1, 2020, to Oct. 26, 2020. This paper’s findings are generally consistent with the audit, which is discussed throughout. DEP’T OF LAB., OFF. OF INSPECTOR GEN., NO. 19-21-003-10-105, COVID-19:



understanding State Plan effectiveness and how OSHA should monitor their performance during an emergency.

Workplace safety in the United States is regulated through a hybrid federal-state system. OSHA is the federal agency responsible for setting and enforcing national standards for workplace safety. OSHA conducts enforcement in twenty-nine states, the District of Columbia, and four territories. Twenty-one states and Puerto Rico enforce federal and state workplace safety laws within their borders through State Plans.⁵ By statute, these State Plans must be “at least as effective” as OSHA.⁶ OSHA is mandated to monitor the State Plans to ensure they are.

Prior scholarship on OSHA and COVID-19 has analyzed and criticized the federal response to the pandemic,⁷ characterizing the response as weak⁸ and highlighting the government’s failure to protect essential workers,⁹ such as meatpackers,¹⁰ who are disproportionately members of minority and immigrant groups.¹¹ The State Plans, meanwhile, have been overlooked, despite their central role in the enforcement and rulemaking scheme.

In short, this Article finds that OSHA did not sufficiently protect workers

INCREASED WORKSITE COMPLAINTS AND REDUCED OSHA INSPECTIONS LEAVE U.S. WORKERS’ SAFETY AT INCREASED RISK (Feb. 25, 2021) [hereinafter 2021 DOL-OIG COVID-19 AUDIT]. The AFL-CIO also presents some of these data in summary form in its annual worker safety report. AFL-CIO, DEATH ON THE JOB: THE TOLL OF NEGLIGENCE 23-25 (May 2021). Bloomberg Law has also written about some of the data presented in this article as part of its regular OSHA coverage. See, e.g., Bruce Rolfsen, *Limited OSHA Virus Inspections Spur Push to Regain ‘Trust’*, BLOOMBERG L. (Mar. 12, 2021), <https://news.bloomberglaw.com/safety/limited-osha-virus-inspections-spur-push-to-reestablish-trust>.

⁵ *State Plans*, OCCUPATIONAL SAFETY & HEALTH ADMIN., <https://www.osha.gov/stateplans> [https://perma.cc/G2HD-4GQM] (last visited Mar. 3, 2023).

⁶ Occupational Safety and Health Act of 1970 § 18(c)(2), 29 U.S.C. § 667(c)(2) [hereinafter OSH Act].

⁷ Nancy Modesitt, *OSHA’s Comprehensive Failure to Protect Workers During the COVID-19 Pandemic*, 126 DICK. L. REV. 193 (2021); Liam Kenney, *OSHA & Addressing the Disparate Impact of COVID-19 Within Vulnerable Communities*, 30 ANNALS HEALTH L. & LIFE SCI. ADVANCE DIRECTIVE 243 (Fall 2020); Lindsay F. Wiley & Samuel R. Bagenstos, *The Personal Responsibility Pandemic: Centering Solidarity in Public Health and Employment Law*, 52 ARIZ. ST. L.J. 1235 (2020).

⁸ See Modesitt, *supra* note 7.

⁹ James J. Brudney, *Forsaken Heroes: COVID-19 and Frontline Essential Workers*, 48 FORDHAM URBAN L.J. 1 (2020).

¹⁰ Kelly K. Dineen, *Meat Processing Workers and the COVID-19 Pandemic: The Subrogation of People, Public Health, and Ethics to Profits and a Path Forward*, 14 ST. LOUIS U. J. HEALTH L. & POL’Y 7 (2020); Ruqaiyah Yearby, *Lack of Enforcement, Political Influence, and Meat and Poultry Processing Workers’ Disproportionate Rates of COVID-19 Infections and Deaths*, 35 ABA J. LAB. & EMP. L. 41 (2020); Sherley Cruz, *Essentially Unprotected*, 96 TUL. L. REV. 637 (2022).

¹¹ Catherine Powell, *Color of Covid and Gender of Covid: Essential Workers, Not Disposable People*, 33 YALE J.L. & FEM. 1 (2021); Ruqaiyah Yearby & Seema Mohapatra, *Systemic Racism, The Government’s Pandemic Response, and Racial Inequities*, 70 EMORY L.J. 1419 (2020).

under its jurisdiction from the virus. During the first year of the pandemic, the agency refused to promulgate binding rules, conducted limited on-site inspections, and issued few penalties. State Plans were all over the map. Certain State Plans grabbed hold of their authority and promulgated specific, binding COVID-19 regulations that clarified employers' responsibilities and enabled vigorous enforcement. Other State Plans relied on existing rules and conducted little or no enforcement, leaving millions of workers with less protection than they would have received under OSHA jurisdiction. Though Congress passed the Occupational Safety and Health Act of 1970 (OSH Act) with the goal of ensuring that workers nationwide were protected from hazards in their workplaces, this aim was not achieved during the pandemic. OSHA did little to encourage or monitor the State Plans, and the federalist structure resulted in protections that varied substantially based on where a worker lived.¹²

The Article draws on a new empirical analysis performed by the author of data obtained from OSHA through the Freedom of Information Act (FOIA). FOIA requests by the author produced data from February 1, 2020 through March 17, 2021 on all inspections relating to COVID-19 by OSHA or a State Plan, including who was inspected, cited, and penalized and what regulations were used. This Article also relies upon federal statutes, regulations, guidance documents, case law, Federal Register notices, and interviews.

Part I describes the history and structure of OSHA as a cooperative federalism program and seeks to clarify the meaning of "at least as effective." The Article argues that the standard refers to a four-component assessment of a State Plan's organization, standards, enforcement, and resources, providing the tools for evaluating OSHA and the State Plans' performance during the pandemic. This Part also considers how OSHA monitors State Plans and the problems that the agency has faced in ensuring continued compliance.

Part II examines the federal-state OSHA program in the context of the COVID-19 pandemic. It argues that OSHA had a duty to protect workers from COVID-19, a health hazard that created serious risks in the workplace. This duty was not substantially limited by the U.S. Supreme Court's recent decision staying the Biden Administration OSHA's controversial vaccine-or-test mandate because that decision does not question OSHA's authority to promulgate targeted rules protecting workers from COVID-19, at least in higher-hazard industries with more common interventions, such as masking, distancing, and ventilation.¹³

12 OSHA was provided an opportunity to comment on the findings of this Article. In an email, an agency spokesperson wrote: "At this time, we do not have a comment to provide. We appreciate your interest in academic work to strengthen our system of occupational health and safety." Email from Office of Public Affairs, Occupational Safety & Health Admin., to author (Dec. 14, 2022) (on file with author).

13 Nat'l Fed'n of Indep. Bus. v. Dep't of Labor, Occupational Safety & Health Admin., 142 S.

Furthermore, it does not affect the State Plans' ability to promulgate rules under state law.

Part II then describes the Article's empirical methodology and compares the responses offered by OSHA and the State Plans using the framework developed in Part I. At the level of standards, OSHA did not promulgate an emergency standard during the first year of the pandemic, instead relying on existing standards and guidance documents that were poor enforcement tools. Most State Plans followed OSHA during the first year of the pandemic, but six State Plans promulgated emergency standards, using their authority to exceed the federal minimum. The data show that State Plans were on average far more active than OSHA, conducting 4.95 times as many inspections and citing 5.33 times as many businesses per covered establishment than OSHA during the first year of the pandemic.¹⁴ Yet, the State Plans were not uniformly more vigorous. A few State Plans conducted the lion's share of enforcement, while several State Plans conducted barely any enforcement. The difference among State Plans was much starker than between OSHA states. On a per-establishment basis, the standard deviation of businesses cited was 7.25 times higher among State Plans than among states under OSHA control.¹⁵ This Part further uses a calculation of the deterrent effect of enforcement as a proxy for effectiveness, finding that some states were more, and others less, effective enforcers than OSHA.

Part III argues that standards are OSHA's best tool for monitoring State Plans during an emergency. Because State Plans are required to adopt them, or an alternative that is "at least as effective," OSHA's monitoring turns on ensuring

Ct. 661, 665-66 (2022) (per curiam) [hereinafter *NFIB v. OSHA*] ("Where the virus poses a special danger because of the particular features of an employee's job or workplace, targeted regulations are plainly permissible."); see COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) [hereinafter *OSHA Vaccine ETS*]; COVID-19 Vaccination and Testing; Emergency Temporary Standard, 87 Fed. Reg. 3,928, 3,928 (Jan. 26, 2022) (withdrawing emergency rule).

¹⁴ The data presented here derive from Freedom of Information Acts request filed with OSHA for records of all state and federal OSHA inspections related to COVID-19 from February 1, 2020 to March 17, 2021. Hereinafter, these data will be referred to in footnotes as FOIA Data. Due to jurisdictional coverage gaps, the analysis focuses exclusively on private sector employees and excludes government workers.

The author lacks a formal data science background, and the analysis of that dataset is relatively rudimentary. The author believes this study reflects important and so far, overlooked elements of the agency's response to the pandemic. She hopes it will encourage future political scientists and legal scholars to conduct further analysis.

The comparison noted in the cited text is drawn from standardized averages of all State Plan and OSHA enforcement. That is, the author summed the private sector inspections conducted and citations issued during this period for State Plans and OSHA, then divided by the number of private business establishments in each group. The state figure was then divided by the federal figure. See Section II.D.2 tbls. 1-3, *infra*, for summary and state-by-state figures.

¹⁵ FOIA Data. See Section II.D.2 tbls. 1-3, *infra*, for summary and state-by-state figures.

standards have been adopted into state law—an easier task than monitoring complicated enforcement outputs or outcomes. An empirical analysis of State Plan use of emergency standards demonstrates how effective they can be during an emergency. Finally, Part IV offers recommendations for reforming the OSH Act to improve nationwide uniformity and vigor during an emergency.

I. THE FEDERAL-STATE SYSTEM OF WORKPLACE PROTECTION

Congress passed the Occupational Safety and Health Act of 1970 (OSH Act) to address severe disparities in state-level workplace protections. At that time, annual state expenditures on worker safety ranged from 2 cents to \$2.11 per nonagricultural worker.¹⁶ In states with the most robust programs, the annual death rate from work accidents was 1.9 per 10,000 workers, while states with poor programs had rates of 11 per 10,000 workers, or 500 percent higher.¹⁷ With the OSH Act, Congress sought to elevate baseline protections and bring uniformity to the system nationwide. For “[c]learly, the life of a worker in one state is as important as a worker’s life in another state, and uniform standards must be required to protect all workers from dangerous substances.”¹⁸

Congress’s solution was to empower the U.S. Department of Labor—and its component Occupational Safety and Health Administration (OSHA)—to promulgate and enforce workplace health and safety regulations.¹⁹ However, Congress also allowed states to retain power over this area if they created a program that was “at least as effective” as OSHA.²⁰ The hybrid system held the promise of capturing the best and avoiding the worst of devolution. It enabled states to be creative and more protective than OSHA while prohibiting them from falling below a federal floor. This Part describes the State Plan system under the OSH Act and provides a framework for understanding when State Plans are “at least as effective” as OSHA—and the dimensions on which they can fall short. Providing this background is key to assessing the federalist system during the pandemic.

This Part also seeks to contribute to the OSHA literature. Despite the central role of State Plans in worker protection, legal scholarship on this topic is thin. Most scholars studying OSHA have focused on the federal agency and its standard-setting, enforcement practices, and relationship to Congress, business groups, and the labor movement.²¹ To a degree, this makes sense: State Plans tend to enforce

16 BENJAMIN W. MINTZ, *OSHA: HISTORY, LAW, AND POLICY* 7 (1984).

17 *Id.* at 7-8.

18 H.R. REP. No. 91-1291, at 15 (1970).

19 *See* OSH Act § 2, 29 U.S.C. § 651.

20 *Id.* § 18(c)(2), 29 U.S.C. § 667(c)(2).

21 The literature on OSHA is vast, but the following books and articles are emblematic of the focus on federal OSHA. THOMAS O. MCGARITY & SIDNEY A. SHAPIRO, *WORKERS AT RISK* (1993);

federal regulations, rather than designing their own, and OSHA's influence in the market and as a monitor makes it the lead player. However, it misses the key enforcement role of State Plans and the potential they exhibit for worker safety regulation amid ossified federal rulemaking and hostile federal courts.

The most comprehensive scholarship on State Plans was published in the 1970s and 1980s.²² One important line of thought explored OSHA's control over the State Plans and whether the threat of substituting OSHA for a State Plan controlled their behavior.²³ While this literature provides an interesting historical perspective, it does not reflect the thirty years of experience since.²⁴ In the past twenty years, State Plans have attracted the most attention from political scientists and economists comparing the effectiveness of State Plans and OSHA with respect to injury, illness, and fatality rates.²⁵ This Article goes beyond the recent research by theorizing the legal framework for State Plans and considering the effectiveness of individual states within the system. Political scientist Gregory Huber's book *The Craft of Bureaucratic Neutrality* offers the most sustained, recent discussion of the State Plans. Professor Huber's book analyzes and contextualizes data from the State Plans and OSHA, reaching conclusions about the comparative resources and effectiveness of each.²⁶ This Article builds on many of his insights.

CHARLES A. NOBLE, *LIBERALISM AT WORK* (1986); John Howard, *OSHA Standards-Setting: Past Glory, Present Reality and Future Hope*, 14 EMP. RTS. & EMP. POL'Y J. 237 (2010); Paula E. Berg, *When the Hazard Is Human: Irrationality, Inequity, and Unintended Consequences in Federal Regulation of Contagion*, 75 WASH. U. L.Q. 1367 (1997).

²² See MINTZ, *supra* note 16.

²³ Frank J. Thompson & Michael J. Scicchitano, *State Implementation and Federal Enforcement Priorities: Safety Versus Health in OSHA and the States*, 19 ADMIN. & SOC'Y 95 (1987); Frank J. Thompson, *The Substitution Approach to Intergovernmental Relations: The Case of OSHA*, Fall 1983 PUBLIUS 59.

²⁴ See Mary K. Marvel, *Implementation and Safety Regulation: Variations in Federal and State Administration Under OSHA*, 14 ADMIN. & SOC'Y 15 (1982) (describing trends in enforcement activity that no longer reflect current practices). For recent articles addressing the State Plans in limited form, see Joseph F. St. Cyr, *OSHA and Federalism in Times of Crisis: Issues in Federal State Relations*, 30 S. ILL. U. L.J. 273 (2006) (discussing OSHA's cooperation with State Plans after September 11th and a destructive fire in a North Carolina chicken plant); Courtney M. Malveaux, *OSHA Enforcement of the "As Effective As" Standard for State Plans: Serving Process or People?*, 46 UNIV. RICH. L. REV. 323 (2011) (former head of Virginia OSHA arguing that OSHA should focus on safety outcomes over process values in monitoring State Plans).

²⁵ See Alison D. Morantz, *Has Devolution Injured American Workers? State and Federal Enforcement of Construction Safety*, 25 J.L. ECON. & ORGS. 183 (2007); John Charles Bradbury, *Regulatory Federalism and Workplace Safety: Evidence from OSHA Enforcement, 1981-1995*, 29 J. REG. ECON. 211 (2006).

²⁶ GREGORY HUBER, *THE CRAFT OF BUREAUCRATIC NEUTRALITY: INTERESTS AND INFLUENCE IN GOVERNMENTAL REGULATION OF OCCUPATIONAL SAFETY* (2007).

A. *Striving for a Uniform Baseline of Protection*

Congress was motivated to pass the OSH Act because many states had failed to protect American workers from health and safety risks. In 1970, Congress recognized the “on-the-job health and safety crisis [as] the worst problem confronting American workers,” resulting in the annual deaths of 14,500 workers.²⁷ Problems were not evenly distributed across the country. Though states began regulating workplace hazards and toxins during the Industrial Revolution, “[t]here were too many holes in the piecemeal system and numerous hazards were left uncontrolled.”²⁸ To the extent some states regulated, “these laws were more often window dressing than anything substantive.”²⁹ One state regulated a toxic chemical, while another would not. Data were muddled by poor reporting of injuries and illnesses among the least regulated states.³⁰ Some state agencies also lacked rulemaking authority and enforced penalties too low to be meaningful.³¹ And states that did enforce risked undermining their competitive status compared to other states.³² The rise in state workers’ compensation did little to improve the situation. Workers’ compensation provided minimal economic incentive for employers to improve workplace safety or health protocols. The schemes provided even less reason for employers to improve health protocols since only an estimated 5 percent of people suffering from workplace-related diseases received benefits.³³

The House and Senate Committees that considered the bill concluded that a “comprehensive, nationwide approach” was needed.³⁴ The OSH Act sought to reduce the number of workplace injuries and fatalities “through the development and administration, by the Secretary of Labor, of uniformly applied occupational safety and health standards.”³⁵ But the bill provided a continued role for states. States would be encouraged “to take over entirely and administer their own programs for achieving safe and healthful jobsites for the Nation’s workers”³⁶—so long as they provided assurances that the program would be well resourced and administer standards that were “at least as effective” as those promulgated by OSHA. OSHA set the floor for workplace protections; states had to meet it.

27 H.R. REP. NO. 91-1291, at 14 (1970).

28 Judson MacLaury, *The Job Safety Law of 1970: Its Passage Was Perilous*, MONTHLY LAB. REV., Mar. 1981, at 18.

29 Lloyd Meeds, *A Legislative History of OSHA*, 9 GONZ. L. REV. 327, 328 (1974) (Meeds was a member of the House Committee on Education and Labor and one of the conferees on the OSH Act).

30 H.R. REP. NO. 91-1291, at 15 (1970).

31 MINTZ, *supra* note 16, at 8.

32 MacLaury, *supra* note 28, at 18.

33 MINTZ, *supra* note 16, at 9; MacLaury, *supra* note 28, at 19.

34 S. REP. NO. 91-1282, at 4 (1970); H.R. REP. NO. 91-1291, at 15 (1970).

35 S. REP. NO. 91-1282, at 1 (1970).

36 *Id.*

Congressional committee reports provide little insight into why Congress permitted states to retain their own programs. The reports speak of a need for uniformity and improved standards, not state-level “laboratories of democracy.”³⁷ But state-level programs are inherently subject to variation. According to OSHA officials who wrote about the Act near the time of passage, the answer probably lies in pragmatism. First, worker safety was long an area of classic state police power authority, and many states did not want to shut down their programs and defer to the federal government.³⁸ Relatedly, some members of Congress favored states’ rights and the value of concentrating power closer to the people.³⁹ Second, it was “a question of manpower.”⁴⁰ At the time of passage, there were about 2,000 state-level inspectors, and Congress was not prepared to take away so many jobs or ramp up the federal program to a similar scale.⁴¹ And finally, there was the issue of cost—allowing states to run their own programs would ultimately be less expensive than a fully federal program.⁴²

The OSHA system works like this: by default, the OSH Act and any regulations promulgated by OSHA preempt state worker safety rules. In default states, OSHA runs an agency office that enforces federal regulations. Because OSHA regulations are preemptive, states subject to federal enforcement may not pass workplace health and safety laws on subjects already regulated by OSHA.⁴³ However, any state may continue to regulate issues for which OSHA does not have a standard, such as second-hand tobacco smoke.⁴⁴ Because OSHA did not promulgate a standard on COVID-19 during the first year of the pandemic, states were able to regulate workplace safety protocols, such as masking.

If states wish to vary from existing OSHA rules, they must establish a “State Plan”—a state worker safety agency that meets federal standards. Today twenty-one states (and Puerto Rico) maintain their own plans, while another six states and the U.S. Virgin Islands cover only state and local government workers.⁴⁵ States

37 *Id.* at 4, 6, 18 (noting that in a “state-by-state approach, the efforts of the more vigorous states are inevitably undermined by the shortsightedness of others”); H.R. REP. NO. 91-1291, at 15 (1970) (discussing the need for “uniform standards” and “uniform reporting”).

38 John Stender, *An OSHA Perspective and Prospective*, 26 LAB. L.J. 71, 73 (1975) (“The Act would not have passed the Congress if provisions for state plans had not been included.”).

39 Barry Brown, *State Plans Under the Occupational Safety and Health Act of 1970*, 38 LAW & CONTEMP. PROBS. 745, 745-46 (1974).

40 *Id.* at 746.

41 *Id.*

42 *Id.*

43 *Gade v. National Solid Wastes Mgmt.*, 505 U.S. 88, 98-103 (1992).

44 OSH Act § 18(a), 29 U.S.C. § 667(a); see *Empire State Rest. & Tavern Ass’n, Inc. v. New York State*, 360 F. Supp. 2d 454 (N.D.N.Y. 2005) (finding state indoor smoking regulation not preempted by OSHA standards).

45 OCCUPATIONAL SAFETY & HEALTH ADMIN., *supra* note 5.

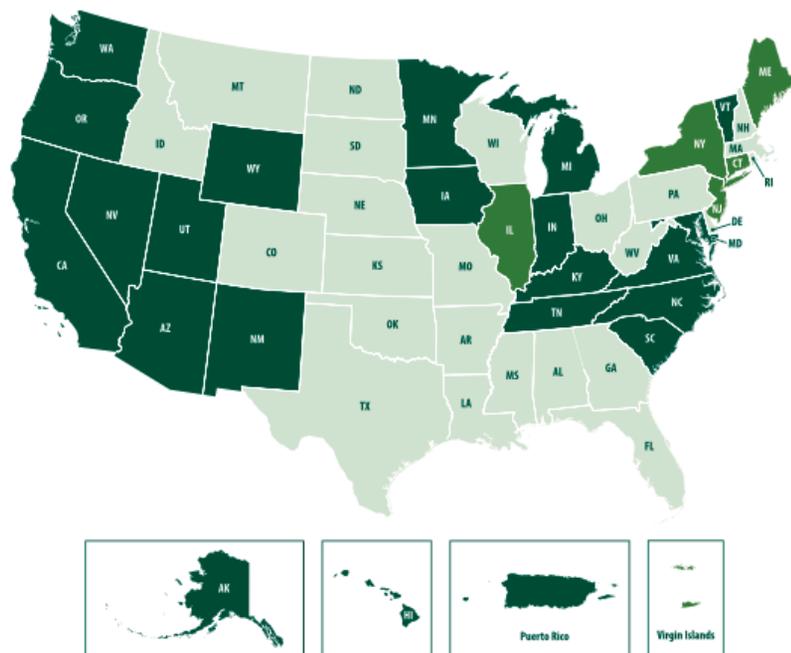
operating their own programs are clustered in the West, Mid-West, Atlantic South, and Appalachia; they do not correlate neatly along political or industrial lines.⁴⁶ Rather, as Professor Huber has shown, State Plans are associated with states having strong business interests and weak labor unions, as well as states with strong labor unions and weak business interests.⁴⁷ “In the aggregate, state adoption is likely both in states where enforcement is likely to surpass OSHA’s and where (in the absence of federal oversight) it is likely to be less stringent than OSHA’s.”⁴⁸ This suggests State Plans will represent the strongest and weakest enforcers in the system.

46 States and territories with comprehensive plans covering private and public sector workers are Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. States and territories with limited plans covering public sector workers are Connecticut, Illinois, Maine, Massachusetts, New Jersey, New York, and the Virgin Islands.

47 HUBER, *supra* note 26, at 183.

48 *Id.*

Map of OSHA and State Plan Coverage



State Plan Programs Covering Private and Public Sectors

Alaska	New Mexico
Arizona	North Carolina
California	Oregon
Hawaii	Puerto Rico
Indiana	South Carolina
Iowa	Tennessee
Kentucky	Utah
Maryland	Vermont
Michigan	Virginia
Minnesota	Washington
Nevada	Wyoming

State Plan Programs Covering Public Sector Only

(Federal OSHA covers private sector)

Connecticut
Illinois
Maine
New Jersey
New York
Virgin Islands

States Covered by Federal OSHA Private Sector Only

Alabama	Montana
Arkansas	Nebraska
Colorado	New Hampshire
Delaware	North Dakota
Dist. of Columbia	Ohio
Florida	Oklahoma
Georgia	Pennsylvania
Idaho	Rhode Island
Kansas	South Dakota
Louisiana	Texas
Massachusetts	West Virginia
Mississippi	Wisconsin
Missouri	

Source: Occupational Safety and Health State Plan Association⁴⁹

⁴⁹ OCCUPATIONAL SAFETY & HEALTH STATE PLAN ASS'N, 2020 GRASSROOTS REPORT 6, https://www.oshspa.org/resources/Documents/Publications/Grassroots/2020_Grassroots.pdf [<https://perma.cc/V379-5NNC>]. Reprinted with permission of the Occupational Safety and Health State Plan Association. Note that Massachusetts received initial approval to operate a public sector

B. Making State Plans “At Least As Effective” as OSHA

The tether that connects State Plans to OSHA is the requirement that State Plans remain “at least as effective” as OSHA. In principle, this should ensure that State Plans provide a baseline of protections for workers while avoiding the trade-offs classically associated with state enforcement.⁵⁰ However, “effective” is not defined in the statute, and the concept has led to policy debates about State Plan effectiveness and OSHA monitoring. This Section aims to flesh out the measures of State Plans through the structure set forth by the Act and provide background on the historical characteristics of the State Plans and their relationship to OSHA. The Act provides for, and OSHA tends to evaluate, State Plans along four axes: plan organization, standards, enforcement, and resources.⁵¹ First, a State Plan may only be approved if it has certain structural components, such as rulemaking authority. State Plans must, second, adopt standards and, third, conduct enforcement that is “at least as effective in providing safe and healthful employment and places of employment” as OSHA’s program. Fourth, State Plans must maintain adequate resources to carry out fully effective enforcement of their approved program. Then it is OSHA’s role to conduct a “continuing evaluation of the manner in which each State . . . is carrying out such plan.”⁵² This framework of features enables comparisons between State Plans and OSHA.

1. Plan Organization

Plan organization is at the center of maintaining effective State Plans. Essentially, State Plans are required to have certain structural components in place before they can receive approval to operate. This is key, because OSHA has maximum leverage before approval is granted.⁵³ To obtain approval to run a program, a state must designate an agency to oversee the program and provide it with authority to make rules and conduct enforcement.⁵⁴ For example, the state agency must have authority to enter and inspect workplaces.⁵⁵ The state must also

state plan in August 2022, and is not included in this map.

50 HUBER, *supra* note 26, at 172. *But see* NOBLE, *supra* note 21, at 97 (arguing that devolution to the states was motivated by business interests who believed they could capture the regulatory apparatus).

51 See OFF. OF AUDIT, OFF. OF INSPECTOR GEN., DEP’T OF LAB., NO. 02-11-201-10-105, OSHA HAS NOT DETERMINED IF STATE OSH PROGRAMS ARE AT LEAST AS EFFECTIVE IN IMPROVING WORKPLACE SAFETY AND HEALTH AS FEDERAL OSHA’S PROGRAMS [hereinafter OSHA STATE EFFECTIVENESS AUDIT] 25-26 (Mar. 31, 2011).

52 OSH Act § 18(f), 29 U.S.C. § 667(f).

53 Indeed, OSHA was very stringent when the states began submitting their plans immediately after passage of the OSH Act, causing ten states to withdraw their proposals because the agency rejected their initial submissions. Thompson, *supra* note 23, at 65.

54 OSH Act § 18(c)(1)-(2), 29 U.S.C. § 667(c)(1)-(2).

55 *Id.* § 18(c)(3), 29 U.S.C. § 667(c)(3).



“provide for the development and enforcement of safety and health standards . . . [which] are or will be as effective in providing a safe and healthful employment and places of employment as the standards promulgated” by the federal program.⁵⁶ OSHA has provided substance to this legal standard through regulations that require, among other things, that the state agency will make inspections “in response to complaints, where there are reasonable grounds to believe a hazard exists.”⁵⁷ State plans must also provide for “prompt and effective standards setting actions for the protection of employees against new and unfor[e]seen hazards, by such means as the authority to promulgate emergency temporary standards.”⁵⁸

2. Standards

Once a State Plan is established, it must keep up with federal rulemaking by adopting federal standards or state standards that are “at least as effective in providing safe and healthful employment and places of employment” as OSHA’s.⁵⁹ OSHA has declined to issue guidance on the meaning of “at least as effective,” claiming it would be neither “practicable [n]or advisable” due to the “very broad variety of contexts” in which it arises.⁶⁰ The statutory text suggests that the rule must have an equal impact on injury or illness rates. But by referring to “places of employment,” the statute suggests regulations must also create an equally safe workplace, which may not be reduced to statistical outcome measures. Thus, it may be relevant that certain protections—physical and procedural—are in place, even if their impact on worker safety outcomes cannot be measured.

States bear the burden of demonstrating the effectiveness of their alternative rules.⁶¹ Rejection is extremely rare. The only recent example involved an Arizona fall protection standard for residential roofers. In 2011, Arizona adopted a law providing for fall protection where roofers were more than fifteen feet above the ground, even though OSHA’s standard protected workers at six feet.⁶² OSHA

⁵⁶ *Id.* § 18(c)(2), 29 U.S.C. § 667(c)(2).

⁵⁷ 29 C.F.R. § 1902.4(c)(2)(i).

⁵⁸ 29 C.F.R. § 1902.4(b)(2)(v).

⁵⁹ David Michaels & Gregory Wagner, *Halting Workplace COVID-19 Transmission: An Urgent Proposal to Protect American Workers*, CENTURY FOUND. (Oct. 15, 2020), <https://tcf.org/content/report/halting-workplace-covid-19-transmission-urgent-proposal-protect-american-workers> [<https://perma.cc/U4EN-5JDT>]. In 2019, coming into the pandemic, OSHA had the lowest number of inspectors in forty years, just 862. Deborah Berkowitz, *Worker Safety in Crisis: The Cost of a Weakened OSHA*, NAT’L EMP. L. PROJECT (Apr. 28, 2020), https://www.nelp.org/publication/worker-safety-crisis-cost-weakened-osha/#_ednref14 [<https://perma.cc/C5NG-UXDP>].

⁶⁰ Changes to State Plans: Revision of Process for Submission, Review and Approval of State Plan Changes, 67 Fed. Reg. 60,123 (Sept. 25, 2002).

⁶¹ *Id.*

⁶² Arizona State Plan for Occupational Safety and Health, 79 Fed. Reg. 49,467 (Aug. 21, 2014).

determined this standard was less effective and rejected it.⁶³ After OSHA threatened to reconsider the State Plan's approval, the state withdrew its standard and adopted OSHA's.⁶⁴ More difficult questions may arise when a State Plan approaches regulation from a different angle entirely.

Most State Plans have adopted federal standards, where they exist, with some amendments or supplemental rules.⁶⁵ A recent survey found that four states—California, Michigan, Oregon, and Washington—were responsible for the “vast majority” of all unique health and safety standards.⁶⁶ But allowing states to exceed federal standards enables them to regulate issues that OSHA has not yet approached. California Division of Occupational Safety and Health (Cal/OSHA) has long been recognized for its innovative State Plan and often promulgates standards ahead of OSHA. For example, prior to the pandemic, Cal/OSHA already had a standard to prevent the transmission of respiratory diseases in health care settings.⁶⁷ The state also has standards pertaining to heat exposure and ergonomics,⁶⁸ which are not regulated by OSHA. Regulation by numerous State Plans on an issue has led OSHA to regulate issues nationwide.⁶⁹

3. Enforcement

State Plans must provide for enforcement that is “at least as effective in providing safe and healthful employment and places of employment” as OSHA's enforcement.⁷⁰ Enforcement consists of programmed inspections, as well as inspections responding to accidents, complaints, and government agency referrals. State Plan officials have historically conducted *more* inspections, but were less

63 Arizona State Plan for Occupational Safety and Health, 80 Fed. Reg. 6,652 (Feb. 6, 2015).

64 Arizona State Plan for Occupational Safety and Health, 84 Fed. Reg. 35,989 (July 26, 2019).

65 Public Citizen, *First Comprehensive Database of State OSHA Regulations and Laws Now Available* (Apr. 1, 2015), <https://www.citizen.org/news/first-comprehensive-database-of-state-osharegulations-and-laws-now-available> [<https://perma.cc/8FXR-TAGQ>].

66 *Id.* See Policy Surveillance Program, *State Occupational Health and Safety Standards Maps*, <https://phlr.org/product/state-occupational-safety-and-health-standards-maps>, for a state-by-state map of unique standards. OSHA also provides state-by-state information about unique standards on its website. QUICK FACTS AND INFORMATION ABOUT STATE PLANS, OCCUPATIONAL SAFETY & HEALTH ADMIN., <https://www.osha.gov/stateplans/approvedstateplans> [<https://perma.cc/6DYM-Q3VU>] (last visited Mar. 3, 2023) [hereinafter OSHA QUICK FACTS].

67 CAL. CODE REGS. tit. 8, § 5199.

68 CAL. CODE REGS. tit. 8, § 3395 (heat exposure for outdoor workers); CAL. CODE REGS. tit. 8, § 5110 (ergonomics).

69 For example, OSHA has recently announced it will begin a rulemaking on excessive heat, an issue on which California, Minnesota, Oregon, and Washington have already developed standards. Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings, 86 Fed. Reg. 59,316 (Oct. 27, 2021).

70 OSH Act § 18(c)(2), 29 U.S.C. § 667(c)(2).

likely to issue a citation, and penalties were lower than OSHA's.⁷¹ For example, a study of construction industry enforcement found that State Plan inspections tend to be more frequent, and enforcement less punitive, than OSHA's.⁷²

As in the case of standards, OSHA has not defined “equally effective” in this context. Scholars have studied the effectiveness of OSHA and State Plan enforcement in two ways—through the lenses of outcomes and inputs. Outcomes are injury, illness, and fatality rates; a State Plan can be understood as being “at least as effective” as OSHA if workers in a State Plan are not more likely to be hurt, sickened, or killed on the job than they would be in an OSHA state.⁷³ Inputs are metrics of agency activity, such as inspections conducted or penalties issued. A State Plan is as effective under this model if, for example, it conducts as many inspections as OSHA on a per-employer basis. The statutory text suggests that equally effective enforcement should result in comparable outcomes, but that State Plans and OSHA need not take identical approaches. Yet, it also suggests similar workplace conditions may be relevant. At least when outcomes are difficult to measure, it is reasonable to rely on standardized enforcement inputs as a proxy for deterrence and thereby effectiveness. OSHA's Inspector General has pressed the agency to focus on outcome metrics.⁷⁴ The agency has pushed back, arguing that self-reported injury and illness rates, changes in the level of economic activity in the economy, and small sample sizes in certain states limit the usefulness of outcome-based comparisons.⁷⁵

71 See *Nevada's Workplace Health and Safety Enforcement Program: OSHA's Findings and Recommendations: Hearing Before the H. Comm. on Educ. & Lab.*, 111th Cong. 62-65 (2009) (Report of Jordan Barab, Acting Assistant Secretary, OSHA) [hereinafter *Nevada OSHA Hearing*].

72 See Morantz, *supra* note 25, at 190 (noting that “[a]lthough state-plan officials conduct more inspections than their federal counterparts, the probability of an inspected company receiving a penalty is markedly higher in OSHA. Most important—regardless of whether one focuses on the penalty initially imposed or the penalty collected after postinspection bargaining has taken place between the firm and the inspector—fines are dramatically lower in state-plan states”).

73 The states with the highest average workplace fatality rates from 2010 through 2019 were Wyoming, North Dakota, Alaska, Montana, West Virginia, South Dakota, Louisiana, Mississippi, Arkansas, and Oklahoma, with only Wyoming and Alaska being State Plans. U.S. BUREAU LAB. STAT., CENSUS OF FATAL OCCUPATIONAL INJURIES, <https://www.bls.gov/iif/oshwc/foi/state-rates.htm> [<https://perma.cc/2UKW-K4V9>]. Because fatalities are relatively infrequent and associated with certain dangerous industries, a better metric would be injuries and illnesses. Unfortunately, studies have shown those figures are seriously underreported, in ways that provide a distorted picture of workplace safety nationwide. Indeed, Mendeloff and Burns found a negative correlation between workplace injuries and fatalities in the construction sector among states. John Mendeloff & Rachel Burns, *States with Low Non-Fatal Injury Rates Have High Fatality Rates and Vice-Versa*, 56 AM. J. INDUS. MED. 509, 517-18 (2013). States in the Southeast tend to have low reported injury rates and high reported fatality rates, where Alaska, Arizona, Hawaii, Iowa, Maine, Montana, Nevada, Oregon, Washington, and Wisconsin have low fatality rates and high injury rates. *Id.* at 513-14.

74 OSHA STATE EFFECTIVENESS AUDIT, *supra* note 51, at 3-7 (Mar. 31, 2011).

75 *Id.* at 27-28 (response of David Michaels, Assistant Secretary, OSHA, to audit findings).

Studies have demonstrated mixed results when comparing OSHA and the State Plans along these lines. In a paper comparing outcomes in the construction sector, Professor Alison Morantz found that fatality rates were generally lower in State Plans, but rates of nonfatal injuries were higher. She theorized that the difference could be caused by the underreporting of nonfatal injuries to OSHA, possibly due to concerns about federal inspections or differing “regulatory styles.”⁷⁶ Professor Gregory Huber has compared the inputs of state and federal enforcement, which he describes as vigor. Vigor is calculated as a function of agency resources (staffing) multiplied by agency stringency (the likelihood that an inspection will result in a violation).⁷⁷ Huber found that while OSHA is almost always more stringent than State Plans, it is less vigorous than most State Plans, which tend to have more inspectors.⁷⁸

Each approach has its value. On the one hand, the outcome-based approach is useful because it is guided by the ultimate goal of the program: to reduce the number of injuries, illnesses, and deaths that result from work. Where reliable data are available, it is probably the best, most faithful approach. On the other hand, the input-based approach recognizes the problems with measuring workplace injuries and illnesses, but insists that regulations are present and enforcers monitor workplaces. Accepting the premise that enforcement has a deterrent effect, inputs provide an indirect way of measuring the outcomes of the program. For a novel situation such as the COVID-19 pandemic, the latter approach is appropriate, because it enables some measurement and comparison of programs when full analysis of the outcomes of certain interventions may be years away.

4. Resources

The final requirement is that a State Plan must give “satisfactory assurances” that it will provide the “adequate funds” and “legal authority and qualified personnel necessary for the enforcement” of workplace standards.⁷⁹ The D.C. Circuit Court of Appeals has interpreted this as a requirement for State Plans to be staffed at such a level as will achieve “fully effective enforcement.”⁸⁰ “Once the standards were set there were to be assurances the state would have the resources ‘necessary to do the job.’”⁸¹ The D.C. Circuit case has resulted in benchmarks for state agency staffing. Those benchmarks have persisted through the present, meaning State Plans tend to be better staffed than OSHA.⁸² The federal agency has

76 Morantz, *supra* note 25, at 207.

77 HUBER, *supra* note 26, at 184-96.

78 *Id.* at 190, 194-96.

79 OSH Act § 18(c)(4)-(5), 29 U.S.C. § 667(c)(4)-(5).

80 AFL-CIO v. Marshall, 570 F.2d 1030, 1033 (D.C. Cir. 1978); *see* 29 C.F.R. § 1902.3(h).

81 AFL-CIO v. Marshall, 570 F.2d at 1037.

82 HUBER, *supra* note 26, at 194-95 (demonstrating that from 1993 to 1996 all State Plans had

recently been underfunded to a degree that limits appropriate staffing.⁸³

However, funding and staffing of State Plans vary significantly from state to state. State funding is set by a formula intended to create parity among the states, but which is not sensitive to state performance or changing needs.⁸⁴ OSHA supplies up to 50 percent of the funding for each State Plan.⁸⁵ Some states fund their programs at exactly the level required to obtain the match, while others supplement. According to Occupational Safety and Health State Plan Association, OSHA provided states with \$108 million in annual funding for enforcement programs. States contributed an additional \$232 million, which includes their 50 percent match.⁸⁶ The “overmatch” is not evenly distributed among the state plans.⁸⁷ A report from 2011 indicates that six states with comprehensive state plans contributed only the mandatory 50 percent, while fifteen State Plans (including Puerto Rico) overmatched. Washington, Oregon, and Alaska spent the most per worker, while the South Carolina, Indiana, and Arizona State Plans spent the least.⁸⁸

C. Monitoring State Plan Effectiveness

The OSH Act requires the federal agency to “make a continuing evaluation of the manner in which [the State] is carrying out such plan.”⁸⁹ Whenever OSHA finds that “in the administration of the State plan there is a failure to comply substantially with any provision of the State plan,” it must withdraw approval and reassert jurisdiction.⁹⁰ This statutory provision implies a duty on the part of OSHA to ensure not only that the statutes and regulations passed by the state meet the federal requirements, but that the State Plan’s enforcement is as effective. Yet OSHA’s levers of control are limited after a State Plan is approved. The agency has two real tools to correct problems: public investigations and threats of plan

more active inspectors relative to the number of businesses overseen than OSHA).

83 Michaels & Wagner, *supra* note 59. In 2019, coming into the pandemic, OSHA had the lowest number of inspectors in forty years, just 862. Berkowitz, *supra* note 59.

84 *Is OSHA Undermining State Efforts To Promote Workplace Safety?: Hearing Before the H. Subcomm. on Workforce Protections, Comm. on Educ. & the Workforce*, 112th Cong. 45 (2011) [hereinafter *Is OSHA Undermining State Efforts*].

85 OSHA STATE EFFECTIVENESS AUDIT, *supra* note 51, at 20 (originally, OSHA would match state dollars 1:1, but later OSHA lacked sufficient funds to meet the state contributions).

86 OCCUPATIONAL SAFETY & HEALTH STATE PLAN ASS’N, *supra* note 49 (including 23(g) funding and 21(d) funding).

87 *Is OSHA Undermining State Efforts*, *supra* note 84, at 61.

88 This figure is derived from the State Plan spending numbers disclosed in *Is OSHA Undermining State Efforts*, *id.*, at 61, compared with 2019 U.S. Census Bureau estimates of the working population.

89 OSH Act § 18(f), 29 U.S.C. § 667(f).

90 *Id.*

revocation. OSHA cannot reduce a State Plan's funding or, in most cases, directly intervene in state enforcement.

Certain high-profile scandals raised questions about the adequacy of State Plan enforcement. In 1991, an OSHA investigation following a deadly cooking fire at a North Carolina chicken plant revealed that the State Plan had never inspected the plant during its eleven years of operation.⁹¹ Moreover, it demonstrated that OSHA had permitted the state to maintain an agency with insufficient resources to conduct adequate inspections.⁹² More recently, a newspaper investigation into a series of construction worker deaths at the Las Vegas Strip revealed that Nevada officials had failed to issue citations that met the seriousness of the incident or follow up to ensure hazards were abated.⁹³ The investigation determined that state inspectors were not properly trained and did not target locations where serious hazards occurred.⁹⁴ Somehow, OSHA missed this in its reviews.

Issues have also arisen with the more mundane updating of state standards in line with federal law. For example, in 2015, Congress passed a law raising the maximum OSHA penalties.⁹⁵ To remain as effective, State Plans were required to adopt the same, with annual increases according to the Consumer Price Index. Some states have been reluctant to follow suit: Maryland *still* has not adopted the penalty adjustments,⁹⁶ and North Carolina⁹⁷ and Arizona⁹⁸ have only acted within the last year.

OSHA seeks to prevent and remedy these issues by regularly monitoring State Plans. Whenever OSHA adopts a new standard, each State Plan must adopt the same standard or one that is equally effective, and OSHA tracks this.⁹⁹ OSHA also meets with state officials on a quarterly basis and investigates public complaints

91 HUBER, *supra* note 26, at 87.

92 *Id.*

93 *Nevada OSHA Hearing*, *supra* note 71, at 17-18 (Report of Jordan Barab, Acting Assistant Secretary, OSHA).

94 *Id.*

95 Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. No. 114-74, § 701, 129 Stat. 584, 599-601.

96 OCCUPATIONAL SAFETY & HEALTH ADMIN., FY 2020 FOLLOW-UP FEDERAL ANNUAL MONITORING AND EVALUATION (FAME) REPORT, MARYLAND OCCUPATIONAL SAFETY AND HEALTH (MOSH) PROGRAM, at 5 <https://www.osha.gov/sites/default/files/2021-07/Maryland-FY-2020-Follow-up-FAME-Report.pdf> [<https://perma.cc/WE3U-BMNM>] [hereinafter MARYLAND FY 2020 FAME REPORT].

97 OCCUPATIONAL SAFETY & HEALTH ADMIN., FY 2021 COMPREHENSIVE FEDERAL ANNUAL MONITORING AND EVALUATION (FAME) REPORT, NORTH CAROLINA DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH DIVISION, at 17, <https://www.osha.gov/sites/default/files/2022-08/north-carolina-fy-2021-comprehensive-fame-report.pdf> [<https://perma.cc/7LYR-LVUZ>].

98 Arizona State Plan for Occupational Safety and Health; Proposed Reconsideration and Revocation; Reopening of Comment Period; Postponement of Public Hearing, 87 Fed. Reg. 50,026 (Aug. 15, 2022).

99 29 C.F.R. § 1902.4(b)(ii).

about State Plan performance.¹⁰⁰ Each year, OSHA issues each State Plan a Federal Annual Monitoring and Evaluation (FAME) Report, which states whether the program is “at least as effective” as OSHA.¹⁰¹

Where a major issue comes to light, investigations provide a mechanism for accountability. After the Las Vegas construction scandal was exposed, OSHA conducted a comprehensive review of the state program, and a Congressional committee held a public hearing about the Nevada situation and the efficacy of State Plan oversight.¹⁰² The leader of Nevada OSHA testified before the committee that it was “committed to change.”¹⁰³ In addition, OSHA can threaten to revoke Plan approval. This is a reasonably powerful threat, but one OSHA seldom makes. OSHA is disincentivized to do this more often, since follow-through would require establishing and paying for the full cost of a state program.¹⁰⁴ Furthermore, the process of withdrawing approval is highly demanding and requires formal administrative hearings.¹⁰⁵ OSHA has never taken this final step of revocation.

In 2014, OSHA threatened to reconsider the approval of Arizona’s plan after the state refused to implement an equally effective fall protection standard.¹⁰⁶ OSHA withdrew its proposal in 2019 after the state adopted the federal standard.¹⁰⁷ More recently, in April 2022, OSHA threatened again to revoke Arizona’s approval following the state agency’s refusal to implement the Biden Administration’s emergency standard for COVID-19, among other alleged failings over the past decade.¹⁰⁸ The threat seems to have worked: since the April 2022 notice, Arizona has made changes, including passing a statute to raise minimum penalties and authorizing the state agency to adopt an emergency standard when either the state agency or OSHA determines that a grave danger is presented.¹⁰⁹ In August 2022, OSHA postponed a hearing on the Plan reconsideration due to the changes implemented by the state.

100 OCCUPATIONAL SAFETY & HEALTH ADMIN., STATE PLAN POLICIES AND PROCEDURES MANUAL 65-69, 89-101 (May 6, 2020), https://www.osha.gov/sites/default/files/enforcement/directives/csp_01-00-005.pdf [<https://perma.cc/35SB-LY9A>].

101 *Id.* at 72-77.

102 *See, e.g., Nevada OSHA Hearing, supra* note 71.

103 *Id.* at 28.

104 HUBER, *supra* note 26, at 215.

105 29 C.F.R. § 1955.

106 Arizona State Plan for Occupational Safety and Health, 79 Fed. Reg. 49,468 (Aug. 21, 2014).

107 Arizona State Plan for Occupational Safety and Health, 84 Fed. Reg. 35,989 (July 26, 2019).

108 Arizona State Plan for Occupational Safety and Health; Proposed Reconsideration and Revocation, 87 Fed. Reg. 23,783 (Apr. 21, 2022).

109 Arizona State Plan for Occupational Safety and Health; Proposed Reconsideration and Revocation; Reopening of Comment Period; Postponement of Public Hearing, 87 Fed. Reg. 50,026 (Aug. 15, 2022).

Both of these steps are burdensome for the agency—not only must OSHA expend agency resources, it also must expend serious political clout. But the greatest challenge to ensuring the effectiveness of State Plans is that it turns squarely on OSHA’s willingness to adopt standards and conduct vigorous accountability measures. As set forth above, State Plan effectiveness is measured by the performance of OSHA. Where OSHA is ineffective in its own enforcement and standard setting, it sets a lower bar for the states. Likewise, where OSHA is less vigorous in enforcing its program, it may be less energetic in monitoring and policing the State Plans. This Article does not purport to assess OSHA’s effectiveness in all cases; others have done so—comprehensively and critically.¹¹⁰ Nor does it purport to argue that the COVID-19 response is necessarily indicative of the overall health of the agency and the federalist system. This was a unique crisis, different in scale than any that OSHA had previously sought to regulate. Nonetheless, assessing the OSHA response to COVID-19 illuminates what can occur if the federal agency is weak—states go in their own directions, offering more and less protection, much like the system that Congress sought to leave behind in 1970 with the passage of the OSH Act. Recommendations that follow from this experience suggest ways that a revitalized OSHA can monitor the State Plans and elevate national performance in case of another emergency.

II. DIVERGENT PROTECTIONS FROM COVID-19

The federalist nature of the OSHA system shaped the protections workers received from COVID-19. This Part demonstrates that OSHA offered one response during the first year of the pandemic: relatively weak enforcement of existing standards. State Plans offered varying responses: certain states, such as California and Washington, aggressively enforced existing and novel regulations to protect workers from COVID-19. Other states, such as Wyoming, North Carolina, and Iowa, relied on existing standards and enforced them with even less vigor than OSHA. In the first year of the pandemic, OSHA did not ensure that all states remained as effective as OSHA. The result was that workers received disparate levels of protection because of where they lived.

This Part proceeds as follows. First, it argues that OSHA has a duty to protect workers from COVID-19. Second, it assesses the political and legal constraints on OSHA’s activity during the first year of the pandemic, including the Supreme Court’s ruling on OSHA’s authority in 2021. Third, this Part lays out the empirical methodology in the article. Finally, this Part compares the responses of OSHA and the State Plans. The assessment builds on the four-part framework of State Plan effectiveness developed in Section I.B—structure, standards, enforcement, and resources. Because the State Plans’ structure preexisted the pandemic, the latter

110 See MCGARITY & SHAPIRO, *supra* note 21.

three elements supply the appropriate axes on which to evaluate the plans. In an emergency such as the COVID-19 pandemic, OSHA and the State Plans should be compared based on the standards they promulgated pursuant to the hazard and the degree to which they enforced them. The proceeding discussion focuses mainly on standards and enforcement. It finds that the approaches differed dramatically among states, with some being more effective than OSHA and many being less.

A. *OSHA's Duty to Protect Workers from COVID-19*

In passing the OSH Act, Congress was uniquely focused on protecting workers from diseases they might develop in the workplace. A Senate Report described the “field of occupational health” as “particularly bleak, and, due to the lack of information and records, it may well be considerably worse than we currently know.”¹¹¹ Accordingly, the statute directs OSHA to promulgate and enforce standards “reasonably necessary or appropriate to provide a safe or *healthful* employment and places of employment.”¹¹²

OSHA has acted on its authority over health-related workplace risks over time. For example, the agency promulgated standards limiting the allowable levels of “dangerous chemicals and dusts” that cause respiratory diseases and cancer.¹¹³ OSHA has also regulated worker exposure to infectious diseases. In 1991, the agency promulgated a rule protecting health care workers from bloodborne pathogens.¹¹⁴ Later during the H1N1 (Swine) Flu outbreak in 2009, OSHA issued a directive to regional offices instructing them to enforce existing standards to protect health care workers from the virus.¹¹⁵ The agency also broadly mandates cleanliness in the workplace to ensure employees are not unnecessarily exposed to unsanitary, disease-causing conditions.¹¹⁶

Whether OSHA’s responsibility to protect workers from health risks extended to COVID-19 was debated during the pandemic. Conservatives and business groups argued that COVID-19 was a ubiquitous risk that was not sufficiently job-related to fall under OSHA’s purview. Liberals and worker advocates argued that the risk was job-related because people were exposed in their workplaces, and most people could not choose not to go to work. The U.S. Supreme Court weighed in on this question in *National Federation of Independent Businesses v. Department of Labor, Occupational Safety and Health Administration*. There, business groups

111 S. REP. NO. 91-1282, at 2 (1970).

112 29 U.S.C. § 652(8) (emphasis added).

113 MCGARITY & SHAPIRO, *supra* note 21, at 13.

114 Berg, *supra* note 21, at 1373 n.32.

115 OCCUPATIONAL SAFETY & HEALTH ADMIN., CPL-02-02-075, ENFORCEMENT PROCEDURES FOR HIGH TO VERY HIGH OCCUPATIONAL EXPOSURE RISK TO 2009 H1N1 INFLUENZA (Nov. 20, 2009).

116 *E.g.*, 29 C.F.R. § 1910.141(a)(4)(ii).

and states challenged the agency’s authority to promulgate a rule requiring employees of large employers to get vaccinated against COVID-19 or wear a mask and submit to weekly testing.¹¹⁷ The Court found that the challengers to the rule were likely to succeed on the merits because a sweeping vaccine mandate was beyond OSHA’s statutory authority.¹¹⁸ However, the Court affirmed that OSHA has significant power to protect workers from COVID-19—and, going forward, other emergent risks and pandemics. After explaining why this rule was unlawful, the Court stated that its opinion did not question OSHA’s authority to “regulate occupation-specific risks related to COVID-19. Where the virus poses a special danger because of the particular features of an employee’s job or workplace, targeted regulations are plainly permissible.”¹¹⁹

Having the power to protect workers from COVID-19, OSHA also had the responsibility to do so. In passing the OSH Act, Congress took over and preempted an area of traditional state authority after deeming the existing scheme deficient. This maneuver implies that Congress both sought to create a coherent national scheme *and* to actively protect workers from unnecessary workplace hazards. This is not to say that private parties have a general claim to sue OSHA for failure to address the pandemic—although unions and workers made viable claims that OSHA was required to conduct enforcement responsive to imminent dangers¹²⁰ and issue emergency standards.¹²¹ But the Act does suggest the agency is responsible for workers’ health, and should be held accountable by Congress and the public. OSHA protection relating to COVID-19 was particularly important because workers’ compensation schemes and the OSH Act tend to displace any private right of action to secure a safe workplace.¹²² In the face of a global pandemic, OSHA and the State Plans had a duty to protect people from COVID-19 at work.

B. Methodology

How did OSHA fulfill its duty to workers during the pandemic? This Article seeks to answer that question for OSHA and the State Plans using the framework put forth in Part I, a review of agency actions and regulations, and an original empirical analysis. The empirical analysis is based on two FOIA requests filed with OSHA in 2021 and 2022. The first request sought data on all inspections relating to COVID-19 that resulted in a violation (Violations Request). The second

117 *NFIB v. OSHA*, 142 S. Ct. 661 (2022) (per curiam).

118 *Id.* at 664-65.

119 *Id.* at 665-66.

120 *Jane Does v. Scalia*, 530 F. Supp. 3d 506 (M.D. Pa. 2021).

121 *In re AFL-CIO*, No. 20-1158, 2020 WL 3125324 (D.C. Cir. June 11, 2020) (per curiam).

122 *See Palmer v. Amazon.com*, 498 F. Supp. 3d 359, 368-71 (E.D.N.Y. 2020); *Rural Comm. Workers Alliance v. Smithfield Foods*, 459 F. Supp. 3d 1228, 1240-41 (W.D. Mo. 2020).

request sought data on all inspections, irrespective of their outcome (Inspections Request). In response to these requests, OSHA provided spreadsheets exported from their Integrated Management Information System, which OSHA and the State Plans use to track enforcement inputs. The data in each request cover inspections opened from February 1, 2020 to March 17, 2021. Each spreadsheet contains fifty-five fields, including inspection number, inspecting office code, establishment name, ownership type, inspection dates, inspection type, standard cited, penalty assessed, and case status at the time of export. The Inspections Request included 8,584 entries, corresponding to all inspections conducted relating to COVID-19. The Violations Request included 7,703 entries, corresponding to all violations issued during inspections relating to COVID-19. An important note: not every violation in the dataset relates to COVID-19. When an inspector visits an establishment, they may encounter and cite *other* safety and health hazards, which are included in the dataset. Because the dataset did not include a description of the hazards cited, it was not possible to exclude secondary violations from the dataset.

To facilitate a comparison of OSHA with individual State Plans, the author matched the FOIA sheets with a reference dataset of inspection office names and codes supplied by OSHA. By matching the inspection office codes from the main sheets, it was possible to associate each inspection and violation with a state or OSHA office. The author also used U.S. Census data to standardize across states. To better understand the industries where enforcement took place, the violations dataset was further matched with the North American Industry Classification System codes. Bringing these datasets together facilitated comparisons along state and industry lines.

The Inspection and Violation Requests covered inspections and violations for private and public sector workplaces. The author limited her analysis to private sector workplaces to enable a better one-to-one comparison between OSHA and the State Plans.¹²³ The author also excluded the small amount of federal auxiliary enforcement that OSHA conducts in State Plans over limited industries and federal enclaves.¹²⁴

An important limitation of this study is recognizing that OSHA and the State Plans was just one part of the national response to COVID-19. States and municipalities issued thousands of different rules, many of which affected workplaces. Mask mandates, for example, were a common local intervention that

¹²³ State Plans must cover state and local government workers, where OSHA is not permitted to do so. This has resulted in six states adopting State Plans solely to regulate government workers. Likewise, only OSHA can inspect federal workplaces, resulting in a small number of federal inspections in comprehensive State Plan states.

¹²⁴ This auxiliary enforcement was included in Table 5, *infra*, which looks exclusively at federal data.

protected workers from each other and from customers. State and local governments also conducted enforcement, often through health department inspectors. Analyzing the state responses, which took place under the auspices of non-OSHA agencies, was beyond the feasible scope of the research for this Article.¹²⁵ However, it does not undermine this project, since OSHA and the State Plans have an independent responsibility to protect worker safety, regardless of local government efforts. It is no answer to the problems raised in this Article that other state agencies tried to fill the void left by lacking OSHA enforcement. Preemptive OSHA regulations also had the unique potential to establish uniform protections nationwide and resolve the disparate protections offered state-by-state.

C. OSHA's Response

During the first year of the pandemic, the Trump Administration's OSHA chose a policy of leniency and flexibility over regulatory standards and enforcement as a means of addressing the COVID-19 pandemic in workplaces. Indeed, a report by the Department of Labor's Inspector General found that "OSHA's enforcement activities did not sufficiently protect workers from COVID-19 health hazards. As a result, there is a heightened risk that workers suffered unnecessary exposure to the virus."¹²⁶ As will be argued more fully in Part III below, OSHA's decision not to issue an emergency standard also likely resulted in weaker enforcement among State Plans. Because OSHA had a responsibility to protect workers from COVID-19 and establish a meaningful baseline of nationwide protection, failure to issue a standard during the first year violated the agency's duty to protect workers from COVID-19.

1. Standards

OSHA had the power to protect workers from COVID-19 by applying existing regulations or drafting new ones. During the Trump Administration, the agency chose to rely on existing regulations and extensive nonmandatory guidance rather than issue emergency standards. A top OSHA official, Loren Sweatt, told a Congressional committee that the guidance-based approach "allowed the agency a more nimble response to the ever-changing understanding of the virus."¹²⁷

125 See Terri Gerstein, *State and Local Workers' Rights Innovations: New Players, New Laws, New Methods of Enforcement*, 65 ST. LOUIS U. L.J. 45 (2020).

126 DEP'T OF LAB., OFF. OF INSPECTOR GEN., NO. 19-23-001-10-105, COVID-19: OSHA'S ENFORCEMENT ACTIVITIES DID NOT SUFFICIENTLY PROTECT WORKERS FROM PANDEMIC HEALTH HAZARDS (Oct. 31, 2022).

127 *Examining the Federal Government's Actions to Protect Workers from COVID-19: Hearing Before the Workforce Protections Subcomm., H. Comm. on Educ. & Lab.* (May 28, 2020) (testimony of Loren Sweatt, Principal Deputy Assistant Sec'y, Occupational Safety & Health Admin.), <https://www.osha.gov/news/testimonies/05282020> [<https://perma.cc/9SFV-EWJK>] [hereinafter

Guidance is easier to update than regulations, she argued, and could be more specifically tailored to different industries.¹²⁸ However, guidance is also nonbinding, meaning it cannot directly support the issuance of violations and penalties. Moreover, the guidance was often drafted to make compliance easier for employers rather than to enhance protection for workers. And it did little to facilitate the enforcement of violations.

OSHA's toolbox going into the pandemic looked like this. First, OSHA had the General Duty Clause (GDC), which functions like a catch-all tort standard that OSHA can use when it lacks a specific standard to capture the violation. Every covered employer has a general duty to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious bodily harm to his employees."¹²⁹ Despite its broad sweep, the GDC is notoriously difficult to enforce.¹³⁰ OSHA also had personal protective equipment standards, which require employers to supply and properly fit respirators where employees are exposed to hazardous agents, including viruses.¹³¹ These standards are immediately applicable to health care and certain manufacturing facilities, but lack general applicability for COVID-19. OSHA also had a rule requiring employers to keep records of workplace illnesses and deaths, which the agency interpreted to include COVID-19 contracted at work.¹³²

OSHA also had authority to issue an emergency temporary standard (ETS) for COVID-19.¹³³ OSHA is required by law to issue an ETS if the agency "determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic of physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from danger."¹³⁴ These standards allow OSHA to respond quickly to a new threat without following the usual and lengthy notice-and-comment procedures that take the agency nearly eight years to complete on average.¹³⁵ Like permanent standards, State Plans must

Sweatt Testimony].

128 *Id.*

129 OSH Act § 5(a)(1), 29 U.S.C. § 654.

130 See Emergency Petition for a Writ of Mandamus at 18-21, *In re AFL-CIO*, No. 20-1158 (D.C. Cir. filed May 18, 2020) (internal quotations omitted), *mandamus denied*, 2020 WL 3125324 (D.C. Cir. June 11, 2020) (per curiam); Section III.A, *infra*.

131 29 C.F.R. § 1910.134. See Respiratory Protection, 63 Fed. Reg. 1160 (Jan. 8, 1998) (noting OSHA's intent to address "bioaerosols," including "epidemics of infections including colds [and] viruses").

132 29 C.F.R. § 1904.

133 OSH Act § 6(c), 29 U.S.C. § 655(c).

134 *Id.* § 6(c)(3), 29 U.S.C. § 655(c)(1).

135 U.S. GOV'T ACCOUNT. OFF., NO. 12-330, WORKER SAFETY AND HEALTH: MULTIPLE CHALLENGES LENGTHEN OSHA'S STANDARD SETTING (2012).

follow by adopting the emergency standards or issuing their own standards that are at least as effective. The statute provides that an emergency standard must be replaced by a permanent rule within six months, although OSHA has never tried to extend an emergency rule past this point.¹³⁶

OSHA declined to issue any emergency standards during the first year of the pandemic. Sweatt stated that existing tools could address the hazard of COVID-19 without an ETS.¹³⁷ “Moreover, attempting to permanently address workplace exposure to SARS-CoV-2 based on the evolving information that is currently available to the agency could have counterproductive consequences, and would deprive the agency of the flexibility that it needs to respond to new information during the current pandemic.”¹³⁸ That decision was opposed by labor groups, with the AFL-CIO calling it “an abuse of agency discretion so blatant and of ‘such magnitude’ as to amount to a clear ‘abdication of statutory responsibility.’”¹³⁹ The federation of labor unions petitioned the D.C. Circuit Court of Appeals for a writ of mandamus ordering OSHA to issue an emergency standard.¹⁴⁰ The unions claimed an ETS was “necessary” to protect working Americans exposed to the “grave danger” of coronavirus, because OSHA’s existing standards did not mandate the kind of precautions most likely to prevent transmission, such as physical distancing and isolation.¹⁴¹ The D.C. Circuit deferred to the agency’s discretion and denied the petition.¹⁴²

OSHA instead issued non-binding guidance.¹⁴³ The agency’s initial March 2020 guidance documents encouraged employers to assess the risk facing their workplace, adopt engineering and administrative controls, and supply personal protective equipment.¹⁴⁴ OSHA viewed health care workers and mortuary workers

136 OSH Act § 6(c)(3), 29 U.S.C. § 655(c)(3).

137 Letter from Loren Sweatt, Principal Deputy Assistant Secretary, OSHA, to Richard Trumka, President, AFL-CIO, at 1-2 (May 29, 2020), <https://www.passnational.org/images/PDFs/COVID-19/OSHAMay292020ResponsetoAFL.pdf> [<https://perma.cc/7VJJ-MXK8>] [hereinafter Sweatt Letter].

138 *Id.* at 5.

139 Emergency Petition for a Writ of Mandamus, *supra* note 130, at 5.

140 *Id.* The American Federation of Teachers and other unions also sought mandamus from the Ninth Circuit to force the agency to move forward on its abandoned infectious disease standard. Petition for Writ of Mandamus, *In re Amer. Fed. Teachers v. OSHA*, No. 10-73203 (9th Cir. filed Oct. 29, 2020). That case was not decided on the merits, and the case was closed after President Biden took office.

141 Emergency Petition for a Writ of Mandamus, *supra* note 130, at 18-19.

142 *In re AFL-CIO*, No. 20-1158, 2020 WL 3125324, at *1 (D.C. Cir. June 11, 2020) (per curiam).

143 See Modesitt, *supra* note 7, at 203-24 (providing a comprehensive critique of OSHA’s policy response).

144 OCCUPATIONAL SAFETY & HEALTH ADMIN., GUIDANCE ON PREPARING WORKPLACES FOR COVID-19 (Mar. 2020), <https://www.osha.gov/sites/default/files/publications/OSHA3990.pdf> [<https://perma.cc/E8FF-VFS4>].

as the highest risk, suggesting ventilation and full respirator use, where possible. For lower-risk workers, OSHA recommended mere monitoring. OSHA would later issue more specific, industry-level guidance documents. For example, OSHA issued guidance that encouraged but did not require meatpackers to create a COVID-19 assessment and control plan, implement physical distancing and barriers, and “consider modifying” sick leave policies to ensure workers were not penalized for staying home if they had COVID-19, among other interventions.¹⁴⁵ OSHA’s guidance in other areas tended to reduce employer obligations rather than elevate them.¹⁴⁶ For example, in light of the “difficulty making determinations about whether workers who contracted COVID-19 did so due to exposures at work,”¹⁴⁷ OSHA interpreted recordkeeping requirements to require minimal reporting of COVID-19 cases, a decision that limited the agency’s ability to track outbreaks.¹⁴⁸

In sum, the Trump Administration’s OSHA issued no enforceable standards during the first year of the pandemic, even though standards were the main way that the 1970 Congress expected OSHA to protect workers from hazards. Instead, it reduced employer obligations and issued nonmandatory guidance. These decisions had far-reaching implications: not only did they apply to workers in OSHA states, but they also set a low baseline for State Plans.

145 OCCUPATIONAL SAFETY & HEALTH ADMIN. & CTRS. FOR DISEASE CONTROL & PREVENTION, MEAT AND POULTRY PROCESSING WORKERS AND EMPLOYERS (July 9, 2020). The choice to issue guidelines over rules and the guidelines themselves have been criticized. See *House Meatpacking Report*, *supra* note 2, at 3; Yearby, *supra* note 10, at 45-49.

146 In anticipation of N95 respirator mask shortages, for example, OSHA stated that it would not enforce the fit-testing requirement if employers were using certified National Institute for Occupational Safety and Health respirators and making a “good-faith effort to comply.” OCCUPATIONAL SAFETY & HEALTH ADMIN., TEMPORARY ENFORCEMENT GUIDANCE—HEALTHCARE RESPIRATORY PROTECTION ANNUAL FIT-TESTING FOR N95 FILTERING FACEPIECES DURING THE COVID-19 OUTBREAK (Mar. 14, 2020), <https://www.osha.gov/laws-regs/standardinterpretations/2020-03-14> [<https://perma.cc/2EBS-3L7L>].

147 OCCUPATIONAL SAFETY & HEALTH ADMIN., ENFORCEMENT GUIDANCE FOR RECORDING CASES OF CORONAVIRUS DISEASE 2019 (COVID-19) (Apr. 10, 2020), <https://www.osha.gov/memos/2020-04-10/enforcement-guidance-recording-cases-coronavirus-disease-2019-covid-19> [<https://perma.cc/8AD2-5X4B>].

148 While employers were required to record work-related COVID-19 cases, they were not required to report them to OSHA unless (a) the employee was hospitalized within twenty-four hours of a work-related exposure or (b) the employee died within thirty days of an exposure. *Frequently Asked Questions: Reporting*, OCCUPATIONAL SAFETY & HEALTH ADMIN., <https://www.osha.gov/coronavirus/faqs#reporting> [<https://perma.cc/G7A4-FLDJ>] (last visited Mar. 3, 2023). This standard is a poor fit for COVID-19, since most people are not hospitalized within a day of exposure. Hospitalization tends to occur from three to ten days after symptom onset. Christel Faes et al., *Time Between Symptom Onset, Hospitalisation and Recovery or Death: Statistical Analysis of Belgian COVID-19 Patients*, 2020 INT’L J. ENV’T RSCH. & PUB. HEALTH 7560. See DEP’T OF LAB., OFF. OF INSPECTOR GEN., *supra* note 126 (noting that OSHA lacked complete data on workplace spread of COVID-19 due to the lacking reporting standard).

These policies should be understood in the context of the Trump Administration’s approach to regulation in general and during the pandemic. President Trump entered office promising to “deconstruct[] the administrative state” by rolling back regulations and reducing funding for federal agencies.¹⁴⁹ Before the pandemic began, the OSHA inspectorate reached its lowest level since the 1970s, and key leadership positions sat vacant.¹⁵⁰ In this deregulatory posture, OSHA stopped work on an airborne infectious disease standard that would have applied to COVID-19 in health care institutions.¹⁵¹ Trump also heralded himself as pro-business and issued an executive order encouraging agencies to honor their good faith efforts to comply with regulations during the pandemic.¹⁵² It has been reported that he was cozy with industry too, and that their priorities, particularly the meatpacking industry’s, influenced the Administration.¹⁵³

But this approach cannot be entirely reduced to Democratic-Republican politics. Little changed in the first six months of the Biden Administration. On his first day in office, President Biden issued an executive order demanding OSHA issue revised guidance within two weeks, review enforcement and target violations putting large numbers of workers at risk, and decide whether an ETS was warranted by March 15, 2021.¹⁵⁴ But wavering support for mandates and the promise of vaccines lessened the sense of urgency and called into question whether a “grave danger” would persist much longer.¹⁵⁵ The new Administration again

149 Gregory Krieg, *What the “Deconstruction of the Administrative State” Really Looks Like*, CNN (Mar. 30, 2017), <https://www.cnn.com/2017/03/30/politics/trump-bannon-administrative-state> [<https://perma.cc/XR9W-FTH8>].

150 Sharon Lerner, *How Trump Gutted OSHA and Workplace Safety Rules*, INTERCEPT (Oct. 20, 2020), <https://theintercept.com/2020/10/20/trump-osha-workplace-safety-covid> [<https://perma.cc/F6YE-BPKB>].

151 *Id.*

152 Exec. Order No. 13924, *Regulatory Relief to Support Economic Recovery*, 85 Fed. Reg. 13924 (May 19, 2020), <https://www.federalregister.gov/documents/2020/05/22/2020-11301/regulatory-relief-to-support-economic-recovery> [<https://perma.cc/88VS-P7SX>].

153 See Michael Grabell & Bernice Yeung, *Emails Show the Meatpacking Industry Drafted an Executive Order to Keep Plants Open*, PROPUBLICA (Sept. 14, 2020), <https://www.propublica.org/article/emails-show-the-meatpacking-industry-drafted-an-executive-order-to-keep-plants-open> [<https://perma.cc/H5LX-6GZP>]; Jane Mayer, *How Trump is Helping Tycoons Exploit the Pandemic*, NEW YORKER (July 20, 2020), <https://www.newyorker.com/magazine/2020/07/20/how-trump-is-helping-tycoons-exploit-the-pandemic> [<https://perma.cc/8WDS-28ED>].

154 Exec. Order No. 13999, *Protecting Worker Health and Safety*, 86 Fed. Reg. 7211 (Jan. 21, 2021) <https://www.federalregister.gov/documents/2021/01/26/2021-01863/protecting-worker-health-and-safety> [<https://perma.cc/M6TG-4DQE>].

155 Bruce Rolfsen, *Labor Chief Walsh Puts Hold on OSHA Virus Rule for More Analysis*, BLOOMBERG L. (Apr. 6, 2021), <https://news.bloomberglaw.com/bloomberg-law-news/labor-chief-walsh-puts-hold-on-osha-virus-rule-for-more-analysis>; Timothy Noah, *Is Biden Ditching His Promise to Protect Workers from COVID-19?*, NEW REPUBLIC (Apr. 14, 2021), <https://newrepublic.com/article/162040/covid-osha-standards-workplace-safety>

issued guidance documents,¹⁵⁶ which experts said had more teeth than the earlier advisory documents,¹⁵⁷ but which did not create mandatory obligations.

The Biden Administration finally implemented emergency standards in mid-2021, including the vaccine and health care standards. In June 2021, OSHA issued an ETS covering health care workers,¹⁵⁸ while quietly giving up a plan to issue an ETS for all workers.¹⁵⁹ In September, OSHA promulgated an ETS requiring employers to mandate vaccination or weekly testing for their workers.¹⁶⁰ The health care standard, which set requirements for health screenings, personal protective equipment, ventilation, physical distancing, and barriers, faced no meaningful challenges from anti-regulatory groups or states,¹⁶¹ while the vaccination standard was struck down based on lawsuits filed by states and business groups, as described in Section II.A.

2. Enforcement

OSHA issued its first violation to an employer on July 13, 2020—more than four months after the pandemic began. The first violations were issued to three skilled nursing facilities in Ohio after seven employees were hospitalized with COVID-19.¹⁶² The agency cited the company for failure to develop a written

[<https://perma.cc/D2SY-CF65>].

156 OCCUPATIONAL SAFETY & HEALTH ADMIN., PROTECTING WORKERS: GUIDANCE ON MITIGATING AND PREVENTING THE SPREAD OF COVID-19 IN THE WORKPLACE (Jan. 29, 2021), <https://www.osha.gov/coronavirus/safework> [<https://perma.cc/N6RH-NNB8>].

157 Kyle Bagenstose & Rachel Axon, *Biden's OSHA Issues COVID-19 Worker Safety Guidelines, Considers Enforceable Orders*, USA TODAY (Jan. 29, 2021), <https://www.usatoday.com/story/news/2021/01/29/bidens-osha-issues-new-covid-19-guidelines-worker-safety/4297364001> [<https://perma.cc/37HF-6TX6>].

158 OSHA Healthcare ETS, 86 Fed. Reg. 32,376 (June 21, 2021).

159 Bruce Rolfsen, *OSHA Virus Rule Intended to Cover All Workers, Draft Shows*, BLOOMBERG L. (June 28, 2021), <https://news.bloomberglaw.com/bloomberg-law-news/osha-covid-19-rule-intended-to-cover-all-workers-draft-shows>.

160 OSHA Vaccine ETS, 86 Fed. Reg. 61,402 (Nov. 5, 2021).

161 Two labor unions petitioned for review on the grounds that it was underinclusive and arbitrarily excluded other workers. But those challenges were stayed or withdrawn as OSHA proceeded on its second standard targeting vaccines. *UFCW v. OSHA*, No. 21-1143 (D.C. Cir. filed June 24, 2021) (held in abeyance); *Nat'l Nurses United v. OSHA*, No. 21-71142 (9th Cir. voluntarily dismissed July 7, 2021). The health care industry did not mount a legal challenge, despite asking for a six-month period in which to implement the rule. Fatima Hussein, *Hospital Group Asks OSHA for 6-Month Halt of COVID-19 Standard*, BLOOMBERG L. (June 30, 2021), <https://news.bloomberglaw.com/safety/hospital-group-asks-osha-for-6-month-halt-of-covid-19-standard>.

162 News Release, U.S. Dep't of Lab., *U.S. Department of Labor Cites Ohio Nursing Facilities for Failing to Fully Implement Respiratory Programs to Protect Employees from Coronavirus* (July 21, 2020), <https://www.dol.gov/newsroom/releases/osha/osha20200721> [<https://perma.cc/AGX6-ZPMK>].

respirator protection program and “failing to provide medical evaluations to determine employees’ ability to use a respirator in the workplace.”¹⁶³

The agency’s policies suggest that early on, OSHA was focused on responding to a deluge of complaints while protecting its inspectors from entering workplaces where they would be exposed to COVID-19, except in the most dire situations.¹⁶⁴ The enforcement plan prioritized “fatalities and imminent danger exposures . . . with particular attention given to healthcare organizations and first responders.”¹⁶⁵ The guidance stated that on-site inspections would be warranted mainly in cases of alleged “unprotected exposures to COVID-19 for workers with high/very high risk of transmission,” such as exposure to COVID-19 patients in hospitals without adequate personal protective equipment.¹⁶⁶ Most other cases, where workers were in lower-risk situations or performing lower-risk tasks, would be handled by phone or letter.¹⁶⁷ In a non-formal, remote inspection, OSHA sends a letter to the employer reporting the complaint and asking for information documenting that the workplace is compliant or that the problem has been resolved.¹⁶⁸ The agency’s Inspector General argued these were less effective than in-person inspections, which frequently result in immediate resolution of the hazard.¹⁶⁹

The guidance document stated that employers could be cited for violations of existing regulations covering recordkeeping, personal protective equipment (including respirator use), sanitation, and the GDC.¹⁷⁰ Even though no standard directly responded to the hazard except for the GDC, the guidance curtailed inspectors’ ability to issue these citations, because any citation under the clause needed formal sign-off by the National Office prior to issuance.¹⁷¹ OSHA maintained that it would take account of employers’ “good faith efforts” at compliance with health and safety standards during the ongoing emergency.¹⁷²

After the initial nursing home citations, OSHA increased its enforcement, issuing 1,552 violations after COVID-19-related inspections of private businesses

163 *Id.*

164 OCCUPATIONAL SAFETY & HEALTH ADMIN., INTERIM ENFORCEMENT RESPONSE PLAN FOR CORONAVIRUS DISEASE 2019 (COVID-19) (April, 13, 2020), <https://www.osha.gov/memos/2020-04-13/interim-enforcement-response-plan-coronavirus-disease-2019-covid-19> [<https://perma.cc/U9MW-DR7S>] [hereinafter OSHA APRIL 2020 INTERIM ENFORCEMENT PLAN].

165 *Id.*

166 *Id.*

167 *Id.*

168 2021 DOL-OIG COVID-19 AUDIT, *supra* note 4, at 5.

169 *Id.* at 8-9.

170 OSHA APRIL 2020 INTERIM ENFORCEMENT PLAN, *supra* note 164.

171 *Id.*

172 OCCUPATIONAL SAFETY & HEALTH ADMIN., DISCRETION IN ENFORCEMENT WHEN CONSIDERING AN EMPLOYER’S GOOD FAITH EFFORTS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC (Apr. 16, 2020), <https://www.osha.gov/laws-regs/standardinterpretations/2020-04-16> [<https://perma.cc/VU34-TAVZ>].

from September through December 2020.¹⁷³ As discussed in more detail below,¹⁷⁴ most of those citations were issued in the health care sector after fatalities or catastrophes in the workplace rather than through proactive investigation. Advocates have argued businesses were not fined and violations were not publicized to amplify their deterrent effect.¹⁷⁵

D. State Plan Responses

The State Plans responded to COVID-19 in ways that were both *more* and *less* effective than OSHA. At the level of standards, no State Plan fell below OSHA's bar during the first year of the pandemic since OSHA did not issue a standard. However, several State Plans adopted emergency standards that provided significantly more protection than existing federal regulations. As for enforcement, more than half of the State Plans operated at a level that produced less of a deterrent effect than OSHA. Despite this, OSHA did not press them into more stringent enforcement.

1. Standards

State Plans remained as effective as OSHA insofar as OSHA did not issue any COVID-19-related standards during the first year of the pandemic. Like OSHA, most State Plans responded to COVID-19 with a combination of guidance and existing standards. For example, South Carolina OSHA issued a guidance document in May 2020 that suggested mitigation measures based on a sector's risk level and identified the OSHA regulations that could be cited.¹⁷⁶ State Plans also conducted informational sessions with employers and consultations relating to safety measures.¹⁷⁷

However, some State Plans issued emergency standards that made them more effective than OSHA. California, Michigan, Oregon, and Virginia issued

173 FOIA Data.

174 See Section III.A, *infra*, for data and a discussion of OSHA's focus on the health care sector.

175 Noam Scheiber, *Labor Department Curbs Announcements of Company Violations*, N.Y. TIMES (Oct. 23, 2020), <https://www.nytimes.com/2020/10/23/business/economy/labor-department-memo.html>.

176 S.C. OCCUPATIONAL SAFETY & HEALTH ADMIN., WORKPLACE RE-ENTRY: PROTECTING THE SAFETY AND HEALTH OF WORKERS—CORONAVIRUS DISEASE (COVID-19) (May 14, 2020), <http://www.scosha.llronline.com/pdfs/2020/SC%20OSHA%20Work%20Re-Entry.pdf> [<https://perma.cc/R CJ6-JHET>].

177 See, e.g., OCCUPATIONAL SAFETY & HEALTH ADMIN., FY 2020 FOLLOW-UP FEDERAL ANNUAL MONITORING AND EVALUATION (FAME) REPORT, NORTH CAROLINA DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH DIVISION (Sep. 30, 2020), at E-14, <https://www.osha.gov/sites/default/files/2021-07/North-Carolina-FY-2020-Follow-up-FAME-Report.pdf> [<https://perma.cc/NW2L-QB36>] [hereinafter NORTH CAROLINA FY 2020 FAME REPORT].

temporary standards that set out specific requirements for employers to protect their workers from COVID-19. New Mexico issued a rule improving reporting of workplace illness, and Washington used a simple standard that empowered the State Plan to enforce the governor’s emergency orders relating to workplaces.¹⁷⁸ In promulgating the standards, the state agencies took public feedback; but because the rules were issued on an emergency basis, they did not need to go through regular notice-and-comment procedures. These states were able to respond nimbly in drafting and implementing new rules. They also were able to coordinate with other state agencies for purposes of policymaking and enforcement.

Virginia was the first state to begin comprehensive emergency rulemaking. The decision to begin a rulemaking in Virginia was prompted by an April 2020 petition from workers’ groups, including an organization representing poultry workers, followed by an executive order from then-Democratic Governor Ralph Northam.¹⁷⁹ Issuance of the Virginia standard was noteworthy not only because it came first, but also because Virginia is a “purple” state. Unlike California or Washington, it is not known for favoring additional, rule-based regulation. On June 12, 2020, the Virginia Department of Labor and Industry opened a ten-day comment period and announced an emergency meeting of the state Safety and Health Codes Board to adopt the standard. The state agency received more than 3,000 comments, with business and industry groups arguing against the rule and workers’ rights organizations arguing for it.¹⁸⁰ The Board held four public hearings to review the proposed rule before adopting the standard on July 15, 2020, with a vote of nine in favor, two against, one abstaining, and two absent. The standard took effect on July 27, 2020.¹⁸¹

The standard required all state employers to assess their workplaces for hazards and job tasks that could result in an exposure.¹⁸² Employers were required to notify workers within twenty-four hours of a known COVID exposure and

178 See discussion, *infra*, for specifics of standards.

179 Telephone Interview with Jay Withrow, Dir., Div. of Legal Support, Va. Occupational Safety & Health Program (Feb. 15, 2022); COMMONWEALTH OF VA., OFF. OF THE GOVERNOR, EXEC. ORD. AMENDED NO. 63 (2020), <https://www.vaodacs.com/assets/Uploads/PDF-Files/Lobbying-State-Government/Executive-Order-63-Amended-November-13-2020.pdf> [<https://perma.cc/BUD8-Y8WN>].

180 John Reid Blackwell, *Virginia Becomes First State to Adopt COVID-19 Worker Safety Rules*, RICHMOND TIMES (July 15, 2020), https://richmond.com/business/virginia-becomes-first-state-to-adopt-covid-19-worker-safety-rules/article_d0e983bd-fa71-5179-80ac-10896e71c6e5.html.

181 FINAL SAFETY AND HEALTH CODES BOARD PUBLIC HEARING AND MEETING MINUTES 19 (July 15, 2020), https://townhall.virginia.gov/L/GetFile.cfm?File=meeting\92\31089\Minutes_DOLI_31089_v2.pdf [<https://perma.cc/94CF-3PBM>].

182 Infectious Disease Prevention: SARS-CoV-2 Virus that Causes COVID-19 (Emergency Temporary Standard), 16 VA. ADMIN. CODE § 25-220 (July 15, 2020).

report clusters of more than three cases to the local health department.¹⁸³ Higher-risk employers were also required to create written COVID-19 response plans and assess their ventilation, among other requirements.¹⁸⁴

California, Oregon and Michigan took similar approaches. California already had a relevant standard on the books when the pandemic began.¹⁸⁵ The state supplemented the existing aerosol transmissible disease standard that applied mainly to health care workers with a new standard specific to COVID-19.¹⁸⁶ The California standard, as well as the standards issued in Oregon and Michigan, required employers to evaluate their workplaces for hazards and develop a COVID-19 protection plan. These rules further required physical distancing, masking, and cleaning.¹⁸⁷ The California standard mandated pay for workers excluded from the workplace due to exposure and regular testing in case of a work-related outbreak.¹⁸⁸ Oregon's standard, issued after an informal public comment period,¹⁸⁹ had heightened requirements for health care settings.¹⁹⁰ The Michigan standard had the feature of prohibiting in-person work "to the extent that their work can feasibly be completed remotely."¹⁹¹ Where it could not, employers were required to conduct daily screenings and notify the health department of cases.¹⁹²

Washington took a different approach. In May 2020, the state OSHA adopted a rule incorporating the governor's emergency proclamations, giving the agency authority to enforce the health and safety orders as they evolved.¹⁹³ Specifically, the rule provides that "[w]here a business activity is prohibited by an emergency proclamation an employer shall not allow employees to perform work."¹⁹⁴ Lastly, New Mexico issued an emergency amendment to its recordkeeping rule, requiring

183 *Id.*

184 *Id.*

185 AEROSOL TRANSMISSIBLE DISEASES, CAL. CODE REGS. tit. 8, § 5199.

186 COVID-19 Prevention, CAL. CODE REGS. tit. 8, § 3205 (effective Nov. 30, 2020 to June 17, 2021).

187 *Id.* § 3205(c); OR. ADMIN. R. 437-001-0744, § 3(h) (2020); MI. OCCUPATIONAL SAFETY & HEALTH ADMIN., EMERGENCY RULES CORONAVIRUS DISEASE 2019, Rule 3 (Oct. 14, 2020).

188 COVID-19 Prevention, CAL. CODE REGS. tit. 8, § 3205(c)(10)(C) (effective Nov. 30, 2020 to June 17, 2021).

189 OR. OCCUPATIONAL SAFETY & HEALTH ADMIN., POTENTIAL OREGON OSHA RULEMAKING TIMELINE, COVID-19/INFECTIOUS DISEASES (Oct. 5, 2020), <https://osha.oregon.gov/rules/advisory/infectiousdisease/Documents/Infectious-Disease-Public-Timeline.pdf> [<https://perma.cc/N4GW-24WR>].

190 OR. ADMIN. R. 437-001-0744(4) (2020).

191 MI. OCCUPATIONAL SAFETY & HEALTH ADMIN., EMERGENCY RULES CORONAVIRUS DISEASE 2019, RULE 5(8) (Oct. 14, 2020), https://www.michigan.gov/-/media/Project/Websites/lara/moahr/Folder2/LEO-MIOSHA_ER_-_Coronavirus_Disease_2019_Covid-19.pdf [<https://perma.cc/8HUD-8RNS>].

192 *Id.*

193 WASH. ADMIN. CODE § 296-800-14035.

194 *Id.*

employers to report employee COVID-19 cases to the state OSHA agency within four hours of discovering the case.¹⁹⁵ None of these emergency standards faced a successful legal challenge.¹⁹⁶

2. *Enforcement*

During the first year of the pandemic, OSHA enforcement related to COVID-19 varied dramatically among the states, leaving workers with disparate levels of protection as the virus surged. While certain State Plans conducted *more effective* enforcement than OSHA, others lagged behind the federal agency’s response. To measure effectiveness, this Article looks at the deterrent effect of enforcement activity in each state, using data derived from FOIA requests to OSHA.¹⁹⁷

OSHA enforcement can rectify existing workplace hazards and deter future ones at the cited employer and in the greater business community. Economists describe this as specific deterrence and general deterrence.¹⁹⁸ Specific deterrence occurs where employers fix workplace hazards after being issued an OSHA penalty.¹⁹⁹ A study finding that workplace injuries decline in the years after an OSHA penalty is imposed supports the rational deterrence model of employer decisions relating to compliance with OSHA standards.²⁰⁰ That is, “employers will comply when noncompliance is more costly than compliance. Generally, the risk-neutral cost of compliance is calculated as the probability of being caught multiplied by the penalty if caught.”²⁰¹ While the study looked at injuries, not illnesses,²⁰² the short onset of COVID-19 makes it more like an injury than many long-onset illnesses concerning OSHA, suggesting the logic would apply in this case. General deterrence is the effect that penalties have on *other* employers, who fear being cited themselves.²⁰³ The general deterrent effect is more difficult to study, because many factors may influence a company’s decision to mitigate

195 N.M. CODE R. § 16.11.5.1 (2020).

196 *Va. Mfrs. Ass’n v. Northam*, No. 0316-21-2 (Va. Ct. App. Dec. 7, 2021) (dismissing challenge to Virginia’s standard as moot); *Nat’l Retail Fed’n v. Ca. Dep’t Indus. Rel’ns*, No. CGC-20-588367 (Cal. Sup. Ct. Feb. 25, 2021) (denying preliminary injunction as to California’s standard); *Western Growers Ass’n v. Cal. Occ. Safety & Health Standards Bd*, No. A162343, 2021 WL 6048875 (Cal. Ct. App. Dec. 21, 2021) (same); *Slidewaters v. Wa. Dep’t Lab. and Industr.*, No. 2:20-cv-00210-TOR, 2020 WL 3979661, (E.D. Wa. July 14, 2020) (denying permanent injunction as to Washington’s standard). In Michigan and Oregon, it appears that no one sought to challenge the rules.

197 See Section II.B, *supra*, for a review of the methodology in this Article.

198 HUBER, *supra* note 26, at 86-88 (reviewing literature on the deterrent effect of OSHA enforcement).

199 *Id.* at 87.

200 *Id.*

201 *Id.* (internal citations omitted).

202 *Id.*

203 *Id.* at 88.



workplace hazards.²⁰⁴ Nonetheless, “[g]eneral deterrence plays some, as yet undetermined, role in encouraging employers to reduce workplace hazards.”²⁰⁵ A recent study found that well-publicized penalties lead to significantly fewer violations at peer facilities within the same region.²⁰⁶ These studies suggest that OSHA enforcement has a deterrent effect on future violations at the same firm and at surrounding firms, at least if the violations are well-publicized.

This Article aims to provide a rough measure for the deterrent effect of an OSHA agency related to COVID-19 and to use deterrence as a proxy for effectiveness in the context of enforcement. This approach enables a comparison between state and federal responses without bringing in the confounding factors that mediate between workplace safety enforcement and COVID-19 cases and deaths. It will be valuable to make these outcome-based comparisons, and it is the author’s hope that others will study the potential correlations in the future.

“The core assumption of [a deterrence metric] is that deterrence is a function of the probability that noncompliance is detected and the degree of punishment conditional on detection.”²⁰⁷ The deterrent effect here is approximated as the product of (a) the likelihood of detection and (b) the cost of detection. The number of inspections conducted per establishment serves as a proxy for the likelihood of detection because it reflects the frequency of citations in a standardized way. The average penalty faced by an employer issued a violation serves as a proxy for the cost of detection.

From a bird’s-eye view, State Plans conducted much more enforcement during the study period—February 1, 2020 through March 17, 2021—than OSHA did. But this high-level perspective obscures the on-the-ground reality. A few states accounted for most State Plan enforcement. State Plans are responsible for protecting workers in 41 percent of American establishments. As demonstrated in Table 1, State Plans issued 5.33 times as many citations to private businesses after

204 *Id.*

205 *Id.*

206 See Matthew S. Johnson, *Regulation by Shaming: Deterrence Effects of Publicizing Violations of Workplace Safety and Health Laws*, 110 AMER. ECON. REV. 1866, 1868 (2020) (finding that “press releases revealing OSHA noncompliance lead to substantial improvements in workplace safety and health”).

207 HUBER, *supra* note 26, at 185. Political scientist Gregory Huber has compared OSHA and the State Plans through their relative deterrent effects. This analysis is roughly modeled on the analysis conducted by Professor Huber, *id.* at 184-96. Professor Huber’s deterrence metric brings together “information about the size of the regulated community, agency resources, and the use of these resources into a single statistic summarizing how aggressively an agency enforces the law.” *Id.* at 185. Professor Huber’s metric is the product of (1) the number of inspectors in each agency relative to the size of the regulated community and (2) a standardized number of serious violations issued after an inspection.

inspections related to COVID-19 than OSHA did.²⁰⁸ This is consistent with prior statistics demonstrating State Plans issue more violations,²⁰⁹ but the ratio was far higher during the pandemic. As demonstrated in Table 2, in 2008, State Plans issued 1.39 times as many violations as OSHA.²¹⁰ During the study period, while State Plans were more likely to issue violations, they were also more likely to issue smaller penalties. The average initial penalties per employer cited by State Plans were 79 percent of the value of penalties imposed by OSHA.²¹¹ This is higher than data from 2008, which indicate average penalties for serious violations were 49 percent of those imposed by OSHA.²¹²

208 FOIA Data. The data exclude violations issued to public sector employers, as well as OSHA enforcement in states with comprehensive State Plans. Public sector workers are excluded because OSHA lacks jurisdiction over state and local employers; State Plans are required to cover them. OSHA enforcement in State Plans is limited to federal enclaves and employers and specific, carveout industries.

209 See *Nevada OSHA Hearing*, *supra* note 71, at 62-65.

210 *Id.*

211 FOIA Data.

212 *Nevada OSHA Hearing*, *supra* note 71, at 62-65.

Table 1: Summary of OSHA Enforcement in COVID-19-Related Inspections for Private Sector Businesses from February 1, 2020 through March 17, 2021

	Federal	State Plans	Ratio of State to Federal
Number of U.S. Business Establishments	4,717,409	3,294,548	
Share of U.S Business Establishments	59%	41%	
Complaints/Referrals	16,192	55,591	3.43
Inspections Conducted	1,703	5,890	3.45
Employers Cited	532	1,988	3.74
Citations Issued²¹³	1,576	6,118	3.88
Inspections Conducted per 10,000 Establishments	3.61	17.87	4.95
Employers Cited per 10,000 Establishments	1.13	6.03	5.33
Total Initial Penalties Imposed²¹⁴	\$6.33 million	\$18.61 million	2.94
Average Penalty per Employer	\$11,902.00	\$9,362.91	0.79
Deterrent Effect	4.30	16.74	3.89

Source: FOIA requests from OSHA, OSHA COVID-19 Response Summary, U.S. Census Data

²¹³ While all inspections related to COVID-19, some violations issued in response to *other* hazards present at the worksite.

²¹⁴ Penalties are often reduced substantially on settlement or after a successful contest. See Martha T. McCluskey et al., *OSHA's Discount on Danger: OSHA Should Revise Its Informal Settlement Policies to Maximize the Deterrent Value of Citations*, CTR. FOR PROGRESSIVE REFORM 5-7, 8-13 (June 2016), https://cpr-assets.s3.amazonaws.com/documents/OSHA_Discount_on_Danger_Report.pdf [<https://perma.cc/3KKT-B98B>]. Given that many of the cases had not fully resolved when the FOIA request was produced, initial penalties represent the best comparative figure. Initial penalties also serve a deterrent effect in that they are often publicized where final settlements may not be.

Table 2: Comparative OSHA Enforcement in Fiscal Year 2008

	Federal	State Plans	Ratio of State to Federal
Citations Issued	87,687	122,288	1.39
Penalties Imposed	\$103,350,367	\$70,248,913	0.68
Average Penalty/Citation	\$1,179	\$574	0.49

Source: 2009 Congressional hearing on OSHA State Plans²¹⁵

Most of this enforcement occurred, however, in a handful of states. Of the 1,988 businesses employers cited in State Plans, 1,719 were in just five states—California, Michigan, Nevada, Oregon, and Washington.²¹⁶ Among those states, employers were cited at a rate of 10.94 per 10,000.²¹⁷ Among the rest of the State Plans, the rate was 1.56 per 10,000.²¹⁸ Together, four of those states—California, Michigan, Nevada, and Washington—accounted for 89 percent of all fines imposed, although those states account for just 45 percent of all business establishments under State Plan jurisdiction.²¹⁹

There was also significantly more variation in enforcement outputs among State Plans than among states under OSHA jurisdiction, as demonstrated by Table 3. The standard deviation of employers cited per 10,000 establishments in State Plans is 7.5, while it is 1.03 among OSHA states.²²⁰ This indicates that State Plans were farther apart with respect to their enforcement levels than OSHA states were. In essence, the disparate enforcement that preceded the OSH Act persisted during the COVID-19 pandemic.

215 *Nevada OSHA Hearing*, *supra* note 71, at 62-65.

216 FOIA Data. See Table 3, *infra*, for a state-by-state comparison.

217 FOIA Data.

218 *Id.*

219 *Id.*

220 *Id.* Considerable variation also existed among OSHA states, many of which saw little to no enforcement. In sixteen states, OSHA issued violations to fewer than ten employers. This finding raises questions about OSHA’s supervision of its regional offices. But given that OSHA operates a singular program, its response may be evaluated as one agency. This is an area for future scholarly research but outside the scope of this Article.



Table 3: State-By-State Private Sector Enforcement Relating to COVID-19 in State Plans from February 1, 2020 through March 17, 2021

State Plan	Deterrence	Inspections per 10,000 Establishments	Employers Cited per 10,000 Establishments	Average Initial Penalty per Employer
Washington	87.92	41.11	15.63	\$21,387
Nevada	40.92	59.94	28.00	\$6,827
Michigan	24.22	60.88	22.32	\$3,978
California	23.72	19.56	5.84	\$12,128
Alaska	19.16	5.14	2.34	\$37,283
Virginia	8.13	7.47	2.41	\$10,885
Minnesota	6.98	12.87	4.29	\$5,423
New Mexico	6.35	6.16	3.88	\$10,294
Utah	5.33	19.54	4.53	\$2,729
Vermont	4.50	4.32	2.40	\$10,404
OSHA	4.30	3.61	1.13	\$11,902.00
Kentucky	4.26	6.58	0.99	\$6,475
Indiana	4.21	5.71	0.54	\$7,372
Iowa	3.93	3.50	1.33	\$11,218
Oregon	3.33	39.98	13.60	\$832
Hawaii	2.37	0.91	0.30	\$26,024
South Carolina	1.98	2.23	0.63	\$8,850
Puerto Rico	1.98	11.62	1.34	\$1,700
North Carolina	1.36	2.31	0.21	\$5,900
Tennessee	0.53	2.50	1.43	\$2,104
Arizona	0.31	2.65	1.09	\$1,152
Maryland	0	1.08	0.50	\$0
Wyoming	0	0.93	0	\$0

Source: FOIA Requests from OSHA, U.S. Census Data

The deterrent effect of State Plans also varied greatly, as shown in Table 3. Ten of the twenty-two State Plans ran enforcement programs with a greater

deterrent effect than OSHA, while twelve states had less of a deterrent effect.²²¹ Washington operated the State Plan with by far the greatest deterrent effect. The response was achieved through the unique use of state resources.²²² In May 2020, Governor Jay Inslee was looking for ways to enforce his emergency proclamations requiring business closures and mitigation measures—without relying on criminal sanctions.²²³ Recognizing the Washington State Plans’ (WISHA) authority to issue civil penalties to all businesses in the state, the governor asked the agency to promulgate a rule enabling the agency to enforce his executive orders. WISHA, which employs around 150 workplace safety inspectors, quickly deputized an additional 450 to 550 inspectors from elsewhere in the Department of Labor & Industries, of which it is a component part.²²⁴ Where those compliance officers might have normally conducted elevator safety or carnival ride inspections, they were now on duty for COVID-19.²²⁵ The agency set up a unit to filter the thousands of complaints to the governor’s office.²²⁶ Then the agency inspectors sent letters and conducted inspections to determine whether businesses were properly closed or complying with safety measures.²²⁷ The proactive response was also informed by Washington’s early tracking of workplace COVID-19 outbreaks.²²⁸ In sum, the agency sought through enforcement to protect both worker health and public health through its state OSHA program.

Contrasted with Washington, it is noteworthy how far behind certain states lagged from OSHA. Arizona, North Carolina, Maryland, Tennessee, and Wyoming stand out for their particularly ineffective programs. In Wyoming, *not a single OSHA citation* was issued relating to a COVID-19 inspection during the study period.²²⁹ In Maryland, officials issued \$0 in fines during the same period in COVID-19-related inspections.²³⁰ It is not conceivable that there simply were no hazards to be remediated in states without regulations or substantial numbers of violations. Rather, those State Plans likely disregarded COVID-19 risks or refused to inspect and penalize employers. Workers there were left without a robust OSHA program to protect them from exposure to COVID-19.

In comparing State Plans and OSHA, it is important to recognize the context in which such decisions were made and the factors associated with stronger and

221 *Id.*

222 *Id.*

223 Telephone Interview with Elliott Furst, Senior Couns., Att’y Gen. of Wash., Lab. & Indus. Div. (Feb. 3, 2021).

224 *Id.*

225 *Id.*

226 *Id.*

227 *Id.*

228 *Id.*

229 FOIA Data.

230 *Id.*



weaker enforcement programs. As a general matter, unique standards and vigorous enforcement are more feasible in certain states than they were in other states and the federal government. State Plans can be more nimble than OSHA, because their rules are not subject to the Administrative Procedure Act or, in general, review in federal court, such as the U.S. Supreme Court’s fateful review of the vaccine-or-test standard.²³¹ They may also have broader authority than OSHA to implement programs that reach public health, as well as worker safety.

Politics matter too. It can be politically difficult for OSHA to promulgate new standards or enforce them vigorously—and depending on the administration, it may be infeasible. OSHA is a component of an executive agency, the Department of Labor, which is headed by a political appointee. Politics is intrinsic to the agency, and policies are shaped by the political party in charge. Meanwhile, the agency has few built-in proponents and an army of critics—including Congress, which has from the 1970s made numerous efforts to repeal the OSH Act or reduce the agency’s authority.²³² During most of the first year of the COVID-19 pandemic, the Department of Labor was headed by Trump appointee Eugene Scalia, son of the conservative Supreme Court Justice Antonin Scalia and, prior to his public service, a frequent representative of business and industry in labor and employment-related disputes.²³³ By contrast, all six states that did COVID-19 rulemaking had a Democratic governor. Those governors likely helped propel the rulemaking, even where Republicans had leverage in the state assembly or regulatory boards. Greater state enforcement generally correlated with Democratic executive political control over the state OSHA agency.²³⁴ This dynamic is particularly visible in North Carolina, which has a Democratic governor but a Republican-elected labor commissioner.

This context does not fully justify OSHA’s or the less regulatory states’ weak approach to enforcement, however. First, two states that pursued regulation—Michigan and Virginia—are famously “purple”; even though they had Democratic leadership during the first year of the pandemic, regulation succeeded despite political hurdles. Second, the statute that allows OSHA to draft an ETS eliminates the requirement to go through the lengthy notice-and-comment process that mires ordinary OSHA standards. The Washington example further suggests that OSHA could have found ways to expand its inspectorate through cooperation with other state and federal agencies. Given the scope and novelty of the emergency, issuing a standard or conducting vigorous inspections was probably not outside the scope of political possibility for the federal government or most states.

231 NFIB v. OSHA, 142 S. Ct. 661, 665-66 (2022) (per curiam).

232 HUBER, *supra* note 26, at 73.

233 Lerner, *supra* note 150.

234 See Table 3, *supra*.

3. *Monitoring*

The enforcement disparity was tacitly permitted by OSHA, which conducted little monitoring of State Plan enforcement responses to COVID-19, leaving states to pursue whatever approach they wished. North Carolina State Plan (OSHNC) conducted one of the weakest enforcement responses.²³⁵ The state's workplace fatalities rose from fifty-four in FY 2019 to seventy-eight in FY 2020, driven in large part by sixteen recorded work-related COVID-19 deaths.²³⁶ But the state OSHA agency issued violations to 0.21 out of every 10,000 businesses in the state during the study period, less than a quarter of OSHA's rate.²³⁷ In FY 2020, OSHNC conducted just twenty-one inspections related to COVID-19 after receiving 1,050 complaints and referrals.²³⁸ Instead, OSHNC provided technical assistance and webinars, participated in working groups, created FAQs, and posted billboards advertising the agency's services.²³⁹ In its annual evaluation, OSHA provided no feedback on OSHNC's COVID-19 efforts except to list them under "Special Accomplishments."²⁴⁰ OSHA concluded that OSHNC "continued to meet all criteria for an effective State Plan."²⁴¹ This was because OSHNC "generally met or exceeded federal activity results."²⁴² Of course, those measures were less meaningful in a year when work shifted dramatically and high-hazard jobs were put on hold for months, facts the report fails to acknowledge.

Even where credible complaints were made about State Plan responses, OSHA did not intervene to correct the State Plan response. During the first year of the pandemic, advocacy groups filed Complaints About State Plan Administration (CASPA) relating to the performance of the State Plans in Iowa²⁴³ and Maryland,²⁴⁴ two states identified in Table 3 as among the least effective. The ACLU of Iowa filed a CASPA noting that the state agency conducted inspections following just 5 of 148 complaints, apparently in violation of its own policies.²⁴⁵ It appeared that Iowa OSHA inspections would generally commence only after

235 See Table 1, *supra*.

236 NORTH CAROLINA FY 2020 FAME REPORT, *supra* note 177.

237 FOIA Data. See Table 3, *supra*.

238 NORTH CAROLINA FY 2020 FAME REPORT, *supra* note 177, at 3.

239 *Id.* at E-12 to E-14.

240 *Id.*

241 *Id.* at 3.

242 *Id.*

243 Letter from Rita Bettis Austen, Legal Dir., ACLU of Iowa Found., to Kim Stille, Reg'l Adm'r, Occupational Safety & Health Admin. (Nov. 13, 2020) [hereinafter Iowa CASPA], https://www.aclu-ia.org/sites/default/files/2020-11-12_final_caspa.pdf [<https://perma.cc/52NT-VWQ2>].

244 Letter from David Rodwin, Att'y, Pub. Just. Ctr., to Michael Rivera, Reg'l Dir., Occupational Safety & Health Admin. (Oct. 16, 2020) (on file with author).

245 Iowa CASPA, *supra* note 243, at 5.

media coverage and political pressure over outbreaks.²⁴⁶ “This pattern creates a perception among Iowa workers that Iowa OSHA is only motivated to investigate dangerous working conditions after significant public pressure,” the ACLU wrote.²⁴⁷ Nonetheless, OSHA concluded that the State Plan “followed protocols and no deficiencies [were] noted.”²⁴⁸

In Maryland, the Public Justice Center (PJC) complained to OSHA that the State Plan did not investigate COVID-19-related complaints but simply forwarded them to local health departments.²⁴⁹ The advocacy group criticized the Maryland agency’s failure to conduct in-person inspections or use the General Duty Clause to enforce COVID-19 protections. The CASPA specifically discussed an incident where Maryland’s State Plan failed to sufficiently investigate a complaint that employees lacked proper respirators to protect them from wood and paint dust exposure that made them “more susceptible to complications from COVID-19.”²⁵⁰ Despite the spread of COVID-19 through that workplace, the Maryland agency initially refused to investigate beyond sending the employer a letter asking them to self-investigate, claiming the most they could enforce was “failure to provide hand sanitizer.”²⁵¹ After follow-up complaints were filed, the agency allegedly conducted an on-site investigation but refused to interview workers through their representative, PJC, opting instead to go through the employer, who workers feared would retaliate against them for speaking out. OSHA’s investigation of the CASPA resulted in no findings or recommendations.²⁵²

OSHA’s statutory responsibility amounts *at least* to ensuring that State Plans conduct enforcement that is at least as effective as the federal agency’s enforcement. As the above demonstrates, certain states greatly exceeded OSHA’s efforts. But OSHA could take little credit for it. Rather, the federal agency’s lack of monitoring of enforcement practices allowed certain State Plans to be less effective than OSHA.²⁵³

²⁴⁶ *Id.*

²⁴⁷ *Id.*

²⁴⁸ OCCUPATIONAL SAFETY & HEALTH ADMIN., FY 2020 FOLLOW-UP FEDERAL ANNUAL MONITORING AND EVALUATION (FAME) REPORT, IOWA OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (IOSHA) (July 2021), at E-4, <https://www.osha.gov/sites/default/files/2021-07/Iowa-FY-2020-Follow-up-FAME-Report.pdf> [<https://perma.cc/T5L5-22WB>].

²⁴⁹ Letter from David Rodwin, *supra* note 244; News Release, Public Justice Center, *Maryland’s Workplace Safety Agency Fails to Protect Workers During Pandemic* (Dec. 10, 2020), <https://www.publicjustice.org/en/news/marylands-workplace-safety-agency-fails-to-protect-workers-during-pandemic> [<https://perma.cc/Q4CV-96K5>].

²⁵⁰ Letter from David Rodwin, *supra* note 244, at 2.

²⁵¹ *Id.*

²⁵² MARYLAND FY 2020 FAME REPORT, *supra* note 96, at 5.

²⁵³ See Section I.C, *supra*, for a discussion of the Biden Administration OSHA’s threatened revocation of Arizona’s final approval to operate a State Plan, in part due to the agency’s failure to adopt an emergency COVID-19 standard for health care workers.

III. STANDARDS AS MONITORING FOR EFFECTIVENESS

A significant distinguishing factor between OSHA and certain State Plans was the existence of a specific standard regulating the risk of COVID-19 or other airborne transmissible diseases. This Part argues OSHA could have enhanced nationwide enforcement during the COVID-19 pandemic by issuing an emergency temporary standard. Standards are better tools to facilitate enforcement than guidance documents or the General Duty Clause (GDC), because they provide clearer instructions for employers and inspectors to follow. This was borne out by the experience of State Plans that deployed temporary standards during the pandemic. Structurally, standards also offer an efficient way for OSHA to monitor State Plan behavior. Far simpler and more sweeping than examination of state-level enforcement outputs, standards provide OSHA a tool to level up State Plan behavior and employer compliance.

A. Enabling Enforcement

Enforceable standards enable OSHA and the State Plans to conduct effective enforcement in a way that guidance and the GDC do not. Most obviously, they provide inspectors concrete issues to look for during an investigation and establish the existence of a hazard when certain conditions are in place. Beyond this, standards set industry norms, which is especially important when the agency is short on resources.

During the COVID-19 pandemic, employers were confronted with myriad guidance documents, FAQs, and state executive orders that frequently changed, causing uncertainty about their duties under the law and possible liability.²⁵⁴ A clear standard would have clarified employer obligations and likely improved workplace conditions, even absent aggressive enforcement. Indeed, OSHA has recognized that “[c]onveying obligations as clearly and specifically as possible makes it much more likely that employers will comply with those obligations and thereby protect workers from COVID-19 hazards.”²⁵⁵

Binding standards relating to COVID-19 would have also been easier and more effective for the agency to enforce, as a comparison between enforcement by OSHA and the State Plans with COVID-19 rules demonstrates. OSHA issued about three-quarters of all violations to health care employers, including nursing homes, hospitals, and ambulance services—usually in response to a reported fatality.²⁵⁶ In these health care settings, OSHA could enforce its respirator

254 Michael J. Cahalane, Kyle E. Bjornlund & Xavier Q. Lawrence, *OSHA in the Time of COVID-19: A Call for Enforceable Standards for the Sake of Employees and Employers*, FED. LAW. Nov.-Dec. 2020, at 20-23.

255 OSHA Covid Vaccine ETS, 86 Fed. Reg. 61,442 (Nov. 5, 2021).

256 OSHA data indicate that during the study period (February 1, 2020 to March 17, 2021), the

protection standard, a detailed regulation that requires employers to maintain a written program, conduct regular fit tests, and train employees on how to wear the masks. As demonstrated in Table 4, respirator protection was the most cited OSHA violation by a wide margin, comprising 976 of 1,585 citations issued by the federal agency during the time period studied.²⁵⁷ The second most cited violation was failure to keep appropriate records or make timely reports to OSHA.²⁵⁸ While appropriate respirator protection was undoubtedly an important measure to protect health care workers, it was not a widely applicable measure, as it did not apply for normal face coverings. And for much of the first year, respirators were neither available nor appropriate for most workers. Thus, enforcement of the existing standard did not serve to protect workers across industries.

Table 4: Federal Citations by Standard in COVID-19-Related Inspections for Private Sector Businesses from February 1, 2020 through March 17, 2021²⁵⁹

Standard	Citations Issued
All	1,585
Respirator Violations	976
Recordkeeping/Reporting	233
Hazard Alert Letter (No Standard)	93
General Duty Clause	85
Personal Protective Equipment	32
Other	166

Source: FOIA Request from OSHA

agency opened 969 inspections because of a fatality/catastrophe, as opposed to 445 because of a complaint. OCCUPATIONAL SAFETY & HEALTH ADMIN., COVID-19 RESPONSE SUMMARY, FEDERAL INSPECTIONS OPENED, https://www.osha.gov/enforcement/covid-19-data#fed_inspections_open [<https://perma.cc/F499-ZWVT>].

²⁵⁷ Table 4, *infra*.

²⁵⁸ *Id.*

²⁵⁹ These figures derive from the FOIA request from OSHA and include federal enforcement in states primarily covered by State Plans where OSHA maintains jurisdiction over some federal enclaves or agencies. See e.g., OCCUPATIONAL SAFETY & HEALTH ADMIN., CALIFORNIA STATE PLAN, <https://www.osha.gov/stateplans/ca> [<https://perma.cc/27VM-WZEY>] (noting that OSHA continues to cover maritime and aircraft employment, private employers within military enclaves, national recreation areas and tribal reservations, and contractors engaged with the U.S. Postal Service) (last viewed Mar. 3, 2023).

The data further suggest that the GDC was no substitute for an enforceable standard, despite OSHA’s early claims.²⁶⁰ During the study period, the GDC was cited just eighty-five times. This is hardly surprising, as enforcing the GDC requires a high degree of agency resources,²⁶¹ and the agency has long struggled to quickly issue and defend citations.²⁶² Thus, the agency historically—and during the pandemic—used it sparingly.²⁶³ Indeed, OSHA later acknowledged that the GDC was “grossly inadequate to protect employees . . . from the grave danger posed by COVID-19 in the workplace.”²⁶⁴ One problem with the standard is that it requires a relatively large amount of proof for the agency to cite. The agency must show in each case that the workplace conditions—such as unmasked workers standing near each other for hours—pose a “COVID-related hazard.”²⁶⁵ By contrast, an OSHA standard itself establishes that a hazard exists.²⁶⁶

An ETS could have mandated the kind of controls suggested in guidance from OSHA or the Centers for Disease Control and Prevention. At its simplest, the rule could have required masks in workplaces—potentially intervening before the issue became highly politicized. A standard could also have implemented many of the other physical interventions, such as ventilation, required by certain State Plans. OSHA could have also used rulemaking, as certain State Plans did, to gather information about ongoing outbreaks, allowing the agency to intervene before a fatality. The rule could have been issued in conjunction with a National Emphasis Program on the emergency. These programs require OSHA and the State Plans to conduct surprise inspections in industries related to hazards of particular concern.²⁶⁷ Instituting such a program early would have signaled to the State Plans

260 Sweatt Testimony, *supra* note 127.

261 Michaels & Wagner, *supra* note 59 (“General duty clause citations require a tremendous amount of work by the OSHA technical staff and attorneys and do often take several months to issue.”).

262 See Marc Linder, *I Gave My Employer a Chicken that Had No Bone: Joint Firm-State Responsibility for Line-Speed-Related Occupational Injuries*, 46 CASE W. L. REV. 33 (1995) (describing the agency’s struggles defending citations issued under the General Duty Clause for working conditions that resulted in musculoskeletal disorders).

263 *House Meatpacking Report*, *supra* note 2, at 11 (noting that OSHA personnel acknowledge to the Subcommittee that “violations under the General Duty Clause ‘can be more difficult to show, than the elements of proof required for violation of a hazard-specific standard’ had an ETS been issued”); 2021 DOL-OIG COVID-19 AUDIT, *supra* note 4, at 12 (arguing that OSHA should have adopted an emergency standard because “under the OSH Act’s General Duty Clause, violations are rarely issued”).

264 OSHA Vaccine ETS, 86 Fed. Reg. 61,443 (noting that “despite publishing a voluminous collection of COVID–19 guidance online and receiving and investigating thousands of complaints, OSHA did not believe it could justify the issuance of more than 20 COVID–19 related General Duty Clause citations over the entire span of the pandemic so far, because of the quantum of proof the Secretary must amass under the General Duty Clause”).

265 *Id.*

266 *Id.*

267 OCCUPATIONAL SAFETY & HEALTH ADMIN., REVISED NATIONAL EMPHASIS PROGRAM—

that they should focus on the emergent hazard, even if it requires postponing or reducing enforcement of other hazards.

Early data indicate that an ETS addressing workplace controls could have enhanced OSHA's response to COVID-19 and enabled the agency to enforce more effectively. As demonstrated by Table 5, states with comprehensive ETSs *used* them—and they likely used them as a replacement for citations under the GDC.²⁶⁸ In Michigan, for example, the percentage of citations under the GDC dropped from 8 percent to 0.3 percent after the ETS was issued; in Oregon, it dropped from 14 percent to 4 percent of citations issued.²⁶⁹ The high percentage of citations issued under the State Plan ETSs suggest that they were immediately applicable for state-level inspectors. Indeed, citations under the temporary standard quickly accounted for 21 percent to 48 percent of all citations issued in all five states that issued a comprehensive ETS.²⁷⁰ It is harder to say whether they increased enforcement overall, since enforcement patterns were very uneven during the first months of the pandemic and were particularly low in the first months. Washington saw a slightly different effect after the standard was issued—an increase in the percentage of violations issued both under the ETS and the GDC.²⁷¹ This may be explained by the overall increase in citations and the evolving nature of the pandemic, particularly given that Washington issued its ETS very early.

CORONAVIRUS DISEASE 2019 (COVID-19) (July 7, 2021), https://www.osha.gov/sites/default/files/enforcement/directives/DIR_2021-03_CPL_03.pdf [<https://perma.cc/9LC8-T9NP>].

²⁶⁸ New Mexico is excluded from this discussion because its emergency standard covered only recordkeeping and was, therefore, not a substitute for the General Duty Clause.

²⁶⁹ FOIA Data. See Table 5, *infra*.

²⁷⁰ Table 5, *infra*.

²⁷¹ *Id.*

Table 5: State Use of Emergency Temporary Standards in COVID-19-Related Inspections for Private Sector Businesses from February 1, 2020, through March 17, 2021

	Date ETS Became Effective	Violations of ETS as percent of all COVID-19-related violations after ETS became effective until March 17, 2021	Violations of the GDC as percent of all COVID-19-related violations <u>before</u> ETS became effective	Violations of the GDC as percent of all COVID-19-related violations <u>after</u> ETS became effective
California ²⁷²	Nov. 30, 2020	21% (19 of 90)	23% (370 of 1,511)	12% (11 of 90)
Michigan	Oct. 14, 2020	29% (329 of 1,154)	8% (93 of 1,214)	0.3% (4 of 1,154)
Oregon	Nov. 16, 2020	34% (24 of 71)	14% (38 of 277)	4% (3 of 71)
Virginia	July 27, 2020	48% (51 of 107)	5% (3 of 63)	1% (1 of 107)
Washington	May 26, 2020	30% (293 of 962)	2% (3 of 121)	11% (106 of 962)

Source: FOIA Request from OSHA

Unlike the federal respirator standard, the state-level emergency COVID-19 standards were suitable across industries, particularly in settings where a respirator mask would not have been accessible or available. Michigan provides an instructive example. The state OSHA agency applied its ETS to protect workers in restaurants, hotels, construction sites, schools, dental offices, hospitals, factories, and retail stores.²⁷³ The agency also publicized its enforcement through press

272 California does not have a state analogue of the General Duty Clause. Rather, Cal/OSHA has an Injury and Illness Protection Program (IIPP) standard that requires employers to evaluate their workplaces for hazards and, if a hazard exists, implement control measures. CAL. CODE REGS. tit. 8, § 3203. Cal/OSHA interpreted this statute to require employers not covered by its aerosol transmissible disease standard to evaluate their workplaces to determine if COVID-19 was a hazard and, if so, to implement infection control measures. DIV. OF OCCUPATIONAL SAFETY & HEALTH, CAL/OSHA INTERIM GENERAL GUIDELINES ON PROTECTING WORKERS FROM COVID-19 (May 14, 2020), <https://www.dir.ca.gov/dosh/coronavirus/general-industry.html> [<https://perma.cc/PY2C-AJFP>]. Because the state uses the IIPP standard in lieu of the General Duty Clause, it is substituted here.

273 See, e.g., Press Release, Mich. Occupational Safety & Health Admin., *23 Employers Cited in Latest Round of COVID-19 Workplace Safety Violations* (Jan. 22, 2021),



releases posted on the website with links to the full citation documents,²⁷⁴ a level of transparency that is extremely rare among federal or state enforcement agencies and which may be valuable for promoting deterrence.²⁷⁵ For example, the agency cited a Christian school for failing to screen employees daily for symptoms, require face masks, place posters around the workplace, and maintain proper records.²⁷⁶ Likewise, a die casting operation was fined for failing to develop and implement a COVID-19 preparedness and response plan.²⁷⁷

Attorneys for State Plans adopting emergency standards had similar impressions. Jay Withrow, Director of Legal Support for the Virginia State Plan, said that the standard improved employer compliance compared to the case-by-case adjudication under the GDC.²⁷⁸ He said that the standard also gave the agency flexibility to issue less serious violations than would be required under the GDC while achieving abatement.²⁷⁹ Elliott Furst, a senior attorney for Washington State Plan, also said the standard helped the state achieve compliance, including business closures.²⁸⁰ The vast majority of citations, he added, were not appealed.²⁸¹

The need to remain flexible amid a changing pandemic does not change the calculus of issuing an emergency standard. As Professor David Super has written, “contemporary legal thinking is in the thrall of a cult of flexibility.”²⁸² So too, were the administrators at OSHA.²⁸³ Professor Super argues that legal decisions have four main inputs: information, applicable norms, decisional capacity, and

<https://www.michigan.gov/coronavirus/news/2021/02/26/23-employers-cited-for-covid-19-workplace-safety-violations> [<https://perma.cc/D6DQ-LGD4>]; Press Release, Mich. Occupational Safety & Health Admin., *Ten Employers Cited in Latest Round of COVID-19 Workplace Safety Violations* (Jan. 22, 2021), <https://www.michigan.gov/coronavirus/news/2021/01/22/ten-employers-cited-in-latest-round-of-covid-19-workplace-safety-violations> [<https://perma.cc/8GTA-ATDV>].

²⁷⁴ *Ten Employers Cited in Latest Round of COVID-19 Workplace Safety Violations*, *supra* note 273.

²⁷⁵ See Johnson, *supra* note 206, at 1868 (finding that “press releases revealing OSHA noncompliance lead to substantial improvements in workplace safety and health”).

²⁷⁶ MICH. OCCUP. SAFETY & HEALTH ADMIN., CITATION AND NOTIFICATION OF PENALTY, TRI-UNITY CHRISTIAN SCHOOL (Jan. 13, 2021), https://www.michigan.gov/documents/leo/MIOSHAcitation_TriUnityChristianSchool_713563_7.pdf [<https://perma.cc/9MHC-CSCR>].

²⁷⁷ MICH. OCCUP. SAFETY & HEALTH ADMIN., CITATION AND NOTIFICATION OF PENALTY, MICHIGAN DIE CASTING LLC (Dec. 28, 2020), https://www.michigan.gov/documents/leo/MIOSHAcitation_MichiganDieCasting_713552_7.pdf [<https://perma.cc/SCE8-ABRF>].

²⁷⁸ Telephone Interview with Jay Withrow, *supra* note 179.

²⁷⁹ *Id.*

²⁸⁰ Telephone Interview with Elliott Furst, *supra* note 223.

²⁸¹ *Id.*

²⁸² David A. Super, *Against Flexibility*, 96 CORNELL L. REV. 1375, 1375 (2011).

²⁸³ Sweatt Testimony *supra* note 127; Sweatt Letter *supra* note 137.

implementation capacity.²⁸⁴ As he notes, only one of those—information costs—declines over time. Postponing decisions until all the information is available tends to underemphasize the cost of delay. During that time, the government’s “decisional capacity may become increasingly scarce.”²⁸⁵ “Decisions rarely become more valuable to society as a whole when rendered later, although particular parties may benefit substantially from delay.”²⁸⁶

While COVID-19 was surprising in its scale, it was not an entirely novel hazard. As described in Part II, the agency has experience with health risks. In particular, the agency had responded to the H1N1 (Swine) Flu pandemic in 2009—an experience that caused OSHA to begin rulemaking to protect health care workers from infectious disease.²⁸⁷ The agency’s knowledge is further demonstrated by early guidance documents, which call for many of the same interventions discussed today, including ventilation, social distancing, and face masks.²⁸⁸

The agency also had far more decisional capacity and clout to issue reasonable rules before the pandemic began—or in the first couple months—than it did once the flood of complaints began. Because OSHA has a built-in set of motivated critics, most rules it issues are subject to litigation. Prior to COVID-19, the agency issued nine emergency standards.²⁸⁹ The agency struggled to defend them, and of the six that were challenged, only one was upheld in full.²⁹⁰ Today, it is especially common for opponents of a regulation to seek relief in court, and business groups may be able to find a friendly ear in Texas, among other conservative courts.²⁹¹ Yet a standard issued early in the pandemic would have been on stronger footing than the later vaccine-or-test standard that was justified by the grave danger to *unvaccinated* people.²⁹² This was a difficult argument where most Americans *were* vaccinated, and those who were not had largely chosen not to get the vaccine.

Since an ETS must be replaced with a permanent standard within six months, OSHA would have also had an opportunity to rapidly develop a permanent standard. To be sure, the tight time frame would have been difficult for OSHA

284 Super, *supra* note 282, at 1401-02.

285 *Id.* at 1405, 1411-12.

286 *Id.* at 1412.

287 See Petition for Writ of Mandamus, *supra* note 140, at 9-10.

288 See GUIDANCE ON PREPARING WORKPLACES FOR COVID-19, *supra* note 144.

289 SCOTT D. SZYMENDERA, CONG. RSCH. SERV., R46288, OCCUPATIONAL HEALTH & SAFETY ADMIN. (OSHA): EMERGENCY TEMPORARY STANDARDS (ETS) AND COVID-19 at 6, 6 app. A-1 (2020).

290 *Id.*

291 Emma Platoff, *By Gutting Obamacare, Judge Reed O’Connor Handed Texas a Win. It Wasn’t the First Time.*, TEX. TRIB. (Dec. 19, 2018), <https://www.texastribune.org/2018/12/19/reed-occonnor-federal-judge-texas-obamacare-forum-shopping-ken-paxton/> [https://perma.cc/S3JT-HNT8].

292 OSHA Vaccine ETS, 86 Fed. Reg. 61,402-24 (Nov. 5, 2021).

because standards usually take the agency several years to develop. However, this timeline would have enabled OSHA to expedite the review process, and the agency might have been able to leave the emergency rule in place longer than six months by demonstrating to a court that it was actively developing a permanent replacement.²⁹³

In developing its ETS, Oregon OSHA provided a thoughtful response to its critics, which applied equally to OSHA.

Oregon OSHA agrees that the rulemaking will need to proceed cautiously so as not to forestall future protective measures that may be superior to those developed by the rule. However, we believe that the science—at least as it relates to the primary protective measures that can be employed in the workplace—has reached a level of relative stability. And the stability and predictability that even a temporary rule provides is one of the strengths of moving toward rulemaking rather than continuing to rely upon workplace applications of evolving public health guidance. Finally, the rule can—if truly necessary—be revised if new developments truly merit such a revision.²⁹⁴

B. Guiding State Plans

Not only do specific rules enable enforcement in workplaces, they also empower OSHA to monitor enforcement by the State Plans. Standards are structurally suited to monitoring State Plans and ensuring their effectiveness. As described in Part I, State Plans must keep up with OSHA standards to remain “at least as effective.” Where OSHA implements an ETS, State Plans must adopt it or an equally effective alternative. Thus, federal standards could have established a baseline that employers in every State Plan must meet at risk of enforcement.

Standards are much easier for OSHA to monitor than enforcement outputs, particularly in an emergency. It is highly resource intensive for OSHA to analyze case files and enforcement statistics in individual states to determine whether they meet the standards set out by OSHA. Particularly in a moment when agency

²⁹³ See Department of Labor’s Opposition to the Petition for a Writ of Mandamus at 23, *AFL-CIO v. Occupational Safety & Health Admin.*, U.S. Dep’t of Lab., No. 22-1002 (D.C. Cir. filed Jan. 21, 2022) (“[N]o court has considered whether an ETS remains in effect and enforceable when the Secretary is unable to finalize a permanent standard in a timeframe approaching the one contemplated by the OSH Act due to competing priorities.”).

²⁹⁴ OR. OCCUPATIONAL SAFETY & HEALTH ADMIN., INITIAL ISSUE PAPER ON OREGON OSHA INFECTIOUS DISEASE RULEMAKING FOR THE GENERAL WORKPLACE (July 15, 2020), <https://osha.oregon.gov/rules/advisory/infectiousdisease/Documents/Initial-Background-Infectious-Disease-Rulemaking.pdf> [<https://perma.cc/L9VU-SM2F>].

resources are stretched to respond to a national workplace emergency such as COVID-19, this is a difficult task. Furthermore, determinations of enforcement effectiveness are contestable and, to some degree, subjective, as the debate over the meaning of “at least as effective” demonstrates.

By contrast, where OSHA requires State Plans to adopt a standard, its only monitoring obligation is to ensure that each agency adopts it or an alternative that is “at least as effective.” Where in an emergency OSHA may struggle to force State Plans to enhance their resources or vigor, the agency can require that State Plans adopt the standard or an equally effective alternative. To be sure, it requires work on OSHA’s part to ensure that State Plans adopt the emergency regulation. Because OSHA regulations are matters of state law within the State Plans, the states need to adopt them before they become effective. But failure to adopt a standard is an obvious violation of the State Plan’s duty to remain effective, providing a strong basis for the agency to threaten revocation of a State Plan or reconsideration of final approval.

And OSHA’s experience with the emergency COVID-19 standard promulgated for the health care industry in June 2021 suggests there would be widespread uptake—even if imperfect.²⁹⁵ Most State Plans quickly adopted the emergency standard—setting nationwide rules for how hospitals needed to protect their workers from infection with COVID-19—while Arizona, South Carolina, and Utah delayed adopting the standard.²⁹⁶ OSHA proceeded with further action only against Arizona, as described in Section I.C. To the extent some State Plans threatened to disregard the vaccine-or-test standard, it may reflect the specific discomfort around that rule.²⁹⁷ And it presents an opportunity for reform, discussed in Part IV.

IV. PREPARING TO REGULATE FOR THE NEXT NATIONWIDE EMERGENCY

The preceding Parts have demonstrated how OSHA’s response to the COVID-19 pandemic was shaped by its federalist structure. OSHA offered a weak response to the COVID-19 pandemic during the first year, in its own standard-setting and enforcement, and in its supervision of State Plans. While certain State Plans took the initiative to provide robust regulation and enforcement during the COVID-19 pandemic, others became less effective than OSHA through their meager

²⁹⁵ OSHA Healthcare ETS, 86 Fed. Reg. 32,376, 32,379 (June 21, 2021).

²⁹⁶ Jonathan J. Cooper, *US Labor Department Warns 3 GOP States over COVID Rules*, ASSOC. PRESS (Oct. 19, 2021), <https://apnews.com/article/coronavirus-pandemic-business-arizona-south-carolina-utah-bfdeb60f777646bbe665a9f92f371699> [<https://perma.cc/HU7G-5M6V>].

²⁹⁷ Bruce Rolfsen, *Employer Shot-or-Test Compliance Delayed Weeks in Some States*, BLOOMBERG L. (Jan. 3, 2022), https://www.bloomberglaw.com/bloomberglawnews/safety/BN%200000017e02f4dc40affe1bfe3b3c0001?bna_news_filter=safety.

enforcement. The result resembled what Congress sought to change with the OSH Act in 1970.

But COVID-19 is not the last emergency OSHA will tackle with the State Plans. As of writing, the pandemic continues. A new, more deadly variant may evolve, and OSHA could be called upon to reinstitute workplace protection measures. COVID-19 will, moreover, not be the last pandemic; new infectious diseases will likely require urgent intervention on a national scale. Other emergencies will also arise as climate change causes rising temperatures and increasingly volatile natural disasters that affect workers. Where OSHA's standard rulemaking process takes an average of more than seven years to complete,²⁹⁸ OSHA may find itself seeking emergency methods to counteract imminent risks nationwide. Like COVID-19, these threats will not be confined to the workplace, and the agency will be challenged to respond within the bounds of *NFIB v. OSHA* and in coordination with the State Plans. What can be learned from OSHA's response to COVID-19, and how can the federalist worker health and safety system be improved to better react to emergencies going forward?²⁹⁹

A. *Unravel the Federalist System*

The most radical solution would be to replace the current system of hybrid federal-state system with a state-only or federal-only system. In a state-only system, every state would have a worker safety program, and OSHA would serve in the role of standard-setter and monitor. Under this system, federal funding could be conditioned on the adoption of OSHA regulations or “at least as effective” alternatives. Retaining OSHA as the standard-setter would preserve a degree of uniformity while relieving states of the burden to study and issue standards on complex health and safety topics. OSHA might retain a small staff of inspectors to intervene in State Plans where enforcement is lagging or special skills are needed.

Under this system, State Plans could reap many of the benefits demonstrated by the responses of some to the COVID-19 pandemic. Outside the constraints of the federal Administrative Procedure Act and federal judicial precedents, State Plans can conduct more nimble and responsive rulemaking. They can also partner with other state agencies in cases of emergency to enhance their clout, as Washington's State Plan did during the COVID-19 pandemic. By reverting to state enforcement, all states could regulate worker safety issues—those without plans

298 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-602T, MULTIPLE CHALLENGES LENGTHEN OSHA'S STANDARD SETTING 2 (2012).

299 This Part does not purport to suggest general reforms to OSHA which are, undoubtedly, also important to improving the State Plan system. For suggestions relating to increasing funding to the agency or worker participation in OSHA regulation and enforcement, see MCGARITY & SHAPIRO, *supra* note 21, and NOBLE, *supra* note 21.

would not be barred by federal preemption if they remained effective.

However, for legal and practical reasons, this solution is unlikely to work. First, it closely resembles the system that states *could* have if they submitted a State Plan. But states have stopped seeking to implement comprehensive State Plans; no state has obtained initial approval for a full public and private sector plan since the 1970s.³⁰⁰ This suggests states would reject Congressional efforts to return worker safety authority to them. Second, the proposal would raise constitutional commandeering concerns if states were required to run a safety program meeting federal standards.³⁰¹ Permitting states to refuse a worker safety program, as a workaround to the commandeering problem, is an unacceptable alternative because it may leave some workers wholly unprotected. Third, because the states would *need* to retain their programs, OSHA would lose its ability to threaten a takeover, which remains a powerful tool to monitor their behavior in extreme cases, as demonstrated by the Arizona experience discussed in Section I.C. Fourth, OSHA's rulemaking would still be subject to notice-and-comment, resulting in long lead times for national standards. Finally, one benefit of OSHA is that it provides a locus for interest group advocacy. By devolving authority primarily to the states, worker and business representatives would struggle to efficiently advocate for their constituents' interests.

The reverse would be for Congress to eliminate State Plans and provide federal enforcement in every state. This would look much like the existing system in OSHA states where the agency operates a central office that conducts rulemakings and overarching policy, while regional offices do local enforcement. First, this option would likely be politically infeasible. State Plans would be reluctant to give up their programs, and the representatives from those states would lobby against it. Moreover, the expense of taking over the State Plans would deter Congress. Second, this proposal would probably result in diminished enforcement nationwide, particularly in the states that have vigorous state programs. The federal government would lose state contributions, and Congress is unlikely to fully replace that funding.³⁰² Third, this proposal would result in the loss of innovation and creativity in certain participating states, as the COVID-19 pandemic demonstrated. Workers in those states benefited from the local rules and enforcement. And when State Plans choose to regulate, they put a spotlight on what OSHA has not done.

That said, the COVID-19 experience demonstrates that OSHA should learn more from and cooperate more readily with State Plans. State Plans often lead the way with standards, which OSHA should consider adopting. During the pandemic,

300 OSHA QUICK FACTS, *supra* note 66.

301 See *Printz v. United States*, 521 U.S. 898, 925 (1977) (“[T]he Federal Government may not compel the States to implement, by legislation or executive action, federal regulatory programs.”).

302 Thompson, *supra* note 23, at 76.

states like Virginia provided models that could have helped OSHA design an emergency and permanent standard relating to COVID-19. Their experience could inform expedited rulemaking on the federal level. OSHA should also encourage State Plans to regulate issues that may be infeasible at the federal level due to politics or administrative delays. State Plans may be able to promulgate rules more efficiently during an emergency, because these regulations may help OSHA build the momentum to act on the same issues, demonstrating that the regulation is not overly burdensome, but rather clarifies employer obligations and facilitates enforcement.

B. Enhance OSHA's Monitoring Tools

Recognizing that the hybrid system is here to stay, Congress and OSHA should take actions to strengthen the monitoring of State Plans, particularly during emergencies. As demonstrated above, certain State Plans will likely lag in their response to an emergent situation. OSHA should be encouraged to monitor State Plans and provided the tools to make a credible threat if they fall behind. After all, empowering OSHA as an agency is key to strengthening the entire system.

First, Congress should clarify the meaning of “at least as effective,” or OSHA should conduct a rulemaking on the subject. The system of adequacy turns on a comparative measure between OSHA and the State Plans. Yet, there is little clarity about what it means. This is particularly difficult with respect to enforcement. State Plans have long conducted a different *kind* of enforcement than OSHA—with more frequent violations and lower penalties. Is this equally effective? Calculated in terms of deterrence, as this Article does, it can be. But Congress has never made this determination. Moreover, some members of Congress, policymakers, and advocates have called for effectiveness to be defined in terms of outcomes—injury and illness rates. But current data do not allow for rigorous comparison on these lines. If this is what Congress means by “effective,” it should say so and fund a better national survey. Having clarity on these points is particularly important during an emergency. Where structural considerations, such as rulemaking and inspection authority, may assure Congress that a State Plan has the tools it needs to be effective, they do not ensure that a State Plan will act vigorously to meet a new hazard. For OSHA to make such determinations quickly and cheaply, it must have a more concrete idea of what it would mean for a State Plan to be effective. Otherwise, when the moment for speedy accountability arises, OSHA will have difficulty justifying its own metrics and standards to the State Plans.

Congress should also authorize OSHA to use State Plan funding as a lever to ensure effectiveness. As written, the OSH Act implies that OSHA cannot alter the

funding scheme when State Plans are insubordinate but not abdicating.³⁰³ Because State Plans rely heavily on federal funding—constituting up to 50 percent of their annual budget—OSHA could condition funding on State Plans meeting targets of effectiveness or implementing standards.³⁰⁴ Funding could be a far more credible threat than withdrawing authority or reconsidering final approval. In an emergency, OSHA could threaten to withhold funding if a State Plan does not perform, for example, a given number of proactive inspections, or if the federal agency receives a credible CASPA. The agency could also use grants in these cases to encourage State Plans to enforce more vigorously.

Finally, Congress should change the meaning of “final approval” to provide OSHA with concurrent jurisdiction. Instead of giving State Plans exclusive jurisdiction over worker protection, states should have primary jurisdiction, with OSHA able to intervene in case of lacking enforcement. Even the process of reconsidering “final approval” may be too slow and uncertain in case of an emergency like COVID-19. Rather, immediate entry of OSHA inspectors could be a more meaningful and expeditious means of control. It would also enable OSHA to supplement and supervise a given State Plan in an emergency. This authority would further allow the agency to help the State Plan through the period. OSHA had done this successfully in a state under an “operational status agreement,” a form of concurrent jurisdiction under which seven State Plans still operate.³⁰⁵ After a deadly chicken plant fire in North Carolina, OSHA temporarily asserted partial control over the state’s workplace safety plan in what was seen as a “clear rebuke of the state program.”³⁰⁶ This encouraged North Carolina to supply the agency with additional resources.³⁰⁷ Indeed, the goal may not be that OSHA *actually* sends its own inspectors to help; rather, the credible threat of intervention may convince politicians in certain states to step up in an emergency. For example, they might, as Washington OSHA did during the pandemic, recruit officers from other parts of the state government to assist them with fielding complaints and conducting enforcement. Urging the state agency to use its own resources would be a profitable result for workers.

C. Strengthen OSHA’s Emergency Rulemaking Authority

As argued above, standards are key to uniform, nationwide OSHA enforcement. Yet the politics of OSHA are such that adoption of these standards is at the discretion of appointed officials, whose politics may favor guidance over

303 See OSH Act § 23(f)-(g), 29 U.S.C. § 672(f)-(g).

304 *Id.*

305 OSHA QUICK FACTS, *supra* note 66.

306 MCGARITY & SHAPIRO, *supra* note 21, at 174-75.

307 HUBER, *supra* note 26, at 187.

explicit rulemaking. How then can agency action be encouraged? Some statutes contain legal rights to sue over agency inaction, such as by providing deadlines. These can give interested parties a means to urge agency action. But they are also difficult for constituents to enforce in court where the agency leaders oppose the action, because courts are hesitant to dictate agency priorities.³⁰⁸

Professor Nancy Modesitt has offered a set of worthy recommendations for easing OSHA's ability to promulgate emergency standards.³⁰⁹ First, Professor Modesitt argues that Congress should permit OSHA to issue such a standard where it would be "reasonably likely to be effective in reducing the risk," as opposed to strictly "necessary," a hurdle that has caused prior ETSs to be struck down.³¹⁰ Second, she argues that Congress should loosen or eliminate the requirement that OSHA replace the standard with a permanent rule in six months, giving OSHA authority to issue an emergency rule for a limited time only.³¹¹ Finally, she argues that Congress should confirm OSHA's authority to modify the standard in light of new information.³¹² This set of reforms would reduce the likelihood that OSHA's emergency standards would be defeated by the courts and assuage some of the concerns about flexibility and information costs.

Congress could further require State Plans to adopt ETSs immediately after OSHA issues them. If they wish to implement an "as effective" alternative, they should be required to enact it as a replacement for the federal rule. Or Congress could give OSHA authority to enforce the standard if the State Plan drags its feet. This would help ensure that when OSHA does adopt an emergency standard, State Plans will be unable to argue that they are slowly developing their own alternatives.

CONCLUSION

The story of OSHA and the State Plans is a story about the choice between state autonomy and federal control. This Article seeks to contribute to this fundamental debate by highlighting an often-overlooked example at a critical moment. There is much more to be studied, elaborated, and evaluated about the role of OSHA during the pandemic and the relationship between OSHA and the State Plans. It is the author's hope that this Article encourages others to continue the research.

308 See *NRDC v. Train*, 510 F.2d 692, 712-14 (D.C. Cir. 1974) (discussing the difficulties in mandating a federal agency to meet a congressionally imposed deadline for regulation).

309 Modesitt, *supra* note 7.

310 *Id.* at 229.

311 *Id.* at 231.

312 *Id.* at 230.

Rewarding Failure with Patents

Robin Feldman*

Abstract:

It is axiomatic that patents promote success. And yet, a contrary notion—that the patent incentive for medicine should be sufficient to compensate for the losses incurred when other research fails—is quietly permeating modern court decisions, commentary, and Congressional discussions, coloring debates relating to pricing and regulation of medicine. The conceptualization is moving forward unchallenged, as if failure compensation follows logically from the innovation incentives built into the patent construct. As this Article demonstrates, however, the notion is antithetical to patent law, putting modern conceptualizations on a collision course with the history and theory of patents reaching back to this nation’s inception.

Reviewing patent theory, federal statutes and cases from 1790 to 1865, and the orientation of the patent system, this Article demonstrates the fallacy of creating incentives to fail. From a theoretical perspective, although patents are designed to encourage innovation, a patent is not a participation trophy. One does not receive a patent for an invention one tried and failed to create, and the patent reward is based on success, rather than failure. From an historical perspective, with limited exceptions, early patent law reveals no act or case suggesting that a patent grant is intended to compensate the patentee even for the costs of developing a successful (i.e., patented) invention, let alone other research failures. Finally, the notion of compensating for failures denies other strains evident in the patent system. Failure compensation in the context of the patent system has the effect of encouraging inefficient invention and can lead to a perverse reality in which the more one fails, the higher the compensation.

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INTRODUCTION

It is axiomatic that patents create incentives for success. Although much ink has been spilled over what types of inventions are patentable¹ and how broadly patents should reach,² no one would ever suggest that patents should create

1 See, e.g., Stefania Fusco, *Is In re Bilski a Déjà Vu?*, STAN. TECH. L. REV. 143 (2009) (arguing that whether the nature of an invention is physical or nonphysical is not a simple matter); Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289 (2011) (advocating for the development of a framework that better delineates the boundaries of patentable subject matter); Robin Feldman, *Coming of Age for the Federal Circuit*, 18 GREEN BAG 27, 31 (2014) (explaining that in *Bilski v. Kappos*, 561 U.S. 593, 612 (2010), the Justices suggested they disagreed with everything the Federal Circuit had ever said about patentable subject matter in the Circuit's thirty-year history); Kristen Osenga, *Institutional Design for Innovation: A Radical Proposal for Addressing § 101 Patent-Eligible Subject Matter*, 68 AM. U. L. REV. 1191 (2019) (arguing that patent rights should be strengthened by locating all patentable subject-matter inquiries in the courts rather than allowing the United States Patent and Trademark Office (USPTO) to make such determinations); Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 591 (2008) (contending that the ambiguity of patentable subject-matter definitions can be resolved by granting a patent to "any invention that satisfies the Patent Act's requirements of category, utility, novelty, nonobviousness, and specification"); Emily Michiko Morris, *Intuitive Patenting*, 66 S.C. L. REV. 61 (2014) (describing all patentable subject-matter determinations as intuitive rather than objective); David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 181 (2009) (arguing that "there is no reason to expand patentable subject matter into fields where innovation is already healthy"); Peter M. Kohlhepp, *When the Invention Is an Inventor: Revitalizing Patentable Subject Matter to Exclude Unpredictable Processes*, 93 MINN. L. REV. 779 (2008) (arguing that existing subject-matter considerations offer overly broad patent protection to algorithms and other nascent forms of artificial creativity); Steven Swan, *Plugging the Rabbit Hole: The Supreme Court's Decision in Alice*, 2016 UTAH L. REV. 891 (2016) (proposing to improve the Supreme Court's decision in *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), with supplemental patent evaluations that help define an abstract idea for purposes of determining patentable subject matter); Jesse D.H. Snyder, *Have We Gone Too Far: Does the Seventh Amendment Compel Fact-Finding Before Reaching A Decision on Patent-Eligible Subject Matter?*, 14 CHI.-KENT J. INTELL. PROP. 436 (2015) (arguing that the invalidation of a patent on *Alice* subject-matter considerations constitutionally requires a jury evaluation and noting that the *Alice* decision instead caused many patents to be invalidated prior to the fact-finding stage); Emily Michiko Morris, *What Is "Technology"?*, 20 B.U. J. SCI. & TECH. L. 24 (2014) (proposing to clarify the definition of "technology" for purposes of determining patentable subject matter); Ben McEnery, *Physicality and the Information Age: A Normative Perspective on the Patent Eligibility of Non-Physical Methods*, 10 CHI.-KENT J. INTELL. PROP. 106 (2010) (contending that subject matter should not need to have a physicality requirement to be patentable).

2 See, e.g., Jeanne C. Fromer, *Claiming Intellectual Property*, 76 U. CHI. L. REV. 719, 731–35 (2009) (describing historic shifts from central to peripheral claiming and remnants of central claiming in patent law); Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1212 (2008) (discussing the importance of the written-description doctrine in resolving formal questions of claim scope beyond the ability of the enablement doctrine); John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439 (2004) (describing

incentives for failure. And yet, if one were to actualize a theory being expounded today, that is precisely what is being advocated in modern arguments related to patent law and policy. In court decisions,³ halls of Congress,⁴ and industry boardrooms,⁵ analysis after analysis follows a simple logic that turns the patent system on its head. And what is that deceptively appealing notion? Quite simply, the notion is that the patent reward for pharmaceuticals should be sufficient to compensate for the losses incurred when unrelated research fails.

Although more familiar in pharmaceutical pricing discussions, the argument also is presented in the context of pharmaceutical patents.⁶ In the pricing context, the argument is that the price of drugs must be sufficient to compensate for failed research attempts. In the patent context, the argument is that the patent reward must include compensation for failed efforts at innovating products other than the one on which a patent has been granted.

This Article will show that the concept is antithetical to patent law. Specifically, the notion of compensating for failed research puts the modern application of patent law on a collision course with the history and theory of

the controversy over Edmund Kitch's prospect theory of patent with its recommendation for early and broad patent rights); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 848–49 (1990) (arguing that legal principles and objective evidence in areas including patent law often leave considerable room for discretion and discussing what policies should influence that discretion); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 268 (1977) (analogizing patents to mineral rights and proposing the prospect theory of patents, which suggests that broad rights should be granted early in the innovation process); Roger L. Beck, *The Prospect Theory of the Patent System and Unproductive Competition*, 5 RSCH. IN L. & ECON. 193 (1983) (suggesting lack of foundation in Edmund Kitch's prospect theory, favoring broad patent rights); Robin Feldman, *RETHINKING PATENT LAW* 32-40 (2012) (analyzing various patent analogies, including mineral rights, fishing rights and hunting licenses, and proposing the bargain theory of patents).

³ See *In re Depomed Pat. Litig.*, No. CV 13-4507 (CCC-MF), 2016 WL 7163647, at *80 (D.N.J. Sept. 30, 2016), *aff'd sub nom.* Grunenthal GMBH v. Alkem Lab'ys Ltd., 919 F.3d 1333 (Fed. Cir. 2019) (citing *Eli Lilly & Co. v. Premo Pharm. Lab'ys., Inc.*, 630 F.2d 120, 137 (3d Cir. 1980)); see also *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 346 (S.D.N.Y. 2006) (noting Sanofi economist's testimony that Plavix's high profits are necessary in order to cover the research and development costs of other Sanofi drugs that either never make it to market or never recoup their associated costs); cf. Tom Wilbur, *IP Explained: Myth vs. Fact About Strong Patent Protections in the Biopharmaceutical Industry*, THE CATALYST (May 2, 2019), <https://catalyst.phrma.org/ip-explained-myth-vs.-fact-about-strong-patent-protections-in-the-biopharmaceutical-industry> [<https://perma.cc/7QMZ-UJUG>] (pharmaceutical industry trade group publication arguing that the well-being of the industry relies on robust patent protections, including method-of-use and secondary patents that prolong drugs' monopoly periods).

⁴ CONG. BUDGET OFF., *RESEARCH & DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY* 2, 14 (2021), <https://www.cbo.gov/publication/57126> [<https://perma.cc/Y32H-Y7QZ>].

⁵ See JOHNSON & JOHNSON, *TRANSFORMING LIVES, ADVANCING HOPE: 2019 JANSSEN U.S. TRANSPARENCY REPORT* 5 (2019), https://transparencyreport.janssen.com/_document/janssen-2019-transparency-report?id=0000017f-4bb2-ddcd-ad7f-7fbb03bf0001 [<https://perma.cc/RHR6-RYW6>].

⁶ See *infra* text accompanying notes 30-34.

patents, reaching back to this nation's inception.

From a theoretical perspective, the patent system is designed to reward success. Yes, patents are designed to provide incentives for innovation, but a patent is not a participation trophy. Perhaps no statement is as telling for underscoring this point than the Supreme Court's language in *Brenner v. Manson*: "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."⁷

Thus, one does not receive a patent for an invention one tried and failed to create. Similarly, a patent's reward should reflect the successful invention rather than compensation for attempts gone bad.

From an historical perspective, an examination of the nation's early patent statutes and cases reveals that the notion of compensation for failures is entirely absent. Indeed, with limited exceptions, early patent law reveals no act or case stating that a patent grant is intended to compensate the patentee even for the costs of developing a *successful* (i.e., patented) invention. These types of perspectives are not present in the historic construct of the patent system.

Moreover, the notion of compensating for failures denies the economic logic of the patent system, as well as common sense. As some economists explain, patents are a compensation for contribution to society, not for costs incurred by inventors.⁸ From this perspective, social contribution, not the development cost, is the touchstone for the value that a patent should confer to its inventor.⁹ Finally, and quite simply, compensating for failures in the context of the patent system has the effect of encouraging inefficient invention. Such an approach would lead to a perverse reality in which the more one fails, the higher the compensation when one succeeds.

In a perfect world, one might expect purchasers to create a natural brake on the system. Regardless of the compensation an industry views as its due, one cannot charge a price unless buyers are willing to pay. Health care is a strange market, however, and buy-side pressures can be dampened. Most important, modern strategic behaviors allow pharma companies to exploit the regulatory environment, further weakening the potential effects of price limitations. Thus, although one would expect certain constraints to counteract the inefficiencies of compensating for failure, characteristics of the pharmaceutical market prevent

7 *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

8 See Carl Shapiro, *Patent Reform: Aligning Reward and Contribution* (Nat'l Bureau of Econ. Rsch., Working Paper No. 1341, 2007); see also MORDECAI KURZ, *THE MARKET POWER OF TECHNOLOGY—UNDERSTANDING THE SECOND GILDED AGE*, ch. 9.1 (Colum. Univ. Press ed., 2022) (describing the economics of patents in contribution-to-society terms by explaining the paradox in which the patent's reward rises as our need for the product rises and the fact that the law's allowance for monopoly prices permits higher prices where the need is greater).

9 See *supra* note 8.

such constraints from operating.

This is particularly problematic in light of an historic shift in the pharmaceutical industry over the last decade.¹⁰ Faced with stagnating innovation, the pharmaceutical industry has shifted to outsourcing innovation. Specifically, the majority of innovation in the pharmaceutical industry comes from academia or small life science companies.¹¹ Large pharmaceutical companies then shepherd the drugs through the FDA approval process and into production.

Ordinarily, there should be little room for excess returns at the top. The little fish invent. The big fish pay the little fish the discounted present value of their invention, and the dollars flow through in an airtight system. Anecdotal evidence, however, suggests that significant leakage occurs in the system. For example, high-profile blockbuster drugs, such as Gilead's Hepatitis C treatment, Sovaldi, and Merck's cancer immunotherapy, Keytruda, demonstrate how the value of the acquisition can fail to reflect the true value of the drug. What results is considerable value leakage and a diluted incentive to take on basic, high-risk research. At the end of the day, society is not only encouraging failure, it is doing so at the wrong part of the innovation chain.

In short, the patent reward must be firmly and solely rooted in the successful invention alone, and the emerging modern notion of including failures in the patent reward threatens to cost society dearly. To be clear, this Article does not suggest that the current patent system has created failures, nor does it provide either empirical or anecdotal evidence of how the current patent system has done so. Rather, this Article presents the thesis that, if embraced in policy implementations, the logical conclusion of an argument that is increasingly propounded today is in tension with patent history and basic logic.

¹⁰ This Article does not explore the question of whether related problems exist outside the pharmaceutical industry. However, the industry structure in health care does present issues that are not necessarily present in those arenas. See *infra* Section III.A (describing lessening of buy-side constraints in the pharmaceutical industry).

¹¹ See Joanna Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. HEALTHCARE L. & POL'Y 1, 2 (2018) (describing the primacy of startup innovation in the modern, vertically disintegrated pharmaceutical ecosystem); ULRICH GEILINGER & CHANDRA LEO, HBM PARTNERS, HBM NEW DRUG APPROVAL REPORT: ANALYSIS OF FDA NEW DRUG APPROVALS IN 2018 (AND MULTI-YEAR TRENDS) 16-17 (2019) (observing that the proportion of new molecular entities that originated in smaller firms has grown from 31 percent in 2009 to 63 percent in 2018, while the new drug approval share of the ten largest pharmaceutical companies declined from 52 percent to 25 percent); Amirah Al Idrus, *Biopharma Converts 24% of NMEs to Drugs, with Celgene Bringing up the Rear: Report*, FIERCEPHARMA (Apr. 29, 2019), <https://www.fiercebiotech.com/biotech/biopharma-converts-24-nmes-to-drugs-celgene-bringing-up-rear-report> [<https://perma.cc/8Q9R-7LK5>] (finding that, of the forty-one new molecular entities launched by Celgene, a large drug-maker, between 2014 and 2018, only eight were innovated internally; most were the product of acquisition or licensing).

I. PATENT THEORY AND THE NARRATIVE OF FAILURE

The pharmaceutical industry today is beset by a staggering growth in prescription drug prices. The United States—where brand-name drugs cost more than triple what they do in other countries¹²—spent 40 percent more on prescription drugs in 2017 compared to 2007, a trend that shows no sign of reversal.¹³ Even after accounting for rebates, brand-name net drug prices rose 60 percent during roughly the same period,¹⁴ causing many patients to skip doses or cease filling prescriptions altogether.¹⁵

Balanced against these soaring prices is the need for innovation. Society would not have such life-saving therapies without an innovative industry to discover and develop them. Although estimates differ widely,¹⁶ pharmaceutical research and development is expensive, with more dry holes than successful wells and failure a constant companion. Perhaps it takes high returns such as these to keep the engines of innovation humming and to bring these innovations forward for the benefit of society. The nation's founders may have understood such needs in establishing the patent system, providing the potential for healthy patent rewards so that pioneers would be inspired to soldier onwards and push through the failures, earning enough to compensate for the long journey.

But is that correct? Only partially. This Article will argue that an essential aspect of this logic is deeply and fundamentally flawed based on the history and theory of the patent system, as well as the modern structure of the pharmaceutical

12 See Andrew W. Mulcahy, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, vii (RAND Corp., RR-2956-ASPEC, 2021), <https://www.rand.org/news/press/2021/01/28.html> [<https://perma.cc/8ZXB-8X7X>] (finding that the price of “brand-name originator drugs” in the United States was 344 percent of 32 OECD countries’ average price in 2018).

13 See *Why Are Prescription Drug Prices Rising and How Do They Affect the U.S. Fiscal Outlook*, PETER G. PETERSON FOUND. (Nov. 14. 2019), <https://www.pgpf.org/blog/2019/11/why-are-prescription-drug-prices-rising-and-how-do-they-affect-the-us-fiscal-outlook> [<https://perma.cc/B4RV-YWKZ>] (reporting that the Centers for Medicare & Medicaid Services expect a further 60 percent increase in spending between 2017 and 2027).

14 Immaculada Hernandez et al., *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018*, 323 JAMA 854 (2020).

15 See Steven G. Morgan & Augustine Lee, *Cost-Related Non-Adherence to Prescribed Medicines Among Older Adults: A Cross-Sectional Analysis of a Survey in 11 Developed Countries*, 7 BMJ OPEN e014287 (2017) (finding that older American patients reported cost-related non-adherence six times more frequently than patients in the U.K.).

16 Compare Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 JAMA INTERNAL MED. 1569 (2017) (finding that the cost to develop a cancer drug is \$648 million), with Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 21 (2016) (study from academic center that receives industry funding concluding that the cost of bringing a drug to market ranges from \$2.588 billion to \$7.87 billion).

industry.

A. Patent Underpinnings

Patents constitute bargains between inventors and society. Rooted in constitutional language,¹⁷ the bargain grants inventors, in general, and pharmaceutical innovators, in particular, the potential to enjoy monopoly profits in exchange for providing new and useful therapies. Distributed through the patent system, these rights provide the opportunity for a handsome profit but are limited in time and scope. As Thomas Jefferson noted, “[c]ertainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. It is equally certain it ought not be perpetual.”¹⁸

As well as limitations in time, the grant of a patent is limited in scope. In 1790, Congress enacted the first patent statute, and George Washington signed the first U.S. patent to Samuel Hopkins for an invention related to making potash.¹⁹ Since then, patent law has required patent holders to disclose their invention so that those skilled in the art can make and use it.²⁰ Patent law even contains a prohibition on patent misuse, which is broadly defined as an impermissible attempt to expand the time or scope of a patent.²¹ Moreover, the art of obtaining a patent involves the delicate dance of balancing the desire to draft claims that reach as broadly as possible with the requirement that claims reach no further than what is new, non-obvious, and fully disclosed.²² Only the invention that one has specifically

17 See US CONST., art. I, § 8, cl. 8 (“The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . .”); see also *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”).

18 Letter from Thomas Jefferson to Oliver Vans (May 2, 1807), in *THE WRITINGS OF THOMAS JEFFERSON* 200–02 (Andrew A. Lipscomb, ed. 1903); see also WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* 42–43 (1890) (historic patent treatise describing the importance of obtaining the use of every invention for society as soon as possible).

19 See U.S. PAT. & TRADEMARK OFF., *Patents Through History*, https://10millionpatents.uspto.gov/_https://perma.cc/98DY-TY5Z].

20 See 3 DONALD S. CHISUM, *CHISUM ON PATENTS* § 7.03 (2003); see also Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539 (2009); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621 (2010); Robin Feldman, *The Inventor’s Contribution*, 2005 UCLA J.L. & TECH 6 (discussing the modern disclosure doctrines and their historic roots).

21 See, e.g., *Blonder-Tongue Labs., Inc. v. Univ. Ill. Found.*, 402 U.S. 313, 343–44 (1971) (discussing in the context of fraud and inequitable conduct a series of decisions in which the Justices condemned attempts to broaden the physical or temporal scope of the patent monopoly); 6 DONALD S. CHISUM, *CHISUM ON PATENTS* § 19.04 (2001).

22 See also Robin Feldman, *The Inventor’s Contribution*, 6 UCLA J.L. & TECH 1, 4 (2005) (describing the disclosure doctrines and explaining that “[w]hat the inventor reveals must be

described will receive the golden patent crown.

Even within that limited concept, there is no guarantee that a patent will garner any returns or even that it will grant a monopoly. Scholars and commentators estimate that more than 90 percent of patents never generate any returns to those who hold the right.²³ Similarly, as the Court has consistently made clear, the patent right does not necessarily convey a monopoly. There may be substitutes for the product invented, patents can overlap, or the market may not be ready to appreciate the value of the patented product during the patent term.

From the beginning, U.S. patent law has been framed in terms of the benefit to society rather than the benefit to inventors. As the Justices noted in *Graham v. John Deere*, “[t]he patent monopoly was not designed to secure the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.” That knowledge, specifically, is the knowledge identified in the patent.²⁴

The notion of bringing forth new knowledge embodies the core of the patent system. The patent system is designed to reward those who not only create, but also share those inventions openly with society.²⁵ Inventors could decide to keep their inventions secret, and the law provides Trade Secret protection for those who choose the secrecy route. Nevertheless, society reserves the stronger, patent protection for those who are willing to disclose for the benefit of society.²⁶ Of

sufficient, regardless of whether any insufficiency is due to the fact that the patent holder has not given us enough of the invention or the fact that the patent holder simply does not have enough to give”). There are five elements of patentability, including also patentable subject matter and utility, but the three listed in the main text are the most relevant to the tension between claims and disclosure. See generally JANICE M. MUELLER, PATENT LAW, 296-329 (describing the elements of patentability).

23 See, e.g., Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PENN. L. REV. 1, 5 n.3 (2005) (noting that most estimates suggest less than 5 percent of patents have any apparent value at all); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U.L. REV. 1495, 1507 (2001) (opining that “the total number of patents litigated or licensed for a royalty (as opposed to a cross-license) is on the order of five percent of issued patents”); Stephen Key, *In Today’s Market, Do Patents Even Matter?*, FORBES (Nov. 13, 2017) (“Around 97% of all patents never recoup the cost filing them.”).

24 *Graham v. John Deere*, 383 U.S. 1, 9 (1966); see also WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 42-43 (1890) (seminal patent treatise of the late 1800s explaining that “[t]he duty which the state owes to the people to obtain for them, at the earliest moment, the practical use of every valuable invention in the industrial arts is . . . a higher and more imperative duty than which it owes to the inventor”); Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 THE WRITINGS OF THOMAS JEFFERSON 326, 334-35 (Andrew A. Lipscomb & Albert Ellery Bergh eds., 1905) (declaring that the “embarrassment of an exclusive patent” is justified only because these “monopolies of invention” serve the “benefit of society”).

25 See, e.g., *Bonito Boats, v. Thundercraft*, 489 U.S. 141, 151 (1989) (observing that “the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure”).

26 See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 490 (1974) (describing the greater strength of patent protection in comparison to trade secrets).



course, there are altruistic souls who simply dedicate their work freely to the world without any reward at all, but society, understandably, does not rest on the hope that we will be blessed with a sufficient number of such generous folks. In short, the goal of the patent system is to benefit society, not simply by encouraging invention but also by encouraging the eventual dedication of that information to the public.

One could certainly imagine a different approach to patenting and innovation. Early American debates on intellectual property rights considered the possibility that intellectual property rights, particularly copyrights, might flow from the natural rights of the authors²⁷ rather than the consequentialist notion of promoting the progress of “the useful arts.”²⁸ Similarly, an innovation incentive system could provide more than merely offering an *opportunity* to garner a return through exclusive marketing rights. The government, for example, could grant prizes for successful invention,²⁹ in exchange for making the information available to the public. And, of course, the system need not involve revealing one’s innovation to the public at all. Innovation incentives can be designed so that the invention remains confidential, as with trade secrets. And even in the context of providing incentives for invention in the interests of the public, an innovation system need not be grounded in an invention that has already been “conceived of or reduced to practice.” The government could provide funding for exploration in the hopes that innovation would result.

Nevertheless, since at least the time of the U.S. Constitution, the nation’s patent system remains firmly rooted in a basic conception: In exchange for bringing forth one’s ideas to the public, an inventor may receive the right to exclude others from the specific sphere of the invention for the term of the patent, during which time the patent holder can attempt to earn a return on that invention in the market. All of this, of course, is grounded in the invention specified in the four corners of the patent.

27 See, e.g., Mass. Act of Mar. 17, 1783, reprinted in COPYRIGHT ENACTMENTS OF THE UNITED STATES, 1783-1906, at 14 (2d ed. 1906) (describing the purpose of copyright law as encouraging inventions and respecting the “natural rights of all men”); see also Jane C. Ginsburg, *A Tale of Two Copyrights: Literary Property in Revolutionary France and America*, 64 TUL. L. REV. 991 (1990) (describing the European influence on Early American copyright laws).

28 See U.S. CONST., art. I, § 8, cl. 8. For a discussion of consequentialist versus rights-based approaches, see UTILITARIANISM AND BEYOND 3-4 (Amartya Sen & Bernard Williams eds., 1982) (describing the consequentialism in which actions are judged by the state of affairs that will result); and SAMUEL SCHEFFLER, THE REJECTION OF CONSEQUENTIALISM 4-5 (1982) (explaining non-consequentialist or rights-based analysis in which actions are right or wrong independent of the resulting consequences). See also Feldman, *supra* note 22, at 2-3 (describing these constructs in the context of patents).

29 For a discussion of prizes and other systems, see Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEXAS L. REV. 303 (2013).

B. *Failure Compensation in the Modern Lexicon*

The patent theory grounding seems to have been forgotten in many modern patent discussions. The problem emanates from the judicial opinions on patent law, the halls of Congress, and some corners of academia in which it is argued that the returns available for a patent should include the costs of other failed inventions.

First, the logic of including failures has seeped into judicial characterizations of patents as companies seek to build the strongest walls possible around their patents. For example, in assessing the public interest effect of enjoining an alleged patent infringer, a decision from the District Court of New Jersey noted that “pharmaceutical research requires the realization of profits from successful drugs to make up for the losses from drugs that never make it to market or prove unsuccessful for other reasons.”³⁰ Consequently, it reasoned, “the public interest weighs in favor” of enjoining the alleged infringer, protecting the brand drug’s monopoly.³¹

The Southern District of New York went further, however. An opinion there argued that a litigated drug ought to be protected because its blockbuster earnings enabled the drug-maker “to expend the research and development costs for drugs that in fact never make it to market, or that make it to market but never recoup the costs associated with their getting there.”³² In other words, a patent serves to safeguard not only the novel drug’s earnings but the drug-maker’s *other* prospective drugs as well, however failing or unviable they may be. Thus, the inclusion of failed costs in the patent power has now traveled from the boardroom to the courtroom.

The pricing arguments also have spread to debates over patent law and policy. For example, congressional witnesses speaking on behalf of PhRMA (the pharmaceutical industry lobbying group) have explained over the last few years

30 *In re Depomed Pat. Litig.*, No. CV 13-4507 (CCC-MF), 2016 WL 7163647, at *80 (D.N.J. Sept. 30, 2016), *aff’d sub nom.* Grunenthal GMBH v. Alkem Lab’s Ltd., 919 F.3d 1333 (Fed. Cir. 2019), (“In enacting the patent laws, Congress recognized that it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the ‘useful arts’ to expend the time and money necessary to research and develop new products and to induce them ‘to bring forth new knowledge.’” (citing *Eli Lilly & Co. v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137 (3d Cir. 1980))). Notably, the *Depomed* court interpreted this innovation inducement described in *Eli Lilly* forty years prior to implicitly include failed or economically unviable drugs.

31 *Id.*; see also *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 346 (S.D.N.Y.), *aff’d*, 470 F.3d 1368 (Fed. Cir. 2006) (“Finally, protecting the patent for Plavix secures the public interest in innovation by providing commercial incentive for Sanofi to begin and continue clinical trials researching new uses for the drug . . . the Court finds the public interest lies slightly in favor of Sanofi.”).

32 *Sanofi*, 488 F. Supp. 2d at 346; cf. *Wilbur*, *supra* note 3 (pharmaceutical industry trade group publication arguing that the well-being of the industry relies on robust patent protections, including method-of-use and secondary patents that prolong drugs’ monopoly periods).

that patent protection supports innovation through compensation for the costly failures of the R&D process.³³ Other congressional witnesses for individual pharmaceutical companies have spoken in the same vein, describing the need for patents to compensate for widespread failures.³⁴

Other academic commentators have evidenced similar thinking. For example, in discussing patents, Erika Lietzan noted that “the company may be able to recover the investment it made in developing the medicine as well as others that are less successful or that failed before approval, and it may be able to enjoy a profit.”³⁵ In a slightly different vein, Emily Morris suggested that patents should compensate both for the patented drugs and for less profitable drugs, as opposed to those that failed.³⁶ Each of these contexts, whether it is the need for injunctive relief, patent enforcement, or patent legislation, imagines the contours of patent rights themselves, and all of this thinking embodies a notion that the reward of the patent should encompass more than the product on which the patent was granted.

33 *A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets: Hearing Before the Subcomm. on Comp. Pol’y, Antitrust, and Consumer Rts. of the S. Comm. on the Judiciary*, 117th Cong. 7 (2021) (statement of Geoffrey Levitt, Of Counsel, DLA Piper (on behalf of Pharm. Rsch. & Mfrs. Am.)); see *Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition: Hearing Before the S. Comm. on the Judiciary*, 116th Cong. 5-6 (2019) (statement of James Stansel, Executive Vice President, Pharm. Rsch. & Mfrs. Am.) (similar).

34 *Unsustainable Drug Prices: Testimony from the CEOs (Part I): Hearing Before the H. Comm. on Oversight & Reform*, 116th Cong. 47 (2020) (statement of Kare Schultz, Chief Executive Officer, Teva Pharm. Indus. Ltd.) (observing that “the system basically rewards innovation by granting patents. . . . And the reason why that’s necessary is that less than 1 out of 100 initial projects actually make it through all the way to the marketplace. The rest, they fail on the way, and that means that that risk nobody would take.”); *The “Innovation Act”*: *Hearing on H.R. 9 Before the H. Comm. on the Judiciary*, 114th Cong. 4 (2015) (statement of Hans Sauer, Deputy General Counsel for Intellectual Property, Biotechnology Indus. Ass’n) (describing how widespread failures in biopharmaceutical drug development necessitate the incentives of robust patent protections for successful drugs); see also *Unsustainable Drug Prices, supra*, at 49 (2020) (statement of Mark Alles, Former Chief Executive Officer, Celgene Corp.) (defending price increases on blockbuster drug Revlimid as a means of compensating for failures “across a number of years of development”).

35 See Erika Lietzan, *The Drug Innovation Paradox*, 83 MO. L. REV. 39, 56 (2018) (describing the period of protection granted by patents and government granted non-patent exclusivities such as protection of clinical trial data); see also Lee Branstetter, *TPP and the Conflict over Drugs: Incentives for Innovation Versus Access to Medicines*, in PETERSON INST. FOR INT’L ECON., ASSESSING THE TRANS-PACIFIC PARTNERSHIP, VOLUME 2: INNOVATIONS IN TRADE RULES 4, 5 (Cathleen Cimino-Isaacs & Jeffrey J. Schott, eds., 2016) (“Pharmaceutical innovation is especially dependent on patent protection . . . the cost of developing new drugs, inclusive of the cost of failures, lies in the billions of dollars per successful drug. Patents allow firms to recoup these costs . . .”).

36 Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 273 (2012) (“Attacking flagship drug patents particularly damages the brand-name pharmaceutical innovators, however, for those are exactly the drugs that subsidize not only their own development costs but also the costs of other beneficial but less profitable drugs.”).

Of course, one cannot have one's cake and eat it, too. If the patent system should compensate for investment in research, patents should not be awarded for discoveries that took little investment, and certainly not accidental discoveries. Creating an enantiomer of an existing drug may not require much investment (and may have different clinical effects in some cases but not in others),³⁷ yet modern companies patent enantiomers of their drugs. To take a more extreme example, penicillin was an accidental invention. If the aim is to compensate for investment in research, these types of inventions—although currently patentable—would not fit the bill.³⁸

To some extent, the failure-compensation argument may have seeped into patent law from a broader societal discussion related to the price of medicine. As the price of drugs has climbed in recent decades,³⁹ industry and some in academia have responded to criticism by arguing that high drug prices flow partly from the general need for funds to invest in innovation, rather than merely compensating for the cost of investment in the drug itself.

One should note that regardless of whether pricing should reflect innovation failures beyond the cost of R&D and manufacturing of the item itself, the patent discussion is fundamentally different from the pricing discussion. The question for patent law is not whether companies are taking advantage of desperate patients—after all, patents do offer an opportunity to garner monopoly returns—but rather whether the contours of those returns are faithful to the dictates of patent law's underlying theory. To engage in hyperbole, one could create greater investment incentives for pharmaceutical companies by allowing them to pay no taxes, use electricity for free, or walk into a laboratory supply company and take materials without paying. Discussions of these sorts, however, would be unrelated to the notion that the patent system provides market exclusivity for a successful invention—and for nothing other than the specific invention. Nevertheless, they may have influenced the patent-related discussions.

The notion that the price of any particular drug flows from the general need to invest in innovation, rather than specific investment in the drug itself, is on

37 Using a simplified explanation, enantiomers are conformations that have the exact same molecular structure but are mirror images, similar to left and right hands. See Silas W. Smith, *Chiral Toxicology: It's The Same Thing . . . Only Different*, 110 TOXICOLOGICAL SCI. 4, 16 (2009) (explaining that using just the right-handed molecule of thalidomide, however, would not have prevented the 1950s thalidomide crisis in Europe because conversions between the left- and right-handed forms of the molecule take place while the drug is being processed in the body), <http://toxsci.oxfordjournals.org/content/110/1/4.full> [<https://perma.cc/JH5H-AEQX>].

38 But see Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 38-39 (1993) (arguing that accidental inventions could receive a patent because the cost of screening out accidental inventions is too great for the system and because there may have been investment in unrelated research that led to the accident).

39 See *supra* text accompanying notes 12-15.

display in a Johnson and Johnson report, which explains that “[w]e have an obligation to ensure that the sale of our medicines provides us with the necessary resources to invest in R&D to address serious, unmet medical needs.”⁴⁰ The report is quite explicit in setting out the argument that the cost of a drug should not reflect the costs related to that drug alone but rather other expenses, as well. In that context, the company explains that failed investments in other drugs must also be one of the costs included:

“Some observers . . . argue that the price of medicines should be pegged to the costs of developing or manufacturing them. However, pricing a medicine based on its R&D or manufacturing costs alone would not take into account the full range of benefits a medicine provides. It would also leave out investments that we must make in drug candidates that fail in development. Pharmaceutical companies and the rest of the scientific community can learn from these failures to improve the research process.”⁴¹

That characterization is part of the normal industry explanation of the reasons for high drug prices.⁴²

Similarly, including the cost of failure has become a standard approach for academic researchers investigating the cost of producing a novel drug.⁴³ Although

40 See JOHNSON & JOHNSON, *supra* note 5.

41 *Id.* at 11.

42 See Ezekiel J. Emanuel, *Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up*, THE ATLANTIC (Mar. 23, 2019) (noting that pharmaceutical companies often claim that the research costs of unsuccessful drugs also have to be taken into account), <https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/> [<https://perma.cc/F2UG-F7G2>].

43 Studies addressing this question tend to focus on the cost of bringing to market a new therapeutic agent or new molecular entity. Many new drug approvals are not new molecular entities, but existing drugs that are repurposed or slightly altered. Research and development of these drugs tends to cost much less, even as they frequently garner lucrative monopoly periods. For more on these “recycled drugs,” see Amy Kapczynski, Chan Park & Bhavan Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLoS ONE e49470 (2012); Kate Gaudry, *Evergreening: A Common Practice to Protect New Drugs*, 29 NATURE BIOTECHNOLOGY 876 (2011); W. Nicholson II Price, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 801 (2020), describing and exemplifying evergreening; and Robin Feldman, *May Your Drug Be Evergreen*, 5 J. L. & BIOSCI. 590, 590 (2018), noting that 78 percent of drugs associated with new patents are not new drugs but existing ones and some of these drugs may even garner new NDAs. See also Steve Shadowen, Keith Leffler & Joseph Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS J.L. 1, 1-2 (2011) (discussing the prevalence of re-designed pharmaceutical products).

data inputs and results vary dramatically from analysis to analysis,⁴⁴ a common feature of studies investigating this question is the inclusion of failed drug innovation efforts in the cost of developing a successful drug.⁴⁵ Even the Congressional Budget Office cites that approach in examining R&D costs of drug development.⁴⁶

The costs of failed candidates may be the most significant driver of rising drug development expenses as they are measured by academics and researchers. DiMasi et al. cited the declining clinical success approval rate (*i.e.*, increasing likelihood of failure) of new drugs to explain why their 2016 estimate of drug development cost more than doubled their 2003 estimate.⁴⁷ Because research failures, according to contemporary academic researchers, help determine drug development cost estimates, new drugs become more expensive to bring to market as fewer are successfully approved.⁴⁸

44 Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844, 844 (2020) (noting that estimates have ranged from \$314 million to \$2.8 billion and reaching own median capitalized R&D investment of \$985 million).

45 *See, e.g., id.* at 846 (“Accurate information on costs of failures, *i.e.*, research and development outlays on candidates being developed by companies but not ultimately approved, is essential to estimating the costs of drug development.”); *see also* Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 21 (2016) (noting that “our approach explicitly links the costs of unsuccessful projects to those that are successful in obtaining marketing approval from regulatory authorities”). It is worth noting that the DiMasi (Tufts) estimate—whose \$2.6B value checks in at one of the highest—has been challenged on multiple fronts. *See* Aaron E. Carroll, *\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES (Nov. 18, 2014), www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html [<https://perma.cc/3F4N-LLEF>] (suggesting that the disparity in the findings stems from methodological mistakes in the Tufts study and noting that the Tufts Center is funded by pharmaceutical companies); TUFTS CTR. FOR STUDY DRUG DEV., *Financial Disclosure*, <https://esdd.tufts.edu/financial-disclosure/> [<https://perma.cc/FK72-AEVB>] (last visited Jan. 22, 2021).

46 CONG. BUDGET OFF., *supra* note 4 (describing in its “at a glance” section the expected cost to develop a new drug as including capital costs and expenditures on drugs that fail to reach the market).

47 *See* DiMasi et al., *supra* note 45, at 28 (“The overall clinical approval success rate declined from approximately one-in-five to approximately one-in-eight. That change alone accounts for a 57.3% increase in total cost [between 2003 and 2016, with the 2016 estimate totaling \$2.6 billion]”); *compare id.*, with Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).

48 In these analyses, researchers consider more than just the failed drug candidates that directly contribute to a successful drug. Instead, the failure costs researchers include in financing a successful drug are aggregated across all drug projects, as opposed to failures only in the same drug class or therapeutic area. *See* Wouters et al., *supra* note 44, at 846 (“We accounted for failures using data on aggregate clinical trial success rates . . . by dividing total research and development expenditures on a drug in a particular year by the corresponding aggregate phase-specific probability of success,

In a different rebuttal to the price-should-reflect-investment argument, some commentators point to the extensive amount of funding the federal government provides for pharmaceutical research.⁴⁹ That funding is undoubtedly extensive. For example, one study found evidence of federal funding in the research history of all 210 new drugs approved by the FDA between 2010-2016.⁵⁰ As one scholar notes, “[i]t is important to recognize that capital investments by shareholders contribute only a small fraction of the costs of research and development.”⁵¹ If the government is already shouldering part of the cost of research, then perhaps society has sufficiently contributed to the financial risks and burdens, at least to some extent.⁵²

The battle lines for this argument are set around the question of what constitutes society’s proper return from funding research (is it the benefit of disease treatments or a monetary return?)⁵³ and what constitutes government

similar to what was done in previous studies of costs of drug development”); *see also* DiMasi et al., *supra* note 45, at 23 (linking “the cost of compound failures to the cost of the successes”). Thus, the millions invested in a failed diabetes drug, for instance, would serve to inflate the cost of developing a successful bipolar therapy a decade later. It may be the case that lessons learned in such failures may contribute to some future therapeutic breakthroughs, as drug-makers contend. *See, e.g.*, JOHNSON & JOHNSON, *supra* note 5, at 11. But with falling approval rates, this method of estimating research costs serves to dilute innovative success in ever-expanding pools of failure.

49 *See, e.g.*, Jason Cone, *Pharmaceutical Corporations Need to Stop Free-Riding on Publicly-Funded Research*, THE HILL (March 3, 2018), <https://thehill.com/opinion/healthcare/376574-pharmaceutical-corporations-need-to-stop-free-riding-on-publicly-funded/> [<https://perma.cc/S8NC-3K99>] (op-ed by Executive Director of Doctors Without Borders, USA).

50 Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010-2016*, 115 PNAS 2329, 2333 (2018); *see also* Rahul K. Nayak, Jerry Avorn & Aaron S. Kesselheim, *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States*, 367 BMJ 5766 (2019) (finding that of the 248 FDA-approved drugs from 2008-2017, 48 benefitted from late-stage public funding).

51 Rena M. Conti & Frank S. David, *Public Research Funding and Pharmaceutical Prices: Do Americans Pay Twice for Drugs?*, F1000 RSCH., July 2020, at 8 (referee Fred D. Ledley’s response to the article as published in the open-access, peer-review report); *see also* Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 JAMA 834 (2020) (finding that large pharmaceutical companies were more profitable than other large companies, although the difference was smaller when controlling for differences in company size, research and development expense, and time trends).

52 A variant of this argument suggests that high drug prices are a form of “paying twice,” in which the taxpayer pays once for funding the research and then again through exorbitant drug prices, *See, e.g.*, Fran Quigley, *Your Tax Dollars Are Making Big Pharma Rich—Twice*, JUST CARE (Nov. 8, 2016), <https://justcareusa.org/your-tax-dollars-are-making-big-pharma-rich-twice/> [<https://perma.cc/S48U-L2YQ>].

53 *Compare* Conti & David, *supra* note 51 (observing that appropriate benefits are improved morbidity and mortality), with *Examining the Actions of Drug Companies in Raising Prescription Drug Prices: Hearing Before the H. Comm. on Oversight and Reform*, 116th Cong. (2019), <https://www.congress.gov/event/116th-congress/house-event/108817?s=1&r=2> [<https://perma.cc/3TWM-TZG4>] (questioning by U.S. Representative Alexandria Ocasio-Cortez

funding of research for a particular drug. Government funding tends to finance basic research, while pharmaceutical companies conduct later-stage development such as clinical research and commercialization of drugs.⁵⁴ Thus, some argue that government funding is beside the point given that such funding is highly attenuated from any particular drug or the role that private industry plays. In contrast, others contend that the underlying research supported by federal funds plays an important role in discovering the drugs that pharmaceutical companies later commercialize.⁵⁵ Moreover, early stages of research are associated with more risks, particularly in comparison to clinical trials.⁵⁶

Although grounded in arguments about pricing, the government-funding issue theoretically relates to patenting. Specifically, when the government funds research that results in a patent, it retains the right to step in and license the patent to others under certain circumstances.⁵⁷ When the 1980 Bayh-Dohle Act provided that those who receive government research funding may patent inventions flowing from that research, the government retained what are known as “march-in” rights, preserving the government’s power to use, or license others to use, such

suggesting that the public’s investment in early drug research does not return licensing fees or other specific monetary return); see also @SSWorks, Twitter (Jan. 31, 2019, 4:04 PM), <https://twitter.com/SSWorks/status/1091079715572592640> [<https://perma.cc/M5TN-BL7Z>] (video of Representative Ocasio-Cortez’s questioning).

54 Theresa Witzmann et al., *Current Model for Financing Drug Development: From Concept Through Approval*, in THE NAT’L ACAD. PRESS, BREAKTHROUGH BUSINESS MODELS: DRUG DEVELOPMENT FOR RARE AND NEGLECTED DISEASES AND INDIVIDUALIZED THERAPIES: WORKSHOP SUMMARY (2009).

55 Compare Benjamin Zycher, Joseph A. DiMasi & Christopher-Paul Milne, *Private Sector Contributions to Pharmaceutical Science: Thirty-Five Summary Case Histories*, 17 AM. J. THERAPEUTICS 101, 101 (arguing that “the scientific contributions of the private sector were crucial”), with Peter S. Arno & Michael H. Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631, 640 (2001) (arguing that “[w]hatever can be said of the scientific advances made with this public investment, the concrete financial return to taxpayers is minimal. But perhaps more importantly than the absence of any concrete return is the inevitability of even greater public or consumer expenditures demanded by the monopolies obtained by industry over publicly financed inventions, and the resulting supracompetitive profits and prices. The public has already paid for the cost of research”), and Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors?*, 30 HEALTH AFFS. 332 (2011) (arguing that there is an indirect influence of public funding on drug development). See also Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 NEJM 6 (2011) (looking at patents from public-sector research institutions to argue that government funding has a more direct role in applied research for drug development than in previous decades).

56 See, e.g., Jonathan Stasior et al., *Valuing Pharmaceutical Assets: When to Use NPV vs rNPV*, ALACRITA (Aug. 2018); see also David A. Hyman & Charles Silver, *Pharmaceutical Pricing When Success Has Many Parents*, 37 YALE J. ON REG. 855 (criticizing the pay-twice theory and examining the complexities of the pathways of pharmaceutical research).

57 See 35 U.S.C. § 200 (2018).

patents, assuming the government pays what is essentially a royalty.⁵⁸

In reality, however, these governmental rights are a paper tiger. The U.S. government simply has not exercised its powers against drug manufacturers since the 1960s and 1970s, although the George W. Bush Administration once threatened to exercise them against Bayer, resulting in a significant reduction of prices of the drug Cipro.⁵⁹

Regardless of the extent to which the pricing arguments have slipped into the patent discussion, the Part above details the fact that there are those in three commanding fields—modern courts determining whether to enjoin an alleged patent infringer, Congressional debates considering patent law provisions, and academics examining the contours of the patent quid pro quo—who approach analyses as if the patent reward appropriately includes compensation for failed research on other products. The following Part examines this argument through the lens of patent legal history.

II. CLASHING WITH THE HISTORY OF PATENT LAW

If it were true that the patent reward should be sufficient to include compensation for investment in failed research projects, one would expect to see historic patent law and theory embracing this conceptualization. On the contrary, historic patent statutes, cases, and classic theoretical discussions fail to reflect the notion that patents are intended to compensate for investment in failed research. Rather, they view the patent reward as tailored to the societal benefit and only the benefit provided within the narrow confines of the specific invention. Thus, the caselaw and statutory history demonstrate how far one would have to stray from the roots of patent law to support modern arguments that the patent reward should be large enough to include expenditures of money invested in failed research—at least as a matter of patent legal history.

The notion of including failed invention costs in the value of a patent finds no home in early American patent history. The nation’s early patent law—*i.e.*, federal statutes and cases from 1790 to 1865—reveals not a single act or case stating that

⁵⁸ See Act of June 25, 1910, Pub. L. No. 61-305, 36 Stat. 851 (1910) (codified as amended at 28 U.S.C. § 1498 (2018)). The Act specifies that the government must pay “reasonable and entire compensation.” See *id.* Although that provision has not been used for pharmaceuticals, court cases related to government use of non-pharmaceutical products have interpreted the language to provide for simple royalty amounts. See, e.g., *Decca Ltd. v. United States*, 640 F.2d 1156 (Ct. Cl. 1980) (assigning a royalty of 7.5 percent); *Tektronix, Inc. v. United States*, 552 F.2d 343 (Ct. Cl.), *opinion modified on denial of reh’g*, 557 F.2d 265 (Ct. Cl. 1977) (assigning a royalty of 10 percent). For a detailed history of § 1498, see Robin Feldman, *Patents as Property for the Takings*, N.Y.U. J. INTELL. PROP. & ENT. L. (forthcoming 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4050135 [<https://perma.cc/QD2N-4Q2Y>]; see also Amy Kapczynski & Aaron S. Kesselheim, ‘Government Patent Use’: A Legal Approach to Reducing Drug Spending, 35 HEALTH AFFS. 792, 794 (2016).

⁵⁹ See Kapczynski & Kesselheim, *supra* note 58, at 794.

a patent grant is intended to compensate the patentee for the costs of developing a failed (*i.e.*, never-patented) invention. Indeed, with limited exceptions,⁶⁰ early patent law reveals no act or case stating that a patent grant is intended to compensate the patentee even for the costs of developing a *successful* (*i.e.*, patented) invention.

A. *Early Cases and Authorities*

Early case law and venerable authorities cited therein state routinely that the reward of a patent grant is intended to encourage the creation of new and useful inventions. The same sources, however, routinely state that the *costs* of developing such inventions are irrelevant to patentability. Moreover, they only rarely state that the reward of a patent grant is intended to permit the recoupment of development costs and thus to encourage the incurrence of such costs (*i.e.*, investment). George Ticknor Curtis’s treatise on patent law⁶¹—“unquestionably the dominant work on patent law” from its initial publication in 1849 until at least 1873⁶²—quoted as a foundational articulation of the point, Chief Justice Tindal’s decision of 1842 in *Crane v. Price*:⁶³

[T]he labor of thought or experiment, and the *expenditure of money*, are not the essential grounds of consideration on which the question, whether the invention is or is not the subject-matter of a patent ought to depend. *For if the invention be new and useful to the public, it is not material whether it be the result of long experiment and profound search, or whether by some sudden and lucky thought, or mere accidental discovery . . .*⁶⁴

60 See *infra* text accompanying notes 71-85.

61 GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA (Boston, Little, Brown, 2d ed. 1854) [hereinafter CURTIS].

62 Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 605 & n.264 (2015). Curtis’s treatise was often cited in contemporaneous patent decisions. See, e.g., *Troy Iron & Nail Factory v. Corning*, 55 U.S. 193, 216 (1852); *Wintermute v. Redington*, 30 F. Cas. 367, 371 (C.C.N.D. Ohio 1856); *Foot v. Silsby*, 9 F. Cas. 385, 387 (C.C.N.D.N.Y. 1851).

63 Webster’s P.C. 411. Chief Justice Tindal was Chief Justice of the Court of Common Pleas in England. See *Massachusetts v. Rhode Island*, 45 U.S. 591 (1846). His decision in *Crane v. Price*, Webster’s P.C. 411, was frequently cited by U.S. courts. See, e.g., *O’Reilly v. Morse*, 56 U.S. 62, 101-02 (1853); *Yearsley v. Brookfield*, 30 F. Cas. 798, 802 (C.C.D.C. 1853); *Aiken v. Manchester Print Works*, 1 F. Cas. 245, 247 (D.N.H. 1865).

64 CURTIS, *supra* note 61, at § 6 n.1 (quoting *Crane*) (emphasis added); see also *Hotchkiss v. Greenwood*, 52 U.S. 248, 269-71 (1850) (Woodbury, J., dissenting) (quoting Justices Story, Kent, and Tindal, and citing *Curtis*); *Forbush v. Cook*, 9 F. Cas. 423, 424-25 (C.C.D. Mass. 1857) (Circuit Justice Curtis charged the jury: “The true inquiries for you to make in this connection are, whether

For the same purpose, Curtis also quoted Justice Story's famous statement of 1825, in *Earle v. Sawyer*, that, in the determination of whether an invention is patentable, "[i]t is of no consequence, whether the thing be simple or complicated; whether it be by accident, or by long, laborious thought, or by an instantaneous flash of mind, that it is first done. The law looks to the fact and not to the process by which it is accomplished."⁶⁵

the combination made by Crompton was new and useful? If it was a new and useful combination within the meaning of the patent law, it was the subject-matter of a patent, and *is not important* whether it required much or little thought, study, or experiment to make it, *or whether it cost much or little time or expense* to devise and execute it. . . . A new or improved, or more economical effect, attributable to the change made by the patentee in the mode of operation of existing machinery, proves that the change has introduced a new mode of operation, which is the subject-matter of a patent; and when this is ascertained, *it is not a legitimate subject of inquiry, at what cost to the patentee it was made . . .*" (emphasis added); *Carr v. Rice*, 5 F. Cas. 140, 142 (C.C.S.D.N.Y. 1856) (observing that "a patent can not be supported by proof that the invention was new to the patentees themselves, but the evidence must be satisfactory that they were actually the first, and original discoverers, of the thing patented. Their title is in no wise strengthened if their invention be proved to have been made *at great expense of time, research, and money*, even if they honestly believed it original with themselves, if in the end it is made to appear that others had previously known and used it." (emphasis added)); *Many v. Sizer*, 16 F. Cas. 684, 685 (C.C.D. Mass. 1849) (charging the jury: "I have been requested to instruct you that *it is of no consequence, as to the validity of a patent, how much, or how little labor, study, or thought the invention cost. And, gentlemen, this is so, if it be really a new and useful invention.* The degree of labor and thought may be sometimes evidence to the jury, upon the question of invention; but *although the invention be accidental, or a sudden flash of thought, the party is entitled to the benefit of his discovery.*" (emphasis added)).

65 *Earle v. Sawyer*, 8 F. Cas. 254, 256 (C.C.D. Mass. 1825). Kent, whose commentaries on American law were commonly cited throughout the early period, was probably the inspiration for Justice Story's comment: "The law has no regard to the process of mind by which the invention was accomplished, whether the discovery be by accident or by sudden or by long and laborious thought." 2 JAMES KENT, COMMENTARIES ON AMERICAN LAW 371 (O. Halsted 1827). While the cost of developing an invention is irrelevant to whether the invention is patentable (as noted by Justices Kent, Story, Tindal, *et al.*), the cost of commercializing an already-patented invention has, on occasion, been regarded as relevant to patent law. The relevance arises insofar as patent law has been regarded as incentivizing patentees and, especially, their assignees to make whatever expenditures are necessary to bring the patented invention to market. *See, e.g., Day v. Union India-Rubber Co.*, 7 F. Cas. 271, 275 (C.C.S.D.N.Y. 1856) ("These privileges are granted for the additional purpose of inducing inventors, and their assignees and grantees, to make the required expenditures and investments *in order to put the patented inventions in practice*, and thereby to give the public the benefits to be derived from a successful use of the inventions, at the earliest day, and to the fullest extent, required by the public interests." (emphasis added)); *see also Rohm & Hass Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) (finding that patent rights can "stimulate the investment of risk capital in the commercialization of useful patentable inventions so that the public gets some benefit from them, which may not occur in the absence of some patent protection." (emphasis added)). *See generally* *Blanchard's Gun-Stock Turning Factory v. Warner*, 3 F. Cas. 653, 657 (C.C.D. Conn. 1846) (noting that it was typically assignees that expended funding necessary to bring patented inventions to market and observing that "[t]he assignees of the original patentee are frequently *most instrumental in putting the invention into general use*, and bringing it successfully before the public, by the *expenditure of their time and money. More than half*, probably, of the useful patented inventions have been thus brought into general public use . . ." (emphasis added)).

These authorities give the purest expression of a view prevalent in the early period: That what is rewarded, and thus encouraged, by the patent grant is the creation of an invention new and useful to the public and that the costs incurred to develop the invention are irrelevant to patentability and play only a minor role in the statutory incentive structure. According to this view, what matters greatly is the statutory requirement of novelty and utility; what matters little is whether the invention resulted from arduous, expensive experimentation or, rather, from one cost-free flash of genius. Thus, the view bespeaks a practical, if hard-nosed, understanding of the purpose of patents: To create a societal benefit and not to give an A for effort. If the proposed invention fails to satisfy the law's uncompromisingly utilitarian prerequisites,⁶⁶ then no point can be served by granting a patent, even if the inventor's entire life and fortune have been devoted to the failure.

None of the foregoing is to say that courts in the early period did not permit patentees to recoup the costs of developing the patented inventions when suing for infringement.⁶⁷ Nor is it to say that such courts did not occasionally attribute to patent law the purpose of promoting investment.⁶⁸ But it is to say that the rarity of such attribution in the early period is itself meaningful.

What does it mean? It cannot mean that a purpose of patent law was so widely understood to be the promotion of *investment* as to need no articulation. Other deeply held concepts are explicitly expressed. Indisputably, a purpose of patent law was widely understood to be the promotion of *invention*, and that

66 See, e.g., Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119 (noting that “any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on” the same).

67 See, e.g., *Pitts v. Edmonds*, 19 F. Cas. 751, 758 (C.C.E.D. Mich. 1857) (observing that, in a patent infringement suit, infringer's profit is not necessarily sufficient measure of damages because it does not reflect the patentee's cost of developing the invention: “[A] party concerned in infringing a patent stands in a different position from the patentee, not having been previously subjected to the expense and labor to which the latter is frequently exposed in the process of invention and experiment. Hence, the person who enters upon the business without previous expense, may very well afford to sell machines at less profit than the patentee. The latter must have his profit, not only for the expense of putting in operation the improvement, but by way of indemnity for the previous time, labor and money which he has been obliged to bestow on the invention. He must, therefore, charge a higher price, to cover these greater expenses. Thus, profits which the party infringing might be satisfied with, and which would afford him compensation, would not afford indemnity to the patentee.”).

68 See, e.g., *Lowell v. Lewis*, 15 F. Cas. 1018, 1020 (C.C.D. Mass. 1817) (“The law confers an exclusive patent-right on the inventor of anything new and useful, as an encouragement and reward for his ingenuity, and for the expense and labor attending the invention.”), *abrogated on other grounds as recognized in* *In re Fisher*, 421 F.3d 1365, 1370-71 (Fed. Cir. 2005). Apparently, Justice Story's comment about “encouragement and reward . . . for the expense and labor attending the invention” has never been quoted or cited in subsequent case law. *Lowell*, 15 F. Cas. at 1020.

understanding is repeated endlessly throughout the early case law.

Rather, the rarity of the attribution more likely reflects the premise that a purpose of patent law is to reward, and thus to encourage, invention *and not necessarily investment*. Recall that, technologically, this was an era in which invention was just as likely to result from a momentary flash of genius as from years of expensive toil in the laboratory. According to this premise, the patented invention is the goal, and whether a particular inventor incurs low or high costs in developing the patented invention or chooses to labor in a low-cost field (*e.g.*, business methods) rather than a high-cost field (*e.g.*, pharmaceuticals), or decides to devote the income from the patent to personal entertainment rather than cost recoupment, is the inventor's private choice, regarding which patent law takes no position.⁶⁹

B. *The Patent Term Extension Provision of 1836*

Of the exceptions mentioned above,⁷⁰ the most important is a statutory provision enacted in 1836 and repealed in 1861. That provision authorized a seven-year extension for any patent upon the patentee's showing that the original fourteen-year patent term was insufficient to allow recoupment of the expense incurred during the development of the patented invention.⁷¹ Under that provision, the application for an extension had to be submitted in writing, with a fee, to the Commissioner of the Patent Office, who was then bound to publish notice of the application and invite any person to oppose the application.⁷² A board consisting of the Secretary of State, the Commissioner of the Patent Office, and the Solicitor of the Treasury would then review the evidence submitted for and against the application.⁷³ In particular, the applicant was obligated to submit, under oath, a written statement of the invention's value, along with the inventor's receipts and expenditures, sufficient to show the inventor's profit and loss from the

69 Some cases mention *en passant* the inventor's "fruitless experiments" or "unsuccessful experiments." But these phrases refer to the ordinary trial and error leading to *the patented invention* (say, vulcanized rubber) rather than to a failed, non-patented invention (say, invisible fabric). See, *e.g.*, *Wilson v. Simpson*, 50 U.S. 109, 117 (1850) (noting that plaintiff's counsel argued: "By reason of great poverty, occasioned by many years of *fruitless experiments* in search of *this* great discovery, [Charles Goodyear] was compelled to grant licenses far below their actual value." (emphasis added)); *McChurg v. Kingsland*, 42 U.S. 202, 205 (1843) (citing fact that inventor's employer bore cost of "unsuccessful experiments" as proof of implicit license from inventor to employer). In any event, these cases do not cite the cost of the "fruitless" or "unsuccessful" experiments as a reason to grant or extend a patent.

70 See *supra* text accompanying note 69.

71 See Act of July 4, 1836, ch. 357, § 18, 5 Stat. 117, 124-25.

72 *Id.*

73 *Id.* The authority given to the board in 1836 was given to the Commissioner alone in 1848. See Act of May 27, 1848, ch. 47, § 1, 9 Stat. 231, 231.

invention.⁷⁴ If the board decided that the applicant failed, without fault, “to obtain, from the use and sale of *his invention*, a reasonable remuneration for the time, ingenuity, and *expense* bestowed upon *the same*, and the introduction thereof into use,”⁷⁵ the Commissioner was obligated to grant the extension.⁷⁶

The provision is instructive for several reasons. First, the only unrecouped “expense” that could justify an extension was an expense incurred *for the patented invention* (“expense bestowed upon *the same*” (emphasis added)). The patentee who applied for an extension could not base the application on expenses incurred for a failed invention, or, indeed, on expenses for a successful invention other than the patented invention at issue.

Second, the extension provision was short-lived. In 1861, Congress withdrew the extension provision and replaced it with a provision permitting a single seventeen-year patent term starting from the grant of the patent.⁷⁷ That seventeen-year provision remained the law until 1994 when it was amended to provide a twenty-year patent term running from the time of the application.⁷⁸ Congress could

⁷⁴ See Act of July 4, 1836, ch. 357, § 18, 5 Stat. 117, 124-25.

⁷⁵ *Id.* (emphasis added). A later committee print understood the phrase “expense bestowed upon the same” to mean “expense [invested in its development].” STAFF H. COMM. ON JUDICIARY, 96TH CONG., THE HISTORY OF PRIVATE PATENT LEGISLATION IN THE HOUSE OF REPRESENTATIVES 7 (Comm. Print 1979) [hereinafter HISTORY] (bracketed material added by Staff of House Committee).

⁷⁶ *Id.* The precursor of this provision was a provision in the Act of July 3, 1832, ch. 162, § 2, 1 Stat. 559, 559, that authorized a patentee to petition Congress directly for a private act to extend the patentee’s patent, provided that the petition be “accompanied by a statement of the ascertained value of the discovery, invention, or improvement, and of the receipts and expenditures of the patentee, so as to exhibit the profit or loss arising therefrom.” *Id.* The 1832 Act did not include any reference to “reasonable remuneration,” “time,” “ingenuity,” or “expense.” Between 1808 and 1836, Congress passed eleven private acts extending patents pursuant to requests of patent holders. See Simon Lester & Huan Zhu, *Rethinking the Length of Patent Terms*, 34 AM. U. INT’L REV. 787, 793 (2019). Even after 1836, many petitions to Congress for a private act to extend a patent were submitted, though few were granted. HISTORY, *supra* note 75, at 8-9. Typically, these petitions were denied because the petitioner had already made a significant profit or because the petitioner’s claim that the petitioner’s “expectations of profit [were] not fully realized” was considered an insufficient basis for an extension. *Id.* Ultimately, these petitions, premised as they were on desire for a “guaranteed income” from the patent at issue, proved “too time-consuming and open to frivolous claims.” *Id.* at 14.

⁷⁷ To be clear, the 1861 Act’s withdrawal of the extension provision was prospective; patents issued before passage of the 1861 Act were still eligible for extension under the 1836 Act. See Act of Mar. 2, 1861, ch. 88, §§ 16-17, 12 Stat. 246, 249 (providing that “all patents *hereafter* granted shall remain in force for the term of seventeen years from the date of issue; and all extension of such patents is hereby prohibited” and that “all acts and parts of acts heretofore passed, which are inconsistent with the provisions of this act, . . . are hereby repealed” (emphasis added)). The 1861 Act also expressly provided for seven-year extensions for design patents (which were first authorized in the Act of Aug. 29, 1842, ch. 263, § 3, 5 Stat. 543, 544); in the Act of 1870, Congress made clear that only design patents issued before passage of the 1861 Act were eligible for extension. See Act of July 8, 1870, ch. 230, § 74, 16 Stat. 198, 210.

⁷⁸ In 1994, the provision for a seventeen-year term was replaced by a provision for a twenty-year term. See Lester & Zhu, *supra* note 76, at 788, 794.

have designed the current patent system to provide an extension of the patent term when needed to allow for recoument of development expenses, but it rejected that approach. In other words, one could characterize the extension provision as a failed experiment of its own.

Third, extensions were infrequent. By 1846, the government had granted 14,526 patents, but only ten extensions were granted under the 1836 Act.⁷⁹ The number of extension applications is unknown. It is, therefore, unknown whether the infrequency of extensions was due to a paucity of applicants or to the parsimony of decision-makers.⁸⁰ The only thing known for sure is that, for this representative ten-year period, one extension a year on average was granted.

Fourth, whatever the term “expense” meant to the drafters of the 1836 Act,⁸¹ the legislative history reveals that by 1860 the greatest, and perhaps the only significant, “expense” incurred by extension applicants was the cost of the litigation following the patent grant, rather than the cost of developing the patented invention in the first place. In a discussion regarding whether the multiple levels of administrative review necessary for the granting of a patent had created too great a burden for the patent applicant and thus whether judicial review would unnecessarily add to that burden, one senator stated:

“[Inventors’] patents are rendered worthless because of the litigation they are subjected to in regard to them; and in every application for an extension of a patent filed here, that I remember since I have been a member of Congress and have been upon this committee, I do not recollect a single instance where the applicant has not based his application upon the ground that he has been unable to make the invention remunerative because of the litigation to which he has been subjected.”⁸²

⁷⁹ *Wilson v. Rousseau*, 45 U.S. 646, 708 (1846)

⁸⁰ A guide to patent practice, published in 1855, notes that “[t]he presumption is always against [the extension] application. . . . Rarely, indeed, are patents extended in this country.” J.G. MOORE, *PATENT OFFICE AND PATENT LAWS: OR A GUIDE TO INVENTORS AND A BOOK OF REFERENCE FOR JUDGES, LAWYERS, MAGISTRATES AND OTHERS* (Philadelphia, Parry & M’Millan 1855). The post-1836 history of petitions for private acts to extend patents shows that Congressional decision-makers were reluctant to grant such petitions, and that such petitions were not generally viewed as meritorious—though there was apparently no lack of interest on the part of patentees in filing such petitions. *See supra* note 76; *HISTORY, supra* note 75, at 8–9.

⁸¹ *See* Act of July 4, 1836, ch. 357, § 18, 5 Stat. 117, 124-25 (providing for “a reasonable remuneration for the time, ingenuity, and *expense* bestowed upon the same” (emphasis added)).

⁸² 82 CONG. GLOBE, 36th Cong., 1st Sess. 1733 (Apr. 16, 1860) (statement of Sen. Trumbull); *see also* *Pitts v. Edmonds*, 19 F. Cas. 751, 752 (C.C.E.D. Mich. 1857) (“No patent in this country has been so much litigated as Woodworth’s planing machine. While this affords the highest evidence of

Finally, the 1861 withdrawal of the extension provision was a considered decision, not an unconsidered result of some omnibus legislative overhaul. A proposed amendment to a draft of the bill that became the 1861 Act included a provision permitting a patent extension only where the applicant for the extension had earned from the invention a net profit of less than \$100,000.⁸³ After debate about whether the net-profit figure should include the net profit of the patentee’s assignees and whether the patentee had the power to obtain profit and loss figures from the assignees,⁸⁴ the proposed amendment containing the \$100,000 limitation

its value, it has involved the holder of the patent in an expense which would have been ruinous had not the renewals been granted, as above stated.”); *Day v. Union India-Rubber Co.*, 7 F. Cas. 271, 276 (C.C.S.D.N.Y. 1856) (“The renewal or extension is granted only because the patentee has not received a sufficient remuneration for the time, ingenuity and expense bestowed upon his invention. It is for this reason only that he is authorized to make further demands upon the public; and *this reason for renewal does not generally exist, unless the just rights of the patentee have been infringed, and his profits under the patent have been expended in the prosecution of suits to establish and maintain his rights.*” (emphasis added)); *Allen v. Hunter*, 1 F. Cas. 476, 477 (C.C.D. Ohio 1855) (“For the maintenance of his [patent] right [the inventor] is subjected to *legal controversies, which, not unfrequently involve him in an expenditure beyond the amount of his profits.*” (emphasis added)); *Blanchard v. Beers*, 3 F. Cas. 617, 617 (C.C.D. Conn. 1852) (charging the jury “[C]ongress became satisfied that it was fit and proper that [Blanchard’s] patent should be continued. Very likely *the great litigation to which the patent has been subjected, and the enormous expenses necessarily attending suits of the description of the one now before you, satisfied that body that Mr. Blanchard had not been reasonably compensated* for the great benefit his invention had conferred upon the country, and they therefore deemed it their duty to prolong the term.” (emphasis added)); *Thompson v. Haight*, 23 F. Cas. 1040, 1042 (C.C.S.D.N.Y. 1826) (“It is unnecessary to look farther than to see the fate of Whitney, Evans, and above all, Fulton, or those who represent him. Instead of deriving peace, honour, and affluence from their incessant labour and incomparable skill, *they have sunk under vexation and the pressure of litigation.* Patent upon patent and privilege upon privilege have been granted, infringing the original rights, until their hopes and anticipated rewards were converted into *despair and poverty.*” (emphasis added)).

83 CONG. GLOBE, 36th Cong., 2d Sess. 792 (Feb. 7, 1861) (statement of Rep. Niblack) (“The last section [of the proposed amendment] is one of some importance. It proposes to limit hereafter the extension of patents, and is intended to cut off an extension of those mammoth patents that have been extended in times past. I am not myself prepared to say that the policy of the section is clear; but a majority of the Committee on Patents, after giving the subject full consideration, have come to the conclusion that there ought to be some limit to this extension of patents, and have instructed me to report the section. It provides that no patent shall be extended hereafter when the net profits of the invention shall equal or exceed \$100,000.”).

84 CONG. GLOBE, 36th Cong., 2d Sess. 1248 (Feb. 27, 1861) (statement of Sen. Bigler) (“The twelfth amendment [proposed by the House to the Senate bill] . . . relates to the extension of patents. The House inserted a new section providing that a patent should not be renewed where the inventor and his assignee shall have made \$100,000 net profit. The Senate amended the section *by excluding the assignees.* We did that for the reason that there is nothing in the present law, and nothing in the bill which would enable an inventor to get an account rendered from his assignee. The section, as insisted upon by the House, in our judgment, is entirely impracticable. The Department does not require the assignee to render an account. The inventor, in making his application, therefore, would be required to render an account not only as to his own profits, but the profits of the assignee; and he



was rejected, and, on the same day, the extension provision was replaced with the provision for the single, unextendible, seventeen-year term.⁸⁵

In sum, early American patent law contains no statement that patent grants are intended to enable recoupment of the costs of a failed invention and—with telling exceptions—no statement that patent grants are intended to enable recoupment of the costs of the patented invention. The extension experiment itself saw few extensions granted and was soon abandoned. The language of the extension provision demonstrated that even where Congress made the inventor's cost relevant to the patent-protection determination, the only cost that could be properly considered was the cost of the patented invention for which the extension was sought, not the cost of a failed invention or the cost of any other patented invention. The infrequency of extension, while perhaps indicating a reluctance by decision-makers to grant extensions, might also indicate a lack of merit among extension applications. In any event, inventors' costs could not have been significant in the main, as inventors were typically too undercapitalized to have incurred major expense in developing the patented invention. That the costs almost universally cited in extension applications were the costs of litigation following the patent grant rather than the costs of development preceding the patent grant shows that those costs of development were a relative non-issue in the determination of whether to grant patent protection. Most important, the notion of including the costs of failed inventions is nowhere to be found.

That concept has remained steady in the various legislative changes to the patent laws in the later centuries. This is not for lack of other comparative models. There is another model in which government ensures that those making the investment are fully compensated for costs, as well as a guaranteed level of return. Beginning with the Energy Policy Act, signed into law by Franklin D. Roosevelt in 1935, Congress established a regulated electric utility regime, which includes the right to a return.⁸⁶

Rate of return regulation is a method for setting the prices of government-regulated monopolies such as public utilities.⁸⁷ Under this method, regulators

would have no power to compel the assignee to render any account. Therefore, the Senate committee could not agree with the House. . . ." (emphasis added)); *see also* CONG. GLOBE, 36th Cong., 2d Sess. 1431 (Mar. 2, 1861) (statement of Rep. Hoard) ("The state of the case is precisely this: this House passed a provision declaring that no extension of any patent shall hereafter be granted when the profits on the sales shall exceed \$100,000, including the sales made both by the patentee and assignee. The Senate proposed to amend that amendment so as to provide that no extension shall be granted when the profits of the patentee, exclusive of the sales made by the assignee, shall exceed \$100,000.").

⁸⁵ CONG. GLOBE, 36th Cong., 2d Sess. 1358, 1431 (Mar. 2, 1861).

⁸⁶ *See* Public Utility Holding Company Act of 1935, 15 U.S.C. § 79, et seq. (1935).

⁸⁷ Will Kenton, *Rate of Return Regulation*, INVESTOPEDIA (Nov. 18, 2020), <https://www.investopedia.com/terms/r/rate-of-return-regulation.asp> [<https://perma.cc/5GUW-YBLH>].

establish a given “rate of return”—the amount of money the monopoly needs to finance the capital it uses to provide its services—which is then combined with the company’s operating and depreciation expenses to generate a target revenue or the amount of money the company must earn in order to make a reasonable profit.⁸⁸ The target is then used to determine how much the company should charge consumers. The goal of rate of return regulation is to protect customers from the high prices that can result from a monopoly market while still ensuring the company can cover its costs and satisfy its investors.⁸⁹

Congress certainly could have followed that model when it amended the Patent Act in 1952,⁹⁰ but it remained steadfast in following the patent path—a path that stands in strong contrast to regulated utilities. With patents, there is no guarantee of a return. There may be substitutes available, other patents may overlap, or the market may not be ready to appreciate the invention during the patent term. Unlike regulated utilities, the vast majority of patents never garner a return for those who hold them. This is not to suggest that patents and regulated utilities are derived for similar goals or through similar logic. The point is simply that Congress could have chosen an entirely different route for pharmaceutical innovation, one ensuring that those making the investment are fully compensated for costs, as well as a guaranteed level of return. And yet, Congress chose a very different path.

Regulated utilities continue to this day in certain parts of the country,⁹¹ with returns far below those of the pharmaceutical industry.⁹² The system certainly insulates companies from risks, but it carries downsides for companies and the nation. From the company perspective, rate of return regulation guarantees the monopoly company a steady profit, just not a dramatic one. From society’s perspective, critics and scholars have pointed out that employing rate of return can inhibit efficiency by contributing to the Averch–Johnson effect, wherein a

88 Mark A. Jamison, *Regulation: Rate of Return*, 3 ENCYCLOPEDIA OF ENERGY ENGINEERING AND TECHNOLOGY 1252 - 53 (Barney Capehart ed., 2007), [https://www.scribd.com/document/349066690/Encyclopedia-of-energy-engineering-and-technology-pdf# \[https://perma.cc/67ER-T7J6\]](https://www.scribd.com/document/349066690/Encyclopedia-of-energy-engineering-and-technology-pdf# [https://perma.cc/67ER-T7J6]).

89 See, e.g., Kenton, *supra* note 87.

90 See 35 U.S.C. 35 (1952). For a general background on the changes enacted with the 1952 Patent Act written by one of the drafters of the Act, see Giles S. Rich, *Infringement Under Section 271 of the Patent Act of 1952*, 35 J. PAT. OFF. SOC. 476 (1952).

91 See generally Severin Borenstein & James Bushnell, *The U.S. Electricity Industry After 20 Years of Restructuring*, 7 ANN. REVS. 437 (2015) (describing various regulated elements of the modern industry).

92 See, e.g., Aswath Damodaran, *Return on Equity by Sector*, N.Y.U. STERN (Jan. 2022), [http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/roe.html \[https://perma.cc/WFC3-JJZ2\]](http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/roe.html [https://perma.cc/WFC3-JJZ2]) (showing return on equity for pharmaceutical industry as 14.55 percent (unadjusted for R&D) and 11.04 percent (adjusted for R&D) versus return on equity for general utilities of 8.44 percent (unadjusted) and 8.44 percent (adjusted)).

company makes excessive and unnecessary investments in order to increase its total profits.⁹³ That is analogous to the type of problem described in this Article in relation to the drive to include failed pharmaceutical costs. Even with a regulated utility model, however, the costs taken into account would be the costs of the specific plant built in Baton Rouge, for example, not other expenditures.

III. HOW REWARDING FAILURE IS COUNTERPRODUCTIVE

As shown in Part II, patent legal history did not conceptualize patents as providing sufficient reward to compensate for the cost of investing in failed drug development. Moreover, providing a patent reward of this kind would raise questions under modern, conventional economic thinking. This Part explores the economic implications within the contours of the patent system.

It is crucial to note the narrow and specific aims of the patent system within any notion of economic incentives. The patent system is not designed to provide incentives for the nation's general economic output. Thus, a broad notion such as "incentivizing investment in innovation" or even "compensating for the risks of invention" would fail to capture the essence of the patent system. As noted in Section I.A, more than 90 percent of patents never garner any return for their owners. If risk-compensation or incentivizing investment were the design, one could easily conclude that the system itself is an abject failure, or at least a grand waste of regulatory time.

Nor is the patent system merely designed to encourage dollar investments. As described in Section II.A, the patent system is agnostic as to the costs of an endeavor, that is, whether the invention took fifty years and billions of dollars or whether the invention came in an instant, cost-free flash. The system's lack of focus on dollar investment is reflected again in the notion of what is rewarded. One is rewarded not just for inventing but also for sharing those inventions for the benefit of society, opting for the patent system's openness over the closed system of trade secrets.⁹⁴ Thus, the entire notion that the patent system's sole design is to attract people into the business of investing in invention misses the mark. These are important caveats before embarking on a discussion of economics and incentives.

As an initial matter, patents provide an opportunity to garner a return in the market through the exclusion of competitors from the sale of a particular product. Patent statutes, cases, and classic theory do not suggest that patents are designed

⁹³ See, e.g., Robert M. Spann, *Rate of Return Regulation and Efficiency in Production: An Empirical Test of the Averch-Johnson Thesis*, 5 BELL J. ECON. & MGMT. SCI. 38 (1974); Ronald R. Braeutigam & John C. Panzar, *Effects of the Change from Rate-of-Return to Price-Cap Regulation*, 83 AM. ECON. REV. 191 (1993).

⁹⁴ See *supra* text accompanying notes 25-26.

to provide some additional return beyond the profit-maximizing price on that item—such as the costs of failed investment. From an inventor-specific perspective, once a drug is awarded a patent monopoly, the profit-maximizing price should be determined by setting marginal revenue equal to marginal cost.⁹⁵ On the other hand, research and development costs are sunk costs, meaning they should not bear on the profit-maximizing price of the drug or the reward available through that price.⁹⁶

More specifically, allowing the patent reward to include the cost of failures has a perverse effect when looking at the invention-specific level. Ideally, one would want to design a system that encourages companies to succeed—and succeed in the most efficient manner possible. When the cost of other failures is included, however, the drive for efficiency is turned on its head. Quite simply, the more one fails, the higher the reward, at least from an invention- or inventor-specific level, rather than system-wide.

One can understand the point on an intuitive level. If I can charge whenever I fail, then the more I fail, the more I get to charge. From a numerical perspective, consider the following example. Imagine that Mega Pharma acquires two promising arthritis treatments—Treatment A and Treatment B—both of which recently advanced through phase II trials.⁹⁷ Mega estimates that each drug has a

95 HAL VARIAN, *INTERMEDIATE MICROECONOMICS* 440 (Jack Repcheck ed., 8th ed. 2010).

96 *See id.* at 574. (“The sunk cost fallacy. Once you have bought something, the amount you paid is sunk, or no longer recoverable. So future behavior should not be influenced by sunk costs”); *see also* Jack Scannell, *Four Reasons Drugs Are Expensive, Of Which Two Are False*, *FORBES* (Oct. 13, 2015) <https://www.forbes.com/sites/matthewherper/2015/10/13/four-reasons-drugs-are-expensive-of-which-two-are-false/?sh=48b89aa34c3b> [<https://perma.cc/Q7JD-7397>] (“Sunk costs are sunk. If companies are going to spend on R&D, they need to believe that there are decent odds that they will make a good return on investment”); CONG. BUDGET OFF., *RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY* 1-2 (2021) (“A drug’s sunk R&D costs—that is, the cost for developing that drug—do not influence its price.”); David Encaoua et al., *Patent System for Encouraging Innovation: Lessons from Economic Analysis*, 35 *ELSEVIER* 1423, 1425 (2006) (“By giving some temporary exclusionary rights to inventors, the government delegates the R&D decision and leaves in the hands of the inventor the responsibility of recovering his R&D investment.”).

97 Note: the example would work equally with internally developed drug candidates (i.e., spending \$1 million on internal R&D for each one of two arthritis drug candidates). The acquisitions in this example, however, better reflect the changing pharmaceutical innovation pipeline, in which startups now increasingly tackle risky early-stage development, while large firms handle late-stage trials and regulatory approval. For more on this structural shift and its possible implications, see Barak Richman, Will Mitchell, Elena Vidal & Kevin Schulman, *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 *LOY. U. CHI. L.J.* 787 (2017); Shepherd, *supra* note 11; and Robin Feldman, *Drug Companies Keep Merging. Why That’s Bad for Consumers and Innovation*, *WASH. POST* (Apr. 6, 2021), <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/> [<https://perma.cc/2SB6-WTNU>]. It is also worth noting that phase II trials tend to be the most selective phase in the road to new drug approval, so advancing past phase II would significantly boost a prospective drug’s risk-adjusted net

50 percent of advancing through the remaining regulatory stages and that, if successful, each would be worth \$200 million.

As a result of the likelihood of success versus failure and the potential rewards, Mega would pay at least \$100 million to acquire each candidate.⁹⁸ In other words, a 50 percent likelihood of success on a \$200 million drug leads to a value of \$100 million. Given that Mega buys both drugs for their respective values, the total cost is \$200 million for the two together.

Treatment A is eventually approved for marketing; Treatment B fails to demonstrate efficacy in clinical trials and is shelved. Using the researchers' methodology, the \$200 million cost of *both* acquisitions would be factored into the R&D cost, and therefore the price, of Treatment A. Thus, Mega should be able to earn \$200 million on the sale of the successful Treatment A.

Now consider Goliath Pharma. Goliath, also excited by the arthritis market, decides to acquire five different treatments in the pipeline. As with Mega's acquisitions, these carry a 50 percent chance of success and expected earnings of \$200 million each. Thus, Goliath would have to pay at least \$100 million for each drug candidate. In total, then, Goliath spends \$500 million. Four of the five treatments fail: After all, Wall Street is littered with stories of drugs that had promising results in phase II but crashed and burned in phase III.⁹⁹ With its five acquisitions and four failures, Goliath needed \$500 million to successfully develop an arthritis treatment, compared to Mega's \$200 million (two acquisitions, one failure). If a drug's price ought to offset its development costs, including failures, Goliath should be able to earn \$500 million. Mega, however, was only justified in earning \$200 million. The one who fails more, brings in more—dampening the incentive to be efficient. This is hardly the outcome the patent system is meant to encourage.

And of course, the fact that a company invests in five companies with each

present value. Phase III drug candidates have become increasingly likely to earn market approval in recent years. See Helen Dowden and Jamie Munro, *Trends in Clinical Success Rates and Therapeutic Focus*, 18 NATURE REVS. DRUG DISCOVERY 495, 495 (2019).

⁹⁸ For simplicity's sake, this hypothetical does not include the discount rate that is used in order to calculate present value of an investment. Robert Shaftoe, *How to Calculate a Risk-Adjusted NPV*, SAPLING (last visited Mar. 20, 2023), <https://www.sapling.com/6708011/calculate-riskadjusted-npv> [<https://perma.cc/5M7M-92F3>].

⁹⁹ For descriptions of disastrous Phase III failures, see, for example, Frank Vinluan, *Theravance's Lead Drug Fails in Phase 3, Triggers a Restructuring Cutting 75% of Staff*, MEDCITY NEWS (Sept. 15, 2021), <https://medcitynews.com/2021/09/theravances-lead-drug-fails-in-phase-3-triggers-a-restructuring-cutting-75-of-staff/> [<https://perma.cc/9HHU-WBNJ>], reporting corporate shakeup after a Phase III failure. See also U.S. FOOD & DRUG ADMIN., 22 CASE STUDIES WHERE PHASE 2 AND PHASE 3 HAD DIVERGENT RESULTS (Jan. 2017), <https://www.fda.gov/media/102332/download> (noting that 90 percent of drugs tested in humans are never submitted to the FDA for approval and examining twenty-two publicly available cases from 1999 through 2017 in which phase II and phase III obtained divergent results).

having a 50 percent chance of success does not guarantee that one will hit. Consider the simple example that each time one flips a coin, the chance of landing on heads or tails remains at 50 percent. Only if one could flip an enormous number of times, or invest in an equivalently enormous number of companies, would one approach a different result.

The illogic of folding research and development costs related to other drugs into the reward for a successful drug can be seen from other perspectives. Imagine that a company tries to develop a cancer drug, a diabetes therapy, and a drug for heart disease. Suppose all three are successful. Would you then allow each drug to be priced to include the costs of all three research programs?¹⁰⁰

To justify including the steep costs of failure in calculating the price tag of bringing a new drug to market, drug-makers often assert that research failures enable or inform future pharmaceutical innovation by allowing drug-makers to “learn from their mistakes.”¹⁰¹ Research, however, casts doubt on this proposition. One preliminary found that failed drug development efforts in a therapeutic area have no significant impact on future drug development in that field and in fact, tend to predict future failures in *other* therapeutic areas.¹⁰² Failure, it seems, simply begets more failure.

Focusing in more specifically, some scholars writing on drug prices, rather than on drug patents, have proposed that prices should be tied to risk-adjusted R&D costs. These proposals are intended to demonstrate the excessive nature of pricing and offer a method of reining in the current runaway prices.¹⁰³ These approaches do an admirable job of showing the gulf between investment and pricing, highlighting the extent to which companies are garnering profits well beyond risk-adjusted R&D costs. However, by linking prices with risk-adjusted

100 An extensive literature has explored game theoretic views of patent races, describing ways in which a system might over-incentivize R&D, distorting the innovative result.

101 See JOHNSON & JOHNSON, *supra* note 5, at 11 (“Pharmaceutical companies and the rest of the scientific community can learn from these failures to improve the research process.”).

102 See Daniela Silvestri, *Sowing Failures, Reaping Success? Evidence from Pharmaceutical R&D Projects* (Druid Society, 2017) (unpublished manuscript) (on file with author) (finding that failed drug development projects have no significant impact on the success of the firm’s future drug development in the same therapeutic area, and actually predicts increased failure in drug development in other therapeutic areas).

103 See Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281 (2016) (arguing against the use of patents as a justification for exorbitant drug price and in favor of comparing a drug’s price to the costs of R&D, including failed attempts, drug production and future R&D, to assess the reasonableness of a drug’s price); Kapczynski & Kesselheim, *supra* note 58 (arguing that compensation to drug companies should be based on the amount invested in the drug, adjusted for the risk of failure and awarding the drug company reasonable profit margin); Suerie Moon et al., *Defining the Concept of Fair Pricing for Medicines*, 368 BMJ I4726 (2020) (arguing that the fair price for medicine falls between the buyer’s maximum affordability and the seller’s costs plus the minimum sustainable profit margin).

investment, the proposals could inadvertently create an incentive to artificially inflate R&D costs to justify additional returns. In other words, if a company's returns will be based on R&D costs, the company has an incentive to inflate those returns.¹⁰⁴ Thus, particularly if extended beyond the pricing context to the patent context, they could serve to spur prices on rather than rein them in.¹⁰⁵

Similarly, some scholars suggest that the patent obviousness doctrine should be risk-adjusted by tailoring it to reflect uncertainty. Merges, in particular, argues that the standard for obviousness should be lowered when the inventor faces a high degree of uncertainty in order to encourage the assumption of that risk.¹⁰⁶

104 See Kiu Tay-Teo, André Ilbawi & Suzanne R. Hill, *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, 2 JAMA NETWORK OPEN 1, 7 (2019) (comparing the incomes generated by sales of cancer drugs to their R&D costs, finding that returns were much higher than “a justifiable return for rewarding and incentivizing innovation” and noting that these excessive returns might contribute to inefficiencies in R&D).

105 Cf. Samson Vermont, *A New Way to Determine Obviousness: Applying the Pioneer Doctrine to 35 U.S.C. § 103(A)*, 29 AIPLA Q.J. 375, 387 (2001) (arguing in the context of the obviousness doctrine that if cost were the sole criterion, applicants would have an incentive to drum up costs). Pharmaceutical literature does suggest that pharmaceutical deals and assets, as opposed to prices, should be valued at risk-adjusted net present value (rNPV). This literature, however, focuses on expected future returns for the purpose of asset valuation. The calculation of rNPV also includes pricing, itself, as an input, and it would make little sense to say that price should be based on rNPV if price is an assumption used to calculate rNPV. In other words, it would be circular to use the current state of expected returns in the market to justify the notion that returns *should* be this amount, let alone that optimal innovation incentives or patent value should be determined in this manner. For examples of recommending rNPV for deal and asset valuation, see, for example, *rNPV: Approaches to Net Present Value (NPV) in Pharmaceutical Research and Development (R&D)*, CONDUCTSCIENCE (Jul. 20, 2018), <https://conductscience.com/npv-approaches-to-net-present-value-npv-in-pharmaceutical-research-and-development-rd/> [<https://perma.cc/NCK7-RW6K>], explaining that rNPV is a tool helpful to investors in assessing the potential profitability of a project; Jonathan Stasior, Brian Machinist & Michael Esposito, *Valuing Pharmaceutical Assets: When to Use NPV vs rNPV*, ALACRITA (2018), explaining that rNPV is calculated to allow investors to account for risk of failure in each stage of development and that extensive historical data on the probabilities of success for R&D across different therapeutic areas are used to calculate the probability of success at each stage of development; and Aitana Peire & Patrik Frei, *What is the Value of a Deal?*, NEWS FEATURE (Jun. 29, 2016), <https://www.nature.com/articles/d43747-020-00160-x> [<https://perma.cc/4UQT-A9NT>], explaining that rNPV is a valuation based on assumptions, including assumptions about the pricing of drugs. See generally Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 9, 2019), <https://time.com/5564547/drug-prices-medicine/> [<https://perma.cc/4Q9F-XL4L>] (explaining the complex process of how drug prices reach consumers and how the absence of regulations governing drug pricing results in pharmaceutical companies pricing drugs based on what they expect the market will withstand).

106 See Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1 (1993). Inspired by Merges, others have suggested variations on the theme. See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 U. VA. L. REV. 1660-62 (2003) (drawing on Merges's theory of uncertainty to propose a new secondary consideration of nonobviousness that, using an industry-wide calculation of invention uncertainty and cost, measures the cost of a new invention

His economic model concludes that patents are more valuable for developing technology than spurring its initial innovation.¹⁰⁷ Thus, the patent system should create incentives to develop and commercialize an invention rather than as an incentive to invent in the first place.

Merges's doctrinal recommendation has been criticized for its unintended potential to create perverse effects on innovation. As scholars have noted, weakening the obviousness standard creates incentives for companies to make minor adjustments to existing innovations rather than undertaking more risky and challenging research.¹⁰⁸ Merges notes an offshoot of the problem in a later article, explaining that in using cost to demonstrate nonobviousness, courts may have "steered biotechnology researchers toward an increasing amount of mundane and repetitive lab work--precisely the opposite of what the patent system seeks to promote."¹⁰⁹ Once again, the goals of the patent system should be the clear focus

alongside other "economic indicia" to evaluate the invention's importance); Ryan Abbott, *Everything Is Obvious*, 66 UCLA L. REV. 2, 45 (2019) (drawing on Merges and other scholars to advocate "a more economic than cognitive nonobviousness inquiry"); Karen I. Boyd, *Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 BERKELEY TECH. L.J. 311, 337-38 (1997) (proposing an additional economic nonobviousness test to provide patent protection for socially useful but economically risky inventions such as those produced by the biotech and pharmaceutical industries); cf. Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 117-19 (2008) (citing Merges to advocate for a nonobviousness standard based on the probability of invention by a person with ordinary skill in the art, but not accounting for the cost of the invention); Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1652 (2011) (building on Merges's nonobviousness criteria of cost and uncertainty to propose an inducement test that assesses patentability based on whether or not an invention significantly accelerates commercialization).

107 See Merges, *supra* note 106, at 3 (arguing that "[t]he patent system is shown to have a stronger effect on the incentive to develop inventions as opposed to the incentive to invent").

108 See W. Nicholson Price II, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 787 (2020) (contending that, in the context of pharmaceuticals, a weaker nonobviousness doctrine serves to incentivize minor adjustments to existing drugs rather than "exploring innovation" that may lead to more socially beneficial discoveries); Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RESV. L. REV. 691, 737 (2004) (arguing that "[l]owering the obviousness threshold makes it more likely that marginal inventions will be patented, but does nothing to encourage inventions that would have met the (already rather modest) obviousness standard anyway"); cf. Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 378 (2008) (noting that, in contrast to the "hindsight bias" that makes inventions in other industries seem more obvious ex post, chemical and pharmaceutical inventions tend to "appear less obvious in hindsight than they seemed ex ante").

109 See Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900-2000*, 88 CAL. L. REV. 2187, 2225-2228 (2000). The relationship between strength of patent protection and incentive to invent is clouded, at best. As Merges notes in his seminal work, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 916 (1990):

While it may seem at first blush that any reduction in patent scope -- indeed, any

of the incentive efforts, rather than the more diffuse goal of encouraging the national production of any output.

Nevertheless, perhaps the problem is simply the obviousness lever chosen, while the insight that patents should be sensitive to uncertainty (and the investment costs of that uncertainty) remains valid.¹¹⁰ The theoretical problem, however, is that Merges's recommendation of including uncertainty flows from the expressly stated perspective that patents do not provide much incentive to invent, at least not in most cases. As he explains, "it is safe to say there is a consensus among economists that in the aggregate, patents offer only a very limited incentive to invent."¹¹¹ If patents do not provide much incentive to invent as an initial matter in most cases, then it is difficult to embrace a vision of patents as being essential for creating the incentive to *invest* in that invention or to embrace the notion of investment in invention as the key goal of the patent system. Rather, the stronger argument emerges from modern economists such as Shapiro and Kurz, who have explained that patents should compensate for the level of contributions to society, irrespective of the cost inventors incur along the way.¹¹² This economic analysis dovetails with the historical approach of U.S. patent law described above.¹¹³ From this perspective, manufacturing cost is irrelevant to the societal benefit of a drug. Thus, including the costs of failed inventions would overcompensate the patent holder for the value provided to society.

At the end of the day, not all innovation efforts are worth it. If the costs outweigh the value, a company should not invest. And when society creates a

lessening of the patentee's potential reward -- may severely undercut the incentive to invent, we do not believe this is the case Ultimately it is important to bear in mind that every potential inventor is also a potential infringer. Thus a "strengthening" of property rights will not always increase incentives to invent; it may do so for some pioneers, but it will also greatly increase an improver's chances of becoming enmeshed in litigation. Indeed this is the very heart of our case. When a broad patent is granted or expanded via the doctrine of equivalents, its scope diminishes incentives for others to stay in the invention game, compared again with a patent whose claims are trimmed more closely to the inventor's actual results.

110 Burk & Lemley, *supra* note 108, at 737 (noting that "it seems to us that while Merges is right to suggest that the standard of patentability should be responsive to the cost and uncertainty of innovation, obviousness is the wrong lever to use in biotechnology").

111 See Merges, *supra* note 106, at 5 (citing PAUL STONEMAN, *THE ECONOMIC ANALYSIS OF TECHNOLOGY POLICY* 115 (1987)) (providing a summary of the economic consensus and observing that "despite a long-standing concern over the nature and impact of the patent system, the importance of the system, in practical terms, may not be particularly great").

112 See Carl Shapiro, *Patent Reform: Aligning Reward and Contribution*, in 8 *INNOVATION POLICY AND THE ECONOMY* 111, 112-13 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2008); cf. KURZ, *supra* note 8, at ch. 9.1 (describing the economics of patents in terms of contribution to society, rather than development costs).

113 See *supra* text accompanying notes 59-93.

buffer that insulates companies from the impact of poor decisions, innovation can become distorted.¹¹⁴ Worse yet, two features of the pharmaceutical industry could enhance the distortion of incentive structures if society were to follow the notion of compensating inventors for the cost of failed inventions: The lack of buy-side constraints and the value leakage of a fragmented drug development supply chain.

A. Lack of Buy-Side Constraint in the Pharmaceutical Industry

Ordinarily, one would expect buy-side constraints to create downward pressures on prices, limiting the impact of incentivizing failure. After all, pharmaceutical manufacturers cannot charge a price unless buyers are willing to pay. Characteristics of the modern pharmaceutical industry, however, dampen any potential effect. These include strategic patent behaviors, strategic behaviors within the reimbursement system, constraints on insurers related to mandated coverage of drugs and limited negotiations, and dampened patient price-sensitivities.

First, modern strategic behaviors allow pharma companies to exploit the regulatory environment, seriously weakening the potential effects of price limitations. These behaviors allow brand companies, who hold market power through patents, to extend their periods of protection and keep cheaper competitors from gaining much traction when they do get to market. Some of these behaviors involve changing aspects of a drug, such as its dosage or delivery system, often by making minor modifications.¹¹⁵ Companies pile these protections on over and over again, extending the length or breadth of protection. Other strategies manipulate the system of regulatory exclusivities. For example, many of the world's top-selling drugs boast Orphan Drug designations, which are intended as incentives to develop disease treatments for small segments of the population.¹¹⁶ Additional behaviors include exploiting the so-called citizen petition process at the FDA. Originally designed to allow the public to participate in regulatory decision-

114 Of course, society may choose to fund efforts that will not turn a profit for companies. Consider the public funding of the COVID-19 vaccine hunt. That, however, is an entirely different approach from the patent system. For implications of the innovation incentive strains, see the controversy over the FDA's approval of Biogen's Alzheimer's drug, despite limited disease effects, launched at a high price.

115 See generally sources cited *supra* note 33

116 In 2018, five of the world's six top-selling drugs, including Humira and Keytruda, had received Orphan Drug indications. Consequently, more than 70 percent of spending on "orphan drugs" was directed to non-orphan indications. See Kao-Ping Chua, Lauren E. Kimmel & Rena M. Conti, *Spending For Orphan Indications Among Top-Selling Orphan Drugs Approved to Treat Common Diseases*, 40 HEALTH AFFS. 453, 453 (2021). The allure of the Orphan Drug designation and its ease of abuse has also helped direct new drug focus toward expensive areas like oncology. See Robin Feldman, *The Cancer Curse: Regulatory Failure by Success*, 21 COLUM. SCI. & TECH. L. REV. 1 (2019).

making, brand companies file more than two-thirds of citizen petitions that pertain to prescription drugs, usually to block a competitor from gaining approval.¹¹⁷ Others involve abusing the FDA's Risk Evaluation and Mitigation Strategies system;¹¹⁸ engaging in pay-for-delay schemes, in which the brand company provides value to the generic in exchange for the generic staying off the market for a period of time;¹¹⁹ and product-hopping, in which the brand company shifts patients to a slightly updated, patent-protected version of the drug before a generic can enter to capture any of its market share.¹²⁰

The most powerful strategic behavior, however, involves the health insurance reimbursement system. Through rebates and volume discounting, companies can share monopoly rents with other players in the system in exchange for agreements to disfavor cheaper competitors.

The process centers on actors, such as pharmacy benefit managers (PBMs), who negotiate rebates from drug companies on behalf of health plans and help those health plans design reimbursement formularies.¹²¹ PBMs are paid by health plans to secure discounts from pharmaceutical companies, who are, in turn, ensured a pool of customers.

Through this system, pharmaceutical companies are able to offer volume discounts—ones that newer entrants cannot meet—in exchange for disadvantaging generic competitors. Imagine a beer company making the following offer to a bar

117 See Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 101 (2012); Michael A. Carrier & Carl Minniti, *Citizen's Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305 (2017); see also Robin Feldman, Evan Frondorf, Andrew K. Cordova & Connie Wang, *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017) (finding that as many as one in five citizen petitions submitted annually is submitted by a pharmaceutical company trying to block a competitor).

118 See generally Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL L. REV. 1 (2017); Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, U. ILL. L. REV. 1, 46-52 (2018); Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 533-543 (2016).

119 See, e.g., *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). See generally C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1153 (2006); Michael A. Carrier, *Payment After Actavis*, 100 IOWA L.R. 7 (2014).

120 See Michael A. Carrier & Steve D. Shadown, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167 (2016); Uri Y. Hacoheh, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 511-523 (2020); Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008); Feldman & Frondorf, *supra* note 118, at 527-33.

121 For an extensive discussion of conflicts of interest inherent in the PBM system, including practices like volume rebating, see Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 YALE L. & POL'Y REV. 360 (2020); and Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303 (2020).

owner:¹²² I will give you a rebate of 50 cents a bottle if you sell a million bottles of my beer. Better yet, I will give you \$1 a bottle if you don't put any of that craft beer on the menu. If the craft beer is only selling a handful of bottles, it could never offer enough of a discount to compensate for the million dollars that the bar owner would forgo by turning down the major company's offer.

In the context of pharmaceuticals, brand companies whose patents are expiring command the volume to engage in this form of rebating. Generic companies, which will start out with only a small number of sales and cannot make a competitive offer, can be unable to gain much traction in the market. For example, a study of all claims for roughly one million Medicare patients over seven years found that generic drugs are increasingly losing out in formulary placements.¹²³ Specifically, the percentage of generics on the most-favorable tier dropped from 73 percent to 28 percent, and the percentage of generics placed inappropriately in relation to the brand version of the drug increased from 47 percent to 74 percent.¹²⁴

In antitrust terms, one can think of this behavior as a form of raising rivals' costs, in which a brand company imposes costs on a generic competitor that are out of proportion to the impact on the brand itself.¹²⁵ As one Medicare health plan administrator noted in describing the volume rebate system for the blockbuster dry-eye medication, Restasis, a new entrant could give the drug away for free, and the numbers still would not work.¹²⁶

In addition, certain federal regulations enhance the ability of manufacturers to exercise the market power that allows above-marginal-cost pricing by limiting health insurers' ability to control pricing. For example, the 2010 Affordable Care Act mandates that all health insurers must cover: 1) at least one drug per class of drugs and 2) all drugs in certain protected classes.¹²⁷ The protected classes are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.¹²⁸ The six protected classes, which include treatments for cancer and HIV, cover a large number of drugs. When an insurer is required to provide coverage for a drug, the insurer's ability to negotiate is severely hampered

122 See Robin Feldman, *The Devil in the Tiers*, 8 J.L. & BIOSCIENCES 1, 15 (2021) (setting out the beer analogy to explain volume discounting); see also sources cited *supra* note 103.

123 See Feldman, *supra* note 122.

124 *Id.*

125 *Id.* at 15; see also Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs To Achieve Power over Price*, 96 YALE L.J. 209 (1986) (seminal work coining the term raising rivals' costs to describe certain forms of anticompetitive behaviors).

126 See Complaint at 6, 21–23, *Shire U.S., Inc. v. Allergan, Inc.*, No. 17–7716 (D.N.J. 2017).

127 See 45 C.F.R. § 156.122 (2022).

128 See CTR. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, ch. 6 § 30.2.5, <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf> [<https://perma.cc/WEH8-5WW3>] (listing protected classes).

because it cannot threaten to walk away if the price is exorbitant. Even when insurers are required to cover only one drug in a class, an insurer's ability may be limited if all of the manufacturers in the class engage in parallel pricing.¹²⁹

The key federal medical insurer, Medicare, is particularly handicapped in controlling drug pricing because congressional legislation generally precludes Medicare from negotiating drug prices.¹³⁰ Instead, each individual health plan under Medicare must negotiate prices without the benefit of the considerable buying power that could be exercised by the federal government if Medicare were permitted to negotiate for plans as a whole.

Most importantly, any analysis of buy-side constraints should note that health care is no ordinary market. In particular, prescription drug users are far less price-sensitive than consumers of other products, which limits the potential effects of buy-side discipline. Thus, prescription drug price increases do not fluidly translate to a decline in demand.

The price inelasticity characteristic of prescription drug markets can be attributed partly to the necessary, often life-saving quality of medication for consumers. Individuals may place great, even unquantifiable, value on their own health. In contrast to other products, there may not be a limit on how much one is willing to pay for a health-preserving drug, especially when taking a drug *is*, without hyperbole, a matter of life or death.¹³¹ Unlike other products, prescription drugs require a physician's authorization, often creating immovable brand loyalty. Even when generic alternatives arrive on the market, physicians may continue to prescribe the brand version, especially for older or at-risk patients. Furthermore,

129 See STAFF OF H. COMM. ON THE OVERSIGHT & REF., 117TH CONG., DRUG PRICING INVESTIGATION: MAJORITY STAFF REPORT 136-143 (Comm. Print 2021) (describing "shadow pricing" by insulin manufacturers, a pricing practice in which companies raise list prices in lockstep with one another); see also *id.* at 143-147 (describing shadow pricing for the rheumatoid arthritis drugs Humira and Enbrel).

130 Specifically, the legislation establishing the Medicare Part D benefit that covers prescription drugs obtained from a retail pharmacy, as opposed to a hospital, states that the Secretary of Health and Human Services, who oversees Medicare, "(1) may not interfere with the negotiations between drug manufacturers and pharmacies and [health plans]; and (2) may not require a particular formulary or institute a price structure for reimbursement of [drugs covered by Medicare]." 42 U.S.C. § 1395w-111(i) (2018). The Inflation Reduction Act, signed into law in 2022, opened the door to changing this approach by giving Medicare the power to negotiate over a limited number of drugs in certain circumstances.

131 Prescription drugs exemplify what the philosopher John Rawls termed a "primary good": a good that makes anyone more likely to achieve one's wants, no matter what one's wants are. See Fritz Allhoff, *Daraprim and Predatory Pricing: Martin Shkreli's 5000% Hike*, STAN. L. & BIOSCIENCES BLOG (Oct. 5, 2015), [https://law.stanford.edu/2015/10/05/daraprim-and-drug-pricing/#:~:text=Daraprim%20was%20developed%20in%20the,is%20in%20fairly%20widespread%20distribution_\[https://perma.cc/ECP4-M97Q\]](https://law.stanford.edu/2015/10/05/daraprim-and-drug-pricing/#:~:text=Daraprim%20was%20developed%20in%20the,is%20in%20fairly%20widespread%20distribution_[https://perma.cc/ECP4-M97Q]). But cf. Morgan & Lee, *supra* note 15 (finding that patients in the United States, which consistently boasts the highest drug prices among developed countries, are more likely to skip doses or not fill prescriptions due to cost).

widespread direct-to-consumer advertising can induce more expensive brand-name drug prescriptions, even though physicians, not patients, make final prescribing decisions.¹³²

Most important, patients are generally insulated from the full force of prescription drug costs by insurance or drug payment assistance.¹³³ Depending on the insurance plan, even the most staggering drug costs may be at least partially absorbed before they can make their mark on a patient's wallet.¹³⁴ Similarly, a drug-maker's price increases, however frequent,¹³⁵ may be sufficiently dulled by rebates and coupons from the manufacturer to retain the patients who do have the option to switch or stop taking a drug. The gap between what is charged and what many patients ultimately pay further dismantles the usual relationship between increasing prices and decreasing demand.¹³⁶

Price distortion in the pharmaceutical industry, in fact, exemplifies a paradox that has afflicted patent law since its inception.¹³⁷ Patent law promotes innovation

132 See Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995, 1998 (2005) (finding that 55 percent of patients who made a brand-specific request received an antidepressant prescription, versus just 39 percent who made a general drug request); see also Tongil Kim, *Direct-to-Consumer Advertising for Doctors? Uncovering the Effect of Pharmaceutical Advertising on Health Care Providers' Prescribing Behavior 1* (Naveen Jindal Sch. of Mgmt., Working Paper, 2020) (on file with author) (finding that physicians exposed to more televised direct-to-consumer advertisements tend to write more prescriptions for the drugs advertised).

133 For a primer on drug manufacturer coupons and co-pay assistance, see generally CONG. RSCH. SERV., R44264, *PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAMS (PAPs)* (2017). Co-pay assistance, distributed for more than 600 brand drugs, helps push patients toward more expensive drug options (a discounted co-pay for an expensive brand drug often costs the patient more out-of-pocket than the generic option), while not reducing the amount the health plan owes the drug-maker. At the same time, the drug-maker's contribution is tax-deductible.

134 Health insurance plans vary significantly in their coverage and out-of-pocket requirements. Medicare Part D, for instance, has four stages of coverage during a given year, ranging from full coverage to the "donut hole" period, during which time the patient is responsible for 25 percent of all their drug costs. Patients may display greater price sensitivity during the "donut hole" phase as compared to the subsequent catastrophic coverage phase, when patient contribution is much lower. See *The Four Coverage Stages of Medicare's Part D Program*, BLUE MEDICARE RX (Oct. 1, 2020), <https://www.rxmedicareplans.com/Learn/Stages> [<https://perma.cc/7NEJ-AVS5>].

135 See Nathan E. Wineinger, Yunyue Zhang & Eric J. Topol, *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States* 5 JAMA OPEN 4791, 4791 (2019) (finding that of the forty-nine top-selling drugs, forty-eight experienced annual or biannual list price increases between 2012 and 2017).

136 Cf. Roger Lee Mendoza, *Effects of Innovation and Insurance Coverage on Price Elasticity of Demand for Prescription Drugs: Some Empirical Lessons in Pharmacoeconomics*, 23 J. MED. ECON. 915 (2020) (empirical evidence confirming the price inelasticity of prescription drugs); Justin Gatwood et al., *Price Elasticity and Medication Use: Cost Sharing Across Multiple Clinical Conditions*, 20 J. MANAGED CARE & SPECIALTY PHARM. 1102, 1106 (2014) (finding that antiplatelet drugs and statins have much lower price elasticity than smoking deterrent medications).

137 See KURZ, *supra* note 8, at ch. 5 (identifying the patent paradox).

to increase social welfare.¹³⁸ However, the more we need a patented invention, such as a prescription drug, the more difficult it becomes to obtain: The more we need it, the lower our sensitivity to changes in its price.¹³⁹ Consumers' low price sensitivity, coupled with the monopoly of patent protection, confers significant power to drug companies in setting drug prices at the expense of affordable access and, therefore, the social welfare that the patent system means to promote.¹⁴⁰

To mitigate this dilemma and limit monopoly pricing power, the government enacts market regulations and policies (e.g., the Hatch-Waxman Act that facilitates generic drug entry). Each policy affects the market value of a patent because any limitation on pricing diminishes the economic value of a patent to its owner.¹⁴¹ Drug-makers, thus, can trumpet the high cost of drug development as a means of dissuading or compromising the passage of policies and regulations that decrease patent value. A discussion of the cost of invention, then, becomes the hidden response to the fear of actual or pending regulation that decreases patent value. Essentially, it is a form of demand for the government to reimburse companies for the cost of regulation.

The operation of the Hatch-Waxman Act may actually enhance these effects. Litigation causes companies to focus on the value of what is being litigated.¹⁴² This heightened focus on the value of patents may encourage the instinct to petition the government to pay for the costs of regulation, along with the failure-compensation justifications used to buttress those arguments. In spawning extensive patent litigation, Hatch-Waxman and its sister regime, the Biologics Price Competition and Innovation Act, may spur these effects.

In short, health care market characteristics, along with opportunities for gaming the regulatory and reimbursement systems, dampen the potential disciplining effects of buy-side constraints on price increases. These factors render the normal constraints unable to limit the price impacts of creating incentives to fail. More failure brings more reward, reducing the drive towards efficient innovation. Thus, in addition to clashing with the history and theory of patents, encouraging failure has the potential to harm innovation.

138 See sources cited *supra*, note 97.

139 KURZ, *supra* note 8, at ch. 5 (explaining that “the more we need an innovated product the more difficult the law makes it for us to use it, since the more we need it the higher is the monopoly price the law allows the innovator to charge us. In short, the more we need a product the more the law requires us to postpone using that exact product whose use by the public was the reason for the law to begin with”); N. GREGORY MANKIW, *THE PRINCIPLES OF ECONOMICS*, 90 (Jane Tufts ed., 8th ed., 2018) (explaining the relationship between consumer’s level of need and sensitivity to price).

140 KURZ, *supra* note 8, at ch. 5.

141 Mark Schankerman, *How Valuable is Patent Protection? Estimates by Technology Field*, 29 *RAND J. ECON.* 77, 79 (1998).

142 Cf. KURZ, *supra* note 8, at ch. 5 (explaining the relationship between litigation over patents and an enhanced focus on value of patents in the context of large pharma buying smaller companies).

B. Value Leakage

As explained in the prior section, creating incentives to fail can lead to inefficient innovation. Moreover, the weakened buy-side constraint means that the normal counter-pressures will not operate to limit the price increases that can result from including failure in the value of a drug. Beyond buy-side constraints, a significant restructuring of the pharmaceutical innovation pipeline has the potential to enhance these effects and further distort the innovation incentive by directing dollars to the wrong part of the innovation chain and diluting the incentive to engage in basic, high-risk research.

Specifically, over the last decade, the pharmaceutical pipeline has undergone a complete transformation. Faced with declining innovation,¹⁴³ large pharmaceutical companies now outsource much of the industry's innovation. Small startups, universities, and other non-profits increasingly handle high-risk, early-stage drug development, while larger pharmaceutical players specialize in navigating late-stage clinical trials and regulatory approval.¹⁴⁴

Academia as an innovation engine is not a new phenomenon. For example, one study looking at transformative medicines approved between 1985 and 2009 found that “the vast majority had intellectual origins in academic research, most of which was funded by the NIH.”¹⁴⁵ Nevertheless, the shift in industry structure over the last decade is striking. The majority of new drug molecules now originate in small startups, even many of those that are marketed by major pharmaceutical

143 KHUSHBOO SHARMA, U.S. FOOD & DRUG ADMIN. CDER NEW DRUGS PROGRAM: 2018 UPDATE 7 (Dec. 11, 2018), <https://www.fda.gov/media/119700/download> [<https://perma.cc/74JY-K3RQ>] (graphing the decline in new molecular entities approved between 1996-2010); see also Iain Cockburn, *The Changing Structure of the Pharmaceutical Industry*, 23 HEALTH AFFS. 10, 13 (2004) (noting the industry-wide decline in new molecular entity output following industry consolidation in the mid-1990s); U.S. FOOD & DRUG ADMIN., CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (2004) (noting ongoing reduction in new drug and biologic applications and the increasing inefficiency in medical research); Kenneth I. Kaitin, *Deconstructing the Drug Development Process: The New Face of Innovation*, 87 CLINICAL PHARMACOLOGY THERAPEUTICS 356, 356 (2010) (citing declining NDA output and rising R&D to show the unsustainability of the pre-2010 large pharmaceutical drug development model).

144 For more on the restructured pharmaceutical industry, and its consequences for new drug innovation, see sources cited *supra* note 97.

145 See Jeffrey S. Flier, *Academia and Industry: Allocating Credit and Discovery for Development of New Therapies*, 10 J. CLINICAL INVEST. 1172 (2019); see also Robert Kneller, *The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs*, 9 NATURE REVS. 867 (2010) (examining the origins of the 252 new drugs approved by the FDA between 1998 and 2007); Jonathan M. Spector, Rosemary S. Harrison, & Mark C. Fishman, *Fundamental Science Behind Today's Important Medicines*, 10 SCI. TRANSLATIONAL MED. 438 (2018); Derek Lowe, *Where Drugs Come From: The Numbers*, SCI. TRANSLATIONAL MED. (Nov. 4, 2010) (discussing the *Nature Reviews* article and pointing out that the drugs from academia outperformed the ones from pharmaceutical companies for which 65 percent companies lacked scientific novelty).

houses.¹⁴⁶ As one scholar explained, “a culture of nimble decision-making and risk-taking facilitates discovery and innovation” at smaller firms.¹⁴⁷ Some commentators, to this point, have characterized pharmaceutical startups as an alternate research & development source for large pharmaceutical companies.¹⁴⁸ Acquisition is the common exit strategy for small firms.¹⁴⁹ Modern innovation, consequently, is driven by larger pharmaceutical firms acquiring, licensing, or co-developing the drug portfolios of smaller companies.¹⁵⁰

In theory, profits should flow smoothly throughout the system without the opportunity for excess returns at the top. Large pharmaceutical companies—acquiring the smaller companies—and the venture capitalists—directing the sale for small companies—should be able to calculate the discounted present value of the asset sold.

There is a dearth of empirical literature evaluating whether, in practice, the flow of revenue through the modern pharmaceutical supply chain properly reflects risk-adjusted net present value calculations. Anecdotal evidence suggests, however, that large firm earnings on a drug may far outstrip what the company paid for its acquisition in present value terms.

Sovaldi (sofosbuvir), the revolutionary hepatitis C treatment, offers one example. Pharmasset, a small startup that licensed university-based research, developed sofosbuvir with significant federal grant funding. Pharmasset successfully advanced the drug through phase II trials,¹⁵¹ elevating its chance of eventual FDA approval.¹⁵² Pharmasset was acquired for \$11 billion in 2012 by the

146 See GEILINGER & LEO, *supra* note 11, at 16-17 (finding that, in 2018, startups originated 63 percent of new molecular entities); Idrus, *supra* note 11 (noting that, of the forty-one new molecular entities Celgene added between 2014-2018, thirty-three were sourced through external acquisitions or licensing).

147 See Shepherd, *supra* note 11.

148 See Shepherd, *supra* note 11, at 2 (“Today, most drug innovation originates not in traditional pharmaceutical companies, but in biotech companies and smaller firms In the later stages of the drug development process, the biotech companies routinely partner with large pharmaceutical companies to advance through expensive late-stage clinical trials and to effectively manufacture, market, and distribute the drugs”).

149 See Rahul Khetan, *Biopharma Licensing and M&A Trends in the 21st-Century Landscape*, 25 J. COM. BIOTECHNOLOGY 37, 49 (2020) (noting that acquisition is the optimal strategy for small firms whose drug candidates require considerable resources to be fully developed and tested).

150 See *id.* at 38-39 (noting that startups often depend on larger firms to bring a drug through the approval process; noting also that, in addition acquisitions, firms may pursue licensing or other partnership arrangements).

151 See generally STAFF OF S. COMM. ON FIN., 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 13-14 (2015) [hereinafter PRICE OF SOVALDI] (describing the research & development of Sovaldi).

152 See David W. Thomas et al., *Clinical Development Success Rates 2006-2015*, BIO 1, 16 (2016) (showing that phase II trials feature the lowest success rates of any phase in the FDA approval

major pharmaceutical house, Gilead, which was struggling with a shortage of new drugs under development.¹⁵³ Gilead ushered the drug through phase III clinical trials and the FDA approval process, which was expedited by “priority review” and “breakthrough therapy designation” awards for sofosbuvir.¹⁵⁴

Although some analysts perceived Gilead’s \$11 billion acquisition of Pharmasset to be a risky play,¹⁵⁵ Gilead ensured a generous return on its investment by pricing a course of Sovaldi at \$84,000, more than double what Pharmasset projected the treatment would cost.¹⁵⁶ One analysis calculated that if Sovaldi were even priced at \$50,000 for a twelve-week course (already well higher than Pharmasset’s prediction of \$36,000), then Pharmasset ought to be worth 30 percent more than what Gilead ultimately paid for the company.¹⁵⁷ As a result of Gilead’s Sovaldi pricing, the company more than recouped its acquisition investment in the first year of drug sales alone.¹⁵⁸ In the first five years, the company reaped more than \$58 billion from sales of the drug, more than five times what the company paid to acquire the drug from the startup that took the initial risk and engaged in the innovation.¹⁵⁹

One can see a similar pattern with Merck’s cancer immunotherapy Keytruda. Organon, a small biotech division of a Dutch conglomerate, conducted the benchwork that identified and isolated pembrolizumab, an antibody for which Organon researchers identified promising oncology applications.¹⁶⁰ As Organon

process). Phase III trials, on the other hand, have generally become more likely to succeed. *See also* Helen Dowden & Jamie Munro, *Trends in Clinical Success Rates and Therapeutic Focus*, 18 NATURE REV. DRUG DISCOVERY 495, 495 (2019).

153 PRICE OF SOVALDI, *supra* note 151, at 15-16.

154 *Id.* at 26.

155 *See, e.g.,* Lewis Kraupkopf & Anand Basu, *Gilead Bets 11 Billion on Hepatitis in Pharmasset Deal*, REUTERS (Nov. 21, 2011), <https://www.reuters.com/article/us-gilead-pharmasset/gilead-bets-11-billion-on-hepatitis-in-pharmasset-deal-idUSTRE7AK0XU20111121> [<https://perma.cc/E5LE-DEZV>] (noting a survey of analysts after the deal found that 82 percent believed Gilead overpaid for Pharmasset).

156 PRICE OF SOVALDI, *supra* note 151, at 17.

157 *Id.* at 19.

158 *See id.* at 17 (noting that Gilead reported more than \$12 billion in 2014 earnings from hepatitis C treatment sales).

159 *See* Keith Speights, *Did Gilead Sciences Make an \$11 Billion Blunder? Spoiler Alert: The Answer Is “No,”* THE MOTLEY FOOL (Dec. 9, 2018) (discussing the fact that Wall Street prefers drugs that patients need to take for a lifetime, rather than drugs that cure).

160 *See generally* David Shaywitz, *The Startling History Behind Merck’s New Cancer Blockbuster*, FORBES (Jul. 26, 2017), <https://www.forbes.com/sites/davidshaywitz/2017/07/26/the-startling-history-behind-mercks-new-cancer-blockbuster/?sh=23b8ca89948d> [<https://perma.cc/8WQF-TEN7>]. Pembrolizumab, a PD1 antagonist, was accidentally discovered by researchers looking for promising PD1 agonists, which are thought to have applications treating autoimmune diseases. In so doing, the discovery behind Keytruda offers a case study in the generative, unpredictable value of the basic research that, ironically, the success of a drug like Keytruda may threaten to disincentivize.

began preparing its investigative new drug filing, however, a series of mergers transferred the program to Merck in 2009, where it was promptly shut down¹⁶¹ until news of a competitor's successful phase III trials for a similar treatment revived the pembrolizumab program.¹⁶²

Although the creation of pembrolizumab preceded Merck's acquisition, the drug giant secured the commercial success of Keytruda through its regulatory savvy and aggressive pursuit of new indications for the drug. A Merck executive, formerly employed by the FDA, gained insight into the agency's new breakthrough designation program, which initiated closer cooperation between regulators and the drug-maker to expedite approval.¹⁶³ Merck elected not to publicize their breakthrough designation for advanced melanoma in order to preserve its competitive advantage, helping the drug-maker close the gap on other immunotherapy developers.¹⁶⁴ The company's decision to initially target advanced melanoma was similarly strategic:¹⁶⁵ Drugs for life-threatening diseases that lack an available treatment may gain approval with fewer trials.¹⁶⁶

At the same time, Merck embarked on a blitz of clinical studies to search for more applications to monetize their new drug.¹⁶⁷ Consequently, the firm has managed to acquire an impressive ten breakthrough designations for Keytruda¹⁶⁸—

161 The road pembrolizumab traveled from Organon to Merck went through two major acquisitions, although the drug candidate was a factor in neither. First, Schering-Plough acquired Organon and its parent company in 2007 to expand its women's health and nervous system therapeutics footprint. *See Press Release: Schering-Plough Corporation Completes \$14.43 Billion Acquisition of Organon*, FIERCE BIOTECH (Nov. 20, 2007), <https://www.fiercebiotech.com/biotech/press-release-schering-plough-corporation-completes-14-43-billion-acquisition-of-organon> [<https://perma.cc/LKP7-MQEQ>]. Two years later, Schering-Plough merged with Merck. *See Merck, Schering-Plough Set to Complete Merger*, REUTERS (Nov. 3, 2009), <https://www.reuters.com/article/us-merck-scheringplough/merck-schering-plough-set-to-complete-merger-idUSTRE5A23YZ20091103> [<https://perma.cc/7CF2-JVRG>]. When it arrived at Merck, the pembrolizumab program was relegated to a term sheet, which meant preparations were made to out-license the product to another firm, reportedly for a negligible price. *See Shaywitz, supra* note 160 (explaining that “[a]fter the program finally wound up at Merck, in 2009, it was considered such a low priority that it was shut down and placed on the out-license list”).

162 *See* Shaywitz, *supra* note 160.

163 Gilead benefitted from the same breakthrough designation with Sovaldi.

164 Shaywitz, *supra* note 160.

165 *Id.*

166 *See* U.S. FOOD & DRUG ADMIN., DEVELOPMENT & APPROVAL PROCESS: DRUGS (Oct. 28, 2019) (observing that “a drug intended to treat patients with a life-threatening disease for which no other therapy exists may be considered to have benefits that outweigh the risks even if those risks would be considered unacceptable for a condition that is not life threatening”).

167 *See* Shaywitz, *supra* note 160 (“Former Merck executive Reicin recalls presenting Perlmutter with a prioritized list of potential Keytruda clinical studies and asking him, based on resources, where to draw the line. ‘There is no line,’ Perlmutter reportedly responded. ‘Do them all.’”).

168 *See* U.S. FOOD & DRUG ADMIN., CDER BREAKTHROUGH THERAPY DESIGNATION APPROVALS (2020).

each for a distinct type of cancer—and twenty-two different indications overall in the first handful of years following its approval.¹⁶⁹ Merck continues to aggressively test new applications for the drug,¹⁷⁰ efforts that have seen handsome recompense: In 2020 alone, the drug’s sales topped \$14 billion, with no signs of flagging.¹⁷¹ Forbes estimates the value of Keytruda as \$200 *billion*—a far cry from the \$300 million the company paid to acquire the drug.¹⁷²

There is no question that Merck assumed significant risk and expense with its aggressive agenda for Keytruda, but the rewards offered by the patent system are earmarked for new innovation, not business savvy.¹⁷³ One has to differentiate between marketing and innovation. Adapting something to a new market does not constitute creating something new. Rather, the company has simply developed a different way to sell it—a new market to pitch it in. Patents do not reward marketing. For that, the company should be able to earn its reward in the market for its marketing prowess.

As its history makes clear, Merck’s principal contributions to the development of Keytruda were its expeditious approval and broad dissemination across the oncology sphere.¹⁷⁴ These efforts, to be sure, did not come cheaply. Clinical trials are expensive to conduct¹⁷⁵ and require extensive networks of physicians and

169 Alex Keown, *Keytruda Set to Become World’s Top-Selling Drug, Forecast Shows*, BIOSPACE (Oct. 4, 2019), <https://www.biospace.com/article/keytruda-set-to-become-world-s-top-selling-drug-forecast-shows/> [https://perma.cc/MZ3W-P55X].

170 *See id.* (as of 2019, Merck had more than 1000 clinical trials ongoing for Keytruda). New indications, as a result, are coming all the time. *See, e.g., Merck Announces Fourth-Quarter and Full-Year 2020 Financial Results*, MERCK (Feb. 4, 2021), <https://www.merck.com/news/merck-announces-fourth-quarter-and-full-year-2020-financial-results/> [https://perma.cc/3VXJ-GK7U] (tabulating recent new approvals and approval filings for Keytruda in the United States and abroad). A recent crackdown by the FDA on insufficient post-launch drug data has compelled Merck to withdraw one of its indications for metastatic small cell lung cancer, which may signal more regulatory stringency for drugs approved through accelerated pathways. *See* Kezia Perkins, *Merck Withdraws Keytruda from SCLC Indication Amid FDA Crackdown*, CLINICAL TRIALS ARENA (Mar. 3, 2021), <https://www.clinicaltrialsarena.com/news/merck-withdraws-keytruda-for-lung-cancer-amid-fda-crackdown/> [https://perma.cc/Y5UR-3CTB].

171 *See id.* (Keytruda’s \$14 billion worth of sales in 2020 represented a 30 percent increase from 2019).

172 *See Could COVID-19 Stop \$200 Billion March for Merck’s Keytruda?*, FORBES (Mar. 23, 2020), <https://www.forbes.com/sites/greatspeculations/2020/03/23/can-mercks-keytruda-be-worth-200-billion/?sh=58a5dec36520> [https://perma.cc/526C-EVAJ].

173 *See supra* Part II.

174 It is true that, in contrast to Sovaldi, Merck brought Keytruda through all FDA trial stages, but their risk was mitigated by the observed success of a similar competitor, in addition to the regulatory cooperation and acceleratory measures they enjoyed.

175 *See* DiMasi et al., *supra* note 45, at 23 (showing that, since 2003, the proportion of phase III costs had risen considerably relative to other phases of development); *see also* Thomas J. Moore, *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug*

hospitals, as well as good relations and experience with the FDA.¹⁷⁶ All of this underscores the investment required to secure Keytruda’s range of indications. Although no doubt beneficial to many patients, these measures are far removed from the initial benchwork that conceived the drug and substantiated its patents.

On the topic of value leakage, one should also consider the case of Ridgeback Biotherapeutics and Merck’s COVID-19 drug, Molnupiravir. Scientists at Emory University developed the drug with funding that included millions of dollars from the National Institutes of Health and the Defense Department.¹⁷⁷ Ridgeback, a young company that had no labs or manufacturing capacity, licensed the drug from Emory and conducted clinical trials in the U.K. through a contract research organization.¹⁷⁸ Two months after signing the deal with the university, Ridgeback sold the drug to Merck in a move that some commentators have called “molecule-flipping.”¹⁷⁹ Thus, in this case, the U.S. government provided the funding, a university made the discovery, and a contract research organization performed the initial clinical trials. None of those parties will walk away with the lion’s share—or, in some cases, any share—of the returns. Any gold at the end of the rainbow will go to speculators and Merck, which raises questions of for whom are we designating lucrative incentives and for what contribution to the process of innovation.

Value leakage can also occur when acquisitions facilitate combined drug products, which can serve as a means of recycling existing drugs for additional profit. A decade before Sovaldi, for instance, Gilead acquired a “cash-strapped” specialty drug company, Triangle Pharmaceuticals, in order to pair Triangle’s HIV

Administration, 2015-2016, 178 JAMA INTERNAL MED. 1451 (2018) (finding that clinical efficacy trials cost an average of \$19M, with some larger trials veering toward half a billion dollars; trials for rare diseases cost much less on account of size and lack of a control group).

176 See Richman et al., *supra* note 97, at 817-18 (noting the importance of personal relationships in the clinical trial and approval space).

177 Press accounts vary on the amount of federal funding. Compare Christopher Rowland, *Hedge Fund Manager Stands to Profit on “Flip” of Taxpayer-Funded Coronavirus Drug*, WASH. POST (June 25, 2020) (last visited Apr. 3, 2023), <https://www.washingtonpost.com/business/2020/06/11/coronavirus-drug-ridgeback-biotherapeutics/> (listing \$16 million of federal funding), with Rae Cook, *Taxpayers Funded Development of COVID-19 Antiviral Pill*, AXIOS (Oct. 5, 2021) <https://www.axios.com/molnupiravir-merck-ridgeback-emory-nih-taxpayers-e0dfda1e-78ec-4a1e-a09f-1437fb20deb9.html> [<https://perma.cc/DHX6-45GA>] (last visited Apr. 3, 2023) (listing \$35 million of federal funding). A whistleblower complaint filed by a former director of the Health and Human Services’ Biomedical Advanced Research and Development Authority (BARDA) alleges that the company improperly tried to circumvent agency procedures in an attempt to obtain additional federal funding. See U.S. OFF. SPECIAL COUNS., COMPLAINT & DISCLOSURE FORM OF RICK BRIGHT 35, <https://apps.npr.org/documents/document.html?id=6882560-Rick-Bright-Whistleblower-Complaint> [<https://perma.cc/8NUR-KW8G>] (last visited Apr. 3, 2023).

178 See Rowland, *supra* note 177.

179 *Id.*

drug Coviracel with Gilead’s own Viread.¹⁸⁰ The one-pill combination of these two drugs—marketed as Truvada—earned annual sales revenue that approximately quadrupled the amount Gilead paid to acquire Triangle.¹⁸¹ Although viewed one way, the acquisition offers an example of the synergy often cited by proponents of consolidation,¹⁸² the reward in this case redounded overwhelmingly to Gilead—in spite of Triangle’s sizable contribution to Truvada.

Truvada’s blockbuster revenue is hardly approximated in the “net present value” of their 2002 acquisition of Triangle. Rather, Triangle’s financial situation may have compelled a buyout,¹⁸³ an exit strategy depended on by many pharmaceutical startups.¹⁸⁴ As such, the history of Truvada exemplifies how the pharmaceutical industry structure can favor the larger players with a disproportionate share of new drug profits. Once again, the reconfigured pharmaceutical industry may generate significant value leakage, overpaying large downstream acquirers while under-rewarding innovators. The risk is a diluted incentive to take on basic, high-risk research, not only promoting failure but doing so at the wrong part of the innovation chain.

The shift in industry structure also may have the effect of invigorating drug companies’ demands to be compensated for their failures. Drug companies have shifted from engaging in internal innovation to the purchase of initial innovation and handling later-stage trials and regulatory approval.¹⁸⁵ As with Hatch-Waxman litigation, focusing on patent value may embolden companies to petition the government to pay for their various costs—including the regulatory costs involved in the clinical trial and approval processes that occupy much of large company activity—along with the “failure compensation” justifications that are used to buttress those arguments.¹⁸⁶

In short, encouraging failure is counterproductive. Rather than promoting

180 Brady Huggett & Christopher Scott, *Gilead’s Deal of a Lifetime*, 27 NATURE BIOTECHNOLOGY 423, 423 (2009).

181 See *id.* (comparing Gilead’s acquisition of Triangle for \$525.2 million with Truvada’s \$2.1 billion in 2008 sales).

182 See, e.g., Jan Bena & Kai Li, *Corporate Innovations and Mergers and Acquisitions*, 69 J. FIN. 1923 (2014) (finding that synergies in drug development pipelines drive many acquisitions in the pharmaceutical industry).

183 See Andrew Pollack, *Acquisition by Gilead to Expand Drug Line*, N.Y. TIMES (Dec. 3, 2002), at C3 (“The acquisition could be one of a spree of mergers that analysts say might take place because many biotechnology companies are running out of cash at a time when low stock prices make raising money difficult. Triangle, based in Durham, N.C., had \$60 million in cash, which would have lasted less than a year.”).

184 Khetan, *supra* note 149, at 38 (noting that early-stage companies lack the experience, sales and marketing competence, and funds necessary to bring drugs over regulatory hurdles and swiftly to market, relying as a result on larger pharmaceutical firms).

185 See *supra* text accompanying notes 139-150.

186 See *supra* text accompanying notes 141-142.

efficient innovation, creating incentives to fail leads to circumstances in which the one who fails more earns more. The problem is exacerbated by a weakened buy-side constraint, which interferes with the normal counter-pressure that could limit the price increases resulting from including failures in the value of a drug. And finally, the recent restructuring of the innovation pipeline risks further distorting innovation by directing dollars to the wrong part of the innovation chain and diluting the incentive to engage in basic high-risk research.

CONCLUSION

The notion of allowing drug companies to recoup the cost of their failures through the rewards of the patent system has steadily progressed from industry to academia and into judicial opinions. Despite the notion's superficial appeal, it is antithetical to the patent system and the innovation interests embodied therein. Patent theory rests on the notion of rewarding success, providing the opportunity to garner a return from an invention that one succeeds in conceiving of or reducing to practice—limited carefully to the actual boundaries of the invention itself. Society does not grant patents for things that an inventor tries and fails to produce. Nor should the patent reward reflect anything but the invention itself.

From an historical perspective as well, federal statutes and cases from early patent law's history reveal not a single act or case stating that a patent grant is intended to compensate the patentee for the costs of developing an invention that was not patented. Even in terms of compensating for the costs of developing the invention itself, patent history suggests the opposite. Despite a brief flirtation in the mid-1800s with the possibility of providing an extension of the patent term, when needed for recoupment of development expenses, Congress rejected that approach. Moreover, the current system does not operate in a manner that links the patent reward to the costs of development; most patents provide no return to the inventor, and returns can be lavished on inventions with no more development costs than a moment of inspiration. One could conceivably design a patent system based on the costs of research and development, but this is not the system in place.

From a practical perspective, creating incentives to fail has the effect of motivating pharmaceutical companies to be less efficient, rather than more efficient, in their innovation efforts, at least on an inventor- and invention-specific level. If the reward one receives includes the costs of failures, then the more one fails, the greater one's reward. Although one might ordinarily expect buy-side constraints to operate to prevent such inefficiencies, characteristics of the pharmaceutical markets, including opportunities for regulatory gaming, serve to dampen such constraints. Moreover, recent shifts in the industry structure, in which universities and small pharma do the heavy lifting of invention while large pharmaceutical companies take the drugs the last mile through approval and

manufacturing, create further distortions of the innovation incentive. Rather than distributing the flow of rewards appropriately throughout the supply chain, pharmaceutical markets demonstrate significant value leakage, in which large pharmaceutical companies are over-rewarded, and innovators are under-rewarded. Such a process dilutes the incentive for research, not only promoting failure but doing so at the wrong part of the innovation chain.

In short, creating incentives to fail is as counterproductive as the phrase sounds. Unless academics, legislators, regulators, and the judicial system recognize that problem, the nation may find itself sliding quietly into an approach that undermines the contours of the patent system from time immemorial, distorting innovation in the process.

Seeing Through Price Transparency

David Edholm*

Abstract:

In light of unprecedentedly high health care prices, legislators have turned to price transparency to lower health care costs. But the benefits behind the theory of price transparency are not easily translated into practical solutions. The Price Transparency Rule, promulgated by the Centers for Medicare and Medicaid Services (CMS), has had underwhelming effects more than eighteen months after its effective date. As of August 2022, only 16 percent of hospitals were compliant with the Rule.

Although price transparency is thought to be an effective tool to fight increasing health care costs, the practical impact is uncertain. Studies demonstrate why the effects of price transparency in the U.S. economy may not be as intended. However, state price transparency tools known as all-payer claims databases (APCDs) have proven that price transparency can indeed provide benefits beyond offering consumers the opportunity to price shop for health care services. Data published through a state's APCD can be analyzed by researchers and governments and can potentially influence the direction of future legislative efforts as they relate to lowering health care prices and combatting anticompetitive effects resulting from price transparency.

CMS should consider shifting its focus away from enforcing the current Price Transparency Rule, given its compliance failures, and explore other means to achieve the Rule's intended purpose. For example, the No Surprises Act allows consumers to request an Advanced Explanation of Benefits or a good faith estimate before receiving services and could provide similar consumer-level benefits. And the APCD model may be a vector to achieving some of the broader policy goals relative to price inflation.

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INTRODUCTION

The cost of health care in the United States is more than double that in comparable industrialized countries, yet the volume of health care goods and services provided in the United States is approximately equal to that of other developed countries.¹ Over the past twenty years, scholars have identified the primary cause of higher health care expenditures as the baseline price for goods and services.² The continued increase in prices raises policy questions about the largest aging population in U.S. history and a patient-saturated and resource-deprived health care market. Although health care inflation has been a rising policy concern in most of America's recent memory, the negative impact on hospital revenues caused by the COVID-19 pandemic, a decrease in health care market competition due to a spike in anticompetitive mergers in the past decade, and the nation's highest rate of general inflation in the past forty years elevate this concern to a level of arguably unprecedented urgency.³ Some countries comparable to the United States support governmental price regulations that directly combat the issue

1 *Health Expenditure and Financing Data*, ORG. FOR ECON. COOP. & DEV., <https://stats.oecd.org/Index.aspx?QueryId=30171> [<https://perma.cc/5EZ9-6RCZ>] (noting that the United States spent 18.8 percent of its GDP on health care in 2020, followed by Canada at 12.9 percent). The United States does not report certain utilization statistics to OECD, however, recent data show that the United States has 26 percent fewer acute care beds per 1,000 people than the median OECD country. Gerard F. Anderson, Uwe E. Reinhardt, Peter S. Hussey & Varduhi Petrosyan, *It's the Prices, Stupid: Why the United States is So Different from Other Countries*, 22 HEALTH AFFS. 89, 90 (2003) [hereinafter *It's the Prices, Stupid*].

2 See Gerard F. Anderson, Peter S. Hussey & Varduhi Petrosyan, *It's Still the Prices, Stupid: Why the U.S. Spends So Much on Health Care, and a Tribute to Uwe Reinhardt*, 38 HEALTH AFFS. 87, 93–94 (2019) (“Because the U.S. is still not devoting more real resources to medical care than the typical OECD country, we believe that the conclusion ‘it’s the prices, stupid,’ remains valid.”) [hereinafter *It's Still the Prices, Stupid*]; see also *It's the Prices, Stupid*, *supra* note 1, at 103 (concluding that the United States has higher health care prices because “spending is a product of goods and services used and their prices,” yet the United States had lower aggregate utilization than comparable countries).

3 See *Report: Hospitals Face Worst Year Financially Since Start of COVID-19 Pandemic, Jeopardizing Access to Patient Care*, AM. HOSP. ASS'N (Sept. 15, 2022), <https://www.aha.org/news/headline/2022-09-15-report-hospitals-face-worst-year-financially-start-covid-19-pandemic> [<https://perma.cc/8XKB-WHEQ>] (listing factors including “severe workforce shortages, broken supply chains, the Medicare 2% sequester kicking back in[,] and rapid inflation . . .”); Brent D. Fulton et al., *The Rise of Cross-Market Hospital Systems and Their Market Power in the U.S.*, 41 HEALTH AFFS. 1652 (2022), <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2022.00337> [<https://perma.cc/8CC2-MTDP>] (showing that more than half of hospital mergers from 2010–2019 were cross-market mergers, and thus have potential anticompetitive effects); Christopher Rugaber, *U.S. Inflation at 9.1 Percent, a Record High*, PBS (July 13, 2022 9:40 AM), <https://www.pbs.org/newshour/economy/u-s-inflation-at-9-1-percent-a-record-high> [<https://perma.cc/K5GV-2XUY>] (“[In 2022, c]onsumer prices soared 9.1 percent . . . the biggest yearly increase since 1981 . . .”).

of price inflation.⁴ These countries, however, operate within a government-funded, single-payer authority. On the contrary, the United States is hesitant to make an equivalent leap of faith in policymaking in order to maintain its capitalistic values. Instead, in a fragmented-payer market, the United States has primarily turned to the theory of price transparency to indirectly lower prices through market forces.⁵

To date, the most prominent regulatory regime aiming to improve price transparency in health care is the Price Transparency Rule (Rule), promulgated by the Centers for Medicare & Medicaid Services (CMS).⁶ The latest of these regulations established that hospitals must publish their “chargemaster rates”—a comprehensive list of “standard charges” for items and services maintained by a hospital—in an easily accessible “machine-readable” file format and a price estimator tool for the 300 most common “shoppable services” by January 1, 2021.⁷ The stated purpose of the Rule is as follows:

By disclosing hospital standard charges, we believe the public (including patients, employers, clinicians, and other third parties) will have the information necessary to make more informed decisions about their care. We believe the impact of these final policies will help to increase market competition, and ultimately drive down the cost of healthcare services, making them more affordable for all patients.⁸

But so far, the Rule’s impact has been underwhelming, largely due to high rates of noncompliance with the technical requirement.⁹ In February 2022, more than one year after the rule’s effective date, 86 percent of hospitals were

4 Robert A. Berenson & Robert B Murray, *How Price Regulation Is Needed to Advance Market Competition*, 41 HEALTH AFFS. 26, 27 (2022) (“Most [OECD] countries now favor regulation to restrain provider prices and strengthen competition over other important aspects of health care that are less amenable to successful regulation.”).

5 See discussion *infra* Part I (delineating the modern legal history of price transparency in the United States).

6 The “Price Transparency Rule” in this article is defined broadly as the collective rules that Health and Human Services’ (HHS) agencies have created to build a system that fixes the problem of price opacity. For more on the legal evolution of the Price Transparency Rule, see discussion *infra* Part I.

7 A machine-readable format is defined as a digital representation of data or information in a file that can be imported or read into a computer system for further processing. In the Price Transparency Rule, examples of machine-readable files include .XML, .JSON, and .CSV formats. Additionally, a shoppable service is defined as a service that a consumer can schedule in advance. 45 C.F.R. § 180.20 (2021) (definitions); 45 C.F.R. § 180.50 (2021) (requirements).

8 CY 2020 Price Transparency Final Rule, 84 Fed. Reg. 65,524 (Nov. 27, 2019), <https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf> [<https://perma.cc/Z5DH-SMN4>] (summary).

9 See discussion *infra* Sections I.C, II.C, II.D (showing trends in noncompliance, analyzing the Rule’s mechanisms, then explaining why the Rule likely will not effectuate its purpose).



noncompliant with the machine-readable or shoppable services requirements, or both.¹⁰ Furthermore, the most recent study, published in August 2022, found that compliance increased by only 2 percent since February.¹¹

This Note scrutinizes the underlying theory of price transparency as a solution for increasing health care costs. But it also serves as a critique of CMS’s existing Price Transparency Rule—namely, the Rule’s required mechanisms—in a fragmented-payer marketplace.

Regarding price transparency writ large, this Note argues that it is a futile tool to directly combat price inflation due to the treatment of health care as a commodity in the U.S. market. On the existing Rule, it dives into the low rate of compliance and the multiple factors contributing to it, including an unworkable technical requirement, industry disdain for publishing standard charges, and, until recently, lack of enforcement. Even with maximal compliance, the Rule is unlikely to achieve its intended purpose due to low consumer awareness and a high burden to derive practical benefit from the machine-readable file.

This Note concludes that alternative mechanisms to achieve price transparency are better-suited to effectuate a public benefit. The No Surprises Act, for example, allows consumers to effectively price shop through its Advanced Explanation of Benefits (AEOB) requirement.¹² And many states use all-payer claims databases (APCDs) as electronic tools to effectuate price transparency rather than the machine-readable requirement.¹³ Collectively, these policies have more potential to provide benefit than the federal Price Transparency Rule in the near- and long-term.

I. BACKGROUND

The United States leads the world in health care spending at 19.7 percent of

¹⁰ *Second Semi-Annual Hospital Price Transparency Compliance Report*, PATIENT RTS. ADVOC. 1–2 (Feb. 2022), <https://www.patientrightsadvocate.org/semi-annual-compliance-report-2022> [<https://perma.cc/EDS4-ECCB>] [hereinafter *PRA Feb. '22*] (noting that compliance with the machine-readable requirement was particularly low at only 14.3 percent in a review of 1,000 hospitals).

¹¹ *THIRD SEMI-ANNUAL HOSPITAL PRICE TRANSPARENCY REPORT*, PATIENT RTS. ADVOC. 2 (Aug. 2022), <https://www.patientrightsadvocate.org/august-semi-annual-compliance-report-2022> [<https://perma.cc/VY7M-DHZA>] [hereinafter *PRA Aug. '22*].

¹² Although Advanced Explanations of Benefits (AEOBs) are non-public, they still benefit individual consumers by allowing them to compare prices between health care entities. See discussion *infra* Part I and Section II.E (relating the No Surprises Act to price transparency and the price shopping process).

¹³ Data from all-payer claims databases (APCDs) can be used by researchers and policymakers to define trends within the health care market, which may be used as the basis for future price control policy. See discussion *infra* Sections I.B, II.E (outlining use cases and system benefits of the APCD price transparency model).

its GDP.¹⁴ The latest research shows that this is slightly more than double the average GDP per capita spent on health care by other developed countries.¹⁵ The quality of care in the United States, however, is not necessarily representative of its higher rate of spending.¹⁶

A well-known article, “It’s the Prices, Stupid,” published in 2003, was the first in-depth analysis into refined international health care data from the Organization of Economic Cooperation and Development (OECD).¹⁷ The article examined factors contributing to higher U.S. health care spending. One proposition is that the inputs (worker salaries, pharmaceuticals, medical technology, etc.) used to provide health care are more expensive in the United States than in other countries.¹⁸ Another is that U.S. health care is potentially more service intensive (i.e., provides more services per patient), less efficient, and requires more administrators than other countries.¹⁹ In any event, the data indicated that aggregate utilization, measured by physician visits and hospital days per capita, was below the OECD median, and thus the reason for higher health care costs was primarily due to pricing rather than overutilization.²⁰ According to a recent poll, 80 percent of Americans believe that reducing health care costs should be a top domestic priority for the President and Congress.²¹

The price of health care is steadily increasing. In 2020, health care spending

14 *National Health Expenditure Data*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical> [https://perma.cc/JTR9-73NG] (increasing from 16.9 percent in 2019).

15 Emma Wager et al., *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON-KFF HEALTH SYSTEM TRACKER (Jan. 21, 2022), <https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries-2> [https://perma.cc/LD75-5TX2] (analyzing National Health Expenditure and OECD data).

16 In several country-to-country comparisons, quality of care is lower in the United States despite higher health care costs. See, e.g., Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?* THE COMMONWEALTH FUND (Jan. 30, 2020), <https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019> [https://perma.cc/9F8R-WGQS].

17 *It’s the Prices, Stupid*, *supra* note 1. Cf. *It’s Still the Prices, Stupid*, *supra* note 2 (repeating the original study using updated data, reinforcing the original conclusion, and then suggesting that policymakers should primarily focus on prices in the private sector).

18 *It’s the Prices, Stupid*, *supra* note 1, at 91.

19 *Id.* at 92.

20 *Id.* at 103.

21 *Americans’ Domestic Priorities for President Trump and Congress in the Months Leading up to the 2020 Election*, POLITICO & HARVARD T.H. CHAN SCH. PUB. HEALTH, (Feb. 2020), <https://www.politico.com/f/?id=00000170-5e12-de37-af75-fe3290bf0000> [https://perma.cc/Q9PJ-T47V] (illustrating that this perspective crosses partisan lines: both Republicans and Democrats ranked lowering the cost of health care as the number one priority, followed by lowering the cost of prescription drugs).

in the United States grew 9.7 percent from the previous year.²² The federal health insurance trust fund is expected to be depleted by 2026.²³ And CMS predicts that health care spending will reach \$6 trillion by 2027, nearly one-third more than the \$4.1 trillion spent in 2020.²⁴ As a result, funding for federal health insurance, which accounted for 25 percent of the federal taxpayer budget in 2022, will require more taxpayer dollars.²⁵

Alongside governmental concerns of intrinsically higher health care inflation are consumer concerns about price variation and unpredictability. In the case of newborn delivery and hospitalization, for example, reports have shown that those with private insurance pay anywhere from nothing to more than \$10,000 out-of-pocket.²⁶ Additionally, a report by the *Wall Street Journal* found that the price of a cesarean section, commonly an emergency procedure, can range from \$6,000 to \$60,000 out-of-pocket depending on the rate a health care provider negotiated with a patient's insurer.²⁷

22 *National Health Expenditure Data*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical> [https://perma.cc/GV8Q-X6HT].

23 2021 ANNUAL REPORT, FED. HEALTH INS. BD. TRUSTEES 6 (Aug. 31, 2021), https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf?utm_campaign=General%20Newsletter [https://perma.cc/AR2G-FZ7V].

24 *CMS Office of the Actuary Releases 2018-2027 Projections of National Health Expenditures*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 20, 2019), <https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2018-2027-projections-national-health-expenditures> [https://perma.cc/UKR2-BUVH]. One contributing factor to increasing health expenditures is the aging baby boomer population. See *The Baby Boomer Effect and Controlling Health Care Costs*, U.S. CAL. SCH. PUB. POL'Y, <https://healthadministrationdegree.usc.edu/blog/the-baby-boomer-effect-and-controlling-health-care-costs/> [https://perma.cc/7WVX-NHJN] (estimating that the Medicare-eligible population will have increased from 35.1 million in 2000 to 69.7 million in 2023). Additionally, federal health care expenditures increased by 36 percent between 2019 and 2020, largely due to the COVID-19 pandemic. Micah Hartman et al., *National Health Care Spending in 2020: Growth Driven by Federal Spending in Response to the COVID-19 Pandemic*, 41 HEALTH AFFS. 13 (2020), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01763> [https://perma.cc/R486-PP3M].

25 *Policy Basics: Where Do Our Federal Tax Dollars Go?*, CTR. BUDGET & POL'Y PRIORITIES (2022), <https://www.cbpp.org/research/federal-budget/where-do-our-federal-tax-dollars-go> [https://perma.cc/2RBA-AGEW].

26 Kao-Ping Chua, A. Mark Fendrick, Rena M. Conti & Michelle H. Moniz, *Out-of-Pocket Spending for Deliveries and Newborn Hospitalizations Among the Privately Insured*, 148 PEDIATRICS e2021050552 (2021), <https://publications.aap.org/pediatrics/article/148/1/e2021050552/179972/Out-of-Pocket-Spending-for-Deliveries-and-Newborn> [https://perma.cc/3ZFQ-NGNE] (arguing that private insurers should waive hospitalization costs for first-born children in line with Medicare and other countries).

27 Anna Wilde Matthews, Tom McGinty & Melanie Evans, *How Much Does a C-Section Cost? At One Hospital, Anywhere from \$6,241 to \$60,584*, WALL ST. J. (Feb. 11, 2021), https://www.wsj.com/articles/how-much-does-a-c-section-cost-at-one-hospital-anywhere-from-6-241-to-60-584-11613051137?mod=article_inline [https://perma.cc/GBQ6-RMB5] (“The rate the

An October 2022 study using data extracted from machine-readable files from more than 1,500 hospitals across the nation found substantial price variation.²⁸ The study found that average “chargemaster prices” and “discounted cash prices” were 164 percent and 60 percent, respectively, above the “payer-specific negotiated rate.”²⁹ Additionally, within these categories, the 90th to 10th percentile ratio indicating markup factors ranged from 3.2 to 11.5 for chargemaster prices, 6.1 to 19.7 for cash prices, and 6.6 to 30.0 for negotiated rates.³⁰ The considerable variability in prices across U.S. hospitals can lead to vastly unpredictable cost obligations.

Some patients are fortunate to have the means to afford a surprise medical bill, but most Americans cannot. The lowest-earning Americans spend one-quarter of their income on health insurance. So, entering into a medical bill lottery can make or break their financial stability.³¹ High charges have been shown to disproportionately affect the uninsured, who are more likely to come from low-income households.³²

hospital charges depends on the insurance plan covering the birth.”).

28 See Sebastian Linde & Leonard E. Egede, *Hospital Price Transparency in the United States: An Examination of Chargemaster, Cash, and Negotiated, Price Variation for 14 Common Procedures*, 60 MED. CARE 768 (2022) (examining chargemaster, cash, and negotiated price data between 14 medical procedures across 1,599 hospitals).

29 *Id.* at 773; see 45 C.F.R. § 180.20 (2021) (definitions).

30 Linde & Egede, *supra* note 28, at 773.

31 See *How Much of Americans’ Paychecks Go to Healthcare, Charted*, ADVISORY BD. (May 2, 2019), <https://www.advisory.com/en/daily-briefing/2019/05/02/health-care-costs> [<https://perma.cc/JME5-AYKM>] (examining the highest 10 percent of wage earners, who pay only 2.3 percent of total wages on health insurance); Lorie Konish, *This is the Real Reason Americans File for Bankruptcy*, CNBC (Feb. 11, 2019), <https://www.cnbc.com/2019/02/11/this-is-the-real-reason-most-americans-file-for-bankruptcy.html> [<https://perma.cc/38JR-HFRP>] (“A new study from academic researchers found that 66.5 percent of bankruptcies were tied to medical issues—either because of high costs for care or time out of work.”).

32 See Melanie Evans, Anna Wilde Mathews & Tom McGinty, *Hospitals Often Charge Uninsured People the Highest Prices, New Data Show*, WALL ST. J. (July 6, 2021) https://www.wsj.com/articles/hospitals-often-charge-uninsured-people-the-highest-prices-new-data-show-11625584448?mod=article_inline [<https://perma.cc/JD7N-JC89>] (showing that, compared to “deep-pocketed insurers,” patients who pay cash are “charged among the highest prices”). In addition to the uninsured, insured patients may find themselves paying an inflated “cash discount” rate if the hospital or service provided is out-of-network. See *id.*; Jennifer Tolbert, Patrick Drake & Anthony Damico, *Key Facts About the Uninsured Population*, KFF (Nov. 6, 2020), <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/> [<https://perma.cc/6HDS-NCEC>] (citing that 73.7 percent of uninsured patients state that the main reason for not purchasing insurance is due to high costs). And statistics show that certain racial and ethnic minorities are more likely to be uninsured. See Samantha Artiga, Latoya Hill & Anthony Damico, *Health Coverage by Race and Ethnicity, 2010-2019*, KFF (July 16, 2021), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity> [<https://perma.cc/GP8Q-BXND>] (recognizing that the Affordable Care Act narrowed the gap by insuring more than 20 million individuals).

These significant, hard-to-predict costs have prompted the federal government to take steps to combat surprise medical billing and price opacity. The No Surprises Act (Act), for example, which became effective on January 1, 2022, protects privately insured patients from “surprise” medical bills.³³ In its early stages, however, research on the Act has shown potential weaknesses, such as not providing equal coverage to government beneficiaries or the uninsured.³⁴ The Act also promotes price transparency by requiring hospitals to provide a “good faith estimate” (GFE) or Advanced Explanation of Benefits (AEOB) to any patient who makes a request before seeking treatment.³⁵ Although the Act provides price transparency on an individual patient basis, the principal tool the federal government has deployed to date in an effort to rein in industry-wide health care prices is the Price Transparency Rule. But most providers are not compliant with the Price Transparency Rule.³⁶

In the modern era, the legal push for price transparency began with a 2006 executive order by former President George W. Bush.³⁷ But the order only required federal agencies to disclose payer rates to federal health care program enrollees.³⁸ The Patient Protection and Affordable Care Act of 2010 (ACA) then expanded the scope and application of price transparency requirements to the general public.³⁹ The ACA added Section 2718(e) to the Public Health Service Act, entitled “Bringing Down the Cost of Healthcare Coverage,” which required hospitals to

33 The Act aims to prevent surprise medical bills for emergency and non-emergency services under certain conditions, among other protections. *See* Consolidated Appropriations Act of 2021, Pub. L. No. 116-260 §§ 101–118, 134 Stat. 1182, 2758–2890 (2020); *see also* Robert H. Shmerling, *Wondering How Much Your Medical Care Will Cost? New Rules Could Help*, HARV. HEALTH. PUB. (Sept. 15, 2021), <https://www.health.harvard.edu/blog/wondering-how-much-your-medical-care-will-cost-new-rules-could-help-202109152593> [<https://perma.cc/BZJ8-Q9WW>] (summarizing key provisions from the No Surprises Act while recognizing potential enforcement challenges).

34 *See* Jay Hancock, *An \$80,000 Surprise Bill Points to a Loophole in a New Law to Protect Patients*, NPR (Feb. 23, 2022), <https://www.npr.org/sections/health-shots/2022/02/23/1082405759/an-80-000-surprise-bill-points-to-a-loophole-in-a-new-law-to-protect-patients> [<https://perma.cc/7R3T-H82Y>] (describing a “loophole” where an insurer does not classify a service as an “emergency” or when the hospital fails to provide the insurer with the appropriate paperwork, a patient may be left with a surprisingly high out-of-pocket bill).

35 *See* Consolidated Appropriations Act of 2021, Pub. L. No. 116-260 §§ 101–118, 134 Stat. 1182, 2861–66 (2020) (providing consumer-protection benefits).

36 *See* discussion *infra* Section I.C (examining noncompliance).

37 *See* Exec. Order No. 13,410, 71 Fed. Reg. 51,089 (Aug. 28, 2006), <https://www.govinfo.gov/content/pkg/FR-2006-08-28/pdf/06-7220.pdf> [<https://perma.cc/HL9G-TSDN>] (directing more transparency of quality measurements and price).

38 *Id.* at 51,090.

39 *See* Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119, 137 (2010) (“The Secretary shall make reports received under this section available to the public on the internet website of the Department of Health and Human Services.”). At its core, the ACA has a “triple aim” of health care: increase access, lower cost, and improve quality. BARRY R. FURROW ET AL., HEALTH LAW 533 (10th ed. 2018).

annually publish standard charges.⁴⁰ A technical provision on the mechanisms of electronic publication was absent, however, until CMS added the machine-readable requirement to the Price Transparency Rule in January 2019.⁴¹

Six months later, an Executive Order charged CMS with amending other aspects of the Rule, which complicated technical compliance with the machine-readable format. Instead of publishing only “gross charges,” the order expanded the definition of standard charges, requiring payer-specific negotiated rates and discounted cash price to be published in the machine-readable format.⁴² Gross charges are largely irrelevant to consumers because they represent the amount that a provider charges for a good or service prior to incorporating the payer-negotiated rate. Without knowing the latter rate, a consumer could not extract any practical benefit from a provider’s gross charge, unless the patient was uninsured, even though providers usually have a separate discounted charge for uninsured, cash-paying patients. The Rule also created the first civil monetary penalty provision for noncompliant entities with enforcement set to begin on January 1, 2021, and required hospitals to publish the prices for 300 shoppable services, such as X-rays or MRIs.⁴³ In theory, these new provisions filled in some crucial spaces left open by previous efforts, such as by including payer-specific negotiated rates and discounted cash prices.⁴⁴ But more than eighteen months after the initial enforcement deadline, the results of the rule were still underwhelming. To illustrate, two of the three largest health care systems in the United States, HCA Healthcare and Ascension, were noncompliant.⁴⁵

40 42 U.S.C. § 300gg-18(e) (2010) (“Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary [of HHS]) a list of the hospital’s standard charges for items and services provided by the hospital . . .”).

41 *FY 2019 Price Transparency Final Rule*, 83 Fed. Reg. 41,144, 41,686 (Aug. 17, 2018) (“[We] require hospitals to make available a list of their current standard charges via the internet in a machine readable file format and to update this information at least annually . . .”).

42 See Exec. Order No. 13,877, 84 Fed. Reg. 30,849, 30,850 (June 27, 2019) (“[The Secretary] shall propose a regulation . . . to require hospitals to publicly post standard charge information, including charges and information based on negotiated rates and for common or shoppable services . . .”); 45 C.F.R. § 180.50(b) (2021) (listing required data elements); 45 C.F.R. §§ 180.50(b)(3), (b)(6) (2021) (payer-specific negotiated rates and discounted cash prices); see also 45 C.F.R. § 180.20 (2021) (definitions).

43 *CY 2020 Price Transparency Final Rule*, 84 Fed. Reg. 65,524, 65,571, 65,589 (Nov. 27, 2019) (final action regarding shoppable services requirement and civil monetary penalty); 45 C.F.R. § 180.20 (2021) (defining “shoppable service” as a service that can be scheduled by a health care consumer in advance); 45 C.F.R. § 180.60 (2021) (requirements for publishing shoppable services); 45 C.F.R. § 180.70(b)(3) (2021) (civil monetary penalty).

44 See 45 C.F.R. §§ 180.50(b)(3), (b)(6) (2021) (payer-specific negotiated rates and discounted cash prices); see also 45 C.F.R. § 180.20 (2021) (detailing definitions).

45 *PRA Aug. ’22*, *supra* note 11, at 2.

A. *Desired Benefits of Price Transparency*

Beyond the direct-to-consumer benefit of allowing patients the opportunity to price shop, there are several other desired benefits that price transparency could indirectly effectuate. But the probability that these benefits will result from maximum price transparency on a national level remains hard to predict a priori.

First, there is the desired benefit that lower health care prices will result from a patient's ability to price shop. Many scholars have predicted that price transparency will promote price-lowering competition in health care markets by appealing to price-conscious consumers.⁴⁶ Under this theory, providers would lower their prices to attract more consumers, resulting in a net decrease in health care spending in the aggregate. This is the aim of the Price Transparency Rule; however, scholars note that industry-wide price-lowering from price transparency largely depends on competitive factors in a particular market.⁴⁷

Others have predicted that prices would be lowered out of a provider concern that publishing overinflated prices would damage their reputation, and thus deter business from consumers driven by social and ethical values.⁴⁸ It is hypothesized that nonprofit and government hospitals that are established for a charitable purpose and to support public health would face the most consumer scrutiny and would be more likely to lower prices for this reason than would for-profit hospitals.⁴⁹ But the impact of this causal factor would most likely also be widely variable between markets.

Moreover, there is a theory that hospital price transparency would shift some of the bargaining power that providers have during contract negotiations with payers to provide for a more balanced market equilibrium. This balance could incentivize providers to lower the rate they charge payers in order to more closely match competitor rates for the purpose of preserving a longstanding relationship,

⁴⁶ See Uwe E. Reinhardt, *Health Care Price Transparency and Economic Theory*, 312 JAMA 1642, 1643 (2014) (analyzing a recently published study that found that employees who used a price transparency tool paid lower prices compared to those who did not; however, emphasizing the authors' own acknowledgement of study weaknesses, including a small sample size).

⁴⁷ See *id.* (“[G]reater transparency about prices [] in health care [is] not helpful if the relevant market for health care is monopolized.”).

⁴⁸ See Hans B. Christensen, Eric Floyd & Mark Maffett, *The Only Prescription is Transparency: The Effect of Charge-Price-Transparency Regulation on Healthcare Prices*, 66 MGMT. SCI. 2861, 2876 (2020) (concluding that “high charge prices have significant reputational costs and that, following [the Rule], hospitals likely alter pricing policies [and mitigate the costs of perceived overpricing] . . .”).

⁴⁹ *Id.* at 2873–74 (“Because nonprofit hospitals must justify the benefits they provide to the community in order to maintain their nonprofit status, these hospitals are likely more sensitive to perceptions of overcharging . . . [And] the public puts pressure on politicians to provide oversight of [government-owned] hospitals.”).

especially in markets with more provider competition.⁵⁰ The impact of lowering costs through any of these mechanisms could provide a tremendous benefit to patients and insurers.

Second, price transparency would benefit policymaking by giving legislators more information on which to base policy decisions. On a case-by-case basis, the data could be used to identify particularly high-charge outliers, which could be a target of state legislative efforts. On a larger scale, price transparency would allow researchers nationwide to have access to a horde of online data and to generate meta-analyses. The results from these systematic studies would be highly valuable to federal legislative efforts aimed to control price inflation in health care and to measure the effectiveness of ongoing legislative efforts.

Despite the convincing list of benefits that price transparency could theoretically provide, compelling contrarian perspectives exist, supported by recent data, that address the likelihood that maximum price transparency would provide a net benefit, particularly as a tool to provide tangible cost-reduction to consumers and insurers.⁵¹

B. State Price Transparency Efforts

States often lead by example in adopting novel legislation, and the case of health care price transparency provides no exception. Several states have adopted means of facilitating health care price transparency through a variety of mechanisms. The most effective has been the adoption of all-payer claims databases (APCDs).⁵²

An APCD is defined as “a comprehensive collection of medical claims data from both public and private payers with information specific to individual plans, patients, and procedures.”⁵³ These APCDs can directly benefit consumers who are

50 See JoAnna Younts & Greg Russo, *The Nitty-Gritty of Price Transparency*, AM. BAR ASS'N (Aug. 2021), https://www.americanbar.org/groups/health_law/publications/health_lawyer_home/2021-august/nit-gri/ [<https://perma.cc/453Z-A4KR>] (explaining how the available data would put pressure on the highest-charging providers to lower rates even if a payer recognizes the provider's importance in a particular market).

51 See discussion *infra* Section II.A (detailing the uncertain impact of price transparency, writ large).

52 See generally *All-Payer Claims Databases*, AGENCY FOR HEALTHCARE RSCH. & QUALITY, <https://www.ahrq.gov/data/apcd/index.html> [<https://perma.cc/JP2D-DZ8N>] (last accessed Nov. 6, 2022) (providing background on APCDs).

53 *Examining State Efforts to Improve Transparency in Healthcare Costs for Consumers: Hearing Before the Subcomm. on Oversight & Investigations*, 115th Cong. 1 (2018) (Statement of Jaime S. King), <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/TeStimony-King-OI-Hrg-on-Examining-State-Efforts-to-Improve-Transparency-of-Health-Care-Cost-2018-07-17.pdf> [<https://perma.cc/CD2R-9TZT>].

interested in finding their out-of-pocket costs rather than “standard charges” that provide little practical benefit on a consumer level. These databases also inform sound policy judgment by consolidating all payer and provider claims data into one consumer-facing website that is easy to access. Additionally, states can develop a variety of price transparency applications that extract data from the APCD. State legislation varies on whether to mandate disclosure or make it voluntary, even though the amount of data disclosed is smaller when disclosures are made on a voluntary basis.

The 2020 APCD Report Card “graded” states on the functionality of their respective databases.⁵⁴ While only sixteen states received a “passing” grade, each state was scored according to the scope of content, ease of use, utility, and timeliness/accuracy.

Colorado received a high score for including cost, utilization, and quality reports, and using the data to assess price variability across the state. The Center for Improving Value in Healthcare, a Colorado nonprofit organization, used the APCD to compare commercial insurer reimbursement rates as a percentage of Medicare.⁵⁵ Massachusetts received a similarly high score as the Health Policy Commission, a state agency, collected data on health care transactions and assessed health care cost growth while facilitating a review of the effect on competition resulting from the transactions, among other purposes.⁵⁶ Further, New Hampshire, one of only two states that received an “A” (Maine is the other state), used the data to create provider network adequacy and balance billing laws.⁵⁷ These three states’ APCDs provide effective examples on how to achieve a high level of benefit from price transparency through an APCD.

C. *Current State of Noncompliance with the Federal Price Transparency Rule*

Notwithstanding the concept of price transparency, the practicability of the Price Transparency Rule was questioned in Proposed Rule comments and in subsequent litigation.⁵⁸

⁵⁴ See Roslyn Murray et al., *Report Card on State Price Transparency Laws: 2020*, CATALYST (May 2020), https://www.dropbox.com/s/gzkvx2mtwpwtrot/2020-Report-Card-on-State-Price-Transparency-Laws_May-2020_Published-uttkwt.pdf?dl=0 [<https://perma.cc/RC8E-C3YL>] (including a scoring rubric as Appendix “A”).

⁵⁵ *Id.* at 15.

⁵⁶ *Id.* at 16.

⁵⁷ *Id.*

⁵⁸ See *CY 2020 Price Transparency Requirements*, 84 Fed. Reg. 65,524, 65,550 (“[M]any commenters asserted that such information is either ‘non-existent’ or is not available without significant manual effort”); *Am. Hosp. Ass’n v. Azar* 983 F.3d 528, 536–38 (D.C. Circ. 2020) (“The Association advances two slightly different arguments under the umbrella of excessive burden. First, many negotiated rates are ‘unknown’—or even ‘unknowable,’ as Association counsel insisted at oral argument—so complying with the rule is ‘impracticable, and often impossible.’”).

One concern had to do with the burden on hospitals to publish a complete and accurate machine-readable file by narrowing down standard charges, including payer-specific negotiated rates, in the vast web of complex payer-provider agreements.⁵⁹ The Proposed Rule far underestimated the number of hours (as twelve) for a hospital to publish standard charges. But this absurd estimate was expanded to 150 hours in the final rule and held “reasonable” by the D.C. Circuit, with little explanation in the opinion.⁶⁰

Next was concern with publishing a complete machine-readable file. During promulgation, CMS specifically sought comment on whether it should require an alternative technological approach with a standards-based Application Programming Interface (API)—a piece of software that allows systems to “talk” to each other by connecting, extracting, translating, sending, and installing a message between systems—rather than a machine-readable file.⁶¹ The API approach may have streamlined the price transparency process by automatically sending data to the consumer upon request.⁶² But ultimately, CMS chose the machine-readable file, labeling its decision as a “good initial step” towards price transparency while leaving open the possibility of a standards-based API requirement as a product of future rulemaking once compliance with the machine-readable requirement has “matured.”⁶³

Since the Price Transparency Rule became effective on January 1, 2021, several reports have shown startlingly low rates of compliance.⁶⁴ In January 2022,

59 See discussion *infra* Section II.B (expanding on the complexity of the fragmented payer marketplace and payer-provider agreements).

60 The American Hospital Association argued that Secretary Azar “failed to adequately address the difficulties that hospitals face in compiling the information the rule requires” and thus violated the Administrative Procedure Act. However, the court responded that the Secretary adequately “acknowledged” the challenges of aggregating their different rates, and therefore expanding the burden estimate and extending the compliance deadline was sufficient evidence that the rule was not overly burdensome. *Am. Hosp. Ass’n v. Azar*, 983 F.3d 528, 536–538 (D.C. Cir. 2020).

61 *CY 2022 Price Transparency Rule with Comment Period*, 86 Fed. Reg. 63,458, 63,953 (Nov. 16, 2021).

62 This technological approach is explored as a means of complying with the No Surprises Act to send consumers a GFE or AEOB before seeking treatment. See discussion *infra* Section II.E.

63 *CY 2022 Price Transparency Rule with Comment Period*, 86 Fed. Reg. 63,458, 63,954 (Nov. 16, 2021). It is likely that CMS’s idea for public machine-readable files was for third-party app-developers to extract the pricing data through an API and send it to a consumer without putting the burden of implementing APIs on providers. But arguably, easily installable standards-based APIs, such as Fast-Healthcare Interoperability Resource (FHIR), would be more effective than the machine-readable file. See generally *What is FHIR?*, OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., <https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf> [<https://perma.cc/4D44-CG4D>].

64 See JOEL ARIO, KEVIN MCAVEY & AMY ZHAN, ASSESSING IMPLEMENTATION OF HOSPITAL PRICE TRANSPARENCY, MANATT HEALTH (2022), https://www.manatt.com/Manatt/media/Documents/Articles/NYSHF-Hospital-Price-Transparency-Report-January-2022_c.pdf [<https://perma.cc/5NGE-ZAZE>] (assessing a sample of thirty-two New



a study of New York-area hospitals found that only 12 percent of hospitals were fully compliant with the machine-readable requirement six months after the Rule's effective date.⁶⁵ Further, the study found that implementation of the machine-readable requirement is lagging compared to the shoppable services requirement, for which 69 percent of hospitals were fully compliant.⁶⁶

A *Patient Rights Advocate* study published in February 2022 found that only 143 out of 1,000 hospitals were fully compliant with the Rule; moreover, it found that the other 857 hospitals were noncompliant for failing to publish a complete machine-readable file. An incomplete machine-readable file was judged based on a failure to provide all required prices for items and services, sometimes listing a zero, an asterisk, or the value "N/A." In some cases, hospitals did not include any prices for some of their accepted insurance plans.⁶⁷

Six months later, in August 2022, *Patient Rights Advocate* published the third semi-annual study, this time reviewing 2,000 hospitals instead of only 1,000 from the February study, with little optimism to report.⁶⁸ Of the hospitals reviewed, only 16 percent were compliant with the machine-readable and shoppable services requirements.⁶⁹ Interestingly, some hospitals that were compliant in the February study became noncompliant by removing entire columns of payer-specific negotiated rates or clearly omitting multiple data points.⁷⁰

II. ANALYSIS

A. *The Uncertain Effects of Price Transparency*

There is a lack of consensus on the effects of price transparency on the health care economy; namely, whether price transparency will stimulate price-shopping and drive down health care prices by market forces or whether it will compel lower prices through other mechanisms.

York-area hospitals); *PRA Feb. '22*, *supra* note 10 (reviewing 1,000 hospitals nationwide); *PRA Aug. '22*, *supra* note 11 (reviewing 2,000 hospitals nationwide).

⁶⁵ ARIO ET AL., *supra* note 64.

⁶⁶ *Id.* at 5 (noting that 69 percent of hospitals *partially* implemented the machine-readable requirement).

⁶⁷ *PRA Feb. '22*, *supra* note 10, at 2; see *Advocacy Group Faults Hospitals for Failing to Comply with Price Transparency Rules*, WASH. POST (July 16, 2021), <https://www.washingtonpost.com/context/advocacy-group-faults-hospitals-for-failing-to-comply-with-price-transparency-rules> [https://perma.cc/M6JL-RE3Y] ("The majority of noncompliant failures were the result of non-posting or incomplete posting of the negotiated prices clearly associated with all of the payers and plans accepted by the hospital. The second significant failure was due to a lack of publishing the full list of discounted cash prices.").

⁶⁸ See *PRA Aug. '22*, *supra* note 11, at 4 (presenting results).

⁶⁹ *Id.* at 2.

⁷⁰ See *id.* at 2 ("[Twenty-six] of the previously compliant hospitals have become noncompliant . . .").

In 2014, one of the first impactful studies measuring the use of an online price transparency tool evaluated its effect on consumer choice in health care decisions.⁷¹ The study examined the use of a platform that allowed employees at firms with self-insured (employer-sponsored) plans to compare out-of-pocket costs between competing providers for lab tests, imaging services, and clinician office visits. The data show that patients who utilized the price transparency tool before receiving services paid lower prices than those who did not access the tool.⁷² The authors recognize the study's limitations—namely, assessing data for only three services and the small patient sample size—but the study nevertheless strengthens the argument for a consumer-driven, market-based approach to lowering prices and has initiated further impactful research.⁷³

Economic theory to support price transparency comes from a market advocacy perspective. To drive down the cost of health care through competition, consumers must know the prices in advance in order to bargain between providers. By giving consumers the ability to shop around and barter, the thinking goes, providers will undercut competitors by lowering their own prices, even slightly below a competitor's rate.

But in 2020, one of the first large-scale studies found that price transparency regulation has no statistically significant impact on consumer payments or behavior.⁷⁴ Although the data show that hospital prices decrease by approximately 5 percent after states adopt price transparency regulation, the authors conclude that the decrease is attributable to hospitals lowering prices of their own accord rather than by consumer-driven market forces.⁷⁵ The study also finds no real benefit to patients resulting from lower prices because the benefits stop short of providing a patient with a lower out-of-pocket cost.⁷⁶ To compensate for lowering baseline

71 See Christopher Whaley, Jennifer Schneider Chafen & Sophie Pinkard, *Association Between Availability of Health Service Prices and Payment for These Services*, 312 JAMA 1670 (2014), <https://jamanetwork.com/journals/jama/fullarticle/1917438> [<https://perma.cc/MWE9-GHUC>] ([analyzing consumer-level financial benefits of using a price transparency tool to price shop](#)).

72 See *id.* at 1673 (finding that employees who accessed the tool prior to receiving services paid 13.9 percent less for lab tests, 13.2 percent less for imaging, and 1.02 percent less for clinician office visits than those who did not access the tool prior to receiving services).

73 See *id.* at 1675 (delineating limitations such as not randomly assigning searching to certain employees, potential bias in contemporaneous events that could have prompted searching, whether the results generalize to those who chose not to search, and omitting quality, convenience, or other nonprice attributes to the decision to choose a particular provider).

74 See Christensen et al., *supra* note 48 (relying on a robust dataset from twenty-seven states with price transparency regulation over a seven-year period).

75 See *id.* at 2869 (“[Analysis] suggests that the majority of the observed decline in charges is attributable to hospitals lowering their charges rather than patients selecting lower-charge hospitals.”).

76 See *id.* at 2872 (“Our evidence [] suggests that, although [the Rule] leads to a decrease in charges for disclosed procedures, hospitals are able to avoid passing these charge reductions on to patients in the form of lower payments.”).

charges, hospitals were shown to reduce discounts offered to consumers via payer contracts.⁷⁷ This study indicates that hospitals decrease charges as a result of price transparency regulation, yet do so out of institutional pressure to protect their reputation rather than changes in consumer shopping behavior.⁷⁸

Moreover, a report that conducted a broad-scope literature review on price transparency measured the impact on overall patient costs.⁷⁹ The results show that transparency benefits only the most financially-conscious patients and that impact on consumers is weak due to low price transparency tool utilization.⁸⁰ The authors suggest reasons why price transparency tools are not highly utilized, such as if a patient has already met their deductible and is therefore not directly responsible for the cost, a patient's loyalty to a particular physician or care provider, or lack of alternate provider options due to geography.⁸¹ The report concludes that policymakers should not assume that consumers will use price transparency tools simply because they exist, without additional incentives or display alongside quality indicators.⁸² And it urges policymakers to consider the limited usefulness of "standard charge" data for insured consumers because the data do not represent the patient's out-of-pocket cost.⁸³

On the argument that price transparency will shift bargaining power towards payers in provider-payer contractual negotiations, it is important to consider that the Payer Price Transparency Rule, effective July 1, 2022, will allow payers to compare provider reimbursement rates for the first time, leveling the playing

77 *See id.* at 2876 (“[Our] results suggest that, in response to PTR, providers do lower charges; however, they also decrease discounts such that these charge reductions do not lead to consumer savings.”).

78 *Id.* (“[W]e find that reputational costs of perceived overcharging is the most likely explanation for the reduction in charges.”).

79 *See* Angela Zhang et al., *The Impact of Price Transparency on Consumers and Providers: A Scoping Review*, 124 HEALTH POL’Y 819 (2020) (categorizing the eighteen articles used in the study by consumer behavior and outcomes, provider behavior, and insurer outcomes).

80 *See id.* at 823 (“The impact on consumer costs was strong within the subset of price-aware patients, however, weak amongst all consumers with access to the tool due to low usage.”).

81 *See id.* at 823 (including an argument that price transparency tools could contribute to health care inequality for low-income and elderly persons who are less tech-savvy or lack an adequate internet connection or the requisite technological equipment).

82 *See id.* at 824 (describing an employer bonus incentive for choosing less expensive providers); *see also* Ethan M.J. Lieber, *Does It Pay to Know Prices in Healthcare?*, 9 AM. ECON. J.: ECON. POL’Y 154, 177 (2017) (“[A]ccess to price information could have large impacts in the market for health care, but considering consumers’ incentives to search is of primary importance.”); Sunita Desai et al., *Offering a Price Transparency Tool Did Not Reduce Overall Spending Among California Public Employees and Retirees*, 36 HEALTH AFFS. 1401, 1406 (2017) (suggesting that combining price transparency tools with alternative benefits for usage, such as offering a cash bonus to employees who switch to lower cost providers, could increase the usage of price transparency tools).

83 A patient can calculate their out-of-pocket cost with “standard charge” data by subtracting the payer-negotiated rate from the hospital’s gross charge. *But see* discussion *infra* Section II.D (illustrating the consumer-facing challenges of the machine-readable file).

field.⁸⁴ With both provider and payer price transparency, each party would have access to information that has historically been kept under wraps.⁸⁵ But, the usefulness of this information in negotiation will likely vary on a case-by-case basis based on the characteristics of a specific market. For example, using prices as a bargaining tool is more effective in markets with more competition in the industry of the party on the opposite side of the contract, whether it is the sell-side or the buy-side.⁸⁶

A number of price transparency skeptics argue that price transparency will have anticompetitive effects and induce price increases. In *American Hospital Association v. Azar*, the American Hospital Association (AHA) asserted that institutions that currently charge less than competitors will increase their prices to match competitors, raising prices market-wide.⁸⁷ It is no secret that the AHA was highly against the idea of allowing payers to access their pricing information, previously concealed under contracts, because of a threat of losing bargaining power during negotiations. The court wrote that Secretary Azar was not required to rely on “definitive” rather than “predictive” economic data in establishing these requirements because of the novelty of the rule and that reliance on studies of similar price disclosure schemes in other industries was sufficient to inform a stable policy judgment.⁸⁸ However, there are economic studies that predict effects opposite to those relied on by the Secretary.⁸⁹

In the late 1990s, the Federal Trade Commission and the Department of Justice provided guidance on the use of surveys that would allow providers to share price information. But the agencies have maintained some skepticism regarding

84 See *Transparency in Coverage Final Rule*, 85 Fed. Reg. 72,158 (Nov. 12, 2020) (requiring health plans and health insurance issuers to provide in-network negotiated rates and out-of-network allowed amounts on machine-readable files).

85 But see discussion *infra* Section II.B (describing the payer-provider challenges of generating precise data).

86 Younts & Russo, *supra* note 50 (“Whether and how much the data may impact contract negotiations will depend on the specific market and the service mix of the providers within each market.”).

87 983 F.3d 528, 538 (D.C. Cir. 2020) (“[T]he Association claims, the [R]ule is likely to . . . ‘facilitate anticompetitive effects.’”).

88 *Id.* at 539.

89 See Christensen et al., *supra* note 48, at 2876 (“[O]ur results suggest that, in response to PTR, providers do lower charges; however, they also decrease discounts such that these charge reductions do not lead to consumer savings.”); Robert F. Graboyes & Jessica McBirney, *Price Transparency in Healthcare: Apply with Caution*, MERCATUS CTR. (Aug. 2020) (articulating the anticompetitive effects of price transparency resulting from supply-side “tacit collusion” to maintain inflated prices). But see Katherine L. Gudiksen, Samuel M. Chang & Jaime S. King, *The Secret of Health Care Prices: Why Transparency Is in the Public Interest*, CHCF 12 (July 2019), <https://www.chcf.org/wp-content/uploads/2019/06/SecretHealthCarePrices.pdf> [<https://perma.cc/ZE4R-QF45>] (recommending that price transparency data be released to subgroup in tiers, beginning with the public, followed by academic or government entities, then to private entities or industry participants).

provider transparency without “safeguards” that could result in anticompetitive effects, like “tacit collusion” to maintain high charges industry-wide.⁹⁰ The agencies created a “zone of reasonableness” that was presumed as long as the survey was (1) managed by a third party, such as a government agency or an academic institution; (2) the data provided was more than three months old; and (3) at least five providers reported data on each statistic and no individual provider’s data accounted for more than 25 percent of each statistic, and that the disclosed information was sufficiently aggregated to avoid identification of a particular provider.⁹¹ These survey guidelines, although more than twenty years old, still exist today and are used by states in establishing their APCDs.⁹²

Another part of the issue in predicting results from price transparency comes from the uniqueness of the health care economy, making it difficult to compare to other markets. For example, many consumers develop loyalty to a particular hospital or physician.⁹³ In these cases, a patient might base their decision primarily on receiving advice from one they trust rather than the out-of-pocket cost of care, especially if the price difference is merely negligible.

Moreover, quality of care may be a consumer’s primary consideration before seeking treatment, trumping price considerations. Although “quality” is an extremely complex measurement, ironically, a consumer might associate paying more with receiving higher-quality care.⁹⁴ Thus, unless this consumer has access to quality-of-care information alongside pricing information, they are more likely to make fallacious assumptions about this correlation. Of the state price-transparency policies reviewed, Colorado, Massachusetts, and Minnesota each use their APCD to generate quality of care reports.⁹⁵

Each of these perspectives speculates on what could occur with prices on a consumer- and industry-wide level with maximal federal price transparency, which is a stretch given the low compliance rates with the existing rule.⁹⁶

B. The Pseudo-Achievability of Price Transparency in a Fragmented

⁹⁰ See Graboyes & McBirney, *supra* note 89 (on the anticompetitive effects of price transparency).

⁹¹ Gudiksen et al., *supra* note 89, at 12.

⁹² *Id.*

⁹³ David Blumenthal, Lovisa Gustafsson & Shanoor Seervai, *Price Transparency in Health Care Is Coming to the U.S.—But Will It Matter?*, HARV. BUS. REV. (July 3, 2019), <https://hbr.org/2019/07/price-transparency-in-health-care-is-coming-to-the-u-s-but-will-it-matter> [<https://perma.cc/E9QV-ZPHL>] (“If you have an orthopedist or neurosurgeon you trust for your back surgery and she uses hospital A which is more expensive, are you going to abandon her for another physician who uses the cheaper Hospital B?”).

⁹⁴ Roslyn Murray et al., *supra* note 54, at 6.

⁹⁵ *Id.* at 15–16.

⁹⁶ See discussion *supra* Section I.C (providing evidence on the current state of noncompliance).

Marketplace

Price transparency is an extraordinarily complex task, especially in a fragmented-payer marketplace.⁹⁷ In countries with single-payer systems, such as Canada or those in Europe, billing is simplified because hospitals bill the same entity over and over again.⁹⁸ But in the United States, the public-private payer dichotomy results in billing frenzies, with hospitals contracting with tens or potentially hundreds of payers, each agreement governed by idiosyncratic terms and conditions.

The rate paid by an insurer is often dependent on a variety of factors that are indeterminable before services are performed.⁹⁹ For example, a certain procedure might cost less if it is “bundled” with another one, but this might be impossible to know before the initial procedure is undertaken (e.g., a surgeon discovers and repairs a torn meniscus during a knee operation to repair a torn ligament). Additionally, a payer might receive a “volume discount,” the foundation of which seems arbitrary because of the frequency with which policy manuals are updated.

Each amendment in a payer’s policy manual can create a butterfly effect on negotiated rates, resulting in the standard practice of retrospective rather than prospective billing. The AHA unsuccessfully asserted that Secretary Azar violated the Administrative Procedure Act by overstating the Rule’s benefits. The Secretary predicted that consumers would have accurate pricing information to rely on as a result of full compliance with the Rule.¹⁰⁰ But the variable nature of a myriad of payer-negotiated rates implies the contrary.

The Rule only requires publishing “baseline” charges, yet the reality is that baseline negotiated-rates are highly susceptible to flux. As described in the next Section, the complexity of payer-provider agreements has resulted in near sweeping noncompliance with the Price Transparency Rule.

C. Persisting Challenges of the Price Transparency Rule’s Mechanisms

Studies show that the primary reason for noncompliance is not publishing a complete machine-readable file.¹⁰¹ This may be due to challenges in data

97 See Joshua D. Gottlieb, Adam Hale Shapiro & Abe Dunn, *The Complexity of Billing and Paying for Physician Care*, 37 HEALTH AFFS. (2018), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1325> [<https://perma.cc/E432-HGPK>] (studying claim resolutions over five public and private payer organizations and finding significant variation in complexity for claim submissions to each payer).

98 See *It’s the Prices, Stupid*, *supra* note 1, at 98 (comparing the fragmented U.S. payer system, which requires more resources, than countries with “simpler” systems).

99 See *supra* note 58 and accompanying text.

100 Am. Hosp. Ass’n v. Azar, 983 F.3d 528, 536–37 (D.C. Cir. 2020).

101 See Waqas Haque et al., *Adherence to a Federal Hospital Price Transparency Rule and Associated Financial and Marketplace Factors*, 327 JAMA 2143 (2022) (finding that, out of 5,239

aggregation, data input into the file, updating the data as rates change, or publishing the file in an easily accessible manner.

The aggregation burden is excessive because the number of price data points required for a complete chargemaster list may reach into the hundreds of millions. Northwell Health, for example, has over 200 million data points to convert into machine-readable format in order to be fully compliant.¹⁰² The Executive Vice President at Northwell has commented on the challenges of meeting this burden, especially during the COVID-19 pandemic.¹⁰³ The results from the New York study show that machine-readable compliance is substantially less than compliance with the 300 shoppable services requirement.¹⁰⁴ These results support the view that volume of data itself is a barrier to compliance.

From a business perspective, providers are generally highly resistant to publicizing their standard charges, especially payer-specific negotiated rates. Such hesitance stems from a concern that the Rule may indeed change consumer behavior, causing them to lower baseline charges, or that other providers would undermine their prices when negotiating with mutual payers. Whatever the motivation, an investigation published by the *Wall Street Journal* in March 2021 reported that several provider systems embedded a web-search blocking code so that prices would be undiscoverable from a mainstream search engine.¹⁰⁵ When

hospitals, 1,542 had no machine-readable file, 729 had no shoppable services display, and only 5.7 percent had both, leaving 2,668 hospitals without either a machine-readable file or a shoppable services display); see also *PRA Feb. '22*, *supra* note 10 (assessing compliance of 1,000 hospitals based on publishing a complete machine-readable file and a price-estimator tool for 300 shoppable services); *PRA Aug. '22*, *supra* note 11 (same assessment for 2,000 hospitals); JOEL ARIO ET AL., *supra* note 64 (assessing New York-area hospitals).

102 This number is likely generated by providers according to a complex equation that includes factors such as the number of payer contracts, the goods and services those contracts cover, the goods and services provided by the hospital, bundled payments, volume discounts; and multiplies by five to accurately reflect the “standard charge” subdivisions required in the machine-readable file for each good, service, or bundle thereof.

103 Richard Miller, Executive Vice President at Northwell Health in Hyde Park, NY, commented on Northwell’s attempt at compliance: “We are working to comply with the new CMS requirement to post a more robust machine-readable list of standard hospital charges, including gross and payer-negotiated rates. This list requires an analysis of *more than 200 million data points*, and we are working toward posting it as soon as possible—while also, like health care institutions around the country, focusing on the rollout of the COVID-19 vaccines and meeting the needs of large numbers of seriously ill patients.” Alia Paavola & Katie Adams, *Where Price Transparency Compliance Stands at the Mayo Clinic, Providence + 6 Other Systems*, BECKER’S HOSP. REV. (Jan. 25, 2021), <https://www.beckershospitalreview.com/finance/where-price-transparency-compliance-stands-at-mayo-clinic-providence-6-other-systems.html> [<https://perma.cc/4U3A-BG6D>] (emphasis added).

104 JOEL ARIO, ET AL., *supra* note 64, at 5.

105 See Tom McGinty, Anna Wilde Mathews & Melanie Evans, *Hospitals Hide Pricing Data from Search Results*, WALL ST. J. (Mar. 22, 2021), <https://www.wsj.com/articles/hospitals-hide-pricing-data-from-search-results-11616405402> [<https://perma.cc/D3AV-T9M8>] (naming some of

Wall Street Journal reporters confronted providers, some of them immediately removed the code; others claimed ignorance or that it was a legacy code.¹⁰⁶ The results of this investigation might indicate that, in some circumstances, industry is proactively making access more difficult. But from a technological perspective, publishing an enormous machine-readable file is unlikely to come without its own set of challenges.

Interestingly, the *Patient Rights Advocate* August 2022 study found that twenty-six hospitals that were compliant with the rule in February were no longer compliant because eighteen of them removed plan names from their files and eight are now missing substantial pricing data.¹⁰⁷ It is hard to speculate why the plan names were removed, but given the fluctuating nature of payer-negotiated rates, the eight formerly compliant hospitals that now omit pricing data may have done so because that data is either impracticable or impossible to pinpoint.¹⁰⁸ It is also possible that the hospitals intentionally omitted these data to preserve what they consider a “trade secret.”¹⁰⁹

i. Potential Ways to Stimulate Compliance

a. Expand the Technical Requirement

As an alternative to the machine-readable requirement, CMS could allow Application Programming Interfaces (APIs) that streamline price information from the hospital billing system to the payer, and then into a user end point, such as a personal computer via a patient portal or a personal smartphone, to achieve compliance. APIs can connect to machine-readable files to streamline data transfer and can also connect with provider Electronic Health Records (EHRs), many of which include billing capabilities. APIs are already being utilized in a variety of Health IT criteria, such as the Meaningful Use of Electronic Health Records requirements that allow patients to view their medical record from an online patient portal via a smartphone or web-device, and could also be designed to facilitate transfer of pricing information. Standards-based APIs, such as Fast Healthcare

the biggest health care systems in the United States including in cities such as New York and Philadelphia).

106 *Id.*

107 *PRA Aug. '22, supra* note 11, at 2.

108 *See supra* note 58 and accompanying text.

109 *See* Kayla Leland Prigid & Shanice Cameron, *Price Transparency in Hospitals—Is Hospital Pricing a Protected Trade Secret?*, JD SUPRA (Sept. 13, 2021), <https://www.jdsupra.com/legalnews/price-transparency-in-hospitals-is-2390227/> [<https://perma.cc/36XR-YH76>] (applying trade secret law from Kansas as an example of a conflict with federal price transparency efforts); Gudiksen et al., *supra* note 89, at 6–10 (presenting trade secret laws; then analyzing the plausibility of a successful trade secret claim as it related to provider charges).

Interoperability Resource (FHIR), are easy to implement and to connect with third-party apps.¹¹⁰ Although CMS does not prohibit providers from streamlining price data through interoperability with APIs directly to consumers, this is deemed insufficient to comply with the Rule. The providers are still required to publish a complete machine-readable file. In light of the benefits and uses of APIs and interoperability to achieve the desired result of the Rule (i.e., allow consumers to price shop), CMS should consider amending the rule to allow alternative means of technical compliance.

b. Increase Enforcement

A July 2021 Executive Order by President Biden aimed to increase competition in health care markets.¹¹¹ This Order prompted CMS to increase the maximum daily penalty for noncompliance from \$300 per day to \$5,500 per day for hospitals with more than 550 beds, with a maximum fine of \$2 million per year.¹¹² So far, only two noncompliant hospitals have been fined: Northside Hospital Atlanta (\$883,180) and Northside Hospital Cherokee (\$214,320).¹¹³ The *Patient Rights Advocate* study found that both hospitals have now posted “exemplary” machine-readable files.¹¹⁴ If CMS wants to stimulate compliance, increasing audits and fining more hospitals could do just that, but this is unlikely to be the most desirable action given agency resource shortages, the failure of the Rule in effectuating its purpose more than eighteen months after the effective date, and the financial and operational struggles that hospitals are experiencing as a result of the recent COVID-19 pandemic.¹¹⁵ But, the effects of price transparency on health care prices are still uncertain, and the potential benefits could plausibly outweigh the drawbacks, especially with the potential for researchers to utilize the data in studies that could influence policy direction. Given that fines seem to

110 See generally *What is FHIR?*, *supra* note 63. The health care app market that connects with FHIR is known as “SMART on FHIR.” A number of apps have been developed and are available through Apple, Microsoft, Google, Epic, and Cerner, among others that perform a variety of services that require interoperability. See, e.g., *Top 5 Groundbreaking SMART on FHIR Apps*, KMS (Apr. 8, 2022), <https://kms-healthcare.com/top-5-smart-on-fhir-apps/> [<https://perma.cc/J7YV-RYU7>] (presenting examples of effective uses of SMART on FHIR apps).

111 See Exec. Order No. 14,036, 86 Fed. Reg. 36,987 (July 14, 2021), <https://www.govinfo.gov/content/pkg/DCPD-202100578/pdf/DCPD-202100578.pdf> [<https://perma.cc/ZFU4-ZEAQ>] (affirming the Biden Administration’s commitment to enforcing antitrust laws in insurance, hospital, and prescription drug markets).

112 45 C.F.R. § 180.90(c) (2021).

113 *PRA Aug. ’22*, *supra* note 11, at 3.

114 *Id.*

115 See *Report: Hospitals Face Worst Year Financially Since Start of COVID-19 Pandemic, Jeopardizing Access to Patient Care*, *supra* note 3 (listing factors including “severe workforce shortages, broken supply chains, the Medicare 2% sequester kicking back in[,] and rapid inflation . . .”).

induce compliance, CMS may consider increasing enforcement as a valid option.

D. Complying with the Price Transparency Rule Provides Little Benefit to Consumers, Stifling the Spirit of the Law

In the inconceivable event that every hospital posted a complete machine-readable file with up-to-date, accurate pricing information, it is still unlikely that consumers would price shop for health care because of its uniqueness as a commodity, low public awareness, and a variety of other reasons.¹¹⁶ One study found that only 9 percent of adults were aware that hospitals were required to publish prices on their website.¹¹⁷ It is possible that awareness would increase if consumers positively benefitted from the price shopping process, but in its current state of near sweeping noncompliance, consumers are highly unlikely to receive any benefit at all. And the machine-readable vector is painstakingly hard for consumers to navigate and does not provide the most desirable levels of price transparency.¹¹⁸

An investigation in California found that the machine-readable requirement prevents the public from adequately price shopping due to the complexity and volume of the data, which makes the consumer-facing file too confusing to organize and comprehend. Spending multiple hours trying to price shop between Kaiser Permanente and Sutter Health, the investigator found that Current Procedural Terminology (CPT) codes for the same procedure were sometimes listed in the spreadsheets multiple times, thousands of rows apart, with entirely different prices.¹¹⁹ From a consumer perspective, the machine-readable price shopping process may even result in adverse physiological effects.¹²⁰ Thus, if the machine-readable requirement is fully complied with, it would likely only benefit patients with a high level of determination and technical competency.

Consider an illustration. Patient A injures their knee in an accident and is immediately rushed to a hospital. At the hospital, a physician orders an MRI and Patient A is eventually diagnosed with a torn ACL. Instead of scheduling surgery with the hospital immediately, Patient A wants to experience the hype of the Price

116 See discussion *supra* Section II.A.

117 Nishi Kurani, Audrey Kearney, Ashley Kirzinger & Cynthia Cox, *Few Adults Are Aware of Hospital Price Transparency Requirements*, PETERSON-KFF HEALTH SYS. TRACKER (June 28, 2021), <https://www.healthsystemtracker.org/brief/few-adults-are-aware-of-hospital-price-transparency-requirements> [<https://perma.cc/GL87-VK7R>].

118 See Bernard J. Wolfson, *Effort to Decipher Hospital Prices Yields Key Finding: Don't Try It at Home*, CAL. HEALTHLINE (July 9, 2021), <https://californiahealthline.org/news/article/effort-to-decipher-hospital-prices-yields-key-finding-dont-try-it-at-home/> [<https://perma.cc/6XNW-YUG3>] (detailing the experience of trying to locate and navigate a machine-readable file, then concluding, “don't try this at home”).

119 *Id.*

120 *Id.* (reporting headaches, eyes “glazing over,” and fatigue).

Transparency Rule and conduct a private search to find the best bargain.

First, Patient A goes through a painstaking trial-and-error process of locating and downloading a provider’s machine-readable file. The file is often more than “two-clicks” away from a homepage, and as the *Wall Street Journal* investigation found, the file is not readily found by simply searching a mainstream search engine.¹²¹

Second, Patient A is confronted with thousands of rows of technical medical jargon accompanied by CPT codes, followed by an overwhelming expanse of dollar-signs, commas, and numbers.¹²² Startled at first, Patient A reasonably tries to conduct a search of the file, entering keyword phrases such as “knee surgery,” “ACL repair,” and “torn ACL,” to no avail. The medical jargon included in these files is incomprehensible to an untrained person.

Deterred but not defeated, Patient A consults a mainstream search engine to narrow down at least one CPT code for an ACL reconstruction. Over the course of their search, however, they discover the intricacies and variations of any particular ACL reconstruction. Assuming that Patient A determines that they want to replace their ACL with a cadaver ligament rather than a patellar tendon, they can pinpoint the corresponding CPT code.

Patient A at last revisits the machine-readable file, successfully conducts a search of the CPT code, and navigates to the provider’s gross charge, only to find that their payer-specific negotiated rate box is left blank or is not up-to-date, falsely misleading Patient A. But even in the highly unlikely chance that the payer-negotiated rate is available, accurate, and updated, Patient A would need to repeat this process of scavenging other machine-readable files from different providers to compare prices.

This extensive process is not likely what CMS envisioned. The intended direct impact of the Price Transparency Rule is to give more economic power to the patient by allowing them the chance to weigh the cost of care into their health care decision-making calculus. Unfortunately, the odds of achieving CMS’s price-shopping vision are incredibly slim. The machine-readable file, while perhaps useful to some researchers, academics, data aggregators, and app-developers, is a price-shoppers’ nightmare.

E. Shifting the Focus of Federal Price Transparency

Price transparency has been an ambitious political goal to combat health care inflation in the 2020s.¹²³ But, the existing empirical research indicates that the

121 See McGinty et al., *supra* note 105.

122 Current Procedural Terminology (CPT) can be understood as a numerical system of health care services.

123 See discussion *supra* Sections I.C, II.C.

current laws may not be effective in lowering overall prices for consumers. Indeed, the large-scale study that examined the market impact of price transparency regulation in twenty-seven states found that hospitals may lower prices of their own volition, but the benefits are unlikely to reach consumers.¹²⁴

However, the benefits of more transparency to researchers and policymakers are hardly deniable. Pricing information from the machine-readable file has already been extracted and analyzed to strengthen existing research on price variation in health care and its potential uses in research go well beyond price variation.¹²⁵ This data could be used to assess the impact of health care mergers on prices in different markets, especially smaller markets where mergers are more likely to have anticompetitive effects. But beyond the research benefits, the Price Transparency Rule in its current form is highly unlikely to fulfill its intended spirit to lower charges through market forces.

As a result, CMS may want to reconsider the current trajectory of the Price Transparency Rule and its decision to continue enforcement in light of potential alternatives. So far, the rollout has resulted in near-sweeping noncompliance, which has hardly improved between February and August of 2022, more than eighteen months after the effective date. And the No Surprises Act gives consumers a more seamless mechanism of obtaining out-of-pocket costs prior to receiving services than the Price Transparency Rule. The Act requires that hospitals provide uninsured consumers with a good faith estimate (GFE) and insured consumers with an Advanced Explanation of Benefits (AEOB) before receiving treatment.¹²⁶ In concept, this requirement provides the same benefit to consumers as the Price Transparency Rule intended, notwithstanding whether the resulting impact on industry prices will be as desired. Furthermore, Health Level Seven International—the American National Standards Institute-accredited standards institute that creates the coding framework for APIs, including FHIR—has created an implementation guide to streamline GFEs and AEOBs to help hospitals achieve this functionality, easing the implementation burden on providers.¹²⁷ In light of this alternative, CMS may consider adjusting its focus from enforcement of the Price Transparency Rule to consumer-promotion and enforcement of the No Surprises Act. In the event a consumer receives a medical bill in excess of their GFE or AEOB, they have dispute resolution rights and

124 See Christensen et al., *supra* note 48, at 2876 (2020) (“[O]ur results suggest that, in response to PTR, providers do lower charges; however, they also decrease discounts such that these charge reductions do not lead to consumer savings.”).

125 See Linde & Egede, *supra* note 28 (studying price variation); see also discussion *supra* Section I.B (describing the uses of data derived from state ACPDs).

126 See Consolidated Appropriations Act of 2021, Pub. L. No. 116-260 §§ 101–118, 134 Stat. 1182, 2758–2890 (2020).

127 *Patient Cost Transparency Implementation Guide*, HL7 INT.—DAVINCI, <https://build.fhir.org/ig/HL7/davinci-pct/> [<https://perma.cc/RP75-W22Q>].

evidence of an upcharge. Consumers can request GFEs and AEOBs from multiple providers and compare them in order to choose a hospital based on cost. This is exactly what the Price Transparency Rule intended on the consumer level.

Price shopping through the mechanisms of the No Surprises Act might benefit some cost-conscious consumers, but making price shopping available on an individual basis would not necessarily provide the broader, systematic benefits to researchers and policymakers as would having hospital standard charges completely public. Although the means of the Price Transparency Rule have been extraordinarily hard to comply with in many circumstances, the theories on the benefits of price transparency are sufficiently plausible for CMS not to abandon this concept altogether. As an alternate form of price transparency, for example, CMS should consider modeling an APCD based on one of the highly-regarded state APCDs discussed in Section I.B.¹²⁸ These reliable APCDs have proven benefits for the state beyond allowing consumers to price shop and can be analyzed to draw on the impacts of health care mergers on price and quality of care, among many other things.¹²⁹

Data have shown that advertising the highest quality APCDs to consumers has increased use, but use has failed to lower costs.¹³⁰ In light of this evidence, perhaps using an APCD model should lead to a more direct solution to controlling health care inflation by implementing, for example, direct price controls. This would be a groundbreaking shift in the way health care has historically been considered in the United States, as a commodity. But even in other countries with direct price control, scholars have demonstrated that directly regulating prices does not eliminate competition per se. Instead of lowering prices, providers rely on other metrics to drive competition, such as quality of care.¹³¹

In any event, there is a growing gap between costs in the public and private sectors, with more than half of U.S. spending on health care coming from private sources.¹³² In the 2019 article, “It’s Still the Prices, Stupid,” authors from the first article concluded that lowering prices in the United States should start with private insurers and self-insured corporations because of this gap.¹³³ This could be an area

128 See discussion *supra* Section I.B.

129 See Murray et al., *supra* note 54 (including a scoring rubric as Appendix “A”).

130 Sunita M. Desai, Sonali Shambhu & Ateev Mehrotra, *Online Advertising Increased New Hampshire Residents’ Use of Provider Price Tool But Not Use of Lower-Price Providers*, 40 HEALTH AFFS. 521 (2021) (noting barriers that may prevent optimal consumer use of price information, including lack of knowledge of benefit plan, lack of incentive, and the uncertainty of price as a factor in selecting health care).

131 Berenson & Murray, *supra* note 4, at 27.

132 See *It’s Still the Prices, Stupid*, *supra* note 2, at 89 (“In 2000 the price differential between what public and private insurers paid was approximately 10 percent. The Medicare Payment Advisory Commission recently estimated that private insurers pay prices that are 50 percent higher than what Medicare pays.”).

133 *Id.*

for CMS to focus on while looking beyond price transparency.

CONCLUSION

The United States spends more than twice as much of its annual GDP on health care than other comparable industrialized countries. In light of increasing health care costs, an aging population and drained clinicians, controlling health care costs is at the top of America's political priorities. Policymakers have turned to price transparency as the solution to controlling health care inflation. But the U.S. health care market, specifically the fragmented-payer market, makes complete and accurate price transparency a fool's errand. The Price Transparency Rule, effective since January 2021, has had substantially underwhelming effects on increasing price transparency and lowering health care prices.

Other mechanisms exist, such as allowing a standards-based API (FHIR) to fulfill the Rule's technical provision or focusing on providing GFEs and AEOBs through the No Surprises Act. But these solutions would likely only benefit individual consumers and lack the desired impact on industry-wide baseline prices.

The potential benefits of systematic price transparency to researchers and policymakers, however, are understated. For example, systematic data can be used to support future policy initiatives, including on topics such as mergers and acquisitions, quality of care initiatives, and price inflation. Future price transparency efforts should include appropriate legal safeguards to counteract potential anticompetitive behavior, such as "tacit collusion" of price inflation. State APCDs have proven to be effective tools by increasing consumer participation in the price shopping process, and have also provided meta data to researchers and policymakers to combat price inflation. The failures of the existing Price Transparency Rule indicate that the Department of Health and Human Services should consider a new approach to price transparency, perhaps using APCDs as a guide.

