WITH REGARD FOR PERSONS

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I
INTRODUCTION

Thorne Auchter was a thirty-five-year-old construction company executive from Jacksonville, Florida, when President Reagan tapped him to become the new head of OSHA in 1981.[1] Plucked from relative obscurity, Auchter came to Washington as part of a vanguard of outsiders who were uniformly hostile to regulation and ready to remake the federal bureaucracy.[2] Like Anne Gorsuch at EPA and James Watt at the U.S. Department of the Interior, Auchter had been active in state politics and eagerly embraced President Reagan's view that government was the problem that ailed the country.[3] In an interview he gave shortly after arriving at OSHA, Auchter laid out his plans for the agency: "Our approach is one of intensive management. I think that's the reason I'm here. In fact, I know that's the reason I'm here. I'm a believer and a creator and an implementer of management systems. I don't feel that rules are a measure of success for an agency."[4]

During his tenure at OSHA, Auchter distinguished himself by pulling dozens of rules, dramatically reducing inspections and enforcement, and getting rid of key staff.[5] In 1981, OSHA even intervened on the side of industry in a case against itself, asking the Supreme Court to remand OSHA's cotton dust standards back to OSHA so that it could redo the rules.[6] The Court declined, but an agency suing

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1. *See* R. Jeffrey Smith, *Reagan Selects New OSHA Director*, 211 SCIENCE 1377, 1404 (1981).

2. *See* Susanna McBee, *When Outsiders Take Over the Bureaucracy*, U.S. NEWS & WORLD RPT. July 13, 1981, at 37 ("As private citizens, they were vocal critics of government policies. Now, as top-ranking bureaucrats under Ronald Reagan, they are handling the very programs they once complained about.").

3. *See* Smith, *supra* note 1, at 1404 (noting that Auchter was active in Florida politics and came to the attention of Reagan administration officials "while serving as director of special events for the state Republican party").

4. R. Jeffrey Smith, *OSHA Shifts Direction on Health Standards*, 212 SCIENCE 1482, 1482 (1981).

5. DAVID NOBLE, LIBERALISM AT WORK: THE RISE AND FALL OF OSHA 193–96 (1986) (detailing the various deregulatory efforts under Auchter).

6. *Id.* at 170 ("In an unusual move, [the Reagan administration] urged the Court to return the [cotton dust] standard to the labor department so that a cost-benefit test could be done."). OSHA

itself is usually a telling sign that times have changed.[7] Auchter's overall goal, as he put it, was to remake OSHA into a friend and partner of the business community as they worked to develop their own strategies of self-regulation and blunt the implementation of onerous health and safety laws.[8]

In his zeal to deregulate, Auchter's embrace of managerialism has sometimes been overlooked. But at the heart of his efforts to transform OSHA was a deliberate and sustained attempt to impose new management systems across the agency. Rules and standards were out. Detailed step-by-step approaches to making decisions were in. Far more than a simple agent of deregulation, Auchter was part of a carrier-class that worked to embed basic practices of regulatory managerialism across the federal bureaucracy.

Although she took a more overtly aggressive approach to slashing budgets and cutting staff, Anne Gorsuch sounded similar themes at EPA.[9] In her reflections on her twenty-two-month tenure at EPA, Gorsuch highlighted lack of managerial capacity as the most important challenge facing EPA: "In my opinion, the single greatest weakness within EPA—and from the very beginning, not just recently—is its lack of solid management skills, from top to bottom."[10] Like Auchter, Gorsuch also developed a series of management systems that she sought to impose across the agency.[11]

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similarly switched sides in a case challenging its workplace standard for lead. *See* Peter Behr, *OSHA Switches Sides in War Over Lead*, WASH. POST (Apr. 18, 1981).

7. *See* Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981) (holding that the feasibility requirement for OSHA workplace standards did not require cost-benefit analysis).

8. *OSHA Proposes Industry Self-Inspections*, CHEM. & ENG. NEWS, Jan. 25, 1982, at 10 (quoting Auchter on his new "voluntary programs" for self-inspections). In true managerialist fashion, Auchter developed special acronyms for OSHA's new self-inspection programs: STAR (Sharing the Accountability for Regulation), PRIME (Positive Results through Intensive Management Efforts), and PRAISE (Positive Results Achieved in Safe Employment). *See also* Noble, *supra* note 5, at 193 (observing that "under Reagan, voluntarism was elevated from a pragmatic response to industry opposition to a philosophy of state action").

9. *See* Joanna Omang, *Internal Rifts, Huge Staff Cut Hint EPA Retreat on Programs*, WASH. POST (Sept. 30, 1981), https://www.washingtonpost.com/archive/politics/1981/09/30/internal-rifts-huge-staff-cut-hint-epa-retreat-on-programs/2481da82-9e8b-48e6-ba3d-fd87a83acbce/ (discussing Gorsuch's efforts to reduce EPA's staffing and budget by thirty percent).

10. *Views from the Former Administrators*, EPA J. (Nov. 1985), https://www.epa.gov/archive/epa/aboutepa/views-former-administrators.html [https://perma.cc/E7CE-LHNB].

11. *Id. See also Environmental Protection Agency Oversight: Hearing Before the S. Comm. on Env't & Pub. Works*, 97th Cong. 13 (Oct. 15, 1981) (statement of Hon. Anne M. Gorsuch, EPA Administrator) (discussing need for new management systems at EPA, including a "new accountability system that will track each Agency senior manager's performance according to predetermined goals and output levels" as "modeled on quality assurance programs used today in the private sector"). Gorsuch elaborated on her approach in her memoir, published in 1986 under her new name Anne Burford. *See* ANNE BURFORD WITH JOHN GREENYA, ARE YOU TOUGH ENOUGH? 122 (1986) (discussing use of budgeting as a tool for management and control of policy, her decision to set up a "mini-OMB" inside EPA, and her development and implementation of a new management system at EPA).

But it was her successor, William Ruckelshaus, who took the managerial agenda to a new level during his second tour as head of EPA.[12] When Ruckelshaus came back to EPA in 1983 after Gorsuch was forced to resign, his top priority was to repair agency morale and restore the public's trust. The main way to do that, he observed, was by changing the way that EPA approached risk.[13] Going forward, Ruckelshaus became an evangelist for quantitative risk assessment at EPA and across the federal government.

As fate would have it, the Supreme Court had already prepared the ground for a much more muscular approach to risk assessment. In a 1980 case on OSHA's benzene standard, the Court ruled that the agency had to make a threshold determination of significant risk before issuing any regulations seeking to control toxics in the workplace.[14] In the wake of the decision, EPA, FDA, and OSHA all embraced formal quantitative risk assessment as the standard approach to understanding and assessing harms from pollution and toxics.[15] Earlier, more precautionary commitments marked by a healthy respect for uncertainty and the desire to find simple, workable approaches to setting standards to protect workers and the public were increasingly viewed as misguided and unrealistic.[16]

Three years after the *Benzene* decision, the National Research Council (NRC) issued its own strong endorsement of quantitative risk assessment in an influential report, *Risk Assessment in the Federal Government: Managing the Process*, providing further support and legitimacy for the new technique.[17] Drawing in part on a concerted campaign by industry groups to advance formal risk assessment, the NRC report called for a strict separation of what it viewed as the technical, largely scientific enterprise of risk assessment from the more value-laden exercise of risk management.[18]

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12. Ruckelshaus had previously served as the first Administrator of EPA under President Nixon and is generally remembered for his role in the so-called Saturday night massacre during the Watergate crisis. *See* Carroll Kilpatrick, *Nixon Forces Firing of Cox; Richardson, Ruckelshaus Quit: President Abolishes Prosecutor's Office; FBI Seals Records*, WASH. POST (Oct. 21, 1973, 2:08 PM) https://www.washingtonpost.com/politics/nixon-forces-firing-of-cox-richardson-ruckelshaus-quit-president-abolishes-prosecutors-office-fbi-seals-records/2012/06/04/gJQAFSR7IV_story.html.

13. *See, e.g.*, William D. Ruckelshaus, *Risk in a Free Society*, 14 ENV'T L. REP. 10190, 10190 (1984) ("When I began my current, and second, tenure as Administrator of EPA, my first goal was the restoration of public confidence in the Agency, and it was impressed upon me that straightening out the way we handled health risk was central to achieving it.").

14. Indus. Union Dep't. v. Am. Petroleum Inst., 448 U.S. 607, 642 (1980) [hereinafter *Benzene*].

15. *See* Richard A. Merrill, *The Red Book in Historical Context*, 9 J. HUM. & ECOLOGICAL RISK ASSESSMENT 1119, 1122 (2003) (concluding that the *Benzene* decision "did not merely legitimate, it effectively mandated the use of risk assessment by regulatory agencies").

16. *See* William Boyd, *Genealogies of Risk*: *Searching for Safety, 1930s-1970s*, 39 ECOLOGY L. Q. 895 (2012) (discussing history of these earlier more precautionary approaches and how they were subsumed by more formal, quantitative approaches to risk).

17. *See* NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter *Red Book*].

18. *See* R.J. Moolenaar, *American Industrial Health Council View of Current Policy Direction in the Federal Establishment*, 3 REGUL. TOXICOLOGY & PHARMACOLOGY 381, 387–88 (1983) (discussing AIHC's views on the importance of separating risk assessment from risk management and the need for

By the early 1980s, then, the Supreme Court, the White House, the science policy establishment, agency heads such as Auchter and Ruckelshaus, and a growing cadre of industry experts and academics all advocated for more formal approaches to risk as a way to improve decision-making and better allocate scarce regulatory resources. By replacing reason and judgment with a stricter rule-governed rationality, these new techniques promised to discipline and constrain the exercise of agency discretion, improve agency performance, and enhance the standing of regulators in the eyes of the public.[19]

The result was a dramatic change in the way that these agencies understood and approached harm. By requiring formal quantitative assessment of the risks posed by individual substances, the new risk assessment paradigm substantially increased the evidentiary requirements needed to show harm. In the process, risk assessment reoriented programs, changed priorities, called forth new tools and techniques from multiple different fields, and opened up agency science and decision-making to engagement with a broad range of external constituencies. All of which worked to hinder responsive, timely, and inclusive health protective regulation. This was partly by design; industry interests pushed for risk assessment precisely because it gave them a tool to stop or at least slow down more precautionary approaches to regulating potential harms and to stifle the ability of agencies to devise creative solutions to the problems they faced. But it was also partly a reflection of the logic of quantitative risk assessment; that is, the presumption that risks could be quantified imposed substantial new analytical demands on the agencies, leading to significant increases in complexity and seemingly interminable disputes over various forms of uncertainty, choice of method, and data.

This article argues that risk assessment has operated as a key technique of managerialism directed at formalizing and constraining agency decision-making. Put another way, risk assessment was first and foremost a political technology intended to discipline agencies, rather than a tool for revealing truths about the world.[20] The premise of the article is that managerialism does much of its work

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thorough risk assessments "covering all scientific data" and subject to "extensive" peer review); Colin N. Park & Ronald D. Snee, *Quantitative Risk Assessment: State-of-the-Art for Carcinogenesis*, 3 FUNDAMENTAL & APPLIED TOXICOLOGY 320, 320 (1983) ("By its very nature, risk assessment is mainly a *scientific* activity whole risk management is principally a *political* activity."). Park and Snee were both affiliated with the AIHC.

19. *See, e.g.*, PAUL ERICKSON ET AL., HOW REASON ALMOST LOST ITS MIND: THE STRANGE CAREER OF COLD WAR RATIONALITY (2013); THEODORE M. PORTER, TRUST IN NUMBERS 8 (1995) ("The appeal of numbers is especially compelling to bureaucratic officials who lack the mandate of a popular election, or divine right. . . . A decision made by numbers (or by explicit rules of some other sort) has at least the appearance of being fair and impersonal.").

20. *Cf.* JULIE E. COHEN, BETWEEN TRUTH AND POWER: THE LEGAL CONSTRUCTION OF INFORMATIONAL CAPITALISM 170 (2016) (observing that "the ascendency of neoliberal managerialism has produced new strategies for disciplining the regulatory state, reshaping its constituent frameworks and processes in ways that align with overarching ideological commitments to privatization, financialization, and informationalized oversight"). For more general discussions of regulatory managerialism, see Julie E. Cohen & Ari Ezra Waldman, *Introduction: Framing Regulatory*

on the front end in the ways that it defines and frames problems for investigation, often under the guise of making them tractable for certain kinds of regulatory interventions. Much of this upstream work, of course, is not transparent or reviewable and not subject to existing forms of public accountability, such as notice-and-comment rulemaking or citizen suits. But it is these upstream knowledge practices that make problems into objects of governance in the first place, setting in motion all manner of calculative practices and simplifications that then get reified in regulatory practice.

Consistent with recent work investigating the relationship between neoliberalism and bureaucracy,[21] this article also illustrates how regulatory managerialism has driven a proliferation of new bureaucratic practices that further constrain and undermine the ability of government to deliver on basic responsibilities. Understanding the mechanisms and techniques by which this has been accomplished and the legacies it has created is critical for any effort to rebuild a more responsive, protective, and empathetic state.

To that end and in keeping with the spirit of this Symposium, this article outlines a series of interventions intended to recenter harm and regard for persons in health, safety, and environmental law. In doing so, the article connects with the Symposium contributions of Hilary Allan, Christie Ford, and Frank Pasquale. Rather than engaging in complex exercises to quantitatively assess risks, the article advocates using simple hazard-based triggers for action that would be provisional and iterative as new evidence develops. Rather than seek to quantify and manage uncertainty, the article emphasizes the use of safety factors as straightforward approaches to building in additional protections to account for uncertainty. And in response to the pervasive lack of knowledge about real-world exposures, cumulative risks, and novel and emerging threats, the article advocates for investment in long-term monitoring and surveillance programs and an emphasis on early warnings. In all cases, the goal is to reorient the knowledge infrastructure that supports health, safety, and environmental regulation toward what matters and to develop a basic commitment to continually assess the totality of the evidence in the light most favorable to public health.

Managerialism as an Object of Study and Strategic Displacement, 86 LAW & CONTEMP. PROBS., no. 3, 2023, at i. *See also* Boyd, *supra* note 16, at 978–81 (discussing the rise of formal approaches to risk and their role in displacing earlier commitments to precaution and endangerment). These arguments regarding the role of risk assessment as a political technology intended to discipline agencies are elaborated further in a forthcoming article, William Boyd, *De-Risking Environmental Law*, 48 HARV. ENVTL L. REV. __ (forthcoming 2024).

21. *See, e.g.*, Peter Fleming, *Hayek Shrugged: Why Bureaucracy Didn't Die Under Neoliberalism but Boomed Instead*, 100 NEW FORMATIONS 114 (2020); DAVID GRAEBER, THE UTOPIA OF RULES: ON TECHNOLOGY, STUPIDITY, AND THE SECRET JOYS OF BUREAUCRACY (2015); Samuel Knafo et al., *The Managerial Lineages of Neoliberalism*, 24 NEW POL. ECON. 235 (2019).

II

RUNNING FROM INFLATION: THE MANAGERIAL TURN IN HEALTH, SAFETY, AND ENVIRONMENTAL LAW

It is impossible to understand the rise of managerialism among administrative agencies such as OSHA and EPA without attending to the pervasive concerns over inflation and economic growth that dominated White House and Executive Branch thinking about regulation during the 1970s and 1980s. Lurching from one crisis to another and with the specter of stagflation looming in the background, Presidents Nixon, Ford, Carter, and Reagan all came to accept or, in Reagan's case, actively embrace the neoliberal critique of regulation as a drag on the economy.[22] Each of them also worked to centralize White House control of agency agendas through more careful attention to cost-effectiveness and balancing of costs and benefits.[23] By the early Reagan administration, regulatory reform had become a near-constant refrain among White House officials seeking to blame someone or something for the state of the economy.[24]

In the process, agency decision-making became a focus of managerial control—a way to discipline and constrain agencies by controlling the ways they produced and used knowledge. These efforts to rationalize decision-making and constrain agency discretion drew upon deep-seated technocratic tendencies that had been maturing for years.[25] Systematic policy planning and budgeting had become standard practice across the federal government, starting in the Johnson Administration.[26] More broadly, a new class of technocrats sought to remake large segments of the federal government to better reflect the latest insights from management science, operations research, and decision theory.

But the rampant inflation and economic crisis of the 1970s gave this all a new urgency, putting a bull's-eye on health and safety regulation as one of the main

22. *See* Noble, *supra* note 5, at 145–75 (discussing the rise and consolidation of White House review programs during the Nixon, Ford, Carter, and Reagan administration focused on the impact of regulation on inflation and economic growth and outlining the extensive interventions by the Council on Wage and Price Stability, OMB, the Regulatory Analysis Review Group and others in various OSHA rulemakings).

23. *See* THOMAS O. MCGARITY, FREEDOM TO HARM: THE LASTING LEGACY OF THE LAISSEZ FAIRE REVIVAL (2013) (discussing regulatory reform initiatives, starting with Carter administration, aimed at rationalizing, slowing, and, in some cases, abandoning the implementation of basic health, safety, and environmental laws).

24. *See, e.g.*, Thomas O. McGarity, *Regulatory Reform in the Reagan Era*, 45 MD. L. REV. 253 (1986).

25. *See, e.g.*, Boyd, *supra* note 16, at 900 (observing that the rise of quantitative risk assessment can be viewed as an element of the more general embrace during the post-World War II period of formal analytic techniques being developed in operations research, decision theory, and systems analysis); Linda Nash, *From Safety to Risk: The Cold War Contexts of American Environmental Policy*, 29 J. POL'Y & HIST. 1 (2017) (discussing this history); ELIZABETH POPP BERMAN, THINKING LIKE AN ECONOMIST: HOW EFFICIENCY REPLACED EQUALITY IN U.S. PUBLIC POLICY (2022).

26. *See* Boyd, *supra* note 16, at 940–41 (discussing "growing influence within the Johnson Administration of planning and management based on systems analysis and operations research"); Berman, *supra* note 25, at 11–12 (discussing spread of systems analysis within the Johnson Administration as a key component of the economic style of reasoning).

obstacles to economic growth.[27] Of all the agencies involved in the rise of social regulation during the 1970s, moreover, OSHA was widely viewed by opponents as the poster child for over-regulation.[28] Ever since Congress passed the Occupational Safety and Health Act in 1970, industry groups mounted a vigorous assault on the agency.[29] Notwithstanding the strong statutory language calling for protections of worker health and safety, the agency found itself on the defensive virtually from its inception.[30] By shifting attention to the larger economy and the impact of health and safety regulation on economic growth, the business community and their allies in government created a strong presumption that worker health and safety, as well as environmental protection, always had to be balanced against society's broader interest in a healthy, prosperous economy.[31]

The consequences of this ideological shift have been significant. Aside from a brief moment during the Carter administration when OSHA made real progress in proposing new regulations and sought to develop creative solutions to the challenges it faced, OSHA has never been able to deliver on its basic statutory responsibilities.[32] EPA has likewise struggled to meet its obligations on toxic chemicals, pollution, and hazardous waste. Although part of this story might

27. *See* Noble, *supra* note 5, at 105 (discussing arguments by industry and business interests "that society's interest in economic growth and capital investment was equal to, if not prior to, its interest in protection").

28. *See* McGarity, *supra* note 23, at 87 (observing that OSHA had become "the poster child of senseless regulation" by the late 1970s). Some of this, as McGarity points out, was self-inflicted. *Id.*

29. Noble, *supra* note 5, at 105 ("Industry began to demand economic relief from health and safety standards as soon as OSHA started regulating.").

30. *Id.* at 2 (describing the Occupational Safety and Health Act "as a remarkable piece of social legislation—radical in scope and vision" that contained strong, nearly universal substantive rights to health and safety for workers but noting that despite this "positive obligation to protect workers from occupational accidents and diseases, administration after administration has balked at taking these rights seriously").

31. This was, of course, a precursor of the fateful jobs versus environment debate that played out in later decades. Charles Noble has argued that the key moment here came with the business community's shift in the mid to late 1970s from "opposition based on the costs of particular standards" to a general call for "economic review of the effects of rules on the macroeconomy." *Id.* at 111. "By shifting attention to the macroeconomy," Noble argued, "this new view undercut the conventional market-failure argument. Viewed from the perspective of the growth of the system as a whole, social regulation imperiled rather than perfected the market system." *Id. See also* Samuel S. Epstein, *Cancer, Inflation, and the Failure to Regulate*, 82 TECH. REV. 48 (1980) ("But industry is now evolving a new set of strategies—as before, to counter and limit regulation of toxic and carcinogenic chemicals—which represent a radical departure from previous policies. Industry is now shifting emphasis from denial of risks to an admission that these risks do exist but must be accepted as part of a trade-off for alleged societal economic benefits.").

32. *Id. See also* DAVID P. MCCAFFREY, OSHA AND THE POLITICS OF HEALTH REGULATION 132–33 (1982) (discussing burst of regulatory activity at OSHA after Eula Bingham was appointed to lead the agency in 1977); David Rosner & Gerald Markowitz, *A Short History of Occupational Safety and Health in the United States*, 110 AM. J. PUB. HEALTH 622, 626–27 (2020) (discussing OSHA's efforts to regulate various toxic substances under Eula Bingham and the ensuing backlash during the Reagan administration); Jim Morris, *How Politics Gutted Workplace Safety*, SLATE (July 7, 2015, 5:45 AM), https://www.slate.com/articles/business/moneybox/2015/07/osha_safety_standards_how_politics_have_undermined_the_agency_s_ability.html (discussing OSHA's challenges since the 1980s to discharge its responsibility to protect American workers from toxic substances)

be seen as a function of what Elizabeth Popp Berman, borrowing from Ian Hacking, calls the economic style of regulation, the focus on cost-benefit analysis and efficiency misses an important part of the story.[33] In fact, the move to adopt more formal approaches to risk at OSHA and EPA that moved into high gear during the early 1980s was central to the managerial agenda and arguably more consequential than cost-benefit analysis because it fundamentally changed the ways these agencies understood the harms that came to provide the key inputs for any future cost-benefit balancing exercises. To fully understand the effects of the managerial turn in health, safety, and environmental law, therefore, we need to investigate the concepts, tools, and practices that were developed and adopted to understand harms, quantify the attendant risks, and make them tractable for health, safety, and environmental regulation. Put another way, we need to focus more carefully on how harms were understood and framed as objects of regulation in the first place and the associated analytical and evidentiary requirements that this entailed—all of which takes us back to OSHA and its struggles during the second half of the 1970s to regulate carcinogens.

III

MAJOR QUESTIONS BEFORE MAJOR QUESTIONS: BENZENE, SIGNIFICANT RISK, AND THE END OF OSHA'S GENERIC CANCER POLICY

When Dr. Eula Bingham was appointed by President Jimmy Carter to be the director of OSHA, one of her first priorities was to break the logjam stifling OSHA's ability to set workplace exposure standards for toxic chemicals, particularly carcinogens.[34] With a background in public and occupational health, Bingham was well aware that workplace exposures to toxic substances were harming American workers and that most of the standards OSHA inherited when the Occupational Safety and Health Act was enacted in 1970 had been developed decades earlier with little or no effort to understand the actual risks they posed.[35] Hundreds of standards for airborne toxics in the workplace needed

33. *See* Berman, *supra* note 25, at 5 (discussing the "economic style" of reasoning and its spread across various domains of policy and regulation starting in the 1960s).

34. *See* McCaffrey, *supra* note 32, at 105–06 (discussing Eula Bingham's background and her eagerness to use the full extent of OSHA's regulatory authority, including the ability to issue emergency temporary standards, to regulate workplace exposures).

35. *See id. See also Occupational Diseases, 1977: Hearings Before the Subcomm. on Lab. of the S. Comm. on Hum. Res.*, 95th Cong. 54 (1977) (statement of Hon. Eula Bingham) ("Diseases suffered by American working men and women as a result of their daily efforts to earn a living represent a tragedy that cannot be measured in monetary terms. The legacy of human suffering that has been a byproduct of our industrial process is one which no just society can tolerate. . . . [W]e in the Occupational Safety and Health Administration believe that this remains a major national problem. Current statistics indicate 100,000 annual deaths from occupational illness in this country. In my opinion, this is a conservative estimate."). As enacted, the Occupational Safety and Health Act provided that existing federal and voluntary consensus-group occupational exposure limits, many of which had been developed by the American Council of Governmental Industrial Hygienists (ACGIH) decades earlier, would be grandfathered in as new federal standards when the Act went into effect in 1971. These included around

to be revised, including dozens involving carcinogens.[36] But after six years of work, the agency had concluded only four rulemakings in the health area.[37] Proceeding chemical-by-chemical, OSHA noted, was simply not feasible and would leave American workers grossly unprotected.[38]

Under Bingham's leadership, OSHA proposed a creative solution that promised to work through the backlog expeditiously and deliver on the agency's statutory mandate to adopt and enforce standards that would protect workers from carcinogens to the maximum extent allowed under the statute.[39] In 1977, OSHA formally proposed a new generic rule that established a broad framework for regulating carcinogens built on simple hazard-based triggers for action.[40] In

400 exposure limits for toxic substances, which were generally recognized to be inadequate and in need of revision. *See* Boyd, *supra* note 16, at 925–27 (describing work of ACGIH in developing threshold limit values for toxics in the workplace during the 1940s and 1950s); *Performance of the Occupational Safety and Health Administration: Hearings Before H. Comm. on Gov't Operations*, 95th Cong. 25–26 (1977) (statement of Gregory J. Ahart, Director, Human Resources Division, General Accounting Office) (describing the process of incorporating existing exposure limits into the Occupational Safety and Health Act and emphasizing the need for revision of these exposure limits for toxic substances).

36. *Performance of the Occupational Safety and Health Administration: Hearings Before H. Comm. on Gov't Operations*, 95th Cong. 24 (1977) (statement of Gregory J. Ahart, Director, Human Resources Division, General Accounting Office) (noting that "workers are exposed to thousands of toxic substances, hundreds of which may cause cancer").

37. *See* Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. 54148, 54149 (Oct. 4, 1977) (noting four completed rulemakings on health standards in OSHA's six-year history). In 1973, OSHA had issued emergency temporary standards for fourteen carcinogens, which after a remand from the Third Circuit, it reissued as permanent standards in 1974. *See* Emergency Temporary Standard on Certain Carcinogens, 38 Fed. Reg. 10929 (May 3, 1973) (issuing temporary standards); Dry Color Mfrs. Ass'n v. Dep't of Lab., 486 F.2d 98, 107 (3rd Cir. 1973) (vacating and remanding emergency temporary standards); Carcinogens, 39 Fed. Reg. 3756 (Jan. 29, 1974) (order issuing permanent standards); Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1161 (3rd Cir. 1974) (upholding standards). *See also Performance of the Occupational Safety and Health Administration: Hearings Before H. Comm. on Gov't Operations*, 95th Cong. 24–25 (1977) (statement of Gregory J. Ahart, Director, Human Resources Division, General Accounting Office) ("Although workers are exposed to thousands of toxic substances, hundreds of which may cause cancer, standards had been promulgated under the 1970 act for only 15 substances as of September 30, 1976. Unless the rate improves, it will take more than a century to establish needed standards for substances already identified as hazards. The problem is compounded because new substances, which may warrant standards, are being introduced faster than standards are being established on existing substances. Thus, the bleak occupational safety and health conditions which the Congress sought to improve still exist and may be getting worse.").

38. Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. at 54154 ("It is OSHA's belief that . . . with present resources the output of standards to protect American workers from carcinogens will never be adequate and may collapse by means of the futility of the effort. Indeed, to follow the present system and procedure for each and every individual substance and hazard would be, we contend, beyond the abilities of any agency, no matter how large a staff it may have."). *See also* Bingham, *supra* note 35, at 56 ("OSHA . . . is well aware that a substance-by-substance approach to regulation of health hazards will not be sufficient to meet the magnitude of the occupational disease problem. We are exploring the possibility of promulgating generic standards applicable to classes of chemicals, to carcinogens and to certain work practices.").

39. *See* McCaffrey, *supra* note 32, at 125–31 (discussing OSHA's generic policy for carcinogens which had been drafted under Morton Corn but was first proposed in 1977 under Eula Bingham).

40. Identification, Classification, and Regulation of Toxic Substances Posing a Potential

essence, this generic cancer policy provided that if there was evidence that the substance at issue caused cancer in animals or humans, OSHA would automatically issue emergency temporary standards, followed by permanent standards requiring employers to reduce the permissible exposure limit to the lowest feasible level.[41] The new approach promised to expedite workplace standard-setting for a large and growing class of dangerous chemicals. As Secretary of Labor Ray Marshall observed when releasing the proposed rule, "[t]rying to control carcinogenic substances on a case-by-case basis is like trying to put out a forest fire one tree at a time."[42]

The proposal sent shockwaves through the business community, reinforcing the widely held view that OSHA posed a significant threat to business interests in an already shaky macroeconomic environment. Within months, several major industry trade associations had formed a new umbrella group, the American Industrial Health Council (AIHC), to lobby against OSHA's approach to carcinogens.[43] According to the AIHC, full implementation of OSHA's new

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Occupational Carcinogenic Risk, 42 Fed. Reg. at 54148. *See also* Thomas O. McGarity, *OSHA's Generic Carcinogen Policy: Rule Making Under Scientific and Legal Uncertainty, in* LAW AND SCIENCE IN COLLABORATION 56–61 (J.D. Nyhart & Milton M. Carrow eds., 1983) (discussing the origins of OSHA's generic cancer policy, including the role of Anson Keller, who moved to OSHA from EPA where he had been associate general counsel for pesticides during the various pesticide cancellation hearings in the early 1970s). John M. Mendeloff characterized OSHA's generic cancer policy "as probably the most massive rule-making procedure that has taken place in the health and safety field. Scores of cancer authorities wrote treatises on the issues it raised, piling up a printed record of a quarter of a million pages." *See* JOHN M. MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCE REGULATION: HOW OVERREGULATION CAUSES UNDERREGULATION 127 (1988).

41. Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. at 54168. As originally proposed, the cancer policy established two categories for carcinogens. Category I included chemicals that induced tumors in humans or in a single mammalian species with concordant evidence. Category II included chemicals for which the evidence was only "suggestive." Category I chemicals would be subject automatically to an emergency temporary standard and then a final permissible exposure limit (PEL) set at the lowest feasible level. Category II chemicals would be regulated as "appropriate and consistent with the statutory requirements." In essence, a single well-conducted bioassay that found positive results of tumor initiation or growth would be enough to trigger category I requirements. *See* Mendeloff, *supra* note 40, at 128–29.

42. Quoted in Helen Dewar, *U.S. Details Plan to Control Worker Exposure to Carcinogens*, WASH. POST (Oct. 4, 1977) https://www.washingtonpost.com/archive/politics/1977/10/04/us-details-plan-to-control-worker-exposure-to-carcinogens/636c0034-65e4-40cf-a9d6-293a55589242/. Secretary Marshall continued: "Instead, we are proposing a systematic way of determining which toxic substances require emergency attention by OSHA . . . [that] will allow us to respond to threats to worker health with much greater speed and efficiency." *Id.*

43. The American Industrial Health Council (AIHC) was established in 1977 as a broad multi-industry organization to oppose OSHA's proposed generic cancer policy. Membership in the AIHC grew rapidly, from eight companies in 1977 to 138 companies and 81 affiliated associations by 1982, including all of the major chemical and petrochemical companies. One of the main objectives of the AIHC was to push for quantitative risk assessment of individual chemicals as the basis for regulations. *See The American Industrial Health Council*, BAKER LIBRARY SPECIAL COLLECTIONS, Harv. Bus. School Retired Case Collection, Box/Volume Folder: 383-047, at 7–8 (discussing AIHC's advocacy of risk assessment as a separate, scientific exercise). *See also* Joseph V. Rodricks, *When Risk Assessment Came to Washington: A Look Back*, 17 DOSE-RESPONSE: INT'L J. 1, 6 (2019) ("Perhaps the most important voice for industry during this time was that of the American Industrial Health Council (AIHC), a group

cancer policy would impose capital costs as high as eighty-eight billion dollars and annual compliance costs of up to thirty-six billion dollars, all of which would increase inflation by one percent.[44] The White House Regulatory Analysis Review Group indicated in its review that the cancer policy could involve regulation of close to two thousand substances at an annual cost of twenty billion dollars.[45]

As Industry groups mobilized to challenge the generic cancer policy, OSHA pushed ahead with a new standard for benzene that it had been developing in parallel and which would ultimately become a referendum on the proposed generic cancer policy.[46] Benzene was a known human carcinogen and had become one of the most widely used industrial chemicals in the American economy, with an annual production volume of some eleven billion pounds by the mid-1970s.[47] Closely associated with the vast petroleum refining and petrochemical industries

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founded in 1977 by several major trade associations, to deal with OSHA's developing cancer policy."); Mendeloff, *supra* note 40, at 127 ("The [generic cancer policy] spawned a new organization: The American Industrial Health Council (AIHC) was formed by the chemical industry to build a broader critique of OSHA's regulatory strategy."). In 1978, AIHC submitted a 143-page document detailing its criticisms and alternatives to OSHA's generic cancer policy. *See* Am. Indus. Health Council, *AIHC Recommended Alternatives to OSHA's Generic Carcinogen Proposa*l, OSHA Docket No. H-090 (Feb. 24, 1978) (available in the UCSF Chemical Industry Documents database at https://www.industrydocuments.ucsf.edu/chemical/ [https://perma.cc/9FSL-YBEW]).

44. *See* The Bureau of Nat'l Affs., Inc., *OSHA Policy Could Cost $88 Billion, Raise Inflation Rate, AIHC Estimates,* 1 CHEM. REG. REP. 2020, 2021 (1978). *See also* McCaffrey, *supra* note 32, at 128 (discussing AIHC economic impact study on OSHA generic cancer policy).

45. Mendeloff, *supra* note 40, at 132.

46. The new benzene standard was actually proposed several months before the generic cancer policy was released. *See* Occupational Exposure to Benzene, 43 Fed. Reg. 5918 (Feb. 10, 1978) (recounting development of benzene rule). *See also* McCaffrey, *supra* note 32, at 106–08 (discussing development of benzene rule); Mendeloff, *supra* note 40, at 122 (noting that upon taking office Bingham was eager to move forward with an emergency temporary standard for benzene). Based on an interview with OSHA's Health Standards Director Grover Wrenn, Mendeloff states that Bingham was keen to pursue the emergency temporary standard approach rather than going with a proposed permanent standard and "persuaded organized labor to prod the head of NIOSH to write her a formal letter reporting the preliminary results of a study his agency was sponsoring" so that she would have new evidence to issues the emergency standard. *Id.* at 122.

47. *See* Occupational Exposure to Benzene, 43 Fed. Reg. at 5918. A colorless liquid that evaporated rapidly under normal conditions, benzene was used in the manufacture of rubber tires, motor fuels, chemical feedstocks, solvents, detergents, pesticides, and other organic chemicals. *Id.* Researchers began documenting acute and chronic health effects associated with exposure to benzene (or benzol as it was also known) in the late nineteenth and early twentieth centuries. *See, e.g.*, ALICE HAMILTON, INDUSTRIAL POISONS IN THE UNITED STATES 457–81 (1925) (discussing literature on benzene toxicity). By the early 1940s, the association of chronic benzene exposure with various blood disorders and, most notably, myeloid leukemia, raised concerns among occupational health experts. Leading cancer researcher Wilhelm Hueper concluded in 1942 that "[t]he combined clinical and experimental evidence . . . concerning the causative interrelations between occupational exposure to benzol and the development of leukemia, seems to indicate that such a connection is not a mere possibility but a great probability, and even an actuality." WILHELM C. HUEPER, OCCUPATIONAL TUMORS AND ALLIED DISEASES 598 (1942). In response, Hueper urged the "complete elimination of benzol fumes from the atmosphere of the working environment." *Id.* at 599. In 1976, the National Institute of Occupational Health (NIOSH) concluded that benzene was a leukemogen with no safe exposure level and recommended that OSHA adopt an emergency standard of 1 ppm. Occupational Exposure to Benzene, 43 Fed. Reg. at 5919.

in the United States, benzene exposure likely affected more than 600,000 American workers during this time.[48] Likewise, much of the general population also experienced low-level exposure, largely through vapors associated with gasoline.[49]

Following the approach that it would soon formalize in its generic cancer policy, OSHA promulgated an emergency standard of one part per million (ppm) for benzene exposure in May 1977, followed by a final permanent standard at the same level the following year.[50] Because the "[e]vidence in the record clearly demonstrates that benzene is a human leukemogen"[51]—a conclusion that industry did not dispute[52]—OSHA assumed that no safe exposure level could be determined and that, accordingly, the exposure limit should be set at the lowest technologically feasible level that would not impair the viability of the industry in question.[53] "Once the carcinogenicity of a substance has been established qualitatively," OSHA concluded, "any exposure must be considered to be attended by risk when considering any given population."[54] And even though the precise manner in which benzene caused leukemia and other blood disorders was a question "on the frontier of scientific and medical knowledge," OSHA could not "wait for answers" while workers were being exposed to this "life-threatening substance."[55] "Given the inability to demonstrate a threshold or establish a safe level," OSHA found that it was "appropriate to prescribe that the permissible exposure to benzene be reduced to the lowest feasible level."[56]

OSHA's embrace of a more precautionary approach in the face of uncertainty reflected a deliberate effort to protect workers from occupational exposures to substances such as benzene. Precise quantification of the harms associated with such exposures was considered impossible.[57] The fact that benzene was a known carcinogen that was impacting a large number of American workers was enough to trigger protective action. And moving quickly was essential to ensure that workers received the protections they were promised under the statute.

Industry groups, led by the American Petroleum Institute, immediately challenged the new standard, and two years later, a divided Supreme Court

48. *See* Occupational Exposure to Benzene, 43 Fed. Reg. at 5918.

49. *Id.*

50. *Id.*

51. *Id.* at 5925. *See also id.* at 5931 ("The evidence in the record conclusively establishes that benzene is a human carcinogen.").

52. *Id.* at 5931 ("Industry participants in the rulemaking did not, for the most part, challenge benzene's leukemogenicity.").

53. *Id.* at 5932.

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.* at 5940 ("While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number may be appreciable . . . . In light of the uncertainties in this area of scientific knowledge, OSHA believes that it is required by prudence and by its statutory mandate to adopt a highly protective posture in considering the evidence for health benefits.").

affirmed a Fifth Circuit decision invalidating the regulation.[58] Writing for the plurality, Justice Stevens concluded that the Occupational Safety and Health Act required OSHA to make a threshold finding of "significant risk" *before* proceeding with any such standard.[59] Referring to OSHA's benzene standard as "an expensive way of providing some additional protection for a relatively small number of employees,"[60] Justice Stevens found that, despite OSHA's own conclusion that it could not quantify the benefits of the new standard, "it appears . . . that those benefits may be relatively small."[61] In a searching review of the administrative record, the plurality found the evidence of adverse non-cancer effects at exposure levels of ten ppm to be "sketchy at best" and the evidence of an increased risk of leukemia from benzene exposure at or below ten ppm to be "even sketchier."[62]

Several other Justices weighed in with concurring opinions that explicitly linked the Supreme Court's decision to the broader agenda of regulatory reform. Chief Justice Burger, for example, concluded that "[w]hen the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant and comprehensive regulation. Perfect safety is a chimera, regulation must not strangle human activity in the search for the impossible."[63] Justice Powell likewise spoke of the imperatives of a "rational system of regulation" and would have required OSHA to perform a cost-benefit analysis even if it found a significant risk.[64] And Justice Rehnquist warned of the dangers of unconstitutional delegation of legislative authority, urging the Supreme Court to declare certain provisions of the statute invalid.[65] All of these themes would resurface in later years as formal approaches to risk assessment became a standard part of the broader regulatory reform agenda and as more strident anti-administrative tendencies gained strength in conservative legal circles.[66]

Despite the plurality's statements that the determination of significant risk did not have to proceed in any particular manner—"the requirement that a

58. Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 628 (1980).

59. *Id.* at 614–15. *See also id*. at 641 (concluding that "both the language and structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of significant risks of harm").

60. *Id.* at 628.

61. *Id.* at 630.

62. *Id.* at 631, 633.

63. *Id.* at 664.

64. *Id*. at 670. Powell was, of course, the author of a famous 1971 confidential memo to the U.S. Chamber of Commerce that canvassed various dimensions of the "attack" on the "American free enterprise system" and urged the business community to take action. Memorandum from J. Lewis F. Powell, Jr. to Eugene B. Sydnor, Jr., Chair, Educ. Comm., U.S. Chamber of Com., *Attack on American Free Enterprise System* (Aug. 23, 1971) (available at https://scholarlycommons.law.wlu.edu/powellmemo/1 [https://perma.cc/4NJB-6MUN]).

65. 448 U.S. at 628, 671–72.

66. *See, e.g.*, Gillian E. Metzger, *Foreward: 1930s Redux: The Administrative State Under Siege*, 131 HARV. L. REV. 1 (2017); Blake Emerson, *Administrative Answers to "Major Questions": A Progressive Theory of Agency Statutory Interpretation*, 102 U. MINN. L. R. 2019 (2018).

'significant' risk be identified is not a mathematical straightjacket"[67]—most observers, including those in the agencies, took the case to require some form of quantitative risk assessment in order to justify regulation.[68] In this respect, as Professor Thomas McGarity has observed, the *Benzene* decision represented an important "inflection point" in the development of U.S. environmental law—a corrective in the eyes of regulatory reform advocates seeking to constrain and discipline agency decision-making after a decade of overreach.[69] By endowing quantitative risk assessment with a legitimacy that it had not previously enjoyed, the *Benzene* decision unleashed efforts across the different agencies to formalize risk assessment as a key element of health, safety, and environmental decision-making.

At OSHA, Thorne Auchter enthusiastically embraced quantitative risk assessment as part of a broader framework that would govern major standard setting efforts.[70] And while OSHA did not formally withdraw the generic cancer policy until 1983, the overall goal of moving quickly to regulate workplace carcinogens based on simple hazard-based triggers was clearly no longer viable.[71]

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67. 448 U.S. at 655 ("Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe'.").

68. *See* Merrill, *supra* note 15, at 1122 (concluding that the *Benzene* decision "did not merely legitimate, it effectively mandated the use of risk assessment by regulatory agencies"); MENDELOFF, *supra* note 40, at 251 ("The Supreme Court's benzene decision mandated some form of quantitative risk assessment.").

69. Thomas O. McGarity, *The Story of the Benzene Case: Judicially Imposed Regulatory Reform Through Risk Assessment*, *in* ENVIRONMENTAL LAW STORIES 141, 144 (R. J. Lazarus & O. A. Houck eds., New York: Foundation Press 2005); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 283 (1991) ("The *Benzene* case was a turning point. OSHA had rejected quantitative risk assessment in favor of a Generic Cancer Policy, but the Supreme Court rejected the generic policy and required OSHA to make a threshold finding in each case that the risk posed by preregulation conditions was 'significant.' Despite the Court's protestations to the contrary, OSHA drew the natural inference from the plurality opinion that the agency must quantify the risk before it can determine its significance.").

70. In the wake of the Supreme Court's *Benzene* and *Cotton Dust* decisions, and in keeping with his broader managerialist agenda, Auchter adopted a four-step process for new health and safety standards: (1) quantitative risk assessment to determine if there was a significant risk; (2) evaluation of whether the proposed standard would lessen that risk; (3) analysis of the economic impact of the proposed standard on the affected industries; and (4) a determination of the least costly way of attaining the needed standard. *See* Thorne G. Auchter, *OSHA: A Year Later*, 33 LAB. L. J. 195, 199 (1982) (discussing new "integrated management system" that included four-step process for setting worker health standards). As Auchter concluded, "[w]e are convinced that this [four-step] process is the key to rational, objective regulation." *Id*. *See also* Occupational Exposure to Benzene, 52 Fed. Reg. 34460, 34490 (Sept. 11, 1987) (discussing use of quantitative risk assessment in rulemakings for benzene, arsenic, ethylene dibromide, ethylene oxide, and asbestos).

71. OSHA issued its final generic cancer policy in January 1980, after making several modifications based on the sustained criticisms it received on the original proposal from industry groups such as the AIHC as well as pressure from the White House. *See* Identification, Classification, and Regulation of Potential Occupational Carcinogens, 45 Fed. Reg. 5001 (1980). In an effort to secure a favorable venue to challenge the rule, both the AIHC and the API immediately filed petitions in a Texas district court and in the 5th Circuit. *See* Am. Indus. Health Council v. Marshall, 494 F.Supp. 941 (S.D. Tex. 1980) (recounting the history of these petitions challenging OSHA's rule). In 1981, OSHA modified the generic

For their part, FDA and EPA also took careful note of the decision and began to frame their efforts in terms of "significant" risk, making detailed quantitative assessments a regular part of their decision-making.[72]

By making the notion of significant risk a threshold requirement for regulation and by denying OSHA the ability to regulate quickly, the *Benzene* decision also reflected the triumph of industry interests, represented in the case by the American Petroleum Institute, but drawing on years of work by the AIHC and its member companies to fight OSHA's generic cancer policy.[73] Going forward, workers would bear the burden of uncertainty, as Justice Marshall noted in dissent.[74] Indeed, after the decision, OSHA spent the better part of a decade gathering additional evidence and evaluating quantitative risk assessments for benzene, coming back with the same proposed one ppm standard in 1987 that it had first proposed ten years earlier.[75] This time, however, industry did not even contest the proposed standard.[76] In the interim, as a result of the higher standard that was allowed to stay in place, the best estimates suggest that some 300 workers suffered benzene exposures that ultimately led to cancer and death.[77]

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cancer policy to reflect the holding of the *Benzene* decision, which effectively gutted the original policy. *See* Identification, Classification and Regulation of Potential Occupational Carcinogens; Conforming Deletions, 46 Fed. Reg. 4889 (Jan. 19, 1981). In 1983, OSHA stayed what was left of the policy. *See* Identification, Classification and Regulation of Potential Occupational Carcinogens; Partial Stay, 48 Fed. Reg. 241 (Jan. 4, 1983).

72. *See* Joseph V. Rodricks et al., *Significant Risk Decisions in Federal Regulatory Agencies*, 7 REGUL. TOXICOLOGY & PHARMACOLOGY 307 (1987) (discussing efforts by FDA, EPA, and OSHA to define "significant" risk thresholds in their efforts to regulate carcinogens).

73. *See* Rodricks, *supra* note 43, at 6 ("Perhaps the most important voice for industry during this time was that of the American Industrial Health Council (AIHC), a group founded in 1977 by several major trade associations, to deal with OSHA's developing cancer policy.").

74. Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 690 (1980) (Marshall, J., dissenting) (charging that the plurality was imposing "the burden of medical uncertainty squarely on the shoulders of the American worker, the intended beneficiary of the Occupational Safety and Health Act").

75. *See* Occupational Exposure to Benzene, 52 Fed. Reg. 34460, 34460 (Sept. 11, 1987) (revising existing permissible exposure limit for benzene from 10 parts per million to 1 part per million). *See also id.* at 34460–64 (summarizing results of multiple additional epidemiological studies, animal studies, and quantitative risk assessments, including at least one sponsored by the Chemical Manufacturers Association, all of which clearly demonstrated an increased risk of cancer and other diseases and toxic effects at the prevailing 10ppm standard and provided a firm basis for concluding that the risk was significant and that the standard should be strengthened).

76. *Id*. at 34463 ("No major party challenged OSHA's decision to reduce exposures from 10 ppm.").

77. Using OSHA's final quantitative risk assessment for benzene and data on exposed workers in the five major industry sectors affected by the standard, one study found that as a result of the delay in promulgating the final benzene standard U.S. workers would suffer an extra 198 deaths from leukemia and 77 extra deaths from multiple myeloma. *See* Peter F. Infante & Mario V. DiStasio, *Occupational Benzene Exposure: Preventable Deaths*, 331 LANCET 1399, 1399 (1988) (reporting estimates of excess deaths); Peter F. Infante, *Benzene: A Historical Perspective on the American and European Occupational Setting, in* LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896-2000, at 41 (Poul Harremoës et al., eds. 2001). These estimates did not include excess deaths from other blood disorders or non-Hodgkins lymphomas. *See also* William J. Nicholson & Philip J. Landrigan, *Quantitative Assessment of Lives Lost Due to Delay in the Regulation of Occupational Exposure to Benzene*, 82 ENV'T HEALTH PERSPS. 185, 187 (1989) (reviewing various risk assessments for benzene and finding that the range of excess leukemia deaths alone—not including deaths from multiple myeloma, lymphoma, and

Benzene was thus much more than an effort by the Supreme Court to bring a wayward agency into the mainstream of regulatory thought.[78] Viewed in historical perspective, it marked a dramatic departure from prior approaches to uncertainty and the concomitant embrace of precautionary regulation by EPA, FDA, OSHA, the DC Circuit, and other appellate courts in their efforts to develop a normative framework for health, safety, and environmental regulation.[79] It also seemed to go well beyond the hard look review that Judges Leventhal and Bazelon had been debating in the 1970s—signaling a new, more searching form of judicial scrutiny of environmental regulation and agency discretion generally.[80] As Jerry Mashaw observed in 1988, the decision imposed "an almost unbearable burden of proof" on agencies seeking to regulate toxic substances.[81]

Benzene is also important in the current moment. Although it predates *Chevron*,[82] the *Benzene* decision articulated a proto version of the so-called major questions doctrine and can be seen as an important precursor of the current Supreme Court's anti-administrative jurisprudence.[83] Despite multiple opinions

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other cancers—resulting from the delay in implementing the 1ppm standard included 30 to 150 premature leukemia deaths on the low end to 80 to 1000 or more on the high end).

78. *Cf.* McGarity, *supra* note 69, at 165 ("The *Benzene* plurality opinion can be viewed as a politic attempt by well-meaning judges to steer an obstreperous agency gently into what they believed to be the mainstream of regulatory thought. The bipartisan 'regulatory reform' movement that was enveloping Washington, D.C. in the late 1970s could hardly have escaped the attention of the Justices.").

79. *See* Boyd, *supra* note 16, at 954–63 (discussing these efforts).

80. *Cf.* Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 695–96 (1980) (Marshall, J., dissenting). As Justice Marshall stated:

> I see no basis . . . for the approach taken by the plurality today, which amounts to nearly *de novo* review of questions of fact and of regulatory policy on behalf of institutions that are by no means unable to protect themselves in the political process. Such review is especially inappropriate when the factual questions at issue are ones about which the Court cannot reasonably be expected to have expertise.

Id. at 695 n. 9.

81. *See* Jerry L. Mashaw, *Mendeloff's The Dilemma of Toxic Substance Regulation: How Overregulation Causes Underregulation*, 19 RAND J. ECONOMICS 489, 490 (1988). Mashaw's elaboration on this point is worth quoting at length:

> In the context of the uncertainties surrounding the effects of benzene, and many other potentially carcinogenic substances, . . . the requirement that the agency demonstrate a "significant risk" saddles the agency with an almost unbearable burden of proof. If the agency must be able to draw a dose-response curve and justify the shape and location of the curve by substantial evidence in the record, it will often be unable to regulate. Equally important, it will in every case be a sitting duck for objections to the epidemiological and laboratory evidence that forms the predicate for its determination of hazardousness.

Id.

82. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

83. *See* 448 U.S. at 645 ("In the absence of a clear mandate in the Act, it is unreasonable to assume that Congress intended to give the Secretary the unprecedented power over American industry that would result from the Government's view of Section 3(8) and 6(b)(5) coupled with OSHA's cancer policy."). *See also* Emerson, *supra* note 66, at 2044 ("The Benzene Case provides the clearest precedent for the major questions doctrine, and links it definitively to the nondelegation doctrine."); Utility Air

producing only a plurality for the key holding, *Benzene* signaled a new, more activist effort to constrain the ability of regulatory agencies to craft workable approaches to pressing problems within their broad statutory mandates.[84] In the words of then Professor Antonin Scalia, "the most noteworthy feature of the benzene decision [was] its application of judicial activism in a new direction—to reduce, rather than augment, health and safety regulatory impositions upon the private sector."[85] Given the enthusiasm among the current Supreme Court's conservative majority for the major questions doctrine as a way to limit agency action, an enthusiasm very much on display in the recent OSHA vaccine mandate case[86] and *West Virginia v. EPA*,[87] *Benzene* can thus be read as a forerunner of conservative efforts to use the federal courts to diminish the regulatory state.

From the perspective of regulatory managerialism, *Benzene* reflected a confluence of judicial skepticism, even hostility, to creative problem solving by agencies and the gathering forces of managerialism that were taking shape within regulatory policy that aimed at formalizing and disciplining agency decision-making. Instead of simply pointing to the absence of clear direction from Congress as a basis for invalidating OSHA's effort to use a simple hazard-based trigger to regulate carcinogens, the plurality went further and substituted its own new threshold requirement of significant risk on the grounds that this was surely what Congress must have intended. That this came to be seen as mandating quantitative risk assessment is somewhat puzzling, given that the plurality made some effort to signal that they were not requiring precise quantification—that the significant risk requirement was "not a mathematical straitjacket."[88] In this respect, the *Benzene* decision worked to validate and reinforce managerialist tendencies that were already in motion across the government. More fundamentally, by redefining hazards and dangers as risks, *Benzene* underwrote

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Regul. Grp. v. Env't Prot. Agency, 573 U.S. 302, 324 (2014) ("We expect Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.") (quoting Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 160 (2000)); Lisa Heinzerling, *The Power Canon*s, 58 WM. MARY L. REV. 1933, 1974–75 (2017) (discussing Justice Scalia's UARG decision and its invocation of *Benzene* as a "tiny hint at a constitutional link" for the major questions canon).

84. *See, e.g.*, Antonin Scalia, *A Note on the Benzene Case,* 4 REGUL. 25, 26 (1980) ("The plurality opinion is an 'activist' opinion, in that it does not give OSHA the benefit of the doubt on the interpretation of either the statute or the agency's findings."). Scalia, of course, was the principal author of the so-called major questions doctrine.

85. *Id.* at 27.

86. *See, e.g.*, Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., 595 U.S. __, 6 (2022) (Gorsuch, J., concurring) (observing that the major questions and non-delegation doctrines "[b]oth serve to prevent 'government by bureaucracy supplanting government by the people'") (quoting Scalia, *supra* note 84, at 27).

87. *See* West Virginia v. EPA, 597 U.S. __, 7(2022) (Gorsuch, J., concurring) ("With the explosive growth of the administrative state since 1970, the major questions doctrine took on special importance. In 1980, this Court held it 'unreasonable to assume' that Congress gave an agency 'unprecedented power[s]' in the 'absence of a clear [legislative] mandate.'") (quoting Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 645 (1980)).

88. Indus. Union Dep't. v. Am. Petroleum Inst., 448 U.S. 607, 655 (1980).

a new way of thinking about harm that has had profound implications for the protection of public health and the environment.

IV

QUANTITATIVE RISK ASSESSMENT AND REGULATORY MANAGERIALISM

Three years after the *Benzene* decision, the NRC gave formal risk assessment another major boost in its landmark report, *Risk Assessment in the Federal Government: Managing the Process*, which elaborated the basic conceptual architecture of risk assessment and, in the process, provided a blueprint for overhauling and formalizing health, safety, and environmental decision-making across the government.[89] Known informally as the *Red Book*—because of its red cover—the study was launched in response to lobbying by the AIHC and others seeking to consolidate and extend their victory in the *Benzene* decision.[90] The stated goal of the *Red Book* was to "strengthen the reliability and objectivity of scientific assessment that forms the basis for federal regulatory policies applicable to carcinogens and other public health hazards" and to ensure that "government regulation rests on the best available scientific knowledge."[91]

Reflecting its mandate "to examine whether altered *institutional arrangements or procedures* can improve regulatory performance," the report distinguished risk assessment from risk management—a distinction that has come to enjoy canonical status in standard approaches to risk ever since.[92] According to the report, risk assessment constituted "the use of the factual base to define the health effects of exposure to hazardous materials and situations," and was comprised of four steps: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization.[93] Risk management, by contrast, was defined as "the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision."[94] Although the report acknowledged the important role that policy choices played in various components of risk assessment, it sought to insulate and

89. *See generally Red Book*, *supra* note 17 (elaborating the basic conceptual architecture of risk assessment). The report was prepared by the NRC's Committee on the Institutional Means for Assessment of Risks to Public Health pursuant to a contract with the Food and Drug Association under authorization from Congress. This was the first of several National Academy reports reviewing the practice of risk assessment and proposing reforms. The most recent comprehensive report was released in 2009. *See* NAT'L RSCH. COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT (2009).

90. *See, e.g.*, Soraya Boudia, *Managing Scientific and Political Uncertainty: Environmental Risk Assessment in Historical Perspective, in* POWERLESS SCIENCE? SCIENCE AND POLITICS IN A TOXIC WORLD 103–07 (Soraya Boudia & Nathalie Jas eds., 2014) (discussing role of AIHC in laying the groundwork for the NRC's *Red Book* and in pushing the science policy establishment to endorse more formal approaches to risk in regulatory policy).

91. *Red Book*, *supra* note 17, at iii, 1.

92. *Id.* at 3.

93. *Id.* at 3, 7.

94. *Id.* at 3.

protect what it conceived as the more technical and scientific exercise of risk assessment from the broader social and economic policy discussions that inevitably affected risk management.[95]

The NRC framework was quickly adopted by EPA under the leadership of William Ruckelshaus, who, as noted above, had just returned to EPA after Anne Gorsuch was forced to resign. Ruckelshaus saw risk assessment as a way to restore credibility to the agency as it navigated a sprawling set of statutory obligations in the face of budgetary constraints and an increasingly hostile political environment. To be sure, Ruckelshaus acknowledged some of the difficulties involved in performing quantitative risk assessments, but he had clearly moved a long way from the more precautionary posture that marked his first tour as EPA's inaugural administrator in the early 1970s.[96]

At the same time, a parallel process was taking shape that sought to provide ongoing review and evaluation of the practices of risk assessment at EPA and beyond. Through a series of Executive Orders, Office of Management and Budget (OMB) guidance, NRC reports, and informal agency guidelines, a new internal administrative law of risk emerged that aimed at further rationalizing and improving environmental decision-making.[97] More formal approaches to risk also received the blessing and support of Congress and the Executive Branch. The 1990 Clean Air Act Amendments, for example, called for a new National Academy study on risk assessment and created a joint Presidential–

95. *Id*. *See also* John Doull, *The "Red Book" and Other Risk Assessment Milestones*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT: INT'L J. 1229, 1232 (2003) ("The greatest impact of this report came from separating the scientific input (toxicology, epidemiology, etc.) from the social input (economic, political, cultural, etc.). This greatly simplified the risk analysis process and enhanced its credibility."); DAVID DEMORTAIN, THE SCIENCE OF BUREAUCRACY: RISK BASED DECISION MAKING AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY 114 (2019) (concluding that the NRC's *Red Book* effort "aimed to reduce the autonomy of an agency that was perceived to overregulate, through a definition of the knowledge it could use and how").

96. *See* Ruckelshaus, *supra* note 13, at 157–58 ("We should remember that risk assessment data can be like the captured spy: if you torture it long enough, it will tell you anything you want to know. So it is good public policy to so structure an agency that such temptation is avoided."). *See also* Boyd, *supra* note 16, at 952–54 (discussing Ruckelshaus's precautionary commitments as first EPA administrator in early pesticide cancellations).

97. *See, e.g*., Executive Order 12866, Regulatory Review, 58 Fed. Reg. 51735 (Sept. 30, 1993) (establishing principles regulatory decision making, including regulatory impact analysis and cost-benefit analysis); OFF. MGMT. & BUDGET, ECONOMIC ANALYSIS OF FEDERAL REGULATIONS UNDER EXECUTIVE ORDER 12866, at § III.A.4. (1996) (providing that regulatory impact analyses should include risk assessments). The EPA issued its first guidelines for carcinogen risk assessment in 1976, following these with multiple updates in subsequent years. *See, e.g*., Health Risk and Economic Impact Assessment of Suspected Carcinogens, 41 Fed. Reg. 21402 (May 25, 1976); Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 34006 (Sept. 24, 1986); Guidelines for Carcinogen Risk Assessment, 70 Fed. Reg. 17766 (Apr. 7, 2005). The agency also developed various other guidelines for risk assessment, including Guidelines for Mutagenicity Risk Assessments, 51 Fed. Reg. 34006 (Sept. 24, 1986), Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 Fed. Reg. 34014 (Sept. 24, 1986), Guidelines for Exposure Assessment, 57 Fed. Reg. 22888 (May 29, 1992), and Guidelines for Developmental Toxicity Risk Assessment, 56 Fed. Reg. 63798 (Dec. 5, 1991). The exposure guidelines were updated in 2019, but the update was not published in the federal register. *See* U.S. ENV'T PROT. AGENCY, GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT: RISK ASSESSMENT FORUM (2019).

Congressional Commission on Risk Assessment and Risk Management to develop more consistent approaches across the federal government.[98] Risk assessment and cost-benefit analysis were also enthusiastically embraced by the Republican leadership in Congress in the mid-1990s, perhaps most famously in Newt Gingrich's *Contract with America*.[99]

On the surface, much of the enthusiasm for the new risk assessment paradigm was predicated on its supposed ability to de-politicize the discussion of public health and environmental protection by rendering it in more technical, seemingly neutral terminology. A transparent, multi-step process combined with uniform guidelines for inference choices and defaults to manage uncertainty would, it was argued, put decision-making on more objective—and, importantly, more defensible—grounds.[100] As such, the effort comported with deeper currents in the relationship between quantification and governance and the need to develop what Theodore Porter calls technologies of distance—methods and practices of quantification that provide a way for bureaucrats to insulate themselves from charges that they are acting arbitrarily, thereby substituting objectivity for trust in the face of an increasingly skeptical public.[101]

But it is also important to recognize the role of the chemical industry and its allies in promoting risk assessment and the basic *Red Book* paradigm. Building on its victory in *Benzene*, the AIHC and its partners worked to promote risk assessment as the default, mainstream approach to harm. In fact, it was the AIHC proposal to create a new independent board of scientists, unaffiliated with any regulatory agency, to carry out all cancer risk assessments that triggered the

98. See Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 112(o), 104 Stat. 2399 (1990), which called for a National Academy of Sciences study on risk assessment. This resulted in the 1994 NRC report, NAT'L RSCH. COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994). The 1994 NRC report is much more formal and detailed than the *Red Book*, spanning more than 600 pages and infused with the language of decision theory and operations research. The Clean Air Act Amendments of 1990 also mandated a Commission on Risk Assessment and Risk Management to "make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances." See Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 303, 104 Stat. 2399 (1990). The Commission was formed in 1994 and released its final two volume report in 1997. *See generally* PRESIDENTIAL/CONG. COMM'N ON RISK ASSESSMENT & RISK MGMT., FINAL REPORT VOL. 2: FRAMEWORK FOR ENVIRONMENTAL HEALTH RISK MANAGEMENT (1997) (promoting consistent approaches to risk assessment across the federal government); PRESIDENTIAL/CONG. COMM'N ON RISK ASSESSMENT & RISK MGMT., FINAL REPORT VOL. 2: RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION MAKING (1997) (same).

99. The Republican *Contract with America*, proposed by House Speaker Newt Gingrich in 1994, included the Job Creation and Wage Enhancement Act that was introduced in 1995 and contained a separate title with extensive provisions for risk assessment and cost-benefit analysis. *See* H.R. Res. 9, 104th Cong. (1995).

100. *See Red Book*, *supra* note 17, at 3–5 (discussing major steps of risk assessment and need for uniform guidelines); Ruckelshaus, *supra* note 13, at 157 (discussing risk assessment as a tool for restoring public confidence in EPA).

101. *See* THEODORE PORTER, TRUST IN NUMBERS: THE PURSUIT OF OBJECTIVITY IN SCIENCE AND PUBLIC LIFE ix (1996) ("[Q]uantification is a technology of distance . . . . [R]eliance on numbers and quantitative manipulation minimizes the need for intimate knowledge and personal trust.").

debate that led directly to the NRC study that culminated in the *Red Book*.[102] The AIHC also drafted the basic appropriations language that funded the study.[103] And the *Red Book* itself contained extensive discussions of various AIHC proposals on risk assessment, including, most prominently, the longstanding AIHC proposal to separate risk assessment from risk management.[104] This separation has been one of the most consequential legacies of the move to quantitative risk assessment because it allowed questions about harm to be characterized as technical questions that could always benefit from more science and more research.[105]

By the end of the 1980s—under the combined influence of *Benzene*, the *Red Book*, and the Ruckelshaus agenda—quantitative risk assessment had become foundational for many of EPA's programs, including chemicals, pesticides, hazardous waste sites, hazardous air pollutants, and toxic water pollutants.[106] During this time, there was a concerted effort to professionalize the practice of risk assessment. Industry, government, and academic experts created new professional associations, such as the Society for Risk Analysis, to develop the field.[107] The National Academy of Sciences established formal programs dedicated to improving the practice of risk assessment. And new industry-supported think tanks and trade associations emerged to advocate for risk assessment as a standard part of the regulatory process. In the early 1990s, for

102. *See, e.g.*, *Red Book*, *supra* note 17, at 132 ("The central proposals for changes in institutional arrangements for risk assessments developed by the office of Science and Technology Policy (OSTP) and the American Industrial Health Council (AIHC) and presented in H.R. 638 have sparked much of the current debate and precipitated this study.").

103. Inside Washington Publishers, *American Industrial Health Council Ceases Operations*, 7 INSIDE EPA'S RISK POL'Y REP. 19, 19 (2000) ("[AIHC] [s]taff wrote the congressional appropriations report language which funded the National Research Council to generate the seminal 1983 "Red Book.").

104. *See, e.g.*, *Red Book*, *supra* note 17, at 135–40 (discussing various AIHC proposals for risk assessment). *See also* Moolenar, *supra* note 18, at 386–88 (discussing AIHC's views on the importance of separating risk assessment from risk management and the need for thorough risk assessments "covering all scientific data" and subject to "extensive" peer review); Park & Snee, *supra* note 18, at 320 ("By its very nature, risk assessment is mainly a *scientific* activity whole risk management is principally a *political* activity.").

105. *See, e.g.*, *A Proposal to Achieve a Cohesive National Cancer Policy: Hearing Before the Subcomm. for Consumers of the S. Comm. on Com., Sci., & Transport.*, 96th Cong. 64–66 (1979) ("The essence of AIHC's proposal for achieving a more cohesive, national cancer policy is to recognize that the determination of whether a material is carcinogenic or not, and its potency, involve scientific rather than regulatory judgments."). See also the National Research Council's 2006 evaluation of EPA's dioxin risk reassessment, where the NRC admonished EPA to "adhere to the division between risk assessment, which is a scientific activity, and risk management, which takes into account other considerations, as described by the National Academy of Science more than two decades ago." NAT'L RSCH. COUNCIL, HEALTH RISKS FROM DIOXIN AND RELATED COMPOUNDS: EVALUATION OF THE EPA REASSESSMENT 142 (2006) (citing *Red Book*, *supra* note 17).

106. *See, e.g.*, U.S. ENV'T PROT. AGENCY, UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS 97 (1987) (defining EPA's "fundamental mission" as one of "reduc[ing] risks" across its various programs).

107. In 1980, for example, a group of risk professionals from industry, academia, and government founded the Society for Risk Analysis with the express goal of improving the practice of risk assessment and taking the rigor and insights of decision theory to create a more comprehensive approach to risk analysis as a basis for policy.

example, none other than Thorne Auchter himself took over as head of the Institute for Regulatory Policy, an organization whose goal, according to Auchter, was "to reform and standardize, within certain parameters, the use of risk assessment in the regulatory process."[108]

While risk assessment, like cost-benefit analysis, did receive criticism from various constituencies, the exercise always had significant surface appeal and rarely provoked the kind of deep normative concerns with putting a price on human life that cost-benefit analysis entailed.[109] In a world of limited resources and in the face of expanding statutory responsibilities, the ability to assess and rank risks promised to provide a neutral set of facts that would provide the basis for making the harder value choices involved in cost-benefit balancing.[110]

The problem, however, is that risk assessment has not worked. Indeed, multiple evaluations of the practice of risk assessment have revealed an approach that has been unable to deliver on even the most basic metrics.[111] As a 2009 National Academy of Sciences study put it, "the regulatory risk assessment process is bogged down," facing substantial challenges in its ability to deliver useful, credible knowledge for regulators even while it confronts an increasingly complex and unpredictable world of environmental harms.[112] "Uncertainty," according to the study, "continues to lead to multiple interpretations and contribute to decision-making gridlock."[113] A 2008 study by the Government

108. Stephen G. Minter, *Mr. Auchter's Return to Washington*, OCCUPATIONAL HAZARDS, April 1995, at 6.

109. *See, e.g.*, Shelia Jasanoff, *The Songlines of Risk*, 8 ENV'T VALUES 135, 141–45 (1999) (discussing ways in which formal risk assessment shapes understandings of environmental harms); John S. Appelgate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxics Substances Control*, 91 COLUM. L. REV. 261, 277 (1991) (observing that the analytical demands of quantitative risk assessment tend to widen the information gap for toxic substances); Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Assessment*, 92 COLUM. L. REV. 562 (1992) (criticizing normative foundations of comparative risk assessment).

110. *See, e.g.*, U.S. ENV'T PROT. AGENCY: SCI. ADVISORY BD., REDUCING RISK: SETTING PRIORITIES AND STRATEGIES FOR ENVIRONMENTAL PROTECTION 2 (1990) ("There are heavy costs involved if society fails to set environmental priorities based on risk . . . . If priorities are established based on the greatest opportunities to reduce risk, total risk will be reduced in a more efficient way, lessening threats to both public health and local and global ecosystems."); STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 59–61 (1993) (proposing a new centralized administrative group with inter-agency jurisdiction and a mission to rationalize risk-based priority setting across the government).

111. *See, e.g.*, NAT'L RSCH. COUNCIL, *supra* note 89, at 3 (discussing problems with current practices of risk assessment); INST. OF MED., ENVIRONMENTAL DECISIONS IN THE FACE OF UNCERTAINTY 4 (2013) (discussing long delays in risk assessments and inability to develop useful approaches to uncertainty); GOV'T ACCOUNTABILITY OFF., TOXIC CHEMICALS: EPA'S NEW ASSESSMENT PROCESS WILL INCREASE CHALLENGES EPA FACES IN EVALUATING AND REGULATING CHEMICALS 4 (2008) (observing that EPA "has not been able to routinely complete timely, credible [risk] assessments").

112. *See* NAT'L RSCH. COUNCIL, *supra* note 89, at ix ("[R]isk assessment is at a crossroads. Despite advances in the field, it faces a number of substantial challenges, including long delays in completing complex risk assessments, some of which take decades to complete; lack of data, which leads to important uncertainty in risk assessments; and the need for risk assessment of many unevaluated chemicals in the marketplace and emerging agents.").

113. *Id.* at 4.

Accountability Office found that EPA's Integrated Risk Information System (IRIS), the foundation of the agency's efforts to conduct risk assessments and establish standards across its different programs, was "at serious risk of becoming obsolete because the agency has not been able to routinely complete timely, credible assessments."[114]

Major risk assessment exercises have taken decades to complete, with some still ongoing and many thousands of additional chemicals waiting in the queue.[115] EPA's dioxin risk reassessment, for example, has been ongoing for more than thirty years, producing cancer risk estimates that vary by three orders of magnitude with no agreed criteria for how to achieve closure.[116] Similar risk assessments for trichloroethylene, formaldehyde, and perchloroethylene—among others—have also taken decades, with substantial variation in risk estimates depending on the models used.[117] Efforts to regulate a widely used pesticide, chlorpyrifos, took more than a decade after evidence of neurodevelopmental impacts became apparent, and then only in the wake of multiple writs of mandamus from the federal courts.[118] The regulation of fine particulates since the late 1990s, which has been the main driver of the many billions of dollars in net benefits associated with the Clean Air Act's National Ambient Air Quality Standards (NAAQS) program, still allows more than 100,000 premature deaths a year in the United States, even as new evidence of more subtle harms at very low levels of exposure, such as contributions to neurodegenerative disease, emerges on a regular basis.[119] Pervasive contamination of water supplies and human tissues with perfluorinated compounds—known as "forever chemicals" because of their extreme persistence

114. GOV'T ACCOUNTABILITY OFF., *supra* note 111.

115. *See* NAT'L RSCH. COUNCIL, *supra* note 89, at 3–4, 17.

116. *See* NAT'L RSCH. COUNCIL, *supra* note 105, at xv–xvi (2006) (noting that EPA started investigating dioxin risks in the mid 1980s and discussing history of the dioxin risk assessment since that time). In 2011, EPA separated the risk assessment for dioxin into non-cancer effects and cancer. The draft non-cancer risk assessment was released in 2012. At the time, EPA stated that the cancer risk reassessment would be finalized "as expeditiously as possible." To date, EPA has not released its final cancer risk assessment and has given no indication of when it expects to do so. U.S. ENV'T PROT. AGENCY, INTEGRATED RISK INFORMATION SYSTEM: 2,3,7,8-TETRACHLORODIBENZO-P-DIOXIN (TCDD), CASRN 1746-01-6, at 10 (2012).

117. *See generally* Toxic Substances Control Act Risk Determination: Trichloroethylene, 88 Fed. Reg. 1222 (Jan. 9, 2023) (final risk assessment and evaluation for trichloroethylene); *Risk Evaluation for Formaldehyde*, U.S. ENV'T PROT. AGENCY (Oct. 4, 2023), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-formaldehyde [https://perma.cc/TE6S-XUBB]; *Risk Evaluation for Perchloroethylene*, U.S. ENV'T PROT. AGENCY (June 8, 2023), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-perchloroethylene [https://perma.cc/ES6S-KHYB].

118. *See* League of United Lat. Am. Citizens v. Regan, 996 F.3d 673, 717 (9th Cir. 2021) (issuing mandamus); Tolerance Revocations: Chlorpyrifos, 86 Fed. Reg. 48, 315 (Aug 30, 2021).

119. *See, e.g.*, Andrew L. Goodkind et al., *Fine-Scale Damage Estimates of Particulate Matter Air Pollution Reveal Opportunities for Location-Specific Mitigation of Emissions*, 116 PROC. NAT. ACAD. SCIENCES 8775, 8779 (2019) (estimating 107,000 premature deaths in US as a result of exposure to PM2.5). *See generally* Y. Wang et al., *Toxicity of Inhaled Particulate Matter on the Central Nervous System: Neuroinflammation, Neuropsychological Effects and Neurodegenerative Disease*, 37 J. APPLIED TOXICOLOGY 644 (2017) (discussing the effects on particulate matter on the nervous system).

in the environment—has only just started to receive serious regulatory attention at EPA, even though these compounds have been widely produced since the 1950s, have been detected all over the world, and have been linked to a range of potential health problems for decades.[120] Despite extensive amendments to the Toxic Substances Control Act (TSCA) in 2016, basic health and safety information is still lacking for the vast majority of industrial chemicals in commerce, and EPA is already falling behind new statutory deadlines for assessing risks of priority chemicals.[121] And then there are the cumulative risks associated with real-world exposures to complex mixtures in various environmental media and across exposure pathways, not to mention how environmental risks interact with and compound the structural violence of poverty and systemic racism.[122] These challenges, together with the multifaceted and deeply systemic nature of climate disruption and broader ecological collapse, are not even cognizable in the basic risk assessment framework.

Although various efforts to reform risk assessment have been launched in the face of these failures, virtually all of them start from the premise that risk assessment is a neutral, predominantly technical exercise that can be fixed. This sort of naïve reformism is a hallmark of managerialism that works to reproduce and entrench the pathologies of the existing framework.[123] But, as Langdon Winner observed many years ago, artifacts have politics, and risk assessment is no exception.[124] The politics of risk assessment are embedded in its posture of anti-politics, which has provided cover for endless delays and an inability to deliver useful, timely results. Rather than viewing risk assessment as a neutral tool for understanding the world, therefore, it seems more accurate to see it as a

120. *See generally PFAS Strategic Roadmap: EPA's Commitments to Action*, 2021–24, U.S. ENV'T PROT. AGENCY (Apr. 24, 2023), https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024 [https://perma.cc/4JSB-83X7] (outlining EPA's various actions on PFAS); Daniel Renfrew & Thomas W. Pearson, *The Social Life of the "Forever Chemical": PFAS Pollution Legacies and Toxic Events*, 12 ENV'T & SOC.: ADVANCES RESEARCH 146 (2021) (recounting industrial and regulatory history of PFAS chemicals); Phillippe Grandjean & Richard Clapp, *Changing Interpretations of Human Health Risks from Perflourinated Compounds*, 129 PUB. HEALTH REP. 482, 482 (2014) (noting that analysis of serum samples showed that perflourinated compounds are detectable in all Americans); Mark Nevitt & Robert V. Percival, *Can Environmental Law Solve the "Forever Chemical" Problem?*, 57 WAKE FOREST L. REV. 239 (2022) (discussing PFAS toxicity crisis and failure of environmental law to respond).

121. *See, e.g.*, *Toxic Substances Control Act Amendments Implementation: Hearing Before the S. Comm. on Env't & Pub. Works*, 117th Cong. 5–6 (2022) (testimony of Dr. Michal Ilana Freedhof, Assistant Administrator, U.S. EPA Office of Chemical Safety and Pollution Prevention) (reporting that EPA will miss statutory deadlines for risk assessments and new regulations under the 2016 TSCA amendments).

122. *See, e.g.*, Gina M. Solomon et al., *Cumulative Environmental Impacts: Science and Policy to Protect Communities*, 37 ANN. REV. PUB. HEALTH 83, 84 (2016) (discussing the connection between cumulative impacts and vulnerable communities).

123. *Cf.* Amna A. Akbar, *Non-Reformist Reforms and Struggles over Life, Death, and Democracy*, 132 YALE L. J. 2497, 2518–20 (2021) (discussing the basic commitments of reformism toward tweaks and fixes that work to entrench existing systems, institutions, and practices rather than overhaul or replace them).

124. Langdon Winner, *Do Artifacts have Politics?* 109 DAEDALUS 121, 134 (1980) (discussing the ways in which "artifacts can have political qualities").

managerial technique aimed at disciplining and constraining the regulatory state in the service of private economic interests. Put bluntly, by working to derail and diminish the deep normative commitments that animated much of health, safety, and environmental law during their formative stages, risk assessment has operated as an anti-regulatory strategy that has undermined and delayed the protection of public health.

V

WITH REGARD FOR PERSONS

The chief advantage of bureaucracy, according to Max Weber, was its ability to generate highly reliable, unambiguous knowledge in a timely manner.[125] Bureaucracy was intentionally "de-humanized;" decisions would be made "without regard for persons."[126] Its technical efficiency and formal rationality made it a power instrument of the first order, giving it unsurpassed durability and influence over modern forms of social life. At the center of Weber's conception of bureaucracy was knowledge. "Bureaucratic administration," he wrote, "means fundamentally domination through knowledge."[127] But as central as it was to the power and reach of bureaucracy, knowledge *production* within the bureaucracy was not a primary concern for Weber. In fact, as the story of risk assessment in health, safety, and environmental law illustrates, it is the actual practices of knowledge production within a bureaucracy that we need to investigate if we want to understand the character of that bureaucracy and the possibilities for reform.

To be sure, important scholarship on the virtues of more flexible, adaptive forms of governance in the face of an uncertain future, a fair amount of which has focused on environmental law, have opened up new possibilities for bureaucracy.[128] Some have even gone so far as to suggest the possibility of post-bureaucratic forms of government as a response to pervasive uncertainty.[129] As this Symposium makes clear, however, much of this work celebrating more

125. MAX WEBER, ECONOMY AND SOCIETY: AN OUTLINE OF INTERPRETIVE SOCIOLOGY 225, 974–75 (Guenther Roth & Claus Wittich eds., 1978).

126. *Id*. at 975.

127. *Id*. at 225.

128. *See, e.g.*, Eric Biber, *Adaptive Management and the Future of Environmental Law*, 46 AKRON L. REV. 933, 933–39 (2013) (observing that adaptive management is the new paradigm of environmental law and summarizing literature).

129. *See, e.g.*, Charles F. Sabel & William H. Simon, *The Management Side of Due Process in the Service-Based Welfare State, in* ADMINISTRATIVE LAW FROM THE INSIDE OUT: ESSAYS ON THEMES IN THE WORK OF JERRY L. MASHAW 75–78 (Nicholas R. Parrillo ed., 2017) (discussing key features of post-bureaucratic experimentalist governance in context of social welfare); Charles F. Sabel & William H. Simon, *Minimalism and Experimentalism in the Administrative State*, 100 GEO. L. J. 53, 78–82 (2011) (discussing basic architecture of experimentalist governance as an alternative to command-and-control bureaucratic style of governance that characterized much of American public law from the New Deal to the 1980s).

flexible and informal modes of governance is often entangled with—and even in service to—managerialist tendencies.

More recently, a new generation of scholars from law and related disciplines have sought to recover a progressive conception of governance built around anti-domination and a new politics of care.[130] These projects of recovery and reimagining are vital for any effort to rebuild a regulatory state capable of responding effectively to pressing public problems. But it is also critical to engage at the more granular level of concepts, tools, and practices to excavate the material and social terrain on which regulatory managerialism does much of its work. Put another way, any broad normative repurposing of the state toward care and human flourishing will depend fundamentally on revising and reorienting the everyday practices of knowledge production within the bureaucracy. The antidote to managerialism lies as much in the habits and conduct of bureaucrats as in the big normative commitments that animate various reform agendas.

This article offers some provisional thoughts on what it might take to reorient agencies such as EPA and OSHA along these lines, focusing on interventions aimed at recentering harm and regard for persons in their everyday work. Part of this involves recovering and updating earlier commitments to precaution, endangerment, and a healthy respect for uncertainty—all matters that have been well canvassed by scholars and advocates for decades.[131] Part of it also involves new forms of civic engagement, deliberation, and public accountability—also topics that have received a great deal of attention from scholars.[132] In essence,

130. *See, e.g.*, SABEEL RAHMAN, DEMOCRACY AGAINST DOMINATION (2017); Blake Emerson, *Public Care in Public Law: Structure, Procedure, and Purpose*, 16 HARV. L. & POL. REV. 101 (2021); Amy Kapczynski & Gregg Gonsalves, *The New Politics of Care*, BOS. REV. (April 27, 2020) https://www.bostonreview.net/articles/gregg-gonsalves-amy-kapczynski-new-deal-public-health-we-need/ [https://perma.cc/Z2X7-WLKB]; Jenna Bednar, *Governance for Human Flourishing*, 132 DAEDALUS 31 (2023); Cristie Ford, *Regulation as Respect*, 86 LAW & CONTEMP. PROBS., no. 3, 2023, at 133. *See also* DOUGLAS A. KYSAR, REGULATING FROM NOWHERE: ENVIRONMENTAL LAW AND THE SEARCH FOR OBJECTIVITY (2010).

131. *See, e.g.*, Noah M. Sachs, *Rescuing the Strong Precautionary Principles from its Critics*, 2011 UNIV. ILL. L. REV. 1285 (2011) (criticizing practice of risk-based toxics regulation and advocating use of precautionary principle); KYSAR, *supra* note 130, at 9–14 (criticizing the economic approach to regulation and advocating a return to an earlier approach based on precaution); David M. Dana, *The Contextual Rationality of the Precautionary Principle*, 35 QUEEN'S L. J. 67 (2009) (defending a contextual approach to the precautionary principle and its appropriateness as a tool for certain kinds of problems); John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 HUM. & ECOLOGICAL RISK ASSESSMENT 413, 420–29 (2000) (discussing historical examples of precaution in various aspects of American environmental law); Boyd, *supra* note 16, at 948–62 (discussing early precautionary commitments in U.S. health, safety, and environmental law).

132. *See, e.g.*, Shelia Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 MINERVA 223, 227 (2003) (calling for new "technologies of humility" that "require not only the formal mechanisms of participation but also an intellectual environment in which citizens are encouraged to bring their knowledge and skills to bear on the resolution of common problems"); Theofanis Christoforou, *The Precautionary Principle and Democratizing Expertise: A European Legal Perspective*, 30 SCI. & PUB. POL. 205, 209–10 (2003) (calling for the democratization of expertise in the EU's efforts to implement the precautionary principle); Kristin Shrader-Frechette, *Analyzing Public Participation in Risk Analysis: How the Wolves of Environmental Injustice Hide in the Sheep's Clothing*

these two bodies of scholarship and engagement have tended to focus on recovering certain normative commitments and cultivating new forms of deliberation by bringing real people into the practice of environmental decision-making, both as objects and subjects.[133] What we really need, these two approaches insist, is more public engagement about what to do in the face of commonly accepted problems and how to channel commonsense, precautionary intuitions into meaningful—and timely—action.

But any serious attempt at reorienting environmental protection must also consider the internal practices of risk assessment at agencies such as OSHA and EPA—that is, the ways that agency scientists and civil servants come to understand the problems they confront, the knowledge they make, and the possibilities for response.[134] The practices that these agencies employ to make facts and produce knowledge, in other words, are as important as the reasons they give for the actions they take—or fail to take. Viewed in this way, managerialism is not simply an ethos or an ideology, but also a set of concrete practices that need to be investigated for their epistemic effects. To that end, this article suggests that we need to be looking for new tools, techniques, and practices—or, equally important, new ways of re-combining and revising existing tools, techniques, and practices—that health, safety, and environmental agencies can adopt as part of an internal agenda aimed at rethinking core knowledge practices and reorienting the ways they understand environmental problems.

A first step in that regard would be to return to simple hazard-based triggers as a basis for additional scrutiny and action. Rather than wait years, even decades, for the results of risk assessments, regulators across health, safety, and environmental fields should be continuously assessing the totality of the evidence available in the light most favorable to public health and worker safety. In doing so, if there is evidence that the substance in question—regardless of whether it is

of Science, 3 ENV'T JUST. 119 (2010) (discussing lack of public participation in risk-based decision making). *See also* Thomas Webler & Seth Tuler, *Four Decades of Public Participation in Risk Decision Making*, 41 RISK ANALYSIS 503 (2021) (discussing history of public participation in risk-based decision making).

133. *Cf.* JERRY L. MASHAW, BUREAUCRATIC JUSTICE: MANAGING SOCIAL SECURITY DISABILITY CLAIMS 198–202 (1983) (discussing features of what he calls "bureaucracy with a human face," including a requirement that disability claim examiners be forced to talk directly to the claimants and engage with them in crafting solutions). *See also* Ford, *supra* note 130.

134. Part of this involves a more critical engagement with the internal administrative law of risk that has evolved over the last several decades, including the proliferation of agency guidance on various aspects of risk assessment. Based on the history of risk assessment provided here, it is clear that such guidance cannot be read simply as a pragmatic, provisional response to uncertainty. *Cf.* Jeremy Kessler & Charles Sabel, *The Uncertain Future of Administrative Law*, 150 DAEDALUS 188, 191 (2021) ("The emerging law of [agency] guidance, and the reality of uncertainty to which it responds, points toward a different, and more defensible, conception of the administrative state, one that is aware of its own fallibility, that routinely invites challenges to its technical and political authority, and that continually responds to these challenges with reasons that are legible to the courts and the public at large."). On guidance and internal administrative law generally, see Nicholas R. Parrillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Institutions*, 36 YALE J. ON REGUL. 165 (2019) and Gillian E. Metzger & Kevin M. Stack, *Internal Administrative Law*, 115 MICH. L. REV. 1239 (2017).

a pollutant, a commercial chemical, a pesticide, or a waste product—causes harm in animals or humans, the activity or the product in question should be subject to regulation pending additional review. The burden of performing detailed quantitative assessments of risk should then be on those seeking access to markets, not on the people that the laws are intended to protect.

This was the basic motivation behind OSHA's generic cancer policy, as well as earlier approaches such as the Delaney amendments on food additives.[135] It is also embedded in some of the basic statutory commands that animate our major health, safety, and environmental laws. So, for example, the core standard at the heart of the Clean Air Act's NAAQS program—"protection of public health" with an "adequate margin of safety"—can be read as an injunction to regulate potential harms in the face of uncertainty without waiting for definitive evidence of actual harm.[136] The Food Quality Protection Act's (FQPA's) standard for pesticide residues on food—"reasonable certainty of no harm"—likewise embraces a strong commitment to requiring sufficient knowledge of safety—no harm—before a pesticide can be released into the world.[137] The 2016 TSCA provisions for new chemicals move in this direction as well, requiring that EPA make an affirmative finding of safety for any new chemical or a significant new use of an existing chemical before that chemical is allowed in the marketplace[138] Even the Occupational Safety and Health Act, notwithstanding the *Benzene* decision, requires that workplace standards for "toxic materials or physical agents" be set at a level that "most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."[139]

Second, regulatory agencies should replace elaborate, time-consuming exercises aimed at quantifying and managing uncertainties with simple approaches to uncertainty, such as the use of safety factors and attention to so-

135. *See* Boyd, *supra* note 16, at 985 (noting the connections between the precautionary commitments at work in the Delaney clause, EPA's early pesticide cancellations, various provisions of the Clean Air and Clean Water Acts, the rulings of the D.C. Circuit and other appellate courts in early environmental cases, and OSHA's generic cancer policy).

136. *See* 42 U.S.C. § 7409(b)(1) (requiring the EPA administrator to establish primary ambient air quality standards at a level "requisite to protect public health," and "allowing for an adequate margin of safety").

137. *See* Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 405, 110 Stat. 1489, 1516 (1996) (codified at 21 U.S.C. § 346a(b)(2)(A)(ii)) (defining "safe" with respect to tolerances for pesticide chemical residues on food as meaning that "the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information").

138. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448, 455–56 (2016) (amending § 5(a)(3)(C) to require that the EPA Administrator make a finding that a new chemical or a significant new use of an existing chemical is "not likely to present an unreasonable risk of injury to health or the environment" before allowing the manufacture of the new chemical or manufacture processing for the significant new use).

139. Occupational Safety and Health Act of 1970 (OSHA) § 6, 29 U.S.C. §655(b)(5)).

called vulnerable subpopulations. Instead of trying to make uncertainty look more like risk through various quantitative techniques that often fail to produce any resolution and are always open to contestation, the use of safety factors recognizes and respects the irreducible fact of uncertainty and builds in additional protections from harm to account for those uncertainties. Safety factors can be adjusted and modified over time as new information becomes available, but as a first line of defense, they recognize that we do not know precisely how toxic substances might cause harm and that many—even most—potentially harmful agents turn out to be more harmful than initially suspected.[140] Again, one can find strong commitments along these lines in existing environmental laws. The NAAQS program requires that standards for air pollutants be set at level that will protect public health with an adequate margin of safety.[141] The FQPA mandates the use of a tenfold safety factor for pesticide residues on food consumed by children to account for the special sensitivities of the developing brain.[142] And TSCA's provisions for new chemicals now require EPA to consider risks to susceptible and highly exposed subpopulations such as infants, pregnant women, children, and workers in making its affirmative finding of safety for a new chemical or significant new use of an existing chemical before it is allowed on the market.[143]

Third, EPA, perhaps in cooperation with the Centers for Disease Control and Prevention and state environmental and public health agencies, should invest in long-term monitoring of the fate and transport of chemicals in the environment and the exposures and body burdens in various populations. Here, new sensor technologies, biomonitoring capabilities, and big data promise to dramatically reduce the costs of such surveillance programs. This effort should also include post-market surveillance of industrial chemicals and pesticides similar to the manner in which this happens for drugs.

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140. *See, e.g.*, Philippe Grandjean, *Science for Precautionary Decision-Making, in* LATE LESSONS FROM EARLY WARNINGS: SCIENCE, PRECAUTION, INNOVATION 623, 624 ("With time, nearly all exposure limits for hazardous agents have decreased as new evidence documented that harm occurred at lower exposure limits than previously believed.").

141. *See* 42 U.S.C. § 7409(b)(1) (requiring the EPA administrator to establish primary ambient air quality standards at a level "requisite to protect public health," and "allowing for an adequate margin of safety").

142. *See* Food Quality Protection Act, Pub. L. No. 104-170, § 405, 110 Stat. 1489, 1518 (1996) (codified at 21 U.S.C. § 346a(b)(2)(C)) (requiring an "additional tenfold margin of safety" when setting tolerances for threshold effects from pesticide chemical residues to account for potential pre- and post-natal toxicity for infants and children).

143. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, § 3, 130 Stat. 448, 449 (2016) (defining new term "potentially exposed or susceptible subpopulation" as "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly"). The 2016 amendments then require that the EPA administrator take account of these potentially exposed or susceptible subpopulations when evaluating the safety of new chemicals or significant new uses of existing chemicals under section 5 and when performing risk assessments on existing chemicals under section 6.

Fourth, EPA and the National Science Foundation should develop formal programs to support environmental and public health researchers in investigating novel and emerging problems. One of the problems with the risk assessment paradigm is that it has reinforced existing incentives within academic and government research to go narrow and deep on particular chemicals and particular harms.[144] By changing funding priorities and incentive structures within the research community, scientists in government and academia would be rewarded not only for replicating and extending knowledge of well-known harms, but also for looking for new harms and new problems that could provide critical early warnings.

Fifth, regulatory agencies should embrace and expand ongoing mandatory reviews to ensure that efforts to understand and assess harms do not drag on for decades and to provide a basis for iterative and provisional standard setting. Again, this is a core design feature of the NAAQS program, which mandates five-year reviews.[145] The FQPA also requires EPA to review the data on pesticide registrations every fifteen years.[146] But even in the absence of clear statutory commands, EPA could make this kind of regular, ongoing review a standard part of its internal approach to understanding environmental harms across its various programs.[147]

Finally, regulatory agencies should take special care to account for—and be accountable for—the impacts of environmental harms on those already suffering from poverty, racism, and other forms of discrimination, which have long been a central component of environmental justice.[148] The problem of structural inequality and racism and the manner in which these are compounded by environmental harms has been largely invisible to standard approaches to risk assessment.[149] Placing harm and regard for persons back at the center of

144. *See* Grandjean, *supra* note 140, at 627–28.

145. 42 U.S.C. §7409(d)(1) (requiring regular five-year reviews of the underlying science supporting the existing NAAQS and revising them when appropriate).

146. *See* Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 105, 110 Stat. 1489, 1491–92 (1996) (codified at 7 U.S.C. § 136a(g)) (requiring periodic review of pesticide registrations with "the goal" of conducting such reviews every fifteen years).

147. *Cf.* Wendy Wagner, SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES 124–28 (2013) (discussing problems of achieving closure in regulatory science and the need for "stopping rules" to allow for policy decisions). The concept of "stopping rules" is from Shelia Jasanoff, *Transparency in Public Science: Purposes, Reasons, Limits*, 69 LAW & CONTEMP. PROBS., no. 3, 2006, at 22, 37–39.

148. On the implications of risk assessment for environmental justice, see Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 UNIV. ILL. L. REV. 103 (1996); Catherine A. O'Neill, *Variable Justice: Environmental Standards Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 STAN. ENV'T L.J. 3, 36–37 (2000); Ken Sexton, *Socioeconomic and Racial Disparities in Environmental Health: Is Risk Assessment Part of the Problem or Part of the Solution?* 6 HUM. & ECOLOGICAL RISK ASSESSMENT 561 (2000).

149. *See, e.g.*, Gina M. Solomon et al., *Cumulative Environmental Impacts: Science and Policy to Protect Communities*, 37 ANN. REV. PUB. HEALTH 83, 84–85 (2016) (discussing need for new tools to understand ways in which environmental risks are compounded by structural vulnerability and inequality); Lara Cushing et al., *The Haves, the Have-Nots, and the Health of Everyone: The Relationship*

environmental protection thus requires a deep and pervasive commitment to equity and environmental justice.

VI

CONCLUSION

As a mode of governance, regulatory managerialism seeks to discipline and constrain regulation in ways that fundamentally shift the activities of government toward private interests and away from trying to solve big complex public problems. In this world, "government has become something that happens to us," rather than something that we invest in as publics.[150] But as the fog of neoliberalism finally begins to lift, what may have looked natural and obvious now seems open to debate. The question looming before us is whether government can be repurposed and redirected to work towards the many pressing public problems that we confront. [151] Answering that question, as this article has argued, requires, as a first step, a critical investigation of the concepts, tools, and practices that allow regulatory managerialism to do its work. In the case of health, safety, and environmental law, that means engaging directly with the practice of risk assessment and the way that it has insinuated itself into our collective, commonsense understanding of what government is supposed to do when it regulates. But any such effort to understand the genealogies of regulatory managerialism also needs to take the next step of trying to rethink and reimagine what comes next. That exercise is, of course, deeply political, and this article has only gestured at some of the ways that this might proceed in health, safety, and environmental law. The goal in all of this is to turn risks back into harms and harms back into matters of public concern—to make clear that the actual harms inflicted on real people living real lives in real places have both a moral and a legal significance that has been largely forgotten in clever arguments about the reciprocal nature of harm and in the formulas and balancing acts we have allowed to colonize the practice of environmental protection.

Between Social Inequality and Environmental Quality, 36 ANN. REV. PUB. HEALTH 193, 194–95 (2015) (discussing relationship between various forms of social inequality and environmental quality).

150. Bednar, *supra* note 130, at 31. *See also* Cohen & Waldman, *supra* note 20, at viii ("As an ideology, managerialism erases publics."). *See generally* JOHN DEWEY, THE PUBLIC AND ITS PROBLEMS (1927).

151. For a discussion in the context of climate policy, see generally William Boyd, *The Poverty of Theory: Public Problems, Instrument Choice, and the Climate Emergency*, 46 COLUM. J. ENV'T L. 399 (2021).