

DE-RISKING ENVIRONMENTAL LAW

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Over the last forty years, risk assessment has come to provide the foundation for EPA's major regulatory programs on toxic chemicals, pollution, and hazardous waste—a development that seems quite natural, even necessary. The standard view holds that risk assessment is a largely technical, scientific exercise that provides the basic facts needed for the more value-laden exercise of risk management, often framed as an exercise in cost-benefit analysis. This has led to a preoccupation among legal scholars with the pros and cons of cost-benefit analysis versus other approaches to managing risk, while risk assessment itself has slipped rather quietly into the mainstream of regulatory practice. This is an oversight of great consequence—one that this Article seeks to remedy. The central claim is that quantitative risk assessment has operated first and foremost as a political technology intended to discipline agencies and constrain their ability to solve complex problems rather than as a tool to generate useful information about the world. This has happened in large part through the displacement of politics into seemingly interminable debates about proper technique, choice of model, and different ways of managing uncertainty (among others). The result has been a series of intractable knowledge problems that have made it virtually impossible for agencies such as EPA to complete major risk assessments in a timely fashion and deliver on their obligations to protect the public from environmental harms. The Article traces the history of formal risk assessment since the early 1980s, showing how it grew out of a broader set of anti-administrative tendencies that were gathering strength during this time and how it has worked in practice to inhibit timely, responsive regulation. The Article also offers some provisional thoughts on a political economy of risk assessment and knowledge making within the administrative state. Finally, the Article articulates the outlines of a new ethics of regulatory science that goes beyond generic calls for scientific integrity—an ethics that recenters law in the commitment to protecting public health, embraces the fact of uncertainty and the limits of our ways of knowing, and acknowledges our collective responsibility to come to terms with the violence embedded in the ways we have chosen to understand and manage risk.

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INTRODUCTION

Bureaucratic administration means fundamentally domination through knowledge.
—Max Weber¹

Few would disagree with Max Weber's observation that knowledge is fundamental to bureaucracy. With limited exceptions, however, his observation has not been fully explored in contemporary approaches to the administrative state.² It needs to be recovered, elaborated, and deepened. This is especially important in science-based fields such as health, safety and environmental regulation and, specifically, in the ways in which these fields have conceptualized and operationalized risk. It takes on additional salience in the current moment when science and fact-making across the government and the public sphere have come under unprecedented attacks.³

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1. See MAX WEBER, *ECONOMY AND SOCIETY: AN OUTLINE OF INTERPRETIVE SOCIOLOGY* 225 (Roth and Wittich eds., 1978).
 2. See, e.g., JERRY L. MASHAW, *BUREAUCRATIC JUSTICE: MANAGING SOCIAL SECURITY DISABILITY CLAIMS* 26 (1985).
 3. See, e.g., CHRISTOPHER SELLERS ET AL., *THE EPA UNDER SIEGE: TRUMP'S ASSAULT IN HISTORY AND TESTIMONY* 3 (2017) ("The Trump administration currently poses the greatest threat to the U.S. Environmental Protection Agency ("EPA") in its entire 47-year history."); Jacob M. Carter, *Strengthen Scientific Integrity Under the Biden Administration*, 371 *SCIENCE*

Much of the response to these attacks has, predictably and with good reason, focused on protecting and enhancing scientific integrity. Upon taking office, President Biden made good on his campaign pledges to restore science to its rightful place within government, moving quickly to issue a Memorandum to all agency and department heads: *Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking*.⁴ Several months later, a special Presidential task force produced its first report: *Protecting the Integrity of Government Science*.⁵ Individual agencies have likewise followed up with their own efforts to protect and enhance scientific integrity.⁶ All of this is a welcome and much needed corrective to the pervasive anti-science agenda of the Trump administration and the systematic attacks on government science and scientists undertaken by members of that administration.

But there is a sense in all of these efforts that if we can keep science pure by insulating it from politics, trust in government will return; that if government officials simply follow the science, they will produce good decisions that will resonate with the public and restore our faith in government. If only it were that easy.

In fact, the very idea that more science will lead to better regulation is part of the problem because it has led to a series of seemingly interminable debates over what counts as good science and what sorts of knowledge is appropriate for decisionmaking rather than a recognition that complex problems plagued with uncertainty require a broader normative framework to guide decisions.⁷ Without such a framework, there is no possibility of closure. One can always do more

668, 671 (2021) (“The previous four years were unprecedented in terms of obstacles and challenges surrounding science-based decision-making.”). *But see* Leif Fredrickson et al., *History of U.S. Presidential Assaults on Modern Environmental Health Protection*, 108 AM. J. PUB. HEALTH 595, 595 (Supp. 2018) (discussing Trump administration’s assault on environmental protection in context of history of efforts by Presidents Reagan and Bush to undermine environmental regulation).

4. *See* *Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking*, 86 Fed. Reg. 8845 (Feb. 10, 2021).

5. *See* Nat’l Sci. & Tech. Council Sci. Integrity Fast-Track Action Comm., WHITE HOUSE OFF. OF SCI. AND TECH. POL’Y, *Protecting the Integrity of Government Science* (2022), <https://perma.cc/J2DM-A2UD>.

6. *See, e.g.*, *Scientific Integrity*, EPA, <https://perma.cc/V9UU-LT2Q>.

7. *See, e.g.*, Roni Neff & Lynn R. Goldman, *Regulatory Parallels to Daubert: Stakeholder Influence, “Sound Science,” and the Delayed Adoption of Health Protective Standards*, 95 AM. J. PUB. HEALTH S81, S81 (Supp. 2005) (“‘Sound science’ pressures and the availability of analytic tools have created an environment in which interested parties can demand more and more data and repeated scientific review for the sole purpose of delaying health-protective standards.”); Sheila Jasanoff & Hilton R. Simmet, *No Funeral Bells: Public Reason in a Post-Truth Age*, 47 SOC. STD. SCI. 751, 759 (2017) (noting “that much of US regulatory discourse is focused on filtering good (objective) from bad (biased, distorted, corrupt) science, instead of on the question what is to be done in cases of uncertainty and ignorance.”); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1617 (1995) (arguing that “agencies exaggerate the contributions made by science in setting toxic

science and more research in the effort to understand the uncertainties a little bit better. Environmental law, it seems, suffers from too much science and not enough law.

To be sure, the widespread and growing lack of faith in expertise represents a profound political and epistemic crisis, though perhaps not as unprecedented as some would like to believe.⁸ That the crisis is in part a product of strategic efforts by economic and political actors is also not new and can be viewed as a continuation of the so-called science wars that have been a fixture of our politics for decades.⁹ But something seems different this time. Knowledge-making within government seems more fragile and fractured than ever before as the basic norms governing regulatory science and expertise are being challenged in fundamental ways.¹⁰

This Article argues that we need to look specifically at how knowledge is made and used within the administrative state in order to develop an adequate response. Put another way, we need to complement our focus on the generic notion of scientific integrity (as well as core administrative law commitments of accountability, participation, and transparency) with much closer attention to the concepts, tools, and practices that make facts and generate the knowledge that is then used in government decision-making. For it is often on this more technical terrain of tools and techniques that the battle over what counts as usable knowledge is being fought.

Thinking carefully (and critically) about knowledge production in law and the administrative state enhances our understandings of bureaucracy and the practice of health, safety, and environmental law. This is important for analytical reasons; it gives us a fuller, more complete picture of how agencies go about generating the knowledge that serves as the basis for regulation and how these processes of knowledge production all too often become sites of intense

standards in order to avoid accountability for the underlying policy decisions” as part of what Wagner calls a “science charade”).

8. See, e.g., GIL EYAL, *THE CRISIS OF EXPERTISE* 4 (2019) (discussing current crisis of expertise and noting that “[w]hat needs to be explained is not a one-sided ‘death of expertise,’ ‘mistrust of experts,’ or ‘assault on science,’ but the two headed *pushmi-pullyu* of unprecedented reliance on science and expertise coupled with increased suspicion, skepticism, and dismissal of scientific findings, expert opinion, or even whole branches of investigation”); Jasanoff & Simmet, *supra* note 7, at 755 (observing “that moral panics about the status of knowledge in the public sphere are as old as knowledge itself”).
9. See, e.g., NAOMI ORESKES & ERIK M. CONWAY, *MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO CLIMATE CHANGE* (2010); DAVID MICHAELS, *DOUBT IS THEIR PRODUCT: HOW INDUSTRY’S ASSAULT ON SCIENCE THREATENS YOUR HEALTH* (2008); CHRIS MOONEY, *THE REPUBLICAN WAR ON SCIENCE* (2005); DANIEL S. GREENBERG, *SCIENCE, MONEY, AND POLITICS: POLITICAL TRIUMPH AND ETHICAL EROSION* (2001).
10. See Wendy Wagner et al., *Whose Science? A New Era in Regulatory Science Wars*, 362 *SCI.* 636, 638 (2018) (noting that the Trump Administration’s “proposed reforms of regulatory science aim to change the nature of the scientific deliberations and underlying record itself”).

contestation. It matters also for normative reasons. By directing attention to how environmental law comes to know the problems it targets for regulation, it goes directly to the norms governing the relationship between knowledge and bureaucracy and, more importantly, to the question of which harms will be imposed on which groups of people.

The Article uses the story of risk assessment in health, safety, and environmental law as a vehicle for investigating this broader relationship between knowledge and bureaucracy. While the concept of risk has become deeply embedded in our approach to regulating environmental harms, this Article shows that there is nothing natural or necessary about the concept of risk and the practice of risk assessment as a way of understanding and managing those harms.¹¹ Indeed, formal quantitative approaches to risk emerged and took hold across the fields of health, safety and environmental law during a particular moment in the late 1970s and early 1980s.¹² Since that time, risk assessment has come to dominate the basic approach to harm in food safety, occupational health, and environmental law.¹³ At EPA, which is the main focus of this Article, quantitative risk assessment now provides the foundation for efforts to understand and regulate harms caused by industrial chemicals and pesticides, various forms of air and water pollution, and hazardous waste sites. In the process, risk assessment has reoriented programs, changed priorities, and connected EPA scientists to a broader community of experts. It has called forth new tools and techniques and mobilized evidence from multiple different fields. In important respects, it has professionalized agency science. But risk assessment has also generated significant new challenges and problems that have preoccupied the agency for decades and that have created substantial opportunities for delay and contestation. Put bluntly, formal risk assessment in practice has all too often hindered rather than enabled responsive, timely, and inclusive health protective environmental regulation.

11. The approach taken here builds upon and extends that developed in a prior Article that showed how risk came to displace prior understandings of harm, hazard, and danger in health, safety and environmental law during the middle decades of the twentieth century. See William Boyd, *Genealogies of Risk: Searching for Safety, 1930s-1970s*, 39 *ECOLOGY L.Q.* 895 (2012).

12. As a formal matter, risk is often defined as the product of probability and consequence (the expected value of an undesirable outcome). See, e.g., Mark J. Machina, *Decision-Making in the Presence of Risk*, 236 *Sci.* 537, 537 (1987) (discussing formal treatment of risk in the presence of expected utility theory). The practice of quantitative risk assessment varies considerably across different domains, from simply actuarial calculations to elaborate multi-step processes that depend on a range of techniques. During the early 1980s, the practice of risk assessment in health, safety, and environmental was formalized into a four-step process: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. See *COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* 3 (1983); see also *infra* Part II.B.

13. See *infra* Parts II and III.

Indeed, any honest evaluation of the practice of risk assessment at EPA over the last forty years would reveal an approach that has been unable to deliver on even the most basic metrics.¹⁴ 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.¹⁵ “Uncertainty,” according to the study, “continues to lead to multiple interpretations and contribute to decision-making gridlock.”¹⁶ A 2008 study by the Government Accountability Office found that EPA’s Integrated Risk Information System, 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.”¹⁷

Major individual risk assessment exercises have taken decades to complete, with many thousands of additional chemicals waiting in the queue.¹⁸ The dioxin cancer 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.¹⁹ Similar risk assessments for trichloroethylene, formaldehyde, perchloroethylene, and naphthalene (among others) have also taken decades, with substantial variation in risk estimates depending on the models used.²⁰ Efforts to regulate a widely used pesticide, chlorpyrifos, took more than a decade after evidence of neurodevelopmental harms became apparent, and then only in the wake of multiple writs

14. See, e.g., NAT’L RSCH. COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 3 (2009) (noting problems and delays with major risk assessments); INST. OF MED., ENVIRONMENTAL DECISIONS IN THE FACE OF UNCERTAINTY 3–5 (2013) (discussing long delays in risk assessments and inability to develop useful approaches to uncertainty); U.S. GOV’T ACCOUNTABILITY OFF., GAO-08-743T, 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”).

15. See NAT’L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 3; see also *id.* 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.”).

16. See *id.* at 4.

17. See U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 14, at 4; see also NAT’L RSCH. COUNCIL, REVIEW OF EPA’S INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROCESS 136 (2014) (discussing long delays of some controversial risk assessments with multiple rounds of review and revision and urging EPA “to consider systematically how delay occurs so that it can be anticipated and addressed”).

18. U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 14, at 3–4, 17.

19. See *infra* Part IV.A (discussing the dioxin risk assessment).

20. See *infra* Part IV.A (discussing the TCE and formaldehyde risk assessments).

of mandamus from the federal courts.²¹ 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 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.²² Pervasive contamination of water supplies and human and animal tissues with perfluorinated compounds (known as "forever chemicals" because of their extreme persistence in the environment) has only just started to receive serious regulatory attention at EPA, even though these compounds were widely produced starting in the 1950s, have been detected all over the world, and have been linked to a range of potential health problems for decades.²³ Despite extensive amendments to the Toxic Substances Control Act ("TSCA")²⁴ 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.²⁵ 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

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21. See *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 677 (9th Cir. 2021); Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48315, 48320 (Aug. 30, 2021).
 22. 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'L ACAD. SCI. 8775, 8779 (2019) (estimating 107,000 premature deaths in US as a result of exposure to PM_{2.5}); see also Yan Wang et al., *Toxicity of Inhaled Particulate Matter on the Central Nervous System: Neuroinflammation, Neuropsychological Effects and Neurodegenerative Disease*, 37 J. OF APPLIED TOXICOLOGY 644, 647 (2017).
 23. See EPA, PFAS STRATEGIC ROADMAP: EPA'S COMMITMENTS TO ACTION 2021-24 (2021), <https://perma.cc/VE9W-FCN9> (outlining EPA's various actions on PFAS); see also Daniel Renfrew & Thomas W. Pearson, *The Social Life of the "Forever Chemical": PFAS Pollution Legacies and Toxic Events*, 12 ENV'T & SOC'Y: ADVANCES RESEARCH 146, 148 (2021) (recounting industrial and regulatory history of PFAS chemicals); Phillippe Grandjean & Richard Clapp, *Changing Interpretations of Human Health Risks from Perfluorinated Compounds*, 129 PUB. HEALTH REP. 482, 482 (2014) (noting that analysis of serum samples showed that perfluorinated compounds are detectable in all Americans); Mark P. Nevitt & Robert V. Percival, *Can Environmental Law Solve the "Forever Chemical" Problem?*, 57 WAKE FOREST L. REV. 239, 241 (2022) (discussing PFAS toxicity crisis and failure of environmental law to respond).
 24. Toxic Substances Control Act, 15 U.S.C. §§ 2601–2697.
 25. See Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114–182, 130 Stat. 448 (2016); *Toxic Substances Control Act Amendments Implementation: Hearing Before the S. Comm. on Env't and 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).

poverty and systemic racism.²⁶ 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.

The consequences of these failures are evident in the ubiquitous presence of toxic chemicals in the tissues of human beings all over the world and widespread contamination of terrestrial and marine environments. The rapidly increasing production and release of so-called novel entities (synthetic chemicals, pollutants, and heavy metals) are now pushing past planetary boundaries, damaging ecosystems and taking an enormous toll on human life and human health.²⁷ On a global scale, the Lancet Commission on Pollution and Health estimates that pollution and toxic substances cause nine million premature deaths a year, which is more than three times the number of deaths from AIDS, tuberculosis and malaria combined, fifteen times the number of deaths from all wars and other forms of violence, and thirty percent more than total global deaths from COVID-19.²⁸ And this number is almost surely an underestimate given that we are still learning how damaging toxic substances can be. One recent study

26. 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).

27. See, e.g., Will Steffen et al., *Planetary Boundaries: Guiding Human Development on a Changing Planet*, 347 SCI. 6223, 736, 1259855-7 (2015) (defining novel entities as “new substances, new forms of existing substances, and modified life forms,” including “chemicals and other new types of engineered materials or organisms not previously known to the Earth system, as well as naturally occurring elements (for example, heavy metals) mobilized by anthropogenic activities”); Linn Persson et al., *Outside the Safe Operating Space of the Planetary Boundary for Novel Entities*, 56 ENV’T. SCI. TECH. 1510, 1512 (2022) (“Production of novel entities is rapidly increasing. The chemical industry is the second largest manufacturing industry globally. Global production increased 50-fold since 1950, and is projected to triple again by 2050 compared to 2010. Material extraction as feed stocks for novel entities was approximately 92 billion tonnes globally in 2017, and is projected to reach 190 billion tonnes by 2060. There are an estimated 350,000 chemicals (or mixtures of chemicals) on the global market. Nearly 70,000 have been registered in the past decade; many chemicals (nearly 30,000) have only been registered in emerging economies, where chemical production has increased rapidly, but chemicals management and disposal capacity often are limited. The production of intended chemicals entails the unintended production of byproducts, transformation products, and impurities which may not be considered under chemicals assessments and management measures.”); Katherine Richardson et al., *Earth Beyond Six of Nine Planetary Boundaries*, 9 SCI. ADVANCES 1, 6 (2023) (“Hundreds of thousands of synthetic chemicals are now produced and released to the environment. For many substances, the potentially large and persistent effects on Earth system processes of their introduction, particularly on functional biosphere integrity, are not well known, and their use is not well regulated. Humanity has repeatedly been surprised by unintended consequences of this release, e.g., with respect to the release of insecticides such as DDT and the effect of chlorofluorocarbons (“CFCs”) on the ozone layer. For this class of novel entities, then, the only truly safe operating space that can ensure maintained Holocene-like conditions is one where these entities are absent unless their potential impacts with respect to the Earth system have been thoroughly evaluated.”).

28. See Philip J. Landrigan et al., *The Lancet Commission on Pollution and Health*, 391 LANCET 462, 462 (2017); Richard Fuller et al., *Pollution and Health: A Progress Update*, 6 LANCET

of the global burden of lead contamination, for example, estimated that lead causes 5.5 million premature deaths per year—a six-fold increase over previous estimates.²⁹ This is in addition to lead’s substantial neurological impacts, including especially on the developing brain.³⁰ Research over the last several decades, moreover, has revealed that low level exposures to a broad range of industrial chemicals, pesticides, and pollution are linked to various neurodevelopmental problems, immunotoxicity, endocrine system disruption, and reproductive harms (among others).³¹ Even on cancer, despite progress in reducing cancer

PLANETARY HEALTH E535, E535 (2022). Pollution and toxics are responsible for one in six deaths worldwide. *Id.*

29. See Bjorn Larsen & Ernesto Sanchez-Triana, *Global Health Burden and Cost of Lead Exposure in Children and Adults: A Health Impact and Economic Modeling Analysis*, 7 LANCET PLANETARY HEALTH E831, E838 (2023) (noting that their central estimate of global cardiovascular disease mortality from lead exposure of 5.5 million deaths in 2019 is six times higher than the central estimate in the Global Burden of Diseases, Injuries, and Risk Factors Study for 2019). The authors note that their estimate does not include the effect of lead exposure on cardiovascular disease mortality mediated through hypertension and observe that “total mortality from lead exposure globally could substantially surpass our estimate.” *Id.*
30. *Id.* at E833–E836 (discussing impacts of lead exposure on early childhood IQ loss and finding that IQ loss in low and middle income countries was nearly 80% higher than previous estimates).
31. See, e.g., Phillippe Grandjean & Philip Landrigan, *Developmental Neurotoxicity of Industrial Chemicals*, 368 LANCET 2167, 2174 (2006) (observing that “[t]he combined evidence suggests that neurodevelopmental disorders caused by industrial chemicals has created a silent pandemic in modern society”); Bruce P. Lanphear, *The Impact of Toxins on the Developing Brain*, 36 ANN. REV. PUB. HEALTH 211, 223 (2015) (“Over the past 50 years, it has become clear that low-level exposures to environmental toxins can result in substantial disease and disability. Emerging evidence indicates that other ubiquitous chemicals are toxic. We can no longer deny the substantial if insidious impact that environmental toxins have on the developing brain.”); Helen Tryphonas, *Approaches to Detecting Immunotoxic Effects of Environmental Contaminants in Humans*, 109 ENV’T HEALTH PERSP. 877, 877 (2001) (“Although a number of systems can be affected by environmental contaminants, experimental animal data indicate that the immune system is one of the most sensitive targets for chemical-induced toxicity, especially for the chlorinated compounds TCDD [dioxin] and PCBs.”); Thaddeus T. Schug et al., *Minireview: Endocrine Disruptors: Past Lessons and Future Directions*, 30 MOLECULAR ENDOCRINOLOGY 833, 834 (2016) (“Epidemiological studies link EDCs [Endocrine Disrupting Chemicals] with reproductive effects, neurobehavioral and neurodevelopmental changes, metabolic syndrome, bone disorders, immune disorders, and cancers in humans. Animal studies show associations with many additional health effects, including asthma, learning and behavioral problems, early puberty, infertility, breast and prostate cancer, Parkinson’s disease, obesity, and other diseases.”); Aleksandra Fucic et al., *Reproductive Health Risks Associated with Occupational and Environmental Exposure to Pesticides*, 18 INT’L J. ENV’T RSCH. PUB. HEALTH 1, 21 (2021) (noting “that multiple epidemiologic studies have reported statistically significant associations between reproductive disturbances and exposure to pesticides”).

deaths in the U.S. and other countries, the incidence of certain cancers, especially in children and young adults, continues to increase.³²

While risk assessment itself can hardly be blamed for all of these problems, its inability to deliver the basic information needed to understand these harms and regulate in a timely manner is clearly a fundamental part of the problem, raising a series of important questions. Why has risk assessment failed to deliver? Why has an approach that was supposed to bring order and discipline to government decision-making by insulating it from politics created ample opportunities for political contestation and delay? And why do we continue to use it in the face of these failures?

Part of the explanation, this Article contends, is that formal risk assessment as practiced at EPA and other agencies was never really intended to produce useful, timely information for regulation. In fact, risk assessment was conceived and implemented primarily to discipline agency decision-making and replace expert judgment with a more formal, rule-governed rationality. As such, it has operated more as a political technology directed at agencies rather than as a neutral tool for generating useful knowledge about the world. Seen in this way, the endless questions over how to perform risk assessments, the proliferation of uncertainties that have attended virtually every choice of method and technique, and the massive expansion in complexity are inherent in the very logic of risk assessment.

There is a political economy at work here that is relatively easy to trace. Starting in the late 1970s, industry groups began to push for more formal approaches to risk assessment precisely because of its capacity to constrain agencies and slow down the regulatory process.³³ In fact, it would not be too much of

32. These include kidney, liver, thyroid, and esophageal cancers; Hodgkins disease and non-Hodgkins lymphoma; colorectal cancers in young adults; and childhood cancers, especially childhood leukemia and brain cancer. See, e.g., A.R. Scott et al., *Trends in Cancer Incidence in US Adolescents and Young Adults, 1973–2015*, 3 JAMA NETWORK OPEN 1, 7 (2020) (noting 29.6% increase in cancer incidence in adolescents and young adults between 1975 and 2015); David A Siegel et al., *Counts, Incidence Rates, and Trends of Pediatric Cancer in the United States, 2003–2019*, J. NAT'L CANCER INST., 1, 4 (2023) (discussing increased incidence of various childhood cancers between 2003 and 2019). Scientists and public health professionals suspect that exposures to pollution and toxic substances are major contributors to these trends. As the Co-Chairs of the 2009 President's Cancer Panel Report on Environmental Cancer concluded: "the true burden of environmentally induced cancers has been grossly underestimated." See LASALLE D. LEFFALL, JR., M.D., F.A.C.S. & MARGARET L. KRIPKE, PH.D., *Transmittal Letter, in 2008-2009 PRESIDENT'S CANCER PANEL: REDUCING ENVIRONMENTAL CANCER RISK: WHAT WE CAN DO NOW* (SUZANNE H. REUBEN, 2009).

33. The American Industrial Health Council ("AIHC") was established in 1977 as a broad multi-industry organization to oppose OSHA's proposed generic cancer policy, which sought to establish a simple, harm-based trigger for regulating carcinogens in the workplace. 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. For an overview of AIHC and its role in

an exaggeration to say that the widespread embrace of quantitative risk assessment since the early 1980s was a direct result of industry sponsored efforts, with significant assistance from the federal courts, government officials, and the science policy establishment, to remake environmental decision-making.³⁴

Understanding how this happened is a key objective of this Article—a task that is particularly important in the current moment for at least three reasons. First, and most importantly, the inexcusable delays in major risk assessments are causing real harm manifest in ongoing exposures to harmful chemicals and pollutants, stalled regulations, less stringent standards, and slower cleanups. Second, the emergence and consolidation of quantitative risk assessment was a direct response to an early intervention by the Supreme Court, backed by industry, to radically diminish the ability of agencies to develop creative, workable solutions to pressing public problems.³⁵ This was an important precursor to the current Court’s enthusiasm for the so-called major questions doctrine and provides a cautionary lesson for agencies going forward.³⁶ Third, much of the Trump Administration’s efforts to “deconstruct the administrative state” centered in large part on the conduct and norms of regulatory science and the use of that science in determining risk and regulating harms.³⁷

advocating against OSHA’s generic cancer policy, *see* JOSEPH L. BOWER, AMERICAN INDUSTRIAL HEALTH COUNCIL: HBS No. 383-0475 (President and Fellows of Harvard College, Harvard Business School, HBS Retired Case Collection, Baker Library) (1982); *see also* R.J. Moolenaar, *American Industrial Health Council View of Current Policy Direction in the Federal Establishment*, 3 REGUL. TOXICOLOGY & PHARMACOLOGY 381, 387 (1983) (“Advances in the science of ‘safety evaluations’ for chemical carcinogens should be reflected in federal policies. Trivial risks need to be separated from significant risks so that regulation can be targeted. Advances in understanding differences in the mechanism of action of chemical carcinogens, the importance of kinetics of chemical distribution and transformation in the body, the appropriate translation of animal data to humans, the role of cell damage in enhancing carcinogenic risk, and a host of other observations all need to be factored into risk assessment procedures. . . . AIHC favors evaluation of chemicals for carcinogenic potential on an individual basis utilizing the complete spectrum of data available.”)

34. *See* discussion *infra* Part II.A and II.B.

35. *See Indus. Union Dep’t v. Am. Petroleum Inst.*, 448 U.S. 628 (1980) [hereinafter *Benzene Decision*]; *see also* discussion *infra* Part II.A.

36. *See, e.g., West Virginia v. EPA*, 597 U.S. ___ (2022) slip op. at 24 (citing *Benzene Decision* as precedent for Court’s skepticism of EPA’s efforts to exercise “unprecedented power over American industry”); *see also* discussion *infra* Part II.A.

37. A large part of the Trump administration’s agenda at EPA, in fact, focused on weaponizing the norms of science. *See, e.g.,* Becky Mansfield, *Deregulatory Science: Chemical Risk Analysis in Trump’s EPA*, 51 SOC. STUD. SCIENCE 28, 30 (2021) (observing that “Trump EPA officials defend their approaches in terms of scientific values, declaring that their approaches are *better* science: more objective and transparent, less speculative, better grounded in evidence and so forth. According to its political appointees, the Trump EPA stands for scientific integrity, because it is promulgating new, evidence-based frameworks that show that regulation is neither necessary nor appropriate.”); Mario Biagioli & Alain Pottage, *Dark Transparency: Hyper-Ethics at Trump’s EPA*, LOS ANGELES REV. OF BOOKS (Mar. 19, 2022), <https://perma.cc/XU22-47ZT> (discussing how the Trump EPA sought to mobilize norms of openness and

The Article proceeds as follows. Part I briefly situates this project within the literature on bureaucracy and the administrative state, with specific attention to the role of knowledge practices in health, safety, and environmental law. It argues for a thicker, more deliberate investigation of knowledge practices in our understanding of risk regulation and the administrative state and claims that the formal approach to risk operates in the first instance as a schema of rationality intended to reshape and discipline knowledge making within the bureaucracy.

Part II traces the rise of formal risk assessment in U.S. health, safety, and environmental law during the 1980s and 1990s. It describes how risk assessment emerged as a central aspect of the broader effort to constrain agency discretion and expert judgment and embed them within a more formal approach to environmental decision-making. It also elaborates on the growing embrace of various forms of computational modeling across EPA's regulatory domains as a key component of the move to formal risk assessment and the implications of this shift for regulation more broadly. The key message here is that quantitative risk assessment was conceived and implemented as a political technology aimed at displacing earlier, more precautionary approaches to environmental harms rather than as a tool to better understand those harms.

Part III turns to practice and addresses some of the knowledge problems that have emerged in the last two decades in the effort to extend and refine quantitative risk assessment. It focuses specifically on the multiple types of uncertainty that inevitably accompany formal risk assessment, the challenges of evaluating computational models and their proper role in assessing risks, the nearly impossible task of accounting for the compounding effects of cumulative exposures to multiple chemicals across multiple exposure pathways, and the general failure to build environmental justice concerns into the practice of risk assessment. The main takeaway here is that these knowledge problems are not a symptom of incomplete or improperly performed risk assessments but an inevitable product of the exercise itself.

Part IV steps back and looks at the broader history of risk assessment over the last forty years and the implications for the relationship between knowledge and bureaucracy. It argues for a more explicit political economy of risk assessment and knowledge making within the administrative state—one that puts the Trump Administration's recent efforts to undermine the infrastructure supporting EPA's regulatory programs in its larger historical context and one that recognizes and calls out the heavy hand of industry influence on risk assessment. It also offers some preliminary thoughts on how to build a new ethics of regulatory science and risk assessment that goes beyond simple calls to restore scientific

transparency to challenge the credibility of scientists). ; *see also* David Pozen, *Transparency's Ideological Drift*, 128 *YALE L.J.* 100 (2018). Philip Rucker & Robert Costa, *Bannon Vows a Daily Fight for 'Deconstruction of the Administrative State'*, *WASH. POST* (Feb. 23, 2017), <https://perma.cc/G3G7-M74P>.

integrity—an ethics that (re)centers law and public health, embraces a more fulsome respect for uncertainty, and acknowledges our collective responsibility to come to terms with the violence embedded in the ways that we have chosen to understand and manage risk.

I. KNOWLEDGE, RISK, AND THE ADMINISTRATIVE STATE

The classic Weberian view of bureaucracy sees it as a form of “legitimate domination.”³⁸ In this conception, the central feature of bureaucracy that makes it technically superior to other forms of organization and allows it to exercise control over vast segments of human affairs lies in its internal and external forms of knowledge. In his brief elaboration on this point, Weber contrasts the technical knowledge for which bureaucracies are known with other less formal, more tacit forms of knowledge that allow officials and others to exercise influence within bureaucracies.³⁹ Both are central to his notion of bureaucracy as a form of domination and both underwrite and are reinforced by the common bureaucratic elements of technical training and expertise, hierarchical organization, delimited spheres of substantive competence, extensive documentation, and files (the files!).⁴⁰

Much of the social science literature on bureaucracy has likewise emphasized formal organization, rule-governed conduct, information processing, and technical expertise, adopting Weber’s instrumental view of knowledge without much attention to the actual practices of knowledge production that take place in different kinds of bureaucracies (or in different parts of the same bureaucracy).⁴¹ Likewise, the mountain of legal scholarship on the administrative state has focused, for obvious and good reasons, on agency discretion, principal-agent problems, and questions of judicial review and accountability (among others).⁴²

38. See WEBER, *supra* note 1, at 223–26 (discussing “monocratic bureaucracy” as a form of legitimate domination).

39. See *id.* at 225 (discussing different forms of knowledge).

40. *Id.*; see also REGINA F. TITUNIK, *Democracy, Domination, and Legitimacy in Max Weber’s Political Thought*, in MAX WEBER’S ECONOMY AND SOCIETY: A CRITICAL COMPANION 143, 150 (Charles Camic et al. eds., 2005).

41. See, e.g., JAMES Q. WILSON, *BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT* xvii–xix (1989); DWIGHT WALDO, *THE ADMINISTRATIVE STATE: A STUDY OF THE POLITICAL THEORY OF AMERICAN PUBLIC ADMINISTRATION* 47 (1948).

42. On agency discretion, see, e.g., Edward L. Rubin, *Discretion and Its Discontents*, 72 CHI-KENT L. REV. 1299 (1997); Martin Shapiro, *Administrative Discretion: The Next Stage*, 92 YALE L.J. 1487 (1983); John M. Rogers, *A Fresh Look at Agency “Discretion”*, 57 TUL. L. REV. 776, 777 (1983); KENNETH CULP DAVIS, *DISCRETIONARY JUSTICE: A PRELIMINARY INQUIRY* (1969). On principal-agent models of administrative law, see, e.g., J.R. DeShazo & Jody Freeman, *The Congressional Competition to Control Delegated Power*, 81 TEX. L. REV. 1443 (2003); Eric A. Posner, *Cost-Benefit Analysis as a Solution to a Principal-Agent Problem*, 53 ADMIN. L. REV. 289 (2001); Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245 (2001); Thomas H. Hammond & Jack H. Knott, *Who Controls the Bureaucracy?: Presidential Power*,

But to a large extent, the collective enterprise of knowledge production that is at the heart of modern bureaucracy gets sidelined in much of administrative law scholarship and is for the most part subordinated in discussions of the problems of the regulatory state. Put another way, administrative law's traditional focus on reason giving has not been matched with sufficient attention to the regulatory state's substantial role in fact making.

That said, it would not be too much of a leap to describe much of administrative law as a field concerned fundamentally with the integrity of agency knowledge practices—a set of procedures for evaluating and ensuring that knowledge production runs along certain well-defined grooves. Indeed, the principal virtues of modern American administrative law—transparency, participation, and accountability—all reflect a commitment to sound knowledge as a basis for legitimacy.⁴³ Leading figures in the field have long recognized this. Jerry Mashaw, for example, references Weber's observation about knowledge and bureaucracy in an early article and describes bureaucratic rationality primarily in terms of information processing, making quick recourse to rules of conduct, formal organization, and judicial review.⁴⁴ Adrian Vermeule has written about “local and global knowledge in the administrative state,” with particular attention to the challenges of centralization and epistemic coordination in the vast, unwieldy American bureaucracy.⁴⁵ Cass Sunstein has also

Congressional Dominance, Legal Constraints, and Bureaucratic Autonomy in a Model of Multi-Institutional Policy-Making, 12 J.L. ECON. & ORG. 119 (1996); Jonathan R. Macey, *Separated Powers and Positive Political Theory: The Tug of War Over Administrative Agencies*, 80 GEO. L.J. 671 (1992); Mathew D. McCubbins et al., *Administrative Procedures As Instruments of Political Control*, 3 J.L. ECON. & ORG. 243 (1987). On accountability, see, e.g., Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667 (1975); Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461 (2003).

43. More recent attention to the practices of “internal administrative law” also implicates agency knowledge practices at multiple levels. See Gillian E. Metzger & Kevin M. Stack, *Internal Administrative Law*, 115 MICH. L. REV. 1239 (2017).
44. See Jerry L. Mashaw, *Conflict and Compromise Among Models of Administrative Justice*, 1981 DUKE L.J. 181, 185 (1981). In their article on automobile safety and administrative law, Mashaw and David Harfst similarly invoke Weber's insight, noting that “[j]udicial review of the rationality of administrative rules operates on the Weberian maxim ‘Bureaucratic administration means fundamentally domination through knowledge.’” Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. REG. 257, 292 (1987).
45. See Adrian Vermeule, *Local and Global Knowledge in the Administrative State*, in LAW, LIBERTY AND STATE: OAKESHOTT, HAYEK AND SCHMITT ON THE RULE OF LAW 296 (Dyzenhaus & Poole eds., 2015). Vermeule usefully divides administrative law scholarship into three major frameworks drawing respectively on constitutional theory, democratic theory, and what he calls “institutional epistemology.” Adrian Vermeule, *The Administrative State: Law, Democracy, and Knowledge*, in OXFORD HANDBOOK OF THE U.S. CONSTITUTION 259–60 (Tushnet et al. eds., 2015). Within this third framework, Vermeule distinguishes between two different forms of knowledge at work in the administrative state, which he designates as global or synoptic on the one hand and local or tacit on the other. This modified Hayekian

emphasized the “knowledge problem” confronting regulation and, specifically, the exercise of cost-benefit analysis, arguing for a more open and more public notice-and-comment process as a corrective to the knowledge limitations that inevitably affect technocrats trying to understand the consequences of particular rules.⁴⁶ Drawing on John Dewey, Charles Sabel and his various co-authors have identified and elaborated the key features of an iterative, experimentalist form of governance that can engage in adaptive problem solving in the face of deep and pervasive uncertainty confronting regulators.⁴⁷ Recent efforts to recover earlier Progressive era conceptions of the administrative state have stressed the importance of building deliberation and participation into the DNA of regulatory agencies, embracing a Deweyan faith that experts can make the technical knowledge that informs government decisions clear to the public and that the public will engage in a sustained manner.⁴⁸ And longstanding calls to focus on the actual practice of public administration have also received new life in more recent efforts to reimagine administrative law as the law of public administration with a focus on administrative competence.⁴⁹

Within environmental law, considerable attention has been directed to the use and abuse of science at EPA, to the normative shortcomings of various decision-making tools, and to the perverse incentives that administrative law creates for agencies seeking to regulate in areas marked with irreducible uncertainty.⁵⁰ Important debates over the proper role of precaution in environmental

taxonomy then provides the basis for a discussion of the relative merits of decentralized decision-making by line agencies versus central coordination (such as that engaged in by OMB’s Office of Information and Regulatory Affairs), as well as the inadequacies of certain standard techniques, such as cost benefit analysis, in the face of uncertainty. *Id.* at 275–77.

46. See CASS R. SUNSTEIN, *THE COST-BENEFIT REVOLUTION* 79 (2018).
47. See, e.g., Jeremy Kessler & Charles F. Sabel, *The Uncertain Future of Administrative Law*, 150 *DAEDALUS* 188, 191 (2021); Charles F. Sabel & William H. Simon, *Minimalism and Experimentalism in the Administrative State*, 100 *Geo. L.J.* 53, 55, 79 (2011); Michael C. Dorf & Charles F. Sabel, *A Constitution of Democratic Experimentalism*, 98 *COLUM. L. REV.* 267, 267 (1998).
48. See, e.g., BLAKE EMERSON, *THE PUBLIC’S LAW: ORIGINS AND ARCHITECTURE OF PROGRESSIVE DEMOCRACY* 168–80 (2019); K. SABEEL RAHMAN, *DEMOCRACY AGAINST DOMINATION* (2017); JOHN DEWEY, *THE PUBLIC AND ITS PROBLEMS* 208–09 (1927).
49. See ELIZABETH FISHER & SIDNEY A. SHAPIRO, *ADMINISTRATIVE COMPETENCE: REIMAGINING ADMINISTRATIVE LAW* (2020); see also EDWARD L. RUBIN, *BEYOND CAMELOT: RETHINKING POLITICS AND LAW FOR THE MODERN STATE* 57 (2005) (calling for more “microanalysis of existing practices and problems” within the administrative state); Wagner, *The Science Charade in Toxic Risk Regulation*, *supra* note 7, at 1706–11.
50. See, e.g. THOMAS O. MCGARITY & WENDY E. WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* 2–7 (2015); Wendy E. Wagner & Rena Steinzor, *Introduction: Principled Science*, in *RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH* (Wendy E. Wagner & Rena Steinzor eds., 2006); Wagner, *supra* note 7; Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 *YALE J. ON REG.* 89, 142 (1988); Marcia R. Gelpe & A. Dan Tarlock, *The Uses of Scientific Information in Environmental Decisionmaking*, 48 *S. CAL. L. REV.* 371 (1974).

law have also often focused on the epistemic limits of various forms of technocratic decision-making and the inadequacies of welfare economics as a baseline for the field.⁵¹ And, of course, there is a rich literature debating the merits of cost-benefit analysis.⁵² All of this work raises fundamental questions regarding the appropriate relationship between knowledge and bureaucracy and, more generally, between science and law.

Risk provides an obvious and important way into these questions, and there is an extensive legal literature on risk going back several decades.⁵³ As arguably the central organizing concept for contemporary environmental law, risk exercises enormous influence on the manner in which problems are defined, assessed, and managed.⁵⁴ Given its deep commitment to an actuarial view of populations, distributions, and averages, risk has been co-constitutive with modern practices of governance—an example of how certain abstractions have

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51. See DOUGLAS A. KYSAR, *REGULATING FROM NOWHERE: ENVIRONMENTAL LAW AND THE SEARCH FOR OBJECTIVITY* (2010); Sheila Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 *MINERVA* 223 (2003); see also William Boyd et al., *Law, Environment, and the Non-Dismal Social Sciences*, 8 *ANN. REV. L. & SOC. SCI.* 183, 184 (2012).
52. See, e.g., CASS R. SUNSTEIN, *THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION* (2002); CASS R. SUNSTEIN, *THE COST-BENEFIT REVOLUTION* (2019); RICHARD L. REVESZ & MICHAEL A. LIVERMORE, *RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH* (2008); Kysar, *supra* note 51; FRANK ACKERMAN & LISA HEINZERLING, *PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING* 35 (2004) (arguing that cost-benefit analysis has become “a powerful weapon in the hand of vocal opponents of regulation”).
53. See, e.g., James P. Leape, *Quantitative Risk Assessment in Regulation of Environmental Carcinogens*, 4 *HARV. ENVTL. L. REV.* 86 (1980); Peter Huber, *The Old-New Division in Risk Regulation*, 69 *VA. L. REV.* 1025 (1983); SHEILA JASANOFF, *RISK MANAGEMENT AND POLITICAL CULTURE* (1986); Christopher H. Schroeder, *Rights Against Risks*, 86 *COLUM. L. REV.* 495 (1986); Clayton P. Gillette & James E. Krier, *Risk, Courts, Agencies*, 138 *U. PA. L. REV.* 1027 (1990); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 *COLUM. L. REV.* 261 (1991); Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Assessment*, 92 *COLUM. L. REV.* 562 (1992); John D. Graham & Jonathan Baert Wiener, *Confronting Risk Tradeoffs*, in *RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT* 33 (John D. Graham & Jonathan Baert Wiener eds., 1995); Wagner, *supra* note 7; Lisa Heinzerling, *Environmental Law and the Present Future*, 87 *GEO. L.J.* 2025 (1999); CASS R. SUNSTEIN, *RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT* (2002); SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, *RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH* (2003); ELIZABETH FISHER, *RISK REGULATION AND ADMINISTRATIVE CONSTITUTIONALISM* (2007).
54. See, e.g., Sheila Jasanoff, *The Songlines of Risk*, 8 *ENV'T VAL* 135, 135 (1999) (“In the world’s industrial nations, ‘risk’ has become the organising concept that gives meaning and direction to environmental regulation.”); SUNSTEIN, *supra* note 53, at viii (observing that “risk reduction has become a principal goal of modern governments”); George Priest, *The New Legal Structure of Risk Control*, 119 *DAEDALUS* 207, 209 (1990) (“The predominant function of modern law is to allocate risk.”).

come to dominate and define modern forms of social life.⁵⁵ As such, the idea of risk and the practices of risk assessment deserve their own concrete history—one that digs beneath the surface-level conflicts between ideas and principles to engage the more social and material terrain of knowledge practices. This entails a thicker and more detailed inquiry into the specific concepts, techniques, working instruments, and practices that make knowledge, render particular problems visible, valorize certain positions and perspectives, and get mobilized in ongoing political struggles to determine which environmental harms will be imposed on whom.

Before proceeding with that inquiry, however, it is important to clarify what we mean by risk. As understood here, risk is not a “first-order ‘thing’ existing in the world.”⁵⁶ Rather, risk is a schema of rationality—a way of organizing our thinking about our relationships to certain things and processes in the world. Seen in this way, risk is not simply an object of governance, but rather a powerful tool for defining and constituting particular problems as objects amenable to particular kinds of regulation.⁵⁷ As noted in a previous Article, risk has a distinctive genealogy, a past, a public life.⁵⁸ And that past matters as we seek to understand how this particular concept and the related practices of risk assessment have come to dominate our approach to health, safety, and environmental law.

Indeed, formal approaches to risk in health, safety, and environmental law did not emerge *sui generis* but drew upon conceptual and technical developments that had been underway for decades in economics, decision theory, operations research, and management science.⁵⁹ Replacing individual judgment and

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55. See NIKLAS LUHMANN, *RISK: A SOCIOLOGICAL THEORY* xxviii (2002) (“The question is rather what we can learn about normal processes in our society from the fact that it seeks to comprehend misfortune in the form of risk”); Francois Ewald, *Risk in Contemporary Society*, 6 CONN. INS. L.J. 365, 366 (2000) (“Risk has become ubiquitous and a kind of conceptual umbrella used to cover all sorts of events, be they individual or collective, minor or catastrophic. Risk presents itself as the modern approach to an event and the way in which, in our societies, we reflect upon issues that concern us.”).
 56. As Justice Rehnquist observed forty years ago, “a *risk* of an accident is not an effect on the physical environment. A risk is, by definition, unrealized in the physical world.” *Metropolitan Edison Co. v. People Against Nuclear Power*, 460 U.S. 766, 775 (1983); see also François Ewald, *Insurance and Risk*, in *THE FOUCAULT EFFECT: STUDIES IN GOVERNMENTALITY* 199 (Graham Burchell et al. eds., 1991) (“[T]here is no risk in reality.”).
 57. See LUHMANN, *supra* note 55, at xxviii; Ewald, *supra* note 56, at 207 (discussing risk and insurance as schemas of rationality and management central to the operation of modern society).
 58. Boyd, *supra* note 11, at 898 (2012).
 59. There is a growing literature on social science during the Cold War emphasizing the embrace of rational choice models of human behavior and its influence on decision theory, management, and organization sciences. See, e.g., PAUL ERICKSON ET AL., *HOW REASON ALMOST LOST ITS MIND: THE STRANGE CAREER OF COLD WAR RATIONALITY* 4 (2013) (“What looks in retrospect like a loose and somewhat motely conglomerate of game theory, nuclear strategy, operations research, Bayesian decision theory, systems analysis, rational choice

discretion with expert systems was viewed across these disciplines as a superior means for solving many of the complex problems facing industrial society.⁶⁰ In the process, uncertainty was increasingly marginalized, a consequence that has had important implications for environmental law and governance and one that we will return to below.⁶¹

But the story of how formal approaches to risk took hold in health, safety, and environmental law is not a simple story of the progressive adoption of new ways of thinking and new approaches to decision-making developed in other fields. Risk assessment was also a product of hard-working government experts looking for better ways to make decisions, strategic interventions by interested parties, and, perhaps most importantly, a robust effort across various branches of government to constrain agency discretion.⁶²

Prior to the mid-1970s, in fact, risk was rarely invoked in the effort to regulate the increasingly complex set of hazards associated with industrial society and quantitative risk assessment was considered too unreliable to serve as a basis for regulatory decision-making.⁶³ With few exceptions, safety, hazard, and endangerment provided the dominant framings, drawing on different conceptual and normative tendencies and leading to different regulatory outcomes.⁶⁴ In all of this, there was also a deep respect for uncertainty and a recognition that decisions to regulate would have to be made on the basis of incomplete knowledge.⁶⁵

Starting in the mid-1970s, however, safety was gradually redefined as acceptable risk as regulators and scientists came to recognize the difficulties of holding onto these earlier commitments.⁶⁶ This was driven in part by a revolution in detection capabilities and analytical techniques that revealed a much

theory, and experimental social psychology then defined the field of contestation about what rationality should be under the radically altered conditions of the Cold War.”); *COLD WAR SOCIAL SCIENCE: KNOWLEDGE PRODUCTION, LIBERAL DEMOCRACY, AND HUMAN NATURE* (Solovey & Cravens eds., 2012); Hunter Heyck, *The Organizational Revolution and the Social Sciences*, 105 *Isis* 1 (2014).

60. Erickson et al., *supra* note 59, at 4 (“What was distinctive about Cold War Rationality was the expansion of the domain of rationality at the expense of that of reason, asserting its claims in the loftiest realms of political decision making and scientific method—and sometimes not only in competition with but in downright opposition to reason, reasonableness, and common sense.”).

61. *See infra* Part III.A.

62. *See* Boyd, *supra* note 11, at 964–78 (tracing early efforts to develop quantitative risk assessment at FDA and EPA); *see also infra* Part II.

63. Al Alm, *Why We Didn't Use Risk Before*, 17 *EPA J.* 13, 13 (1991) (“The term ‘risk’ was rarely used during EPA’s formative years.”)

64. *See* Boyd, *supra* note 11.

65. *Id.*

66. *Id.* at 944–47 (describing these developments); *see also* Linda Nash, *From Safety to Risk: The Cold War Contexts of American Environmental Policy*, 29 *J. POL. HIST.* 1, 3–7 (2017).

more complicated world of environmental harms.⁶⁷ Between 1958 and 1978, for example, the ability of instruments to detect chemical substances in food and the environment increased by as much as five orders of magnitude.⁶⁸ A substantial and ongoing expansion of animal testing throughout the post WWII decades likewise revealed a growing number of substances that induced cancer at some site in some strain of laboratory animal.⁶⁹ Taken together, these developments indicated that the world of toxic harms was far more extensive than previously understood, leading civil servants and agency scientists, prodded by a growing cadre of industry experts, to push for more quantitative approaches to risk as a pragmatic way forward in the face of challenging statutory mandates.⁷⁰

It is tempting to view this formalization of risk assessment as part of EPA's response to the new "public interest" model of administrative law that Richard Stewart described in the 1970s.⁷¹ In this interpretation, the move from New Deal inspired visions of expertise to a more de-personalized and disciplined approach to environmental decision-making reflected the strongly felt need by agencies such as EPA to insulate themselves from a diverse and increasingly adversarial mix of interest groups.⁷² Surely there is truth in this assessment, as EPA was clearly subjected to deepening public mistrust starting in the latter half of the 1970s and was looking for ways to restore its credibility by appealing to more objective procedures.⁷³ But the embrace of formal risk assessment was also the product of a systematic campaign pursued by certain segments of the

67. Boyd, *supra* note 11, at 944–47.

68. By the early 1970s, advances in gas chromatograph mass spectrometry allowed for the detection of trace organic compounds and other hazardous substances in the environment in the low parts per billion range, several orders of magnitude below what had been possible only a decade earlier. *Id.* at 944–45.

69. *Id.* at 944; see also L. A. Beyer et al., *Historical Perspective on the Use of Animal Bioassays to Predict Carcinogenicity: Evolution in Design and Recognition of Utility*, 41 *CRITICAL REV. TOXICOLOGY* 321 (2011).

70. Boyd, *supra* note 11, at 965–71 (discussing early efforts at FDA to develop quantitative risk assessment for DES residues in food and at EPA to develop quantitative risk assessment for vinyl chloride emissions under section 112 of the Clean Air Act). As Peter Hutt, former Chief Counsel to the FDA, observed in 1985: "When FDA entered the 1970s, the Agency believed that it was feasible to eliminate virtually all carcinogens from the food supply. By the end of the 1970s, the Agency had indisputable proof that it [was] impossible. Thus, it became essential to adjust regulatory policy to accommodate this new scientific information." Peter Hutt, *Use of Quantitative Risk Assessment in Regulatory Decisionmaking under Federal Health and Safety Statutes*, in *RISK QUANTITATION & REGULATORY POLICY* 24–25 (David G. Hoel et al. eds., 1985).

71. See Richard B. Stewart, *The Reformation of American Administrative Law*, 88 *HARV. L. REV.* 1667 (1975).

72. *Id.*

73. See *infra* Part II.B.

business community and the gathering strength of an anti-administrative jurisprudence in the federal courts.⁷⁴

According to its proponents, the formalization of risk assessment offered a decision framework in which various environmental risks could be quantified, reduced to some common metric, and compared as a basis for establishing agency priorities and allocating scarce regulatory resources.⁷⁵ “Delegation to formula,” to use Theodore Lowi’s phrase, promised to cabin the subjectivity inherent in expert judgment and replace it with a more rule-governed rationality.⁷⁶

Seen in this way, risk assessment was the handmaiden of cost-benefit analysis—the ostensibly scientific half of what Doug Kysar has called “the risk assessment-and-cost-benefit-analysis paradigm.”⁷⁷ But while cost-benefit analysis has received a great deal of critical attention from environmental law scholars and others in related fields, risk assessment has received less scrutiny.⁷⁸ Part of the argument of this Article is that the prior work of risk assessment in determining how particular hazards or harms get selected, defined, and quantified as risks has as much or more influence on regulatory outcomes as cost-benefit balancing. Put simply, risk assessment creates many of the facts that serve as inputs for cost-benefit analysis and thus deserves its own critical evaluation.

Indeed, risk assessment’s role in fact-making has had profound implications for environmental law. Simple hazard-based triggers combined with safety factors to account for uncertainty have been subsumed by elaborate, multi-step procedures using sophisticated models and techniques that seek to quantify the risks associated with uneven exposures across vast populations. Massive resources, whether measured in staff time, agency budgets, or the proliferation of internal and external guidance, have been dedicated to the effort. This has precipitated a radical opening of agency practice through outsourcing,

74. See William Boyd, *With Regard for Persons*, 86 *LAW & CONTEMP. PROBS.* 101, 118-19 (2023) (discussing role of chemical industry and its allies in promoting risk assessment); *infra* Parts II.A and II.B (detailing various interventions by industry to promote risk assessment); see also Gilian Metzger, *1930s Redux: The Administrative State Under Siege*, 131 *HARV. L. REV.* 1, 78-85 (2017).

75. See *infra* Parts II.B and II.D; see also GIL EYAL, *THE CRISIS OF EXPERTISE* 115-118 (2019) (discussing mechanical objectivity).

76. See Theodore J. Lowi, *The State in Political Science: How We Become What We Study*, 86 *AM. POL. SCI. REV.* 1, 5 (1992) (“The rise of economics as the language of the state parallels the decline of Congress as a creative legislature. . . . Policymaking powers are delegated less to the agency and more to the decisionmaking formulas residing in the agency.”); see also Erickson et al., *supra* note 59.

77. See KYSAR, *supra* note 51, at 71; see also *id.* at 16-17 (describing risk assessment and cost-benefit analysis as “foundational elements of the economic approach to environmental law and policy”).

78. See, e.g., Myra Karstadt, *Quantitative Risk Assessment: Qualms and Questions*, 8 *TERATOGENESIS, CARCINOGENESIS, & MUTAGENESIS* 137, 137 (1988) (“Since the late 1970s, quantitative risk assessment has come to play a leading role in regulation of carcinogenic chemicals in the United States. Its methodology, utilization, and flaws have received little public scrutiny, despite its impact on regulatory decision-making.”).

peer review, and involvement of various expert communities in the development and evaluation of the overall framework for risk assessment as well as the results of individual risk assessment exercises.⁷⁹

But the ongoing diminishment of earlier commitments to expert judgment in favor of a more formal, rule-governed rationality has not succeeded in reducing the intense political conflict over environmental risks. If anything, the widespread embrace of formal risk assessment has worked to displace politics into a series of highly technical debates over the tools, techniques, and methods used to generate facts for decisionmaking. As we will see, while quantitative risk assessment has often been presented as an effort to mobilize science in the service of regulation, in practice it has operated more as a disciplinary technique to control regulatory agencies and delay regulation.

II. FORMALIZING RISK, DISCIPLINING GOVERNMENT: THE RISE OF QUANTITATIVE RISK ASSESSMENT

In 1983, William Ruckelshaus returned to EPA to repair an Agency that had been badly damaged by President Reagan's first EPA Administrator, Anne Gorsuch.⁸⁰ 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.⁸¹ When he came back to

79. See discussion *infra* Part IV.A.

80. Gorsuch came to Washington at the beginning of Reagan's first term as part of the so-called Colorado mafia (the other two members were Interior Secretary James Watt and Bureau of Land Management Director Bob Burford). Working from an ideological script crafted by their political mentor and patron, Joseph Coors, the Colorado mafia pursued a vigorous and open attack on environmental regulation and the protection of public lands. See William E. Schmidt, *The 'Colorado Mafia' Puts Its Stamp on the Government*, N.Y. TIMES, Sept. 6, 1981, at E5. For her part, Gorsuch sought to reduce EPA's budget and staffing by some thirty percent and to roll back regulations across the Agency's programs. A front-page *Washington Post* article described her agenda in 1981:

Budget cuts at the Environmental Protection Agency will strip 3,200 personnel of their jobs by the end of 1983, eliminating 30 percent of the agency's 10,380 employees at a cost of \$17.6 million just for severance pay. The cuts are so massive that they could mean a basic retreat on all the environmental programs of the past 10 years, according to agency sources and administration critics. At the same time, divisions between Administrator Anne M. Gorsuch and career agency staff over her approach to policymaking have all but reached open warfare.

See Joanne Omang, *Internal Rifts, Huge Staff Cut Hint EPA Retreat on Programs*, WASH. POST, Sept. 30, 1981, at A1.

81. The Saturday night massacre refers to President Nixon's efforts to force Justice Department officials to fire independent counsel Archibald Cox, who had issued a subpoena for White House tapes as part of his investigation of the Watergate burglary and other related activities. Nixon first directed Attorney General Elliot Richardson to fire Cox. Richardson refused and resigned. Nixon then ordered Ruckelshaus, who had recently

the Agency in 1983, his immediate task was to deal with the fallout from Gorsuch's efforts to slash budgets and staffing and roll back regulations.⁸² But Ruckelshaus also had to contend with a very different external political environment and a vastly expanded set of statutory responsibilities. By the early 1980s, the Agency faced a daunting set of new challenges, particularly with respect to toxic chemicals and hazardous waste.⁸³ Compared to reducing gross insults to air and water, these problems were far more complex and dealing with them seemed to call for a new approach to environmental decision-making.⁸⁴

For Ruckelshaus, formal risk assessment provided a way forward. In a speech delivered at Princeton in February 1984, he made the point directly:

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 [that].⁸⁵

Better risk assessments, in Ruckelshaus's view, would bolster the Agency's credibility with critics on the left and the right while also providing a set of tools and a framework for decision-making that would allow EPA to bring order and efficiency to its expanding set of responsibilities.⁸⁶ In embracing risk assessment, he was able to capitalize on a consensus that had been building since the late 1970s across government, industry, and the science policy establishment to use risk assessment as a means for putting environmental decision-making on more objective foundations. The overarching goal, as Ruckelshaus noted in a

taken over the job of Deputy Attorney General, to fire Cox. Ruckelshaus refused and resigned. Nixon then turned to Solicitor General Robert Bork, who dismissed Cox. See Carroll Kilpatrick, *President Abolishes Prosecutor's Office; FBI Seals Records*, WASH. POST, Oct. 21, 1973, at A1.

82. See Omang, *supra* note 80 (describing budget and staffing cuts). Gorsuch was the subject of a Congressional investigation on the mismanagement of Superfund money and, after refusing to turn over documents, was cited for contempt of Congress (the first Agency head ever to be so cited). In 1983, she resigned from EPA under considerable pressure; David Burnham, *2 High Officials of EPA Resign, Reportedly at White House Urging*, N. Y. TIMES, Feb 24, 1983, at B-14.
83. See, e.g., Al Alm, *Why We Didn't Use "Risk" Before*, 17 *EPA J.* 13, 15 (1991) (discussing impact of new hazardous waste programs, particularly after the 1984 RCRA reauthorization, on EPA budgets and priorities and move to risk-based decision making).
84. *Id.* at 13 ("The term 'risk' was rarely used during EPA's formative years. In the early 1970s, the public, Congress, and EPA were primarily focused on curbing the damages from gross air and water pollution. . . . However, as the agency began to deal with an onslaught of chemical contamination problems—Kepone in the James River, mercury in the Great Lakes, and PCBs almost everywhere—it became clear that a new decision-making process was necessary.").
85. William D. Ruckelshaus, EPA Adm'r, *Risk in a Free Society: A Reservoir of Trust*, Speech Delivered at Princeton University (Feb. 18, 1984), in 50 *VITAL SPEECHES OF THE DAY* 354, 354 (1984).
86. *Id.*

1983 speech to the National Academy of Sciences, was “to help achieve a better conceptual, statutory, and societal framework to cope with risk in our country.”⁸⁷ “What I’m after,” he continued, “is a government-wide process for assessing and managing health, safety, and environmental risks.”⁸⁸

To be sure, Ruckelshaus recognized that risk assessment had limits. He knew that any risk assessment exercise inevitably involved policy choices.⁸⁹ He also understood that uncertainty plagued virtually all efforts to assess the risks of low-level exposures to toxic substances, and he knew that this uncertainty provided a point of leverage for those opposed to regulation.⁹⁰ But he also needed a defensible approach to regulation, and risk assessment appeared to provide a coherent framework for decision-making in the face of the technical complexity and political challenges that came with a whole new class of environmental harms. The older normative commitments of precaution, endangerment, and safety that had informed so much of the expansive environmental law-making moment of the early 1970s seemed overbroad and imprecise in the face of new threats from minute quantities of toxic substances in air, water, and food.⁹¹

Ruckelshaus’s embrace of risk assessment thus seems to have been born as much from a sense of political crisis as from a conviction that regulatory decisions could be placed on more objective foundations.⁹² He knew that it would be difficult and challenging for the Agency to get it right, and that this would

87. William D. Ruckelshaus, EPA Adm’r, *Science, Risk, and Public Policy: Our Laws Must Reflect Scientific Realities*, Speech Delivered at the National Academy of Sciences, Washington D.C. (June 22, 1983), in 49 VITAL SPEECHES OF THE DAY 612, 615 (1983).

88. *Id.*

89. See Ruckelshaus, *supra* note 85, at 355 (“[W]e have found that separating the assessment of risk from its management is rather more difficult to accomplish in practice. In the first place, values, which are supposed to be safely sequestered in risk management, also appear as important influences on the outcomes of risk assessments.”).

90. *Id.* (noting that the “uncertainties inherent in risk assessment combine to produce an enormously wide range of risk estimates in most cases”).

91. See William D. Ruckelshaus, *Putting the Environmental Issue in Perspective*, 10 EPA J. 12, 14 (1984) (discussing significant reductions in air and water pollution since 1970 and observing that “dealing with toxics, either as products, emissions, or leakage from waste dumps, puts us in a very different sort of business. Instead of being able to speak of allowable doses and adequate margins of safety we now must speak in terms of risk.”).

92. See, e.g., William D. Ruckelshaus, *Risk, Science, and Democracy*, 1 ISSUES IN SCI. & TECH. 19, 27 (1985) (“[T]here appears to be no substitute for risk assessment, in that some sort of risk finding is what tells us that there is any basis for regulatory action in the first place. The alternative to not performing risk assessment is to adopt a policy of either reducing all *potentially* toxic emissions to the greatest degree technology allows (of which more later) or banning all substances for which there is any evidence of harmful effect, a policy that no technological society could long survive. Beyond that, risk assessment is an irreplaceable tool for setting priorities among the tens of thousands of substances that could be subjects of control actions—substances that vary enormously in their apparent potential for causing disease. In my view, therefore, we must use and improve risk assessment with full recognition of its current shortcomings.”).

require a much more forthright engagement with the assumptions and complexities of risk assessment. In his speech at Princeton, he made the point explicit: “We have to expose the assumptions that go into risk assessment. We have to admit our uncertainties and confront the public with the complex nature of decisions about risk.”⁹³

Notwithstanding his recognition of these challenges, however, history has shown that Ruckelshaus was far too optimistic about the ease with which EPA could operationalize risk assessment across its programs. He also overestimated the potential for public engagement on risk assessment, something that he felt was critical to the success of the enterprise.⁹⁴ Perhaps most importantly, he did not grasp the challenges of controlling the broader analytical demands that came with risk assessment, the implications of this for EPA’s mission, and the ways in which industry would use the increasingly elaborate procedures of risk assessment to delay regulation.⁹⁵

Indeed, once set in motion, formal risk assessment seemed to take on a life of its own—unleashing a profound shift in the knowledge practices that underwrote EPA’s regulatory programs. Rather than acting on visible and widespread evidence of gross insults to the environment, as was the case with early efforts to reduce air and water pollution, EPA was now in the business of trying to predict future harms from toxic substances, often at very low levels of exposure, based on incomplete understanding of the basic biological mechanisms that might produce harm and across a wide range of circumstances and possible exposure pathways.⁹⁶ This was most evident in efforts to regulate pesticides, industrial chemicals, and hazardous wastes but it also became an increasingly prominent part of efforts to regulate toxic pollutants in air and water and even in more standard programs such as the National Ambient Air Quality Standards (“NAAQS”).

93. William D. Ruckelshaus, *supra* note 85, at 356.

94. *Id.* at 355 (“I now believe that the main road out of [the quandary of balancing risks and benefits] lies through a marked improvement in the way we communicate the realities of risk analysis to the public. The goal is public understanding. We will only retain the administrative flexibility we need to effectively protect the public health and welfare if the public believes we are trying to act in the public interest.”).

95. *See infra* Part IV.A.

96. *Cf.* Ruckelshaus, *supra* note 92, at 20 (“During the past 15 years, there has been a shift in public emphasis from visible and demonstrable problems, such as smog from automobiles and raw sewage, to potential and largely invisible problems, such as the effects of low concentrations of toxic pollutants on human health. This shift is notable for two reasons. First, it has changed the way in which science is applied to practical questions of public health protection and environmental regulation. Second, it has raised difficult questions as to how to manage chronic risks within the context of free and democratic institutions. People are afraid of these environmental risks, and fearful people have too often traded freedom for the promise of security. Our current efforts to control environmental pollution represent, in a sense, an attempt by society to deal with this immense issue of environmental risk.”).

It is important to recognize here that while the move to quantitative risk assessment may have reflected deeply held commitments to improved environmental decision-making on the part of many of its proponents, it also grew out of a sophisticated effort by the petroleum and chemical industries (among others) to reshape environmental regulation. This effort moved into high gear during the mid 1970s, with intense lobbying over the Toxic Substances Control Act—an effort that transformed earlier, more precautionary legislative proposals into a complex, procedurally burdensome statute that made it all but impossible for EPA to regulate industrial chemicals effectively.⁹⁷ But perhaps the most consequential effort involved the formation of a new coalition of businesses and industry trade associations operating through the newly formed American Industrial Health Council (AIHC) to oppose OSHA's efforts to establish a generic cancer policy that would allow it to move quickly to regulate carcinogens in the workplace without having to do detailed risk assessments.⁹⁸

As envisioned, OSHA's generic cancer policy dispensed with elaborate, time-consuming chemical-by-chemical approaches to carcinogens in the workplace in favor of simple hazard-based triggers that would result in automatic regulations if there was evidence that the substance in question caused cancer

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97. See, e.g., *Senate Consideration of Conference Report on Toxic Substances Control Act*, 1 LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT: TOGETHER WITH A SECTION-BY-SECTION INDEX 722, 736 (1976) (statement of Sen. Durkin) (discussing intensive lobbying effort by petrochemical industry to “prevent enactment of meaningful toxic substance control legislation”); *id.* at 210 (statement of Sen. Tunney) (“I must say that I have never seen such an effective lobbying effort as was done against this legislation.”); *id.* at 208 (statement of Sen. Tunney) (“[W]hile the record of chemical dangers continues to grow, segments of the chemical industry have presented roadblocks at every juncture of the bill’s development. There is no question in my mind that a statute would now be on the books providing effective protection against chemical hazards had it not been for the concerted effort of certain segments of the chemical industry to gut essential provisions of this legislation.”); *id.* at 219 (introducing into the record a letter from Dow Chemical urging “the broadest and strongest possible grass roots political action campaign in opposition to Toxic Substances legislation”).
98. See *Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk*, 42 Fed. Reg. 54148, 54149 (Oct. 4, 1977) [hereinafter OSHA Generic Cancer Policy]. 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. BOWER, *supra* note 33, 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: INTL. 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 founded in 1977 by several major trade associations, to deal with OSHA’s developing cancer policy.”); Boyd, *supra* note 74, at 107-11 (discussing development of OSHA’s Generic Cancer Policy and industry response).

in animals or humans.⁹⁹ Given that OSHA had only been able to complete four rulemakings in the health area during its first six years and given the presence of thousands of chemicals in the workplace, hundreds of which might be carcinogenic, OSHA needed a creative and workable solution that would allow it to move quickly to protect American workers.¹⁰⁰

The stakes were high. At the same time that OSHA was developing its generic cancer policy, EPA, FDA, and the CPSC were also actively engaged in the development of principles and approaches for regulating carcinogens.¹⁰¹ If OSHA's generic cancer policy succeeded, other agencies might also adopt simple, hazard-based approaches that would allow them to regulate quickly.¹⁰²

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99. 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 OSHA Generic Cancer Policy, *supra* note 98, at 54148.
100. See OSHA Generic Cancer Policy, *supra* note 98, at 54149 (noting four completed rulemakings on health standards in OSHA's six-year history); see also *Performance of the Occupational Safety and Health Admin., Hearing Before the 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." A 1976 report by the National Institute for Occupational Safety and Health (NIOSH) identified 2,415 substances as potential carcinogens. See DEP'T OF HEALTH, EDUC., & WELFARE, SUSPECTED CARCINOGENS: A SUBFILE OF THE NIOSH REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES ix (2nd ed., 1976).
101. EPA, for example, developed a set of interim guidelines and procedures for assessing cancer risk in the mid 1970s in an effort to bring some order to its expanding set of responsibilities under multiple statutes. See Health Risk and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21402 (May 25, 1976). In 1977, EPA, OSHA, FDA, and the CPSC formed an Interagency Regulatory Liaison Group ("IRLG") to develop common principles and guidelines for assessing cancer risk. See, e.g., Interagency Regulatory Liaison Group, Work Group on Risk Assessment, *Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks*, 63 J. NAT'L CANCER INST. 241, 245 (1979).
102. See, e.g., EPA, National Emission Standards for Hazardous Air Pollutants; Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer, 44 Fed. Reg. 58642, 58642 (proposed Oct. 10, 1979) (proposing to use available information to determine if an airborne pollutant presented a significant risk of cancer, which would then trigger generic controls for source categories to achieve rapid control of emissions, which could then be adjusted pending additional analysis). At the time of the proposed new policy, EPA had listed only three air pollutants as carcinogens under section 112 of the Clean Air Act. *Id.* at 58645. Given the large number of potential airborne carcinogens and the general lack of epidemiological data for determining carcinogenicity and potential risks, the agency proposed to take a generic approach that would allow it to move quickly to regulate potential carcinogens. *Id.* at 58642. The proposed new rule called for the administrator of EPA to make a judgment regarding significant risk and therefore appropriate for listing

As Monte Throdahl, senior Vice President at Monsanto and a leading figure in the AIHC, stated in 1978, OSHA's generic cancer policy and the broader effort to regulate carcinogens across the federal government was "the most important regulatory issue that has ever come down the pike" for the chemical industry.¹⁰³ In the view of Throdahl and other industry advocates, quantitative risk assessment offered a strong "science-based" alternative to the simple hazard-based approach that OSHA was developing—a tool to discipline decision-making and constrain the ability of agencies to devise creative solutions to pressing problems.¹⁰⁴ The science policy establishment, operating through the National Research Council and various National Academy of Sciences committees was an active partner in much of this effort, as was the Supreme Court.¹⁰⁵

A. Hard Looks and Regulatory Reform

In many respects, the Supreme Court's famous 1980 decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute* (known as the *Benzene* decision), represented the most dramatic break with the past.¹⁰⁶ In that case, a plurality of the Supreme Court rejected OSHA's benzene standard and imposed a new threshold requirement that OSHA make a finding of "significant risk" before establishing any such standard.¹⁰⁷ The decision brought an end

and regulation under section 112 based on evidence that the substance in question had a high probability of human carcinogenicity and evidence of significant public exposure via the ambient air. *Id.* at 58647–48. Quantitative assessments of risk would be treated as "supplementary evidence" that could be used to list a pollutant but that could not serve as the basis for a decision not to list a pollutant. *Id.* at 58648. As EPA noted, "quantitative estimates are too imprecise and uncertain to use as a factor in deciding *not* to list a substance." *Id.*

103. See BOWER, *supra* note 33, at 2 (quoting Throdahl). 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).
104. AM. INDUS. HEALTH COUNCIL, 1980 REPORT TO THE MEMBERSHIP 9–13 (1980) (discussing efforts by various AIHC agency task forces to advocate for quantitative risk assessment of carcinogens); AM. INDUS. HEALTH COUNCIL, *A COMMITMENT TO SOUND SCIENCE IN THE DEVELOPMENT OF NATIONAL CHRONIC HEALTH HAZARDS POLICY* 3 (1980) (discussing AIHC's efforts to contest "generic carcinogen" rulemaking efforts at OSHA, EPA, CPSC, and FDA and to advocate instead for "the best and most cost-effective alternatives based on scientific determination of carcinogenic risk"); see also *id.* ("With further encouragement from the scientific community and the public, AIHC continues to promote the need for applications of sound science to *all* regulatory decision-making."); Moolenaar, *supra* note 33.
105. See *infra* Parts II.A and II.B.
106. *Benzene Decision*, at 628.
107. *Id.* at 614–15, 639; 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"). For a detailed history of OSHA's efforts to regulate benzene and the litigation that followed, see Rachel Rothschild, *Juristocracy and*

to OSHA's efforts to develop a generic cancer policy that would have allowed it to move quickly in the face of uncertain harms and was generally viewed as strongly endorsing if not requiring quantitative risk assessment as a basis for regulation.¹⁰⁸

The significance of the *Benzene* decision has been widely attested to, but it did not, as some have suggested, initiate the move to quantitative risk assessment; efforts had already been underway at both FDA and EPA since the mid-1970s to develop quantitative approaches to risk.¹⁰⁹ What the decision did do, however, was to give these efforts a substantial boost and to endow the entire enterprise with a legitimacy and urgency that it had not previously enjoyed.¹¹⁰ In doing so, it unleashed efforts across the different agencies to formalize risk assessment as a key element of health, safety, and environmental decision-making. As such it fit within broader currents of regulatory reform and the professionalization of risk

Administrative Governance: From Benzene to Climate (U. Michigan Pub. L. Rsch. Paper No. 24-008), <https://ssrn.com/abstract=4602927>.

108. See Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. 54148 (Oct. 4, 1977) (OSHA proposed its Generic Cancer Policy in 1977.) The basic objective was to streamline the assessment of carcinogen risks in the workplace: if there was evidence that the substance in question induced cancer in animals or humans, OSHA would set the Permissible Exposure Limit ("PEL") at the lowest feasible level.; See Boyd, *supra* note 11, at 962–63 (discussing OSHA's generic cancer policy); see Matthew D. Adler, *Against "Individual Risk": A Sympathetic Critique of Risk Assessment*, 153 U. PENN. L. REV. 1121, 1127 (2005) (observing that the *Benzene* decision, "more than any other single event, triggered the rapid growth of risk assessment in the federal government"); On the significance of the *Benzene* decision, generally, see Thomas O. McGarity, *The Story of Benzene: Judicially Imposed Regulatory Reform Through Risk Assessment in ENV'T LAW STORIES* 141 (Richard J. Lazarus & Oliver A. Houck eds., 2005).
109. See, e.g., Gail Charnley and E. Donald Elliott, *Risk versus Precaution: Environmental Law and Public Health Protection*, 32 ELR 10363 (2002) ("The preeminent role of risk assessment in U.S. regulation emerged from the U.S. Supreme Court's decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, commonly known as the *Benzene* decision, which established the requirement for factual support in the administrative record for deciding that a risk to health is 'significant' enough to merit regulation. In practice, the record-building requirement has traditionally been satisfied by quantitative risk assessment."); see also Boyd, *supra* note 11, at 965–71 (recounting history of pre-*Benzene* efforts to use quantitative risk assessment and arguing that these early efforts were driven in part by the challenge of finding defensible ways to discharge aggressive statutory responsibilities under the Delaney Clause (FDA) and section 112 of the Clean Air Act (EPA) in the face of a much more complex world of environmental harms that had been brought into view by the revolution in measurement and analytical techniques that transpired during the 1960s and 1970s); Arnold M. Kuzmack and Robert E. McGaughy, *Quantitative Risk Assessment for Community Exposure to Vinyl Chloride* (EPA, 1975); Christopher Schroeder, *Foreword: A Decade of Change in Regulating the Chemical Industry*, 46 L. & CONTEMP. PROBS. 1, 31–32 (1983) (discussing EPA's efforts to regulate vinyl chloride under section 112).
110. See Richard A. Merrill, *The Red Book in Historical Context*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT: INT'L J. 1119, 1122 (2003) (concluding that the *Benzene* decision "did not merely legitimate, it effectively mandated the use of risk assessment by regulatory agencies").

analysis aimed at disciplining wayward agencies by putting decision-making on more objective grounds.

In the wake of the decision, OSHA largely abandoned its effort to move swiftly to regulate carcinogens in the workplace in favor of a more systematic and resource intensive focus on quantitative risk assessment for particular chemicals and the determination of significant risk before embarking on major standard setting efforts.¹¹¹ Likewise, FDA and EPA both took careful note of the decision and began to frame their efforts in terms of “significant” risk, making detailed quantitative assessments a key part of their decision-making.¹¹²

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.¹¹³ Going forward, workers would bear the burden of uncertainty while OSHA worked to assess the risks of individual chemicals, as Justice Marshall noted in dissent.¹¹⁴ Indeed, after the decision, OSHA spent the better part of a decade gathering additional evidence and performing quantitative risk assessments for benzene, coming back with the same proposed 1ppm standard in 1987 that it had first proposed ten years earlier.¹¹⁵ This time, however, industry did not even contest

111. 52 Fed. Reg. 34490 (Sept. 11, 1987) (discussing use of quantitative risk assessment in rulemakings for benzene, arsenic, ethylene dibromide, ethylene oxide, and asbestos).

112. See Joseph V. Rodricks et al., *Significant Risk Decisions in Federal Regulatory Agencies*, 7 REGUL. TOXICOLOGY & PHARMACOLOGY 307, 307–308 (1987) (discussing efforts by FDA, EPA, and OSHA to define “significant” risk thresholds in their efforts to regulate carcinogens).

113. See American Industrial Health Council, *AIHC Recommended Alternatives to OSHA’s Generic Carcinogen Proposal*, OSHA Docket No. H-090 at 14 (Feb. 24, 1978) (arguing that OSHA should perform a “complete risk assessment” for individual chemical substances as a basis for individual rulemakings); *id.* at 17–18 (arguing that OSHA’s generic cancer policy was based on “the illusion of a no-risk society” and arguing that “[e]ven in an emotional context such as cancer, sound public policy must take into account the inevitability of some risk, and the necessity of evaluating such risk not only against alternative risk but also in light of the benefits of the substance being regulated.”). Joseph V. Rodricks, *When Risk Assessment Came to Washington: A Look Back*, 17 DOSE-RESPONSE: INTL J. 1, 6 (2019) (“Perhaps the most important voice for industry during this time was that of the American Industrial Health Council, a group founded in 1977 by several major trade associations, to deal with OSHA’s developing cancer policy.”).

114. *Benzene Decision*, at 690 (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”).

115. 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

the proposed standard.¹¹⁶ 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.¹¹⁷

Benzene was thus much more than an effort by the Supreme Court to bring a wayward agency into the mainstream of regulatory thought.¹¹⁸ 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 and the DC Circuit and other appellate courts in their efforts to develop a normative framework for health, safety, and environmental regulation.¹¹⁹ 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.¹²⁰

and provided a firm basis for concluding that the risk was significant and that the standard should be strengthened).

116. *Id.* at 34463 (“No major party challenged OSHA’s decision to reduce exposures from 10 ppm.”)
117. 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, 1399–400 (1988) (reporting estimates of excess deaths); Peter F. Infante, *Benzene: An Historical Perspective on the American and European Occupational Setting*, in LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896–2000, 41 (Harremoës et al. eds., European Environment Agency, 2001) (same). Infante and DiStasio both worked at OSHA. These estimates did not include excess deaths from other blood disorders or non-Hodgkins lymphomas. *Id.*; *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 PERSP. 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 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).
118. *Cf.* McGarity, *supra* note 108, 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.”).
119. *See* Boyd, *supra* note 11, at 954–63 (discussing these efforts).
120. *Cf. Benzene Decision*, at 695–96 (Marshall J. dissenting); *see also id.* at 695 n. 9 (“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.”).

Benzene is also important in the current moment. Although it predates *Chevron*, the *Benzene* decision articulated a proto version of the so-called major questions doctrine and can be seen as an important early example of the Supreme Court's anti-administrative jurisprudence.¹²¹ And in this respect, as Justice Stevens noted in his plurality opinion, it was OSHA's generic cancer policy rather than the benzene standard itself that was the key source of concern:

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. Expert testimony that a substance is probably a human carcinogen—either because it has caused cancer in animals or because individuals have contracted cancer following extremely high exposures—would justify the conclusion that the substance poses some risk of serious harm no matter how minute the exposure and no matter how many experts testified that they regarded the risk as insignificant. That conclusion would in turn justify pervasive regulation limited only by the constraint of feasibility. In light of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspected carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit.¹²²

As Justice Stevens went on to observe in a footnote: “OSHA's proposed generic cancer policy indicates that this possibility is not merely hypothetical.”¹²³ Thus, despite multiple opinions 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.¹²⁴ In the words of then Professor Antonin Scalia, “the most noteworthy feature of the *Benzene* decision [was] its application of judicial

121. See, e.g., Blake Emerson, *Administrative Answers to Major Questions: On the Democratic Legitimacy of Agency Statutory Interpretation*, 123 MINN. L. R. 2019, 2044 (2018) (“The Benzene Case provides the clearest precedent for the major questions doctrine, and links it definitively to the nondelegation doctrine.”). *Utility Air Regulatory Group (“UARG”) v. Environmental Protection 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’ (citing *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)); Lisa Heinzerling, *The Power Canons*, 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).

122. *Benzene Decision*, at 645.

123. *Id.* at 645 n.51.

124. 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.”).

activism in a new direction—to reduce, rather than augment, health and safety regulatory impositions upon the private sector.¹²⁵ 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 and *West Virginia v. EPA, Benzene* can thus be read as a forerunner of conservative efforts to use the federal courts to diminish the regulatory state.¹²⁶ Put bluntly, if one wants to see what the future looks like for regulatory agencies in a world where the Court has embraced a muscular version of the major questions doctrine, OSHA after *Benzene* offers a sobering lesson.¹²⁷

It is no surprise, moreover, that the *Benzene* decision came in the midst of an ongoing push to constrain and reduce regulation across the government.¹²⁸ Although the basic agenda for these “regulatory reform” efforts had been taking shape for some time (the first tangible steps were taken during the Carter Administration), they moved into high gear during President Reagan’s first term.¹²⁹ President Reagan’s appointments to lead key agencies thus embraced

125. *Id.* at 26–27.

126. See, e.g., *Nat’l Fed’n of Indep. Bus. V. Dep’t of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109, 125 (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 A. Scalia, *A Note on the Benzene Case*, AM. ENTER. INST. J. ON GOVT. & SOC., July–Aug. 1980 p. 27); see also *West Virginia v. EPA*, 597 U.S. __ (2022) (Gorsuch, J., concurring) slip op at 7 (“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 the *Benzene* plurality decision).

127. See 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 in the late 1970s and the ensuing backlash during the Reagan administration); Jim Morris, *How Politics Gutted Workplace Safety*, Slate (July 7, 2015), <https://perma.cc/3NYL-558Q> (discussing OSHA’s challenges since the 1980s to discharge its responsibility to protect American workers from toxic substances).

128. The impetus for regulatory reform was apparent in several of the Justice’s opinions. Chief Justice Burger, for example, concluded in his concurring opinion 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.” *Benzene Decision*, at 664 (Burger, J., concurring). Justice Powell likewise spoke of “rational system[s] of regulation.” *Id.* at 670 (Powell, J., concurring in part and concurring in the judgment). On the broader concerns with inflation and economic growth and how this impacted the reception of OSHA’s generic cancer policy, see Boyd, *supra* note 74, at 105–07.

129. See Thomas O. McGarity, *Regulatory Reform in the Reagan Era*, 45 MD. L. REV. 253, 261 (1986) (discussing Reagan task force and history of regulatory reform efforts during Reagan administration). But as Theodore Lowi pointed out in the late 1980s: “Contrary to the expectations of most people, there was more real deregulation in the four years of the Carter administration than in the [first] six years of the Reagan administration[.] . . . President Reagan has not once confronted Congress with requests for legislation actually terminating

a very different view of regulation. In some cases, such as Reagan's first EPA administrator Anne Gorsuch, the result was overt hostility to the regulatory enterprise itself.¹³⁰ But in others, there was a strong undercurrent of managerialism at work, with the overall goal of constraining and disciplining government.¹³¹

There was also a concerted effort during this time to professionalize the practice of risk assessment.¹³² In 1980, 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.¹³³ The National Science Foundation and the National Academy of Sciences also developed formal programs during the 1980s dedicated to improving risk assessment and risk management with more systematic attention to its connections to decision theory and management science.¹³⁴ Going forward, in fact, the National Academy played a critical role in legitimating quantitative risk assessment as the default approach to harm across the federal government.

any regulatory authority. . . . Instead, the Reagan administration has sought and has taken on significant increases in managerial power. President Reagan has sought to use this managerial power . . . not by terminating or shrinking any of the authority now held in the executive branch, but by retaining the power and using it to control the agencies so as to reduce or delay the output of rules." Theodore J. Lowi, *Two Roads to Serfdom: Liberalism, Conservatism, and Administrative Power*, 36 AM. U. L. REV. 295, 311–12 (1987).

130. See, e.g., David L. Noll, *Administrative Sabotage*, 120 MICH. L. REV. 753, 760 (2022).

131. To take one example, Thorne Auchter, head of OSHA under President Reagan, worked to dismantle much of what the previous administration had done. In doing so, he offered an explicit endorsement of a more systems-oriented approach to management. "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 implementor of management systems. I don't feel that rules are a measure of success for an agency." R. Jeffrey Smith, *OSHA Shifts Direction on Health Standards*, 212 SCI. 1482, 1482 (1981); see also Boyd, *supra* note 74, at 101-02, 113-14 (discussing Auchter and his embrace of managerialism at OSHA in the early 1980s).

132. See, e.g., K.M. Thompson et al., *Interdisciplinary Vision: The First 25 Years of the Society for Risk Analysis (SRA), 1980–2005*, 25 RISK ANALYSIS 1333, 1334–36 (2005) (discussing history of risk assessment during late 1970s and early 1980s and the growing number of risk professionals).

133. *Id.* at 1337–43 (discussing establishment of the Society for Risk Analysis).

134. See, e.g., Dominic Golding, *A Social and Programmatic History of Risk Research*, in SOCIAL THEORIES OF RISK 26–34 (Krimsky and Golding eds., 1992) (discussing various National Science Foundation and National Academy of Sciences programs supporting risk research). As discussed *infra* Part II.B, the most important early intervention by the National Academy of Sciences was the National Research Council's 1983 report on risk assessment in the Federal government or what came to be known as the Red Book. See, e.g., COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS, *supra* note 12.

All of these efforts drew sustenance from *Benzene* and the ethos of managerialism that had been gaining traction across the government.¹³⁵ In addition to rationalizing risk assessment, the goal was to cultivate a carrier class of professionals who would spread these new techniques across the government and the broader policy community.¹³⁶ The overall effect was a decisive move away from earlier visions of expert judgment toward a more constrained and disciplined approach to decision-making. Reasoned deliberation and judgment were being replaced by a more formal, rule-governed rationality. Environmental law was losing its mind.¹³⁷

B. *The Rise of Quantitative Risk Assessment*

Three years after the *Benzene* decision, the National Research Council (“NRC”) issued a landmark report, *Risk Assessment in the Federal Government: Managing the Process*, that 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.¹³⁸ Known informally as the *Red Book* (because of its red cover), the study was launched in response to lobbying by the American Industrial Health Council (“AIHC”) and others seeking to consolidate and extend their victory in the *Benzene* decision.¹³⁹ 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.”¹⁴⁰

135. On risk assessment as an example of regulatory managerialism, see Boyd, *supra* note 74.

136. See, e.g., Thompson et al., *Interdisciplinary Vision: The First 25 Years of the Society for Risk Analysis (SRA), 1980–2005*, *supra* note 132, at 1342.

137. Cf. ERICKSON ET AL., *supra* note 59, at 2 (“Cold War rationality in all its variants was summoned into being in order to tame the terrors of decisions too consequential to be left to human reason alone, traditionally understood as mindful deliberation.”); Theodore J. Lowi, *Two Roads to Serfdom: Liberalism, Conservatism, and Administrative Power*, 36 AM. U. L. REV. 295, 304 (1987) (“The derangement of agency professionalism takes two paradoxical forms. First, substantive specialization and the reputation for professional judgment are displaced by formula decisionmaking, formalistic analysis, and the appearance of theoretical science. Second, law is replaced by economics as the language of the state.”).

138. See generally NAT’L RSCH. COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS*, *supra* note 12. 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 & DECISIONS: ADVANCING RISK ASSESSMENT* (2009), *supra* note 14.

139. *Id.*

140. *Id.* at iii, 1.

To that end, the report strongly endorsed the longstanding AIHC recommendation to separate risk assessment from risk management—a separation that has come to enjoy canonical status in standard approaches to risk ever since.¹⁴¹ 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.¹⁴² 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.”¹⁴³ Although the report acknowledged the important role that policy choices played in various components of risk assessment, it sought to insulate and 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.¹⁴⁴

The NRC framework was quickly adopted by EPA under Ruckelshaus.¹⁴⁵ Hailing the report as “a great service to those of us in the business of protecting public health and the environment,” Ruckelshaus embraced the *Red Book* as a way to make regulatory decision-making “more consistent and rational and, thus, more understandable and acceptable to the American public.”¹⁴⁶ Although Ruckelshaus acknowledged some of the difficulties involved in performing

141. *Id.* at 3 (distinguishing between risk assessment and risk management); *see also* BOWER, *supra* note 33, at 7–8 (discussing AIHC’s advocacy of risk assessment as a separate, scientific exercise); Moolenaar, *supra* note 33, 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); 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 while risk management is principally a *political* activity.”). Park and Snee were both affiliated with the AIHC. *Id.*

142. NAT’L RSCH. COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT*, *supra* note 12, at 3.

143. *Id.* at 3.

144. *Id.*; *see also* John Doull, *The “Red Book” and Other Risk Assessment Milestones*, 9 *HUM. & ECOLOGICAL RISK ASSESSMENT* 1229, 1232 (2003); *see also* 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”).

145. *See, e.g.*, EPA, *RISK ASSESSMENT AND MANAGEMENT: FRAMEWORK FOR DECISION MAKING* (1984) (endorsing the *Red Book* paradigm and providing guidance for implementation at EPA).

146. *See* William S. Ruckelshaus, *Preface to EPA’s RISK ASSESSMENT AND MANAGEMENT: FRAMEWORK FOR DECISION MAKING* (1984) (The Agency would “adopt as many as possible of the report’s risk assessment and risk management goals” and had “initiated a wide range of activities designed to implement Academy recommendations.”).

quantitative risk assessments, he had clearly moved a long way from the more precautionary posture that marked his first tour as the Agency's inaugural administrator in the early 1970s.¹⁴⁷ With the science policy establishment now weighing in firmly on the side of quantitative risk assessment, he had all the support he needed to remake environmental decision-making.

In the view of its proponents, risk assessment would de-politicize the discussion of public health and environmental protection by rendering it in more technical, seemingly neutral terminology, thereby restoring much needed credibility to the Agency's mission. A transparent, multi-step process combined with uniform guidelines for inference choices and defaults to manage uncertainty would, it was hoped, put decision-making on more objective (and, importantly, more defensible) grounds.¹⁴⁸

But risk assessment was also a direct result of industry efforts to define it as an ostensibly scientific exercise and isolate it from the more value-laden exercise of risk management, which in their view meant cost-benefit analysis.¹⁴⁹ In fact, one can trace a direct line from industry efforts to oppose OSHA's generic cancer policy to the *Red Book*. The AIHC's proposal to create a new independent board of scientists unaffiliated with any regulatory agency to carry out all cancer risk assessments, which triggered the debate that led directly to the NRC study that culminated in the *Red Book*, was first advanced in its proposed alternative to OSHA's generic cancer policy.¹⁵⁰ The AIHC also drafted the basic

147. See William D. Ruckelshaus, *Risk in a Free Society*, 4 RISK ANALYSIS 157, 157-58 (1984) ("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.").

148. See, e.g., NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 12, at 3-5 (discussing need for standard guidelines for inference choice).

149. See Am. Indus. Health Council, *AIHC Recommended Alternatives to OSHA's Generic Carcinogen Proposal*, OSHA Docket No. H-090 at 13-15 (Feb. 24, 1978) (available in the UCSF Chemical Industry Documents database at <https://perma.cc/9FSL-YBEW>) (advocating comprehensive risk assessment as a basis for rulemakings to regulate individual chemicals in opposition to OSHA's generic, hazard-based approach); Am. Indus. Health Council, *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."); Moolenaar, *supra* note 33, at 387-88 (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).

150. See Am. Indus. Health Council, *AIHC Recommended Alternatives to OSHA's Generic Carcinogen Proposal*, *supra* note 149 ("Unlike the OSHA proposal, the AIHC alternate would rely upon a scientific body separate from federal regulatory authorities to make the essential scientific judgment or decision as to the appropriate categorization of a particular chemical substance with respect to carcinogenic potential."); see also NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 12, at 132 ("The central proposals for changes in institutional arrangements for risk assessments developed by the office

appropriations language that funded the development of the *Red Book*.¹⁵¹ And the *Red Book* itself contained extensive discussions of various AIHC proposals on risk assessment.¹⁵² By pushing for a strict separation of risk assessment from risk management, industry advocates re-posed questions about harm as scientific questions that could always benefit from more research and more analysis.¹⁵³ This separation, which is treated with some nuance in the *Red Book* itself, has been one of the most profound legacies of the move to quantitative risk assessment.¹⁵⁴

By the end of the 1980s, then, 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 and pesticides, hazardous waste sites, hazardous air pollutants and toxic water pollutants.¹⁵⁵ In an effort to bring consistency to this effort, the Agency established a new Integrated Risk Information System that would serve as a repository for all the relevant studies and data on specific substances.¹⁵⁶ Cross-cutting agency

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.”); Soraya Boudia, *Managing Scientific and Political Uncertainty: Environmental Risk Assessment in a Historical Perspective*, in *POWERLESS SCIENCE? SCIENCE AND POLITICS IN A TOXIC WORLD* 103–07 (Boudia and Jas eds., 2014) (discussing role of AIHC in process leading to *Red Book*).

151. Inside Washington Publishers, *American Industrial Health Council Ceases Operations*, 7 *INSIDE EPA'S RISK POL'Y REP.* 19, 19 (2000) (“[AIHC] staff wrote the congressional appropriations report language which funded the National Research Council to generate the [Red Book]”).
152. See, e.g., NAT'L RSCH. COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT*, *supra* note 12, at 135–40.
153. See, e.g., AIHC, *A Proposal to Achieve a National Cancer Policy in Chronic Hazard Programs: Hearing before the S. Subcomm. for Consumers of the Comm. on Com., Sci. and Transp.*, 96th Cong., 1st Sess. at 64 (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.”); Moolenaar, *supra* note 33, at 382; Park & Snee, *supra* note 141, at 320.
154. See, e.g., NAT'L RSCH. COUNCIL, *HEALTH RISKS FROM DIOXIN AND RELATED COMPOUNDS: EVALUATION OF THE EPA REASSESSMENT* 142 (2006) (citing the *Red Book*) (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”); see also Ruckelshaus, *supra* note 87, at 614 (“The NAS report recommends that these two functions [risk assessment and risk management] be separated as much as possible within a regulatory agency. This is what we now do at EPA and it makes sense.”).
155. See, e.g., EPA, *UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS* 1 (1987) (defining EPA's “fundamental mission” as one of “reduc[ing] risks” across its various programs).
156. See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 14, at 1; NAT'L RSCH. COUNCIL, *REVIEW OF EPA'S INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROCESS* 10–11 (2014) (discussing history and challenges of the IRIS program).

working groups were created to further refine risk assessment practices and the Agency's political appointees and senior staff all embraced risk assessment as the foundation of EPA's work.¹⁵⁷

The *Red Book* framework was so pervasive, in fact, that EPA leaders used the four components of risk assessment articulated by the *Red Book* as the basis for reorganizing the agency's entire research program in the 1990s.¹⁵⁸ Prior to this time, the agency's Office of Research and Development ("ORD") operated on the basis of a "discipline-based structure" with twelve laboratories, three field stations, and four assessment centers.¹⁵⁹ The new structure adopted in the 1990s consolidated EPA's research into four new laboratories aligned with the elements of the *Red Book* paradigm.¹⁶⁰ In a direct material sense, then, the risk assessment paradigm became inscribed in the basic organization of knowledge production within the agency.¹⁶¹

C. *The Move to Modeling and Expert Systems*

At the same time that EPA was embracing these more formal, quantitative approaches to risk, it was also confronting a rapidly expanding set of statutory responsibilities. By the early 1980s, the scale and scope of EPA's regulatory task had grown substantially with new responsibilities under the Safe Drinking Water Act ("SDWA"), the Toxic Substances Control Act, the Resource Conservation and Recovery Act ("RCRA"), and the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA", commonly known as

157. See, e.g., Alm, *supra* note 63, at 13–15.

158. See Dorothy E. Patton & Robert J. Huggett, *The Risk Assessment Paradigm as a Blueprint for Environmental Research*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT: INT'L J. 1337, 1338 (2003) (observing that the Red Book's "risk assessment/risk management paradigm was instrumental in reorganizing the laboratories and in decision-making on environmental research priorities").

159. EPA, RESEARCH, DEVELOPMENT AND TECHNICAL SERVICES AT EPA: A NEW BEGINNING, REPORT TO THE ADMINISTRATOR 16–19 (1994) (observing that ORD's "discipline-based structure" did not track well with "science based on risk assessment/risk management" and proposing instead a "risk assessment/risk management research laboratory structure" organized into "four National laboratories aligned to match the risk-paradigm used in EPA decision making").

160. The four laboratories included the National Health and Environmental Effects Laboratory, the National Exposure Research Laboratory, the National Center for Environmental Assessment, and the National Risk Management Laboratory. *Id.*

161. Patton & Huggett, *supra* note 158, at 1340 ("The universal language of the Red Book's risk paradigm assures that disciplinary interests, expertise and experience are lodged in their respective laboratories."); see also DEMORTAIN, *supra* note 144, at 186–87 (discussing reorganization of EPA science and research under the Red Book paradigm).

Superfund) added to an already heavy and growing set of duties under its existing programs.¹⁶²

As EPA struggled to discharge its new responsibilities in the face of budgetary constraints and a hostile political environment, the agency turned almost by necessity to computational modeling as a tool to generate the requisite facts for decision-making across its most important programs.¹⁶³ This move was reinforced by the *Benzene* decision and the concomitant enthusiasm for quantitative risk assessment across the government, pushing the agency to look for tools and techniques that would provide a defensible basis for calculating risks and establishing priorities in a timely manner. Modeling, in short, provided a relatively cheap way for the agency to carry out its statutory mandates and survive judicial review.

To be sure, the models that EPA employed (and continues to employ) across its many programs varied significantly in terms of subject matter, design, function, and purpose.¹⁶⁴ Some have been subjected to systematic evaluation, while others have not.¹⁶⁵ Many have been developed and refined by outside experts and research communities, while some have been built in-house.¹⁶⁶ The key point, however, is that the general move to modeling was precipitated in some cases and reinforced in others by the substantial new knowledge demands associated with efforts to operationalize risk assessment across EPA's various programs. Because risk assessment by its nature rested on predictions about the future rather than focusing simply on evidence of hazard and potential harm, EPA had little choice but to turn to various modeling exercises.¹⁶⁷

While EPA had long used models to simulate ambient environmental conditions in air and water, the challenges of regulating toxic chemicals and

162. See, e.g., Alm, *supra* note 63, at 14–15 (discussing expanding statutory responsibilities during 1970s and early 1980s and significant budget cuts in early 1980s as precipitating move to risk assessment).

163. See NAT'L RSCH. COUNCIL, *MODELS IN ENVIRONMENTAL REGULATORY DECISION MAKING* 20 (2007) (“The past 25 years has seen a vast increase in the number, variety, and complexity of computational models available for regulatory purposes at EPA.”).

164. *Id.*, at 43–62 (discussing different types and uses of regulatory models at EPA).

165. *Id.*, at 108 (discussing inconsistent evaluation of models used by EPA); see also NAT'L RSCH. COUNCIL, *SCIENCE AND DECISIONS*, *supra* note 14, at 115–16 (discussing lack of systematic evaluation of various models used by EPA).

166. See, e.g., Robert B. Ambrose et al., *Development of Water Quality Modeling in the United States*, 14 ENV'T ENG. RSCH. 200, 200 (2009) (noting role of government, academic, and private sector entities in developing water quality models); see also P. D. Moskowitz et al., *Computer Models Used to Support Cleanup Decision-Making at Hazardous and Radioactive Waste Sites*, 12 RISK ANALYSIS 591, 603–15 (1992) (discussing various fate and transport models developed by government and non-government entities for cleanup of hazardous waste).

167. See, e.g., Joel Yellin, *Science, Technology, and Administrative Government: Design for Environmental Decisionmaking*, 92 YALE L.J. 1300, 1300 (1983) (“[T]he use of sophisticated mathematical and biological models distinguishes modern administrative experts from their Roosevelt-era predecessors. These models distance a modern agency's reasoning from ordinary experience and insulate regulatory decisions from generalist review.”)

hazardous wastes pushed EPA to substantially expand the scale and scope of its modeling efforts. The use of modeling to assess the risk of toxic chemicals is particularly instructive. With the passage of TSCA in 1976, EPA suddenly had to determine if chemicals in commerce posed an “unreasonable risk.”¹⁶⁸ At the time, there were more than 60,000 chemicals already in commerce—all of which were essentially grandfathered under the law; that is, their safety was presumed and EPA had the burden of establishing whether they posed an unreasonable risk before they could be regulated.¹⁶⁹ Additionally, close to a thousand new chemicals were being introduced into commerce every year.¹⁷⁰ While TSCA required the industry to submit pre-manufacturing notices for new chemicals and to notify EPA of significant new uses of existing chemicals, there were no specific data requirements—only test results and data that already existed were required to be submitted.¹⁷¹ EPA then had a short window (90 days) to respond with a request for more information and/or testing, but only on the basis of a finding of unreasonable risk.¹⁷² Various regulatory options, including outright bans, were available under the statute, but, again, only after a finding of unreasonable risk.¹⁷³

Although TSCA was supposed to be an information-forcing statute, in many respects it had the opposite effect. Industry had no incentive to generate any new information under the statute; in fact, it had every incentive not to do so.¹⁷⁴ And due to the complex procedural burdens the statute placed on EPA combined with expansive protections for confidential business information, EPA faced considerable obstacles in using the limited information that did exist, much less in forcing the production of new information.¹⁷⁵ The result was what one environmental group referred to as “toxic ignorance”—a massive lack

168. Toxic Substances Control Act of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (1976).

169. See Charles W. Schmidt, *TSCA 2.0: A New Era in Chemical Risk Management* 124 ENV'T. HEALTH PERSP. 182, 183 (2016) (noting that the “roughly 62,000 chemicals already in commerce when TSCA was first enacted were for all intents and purposes exempted from the law”); see also 15 U.S.C. § 2605 (1976).

170. See M. Zeeman et al., *U.S. EPA Regulatory Perspectives on the Use of QSAR for New and Existing Chemical Evaluations*, SAR AND QSAR IN ENV'T RESEARCH 179, 181 (1995) (noting that between 1979 and 1994, EPA received over 26,000 notifications for new chemicals, 2,644 in 1994 alone).

171. See 15 U.S.C. §§ 2603–04 (1976).

172. See *id.* at §§ 2604–05.

173. *Id.* at § 2605.

174. See Angela N. H. Creager, *To Test or Not to Test: Tools, Rules, and Corporate Data in US Chemicals Regulation*, 46 SCI. TECH. HUM. VALUES 975, 987–89 (2021) (discussing lack of testing requirements under TSCA).

175. As originally enacted, TSCA allowed companies to claim the identities of any of their chemicals as confidential business information (“CBI”). Out of the 85,000 chemicals on the TSCA inventory, the identities of some 17,000 were claimed as CBI. Although EPA could challenge CBI claims on a case-by-case basis, it did not have any mandate to review them and rarely mounted challenges because of the time and expense. See TSCA 15 U.S.C. § 2613; see also David J. Hansen, *Trade Secrets*, CHEM. & ENG'G NEWS (Jan. 10, 2010), <https://perma>

of basic health and safety data on industrial chemicals that persists to this day.¹⁷⁶ One study from the 1990s, for example, found that basic health and safety data existed for only a handful of chemicals in commerce, while almost 75% lacked any toxicological testing data.¹⁷⁷

In response to these significant data shortfalls and in the face of a statutory mandate to determine whether an individual chemical posed an “unreasonable risk” before it could regulate, EPA was forced to look for proxies and turned increasingly to what are known as structure-activity relationship (“SAR”) models and, specifically, to Quantitative SAR or QSAR models, to judge whether chemicals posed an unreasonable risk.¹⁷⁸ As one group of EPA professionals noted,

the fundamental reason why EPA has applied the QSAR approach in its efforts to assess the hazards (or toxicity), chemical properties, and environmental fate of industrial chemicals is that insufficient data are available to do otherwise. These tools were developed and refined because frequently no data were available and rapid regulatory risk-based decisions had to be made on thousands of new chemicals every year, or these chemicals could have been manufactured in (or imported into) the United States without any regulation whatsoever.¹⁷⁹

Another group of EPA scientists put the matter more succinctly: “SAR provides the only real alternative to expensive and time-consuming laboratory testing.”¹⁸⁰

In essence, SAR models worked from the observation that in closely related series or families of chemicals, the biological activity of the compounds vary according to certain structural properties, which can be expressed mathematically. One can thus think of these SAR models as a form of reasoning by analogy. Chemicals with similar structures and properties are assumed to behave

cc/2JWC-3B6X (reporting results of survey that found CBI claims on 17,000 chemicals under TSCA).

176. See ENV'T DEF. FUND, TOXIC IGNORANCE: THE CONTINUING ABSENCE OF BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE UNITED STATES 7 (1997), <https://perma.cc/D9CE-LHRW>.

177. *Id.* at 15; see also Zeeman et al., *supra* note 170, at 181 (noting that about 75% of the chemicals already in commerce “have no toxicologic test data available”).

178. See also Ellen K. Silbergeld et al., *Regulating Chemicals: Law, Science, and the Unbearable Burdens of Regulation*, 36 ANN. REV. PUB. HEALTH 175, 182 (2015) (“The “science” of what is called Quantitative Structure Activity Relationships (“CSAR”) was born from the need for rapid response to new chemicals notifications of much real data.”).

179. See Zeeman et al., *supra* note 170, at 180; see also *id.* at 181 (“EPA is confronted with the real and difficult problem of assessing the toxicity, environmental fate, and risks of chemicals to organisms in the environment in the presence of limited or no test data. From this difficulty flowed the need to develop QSARs, to set pragmatic conditions for their use, and to provide for their validation.”).

180. OFF. TECH. ASSESSMENT, SCREENING AND TESTING CHEMICALS IN COMMERCE 113 (1995).

similarly with respect to specific biological endpoints.¹⁸¹ The reliability of these models, of course, is dependent on the closeness of fit between the compounds in question and the quality of the data on the existing chemicals.¹⁸² There is always a danger, in this respect, that SAR models will be “invoked prematurely for some toxicity endpoints, will be extended beyond where they are likely to be valid or reliable, and will be used without sufficient oversight and testing verification.”¹⁸³ But without any meaningful testing requirements and in the absence of post-market surveillance, it is impossible to know.¹⁸⁴

As with industrial chemicals, EPA’s new hazardous waste responsibilities also created substantial analytical challenges for the agency. With the passage of CERCLA (the Superfund law) in 1980, EPA found itself having to make decisions about remediation targets and residual risk at thousands of contaminated sites around the country, each of which varied significantly in terms of the nature of the wastes and bio-geophysical circumstances.¹⁸⁵ As enacted,

181. Henri Boullier et al., *Inventing Prediction for Regulation: The Development of (Quantitative) Structure-Activity Relationships for the Assessment of Chemicals at the U.S. Environmental Protection Agency*, 32 SCI. TECH. STUDY 137, 138 (2019) (discussing EPA’s efforts to deploy quantitative structure-activity relationship models to infer the toxicity of chemicals based on comparison to other similar chemicals).

182. See Silbergeld et al., *supra* note 178, at 182 (“[T]he rationale for QSAR has some validity only for certain endpoints, such as mutagenicity and carcinogenicity, which are based strongly on decades of research supporting specific and well-defined mechanisms. More complex and less well understood outcomes—such as reproductive and developmental toxicity—involve multiple mechanisms, and under these conditions, approaches based on structural activity relationships (“SAR”) are considerably less justifiable on scientific grounds.”).

183. Off. Tech. Assessment, *supra* note 180, at 114.

184. See Silbergeld et al., *supra* note 178, at 182 (“We do not consider QSAR a science because it is not possible to test its outcomes in terms of the accuracy of QSAR-based decisions about new chemicals. We have no way to know if in the postmarket world any of these QSAR-assessed and -approved chemicals have proven to be without significant risk of harm. Unlike drugs there is no postmarket surveillance of industrial chemicals.”).

185. See Comprehensive Environmental Response, Compensation, and Liability Act of 1980, Pub. L. no. 96-510, 94 Stat. 2767 (1980) (codified at 42 U.S.C. § 9601 et seq.). EPA developed extensive guidance for risk assessment at superfund sites during the 1980s and 1990s. See, e.g., EPA, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOL. I HUMAN HEALTH EVALUATION MANUAL PART A (1989); EPA, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOL. II ENVIRONMENTAL EVALUATION MANUAL (1989); EPA, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOL. I HUMAN HEALTH EVALUATION MANUAL (PART B, DEVELOPMENT OF RISK-BASED PRELIMINARY REMEDIATION GOALS) (1991); see also U.S. GOV’T ACCOUNTABILITY OFF., GAO/T-RCED-95-231, EPA’S USE OF RISK ASSESSMENT IN CLEANUP DECISIONS 3-5 (June 22, 1995) (discussing use of risk assessment in cleanup decisions at almost 200 superfund sites); U.S. GOV’T ACCOUNTABILITY OFF., GAO/T-RCED-93-74, SUPERFUND: RISK ASSESSMENT PROCESS AND ISSUES 9 (1993) (“[C]haracterizing risks at Superfund sites is, perhaps, one of the most difficult tasks that EPA undertakes. EPA must deal with unpredictable patterns of human behavior that affect the way individuals and communities are exposed to hazardous wastes, as well as with the scientific uncertainty about the extent to which contaminants adversely affect human health. In addition, risk assessments require an accurate knowledge of the type of contaminants present at a site and procedures

CERCLA directed EPA to develop criteria for determining cleanup priorities “based upon relative risk or danger to public health or welfare or the environment” and required that these criteria be used to establish a national priority list of sites most in need of cleanup.¹⁸⁶ Extensive testing and monitoring at each individual site would be expensive and time consuming and would not provide estimates of future exposures under different cleanup scenarios.¹⁸⁷ And without a consistent approach to assessing and ranking the hazards at different sites, the agency would not be able to establish priorities for cleanup.¹⁸⁸ EPA thus needed new systems and tools that would allow it to model the fate and transport of hazardous substances, particularly in subsurface environments, the bioaccumulation of certain substances in food webs, and the various possible human exposure pathways in order to assess the risks posed by specific sites and compare them with those at other sites.¹⁸⁹ As an EPA Superfund document from the mid 1990s put it: “[m]ultimedia modeling begins with a source of contamination and ends with a calculation of risk for the final assessment.”¹⁹⁰ During the 1980s and 1990s, EPA developed a portfolio of general fate and transport models that

for quantifying how these contaminants might interact under a variety of scenarios.”); Adler, *supra* note 108, at 1135 (noting that “the overwhelming majority of EPA risk assessments do not involve major rules, but other categories of administrative decision, such as clean-up decisions with respect to individual Superfund sites”).

186. See 42 U.S.C. § 9605(a)(8); see also Edmund B. Frost, *Risk Assessment Under the Revised National Contingency Plan of Superfund*, in *RISK ASSESSMENT AT HAZARDOUS WASTE SITES* 2–3 (Long and Schweitzer eds., 1982) (discussing CERCLA’s emphasis on relative risk and need for risk assessment to develop priorities). Frost also notes that earlier legislation that would have required cleanup down to no-detect levels with no need for risk assessment was rejected in favor of a risk-based approach. See *id.* at 1–2.
187. See Curtis C. Travis et al., *Limitations of Multimedia Models for Use in Environmental Decision Making*, 71 ENV’T MONITORING & ASSESSMENT 51, 52 (2001) (discussing challenges of direct measurement of toxic substances at contaminated sites and noting that “in cases where estimates of *future* contaminant concentrations and fluxes are needed, predictive analytical expressions are indispensable” and that “[c]omputer-based models allow the risk assessor to generate such estimates”).
188. See NAT’L RSCH. COUNCIL, *RANKING HAZARDOUS-WASTE SITES FOR REMEDIAL ACTION* 86–99 (1994) (discussing development and use of hazard ranking system as the basis for assessing relative risk posed by different sites and establish national priorities list for cleanup).
189. See Moskowitz et al., *supra* note 166 at 591–92 (1992) (discussing use of different computational models to characterize the source, fate, transport, and effects of hazardous substances identified at contaminated sites in order to evaluate the nature and extent of cleanup required).
190. See EPA, *THREE MULTIMEDIA MODELS USED AT HAZARDOUS AND RADIOACTIVE WASTE SITES* 3 (1996) (reviewing use of multimedia models in superfund remediation); Matthew Macleod et al., *The State of Multimedia Mass-Balance Modeling in Environmental Science and Decision-Making*, 44 ENV’T SCI. TECH. 8360 (2010) (discussing development and elaboration of multimedia mass balance models starting in the late 1970s).

could be used at different sites, as well as a number of site-specific models for particularly complex remediation efforts.¹⁹¹

To take one example, polychlorinated biphenyl (“PCB”) contamination of the river-bottom sediments in New York’s Hudson River, which resulted from discharges by General Electric over a thirty-year period ending in 1977, posed exceedingly difficult analytical challenges for EPA in evaluating different remediation options.¹⁹² Removing contaminated river sediments could make the problem worse if significant quantities of PCBs were released in the process.¹⁹³ Leaving sediments in place could also be problematic if PCBs were migrating in the aquatic environment.¹⁹⁴ In its initial 1984 remedy for the site, EPA required in-place containment via capping of various shoreline deposits, but chose not to remediate the much more extensive contamination of submerged river bottom sediments because of “the lack of existing data to establish that existing technology would be effective and reliable” in remediating the sediments.¹⁹⁵ In effect, this meant that EPA was not requiring any remediation of the main source of PCBs in fish in the Hudson river, which was the primary source of human exposure.¹⁹⁶

In 1989, EPA decided to reassess its 1984 decision to leave the PCB contaminated river sediments in place.¹⁹⁷ The agency then spent more than a decade assessing the risks of various remedial alternatives.¹⁹⁸ In 2000, EPA released the results of its revised remedial investigation and feasibility study for the site,

191. See Moskowitz et al., *supra* note 166, at 603–15 (reporting results of a survey of models used by EPA, the U.S. Department of Energy, and the U.S. Nuclear Regulatory Commission to support decision-making at hazardous and radioactive waste sites and identifying 127 different models in use across eight major categories); Roy L. Smith, *Use of Monte Carlo Simulation for Human Exposure Assessment at a Superfund Site*, 14 RISK ANALYSIS 433, 433 (1994) (“Federal Law requires the U.S. Environmental Protection Agency (EPA) to conduct site specific risk assessments to support the selection of remedies for Superfund sites.”).

192. EPA placed the Hudson River PCBs Superfund Site on the National Priorities List in September 1984. See EPA, SUPERFUND RECORD OF DECISION: HUDSON RIVER PCBs SITE, NY (1984).

193. *Id.* at 5–10 (discussing challenges involving remediation of river sediments contaminated with PCBs).

194. *Id.*

195. *Id.* at ROD Issues Abstract p. 1.

196. *Id.* (“No remedial action will be taken for the Hudson River PCB sediments to mitigate the primary route of exposure through the environment (consumption of PCB contaminated fish). Because the effectiveness of available technologies to dredge PCB contaminated sediments in a dynamic, riverine environment is not known, a cost-effective alternative was not selected.”).

197. See EPA, HUDSON RIVER PCBs SITE NEW YORK: RECORD OF DECISION 6 (2002), <https://perma.cc/N4ZY-KVZU> (discussing 1989 decision to reassess the prior 1984 no-action remedy for PCB contaminated river sediments).

198. *Id.* (discussing the three phases of the reassessment).

including revised human and ecological risk assessments.¹⁹⁹ Both of these risk assessments concluded that absent remediation of the contaminated river bottom sediments, current and future concentrations PCBs in Hudson River fish would be “above levels of concern” for human health and the environment.²⁰⁰ Three major models—a fate and transport model developed for the site known as the Upper Hudson River Toxic Chemical Model (“HUDTOX”), a Depth and Scour Model (“DOSM”) to understand sediment erosion during high flow events, and a food-web bioaccumulation model known as FISHRAND—were developed to guide the effort.²⁰¹ The results from the HUDTOX model, as modified by the DOSM model, were used as inputs to the FISHRAND model, which was then used to estimate PCB levels in fish, possible human exposures, and overall risk of different remediation strategies.²⁰² Models all the way down.

Based on these assessments, EPA issued a new Record of Decision for the site in 2002 requiring targeted environmental dredging of approximately 2.65 million cubic yards of PCB-contaminated sediment from the Upper Hudson River.²⁰³ Obviously, the reliability of the entire exercise was dependent upon the quality of the models employed. And while there is no reason to presume that any of the models used in the Hudson River cleanup were flawed at the time

199. See TAMS Consultants, Inc. and Gradient Corporation, *Volume 2F—Revised Human Health Risk Assessment Hudson River PCBs Reassessment RI/FS*, prepared for U.S. EPA Region 2 and U.S. Army Corps of Engineers, Kansas City District (Nov. 2000), <https://perma.cc/VBP6-EPKK>; TAMS Consultants, Inc. & Menzie-Cura & Associates, Inc., *Volume 2E—Revised Baseline Ecological Risk Assessment Hudson River PCBs Reassessment* (Nov. 2000), <https://perma.cc/ZLT3-DW22>.

200. See TAMS Consultants, Inc., *Hudson River PCBs Reassessment RI/FS Phase 3 Report: Feasibility Study*, Book 1 of 6, prepared for U.S. EPA Region 2 and U.S. Army Corps of Engineers, Kansas City District, at ES-4 (Dec. 2000), <https://perma.cc/5J54-SHM7> (summarizing site risks and noting that both the human health and the ecological risk assessments “conclude that current and future concentrations of PCBs in fish are above levels of concern to human health and ecological receptors” and that “eating PCB-contaminated fish is the primary exposure pathway”).

201. The basic assumptions and mechanics of the different models are described in background documents prepared for EPA by various consultants working on the project. See TAMS Consultants, Inc., et al., *Volume 2D—Revised Baseline Modeling Report Hudson River PCBs Reassessment RI/FS*, prepared for U.S. EPA Region 2 and U.S. Army Corps of Engineers, Kansas City District at ES-2–ES-3 (Jan. 2000), <https://perma.cc/Q5R4-XQ3U> (describing the assumptions and mechanics for the HUDTOX, DOSM, and FISHRAND models used for the assessment and development of the remedy for the Hudson River PCBs site); *Hudson River PCBs Superfund Site Cleanup Plans and Documents*, EPA, <https://perma.cc/D6CN-S9W7> (additional background reports and documents related to the Hudson River PCBs cleanup).

202. See Elsie Sunderland et al., *Environmental Fate and Bioaccumulation Modeling at the US Environmental Protection Agency: Applications to Inform Decision Making*, in *MODELING OF POLLUTANTS IN COMPLEX ENVIRONMENTAL SYSTEMS*, Vol. II, 3,25–32 (G. Hanrahan ed., 2010).

203. See EPA, HUDSON RIVER PCBs SITE NEW YORK: RECORD OF DECISION, *supra* note 197, at 94–98 (2002), <https://perma.cc/MTY9-9NV3> (describing selected remedy).

they were developed, much less that there were better alternatives for making these determinations, an extensive review based on sampling conducted after the cleanup had been initiated revealed that the modeling used to support the remedy had significantly under-estimated the extent of PCB contamination and the attendant risks and over-estimated the river's rate of natural recovery.²⁰⁴

More generally, various evaluations of the use of models in Superfund decision-making conducted over the last several decades have raised important questions about the reliability and testing of these models. A 1989 internal EPA study, for example, found that more than 300 models were in use by agency staff to determine off-site migration and exposure at Superfund sites and that the agency had no systematic approach to model assessment and validation.²⁰⁵ Twenty years later, the National Research Council concluded that “[t]he number of transport, fate, and exposure models in active use in EPA or elsewhere is too large to evaluate them individually or to make general statements about their utility and reliability.”²⁰⁶

Similar challenges have arisen with respect to pesticide residues and food safety. With passage of the 1996 Food Quality Protection Act (“FQPA”), pesticide residues for which there was evidence of potential carcinogenicity were no longer subject to the strict zero-risk approach of the Delaney Clause—a standard that, if strictly enforced, would have required EPA to cancel the

204. See L. Jay Field et al., *Re-visiting Projections of PCBs in Lower Hudson River Fish Using Model Emulation*, 557 *SCI. TOTAL ENV.* 489, 490 (2016). These findings validated some of the earlier concerns raised about the modeling effort; see, e.g., EPA, HUDSON RIVER PCBs SITE EPA PHASE 1 EVALUATION REPORT, ES1, ES-18 (2010), <https://perma.cc/BD9X-T6CT> (discussing problems with the models EPA used in developing the remedy); Todd Bridges et al., HUDSON RIVER PCBs SITE: PEER REVIEW OF PHASE 1 DREDGING FINAL REPORT 1, 13 (2010), <https://perma.cc/Z66P-NB36> (concluding that the “HUDTOX/FISHRAND models are outdated and inadequate to accurately project MNR [monitored natural recovery] and post-dredge fish recovery rates). In 2023, GE agreed to perform additional sampling of water, fish, and sediment as part of an ongoing investigation of the Lower Hudson River to determine if additional cleanup is necessary. See Hudson River PCBs Superfund Site, Admin. Settlement Agreement and Order on Consent for Testing/Investigation Lower Hudson River, CERCLA-02-2022-2020 (EPA, Region 2) (Sept. 13, 2022) (providing for additional investigation and sampling contamination in the Lower Hudson River).

205. See EPA OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE, OSWER MODELS STUDY: PROMOTING APPROPRIATE USE OF MODELS IN HAZARDOUS WASTE/SUPERFUND PROGRAMS, PHASE 1, FINAL REPORT ii, 2-1-2-3 (May 26, 1989). Similar problems were identified in other EPA programs. See, e.g., NAT’L RSCH. COUNCIL, HUMAN EXPOSURE ASSESSMENT FOR AIRBORNE POLLUTANTS: ADVANCES AND OPPORTUNITIES 173 (1991) (“Limited information is available regarding the accuracy of most contaminant concentration models and less is known about exposure models because most models have not been adequately validated.”); NAT’L RSCH. COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 117 (1994) (noting that, in the context of air quality, “[t]he validity of population-exposure models used by EPA remains largely untested” and there had been “no systematic attempts” to validate the main exposure models used for regulatory purposes”).

206. NAT’L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 115 (2009).

registrations of various pesticides.²⁰⁷ In place of Delaney, the FQPA imposed a new “reasonable-certainty-of-no-harm” standard for all pesticide residues in food.²⁰⁸ The new standard was widely praised in part because it allowed regulators to ignore so-called *de minimis* risks and to allocate resources to more pressing problems.²⁰⁹ The FQPA also required specific attention to children and other vulnerable sub-populations in regulating pesticides.²¹⁰ But it also imposed significant new analytical burdens on the agency, requiring a much more information-intensive exercise and a deeper embrace of models to understand different human exposure pathways.²¹¹ Abandoning the simple but rigid approach of Delaney, in other words, meant that the agency would have to perform detailed risk assessments based on extensive exposure modeling for many pesticides.²¹² Since the FQPA was enacted, EPA has adopted more than two dozen different models covering aquatic, terrestrial, and atmospheric pathways as well as multiple different health effects in order to assess the health risks of different pesticides.²¹³

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207. Sponsored by Congressman James Delaney of New York, the Delaney Clause was part of a package of amendments added to the Federal Food Drug and Cosmetics Act in 1958. The clause provided that no food additive “shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.” Food Additives Amendment, Pub. L. No. 85-929, 72 Stat. 1784, 1786 (1958) (codified at 21 U.S.C. § 348(c)(3)(A)). Pesticide residues on food crops that concentrated during processing were treated as food additives and thus subject to the Delaney Clause’s prohibition if there was evidence that the pesticide was carcinogenic. EPA had been using a *de minimis* exception to Delaney, which was rejected by the Ninth Circuit. *See Les v. Reilly*, 968 F.2d 985, 990 (9th Cir. 1992) (rejecting EPA’s efforts to apply a *de minimis* risk exception to the Delaney clause for certain pesticide residues); *see also* NAT’L RSCH. COUNCIL, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX 31 (1987).
208. *See* Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, 1514–20 (requiring EPA to set tolerances for pesticide residues on food at a level that will ensure “reasonable certainty of no harm”).
209. *See* Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA’s Implementation of the Food Quality Protection Act*, 653 ADMIN. L. REV. 103, 107, 114–17 (2001) (describing how the FQPA emerged as a deal between EPA, the agricultural chemical companies, and environmental groups).
210. *See* Food Quality Protection Act of 1996, 110 Stat. 1489, 1517–18 (requiring application of specific safety factors to accommodate the special sensitivities of infants and children in setting standards).
211. *See, e.g.*, JOHN WARGO, OUR CHILDREN’S TOXIC LEGACY: HOW SCIENCE AND LAW FAIL TO PROTECT US FROM PESTICIDES 303 (2nd ed. 1998) (noting the additional analytical demands of assessing pesticide exposure in diverse environments required by the FQPA).
212. *Id.* at 92–97; *see also* NAT’L RSCH. COUNCIL, EXPOSURE SCIENCE IN THE 21ST CENTURY: A VISION AND STRATEGY 20 (2012) (evaluating use of exposure models); McGarity, *supra* note 209, at 147 (“Despite its clear authority to do so, EPA has not ordered registrants to conduct direct exposure measurements but has instead relied almost exclusively on mathematical models to predict such exposures.”).
213. *See Models for Pesticide Risk Assessment*, EPA, <https://perma.cc/TR5G-2W4S>.

To be sure, modeling rarely operated as a complete substitute for monitoring and testing, but it did displace and in some respects diminish their importance.²¹⁴ Part of this likely reflected broader changes in scientific practice and the growing currency of models (and modelers) across the environmental sciences.²¹⁵ Part of it also stemmed from the sheer size of the analytical burden that EPA confronted as it sought to operationalize risk-based decision-making across its many programs; the move to modeling, in other words, was partly an act of triage. But part of it also derived from the type of knowledge that risk assessment demanded—knowledge about potential future harms and their significance under a range of circumstances. Instead of using simple hazard-based triggers for regulation (where evidence of harm in animal or human studies provided the trigger), risk assessment required detailed information about dose-response relationships, exposure pathways, and variability across populations. The analytical challenges of such an exercise greatly exceeded those entailed by the more precautionary approaches of earlier years. As the exercise unfolded, moreover, it was not always clear how to assess and evaluate the outputs of some of these models, raising questions of epistemic competence and providing opportunities for ongoing contestation and delay. As discussed in more detail

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214. Multiple assessments (internal and external) of EPA science practices over the last twenty years have stressed the importance of monitoring and several have expressed concern that the agency has moved too far in the direction of modeling at the expense of environmental monitoring. *See, e.g.*, EPA SCIENCE ADVISORY BOARD, REPORT OF THE ENVIRONMENTAL ENGINEERING COMMITTEE: RESOLUTION ON THE USE OF MATHEMATICAL MODELS BY EPA FOR REGULATORY ASSESSMENT AND DECISION-MAKING 1 (Jan. 1989) (identifying various problems regarding the development and application of models at EPA, including “increased reliance on models rather than background data collection and analysis”); NAT’L RSCH. COUNCIL, BUILDING A FOUNDATION FOR SOUND ENVIRONMENTAL DECISIONS 55–57 (1997) (discussing importance of and need for investment in long term monitoring of environmental conditions and trends); NAT’L RSCH. COUNCIL, MODELS IN ENVIRONMENTAL REGULATORY DECISION MAKING, *supra* note 163, at 190–92 (discussing need for models to accommodate increasing availability of new environmental monitoring and measurement systems); NAT’L RSCH. COUNCIL, EXPOSURE SCIENCE IN THE 21ST CENTURY *supra* note 212, at 117–18 (discussing lack of fine-scale exposure data as major problem for evaluating dose-response models and assessing risk); *see also* WARGO, *supra* note 211, at 304–05 (discussing widespread failure to adequately monitor pesticides in the environment); Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1625–30 (2004) (discussing widespread lack of basic monitoring of environmental conditions and trends across multiple EPA programs and overreliance on rudimentary models that lack proper evaluation); Eric Biber, *The Problem of Environmental Monitoring*, 83 U. COLO. L. REV. 1, 4 (2011) (discussing “the surprising lack of reliable information about the conditions of the environment in which we live”).
215. *See* Theodore Porter, *Speaking Precision to Power: The Modern Political Role of Social Science*, 73 SOC. RSCH. 1273, 1292–93 (2006) (“The relation of science to public reason seems now to be undergoing a critical shift, away from the twentieth-century idealization of disciplinary autonomy and rigorous objectivity. New scientific practices, including more and more reliance on modeling in order to deal with complexity, have participated in this shift.”).

in Part III below, these sorts of knowledge problems would become an endemic feature of risk assessment during the 1990s and 2000s.

D. *Comparative Risk Assessment and the Synoptic View*

One of the most attractive features of risk assessment, according to its proponents, lays in its ability to render different kinds of hazards commensurable—to put them into an equivalence space that allowed them to be ranked on the basis of relative risk. Acceptable risk, significant risk, *de minimis* risk—all of these ideas contained within them the notion that different hazards could be reduced to a common metric (e.g., excess deaths) and compared to other risks impinging on everyday life. During the 1980s, as EPA struggled with its new responsibilities and in the face of shrinking budgets, agency leaders directed senior staff across the agency to develop a framework for establishing risk-based priorities across the agency's programs. The resulting report, *Unfinished Business: Comparative Assessment of Environmental Problems*, was released in 1987 and indicated a wide disparity between what agency experts viewed as priority risks and public perceptions.²¹⁶

When William Reilly took over as Administrator in 1989, he asked EPA's Science Advisory Board ("SAB") to evaluate *Unfinished Business* and develop strategic options for the agency. The SAB's final report, *Reducing Risk*, highlighted different categories of risks (cancer, non-cancer, ecological, and welfare) and strongly recommended an overall approach based on risk-based priorities.²¹⁷ It also pointed to various analytical shortcomings and called for more and better data and improved methodologies to support the overall exercise.²¹⁸ In broadest terms, the report emphasized that risk assessment could be used not only to guide individual decisions but also to compare and rank risks against each other. "The concept of environmental risk," the report noted, "together with its related terminology and analytical methodologies, helps people discuss disparate environmental problems with a common language. It allows many environmental problems to be measured and compared in common terms, and it allows different risk reduction options to be evaluated from a common basis."²¹⁹

From the perspective of administrative efficiency, the exercise had significant appeal, providing a framework for directing limited resources toward the

216. See generally 1 EPA, UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS, Overview Report (1987).

217. EPA SCI. ADVISORY BD., REDUCING RISK: SETTING PRIORITIES AND STRATEGIES FOR ENVIRONMENTAL PROTECTION (1990), <https://perma.cc/6QJG-YGHT>.

218. *Id.*

219. *Id.*

most serious potential harms.²²⁰ But the challenges facing any such effort were considerable.²²¹ As Reilly himself acknowledged in 1991:

Setting priorities for the whole nation and bringing our Agency's resources into alignment with those priorities are supremely daunting tasks. It is only a slight exaggeration to say they demand the rigorous thinking of a mathematician, the resolute discipline of a Zen master, and the extended vision of an astrophysicist.²²²

Notwithstanding such challenges, however, Reilly was steadfast in his overall commitment to the exercise and its ability to bring about what he called a "quiet revolution" in environmental policy.²²³

Two years later, then Judge Stephen Breyer published *Breaking the Vicious Circle: Toward Effective Risk Regulation*, based on his 1992 Holmes lectures at Harvard Law School.²²⁴ Coming in the midst of EPA's efforts to rationalize its own approach to risk assessment, Judge Breyer's book clearly embraced the basic *Red Book* paradigm and the value of a single framework in which hazards could be made equivalent, compared, weighed, and evaluated.²²⁵ And while he recognized the challenges facing such an effort, Judge Breyer also proposed an ambitious institutional reform—a new centralized administrative group with inter-agency jurisdiction and a mission to rationalize risk-based priority setting across the government.²²⁶

In important respects, Breyer's vision of comparative risk assessment and EPA's efforts to establish a program of risk-based priority setting can be seen as the high point of technocratic risk thinking—a culmination of the basic logic embedded in risk assessment and the broader normative framework of expected

220. *See id.* ("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.").

221. *See* Hornstein, *Reclaiming Environmental Law*, *supra* note 53, at 626 (discussing normative and analytical shortcomings of comparative risk assessment); Ian Hacking, *Culpable Ignorance and Interference Effects*, in *VALUES AT RISK* 146 (MacLean ed., 1986) (discussing "the complete instability of grandiose computations of relative risk" because of unforeseen and unknown interference effects in the real world).

222. William K. Reilly, *Why I Propose a National Debate on Risk*, 17 EPA J. 2, 2 (1991).

223. William K. Reilly, EPA Adm'n, *Aiming Before We Shoot: The Quiet Revolution in Environmental Policy*, Address to The National Press Club, Washington, D.C. (Sept. 26, 1990), <https://perma.cc/5BUZ-5E76>.

224. STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* (1993).

225. *Id.* at 9 (discussing four elements of the risk assessment/risk management paradigm).

226. *Id.* at 3–29 (discussing problems), 59–61 (proposing new administrative group to rationalize risk-based decision across the government); *see also* Vermeule, *Local and Global Knowledge in the Administrative State*, *supra* note 45, at 296 (characterizing Breyer's project as an example of "synoptic regulation").

utility. Operationalizing comparative risk assessment, however, proved difficult given the challenging politics involved in public perceptions of certain risks, specific statutory requirements, and the need for institutional reforms to fully realize its promise. Critics argued, moreover, that the whole effort to compare different kinds of harms and regulate on the basis of a common risk metric could have serious distributional consequences.²²⁷ Likewise, the static nature of the exercise and its embrace of a unitary view of risk was inherently unstable given that the context for any particular risk was always changing, undermining the possibility of meaningful comparisons.²²⁸ And because the knowledge practices used to generate different risk assessments varied (quite substantially in some cases), it was not always clear how far one could push any particular comparison.²²⁹ How, for example, can one really compare a risk estimate based on standard actuarial techniques using real data about events in the world with one derived from extensive computational modeling, extrapolation techniques, and various assumptions regarding inferences in the face of uncertainty? In the end, comparative risk assessment failed to get traction at EPA and across the federal government. While some likely saw this as a missed opportunity, it more accurately reflected a larger set of knowledge problems that were deeply embedded in

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227. Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Assessment*, 92 COLUM. L. REV. 562, 632 (1992) (criticizing normative foundations of comparative risk assessment). Under the Clean Air Act's NAAQS program, for example, there is no obvious way (no common risk metric) to use diverse health effects such as reduced IQ, angina, or impaired lung capacity as a basis for determining a standard that would protect public health with an adequate margin of safety. See, e.g., John Bachmann, *Will the Circle Be Unbroken: A History of the U.S. National Ambient Air Quality Standards*, 57 J. AIR & WASTE MGMT. ASS'N 652, 690 (2007).
228. See Hacking, *supra* note 221; see also NAT'L RSCH. COUNCIL, EXPOSURE SCIENCE IN THE 21ST CENTURY, *supra* note 212, at 60 (noting how changes in exposure patterns over time affect the nature of the risk and undermine the ability to assess and compare risks).
229. Difficulties arise in the relative degrees of reliability of the risk estimates being compared. Some "acceptable" risks from everyday life that are often used as a basis for comparison are true actuarial risks. We know, for example, what the general population risk of traffic fatalities is based on real evidence. Other risks, particularly those associated with toxic substances, are not actuarial but predicted. Is it appropriate to compare these two types of risk estimates? See Joseph V. Rodricks et al., *Significant Risk Decisions in Federal Regulatory Agencies*, 7 REGUL. TOXICOLOGY & PHARMACOLOGY 307, 317 (1987) (discussing difficulties of comparing "actuarial risks to those that are merely predicted"). FDA made this point explicitly in 1986. See Listing of D&C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28331, 28344 (Aug. 7, 1986) (noting that the risk assessment it had performed did not generate "an actuarial risk. An actuarial risk is the risk determined by the actual incidence of an event. In contrast, the computed risk is a projection based on certain conservative assumptions that do not understate risk."). There are also questions of comparability that emerge in the distinction between individual and population risks. How, for example, do we compare a large risk to a small number of people with a small risk to a large number of people? Rodricks et al., *supra* note 229, at 318; see also Adler, *supra* note 108, at 1146-47.

the logic of quantitative risk assessment and the effort to remake environmental decision-making.

III. KNOWLEDGE PROBLEMS: QUANTITATIVE RISK ASSESSMENT IN PRACTICE

Notwithstanding the challenges of implementing a program of comparative risk assessment across the government, by the 1990s risk assessment had become a cornerstone of regulatory science at EPA. A new integrated risk information system had been established to create a clearinghouse for all of the various studies involved in EPA risk assessments.²³⁰ Major risk reassessments were launched for important chemicals such as dioxin, trichloroethylene, and formaldehyde.²³¹ The National Academy was paying close attention, weighing in with general reviews of the risk assessment process and intervening in individual risk assessments.²³² And Congress and the White House were engaged in efforts to rationalize and expand the use of risk assessment across the government.²³³ The overall result was a decisive retreat from an earlier technocratic ideal centered on expert judgment and deliberation toward a much more disciplined and constrained internal administrative law of risk, elaborated through a series of Executive Orders, more pervasive involvement of OMB, and ever more detailed guidelines.²³⁴

230. See, e.g., Amy Mills & Gary L. Foureman, *US EPA's IRIS Pilot Program: Establishing IRIS as a Centralized, Peer-reviewed Data Base with Agency Consensus*, 127 *TOXICOLOGY* 85, 86 (1998) (discussing development of EPA's integrated risk information system starting in the mid 1980s).

231. See *infra* Part IV.A (discussing history of dioxin, trichloroethylene, and formaldehyde risk assessments).

232. See, e.g., NAT'L RSCH. COUNCIL, *SCIENCE AND JUDGMENT IN RISK ASSESSMENT*, *supra* note 205.

233. 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." Pub. L. No. 101-549, § 303, 104 Stat. 2399, 2574-76 (1990). The Commission was formed in 1994 and released its final two volume report in 1997; see also Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (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); see generally PRESIDENTIAL/CONG. COMM'N ON RISK ASSESSMENT & RISK MGMT., *FINAL REPORT VOL. 2: FRAMEWORK FOR ENVIRONMENTAL HEALTH RISK MANAGEMENT* (1997) and PRESIDENTIAL/CONG. COMM'N ON RISK ASSESSMENT & RISK MGMT., *FINAL REPORT VOL. 2: RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION MAKING* (1997).

234. See, e.g., Exec. Order No. 12866, 58 Fed. Reg. 51735 (Sept. 30, 1993) (establishing principles regulatory decision-making, including regulatory impact analysis and cost-benefit analysis);

As EPA worked to operationalize risk assessment during the 1990s and 2000s, however, new problems emerged. Instead of reducing uncertainty, risk assessment seemed to generate a range of new uncertainties with no obvious way to resolve them.²³⁵ Increased reliance on computational models at EPA and other agencies also raised questions not only about the reliability of the tools themselves but also about how the modeling enterprise should be managed across multiple statutory domains and how it should be evaluated by reviewing courts.²³⁶ The traditional single-chemical, single-endpoint approach of risk assessment likewise failed to capture the fact of multiple exposures to multiple substances and pollutants in the real world.²³⁷ Finally, increasingly vocal challenges from frontline communities and environmental justice advocates pointed to the radically incomplete treatment of structural vulnerabilities and marginalized groups in the standard approach to risk assessment.²³⁸

A. Managing Uncertainty

In seeking to assess future risks of harm associated with very low levels of exposure to toxic substances, risk assessment inevitably had to find ways to deal with pervasive uncertainties about such exposures and the basic mechanisms that caused harm. Uncertainty, of course, was not a new problem confronting

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). 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. 33992 (Sept. 24, 1986); Notice of Availability of the Document Entitled 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* EPA RISK ASSESSMENT FORUM, GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT (2019). On internal administrative law generally, see Gillian E. Metzger & Kevin M. Stack, *Internal Admin. Law*, 115 MICH. L. REV. 1239 (2017).

235. *See* M. GRANGER MORGAN & MAX HENRION, UNCERTAINTY: A GUIDE TO DEALING WITH UNCERTAINTY IN QUANTITATIVE RISK AND POLICY ANALYSIS 56–71 (1990) (discussing different sources of uncertainty).

236. *See* Wendy Wagner et al., *Misunderstanding Models in Environmental and Public Health Regulation*, 18 N.Y.U. ENV'T L.J. 293 (2010); NAT'L RSCH. COUNCIL, *supra* note 163, at ix. James D. Fine and Dave Owen, *Technocracy and Democracy: Conflicts Between Models and Participation in Environmental Law and Planning*, 56 HASTINGS L.J. 901 (2005); Thomas O. McGarity & Wendy E. Wagner, *Legal Aspects of the Regulatory Use of Environmental Modeling*, 10 ENV'T. REP. 10751 (2003).

237. *See infra* Part III.C.

238. *See infra* Part III.D.

health, safety, and environmental law. Longstanding use of safety factors and conservative assumptions in dose-response estimates, for example, were adopted as relatively simple ways to manage uncertainty during the middle decades of the twentieth century.²³⁹ But during the 1990s, as formal risk assessment came to provide much of the foundation for EPA's major programs, the agency sought to develop and deploy more formal approaches to managing uncertainty. The problem was that the very exercise of quantitative risk assessment itself generated new sources of uncertainty. With every new model, every new extrapolation technique, every new approach to quantifying low-level exposure across diverse conditions and populations, additional uncertainties arose. Finding ways to manage those proliferating uncertainties thus became a central part of the risk assessment exercise.

There is a longer history here that is worth recalling briefly. During the first half of the twentieth century, the relationship between risk and uncertainty had been an important topic of discussion across multiple disciplines. In the 1920s, economists such as Frank Knight and John Maynard Keynes developed the now canonical distinction between risk, or calculable uncertainty, and true uncertainty, that which was incalculable by definition, and both of them considered uncertainty to be a core part of their respective theories and a central fact of economic life.²⁴⁰ There was no sense in which true uncertainty could be managed or made to look like risk. It was fundamentally different, with distinctive epistemic and practical challenges.²⁴¹

By the middle of the twentieth century, however, experts in various fields began looking for ways to cabin and manage uncertainty. The turn toward an increasingly quantitative, model-driven approach in economics, the formalization of expected utility in John von Neumann and Oscar Morgenstern's game theory, the rise of operations research and decision theory, and the growing use

239. See Boyd, *supra* note 11, at 916 (detailing these efforts).

240. See FRANK KNIGHT, RISK, UNCERTAINTY, AND PROFIT 19–20, 233 (1921) (distinguishing between “measurable risk” and “unmeasurable uncertainty”); see also John M. Keynes, *The General Theory of Employment*, 51 Q.J. ECON. 209, 214 (1937) (describing as uncertain matters for which “there is no scientific basis on which to form any calculable probability whatever. We simply do not know.”). On this distinction and its relevance to environmental law, see RICHARD A. POSNER, CATASTROPHE: RISK AND RESPONSE 171–75 (2004); CASS R. SUNSTEIN, WORST-CASE SCENARIOS 147, 162 (2007); Daniel A. Farber, *Uncertainty*, 99 GEO. L.J. 901, 903 (2011). *But see* NIKLAS LUHMANN, RISK: A SOCIOLOGICAL THEORY 1 (2017) (noting that “Knight’s distinction between risk and uncertainty has . . . petrified into a sort of dogma—so that conceptual innovation earns the reproach of not having applied the concept correctly”); MORGAN AND HENRION, *supra* note 235, at 49 (noting that this distinction between risk and uncertainty is “unhelpful”).

241. Cf. JOHN DEWEY, THE QUEST FOR CERTAINTY 6 (1929) (“The distinctive characteristic of practical activity, one which is so inherent that it cannot be eliminated, is the uncertainty which attends it. . . . Judgment and belief regarding actions to be performed can never attain more than a precarious probability. Through thought, however, it has seemed that men might escape from the perils of uncertainty.”).

of formal modeling and simulations across a range of disciplines, pushed uncertainty further to the margins.²⁴² The result was a thinner, more domesticated version of uncertainty—one that was subordinated to risk through a range of calculative practices.²⁴³

Simply put, the problem with uncertainty as conceived by Keynes, Knight, and others was that it was not accessible to the formal, mathematical approaches that rose to prominence during the second half of the twentieth century. As these more formal approaches gained traction, however, uncertainty was increasingly viewed through the lens of risk, relegating it to a residual status—something to be managed. As a result, and notwithstanding the importance of powerful new tools and techniques to manage uncertainty, it became increasingly difficult to engage uncertainty on its own terms.²⁴⁴ This had profound implications across economics and other domains.

The story in health, safety, and environmental law is similar. During the middle decades of the twentieth century, regulators employed simple, qualitative rules of thumb such as margins of safety or safety factors to compensate for uncertainty in their efforts to estimate non-cancer risks and they embraced

242. See, e.g., MARY S. MORGAN, *THE WORLD IN THE MODEL: HOW ECONOMISTS WORK AND THINK* 2–3 (2012) (discussing rise of quantitative, model-based reasoning in economics during the 20th century); JOHN VON NEUMANN & OSKAR MORGENSTERN, *THEORY OF GAMES AND ECONOMIC BEHAVIOR* 1 (60th anniversary commemorative ed., 2007) (characterizing their effort as the application of new mathematical methods to the challenge of finding an exact description of utility maximizing behavior); ERIK P. RAU, *THE ADOPTION OF OPERATIONS RESEARCH IN THE UNITED STATES DURING WORLD WAR II*, IN *SYSTEMS, EXPERTS, AND COMPUTERS: THE SYSTEMS APPROACH IN MANAGEMENT AND ENGINEERING, WORLD WAR II AND AFTER* 57 (Agatha C. Hughes & Thomas P. Hughes eds., 2000) (discussing rise of operations research in the United States and its emphasis on mathematical modeling and computer simulation).

243. See Pat O'Malley, *Uncertain Subjects: Risks, Liberalism, and Contract*, 29 *ECON. & SOC'Y* 460, 462–66 (2010) (discussing move from uncertainty to risk in modern economics); Geoffrey Hodgson, *The Eclipse of the Uncertainty Concept in Mainstream Economics*, 45 *J. ECON. ISSUES* 159 (2011) (discussing displacement of uncertainty by risk in mainstream economics as result of increasing formalization of the discipline in post-World War II period); STEPHEN A. MARGLIN, *THE DISMAL SCIENCE: HOW THINKING LIKE AN ECONOMIST UNDERMINES COMMUNITY* 288 (2008) (“The fact is that contemporary economics, including behavioral economics, has pretty much abandoned the distinction between radical uncertainty and risk.”); JAMES C. SCOTT, *SEEING LIKE A STATES: HOW CERTAIN SCHEMES TO IMPROVE THE HUMAN CONDITION HAVE FAILED* 321–22 (1998) (“The intellectual ‘career’ of risk and uncertainty is indicative of many fields of inquiry in which the realm of analysis was reformulated and narrowed to exclude elements that could not be quantified and measured but could only be judged.”).

244. See Sanjay G. Reddy, *Claims to Expert Knowledge and the Subversion of Democracy: The Triumph of Risk Over Uncertainty*, 25 *ECON. & SOC'Y* 222, 244–45, 248 (1996) (discussing triumph of risk over uncertainty and arguing that “rehabilitation of the idea of ‘uncertainty’” opens up new possibilities for democratic participation).

conservative default rules for potential carcinogens.²⁴⁵ In effect, they recognized uncertainty as an irreducible fact about these potential harms and developed precautionary approaches in response.²⁴⁶ Starting in the 1960s, however, formal extrapolation models were developed to translate high-dose animal studies into risk estimates for low-dose human exposures.²⁴⁷ Regulatory agencies such as EPA and FDA began to use such techniques in the second half of the 1970s.²⁴⁸ These extrapolation techniques allowed investigators to circumvent vast areas of uncertainty and develop formal, quantitative risk assessments for low level exposures. The problem was that different extrapolation models often fit the data equally well, while generating risk estimates that varied by several orders of magnitude. And because there was no neutral, agreed upon criteria for choosing among these different estimates the result was all too often conflict and delay.²⁴⁹

Efforts to formalize risk assessment during the early 1980s acknowledged the problem of uncertainty and sought ways to manage it. The *Red Book*, for example, identified “pervasive uncertainty” as a fundamental challenge (“the dominant analytical difficulty”) confronting the practice of quantitative risk assessment.²⁵⁰ There was a recognition during this time that systematic and, where possible, quantitative treatment of uncertainty was an important part of the risk assessment process.²⁵¹ As William Ruckelshaus put it, risk calculations were not “magic numbers” and EPA needed “new tools for quantifying and ordering sources of uncertainty and putting them into perspective.”²⁵² One

245. See, e.g., Boyd, *supra* note 11, at 932–33 (discussing development and use of a 100-fold margin of safety at FDA during the middle decades of the twentieth century to compensate for uncertainty in extrapolations from animal tests (10X) and in the susceptibility to harm among the general population (10X)); see also *id.*, at 971 (discussing development of default no-threshold view of carcinogens and its use in food safety regulation).

246. *Id.* at 938.

247. *Id.* at 964–70 (discussing development and use of low-dose extrapolation models as basis for early risk assessments).

248. See, e.g., Joseph V. Rodricks, *When Risk Assessment Came to Washington: A Look Back*, 17 DOSE-RESPONSE: AN INT'L J. 1, 4 (2019) (discussing “the proliferation, during the mid-to-late 1970s, of statistical models proposed for low-dose extrapolation”).

249. See, e.g., discussion of risk reassessments for dioxin, TCE, and formaldehyde, *infra* Part IV.A.

250. See NAT'L RSCH. COUNCIL, *supra* note 12, at 11. (“The dominant analytical difficulty is pervasive uncertainty. . . there is often great uncertainty in estimates of the types, probability, and magnitude of health effects associated with a chemical agent of the economic effects if a proposed regulatory action, and of the extent of current and possible future human exposures. These problems have no immediate solutions, given the many gaps in our understanding of the causal mechanisms of carcinogenesis and other health effects and in our ability to ascertain the nature or extent of the effects associated with specific exposures.”).

251. See, e.g., M. Granger Morgan, *Uncertainty Analysis in Risk Assessment*, 4 HUM. & ECOLOGICAL RISK ASSESSMENT: INT'L J. 25, 25 (1998) (“The quantitative characterization and treatment of uncertainty has been a central preoccupation of the field of risk analysis since its inception.”).

252. Ruckelshaus, *supra* note 84, at 161.

way to deal with this was via the use of inference guidelines and defaults such as the linear no-threshold dose-response model for carcinogens.²⁵³ EPA and its internal and external science advisors thus issued various guidance documents elaborating on these approaches and pointing to the importance of more systematic attention to uncertainty.²⁵⁴

At the same time, however, EPA continued to express concerns about pushing too far with efforts to quantify uncertainties in particular contexts. In its 1989 Policy statement on hazardous air pollutants, for example, the agency responded to comments recommending that it use elaborate techniques, such as Monte Carlo simulations,²⁵⁵ to quantify the uncertainties associated with cancer risk estimates for certain air toxics with skepticism about the use of sophisticated tools in the absence of data on key parameters. “In the absence of such data,” EPA noted, “any simulation of the combined uncertainties would be misleading in that it would create an impression of more knowledge and understanding than is presently feasible.”²⁵⁶ Given the general lack of knowledge regarding the mechanisms of carcinogenesis and the lack of information needed to provide the input parameters to perform the uncertainty analysis, EPA concluded that it was best to stick with its more pragmatic and conservative default assumptions in estimating the cancer risks²⁵⁷—an approach that was consistent with the general guidance that EPA was articulating in its cancer risk guidelines.²⁵⁸

253. See Rita Schoeny, *US EPA's Risk Assessment Practice: Default Assumptions, Uncertainty Factors*, 13 HUM. & ECOLOGICAL RISK ASSESSMENT 70, 70–73 (discussing EPA's use of default factors).

254. See, e.g., EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT 3-21-3-32 (2005), <https://perma.cc/UR7D-6NAW> (discussing different extrapolation techniques for carcinogens and ways of handling uncertainty); EPA OFF. SCI. ADVISOR, RISK ASSESSMENT PRINCIPLES AND PRACTICES STAFF PAPER 51-71 (2004), <https://perma.cc/Q5G4-4VVA> (discussing use of default assumptions, extrapolation techniques, and uncertainty factors in risk assessment); NAT'L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 188–212 (discussing selection and use of defaults in risk assessment).

255. The Monte Carlo simulation was developed in the context of efforts to model neutron diffusion in the hydrogen bomb. See Peter Galison, *Computer Simulations and the Trading Zone*, in FROM SCIENCE TO COMPUTATIONAL SCIENCE (Gramelsberger ed., 2011) (tracing history of Monte Carlo simulation as a technique for simulating neutron diffusion in the hydrogen bomb); Pamela Rugen and Barbara Callahan, *An Overview of Monte Carlo, a Fifty Year Perspective*, 2 HUM. & ECOLOGICAL RISK ASSESSMENT: INT'L J. 671, 674 (1996) (discussing use of Monte Carlo techniques by EPA in risk assessment); Dwayne R.J. Moore, *Using Monte Carlo Analysis to Quantify Uncertainty in Ecological Risk Assessment: Are We Gilding the Lily or Bronzing the Dandelion?*, 2 HUM. & ECOLOGICAL RISK ASSESSMENT 628, 628 (1996) (noting that Monte Carlo analysis “has become the tool of choice for quantifying uncertainty in ecological risk assessment”); MORGAN & HENRION, *supra* note 235, at 198–209 (discussing Monte Carlo and other techniques for managing uncertainty).

256. *NESHAPS Policy Statement*, 54 Fed. Reg. 38044 at 38066 (Sept. 14, 1989).

257. *Id.* at 38066–67; see also Moore, *supra* note 255 (“[L]ike any tool, Monte Carlo analysis is not the appropriate tool in all situations, particularly when empirical information is lacking.”).

258. See Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33992 (Sept. 24, 1986) (revising 1976 cancer risk guidelines and providing guidance on defaults and inference choices

Still, the agency continued to receive criticism for what some identified as a largely *ad hoc* approach to uncertainty.²⁵⁹ In response, EPA initiated several internal efforts beginning in the early 1990s to organize its overall approach to uncertainty in its various risk assessment exercises.²⁶⁰ In 1992, for example, Deputy Administrator Henry Habicht issued an internal agency memorandum on risk characterization declaring that “effective immediately” EPA policy would require that information on the range of exposures and multiple risk descriptors be presented in all exposure and risk characterizations.²⁶¹ Later that year a group of analysts from various EPA programs formed an “uncertainty circle” that met periodically to discuss issues related to analysis of uncertainty and variability, inventory the use of particular approaches to uncertainty analysis, convene seminars on methodological issues, and discuss aspects of probabilistic risk assessment.²⁶²

Notwithstanding these developments, the NRC observed in 1994 that EPA had made little progress in developing a more systematic approach to uncertainty.²⁶³ In the wake of this report, EPA developed additional guidance

to bridge knowledge gaps in estimating dose-response and cancer risk). In particular, the Guidelines continued to promote the use of a linear, no-threshold dose-response model as a conservative default for estimate cancer risk at low-level exposures. *See id.* at 33997. The Guidelines were revised again in 1996 and, most recently, in 2005. In both cases, the agency again promoted the use of default options and the linear, no-threshold dose-response model for cancer risk. *See* Notice of Availability of the Document Entitled Guidelines for Carcinogen Risk Assessment, 70 Fed. Reg. 17766 (Apr. 7, 2005).

259. *See* Morgan, *supra* note 251, at 28–30 (criticizing EPA for selective and uneven use of formal uncertainty analysis); *see also* NAT’L RSCH. COUNCIL, HEALTH RISKS FROM DIOXIN AND RELATED COMPOUNDS, *supra* note 154, at 192 (concluding that EPA “failed quantitatively to sufficiently address uncertainty and variability that resulted from the numerous decisions EPA made in deriving point estimates of risk in the comprehensive risk assessment [of dioxin]”).
260. *See* EPA, OFF. SCI. ADVISOR, STAFF PAPER: RISK ASSESSMENT PRINCIPLES AND PRACTICES 30 (2004) (discussing EPA’s efforts since the mid-1980s to understand and characterize uncertainty in its risk assessments).
261. Memorandum from F. Henry Habicht II to EPA Assistant Administrators and Regional Administrators (on Guidance on Risk Characterization for Risk Managers and Risk Assessors) (Feb. 26, 1992).
262. *See* H. CHRISTOPHER FREY, QUANTITATIVE ANALYSIS OF UNCERTAINTY AND VARIABILITY IN ENVIRONMENTAL POLICY MAKING 9–11 (1992), <https://perma.cc/FQ9D-S7LF> (discussing Habicht memo on uncertainty and formation of “uncertainty circle” within EPA). At the time, there were only a few examples of explicit use of Monte Carlo analysis in the agency, primarily in the area of exposure modeling; *see also* DEMORTAIN, *supra* note 144, at 254–55 (discussing increased attention to uncertainty analysis in 1990s and showing influence of reactor safety debates).
263. *See* NAT’L RSCH. COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT, *supra* note 205, at 161 (1994) (noting that EPA had made “little headway” over the previous ten years in developing an effective approach to uncertainty analysis in its risk assessments); *id.* at 166–75 (discussing problems with EPA’s approach to uncertainty and recommending more robust quantitative alternatives).

and an overall policy framework on uncertainty analysis that included specific guidance on the use of Monte Carlo techniques and probabilistic risk assessment.²⁶⁴ Fifteen years later, however, the NRC concluded again that EPA still had not developed an effective and consistent approach to uncertainty in its risk assessments.²⁶⁵

As a result, EPA has struggled to complete high profile risk assessments, such as those for dioxin, formaldehyde, and TCE in part because of disagreements about how to characterize and resolve various uncertainties.²⁶⁶ Presumably, when these risk assessments were initiated, there was an assumption that any uncertainties would be at least partially resolved or narrowed in the process of assessing risk. Yet, if anything, the opposite seems to have occurred. “Uncertainty,” as the NRC noted in its 2009 evaluation of risk assessment, continues to lead “to multiple interpretations and . . . decision-making gridlock.”²⁶⁷ A 2013 report by the Institute of Medicine made a similar observation: “analyses and concerns about uncertainties have in some cases (such as the [EPA’s] work involving dioxin contamination) delayed rulemaking.”²⁶⁸ The report “cautioned against excessively complex uncertainty analysis” in risk assessments, pointing to the need for “decision driven” analyses.²⁶⁹ EPA’s ongoing effort to manage uncertainty, in short, has not been able to deliver high-quality information to decision-makers in a timely manner.

Some of this likely reflected the widely remarked upon effort by industry advocates to “manufacture” uncertainty and doubt.²⁷⁰ On this reading, risk assessment opened up multiple opportunities for industry to point to various sources of uncertainty as a basis for near constant calls for more data and more research. But the problem went deeper than this, and also reflected the epistemic consequences of trying to make uncertainty look more like risk. By seeking to make that which is by definition not calculable into something that can be

264. See EPA, GUIDING PRINCIPLES FOR MONTE CARLO ANALYSIS 3 (1997); EPA, POLICY FOR USE OF PROBABILISTIC ANALYSIS IN RISK ASSESSMENT AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY (1997).

265. See NAT’L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 6 (“EPA does not have a consistent approach to determine the level of sophistication or the extent of uncertainty analysis needed to address a particular problem . . . Inconsistency in the treatment of uncertainty among components of a risk assessment can make the communication of overall uncertainty difficult and sometimes misleading.”).

266. *Id.* at 3.

267. *Id.* at 4.

268. INST. MED., *supra* note 14, at 5 (observing that “EPA has been a leader in the development of quantitative approaches for uncertainty analysis, such as applying Monte Carlo analysis and Bayesian methods to environmental risk assessments” but that the agency’s “analyses and concerns about uncertainties have in some cases (such as the agency’s work involving dioxin contamination) delayed rulemaking” and “some uncertainty analyses have not provided useful or necessary information for the decision at hand”).

269. *Id.* at 6.

270. See ORESKES & CONWAY, *supra* note 9, at 5–8; MICHAELS, *supra* note 9, at xi–xii.

cabined and constrained through calculation, EPA was assuming that improved techniques would continue to make progress in resolving uncertainties. The result, as noted, was a thinner, more domesticated version of uncertainty that could be accommodated and managed within the risk assessment framework.

Rather than seeing quantitative risk assessment as a practice of carving out and making tractable a set of risk estimates from a world of uncertainty, however, it seems important to also turn this around and examine the ways in which some of the specific knowledge practices that underwrite risk assessment actually generate uncertainties. That is, as we engage with and advance our knowledge of complex systems and seek to assess and characterize the risks of a particular set of activities or events, our knowledge practices themselves also generate new uncertainties.²⁷¹ Abstract notions of populations and averages, extrapolation techniques, assumptions about exposure pathways, and computational models all bring with them, and in a very real sense produce, uncertainties precisely because they represent formalized and often highly simplified versions of complex, open systems. Uncertainty, in this sense, can be understood as a feature of particular ways of knowing as much as it is an irreducible fact about the world.²⁷² If this is true, then no amount of effort will ever fully succeed in reducing uncertainty and subordinating it to risk.

B. *Models and Epistemic Competence*

The turn to computational modeling at EPA and the widespread use of models in making decisions about risk also posed challenges to the Agency's ability to ensure the integrity and timeliness of its decisions.²⁷³ While EPA has worked to bring some order to the steadily growing use of models across its

271. See EYAL, *supra* note 8, at 69 (observing that “in most cases other than insurance, the assumptions, heuristics, and boundary conditions necessary to reduce and tame uncertainty produce, as their inescapable price, ignorance (which means that we do not even know what we do not know) about what was left outside the boundary conditions, as well as genuine indeterminacy (because whether the conditions hold or not depends on the future behavior of relevant agents”); Marjolein B. A. van Asselt & Ellen Vos, *The Precautionary Principle and the Uncertainty Paradox*, 9 J. RISK RSCH. 313, 316 (2006) (“Uncertainty can still prevail in situations where a lot of information is available. New information can decrease, but also increase uncertainty, as it may reveal the presence of uncertainties that were previously unknown or were underestimated. Advances in knowledge may illuminate that our understanding was more limited or the processes more complex than thought before.”).

272. See van Asselt & Vos, *supra* note 271, at 316 (distinguishing between uncertainty as a result of variability in the systems being investigated and epistemic uncertainty rooted in the limits of particular ways of knowing).

273. These challenges echoed earlier concerns raised about the use of model-based proxies as basis for setting regulatory standards. In their 1974 book on water pollution in the Delaware River, for example, Bruce Ackerman and his colleagues offered a powerful illustration of the problems associated with model-based proxies. BRUCE ACKERMAN ET AL., *THE UNCERTAIN SEARCH FOR ENVIRONMENTAL QUALITY* 10 (1974).

different programs, various outside reviews during the 1990s and 2000s documented a general lack of attention to modeling practice and to the evaluation of models within EPA. The National Research Council's 1994 *Science & Judgment* report, for example, noted that "[t]he validity of the population-exposure models used by EPA remains largely untested."²⁷⁴ Fifteen years later, the NRC's 2009 *Science and Decisions* report concluded that "[t]he number of transport, fate, and exposure models in active use in EPA or elsewhere is too large to evaluate them individually or to make general statements about their utility and reliability."²⁷⁵ Without evaluation and validation, of course, it is not possible to know what models are really telling us.²⁷⁶

In a perverse way, basic features of administrative law worked to inhibit evaluation and adjustment of the modeling practices used to support ongoing regulatory initiatives. Because any formal re-evaluation and adjustment of a model used to support a particular rule would arguably be subject to notice-and-comment requirements, there has been a tendency to lock-in certain models rather than adjusting them over time in the face of new information and improved practices.²⁷⁷ Courts have also typically been quite deferential when it comes to the modeling practices used by EPA and other agencies, sometimes endowing these practices with more authority than they deserve.²⁷⁸ One danger here is that EPA may sometimes focus more on surviving legal challenges than advancing understanding of the problem at hand. Another danger, however, is that courts may not know how to evaluate the use of models and may end up pushing for more confidence in models than is warranted.

274. NAT'L RSCH. COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT *supra* note 205, at 117.

275. NAT'L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 115.

276. *Cf.* ERICA THOMPSON, ESCAPE FROM MODEL LAND: HOW MATHEMATICAL MODELS CAN LEAD US ASTRAY AND WHAT WE CAN DO ABOUT IT 8 (2022) (arguing that "the continued success of modeling depends on creating a programme of understanding that uses models as a tool and a guide for thinking and communication, and that recognizes and is clear about its own limits").

277. *See, e.g.*, NAT'L RSCH. COUNCIL, MODELS IN ENVIRONMENTAL REGULATORY DECISION MAKING, *supra* note 163, at 80–81 ("Formal evaluation processes required by administrative law may deter meaningful model reevaluation and adjustment over time. . . . Indeed, rule-making requirements can be read to require that the agency undergo notice and comment and the risk of judicial review every time it revises a model that supports a rule-making, since it must ensure that there has been 'meaningful public comment' on all aspects of its final rule. . . . This inertia is not ideal for any regulatory decision, but it is particularly unfortunate for models. The cumbersome regulatory procedures and the finality of the rules that survive them are directly at odds with the dynamic nature of modeling and the goal of improving models in response to experience."); McGarity & Wagner, *Legal Aspects of the Regulatory Use of Environmental Modeling*, *supra* note 236, at 10,756 n. 42.

278. *See* McGarity & Wagner, *Legal Aspects of the Regulatory Use of Environmental Modeling*, *supra* note 236 (collecting cases); NAT'L RSCH. COUNCIL, MODELS IN ENVIRONMENTAL REGULATORY DECISION MAKING, *supra* note 163, at 76–79 (discussing various legal challenges to EPA's use of models).

A couple of examples to illustrate. In *Northwest Coalition for Alternatives to Pesticides v EPA*,²⁷⁹ the Ninth Circuit addressed the use of models to determine children's exposure to certain pesticides under the Food Quality Protection Act. Under the statute, EPA is required to apply a 10-fold safety factor when establishing standards for pesticide residues in food in order to accommodate the uncertainties associated with special sensitivities of children.²⁸⁰ But if EPA can make a showing on the basis of "reliable data" about the actual risk to children, it can dispense with the safety factor.²⁸¹ In this case, EPA claimed to have made such a showing on the basis of modeling results.²⁸² Several environmental groups challenged EPA's claim on the grounds that its reliance on modeling results rather than actual monitoring did not meet the "reliable data" requirement under the statute.²⁸³

The Ninth Circuit rejected the challenges, noting that "[t]here is nothing inherently unreliable about the use of models in scientific assessments."²⁸⁴ For support, the court cited a 1983 D.C. Circuit case that evaluated EPA's use of a cost and feasibility model for determining compliance obligations for small refineries under a lead phase down rule under the Clean Air Act.²⁸⁵ Needless to say, this was a very different kind of modeling exercise, yet the court soldiered on, unmindful of the differences in technique and corresponding knowledge claims that were at issue in the two cases. Indeed, from the court's perspective, EPA had little choice but to rely on these modeling exercises in estimating exposures. "Because of the difficulty in sampling the entire nation's water supply," the court observed:

Modeling is necessary to determine whether drinking water has been contaminated with pesticides. Topography, geology, and hydrology differ greatly across the nation and constantly change. In many

279. 544 F.3d 1043 (9th Cir. 2008).

280. See Food Quality Protection Act, Pub. L. No. 104-170, 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).

281. *Id.* (providing that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children").

282. See Order Denying Objections to Issuances of Tolerances, 70 Fed. Reg. 46706, 46726-27 (Aug. 10, 2005) (discussing use of exposure models to estimate levels of exposure to pesticides in drinking water and concluding that the use of such models satisfies the "reliable data" requirement as basis for departing from the 10X safety factor).

283. See Brief for Petitioners at 38-44, *Nw. Coal. For Alt. to Pesticides et al. v. EPA*, 544 F.3d 1043 (2008) Nos. 05-75255, 05-76807 (arguing that EPA's reliance on pesticide exposure models in the absence of any monitoring data did not satisfy the "reliable data" requirement for EPA to depart from the 10X safety factor default).

284. *Nw. Coal. For Alts. To Pesticides*, 544 F.3d at 1048.

285. *Id.* at 1048 (citing *Small Refinery Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 535 (D.C. Cir. 1983)).

cases, computer modeling can more accurately incorporate these elements and provide more reliable data than actual water sampling can provide.²⁸⁶

It is worth pausing for a moment to consider the full implications of this statement—to consider, that is, how far the modern practice of environmental protection has moved beyond direct experience in assessing risks and regulating potential harms.²⁸⁷ While one can be sympathetic to the reviewing court, the court’s reasoning begs the obvious question of how it, or EPA for that matter, could possibly know if the model’s outputs were better representations of reality than sampling.²⁸⁸ Indeed, the only way of actually answering such a question would be to engage in widespread and systematic sampling.

The 2004 decision by the D.C. Circuit vacating EPA’s health and environmental protection standards for the Yucca Mountain high-level radioactive waste repository provides another interesting window into how regulatory models are perceived by courts and the challenges facing agencies seeking to make use of such models.²⁸⁹ In that case, the court vacated EPA’s standards on the grounds that the agency’s decision to limit the “compliance period” for the repository—that is, the period over which EPA projected repository behavior using computer simulation models—to 10,000 years was inconsistent with advice from the National Academy of Sciences.²⁹⁰ The National Academy, which had been charged by Congress in the Energy Policy Act of 1992 to study the matter and provide guidance to EPA,²⁹¹ had concluded in its report that “there is no scientific basis for limiting the time period of the individual risk standard to 10,000 years or any other value.”²⁹² The Academy went on to note, however, that the period of “peak risk” to human health posed by the repository likely stretched

286. *Id.* at 1048–49. The court went on to conclude that “[a]lthough the FQPA does not define ‘reliable data,’ we are confident that modeling results can satisfy this statutory requirement.” *Id.* at 1049.

287. *See, e.g.*, Nat. Res. Def. Council, Comment Letter on EPA Organophosphate Cumulative Risk Assessment 6–7 (Oct. 3, 2006), <https://perma.cc/RH26-63JR> (discussing lack of validation for pesticide exposure models in cumulative risk assessment for organophosphates). *See also* Yellin, *supra* note 167, at 1300 (discussing how models can “distance a modern agency’s reasoning from ordinary experience”).

288. *See* Brief for Petitioners at 40–42, *Nw. Coal. for Alt. to Pesticides et al. v. EPA*, 544 F.3d 1043 (2008) Nos. 05-75255, 05-76807.

289. *Nuclear Energy Inst. v. EPA*, 373 F.3d 1251 (D.C. Cir. 2004).

290. *Id.* at 1315.

291. Energy Policy Act of 1992, Pub. L. No. 102-486, § 801(a)(2), 106 Stat. 2776, 2922 (1992).

292. COMM. ON TECH. BASES FOR YUCCA MOUNTAIN STANDARDS, ET AL., TECHNICAL BASIS FOR YUCCA MOUNTAIN STANDARDS 55 (1995). The National Academy of Sciences noted further “that the ultimate restriction on time scale is determined by the long-term stability of the fundamental geologic regime—a time scale that is on the order of 10⁶ years at Yucca Mountain.” *Id.*

beyond 10,000 years and that “the 10,000-year limitation might be inconsistent with protection of public health.”²⁹³

In its proposed and final rules on the matter, EPA struggled with the challenge of trying to develop a risk assessment that could somehow comprehend the “far future” in a meaningful way.²⁹⁴ Ten thousand years, as EPA noted, was “twice as long as recorded human history.”²⁹⁵ And although there was precedent for using a 10,000-year compliance period (deep well injection and other land-based disposal of hazardous waste in the United States use this period as do geologic disposal programs in other countries), there were fundamental questions about the reliability of the exercise. Notwithstanding the National Academy’s own conclusion that “there was no scientific basis for limiting the time period to 10,000 years,” EPA concluded that:

There is still considerable uncertainty as to whether current modeling capability allows development of computer models that will provide sufficiently meaningful and reliable predictions over a time frame of tens-of-thousands to hundreds-of-thousands of years. Simply because such models can provide projections for those time periods does not mean that those projections are meaningful and reliable enough to establish a rational basis for regulatory decisionmaking.²⁹⁶

The DC Circuit was not sympathetic. Even with the deference accorded under *Chevron*, the court found that because EPA had “unabashedly rejected [the National Academy of Science’s] findings, and then went on to promulgate a dramatically different standard, one that the Academy had expressly rejected,” its actions were unreasonable.²⁹⁷ Here too the court seemed confused. In fact, the National Academy had not summarily rejected the use of a shorter time frame. And even though environmental groups argued that EPA was avoiding

293. *Id.*; see also *id.* at 56 (“We recognize that there are significant uncertainties in the supporting calculations and that the uncertainties increase as the time at which peak risk occurs increases. However, we see no technical basis for limiting the period of concern to a period that is short compared to the time of peak risk or the anticipated travel time.”).

294. See Environmental Radiation Protection Standards for Yucca Mountain, 64 Fed. Reg. 46976, 46994–95 (proposed Aug. 27, 1999) (discussing problem of “cumulative uncertainty” in “dealing with the far future”).

295. *Id.* at 46996.

296. See Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV, 66 Fed. Reg. 32074, 32097 (June 13, 2001). As the agency continued, “[f]urthermore, we are unaware of a policy basis that we could use to determine the ‘level of proof’ or confidence necessary to determine compliance based upon projections of hundreds-of-thousands of years into the future.” *Id.*

297. *Nuclear Energy Inst. v. EPA*, 373 F.3d 1251, 1270, 1273 (D.C. Cir. 2004). The court found that the language of the statute, which required that EPA’s standard be “based upon and consistent with NAS’s findings,” was ambiguous, but that even so, EPA’s actions had “so completely diverge[ed] from any realistic meaning of the [statute] that it cannot survive scrutiny under *Chevron* Step Two.” *Id.* at 1270.

the longer time frame because it would allow it to set a less stringent standard,²⁹⁸ the Agency's broader point about the absurdity of the whole enterprise is not so easily dismissed. On remand, EPA went back to its simulation models and adopted a new compliance period of one million years.²⁹⁹ One can only wonder whether future generations will feel safer as a result.³⁰⁰

These and other cases suggest that we have a long way to go in order to fully understand the distinctive kinds of knowledge claims made possible by these models and their implications for environmental law. By providing ways of seeing "systems that are too large, too complex, or too far away to study by other means," modeling allows us to see problems in new ways, opening up new frontiers of knowledge and new possibilities for governance.³⁰¹ Yet, although predictive models operate as "a surrogate for access to the future" it is often difficult to evaluate "how good a surrogate they are."³⁰² How exactly are we supposed to evaluate the predictions of repository behavior at Yucca Mountain (or some other place) one million years in the future?³⁰³

298. See, e.g., *Testimony of Geoffrey H. Fettus, Nat. Res. Def. Council Before the Senate Comm. on Energy and Nat. Res.* 109th Cong. 4 (2006) ("EPA has repeatedly issued standards that are concerned more with licensing the site than with establishing protective standards."), available at: <https://perma.cc/7K4B-NADG>.

299. EPA released its final revisions to the remanded 2001 standard in 2008. See *Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada*, 40 C.F.R. § 197 (2008). The new standards retained the previous standards up through the initial 10,000 years and then adopted a second set of standards for the period between 10,000 and 1 million years. In doing so, the agency noted "great concern in extending the compliance period to 1 million years" given "the increasing uncertainty associated with numerical projections of radionuclide releases from the Yucca Mountain disposal system and subsequent exposures incurred by the Reasonably Maximally Exposed Individual (RMEI)." *Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada*, 73 Fed. Reg. 61260 (Oct. 15, 2008). EPA went on to note that "[t]here is general agreement in the international community that dose projections over periods as long as 1 million years cannot be viewed in the same context or with the same confidence as projections for periods as 'short' as 10,000 years. As a result, the nature of regulatory decision-making fundamentally changes when faced with the prospect of compliance periods for the next 1 million years." *Id.*

300. One might, of course, also wonder whether there will even be future generations of homo sapiens one million years in the future. Cf. Peter Galison, *Containment: Discussing Nuclear Waste with Peter Galison*, in *INEVITABLY TOXIC: HISTORICAL PERSPECTIVES ON CONTAMINATION, EXPOSURE, AND EXPERTISE* 287 (Sarathy et al. eds., 2018) ("A million years from now, we may not even be the us of our species self. I mean that literally: 'we,' as homo sapiens, emerged from homo erectus around 200,000 to 300,000 years ago; we homo sapiens were surely not in existence in our anatomically modern form a million years ago. There is no reason to expect that 'we' (in that sense) would be around a million years from now. Does that mean giving up on the far future altogether?").

301. Naomi Oreskes, *Why Believe a Computer? Models, Measures, and Meaning in the Natural World*, in *THE EARTH AROUND US* 70, 70–71 (Jill Schneiderman ed., 2000).

302. *Id.* at 79.

303. *Id.* at 79. Cf. *Nuclear Energy Inst. v. EPA*, 373 F.3d 1251 (D.C. Cir. 2004). Galison, *Containment*, *supra* note 300.

As various commentators have pointed out, the technical sophistication associated with modeling can lead to overconfidence in the validity of their results.³⁰⁴ Put differently, there is a danger that the sophistication of these tools and the elegance of their results may inhibit our capacity for reflection about what we actually know.³⁰⁵ As Naomi Oreskes and Kenneth Belitz observe, “if our mathematical and computational prowess exceed our empirical understanding, we may achieve sophistication at the expense of knowledge. We may also achieve it at the expense of the open-mindedness necessary to learn from our mistakes.”³⁰⁶

All of which raises important questions about traditional notions of expertise and accountability and whether increasingly sophisticated tools will actually lead to better decisions.³⁰⁷ These are questions of epistemic competence that surely deserve more attention in the context of environmental decision-making.³⁰⁸ As such, they implicate a broader set of concerns about fact-making and knowledge production within regulatory agencies. Wendy Wagner, Elizabeth Fisher, and Pasky Pascual have argued that the problem with models

304. Oreskes, *Why believe a computer?*, *supra* note 301, at 81 (models “may propagate the illusion that things are better known than they really are”). In fact, such models cannot really be “validated” in any meaningful sense. Naomi Oreskes & Kenneth Belitz, *Philosophical Issues in Model Assessment*, in MODEL VALIDATION: PERSPECTIVES IN HYDROLOGICAL SCIENCE at 23 (“Models cannot be validated.”); *id.* at 23–25 (discussing reasons why models cannot be validated and concluding that the “language of validation is unhelpful and should be avoided”). The more complex the model is, moreover, the more difficult it is to evaluate it. *Id.* at 30.

305. See Oreskes, *The Role of Quantitative Models in Science*, in MODELS IN ECOSYSTEM SCIENCE 15 (2003) at 15 (“[I]t is not even clear that time-forward model output necessarily contributes to basic scientific understanding. If our goal is to understand the natural world, then using models to predict the future does not necessarily aid that goal. If our goal is to contribute usefully to society, using models to predict the future may not do that either.”).

306. Oreskes & Belitz, *supra* note 306, at 25; see also Oreskes, *supra* note 305, at 25 (“Perhaps for this reason, data-collection programs have proved difficult to sustain. Scientists should ponder why this is so and consider whether the public interest is being served by our emphasis on models. A better balance between modeling and data collection may be called for.”)

307. See, e.g., NAT’L RSCH. COUNCIL, MODELS IN ENVIRONMENTAL REGULATORY DECISION MAKING, *supra* note 163, at 193 (noting that “ever-larger and more sophisticated models may not necessarily make better regulatory tools” and discussing “the possibility that pursuing larger and more-sophisticated models make them less and less able to be evaluated and more impenetrable to the public and decision makers”); see also Paul Humphreys, *The Philosophical Novelty of Computer Simulation Methods*, 169 SYNTHESIS 615, 617 (2009) (“For an increasing number of fields in science, an exclusively anthropocentric epistemology is no longer appropriate because there now exist superior, non-human, epistemic authorities. So we are now faced with a problem . . . of how we, as humans, can understand and evaluate computationally based scientific methods that transcend our own abilities.”).

308. Cf. Jennifer L. Mnookin, *Expert Evidence, Partisanship, and Epistemic Competence*, 73 BROOK. L. REV. 1009, 1012–13 (2008) (discussing challenge of epistemic competence in the context of the jury’s ability to evaluate expert testimony in litigation).

stems largely from a general misunderstanding of their role and purpose in environmental law; that is, the tendency to treat them as “truth machines” rather than as tools for trying to understand problems.³⁰⁹ “All models are wrong, but some are useful,” they observe, quoting a favorite saying of modelers.³¹⁰ But, of course, once we recognize that modeling results are always provisional and incomplete, we still have to face the question of how to use these provisional “facts” in regulation. Thus, even in a world where courts extend substantial deference to the use of models, achieving closure for regulatory purposes can be exceedingly difficult.³¹¹

The larger point here is that because choice of model always involves discretion and because all models are incomplete, the use of models to support regulatory decision-making provides multiple opportunities to question, contest, and criticize the choices made. By changing the model, one can change the facts used to make regulatory decisions. That fact, combined with pervasive questions about epistemic competence in evaluating models, argues for an approach that is prepared to make use of multiple lines of evidence and that, once again, is founded upon a deep respect for the uncertainties embedded in any modeling exercise.

C. Cumulative Risks and the Challenge of Complexity

Since its inception, the standard approach to risk assessment has tended to focus on single chemicals (e.g., dioxin) with single health end-points (e.g., cancer).³¹² While this highly reductionist approach was arguably necessary to make the risk assessment exercise tractable, critics have long pointed to a range of obvious problems. First, many chemicals that are known to be hazardous with respect to one type of harm, such as cancer, also contribute to other types of harms, including reproductive harms, neurotoxicity and neurodevelopmental harms, endocrine system disruption, and immune system suppression (among others).³¹³ Second, people are exposed to multiple chemicals and other stressors

309. See Wendy Wagner, et al., *Misunderstanding Models in Environmental and Public Health Regulation*, 18 N.Y.U. ENV'T L. J. 293, 296 (2010) (arguing that models are often understood as “truth machines” in environmental law).

310. *Id.* at 335 (quoting GEORGE E.P. BOX & NORMAN R. DRAPER, *EMPIRICAL MODEL-BUILDING AND RESPONSE SURFACES* 424 (1987)).

311. See NAT'L RSCH. COUNCIL, *MODELS IN ENVIRONMENTAL REGULATORY DECISION MAKING*, *supra* note 163, at 76 (noting that courts often give EPA “considerable deference” when parties challenge EPA’s use of regulatory models).

312. See, e.g., Jane Ellen Simmons, *Chemical Mixtures: Challenge for Toxicology and Risk Assessment*, 105 TOXICOLOGY 111, 112 (1995) (reporting that the “vast majority of toxicology studies examine the cancer and non-cancer health effects of single chemicals”); Maricel V. Maffini et al., *Advancing the Science on Chemical Classes*, 21 ENV HEALTH 1,2 (2023) (noting that the “chemical-by-chemical risk assessment has been the standard approach for several decades”).

313. See, e.g., A. Fan et al., *Risk Assessment of Environmental Chemicals*, 35 ANN. REV. PHARMACOL. TOXICOL. 341, 346–60 (1995) (discussing various cancer and non-cancer harms from

across multiple exposure pathways in their daily lives, some of which may interact in ways that are additive or even synergistic.³¹⁴ Third, environments and exposure pathways are constantly shifting, undermining the stability of any particular risk assessment.³¹⁵ These problems, which are often grouped under the rubric of cumulative risk, have bedeviled risk assessment for decades.³¹⁶

The overall problem of evaluating cumulative risk became particularly acute in the mid-1980s as EPA confronted the need to assess the potential health risks

exposure to chemicals and the challenges of accommodating these in the traditional risk assessment framework).

314. See, e.g., Peter Montague, *Reducing the Harms Associated with Risk Assessments*, 24 ENV'T IMPACT ASSESS. REV. 733, 740–41 (2004) (“Risk assessments should acknowledge that most people are exposed to mixtures of chemicals (pharmaceuticals, food additives, pesticide residues, second-hand tobacco smoke, vehicle exhausts, disinfectants and cleaning agents, fine and ultrafine particles from combustion sources, pollutants in drinking water, and exudates from consumer products, among others) along with other stresses (ultraviolet radiation, bacteria and viruses, genetic disorders, aging, etc.). Such combinations of complex chemical exposures and stresses are rarely acknowledged, and their combined effects on health and behavior obviously cannot be assessed with any substantial degree of confidence.”).
315. See, e.g., NAT'L RSCH. COUNCIL, EXPOSURE SCIENCE IN THE 21ST CENTURY *supra* note 212, at 60 (“Exposure assessment poses numerous challenges for risk assessment. Exposures change, so a risk assessment that uses data that are available today may no longer be valid months or years from now. . . . Important exposure pathways may be missed, and this can lead to underestimation of overall exposure or neglect of highly exposed populations. Risk assessments and exposure assessments tend to focus on one chemical at a time and potentially miss interactive effects that could influence both exposure and risk.”); see also Catherine O'Neill, *Exposed: Asking the Wrong Question in Risk Regulation*, 48 ARIZ. ST. L.J. 703, 710 (2016) (“[E]xposure assessment as practiced also sets up a moving target, as there will always be an argument that newer data would more accurately capture people's current practices. With each of the numerous inputs to an exposure equation subject to constant revision and renewed debate, the occasions for delay are many. These contests in practice have often diserved the aims of environmental health.”).
316. See, e.g., Simmons, *supra* note 312, at 117 (“The toxicology and risk assessment of chemical mixtures are among the most perplexing and difficult areas of toxicology and risk assessment.”); WARGO, *supra* note 211, at 241 (“Perhaps the greatest challenge to experts in environmental health is to evaluate risks associated with complex mixtures of toxic substances.”); David O Carpenter et al., *Understanding the Human Health Effects of Chemical Mixtures*, 110 ENV. HEALTH PERSP. 25, 25 (2002) (“The study of chemical mixtures is limited for a number of reasons. It is much easier to study a single compound in an animal study and to obtain traditional dose-response information. An almost infinite number of combinations of contaminants is possible, and often we do not know which is most important, or which dose ranges should be investigated, or which biologic end points should be studied. Although relatively few studies have investigated the interactions of even two chemicals, in real life we are all exposed to multiple substances, and the biologic effects of 20 different chemicals may be very different than those of just two. Furthermore, even the statistics relating to how one deals with complex mixtures is a newly developing science.”); Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2316 (2017), (observing that despite widespread recognition of the need for cumulative risk assessment, the practice exists “only at the regulatory fringe” and that “without a concerted effort . . . the trend toward a myopic, chemical-by-chemical analysis of . . . risks is likely to continue.”).

of possible exposure to multiple chemicals at contaminated superfund sites under CERCLA.³¹⁷ Many of these sites contained hundreds of different substances, confronting EPA's efforts to assess the risks of each site (and to determine when a site was "clean" and thus eligible to be taken off the National Priorities List) with a daunting set of challenges.³¹⁸ In 1986, EPA developed guidelines for assessing the risks of chemical mixtures and introduced the concept of Toxic Equivalency Factors as a tool to evaluate the health risks associated with closely related chemicals that had similar mechanisms of action but different levels of cancer potency such as dioxin and dioxin-like compounds, organophosphate pesticides, and chlorinated organic compounds.³¹⁹

By the early 1990s, the complex mixture problem, as it came to be known, had also become a prominent topic of discussion in efforts to understand the health risks from cumulative exposures to multiple pesticide residues in food, particularly for children and infants.³²⁰ According to a growing chorus of public

317. See Gina M. Solomon et al., *Cumulative Environmental Impacts: Science and Policy to Protect Communities*, 37 ANN. REV. PUB. HEALTH 83, 87 (2016) ("Risk assessments for cleanups of contaminated sites were among the earliest to evaluate the potential health risks of multiple chemicals.").

318. See, e.g., Barry L. Johnson & Christopher T. DeRosa, *Chemical Mixtures Released from Hazardous Waste Sites: Implications for Health Risk Assessment*, 105 TOXICOLOGY 145, 147 (1995) (reporting data from the early 1990s finding more than 2000 unique substances identified in environmental media sampled by EPA during hazardous waste site characterizations studies). *Id.* at 148 (noting that "a hundred or more different chemicals can be found at a single waste site . . . in widely varying combinations in water, soil and air" and that "[s]ome of these chemical combinations may be much more hazardous than any of the individual chemicals").

319. See EPA, Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 Fed. Reg. 34014 (Sept. 24, 1986). These guidelines were supplemented in 2000, but still provide the governing framework for EPA's efforts to assess the risks of chemical mixtures. See EPA, SUPPLEMENTARY GUIDANCE FOR CONDUCTING HEALTH RISK ASSESSMENT FOR CHEMICAL MIXTURES ix (2000); see also NAT'L RSCH. COUNCIL, *supra* note 154, at 33 ("The TEF concept originated as a method for evaluating health risks associated with closely related chemicals with similar mechanisms of action but different potencies."). On some of the limitations of the TEF approach, see H.G. Neumann, *Toxic Equivalence Factors, Problems and Limitations*, 34 FOOD & CHEM. TOXICOLOGY 1045, 1045 (1996).

320. See, e.g., NAT'L RSCH. COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 297 (1993) ("Pesticide regulation in the United States has been focused on single chemicals rather than on combinations of compounds likely to appear as mixtures in the human diet. This practice can be attributed not only to the absence of data on the residues of multiple compounds that coexist on foods but also to the lack of methods for estimating simultaneous exposures to multiple chemicals, which cannot be accomplished merely by combining mean values (or other statistical summaries) of food intake and residue data. The regulatory process has therefore progressed on a chemical-by-chemical basis without consideration of possible additive and synergistic effects that could result from exposures to mixtures."); see also WARGO, *supra* note 210, at 235 ("Since its inception, EPA has been overwhelmed by questions concerning the toxicity, exposure, and risks posed by single pesticides. The situation has prevented the agency from examining the distribution of and effects of pesticide mixtures in the diet and other environments.")

health professionals, the standard approach to risk assessment for pesticides was missing major potential sources of harm because of the failure to appreciate the ways that children were exposed to multiple pesticides that might have “additive” or even “synergistic” effects.³²¹ The FQPA recognized these shortcomings and required EPA to look at aggregate exposures to pesticides across multiple exposure pathways and to include in its assessment of pesticide risks attention to the cumulative effects of multiple pesticides with a “common mechanism of toxicity.”³²² In 1999, EPA identified the organophosphate pesticides as the first group with a common mechanism of toxicity, releasing its first cumulative risk assessment for these pesticides in 2002, which it revised and updated in 2006.³²³ This was followed by cumulative risk assessments for four other pesticide groups.³²⁴ While these efforts are commendable as a step toward more realistic risk assessments, they have also compounded the considerable analytical difficulties of mapping exposure pathways, assessing interactions between chemicals, and determining how to combine different measures of toxicity.³²⁵

The problem of cumulative risk, of course, also stretched well beyond superfund sites and pesticide exposures to implicate virtually all of EPA’s major programs. In recognition of this, EPA Administrator Carol Browner called for a formal, agency-wide approach to cumulative risk in 1997, and issued new guidelines to assist agency professionals in performing cumulative risk assessments.³²⁶

321. NAT’L RSCH. COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 297 (1993).

322. Food Quality Protection Act, Pub. L. No. 104–170, 110 Stat. 1489, 1518 (1996) (codified at 21 U.S.C. §346a(b)(2)(C)(III)).

323. See, e.g., EPA, ORGANOPHOSPHATE CUMULATIVE RISK ASSESSMENT 2006 UPDATE 3 (2006) (discussing the history of these efforts regarding organophosphate pesticides and noting that “pesticides are determined to have a ‘common mechanism of toxicity’ if they act the same way in the body—that is, the same toxic effect occurs in the same organ or tissue by essentially the same sequence of major biochemical events”); see also EPA, GUIDANCE ON CUMULATIVE RISK ASSESSMENT OF PESTICIDE CHEMICALS THAT HAVE A COMMON MECHANISM OF TOXICITY iii (2002) (noting that before EPA conducts a cumulative risk assessment for a group of pesticides with a common mechanism of toxicity, it will conduct risk assessments for all of the individual chemicals in the group across all exposure pathways).

324. The four additional groups are: N-methyl carbamates, Triazines, Chloroacetanilides, and Pyrethrins/Pyrethroids. See EPA, *Cumulative Assessment of Risk from Pesticides*, EPA (March 10, 2023), <https://perma.cc/69SK-44UC>.

325. See, e.g., Ken Sexton, *Cumulative Risk Assessment: An Overview of Methodological Approaches for Evaluating Combined Health Effects from Exposure to Multiple Environmental Stressors*, 9 INT’L J. ENV’T RSCH. PUB. HEALTH 370, 383 (2012) (“Cumulative risk assessments are intended to answer difficult and formerly unaddressed questions regarding combined risk burdens and disproportionate health impacts. As a result, they tend to be more theoretically complex, methodologically complicated, and computationally challenging than traditional single- chemical assessments.”)

326. See Carol Browner, Memorandum: Cumulative Risk Assessment Guidance-Phase I Planning and Scoping (July 3, 1997), <https://perma.cc/9L5V-5GZ5>; EPA, GUIDANCE ON CUMULATIVE RISK ASSESSMENT: PART 1. PLANNING AND SCOPING (1997).

The objective, according to Browner, was “to consider a broader scope that integrates multiple sources, effects, pathways, stressors and populations for cumulative risk analyses.”³²⁷ Six years later, the agency released a new framework with the intention of initiating a process that would result in concrete steps the agency could take to implement cumulative risk assessment across its various programs.³²⁸ But aside from the work on common mechanism pesticides noted above and an effort to assess the cumulative risks associated with drinking water disinfectants, very little progress was made over the next two decades.³²⁹ In 2023, EPA released yet another draft set of guidelines on cumulative risk assessment, this time focused on planning and problem formulation.³³⁰ If anything, the new guidelines look more like a repackaged version of the 1997 guidelines than an actual step forward on how to actually conduct such assessments. EPA’s ongoing difficulties in making cumulative risk assessment work in practice thus begs the question of whether the way to resolve the shortcomings of quantitative risk assessment is to double-down and do more or consider alternatives. Given the sheer number of industrial chemicals and pesticides that are currently in commerce or registered for use (perhaps as many as 80,000 industrial chemicals (we don’t know the actual number) and some 17,000 pesticide products), not to mention the many different kinds of pollutants and contaminants that people are exposed to in air and water, efforts to apply the basic framework of quantitative risk assessment to such complex real-world exposures look like an impossible task.³³¹

327. Browner, *supra* note 326, at 1.

328. See EPA RISK ASSESSMENT FORUM, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT (2003); see also NAT’L RSCH. COUNCIL, SCIENCE FOR ENVIRONMENTAL PROTECTION: THE ROAD AHEAD 137 (2012) (observing that “many of the trends in both science and risk-assessment practice in recent years involve moving from a single-chemical perspective to a multistressor perspective. EPA has grappled with chemical mixtures for some time, and cumulative risk assessment has come to the forefront of the agency’s thinking over the last decade, although the agency has rarely used it.”)

329. See, e.g., HERTZBERG ET AL., RESEARCH REPORT: CONDUCTING A RISK ASSESSMENT OF MIXTURES OF DISINFECTION BY-PRODUCTS (DBPs) FOR DRINKING WATER TREATMENT xxviii (2000).

330. See Public Comment on the Cumulative Risk Assessment Guidelines for Planning and Problem Formulation, 88 Fed. Reg. 39424 (June 16, 2023).

331. See Carpenter et al., *supra* note 316, at 25 (discussing challenges of assessing risk of chemical mixtures); Michael A. Callahan and Ken Sexton, *If Cumulative Risk Assessment is the Answer, What is the Question?*, 115 ENV. HEALTH PERSP. 799, 802 (2007) (“Assessing combined effects, including the potential for antagonistic and synergistic interactions, among diverse mixture constituents that may include biological, chemical, physical, and psychosocial stressors is substantially more complex methodologically and computationally than traditional single-chemical, source-oriented assessments. Although a few examples of cumulative risk assessments attempt to evaluate joint effects of a variety of different kinds of stressors, in most cases the underlying scientific uncertainties, technical challenges, and methodologic complications have discouraged extensive application of these approaches.”) (citations omitted).

And yet, major reviews of EPA's approach to risk assessment have consistently emphasized that the single-chemical, single-endpoint approach is of limited utility and have urged EPA to develop new tools that will allow it to perform more realistic risk assessments.³³² As the NRC concluded in a 2012 report on science for environmental decision-making:

Narrowly focused risk assessments that omit complex interactions will be increasingly uninformative and unresponsive of effective preventive decisions. The broad challenge before the agency will involve developing tools and approaches to characterize cumulative effects in complex systems and harnessing insights from multistressor analyses without paralyzing decisions because of analytic complexities or missing data.³³³

A broad challenge indeed, with no obvious way forward given that it is already taking decades for EPA to complete single risk assessments for individual data-rich chemicals such as dioxin, TCE, and formaldehyde. In short, as EPA has struggled to develop a viable approach to assessing cumulative risks, it has found itself facing more questions than it can answer.³³⁴ Calls to extend the practice of risk assessment to address well characterized harms associated with multiple chemicals and pollutants across multiple exposure pathways and to combine

332. See, e.g., NAT'L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 213–36 (discussing need for a new approach to cumulative risk); see also Richard Levins, *Strategies of Abstraction*, 21 BIOLOGY & PHIL. 741, 741–42 (2006) (“Complexity is now in fashion. Books, meetings, even whole institutes are devoted to complexity. It is a recognition that the long traditions of reductionist science, so successful in the past, are increasingly inadequate to cope with the systems we are now trying to understand and influence. The great errors and failings of attempts to apply science to matters of urgent concern have come from posing problems too narrowly, too linearly, too statically.”)

333. NAT'L RSCH. COUNCIL, SCIENCE FOR ENVIRONMENTAL PROTECTION, *supra* note 328, at 138. Risk assessment professionals have also voiced repeated calls for more attention to cumulative risks; see, e.g., Ken Sexton, *Cumulative Risk Assessment: An Overview of Methodological Approaches for Evaluating Combined Health Effects from Exposure to Multiple Environmental Stressors*, 9 INT'L J. ENV'T'L RES. & PUB. HEALTH 370, 371 (2012) (“There is a growing mismatch between the broader, real-world questions being asked by decision makers and important stakeholders, and the narrow, limited answers provided by conventional risk assessments. To rectify this situation, traditional chemical-by-chemical risk assessments must expand to incorporate consideration of combined health effects from exposure to a diverse array of environmental agents such as people encounter during their normal daily routines.”).

334. See, e.g., NAT'L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 94 (“The reach and depth of risk assessment are sure to improve with expanding computer tools, additional biomonitoring data, and new toxicology techniques. But such advances will bring new challenges and an increased need for wisdom and creativity in addressing uncertainty and variability.”) See also Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2320 (2017) (calling for a “paradigm shift . . . where cumulative risk moves from regulatory fringe to center stage”).

this with an assessment of more subtle and less well understood harms such as endocrine system disruption, reproductive and immune system toxicity, and neurodevelopmental effects further complicate matters. Put bluntly, trying to assess these cumulative risks within the standard risk assessment framework seems completely unrealistic based on the record to date.

D. Structural Vulnerabilities and Environmental Justice

EPA's efforts to understand and accommodate cumulative risks within the risk assessment paradigm also raised questions about the impacts of environmental harms on those already suffering from poverty, racism, and other forms of discrimination. This problem of structural vulnerability and the manner in which environmental harms compound these vulnerabilities has been largely invisible to standard approaches to risk assessment. By design, quantitative risk assessment employs a series of strategic simplifications that often erase or minimize the differential effects that certain harms have on certain people and communities. Not surprisingly, quantitative risk assessment has faced deep skepticism from environmental justice advocates.³³⁵ Most fundamentally, they have pointed out that the practice often ignores the uneven and inequitable distribution of environmental harms across the population.³³⁶ By focusing on averages and aggregates; by building assumptions about "normal" exposure into the structure of models, risk assessment has all too often been willfully blind to the disparate impacts on marginalized people and frontline communities.³³⁷

Quantitative risk assessment also disempowers public participation by design. Despite repeated calls for more stakeholder engagement and participation by affected communities, risk assessment has always been a highly technocratic exercise that excludes certain facts, voices, and lived experiences.³³⁸ This is not just an oversight or a shortcoming that can be remedied by more stakeholder

335. See, e.g., 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: AN INT'L J. 561, 561 (2000).

336. See, e.g., Clifford Rechtschaffen, *Advancing Environmental Justice Norms*, 37 U.C. DAVIS L. REV. 95, 105 (2003) ("Risk assessments typically consider aggregate effects, such as total population risk, and downplay or fail to consider how these are distributed.").

337. See, e.g., Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 U. ILL. L. REV. 103, 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).

338. See Kristin Shrader-Frechette, *Analyzing Public Participation in Risk Analysis: How the Wolves of Environmental Injustice Hide in the Sheep's Clothing of Science*, 3 ENV'T JUSTICE 119, 119–20 (2010) (noting how the separation of risk assessment and risk management worked to exclude participation in the process by various stakeholders); Sheila R. Foster, *Meeting the Environmental Justice Challenge: Evolving Norms in Environmental Decisionmaking*, 30 ENV'T L. REP. 10,992, 10,999 (2000) (noting limited roles for affected and disadvantaged communities in formal risk assessments).

engagement and improved deliberation.³³⁹ In fact, the very logic of risk assessment and the general presumption that “ordinary people” are irrational and prone to various mistakes about risk creates a fundamental hostility to public participation.³⁴⁰

Attention to the special susceptibilities of what are often referred to as vulnerable sub-populations under certain statutes are, at best, a modest step in the right direction. The 1996 FQPA, for example, requires additional safety factors to account for the heightened impacts of certain pesticides on children.³⁴¹ The new amendments to TSCA also include explicit language directing EPA to protect vulnerable groups and highly exposed populations, but that statute is badly broken with risk assessments dragging on for decades.³⁴² In short, none of these efforts address the more fundamental question raised by environmental justice advocates regarding whether the risk assessment exercise itself, which provides the foundation for EPA’s efforts to regulate toxic chemicals, pesticides, pollution, and hazardous waste sites, can ever accommodate the broader stresses and vulnerabilities that affect frontline communities. For many of the same reasons that risk assessment is incapable of making cumulative risks cognizable, it has been unable to account for the subtle and not-so-subtle ways that toxic harms interact with and compound the structural violence of poverty and racism. In fact, one can go further and argue that the concept of risk itself and the practice of risk assessment operate to mask various forms of domination and violence. To ask how and why we have come to view misfortune through the lens of risk, therefore, will always be partial and incomplete questions if they fail to recognize the structures of domination that stand behind, enable, and activate so much of the harm and suffering in our world today.

339. Cf. NAT’L RSCH. COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 3–6 (1996) (discussing challenges facing and need for broad public participation in risk assessment exercises); NAT’L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 234–35 (discussing need for stakeholder involvement in risk assessment).

340. See, e.g., SUNSTEIN, RISK AND REASON, *supra* note 53, at 7–9 (defending a highly technocratic approach to risk assessment and arguing for skepticism and discounting of popular concerns and intuitions about risks).

341. See Food Quality Protection Act, Pub. L. No. 104–170, 110 Stat. 1489, 1518 (1996) (codified at 21 U.S.C. §346a(b)(2)(C)(ii)(II)) (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).

342. See Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114–182, 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.

IV. DE-RISKING ENVIRONMENTAL LAW

Modern environmental law was born at the beginning of what historian Daniel Rodgers has called the age of fracture—a period stretching from the 1970s through the end of the twentieth century during which basic categories of social reality and longstanding institutional settlements were dismantled and discarded in favor of a more individualistic, neoliberal project premised on a general distrust of government.³⁴³ The core commitments of environmental law, which drew on earlier notions of endangerment, precaution, and a healthy respect for uncertainty, were almost immediately at odds with the culture of adversarialism and hostility to regulation that was gathering momentum throughout the 1970s.³⁴⁴ By the end of that decade, facing a substantial expansion in its statutory responsibilities and diminished public confidence, EPA was under considerable pressure to change course and revamp its approach to environmental decision-making.³⁴⁵

The Supreme Court, as noted, provided a major boost to this effort with its 1980 *Benzene* decision.³⁴⁶ The Court's hostility to OSHA's efforts to find a creative and workable solution to the challenge of regulating carcinogens in the workplace left OSHA with no real options to craft a creative and timely response to the problem.³⁴⁷ *Benzene*, as noted, is also enjoying something of a revival with the Court's current conservative majority, providing an early example of a more muscular commitment to judicial intervention in regulatory decision-making.³⁴⁸ As such, the case provides a cautionary lesson about what happens to agencies in the wake of a "major questions" type of intervention. Indeed, OSHA never really recovered from *Benzene* and has been unable to deliver on its basic responsibilities to regulate workplace hazards.³⁴⁹ The spillover effects of the decision for EPA and FDA were also, as noted, of enormous import. By the early 1980s, in

343. See DANIEL RODGERS, AGE OF FRACTURE 5–11(2011).

344. See, e.g., RICHARD LAZARUS, THE MAKING OF ENVIRONMENTAL LAW 103–07 (2nd ed. 2023) (discussing the growing culture of adversarialism, polarization, and disillusionment during the 1970s and its impacts on environmental law).

345. *Id.* at 106.

346. *Benzene Decision*, at 607

347. See Boyd, *With Regard for Persons*, *supra* note 74, at 113–16 (discussing impacts of *Benzene* decision on OSHA and other agencies).

348. See *supra* Part II.A.

349. See, e.g., THOMAS MCGARITY ET AL., CENTER FOR PROGRESSIVE REFORM, WORKERS AT RISK: REGULATORY DYSFUNCTION AT OSHA 8–9 (2010); 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 during the second half of the 1970s and the ensuing backlash during the Reagan administration); Jim Morris, *How Politics Gutted Workplace Safety*, SLATE (July 7, 2015), <https://perma.cc/QQ7P-EBCE> (discussing OSHA's challenges since the 1980s to discharge its responsibility to protect American workers from toxic substances).

the wake of *Benzene* and the *Red Book*, quantitative risk assessment had become the default approach to harm across these various agencies.

In important respects, William Ruckelshaus was the key player in this transition. More than any other EPA Administrator (or any other government official), it was Ruckelshaus who, during his second term at EPA in the early 1980s, established the basic framework that has guided much of the agency's approach to risk assessment and regulatory science ever since. With its promise to constrain discretionary policy judgments, risk assessment would, it was hoped, insulate the agency from politics and restore credibility. "The public agency," Ruckelshaus observed, "is the repository of the facts; you can't operate a democratic society, particularly a complex technological one, unless you have such a repository. Above all, the factual guardian must be trusted, a failure of trust courts chaos."³⁵⁰ Making EPA the "factual guardian" on matters of environmental harm, risk assessment, it was hoped, would restore public trust and avoid chaos.³⁵¹

But efforts to implement risk assessment across EPA's various programs—from air and water pollution to pesticides, toxic chemicals, and hazardous wastes—have proved immensely challenging given the diverse nature of the problems at issue, different statutory requirements, the massive analytical effort that the exercise entails, and the high political and economic stakes involved. This has meant that almost every decision about how to perform risk assessments has served as an opportunity for contestation and delay, often resulting in a proliferation of uncertainties that have proved incapable of easy resolution.³⁵² As this Article has argued, this was largely by design, and much of the standard history of risk assessment has failed to recognize that it operates more as a political technique to constrain regulation than a scientific exercise for generating useful knowledge about the world. This Part steps back and offers some preliminary thoughts on what a political economy of risk assessment might look like. It also offers some provisional reflections on what a new ethics of regulatory science might entail—one that recenters law in the commitment to protecting human health, embraces the fact of uncertainty and the limits of our knowledge, and seeks to come to terms with the everyday violence embedded in the practice of risk assessment.

350. See Ruckelshaus, *Risk in a Free Society*, *supra* note 85, at 157.

351. As Ruckelshaus noted, quantitative risk assessment and its strict separation from risk management offered "a possible solution to this problem." *Id.*

352. John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991); Catherine O'Neill, *Exposed: Asking the Wrong Question in Risk Regulation*, 48 ARIZ. ST. L.J. 703, 710 (2016).

A. *Toward a Political Economy of Risk Assessment*

Although the move to more formal approaches to risk during the 1980s and 1990s cannot be attributed solely to the push for regulatory relief, industry groups such as the American Industrial Health Council, the American Petroleum Institute, and the Chemical Manufacturers Association (now known as the American Chemistry Council) were instrumental in pushing the broader science policy establishment to embrace quantitative risk assessment and separate it from risk management.³⁵³ Starting with the attack on OSHA's generic cancer policy in the late 1970s and continuing through the Supreme Court's *Benzene* decision in 1980 to the *Red Book* and the various guidance documents, external evaluations, and multiple rounds of engagement on individual risk assessments, the hands of industry have been all over the push to make quantitative risk assessment the basis of environmental decision-making. That this has often been framed as a defense of science-based decisions should not obscure the fact that these efforts have succeeded in providing ample opportunities for opponents of regulation to slow the regulatory process—not only by contesting the legal basis for various agency actions but also by emphasizing uncertainties, challenging assumptions, and raising questions about the methods employed.³⁵⁴ By construing risk assessment as a scientific and technical exercise, opponents of regulation can always find ways to argue for more science, more research, and more data.³⁵⁵

One response from the agencies, and EPA in particular, has been to effectively outsource more of the contested risk decisions they have been called upon to make by submitting draft assessments to various rounds of review by EPA's own Science Advisory Board as well as the National Research Council.³⁵⁶

353. See *supra* Parts II.A and II.B; DEMORTAIN, *supra* note 144, at 286 (discussing some of this history); Boudia, *supra* note 150, at 103–107 (same).

354. See, e.g., Neff & Goldman, *supra* note 7, at S81. (“There is broad agreement that regulatory decisions about the environment, safety, and health should be based on evidence. But pressures for ever-increasing documentation, review, and “sound science” have been used to create unreasonable standards of evidence, interfering with the government’s task of protecting the public. “Sound science” pressures and the availability of analytic tools have created an environment in which interested parties can demand more and more data and repeated scientific review for the sole purpose of delaying the adoption of health-protective standards.”).

355. See NAOMI ORESKES, *WHY TRUST SCIENCE?* 246 (2019) (observing that “the core strategy of ‘the merchants of doubt’ is to create the impression that the relevant science is unsettled, the pertinent scientific issues still appropriately subject to contestation. If we respond on their terms—offering more facts, insisting that these facts *are* facts—then they win, because now there *is* contestation.”); see also MICHAELS, *supra* note 9, at ix (2008).

356. See, e.g., Sheila Jasanoff, *Science, Politics, and the Renegotiation of Expertise at EPA*, 7 *OSIRIS* 195, 205–06 (1992) (discussing move by EPA starting in the late 1970s to enlist outside experts in evaluating its risk assessments).

This sort of peer review was explicitly called for in the *Red Book* and has been a key feature of the risk assessment process ever since.³⁵⁷ But it has also long been a central demand of industry, and it is not hard to see why.³⁵⁸ Multiple rounds of peer review together with various expert assessments of the process of risk assessment have meant that difficult risk assessments go through multiple iterations and outside reviews, leading to years, even decades of delay.³⁵⁹ The amount of documentation and evidence associated with such reviews (and their overall complexity) has grown accordingly.³⁶⁰ Peer review in this context often looks more like a disciplinary exercise than an error-correction device.

The overall result—significant delay in risk assessments and associated rulemakings—might be seen as one manifestation of what various commentators have referred to as the ossification of rulemaking and regulation.³⁶¹ The heavy emphasis on decision-making frameworks and procedures has not only failed to deliver the legitimacy and public trust that defenders of the administrative state have long sought, it has also turned into a weapon that can be used to undermine and derail substantive regulatory goals.³⁶² Politicians and legislators,

357. See NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 12, at 144–48 (discussing need for independent scientific review panels and other forms of peer review for risk assessments); *id.* at 156 (recommending that “[a]n agency’s risk assessment should be reviewed by an independent science advisory panel before any major regulatory action or decision not to regulate. Peer review may be performed by science panels already established or authorized under current law, or, in their absence, by panels created for this purpose.”).

358. See, e.g., Moolenaar, *supra* note 33, at 388 (“AIHC [the American Industrial Health Council] endorses the basic concepts presented in the NAS Report [the *Red Book*]. Initiatives already taken by Congress and the agencies for peer review of scientific analyses have been well received. We support even more extensive use of outside scientists and peer review programs at the federal level. In the area of federal guidelines for risk assessment, . . . care must be exercised so that well-intentioned guidance does not become so rigid that it precludes the most thorough evaluation of complicated and unique data bases for individual chemicals or that it does not ‘freeze’ science.”).

359. See, e.g., *infra* Part IV.A for a discussion of multiple rounds of peer review in EPA’s risk assessments for dioxin, TCE, and formaldehyde; see also Stuart Shapiro & David Guston, *Procedural Control of the Bureaucracy, Peer Review, and Epistemic Drift*, 17 J. PUB. ADMIN. RSCH. & THEORY 535, 536 (2006) (discussing role of regulatory peer review in addressing principal-agent problems in control of bureaucracy and noting that “peer review and regulatory science will become increasingly politicized”).

360. See Neff & Goldman, *supra* note 7, at S81 (observing that “pressures for ever-increasing documentation, reviewing, and ‘sound science’ have been used to create unreasonable standards of evidence, interfering with government’s task of protecting the public.”).

361. See, e.g., Thomas O. McGarity, *Some Thoughts on ‘Deossifying’ the Rulemaking Process*, 41 DUKE L.J. 1385, 1387–96 (1992) (discussing the “ossification” of informal rulemaking); see also *id.* at 1400–03 (highlighting judicially imposed analytical requirements as a cause of ossification and discussing the *Benzene* case as a leading example).

362. Cf. Nicholas Bagley, *The Procedure Fetish*, 118 MICH. L. REV. 345, 400 (2019) (“Proceduralism has a complex, contingent, and often ambiguous connection to legitimacy and capture. Many well-intentioned efforts to promote good governance can—and do—drain agencies of

of course, have long recognized this. As John Dingell, the formidable Congressman from Michigan, was fond of saying: “If I let you write the substance and you let me write the procedure, I’ll screw you every time.”³⁶³

TSCA is perhaps the best example of this triumph of proceduralism in the statutory context. In the initial versions of the proposed legislation, the statute was straightforward and precautionary.³⁶⁴ By the time of enactment, the statute had been transformed by intense industry lobbying into a procedural maze that created significant obstacles to EPA’s ability to regulate existing chemicals.³⁶⁵ At almost every stage, EPA had to make findings of unreasonable risk before proceeding and there were virtually no meaningful requirements for industry to produce the necessary information to make such findings.³⁶⁶ This was further compounded by the fact that the statute grandfathered the more than 60,000 chemicals in commerce at the time of enactment, creating a presumption that these chemicals were safe unless EPA could prove otherwise.³⁶⁷ When EPA decided to use asbestos to test its authority to regulate existing chemicals under TSCA, the results were disastrous.³⁶⁸

Starting in 1979, EPA proceeded to build a 45,000–page record to support its efforts to regulate asbestos and issued a final risk assessment in 1986.³⁶⁹ Three years later, it issued its final rule banning all uses of the substance.³⁷⁰ But two years after that, in 1991, the Fifth Circuit agreed with industry and struck down the ban, holding that EPA had “failed to muster substantial evidence” to justify its action.³⁷¹ Channeling *Benzene*, the court criticized EPA on various methodological and evidentiary grounds; it also read into the statute a requirement that

their legitimacy, impair their responsiveness to the public, and expose them to capture.”); see also Stuart Shapiro & David Guston, *Procedural Control of the Bureaucracy, Peer Review, and Epistemic Drift*, 17 J. PUB. ADMIN. RES. THEORY 535, 535–36 (2006); Kessler & Sabel, *supra* note 46, at 192.

363. David Nather, *The “Babe Ruth” of Legislators*, POLITICO (Feb. 24, 2014), <https://perma.cc/4Q43-FJ3V>.

364. See Boyd, *Genealogies of Risk*, *supra* note 11, at 972–76 (recounting this history).

365. *Id.* at 976.

366. See, e.g., Toxic Substances Control Act, Pub. L. 94–469, 90 Stat. 2003, 2006, 2014, and 2020 (1976) (requiring EPA to make a finding of “unreasonable risk” before issuing testing rules for chemicals, before regulating new chemicals or significant new uses of existing chemicals, and before regulating existing chemicals).

367. See Schmidt, *supra* note 169, at 183 (noting that the “roughly 62,000 chemicals already in commerce when TSCA was first enacted were for all intents and purposes exempted from the law”).

368. See Rachel Rothschild, *The Failure to Ban Asbestos and the Future of Toxic Substances Regulation*, 47 HARV. ENV’T L. REV. 529, 529 (2023) (recounting history of EPA’s effort to ban asbestos under TSCA).

369. Asbestos Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions 54 Fed. Reg. 29460, 29461 (July 12, 1989) (to be codified at 40 C.F.R. pt. 763). The proposed rule and final risk assessment were released in 1986. *Id.* at 29460, 29473.

370. *Id.*

371. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1207 (5th Cir. 1991).

the agency evaluate systematically all other possible regulatory options that were less burdensome than a ban.³⁷² That is, if EPA were intent on pursuing the most burdensome regulatory option available under the statute (a ban), it had an obligation to justify this by evaluating all other options to determine whether they might reduce the unreasonable risk posed by asbestos in the least burdensome way.³⁷³ EPA also had an obligation, according to the court, to assess the risks of any substitutes.³⁷⁴ Given that it had already taken seven years to complete a risk assessment for asbestos—arguably the most data-rich substance EPA has ever tried to regulate with a clear signature disease and voluminous epidemiological data showing extensive harm, this would be an impossible task.

The *Corrosion Proof Fittings* decision was a crushing defeat for EPA, which all but abandoned its efforts to regulate existing chemicals under TSCA. Indeed, EPA did not issue another final risk assessment for an existing chemical under TSCA until 2014 (a draft risk assessment for trichloroethylene (“TCE”) was issued in June 2014, twenty-eight years after it was initiated), and did not use its TSCA authority to regulate an existing chemical again until 2015.³⁷⁵

At roughly the same time that EPA was trying to regulate asbestos under TSCA, OSHA launched another ambitious effort to regulate hazardous substances in the workplace. By the end of the 1980s, since OSHA’s creation almost twenty years earlier, the Agency had promulgated Permissible Exposure Limits (“PELs”) for only twenty-four substances, and it had yet to revise any of the more than 400 standards that it inherited as part of the statute’s incorporation of the threshold limit values (“TLVs”) that existed prior to its enactment in 1970.³⁷⁶ Recognizing the importance of revising these standards, the agency launched a generic rulemaking to establish or revise PELs for 428 air contaminants.³⁷⁷ In a reprise of the position it had advanced a decade earlier in its Generic Cancer

372. *Id.* at 1214–22.

373. *Id.* at 1223–29.

374. *Id.* at 1221.

375. EPA, TSCA WORKPLAN CHEMICAL RISK ASSESSMENT, TRICHLOROETHYLENE: DEGREASING, SPOT CLEANING, AND ARTS AND CRAFTS USES (June 2014).

376. *See* Air Contaminants, 53 Fed. Reg. 20960, 20963 (proposed June 7, 1988) (“OSHA has issued only 24 substance-specific health regulations since its creation. It has not been able to review the many thousands of currently unregulated chemicals in the workplace nor to keep up with reviewing the several thousand new chemicals introduced since its creation. It has not been able to fully review the literature to determine if lower limits are needed for many of the approximately 400 substances it now regulates.”); *see also id.* at 20962 (discussing how 400 TLVs and some 25 other “national consensus” standards that existed at the time of enactment of the Occupational Safety and Health Act were grandfathered in under the new statute as OSHA standards).

377. *Id.*; *see also* Air Contaminants, 54 Fed. Reg. 2332, 2333 (1989) (codified at 29 C.F.R. pt. 1910) (“OSHA determined that it was necessary to modify this [chemical-by-chemical] approach through the use of generic rulemaking, which would simultaneously cover many substances. . . . Without a generic approach OSHA would not be able to provide the level of health protection required for many work situations.”)

Policy, the agency noted in its proposed rule that evaluating these contaminants chemical-by-chemical would take decades.³⁷⁸ Meanwhile, American workers would continue to be exposed to hundreds of chemicals in the workplace that were largely unregulated, with hundreds of new chemicals being introduced every year.³⁷⁹

The Eleventh Circuit was not sympathetic.³⁸⁰ Invoking *Benzene*, the court rejected the entire rulemaking because OSHA had failed to demonstrate that the risk associated with each individual substance was significant.³⁸¹ As the court noted:

OSHA has a responsibility to quantify or explain, at least to a reasonable degree, the risk posed by *each* toxic substance regulated. . . . Otherwise, OSHA has not demonstrated, and this court cannot evaluate, how serious the risk is for any particular substance, or whether *any* workers will in fact benefit from the new standard for any particular substance. If each of these 428 toxic substances had been addressed in separate rulemakings, OSHA would clearly have been required to estimate in some fashion the risk of harm for each substance. OSHA is not entitled to take short-cuts with statutory requirements simply because it chose to combine multiple substances in a single rulemaking.³⁸²

The court also rejected OSHA's arguments that quantitative approaches were not feasible for many of the non-carcinogenic effects of some of these substances and that safety factors were an appropriate means to deal with

378. *See* Air Contaminants, 53 Fed. Reg. 20960, 20963 (proposed June 7, 1988) ("Using past approaches and practices, OSHA could continue to regulate a small number of the high priority substances and those of greatest public interest. However, it would take decades to review currently used chemicals and OSHA would never be able to keep up with the many chemicals which will be newly introduced in the future.").

379. *Id.* (noting that "millions of employees in total are exposed to levels of these chemicals which, the literature or expert opinion indicates, do or may create deleterious health effects"). The final rule also noted that the new rule, taken as a whole, would prevent 55,000 occupational illnesses and 683 deaths per year. *See* Air Contaminants, 54 Fed. Reg. 2332, 2725 (1989) (codified at 29 C.F.R. pt. 1910).

380. *AFL-CIO v. OSHA*, 965 F.2d 962 (11th Cir. 1992). OSHA's rule was challenged by both industry groups, arguing against the procedures that OSHA used to set a large number of new standards on the grounds that it might result in overregulation, and organized labor, arguing that the rule was systematically under-protective. *Id.* at 971.

381. *Id.* at 973 ("OSHA is not entitled to regulate *any* risk, only those which present a 'significant' risk of 'material' health impairment. . . . The agency 'has no duty to calculate the exact probability of harm,' or 'to support its finding that a significant risk exists with anything approaching scientific certainty.' However, OSHA must provide at least an estimate of the actual risk associated with a particular toxic substance and explain in an understandable way why that risk is significant.").

382. *Id.* at 975.

uncertainty.³⁸³ Even though OSHA had “probably established that most or all of the substances involved . . . pose[d] a significant risk at some level, it ha[d] failed to establish that existing exposure levels in the workplace presented a significant risk of material health impairment or that the new standards [would] eliminate or substantially lessen the risk.”³⁸⁴

While these cases may represent extreme instances of judicial scrutiny, they had important signaling effects that went beyond the facts at issue.³⁸⁵ EPA essentially abandoned TSCA as a tool to regulate existing chemicals (which constituted the bulk of the toxics chemicals problem) until the statute was finally overhauled in 2016.³⁸⁶ OSHA went back to the drawing board, resigned to proceed on a chemical-by-chemical basis, leaving American workers to bear the burden of uncertainty and delay.³⁸⁷ More generally, these cases signaled that agencies would need to double down on quantitative risk assessments. EPA, in particular, re-doubled its efforts on several major risk assessments for dioxin, formaldehyde, and trichloroethylene and, in doing so, looked increasingly to outside peer review as a means to provide more legitimacy to the exercise. As noted, however, all of these major risk assessment exercises have taken decades to complete, with many thousands of additional chemicals waiting in the queue.³⁸⁸

In the case of the dioxin risk reassessment, although multiple low-dose extrapolation models appear to fit the data equally well, they generate risk estimates that vary by several orders of magnitude.³⁸⁹ Since the mid 1980s the fight has been over the mode of action or mechanism by which dioxin causes cancer, which affects the shape of the dose-response curve and the associated extrapolation models.³⁹⁰ Put simply, the question is whether dioxin acts an initiator of cancer or a promoter of cancer, or both, or neither.³⁹¹ The data are inconclusive.

383. *Id.* at 977–79.

384. *Id.* at 980.

385. *See, e.g.*, Matthew Stephenson, *A Costly Signaling Theory of Hard Look Judicial Review*, 58 ADMIN. L. REV. 753, 755–56 (2006).

386. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114–182, 130 Stat. 448.

387. *Benzene Decision*, at 686 (Marshall, J., dissenting).

388. *See* NAT’L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 3–4, 17.

389. *See, e.g.*, Peter C. Wright et al., *Twenty-Five Years of Dioxin Cancer Risk Assessment*, 19 NAT. RES. & ENV’T 31, 34–35 (2005) (discussing range of cancer risk estimates for dioxin using different standards and guidelines for extrapolation from same data); *see also* NAT’L RSCH. COUNCIL, *supra* note 154, at 190.

390. Ellen K. Silbergeld, *Commentary: The Role of Toxicology in Prevention and Precaution*, 11 HUM. & ECOLOGICAL RISK ASSESSMENT 125, 131 (2005) (“At best, the search for mechanism can introduce extraordinary delay. Lack of mechanistic insight is not a justification for delay, especially where the observational data from epidemiology and toxicology are strong. The dioxin risk assessment process in the US is an egregious example of how ‘more research’ has been used to excuse nearly 20 years of failure to set final guidelines.”).

391. *See* NAT’L RSCH. COUNCIL, *supra* note 154, at 113–18 (reviewing scientific literature seeking to characterize dioxin’s mode of action as an initiator and/or a promoter of cancer); *see also* Linda S. Birnbaum, *The Mechanism of Dioxin Toxicity: Relationship to Risk Assessment*,

There are studies going in different directions. But we do know from animal studies that dioxin is one of the most potent carcinogens ever tested—the “Darth Vader of chemicals” as one observer put it.³⁹² We know that exposures to trace amounts of dioxin from the use of Agent Orange in Viet Nam have resulted in a range of cancers and other very serious health problems for veterans and the people of Viet Nam.³⁹³ We also know that dioxin is extremely persistent in the environment and we know that it bioaccumulates.³⁹⁴ All of this we know and yet because the data do not resolve the question of precisely how dioxin causes cancer in humans, industry and the science policy establishment have urged EPA on multiple occasions to go back to the drawing board and develop alternative dose-response curves, conduct more formal uncertainty analyses, and review more studies.³⁹⁵ To describe this as Kafkaesque would be an

102 ENV'T HEALTH PERSP. 157, 159–60 (1994) (reviewing science on dioxin's mechanism of action); Barry Commoner, *The Hazards of Risk Assessment*, 14 COLUM. J. ENV'T L. 365, 373–74 (1989) (discussing debates over dioxin's potential function as an initiator or as a promoter of cancer and suggesting that this conventional distinction may not be appropriate for dioxin).

392. See George Clark et al., *Integrated Approach for Evaluating Species and Interindividual Differences in Responsiveness to Dioxins and Structural Analogs*, 98 ENV'T HEALTH PERSP. 125, 126 (1992) (reviewing evidence from animal studies and concluding that TCDD, the most potent form of dioxin, “is clearly among the most potent of all identified chemical carcinogens”); Birnbaum, *supra* note 391, at 158 (“Dioxin is often described as the most toxic man-made chemical because of the low doses which cause lethality in certain animal species such as the guinea pig.”); Cindy Skrzycki & Jo Warrick, *EPA Links Dioxin to Cancer*, WASH. POST (May 17, 2000) (quoting cancer epidemiologist Richard Clapp: “It’s the Darth Vader of toxic chemicals because it affects so many systems [of the body]”).
393. See Howard Frumkin, *Agent Orange and Cancer: An Overview for Clinicians* 53 CA: CANCER JOURNAL FOR CLINICIANS 245, 246–52 (2003) (reviewing evidence of cancer and other health effects from exposure to dioxin in Agent Orange); PETER H. SCHUCK, *AGENT ORANGE ON TRIAL: MASS TOXIC DISASTERS IN THE COURTS* 20–22 (1986).
394. See NAT'L RSCH. COUNCIL, *supra* note 154, at 1.
395. See INST. OF MED., *ENV'T DECISIONS AND UNCERTAINTY* 234 (2013) (noting that different extrapolation models for low dose exposures to dioxin could lead to regulatory standards that varied by “more than an order of magnitude” and that “[d]isagreements about which model is appropriate for low dose extrapolations of the cancer risks of dioxin have resulted in extensive delays in finalizing the dioxin health risk assessment”); see also Roni A. Neff and Lynn R. Goldman, *Regulatory Parallels to Daubert: Stakeholder Influence, “Sound Science,” and the Delayed Adoption of Health Protective Standards*, 95 AM. J. PUB. HEALTH SUPP. S81, S81–S82 (2005) (discussing industry influence on EPA dioxin risk reassessment); Peter C. Wright et al., *Twenty-Five Years of Dioxin Cancer Risk Assessment*, 19 NAT. RES. & ENV'T 31, 35 (2005) (noting that cancer risk estimates in dioxin risk assessments vary by three orders of magnitude); NAT'L RSCH. COUNCIL, *supra* note 154, at 45–46 (“Significant uncertainties remain in understanding human health risks from 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), other dioxins, and dioxin-like compounds (DLCs), in spite of very large investments in data collection and research.”).

understatement.³⁹⁶ One study found that between 1975 and 2002, more than 7,000 studies were published on dioxin and that some \$5 billion had been expended researching the chemical, making it one of the most studied chemicals ever.³⁹⁷ And yet, as of 2023, the dioxin cancer risk reassessment has still not been released (thirty-two years and counting) and EPA has given no indication of when it expects to finish.³⁹⁸

As with dioxin, EPA began investigating the risks of trichloroethylene or TCE (a widely used solvent) in the early 1980s and published its first health risk assessment in 1985, followed by a 1987 addendum concluding that TCE was a probable human carcinogen.³⁹⁹ TCE has also been linked to fetal heart abnormalities and it readily crosses the blood-brain barrier (particularly in developing brains) causing neurotoxic and neurodevelopmental harms.⁴⁰⁰ Facing criticisms that it relied too heavily on inconclusive animal studies, however, EPA withdrew its initial TCE cancer risk assessment in 1989 and launched a new process to reassess the risks of TCE.⁴⁰¹ Twelve years later, the agency released a

396. Over the thirty plus years (and counting) that the dioxin cancer risk re-assessment has been ongoing, EPA's Science Advisory Board and the National Research Council have weighed in on multiple occasions, often with hundreds of pages of analysis directing EPA to further revise its approach. See NAT'L RSCH. SOUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 28–30 (recounting history of EPA and external review efforts on dioxin risk).

397. See Dennis J. Paustenbach, *The U.S. EPA Science Advisory Board Evaluation (2001) of the EPA Dioxin Reassessment*, 36 REGUL. TOXICOLOGY & PHARMACOLOGY 211 (2002).

398. In 2012, EPA released its reassessment for noncancer risks associated with dioxin exposure in response to the NRC's 2006 evaluation of EPA's previous 2001 draft risk reassessment. See EPA, 1 EPA'S REANALYSIS OF KEY ISSUES RELATED TO DIOXIN TOXICITY AND RESPONSE TO NAS COMMENTS (2012). As explained in the document, a second volume on cancer risk was intended to follow. As of November 2023, EPA still has not released the second volume on cancer risk.

399. See EPA, HEALTH ASSESSMENT DOCUMENT FOR TRICHLOROETHYLENE (1985); EPA, ADDENDUM TO THE HEALTH ASSESSMENT DOCUMENT FOR TRICHLOROETHYLENE: UPDATED CARCINOGENICITY ASSESSMENT FOR TRICHLOROETHYLENE, EXTERNAL REVIEW DRAFT (1987).

400. See DEP'T OF HEALTH AND HUM SERVS. AGENCY FOR TOXIC SUBSTANCES AND DISEASE REG., TOXICOLOGICAL PROFILE FOR TRICHLOROETHYLENE (TCE) 261 (2019) (discussing health impacts); Weihshueh A. Chiu et al., *Human Health Effects of Trichloroethylene: Key Findings and Scientific Issues*, 121 ENV'T HEALTH PERSP. 303, 309 (2013) ("TCE is carcinogenic to humans by all routes of exposure and poses a potential human health hazard for noncancer toxicity to the central nervous system, kidney, liver, immune system, male reproductive system, and the developing embryo/fetus. These conclusions are based on analyses of a broad spectrum of information from thousands of scientific studies and input from numerous scientific reviews."). An extensive recent cohort study of personnel exposed to TCE in drinking water at Camp Lejeune, North Carolina found a 70% increase in the risk of Parkinson's disease. See Samuel M. Goldman et al., *Risk of Parkinson Disease Among Service Members at Marine Corps Base Camp Lejeune*, 80 JAMA NEUROLOGY 673, 676 (2023).

401. See U.S. GOV'T ACCOUNTABILITY OFF., EPA SCIENCE: NEW ASSESSMENT PROCESS FURTHER LIMITS THE CREDIBILITY AND TIMELINESS OF EPA'S ASSESSMENT OF TOXIC CHEMICALS 24 (2008) ("Because of questions raised by peer reviewers about the IRIS cancer

draft reassessment,⁴⁰² which was heavily criticized by industry and the Defense Department (both of which have historically used large amounts of TCE and contributed to widespread TCE contamination across the country) and which demanded that the National Academy of Sciences review the entire effort. Another thirteen years later, after multiple additional rounds of review, EPA then published its final draft risk assessment for TCE in 2014. But then the Trump administration changed course, releasing a revised and heavily criticized draft risk assessment in 2020. Upon taking office, the Biden EPA revisited the entire effort and issued a final revised risk assessment for trichloroethylene in December 2022.⁴⁰³

Much of the controversy over TCE has turned on whether the associations between TCE exposure and various cancers are causal and the vast differences in the estimates of cancer potencies from human and animal studies.⁴⁰⁴ The science is inconclusive on these questions and the data support a range of possible risk estimates. So the risk assessment process soldiers on (thirty-five years in this case) even as the overall evidence indicates that the risks of TCE are more serious than previously suspected.⁴⁰⁵

On formaldehyde, another widely used chemical, EPA published its first risk assessments in 1989 (for exposure via diet and drinking water) and 1991 (for inhalation).⁴⁰⁶ Seven years later, EPA launched a formal process to reassess the risks of formaldehyde based on new studies indicating a possible link to leukemia.⁴⁰⁷ By the early 2000s, an industry research group (the Chemical Industry Institute of Toxicology) and a new industry coalition (the Formaldehyde Council) were actively sponsoring researchers who developed new mathematical models suggesting that the health risks of formaldehyde risks were a thousand

assessment for TCE, EPA withdrew it from IRIS in 1989 but did not initiate a new TCE cancer assessment until 1998.”)

402. See EPA, TRICHLOROETHYLENE HEALTH RISK ASSESSMENT: SYNTHESIS AND CHARACTERIZATION, EXTERNAL REVIEW DRAFT (2001).

403. See EPA, FINAL RISK EVALUATION FOR TRICHLOROETHYLENE (2022), <https://perma.cc/FBL5-PCTZ>.

404. Estimates of cancer potency varied by up to 100-fold based on data from different human studies and by up to 500-fold based on data from different animal studies. See INST. OF MED., *supra* note 14, at 54–55 (summarizing the uncertainties plaguing the TCE risk assessment).

405. See, e.g., Goldman et al, *supra* note 400 (linking TCE exposure to Parkinson’s disease).

406. See EPA, FORMALDEHYDE; CASRN 50-00-00 (1989); EPA, DRAFT FINAL FORMALDEHYDE RISK ASSESSMENT (1991). EPA had also released a prior report in 1987 assessing the health risks of formaldehyde for garment workers and home residents. See EPA, ASSESSMENT OF HEALTH RISKS TO GARMENT WORKERS AND CERTAIN HOME RESIDENTS FROM EXPOSURE TO FORMALDEHYDE (1987); see also Oscar Hernandez et al., *Risk Assessment of Formaldehyde*, 39 J. HAZ. MAT. 161, 161–62 (1994) (discussing history of EPA’s early efforts to assess health risks of formaldehyde).

407. See NAT’L RSCH. COUNCIL, REVIEW OF EPA’S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE 18–19 (2011) (providing timeline for EPA’s reassessment of cancer and noncancer risks of formaldehyde initiated in January 1998).

times lower than EPA had estimated.⁴⁰⁸ While there was clear evidence from both animal and human studies that formaldehyde exposure could cause a rare form of nasal cancer, the fight was over the relationship between low-level formaldehyde exposure and leukemia.⁴⁰⁹ Given the widespread use of formaldehyde in wood products and other industries, the stakes were high. As a result, EPA's efforts to reassess the risks of formaldehyde were subjected to multiple rounds of external and internal review, direct interventions by members of Congress, and interference by senior EPA officials.⁴¹⁰ In 2010, when EPA finally released its draft risk reassessment, it was immediately subjected to a Congressionally mandated review by the National Research Council at the behest of Senator David Vitter of Louisiana.⁴¹¹ That review, which was released in 2011, raised a number of concerns about EPA's risk assessment, resulting in another six years of work that culminated in a new draft risk reassessment in 2017.⁴¹² The following year, the Trump EPA formally suspended the formaldehyde risk assessment, which

408. See, e.g., Rory B. Conolly et al., *Biologically Motivated Computational Modeling of Formaldehyde Carcinogenicity in the F344 Rat*, 75 TOXICOLOGICAL SCI. 432 (2003); Rory B. Conolly et al., *Human Respiratory Tract Cancer Risks of Inhaled Formaldehyde: Dose Response Predictions Derived from Biologically-Motivated Computational Modeling of a Combined Rodent and Human Dataset*, 82 TOXICOLOGICAL SCI. 279 (2004); Gary M. Marsh et al., *Reevaluation of Mortality Risks from Leukemia in the Formaldehyde Cohort Study of the National Cancer Institute*, 40 REGUL. TOXICOLOGY & PHARMACOLOGY 113 (2004).

409. Concerns about leukemia had long been apparent. In 2003, the National Cancer Institute reported evidence from a study of 26,000 workers showing an association between formaldehyde exposure in the workplace and leukemia. See Michael Hauptmann et al., *Mortality from Lymphohematopoietic Malignancies among Workers in Formaldehyde Industries*, 95 J. NAT'L CANCER INST. 1615, 1615 (2003). A second study by the National Institute of Occupational Safety and Health found a similar association. See L.E. Pinkerton et al., *Mortality Among a Cohort of Garment Workers Exposed to Formaldehyde*, 61 OCC. ENV'T MED. 193, 193 (2004).

410. See U.S. GOV'T ACCOUNTABILITY OFF., GAO 08-810-T, CHEMICAL ASSESSMENTS: EPA'S NEW ASSESSMENT PROCESS WILL FURTHER LIMIT THE PRODUCTIVITY AND CREDIBILITY OF ITS INTEGRATED RISK INFORMATION SYSTEM, TESTIMONY BEFORE THE SUBCOMM. ON INVESTIGATIONS & OVERSIGHT, COMM. ON SCI. AND TECH. OF THE H. OF REPS., 19-20 (2008) (discussing delays in EPA's formaldehyde risk assessment including intervention by then Chairman of the Senate Environment and Public Works Committee, James Inhofe, requesting delay pending a report from the National Cancer Institute, which took an additional four years).

411. Senator Vitter put a hold on the confirmation of one of President Obama's nominees to EPA, which he lifted only after EPA agreed to send its draft risk assessment to the NRC for an external review. See Eric Lipton and Rachel Abrams, *The Uphill Battle to Regulate Formaldehyde*, N.Y. TIMES (May 3, 2015), <https://perma.cc/R5U2-U2FK> (discussing industry opposition and interference with EPA's formaldehyde risk assessment).

412. See NAT'L RSCH. COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011); IRIS, EPA, *Formaldehyde: IRIS Toxicological Review of Formaldehyde-Inhalation (External Review Draft, 2022)* (Aug. 15, 2023), <https://perma.cc/2GXT-VM8C>.

was then “unsuspended” by the Biden administration in 2021.⁴¹³ Finally, in 2022 EPA released the latest version of its draft reassessment, thirty-three years after it issued its first risk assessment for formaldehyde and twenty-four years after it launched the reassessment.⁴¹⁴ The NRC has also weighed in, yet again, with its own assessment of EPA’s latest draft—this time voicing general support for EPA’s process and conclusions.⁴¹⁵ In September 2023, the American Chemistry Council filed suit against both EPA and the National Academy of Sciences for failing to meet the requisite standards of transparency and independence in reviewing the latest risk assessment.⁴¹⁶

What is clear from these examples (and others like them) is that the entire exercise of assessing the risk of high stakes chemicals has become deeply and perhaps irretrievably politicized. This type of politicization, however, is not simply limited to a few blockbuster chemicals, but rather is built into the logic of risk assessment given the myriad ways that one can estimate the risk of cancer and other diseases from low-level exposures depending on the choice of animal studies, interpretation of tissue samples, animal-to-human extrapolation methods, exposure data, and assumptions about exposure pathways.⁴¹⁷ The uncertainties that emerge from such an exercise provide virtually endless opportunities for technical and legal challenges and calls for more outside review, making it effectively impossible to deliver in a timely manner on environmental law’s foundational commitment to protect public health.⁴¹⁸

Despite repeated criticisms and widespread calls to overhaul risk assessment, including from Congress and the National Academy of Sciences, efforts

413. See NAT’L RSCH. COUNCIL, REVIEW OF EPA’S 2022 DRAFT FORMALDEHYDE ASSESSMENT 12–16 (2023) (providing background and timeline for EPA formaldehyde reassessment).

414. EPA, ASSESSMENT OVERVIEW FOR THE TOXICOLOGICAL REVIEW OF FORMALDEHYDE – INHALATION (2022).

415. See NAT’L RSCH. COUNCIL, REVIEW OF EPA’S 2022 DRAFT FORMALDEHYDE ASSESSMENT, *supra* note 413, at xii.

416. See *Am. Chemistry Council Inc. v. Nat’l Acad. Of Sciences et al.*, No. 23-cv-2113 (D.D.C. filed Sept. 15, 2023); Krystal Vasquez, *The ACC Sues the US EPA and the National Academies Over Formaldehyde Risk Assessment*, 101 CHEM. & ENG’G NEWS 25, July 26, 2023, <https://perma.cc/WG7R-H93P>.

417. See NAT’L RSCH. COUNCIL, SCIENCE AND DECISIONS, *supra* note 14, at 113–119 (discussing uncertainty and variability in various components of risk assessment); WARGO, *supra* note 211, at 111–12 (discussing “infinite number of ways” that one in one million risk threshold could be calculated depending on choice of animal studies, extrapolation models, exposure data, etc.); see also O’Neill, *supra* note 315, at 736 (“As exposure assessment became more sophisticated, the value for each input came to provide a potential site for contest.”)

418. See generally Thomas A. Burke, *The Red Book and the Practice of Environmental Public Health: Promise, Pitfalls, and Progress*, 9 J. HUM. & ECOLOGICAL RISK ASSESSMENT: INT’L J. 1203, 1206 (2003) (“The inherent uncertainties of the risk paradigm provide the battleground for dueling risk assessments.”); O’Neill, *supra* note 315, at 783 (“Exposure assessment as practiced turns out to provide a powerful lever for delay.”)

to reform the process have so far failed to deliver.⁴¹⁹ The most important recent effort in this respect came in 2016, when a bipartisan majority in Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act.⁴²⁰ A result of decades of work to amend TSCA, the legislation passed by an overwhelming majority in the House and unanimous consent in the Senate and was hailed as a breakthrough by both environmental groups and the chemical industry.⁴²¹ Among other things, it established a new risk-based screening system to deal with priority chemicals, created firm deadlines for assessing risks, and removed some of the procedural obstacles that had plagued the statute for decades, including the additional burdens imposed by the Fifth Circuit's *Corrosion Proof Fittings* decision on the 1989 asbestos rule.⁴²² For a brief moment, there was a sense that Congress might be able to find enough common ground to fix the severe problems that had plagued risk assessment and chemicals regulation since the 1980s.

But it did not last. With the election of Donald Trump in 2016, EPA officials moved quickly to roll back the Obama administration's efforts to establish new framework rules to implement the new TSCA provisions.⁴²³ Nancy Beck,

419. See, e.g., NAT'L RSCH. COUNCIL, *supra* note 14, 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.”); see also U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 14 (concluding that EPA's Integrated Risk Information System, which provides 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”).

420. See Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016).

421. See Press Release, U.S. S. Env't & Pub. Works Comm., Inhofe Announces Groundswell of Support for Final TSCA Deal (May 24, 2016), <https://perma.cc/SHH4-5NU5> (compiling record of support from industry and environmental groups).

422. See Schmidt, *supra* note 169, at 183–86 (discussing key changes to TSCA under 2016 amendments).

423. During the last days of the Obama administration, EPA proposed two “framework” rules setting how it would prioritize and evaluate chemicals under the new provisions of TSCA. See Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825 (proposed Jan. 17, 2017); Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 7562 (proposed Jan. 19, 2017). Among other things, the proposed rules took an expansive approach to the interpretation of “conditions of use” of chemical substances as a basis for evaluating their risks. In June 2017, after the Trump Administration took office, EPA changed course and issued final rules that took a much more restrictive approach to “conditions of use.” See Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 40 C.F.R. pt. 702 (2017); Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33726 (proposed Jul. 20, 2017).

who had been the director of regulatory science policy for the chemical industry's main trade association before joining the Trump EPA, was put in charge of the program and used her new office to interfere with and delay ongoing risk assessments for various chemicals such as TCE and to rewrite the Obama administration's proposed framework rule on risk evaluations under TSCA.⁴²⁴ EPA also received no additional budget for TSCA implementation throughout the entire Trump administration.⁴²⁵ As a result, EPA will miss nearly all of the statutory deadlines for risk assessments and regulations under the 2016 amendments.⁴²⁶

What is crucial to recognize here, however, is that even if EPA were able to stay on track and meet the statutory deadlines for new risk assessments, the new TSCA will take slightly less than forever to get the job done. Given that there are tens of thousands of chemicals in commerce (we don't even know the actual number), some 17,000 of which are unknown because of industry claims of confidential business information, it would take centuries for the agency to complete the job of determining whether chemicals in commerce pose an unreasonable risk to human health.⁴²⁷ That is not a good outcome by any measure,

424. Beck served as Senior Director of Regulatory Science Policy at the American Chemistry Council for five years before becoming Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention. Beck worked at EPA until 2019, when she joined the White House Council of Economic Advisors. In March 2020, President Trump nominated Beck to lead the Consumer Products Safety Commission. During her time at EPA and in the White House, Beck worked to delay and revise the ongoing risk assessment for TCE. See Elizabeth Shogren, *EPA Scientists Found a Toxic Chemical Damages Fetal Hearts. The Trump White House Rewrote Their Assessment*, REVEAL (Feb. 28, 2020), <https://perma.cc/4YM4-PL88>; Eric Lipton, *Why Has the E.P.A. Shifted on Toxic Chemicals? An Industry Insider Helps Call the Shots*, N.Y. TIMES (Oct. 21, 2017), <https://perma.cc/U2TE-TL4K>. On Beck's background and earlier work, see CONSUMER FED'N AMERICA, *A CHRONICLE OF DECEPTION—A NANCY BECK RETROSPECTIVE* (2020), <https://perma.cc/9D6Q-7YM5>; see also Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act; 40 C.F.R. § 702 (2017) (new framework rules for risk evaluation under TSCA); *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir., 2019) (reviewing EPA's risk evaluation rule under TSCA).

425. See EPA, REPORT TO CONGRESS ON THE EPA'S CAPACITY TO IMPLEMENT CERTAIN PROVISIONS OF THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY, TSCA 5-YEAR REPORT TO CONGRESS 1 (2022), <https://perma.cc/2ZK4-8R9Z> ("While the Lautenberg Act ("Act") was passed with bipartisan support, the EPA's TSCA program funding level has remained largely unchanged from levels prior to the law's amendment in 2016. As a result, the EPA has not met many of the statutory deadlines in the Act, including completing only one of the first 10 agency-initiated chemical risk evaluations on time.").

426. *Id.*; see also *supra* note 25.

427. See *supra* note 175 (describing use and extent of industry claims that chemical identities are confidential business information under TSCA); see also Carl F. Cranor, *How the Law Promotes Ignorance: The Case of Industrial Chemicals and Their Risks*, in SCIENCE AND THE PRODUCTION OF IGNORANCE 186 (Kourney & Carrier eds., 2020) ("[E]ven if the EPA could conduct risk assessments and improve health protections for twenty existing substances per year, an utterly astounding rate, it would take fifteen hundred years to review the likely

and the fact that the 2016 amendments were widely viewed as progress shows just how broken the system is. By institutionalizing risk assessment and committing EPA to hundreds of years of work assessing the risks of chemicals, the TSCA amendments further entrenched a set of knowledge practices that have proven incapable of delivering the information needed to protect public health in a timely manner. Put bluntly, what looked like a breakthrough to some at the time now looks like a failed strategy of appeasement that has created yet more opportunities for contestation and delay.⁴²⁸

The tragedy here is that the Trump administration's efforts to derail implementation of the new TSCA amendments, together with its broader efforts to "deconstruct" the administrative state, have deflected attention from the larger failures of risk assessment.⁴²⁹ In effect, by provoking opponents into a full-throated defense of scientific integrity, the Trump assault on EPA worked to reinforce the longstanding industry agenda of keeping the public debate focused on the need for "sound science."⁴³⁰ This is where the Biden Administration's vocal and understandable calls to restore scientific integrity fall short.⁴³¹ In fact,

thirty thousand 'active' commercial substances meriting review. The history of EPA actions and industry intransigence, however, raises concerns about the likely success of these requirements. At the legally mandated rate of six to seven years per twenty substances, the legacy chemicals that have already entered commerce from the 1976 TSCA will exist for centuries.").

428. Cf. Rachel Rothschild, *The Failure of Unreasonable Risk: The Failure to Ban Asbestos and the Future of Toxic Substances Regulation*, 47 HARV. ENVTL. L. REV. 529, 529 (2023) (arguing that Democrats struck the wrong bargain on the TSCA 2016 amendments by focusing on cost benefit analysis). They also struck the wrong bargain by continuing to embrace formal risk assessment.

429. Metzger, *supra* note 74, at 2. For discussion of the Trump Administration's attacks on regulatory science at EPA, see, e.g., Richard L. Revesz, *Destabilizing Environmental Regulation: The Trump Administration's Concerted Attack on Regulatory Analysis*, 47 ECOLOGY L. Q. 887, 890 (2020); Albert Lin, *President Trump's War on Regulatory Science*, 43 HARV. ENVTL. L. REV. 247, 249 (2020); Richard J. Lazarus, *The Super Wicked Problem of Donald Trump*, 73 VAND. L. REV. 1811, 1845–1851 (2020); see also David E. Lewis, *Deconstructing the Administrative State*, 81 J. POLITICS 767, 776 (2019) (discussing increased departures of senior career executives at various agencies and the loss of expertise, managerial competence, and continuity that this entails); Wendy Wagner, et al., *supra* note 10, at 636 (observing that the Trump administration's proposals "require the exclusion of potentially relevant research during agencies' initial review of the literature, dictate the types of computational models that must be considered in analyzing that information, and exclude respected scientists from peer reviewing the analysis"); see also *id.* at 638 ("the proposed reforms of regulatory science aim to change the nature of the scientific deliberations and underlying record itself").

430. See Neff & Goldman, *supra* note 7, at S81 (discussing industry demands for "sound science" as a delay tactic); Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897, 900-01 (2004) (identifying ongoing industry calls for "sound science" as part of a carefully coordinated effort to "reform" both tort and regulation in a manner that protects the interests of "risk-producing industries").

431. See *supra* notes 4–5 and accompanying text.

restoration of the status quo on regulatory science and risk assessment will never address the fundamental problems that have plagued the effort from the start.

Addressing those problems, this Article contends, requires a more explicit political economy of risk assessment that focuses on the practices of fact making and knowledge production within the administrative state. Seen in this way, risk assessment has operated first and foremost as a political technology intended to discipline the way agencies make facts and produce knowledge about harms—all as part of a broader distributional struggle over which harms will be imposed on which groups of people. At a basic level, of course, one could explain the rise of quantitative risk assessment largely as a triumph of class interests. Indeed, it is hard not to see the *Benzene* case as an exercise in class power, with truly lethal effects. It seems quite clear, moreover, that industry advocates have long understood and made use of Weber's insight that "bureaucratic administration means fundamentally domination through knowledge" as they worked to commandeer the process of fact making that serves as the basis for understanding and regulating harms.⁴³²

There is also a powerful ideological component operating in all of this. Through endless appeals to "sound science" and the push for ever more elaborate exercises in risk assessment, industry groups such as the AIHC effected a decisive retreat from earlier precautionary approaches toward the neutral, technical language of risk. This then allowed them to get down into the trenches of agency guidance and rulemakings, ongoing debates about science policy, and individual risk assessments to push for revisions, elaborations, and refinements, all in the name of marshalling the best science and best data available to improve environmental decision-making. By turning hazards and potential harms into risks and by creating a presumption that these risks could be quantified, risk assessment has thus tended to operate as a powerful "anti-politics machine" vis-à-vis the public while at the same time providing a tool to discipline agency decision-making by replacing reason and deliberation with a stricter, rule-governed rationality.⁴³³

As this Article has sought to demonstrate, this deeper story about the political economy of knowledge production within the bureaucracy requires close attention to the specific concepts, tools, and practices that underwrite risk assessment. Standard notions of capture or appeals to the raw politics of industry

432. WEBER, *supra* note 1.

433. Cf. JAMES FERGUSON, *THE ANTI-POLITICS MACHINE: "DEVELOPMENT," DEPOLITICIZATION AND BUREAUCRATIC POWER IN LESOTHO* 256 (1994) (showing, through a detailed case study in Lesotho, how the international "development apparatus" operates as "the principal means through which the question of poverty is de-politicized in the world today"); see also Jedediah Britton-Purdy et al., *Building a Law-and-Political-Economy Framework: Beyond the Twentieth-Century Synthesis*, 129 *YALE L. J.* 1784, 1835 (2020) (characterizing anti-politics as a core element of the twentieth century neoliberal synthesis).

influence only go so far in this respect.⁴³⁴ Indeed, any serious attempt to unwind and de-ossify the dysfunctional and maladaptive approaches to harm that have become entrenched in environmental law over the last forty years requires close attention to the question of *how* these upstream practices of knowledge production and fact making within regulatory agencies have become key sites in the struggle to frame what counts as useful knowledge for the project of environmental protection.

B. *Reconstructing Regulatory Science*

Protecting the public from harms caused by pollution and toxic substances is surely one of the most important responsibilities that government undertakes in a complex industrial society. These harms are often invisible. They can take many years to develop. They can travel across generations. And they can be difficult if not impossible to trace back to particular exposures. Understanding how these toxic harms emerge, how prevalent they are, and how they impact different groups of people is, needless to say, a science-intensive exercise that poses exceedingly difficult challenges no matter how sophisticated our scientific practices turn out to be. But these challenges are not in themselves primarily scientific or technical. Rather, they are legal and ethical in nature because they go to the conduct and organization of regulatory science in the face of deep and pervasive uncertainties and in the presence of real harm. That is, they go to the ways that knowledge is made and used in the administrative state and to the thresholds, triggers, and factual predicates needed for action. While this Article certainly does not claim to have the final word on how to re-organize the knowledge practices involved in risk assessment, it recognizes that any such effort must begin with an inquiry into the nature and conduct of regulatory science.⁴³⁵

434. *But see* Thomas McGarity, *Regulatory Reform in the Reagan Era*, 45 MD. L. REV. 253, 260 (1986) (describing cost-benefit analysis as an example of “cognitive regulatory reform” intended to reshape the nature and possibilities of agency decision-making); MCGARITY & WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH*, *supra* note 50; Jodi Short, *The Paranoid Style in Regulatory Reform*, 63 HASTINGS L.J. 633, 652 (2012); Andrea Saltelli et al., *Science, the Endless Frontier of Regulatory Capture*, 135 FUTURES 1, 2 (2022).

435. As the name suggests, regulatory science is a term used to refer to the various scientific practices that are used to generate facts for regulatory decision-making. As a result, regulatory science is subject to a different set of requirements and pressures than basic research science and is, accordingly, more vulnerable to contestation. For an important early discussion of the various characteristics of regulatory science, *see* Sheila Jasanoff, *Procedural Choices in Regulatory Science*, 17 TECH. IN SOC’Y 279, 280–83 (1995). Discussions about the nature and practice of regulatory science emerged in parallel with the rise of quantitative risk assessment and other frameworks for decision-making that appealed to science and objectivity for authority. *See, e.g.*, Sheila Jasanoff, *The Practices of Objectivity in Regulatory Science*, in *SOCIAL KNOWLEDGE IN THE MAKING* 317–19 (Camic et al. eds., 2011) (describing quantitative risk

The goal is to articulate some relatively simple commitments that can guide regulatory science in a manner that avoids the various knowledge problems generated by quantitative risk assessment. While some of these commitments will likely run up against the hard edge of the major questions doctrine, others could be adopted in various ways by EPA without formal rulemaking. Indeed, one virtue of the expansive internal administrative law of risk assessment that has developed over the last forty years may turn out to be its provisional nature, a fact that is particularly important in the face of a deeply polarized Congress and a hostile Supreme Court.⁴³⁶

To be sure, many good suggestions for reforming risk assessment have been identified by legal scholars and others over the years, including arguments for more pre-market testing and screening, more investment in post-market surveillance, a more fulsome embrace of uncertainty, burden shifting with respect to testing and data production, more research on early warnings, stopping rules that bring risk assessments to an end, and sunset provisions for harmful classes of chemicals. But there are also some larger lessons from the long history of risk assessment that might serve as useful guides for a reconstructed regulatory science that focuses less on tweaking and improving the existing framework and more on new approaches to regulation that drive innovation in the chemical industry toward sustainability and health.⁴³⁷ Put another way, it is time

assessment as an example of the quest for objectivity in regulatory science). It is important to recognize here that the practices of regulatory science can range broadly, with different starting points, norms, and procedures. Hence, the need for attention to the broader legal and normative frameworks that guide regulatory science. Cf. Kristin Shrader-Frechette, *Introduction: Assessing Toxic Substances Through a Glass Darkly*, in REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND THE LAW 3 (Carl F. Cranor, 1993) (“[T]he risk assessment and scientific procedures in our legal institutions must be reoriented—we face ‘paradigm’ choices in the use of science for legal purposes. By this I mean that we need to face explicitly how we think about and how we conceive of the use of science in the law. In particular, we should avoid the temptation to adopt wholesale the practices of research science into our legal institutions, as a number of commentators are recommending, for to do so would frustrate the aims of these institutions.”).

436. See, e.g., Kessler & Sabel, *supra* note 47, at 194 (“[T]he signal feature of guidance is its provisionality. Agency rules are generally issued and amended by means of a costly and time-consuming process . . . in which the agency must elaborately explain its purposes, expose its evidence-gathering and deliberation to public scrutiny, and explain its reactions to criticism. Guidance, in contrast, can be issued and amended quickly, with little if any formal process.”).

437. See, e.g., Joe Thornton, *Implementing Green Chemistry: An Environmental Policy for Sustainability*, 73 PURE APPL. CHEM. 1231, 1232–33 (2001) (“The ultimate reason why most firms have not invested in safer products and processes is that current policies have put little or no pressure on them to do so. . . . In the current regime, society attempts to manage pollution by permitting chemical production, use, and release, as long as discharges of individually regulated substances from individual facilities do not exceed some quantitative standard of acceptable contamination. . . . The effect of this regulatory regime is to protect firms from pressure to adopt safer technologies.”).

(past time in fact) to think about how regulation, and the regulatory science that supports it, can operate as a form of green industrial policy for chemicals rather than as a forum for seemingly interminable debates over the nature and magnitude of harms and the zero-sum logic of risk-benefit balancing.⁴³⁸

Viewed from this perspective, the earlier approach to harm that OSHA was groping towards in its generic cancer policy and that the Delaney clause embodied in its prohibition on the deliberate addition of carcinogens to the food supply look less like the rigid, unrealistic examples of over-regulation that they are often portrayed as than innovative uses of generic approaches built on simple hazard-based triggers for action. In both cases, the goal was to ensure a broad scope of protection without delay, while also providing a clear signal to industry that certain lines of activity were no longer viable.⁴³⁹ Thus, rather than wait years for risk assessments to determine how much harm could be expected from exposure to individual substances, these simple default rules were motivated by a desire to move fast and protect people.

The takeaway for regulatory science is that the focus should be less on understanding and quantifying the precise nature of the risks associated with

438. The European Union is now moving in this direction, based on a recognition that its previous reform of chemicals regulation, known as REACH, has not been sufficient to drive innovation toward sustainability. See, e.g., *European Commission, Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment*, at 5, COM (2020) 667 final (Oct. 14, 2020) (“Regulatory tools need be exploited to drive and reward the production and use of safe and sustainable chemicals. It is particularly important to incentivize industry to prioritize innovation for substituting, as far as possible, substances of concern.”); see also *id.* at 2 (observing that “innovation for the green transition of the chemical industry and its value chains must be stepped up and the existing EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals”).

439. In the case of Delaney, that meant shutting off market opportunities by prohibiting the deliberate addition of carcinogens to the food supply. In the case of OSHA’s generic cancer policy, it meant an automatic requirement that permissible exposure limits for carcinogens be set at the lowest feasible level. One can find similar examples in other areas of environmental law. After EPA failed for two decades to regulate air toxics under section 112 of the Clean Air Act, largely because of the difficulties of determining acceptable risk in the context of the statute’s ample margin of safety requirement, Congress stepped in with the 1990 amendments to overhaul section 112, providing EPA with a list of 189 air pollutants and strict deadlines for imposing a new maximum achievable control technology standard on industrial sources. See 42 U.S.C. § 7412; see also *European Commission, Chemicals Strategy for Sustainability*, *supra* note 438, at 9–10 (discussing the EU’s efforts to develop a generic approach to harmful chemicals that uses automatic hazard-based triggers for pre-determined regulatory measures such as restrictions and bans). As the Commission observes, this sort of “preventive approach is simpler, generally faster and provides clear signals to all actors—enforcement authorities, industry, and downstream users on the types of chemical substances where innovation should be prioritized by the industry”). *Id.* at 9. Recent work on the problem of novel entities and planetary boundaries has advocated a similar approach. See, e.g., Persson et al., *supra* note 27, at 1517 (concluding that “a more preventive and precautionary hazard-based approach is needed to address novel entities” in order “to mitigate current damage and avoid future surprises”).

such substances and more on broad screening for hazards across a range of potential harms, including cancer, reproductive harms, endocrine disruption, immunotoxicity, and neurodevelopmental harms (among others). These could be combined with existing screens for environmental persistence and bioaccumulation. The goal would be to identify quickly certain classes of chemicals and pollutants that had a propensity for harm and to use this as an automatic trigger for an initial round of regulatory action. Thus, rather than use these initial screens to identify priority chemicals for detailed risk assessment as a basis for regulation in the future, a generic, hazard-based screening system would require a pre-determined level of regulation and control at the outset. To the extent that industry wanted additional testing and risk assessment, they would bear the burden of delay going forward. In the case of essential uses or other special circumstances, it would be relatively easy to include provisions for exemptions or waivers. The key, again, is to adopt simple default rules that recognize the fact of uncertainty and make use of the available evidence regarding hazards to trigger regulation.

Such an approach resonates with many of the core commitments of our environmental laws. So, for example, the standard at the heart of the Clean Air Act's National Ambient Air Quality Standards program—"protection of public health with an adequate margin of safety"—can be read as a mandate to regulate potential harms in the face of uncertainty without waiting for definitive evidence of actual harm.⁴⁴⁰ The 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.⁴⁴¹ 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.⁴⁴² Even the Occupational Safety and Health Act, notwithstanding the *Benzene* decision, requires that workplace standards for "toxic materials or harmful physical agents" be set at a

440. See 42 U.S.C. § 7409(b)(1) (requiring 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").

441. 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").

442. 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).

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.”⁴⁴³

Critics will surely argue that adopting a generic, hazard-based approach would inevitably lead to the regulation of *de minimis* or insignificant risks, and thus would be contrary to the Supreme Court’s *Benzene* decision. But here it is important to recognize another lesson from the long history of toxic harms: even though we may not know precisely how toxic substances might cause harm in the future, we do know from experience that many (even most) potentially harmful agents turn out to be more harmful than initially suspected.⁴⁴⁴ We also know that the growing volume of novel chemical entities that we have released into the environment over the last century has pushed far beyond any reasonable conception of safe planetary operating boundaries and that ecological systems and human health are experiencing far more insults and burdens as a result.⁴⁴⁵ Both of these facts make clear that we are now operating in a very different context than we were even in the 1970s and 1980s, all of which counsels in favor of

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

444. See, e.g., Philippe Grandjean, *Science for Precautionary Decision-Making*, in LATE LESSONS FROM EARLY WARNINGS: SCIENCE, PRECAUTION, INNOVATION 656 (European Environment Agency, 2013) (“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.”); RACHEL CARSON, SILENT SPRING 360 (First Mariner Books 2002) (1962) (observing that “what the public is asked to accept as ‘safe’ today may turn out tomorrow to be extremely dangerous”). Benzene exposure, for example, has been linked to various hematologic effects at levels below OSHA’s 1ppm standard. See, e.g., Qing Lan et al., *Hematotoxicity in Workers Exposed to Low Levels of Benzene*, 306 SCI. 1774, 1776 (2004) (presenting evidence from a study of Chinese workers “that benzene causes hematologic effects at or below 1ppm, particularly among susceptible subpopulations”); Rory M. Shallis et al., *A Clandestine Culprit with Critical Consequences: Benzene and Acute Myeloid Leukemia*, 47 BLOOD REV. 1, 13 (2021) (concluding based on a review of existing studies that there may be no safe level of benzene exposure and that “ambient benzene may contribute to many cases of *de novo* AML [Acute Myeloid Leukemia]”). The history of lead is also instructive here. Even though lead’s toxicity has been known for thousands of years, we continue to learn more about just how damaging it is to the developing brain and cardiovascular health. Recent studies investigating the health burden of low-level lead exposure in the U.S. and globally indicate significantly higher impacts than previously understood. See, e.g., Bruce P. Lamphear et al., *Low-Level Lead Exposure and Mortality in US Adults: A Population-based Cohort Study*, 3 LANCET PUB. HEALTH e177, e182 (2018) (“Our findings suggest that, of 2.3 million deaths every year in the USA, about 400,000 are attributable to lead exposure, an estimate that is about ten times larger than the current one.”); Larsen & Sanchez-Triana, *supra* note 29, at E838 (providing global estimates of IQ loss and cardiovascular disease mortality from lead exposure that are substantially higher than previous estimates, including 5.5 million premature deaths from lead exposure in 2019, which is six times higher than the previous estimate).

445. See *supra* note 26.

a much more aggressive approach to preventing additional releases of potentially toxic substances.⁴⁴⁶

Any effort to reconstruct regulatory science must also work to develop safeguards to protect against industry influence and manipulation. Here again we know that corporations and their enablers will lie, mislead, conceal, deflect, and delay in the face of facts that threaten their interests and their profits. We have learned this the hard way over the last century, from lead to DDT, tobacco, glyphosate, and forever chemicals (to name only a few of the most egregious examples where industry has covered up evidence of harm and delayed regulation for decades).⁴⁴⁷ The point here, however, is not to engage in further muck-raking but to recognize this behavior as a basic feature of the broader political economy of regulatory science and fact making within the administrative state. Regulatory science conducted by and for industry should be disclosed in all cases and discounted accordingly unless and until it can be confirmed by independent reviews.⁴⁴⁸ More important, industry calls for more science and more research

446. See Persson et al., *supra* note 27, at 1517 (“Despite major efforts in recent decades, safety assessment and subsequent regulations of chemical substances and other [novel entities], and the capacity of many countries to conduct these assessments and to enforce regulatory compliance, are not keeping up with the speed of introduction of new [novel entities]. An ever-growing number of [novel entities] are found in remote locations of the planet and the number of grossly contaminated locations is increasing despite remediation efforts. In addition, many distinct and partly interacting (e.g., synergistic) effects of [novel entities] on Earth’s physical and ecological systems are being reported. In short, rapid growth in diversity and production volumes and releases outstrips society’s ability to assess, let alone manage, [novel entities]. Planetary burdens are already considerable.”).

447. See, e.g., William Kovarik, *Ethyl-leaded Gasoline: How a Classic Occupational Disease Became an International Public Health Disaster*, 11 INT’L J. OCCUPATIONAL & ENV’T HEALTH 384, 390–93 (2005) (discussing the role of the lead industry starting in the 1920s to shape and influence research on lead poisoning); GERALD MARKOWITZ & DAVID ROSNER, *DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION* 108–17 (2002) (documenting efforts by lead industry to support research that criticized and questioned any suggestion that lead in gasoline was harmful); ELENA CONIS, *HOW TO SELL A POISON: THE RISE, FALL, AND TOXIC RETURN OF DDT* 3–4 (2022) (discussing industry efforts to manufacture uncertainty and doubt about the science of DDT); MICHAELS, *supra* note 9, at 4 (discussing strategy of tobacco industry to manufacture doubt and uncertainty about health effects of tobacco); Leemon B. McHenry, *The Monsanto Papers: Poisoning the Scientific Well*, 29 INT’L J. RISK. & SAFETY MED. 193, 194–202 (2018) (using internal Monsanto documents produced in litigation to demonstrate efforts by Monsanto to ghost write scientific articles and interfere with the scientific process at multiple levels to raise doubts about the links between glyphosate and non-Hodgkins lymphoma and other health effects); Renfrew & Pearson, *supra* note 23, at 150–53 (documenting efforts by DuPont and 3M to cover up internal studies suggesting toxicity of PFOA and PFAS chemicals); see generally, MCGARITY & WAGNER, *BENDING SCIENCE*, *supra* note 50, at 5 (discussing tactics used by industry to shape and influence science).

448. Clair Patterson, a geochemist from CalTech who demolished the lead industry’s arguments that background levels of lead were “natural” rather than a result of lead pollution and who was the subject of a concerted campaign by the lead industry to discredit his research,

should be seen as the delaying tactic that it almost always turns out to be. Ongoing public investment in public science is thus essential to develop the knowledge base needed for meaningful regulation.

Regulatory science also needs to rebalance its extensive reliance on computational models with more investment in testing, sampling, and long-term monitoring programs, which together provide the essential empirical basis for the continuous learning and improvement that is so critical to governing effectively in the face of uncertainty. This should also include much more attention to the development of early warning systems that can alert us to novel and emerging problems.⁴⁴⁹ By changing funding priorities and incentive structures within the research community, scientists in government and academia should 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.⁴⁵⁰

Finally, regulatory science desperately needs a new approach to cumulative risks and to the ways that toxic harms compound and are reinforced by structural inequalities. Both of these challenges require a broader field of vision

terminate his funding, and get him fired, testified on this general issue in 1966: "It is not just a mistake for public health agencies to cooperate and collaborate with industries in investigating and deciding whether public health is endangered—it is a direct abrogation and violation of the duties and responsibilities of those public health organizations." See Air Pollution-1966: Hearings on S. 3112 and S. 3400 Before the Subcomm. on Air and Water Pollution of the S. Comm. on Public Works, 89th Cong. 315 (1966) (testimony of Clair Patterson); see also Clair C. Patterson, *Contaminated and Natural Lead Environments of Man*, 11 ARCHIVES ENV'T HEALTH 344, 344, 357 (1965) (concluding that "the average resident of the United States is being subjected to severe chronic lead insult" and observing that "[i]t would be tragic, if many decades from now, it were recognized from accumulated evidence that large segments of the population in ours and other nations had suffered needless disability and torment because early warning signs like those indicated in this report went unheeded"). The industry attacks on Patterson and his research are documented in Kovarik, *supra* note 447, at 392.

449. See Grandjean, *supra* note 444, at 657 ("[T]raditional risk assessment is sometimes anti-precautionary when it demands convincing evidence and thus ignores emerging insight and incomplete documentation. Due to its focus on scientific justification, risk assessment may inspire continued elaboration of fairly well documented hazards.").

450. *Id.* at 668–69 (discussing biases in funding for research in environmental health); Julia G. Brody, *Everyday Exposures and Breast Cancer*, 25 REV. ENV'T HEALTH 1, 5 (2010) ("Current grants programs emphasize additional study of the chemicals we already know the most about, such as lead, mercury, and tobacco smoke . . . often rejecting higher-risk proposals to study exposure sources and health effects of chemicals with little prior evidence."); David Kriebel et al., *The Precautionary Principle in Environmental Science*, 109 ENV'T HEALTH PERSP. 871, 873 (2001) ("There is also a tendency for researchers to refine understanding of old problems rather than investigating new ones. Greater and greater levels of detail are sought about well-defined problems, rather than the higher stakes enterprise of searching for entirely new phenomena. . . . Funding agencies and skeptical peer reviewers reinforce this tendency by favoring tightly focused proposals that repeat or incrementally build upon work in well-established areas.").

capable of grasping the larger context in which actual harms materialize and insinuate themselves into the lives of actual people in the world. The history of risk assessment makes clear, moreover, that the reductionism at the very heart of quantitative risk assessment will never be able to accommodate such concerns precisely because it is focused on isolated parts of a problem rather than the whole. Taking account of vulnerable subpopulations and including safety factors to account for heightened susceptibilities is surely better than nothing, and these sorts of proxies may be the best we can hope for in the near term. Over the longer term, more preventive and precautionary hazard-based approaches would go a long way to reducing the overall burden of toxic harms and the potential for adverse cumulative effects. But much of this also goes to the way that the problems are formulated in the first place. As long as we continue to see toxic harms as a problem of biological responses to specific exposures, all too often based on outdated assumptions regarding thresholds of safety and acceptable risk, we will continue to miss the many ways that toxic harms are embedded in structures of domination and violence. A reconstructed regulatory science needs to be especially vigilant in not losing sight of these facts and building them into a more holistic inquiry that seeks to understand and account for the many ways that specific harms are imposed on specific groups of people.

Taken together, these commitments add up to a provisional sketch of some elements of a larger effort directed at driving and sustaining a broad collective search for new approaches that will reduce or avoid altogether the harms of pollution and toxic chemicals. Recent efforts to develop “green chemistry” and the “circular economy” offer glimpses of what this might look like.⁴⁵¹ In many ways, this was the “other road” that Rachel Carson wrote about more than sixty years ago.⁴⁵² It was the moment of possibility that animated so much of environmental law’s initial burst of activity in the early 1970s.⁴⁵³ And it was a big part of what OSHA was trying to do with its generic cancer policy.

Recognizing these earlier moments of possibility, however, should not deflect from the recognition of just how hard it would have been to hold onto

451. See, e.g., Mary Kate M. Lane, *Green Chemistry is Just Chemistry*, 6 *NATURE SUSTAINABILITY* 502, 502 (2022) (“Green chemistry fundamentally shifts the very paradigm of the chemical enterprise from one that produces chemicals and chemistries for functional performance to one that simultaneously designs for functional performance and sustainability including multifaceted environmental, economic, and social considerations, such as EJ [Environmental Justice].”).

452. See Carson, *supra* note 444, at 441 (“The other fork of the road—the one ‘less traveled by’—offers our last, our only chance to reach a destination that assures the preservation of our earth. The choice, after all, is ours to make. If having endured much, we have at last asserted our ‘right to know,’ and if, knowing, we have concluded that we are being asked to take senseless and frightening risks, then we should no longer accept the counsel of those who tell us that we must fill our world with poisonous chemicals; we should look about and see what other course is open to us.”).

453. See Boyd, *supra* note 11, at 902 (discussing this moment of possibility).

the precautionary commitments that motivated them. In many ways, the move to quantitative risk assessment looks overdetermined and, obviously, has proven to be highly durable even in the face of repeated failures. But overdetermination itself is always in part a product of political choices, and it is still worth contemplating what might have happened in that counterfactual world. Perhaps we would have foregone many of the wonders of the chemical age. Perhaps our lives would be more impoverished in ways that we are unable to recognize or admit. But maybe we would have found safer, gentler alternatives—maybe we would have developed the broad social intelligence necessary to harness industry’s considerable powers of innovation to put our economy on a truly sustainable path.

C. *Coming to Terms with the Violence of Abstraction*

In all of this, there is also a pressing need to develop a more forthright engagement with the actual consequences of our practices of assessing and managing risk. Virtually every decision to regulate on the basis of risk means that some group of people somewhere will have their lives diminished or cut short in some way.⁴⁵⁴ And while it may well be the case that in the aggregate more lives will be saved from the action in question, this does not absolve environmental law from responsibility to acknowledge those lives that are lost or diminished. As noted above, during the years that OSHA spent re-assessing the risks of benzene in the workplace in order to satisfy the Supreme Court’s significant risk requirement as a basis for promulgating the same standard (1 ppm) that had been rejected ten years earlier, the best estimates indicate that some 300 workers, maybe more, suffered benzene exposures that led to premature death from leukemia, multiple myeloma, and other blood-related cancers.⁴⁵⁵ Of course, no one will ever know how many actual deaths resulted from the additional exposures suffered during this period, much less the impact of benzene-induced sickness and death on the individuals who did contract cancer and on the people who cared about them. But the question this leaves us with is this: Does environmental law have an obligation not only to acknowledge but also to account

454. Viewed in this way, risk assessment has a distinctive “politics of life” that needs to be acknowledged and interrogated. See DIDIER FASSIN, *LIFE: A CRITICAL USER’S MANUAL* 85 (2018) (observing that the “politics of life” asks “not how technologies govern populations but what politics does to human lives”—a perspective in which “the question of inequality becomes essential, since not all lives are treated equally and since these differences in treatment convey differences in the value they are granted”).

455. See discussion and citations *supra* note 117; see also Philip J. Landrigan, *Benzene and Blood: One Hundred Years of Evidence*, 29 AM. J. INDUS. MED. 225, 225–26 (1996) (“The tragedy of benzene is that it has taken so long for science to be translated into protective action. Many thousands of workers and other persons in nations around the world have suffered unnecessarily and died prematurely while regulatory agencies, industry, and the courts debated the carcinogenicity of benzene and argued about the need for protective regulation.”).

for (that is, to be accountable for) those lives? How much closer can we hope to get—how much closer should we hope to get—to the singularity of those lives?

Normative critiques of risk assessment and cost-benefit analysis may well be unrealistic in their proposals for reform given the current state of our politics and given the inevitable tradeoffs involved in any such exercise. But even if these tools are the best that we have when measured in terms of social welfare or set against the politics of the moment (and this Article has provided plenty of reasons to doubt that they are), we still have to acknowledge the actual consequences that they entail. To say this is to recognize that risk assessment and the ways in which it informs law never operate only at the level of ideas and concepts. Part of any concrete history of abstraction must surely include reckoning with the real-life, material consequences of such abstractions. And when that reckoning is measured in human lives, there would seem to be a special responsibility.⁴⁵⁶

Given the tremendous influence that the various abstractions embodied in the general practice of quantitative risk assessment have on human health and the environment, they can, quite literally, make the difference between life and death—not in an abstract statistical sense, but life and death for real people living real lives in real places. To be sure, this is inherent in the aggregative logic that is at the heart of risk thinking, an inevitable consequence, perhaps, of consequentialist thinking.⁴⁵⁷ But the uneven, real-life effects of this way of thinking are all too often forgotten or erased in the process of rendering certain hazards in the seemingly neutral language of risk. Put starkly, there is a violence to these abstractions—a quiet, slow violence—that must be acknowledged, even if it cannot be remedied in any systematic fashion.⁴⁵⁸ Environmental law cannot be silent or indifferent in the face of these facts. At the very least, it must be vigilant in asking about the consequences of its decisions—about the actual people caught up in the tragic choices it is called upon to make.⁴⁵⁹ How many lives cut down, damaged, broken; how many dreams deferred, changed forever?

456. Cf. RICHARD NEUSTADT AND ERNEST R. MAY, *THINKING IN TIME: THE USES OF HISTORY FOR DECISION MAKERS* 256 (1986) (quoting George Marshall's reflections on his letters to President Roosevelt during World War II: "I tried to keep before him all the time the casualty results because you get hardened to these things and you have to be very careful to keep them always in the forefront of your mind."); see also Lisa Heinzerling, *Knowing Killing and Environmental Law*, 14 N.Y. UNIV. ENV'T L.J. 521, 534 (2006) ("For too long, we have elided the moral content of decisions about the environment by talking about deaths caused by environmental problems in amoral terms.")

457. Priest, *supra* note 54, at 215 (observing that risk is "relentlessly utilitarian").

458. Cf. ROB NIXON, *SLOW VIOLENCE AND THE ENVIRONMENTALISM OF THE POOR*, 4 (2013).

459. GUIDO CALABRESI & PHILIP BOBBIT, *TRAGIC CHOICES* 1 (1978).

CONCLUSION

It is past time to recognize and admit that the forty-year experiment with quantitative risk assessment has been a failure. As this Article has demonstrated, this failure was partly by design. Risk assessment was never really intended to generate useful information for regulators. Rather, it was directed almost from the start at disciplining agencies and replacing expert judgment with a more formal, rule-governed rationality. From that vantage, risk assessment has been wildly successful. But from a public health perspective, it has failed in every way that matters.

This failure has been most apparent in the area of toxic chemicals, but it is a failure that reaches across virtually all of environmental law as well as into ancillary fields of occupational health, food safety, and consumer protection. As this Article has shown, formal risk assessment has turned out to be a highly durable machine for generating knowledge problems and paralyzing the regulatory process. It is time to move on.

Doing that, of course, is easier said than done. This Article has sketched some elements of a way forward, calling for a more critical political economy of risk assessment and knowledge making within the administrative state and a more responsive and inclusive normative framework for regulatory science. But in all of this the way ahead ultimately lies in politics. As such, we need not be under any illusion that saying anything will change things, much less that any particular change will fix things. But we have to keep at it in any event; we have to keep doing the hard work of trying to get it right. "Politics," Weber wrote near the end of his life, "is a strong and slow boring of hard boards."⁴⁶⁰

460. Max Weber, *Politics as a Vocation*, in FROM MAX WEBER 128 (Gerth and Mills eds., 1946).