

# Genealogies of Risk: Searching for Safety, 1930s-1970s

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*Health, safety, and environmental regulation in the United States are saturated with risk thinking. It was not always so, and it may not be so in the future. But today, the formal, quantitative approach to risk provides much of the basis for regulation in these fields, a development that seems quite natural, even necessary. This particular approach, while it drew on conceptual and technical developments that had been underway for decades, achieved prominence during a relatively short timeframe; roughly, between the mid-1970s and the early 1980s—a time of hard looks and regulatory reform. Prior to this time, formal conceptions of risk were rarely invoked in the effort to regulate the increasingly complex set of hazards associated with industrial society and quantitative risk assessment was considered too uncertain to serve as a basis for regulatory decision making. With few exceptions, safety, hazard, and endangerment provided the dominant framings, drawing on different conceptual and normative tendencies and leading to different regulatory outcomes. This Article investigates the emergence and development of formal approaches to risk in health, safety, and environmental law during the twentieth century. It focuses specifically on the concepts, tools, and practices that have underwritten risk thinking in these fields, developing a perspective on health, safety, and environmental regulation that seeks to historicize risk and situate the contemporary debate regarding the merits of risk versus precaution in its proper historical context. In doing so, the Article demonstrates how both approaches struggled to address the much more vast and complicated world of potential environmental harm brought into view as a result of substantial advances in analytical techniques during the 1960s and early 1970s, thereby revealing the contours of a more fundamental clash over environmental law's distinctive problem of knowledge. The Article covers the formative period from*

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*the New Deal through the 1970s, showing how efforts to operationalize safety in the middle decades of the twentieth century led to many of the foundational concepts and techniques that would structure risk thinking in subsequent decades, highlighting the critical role of analytical advances in pushing toward a redefinition of safety as acceptable risk and a corresponding move toward quantitative risk assessment, and revealing how earlier precautionary impulses were ultimately subsumed under an emerging administrative law of risk.*

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## INTRODUCTION

*Let us first clarify what this intellectualist rationalization, created by science and scientifically oriented technology, means practically. . . . [I]t means that principally there are no mysterious incalculable forces that come into play, but rather that one can, in principle, master all things by calculation. This means that the world is disenchanting. One need no longer have recourse to magical means in order to master or implore the spirits, as did the savage, for whom such mysterious powers existed. Technical means and calculation perform the service.*

—Max Weber, *Science as a Vocation*<sup>1</sup>

Risk thinking is everywhere. Health and environmental threats, social deviance and criminality, financial crises, terrorism, emerging diseases, the fate of the planet: all of these (and many more) are now to a very considerable degree conceived, assessed, and managed as risk—a concept that emerged in the early modern period, but one that has taken on its contemporary, increasingly formal usage only in the last century. To say that we live in a risk society is cliché. To ask why we have come to view misfortune through the lens of risk seems almost out of place. How did this happen? What does the story of risk thinking say about the ways in which certain abstractions have come to dominate modern forms of social life—forms of life that we have naturalized to the point that even asking the question seems strange? How, in particular, has the concept of risk come to structure so much of environmental decision making and what are the implications for our ongoing efforts to organize and manage responses to an increasingly complex set of environmental challenges?

This Article seeks to answer the last of these questions through an investigation of the emergence and development of risk thinking in health, safety, and environmental law in the United States during the crucial period from the New Deal through the 1970s. As understood here, risk thinking is intended as shorthand for the various concepts, tools, and practices that underwrite the formal understanding and assessment of risk.<sup>2</sup> The Article is

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1. MAX WEBER, *Science as a Vocation* (1919), in FROM MAX WEBER: ESSAYS IN SOCIOLOGY 139 (Hans H. Gerth & C. Wright Mills eds., trans., 1946).

2. In a formal sense, risk has come to be defined as the product of probability and consequence (the expected value of an undesirable outcome). The key element of formal risk thinking is calculability. See, e.g., Mark J. Machina, *Decision-Making in the Presence of Risk*, 236 SCIENCE 537 (1987) (discussing formal treatment of risk in context of expected utility theory). But the calculation of specific risks, or risk assessment, varies considerably across subject matters, from relatively simple actuarial calculations to elaborate, multi-step processes that depend on a range of extrapolative techniques. In the fields of health, safety, and environmental regulation, the general approach to risk assessment was formalized in the early 1980s into a four-step process involving (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization. See, e.g., NAT'L RESEARCH COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* (1983) [hereinafter NRC, *RISK ASSESSMENT*]. A key objective of this Article and the larger project of which it

part of a larger, ongoing project on risk and the problem of knowledge in environmental law.

The concept of risk has become so pervasive in contemporary life that any effort to historicize it runs up hard against a deeply embedded naturalism. Obviously, human beings have always confronted dangers, hazards, the prospect of misfortune (one searches in vain for a neutral vocabulary), but it is a fallacy to view risk in transhistorical terms. Like all concepts, risk has a distinctive genealogy, a past, a public life. And that past matters as we seek to understand how this particular concept and the related practices of risk assessment have come to exercise such tremendous influence over the institutions and activities directed at protecting public health and the environment over the last century.

Such a perspective is contrary to much of the conventional thinking about risk in environmental law. Leading legal scholars, prominent jurists, and much of the scientific and policy establishment tend to view the concept of risk in neutral, ahistorical terms, implicitly assuming that the contemporary practice of risk assessment represents a natural and obvious extension of rational, technocratic decision making.<sup>3</sup> To be sure, there is no shortage of criticism, official and otherwise, of prevailing practices of risk assessment.<sup>4</sup> And there is a vocal minority—including a number of environmental law scholars—who have leveled substantial normative critiques at risk assessment and related tools such as cost-benefit analysis while mounting a strong defense of alternative approaches founded on the precautionary principle.<sup>5</sup> But that critique is also,

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is part is to understand how this particular approach to risk assessment emerged and took hold when it did.

3. See, e.g., NAT'L RESEARCH COUNCIL, *SCIENCE & DECISIONS: ADVANCING RISK ASSESSMENT* 26–36 (2009) [hereinafter NRC, *SCIENCE AND DECISIONS*] (discussing evolution of risk assessment at EPA as a natural process emerging out of interactions between statutory mandates, agency precedent, and input from expert advisory bodies); NRC, *RISK ASSESSMENT*, *supra* note 2, at 151 (advocating for a “clear conceptual distinction” between the largely scientific and technical practice of risk assessment and the more policy-based exercise of risk management); STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 9–10 (1992) (discussing risk assessment as a technical exercise separate and distinct from risk management and advocating for a centralized risk authority in the executive branch); CASS R. SUNSTEIN, *RISK AND REASON: SAFETY, LAW AND THE ENVIRONMENT* 294 (2002) (defending “a highly technocratic approach to risk regulation”).

4. See, e.g., NRC, *SCIENCE AND DECISIONS*, *supra* note 3, at 3–4 (noting that the risk assessment process is “bogged down” and discussing significant challenges facing contemporary practice of risk assessment); CARL F. CRANOR, *REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND THE LAW* (1993) (discussing technical and normative problems facing risk assessment); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991) (discussing problems associated with quantitative risk assessment in toxics regulation).

5. See, e.g., Noah M. Sachs, *Rescuing the Strong Precautionary Principle from its Critics*, 2011 U. ILL. L. REV. 1285 (2011) (criticizing current practice of risk-based toxics regulation and advocating use of precautionary principle); DOUGLAS A. KYSAR, *REGULATING FROM NOWHERE: ENVIRONMENTAL LAW AND THE SEARCH FOR OBJECTIVITY* 9–14 (2010) (criticizing the prevailing “risk-assessment-cost-benefit analysis paradigm” in environmental law and advocating a return to an earlier approach based on precaution); David A. Dana, *The Contextual Rationality of the Precautionary Principle*, 35 QUEEN'S

with few exceptions, carried out with little attention to the history of how these different approaches to environmental hazards emerged.<sup>6</sup> Indeed, one sometimes gets the sense that the vitally important debate between risk and precaution can be reduced to a contest between rival theories, ideas, and principles.<sup>7</sup> But such a framing, which has done so much to shape our views of the normative terrain of contemporary environmental law, obscures some of the more subterranean aspects of how these different kinds of thinking became possible in the first place and why particular approaches gained traction when they did.

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L.J. 67, 68–70 (2009) (defending a contextual approach to the precautionary principle and its appropriateness as a policy tool in the face of particular kinds of problems); Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Assessment*, 92 COLUM. L. REV. 562 (1992) (criticizing normative foundations of comparative risk assessment). There are multiple versions of the precautionary principle in use in domestic and international legal contexts throughout the world. One widely referenced definition is Principle 15 of the 1992 Rio Declaration of the United Nations Conference on Environment and Development: “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” See United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 13–14, 1992, *The Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/5/Rev.1 (June 13, 1992), reprinted in 31 I.L.M. 874, 879 (1992). This relatively “weak” version of the precautionary principle can be contrasted with “strong” versions embracing a presumption in favor of regulation in the face of serious threats marked by significant scientific uncertainty and imposing the burden of overcoming such a presumption on those responsible for the activities that generate the potential threats. See Sachs, *supra* at 1295–99 (discussing the “strong” version of the precautionary principle); see also DAVID VOGEL, *THE POLITICS OF PRECAUTION: REGULATING HEALTH, SAFETY, AND ENVIRONMENTAL RISKS IN EUROPE AND THE UNITED STATES* 252–78 (2012) (discussing precautionary principle in U.S. and EU law); JONATHAN B. WIENER, *The Rhetoric of Precaution*, in *THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE* 9–12 (Wiener et al. eds., 2011) (discussing development of the precautionary principle in U.S. and EU legal contexts).

6. In his recent book, Douglas Kysar makes the important point that the rise of formal approaches to environmental decision making displaced an earlier approach based on precaution that was “messy, pluralistic and pragmatic,” but nonetheless a source of important but forgotten “wisdoms” regarding the practice of environmental law and policy. See KYSAR, *supra* note 5, at 2–3. One of the goals of this Article is to investigate how this earlier precautionary approach to environmental law emerged in particular contexts and how it was displaced by formal quantitative approaches to risk starting in the mid-1970s. See also John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 HUM. & ECOLOGICAL RISK ASSESSMENT 413, 420–29 (2000) (discussing historical examples of precaution in various aspects of American environmental law); Shelia Jasanoff, *A Living Legacy: the Precautionary Ideal in American Law*, in PRECAUTION, ENVTL. SCI., & PREVENTIVE PUB. POLICY 230, 230–33 (Joel A. Tickner ed., 2003) (discussing historical examples of precaution in American environmental law); Shelia Jasanoff, *The Songlines of Risk*, 8 ENVTL VALUES 135, 141–45 (1999) [hereinafter Jasanoff, *Songlines of Risk*] (discussing historical context of formal risk assessment and the ways in which it shapes understandings of environmental harms).

7. See, e.g., Gail Charnley & Donald E. Elliott, *Risk Versus Precaution: Environmental Law and Public Health Protection*, 32 ENVTL L. REP. 10,363 (2002) (characterizing the debate between risk and precaution in U.S. environmental law as a debate between normative principles); CASS R. SUNSTEIN, *LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE* 14–15 (2005) (criticizing the precautionary principle as “incoherent,” “paralyzing,” and “self-blinding”); Sachs, *supra* note 5, at 1288 (defending the “strong precautionary principle” against the predominant approach of “unreasonable risk” in U.S. chemicals regulation).

This Article focuses on those more subterranean developments. It contends that we cannot properly gauge what is at stake in the debate between risk and precaution without looking carefully at how the concept of risk and the related practices of risk assessment emerged and took shape in particular contexts. It recognizes that ideas and theories matter a great deal—that this is not simply a story about politics and material interests—but it starts from the premise that we cannot really appreciate how they matter and how they gain force without looking at how specific constellations of concepts, tools, and practices come together in an effort to solve particular problems, thereby opening up new opportunities for the expansion and elaboration of certain ways of thinking.

In investigating this deeper history, the Article sheds new light on how this remarkably powerful way of looking at the world came to dominate health, safety, and environmental law in the United States and the implications of this mode of thinking going forward. It shows that the conventional view of risk in these fields is both descriptively and normatively incomplete; that the rise of quantitative risk assessment was much messier and more contingent than previously recognized; and that the ongoing debate between risk and precaution cannot be viewed simply as a battle between ideas or theories but instead must be situated in a broader, more complex (and more social) terrain of knowledge practices. This is important not merely as an intellectual exercise aimed at a more complete understanding, but also for normative reasons, as various constituencies seek to engage more directly the challenges and the opportunities facing efforts to revitalize health, safety, and environmental decision making in the face of a host of new problems. The Article also speaks to larger debates (positive and normative) regarding risk regulation and its relationship to more general tendencies toward calculation and control in the post-World War II United States.<sup>8</sup>

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8. Quantitative risk assessment can be viewed as an element of the more general embrace during the post-World War II period of formal analytic techniques directed at the study and solution of complex problems. Systems analysis, operations research, and decision theory emerged during the postwar decades in response to a perceived need for more systematic and quantitative approaches to decision-making. As risk assessment became an increasingly professional discipline during the late 1970s and early 1980s, it borrowed heavily from these broader developments. See, e.g., Laurence H. Tribe, *Policy Science: Analysis or Ideology?*, 2 PHIL. & PUB. AFFAIRS 66 (1972) (discussing the growing prominence of fields such as policy science, cost-benefit analysis, operations research, systems analysis, and decision theory in the post-World War II period and their implications for law); M. Fortun & S.S. Schweber, *Scientists and the Legacy of World War II: The Case of Operations Research*, 23 SOC. STUD. SCI. 595, 698 (1993) (noting that World War II “initiated a revolution in management science, risk assessment, and military planning” through the development and consolidation of operations research and systems analysis); David R. Jardini, *Out of the Blue Yonder: The Transfer of Systems Thinking from the Pentagon to the Great Society, 1961–1965*, in SYSTEMS, EXPERTS, AND COMPUTERS: THE SYSTEMS APPROACH IN MANAGEMENT AND ENGINEERING, WORLD WAR II AND AFTER 311 (Hughes & Hughes eds., 2000) (discussing diffusion of systems analysis and program budgeting from the Defense Department to federal civilian departments during the 1960s); IDA R. HOOS, SYSTEMS ANALYSIS IN PUBLIC POLICY: A CRITIQUE 42–85, 271–80 (rev. ed. 1983) (discussing historical development of

Part I of the Article briefly situates the overall approach within the context of previous scholarship on risk and elaborates on some of the key conceptual and regulatory developments prior to the 1930s that underwrote later applications of risk thinking in health, safety, and environmental law. It traces the emergence of particular concepts and techniques of aggregation that were instrumental in elaborating a more formal definition of risk and distinguishing it from uncertainty; describes the increase in government attention during the late nineteenth and early twentieth centuries to problems of public health, industrial disease, and food safety; and discusses the implications of new ways of thinking about populations and environmental hazards for the future development of risk regulation.

Part II assesses efforts to operationalize the concept of safety between the 1930s and the 1960s, with particular attention to radiation, industrial exposures, food safety, and the special problem of carcinogens. It shows how key elements of risk thinking started to take shape in the context of specific problems: attention began to shift from individuals to populations and averages, regulatory tasks were increasingly defined as the setting of tolerances and thresholds, dose-response models were formalized and used to define the boundary between harm and no harm, and safety came to be seen as an increasingly relative term. But it also highlights the continued reluctance to embrace formal notions of risk as a basis for regulation in the face of a growing appreciation for the significant uncertainty, even ignorance, that confronted efforts to regulate an increasingly complex set of hazards. This Part then reveals how tendencies that had been underway in a variety of areas coalesced at the end of this period in a strong precautionary posture, manifest most prominently in the famous Delaney “anti-cancer” clause that was added to the Federal Food Drug and Cosmetics Act in 1958, establishing a “zero tolerance” for chemicals added to the food supply in any quantity if there was evidence that such chemicals induced cancer in animals or humans.<sup>9</sup> Contrary to conventional accounts of the Delaney Clause, moreover, this Part demonstrates that it was not a naïve, overly rigid effort by Congress to respond to public hysteria about cancer but was instead explicitly grounded upon widely accepted views in the scientific community regarding the challenges of understanding and regulating carcinogens.<sup>10</sup>

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systems approach in military and civilian contexts and elaboration as risk analysis in health, safety, and environmental regulation).

9. The so-called Delaney Clause, named for its sponsor, Representative James J. Delaney (D-NY), was enacted as an amendment to the Federal Food, Drug, and Cosmetics Act in 1958. In its original form, the Delaney Clause prohibited the use of food additives that had been shown to induce cancer in humans or animals. See Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784, 1785 (1958); see also discussion *infra* Part II.A.3.

10. Cf. Wendy Wagner, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181, 219–20 (1999) (recounting views of Delaney Clause as “rigid” and “unwise”); BREYER, *supra* note 3, at 41 (describing Delaney Clause as “unreasonably and pointlessly strict”); Charles H. Blank, *The Delaney Clause: Technical Naïveté and Scientific Advocacy in the Formulation of Public Health Policies*, 62

Part III, which covers the 1960s through the 1970s, shows how significant advances in environmental monitoring, detection capabilities, and analytical techniques during this period facilitated a dramatic transformation in the ability to see environmental problems—from chemicals in the food supply to air and water pollution to persistent organic compounds in the global environment.<sup>11</sup> This Part argues that the new world that was brought into focus by these new ways of seeing represented an important rupture in the development of health, safety, and environmental law—opening up a moment of possibility when competing views regarding the distinctive problem of knowledge confronting these fields crystallized, leading to very different regulatory commitments and approaches. Specifically, this Part shows how early decisions by the Environmental Protection Agency (EPA) and the courts to ban DDT and other pesticides, strong precautionary directives in the Clean Air and Clean Water Acts, and efforts by the Occupational Safety and Health Administration (OSHA) to establish a generic cancer policy reflected a deep and longstanding concern with uncertainty and the challenge of securing environmental knowledge that drew directly upon hard thinking about hard problems in industrial hygiene, food safety, and environmental cancer that had been underway since at least mid-century.<sup>12</sup> It was during this moment (and it really was little more than a moment) when the emerging field of environmental law took seriously the daunting task of regulating “on the frontiers of scientific knowledge,”<sup>13</sup> posing important questions about the feasibility of quantitative risk assessment, and recognizing, at least partially, that such an approach carried with it important epistemic decisions about what counted as uncertainty and what sorts of knowledge claims could be made on the basis of the techniques and evidence available.

And yet, as Part III shows, this was also the moment when formal, quantitative approaches to risk in health, safety, and environmental law began to emerge, stemming in large part from a perceived crisis and need for triage as it became apparent that the world of possible harms was much more vast and complicated than previously recognized.<sup>14</sup> Drawing on previous conceptual and technical developments, regulators and other professionals explicitly redefined

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CALIF. L. REV. 1084 (1974) (criticizing the Delaney Clause as scientifically and technically naïve). *But see* Richard A. Merrill, *Food Safety Regulation: Reforming the Delaney Clause*, 18 ANN. REV. PUB. HEALTH 313, 322 (1997) (discussing prevailing view in 1958 that Delaney Clause would not have broad application because only a “handful of chemicals” had been shown to induce cancer in animals); Cass R. Sunstein, *Interpreting Statutes in the Regulatory State*, 103 HARV. L. REV. 405, 496–97 (1989) (noting the significant differences in “[t]he factual background against which the Delaney Clause was written” compared to “present circumstances” and the increasing “obsolescence” of the Clause in the context of new facts and understandings). *See also* discussion *infra* Part III.B.1.

11. *See* discussion *infra* Part III.A.

12. *See* discussion *infra* Part III.B.

13. *See, e.g.*, *Indus. Union Dep’t, AFL-CIO v. Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974); *Ethyl Corp. v. EPA*, 541 F.2d 1, 71–72 (D.C. Cir. 1976) (en banc).

14. *See* discussion *infra* Part III.C.



safety as “acceptable risk” and began to explore the possibility of formal, quantitative approaches to risk as a way forward.<sup>15</sup> Contrary to the conventional account, this Part demonstrates that quantitative risk assessment did not emerge as some sort of natural progression in the ongoing effort to understand and regulate environmental harms. Nor did it arise as a result of the push for regulatory reform or as a reaction to the hard look doctrine in administrative law. While those developments surely helped to consolidate the role of quantitative risk assessment, they do not explain how it first arose and took shape within governmental practices.

Part IV offers a brief look at developments in the late 1970s and early 1980s and distills some of the lessons and insights from the Article. It shows how the Supreme Court’s famous 1980 *Benzene* decision consolidated an ongoing but fragile embrace of quantitative risk assessment by repudiating OSHA’s efforts to develop a generic cancer policy, thereby marking a *de facto* end to the Delaney era and opening up a more systematic approach to risk that was eventually embraced across multiple regulatory domains.<sup>16</sup> More abstractly, Part IV demonstrates how the redefinition of safety as “acceptable risk” and the move to quantitative risk assessment effectively reformatted what were previously viewed as discrete problems of food safety, environmental pollution, or the possibility of accidents at nuclear power plants (to name a few) in a manner that made them amenable to a common evaluative framework. It also explains how the shift from earlier conceptions of hazard or danger to risk worked to bring the future into the present and make it calculable, reframing what were previously viewed as external threats to be avoided as possible future losses or consequences stemming from decisions that had to be made.<sup>17</sup> Part IV concludes by showing how the consolidation of formal approaches to risk in the early 1980s worked to marginalize uncertainty and cabin the precautionary impulse of earlier years, raising important normative questions regarding the continued but troubled role of risk assessment in contemporary health, safety, and environmental regulation.

As for the broader lessons from the study, there are several. First, it is clear that true moments of possibility in law—that is, moments when the development of a field such as environmental law could have gone in one of

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15. See, e.g., WILLIAM W. LOWRANCE, OF ACCEPTABLE RISK: SCIENCE AND THE DETERMINATION OF SAFETY 8 (1976) (“[A] thing is safe if its attendant risks are judged to be acceptable”); see also discussion *infra* Part III.C.

16. *Indus. Union Dep’t. v. Am. Petroleum Inst. (Benzene)*, 448 U.S. 607 (1980); see also *infra* Part III.C.

17. See NIKLAS LUHMANN, RISK: A SOCIOLOGICAL THEORY 101–02 (Rhodes Barrett trans., 1993) (“The concept of risk is, however, clearly distinguished from the concept of danger, this to say, from the case where future losses are seen not at all as the consequences of a decision that has been made, but are attributed to an external factor.”); LANGDON WINNER, THE WHALE AND THE REACTOR: A SEARCH FOR LIMITS IN AN AGE OF HIGH TECHNOLOGY 142–47 (1986) (discussing significant intellectual and practical differences entailed in the move from hazard/danger/threat to risk).

several different directions—are few and far between.<sup>18</sup> Much more common are the deep, settled grooves of path dependency in which styles of thinking and their affinities with particular modes of governance take hold and develop a stubborn recalcitrance to change.<sup>19</sup> Historicizing how particular ways of thinking emerge and take hold, therefore, does not suddenly open up the possibility of revision or reform, but it is an important step towards recognizing the contingency and the limits of such ways of thinking, forcing us to confront the fact that things could have been (and still could be) otherwise.

Second, it would be a mistake to interpret the giving way or the settling in as a wholesale displacement or victory of one paradigm over another. In health, safety, and environmental law, as in so many other fields, the reality is more complex, reflecting a (re)combination of different forms and practices of making knowledge; a mash-up of different ways of viewing and governing the world that mixes the old with the new. Thus, the precautionary impulse that motivated early efforts to grapple with the challenges of health, safety, and environmental law lives on in various guises, albeit as a pale shadow of its earlier manifestation. Put another way, precaution and endangerment persist as important but recessive strains in contemporary health, safety, and environmental law, subordinated to the dominant logic of risk assessment and cost-benefit analysis. We cannot, in this view, simply recover the wisdoms of an earlier time and deploy them in the face of problems that seem to outstrip our current ways of thinking and governing. For although these recessive strains can and do provide resources with which to grapple with new and different problems, their capacity to serve as such is limited by the broader material and institutional substrates in which they are now embedded and, as always, by the different and changing politics of the day.

Third, understanding these moments of possibility and their giving way requires that we get beneath the surface conflicts between ideas and principles to explain how specific knowledge *practices* shape and constrain these more general ways of looking at the world. It is on this more social terrain of knowledge practices, in other words, that important normative debates such as that between risk and precaution need to be engaged. Specific concepts, particular techniques, working instruments, actual practices—these together are the stuff 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.

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18. Christopher Tomlins provides an important discussion of this point in his recent article on critical legal history. See Christopher L. Tomlins, *After Critical Legal History: Scope, Scale, Structure*, 8 ANN. REV. L. & SOC. SCI. 31, 36 (2012) (“Moments of uncertainty and opportunity, in other words, are not constant but fleeting—fragile, fragmentary, and easily overborn. Moments when history breaks free of repetitions and regularities are rare. They demand a means of recognition than that can explain their rarity rather than one that treats them as immanent.”).

19. *Id.*

Finally, from a more self-consciously normative perspective, it is hard not to follow Max Weber and embrace a deep ambivalence about these developments. In the seemingly relentless march of disenchantment, in the never-ending quest for calculability, it is clear that something important *was* lost as the strong precautionary impulse of earlier years was subsumed by more formal approaches to risk and embedded within increasingly elaborate bureaucratic routines and expert systems. And while we should not deceive ourselves about the difficulties of holding onto such an approach in the context of the far more complicated and increasingly politicized world of environmental harms that came into view during the 1970s, and while we cannot ignore the remarkable advances that have been made in understanding and managing the risks of industrial society, neither should we dismiss these earlier approaches to environmental harms as hopelessly antiquated and out of reach as we continue to grapple with environmental problems—old and new—and strive to make sense of our place in the world.

#### I. RISK AND THE PROBLEM OF KNOWLEDGE IN HEALTH, SAFETY, AND ENVIRONMENTAL LAW

There is no shortage of commentary on risk and its place in health, safety, and environmental regulation. The extensive legal literature goes back several decades.<sup>20</sup> Leading scholars have identified risk management as a key problematic for contemporary governance, the “market state,” and the legal system.<sup>21</sup> Social theorists have integrated risk into theories of modernity and modern forms of government.<sup>22</sup> Behavioralists of various persuasions have

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20. 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); SHELIA 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); Applegate, *supra* note 4; Hornstein, *supra* note 5; BREYER, *supra* note 3; 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); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995); Lisa Heinzerling, *Environmental Law and the Present Future*, 87 GEO. L.J. 2025 (1999); SUNSTEIN, *supra* note 3; SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, *RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH* (2003); ELIZABETH FISHER, *RISK REGULATION AND ADMINISTRATIVE CONSTITUTIONALISM* (2007); KYSAR, *supra* note 5.

21. See SUNSTEIN, *supra* note 3, at viii (noting that “risk reduction has become a principal goal of modern governments”); PHILIP BOBBITT, *TERROR & CONSENT: THE WARS FOR THE TWENTY-FIRST CENTURY* (2008) (discussing the critical role of the “market state” in managing various types of risks); George Priest, *The New Legal Structure of Risk Control*, in *RISK* 209 (Edwin J. Burger ed., 1993) (“The predominant function of modern law is to allocate risk.”).

22. See, e.g., MARY DOUGLAS & AARON WILDAVSKY, *RISK & CULTURE: AN ESSAY ON THE SELECTION OF TECHNOLOGICAL AND ENVIRONMENTAL DANGERS* (1982); ULRICH BECK, *RISK SOCIETY: TOWARDS A NEW MODERNITY* (Mark Ritter trans., 1992); LUHMANN, *supra* note 17; Anthony Giddens, *Risk & Responsibility*, 62 MOD. L. REV. 1 (1999); Jasanoff, *Songlines of Risk*, *supra* note 6; PAT O’MALLEY, *RISK, UNCERTAINTY, AND GOVERNMENT* (2004).

created a cottage industry of analyzing risk perception by “ordinary people” (their label) and the effects of heuristics and biases on judgment and decision making about risk.<sup>23</sup> Popular writers have traced its history and offered countless tales of the many specific risks confronting people in their everyday lives.<sup>24</sup> And, of course, there is a massive and growing technical literature on risk spanning a huge range of disciplines and subject matters, not to mention a vast library of government reports on the practice of risk assessment itself that stretches back several decades.<sup>25</sup> This Part briefly situates the approach developed in this Article in the context of existing perspectives and elaborates on some of the early conceptual and regulatory foundations of risk thinking in U.S. health, safety, and environmental law.

#### A. *Risk and the Public Life of Concepts*

Much of the extensive environmental law literature on risk regulation is normative in orientation, often framed in the context of larger debates about the proper role of agency expertise and judgment,<sup>26</sup> the need for objective measures to allocate scarce regulatory resources among competing priorities,<sup>27</sup> and the merits of precautionary stances toward particular types of hazards.<sup>28</sup> Many valuable insights have come out of these debates, and it would be wrong to suggest that one can escape the normative implications of risk and the related practices of risk assessment. Risk thinking has a deep affinity with consequentialist thinking, giving it a distinctive normative valence that belies its seeming neutrality.<sup>29</sup> It is, as George Priest says, “relentlessly utilitarian.”<sup>30</sup>

Rather than arguing for or against a particular position in the risk debates, however, this Article focuses on the technical and normative structuring of risk thinking as it has emerged and developed in U.S. health, safety, and environmental law and the implications of this way of thinking in the face of an

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23. See, e.g., BARUCH FISCHHOFF ET AL., ACCEPTABLE RISK (1981); GERD GIGERENZER, RECKONING WITH RISK: LEARNING TO LIVE WITH UNCERTAINTY (2002); THE PERCEPTION OF RISK (Paul Slovic ed., 2001).

24. See, e.g., PETER L. BERNSTEIN, AGAINST THE GODS: THE REMARKABLE STORY OF RISK (1986).

25. NRC, SCIENCE & DECISIONS, *supra* note 3; ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, RISK AND REGULATORY POLICY: IMPROVING THE GOVERNANCE OF RISK (2010).

26. Compare Richard Stewart, *The Role of Courts in Risk Management*, 15 ENVTL. L. REP. 10,208, 10,209 (1986) (concluding that “primary responsibility for managing risk must be given to administrative agencies”), and Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 333 (1985) (concluding that in the area of public risk management, courts “should defer to the experts”), with Gillette & Krier, *supra* note 20, at 1031 (concluding that “ambitious proposals to increase the scope of agency authority at the expense of judicial scrutiny are remarkably premature” and questioning “the wisdom of wholesale abdication to technocratic rule”).

27. See, e.g., BREYER, *supra* note 3; SUNSTEIN, *supra* note 3; Graham & Wiener, *supra* note 20.

28. See e.g., KYSAR, *supra* note 5; Hornstein, *supra* note 5; Sachs, *supra* note 5.

29. See Hornstein, *supra* note 5.

30. Priest, *supra* note 21, at 215.

increasingly complex set of environmental challenges. In doing so, it draws on a broader legal and social science literature on risk that touches on several different fields but has not been widely engaged by environmental law scholars.<sup>31</sup> By emphasizing the historical development and cultural contexts of risk thinking in various domains, these perspectives provide an important point of departure for investigating how risk and its associated knowledge practices have become embedded in the contemporary practice of health, safety, and environmental regulation. To that end, this Article can be viewed as an inquiry into the “public life of concepts,” focusing specifically on the conditions of possibility for the emergence and organization of concepts such as risk, their translation into specific governmental practices, and the ways in which they gain authority as they mutate and migrate across different domains.<sup>32</sup> The influence of politics and special interests, the structural constraints of material conditions, the role of institutions, the values and experiences of everyday life—all of these are given less attention than they surely deserve. But they are necessarily pushed to the background in order to maintain the focus on how techniques and ways of thinking shape what comes to count as official knowledge and how this in turn gets translated into official practice. One of the goals of such an inquiry is to reveal a deeper political economy, shedding some light on how specific practices tend to naturalize, and thereby privilege, certain ways of looking at the world vis-à-vis others.<sup>33</sup>

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31. Examples of key works from the multiple literatures on risk that have informed this project include LUHMANN, *supra* note 17, at viii (“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.”); François 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.”); JASANOFF, *supra* note 20 (analyzing approaches to risk assessment and risk management in comparative context and highlighting the importance of national political cultures and styles of regulation in understanding different approaches to risk); David Garland, *The Rise of Risk*, in RISK AND MORALITY (Richard V. Ericson & Aaron Doyle eds., 2003) (discussing various social, cultural and political studies of risk and its place in modern society); Mariana Valverde et al., *Legal Knowledges of Risk*, in LAW AND RISK 86–87 (Law Commission of Canada ed., 2005) (discussing how participants in “particular legal networks” shape and deploy different “risk knowledge practices”); Jonathan Simon, *Risk and Reflexivity: What Socio-Legal Studies Add to the Study of Risk and the Law*, 57 ALA. L. REV. 119, 123 (2005) (advocating a socio-legal analysis of risk that is pluralistic, historical and reflexive); Jonathan Simon, *The Ideological Effects of Actuarial Practices*, 22 LAW & SOC’Y REV. 771 (1988) (discussing impacts of actuarial practices on conception of individuals and the concept of the individual and the relationship between individuals and the state); IAN HACKING, *THE TAMING OF CHANCE* (1990) (investigating the rise of probability and related practices of statistical reasoning and their profound impacts on assessment and management of risk in modern society); and François Ewald, *Insurance and Risk*, in THE FOUCAULT EFFECT: STUDIES IN GOVERNMENTALITY 201–05, 209 (Graham Burchell et al. eds., 1991) (discussing risk and insurance as schemas of rationality and management central to the operation of modern society).

32. See HACKING, *supra* note 31, at 7 (“I am concerned with the public life of concepts and the ways in which they gain authority. My data are published sentences.”).

33. Cf. PIERRE BORDIEU, *OUTLINE OF A THEORY OF PRACTICE* 164 (Richard Nice trans., 1977) (“Every established order tends to produce (to very different degrees and with very different means) the naturalization of its own arbitrariness.”).

Such an approach has particular relevance for environmental law, a field that has never been particularly reflective about its distinctive ways of knowing, but one in which the problem of knowledge has long been front and center. To be sure, the general critique of technocratic forms of decision making has been a recurring, if recessive, theme in environmental law scholarship for more than thirty years and draws upon older philosophical and sociological critiques of instrumental reason.<sup>34</sup> Moreover, various scholars inside and outside of law continue to investigate how specific ideas, tools, and ways of thinking structure the field.<sup>35</sup> But for the most part, environmental law, along with the related fields of health and safety law, is still waiting for a detailed intellectual history.<sup>36</sup>

Risk provides an important, albeit daunting, way into such an effort. Indeed, much of the history of modern health, safety, and environmental law can be told as the story of efforts to define, assess, and manage various types of risk, and many aspects of this story are quite technical, spanning multiple disciplines.<sup>37</sup> It should be made clear at the outset, therefore, that this project does not pretend to offer a comprehensive history of risk and its place in health, safety, and environmental law. The notion of “genealogies” in the title is

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34. See, e.g., MAX HORKHEIMER & THEODOR W. ADORNO, *DIALECTIC OF ENLIGHTENMENT* 9 (John Cumming trans., 1991) (1944) (“Men pay for the increase of their power with alienation from that over which they exercise their power. Enlightenment behaves toward things as a dictator toward men. He knows them in so far as he can manipulate them.”); Laurence Tribe, *Policy Science: Analysis or Ideology?*, 2 PHIL. & PUB. AFF. 66, 76 (1972) (showing how seemingly technical exercises in policy science entail substantive conclusions and outcomes); Laurence Tribe, *Ways Not to Think About Plastic Trees: New Foundations for Environmental Law*, 83 YALE L.J. 1315, 1331–32 (1974) (showing how emerging welfarist approaches to environmental law and policy could only be understood and engaged if situated within the larger framework of instrumental reason and an overarching value system of liberal individualism); BRUCE A. ACKERMAN ET AL., *THE UNCERTAIN SEARCH FOR ENVIRONMENTAL QUALITY* (1974) (demonstrating the limits of “technocratic intelligence” in environmental law).

35. See William Boyd, Douglas A. Kysar & Jeffrey J. Rachlinski, *Law, Environment, and the ‘Non-Dismal’ Social Sciences*, 8 ANN. REV. L. SOC. SCI. 183, 192–98 (2012) (reviewing various literatures).

36. There are several excellent general histories of U.S. environmental law and policy that touch upon a number of the developments discussed in this article and provide important context for the more specific focus on the rise of formal, quantitative approaches to risk. See, e.g., RICHARD J. LAZARUS, *THE MAKING OF ENVIRONMENTAL LAW* (2004); RICHARD N.L. ANDREWS, *MANAGING THE ENVIRONMENT, MANAGING OURSELVES: A HISTORY OF AMERICAN ENVIRONMENTAL POLICY* (1999). Of course, there are also many detailed histories of specific events or issues that are relevant to this project, some of which are discussed in the pages that follow. Finally, more than twenty years ago, Professor Robert Blomquist offered a brief prospectus on what an intellectual history of American environmental law might look like. See Robert F. Blomquist, “*Clean New World*”: *Toward an Intellectual History of American Environmental Law, 1961-1990*, 25 VAL. U. L. REV. 1 (1990).

37. The more technical literature on the history of risk analysis has also been important for this project. See e.g., Terje Aven, *The Risk Concept—Historical and Recent Development Trends*, 99 RELIABILITY ENG’G & SYS. SAFETY 33 (2012); John D. Graham, *Historical Perspective on Risk Assessment in the Federal Government*, 102 TOXICOLOGY 29 (1995); Vincent T. Covello & Jeryl Mumpower, *Risk Analysis and Risk Management: An Historical Perspective*, 5 RISK ANALYSIS 103 (1985).

intended as recognition that there is no one right way to do that history.<sup>38</sup> It is also intended to signal a different way into these fields—one that takes the concepts, tools, techniques, and ways of thinking that structure and animate particular approaches to particular problems as objects of inquiry in their own right.<sup>39</sup> Viewed from this perspective, the “making of environmental law”<sup>40</sup> becomes more than a story about efforts to manage spillovers, externalities, commons problems of various kinds, or particular types of ecological and human harm; more than a story about the political and institutional dynamics of

38. Several broader contextual developments are worth identifying here, if only for the purpose of bracketing them and putting them to the side. Specifically, the move to particular forms of social insurance in the late nineteenth and early twentieth centuries and the rise of the welfare state are deeply implicated with risk thinking. *See, e.g.*, FRANÇOIS EWALD, *L'ÉTAT PROVIDENCE* (1986) (discussing the central role of risk thinking and the rise of the welfare state in France); PIERRE ROSANVALLON, *THE NEW SOCIAL QUESTION: RETHINKING THE WELFARE STATE* 16–19 (Barbara Harshav trans., 2000) (describing key role of risk and the “insurance paradigm” in underwriting the welfare state). Likewise, risk thinking has been intimately connected to the development of tort law, and there surely are important and interesting connections to be developed between risk/benefit balancing in tort and environmental law. *See, e.g.*, Henry Terry, *Negligence*, 29 HARV. L. REV. 40 (1915) (proposing a “risk theory” of negligence); *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947). Finally, risk has obviously played a fundamental role in economics and modern finance, a vast territory that has been well canvassed by specialists in those fields, but one that is also beyond the scope of this project except with respect to the influence of expected utility and decision theory on formal approaches to risk in environmental law. *See, e.g.*, BERNSTEIN, *supra* note 24 (providing a popular historical account of risk in economics and finance).

39. This is not the place for an extended discussion of the rich set of methodological debates on genealogy and its relationship to historical research, and this Article does not use the term genealogy out of fidelity to any particular thinker or approach. As employed here, genealogy denotes an effort to trace the historical formation and migration of concepts, knowledge practices, and styles of thinking across various domains with particular attention to how they get refashioned and gain authority in specific contexts. *See, e.g.*, IAN HACKING, *HISTORICAL ONTOLOGY* 198 (2002) (characterizing his mode of inquiry as “a study of the ways in which the styles of reasoning provide stable knowledge and become not uncoverers of objective truth but rather standards of objectivity”). The approach taken here embraces the nominalism of both Max Weber and Michel Foucault, attending in detail to the circumstances and conditions of possibility for the emergence of specific concepts and knowledge practices. In that sense, it may be closer in some respects to Foucault’s earlier archaeological approach to knowledge than to his later genealogical inquiries. *See, e.g.*, MICHEL FOUCAULT, *THE ARCHAEOLOGY OF KNOWLEDGE* 4 (A.M. Sheridan Smith trans., 1972) (“[T]he history of a concept is not wholly and entirely that of its progressive refinement, its continuously increasing rationality, its abstraction gradient, but that of its various fields of constitution and validity, that of its successive rules of use, that of the many theoretical contexts in which it developed and matured.”); Max Weber, “*Objectivity*” in *Social Science and Social Policy*, in *THE METHODOLOGY OF THE SOCIAL SCIENCES* 72 (Edward A. Shils & Henry A. Finch trans. eds., 1949) (“The social science that we wish to pursue is an *empirical science* of concrete *reality*. Our aim is an understanding of the characteristic uniqueness of the reality in which we move. We wish to understand on the one hand the relationships and the cultural significance of individual events in their contemporary manifestations and on the other the causes of their being historically *so* and not *otherwise*.”). For discussions of some of the similarities between Weber and Foucault, including their mutual embrace of nominalism and their shared concern with a historical treatment of “rationalization,” see PAUL VEYNE, *FOUCAULT: HIS THOUGHT, HIS CHARACTER* 34–35, 54 (Janet Lloyd trans., 2010). *See also* HERBERT L. DREYFUS AND PAUL RABINOW, MICHEL FOUCAULT: BEYOND STRUCTURALISM AND HERMENEUTICS 133 (2d ed., 1983) (describing Foucault’s efforts to “isolate[] and identif[y] the mechanisms of the power of rationalization with a finer grained analysis than Weber . . . as an advance, not a refutation of the Weberian project”).

40. *See* LAZARUS, *supra* note 36.

particular legislative efforts, judicial review, agency practice, or the search for optimal policy design. It becomes a story also about how certain ways of understanding environmental problems have become possible, about how distinctive knowledge practices have conditioned the possibilities for response, and about what is gained and what is lost as these practices become routine features of the administrative state.

### B. Early Conceptual Developments

Although the word is much older,<sup>41</sup> modern understandings of “risk” appear to have come into common use in Europe during the sixteenth and seventeenth centuries, with the word coming to mean “a chance of peril or loss.”<sup>42</sup> Niklas Luhmann argues that embedded within this new conception was an understanding of risk that tied outcomes to the consequences of human decisions and actions, thereby taking on for the first time an explicit understanding of time and rationality and an explicit orientation toward the future.<sup>43</sup> Because the existing languages in use at the time already had words for danger, venture, chance, luck, courage, fear, and adventure, we may assume, Luhmann argues, that the new term “risk” came into use to indicate a problem situation that could not be expressed precisely enough with the vocabulary at hand.<sup>44</sup> In his view, these early instances of risk thinking stemmed from the realization that certain advantages are to be gained only if something is at stake; nothing ventured, nothing gained.<sup>45</sup> This volitional conception of risk, where possible future loss is perceived as a consequence of a decision to be made, signals an important departure from previous views of hazard or danger as external threats to be avoided.<sup>46</sup>

It is, of course, difficult to evaluate the merits of these claims regarding the manner in which certain practical and intellectual problems motivated early use of the term risk. What is clear, though, is that writing about risk took off during the late eighteenth century with the significant expansion of commercial activity and various forms of insurance (marine, property, life) reflecting in part the adoption and refinement of actuarial techniques to assess risk and price

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41. The etymology of the word risk is subject to debate. Some claim Arabic origins, while others point to Greek and Latin roots. See PIET STRYDOM, RISK, ENVIRONMENT, AND SOCIETY 75 (2002) (noting that the origin of the word is unknown and much debated); LUHMANN, *supra* note 17, at 9 (“There are no comprehensive studies on the etymology and conceptual history of the term”); Catherine E. Althaus, *A Disciplinary Perspective on the Epistemological Status of Risk*, 25 RISK ANALYSIS 567, 570 (2005) (discussing disputed origins of the term).

42. STRYDOM, *supra* note 41, at 75; Althaus, *supra* note 41, at 570.

43. See LUHMANN, *supra* note 17, at 10–11.

44. *Id.*

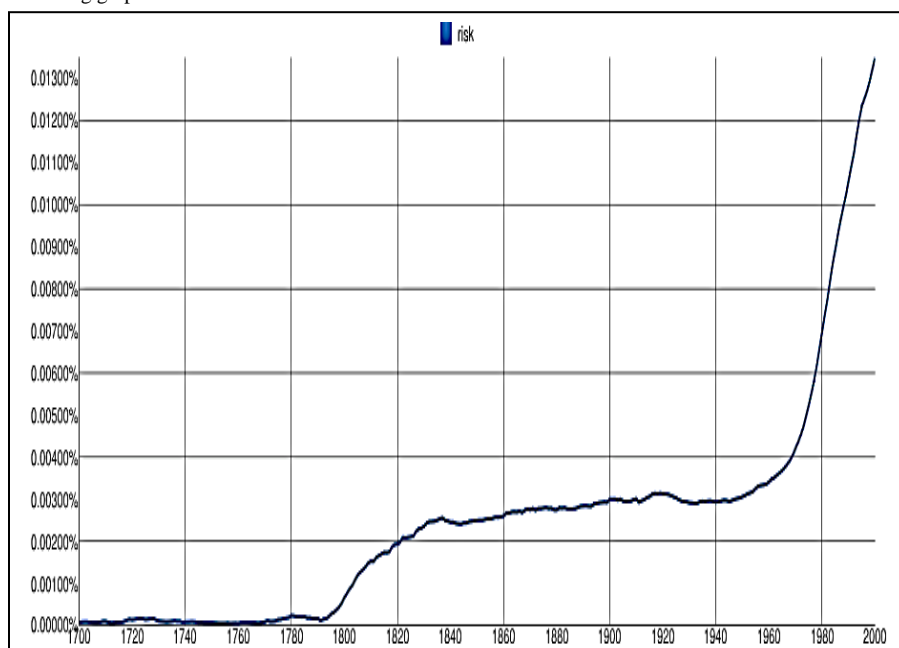
45. *Id.*

46. *Id.* at 101–02. Luhmann discusses how “distinct forms of social solidarity develop differently depending on whether the future is seen from the angle of risk or from the angle of danger.” *Id.* at 102.



insurance contracts.<sup>47</sup> These developments depended upon a host of important conceptual and administrative advances that had been underway since the seventeenth century: collection of vital statistics and other information on populations,<sup>48</sup> the development of probability,<sup>49</sup> the advent of statistical

47. See, e.g., Lorraine J. Daston, *The Domestication of Risk: Mathematical Probability and Insurance, 1650–1830*, in *THE PROBABILISTIC REVOLUTION* (Lorenz Kruger et al. eds., 1987) (noting that mathematical probability was not widely used in insurance until the end of the eighteenth century); GERD GIGERENZER ET AL., *THE EMPIRE OF CHANCE: HOW PROBABILITY CHANGED SCIENCE AND EVERYDAY LIFE* 23–26 (1989) (discussing adoption of mathematical probability in insurance in late eighteenth century); MORTON J. HORWITZ, *THE TRANSFORMATION OF AMERICAN LAW, 1780–1860* 226–37 (1977) (discussing development of actuarial conceptions of risk in American insurance law during the nineteenth century). The Google n-gram explorer provides one method for tracking use of the word “risk” over time. For general information on the n-gram application, see <http://books.google.com/ngrams>. Searching for the word “risk” between 1700 and 2000 generates the following graph:



48. Systematic thinking about populations did not begin until the late seventeenth century with the methodical collection of vital statistics on births, deaths, marriage, illness, and the like. This new information provided the basis for the construction of the first mortality tables and, more generally, facilitated the charting of trends and patterns across populations. See ANDREA A. RUSNOCK, *VITAL ACCOUNTS: QUANTIFYING HEALTH AND POPULATION IN EIGHTEENTH CENTURY ENGLAND AND FRANCE* 4 (2002) (“The modern concept of population and its measurement were mutually constitutive.”); HACKING, *supra* note 31, at 6–7 (“But even the very idea of an exact population is one which has little sense until there are institutions for establishing and defining what ‘population’ means.”).

49. See generally GIGERENZER ET AL., *supra* note 47, at 23–26 (1989); IAN HACKING, *THE EMERGENCE OF PROBABILITY: A PHILOSOPHICAL STUDY OF EARLY IDEAS ABOUT PROBABILITY, INDUCTION AND STATISTICAL INFERENCE* (1975).

techniques and concomitant attention to regularities as a way of understanding the world.<sup>50</sup>

By stabilizing new objects of inquiry, these new ways of thinking made possible a coherent approach to understanding regularities at the level of the collective, underwriting the development of modern aggregative techniques that would prove transformative across multiple domains.<sup>51</sup> Mean values, averages, the normal distribution—these new concepts promised to reveal a deeper social reality beyond individual variation and seemingly random events, opening up in the process new ways of being objective about human beings.<sup>52</sup>

As such, they provided the basis for the more formal conceptualizations of risk that started to take shape in the early twentieth century.<sup>53</sup> In viewing risk as a distribution of possible outcomes (deaths, accidents, or other misfortune) across a population or group of instances, what were previously seen as random or uncertain events could now be aggregated and subjected to probability estimates. Put another way, risk came to be understood as some future consequence or outcome whose probability could be calculated. This basic element of calculability provided the foundation for efforts to distinguish situations of risk (understood as “measurable uncertainty”) from those of true uncertainty, a distinction made famous during the 1920s by Frank Knight, John Maynard Keynes, and others, and one that has been well rehearsed ever since.<sup>54</sup> Yet, despite these important conceptual advances, it would take another half century before this more formal, actuarial conception of risk would become part of the standard vocabulary for understanding health, safety, and environmental hazards.

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50. See generally ALAIN DESROSIERES, *THE POLITICS OF LARGE NUMBERS: A HISTORY OF STATISTICAL THINKING* (1998); THEODORE M. PORTER, *THE RISE OF STATISTICAL THINKING, 1820–1900* (1986).

51. See, e.g., Theodore M. Porter, *Statistics and Statistical Methods*, in 7 *THE CAMBRIDGE HISTORY OF SCIENCE* 241 (Porter & Ross eds., 2003) (identifying as “the most fundamental principle of statistical reasoning” the idea that “[i]t is possible to build a coherent science at the level of the collective by attending only to frequencies or rates without seeking causes of individual behavior”).

52. See GIGERENZER ET AL., *supra* note 47, at 41 (discussing implications of new statistical aggregates on understanding of social reality); HACKING, *supra* note 31, at 160 (“The word [normal] became indispensable because it created a way to be objective about human beings.”). Hacking describes the “benign and sterile sounding word normal” as “one of the most powerful ideological tools of the twentieth century.” *Id.* at 169.

53. See, e.g., ALLAN H. WILLETT, *THE ECONOMIC THEORY OF RISK AND INSURANCE* (1901) (offering one of the first systematic treatments of the nature of risk and its relationship to uncertainty).

54. 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* LUHMANN, *supra* note 17, at 1 (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”).

### C. Regulatory Foundations

Notwithstanding the relatively slow uptake of the formal nomenclature of risk, the new techniques of aggregation that emerged in the seventeenth and eighteenth centuries provided an important basis for a deepening engagement by governments during the late nineteenth and early twentieth centuries in the overall health and well-being of their citizens, establishing a crucial part of the foundation for future government involvement in risk regulation.<sup>55</sup> Workers compensation and other social insurance programs in Europe and the United States constituted the most obvious government interventions in this respect, building directly upon the application of actuarial thinking to accidents and other potential harms.<sup>56</sup> At the same time, governments in Europe and the United States also began to regulate sanitation and public health, food safety, and industrial hygiene. In each of these areas, important conceptual and technical developments underwrote a more proactive role for government in regulating the hazards of industrial society.

Thus, the late nineteenth century sanitation movement, and what came to be known as “the new public health,”<sup>57</sup> led directly to new laws and regulations regarding sanitation and public hygiene and provided the general population-based framing necessary for the subsequent application of risk thinking to all manner of environmental hazards.<sup>58</sup> Likewise, early twentieth century efforts to

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55. See Alain Desrosieres, *How to Make Things Which Hold Together: Social Science, Statistics, and the State*, in *DISCOURSES ON SOCIETY* 195, 197 (Peter Wagner ed., 1991) (noting “the extent to which the setting up of systems of statistical recording goes hand in hand with the construction of the State”); Karl H. Metz, *Paupers and Numbers: The Statistical Argument for Social Reform in Britain During the Period of Industrialization*, in *THE PROBABILISTIC REVOLUTION*, *supra* note 47, at 345 (“Statistics made the social state of the nation an affair that could be measured, and in this way it contributed significantly to the bureaucratization of disease and poverty that was to pave the way for the development of the welfare state.”).

56. This history has been well documented. See, e.g., JOHN FABIAN WITT, *THE ACCIDENTAL REPUBLIC: CRIPPLED WORKINGMEN, DESTITUTE WIDOWS, AND THE REMAKING OF AMERICAN LAW* (2004); Lawrence M. Friedman & Jack Ladinsky, *Social Change and the Law of Industrial Accidents*, in *AMERICAN LAW AND THE CONSTITUTIONAL ORDER: HISTORICAL PERSPECTIVES* 279 (Friedman & Scheiber eds., 1978) (“Workmen’s compensation was designed to replace a highly unsatisfactory system with a rational, actuarial one.”).

57. See STEVEN JOHNSON, *THE GHOST MAP: THE STORY OF LONDON’S MOST TERRIFYING EPIDEMIC—AND HOW IT CHANGED SCIENCE, CITIES, AND THE MODERN WORLD* 97 (2006) (discussing the crucial breakthrough of population thinking as a basis for John Snow’s efforts to understand the cholera epidemic in London in the 1850s and the foundation for epidemiology and the new public health); JOHN DUFFY, *THE SANITARIANS: A HISTORY OF AMERICAN PUBLIC HEALTH* 205–18 (1992) (discussing emergence during late nineteenth and early twentieth centuries of the “new public health” founded upon revolutionary advances in bacteriology and epidemiology); GEORGE ROSEN, *A HISTORY OF PUBLIC HEALTH* 295–319 (rev. ed. 1993) (1958) (discussing the growing sophistication of public health in combating infectious disease during the late nineteenth and early twentieth centuries).

58. This new way of thinking about public health as a target of government regulation gained considerable traction in the United States during the second half of the nineteenth century. In his history of law and regulation in nineteenth century America, William Novak concludes that far from being a narrow interest of certain professionals, “public health was at the center of a legal and political revolution that culminated in the creation of modern constitutional law and a positive administrative state.” WILLIAM J. NOVAK, *THE PEOPLE’S WELFARE: LAW & REGULATION IN NINETEENTH CENTURY*

protect the public from unsafe food, most notably through the Pure Food and Drug Act of 1906,<sup>59</sup> got the government into the business of establishing tolerances for “poisonous” or “deleterious” substances and represented one of the first efforts by the federal government to establish a science-based approach to harmful substances.<sup>60</sup> Finally, pioneering efforts in industrial hygiene during the 1920s, marked most prominently by the work of professionals such as Alice Hamilton, shifted attention from acute to chronic industrial poisonings associated with ongoing low-level exposures to substances such as lead, arsenic, mercury, and benzene in the workplace<sup>61</sup> and ushered in the modern idea of a stable relationship between dose and response—a conceptual innovation that would prove central to the effort to understand and regulate the health effects of various industrial chemicals and other hazardous substances in the years ahead.<sup>62</sup>

These developments opened up new worlds of possibility: the health of the general population became an explicit object of government regulation, establishing tolerances and thresholds for exposures to harmful substances came to be viewed as a key responsibility of government, and formal understandings of the dose-response relationship emerged as an important tool for assessing potential harms associated with exposure to hazardous agents across large segments of the population. In the process, individuals, the human body, and their relationship to the environment were reconceived in the context

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AMERICA 194 (1996). Enactment of new state and local laws together with the creation of municipal health departments, which Novak refers to as the “first real administrative agencies in the United States,” and later state boards of health represented a substantial expansion of state police powers directed at maintaining the health of the population. *Id.* at 202.

59. Federal Food & Drugs (Wiley) Act, Pub. L. No. 59-384, 34 STAT. 768 (1906) [hereinafter Pure Food & Drugs Act] (repealed in 1938 by Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 (1938))). As its name suggested, the main objective of the new law was to secure the purity of food and drugs and to inform purchasers. *See* United States v. Antikamnia Chem. Co., 231 U.S. 654, 665 (1913) (“The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying.”).

60. *See* Pure Food & Drugs Act, *supra* note 59, § 7 (providing that food containing “any added poisonous or other added deleterious ingredient which may render such article injurious to health” would be considered adulterated under the Act); *see also* United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 410–11 (1913) (interpreting § 7 as requiring only that the Government show possible rather actual harm before regulating).

61. *See* ALICE HAMILTON, INDUSTRIAL POISONS IN THE UNITED STATES 1 (1925) (“Industrial poisoning is typically chronic, the acute forms are relatively rare”). For historical overviews of industrial hygiene and occupational health in the United States, *see* CHRISTOPHER C. SELLERS, HAZARDS OF THE JOB: FROM INDUSTRIAL DISEASE TO ENVIRONMENTAL HEALTH SCIENCE (1997); JACQUELINE KARNELL CORN, RESPONSE TO OCCUPATIONAL HAZARDS: A HISTORICAL PERSPECTIVE (1992).

62. *See* ROBERT N. PROCTOR, CANCER WARS 154–55 (1995) (“[I]t is first with industrial diseases that one gets the notion that the probability or severity of a disease can be understood as a well-behaved function of the frequency, intensity, and duration of exposure.”). During this time, moreover, a number of states began to broaden their workers compensation laws to cover certain occupational diseases. *See* Christopher Sellers, *Factory as Environment: Industrial Hygiene, Professional Collaboration and the Modern Sciences of Pollution*, 18 ENVTL. HIST. REV. 55, 63–64 (1994) (discussing broadening of compensation laws to cover occupational disease starting in the 1920s).

of a more abstract, aggregative logic. New forms of sociability came into being.<sup>63</sup> New relations were forged between citizen and government.<sup>64</sup>

## II. SEARCHING FOR SAFETY, 1930S-1960S

By the 1930s, as the challenges of understanding and regulating a proliferating set of industrial hazards became more apparent, experts of various persuasions struggled to operationalize safety. In the process, governmental thinking about health and environmental harms developed along more formal lines, taking its place in the emerging administrative state. This period (1930s-1960s), particularly during the years following World War II, also witnessed growing *public* anxiety about the hazards of industrial society, with considerable attention to cancer.<sup>65</sup> Deepening awareness of and concern for the impacts of radiation, largely as a result of the radioactive fallout controversy of the mid-1950s, combined with the proliferation of new, synthetic chemicals that appeared to pose a range of ecological and health harms, demonstrated most dramatically by the publication of Rachel Carson's *Silent Spring* in 1962, stoked public fears of a mounting, largely unchecked series of industrial hazards that went well beyond the workplace to impinge upon daily life in novel ways.<sup>66</sup> Calls for more protective approaches led to significant reductions in radiation limits, strong precautionary stances in the context of carcinogens and food, including the 1958 Delaney Clause, and a first wave of federal environmental laws that included explicit mandates to protect public health with an adequate margin of safety.

With the partial exception of radiation, these efforts were almost always framed in terms of safety, hazard, and danger. Despite widespread use in insurance and other areas, formal conceptions of risk were rarely invoked as a means of understanding and regulating the harms posed by radiation, occupational exposures, chemicals in the food supply, and carcinogens. To be

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63. Cf. CHARLES TAYLOR, *MODERN SOCIAL IMAGINARIES* 17–19, 64–67 (2004) (discussing new forms of sociality—new social imaginaries—that made possible the rise of modern individualism); LUHMAN, *supra* note 17, at 102 (discussing the “distinct forms of social solidarity” entailed by the concept of risk).

64. See NOVAK, *supra* note 58, at 198, 191–233 (discussing rise of public health in the nineteenth century as “an ongoing practice and technique of governance” central to the rise of the modern administrative state).

65. See SIDDHARTHA MUKHERJEE, *THE EMPEROR OF ALL MALADIES: A BIOGRAPHY OF CANCER* (2010) (discussing increased public attention to cancer in post-World War II United States); DEVRA DAVIS, *THE SECRET HISTORY OF THE WAR ON CANCER* (2007) (same); JAMES T. PATTERSON, *THE DREAD DISEASE: CANCER AND MODERN AMERICAN CULTURE* (1987) (same).

66. See CATHERINE CAUFIELD, *MULTIPLE EXPOSURES: CHRONICLES OF THE RADIATION AGE* 123–32 (1989) (discussing fallout controversy during the 1950s); BARRY COMMONER, *THE CLOSING CIRCLE: NATURE, MAN, AND TECHNOLOGY* 51–56 (1972) (discussing fallout controversy and its crucial role in raising awareness about the environment and human exposure to toxic agents); RACHEL CARSON, *SILENT SPRING* 6 (1962) (identifying “universal contamination of the environment” by chemicals and radioactive fallout); see also ANDREWS, *supra* note 36, at 213–18 (discussing radiation and pesticide controversies during the 1950s and 1960s).

sure, efforts to operationalize safety during this time were marked by an ongoing effort to quantify potential harm and develop specific standards or thresholds that would define safe levels, often with safety factors built in to compensate for uncertainty. But, for the most part, the world of environmental harms was viewed in terms of hazard and danger rather than risk and there was a general view that the precise, quantitative assessment of potential harm was beyond the reach of current capabilities.

And yet, as safety determinations came to depend increasingly on a set of extrapolative techniques that went beyond experience, important elements of risk thinking began to take hold: attention began to shift from individuals to populations and averages, regulatory tasks were defined as setting quantitative thresholds and tolerances, dose-response models were formalized, safety factors and other tools were developed to manage uncertainty, and safety itself came to be viewed as a fluid, relative concept. In all of this, however, experts and regulatory officials showed a continuing reluctance to embrace formal risk thinking as a basis for regulation, and there was a strong impulse in certain areas, notably carcinogens, toward precaution. This Part discusses the difficult search for ways to operationalize safety during the interwar and post-World War II decades in the context of efforts to regulate the potential harms associated with radiation, occupational hazards, chemicals in the food supply, and carcinogens.

#### A. *Tolerances and Thresholds*

Government regulators and public health professionals charged with ensuring safety during the middle decades of the twentieth century faced the challenging task of understanding and defining levels of exposure to harmful substances or activities that could be classified as “safe” and then embedding these in specific standards. Tolerances, threshold limit values, and maximum allowable concentrations all drew from the same general conviction that the human body could tolerate a certain level of exposure without experiencing harm—that there was a safe, threshold dose for harmful substances. This relatively simple idea proved immensely important in the development of environmental, health, and safety regulation and quite vexing to those charged with putting it into practice.

This was made all the more challenging by ongoing improvements in analytical capabilities that could detect responses at lower levels of exposure and, more importantly, the recognition that certain types of harmful agents might not have thresholds—a fact that was apparent early on in the case of radiation and later with certain industrial chemicals, particularly carcinogens.<sup>67</sup>

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67. Peter Hutt notes that detection capabilities for food chemicals in the 1950s were generally sensitive in the range of twenty to fifty parts per million. By the end of the 1960s, detection capabilities were sensitive in the very low parts per billion range. See Peter Hutt, *Use of Quantitative Risk*

Determining safety came to depend increasingly on the development and use of new techniques that allowed scientists and others to move beyond direct experience in their efforts to understand the world of environmental harms. Starting in the 1940s, animal testing became an established part of regulatory toxicology, providing a basis for efforts to operationalize safety in the face of low-level chronic exposures—an exercise that brought with it a host of uncertainties.<sup>68</sup> Extrapolating from high-dose animal studies undertaken on genetically identical populations in controlled conditions to the messy realities of low-dose human exposures in the real world of significant individual variability was no easy task. And it was one that would pose significant challenges to efforts aimed at developing a precise, objective approach to safety in the years to come.

### 1. *Radiation and Permissible Dose*

Low-level radiation and its implications for human health garnered considerable attention from scientists, regulators, and the public during the middle decades of the twentieth century.<sup>69</sup> In important respects, radiation provided the first opportunity to grapple with some of the fundamental aspects of risk thinking in the context of a new wave of environmental harms associated with exposure to toxic agents in minute quantities.<sup>70</sup> As X-rays and other forms of radiation became a more common part of daily life, experts and medical professionals recognized that safeguards would be needed to protect workers and the general public from the potentially harmful effects of low-level exposures. During the 1930s, both the U.S. and international committees on radiation protection proposed the first “tolerance doses” for exposure to external radiation.<sup>71</sup> These early standards were based on the presence of erythema or visible burning of the skin, an approach that led to tolerance doses that were several orders of magnitude more permissive than those adopted in later years.<sup>72</sup>

As understanding of the potential genetic damage and somatic effects of radiation improved, however, it became increasingly apparent that any

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*Assessment in Regulatory Decisionmaking under Federal Health and Safety Statutes*, in RISK QUANTIFICATION AND REGULATORY POLICY 20–21 (D.G. Hoel et al. eds., 1985).

68. FDA proposed its first rule on animal toxicity testing in 1948. *See id.* at 20 (“With the advent of controlled animal experimentation, operational definitions of safety were for the first time feasible.”).

69. *See, e.g.*, CAUFIELD, *supra* note 66 (providing a detailed history of ionizing radiation in the twentieth century United States).

70. *Id.* at viii (“Ionizing radiation is the best-understood and most tightly controlled toxic substances known to man.”).

71. *See The Nature of Radioactive Fallout and its Effects on Man: Hearings before the Special Subcomm. on Radiation, J. Comm. on Atomic Energy*, 85th Cong. 828–29, 856 (1957) [hereinafter *Nature of Radioactive Fallout*] (statement of Lauriston Taylor, discussing early efforts to establish tolerance doses and standards for radiation exposure).

72. *Id.* at 828–29.

exposure to radiation had an impact on the human body.<sup>73</sup> By the late 1940s, the U.S. National Committee on Radiation Protection (NCRP) had abandoned the tolerance dose concept, adopting in its place the notion of “permissible dose” in recognition of the widely accepted view that there was no threshold level below which exposure to radiation was “safe.”<sup>74</sup> Radiation, in other words, could not be tolerated by the human body in any absolute sense; there was always a potential for harm at even *de minimis* levels of exposure. For external sources of radiation, permissible dose was defined as “the dose of ionizing radiation that, in light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his lifetime.”<sup>75</sup> Although the NCRP acknowledged the possibility of harm from radiation exposures below the permissible level, it defended the concept on the grounds that the chance of such injury occurring was so low that the risk would be “readily acceptable to the average individual,”<sup>76</sup> providing an early example of the notion of acceptable risk as determined by reference to the “average individual.”<sup>77</sup>

More importantly, the NCRP also recognized the fluid, relative nature of “acceptable risk” as well as its relationship to advances in detection capabilities and new understandings of the effects of radiation exposure. As one NCRP member put it, “as the means of detection become more refined it will be possible to determine changes of smaller and smaller magnitude. Also new kinds of effect will be found. Therefore, at some point it will become necessary to decide what degree of any particular change is to be considered injurious.”<sup>78</sup>

Despite the best efforts of the NCRP, the Atomic Energy Commission (AEC), and other experts to contextualize the hazards of radiation, the issue

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73. *Id.*

74. See NAT'L COMM. ON RADIATION PROTECTION, PERMISSIBLE DOSE FROM EXTERNAL SOURCES OF IONIZING RADIATION 26 (1954) (“The concept of a tolerance dose involves the assumption that if the dose is lower than a certain value—the threshold value—no injury results. Since it seems well established that there is no threshold dose for the production of gene mutations by radiation, it follows that strictly speaking there is no such thing as a tolerance dose when all possible effects of radiation on the individual and future generations are included. In connection with the protection problem the expression has been used in a more liberal sense, namely, to represent a dose that may be expected to produce only ‘tolerable’ deleterious effects, if any are produced at all. Since it is desirable to avoid this ambiguity the expression ‘permissible dose’ is much to be preferred.”).

75. *Id.* at 27.

76. *Id.* at 21.

77. *Id.* (“Because there is at present no way of determining in advance who is most susceptible to radiation, each person has, in effect, the same chance of escaping injury as anyone else. Under these conditions and in this sense, then, the risk of radiation injury has essentially the same characteristics as more common risks readily accepted by the average person in his ordinary pursuits.”); see also *Nature of Radioactive Fallout*, *supra* note 71, at 856 (testimony of Lauriston Taylor) (“There is always some risk involved in radiation exposure but also there is risk in virtually everything else that we do. With radiation the challenge is to balance the risk by exposure against the tangible and intangible gains to be gained by this exposure and against the risks that occur from a variety of other sources.”).

78. See NAT'L COMM. ON RADIATION PROTECTION, *supra* note 74, at 22.



became a prominent source of public concern during the 1950s.<sup>79</sup> The 1954 *Lucky Dragon* incident, in which Japanese fishermen suffered severe radiation injuries and at least one death as a result of exposure to fallout from weapons testing at Bikini Atoll,<sup>80</sup> as well as weapons testing in the Nevada desert, raised the prospect of “global” contamination of the environment and widespread exposure among human populations. When strontium-90, a radioisotope that moves through the environment in a manner similar to calcium, appeared in milk, food, and human bone samples, it illustrated in dramatic and novel ways how toxic agents could travel through the global environment, concentrate in food chains, and pose new dangers for human health.<sup>81</sup> All of these developments put the issue of whether there could be a “safe” dose of radiation exposure squarely on the public agenda.<sup>82</sup> The general view was that radiation acted as a mutagen and, thus, had the potential to cause harm at any level of exposure.<sup>83</sup> For its part, the AEC insisted that levels of radioactivity associated with fallout from weapons testing were too low to pose any significant threat to public health and that such tests were necessary in the face of the growing Soviet menace.<sup>84</sup> As an AEC report put the matter in February 1955: “The degree of risk must be balanced against the great importance of the test programs to the security of the nation.”<sup>85</sup>

But in a time of heightened fear about new, invisible hazards and increased incidence of cancer, doubts about the AEC’s credibility persisted.<sup>86</sup>

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79. See CAUFIELD, *supra* note 66, at 123–32 (discussing fallout controversy in the United States during the second half of the 1950s).

80. In March 1954, Japanese fishermen aboard the *Lucky Dragon*, which was fishing in waters some eighty to ninety miles from Bikini Atoll, suffered injuries and death from exposure to the fallout from the U.S. atomic weapons test at Bikini. See J. SAMUEL WALKER, *PERMISSIBLE DOSE: A HISTORY OF RADIATION PROTECTION IN THE TWENTIETH CENTURY* 19 (2000).

81. See, e.g., J.L. Kulp et al., *Strontium-90 in Man*, 125 *SCIENCE* 219, 219 (1957) (reviewing previous studies, reporting results of world-wide investigation of strontium-90 contamination, and concluding that the radioisotope could be “found in all human beings, regardless of age or geographic location” as a result of radioactive fallout); see also COMMONER, *supra* note 66, at 51–57 (discussing strontium-90 fallout contamination, implications for new understandings of the environment, and relationship to human health).

82. See, e.g., E. Anderson et al., *Radioactivity of People and Foods*, 125 *SCIENCE* 1273 (1957) (pointing to increased public concern regarding the “problems of widespread, low-level radioactive contamination from nuclear weapons testing”). Much of the concern was directed at the movement of strontium-90 through the biosphere and its residual deposition in the human body, leading scientists to focus increasingly on an overall “body burden” for such substances. *Id.*

83. *Id.* Although there was some debate regarding the reparative abilities of cells and others questioned whether there might be a “safe” threshold dose for somatic injury, the general view was that radiation was a mutagen with no safe dose.

84. See WALKER, *supra* note 80, at 20.

85. *Id.* (quoted in WALKER, *supra* note 80, at 20).

86. Dr. Hermann J. Muller offered the following assessment to the National Academy of Sciences in 1955:

So many of the public are already aware of the genetic damage produced by radiation that their morale is weakened and their apprehensions are increased when they see that the damage is denied by prominent sponsors of our national defense. Thus the door is opened for their acceptance of the defeatist propaganda, which alleges that even the tests are seriously

In an effort to resolve the controversy, the AEC and the National Academy of Sciences (NAS) launched a comprehensive study culminating in the 1956 Report, *The Biological Effects of Atomic Radiation*, the first of a series of NAS reports on the health effects of low-level radiation and one of the earliest efforts to comprehensively assess a specific environmental hazard.<sup>87</sup> The report did not exactly provide the resolution the AEC sought but instead emphasized the potential harm from low doses of radiation and urged that exposure to all sources of radiation be kept as low as possible.<sup>88</sup> Given the cumulative nature of radiation exposure and the fact that people were already receiving a sizeable dose from increasingly routine use of X-rays (not to mention background radiation), the NAS report stressed the vital importance of focusing on the total lifetime dose from all sources and keeping overall cumulative exposure to a minimum.<sup>89</sup> In response, the NCRP and its international counterpart both reduced their permissible dose limits by one-third, and re-emphasized their view that radiation exposures should be kept as low as practicable.<sup>90</sup>

The following year, Congress convened extensive hearings on “the nature of radioactive fallout and its effects on man.”<sup>91</sup> Much of the attention was directed at efforts to get a handle on the nature and scope of the fallout problem in the United States.<sup>92</sup> Early fate and transport models were presented for the purpose of mapping the distribution of radionuclides in the environment and leading scientists gave extensive testimony on the potential harm posed to the

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undermining the biological integrity of mankind. In this situation the only defensible or effective course for our democratic society is to recognize the truth, to admit the damage, and to base our case for continuance of tests on the weighing of the alternative consequences.

*Nature of Radioactive Fallout*, *supra* note 71, at 1057 (statement of Hermann J. Muller).

87. See NAT'L RESEARCH COUNCIL, *THE BIOLOGICAL EFFECTS OF ATOMIC RADIATION: SUMMARY REPORTS FROM A STUDY BY THE NATIONAL ACADEMY OF SCIENCES* (1956) [hereinafter NRC, *BIOLOGICAL EFFECTS*].

88. *Id.* at 28 (noting the “basic fact that any additional radiation is undesirable . . . [and that] society should hold additional radiation exposure as low as it possibly can”).

89. *Id.* at 30 (“We ought to keep all of our expenditures of radiation as low as possible. . . . From the point of view of genetics, they are all bad.”).

90. See, e.g., NAT'L COMM. ON RADIATION PROT. & MGMT., *MAXIMUM PERMISSIBLE RADIATION EXPOSURES TO MAN 1-2* (1958) (discussing downward revisions in maximum permissible dose and noting that the NCRP “reemphasizes its long-standing philosophy that radiation exposures from whatever sources should be as low as practical”); see also WALKER, *supra* note 80, at 22-23 (discussing reaction of NCRP and ICRP to 1956 NAS report); FED. RADIATION COUNCIL, *BACKGROUND MATERIAL FOR THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS*, 23-25, 37 (1960) (discussing development of radiation protection standards and endorsing approach of maintaining radiation doses as far below the recommended limits as practical).

91. See *Nature of Radioactive Fallout*, *supra* note 65.

92. *Id.* at 1 (statement of Representative Chet Hollifield, Chairman of the Special Subcommittee on Radiation) (“It is the committee’s intention through the presentation of expert scientific testimony, to trace the fallout cycle from the moment of the nuclear explosion, through the scattering of radioactive debris in the atmosphere, its descent to the ground, and finally its effects on human beings, livestock, and agriculture.”).

general public and future generations.<sup>93</sup> The question of safety came up most directly in the context of establishing permissible dose levels. Lauriston Taylor, head of the Atomic and Radiation Physics Division of the National Bureau of Standards and a member of the NCRP, discussed the difficulties involved in such an exercise:

In connection with the question of permissible dose standards, there are, as I have indicated, a large number of variables, and a large number of uncertainties. We do not now have, and probably will not have for a long time, any quantitative evaluation of the risks involved. What somebody has to do is to evaluate the risk due to radiation against the benefits from the use of radiation, and the risk due to other things that affect our normal life. In this connection I frequently feel compelled to say that this question of radiation safety and permissible dosage standards is not a subject for which there is a clean and simple answer. The whole question of setting radiation exposure limits depends on physics and biology. It depends enormously on ethics and morality, and on an enormous amount of good judgment and good wisdom on the part of the people who are responsible for setting them. It is by no means a clean-cut quantitative physical problem.<sup>94</sup>

Setting standards was hardly a simple technical exercise, nor would it ever be. In radiation, well before it was the case for chemicals and other industrial hazards, experts charged with assessing hazards and determining what was “acceptable” recognized that they were aiming at a moving target. Safety, in this view, could only be evaluated in the context of the hazards of everyday, “normal life.” And there was certainly no reason to believe that expertise—“good judgment and good wisdom” as Taylor put it—should not be at the center of the exercise. Quantitative assessments, even where feasible, were viewed as tools to guide the overall assessment rather than as ends in themselves.

By the end of the 1950s, with the fallout controversy in full swing, President Eisenhower appointed a new Federal Radiation Council (FRC) in an effort to bring some coherence to the federal role in radiation safety.<sup>95</sup> In 1960, the FRC released its first set of radiation protection standards for workers and the general population, recommending levels that were very similar to those of the NCRP.<sup>96</sup> In doing so, the FRC framed radiation protection as an exercise in determining what level of health hazard would be acceptable in light of the

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93. See, e.g., *id.* at 104–28, 130–34 (testimony and statement of Dr. W.W. Kellogg, Rand Corporation) (reporting on efforts to model atmospheric transport and fallout of radioactive debris from atomic explosions); *id.* at 141–70 (testimony and statement of Dr. Lester Machta, U.S. Weather Bureau) (discussing worldwide transport of radioactive debris from weapons testing).

94. *Id.* at 793 (statement of Lauriston Taylor).

95. See Executive Order 10,831 (1959); Pub. L. No. 86-373; 73 Stat. 688 (1959). The FRC was abolished in 1970 and its responsibilities were transferred to the EPA.

96. See Fed. Radiation Council, *Radiation Protection Guidance for Federal Agencies*, 25 Fed. Reg. 4402, 4402 (May 18, 1960).

benefits of radiation.<sup>97</sup> It noted, however, that there was “particular uncertainty with the respect to the biological effects at very low doses and low-dose rates.”<sup>98</sup> In light of such uncertainty, the FRC concluded that it was “not prudent . . . to assume that there is a safe level of radiation exposure below which there is absolute certainty that no effect may occur.”<sup>99</sup> Based on the conservative assumption of a linear relationship between dose and biological effect, the Council determined that radiation standards should thus be set at a level that would build in as much safety as possible.<sup>100</sup> In addition, “every effort should be made to encourage the maintenance of radiation doses as far below [the proposed radiation limits] as practicable.”<sup>101</sup> This “as low as practicable” standard, which would become a cornerstone of radiation protection in the decades ahead, reflected a precautionary impulse in the face of persistent uncertainty and the general inability to come up with precise risk estimates.<sup>102</sup> As such it comported with efforts underway in food safety and other areas to develop a precautionary basis for protecting against a growing number of environmental hazards.<sup>103</sup>

In a deeper sense, the mid-century controversy over low-level radiation posed for the first time questions about widespread contamination of the global environment as well as the long-term “biological integrity of mankind” in the context of a vast new range of hazards.<sup>104</sup> Even though the dangers associated with fallout turned out to be relatively minor, the notion of cumulative body burdens resulting from exposures to mutagenic agents that could travel very long distances, persist in the environment for centuries, and cause harm to future generations, seemed qualitatively different when compared to previous hazards.<sup>105</sup> The view that there was no absolutely “safe” level of exposure to radiation, that biological effects were present at any dose, that some of these

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97. *Id.* (“Fundamentally, setting radiation protection standards involves passing judgment on the extent of the possible health hazard society is willing to accept in order to realize the known benefits of radiation.”).

98. *Id.*

99. *Id.*

100. *Id.* (noting that the uncertainty regarding low-level exposures combined with the “adoption of the conservative hypothesis of a linear relation between biological effect and the amount of dose, determines our basic approach to the formulation of radiation protection guides”).

101. *Id.*

102. This would come to be known as the ALARA (“as low as reasonably achievable”) standard. See D.C. Kocher, *Perspective on the Historical Development of Radiation Standards*, 61 HEALTH PHYS. 519, 524–25 (1991) (discussing development of ALARA standard).

103. See *infra* discussion parts II.A.3 and II.A.4.

104. See Muller, *supra* note 86; see also Kulp et al., *supra* note 81; COMMONER, *supra* note 66, at 49–65.

105. See, e.g., NRC, BIOLOGICAL EFFECTS, *supra* note 87, at 29 (“The basic fact is—and no competent persons doubt this—that radiations produce mutations and that mutations are in general harmful. It is difficult, at the present state of knowledge of genetics, to estimate just how much of what kind of harm will appear in each future generation after mutant genes are induced by radiations. Different geneticists prefer differing ways of describing this situation: But they all come out with the unanimous conclusion that the potential danger is great.”).

effects, no matter how small, would persist across generations, and that “acceptable risk” provided the proper normative frame for evaluating these risks would prove to be a harbinger of the challenges in the years ahead to deal with the far more ubiquitous, and far more serious, problem of low-level exposure to carcinogenic chemicals.<sup>106</sup>

## 2. *Occupational Exposures and Threshold Limit Values*

Like radiation, chemical hazards in the workplace became an increasingly prominent concern during the middle decades of the twentieth century. As America’s industrial economy expanded, the links between human health and the working environment were subjected to more intense scrutiny. By the 1930s, industrial hygiene had become a professional lab-based pursuit, facing the same basic challenge that confronted efforts to deal with the dangers of radiation: how to establish “safe” levels of exposure.<sup>107</sup> Given the many factors involved and the different kinds of possible injury, however, efforts to establish safe levels of exposure in the workplace proved far more complicated than setting permissible limits for radiation exposure. Making the problem tractable required moving away from the earlier field-based methods pioneered by Alice Hamilton and others to embrace a more self-consciously scientific and increasingly abstract way of thinking about hazards based on extrapolations from laboratory research and animal experiments.<sup>108</sup>

This was made all the more challenging by the rapidly growing number of chemicals in the workplace and the recognition that low-level exposures, long latency periods, and chronic poisonings posed a formidable set of challenges. For the first time, industrial hygienists began directing sustained attention to carcinogens in the workplace and the incidence of occupational cancer. Building on the pioneering work of Hamilton and others, Wilhelm Hueper published his monumental study, *Occupational Tumors and Allied Diseases* in 1942,<sup>109</sup> providing the first major survey of the international literature on occupational causes of cancer and a hard-hitting assessment of the proliferation of hazards associated with new synthetic chemicals in the workplace. Hueper’s encyclopedic study offered a strong endorsement of “precaution” (his word) in the face of a rapidly growing set of chemical hazards that was wreaking havoc on the lives of countless workers across the industrialized world.<sup>110</sup> In

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106. See Part II.A.4 *infra*.

107. See Christopher Sellers, *Factory as Environment: Industrial Hygiene, Professional Collaboration and the Modern Sciences of Pollution*, 18 ENVTL HIST. REV. 55, 67–68 (1994) (discussing increasing professionalization and reliance on laboratory-based techniques in industrial hygiene during first quarter of the twentieth century).

108. See SELLERS, *supra* note 61, at 179–84 (discussing shift from Alice Hamilton’s more informal, field-based approach to laboratory and experimental methods).

109. WILHELM C. HUEPER, *OCCUPATIONAL TUMORS AND ALLIED DISEASES* (1942).

110. See *id.* at 9 (“Occupational cancers represent . . . a challenge to the industry as well as to public health agencies, as they are the only malignant neoplasms the development and occurrence of

Hueper's view, "the new artificial environment" created by the proliferation of industrial chemicals posed a distinct set of challenges for efforts to protect the health of workers and the general public.<sup>111</sup> Echoing sentiments expressed by earlier public health researchers but reflecting a more expansive sense of the possible role of law in preventing, rather than merely compensating for industrial injury, Hueper concluded his study with a call for strong government action to protect all citizens, rich and poor, against the new threats to human health posed by industrialization:

The care, preservation, and improvement of the health of the people as a whole represents one of the noblest and most important tasks of every genuine and honest government. . . . The fundamental requirements for a healthful living, not merely for a small, select, and socially privileged group, but for the entirety of its citizens, must be safeguarded by suitable laws adequately enforced.<sup>112</sup>

Translating this into practice, of course, was easier said than done.

In their efforts to develop a more rigorous, science-based approach to workplace hazards, the new generation of industrial hygiene researchers that came of age during the mid-twentieth century worked to formalize the concept of a safe or threshold concentration level for particular substances in the workplace as the key tool for protecting workers and maintaining a safe working environment.<sup>113</sup> This deceptively simple and quite powerful conceptual innovation illustrated how abstract, general concepts could transform complex, uncertain situations, often saturated with significant political and ethical concerns, into technical matters.<sup>114</sup> As Christopher Sellers

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which can be largely or completely eliminated, if proper precautionary measures are taken to prevent any undue contacts of the workers with the offending agents, or if the cancerogenic factors are excluded from industrial operations."); *id.* at 845 ("It is unfortunate that most laws dealing with occupational disease including cancer emphasize the compensation feature for disability sustained, and neglect the preventive aspect of these disorders."). Hueper later became the founding director of the environmental cancer section of the National Cancer Institute and had a major influence on efforts to regulate carcinogens in the food supply. *See* discussion *infra* Part II.A.4.

111. *See id.* at 3–5 (discussing new artificial environment created by industrial chemicals and multiple potential routes of human exposure).

112. *Id.* at 848. That Hueper was able to articulate a much more expansive view of government involvement in health and safety regulation compared to the approach advanced by Alice Hamilton and others in the 1920s, which identified company physicians as the primary agents responsible for ensuring worker health and safety, indicated how much the world had changed since the New Deal and the rise of the administrative state. *See* HAMILTON, *supra* note 61, at 541–42 (urging industrial physicians to carry out their "duty" to safeguard the health of workers).

113. *See* SELLERS, *supra* note 61, at 174–75 (discussing development of safe or threshold concentration in industrial hygiene); Sellers, *supra* note 107, at 57 (characterizing industrial hygiene as "the first public health field in which the biomedical concepts of chemical physiology and toxicology came to be regularly translated into more precise, quantitative ways of dealing with environmental chemical hazards").

114. *See* Dietrich Henschler, *Exposure Limits: History, Philosophy, Future Developments*, 28 ARCH. OCCUP. HYG. 79 (1984) (tracing historical development of occupational exposure limits); Jeffrey M. Paull, *The Origin and Basis of Threshold Limit Values*, 5 AM. J. INDUS. MED. 227 (1984) (same);

put it, “the safe concentration level purported to fasten on the point at which worker and workplace fell out of physiological balance—the highest atmospheric concentration at which a chemical remained harmless or the lowest at which it turned harmful.”<sup>115</sup>

To be sure, many compromises and value choices were embedded in this seemingly objective exercise, and the very idea of a sharp distinction between safety and harm represented a dramatic simplification of the real working environment.<sup>116</sup> Writing in 1955, Herbert Stokinger, Chief Toxicologist for the U.S. Public Health Service, cautioned that these concentration limits “should not be regarded as fine lines between safe and dangerous concentrations, that is, a point above which injury is bound to occur and below which complete safety may be expected for all exposed persons.”<sup>117</sup> “Competent judgment,” in Stokinger’s view, was required to interpret and apply these standards in particular situations.<sup>118</sup>

But these techniques and the quantitative standards that resulted tended to take on a life of their own as they migrated from research to regulation. When the first lists of concentration limits were compiled in the 1940s, everyone seemed to recognize their provisional nature and few would have suggested that they could substitute for experience and medical monitoring. In 1942, the American Council of Governmental Industrial Hygienists (ACGIH), a group established four years earlier, compiled a list of existing state government exposure limits for various chemicals, noting that the compilation was “not to be construed as recommended safe concentrations.”<sup>119</sup> Three years later, industrial hygienist Warren Cook published a list of 136 exposure limits based on his own analysis and a review of existing limits.<sup>120</sup> As the first effort to codify the available data on concentration limits, Cook’s list would prove to be enormously influential.<sup>121</sup> But Cook took pains to point out that his effort was intended “to provide a handy yardstick to be used as guidance for the routine control of these health hazards—not that compliance with the figures listed

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SELLERS, *supra* note 61, at 175–76 (discussing development of concept of safe concentration levels in the United States and the ways in which the exercise marginalized moral and political concerns).

115. *Id.* at 175.

116. See Henschler, *supra* note 114, at 83–89 (discussing “compromises” and simplifications involved in establishing exposure limits, including inattention to variations in individual susceptibilities, lack of knowledge and basic data, lack of long-term studies and reliance on animal testing, focus on time-weighted average exposures rather than peak concentrations, single chemical approach with no attention to “mixed exposures,” and the special challenge of carcinogens).

117. Herbert Stokinger, *Standards for Safeguarding the Health of the Industrial Worker*, 70 PUB. HEALTH RPTS. 1, 6 (1955).

118. *Id.*

119. Quoted in Grace E. Zeim & Bary I. Castleman, *Threshold Limit Values: Historical Perspectives and Current Practice*, 31 J. OCCUP. MED. 910, 911 (1989).

120. Warren A. Cook, *Maximum Allowable Concentrations of Industrial Atmospheric Contaminants*, 14 J. INDUS. MED. 936 (1945).

121. *Id.* See also Paull, *supra* note 114, at 230. See also Zeim & Castleman, *supra* note 119, at 911.

would guarantee protection against ill health.”<sup>122</sup> Adherence to such limits, in his view, was no substitute for continued monitoring and adjustment as needed to protect workers’ health.<sup>123</sup>

Within a few years, however, Cook’s warnings had been all but forgotten. The ACGIH used Cook’s list as the basis for its own standards, referred to initially as “maximum allowable concentrations” (MACs) and then as “threshold limit values” (TLVs), endowing them in the process with a certain authority that went well beyond their scientific basis.<sup>124</sup> By defining TLVs as “maximum average concentrations of contaminants to which workers may be exposed for an 8-hour working day (day after day) without injury to health,” the ACGIH indicated that these were health hazard thresholds and that keeping exposures below the limits would provide protection against possible harm.<sup>125</sup> In fact, most of the TLVs published by the ACGIH were the same values published by Warren Cook in 1945, and there is no evidence that the group performed any systematic review of these limits before repackaging them as threshold limits capable of protecting workers’ health.<sup>126</sup> Nevertheless, soon after their release, TLVs were widely adopted by state and local governments across the country eager to remove themselves from such a thorny area.<sup>127</sup> What started as a “handy yardstick” intended to provide guidance to industrial hygiene researchers had morphed into a set of uniform limits that purported to draw a bright line between safe and unsafe.

In offering such precision, even if unwarranted by the facts, TLVs catered to a general enthusiasm for scientific management in the modern factory and to the desire of regulators and others for techniques that would allow them to make legible and thereby govern the increasingly complex and contested world of chemical hazards in the industrial workplace.<sup>128</sup> At the heart of this effort was a process of normalization, a triumph of population thinking that redefined

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122. See Cook, *supra* note 120.

123. *Id.*

124. See CORN, *supra* note 61. MACs were renamed as TLVs in 1948. See Zeim & Castleman, *supra* note 119, at 911.

125. See Zeim & Castleman, *supra* note 119, at 911; Paull, *supra* note 114, at 233.

126. See Zeim & Castleman, *supra* note 119, at 911 (“Both the term used and its definition now promoted the TLVs as health-hazard thresholds for exposure to chemical and mineral substances, many of which were known to have serious, irreversible effects. . . . Despite the accompanying . . . assertion that TLVs were based on the best available information, there is no evidence that any review was done or new rationale offered to justify this sweeping disregard for the uncertainties underlying the TLVs.”).

127. *Id.* (noting that state and local agencies reduced their personnel in this area and stopped issuing their own MACs in the early 1950s). Prior to this time, there had been significant variation in the limits adopted by state and local governments.

128. See Sellers, *supra* note 107, at 74 (discussing role of industrial hygiene in laying the foundation for a modern “toxicological approach” to industrial chemicals thereby “constitut[ing] another step along the pathway blazed by scientific management: towards displacement of worker control of the shop floor by that of trained middle-class professionals”). As Sellers also discusses, the expertise developed in the area of industrial hygiene would translate directly into early investigations of air pollution in the years to come. *Id.* at 74–75. See also THEODORE M. PORTER, TRUST IN NUMBERS: THE PURSUIT OF OBJECTIVITY IN SCIENCE AND PUBLIC LIFE (1995).



worker safety in terms of time-weighted average exposures to and responses by the average worker based largely on laboratory research and animal toxicity tests.<sup>129</sup> “Man” (and it was almost always adult white men who provided the basis for these averaging exercises) became an abstract “standardized machine” in the conceptual models and extrapolative exercises used to develop TLVs.<sup>130</sup> The inherent variability among individuals, the problems involved in extrapolating from animals to humans, the difficulties of sorting out interactions between multiple chemical exposures, the possibilities of longer-term sub-clinical effects such as subtle neurological harms—all of these were marginalized, even erased, by the deep simplifications embedded in the concept of threshold limits values.

Viewed as a technology, TLVs proved to be an immensely important innovation in occupational health and safety and, increasingly, in the larger world of environmental science and regulation. In purporting to delineate the boundary between safe and unsafe, these standards exercised considerable epistemic authority regarding the complex world of industrial chemicals, implying that the hazards associated with industrial chemicals could be known and controlled, that safety was attainable.<sup>131</sup> But in practice TLVs were like any standard; they could always be challenged, even manipulated. And there is little question that some of the resulting standards reflected the professional and political-economic biases of those responsible for developing them.<sup>132</sup> Moreover, as standards based on a dynamic set of knowledge practices regarding the impacts of industrial chemicals on workers’ health, TLVs were inherently unstable. As new and improved analytical techniques allowed occupational health researchers to move further beyond experience in determining whether low-level exposures led to increasingly subtle responses, the logic behind TLV’s pushed relentlessly towards downward revision. In the process, safety became increasingly relative—a fluid concept dependent upon a rapidly changing set of underlying knowledge practices and an increasingly abstract conception of the normal, average man.

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129. See SELLERS, *supra* note 61.

130. A.I.G. McLaughlin, Medical Inspector of Factories for the United Kingdom, voiced significant concern about the use of these techniques to protect worker health and safety. See A.I.G. McLaughlin, *The Prevention of the Dust Diseases*, 262 LANCET 49, 52 (1953) (“Individuals, too, vary greatly in their capacity to deal with dusts, and of two men who have been working at the same job for the same length of time one may get a disease of the lungs and the other may be unaffected. This is one reason why I am not greatly impressed by the validity of what are known as the maximum allowable concentrations of dusts (M.A.C.), of which lists have been drawn up in various countries. The MACs seem to be based on the assumption that man is a standardized machine, which clearly he is not.”); see also Ziem & Castleman, *supra* note 119, at 912 (quoting McLaughlin and other British authorities on the problems with the TLV concept).

131. See generally SELLERS, *supra* note 61 (discussing general issues with establishing health thresholds).

132. See Ziem & Castleman, *supra* note 119, at 912–14 (noting that very few physicians were involved in the work of the TLV committee and that representatives of various industrial firms and trade associations exercised considerable influence on the work of the committee and its leadership).

### 3. *Tolerances and Safety Factors*

If the effort to understand and regulate occupational exposures proved more challenging than radiation, it paled in comparison to the difficulties of dealing with chemicals in food. Diet was a major pathway of potential low-level exposures to various chemicals for the general population. The universe of chemicals in food, including additives, dyes, pesticide residues, and other environmental contaminants was also far larger than the number of chemicals relevant to occupational exposures and it was growing rapidly. Significant variability in diet and sensitivities across the population made it very difficult to identify, much less quantify, possible harm from the range of actual exposures. During the 1920s and 1930s, moreover, the ongoing problems with pesticide residues on foods combined with increased use of chemical preservatives and other additives underscored the severely limited ability of federal regulators to maintain even a semblance of adequate protection.<sup>133</sup>

In light of these limitations, efforts to update the 1906 Pure Food and Drug Act had been underway for years. But for various reasons the legislation had stalled until 1937, when more than 100 people died after ingesting *Elixir Sulfanilamide*, a commercial compound developed using the highly toxic solvent diethylene glycol—because of its agreeable smell and taste—without any testing of the solvent’s toxicity.<sup>134</sup> This dramatic case of mass poisoning made it impossible to stop enactment of the Federal Food Drug and Cosmetics Act of 1938 (FFDCA), one of the last significant pieces of New Deal legislation.<sup>135</sup> The FFDCA strengthened the 1906 Act in several respects: requiring new drugs to be tested for safety by the manufacturer before they could be sold to the public; prohibiting all unnecessary or avoidable “poisonous” or “deleterious” substances added to foods; and charging the newly created Food and Drug Administration (FDA) with determining “safe tolerances” for those substances that were required as part of the production process or could not be avoided in good manufacturing practice.<sup>136</sup> Like other New Deal statutes, the FFDCA delegated significant authority to the newly created FDA to investigate potentially hazardous substances and establish safety regulations, creating the basis for one of the first modern regulatory systems built around the concept of safety.

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133. See W.B. White, *Poisonous Spray Residues on Vegetables*, 25 *INDUS. & ENG'G CHEMISTRY* 621, 621–23 (1933) (discussing “reckless use of insecticides” on vegetable crops and limits of federal authority to protect public health from spray residues); Walter S. Frisbie, *Federal Control of Spray Residues on Fruits and Vegetables*, 26 *AM. J. PUB. HEALTH* 369, 369–73 (1936) (discussing challenges confronting federal regulation of spray residue problem).

134. See PHILIP J. HILTS, *PROTECTING AMERICA’S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* 89–93 (2003).

135. Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 (1938)).

136. *Id.* § 402(a)(1).

As such, the FFDCFA reflected a growing sense that government played a necessary role in protecting people against the gathering, largely unseen forces of industrialism.<sup>137</sup> Yet, by the time it was enacted, the 1938 FFDCFA was badly outmatched by the flood of new food chemicals and pesticides coming to market—a problem that only worsened with the end of World War II when a whole new suite of synthetic organic pesticides, some of them developed as part of the war effort, became commercially available, overwhelming the ability of government to do even the most basic testing, much less regulate in an orderly fashion. Although DDT was the most famous of these, and garnered the most attention, it was only the beginning of a “new era in pesticides” that raised a host of challenging questions about the adequacy of current laws and the ability of the government to ensure safety.<sup>138</sup> By 1947, the U.S. Department of Agriculture (USDA) estimated that some 25,000 pesticides had been registered or licensed for use under the original Insecticide Act of 1910 and the numbers were growing rapidly.<sup>139</sup>

Congress responded with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 in an effort to create a more robust licensing framework for the growing number of “economic poisons” being deployed in U.S. agriculture.<sup>140</sup> But unlike the FFDCFA passed almost a decade earlier, FIFRA provided no authority for the government to ban individual chemicals on the basis of possible harm. Rather, the new statute focused exclusively on labeling to ensure proper handling and use.<sup>141</sup> Even if the Secretary of Agriculture had serious concerns about the safety of a particular pesticide, he was compelled to issue the registration “under protest” and then pursue withdrawal in a judicial forum.<sup>142</sup> This left the FFDCFA system of tolerances, which placed the burden of establishing such tolerances on the government, as

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137. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (“The purposes of this legislation [FFDCFA] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.”).

138. *See, e.g., C.W. Crawford, Pesticides and the Food Law*, 4 FOOD DRUG COSM. L.Q. 132, 134 (1949) (“The new era in pesticides, ushered in by the advent of DDT, has brought with it a host of public-health problems. Accurate knowledge of the seriousness and extent of those problems is not keeping pace with the development and use of the newer pesticides. . . . [I]t is apparent that too many of the newer products have been rushed into production and use before sufficient investigation of their potential hazards and before users are sufficiently educated to avoid procedures that unnecessarily contaminate foods, and thus jeopardize public safety.”); *see also* THOMAS R. DUNLAP, *DDT: SCIENTISTS, CITIZENS, AND PUBLIC POLICY* (1981) (discussing history of DDT and efforts to regulate the pesticide).

139. *See* JOHN WARGO, *OUR CHILDREN’S TOXIC LEGACY: HOW SCIENCE & LAW FAIL TO PROTECT US FROM PESTICIDES* 70 (1996).

140. *See* Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (codified as amended 7 U.S.C. § 136 (1947)).

141. *Id.* § 136(a).

142. The 1964 amendments to FIFRA eliminated this system of “protest registrations” and allowed the Secretary to refuse to register the compound or to cancel or suspend an existing registration. Pub. L. No. 88-305, 78 Stat. 190 (1964).

the only potential source of federal authority that could protect the food supply from dangerous pesticide residues and other chemicals.<sup>143</sup>

The main problem with this overall approach was that the tools and techniques for evaluating many of these chemicals were just being developed and could not keep up with the increased number of synthetic organic pesticides.<sup>144</sup> More importantly, understanding and assessing latent effects from chronic, low-level exposure to these new chemicals posed a qualitatively different set of challenges for regulators than acute poisonings. The challenge was similar in many respects to that of understanding health impacts from low-level exposures to radiation and chemicals in the workplace. In its 1949 annual report, the FDA summarized the dilemma facing efforts to protect public health:

Many new and very potent insecticides were developed during the war and came into general use before their safety, over a long period of continued use, was established. . . . The real danger in inadequately tested insecticides lies in chronic poisoning resulting from the long-time consumption of minute amounts of the substances. Studies of chronic poisoning require nearly 3 years, and many compounds have been put into commercial use before such tests could be completed. Under the law, the Food and Drug Administration cannot take action against a suspected chronic poison until its toxicity has been proven.<sup>145</sup>

Indeed, under the law, before the FDA could even convene the requisite hearings on a chemical to establish a tolerance, the Agency had to compile the necessary scientific evidence to propose a tolerance. The process proved woefully inadequate. As Paul Dunbar, Commissioner of Food and Drugs during the late 1940s, put the matter: “We knew too little about many of these insecticides to hold hearings and establish safe tolerances.”<sup>146</sup>

The situation raised serious concerns. “To commercialize a poison before its potentialities are known is to use the public as guinea pigs,” wrote C.W.

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143. Food, Drug, and Cosmetics Act, 21 U.S.C. § 402(a)(1).

144. See, e.g., FOOD AND DRUG ADMIN., FED. SEC. AGENCY ANN. REP. 572 (1949) (“The synthetic organic insecticides, of which DDT was the forerunner, have increased in number and complexity. The need for more refined methods of detecting their residues in foods, and of evaluating the toxicity of such residues, continues unabated.”).

145. See FOOD AND DRUG ADMIN., FED. SEC. AGENCY ANN. REP. 514 (1950).

146. See Paul B. Dunbar, *The Food and Drug Administration Looks at Insecticides*, 4 FOOD DRUG COSM. L.J. 233, 235 (1949). Dunbar elaborated:

During the war, a large number of new and very potent insecticides had been developed. Little was known about their toxicity to the person who applied the sprays or to the consumer who ate the finished food product. In several cases we didn't even have methods for accurate estimation of the residual spray left on or absorbed by the food product. We didn't know whether the residues remained intact, whether they were altered by weathering to nontoxic or more toxic residues, whether they could be removed by washing, or whether they were absorbed into the plant structures and, therefore, could not be removed.

*Id.*

Crawford, Assistant Commissioner for Food and Drugs.<sup>147</sup> “It is true,” he continued, “that a proper investigation of toxicity is expensive and time-consuming, but it is equally true that this is a far more sound and prudent investment than to rush into production and use without the insurance against disaster that such investigations give.”<sup>148</sup> A 1948 editorial in the *Journal of the American Medical Association* made a similar point, lamenting that “so little [was] known about either the acute or chronic pathologic effects on man of these new pesticides” and noting that “[e]ven though added controls may impede the development of pesticides, these are essential precautions which must be taken to avoid the danger of mass poisoning.”<sup>149</sup>

In response to these concerns, the House of Representatives convened a Select Committee to Investigate the Use of Chemicals in Food Products in 1950.<sup>150</sup> Chaired by Congressman James Delaney of New York, the Delaney Committee, as it was known, conducted a series of hearings over the next several years on the “nature, extent, and effect of the use of chemicals, compounds, and synthetics in the production processing, preparation and packaging of food products.”<sup>151</sup> Much of the attention at the initial hearings focused on the current state of tolerances for pesticide residues.<sup>152</sup>

Given the inadequacies of the current approach, many of the witnesses recommended that no chemical be permitted entry into the nation’s food supply unless its safety had been documented—standard practice for new drugs under the 1938 FFDCA.<sup>153</sup> By placing the burden of establishing pesticide tolerances squarely on the government and by failing to provide any ability to control or regulate the use of pesticides in advance of an issued tolerance, the FFDCA failed to protect the public from pesticide residues while it conducted the

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147. Crawford, *supra* note 138, at 135.

148. *Id.*

149. Editorial, *Pesticides: Chemical Contaminants in Foods*, 137 J. AM. MED. ASS’N 1604, 1605 (1948).

150. *See Investigation of the Use of Chemicals in Food Products*, H.R. Res. 323, 81st Cong. (1950).

151. *Id.* In 1951, the Committee was given the additional mandate of investigating the use of chemicals in the production of cosmetics, and the Committee’s name was changed to the Select Committee to Investigate the Use of Chemicals in Food and Cosmetics. The Committee held extensive hearings between 1950 and 1952, receiving testimony from over 200 witnesses, including government officials, prominent scientists, industry representatives, medical and health organizations, and consumer groups. *See Investigation of the Use of Chemicals in Foods and Cosmetics*, H.R. REP. NO. 82-2356, at 1–3 (1952), *reprinted in* 12 LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, & COSMETIC ACT AND ITS AMENDMENTS 499, 499–501 (1979) [hereinafter *Delaney Committee Report*] (recounting history of the Select Committee).

152. *See Delaney Committee Report*, *supra* note 151.

153. *Id.* at 523 (“The strong recommendation of most of the witnesses before the committee was that no chemical should be permitted entry into the nation’s food supply until its safety for use has been demonstrated beyond a reasonable doubt.”); *see also id.* at 525 (recommending amendment to FFDCA “to require that chemicals employed in or on our foods be subjected to substantially the same safety requirements as now exist for new drugs and meat products”).

necessary proceedings to establish tolerances.<sup>154</sup> By the early 1950s, more than fifteen years after passage of the FFDCA, the FDA had issued tolerance regulations limiting pesticide residues in only a single instance.<sup>155</sup>

In response to these shortcomings and the publicity created by the Delaney Committee's hearings, Congress amended the FFDCA in 1954,<sup>156</sup> establishing that any raw agricultural commodity with a pesticide residue would be considered adulterated under the Act unless the residue was within a tolerance that had been issued by the Secretary of Health, Education, and Welfare.<sup>157</sup> Henceforth, all residues had to have a tolerance and the burden was shifted to the manufacturer to "establish the safety of such pesticide-chemical residue" in tolerance proceedings.<sup>158</sup> Finally, the amendments expressly provided that the Secretary could establish a "zero tolerance" if the scientific data did not justify a higher level.<sup>159</sup>

Notwithstanding these welcomed burden-shifting provisions, the new amendments reinforced the significant knowledge gap confronting government regulators. The FDA still faced the enormous task of evaluating individual safety cases and establishing tolerances for thousands of compounds. And even if the government could find the capacity to manage such a process, the underlying challenge of interpreting animal tests and extrapolating to humans had no obvious resolution.

To address these challenges, Dr. Arnold Lehman and others at the FDA developed the concept of safety factors in the early 1950s as way of compensating for some of the uncertainties in the translation of animal test data into regulatory standards. In a 1954 article, Lehman and his colleague O.G. Fitzhugh advanced the notion that chemicals in food should be subjected to a "100-fold margin of safety" in extrapolating from animal tests.<sup>160</sup> The rationale for choosing such a safety factor was based on the assumption that human

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154. *Id.* at 520 ("But the setting of tolerances does not give the Food and Drug Administration any advance control over the use of pesticides. Unless the manufacturer conducts adequate chronic toxicity tests for a new pesticide, the Government is powerless until it completes its own toxicity tests and conducts a formal public hearing for the purpose of issuing tolerance regulations. Both procedures consume more time than is consistent with efficient protection of the public health.").

155. See REPORT TO ACCOMPANY H.R. 7125 AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO RESIDUES OR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES, H.R. REP. NO. 82-1385, at 2 (1954), *reprinted in* 12 LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS 833, 834 (1979) [hereinafter 1954 Pesticide Amendment Committee Report].

156. An Act to Amend the Federal Food, Drug and Cosmetic Act with Respect to Residues of Pesticide Chemicals in or on Raw Agricultural Commodities, Pub. L. No. 518-559, 68 Stat. 511 (1954).

157. *Id.* (codified as § 408(a)(a)) (providing that pesticide chemical will be deemed unsafe unless within a tolerance prescribed by the Secretary of Health, Education, and Welfare). This authority was transferred to EPA in 1970.

158. See 1954 Pesticide Amendment Committee Report, *supra* note 155, at 837.

159. *Id.* at 512.

160. See A.J. Lehman & O.G. Fitzhugh, *100-Fold Margin of Safety*, 18 ASS'N FOOD & DRUG OFFICIALS U.S. Q. BULL. 33 (1954) (advancing notion of 100-fold margin of safety as a way to establish "safe" levels of exposure for humans based on animal toxicity tests).

beings were “about 10 times as sensitive to poisons as the rat” and that a “sick individual may be as much as 10 times more susceptible to toxic substances than an individual in good health.”<sup>161</sup> In other words, Lehman and Fitzhugh concluded, largely on the basis of their own judgment and experience, that a potentially 10-fold greater sensitivity in humans when compared to test animals combined with a potentially 10-fold difference in susceptibility among members of the human population yielded a safety factor of 100. Accordingly, the “safe” level for any particular food chemical in humans was determined by dividing the lowest “no effect level” observed in animal tests by the safety factor of 100.<sup>162</sup> This pragmatic approach to the problem of uncertainty was obviously more intuitive than scientific:

The “100-fold margin of safety” is a good target but not an absolute yardstick as a measure of safety. There are no scientific or mathematical means by which we can arrive at an absolute value. . . . Since man can seldom be used as an experimental subject, reliance for the evaluation of the toxicity of a substance must ordinarily be placed upon studies in laboratory animals. Even then it cannot be said for certain that lack of toxicity in animals will necessarily forecast what may occur in man. However, the selection of the 100-fold margin of safety serves as a reasonable safeguard to minimize the danger.<sup>163</sup>

The 100-fold safety factor was subsequently codified in FDA regulations and found widespread use throughout the world.<sup>164</sup> As a tool for managing uncertainty, it allowed animal testing to be translated into “safe” concentrations of chemicals in food without having to develop complex mathematical extrapolation models,<sup>165</sup> reflecting a frank recognition of the limits of knowledge and a prudent approach to the task of operationalizing safety.

#### 4. *The Special Problem of Carcinogens*

Although the Delaney Committee was charged with investigating the use of all chemicals in food, the problem of carcinogens occupied a special place in its mandate.<sup>166</sup> This reflected both the growing public face of cancer in the United States<sup>167</sup> and the recognition that carcinogens posed particular

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161. *Id.* at 34.

162. *Id.*; see also Hutt, *supra* note 67, at 20 (discussing history of 100-fold safety factor); Michael L. Dourson & Jerry F. Stara, *Regulatory History and Experimental Support of Uncertainty (Safety Factors)*, 3 REG. TOXICOLOGY & PHARMACOLOGY 224, 225 (1983) (same).

163. Lehman & Fitzhugh, *supra* note 160, at 35.

164. See Dourson & Sara, *supra* note 162.

165. See Daniel Krewski et al., *Determining ‘Safe’ Levels of Exposure: Safety Factors or Mathematical Models*, 4 FUNDAMENTAL & APPLIED TOXICOLOGY 383 (1994) (discussing differences between safety factor approach and mathematical models in extrapolating from animal tests to humans).

166. See *Delaney Committee Report*, *supra* note 151, at 5 (discussing attention of Delaney Committee to possible carcinogens in food additives and pesticides and noting “the definite lack of knowledge on the subject”).

167. See MUKHERJEE, *supra* note 65; PATTERSON, *supra* note 65.

challenges for regulation. The basic question was whether a threshold dose could be established (standard practice in the case of non-carcinogens) or whether cancer-inducing compounds should be treated differently. If it turned out that certain chemicals acted as mutagens, like radiation, then the conclusion was obvious: there was no absolutely safe, threshold dose.

Given the very limited understanding of the mechanisms of carcinogenesis, the lack of any systematic effort to determine the number, much less the potency, of carcinogens in the food supply and the broader environment, and only a vague appreciation for the fact that many environmentally induced cancers emerged after long latency periods, it was not at all clear that the question whether a "safe" level of exposure existed could ever be answered. One possible way forward was to refine and elaborate the use of animal tests as proxies for human experience. But this approach also involved a series of challenging analytical and normative questions. Decisions had to be made about the appropriate types of animals, relevant levels of exposure, and techniques for extrapolating from animal models to human beings. Embedded within this exercise were important technical and logistical questions regarding study design as well as questions about the availability of resources needed to test thousands of chemicals in a manner that would generate the information needed to evaluate whether long-term exposures to low-levels of chemicals in the environment would cause cancer.<sup>168</sup> And, of course, the big question looming in the background was whether evidence that a particular chemical caused cancer in test animals meant that it was a potential human carcinogen.

For a number of leading cancer researchers, the prudent course was to assume that evidence of carcinogenicity in animals provided a sufficient basis for treating such chemicals as potential carcinogens for humans. In an early 1950 article on chemical carcinogens, the Director of the National Cancer Institute, J.R. Heller articulated the basic idea:

Considering that a danger of the chemical carcinogens lies in the slow, almost unnoticeable harm that comes from contact with them, it might be wise from a preventive point of view to consider all chemical agents which have elicited cancer in animals as having the potential properties for producing cancer in the human organism.<sup>169</sup>

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168. The 1970 Ad Hoc Committee Report to the Surgeon General on the Evaluation of Low Levels of Environmental Carcinogens estimated that 20,000 compounds would need to be tested by bioassay as part of a comprehensive screening program. Such an endeavor would cost \$1 billion and greatly exceeded the laboratory and professional resources then available. See AD HOC COMM. EVALUATION OF LOW LEVELS OF ENVTL CHEM. CARCINOGENS, EVALUATION OF ENVIRONMENTAL CARCINOGENS: REPORT TO THE SURGEON GENERAL (1970), reprinted in *Chemicals and the Future of Man, Hearings Before the Subcomm. on Executive Reorganization and Government Research of the S. Comm. on Government Operations*, 92d Cong. 187 (1971) [hereinafter EVALUATION OF ENVIRONMENTAL CARCINOGENS].

169. J.R. Heller, *Chemical Carcinogens*, 2 ARCH. IND. HYGIENE 390, 393 (1950); see also *id.* at 399 ("In view of the lack of knowledge of where the danger lies, or the extent of it, no one is in position



This view was later endorsed by the International Union Against Cancer (IUAC), the leading international forum for cancer research and policy. At its Sixth International Cancer Congress in Sao Paulo, Brazil in 1954, the IUAC adopted a resolution addressing the animal-to-human extrapolation challenge:

In the case of agents whose carcinogenicity for man is not known but which elicit cancer in experiments conducted upon animals—although it is recognized that the development of cancer in response to such materials may be conditioned by the type of exposure, notably the species of animals or the route of administration—it is not prudent to regard such agents as harmless for man.<sup>170</sup>

At the same time, the IUAC also adopted a resolution rejecting the notion that there could be a safe or threshold dose for carcinogens: the “concept of ‘safe threshold doses’ are [sic] dubious where complete control of a hazard [sic] involving exposure to carcinogenic agents is desired.”<sup>171</sup> The leading international forum on cancer thus drew a sharp distinction between substances with threshold effects and those inducing irreversible effects, such as carcinogens, for which no safe threshold level of exposure could be defined, and it endorsed the view that animal tests could serve as indicators of carcinogenicity in humans.

Two years later, the participants at the 1956 IUAC meeting extended this line of thinking, recommending unanimously that “as a basis for active cancer prevention, the proper authorities of various countries promulgate and enact adequate rules and regulations prohibiting the addition to food of any substances having potential carcinogenicity.”<sup>172</sup> As understood by the IUAC, a potential carcinogen referred to “any substance which has been convincingly demonstrated to be carcinogenic to animals, and though not yet shown to act as such in man, could be suspected of possibly having a similar effect in man.”<sup>173</sup>

Early cancer researchers thus urged extensive laboratory testing with animals *before* new chemicals would be permitted for use in the food supply. If such studies revealed evidence of carcinogenicity, the chemicals should not be allowed in the food supply. Although far from perfect, such an approach appeared to offer the only viable way forward given the obvious problems of trying to draw any sort of definitive conclusions based on direct experience. Animal testing, in other words, provided the only realistic means for confronting the basic problem of ignorance that confronted cancer researchers and regulators.

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to say today just what remedial action is needed. But in view of what we do know, we have to consider precautionary action now to protect the workers involved and the general public.”).

170. See *Resolutions Adopted by the Symposium on Cancer Prevention, 6th International Cancer Congress* (1954), reprinted in 11 ACTA 1, 72 (1955).

171. *Id.* at 73.

172. See Int'l Union Against Cancer, *Report of Symposium on Potential Cancer Hazards from Chemical Additives and Contaminants to Foodstuffs*, 13 ACTA 170, 193 (1957).

173. *Id.* at 187.

But even this approach was fraught with uncertainty and made all the more challenging by the fact that existing screening and testing programs were weak to non-existent. Hueper, serving at the time as chairman of the Cancer Prevention Committee of the IUAC, emphasized “[t]he present state of highly defective knowledge in such matters as well as the almost universal lack of a comprehensive and competent program of investigation and supervision of health and cancer hazards from food additives and contaminants . . . .”<sup>174</sup> In his testimony at the 1957 Food Additives hearings, Hueper elaborated:

I do not believe that one can establish a safe dose of carcinogens. I do not think that we have the method or evidence available by which we can reliably determine a safe dose. In fact, we have no safe dose for any environmental carcinogen including radioactive substances. You probably know or you remember that the so-called maximum permissible dose of radioactive exposure has been lowered in recent years several times. So we are still in the twilight area in which we do not know exactly when and where a safe dose for an environmental carcinogen may be placed. I believe from the total evidence we have on environmental carcinogenic agents . . . that we would be wise as a precautionary measure to exclude as far as that is practicable any addition of carcinogens to our food supply.<sup>175</sup>

Others prominent scientists agreed.<sup>176</sup> The implication for policy was straightforward: given the significant uncertainty, even ignorance, confronting efforts to understand whether certain chemicals caused cancer, evidence of carcinogenicity in animals provided a useful proxy for human experience.

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174. W.C. Hueper, *The Potential Role of Non-Nutritive Food Additives and Contaminants as Environmental Carcinogens*, 13 ACTA 220, 243 (1957). Hueper further noted that a “disturbing aspect of [rapid introduction of new chemicals in the food supply] is that there exists no mandatory provision for assuring, *a priori*, that biologic properties of each of these additives and contaminants, particularly later long term or delayed effects, have adequately been studied.” *Id.* at 220.

175. *Food Additives, Hearing before a Subcomm. of the H. Comm. on Interstate and Foreign Commerce on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food*, 85th Cong. 372 (1957) (statement of Dr. W.C. Hueper), reprinted in 14 LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS 163, 534 (1979) [hereinafter *Food Additives Hearings*]; see also *id.* (concluding that “it would be a wise precautionary measure not to add any chemicals to our food supply which produce cancer either in man or in experimental animals”).

176. See, e.g., *Food Additives Hearings*, *supra* note 175, at 337 (statement of Dr. Blackwell Smith) (“I do not think that the exclusion of carcinogens would in itself cause any serious inconvenience. The basic problem, it seems to me, is that we cannot know what the long-term effect of any new chemical on human beings will be until those human beings have lived out their life span and we have had a chance to observe them throughout their lives. That means a whole generation of observation.”); *id.* at 538 (statement of Dr. Herbert E. Carter) (“One of the most important difficulties is the lack of an adequate basis for evaluating the dose-response relationship. Establishment of such a relationship is necessary in order to decide whether there is really a harmless dose level of a carcinogen. I would not go so far as Dr. Hueper and say unconditionally that there is no such thing as a harmless level for a carcinogen; without present knowledge it simply is not possible to answer this question one way or another.”).

Moreover, given that there was no “safe” dose for carcinogens, a principle of “zero tolerance” appeared to be the only way to ensure safety.<sup>177</sup>

In 1958, Congressman Delaney added his famous anti-cancer clause to a package of food additives amendments to the FFDCA, giving this strong precautionary approach to carcinogens the force of law by effectively banning food additives that had been shown to induce cancer in animals or humans.<sup>178</sup>

Under the new provision, 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.<sup>179</sup>

The Delaney Clause, as it came to be known, traced its origins directly to the work of early cancer researchers such as Hueper and the IUAC,<sup>180</sup> firmly embedding the non-threshold view of carcinogenesis in U.S. law as part of an affirmative embrace of precaution in the face of uncertainty.

Almost immediately, the Delaney Clause came under attack, initially on grounds that it did not allow scientists to exercise judgment and, later, on grounds that it was unrealistic in the face of a burgeoning universe of potential carcinogens.<sup>181</sup> But the clause also had many staunch defenders, including prominent scientists, and it would prove to have remarkable staying power

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177. Some of the witnesses at the 1957 hearings on Delaney’s proposal put the matter in ethical terms. *See, e.g., Food Additives Hearings, supra* note 175, at 337 (testimony of Dr. Blackwell Smith) (“There is . . . no moral justification for obliging consumers, many of whom are children, with life expectancies serving the long latent period of carcinogens, to accept such needless risks. Most of us are dependent upon processed foods for life. We do not have the opportunity to exercise choice, as we do have in the case of exposure to carcinogens in smoking.”).

178. Food Additives Amendment, Pub. L. No. 85-929, 72 Stat. 1784, 1786 (1958) (codified at 21 U.S.C. § 348(c)(3)(A)).

179. *Id.*

180. Congressman Delaney made this point directly in his remarks during the floor debate on the proposed amendments. *See* 1958 Cong. Rec. 17,420 (1958) (statement of James J. Delaney), *reprinted in* 14 LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS 866, 874 (1979) (“This particular provision followed the recommendation of the International Union Against Cancer at its cancer symposium held in Rome in 1956. At that time, the members of the conference, consisting of over 40 cancer experts from some 21 countries, unanimously recommended that as a basis for active cancer prevention, the proper authorities of various countries promulgate and enact adequate rules and regulations prohibiting the addition to food of substances found to be cancer inducing.”).

181. *See* discussion *infra* note 229. The famous “cranberry scare” of 1959 provided fodder for early critics of the Delaney Clause. In November 1959, some two weeks before Thanksgiving, the Department of Health, Education, and Welfare announced that traces of the herbicide aminotriazole (3-AT) had been detected on cranberries from Oregon and Washington. Because there was evidence that aminotriazole was carcinogenic, the Department, acting on the same principle that motivated the Delaney Clause, ordered the impoundment of more than 3 million pounds cranberries for testing, causing significant losses for the cranberry industry and fueling public fears about carcinogens in food despite the fact that there was very little evidence of any health hazard at the levels detected. *See* Andrews, *supra* note 36, at 213–14 (discussing cranberry scare and its relationship to recently enacted Delaney Clause).

despite all of the criticism.<sup>182</sup> In 1960, Arthur Flemming, the Secretary of Health, Education, and Welfare, offered a strong early defense of the Delaney Clause, rejecting the notion that it somehow undermined the exercise of scientific judgment:

The rallying point against the anticancer provision is the catch phrase that it takes away the scientist's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough on this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive.<sup>183</sup>

It is important to recognize, therefore, that the Delaney Clause reflected, and was seen to reflect, the state of scientific knowledge at the time. It *was* a science-based approach to carcinogens.

Without question, there were problems with its application and contradictory results depending on how a specific chemical ended up in or on food.<sup>184</sup> When viewed from the contemporary perspective of hard-path risk assessment, moreover, the efforts of Hueper, Delaney, and others to prevent the release of cancer causing chemicals (whether in the workplace, the food supply, or the broader environment) seem naïve and unworkable—a misguided attempt to establish a blanket prohibition on cancer-causing chemicals that failed to take account of the benefits that might come from such substances.<sup>185</sup> Taken on its own terms and placed in proper historical context, however, the Delaney Clause and the approach to scientific knowledge that it stood for represented a perfectly defensible approach to the regulation of carcinogens. It was a different kind of thinking that reflected a different view of the world—one marked by recognition of irreducible uncertainties and a sense of humility regarding the limits of human understanding in the face of an unknown universe of potentially carcinogenic chemicals.

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182. Although FDA and EPA found various ways to work around some of the more difficult implications of Delaney, the clause itself was not “fixed” until the 1996 Food Quality Protection Act. These developments are beyond the scope of this Article.

183. *Color Additive Hearings Before the H. Comm. on Interstate and Foreign Commerce*, 86th Cong. 499–501 (1960) (statement of Arthur S. Flemming, Secretary of Department of Health, Education, and Welfare).

184. See Richard A. Merrill, *Food Safety Regulation: Reforming the Delaney Clause*, 18 ANN. REV. PUB. HEALTH 313 (1997) (discussing problems with application of Delaney Clause); NAT'L RES. COUNCIL, *REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX* (1987) (discussing uneven application of the Delaney Clause with respect to pesticide residues in raw and processed foods).

185. See, e.g., Blank, *supra* note 10 (criticizing the Delaney Clause as scientifically and technically naïve).

### B. Searching for Safety

In the years following passage of the Delaney Clause, the connections between industrial chemicals, environmental contamination, and chronic disease, most notably cancer, became a major national issue. Rachel Carson published *Silent Spring* in 1962, drawing extensively on the work of Hueper and others and raising serious questions about the adequacy of existing laws.<sup>186</sup>

“The most alarming of all man’s assaults upon the environment,” she wrote, is the contamination of air, earth, rivers, and sea with dangerous and even lethal materials. This pollution is for the most part irrecoverable; the chain of evil it initiates not only in the world that must support life but in living tissues is for the most part irreversible. In this now universal contamination of the environment, chemicals are the sinister and little-recognized partners of radiation in changing the very nature of the world—the very nature of its life.<sup>187</sup>

During this time, a new focus on “environmental health” emerged as part of a larger embrace of ecology and a recognition that technology, broadly understood, posed a very real threat to human and natural communities.<sup>188</sup> Thus, in its inaugural 1962 report to the Surgeon General, the U.S. Public Health Service’s newly formed Committee on Environmental Health Problems urged that the mission of public health needed to be “enlarged to include provision for the positive protection of the healthy against the adverse influences of a more complex technological society which operates in evermore crowded communities.”<sup>189</sup> Echoing these sentiments, Secretary of the Interior Stewart Udall warned in his 1963 classic, *The Quiet Crisis*, of “the growing imbalance between the works of man and the works of nature.”<sup>190</sup> In the new

186. See CARSON, *supra* note 66.

187. *Id.* at 6.

188. See, e.g., Eugene P. Odum, *The New Ecology*, 14 BIOSCIENCE 14, 15 (1964) (advocating for a “new ecology” based on a more holistic, systems-based approach with applications for understanding and solving problems of resource depletion and environmental degradation); Eugene P. Odum, *The Strategy of Ecosystem Development*, 164 SCIENCE 262, 266–67 (1969) [hereinafter Odum, *The Strategy of Ecosystem Development*] (“Until recently mankind has more or less taken for granted the . . . protective functions of self-maintaining ecosystems, chiefly because neither his numbers nor his environmental manipulations have been great enough to affect regional and global balances. Now, of course, it is painfully evident that such balances are being affected, often detrimentally.”).

189. PUB. HEALTH SERV., U.S. DEP’T OF HEALTH, EDUC., AND WELFARE, REPORT OF THE COMMITTEE ON ENVIRONMENTAL HEALTH PROBLEMS TO THE SURGEON GENERAL 7 (1962); see also ROSEN, *supra* note 57, at 463 (“With our expanding and changing industrial technology have come environmental problems of increasing complexity. The once dominant problems of bacterially contaminated air, water, and food have now been replaced in considerable degree by chemical pollution, and the possible relation of this condition to the induction of cancer.”).

190. STEWART L. UDALL, *THE QUIET CRISIS* 201 (1963). See also *id.*, at 189 (“Our accomplishments in minerals and energy, in electronics and aircraft, in autos and agriculture have lifted us to new heights of affluence, but in the process we have lost ground in the attempt to provide a habitat that will, each day, renew the meaning of the human enterprise. A lopsided performance has allowed us to exercise dominion over the atom and to invade outer space, but we have sadly neglected the inner space that is our home. We can produce a wide range of goods and machines, but our manipulations

“era of ecology,” where the connections between human health and the environment were ever more apparent, safety and survival depended on restoring that balance:

As history moves on, our time will be known as the age in which man learned to admit that he is part of the balance of nature—the age in which man began to assess the negative as well as the positive sides of his actions—the age in which man joined his perspective on technology with a perspective on his environment.<sup>191</sup>

Along with Carson and others, Udall urged his fellow citizens to embrace a more humble approach to technology and progress, one founded on a renewed ethic of responsibility and oriented toward the long view.

Three years after Carson published *Silent Spring*, President Johnson’s Science Advisory Committee issued its landmark report, *Restoring the Quality of Our Environment*, detailing the nation’s growing pollution problems, calling for an expanded government response to deal with existing problems, and advocating for the exercise of “ecological foresight” as a means to prevent new problems in the future.<sup>192</sup> Consistent with the general attitude of the emerging environmental movement, the report stressed the importance of precaution in the face of uncertainty:

We now know that the full effects of environmental changes produced by pollution cannot be foreseen before judgments must be made. The responsible judgment, therefore, must be the conservative one. Trends and indications, as soundly based as possible, must provide the guidelines; demonstration of disaster is not required. Abnormal changes in animal populations, however small, at whatever stage in the life history of the individual, or in whatever niche of the species complex, must be considered warnings of potential hazard.<sup>193</sup>

In elaborating principles to guide governmental responses at multiple levels, the report also embraced the predominant rights-based framing of environmental quality that animated much of the early environmental movement, stressing the rights of individuals to “improved quality of life from reduced pollution” and pointing to the “responsibility of each polluter for all forms of damage caused by his pollution.”<sup>194</sup>

Yet, throughout the report, there were unmistakable signs of a gathering bureaucratic approach to environmental regulation that clearly reflected the growing influence within the Johnson administration of planning and

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have multiplied waste products that befoul the land, and have introduced frightening new forms of erosion that diminish the quality of indispensable resources and even imperil human health.”).

191. Stewart L. Udall, *A Message for Biologists*, 14 BIOSCIENCE 17, 17 (1964)

192. See U.S. PRESIDENTIAL SCI. ADVISORY COMM. ENV’T POLLUTION PANEL, *RESTORING THE QUALITY OF OUR ENVIRONMENT* 14 (1965).

193. *Id.*

194. *Id.* at 16.

management based on systems analysis and operations research.<sup>195</sup> Embedded within this approach was a strong preference for technocratic judgment and decision making that would insulate the crucial responsibility for establishing environmental protection standards from Congress and the political process.<sup>196</sup> These deeper currents of bureaucratization and managerialism would provide fertile ground for the rise of quantitative risk assessment in the years ahead.

But if there was a central insight that emerged during this period, it was that human health and the environment were deeply connected and faced considerable dangers from the galloping advance of technology.<sup>197</sup> Chemical hazards in particular came to be seen as a problem of the “total environment.”<sup>198</sup> The potential harms associated with carcinogens were no longer restricted to the industrial workplace or food, but also part of a growing concern with air and water pollution.<sup>199</sup> Efforts to operationalize safety in the

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195. See, e.g., *id.* at 17 (recommending administrative and budgetary separation between agency responsibility for research on pollution issues and enforcement); *id.* at 23–25 (outlining a multi-agency approach to coordination and systems studies in the area of pollution); *id.* at 33–38 (outlining an approach to meeting manpower needs across the government); *id.* at 48–56 (discussing organizational strategy and framework for understanding and controlling environmental pollution). For a general discussion of the rise of systems analysis and operations research and its influence on government during this time, see *supra* note 8 and references therein. For a more specific discussion of the importance of “systems thinking” in ecology and operations research in the context of federal water pollution control, see PAUL CHARLES MILAZZO, UNLIKELY ENVIRONMENTALISTS: CONGRESS AND CLEAN WATER, 1945–1972 at 99–111 (2006).

196. See *Restoring the Quality of Our Environment*, *supra* note 192, at 60–61 (“The setting of standards is highly technical; there must be provision for appropriate revision of standards from time to time as new scientific knowledge and improved methods of measurement become available. These necessary judgments are best exercised by highly knowledgeable scientists and engineers. Difficulties and inequities would be avoided if Federal responsibility for setting these standards resided in the Department of Health, Education, and Welfare. It would be desirable if the legislative branch of the government refrained from setting standards or tolerance limits directly by law.”). This last sentence was almost certainly a reference to the Delaney Clause.

197. See, e.g., BARRY COMMONER, SCIENCE AND SURVIVAL (1966) (discussing various human health and ecological threats associated with modern technology).

198. The phrase “total environment” gained increasing currency during the 1960s as part of the new ecological approach to health and environment that focused specifically on the effects of chemicals and ionizing radiation. See, e.g., René Dubos, *Environmental Biology*, 14 BIOSCIENCE 11, 11 (1964) (arguing for an approach to pollution and human health that situated man within his “total environment”); Leroy E. Burney, *Governmental Responsibilities in Environmental Health*, 76 PUB. HEALTH REPORTS 291, 291–94 (1961) (discussing need to understand challenges of chemical contamination and ionizing radiation in the context of the “total environment of modern man”). Burney was the Surgeon General of the U.S. Public Health Service from 1956–61. See also NAT’L RESEARCH COUNCIL, THE EFFECTS ON POPULATIONS OF EXPOSURE TO LOW LEVELS OF IONIZING RADIATION 34 (1972) (“In general, man’s welfare depends upon the long-range quality of his total environment. Substances removed or added in large enough amounts can lead to imbalance or disorder of a life support system that is the result of evolutionary development over the ages.”). The journal SCIENCE OF THE TOTAL ENVIRONMENT, which was (and is) dedicated to documenting the effects of human activities on the environment, was established in 1972.

199. See ROSEN, *supra* note 57, at 465 (noting that “the atmosphere of the modern industrial community is a carcinogenic sea, polluted and made murky by many sorts of individual waste. In such an environment it is hardly possible to avoid daily contact with cancer-producing agents.”); W.C. Hueper, *Environmental Carcinogenesis and Cancers*, 21 CANCER RESEARCH 842, 842 (1961)

face of such hazards, moreover, could no longer rely on direct experience. Proxies and new extrapolative techniques had to be developed. In the process, human health would be subjected to various abstractions and averaging exercises. Policy choices would have to be made about how to interpret what little data existed, whether to build in safety factors and other protections, and how far to push efforts to quantify potential harms.

Without question, the larger statutory frameworks for regulating the new harms posed by radiation and chemicals were sorely lacking, even non-existent, and throughout this period (and beyond) the law seemed to be in a constant chase to catch up with a rapidly proliferating set of hazards.<sup>200</sup> In several instances, notably radiation, there was also a growing recognition that safety was an increasingly fluid, relative term—an interpretation that would take on added salience in the years ahead as regulators came to embrace the notion of “acceptable risk.” But there was also a strong precautionary impulse at work during this period, manifest in the push to keep radiation exposures “as low as practicable,” the burden shifting provisions of the 1954 pesticide amendments, the use of safety factors to compensate for uncertainty, and, most prominently, the 1958 Delaney Clause. All of these developments shared the same basic concern of protecting human health in the face of significant uncertainty, a general sensibility and approach to regulation that would carry over into the early 1970s and to the effort to establish a coherent normative framework for environmental law during its formative years.

### III. REGULATION AND THE FRONTIERS OF SCIENTIFIC KNOWLEDGE, 1960S-1970S

By the end of the 1960s, the concept of safety thresholds that had occupied so much attention during the middle decades of the twentieth century was under considerable strain. Revolutionary advances in analytical techniques during the 1960s and 1970s opened up a vast new world of invisible hazards impinging on everyday life, challenging the binary approach to safety that underwrote previous efforts. As this new world came into view, Congress, regulators, judges, and other professionals confronted an important, even fateful, choice:

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(discussing “the long neglected fact that many of the known environmental carcinogens initially encountered in certain occupational activities are subsequently being introduced into the general human environment as pollutants of the air, water, and soil and as constituents and impurities of many consumer goods, and are creating through this mechanism a serious public health problem”); Sellers, *Factory as Environment*, *supra* note 107, at 74–75 (discussing key role of industrial hygienists in extending the toxicological approach beyond the workplace to studies of air pollution).

200. Beginning in the early 1960s, policymakers and commentators also began to call for more systematic attention to “environment” as an organizing principle for law and public decision making. See, e.g., Lynton K. Caldwell, *Environment: A New Focus for Public Policy?*, 23 PUB. ADMIN. REV. 132, 138–39 (1963) (tracing a number of environmental problems to the fragmentation of public decision making and the inability to see environmental problems in comprehensive terms and calling for a more systematic focus on environment as a key organizing principle for public policy). Caldwell was deeply involved in drafting the National Environmental Policy Act.



whether and how to extend and elaborate the earlier precautionary impulse or to push forward with more formal, quantitative approaches to assessing risk.

Looking back, it is easy to identify the major trend during this period as the embrace across multiple domains of more formal risk-based approaches as the foundation for rational decision making. But up until the mid-1970s, much of the form and substance of the overall approach to environmental harms was up for grabs. It was by no means obvious, in other words, that the appropriate response to a larger and more complicated world of environmental harm was to embrace more formal, quantitative approaches to risk. This was a true moment of possibility, as evidenced in some of the early pesticide cancellation proceedings, in OSHA's efforts to develop a generic cancer policy, in landmark environmental laws such as the Clean Air and Clean Water Acts, and in appellate court decisions such as *Reserve Mining* and *Ethyl Corp.*<sup>201</sup> With the proliferation of new laws and agencies charged with regulating potential environmental harms, Congress, regulators, and the courts sought to develop a general, flexible framework that would allow agency professionals to exercise their expert judgment and regulate in a manner that would protect public health. Early environmental statutes used the language of "endangerment" and "margin of safety" far more often than the language of "risk," drawing on different conceptual and normative tendencies.<sup>202</sup> There was a view, at least initially, that the practice of assessing hazards was tractable and that much of its development could be left to the agencies.

By the middle of the 1970s, however, this all began to change as the notion of safety was explicitly redefined as "acceptable risk," giving rise to an unambiguous move toward quantitative risk assessment as the basis for health, safety, and environmental regulation. During this time, the courts also began to take a harder look at agency practice. And there was a marked retreat from earlier precautionary stances toward a more muscular embrace of formal risk assessment and an explicit effort to discipline agency decision making, epitomized by the Toxic Substances Control Act's "unreasonable risk" standard and its elaborate procedural requirements, the Supreme Court's 1980 *Benzene* decision, and the push for regulatory reform in the 1980s.<sup>203</sup>

This Part discusses these developments, focusing on the revolutionary advances in analytical techniques that occurred during the 1960s and early 1970s and their implications for health, safety, and environmental regulation; efforts to extend the precautionary impulse of earlier years to new challenges involving chemicals, air and water pollution, and carcinogens in the workplace; and parallel efforts to redefine safety as acceptable risk and move toward more

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201. See *infra* Part III.B.

202. See, e.g., Clean Air Act, 42 U.S.C. §§ 7401–7671q (2006); Clean Water Act, 33 U.S.C. §§ 1251–1387 (2006).

203. See discussion *infra* Parts III.C and IV.

formal, quantitative approaches to risk in the face of the new world of environmental harms that was coming into view.

### A. *New Ways of Seeing*

In 1958, when the Delaney Clause was adopted, there were only four substances that were known to induce cancer in humans: soot, radiation, tobacco smoke, and *beta*-naphthylamine.<sup>204</sup> Twenty years later, scientists had identified thirty-seven human carcinogens and over 500 animal carcinogens.<sup>205</sup> With significantly expanded animal testing, it was becoming clear that a growing number of substances induced cancer at some site in at least some strain or sex of laboratory animal.<sup>206</sup> At the same time, new techniques highlighted the significant range in cancer potencies among different chemicals.<sup>207</sup> Not all carcinogens were created equal, in other words; some were strong, others were relatively weak.<sup>208</sup> This mattered, of course, for any effort to weigh the relative hazards or risks associated with a particular chemical, and it raised questions about the blanket application of the principle of zero tolerance.

Major advances in analytical techniques and detection capabilities during this time also revealed chemical residues and other substances in food, air, water, and living tissues at far lower concentrations than was possible in previous decades. Thus, FDA reported that between 1958 and 1978 the sensitivity of detection methods for monitoring chemicals in food increased by “between two and five orders of magnitude,”<sup>209</sup> an improvement that allowed the detection of carcinogens at the parts per trillion level.<sup>210</sup> As one scientist writing in the late 1970s stated, “[T]oday substances can be routinely measured at concentrations up to a million times less than was possible in 1958.”<sup>211</sup>

Similar advances were underway in the effort to detect chemicals in the environment. During the early 1970s, environmental scientists and the newly created Environmental Protection Agency (EPA) began to use gas chromatograph mass spectrometry (GC-Mass Spec) and other techniques that could detect trace organic compounds and other hazardous substances in the

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204. See Richard Wilson, *Risks Caused by Low Levels of Pollution*, 51 YALE J. BIO. 37, 48 (1978).

205. *Id.*

206. *Id.* See also Listing of D&C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,331, 28,343 (Aug. 7, 1986) (recounting developments in animal testing).

207. See Section 409 Food Additive Regulations; Order Responding to Objections to EPA’s Response to Petition Requesting Revocation of Food Additive Regulations, 56 Fed. Reg. 7750, 7772–73 (Feb. 25, 1991) (“Unlike the Congressional understanding in 1958, scientists now recognize that the degree of human risk posed by substances found to be carcinogens can vary immensely.”).

208. *Id.* (noting that the Carcinogenic Potency Database showed a range of cancer potencies that was greater than ten million-fold).

209. See Chemical Compounds in Food Producing Animals, 44 Fed. Reg. 17,070, 17,075 (Mar. 20, 1979) (discussing advances in detection capabilities).

210. *Id.*

211. Wilson, *supra* note 204, at 48.

low parts per billion range, several orders of magnitude below what had been possible only a decade earlier.<sup>212</sup> When combined with expanded environmental monitoring, it soon became apparent that the world of potential environmental harms was far greater than previously recognized. To take only one example, the use of computerized GC-Mass Spec techniques to analyze water samples during the late 1960s and early 1970s “revolutionized” efforts to test for trace organics in surface waters, revealing a much more extensive problem of water pollution than previously recognized.<sup>213</sup> The new techniques, according to EPA scientists, made “identification of pollutants in the part-per-billion range with a high degree of confidence . . . routine. . . . What was once an impossible task for a staff of 100 working six months . . . [could] be accomplished by a skilled individual in a few hours.”<sup>214</sup> By the early 1970s, various studies using these techniques had revealed hundreds of compounds, some of them suspected carcinogens, in surface waters and drinking water systems around the country.<sup>215</sup> This led directly to enactment of the Safe

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212. See EVALUATION OF ENVIRONMENTAL CARCINOGENS, *supra* note 168, at 184–85 (discussing role of gas-liquid chromatographic techniques in facilitating significant improvements in detection capabilities since the late 1950s); EPA, MEASUREMENT OF CARCINOGENIC VAPORS IN AMBIENT ATMOSPHERES, EPA-600/7-78-062, 1 (1978) (discussing development of analytical techniques to collect and analyze air samples to detect presence of toxic and/or carcinogenic organic compounds); *Air Quality Criteria: Hearing Before the Subcomm. on Air and Water Pollution of the S. Comm. On Public Works*, 90th Cong. (1970), reprinted in 1 CLEAN AIR ACT AMENDMENTS OF 1970 608, 615–16 (1970) (statement of Dr. Samuel S. Epstein) (discussing development of new “high sensitive biological techniques for measuring the carcinogenicity of organic extracts of atmospheric pollutants”); L.A. Wallace, *Human Exposure to Environmental Pollutants: A Decade of Experience*, 25 CLINICAL & EXPERIMENTAL ALLERGY 4, 4 (1995) (discussing “exquisite sensitivities” of gas chromatography-mass spectrometry and their use by the EPA during the early 1970s); William L. Budde & James W. Eichelberger, *Organics in the Environment*, 51 ANALYTICAL CHEMISTRY 567A, 567A (1979) (discussing new “measurements of the presence and concentration of a variety of pollutants . . . made possible by significant advances in analytical instrumentation, electronics, computer science, and analytical chemistry during the 1960s and early 1970s”).

213. See W.M. SHACKELFORD & L.H. KEITH, FREQUENCY OF ORGANIC COMPOUNDS IDENTIFIED IN WATER, EPA-600/4-76-062 at 1 (1976) (“Rapid technical advances in gas chromatography-mass spectrometry after 1970 enabled many more compounds in water to be identified.”); Stephen R. Heller et al., *Trace Organics by GC/MS* 9 ENV'TL SCI & TECH. 210, 210 (1975) (noting that computerized GC-Mass Spec capabilities developed in 1960s “quickly revolutionized the field of trace organics analysis” leading to major commitment by EPA in 1971 to install computerized GC-Mass Spec systems at laboratories across the country).

214. See Heller et. al., *supra* note 213, at 211.

215. See, e.g., EPA, INDUSTRIAL POLLUTION OF THE LOWER MISSISSIPPI RIVER IN LOUISIANA 66–67 (1972) (discussing presence of large numbers of synthetic organic chemicals present in Lower Mississippi River, including several suspected carcinogens found in New Orleans drinking water systems); EPA, PRELIMINARY ASSESSMENT OF SUSPECTED CARCINOGENS IN DRINKING WATER: INTERIM REPORT TO CONGRESS at i (1975) (discussing 1974 EPA study finding “small quantities of 66 organic chemicals, some of which were suspected carcinogens” in the New Orleans drinking water supply).

Drinking Water Act in 1974<sup>216</sup> and a much more expansive effort to deal with toxic water pollutants under the Clean Water Act.<sup>217</sup>

This period also witnessed significant improvements in the ability to track the fate and transport of chlorinated organic compounds and other synthetic chemicals in the global environment, building directly on earlier fallout studies that tracked the distribution of strontium-90 and other radionuclides.<sup>218</sup> Thus, during the 1960s, scientists began detecting DDT, PCBs, and other persistent, bioaccumulative compounds throughout the world—from marine mammals in the Arctic to the breast milk of tribal women in remote areas of Papua New Guinea—illustrating the ever-widening reach of industrial chemicals and serving as a major source of motivation for the early environmental movement.<sup>219</sup> Food chains, the underlying architecture of ecological systems, the process of bio-magnification: these “patterns of nature” became visible in new ways and provided powerful evidence of the deep connections between human health and the environment.<sup>220</sup>

Finally, new extrapolative techniques were also developed and refined during this period, allowing scientists to extend dose-response relationships from the observable to the unobservable range in a quantitative manner. Starting in the early 1960s, various techniques, such as the Mantel-Bryan or log-probit model, were debated in the scientific literature.<sup>221</sup> By the early 1970s, regulatory scientists had begun to experiment with these new techniques in assessing chemical hazards.<sup>222</sup> In providing a formal, mathematical basis for

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216. Pub. L. No. 93-523, 88 Stat. 1661 (1974) (codified as amended at 42 U.S.C. §§ 300f to 300j-26 (2000)).

217. In 1976, EPA entered into a consent decree under which it would spend the rest of the decade (and beyond) developing water quality criteria and effluent standards for 65 toxic chemicals and families of chemicals. See *NRDC v. Train* (Flannery Decree), Civ. A. No. 2153-73 (D.D.C. June 9, 1976), reprinted in 6 ELR 20,588; see also Oliver A. Houck, *The Regulation of Toxic Pollutants Under the Clean Water Act*, 21 ELR 10528 (1991).

218. See George M. Woodwell, *Toxic Substances and Ecological Cycles*, 216 SCI. AM. 24 (Mar. 1967) (discussing contributions of fallout studies to understanding “global, long-term ecological processes that concentrate toxic substances” in the environment).

219. See generally H.L. Harrison et al., *Systems Studies of DDT Transport*, 170 SCIENCE 503 (1970) (discussing use of systems models for understanding long-term impacts of DDT in ecosystems); David B. Peakall & Jeffrey L. Lincer, *Polychlorinated Biphenyls: Another Long-Life Widespread Chemical in the Environment*, 20 BIOSCIENCE 958 (1970) (documenting presence of PCBs in various environmental media and animal tissues).

220. See, e.g., Odum, *The Strategy of Ecosystem Development*, *supra* note 188, at 264 (discussing the role of radionuclide tracers in “providing a means of charting food chains in the intact outdoor ecosystem”); Woodwell, *supra* note 218 (discussing role of fallout studies in understanding bioaccumulation of toxic substances).

221. See, e.g., N. Mantel & W.R. Bryan, *Safety Testing of Carcinogenic Agents*, 27 J. NAT. CANCER INST. 455 (1961) (proposing log-probit model for low dose extrapolation).

222. See David G. Hoel, *Statistical Models for Estimating Carcinogenic Risks from Animal Data*, *Proceedings of the 5th Annual Conference on Environmental Toxicology*, AMRL-TR-74-125 285-91 (1974) (discussing statistical techniques for low-dose extrapolations to estimate cancer risk in humans associated with exposure to various environmental agents and their applications in regulatory context); NAT'L RESEARCH COUNCIL, *DRINKING WATER AND HEALTH* 29–59 (1977) (discussing use and

extrapolating from high-dose animal experiments to the unobservable range of low-dose human exposures, these new ways of seeing opened up the possibility of developing quantitative estimates of risk associated with low-level exposures.

It would be difficult to overstate the significance of these revolutionary advances in environmental monitoring and analysis. The new ways of seeing that resulted brought a whole new world into view, creating considerable challenges for law and regulation. In fundamental ways, these new techniques underwrote the changing conceptions of time and space that Richard Lazarus posits as a driving force behind the rise of environmental law,<sup>223</sup> revealing a world of environmental hazards that far exceeded, in scale and scope, previous understandings.

The challenges confronting regulators were profound. As Peter Hutt, former Chief Counsel to the FDA, noted,

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.<sup>224</sup>

According to Hutt, FDA was “forced to admit” at the end of the decade that “[a] requirement for warnings on all food that may contain an inherent carcinogenic ingredient or a carcinogenic constituent (in contrast to a deliberately added carcinogenic substance) would apply to many, perhaps most, foods in a supermarket.”<sup>225</sup> EPA likewise struggled to prioritize its efforts across its multiple statutory responsibilities in the face of a much larger universe of potential environmental harms.<sup>226</sup> The big question looming in all of this was whether the older, precautionary posture exemplified by the Delaney Clause could be adapted to this new reality or whether some other approach would be needed.

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associated challenges of extrapolation techniques in chemical safety assessment); *see also infra* Part III.C.

223. *See Lazarus, supra* note 36, at 54–66 (discussing how “changing conceptions of time and space compelled a transformation in law generally and the emergence of a comprehensive regime for environmental protection in particular”).

224. Hutt, *supra* note 67, at 24–25.

225. *Id.* at 15.

226. *See, e.g.,* NAT’L RESEARCH COUNCIL, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY (1977) (discussing multiple decision making challenges confronting EPA in its efforts to carry out its various statutory responsibilities); NATIONAL RESEARCH COUNCIL, 1 PERSPECTIVES ON TECHNICAL INFORMATION FOR ENVIRONMENTAL PROTECTION: A REPORT TO THE U.S. ENVIRONMENTAL PROTECTION AGENCY 12 (1977) (noting the increasingly difficult and complex challenges facing environmental regulation as refinements in research and monitoring revealed more subtle and unexpected impacts from a range of different agents and interactions).

B. *Environment, Margin of Safety, and the Frontiers of Scientific Knowledge*

Elaborating and adapting the precautionary approach embodied in the Delaney Clause in the face of a much more vast and complicated world of potential environmental harms would not be easy. Rigid application of “zero tolerance” within and outside of the food safety context was simply not possible without dramatic disruptions, and the Delaney Clause itself would be revised over time, first through agency practice and, then, in the 1996 Food Quality Protection Act, to reflect the increasingly complex world that was coming into view.<sup>227</sup> But to suggest that these new challenges called for or even required a move to more formal exercises in quantitative risk assessment is to miss a great deal. In fact, during much of the 1970s, there were multiple efforts across the burgeoning fields of health, safety, and environmental law to adapt earlier precautionary impulses to the new world of environmental harm that had become visible.

1. *Chemicals and the Future of Man*

By the late 1960s, in the midst of the remarkable advances in analytical techniques that revealed a vast and growing world of potential carcinogens in the environment, criticisms of the Delaney Clause shifted from the previous charge that it posed too many constraints on the exercise of scientific judgment<sup>228</sup> to a more general concern that the zero tolerance approach was simply not feasible in a world where carcinogens were far more prevalent.<sup>229</sup> The science that had supported the Delaney Clause was outdated, the argument went; the anti-cancer clause had become an “article of faith” badly out of synch with the realities of a complex industrial society.<sup>230</sup> Had Congress understood the true extent of the cancer hazard, it surely would never have imposed zero tolerance.<sup>231</sup>

And yet, many of the same scientists who had supported the Delaney Clause from its inception mounted a vigorous defense of the zero tolerance principle. In their view, zero tolerance provided the most prudent approach to

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227. See Merrill, *supra* note 184.

228. See discussion *supra* notes 174–82.

229. EVALUATION OF ENVIRONMENTAL CARCINOGENS, *supra* note 168 (discussing agreements that zero tolerance was not feasible in the wake of significant advances in analytical techniques that allowed for detection of carcinogens at lower concentrations). See also B.L. Oser, *An Assessment of the Delaney Clause After 15 Years*, 11 FOOD & COSM. TOXICOLOGY 1121, 1125–26 (1973) (“One of the main difficulties with the Delaney clause, as with other statutory provisions for ‘no residue’ or ‘zero tolerance,’ has been the continuing improvement, without apparent limit, in the sensitivity of analytical instrumentation and techniques, as a result of which substances prohibited on a ‘no residue’ basis have later been detected in traces so small as to be beyond the range of any conceivable toxicological significance.”).

230. See, e.g., Nicholas Wade, *Delaney Anti-Cancer Clause: Scientists Debate an Article of Faith*, 177 SCIENCE 588 (1972) (discussing heated debates during 1970s regarding the Delaney Clause).

231. *Id.*

the considerable uncertainties that remained and, in many cases, had been amplified by the fact that the world of potential carcinogens had turned out to be more vast and complex than previously understood. That there were more carcinogens impinging on daily life than previously thought, in other words, provided all the more reason to hold onto zero tolerance. Two prominent National Cancer Institute scientists made this point emphatically in 1968. "It is fair to say," they wrote, "that trace amounts of carcinogens surround us and probably enter our bodies with our food, air or water. What zero tolerance in respect of food additives really means is that deliberate addition to the carcinogenic burden already upon us should be avoided where this is at all feasible."<sup>232</sup> Given the growing universe of potential carcinogens and the recognition that cancer often resulted from an accumulation of insults, any deliberate release of carcinogens to the environment should be avoided if at all possible.

The following year, a special commission formed by the Department of Health, Education, and Welfare, known as the Mrak Commission, released a comprehensive report on the pesticides problem that underscored the difficulties confronting efforts to regulate the hazards associated with industrial chemicals.<sup>233</sup> "[T]he field of pesticide toxicology," according to the Commission,

exemplifies the absurdity of a situation in which 200 million Americans are undergoing life-long exposure, yet our knowledge of what is happening to them is at best fragmentary and for the most part indirect and inferential. While there is little ground for forebodings of disaster, there is even less for complacency.<sup>234</sup>

The Commission's report went on to discuss the "formidable inherent difficulties in fully evaluating the risks to human health consequent upon the use of pesticides"<sup>235</sup> and stressed the qualitatively different type of human health hazard presented by pesticides and industrial chemicals.<sup>236</sup>

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232. J. H. Weisburger & E. K. Weisburger, *Food Additives and Chemical Carcinogens: On the Concept of Zero Tolerance*, 6 FOOD & COSM. TOXICOLOGY 235, 242 (1968).

233. U.S. DEP'T OF HEALTH, EDUC., AND WELFARE, REPORT OF THE SECRETARY'S COMMISSION ON PESTICIDES COMMISSION ON PESTICIDES AND THEIR RELATIONSHIP TO ENVIRONMENTAL HEALTH (1969) [hereinafter MRAC COMMISSION REPORT]; see also William H. Rodgers, *The Persistent Problem of the Persistent Pesticides: A Lesson in Environmental Law*, 70 COLUM. L. REV. 567 (1970) (providing detailed critical review and discussion of the Mrak Commission's recommendations).

234. See MRAC COMMISSION REPORT, *supra* note 233, at 37.

235. *Id.* at 231.

236. *Id.* at 243 ("While the risks to health that abound in the home, in the street and at work are accepted as inevitable and are limited as far as possible, the hazards to health that stem from environmental exposure to chemical agents are usually beyond the capacity of the individual to control. By their very nature—such as chronicity or subtlety of effects produced—the risks deriving from this source constitute an altogether different dimension from all others (except for radiation) in their threat to human safety. Pesticide exposure is but one sector of environmental chemical hazard, yet its problems typify the complexities of the chemical sophistication of our society.")

On the vexing issue of extrapolating from animals to humans and from high to low doses outside of the observable range, the report pointed to the complexity and irreducible uncertainties that attended such an effort.<sup>237</sup> “The basic problem is that extrapolation outside the range of observation must be based on a generally unverifiable assumption about the mathematical nature of the dose-response relationship near zero dosage.”<sup>238</sup> Given “the perplexities and imponderables” involved in such an exercise, “it would be imprudent to place excessive reliance on mathematical sleight of hand, particularly when the dose-response curves used are largely empirical descriptions lacking any theoretical physical or chemical basis.”<sup>239</sup> Based on its review of the scientific literature, the Commission called for the elimination within two years of all uses of DDT except those deemed essential to the preservation of human health and welfare, and similar restrictions on other persistent pesticides.<sup>240</sup> On the question of zero tolerance, the Commission recognized the challenges entailed in applying the principle in the face of greatly enhanced ability to detect chemicals in the environment, but it stopped well short of embracing any sort of risk-based approach, invoking instead the margin of safety concept and calling for strict limits of potentially toxic chemicals.<sup>241</sup>

On the heels of the Mrak Commission’s report, the National Cancer Institute’s Ad Hoc Committee on the Evaluation of Low Levels of Environmental Carcinogens issued its report to the Surgeon General, *Evaluation of Environmental Carcinogens*.<sup>242</sup> Chaired by veteran cancer researcher Umberto Saffiotti, the Ad Hoc Committee reviewed in detail the significant advances in animal bioassay research and chemical detection methods, acknowledging that these advances constituted a major argument against the Delaney Clause.<sup>243</sup> Yet, in spite of the increased difficulties posed by the fact that carcinogens were much more prevalent in the environment and

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237. *Id.* at 464 (“Many different factors may influence dose-response in carcinogenesis in man and animals. Their complexity is such that no assuredly safe level for carcinogens in human food can be determined from experimental findings at the present time.”); *id.* at 492–95 (discussing difficulties of extrapolating dose-response relationships from animal studies to no-effect levels in humans).

238. *Id.* at 493.

239. *Id.* at 495 (quoting SUBCOMM. ON CARCINOGENESIS, FDA COMM, REPORT ON PROTOCOLS FOR SAFETY EVALUATION (1969)) (“Although it is possible in principle to estimate ‘safe’ levels of a carcinogen, uncertainties involved in downward extrapolation from test levels will usually result in permissible levels that are the practical equivalent of zero.”).

240. *Id.* at 8–10.

241. *Id.* at 10 (“Modern techniques have greatly increased the sensitivity of the analytical methods available when the zero tolerance concept was advanced. This fact must be recognized in judging the possibilities of hazards and establishing tolerance limits with a sufficient margin of safety to protect human health and welfare.”). *See also id.* at 481 (noting that improved analytical techniques had increased “the sensitivity of chemical detection more than one thousand-fold in the past 15 years”).

242. *See* EVALUATION OF ENVIRONMENTAL CARCINOGENS, *supra* note 168.

243. *Id.* at 186. (“The major new argument presented today against the ‘anticancer clause’ is that the marked increase in sensitivity of many analytical methods makes it possible to detect low levels of carcinogens in a broader segment of the environment and that, therefore, the immediate enforcement of regulations requiring a zero tolerance become more difficult, in some instances impossible.”).



the food supply than previously recognized, the Ad Hoc Committee did not yield in its unqualified support of zero tolerance: “The principle of zero tolerance for carcinogenic exposures should be retained in all areas of legislation presently covered by it and should be extended to cover other exposures as well.”<sup>244</sup> According to the Committee, “[o]nly in the cases where contamination of an environmental source by a carcinogen has been proven to be unavoidable should exception be made to the principle of zero tolerance.”<sup>245</sup>

These issues of the applicability and scope of zero tolerance became a major focus during Congressional hearings convened in 1971 under the rather modest title, “Chemicals and the Future of Man.”<sup>246</sup> Several of the nation’s leading cancer researchers testified at the hearings, virtually all of whom supported the same basic conclusion regarding the challenges of assessing chemical hazards and the need for prudence and precaution in the face of such hazards.<sup>247</sup> There were, in short, intractable epistemological challenges facing efforts to get a handle on the chemicals problem—challenges that were particularly apparent in the case of ‘weak carcinogens’ such as pesticides, food additives and air pollutants, which proved “far more difficult to assess toxicologically or epidemiologically.”<sup>248</sup> The “gross insensitivity of animal test systems” together with the “impossibility of gauging human sensitivity from animal tests” and the lack of “ample data on interactions between carcinogens” made it impossible “to predict safe levels of carcinogens based on an arbitrary fraction of the lowest effective animal dose in a particular experimental situation.”<sup>249</sup> In other words, the entire process of evaluating the hazards associated with low-level exposures to chemicals was marked by a certain arbitrariness in choosing extrapolation models, in selecting safety factors, and in defining what might count as acceptable risk.<sup>250</sup> Given the irreducible

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244. *Id.* at 181.

245. *Id.*

246. *Chemicals and the Future of Man: Hearings before the Subcomm. on Executive Reorganization and Government Research of the Comm. on Government Operations*, 92d Cong. (1971) [hereinafter *Chemicals and the Future of Man*].

247. *See, e.g., id.* at 50–53 (statement of Dr. Samuel S. Epstein) (discussing challenges of assessing chemical hazards); *id.* at 177 (statement of Dr. Umberto Saffiotti) (same).

248. *Id.* at 10, 50–53; *see also id.* at 53 (testimony of Dr. Samuel S. Epstein) (“Current toxicological techniques are insensitive and relatively limited in their ability to detect weak carcinogens, and other toxic agents, individually and in various combinations or mixtures realistically reflecting low or ambient levels and patterns of environmental exposure. Similarly, epidemiological techniques are unlikely to detect weak carcinogens and other toxic agents, unless there are sharp differentials in exposure of the general population, as with cigarette smoking. For widely dispersed agents, such as intentional or accidental food additives, to which the population at large is generally exposed, human experience is unlikely to provide any meaningful indication of safety or hazard.”).

249. *Id.* at 51.

250. *Id.* at 177 (statement of Umberto Saffiotti) (“[T]he evaluation of cancer hazards for man is a complex scientific problem for which different inputs are necessary: chemical analytical data on the environmental distribution of a compound and the levels of exposure in man; biological data on its carcinogenic activity in animal tests; dose-response data in the selected animal models; arbitrary selections of mathematical models for extrapolation to low level effects; arbitrary selection of the so-

uncertainties involved in such an effort, the zero tolerance approach of the Delaney Clause offered the only prudent response.<sup>251</sup> As one witness put it: “Special pleadings, reflecting narrow economic and social interests, for the continued use of carcinogenic chemicals—*albeit* at reduced levels based on arbitrarily derived supposed safety margins—are unacceptable.”<sup>252</sup>

Leading regulatory officials agreed. In a 1970 address to the American Society of Toxicology, EPA Administrator William Ruckelshaus spoke of the “chemical barrage to which we are so recklessly exposing ourselves” with very little understanding of the potential impacts on human health and the environment.<sup>253</sup> “We need to know more—far more—about what we are doing to ourselves and our planet, and to the fetuses of our unborn children, and to the genetic heritage of those children by the pervasive use of the chemical wonders of our age.”<sup>254</sup> But action could not wait for complete understanding:

[W]e cannot suspend action until we know everything there is to know, for science is never complete. Our knowledge in these matters is . . . ‘a receding mirage in a vast desert of ignorance.’ Therefore, as we seek more and better data in the toxicological field, it is absolutely essential that we act on the knowledge we already have or face the possibility of irreversible environmental harm and even tragic damage to the lives and health of our own or future generations.<sup>255</sup>

In the face of ignorance and uncertainty, prudence required action to avoid such hazards and minimize the possibility of irreversible environmental harm.

This basic approach to the pressing challenge of chemical hazards animated efforts to deal with DDT and other synthetic organic pesticides. As discussed above, many of these compounds came to market right after World War II with little if any testing of their potential hazards. But in the wake of *Silent Spring* and in the face of mounting evidence of the persistent, bioaccumulative nature of these chemicals, many began to question the safety of DDT and other pesticides.<sup>256</sup> In 1969, the newly formed Environmental Defense Fund (EDF) petitioned the Secretary of Agriculture to issue notices of cancellation under the pre-1972 version of FIFRA for all DDT-based pesticides

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called ‘safety factors’ for the extrapolation from animals to man; and finally the selection of a ‘socially acceptable risk.’”).

251. *Id.* at 51 (statement of Dr. Samuel S. Epstein) (defending zero tolerance approach for carcinogens); *id.* at 171 (statement of Dr. Umberto Saffiotti) (“[P]roof that a substance, which had been recognized as carcinogenic in animals, actually causes cancer in man would require in most cases extremely complex and lengthy epidemiologic studies. In some cases it may be impossible to obtain such proof because of the complexity of controls that would be needed for a satisfactory demonstration. Therefore, the only prudent approach is to assume that chemicals which are carcinogenic in animals could also be such in man, although the direct demonstration in man is lacking.”).

252. *Id.* at 51 (statement of Dr. Samuel S. Epstein).

253. *Chemicals and the Future of Man*, *supra* note 246, at 66.

254. *Id.*

255. *Id.*

256. See, e.g., MRAK COMMISSION REPORT, *supra* note 233, at 8–9 (recommending elimination of all non-essential uses of DDT); *id.* at 382–98 (reviewing research on hazards associated with DDT).

and to suspend the existing registration during the pendency of the cancellation proceedings because of the “imminent hazard” posed by the compound.<sup>257</sup> USDA deferred its decision on cancellation and took no action on the emergency suspension request.<sup>258</sup> In 1971, the D.C. Circuit, with Judge Bazelon writing for the court, concluded that cancellation proceedings should proceed whenever a pesticide registration raised a “substantial question of safety” and remanded the case for a decision on suspension and a statement of reasons on the decision to defer cancellation.<sup>259</sup> The following year, in one of the first major exercises of regulatory authority by the recently created EPA, William Ruckelshaus issued his decision canceling most of the existing registrations for DDT.<sup>260</sup>

Based on three years of “intensive administrative inquiry into the uses of DDT,” Ruckelshaus concluded “that the long-range risks of continued use of DDT on cotton and most other crops is unacceptable and outweighs any benefits.”<sup>261</sup> The case against the pesticide rested primarily on evidence of DDT’s toxic, persistent, bioaccumulative properties as well as the fact that the benefits of DDT usage were “marginal, given the availability of alternative insecticides and pest management programs, and also the fact that the crops produced with DDT are in ample supply.”<sup>262</sup> “Persistence and biomagnification in the food chain,” Ruckelshaus wrote, “are, of themselves, a cause for concern, given the unknown and possibly forever undeterminable long-range effects of DDT in man and the environment.”<sup>263</sup>

On carcinogenicity, Ruckelshaus cited animal studies and expert opinion that DDT should be classified as a potential carcinogen.<sup>264</sup> He also noted that the long latency period of many cancers made it impossible to determine with certainty whether DDT was carcinogenic in humans. There were simply too many unknowns *not* to regulate:

The Agency and EDF have established that DDT is toxic to nontarget insects and animals, persistent, mobile, and transferable, and that it builds up in the food chain. . . . In short, they have established at the very least the risk of the unknown. That risk is compounded where, as is the case with DDT, man and animals tend to accumulate and store the chemical. These facts alone constitute risks that are unjustified where apparently safer alternatives exist to achieve the same benefit. . . . The evidence of record

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257. See *EDF v. Ruckelshaus*, 439 F.2d 584, 593 (D.C. Cir. 1971) (recounting procedural history of the DDT cancellation). In 1972, a new version of FIFRA was enacted, transforming a law focused almost exclusively on registration and labeling law into a regulatory statute.

258. *Id.*

259. *Id.* at 593.

260. See Consolidated DDT Hearings: Opinion and Order of the Administrator, 37 Fed. Reg. 13,369 (July 7, 1972).

261. *Id.* at 13,369.

262. *Id.* at 13,370.

263. *Id.* at 13,371.

264. *Id.*

showing storage in man and magnification in the food chain is a warning to the prudent that man may be exposing himself to a substance that may ultimately have a serious effect on his health. . . . The possibility that DDT is a carcinogen is at present remote and unquantifiable; but if it is not a siren to panic, it is a semaphore which suggests that an identifiable public benefit is required to justify continued use of DDT.<sup>265</sup>

No effort was made, and none was deemed feasible, to quantify the actual health risks of DDT.<sup>266</sup> It was enough that it had been linked to cancer in animals, persisted in the environment, accumulated in the food chain, and was present in human tissues.<sup>267</sup> Notwithstanding its mandate to balance risks and benefits, in exercising its statutory authority to prohibit major uses of DDT, EPA embraced an approach that was very much in line with the general motivations behind the Delaney Clause. The world had changed. New synthetic organic pesticides posed a qualitatively different set of hazards, raising the stakes for efforts to protect human health and the environment. “[G]iven the unknown and possibly forever undeterminable long-range effects of DDT in man and the environment,”<sup>268</sup> precaution was the appropriate response.<sup>269</sup>

EPA took the same approach with other pesticides during these early years. Aldrin and dieldrin, two particularly toxic compounds used against corn soil insects, were challenged at roughly the same time as DDT. Like DDT, these compounds were persistent and mobile in the environment, with a propensity to accumulate in plant and animal tissues, ending up in “the milk, meat, poultry, and soy products consumed by humans.”<sup>270</sup> A National Human Monitoring Survey conducted by EPA had detected dieldrin residues in 96.5, 99.5, and 98.2 percent of human fat samples tested during 1970, 1971, and 1972, respectively.<sup>271</sup> After EPA initiated cancellation proceedings in 1971 but refused to issue an emergency suspension,<sup>272</sup> the case came before the D.C. Circuit.<sup>273</sup> Writing for the court, Judge Leventhal quoted EPA on the evolving concept of safety:

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265. *Id.* at 13,373.

266. See EPA, REASONS UNDERLYING THE REGISTRATION DECISIONS CONCERNING PRODUCTS CONTAINING DDT, 2,4,5-T, ALDRIN, AND DIELDRIN (1971) (document on file with author) [hereinafter EPA STATEMENT OF REASONS].

267. *Id.*

268. *Id.*

269. The wisdom of the decision banning most uses of DDT in the United States has been the subject of considerable debate. At least one recent study, however, showed a five-fold increase in breast cancer risk among young women exposed to DDT during the period of peak DDT use in the 1940s and 1950s, suggesting that the public health implications of DDT use are still not fully understood. See Barbara A. Cohn et al., *DDT and Breast Cancer in Young Women: New Data on the Significance of Age at Exposure*, 115 ENVTL. HEALTH PERSPECTIVES 1406 (2007).

270. *EDF v. EPA*, 510 F.2d 1292, 1301 (D.C. Cir. 1975).

271. *Id.*

272. *EDF v. EPA*, 465 F.2d 528 (D.C. Cir. 1972) (recounting procedural history).

273. *Id.*

[T]he final decision with respect to whether a particular product should be registered initially or should continue to be registered depends on the intricate balance between the benefits and the dangers to the public health and welfare resulting from its use. The concept of the safety of the product is an evolving one which is constantly being further refined in light of our increasing knowledge.<sup>274</sup>

Given that there were at the time some 45,000 outstanding pesticide registrations with “hundreds of substances in use,” EPA faced “immense difficulties of achieving a comprehensive solution to pesticide control.”<sup>275</sup> With respect to the “imminent hazard” standard for suspension orders, the court noted, “It is enough if there is *substantial likelihood* that serious harm will be experienced during the year or two required in any realistic projection of the administrative process.”<sup>276</sup> Still, the court deferred the matter pending a report from an Advisory Committee formed to review the issue.<sup>277</sup>

Two years later, EPA issued the suspension order and the matter was soon back before the D.C. Circuit and Judge Leventhal.<sup>278</sup> The court reiterated its approach to the “imminent hazard” question, pointing out that the standard was “not limited to a concept of crisis.”<sup>279</sup> In the case of aldrin and dieldrin, EPA had made the requisite “imminent hazard” finding on the basis of widespread human exposure and data indicating carcinogenicity in mice and rats.<sup>280</sup> This was well within the agency’s expertise, according to the court, even though “the extrapolation of data from mice to men may be quantitatively imprecise, it is sufficient to establish a ‘substantial likelihood’ that harm will result.”<sup>281</sup> Here again, no effort was made to quantify the risks.

The following year, the court with Judge Leventhal again writing for the panel employed the same general reasoning to uphold EPA’s suspension of heptachlor and chlordane.<sup>282</sup> In response to the manufacturer’s argument that dietary exposure to these pesticides was “insignificant” and “well below ‘safe’ dose levels as calculated by the Mantel-Bryan formula, or by the World Health Organization’s Acceptable Daily Intake figures,” the court upheld EPA’s decision to

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274. *Id.* at 535 n.5 (quoting EPA STATEMENT OF REASONS, *supra* note 266).

275. *Id.* at 535–36.

276. *Id.* at 540.

277. *Id.*

278. *EDF v. EPA*, 510 F.2d 1292, 1297 (D.C. Cir. 1975) (detailing procedural history).

279. *Id.* at 1297.

280. *Id.* at 1298.

281. *Id.* at 1299. As the court elaborated “[u]se of animal data is particularly appropriate where, as here, accurate epidemiological studies cannot be conducted because the virtually universal contamination of humans by residues of aldrin/dieldrin make it impossible to establish an uncontaminated human control group. The long latency period of carcinogens further hinders epidemiological research, and the ethical problems of conducting cancer experiments on human beings are too obvious to require discussion.”

282. *EDF v. EPA*, 548 F.2d 998 (D.C. Cir. 1976) (affirming EPA order suspending registrations of heptachlor and chlordane).

reject[] the concept of a “safe” dose level defined by mathematical models because of “the incomplete assumptions made . . . about the sources of human exposure in the environment, the natural variation in human susceptibility to cancer, the lack of any evidence relating the level of human susceptibility to cancer from heptachlor and chlordane as opposed to that of the mouse, and the absence of precise knowledge as to the minimum exposure to a carcinogen necessary to cause cancer.”<sup>283</sup>

Here again, the court found it unnecessary to push EPA to develop a quantitative estimate of risk.

In all of these pesticide cases, neither EPA nor the D.C. Circuit found that it was appropriate, much less possible, to develop a precise quantification of risk as a basis for regulation even though the underlying statute expressly called for a balancing of risks and benefits. Mathematical extrapolation models were viewed as too arbitrary and uncertain to provide any real guidance. Humility and a deep-seated concern about lack of knowledge provided the normative backdrop for these early exercises in precautionary regulation.

## 2. *Endangerment, Precaution, and Environmental Law*

Pesticides and chemicals, of course, were only part of a broader set of concerns about environmental degradation that gained traction throughout the 1960s and 1970s. Widespread air and water pollution, in particular, pushed Congress steadily toward a much stronger federal role in environmental protection. With passage of the 1970 Clean Air Act Amendments<sup>284</sup> and the Federal Water Pollution Control Act Amendments of 1972,<sup>285</sup> the modern foundations for federal pollution control law were established. Drawing on years of extensive hearings, deep bipartisan support, and strong leadership from Senator Muskie and others in Congress, these new flagship environmental statutes embodied a commitment to bold federal action in the face of a deepening crisis.<sup>286</sup> Despite their differences, moreover, both statutes embraced a precautionary stance, calling on the EPA to act in the face of uncertainty, to build in margins of safety to protect against hazards not yet identified, and to

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283. *Id.* at 1009.

284. *See* Clean Air Amendments of 1970, Pub. L. 91-604, 84 Stat. 1676 (1970).

285. *See* Federal Water Pollution Control Act Amendments of 1972, Pub. L. 92-500, 86 Stat. 816 (1972).

286. *See, e.g.*, Senate Debate on S. 4358, September 21, 1970, *reprinted in* 1 LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1970 at 223 (1974) (statement of Sen. Muskie) (“Our environmental problems have contributed heavily to . . . self-doubt and fear. A nation which has been able to conquer the far reaches of space, which has unlocked the mysteries of the atom, and which has an enormous reserve of economic power, technological genius and managerial skills, seems incapable of halting the steady deterioration of our air, water, and land. The legislation we take up today provides the Senate with a moment of truth: a time to decide whether or not we are willing to let our lives continue to be endangered by the wasteful practices of industrial society, or whether we are willing to breathe new life into our fight for a better quality of life.”).

move forward with technology-based controls without waiting for precise estimates of risk.<sup>287</sup>

The critical task confronting regulators and courts seeking to give effect to these statutory commands was to determine when a potential threat to human health became legally cognizable. This was the question that EPA and the D.C. Circuit confronted in the pesticide cases; it was also the question confronting early efforts to regulate air and water pollution under the newly enacted Clean Air and Clean Water Acts. In the well-known *Reserve Mining* case involving discharges of asbestos fibers into the air and the waters of Lake Superior, the Eighth Circuit found that even though no harm had been demonstrated to have occurred, the precautionary command of the Clean Water Act compelled a finding that the potential threat of harm was “of sufficient gravity to be legally cognizable.”<sup>288</sup> The court noted that it was in uncharted territory, confronting a case that did not involve “‘historical’ facts subject to ordinary means of judicial resolution,” but rather “disputes involving conflicting theories and experimental results, about which it would be judicially presumptuous to offer conclusive findings.”<sup>289</sup> As in the pesticide area, the court was operating well beyond the realm of experience, forced to grapple with complex and contested lines of evidence “on the frontiers of scientific knowledge.”<sup>290</sup> Following an earlier panel dissent by D.C. Circuit judge Skelly Wright in the *Ethyl Corp.* case involving leaded gasoline and the Clean Air Act, the court interpreted the “endangering” language of the Clean Water Act to require a “precautionary or preventive approach” that clearly contemplated action in the face of “potential

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287. See, e.g., Clean Air Amendments of 1970, Pub. L. 91-604, 84 Stat. 1676, 1680 section 109(b)(1) (requiring national primary ambient air quality standards to be set at a level that provides “an adequate margin of safety”); *id.* at 1684 (section 111(b)(1)(A)) (establishing “endangerment” threshold for listing of stationary source categories for new source performance standards); *id.* at 1685 (section 112(b)(1)(A)) (requiring emissions standards for hazardous air pollutants to be set at level providing “ample margin of safety”); *id.* at 1690 (section 202(a)(1)) (establishing “endangerment” threshold for mobile source standards); Federal Water Pollution Control Act Amendments of 1972, Pub. L. 92-500, 86 Stat. 816, 816 (sections 101(a), 101(a)(1), and 101(a)(3)) (declaring objective of Act to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters” and establishing “national goal that the discharge of pollutants into navigable waters be eliminated by 1985” and “national policy that the discharge of toxic pollutants in toxic amounts be prohibited”); *id.* at 857 (section 307(a)(4)) (requiring that any effluent standard established for toxic pollutants be set at a level “which the Administrator determines provides an ample margin of safety”).

288. *Reserve Mining Co. v. EPA*, 514 F.2d 492, 500 (8th Cir. 1975) (en banc); see also John S. Applegate, *The Story of Reserve Mining: Managing Scientific Uncertainty in Environmental Regulation*, in ENVIRONMENTAL LAW STORIES 43–76 (Lazarus & Houck eds., 2005) (discussing background and details of case and noting its importance for environmental law as early example of effort to grapple with scientific uncertainty); DANIEL A. FARBER, ECO-PRAGMATISM: MAKING SENSIBLE ENVIRONMENTAL DECISIONS IN AN UNCERTAIN WORLD 15–34 (1999) (discussing *Reserve Mining* and highlighting its importance as “the first major judicial confrontation with environmental risk”).

289. *Id.* at 507.

290. *Id.* at 519 (“The preceding extensive discussion of the evidence demonstrates that the medical and scientific conclusions here in dispute clearly lie ‘on the frontiers of scientific knowledge.’”) (citation omitted).

harm as well as actual harm.”<sup>291</sup> In this case, not only was there no evidence of actual harm from the discharges, it was not possible to quantify the risks. Animal tests were suggestive at best and any effort to extrapolate to human risk estimates was a non-starter.<sup>292</sup> Instead, “the hazard . . . [could] be measured in only the most general terms as a concern for the public health resting upon a reasonable medical theory.”<sup>293</sup> And because “[s]erious consequences could result if the hypothesis on which [this theory was] based should ultimately prove true,” the court found that it was empowered to act under the statute.<sup>294</sup>

The following year, the D.C. Circuit sitting en banc reheard the famous *Ethyl Corp.* case involving a challenge to EPA’s efforts to regulate leaded gasoline under section 211 of the Clean Air Act on the grounds that airborne lead endangered human health.<sup>295</sup> Writing for the majority, Judge Skelly Wright offered a powerful endorsement of a precautionary approach to environmental hazards. In doing so, he drew directly on the earlier pesticide cases and *Reserve Mining*, grounding his opinion on an approach to environmental law that put the problem of knowledge front and center and embraced a deep respect for uncertainty. Thus, Wright began the opinion by pointing to the considerable epistemic challenges embedded in the modern task of health, safety, and environmental regulation:

Man’s ability to alter his environment has developed far more rapidly than his ability to foresee with certainty the effects of his alterations. It is only recently that we have begun to appreciate the danger posed by unregulated modification of the world around us, and have created watchdog agencies whose task it is to warn us, and protect us, when technological “advances” present dangers unappreciated or unrevealed by their supporters. Such agencies, unequipped with crystal balls and unable to read the future are nonetheless charged with evaluating the effects of unprecedented environmental modifications, often made on a massive scale. Necessarily they must deal with predictions and uncertainty, with developing evidence, with conflicting evidence, and, sometimes, with little or no evidence at all.<sup>296</sup>

The challenges confronting regulators were unprecedented.<sup>297</sup> And while all of these challenges were marked by significant uncertainty—the dangers they

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291. *Id.* at 528. As the court noted, the specific “endangerment” language that was at issue in the case predated the 1972 amendments. *Id.*

292. *Id.*

293. *Id.* at 536.

294. *Id.* at 535 (“Reserve’s air and water discharges pose a danger to the public health and justify judicial action of a preventive nature.”). The remedies imposed included immediate action to reduce air emissions and a reasonable time to convert the water discharges to land disposal. *Id.* at 500.

295. *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (en banc).

296. *Id.* at 2–3.

297. *Id.* at 25 (“Never before have massive quantities of abestiform tailings been spewed into the water we drink. Never before have our industrial workers been occupationally exposed to vinyl chloride or to asbestos dust. Never before has the food we eat been permeated with DDT or the pesticides aldrin



posed very much “a question on the frontiers of scientific knowledge”<sup>298</sup>—waiting for certainty was not feasible: “[T]he statutes—and common sense—demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.”<sup>299</sup>

What is critical to recognize here is that underneath this strong normative embrace of precaution, Judge Wright was advancing a flexible, pragmatic theory of knowledge and risk assessment that recognized the provisional nature of “facts” and the difficulties entailed by a pure science-based approach. Indeed, while certainty was an important scientific ideal, it was not feasible in the complex world of environmental health.<sup>300</sup> As Judge Wright noted,

Even scientific “facts” are not certain, but only theories with high probabilities of validity. . . . While awaiting statistical certainty may constitute the typical mode of scientific behavior, its appropriateness is questionable in environmental medicine, where regulators seek to prevent harm that often cannot be labeled “certain” until after it occurs. . . . The uncertainty of scientific fact parallels the uncertainty of all fact.<sup>301</sup>

Invoking the work of David Hume and Thomas Kuhn, Judge Wright recognized that scientific knowledge was dynamic, partial and contingent and, accordingly, always subject to redescription, revision and, on occasion, even wholesale abandonment by expert communities.<sup>302</sup> The implication for regulators operating under the mandate of a precautionary statute was clear: uncertainty was not a legitimate basis for inaction. But neither could there be any guarantee that a particular decision to regulate would turn out as expected, and the regulatory enterprise itself should be seen as a pragmatic, “essentially experimental” activity.<sup>303</sup> “[T]he search for intelligent means of regulating our economy, industry, and ecology,” according to Judge Wright, was best “carried on . . . through informed, candid, and careful experimentation.”<sup>304</sup>

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and dieldrin. And never before have hundreds of thousands of tons of lead emissions been disgorged annually into the air we breathe.”)

298. *Id.* at 26 n.55.

299. *Id.* at 25. On the question of whether the threatened harm must be “probable” in order to merit action, Wright rejected arguments that a particular formula could be applied, finding instead that the determination of what constituted a danger sufficient to merit regulation under the statute depended on the facts of each case. *Id.* at 18.

300. *See id.* at 25 (“Undoubtedly, certainty is the scientific ideal to the extent that even science can be certain of its truth. But certainty in the complexities of environmental medicine may be achievable only after the fact, when scientists have the opportunity for leisurely and isolated scrutiny of an entire mechanism.”).

301. *Id.* at 25 n.52 (citing Thomas Kuhn and David Hume).

302. *Id.*

303. J. Skelly Wright, *Court of Appeals Review of Federal Regulatory Agency Rulemaking*, 26 ADMIN. L. REV. 200, 211 (1974).

304. *Id.* As Judge Wright elaborated,

In this very human society, there is no guarantee that regulatory policy will achieve its purported objectives or not have unforeseen consequences along the way. But new approaches, including even de-regulation, must be considered. And this inescapable truth calls for acknowledgement that ringing demands for certainty and dryly logical perfection in

In the specific case of airborne lead, the techniques and lines of evidence available to determine the potential health impacts—toxicology, epidemiology, and clinical research—should be evaluated together in Judge Wright’s view as part of a flexible approach to risk assessment. Such an exercise constituted a “normal part of judicial and administrative fact finding,” saturated with “normative conflicts, projections from imperfect data, experiments and simulations, educated predictions, differing assessment of possible risks, and the like.”<sup>305</sup> The key point in all of this, moreover, was that law, rather than science, provided the normative foundation for the overall effort, and courts and administrative agencies need not (indeed should not) try to make risk assessment into a purely scientific enterprise.<sup>306</sup> At the end of the day,

[s]ome of the information will be factual, but much of it will be more speculative—scientific estimates and “guesstimates” of probable harm, hypotheses based on still developing data, etc. Ultimately [the Administrator] must act, in part on “factual issues,” but largely “on choices of policy, on an assessment of risks, [and] on predictions dealing with matters on the frontiers of scientific knowledge. A standard of danger—fear of uncertain or unknown harm—contemplates no more.”<sup>307</sup>

In the case at hand, even though scientists had “questioned whether the addition of lead to gasoline, and its consequent diffusion into the atmosphere from the automobile emission, pose[d] a danger to public health” and even though “hard proof of any danger caused by lead automotive emissions ha[d] been hard to come by,” the court found that EPA was justified in taking a precautionary approach and finding that such emissions did in fact endanger the public health.<sup>308</sup> As it turned out, the subsequent removal of lead from gasoline translated directly into dramatic decreases in blood lead levels across all

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new techniques of agency regulation are more likely to foster despair and stagnation than progress.

*Id.* at 211–12.

305. *Ethyl Corp.*, 541 F.2d at 28 n.58.

306. *Id.*

307. *Id.* at 29 (citations omitted).

308. *Id.* at 7–8. It is important to recognize that up until the early 1970s, the lead industry was the primary supporter of research on the health effects of lead and played a very active role in shaping the science that informed these early regulatory efforts. See Kenneth Bridford & David Hanson, *A Personal Perspective on the Initial Federal Health-Based Regulation to Remove Lead from Gasoline*, 117 ENVTL. HEALTH PERSPECTIVES 1195, 1195 (2009) (noting that because of its role as primary supporter of research on lead, the industry “was in a position to impede the free flow of scientific information related to the hazards of lead in gasoline, including restrictions on the ability to publish this information without prior approval. Consequently, the vast majority of relevant studies of lead in gasoline published until the early 1970s were favorable to the lead industry.”). Both Bridford and Hanson worked at EPA during the 1970s and played “major roles in developing the rationale for and drafting the initial federal health-based regulation to remove lead from gasoline.” *Id.*

segments of the population and has been widely hailed as one of the great public health achievements of the twentieth century.<sup>309</sup>

Other cases embraced this general approach and line of reasoning.<sup>310</sup> Margin of safety—a term borrowed from engineering as well as earlier approaches in food safety and embedded in both the Clean Air and Clean Water Acts—was viewed as the most appropriate tool to deal with uncertainty and the general lack of experience with these new potential harms.<sup>311</sup> The use of extrapolation models to generate quantitative risk estimates was considered too arbitrary and unreliable in these early efforts to regulate on the frontiers of scientific knowledge.<sup>312</sup> More generally, there was a conviction in these and other cases that uncertainty and lack of knowledge had to be engaged in a fulsome and forthright manner—that risk assessment, however conducted, had “to face the hard questions created by lack of knowledge.”<sup>313</sup> As Judge Bazelon put it in the *Vermont Yankee* case, which involved the Nuclear Regulatory Commission’s responsibilities to assess the hazards associated with nuclear waste: “To the extent that uncertainties necessarily underlie predictions of this importance on the frontiers of science and technology, there is a concomitant necessity to confront and explore fully the depth and consequences of such

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309. See, e.g., H.L. Needham, *Childhood Lead Poisoning: The Promise and Abandonment of Primary Prevention*, 88 AM. J. PUB. HEALTH 1871, 1871 (1998) (recognizing removal of lead from gasoline as one of the great public health triumphs of the twentieth century).

310. See, e.g., *EDF v. EPA*, 598 F.2d 62, 83 (D.C. Cir. 1978) (endorsing precautionary approach of EPA in regulating PCBs under section 307 of the Clean Water Act: “[B]y requiring EPA to set standards providing an ‘ample margin of safety,’ Congress authorized and, indeed, required EPA to protect against dangers before their extent is conclusively ascertained.”); *id.* at 81 n.73 (“The toxics section reflects a policy behind the 1972 Act: a congressional determination that pollution standards must be set to protect against dangers concealed by the limitations of current scientific knowledge.”); *Lead Indus. Assoc., Inc. v. EPA*, 647 F.2d 1130, 1152–56 (D.C. Cir. 1980) (discussing the precautionary nature of the statutory mandate to protect public health under the Clean Air Act’s provisions regarding national ambient air quality standards (NAAQS)).

311. See discussion *supra* note 287 (citing use of “margin of safety” language in various sections of Clean Air and Clean Water Acts); National Air Quality Standards Act of 1970, S. Rep. No. 91-1196, at 10 (1970) (“Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against the hazards which research has not yet identified.”); *EDF v. EPA*, 598 F.2d at 81 (noting that the “term ‘margin of safety’ was intended to provide protection ‘against hazards which research has not yet identified’”); *id.* at 81 n.72 (quoting legislative history on margin of safety which was employed “to reflect the lack of data on potential toxicity where there is no experience under conditions of human or environmental exposure.”); *Hercules Inc. v. EPA*, 598 F.2d 91, 104 (D.C. Cir. 1978) (“Under the ‘ample margin of safety’ safety directive, EPA’s standards must protect against incompletely understood dangers to public health and the environment in addition to well-known risks.”); *Lead Indus. Assoc.*, 647 F.2d at 1154 (discussing role of margin of safety requirement “to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement”).

312. See, e.g., *Society of the Plastics Indus. v. OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1975) (upholding OSHA’s decision to regulate vinyl chloride even though the facts in dispute were “on the frontiers of scientific knowledge” and notwithstanding the Secretary’s policy judgment “in extrapolating . . . from mouse to man” to reduce the permissible level to the lowest detectable level).

313. David L. Bazelon, *Risk and Responsibility*, 205 SCIENCE 277, 279 (1979).

uncertainties.”<sup>314</sup> Figuring out how to operationalize this, of course, was the crux of the matter. But there was a clear recognition in these cases that much was at stake in the many choices confronting regulators seeking to organize environmental decision making in the face of a host of new problems. Environmental law, only just born, was already at an important crossroads, its future very much up for grabs.

### 3. *The Quest for a Generic Cancer Policy*

OSHA too was at a crossroads, struggling with its own regulatory challenges. In its first six years, the agency had concluded only four rulemakings in the health area,<sup>315</sup> and was facing significant pressure from Congress and others to develop a more effective approach.<sup>316</sup> Most pressing among the challenges confronting the agency was the need to deal with an increasing number of carcinogens in the workplace. In 1973, OSHA had issued emergency temporary standards for fourteen carcinogens, which after a remand from the Third Circuit, it reissued as permanent standards in 1974.<sup>317</sup> In developing these standards, OSHA drew directly on the 1970 Ad Hoc Committee report on Environmental Carcinogenesis, with particular reliance on the basic principles that evidence of carcinogenicity in animals provided a sufficient basis on which to conclude that such substances were carcinogenic in humans and that there was no safe exposure level for carcinogens.<sup>318</sup> Over the next several years, OSHA refined its overall approach to carcinogens, proposing a Generic Carcinogen Policy (GCP) in 1977.<sup>319</sup>

In its GCP proposal, the Agency highlighted the intractable regulatory challenges confronting the effort to develop standards for a growing number of

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314. *NRDC v. NRC*, 547 F.2d 633, 653 (D.C. Cir. 1976), *rev'd*, 435 U.S. 519 (1977). Judge Bazelon's procedural version of "hard look" review was rejected by the Supreme Court in the *Vermont Yankee* case.

315. *See* Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. 54,148, 54,149 (Oct. 4, 1977) (noting four completed rulemakings in OSHA's six year history).

316. *See* Thomas O. McGarity, *OSHA's Generic Carcinogen Policy: Rule Making Under Scientific and Legal Uncertainty*, in *LAW AND SCIENCE IN COLLABORATION* 55-56 (Nyhart et al. eds., 1983) (discussing pressures on OSHA to develop a generic approach to cancer).

317. *See* Emergency Temporary Standard on Certain Carcinogens, 38 Fed. Reg. 10,929 (May 3, 1973) (issuing temporary standards); *Dry Color Mfrs. Assoc. v. Dep't of Labor*, 486 F.2d 98 (3rd Cir. 1973) (vacating and remanding emergency temporary standards); *Carcinogens*, 39 Fed. Reg. 3756 (Jan. 29, 1974) (order issuing permanent standards); *Synthetic Organic Chem. Mfrs. Assoc. v. Brennan*, 503 F.2d 1155 (3rd Cir. 1974) (upholding standards).

318. *See* Carcinogens, *supra* note 317; Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, *supra* note 315, at 54, 154. *See also* McGarity, *supra* note 316, at 57-61.

319. OSHA issued its proposed GCP in 1977. *See* Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, *supra* note 315.

environmental carcinogens.<sup>320</sup> A substance-by-substance approach to setting health standards for occupational carcinogens was simply not feasible:

It is OSHA's belief that if this proposal or something like it is not promulgated, with present resources the output of standards to protect American workers from carcinogens will never be adequate and may collapse by means of the futility of the effort. Indeed, to follow the present system and procedure for each and every individual substance and hazard would be, we contend, beyond the abilities of any agency, no matter how large a staff it may have.<sup>321</sup>

On the issue of quantitative risk assessment, OSHA stated that the significant uncertainties involved in extrapolating from high-dose animals studies to low-level human exposures precluded use of such techniques to determine specific risk estimates.<sup>322</sup> Instead, the agency sought to develop a more streamlined approach that would allow the agency to regulate automatically on the basis of certain findings regarding potential carcinogenicity. If a chemical induced tumors (benign or malignant) in animal tests, emergency temporary standards, followed by permanent standards, would immediately issue requiring employers to reduce employee exposure to the lowest feasible level.<sup>323</sup> This deliberate departure from the chemical-by-chemical approach reflected a conscious and, in many respects, courageous effort by OSHA to hold onto a precautionary approach in the face of an increasingly complex and growing set of hazards. Quoting extensively from the Ad Hoc Committee's report and from Judge Wright's decision in *Ethyl Corp.*, OSHA sought to ground the GCP proposal on a forthright recognition of the uncertainties that were endemic to such an exercise and the concomitant need for pragmatic solutions to the cancer problem.<sup>324</sup> This was very much in the spirit of the Delaney Clause.<sup>325</sup> But it would not last.

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320. *Id.* at 54,149 (noting that increasing number of environmental chemicals would lead to increased number of carcinogens and concomitant increase in the size and complexity of OSHA's rulemakings).

321. *Id.* at 54,154.

322. *Id.* at 54,167. In its final rule issued in 1980, OSHA rejected the use of quantitative risk assessment in these circumstances. *See* Identification, Classification, and Regulation of Potential Carcinogens (Final Rule), 45 Fed. Reg. 5002, 5200-01 (Jan. 22, 1980) ("The uncertainties involved in extrapolating from high-dose animal experiments to predict low-dose risks to humans are far too large at present to justify using the estimates as the basis for quantitative risk/benefit analysis. This conclusion is well illustrated by the more than million-fold variation in the estimates of risk derived by different authors for risks to persons exposed to vinyl chloride at the OSHA standard of 1 ppm.").

323. *Id.* at 54,168.

324. *Id.* at 54,153 (quoting extensively from *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (en banc)); *id.* at 54,166 (quoting EVALUATION OF ENVIRONMENTAL CARCINOGENS, *supra* note 168).

325. *Id.* at 54,166-67 (citing the Delaney Clause and its defenders in support of OSHA's "regulatory decision" to treat carcinogens as having no "safe" levels).

*C. Acceptable Risk & the Changing Technocratic Ideal*

In fact, at the same time that OSHA was developing its Generic Cancer Policy, more formal approaches to risk were already taking shape, in large part as a response to the greatly enhanced ability to detect potential environmental hazards. Recourse to mathematical extrapolation models along with more systematic treatment of inference choices and default assumptions came to occupy an increasing amount of attention by regulators as safety came to be redefined as acceptable risk and regulators looked for new tools to quantify and compare risks to determine whether they met a threshold of acceptability.<sup>326</sup> These efforts took on additional salience in the world of hard looks and regulatory reform that gained traction during the second half of the 1970s. As the decade wore on, the pragmatic, flexible theory of knowledge that underwrote the normative posture of endangerment and precaution seemed increasingly untenable. The New Deal inspired view of expert judgment was giving way to a more disciplined “systems” approach to technology and hazard assessment that drew upon a growing enthusiasm for the methods of operations research and decision theory.<sup>327</sup>

But the first efforts to use formal, quantitative risk assessment as a basis for regulatory decisions were not direct responses to the emerging hard look doctrine in administrative law or the growing enthusiasm for regulatory reform that gained traction in the late 1970s and early 1980s. Rather, at both FDA and EPA, the first steps toward quantitative risk assessment were taken in an effort to make sense of the much more complicated world of environmental hazards brought into view by new analytical techniques. Thus, beginning in the early 1970s, FDA pioneered the use of quantitative risk assessment based on low-dose extrapolation models as part of an effort to deal with the fact that new detection methodologies had rendered the previous “no residue” exception for carcinogenic animal drugs untenable.<sup>328</sup> At about the same time, EPA deployed quantitative risk assessment in an effort to get a handle on a whole new world of risks associated with vinyl chloride exposure among the general population.<sup>329</sup> The agency also began to develop its own set of guidelines for carcinogen risk assessment as a basis for regulation under multiple statutes, taking a very different approach than OSHA.<sup>330</sup> By the second half of the 1970s, the standard of “acceptable risk,” along with its mirror image “unreasonable risk,” was embraced across various regulatory domains by

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326. See, e.g., NAT'L RESEARCH COUNCIL, *supra* note 222, at 29–59 (discussing use of various extrapolation techniques for chemical safety assessment).

327. See, e.g., Tribe, *supra* note 8 (discussing influence of operations research and systems theory on risk assessment and other forms of policy analysis during the post-World War II period).

328. See discussion *infra* Part III.C.1.

329. See discussion *infra* Part III.C.2.

330. See discussion *infra* Part III.C.3.

Congress and agencies as they sought to develop more formal, objective approaches to protecting public health and the environment.

### 1. *DES and Quantitative Risk Assessment at FDA*

Not surprisingly, the first regulatory use of quantitative risk assessment occurred in the area of food safety, largely in response to the substantial advances in detection capabilities during the 1960s and 1970s. Specifically, FDA's struggle to deal with diethylstilbestrol, or DES, in animal feeds provided the impetus for the Agency's first effort to develop formal, quantitative risk assessment as a basis for regulation.<sup>331</sup> In 1962, Congress had added the "DES proviso" to the FFDCFA, providing that carcinogenic animal drugs could be approved for use in food-producing animals if, under proper use and on the basis of "approved methods" for residue detection, "no residue" of the carcinogenic substance would be present in food derived from the animals after slaughter.<sup>332</sup> The primary motivation behind this was to allow continued use of DES, a known carcinogen, as a growth promoter in chickens and beef cattle. At the time of the amendment, state-of-the-art analytical methods were sensitive to a level of 2 parts per billion (2 ppb) and did not detect residues after slaughter.<sup>333</sup> By the early 1970s, the USDA began using gas chromatography methods sensitive to the 0.5 ppb and later moved to even more sensitive radiotracer studies.<sup>334</sup> Based on the new methods, residues of DES began to show up in slaughtered animals at dosage levels previously found to satisfy the "no residue" threshold.<sup>335</sup> FDA responded by withdrawing pending applications for new DES animal drugs on the grounds that the Delaney Clause prohibited their use.<sup>336</sup> And even though the courts overturned these

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331. See, e.g., Joseph V. Rodricks, *Origins of Risk Assessment in Food Safety Decision Making*, 7 J. AM. C. TOXICOLOGY 539, 539 (1988) (tracing "origins of risk assessment as a regulatory tool to FDA's attempt, during the 1960s and 1970s, to deal with various uses of diethylstilbestrol (DES)").

332. 21 U.S.C. § 512(d)(1)(H) (2006).

333. See BASF Notice of Withdrawal of Petition for Food Additives, 38 Fed. Reg. 10,485, 10,487 (Apr. 27, 1973) (discussing evolution of detection methodologies and sensitivities for DES residues). This was also the period during which links were established between DES use by pregnant women and certain gynecological cancers in their daughters. In 1971, a study published in the *New England Journal of Medicine* showed that seven of eight girls and young women (ages 14 to 22) who had been diagnosed with a rare form of vaginal cancer had been exposed prenatally to DES. See Arthur L. Herbst et al., *Adenocarcinoma of the Vagina*, 284 NEW ENG. J. MED. 878 (1971).

334. *Id.*

335. These residues were detected in spite of the fact that the USDA sampling program was widely viewed as inadequate. See, e.g., *Chemicals and the Future of Man*, *supra* note 246, at 55 (statement of Dr. Samuel S. Epstein).

336. See Order Denying Hearing and Withdrawing Approval of New Animal Drug Applications for Liquid and Dry Premixes, and Deferring Ruling on Implants, 37 Fed. Reg. 15,747, 15,749 (Aug. 4, 1972) ("The new USDA study clearly shows [DES] residues that are in the range of current detection methodology; new detection methodology is being developed that would be significantly more sensitive. Thus, under the law there is no alternative but to withdraw approval of the drug, even though there is no known public health hazard resulting from its use."); BASF Notice of Withdrawal of Petition for Food Additives, 38 Fed. Reg. 10,485, 10,487 (Apr. 27, 1973) ("The data obtained from the USDA

withdrawals on the basis of improper notice and the technical point that the Delaney Clause did not apply because the new methods had not been formally established as “approved methods,” it was obvious that the world had changed.<sup>337</sup>

Simply put, by the early 1970s, it had become quite clear that the “no residue” standard was entirely contingent upon the sensitivity of the analytical technique used to detect residues and that, as such techniques improved, a literal interpretation of the standard—what some referred to as a “no molecules” approach—would become impossible to meet in the absence of a complete ban.<sup>338</sup> In an effort to bring some coherence to the issue, the FDA initiated a rulemaking in 1973 that included the first published criteria on sensitivity of method and the first explicit call for a quantitative risk-based approach.<sup>339</sup> Rather than specify a particular analytic technique that would provide the basis for the no residue standard, the agency proposed a particular dose-response model for extrapolation to low doses and defined an “acceptable” level of risk as one in 100 million.<sup>340</sup> This was the first proposed regulatory use of a low-dose extrapolation model and a landmark on the road to quantitative risk assessment.<sup>341</sup> As such, it elicited wide-ranging reactions from various constituencies and it took well into the 1980s for the FDA to resolve the matter.<sup>342</sup>

In a more general sense, the new approach represented a deeper shift in the conception of expertise. Expert judgment was giving way to a more anonymous and increasingly formal systems approach built on standard methods and procedures. As the pluralism and interest group politics of the 1970s gained

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radioactive-tagged DES implant study clearly establish the presence of residues of DES and/or its conjugates 120 days after implantation. No known data utilizing comparably sensitive methodology shows the absence of DES residues. . . . The Commissioner is taking this action [withdrawing the application] because of a lack of proof of safety, not because of proof of a public health hazard. No human harm has been demonstrated as a result of the use of DES implants. Because the new USDA test clearly shows DES residues in cattle liver, the law requires that use of the drug must be discontinued.”).

337. See *Hess & Clark v. FDA*, 495 F.2d 975, 994–95 (D.C. Cir. 1974) (vacating on grounds that agency failed to provide proper notice and hearing); *Chemetron v. U.S. Dep’t of Health, Educ., and Welfare*, 495 F.2d 995, 999–1000 (D.C. Cir. 1974) (vacating DES withdrawals on grounds that decision was not based on use of an “approved method” for detecting DES residues).

338. See *Chemical Compounds in Food Producing Animals*, 44 Fed. Reg. 17,070, 17,073–17,074 (Mar. 20, 1979) (discussing “no molecules” interpretation of the DES proviso and its implausibility).

339. See *Compounds Used in Food-Producing Animals*, 38 Fed. Reg. 19,226, 19,227 (July 19, 1973).

340. *Id.* The agency proposed a modified version of the Mantel-Bryan or log-probit extrapolation model. Based on the proposed approach, the level of a specific drug residue could be calculated on the basis of a low-dose extrapolation from the relevant animal studies and, if it was below the “acceptable” one in 100 million level, the sponsor of the drug would then be required to submit a detection method capable of measuring residues at or below this level.

341. See Hutt, *supra* note 67.

342. FDA issued its final rule on the “no residue” issue in 1987. See *Sponsored Compounds in Food-Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues*, 52 Fed. Reg. 49,572 (Dec. 31, 1987) (final rule on the operational definition of “no residue” and tying it to “significant” risk threshold in one in one million).



momentum and in the midst of a growing enthusiasm for regulatory reform, embattled agencies facing gargantuan regulatory tasks looked to quantitative risk assessment as an increasingly attractive way of insulating their decision making from criticism. There was a view that management systems, protocols, and frameworks could be developed to rationalize agency decision making and remove, as much as possible, the elements of individual judgment.<sup>343</sup>

## 2. *Vinyl Chloride and Quantitative Risk Assessment at EPA*

At roughly the same time that FDA was developing its approach to quantitative risk assessment, EPA was moving in the same direction as it grappled with the possible risks of exposure to vinyl chloride—a compound that came into widespread use after World War II.<sup>344</sup> Between 1943 and 1973, vinyl chloride production in the United States soared from less than 99 million pounds to more than 5.2 billion pounds.<sup>345</sup> The first reports of adverse health effects in workers exposed to vinyl chloride were published in the late 1940s,<sup>346</sup> but it was not until 1971 that the first scientific article was published demonstrating the carcinogenicity of vinyl chloride in experimental animals.<sup>347</sup> Three years later, it was reported that several workers from the B.F. Goodrich plant in Louisville, Kentucky had died from a rare form of liver cancer linked directly to vinyl chloride exposure.<sup>348</sup> OSHA responded first with an emergency standard of fifty parts per million (ppm) and then a new permanent standard of one ppm, following the approach that it would soon seek to validate in its Generic Cancer Policy.<sup>349</sup>

The larger concern in all of this was whether the general public was at risk. Shortly after the Goodrich deaths came to light, a joint investigation by the National Institute of Occupational Safety and Health and the Centers for Disease Control suggested that the carcinogenic hazards facing industrial

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343. See, e.g., NAT'L RESEARCH COUNCIL, *supra* note 226.

344. See EPA, EPA-600/6-75-004, SCIENTIFIC AND TECHNICAL ASSESSMENT REPORT ON VINYL CHLORIDE AND POLYVINYL CHLORIDE 3 (1975) (documenting production and use of vinyl chloride in the United States after World War II).

345. *Id.*

346. *Id.* at 70.

347. See P.L. Viola et al., *Oncogenic Response of Rat Skin, Lungs, and Bones to Vinyl Chloride*, 31 CANCER RES. 516 (1971) (documenting carcinogenic effects of vinyl chloride exposure in experimental rats).

348. See *Vinyl Chloride Hearing before the Subcomm. on Environment, S. Commerce Comm.*, 93d Cong. 40 (1974) [hereinafter *Vinyl Chloride Hearing*] (statement by Dr. Marcus Key, Director National Institute for Occupational Safety and Health) (describing liver angiosarcoma deaths among workers at Goodrich facility).

349. See Emergency Temporary Standard for Exposure to Vinyl Chloride, 39 Fed. Reg. 12,342 (April 5, 1974); Vinyl Chloride: Proposed Standard, 39 Fed. Reg. 16,896 (May 10, 1974) see also Jacqueline Karnell Corn, *Vinyl Chloride: Setting a Workplace Standard: An Historical Perspective on Assessing Risk*, 5 J. PUB. HEALTH POL'Y 497 (1984) (discussing OSHA's efforts to set a workplace standard for vinyl chloride).

workers could extend to those living in proximity to vinyl chloride facilities.<sup>350</sup> At the time, no one had any understanding of the relevant population, much less exposure levels and pathways. EPA responded by establishing a task force to investigate the risks associated with vinyl chloride exposure for the general population, an investigation that resulted in the agency's first formal quantitative risk assessment.<sup>351</sup>

The task confronting EPA in carrying out such an exercise was immense. By the early 1970s, there were more than fifty vinyl chloride plants scattered around the country with cumulative emissions estimated at more than 220 million pounds per year.<sup>352</sup> More than 4.5 million people lived within five miles of these facilities.<sup>353</sup> In order to understand the hazards confronting these people, new procedures would have to be established to sample and monitor the ambient air, models would have to be constructed to better understand exposure pathways and incorporate relevant toxicological studies, decisions would have to be made regarding how to interpret animal studies and apply them to human exposures, and arguments would have to be advanced regarding the appropriate regulatory instrument.<sup>354</sup>

As with DES, moreover, the issue turned in large part on whether and how the agency would extrapolate from existing human and animal studies to low doses among the general population. During congressional hearings on the matter, Dr. Kenneth Bridbord, a member of the EPA task force, responded to questions on this issue, pointing to low-dose extrapolations under development by researchers at the National Cancer Institute.<sup>355</sup> "We have to stress," he said, that these are extrapolations and judgments based upon models that many people feel are reasonable, but are by no means perfect. . . . I am not a prophet and cannot speculate whether or not we will find a level where all of a sudden the risk becomes zero. These are estimates based on projections beyond the limits of availability in the data. But nonetheless they are highly

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350. See *Vinyl Chloride Hearing*, *supra* note 348, at 43 (statement of Dr. Joseph Wagner, NIOSH Director of Field Studies and Clinical Investigations) ("In conclusion, the NIOSH-CDC investigation into vinyl chloride points out the importance of industrial studies for identifying potential carcinogenic hazards which may extend into the general population, and the need for pretesting chemical substances by animal bioassays.").

351. See *id.* at 348 (statement of James Agee, Assistant Administrator EPA) (identifying Goodrich incident as "trigger for EPA concern" and describing formation of EPA task force). EPA also issued an emergency order banning the sale of pesticide sprays containing the substance. In April 1974, FDA recalled and then banned all hair sprays and cosmetics using vinyl chloride as a propellant. The risk assessment for vinyl chloride was published in December 1975. See EPA, *QUANTITATIVE RISK ASSESSMENT FOR COMMUNITY EXPOSURE TO VINYL CHLORIDE* (1975).

352. See EPA, *supra* note 344, at 3.

353. See National Emission Standard for Hazardous Air Pollutants, Standard for Vinyl Chloride, 41 Fed. Reg. 46,560, 46,560 (Oct. 21, 1976) (citing estimates of 4.6 million people living within five miles of vinyl chloride and polyvinyl chloride facilities).

354. See *Vinyl Chloride Hearing*, *supra* note 348, at 64-74 (statements of Agee, Bridbord, and Schweitzer) (discussing challenges facing EPA in assessing risks of vinyl chloride); EPA, *supra* note 344, at 4 (discussing challenges of assessing vinyl chloride risks).

355. See *Vinyl Chloride Hearing*, *supra* note 348, at 70.

suggestive of a continuing but a diminishing risk at lower levels of exposure. . . . Does that risk extend to 1 ppm? Does it extend to 100 ppb? Again we are operating in the avenue of the unknown. . . .<sup>356</sup>

In its risk assessment for vinyl chloride, EPA scientists used two extrapolation models (linear and log-probit) that yielded a range of less-than-one to twenty annual excess cancers of all types among residents living in the vicinity of these plants.<sup>357</sup> Based on this risk assessment, EPA promptly listed vinyl chloride as a hazardous air pollutant under section 112 of the Clean Air Act<sup>358</sup> and proposed a national emissions standard for it.<sup>359</sup> In its proposed standard, the Agency recounted the evidence of vinyl chloride's carcinogenicity and concluded that it was an "apparent non-threshold pollutant."<sup>360</sup>

EPA further noted that "for a carcinogen it should be assumed, in the absence of strong evidence to the contrary, that there is no atmospheric concentration that poses absolutely no public health risk."<sup>361</sup> Given this assumption, the agency thus confronted a dilemma in discharging its duty under section 112 to set emissions standards "at the level which in [the judgment of the Administrator] provides an ample margin of safety to protect the public health from such hazardous air pollutants."<sup>362</sup> EPA could either choose a "zero emission limitation," which "would be the only emission standard which would offer absolute safety from ambient exposure," or it could go with "[a]n alternative interpretation of section 112" that would reduce emissions "to the lowest level achievable by use of the best available control technology."<sup>363</sup> In cases of "apparent non-threshold pollutants," such as vinyl chloride, where "complete emission prohibition would result in widespread industry closure" and where the agency "determined that the cost of such closure would be grossly disproportionate to the benefits of removing the risk that would remain after imposition of the best available control technology," EPA went with the technology-based approach. It proposed a standard that would limit emissions of vinyl chloride from most sources to ten ppm.<sup>364</sup> Notwithstanding the language of the statute, the agency felt confident in choosing such an approach

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356. *Id.* at 70–71.

357. EPA, *supra* note 351.

358. *See* Air Pollution Prevention and Control: Hazardous Air Pollutants, Addition to List, 40 Fed. Reg. 59,477 (Dec. 24, 1975) (adding vinyl chloride to the section 112 list).

359. *See* National Emissions Standards for Hazardous Air Pollutants, Proposed Standard for Vinyl Chloride, 40 Fed. Reg. 59,532 (Dec. 24, 1975) (proposing standard limiting various sources of vinyl chloride emissions to ten ppm).

360. *Id.* at 59,534.

361. *Id.*

362. *See* 42 U.S.C. § 7412 (2006); *see also* Proposed Standard for Vinyl Chloride, *supra* note 359, at 59,534 ("The issue was how far the level of such pollutants should be reduced to provide 'an ample margin of safety.'").

363. *See* Proposed Standard for Vinyl Chloride, *supra* note 359, at 59,534.

364. *Id.*

on the grounds that Congress could not have intended to impose such draconian costs on the American economy.<sup>365</sup>

In its final rule promulgating the proposed ten ppm standard, EPA rehearsed the basic findings of the vinyl chloride risk assessment but did not state whether it considered the resulting risks to be significant or acceptable.<sup>366</sup> Nor did the agency provide any elaboration of its responsibilities under section 112 or the legal basis for choosing a technology-based approach.<sup>367</sup> The EDF immediately challenged the rule on the grounds that section 112 was a pure health-based standard that prohibited consideration of costs and technology.<sup>368</sup> In its challenge, EDF sought to move EPA into alignment with the Generic Cancer Policy approach that OSHA was developing.

In the resulting settlement, EPA agreed to propose new, more stringent standards and to establish a goal of zero emissions.<sup>369</sup> The agency then proposed a new rule in June 1977, imposing a more stringent five ppm standard and embracing a goal of zero emissions, but it reiterated the view that a complete prohibition on emissions of non-threshold pollutants was not consistent with Congressional intent.<sup>370</sup> For the next seven years, EPA sat on the proposal and eventually withdrew it in 1985, an action that resulted in another lawsuit and, ultimately, a revision to section 112 as part of the 1990 Clean Air Act Amendments.<sup>371</sup> While the details of that episode are beyond the scope of this Article, what is important to recognize is that with vinyl chloride, EPA had embraced a more formal, quantitative approach to assessing risk—one that rested increasingly on the use of mathematical extrapolation models to develop specific risk estimates for individual substances as a means of bringing order to its burgeoning regulatory responsibilities.<sup>372</sup> Over time and under the

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365. *Id.*

366. See National Emission Standard for Hazardous Air Pollutants, Standard for Vinyl Chloride, 41 Fed. Reg. 46,560, 46,560 (Oct. 21, 1976).

367. *Id.*

368. See *NRDC v. EPA*, 824 F.2d 1146, 1149 (1987) (recounting history of the litigation on the vinyl chloride standard). See also David D. Doniger, *Federal Regulation of Vinyl Chloride: A Short Course in the Law and Policy of Toxic Substances Control*, 7 *ECOLOGY L. Q.* 497, 579–81 (1978) (discussing EDF challenge to EPA's vinyl chloride standard).

369. See *NRDC v. EPA*, 824 F.2d at 1149; Doniger, *supra* note 368, at 581–85 (discussing settlement).

370. See Vinyl Chloride, 42 Fed. Reg. 28,154, 28154 (June 2, 1977). As EPA put the matter:

In the absence of strong evidence to the contrary, then, the only level of vinyl chloride which would appear to be absolutely protective of health is zero, which may be achievable only by banning vinyl chloride emissions completely. That, in turn, would require closing the entire industry. As explained in the earlier rulemaking, it is not clear that Congress would have intended this result, so instead EPA required the lowest level achievable using technological means.

*Id.*

371. See *NRDC v. EPA*, 824 F.2d at 1149. These developments will be dealt with in a subsequent article.

372. EPA was moving down this same path at the same time in the context of its efforts to regulate toxic water pollutants under the Flannery Decree. See *supra* note 217; EPA, Water Quality

influence of greater public and judicial scrutiny, this approach would come to constrain the exercise of judgment that EPA had embraced in the early pesticide cases and that Judge Skelly Wright and others had held up as a technocratic ideal. Quantitative risk assessment was thus much more than a simple tool; it was a rationale and general approach to agency decision making that departed dramatically from earlier conceptions of expert judgment.

### 3. *Carcinogen Risk Guidelines*

During the same period that EPA was struggling to make sense of the vinyl chloride problem, it also released a set of “interim guidelines and procedures for carcinogen risk assessment” in an attempt to deal with an expanding universe of chemical carcinogens that implicated multiple statutory responsibilities.<sup>373</sup> The agency noted that regulatory action against carcinogens other than ionizing radiation was relatively recent, dating from the Delaney Clause of the late 1950s, and that the “no-threshold concept” for carcinogens that emerged during this time made it increasingly untenable to adopt a zero-risk approach:

In the debate over the health effects of radioactive fallout from atomic weapons in the 1950s, the evidence for a no-threshold concept for cancer induction emerged, which supported the idea that there is no such thing as a completely safe dose; in other words, any exposure, however small, will confer some risk of cancer on the exposed population. Evidence has accumulated that the no-threshold concept can be applicable to chemical carcinogens. On the basis of this concept, the first significant regulatory legislation relating to chemical carcinogens, the Delaney Clause of the Pure Food and Drug Act, imposed a complete ban on any food additive that showed evidence of tumorigenic activity for humans or animals. This statutory requirement represents the approach of eliminating all risk. However, it has become increasingly clear that in many areas risk cannot be eliminated completely without unacceptable social and economic consequences.<sup>374</sup>

As with ionizing radiation, “acceptable risk” appeared to offer a more viable approach to conceptualizing and regulating the potential harm associated with chemical carcinogens. “We thus have a comparable conceptual basis for the regulation of chemicals as for ionizing radiation where the philosophy has been to eliminate or reduce exposure to the greatest extent possible consistent with the acceptability of the costs involved.”<sup>375</sup> Any substance that “causes a

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Criteria Documents, 45 Fed. Reg. 79,318 (1980) (describing the quantitative procedures used in risk assessment for toxic water pollutants). *See also* NAT’L ACAD. SCI., DRINKING WATER AND HEALTH 27–59 (1977) (providing detailed description of risk assessment and its application to toxic water pollutants).

373. Health Risk and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21,402 (May 25, 1976).

374. *Id.* at 21,402–03.

375. *Id.* at 21,403.

statistically significant excess incidence of benign or malignant tumors in humans or animals” would be considered a “presumptive cancer risk.”<sup>376</sup> But the ultimate decision to regulate would be based on a detailed “risk benefit assessment,” an exercise that was automatic under FIFRA but one that would need to proceed on a priority basis under the Clean Air Act, Clean Water Act, and Safe Drinking Water Act. Finally, EPA Administrator Russell Train pointed to the administrative law implications of the new guidance: “In my opinion, the current guidelines represent a significant improvement in the Agency’s approach to the processes of decision making for carcinogens by providing improved procedures for making risks and benefit assessments for public review of the Agency’s deliberations.”<sup>377</sup> Here again, we see a reflection of the new view of expertise as embedded with a system of procedures that could be disciplined and standardized through administrative law and agency practice.

Viewed in retrospect, perhaps the most important practical aspect of this overall approach, and what distinguished it from OSHA’s efforts to develop a generic cancer policy, was that it contemplated—demanded in fact—a case-by-case, chemical-by-chemical approach to carcinogen risk assessment. EPA had started down a road that, while seeming to promise a more rigorous and objective basis for regulatory decision making, would come to consume enormous resources in the years ahead, without always generating definitive or timely results.<sup>378</sup>

#### 4. *Unreasonable Risk*

During this time, Congress also started to embrace a more self-conscious approach to risk. As early as 1972, in both the substantial overhaul of FIFRA and the newly enacted Consumer Products Safety Act, Congress employed the concept of “unreasonable risk” as the basic standard of protection.<sup>379</sup> The 1977 amendments to the Clean Water Act likewise framed the regulation of so-called non-conventional water pollutants partly in terms of acceptable risk.<sup>380</sup> And the

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376. *Id.*

377. *Id.*

378. See NRC, SCIENCE AND DECISIONS, *supra* note 3, at 3–4 (discussing problems with current chemical risk assessments).

379. See, e.g., Federal Environmental Pesticide Control Act of 1972, Pub. L. 92-516, 86 Stat. 973, 979 (Oct. 21, 1972) (defining “unreasonable adverse effects on the environment” as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide”); *id.* at 981 (establishing as requirement for registration that proper use of pesticide not cause unreasonable adverse effects on the environment); *id.* at 984 (employing “unreasonable adverse effects on environment” standard as basis for cancellation or change in classification); Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207, 1208 (Oct. 27, 1972) (declaring purposes of Act, including protection of “the public against unreasonable risks of injury associated with consumer products”).

380. See 33 U.S.C. § 1311(g)(2)(C) (2006) (giving EPA limited authority to control non-conventional pollutants that “may reasonably be anticipated to pose an unacceptable risk to human

1977 Clean Air Act amendments included references to “unreasonable risk” in some of the waiver provisions added to the new source performance standards in section 111.<sup>381</sup>

The most dramatic example of this shift in thinking, however, was the evolution of the legislation that culminated in passage of the 1976 Toxic Substances Control Act (TSCA).<sup>382</sup> The legislation grew out of the increased awareness during the 1960s and early 1970s that a single-media approach to environmental protection would never be sufficient to address the potential hazards associated with the large and growing universe of industrial chemicals.<sup>383</sup> As with pesticides and new drugs, these chemicals needed to be addressed in a separate, comprehensive statute that would generate the necessary health and safety information before allowing chemicals into commerce and provide tools to regulate their production, use, and distribution.<sup>384</sup> As Russell Train, Chairman of the Council on Environmental Quality (CEQ), remarked during the initial hearings on a toxic substances bill in 1971,

Our awareness of environmental threats, our ability to screen and test substances for adverse effects, and our capabilities for monitoring and predicting, although inadequate, are now sufficiently developed that we need no longer remain in a purely reactive posture with respect to chemical hazards. We need no longer be limited to repairing damage after it has been done; nor should we allow our population to be used as a laboratory for discovering adverse health effects. There is no longer any valid reason for continued failure to develop and exercise reasonable controls over toxic substances in the environment.<sup>385</sup>

Here was a strong endorsement of precaution as the foundation for new chemicals legislation.

The drafting of a new toxic substances control statute began in 1970, spearheaded by two staffers at the newly created CEQ, J. Clarence Davies and

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health or the environment because of bioaccumulation, persistency in the environment, acute toxicity, chronic toxicity (including carcinogenicity, mutagenicity or teratogenicity), or synergistic propensities”).

381. Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685, 701-02 (codified at 42 U.S.C. § 7411(k)(1)(A)).

382. See *Toxic Substances Control Act*, Pub. L. No. 94-469, 90 Stat. 2003 (1976). For an overview and some general background on TSCA, see David Markell, *An Overview of TSCA, its History and Key Underlying Assumptions, and its Place in Environmental Regulation*, 32 J. LAW & POL’Y 333 (2010).

383. See *The Toxic Substances Control Act of 1971 and Amendment, Hearings before the Subcomm. on the Environment of the S. Comm. on Commerce*, U.S. Senate, 92d Cong. 63–67 (1972) (testimony of Russell Train, Chairman, Council on Environmental Quality) (discussing growing public health threat posed by chemical hazards, inadequacies of existing environmental laws, and need for new comprehensive and systematic approach to controlling toxic substances).

384. See COUNCIL ON ENVTL. QUALITY, TOXIC SUBSTANCES iv–vii (1971) (discussing need for new legal authorities to deal with problem of toxic substances).

385. *The Toxic Substances Control Act of 1971 and Amendment, Hearings before the Subcommittee on the Environment of the Committee on Commerce*, U.S. Senate, 92d Cong. 66 (1972) (testimony of Russell Train, Chairman, Council on Environmental Quality).

Charles Lettow.<sup>386</sup> After considerable debate within the Administration, which Davies contends weakened the initial CEQ proposal, the President submitted a draft law to Congress in 1971.<sup>387</sup> Notwithstanding the compromises, the proposed legislation was simple and expansive, employing the language of endangerment and safety and giving EPA broad authority to require testing of chemicals in order to ensure the “protect[ion] of health and the environment.”<sup>388</sup> Unreasonable risk is nowhere to be found in the first several iterations of the proposed legislation, nor does it appear in any substantive way in the extensive legislative hearings that occurred during 1971 and 1972.<sup>389</sup> Some of the early amendments to the legislation, and a significant number of the witnesses who testified, also drew directly on past experiences with pesticides and new drugs, calling for express provisions in the law that would make it abundantly clear that chemical manufacturers had the burden of demonstrating safety before they would be allowed to sell their products.<sup>390</sup>

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386. See *The Toxic Substances Control Act: From the Perspective of J. Clarence Davies*, Interview Transcript at 10–12 (Chemical Heritage Society, 2009) (on file with author) (discussing early development of legislation at CEQ).

387. The Administration’s proposed bill is contained in COUNCIL ON ENVTL. QUALITY, THE PRESIDENT’S 1971 ENVIRONMENTAL PROGRAM 146–62 (1971). One of the most important gaps in the new legislation, as initially introduced (and ultimately enacted), was the fact that the testing requirements applied only to chemicals that were produced in commercial quantities *after* the date of enactment, leaving many tens of thousands of chemicals effectively unregulated—a fact that continues to plague chemicals regulation.

388. See *The Toxic Substances Control Act of 1971 and Amendment, Hearings before the Subcomm. on the Environment of the S. Comm. on Commerce*, 92d Cong. 4 (1972) (citing section 201 of Senate Bill 1478: “[I]t is the policy of the United States . . . that such authority over chemicals be exercised in such a manner as not to unduly impede technological innovation while fulfilling the primary purpose of this title to assure that such innovation and commerce does not endanger human health or the environment.”); *id.* at 12–13 (citing section 205 of Senate Bill 1478, which required the administrator to “prescribe by regulation standards for test protocols, and for the results to be achieved therefrom, as are necessary to protect human health and the environment” from various classes and uses of chemicals). The impetus for the legislation came from the newly established Council on Environmental Quality (CEQ). In 1970, CEQ staff members J. Clarence Davies and Charles L. Lettow drafted a strong toxic substances bill that met stiff resistance from the Department of Commerce and OMB. In an oral history interview with Davies conducted by the Chemical Heritage Foundation, Davies observed that the bill was weakened considerably *before* it was even introduced on Capitol Hill, with new legal and procedural hurdles added. See *The Toxic Substances Control Act: From the Perspective of J. Clarence Davies*, Interview Transcript at 10–12 (Chemical Heritage Society, 2009) (on file with author).

389. See *The Toxic Substances Control Act of 1971 and Amendment, Hearings before the Subcomm. on the Environment of the S. Comm. on Commerce*, 92d Cong. (1972); *Toxic Substances Control Act, Hearings before the Subcomm. on Commerce and Finance of the H. Comm. on Interstate and Foreign Commerce*, 92d Cong. (1972).

390. See, e.g., *The Toxic Substances Control Act of 1971 and Amendment, Hearings before the Subcomm. on the Environment of the S. Comm. on Commerce*, 92d Cong. 31 (1972) (citing amendment from Senator Spong stating in section 201 of TSCA that testing of new chemicals “should be the responsibility of those who produce such chemicals”); *id.* at 116 (statement of Louise Dunlap, Friends of the Earth) (arguing in favor of imposing responsibility for testing new and potentially hazardous existing chemicals on manufacturers); *id.* at 137 (statement of William H. Rodgers, University of Washington School of Law) (“It is indisputable that the burden of proving that the benefits derived from use exceed the risks should be on the manufacturer. The legislation should be explicit in slamming the door on



Over the next five years, however, the focus of the statute evolved to “unreasonable threat” and then, finally, to “unreasonable risk,” and the burden was shifted decisively to EPA to demonstrate that a particular chemical posed an unreasonable risk before issuing any testing requirements and before regulating the production, use, or distribution of any individual chemical substance.<sup>391</sup> During the floor debates that accompanied passage of the final legislation, it was made very clear that these changes were intended to avoid over-regulation and to constrain any “arbitrary action on the part of EPA.”<sup>392</sup> As several participants in the legislative debates pointed out, moreover, these changes reflected in part (perhaps significant part) the concerted efforts of the chemical industry to shape the legislation—a sign of the increasing

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future efforts to assure operational annihilation of this generally accepted premise); *id.* at 140 (testimony of Karin Sheldon, Public Interest Research Group) (“Manufacturers must bear the burden of testing, of showing that something is safe before it is permitted to go into the market.”). It is interesting to note, however, that several witnesses were concerned about the potential conflicts of interest that might arise from requiring industry to test its own chemicals. *See, e.g., id.* at 111 (statement of Harrison Wellford, Center for Responsive Law).

391. *See Toxic Substances Control Act of 1973, Hearings before the Subcomm. on the Environment of the Comm. on Commerce*, 93d Cong. 3–4, 12–13 (1973) (reproducing draft legislation (S. 426) framing policy rationale and standard for regulating toxic substances in terms of “unreasonable threat to human health or the environment”); *Toxic Substances Control Legislation—1973, Hearings before the Subcomm. on Commerce and Finance, Comm. on Interstate and Foreign Commerce*, 93d Cong. 3, 11–12 (1973) (reproducing draft legislation (H.R. 5087) framing regulation of toxic substances in terms of endangerment and unreasonable threat). As finally enacted in 1976 (and the bill passed largely because of the additional pressures that resulted from the heavily publicized Kepone disaster on the James River and an imminent new Democratic administration), the new legislation required the EPA to find “unreasonable risk” before doing anything. *See, e.g.*, 15 U.S.C. § 2601(b)(2), (3) (2006) (“It is the policy of the United States that . . . adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment.”); *id.* § 2603(a) (requiring finding of “unreasonable risk” as basis for testing requirements); *id.* § 2605(4) (requiring finding of “unreasonable risk” as basis for regulation of hazardous chemical substances or mixtures); *see also* Applegate, *supra* note 4 (discussing importance of unreasonable risk standard under TSCA); J. CLARENCE DAVIES, SAM GUSMAN & FRANCES IRWIN, DETERMINING UNREASONABLE RISK UNDER THE TOXIC SUBSTANCES CONTROL ACT 23 (1979) (noting that the term unreasonable risk appears 38 times in TSCA, half of which occur in sections 5 and 6 which provide for premanufacture notifications for new chemicals and regulation of chemicals).

392. *See, e.g., House Consideration of Conference Report on S. 3149, Toxic Substances Control Act*, 1 LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT TOGETHER WITH A SECTION-BY-SECTION INDEX 741, 742 (1976) (statement of Rep. Broyhill) (“The general standard for taking action under this legislation is that the substance may present an unreasonable risk. The conferees intend to limit the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that Congress does not make. Although the authorities granted to EPA are extremely broad, the conferees have made a concerted effort to include in the conference report safeguards against arbitrary action on the part of EPA.”) *see also 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, 738 (1976) (statement of Sen. Durkin) (discussing constraints imposed on EPA in new legislation and noting that “[h]opefully next year, with the cooperation of a Democratic President the Congress will put the shoe where it really belongs, and require the chemical companies to prove all their products are safe for future generations of Americans before proving they are safe for this generation of stockholders”).

politicization of environmental law during the fractured decade of the 1970s and the growing influence of professional lobbying operations.<sup>393</sup>

Thus, in several of its initial manifestations, TSCA embraced the earlier, more precautionary thrust of the Clean Air and Clean Water Acts, employing the language of endangerment and safety and giving EPA fairly broad authority to require the testing necessary to protect human health and the environment. By the time of enactment, however, EPA bore the burden of establishing whether an individual chemical substance posed an “unreasonable risk” *before* it could require testing, much less regulate, and the whole issue of generating health and safety information for the tens of thousands of chemicals already in commerce had been taken off the table.<sup>394</sup> Going forward, this basic fact of “toxic ignorance,” combined with the substantive burdens and procedural hurdles that TSCA imposed on EPA, rendered the statute grossly inadequate, providing the motivation for ongoing calls to reform what some observers view as the least effective of all U.S. environmental laws.<sup>395</sup>

The implications of TSCA’s shift from endangerment to unreasonable risk thus went well beyond word choice, signaling an important reorientation by Congress toward notions of acceptable risk that would come to inform major legislative and regulatory efforts in the years ahead.<sup>396</sup> Whereas the earlier language of endangerment trained attention to the actors and activities that

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393. 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”); *Senate Consideration of S. 3149*, 1 LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT: TOGETHER WITH A SECTION-BY-SECTION INDEX 207, 210 (1976) (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 (“[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 219–20 (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”).

394. EPA estimated that there were more than 60,000 chemicals in commerce at the time of TSCA’s enactment.

395. See, e.g., NAT’L RESEARCH COUNCIL, TOXICITY TESTING 84, tbl.7 (1984) (reporting that 78% of the chemicals in U.S. commerce with production volume of 1 million pounds or more per year lacked even “minimal toxicity information”); EDF, TOXIC IGNORANCE: THE CONTINUING ABSENCE OF BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE US 15 (1997) (finding that more than 70% of high production volume chemicals in the U.S. do not meet the minimum data requirements for health hazard screening set by the Organization for Economic Cooperation and Development Chemicals Program); see also Richard Denison, *Ten Essential Elements in TSCA Reform*, 39 ENVTL L. REP. 10,020 (2009) (criticizing TSCA and discussing various elements of TSCA reform); Lynn R. Goldman, *Preventing Pollution? U.S. Toxic Chemicals and Pesticides Policies and Sustainable Development*, 32 ENVTL L. REP. 11,018 (2002) (same); Sachs, *supra* note 5 (same).

396. In a somewhat ironic twist, this new standard would be invoked in later years as a rationale for redefining safety as acceptable risk in the context of the hazardous air pollutant provisions of the Clean Air Act. See *NRDC v. EPA*, 824 F.2d 1146, 1163 (D.C. Cir. 1987).

were imposing hazards on the public, unreasonable risk suggested that the public should only be allowed to regulate the underlying activity if the associated risks were deemed to be unacceptable, translating almost seamlessly into a balancing of costs and benefits that some observers argued tilted all too easily in favor of industry. This change in language also reflected a very different posture toward uncertainty and the possibility of knowledge regarding complex and emerging environmental hazards. Unreasonable risk, and the balancing that it entailed, demanded a degree of quantification and precision that was largely absent in the earlier conceptions of endangerment. There was an assumption, in other words, that risks could be quantified and understood sufficiently in order to run them through a risk-benefit analysis as a prerequisite for regulation. The previously held conviction that the whole enterprise of assessing these sorts of environmental hazards was operating on the frontiers of scientific knowledge, that uncertainty was a basic, irreducible fact of any such exercise, had largely given way. In the process, expert judgment and agency discretion were replaced with a much more constrained and disciplined approach to agency decision making that was increasingly embedded in new structures of accountability. Finally, in concert with all of these trends, the shift in language signaled in important ways the rise of professional advocacy and lobbying efforts and the increasingly adversarial nature of environmental politics.

At a more basic level, these developments also drew on a broader set of trends that had been underway for some time, further validating and supporting the embrace of risk thinking across health, safety, and environmental regulation. Beginning in the late 1960s, systematic thinking about risk within the framework of decision theory and expected utility began to influence those interested in technology assessment and environmental protection,<sup>397</sup> and leading professionals at EPA and other agencies began to discuss more formal approaches to risk within these frameworks.<sup>398</sup> Research on risk perception during this time also gained considerable currency as the emerging class of risk professionals sought to understand why “ordinary people” failed to see risks in the way that experts did—a reaction to the growing formalization of risk and the elevation of expert epistemology as well as the pressing need to understand why some risks remained “unacceptable” despite what the numbers indicated.<sup>399</sup> In all of this, acceptable risk was becoming the baseline against which efforts to evaluate hazards would proceed, a development that would feed directly into efforts during the 1980s to elaborate a more comprehensive

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397. See, e.g., Chauncey Starr, *Social Benefit versus Technological Risk*, 165 *SCIENCE* 1232 (1969) (developing formal basis for comparing and evaluating acceptability of different risks).

398. See, e.g., William D. Rowe, EPA, *The Anatomy of Risk* (1975) (providing extensive discussion of risk assessment in the context of decision theory and expected utility).

399. See, e.g., Starr, *supra* note 397; LOWRANCE, *supra* note 15; FISCHHOFF, *supra* note 23; MARY DOUGLAS, *RISK ACCEPTABILITY ACCORDING TO THE SOCIAL SCIENCES* (1986).

framework for comparative risk assessment, and reflecting a much more self-conscious effort to rationalize and constrain agency decision making.<sup>400</sup>

#### IV. GOVERNING THE FUTURE

The move to acceptable risk thus promised a new framework for evaluating different types of hazards, one that seemed to require the application of quantitative risk assessment as a tool for developing more precise risk estimates and one that translated seamlessly into a larger framework of cost-benefit analysis. By bringing the future into the present and making it calculable, by transforming external hazards into consequences of collective decisions, risk worked to socialize hazards and subject them to a more objective exercise aimed at prioritizing the allocation of scarce regulatory resources. This new form of “equivalence” brought with it new forms of sociability and new relations between citizens and the regulatory state.<sup>401</sup> By making hazards a product of our collective actions, risk assessment also highlighted the differences between “expert” and “lay” understandings of risk, giving rise to a robust and growing literature on risk perception. This new and growing appreciation for the ways in which different groups of people perceived risk in turn fed back into the regulatory process and the broader effort to subsume risk within the framework of expected utility.<sup>402</sup>

By the early 1980s, efforts to formalize the practice of risk assessment and marry it to risk management in a single framework were in full swing.<sup>403</sup> This was a period of almost hyper-formalism, marked by the strong endorsement of quantitative risk assessment as a basis for agency decision making and driven in part by the dramatic push for regulatory reform that gained traction during the first Reagan administration.<sup>404</sup> There was a decisive retreat from the earlier technocratic ideal toward a more disciplined and constrained administrative law

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400. See Hornstein, *supra* note 5.

401. See Graham & Wiener, *supra* note 20, at 33 (discussing challenges of comparing certain kinds of risks, but noting that “it is chiefly our lack of methods of comparison—of ways of seeing commonality among these risks—that makes these risks seem ‘dissimilar’ or noncomparable, not an inherent incommensurability”); William Boyd, *Ways of Seeing in Environmental Law: How Deforestation Became an Object of Climate Governance*, 37 *ECOLOGY L.Q.* 843, 911–15 (2010) (discussing role of various technologies of equivalence, including risk assessment and cost-benefit analysis, in environmental law).

402. See, e.g., LOWRANCE, *supra* note 15; Hornstein, *supra* note 5.

403. See, e.g., NRC, *RISK ASSESSMENT*, *supra* note 2 (proposing formal framework of risk assessment and risk management).

404. See, e.g., THOMAS O. MCGARITY, *REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY* xiv–xv (1991) (discussing regulatory reform movement of the early 1980s); William H. Rodgers, Jr., *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 *HARV. ENVTL. L. REV.* 191, 191 (1980) (discussing push for more “efficient” regulation through use of tools such as cost-benefit analysis as part of broader regulatory reform movement of the late 1970s and early 1980s); James P. Leape, *Quantitative Risk Assessment in Regulation of Environmental Carcinogens*, 4 *HARV. ENVTL. L. REV.* 86, 87–88 (1980) (discussing push for quantitative risk assessment by regulatory reform advocates as an essential input for cost benefit analysis).

of risk elaborated through judicial decisions, a series of Executive Orders, more pervasive involvement of the Office of Management and Budget, and ever more detailed guidelines that sought to establish a systematic approach to default assumptions and inference choice in the practice of risk assessment for cancer and various other endpoints.<sup>405</sup>

In many respects, this new way of thinking received its biggest boost from the Supreme Court in its 1980 decision *Industrial Union Department, AFL-CIO v. American Petroleum Institute*—known to virtually all students of U.S. environmental law as the *Benzene* decision.<sup>406</sup> In rejecting OSHA's proposed benzene standard, which had been developed in a manner consistent with the agency's generic cancer policy, a plurality of the Supreme Court imposed a new threshold requirement that OSHA make a finding of "significant risk" before establishing any such standard.<sup>407</sup> *Benzene* thus marked a dramatic break with the past, bringing an end to OSHA's efforts to develop a generic cancer policy that would allow the agency to move quickly on suspected carcinogens, and providing a strong endorsement, if not a mandate, that agencies involved in health, safety, and environmental regulation base their decisions to regulate on findings of significant risk.<sup>408</sup> Despite the plurality's statements that such findings did not have to proceed in any particular manner—that the determination of significant risk was "not a mathematical straightjacket"<sup>409</sup>—most observers took the case to require some form of quantitative risk assessment in order to justify regulation.<sup>410</sup> This was a very different posture than that endorsed by those favoring a more precautionary approach.

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405. See, e.g., Executive Order 12866, Regulatory Review, 58 Fed. Reg. 51,735 (Sept. 30, 1993) (establishing principles for regulation, including risk assessment, impact analysis, and cost-benefit analysis); Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (Sept. 24, 1986) (setting forth principles and procedures to guide EPA personnel in the conduct of carcinogen risk assessments); Guidelines for Mutagenicity Risk Assessment, 51 Fed. Reg. 34,006 (Sept. 24, 1986) (setting forth principles and procedures to guide EPA personnel in the conduct of risk assessments for mutagens); Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 Fed. Reg. 34,014 (Sept. 24, 1986) (setting forth principles and procedures to guide EPA personnel in the conduct of risk assessments for chemical mixtures). See also Robert V. Percival, *Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency*, 54 LAW & CONTEMP. PROBS. 127 (1991) (discussing White House review of EPA programs); Shelia Jasanoff, *Science, Politics, and the Renegotiation of Expertise at EPA*, 7 OSIRIS 194, 203-17 (1992) (discussing EPA's effort to develop "principles" to guide its risk assessment efforts and, during the 1980s, its increasing reliance of satellite scientific bodies for expertise and peer review).

406. *Indus. Union Dep't., AFL-CIO v. Am. Petroleum Inst. (Benzene)*, 448 U.S. 607 (1980); see also Thomas O. McGarity, *The Story of the Benzene Case: Judicially Imposed Regulatory Reform through Risk Assessment*, in ENVIRONMENTAL LAW STORIES (Lazarus & Houck eds., 2005).

407. *Benzene*, 448 U.S. 607, 653; see also McGarity, *supra* note 406, at 154-56.

408. See McGarity, *supra* note 406.

409. *Benzene*, 448 U.S. at 655.

410. *Id.*; see also McGarity, *supra* note 406 (describing *Benzene* as "a critical inflection point in the historical flow of U.S. environmental law").

In repudiating OSHA's efforts to develop a generic cancer policy, the *Benzene* plurality thus signaled the end of the Delaney era. Although it would take well into the 1990s to fully complete this, *Benzene* made it clear that the robust view of precaution in the face of uncertainty advanced during the early to mid-1970s was no longer viable. As the plurality opinion pointed out, safety could no longer be defined as "risk free."<sup>411</sup> It was time to grow up and face the reality of a world that would never be rid of environmental harms and take on the tough choices of how best to allocate scarce regulatory resources. By enshrining a new threshold requirement of "significant risk," the decision unleashed efforts across the regulatory state to complete the transformation of health, safety, and environmental decision making into a formal, quantitative exercise.

These developments, which cannot be treated in any detail in this Article, seemed to go well beyond the hard look that Judges Leventhal, Bazelon, and others had been developing in some of the early environmental cases.<sup>412</sup> As such, they represented a triumph through administrative law of a particular view of knowledge (and the possibility of such knowledge), marking a definitive end to the New Deal-inspired approach to health, safety, and environmental regulation that put faith in expert regulators, placed a premium on the exercise of pragmatic judgment, and sought to develop relatively simple approaches to uncertainty. Henceforth, the political environment would turn increasingly hostile to regulation. Regulatory reform became the new mantra for those seeking to rein in wayward agencies and bring an increasingly fashionable economic discipline to the enterprise.<sup>413</sup> As a tool for bringing the future into the present and making it calculable, risk had come to govern much of the future of health, safety, and environmental law. In the process, the uncertainty that had been so prominent in prior years was increasingly pushed to the margins.

Indeed, despite the constant call for more attention to uncertainty in virtually every official statement on risk assessment since the early 1980s, the response has almost always been directed at ways of measuring and managing uncertainty; that is, of making it look more like risk.<sup>414</sup> This triumph of risk

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411. *Benzene*, 448 U.S. at 642 ("The word 'safe' does not mean 'risk free'").

412. See, e.g., *EDF v. Ruckelshaus*, 439 F.2d 584, 593 (D.C. Cir. 1971) (Bazelon, J.); *EDF v. EPA*, 465 F.2d 528, 541 (D.C. Cir. 1972) (Leventhal, J.); see also Daniel R. Ernst, *Law and the State, 1920-2000*, in 3 *THE CAMBRIDGE HISTORY OF LAW IN AMERICA* 26 (Grossberg and Tomlins eds., 2008) (discussing the rise of "hard look" review in the 1970s and the debate between Judge Bazelon and Judge Leventhal on procedural versus substantive hard look review—a debate that was resolved with the Supreme Court's 1978 *Vermont Yankee* decision that rejected Judge Bazelon's procedural approach in favor of Judge Leventhal's substantive hard look).

413. See Ernst, *supra* note 412, at 27 ("The early 1970s would prove to be the high-water mark of the federal administrative state in the twentieth century. Thereafter the regulatory environment turned increasingly hostile.").

414. See, e.g., NRC, *RISK ASSESSMENT*, *supra* note 2; NRC, *SCIENCE & JUDGMENT IN RISK ASSESSMENT* (1994); NRC, *SCIENCE & DECISIONS*, *supra* note 3.

over uncertainty reflected broader trends in post-World War II economics and social science, manifest in the rise of formal decision theory, the influence of operations research on organization thinking, and the incorporation of risk into the framework of expected utility.<sup>415</sup> In a world where formal, quantitative models were fast becoming the standard for rigorous, objective knowledge, uncertainty had no real place.<sup>416</sup> For environmental law, the move from uncertainty to risk represented a departure from a more situated, pragmatic approach to regulation to one dominated by expert systems and premised on calculability and control.<sup>417</sup> “Regulating from nowhere,” to use Douglas Kysar’s evocative phrase, became the technocratic ideal.<sup>418</sup>

Thus, except for some vestigial echoes in existing statutes and the use of conservative assumptions in various steps of the risk assessment process, the world in which endangerment and precaution were plausible alternatives to risk seemed to have passed by the 1990s. Risk could no longer be differentiated from the institutions and the practices that administered its intellectual and material deployment. Disenchantment had been relentlessly set in motion and the limits of earlier precautionary stances became an accepted fact for much of mainstream environmental law.

Or so it seemed. Since the 1990s, attention to the limits of risk assessment and the importance of uncertainty has moved back from the margins to the center of established thinking about risk. As a recent 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 confronted an increasingly complex and unpredictable world of environmental harms.<sup>419</sup> “Uncertainty,” according to the study, “continues to lead to multiple interpretations and contribute to decision making gridlock.”<sup>420</sup> Thus, major risk assessment exercises for formaldehyde, trichloroethylene, and dioxin have been going on for decades, with many thousands of additional chemicals waiting in the queue.<sup>421</sup> In the

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415. See Pat O’Malley, *Uncertain Subjects: Risks, Liberalism, and Contract*, 29 *ECON. & SOC’Y* 460, 462–66 (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); Hornstein, *supra* note 5 (discussing role of expected utility in providing theoretical basis for comparative risk assessment).

416. See Hodgson, *supra* note 415.

417. See Jasanoff, *Songlines of Risk*, *supra* note 6, at 144–45 (discussing impacts of quantitative risk assessment and other “reductive techniques” on broader understandings of uncertainty).

418. See KYSAR, *supra* note 5.

419. See *SCIENCE AND DECISIONS*, *supra* note 3, 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.”).

420. See *SCIENCE AND DECISIONS*, *supra* note 3, at 4.

421. *Id.* at 3–4, 17.

case of the dioxin risk reassessment, although multiple extrapolation models appear to fit the data equally well, they generate risk estimates that vary by three orders of magnitude.<sup>422</sup> More fundamentally, the entire exercise of determining whether the risk of exposure to a particular carcinogen is “significant”—that it exceeds the one-in-one million threshold, to take the most commonly accepted measure of significance—suggests the possibility of precise quantification and relatively simple classification of risks despite the fact that the threshold itself, as various commentators have observed, can be calculated in an almost infinite number of ways depending, for example, on the choice of animal studies, interpretation of tissue samples, animal-to-human extrapolation methods, exposure data, and assumptions about exposure pathways.<sup>423</sup> And, of course, the practice of chemical risk assessment has only just started to address the many non-cancer risks associated with industrial chemicals such as endocrine system disruption, neurodevelopmental effects, the complexities of multiple, cumulative exposures, the special sensitivities of vulnerable populations, and so on. To say nothing of novel technologies such as synthetic biology or nano-scale engineering or complex global problems such as climate change.<sup>424</sup>

It is, of course, easy enough to criticize the shortcomings of risk assessment, much harder to come up with an alternative. Given the momentum embedded in risk thinking, there appear to be few if any viable alternatives waiting in the wings ready to serve as a basis for collective decision making. It is hard not to be impressed, moreover, by the sophisticated apparatus that we have built to assess the risks of industrial society. And it would be folly to suggest that objectivity, viewed less as some sort of end state than as an epistemic virtue to be realized in practice, should be abandoned as an

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422. See, e.g., Peter C. Wright et al., *Twenty-Five Years of Dioxin Cancer Risk Assessment*, 19 NAT. RESOURCES & ENV'T 31, 35 (2005) (discussing range of cancer risk estimates for dioxin using different standards and guidelines for extrapolation from same data).

423. See SCIENCE AND DECISIONS, *supra* note 3, at 113–19 (discussing uncertainty and variability in various components of risk assessment); JOHN WARGO, OUR CHILDREN'S TOXIC LEGACY: HOW SCIENCE AND LAW FAIL TO PROTECT US FROM PESTICIDES 111–12 (1996) (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.).

424. The D.C. Circuit's recent decision upholding EPA's endangerment finding for greenhouse gases and rejecting efforts by challengers to require a quantitative determination of the threshold at which greenhouse gases endanger public health is instructive. Citing *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (en banc), and pointing to the substantial record of scientific evidence on the effects of climate change, the court noted that EPA's “failure to distill this ocean of evidence into a specific number at which greenhouse gases cause ‘dangerous’ climate change is a function of the precautionary thrust of the [Clean Air Act] and the multivariate and sometimes uncertain nature of climate science, not a sign of arbitrary and capricious decision making.” *Coal. for Responsible Regulation, Inc. v. EPA*, 684 F.3d 102, 123 (D.C. Cir. 2012). On nanotechnology, see David A. Dana, *The Nanotechnology Challenge*, in *THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS* 6–7 (David A. Dana ed., 2012) (arguing for “a more flexible, adaptive, and fluid model” for regulating nanotechnology that avoids the problems of a strong precautionary model as well as those of the more reactive, risk-based approach).



organizing principle for thinking about hazards.<sup>425</sup> As a distinctive form of knowledge crucial to the rise of modern society, risk thinking migrated with relative ease into new areas, offering a new, objective basis for health and environmental decision making and lining up with deep-seated tendencies of bureaucratic rationality. Part of its success as a modern abstract form of knowledge—decontextualized, formally neutral, mobile—surely stemmed from its efficacy in translating external hazards into the possibility of future loss, but with an implicit commitment to the possibility of future gains as well.

But does this also mean that risk must be the basis for how we organize health and environmental decision making; for how we make choices about the environmental and human damage associated with our current economic order; for how we deal with the prospect of continued degradation and disruption of the biophysical conditions necessary to support life? Given the problems confronting risk assessment and its notable deficiencies in the face of a rapidly expanding and increasingly complex set of challenges, it seems important and fair, even prudent, to take a critical look at what we have learned from the experience and to ask whether the way forward is to double-down and push harder or to step back and try to change course. In doing so, we would do well to look back at some of the paths not taken and, in any event, to remember that what ultimately matters is not the body count, the statistics, the trends, but the contingent, singular genealogies of real people living real lives in real places with their distinctive exposure histories and body burdens—their lives (our lives) transformed in subtle and not so subtle ways by the industrial hazards that impinge upon so many aspects of contemporary life, albeit in deeply uneven ways, and by the manner in which those hazards and their effects are subsumed within the standardized, abstract rubric of risk.

#### CONCLUSION

*We live only by knowing something about the future; while the problems of life, or of conduct at least, arise from the fact that we know so little.*

—Frank Knight, *Risk, Uncertainty, Profit*<sup>426</sup>

“Environmental law,” Judge Leventhal wrote in one of the early pesticide cases, “marks out a domain where knowledge is hard to obtain and appraise.”<sup>427</sup> As much as any other area of law, the field has always faced difficult challenges in acquiring knowledge of the specific problems that it seeks to regulate and translating that knowledge into regulatory practice. Operating at the “frontiers of scientific knowledge,” regulators have had to develop frameworks and tools for making decisions in the context of significant

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425. See LORRAINE DASTON AND PETER GALISON, OBJECTIVITY 39–42 (2007) (discussing objectivity as an epistemic virtue in scientific inquiry).

426. KNIGHT, *supra* note 54, at 199.

427. *EDF v. EPA*, 465 F.2d 528, 541 (D.C. Cir. 1972).

uncertainty, even ignorance.<sup>428</sup> This basic, irreducible fact of uncertainty was a constant refrain in efforts to protect workers, public health, and food quality during the middle decades of the twentieth century and it carried over into the formative years of environmental law during the early to mid-1970s. As Judge Wright observed in the famous *Ethyl Corp.* case, “Questions concerning the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable.”<sup>429</sup>

Not surprisingly, many of the early environmental statutes put the problem of knowledge at the center of their regulatory regimes, seeking ways to force the generation of new information about the problems at issue, embracing particular regulatory triggers and standards that reflected certain assumptions about the state of knowledge regarding those problems, and requiring margins of safety as a way of dealing with uncertainty.<sup>430</sup> To be sure, much of this proved to be inadequate, perhaps even naïve, when faced with the true challenges of securing environmental knowledge. But the premise was sound, and the enterprise itself was folded into a flexible, pragmatic approach to using knowledge, however incomplete, to get on with the hard work of environmental regulation.

As this Article has demonstrated, these efforts drew on a longer history stretching back to the middle decades of the twentieth century and before—one that saw similar challenges confronting efforts to operationalize safety in the context of public health, industrial hygiene, and food safety. In each of these areas, moreover, efforts to regulate were often marked by a healthy respect for uncertainty and a view that knowledge of particular hazards was provisional, contingent, and always incomplete. Without question, there were plenty of examples of grossly inadequate legislative and regulatory responses to the proliferating hazards of industrial society, but there were also strong

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428. See, e.g., *Indus. Union Dep’t, AFL-CIO v. Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974); *Ethyl Corp. v. EPA*, 541 F.2d 1, 71–72 (D.C. Cir. 1976) (en banc) (“Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.”).

429. *Ethyl Corp.* 541 F.2d at 61.

430. Examples include the environmental assessment and impact statement provisions of the National Environmental Policy Act (NEPA), 42 U.S.C. § 4332 (2006); the provisions regarding criteria documents and review and revision of the NAAQS under the Clean Air Act, 42 U.S.C. §§ 7408–7409 (2006); the various margin of safety requirements in the Clean Air, 42 U.S.C. §§ 7409(b)(1), 7412(d)(4) (2006), and Clean Water, 33 U.S.C. §§ 1313(d)(1)(A), 1317(a)(4) (2006) Acts; testing and data requirements for pesticide registration under FIFIRA, 7 U.S.C. §§ 136a to a-1 (2006); the testing, pre-manufacturing notices, and new use requirements under TSCA, 15 U.S.C. §§ 2603–2604, 2608–2609 (2006). The Senate Commerce Committee Report on one of the early versions of TSCA, made the point explicit: “It is the object of this legislation to provide knowledge of those [potential health and environmental problems associated with new chemicals] before the substance is introduced into the environment, rather than at some later date as is all too frequently the case now.” U.S. S. COMMERCE COMM., REPORT ON TOXIC SUBSTANCES CONTROL ACT OF 1972, S. DOC. NO. 1478 (1976).

precautionary impulses that sometimes found their way into actual law. Thus, one can draw a direct line from the pioneering work of Alice Hamilton and Wilhelm Hueper in industrial hygiene through the Delaney Clause, EPA's early pesticide cancellations, the precautionary thrust of the Clean Air and Clean Water Acts, the rulings of the D.C. Circuit and other appellate courts in many of the early environmental cases, and OSHA's quest for a generic cancer policy, among others. What all of these efforts shared was an underlying theory or approach to knowledge marked by humility and a faith in the exercise of human judgment.<sup>431</sup>

By the second half of the 1970s, this ideal was fading fast, giving way to a different theory of knowledge, one that drew on trends that had also been underway for decades and one premised on a more muscular, confident view that environmental hazards could, and should, be subjected to quantitative risk assessment. In some respects, this shift comported with efforts by certain segments of industry to push for more rigor in environmental decision making as a means of slowing down and contesting the regulatory process as well as with the growing enthusiasm for the concepts and tools of welfare economics. But it also stemmed from a conviction that quantitative risk assessment provided the most defensible approach to dealing with a much more complicated world that had been brought into view by the revolution in analytical techniques that occurred during the late 1960s and early 1970s. Quantitative risk assessment, like cost-benefit analysis and other efforts to render decision making more technical and quantitative, offered a key "technology of distance" for regulators seeking to insulate their decisions from the increasingly rough push-and-pull of politics.<sup>432</sup> One suspects (and this is largely speculation) that at least some of those who experienced the transition were sympathetic to the earlier technocratic ideal; that they perhaps recognized the continuing merits of a less constrained, more pragmatic approach to regulating risk. Maybe. But it would also be a mistake, it seems, not to acknowledge how difficult it would be to maintain the earlier approach in the face of a much more complex set of hazards and a growing culture of

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431. Cf. Shelia Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 MINERVA 223, 227 (2003) (arguing for the adoption of "technologies of humility," which she characterizes as "methods, or better yet, institutionalized habits of thought, that try to come to grips with the ragged fringes of human understanding—the unknown, the uncertain, the ambiguous, and the uncontrollable").

432. See PORTER, *supra* note 51, at ix (discussing role of quantification as a "technology of distance" that minimizes the need for "intimate knowledge and personal trust" and is "well suited for communication that goes beyond the boundaries of locality and community"); see also Lazarus, *supra* note 36, at 87–91 (discussing significant and growing distrust of EPA by multiple constituencies during 1970s); Shelia Jasanoff, *Acceptable Evidence in a Pluralistic Society*, in ACCEPTABLE EVIDENCE: SCIENCE AND VALUES IN RISK MANAGEMENT 43–44 (Mayo & Hollander eds., 1991) ("In the United States, then, the use of quantitative risk analysis can be seen as a response to the exceptionally exposed position in which regulatory agencies are placed.").

adversarialism and distrust.<sup>433</sup> How many Skelly Wrights can one expect to have in any single generation?

Depending on one's normative leanings, one might view this transition to hard-path risk assessment as progress—a triumph of utilitarian thinking in forging a coherent basis for regulating harms in a world of limited resources through a more accountable and rigorous exercise in administrative law; or as tragedy—a deathblow to the strong precautionary impulse that animated early U.S. environmental law through a less overt but more fundamental form of regulatory capture. As noted, that debate is well rehearsed and vitally important to the future of environmental law, but it has not been my primary concern. This Article has focused more on understanding the conditions of possibility for different ways of thinking about safety, hazard, and risk and how they got incorporated into efforts to organize and mobilize the institutional capacities of the administrative state to govern the hazards of industrial society.

One of the defining features of this transition, as noted earlier, was the displacement of incalculable uncertainty by calculable risk—a shift that paralleled in some respects a similar transition in economics and other fields during the middle decades of the twentieth century.<sup>434</sup> In looking back at this aspect of this long and complicated history, however, it seems that the simple Knightian distinction between risk and uncertainty may not be as useful as some suggest.<sup>435</sup> In health, safety, and environmental law, the move to quantitative risk assessment was underwritten largely by a set of techniques that allowed scientists and regulators to go beyond experience; that is, the various extrapolative techniques that were deployed to understand potential hazards and the risk estimates that resulted could hardly be considered the kind of actuarial risk that Knight and others were thinking about.<sup>436</sup> Perhaps then it would be better to focus on the range of calculative practices that are being deployed to govern the future in these areas, and the nature and limits of specific knowledge claims entailed by these practices. In doing so, we would do well to recall Max Weber's admonition that even if we can, in principle,

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433. See Lazarus, *supra* note 36, at 87 (“The legal area of environmental protection came to be dominated by unkept promises and the promotion of a culture within that area dominated by adversarialism, polarization, and distrust.”).

434. See Hodgson, *supra* note 415; see also JAMES C. SCOTT, SEEING LIKE A STATE: 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.”).

435. Cf. Posner, *supra* note 54; Sunstein, *supra* note 54.

436. 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. 28,331, 28,344 (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.”).

master all things by calculation, this tells us nothing at all about “whether it ultimately makes sense to do so.”<sup>437</sup>

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437. Weber, *supra* note 1, at 144.

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