DEATH V. TAXES: AGENCY APPROACHES TO SETTING SAFETY GOALS USING RISK MANAGEMENT IN AN EVOLVING LEGAL ENVIRONMENT

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"Scientists assess a risk to find out what the problems are. The process of deciding what to do about the problems is risk management."[1]

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1 U.S. ENVTL. PROT. AGENCY, EPA 600 9-85-002, RISK ASSESSMENT AND MANAGEMENT: FRAMEWORK FOR DECISION MAKING (1984) (quoting former EPA Administrator Ruckelshaus). *See generally* Richard L. Degrandchamp & Devraj Sharma Terranext, *Risk Assessment Methodologies and Considerations for Their Application to Environmental Issues Beyond U.S. Boundaries*, 45 ROCKY MTN. MIN. L. FOUDN. 2 (1997).

INTRODUCTION

There is an old saying that nothing is certain in this world except for death and taxes. And in fact, death is an ever-present risk, and taxes are a perennial cost. But the uncertainty we must grapple with is how and when death will occur, and how and when people should be taxed. As with life's other risks and costs, the answer to these questions depends on probabilities. Government agencies attempt to account for, and regulate the risk of, death or bodily harm by imposing costs or taxes on various economic activities. This regulatory effort rests on many interconnected disciplines that seek to understand and ultimately take prudent action based on these probabilities. These disciplines must account for an array of underlying factors: science (anatomy, genetics, and

psychology help determine how a person's body and mind will function and respond),[2] politics, economics (measuring the statistical value of human life), philosophy (coping with risk,[3] the proper role of government[4]), and public perception (how perception impacts people's actions).[5] And, of course, the law.

Statutes frequently task administrative agencies with navigating this maze of provocative topics to protect public health and safety. As countless commentators and courts have noted, agencies often rely on risk assessments to guide their decision making.[6] These risk assessments seek to scientifically examine

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2 *See* JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 1 (1988) (noting that cancer "accounts for roughly one in four fatalities in the United States each year.").

3 Some people assume more risk than others. We all know someone who likes to skydive, smokes cigarettes, or jay walks. Likewise, we all know someone who is afraid to fly, has never touched a cigarette, and always waits for the walk sign (and still looks both ways before crossing).

4 The United Kingdom's decision to leave the European Union, Brexit, is a good example of differing opinions on the question of how aggressively government agencies should approach regulatory questions. *See, e.g.*, Holly Ellyatt, *Why Stephen Hawking Thinks the Brexit Vote Could Threaten Humanity*, YAHOO (July 29, 2016) https://www.yahoo.com/finance/news/why-stephen-hawking-thinks-brexit-104803515.html. Brexit also illustrates the potential risks that follow from significant policy choices. *See* Zachary Cohen & Ryan Browne, *Why Brexit Could Hurt America's Security and Help Russia's*, CNN (July 1, 2016), http://www.cnn.com/2016/07/01/politics/eu-referendum-putin-uk-brexit-us-security/index.html.

5 See, e.g., Thomas G. Feld, Jr., *Which Scientist Do You Believe? Process Alternatives in Technological Controversies*, 6 RISK 97, 98 (1995) ("[I]f fear of electromagnetic radiation reduces residential property values near power lines, its scientific rationality should be irrelevant in actions to recover for landowners' economic losses.") (internal citations omitted). *See also id.* at n.12 (citing the riots following the police brutality case involving Rodney King as an example of the serious consequences that can result if people lack faith in the process); Jeff Cox, *Remember the Brexit Recession? Yeah, Well, Never Mind*, CNBC (July 21, 2016), https://finance.yahoo.com/news/remember-brexit-recession-yeah-well-182314040.html (noting perceptions of what would happen following Brexit and what did happen). *See* Matt Egan, *Ford's Darkest Day in 5 Years*, CNN (July 28, 2016), http://money.cnn.com/2016/07/28/investing/ford-earnings-warns-us-auto-slowdown/index.html (noting that Ford auto maker suffered a $60 million hit due to the collapse in the British pound after the "turmoil" from Brexit).

6 *See, e.g.*, Diana R. H. Winters, *False Certainty: Judicial Forcing of the Quantification of Risk*, 85 TEMP. L. REV. 315, 317 (2013) ("First, an agency charged with passing regulation to protect the public health and safety will initially assess the risk posed by a substance, activity, or event to the public, and this assessment will be communicated in numbers. When a regulation based on such an assessment is challenged in court, the court must determine the extent to which it will delve into the preliminary risk assessment.").

how risky a given behavior is; for example, risk assessments may determine the relationship between exposure to a chemical and cancer.[7] But risk assessment only tells you the problem (for example, the likelihood that a certain exposure to a chemical will harm a child).[8] Agencies are then faced with solving the problem: they must determine just how much risk is acceptable and set rules reflecting this. This determination is termed risk management.[9] Risk management is complicated by the reality that different agencies have different missions and that people's perceptions of risk vary.[10] Thus, producing a one-size-fits-all approach to risk through risk management is inherently difficult, and perhaps an impossible task from the outset.[11]

While many commenters have provided extensive critiques of different risk assessment practices, there is significantly less scholarly discussion of what constitutes effective risk management, particularly how agencies approach the complex problem of determining how much risk is enough in practice, or how agencies' risk management decisions are analyzed by reviewing courts. This Article will seek to add to the existing

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7 *See, e.g.*, U.S. *ENVTL. PROT. AGENCY, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT* (2005), https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment. *See also* U.S. *ENVTL. PROT. AGENCY, RISK ASSESSMENT FOR CARCINOGENIC EFFECTS,* https://www.epa.gov/fera/risk-assessment-carcinogens (last visited Feb. 23, 2017).

8 *See, e.g.*, Luthein L. Niland, *The Cost of the Bright Red Strawberry: The Dangerous Failure of Pesticide Regulations to Account for Child Farmworkers*, 4 GOLDEN GATE U. ENVTL. L.J. 363, 366 (2011) (noting deficiencies in current pesticide laws that result in inadequate protection for child farmworkers and a proposed policy paper from EPA that would change risk-assessment methods to include children in pesticide registrations).

9 *See* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 10 (1992).

10 This is true not only about how much risk is acceptable, but also about how much regulation is the "right" amount. *See, e.g.*, Richard W. Parker, *Grading the Government*, 70 U. CHI. L. REV. 1345, 1347 (2003) ("If the traditional concern was that agencies would be captured by regulated interests and, consequently, would regulate too little, the modern critique is led by charges that agencies—driven by ideology, bureaucratic ambition, or 'public interest' pressures—are regulating too strictly and too much.").

11 Justice Breyer has noted that as a whole, regulators are wildly inconsistent in assessing a cost value to human life saved by regulation. *See,* BREYER, *supra* note 9, at 14. Moreover, agencies can have different "acceptable" levels of risk for different stakeholders. For example, the Nuclear Regulatory Commission has different radiation protection standards for plant workers, members of the public, declared pregnant women, and minors. *See* 10 C.F.R. pt. 20, subpt. C, D (providing dose limits).

literature by providing an overview of agency risk management practices and highlighting recent judicial trends in this area—namely, that in recent times, courts are more willing for agencies to use objective criteria in their decision making.

To best understand these practices and trends, this Article will first define risk assessment and risk management and discuss how they have been used to inform rules related to harmful substances. Second, this Article will provide a brief overview of the scholarly literature regarding risk assessment and risk management. This Article will not add to the voluminous literature critiquing risk assessment; instead, this Article will only provide some critiques of risk assessment to highlight how risk management is often neglected in scholarly discussions. Third, this Article will discuss different agencies' risk management practices. In surveying the safety goals and standards different agencies set using risk management, one can see how and why agencies use risk management, what they consider when doing so,[12] and how practices differ between agencies—even among various parts of a single agency. Notably, it is evident that agencies are influenced by prior judicial formulations of risk management.

Finally, this Article will examine how the courts have considered challenges to risk-informed regulations. While early court decisions generally sought to limit agencies' discretion to the specific terms of the enabling statute, these cases often had the odd result of invalidating regulators' attempts to bring greater certainty to risk assessment by fixing risk management on objective standards. In recent years, courts have shown a greater willingness to allow agencies to use objective criteria, such as cost benefit analysis, to resolve risk management questions, and have even insisted on such approaches in some cases.

This Article concludes by providing recommendations for practitioners working with regulatory risk management. Particularly with the Supreme Court apparently more sympathetic to objective approaches to risk management than it has been in the past, now may be the time for administrative agencies to re-think prior risk management decisions and consider using more

12 *See, e.g.*, Margaret Gilhooley, *Plain Meaning, Absurd Results and the Legislative Purpose: The Interpretation of the Delaney Clause*, 40 ADMIN. L. REV. 267, 267 (1988) (discussing the Food and Drug Administration's (FDA) interpretation of the Delaney Clause, which is "a noted example of the establishment of a stringent statutory standard to determine regulatory policy.").

objective criteria going forward. Additionally, agencies should take a fresh look at risk management practices across the government and consider these practices in light of the evolving risk management case law to both improve risk management and bring greater consistency among agency risk assessments.

I. RISK ASSEMENT AND MANAGEMENT: DEFINITIONS, INTERPLAY, AND EVOLUTION

Regulation of hazardous substances is typically divided into two processes: risk assessment and risk management.[13] Before delving into why and how different agencies use these tools to regulate risk, it is critical to understand how these terms are defined, the interplay between them, and how they have evolved in the regulatory decision making context.

A. *Definitions*

This Article largely focuses on agencies' risk management practices based on risk assessments. Human health risk assessment "uses toxicology data collected from animal studies and human epidemiology, combined with information about the degree of exposure, to quantitatively predict the likelihood that a particular adverse response will be seen in a specific human population."[14] This human health risk assessment is in contrast to risk assessment used in other fields.[15]

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13 *See* U.S. ENVTL. PROT. AGENCY, *supra* note 1, at 3; Alon Rosenthal, George M. Gray, & John D. Graham, *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269, 270 n.2 (1992) (noting that "[f]ormer EPA Administrator William Ruckelshaus popularized the distinction between risk assessment and risk management.").

14 Dennis J. Paustenbach, *Retrospective on U.S. Health Risk Assessment: How Others Can Benefit*, 6 RISK: HEALTH SAFETY & ENV'T 283, 283 (1995). *See also* NATIONAL ACADEMY OF SCIENCES, SCIENCE AND POLICY IN RISK ASSESSMENT 27 (1994); *see generally* DENNIS J. PAUSTENBACH, THE RISK ASSESSMENT OF ENVIRONMENTAL HAZARDS: A TEXTBOOK OF CASE STUDIES (1989).

15 *See* U.S. *ENVTL. PROT. AGENCY, HUMAN HEALTH RISK ASSESSMENT,* https://www.epa.gov/risk/human-health-risk-assessment (last visited Sept. 12, 2017) (defining human health risk assessment). *See also* Dennis J. Paustenbach, *Retrospective on U.S. Health Risk Assessment: How Others Can Benefit*, 6 RISK: HEALTH SAFETY & ENV'T 283, 283 (1995) (internal citations omitted) (noting that risk assessment can be used to predict the likelihood of many unwanted events, including industrial explosions, workplace injuries, failures of machine parts, natural catastrophes, injury or death from an array of voluntary activities, diseases, natural causes, life-style or others).

Notably, human health risk assessment is described slightly differently by different organizations. For example, the National Resource Council (NRC) defines it as "the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations."[16] The Environmental Protection Agency (EPA) has explained that "[r]isk assessment characterizes the likelihood of a chemical agent or mixture to cause an adverse health effect for humans and on a case-by-case basis provides a numerical way to gauge the possible impact on a population(s) if exposure were to occur."[17] Scholars have described risk assessment as "an analytical report that provides qualitative and quantitative indications of the human health risks attributable to exposure to an environmental agent."[18]

Likewise, there are slightly different definitions of risk management. The NRC defines risk management as "the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision."[19] The EPA defines risk management as "the action taken based on consideration of [the risk assessment] and other information . . .", with the "other information" including more factors than the NRC's list.[20] Scholars have defined risk management as the "process of making priority-setting and standard-setting decisions."[21]

These varying definitions of risk assessment and risk management likely explain some of the variation in agencies' decision making and the courts' analysis of those decisions, which are discussed below in Sections III and IV, respectively. Simply

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16 Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 89 (1988) (*citing* NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 3 (1983)).

17 U.S. *ENVTL. PROT. AGENCY, ENVIRONMENTAL EQUITY REDUCING RISK FOR ALL COMMUNITIES VOLUME 2: SUPPORTING DOCUMENT* 30 (1992). *See also* Brian D. Israel, *An Environmental Justice Critique of Risk Assessment*, 3 N.Y.U. ENVTL. L.J. 469, 476 (1995) (noting the same). On its website, EPA notes that "[r]isk assessment provides information on potential health or ecological risks." Risk Management, U.S. *ENVTL. PROT. AGENCY*, https://www.epa.gov/risk/risk-management (last updated May 1, 2017).

18 Rosenthal et al., *supra* note 13, at 270.

19 NATIONAL RESEARCH COUNCIL, *supra* note 16, at 3.

20 Risk Management, supra *note 17*. For example, EPA includes public values and laws and legal decisions.

21 Rosenthal et al., *supra* note 13, at 270. *See also id*. at 270 n.2.

put, how a problem is defined helps determine the best solution, and the nature of the problem influences how the solution is judged. For example, some agencies might weigh policy considerations more than adverse consequences, or vice versa. And given the varying definitions of "adverse consequences," agencies may weigh risk differently. Likewise, courts may be more or less sympathetic to an agency's approach depending on the particular consequences.

B. *Interplay Between Risk Assessment and Risk Management*

While the definitions of risk assessment and risk management vary somewhat, under each of the definitions, risk assessment is considered the "science" portion of the (supposedly objective) process of measuring risk.[22] It can include "information drawn from toxicology, chemistry, epidemiology, ecology, and statistics," among other things.[23] And risk management is the "policy" portion of the process, which may or may not take the law, social factors, technological factors, political factors, and public values into account.[24] The first EPA administrator described the processes of risk assessment and risk management as follows:

> Scientists assess a risk to find out what the problems are. The process of deciding what to do about the problems is risk management. The second procedure involves a much broader array of disciplines, and is aimed toward a decision about control. Risk management assumes we have assessed the risks of a suspect chemical. We must factor in its benefits, the costs of the various methods available for its control, and the statutory framework for decision.[25]

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22 *See* Latin, *supra* note *16*, at 89.

23 Risk Management, *supra* note 17.

24 *See id*. at 1–2. *See also* Jay Michaelson, *Rethinking Regulatory Reform: Toxics, Politics, and Ethics*, 105 YALE L.J. 1891, 1891 (1996) ("Most discussions of toxics regulation, however, focus on the 'science' of risk assessment and the politics of risk management."). Understandably, each of these factors has countervailing considerations. *See, e.g*., Cass R. Sunstein, *Beyond the Republican Revival*, 97 YALE L.J. 1539, 1590 n.238 (1988) (noting that "there is no uncontroversial metric with which to measure social costs and social benefits."). *See id*. ("If courts understand benefits and costs technically—as in the economic formulation—and make the assessment turn on private willingness to pay, they will be relying on a highly controversial approach, one that is likely to have been repudiated by the legislature that enacted the program in question.").

25 Degrandchamp & Terranext, *supra* note 1, at 2.

Thus, risk assessment "informs decision makers about the science implications of the risk in question."[26] Risk assessment does not "make or recommend any particular decisions; rather, it gives the risk manager information to consider along with other pertinent information."[27] That risk manager is trying to accomplish a goal: to "protect an appropriate fraction of the population from exposures that produce unacceptable risk (of adverse effects), and to do so with some appropriate degree of confidence."[28]

As discussed below, both risk assessment and risk management have evolved over time and can be impacted by differences found in agencies' implementing statutes or procedures.[29]

C. *The Evolution of the Use of Risk Assessment and Risk Management*

Quantitative risk assessment was "developed by engineers to study safety, failure rates, and integrity of structures and processes."[30] In its early days, risk assessment was applied to estimate the calculated exposures to survivors of the atomic bombings of Hiroshima and Nagasaki.[31] The NRC then prepared a report[32] to "examine the health consequences of large scale application of nuclear power in the United States."[33]

Agencies, especially those tasked with regulating toxic substances, soon began using risk assessment to inform their regulatory decision making[34] even though in most cases this was

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26 Robert G. Hetes, *Science, Risk, and Risk Assessment and Their Role(s) Supporting Environmental Risk Management*, 37 ENVTL. L. 1007, 1010 (2007).

27 *Id*. (internal citations omitted).

28 *Id*. at 1012 (internal citations omitted).

29 *See* Hetes, *supra* note 26, at 1017 (internal citations omitted) (noting that a single EPA entity administers statutes with mandates varying from "[p]rotect public health with 'an adequate margin of safety'" to "[m]itigate . . . environmental and health risks," among others).

30 Rosenthal et al., *supra* note 13, at 270 n.1.

31 *See id*.

32 The report is U.S. NUCLEAR REGULATORY COMMISSION, WASH-1400, NUREG-75-014 REACTOR SAFETY STUDY: AN ASSESSMENT OF ACCIDENT RISKS IN THE U.S. COMMERCIAL NUCLEAR POWER PLANTS, App. VI, (1975) (WASH-1400) and is commonly referred to as "the Rasmussen Report." Rosenthal et al., *supra* note 13, at 270 n.1.

33 *Id*.

34 This was looked at with more favor than making decisions "from volumes of toxicology and epidemiology data collected over" decades. *Id*. at 270.

not required by statute.[35] For example, risk assessment became a formally recognized process within the EPA when the EPA completed its first risk assessment document in December 1975.[36] The EPA adopted a four step risk assessment process, namely (1) hazard identification (i.e., what health problems are caused by the pollutant?), (2) dose-response assessment (i.e., what are the health problems at different exposures?), (3) exposure assessment (i.e., how much of the pollutant are people exposed to during a specific time period? How many people are exposed?), and (4) risk characterization (i.e., what is the extra risk of health problems in the exposed population?).[37]

Other federal and state agencies looked to the EPA's methods of conducting risk assessments.[38] Agencies began using risk assessment more and became more nuanced in performing the assessments. For example, the EPA's Risk Characterization Policy "calls for all risk assessments performed at EPA to include a risk characterization to ensure that the risk assessment process is transparent and that the risk assessments are clear, reasonable and consistent with other risk assessments of similar scope prepared by programs across the Agency."[39] According to the EPA, "[e]ffective

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35 *See* David A. Wirth & Ellen K. Silbergeld, *Risky Reform*, 95 COLUM. L. REV. 1857, 1860–61, 1860 n.8 (1995) (book review) (noting that "relatively few" statutes expressly require risk assessment "by name" and the Toxic Substances Control Act (15 U.S.C. 2601, *et seq*.) was the first). *Id*. (listing Clean Air Act § 112, 42 U.S.C. § 7412 (1988) (hazardous air pollution); Comprehensive Environmental Response, Compensation, and Liability Act of 1980 § 104, 42 U.S.C. § 9604 (1988) (response authorities for hazardous waste disposal sites). *Cf*. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Agreement on the Application of Sanitary and Phytosanitary Measures, Dec. 3, 1993, G.A.T.T. Doc. MTN/FA II-A1A-4 (risk assessment expressly required under agreement); North American Free Trade Agreement art. 715, Can.-Mex.-U.S., Dec. 17, 1992, 32 I.L.M. 289, 378 (requiring risk assessments for food safety measures)).

36 *See* U.S. *ENVTL. PROT. AGENCY, ABOUT RISK ASSESSMENT*, https://www.epa.gov/risk/about-risk-assesment (last visited Mar. 9, 2017). That document was the Quantitative Risk Assessment for Community Exposure to Vinyl Chloride by Kuzmack and McGaughy. *Id*.

37 *See also* U.S. *ENVTL. PROT. AGENCY, CONDUCTING HUMAN HEALTH ASSESSMENTS*, https://www.epa.gov/risk/conducting-human-health-risk-assessment (last visited Mar. 6, 2017) (including a planning stage before the four step process).

38 *See* Rosenthal et al., *supra* note 13, at 277 (noting that EPA's methods of conducting risk assessment were "very influential in the many other federal and state agencies which also perform risk assessments.") (internal citations omitted).

39 *See* U.S. *ENVTL. PROT. AGENCY, RISK CHARACTERIZATION HANDBOOK 7*

risk characterization is achieved through *transparency* in the risk assessment process and *clarity*, *consistency*, and *reasonableness* of the risk assessment product."[40]

Likewise, risk management was increasingly used as a way to protect public health, as risk assessment and risk management go hand in hand in agency decision making.[41] In particular, an agency's statute, or the agency's policy officials would make policy judgments of how much risk is tolerable.[42] In doing so, agencies could look to any number of risk management decision frameworks.[43] As one scholar noted, risk management frameworks "are indispensable to rational government because we have finite resources available to allocate toward risk mitigation. We need some way to reasonably, consistently, and with limited information, prioritize certain risks over others and choose among available policy instruments."[44]

These frameworks not only guide risk management decisions,[45] but they are also embedded within the agencies' implementing statutes. For example, "[t]echnology-based risk management standards are incorporated in different respects into the Safe Drinking Water Act, the Clean Water Act, and the Resource Conservation and Recovery Act."[46] Therefore,

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(2000).

40 *See id*. (emphasis added).

41 As one commentator noted in discussing EPA's regulation of pharmaceutical and personal care products contaminants in water supplies, "appropriate risk management decisions [cannot be made] without adequate risk assessment. . . ." John D. Wood, *Can We Teach Old Laws a New Risk? Federal Environmental Law, Risk Management Theory, and Contamination of U.S. Water Supplies with Pharmaceutical and Personal Care Products*, 21 N.Y.U. ENVTL. L.J. 193, 203 (2014).

42 *See* Timothy F. Malloy, *Principled Prevention*, 46 ARIZ. ST. L.J. 105, 113 (2014). *See id*. at 124 n.74 (noting that the Occupational Safety and Health Act requires OSHA to establish reasonably necessary health standards to provide "safe or healthful employment and places of employment.").

43 *See* Wood, *supra* note 41, at 210. These frameworks include market regulation, no-risk, precautionary principle, sustainability, technology-based standards, risk-risk, risk-benefit, cost-effectiveness, regulatory budget, cost-benefit analysis. *Id*. at 210–228 (discussing these risk management theories).

44 *Id*. at 210.

45 See, e.g., *id*. at 215 (noting that sustainability is one of EPA's guiding principles). EPA defines sustainability as "the condition of productive harmony between humans and nature, which permits present and future generations to fulfill social, economic, and environmental requirements for survival and well-being." *Id*. at 215 n.76.

46 *Id*. at 217. "Technology-based risk management standards require only the

technology may trump cost when it comes to making decisions under these provisions. And certain statutes do not allow for any risk. For example, the Delaney Clause of the Food, Drug, and Cosmetic Act embodies a no-risk theory. Specifically, this clause provides that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal."[47] Thus, the Delaney Clause "does not ask whether the additive was otherwise nutritional or beneficial and does not leave open the possibility that a useful additive that caused incidences of cancer occurring at a rate of only one in one billion might be desirable."[48]

Most statutes do not contain such a no-risk approach. This is not surprising, in light of the widespread use of chemicals.[49] Thus, many risk management decisions are made under what is termed a "conventional" risk management paradigm, which accepts the use of hazardous chemicals as a "given," and looks to mitigate their "harmful impacts through engineering controls or work practices."[50] Under this approach, the focus is not on preventing all exposure (akin to no-risk theory) but on managing exposures[51] and

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determination of the best available technical processes that would mitigate an identifiable hazard." *Id*. (internal citations omitted). *See* 42 U.S.C. § 300g-4(a)(1)(A) (2012) ("The Administrator shall propose and promulgate his finding of the best available technology, treatment techniques or other means available for each contaminant for purposes of this subsection at the time he proposes and promulgates a maximum contaminant level for each such contaminant."). *See also Understanding the Safe Drinking Water Act*, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/sites/production/files/2015-04/documents/epa816f04030.pdf (last visited Mar. 9, 2017) (discussing how best available technology is used to determine the feasible maximum containment level).

47 Federal Food, Drug, and Cosmetic Act of 1938 § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (including the Food Additives Amendment). The clause applies not only to food additives, but to animal drugs in meat and poultry, *id*. at § 512(d)(1)(i), 21 U.S.C. § 360b(d)(1)(i), and food color additives, *id*. at § 721(b)(5)(B), 21 U.S.C § 379e(b)(5)(B).

48 Wood, *supra* note 41, at 212–13.

49 *See* Malloy, *supra* note 42, at 107 ("We clean with chemicals in our homes, eat and drink them, treat our diseases with them, grow our food with them, slather them on to moisturize and protect our skin, and then wash them off with still other chemicals. We are a society deeply invested in the development and use of chemicals. Many of these chemicals are known to be hazardous, linked with a range of diseases and conditions including cancer, reproductive problems, birth defects, neurologic disorders, asthma, and other impairments.").

50 *Id*. at 109 n.6 (citing Timothy F. Malloy, *Of Natmats, Terrorists, and Toxics: Regulatory Adaptation in a Changing World*, 26 UCLA J. ENVTL. L. & POL'Y 93, 96–97, 109 (2008)).

51 *See id*. at 109. *See also id*. at 111–12 (noting that prevention-based risk management is an "emerging" approach); *id*. at 113 ("The central principle

their effects.[52] For example, the risk management response to the toxic effects of hexavalent chromium emissions on workers at electroplating shops could involve "identifying an acceptable exposure level based upon use of a ventilation system, and [requiring] companies to meet that exposure level."[53] This conventional risk management approach presumes: "(1) that regulators are able to identify acceptable or safe exposure levels; and (2) that engineering controls . . . can attain those levels consistently."[54]

Thus, risk management frameworks provide a "stance toward decision making, not a meticulously detailed prescription for action."[55] And the implementing legislation provides the details of regulatory design that drive agency action. These details "will necessarily vary from one regulatory context to another."[56] However, despite the significant role risk management plays, few scholarly articles have systematically addressed the larger questions of how agencies and courts approach the potentially subjective question of what levels of exposure to risk are acceptable in practice.

II. SCHOLARLY DISCUSSION AND CRITIQUES

The academic quarter has much to say about the risk assessments behind risk management decisions. In particular, there is considerable literature detailing the benefits and drawbacks of risk assessment, as well as how to "fix" risk assessment.[57] For

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underlying prevention-based regulation is to avoid the risk by avoiding the chemical. Accordingly, it seeks to minimize the use of toxic chemicals by mandating or directly incentivizing the adoption of safer alternative chemicals or processes wherever feasible.").

52 *See id*. at 112.

53 *Id*. at 109. *See also id*. at 124 (discussing how "OSHA has regulated electroplating operations under the Occupational Safety and Health Act since 1971.").

54 *Id*. at 109.

55 Noah M. Sachs, *Rescuing the Strong Precautionary Principle from Its Critics*, 2011 U. ILL. L. REV. 1285, 1297 (2011).

56 *Id*. *See also id*. at 1288 (noting that while these frameworks vary, they typically place the burden of proof on the government to show an unacceptable risk before the government can restrict a product or activity).

57 *See, e.g*., Niland, *supra* note 8, at 392 ("Risk-assessment techniques contradict the precautionary nature of environmental law by requiring workers to accept a certain level of risk from a man-made harm, rather than trying to prevent the risk before it occurs."); *Id*. at 395 ("If done correctly, risk assessment can

example, some have noted that a "failure to separate facts and values in scientific disputes allows both scientists and policy makers to advance non-technical agendas with claims of expertise."[58] Some assert that risk assessment does not identify the relevant risk.[59] Others make more pointed claims about how flawed risk assessment techniques have led to the approval of rules that do not protect vulnerable populations, such as children.[60]

Justice Breyer devoted a book to discussing the "vicious cycle" of simultaneous over and under regulation created by inconsistent risk assessments and his proposal for how to break that cycle.[61] Justice Breyer describes several problems that "plague efforts to regulate small, but significant, risks to our health."[62] For example, he notes that there are "serious inconsistencies within and among both programs and agencies" when it comes to risk assessment.[63] These inconsistencies include different calculation methods, values placed on the saving of a statistical life, interaction of other programs' safety or environmental effects with another's, accounting for countervailing lethal effects, and offsetting consumer behavior.[64] Justice Breyer asserts that these inconsistencies lead to incongruous results, including imposing costly standards that seek to save a few statistical lives, but that, on balance, likely save no lives at all.[65]

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provide a systematic, quantifiable method for evaluating risks while still acknowledging areas of uncertainty and gaps in data.").

58 Feld, Jr., *supra* note 5, at 98.

59 *See, e.g.*, Howard F. Chang, *Risk Regulation, Endogenous Public Concerns, and the Hormones Dispute: Nothing to Fear But Fear Itself?*, 77 S. CAL. L. REV. 743, 744 (noting the possibility that "risk assessment fails to identify a significant risk at stake."); *Id.* (noting that the "persistent split between experts and ordinary people" regarding risks "raises some of the most interesting problems in all of social science.").

60 *See, e.g.*, Niland, *supra* note 8, at 396 ("Because of the use of flawed risk-assessment techniques to approve pesticides, children exposed to pesticides in quantities beyond what they can tolerate will lose more than just their summer and could have long-lasting health effects.").

61 *See* Breyer, *supra* note 9. *But see* Parker, *supra* note 10, at 1350–54 (noting that some of the cited studies in Breyer's critique reached "dramatic" conclusions that may not have solid empirical foundation).

62 Breyer, *supra* note 9, at 10. *See id.* at 10–29 (describing three major problems that plague efforts to regulate small, but significant, risks to our health).

63 *Id.* at 21.

64 *See id.* at 22–23.

65 *See id.* at 23. *See also id.* at 11–19 (discussing the last 10% problem, wherein millions are spent to save some and thousands are not spent to save

The existing scholarly discussion on risk management is similar, though much less considerable in volume. Specifically, there are critiques of the risk management process used and recommendations for how to improve the process or reach different decisions.[66] And as with risk assessment, there does appear to be widespread recognition that risk management has benefits,[67] and that agencies making risk management decisions are not acting wickedly or foolishly in doing so.[68] This Section will briefly describe the existing critiques of risk management, which claim that risk management practices can miss the mark and lead to counterproductive results. However, as discussed below, most of these critiques of risk management generally take issue with larger questions associated with risk assessment itself.

A. *The Drawbacks of Regulatory Risk Management*

1. *Conventional Risk Management Ignores Statutory Language*

Some scholars argue that risk management often incorrectly takes a conventional management approach (e.g., control strategies) as opposed to a prevention approach in contravention of statutory language. For example, Timothy F. Malloy notes, "Clean Air Act Section 101(c) identifies promoting pollution *prevention* as a fundamental goal of the statute. The Act's [maximum achievable control technology (MACT)] provisions explicitly charge EPA with *eliminating* [hazard air pollutants (HAP)] emissions where possible 'through process changes, substitution of materials, or other modifications.'"[69]

However, rather than study the agency's process for structuring risk management decisions, Malloy takes aim at the EPA's decision to proceed under a risk assessment framework in

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others).

66 *See, e.g.*, Malloy, *supra* note 42, at 150 (discussing prevention-based regulation as a preferable alternative solution whereby an environmentally-benign, viable alternative would be selected over a hazardous chemical or process).

67 There are certainly statements of the benefits of risk management. *See* Breyer, *supra* note 9, at 59 (noting that government regulation by rule is better than leaving up how much risk is acceptable to a jury, which would result in a random lottery-like system with high transaction costs).

68 *See id.* at 11. *See also id.* (noting that the EPA generally receives high marks for its works).

69 Malloy, *supra* note 42, at 128 (emphasis added).

the first place. He argues that the EPA has favored control strategies setting MACT standards and is "reluctant to consider process change in setting MACT standards," with courts repeatedly "forc[ing] EPA to honor the preference for pollution prevention set out in the Clean Air Act."[70]

2. *Conventional Risk Management is Not Protective, Overall Effective, Cost-Effective, or Efficient*

There are also more pointed critiques of the conventional risk management approach.[71] The "most common critiques fall into four general categories: protectiveness, overall effectiveness, cost-effectiveness, and dynamic efficiency."[72] Notably, academics describing the limitations of conventional risk management admit that similar arguments could be made against other approaches to regulation.[73]

a. *Protectiveness*

A frequent critique of conventional risk management is that it offers limited, or even illusory, protection, although this critique appears to be more generally aimed at underlying risk assessments.[74] Critics often challenge the idea that "a single safe level (or even range of safe levels) can be identified and attained."[75] Evidence of prior assessments mistakenly identifying certain levels of substance exposure as "safe" supports this

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70 *Id*. at 129 (citing Cement Kiln Recycling Coal. v. EPA, 255 F.3d 855, 859 (D.C. Cir 2001) (standards for hazardous waste combustors); Nat'l Lime Ass'n v. EPA, 233 F.3d 625, 634 (2000) (emission limits for cement plants); Monsanto Co. v. EPA, 19 F.3d 1201, 1208 (7th Cir. 1994) (extension of compliance waiver under Section 112 for a company seeking to implement a pollution prevention strategy)). Given the interplay between risk assessment and risk management, it is not surprising that some of the critiques of risk management necessarily flow from the critique that risk assessment is flawed.

71 The critiques discussed below come from advocates of the prevention approach. As one prevention proponent observed, "[w]hat you don't have can't leak." *See* Trevor A. Kletz, *What You Don't Have Can't Leak*, 6 CHEMISTRY & INDUSTRY 287 (1978) (discussing the principles of inherently safer design in industrial processes).

72 Malloy, *supra* note 42, at 130.

73 *See id*. at 130–31 ("[I]t is worthwhile noting that some of the criticisms asserted against conventional risk management could be fairly made against prevention-based regulation, particularly with respect to cost-effectiveness and dynamic efficiency.").

74 *See id*. at 131.

75 *Id*.

criticism.[76] For example, advances in scientific knowledge have indicated that there is no "safe" threshold for lead. In fact, "lead affects intellectual development among children at blood lead levels well below the ten micrograms/deciliter standard commonly viewed as acceptable in the United States."[77] Likewise, recent studies have linked cancer, cardiovascular disease, asthma, autism, and obesity, among other diseases and conditions, "to extremely low level chemical exposures."[78] But, rather than challenge risk management decisions, these arguments tend to suggest that the underlying risk assessments were flawed.

Second, as explained above, critics claiming that conventional risk management is underprotective point out that the underlying risk assessments, which are used to trigger the development of an exposure limit or to generate the limit, are "malleable" and lack objectivity and precision.[79] Moreover, critics note that risk assessments are "often excessively time consuming."[80] Thus, critics argue that this leads to transient exposure limits fraught with "uncertainty, politicization, and delays."[81] Again, these risk management criticisms seem primarily aimed at supposed flaws in the underlying risk assessments.

Third, critics claim that conventional risk management merely shifts risk to future generations, instead of preventing risk.[82] Critics contend that even a well-designed risk management strategy for capturing hazardous air emissions from a production facility "leaves behind landfills, containment structures, and residual air, water and soil contamination."[83] These types of impacts then affect future generations by "subjecting them to risks from exposure,

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76 *See id*.

77 *Id*. (citing Bruce P. Lanphear et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSPS. 894 (2005)).

78 *Id*. (citing NICHOLAS A. ASHFORD & CLAUDIA S. MILLER, LOW-LEVEL CHEMICAL EXPOSURES: A CHALLENGE FOR SCIENCE AND POLICY 74–84 (2d ed. 1998); James E. Trosko & Brad L. Upham, *A Paradigm Shift is Required for the Risk Assessment of Potential Human Health After Exposure to Low Level Chemical Exposures: A Response to the Toxicity Testing in the 21st Century Report*, 29 INT'L J. TOXICOLOGY 344 (2010)).

79 *See* Malloy, *supra* note 42, at 132.

80 *Id*. (citing risk assessment process for rulemaking and noting that many assessments take from ten to twenty years to complete).

81 *Id*.

82 *See id*. at 133.

83 *Id*. at 133–34.

restricting their use of resources contaminated or otherwise spoiled by wastes and discharges, and imposing on them future costs of response."[84] But, once again, these arguments suggest that risk assessment models do not fully describe the spectrum of risk associated with a regulatory decision rather than take issue with the process by which agencies manage risk.

b. *Overall Effectiveness*

Conventional risk management is also criticized because of the lack of effectiveness in the measures it relies on to reduce risk.[85] For example, even when a regulated entity makes a good faith attempt to implement a control measure, because the control measure can have a high possibility of failure due to underlying complexities in the modelling, there are inevitable setbacks.[86]

Relatedly, not all regulated entities implement the control measures correctly, and some do not implement them at all. Critics note that the implementation of control measures and practices is "highly variable, whether because of intentional noncompliance, negligence or confusion on the part of the responsible party."[87] Therefore, critics do not see conventional risk management as effective, and instead recommend other approaches, including substituting a hazardous chemical with a safer one.[88] But these arguments appear to miss the mark of risk management and instead focus on the reliability of control measures.

c. *Cost-effectiveness*

Another criticism of conventional risk management is that it is

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84 *Id*. at 134 (citing EDITH BROWN WEISS, IN FAIRNESS TO FUTURE GENERATIONS AND SUSTAINABLE DEVELOPMENT: INTERNATIONAL LAW, COMMON PATRIMONY, AND INTERGENERATIONAL EQUITY 38 (Richard Falk ed., 1989) (discussing the impacts on and interests of future generations); Braden Allenby, *Supporting Environmental Quality: Developing an Infrastructure for Design*, 2 ENVTL. QUALITY MGMT. 303 (1993)).

85 *See id*. (noting that control measures can include things like "engineering controls–including air pollution controls, wastewater treatment, pesticide application equipment, and the like.").

86 *See id*. (internal citations omitted) (citing the phenomenon of the "normal accident" as an example).

87 *Id*. at 135 (citing Joel Hirschhorn et al., *Toward Prevention: the Emerging Environmental Management Paradigm*, *in* CLEAN PRODUCTION STRATEGIES: DEVELOPING PREVENTIVE ENVIRONMENTAL MANAGEMENT IN THE INDUSTRIAL ECONOMY 125, 127 (Tim Jackson ed., 1993)).

88 *See id*.

not cost-effective.[89] As explained by Timothy F. Malloy:

> Cost-effectiveness is one measure often used to evaluate the relative efficiency of regulatory approaches, the other being social efficiency (or maximization of social welfare).[90] Cost-effectiveness analysis estimates the cost of achieving a specified goal under alternative policies, allowing identification of the least cost approach. The targeted goal itself is a given, and thus cost-effectiveness measures say nothing regarding the wisdom of pursuing the goal.[91]

Critics claim that conventional risk management is not cost-effective because it adds "costly add-on controls, administrative requirements and remediation obligations intended to capture, manage and cleanup the pollutants and wastes"[92] onto an already inefficient process (i.e., "the pollution and hazardous exposures resulting from typical production processes and products").[93] This cost can be enormous. For example, a widely cited study by an OMB economist asserts that "government regulations cost up to $72 billion per life saved."[94]

Critics argue that a preventive approach would be more cost-effective than a conventional risk management approach. Specifically, a preventive approach would "adopt process improvements that substantially reduce the amount of the raw material needed in the first place—minimizing emissions and also reducing raw material costs,"[95] while also "shrink[ing] or even entirely avoid[ing] the often substantial regulatory compliance costs . . . that almost inevitably accompany risk management

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89 *See id*.

90 *See id*. (noting that "social efficiency measures both the costs and benefits of alternative options, comparing those options in terms of net benefits produced.").

91 *Id*.

92 Malloy, *supra* note 42, at 136 (citing Mark Dorfman et al., *Profiting from Prevention, in* CLEAN PRODUCTION STRATEGIES: DEVELOPING PREVENTIVE ENVIRONMENTAL MANAGEMENT IN THE INDUSTRIAL ECONOMY 189, 189–91 (Tim Jackson ed., 1993)).

93 *Id*. (citing Kirsten U. Oldenburg & Kenneth Geiser, *Pollution Prevention and . . . or Industrial Ecology?* 5 J. CLEANER PRODUCTION 103, 106 (1998)); Dorfman et al, *supra* note 92.

94 Parker, *supra* note 10, at 1345. But *see id*. (claiming that the study, and others like it, rely on "undisclosed data and non-replicable calculations; use biased regulatory samples; misrepresent ex ante guesses about costs and benefits as actual measurements; and grossly underestimate the value of lives saved, or the number of lives saved, or both.").

95 Malloy, *supra* note 42, at 136.

strategies."[96]

However, there is "apparently no systematic evidence demonstrating that prevention strategies are necessarily or even generally more cost-effective than risk management approaches."[97] In fact, "a safer substitute chemical could easily be more expensive than the more hazardous material it replaces; for example, lead-free solder, lithium-ion batteries, and steel wheel weights are all more expensive than their lead-dependent counterparts."[98] Thus, it is important to remember that the question of what is cost-beneficial is highly variable and dependent on the process and the chemicals at issue.

d. *Dynamic Efficiency*

A fourth criticism of conventional risk management is that the approach has "inferior" dynamic efficiency.[99] "Dynamic efficiency refers to the capacity to encourage innovation, defined as the development, commercialization, and adoption of new technology."[100] As one might imagine, keeping pace with innovations in technology are important to effective, efficient regulation.[101] The argument is that "[i]nnovation allows environmental engineers to keep pace with the growing technological demands placed upon them by economic growth and industrial development. Likewise, environmental innovations can also reduce production costs and improve operating efficiencies, thus providing added value to the business itself."[102]

Critics of traditional risk management claim that the approach relies on "engineering controls coupled with a static exposure level [which] tends to lock in existing technology."[103] Critics claim that other approaches (for example, the prevention-based approach) enhance dynamic efficiency of regulation, "both in terms of the

96 *Id*. at 137. *See also id*. (giving an example of how a substitution strategy from the dry cleaning sector would reduce these regulatory compliance costs).

97 *Id*.

98 *Id*.

99 Malloy, *supra* note 42, at 137.

100 *Id*. (citing Adam B. Jaffe & Robert N. Stavins, *Dynamic Incentives of Environmental Regulations: The Effects of Alternative Policy Instruments on Technology Diffusion*, 29 J. ENVTL. ECON. & MGMT. S-43, S-44 (1995)).

101 *See id*. (noting that innovation in environmental technologies has "long been hailed as a primary goal of effective, efficient regulation.").

102 *Id*. at 137–38.

103 *Id*. at 138.

rate of innovation and the social value of those innovations."[104] In particular, critics assert that "prevention-based regulation that focuses on the product or process itself, rather than on discharges and add-on controls, will engender more creative engagement by process engineers, managers and other personnel beyond the firm's compliance staff."[105] And in light of these cost reductions, critics claim that firm staff and management would be encouraged to seek out innovative alternatives. Further, critics claim that traditional risk management only leads to innovation in control technologies, whereas prevention-derived innovations "are likely to result in product or process improvements having beneficial spillover benefits such as increased competitiveness."[106]

Notably, the critics then qualify the benefits of a different approach with the disclaimer that "the rate and nature of innovation flowing from alternative regulatory approaches is likely to be highly contextual."[107] The bottom line is that risk management critics are typically focused on concerns with risk management *frameworks*, as opposed to an agency's specific risk management *decision,*[108] or are concerned with the flaws in the "input" (usually created by risk assessment). The critics have much to say about why particular frameworks are better (or worse) than another and how risk assessment should be overhauled. However, it is easy to critique one method and theorize why another method would be better (safer, cheaper, quicker, more effective). But there is little substance behind the claims, making the critiques ring a

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104 *Id*.

105 *Id*. (citing LEO BASS, CLEANER PRODUCTION AND INDUSTRIAL ECOLOGY: DYNAMIC ASPECTS OF THE INTRODUCTION AND DISSEMINATION OF NEW CONCEPTS IN INDUSTRIAL PRACTICE 26–27 (2005); Margaret M. Quinn et al., *Sustainable Production: A Proposed Strategy for the Work Environment*, 34 AM. J. INDUS. MED. 297, 300 (1998); Kurt A. Strasser, *Cleaner Technology, Pollution Prevention and Environmental Regulation*, 9 FORDHAM ENVTL. L.J. 1, 3 (1998)).

106 Malloy, *supra* note 42, at 138.

107 *Id*. For example, "market distortions, information asymmetries in the market, organizational features of the firm and the specific attributes of the new technology" are all factors that affect innovation. *Id*. (citing Dorfman et al., *supra* note 92, at 191–93; Timothy F. Malloy & Peter S. Sinsheimer, *Innovation, Regulation and the Selection Environment*, 57 RUTGERS L. REV. 183, 192–98 (2004)). Nicholas A. Ashford, *An Innovation-Based Strategy for the Environment*, *in* WORST THINGS FIRST: THE DEBATE OVER RISK-BASED NATIONAL ENVIRONMENTAL POLICIES 275, 291 (Adam M. Finkel & Dominic Golding eds., 1994).

108 For example, Cass Sunstein is noted as the "most vociferous" opponent of the so-called "strong precautionary" principle. Sachs, *supra* note 55, at 1293.

little hollow and the critics a bit like Monday morning quarterbacks. We all, after all, play a perfect sideline game.

B. *Potential Process Improvements*

Other critics offer process improvements to conventional risk management. For example, one scholar argues that a better approach to risk regulation would shift the burden of proof on safety to the "risk creators" (e.g., chemical companies).[109] Under this proposed system, "chemical manufacturers would carry the burden to demonstrate that their products do not pose significant risks to human health or the environment."[110] Such a system would not aim to eliminate risk; instead, it would ensure that companies "must research the health and environmental risks of their products, before harm occurs."[111]

Arguably, this principle is already in place in existing law. For example, under the Federal Food, Drug, and Cosmetic Act, "all substances meeting the definition of a drug are presumptively banned from sale in the United States, unless the manufacturer produces relevant data on risks, side effects, and efficacy; conducts clinical trials, and receives affirmative FDA approval for sale."[112] This prohibition "backed by criminal penalties, remains in place (without any cost-benefit analysis) until the drug manufacturer can overcome the default and carry its burden of proof on safety and efficacy."[113] Notably, this process has not stunted innovation or profit.[114]

However, there are several scholars who believe that this proposal would be "paralyzing as an approach to risk decision making."[115] Critics claim that this approach is "extreme, inflexible,

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109 *Id*. This advocate of a "strong precautionary principle" also references "weaker" versions of this principle. *See id*. at 1292–93 (describing the precautionary principle contained in principle 15 of the Rio Declaration, which has been adopted by consensus by 172 countries, including the United States).

110 *Id*. at 1285–86.

111 *Id*. *See also id*. (advocating implementing the Strong Precautionary Principle in a replacement statute for the Toxic Substances Control Act of 1976).

112 *Id*. at 1307–08.

113 *Id*. at 1308.

114 *See id*. ("Belying the argument that a gatekeeping role for government is inherently anti-science or anti-technology, the United States has maintained this FDA review process for decades while also developing the most innovative and profitable pharmaceutical industry in the world.").

115 *Id*. at 1306 (citing Cass Sunstein's critique). *See also id*. at 1285 (noting that other scholars have consistently criticized the Strong Precautionary principle

anti-science, anti-growth, or anti-technology."[116] Further, there is a sense by some that this "guilty-until-proven innocent" approach to addressing risk is "contrary to U.S. values."[117]

These sharp divides in scholars' views of how risk management should be addressed illustrate the emotion, passion, and importance of the issue. Each of these scholars, as well as each of us, is part of the public whose health and safety is at stake. However, these scholarly discussions and critiques of risk management appear to be missing a theme—namely, a close examination of how agencies and courts approach the difficult question of determining how much risk is enough. The following Section attempts to address the gap by examining some recent and influential agency approaches to risk management.

Further, these scholars' work does not appear to have significantly influenced judicial review of risk management. As explained below, recent Supreme Court cases have taken an increasingly hospitable view toward risk management, particularly regarding agency use of objective criteria, such as cost-benefit analysis, in the process.

III. AGENCY APPROACHES TO RISK MANAGEMENT

This Section discusses agencies' risk management practices and provides a survey of the safety goals and standards set by a variety of agencies. Additionally, this Section explores how agencies utilize risk management, what they consider when doing so, and how practices differ between agencies (and even among different parts of the same agency.)

As discussed below, agencies appear to be embracing an evolving view of risk management. For example, some agencies, such as the Occupational Safety and Health Administration (OSHA), have based their risk management practices primarily on

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as "paralyzing, inflexible, and extreme.").

116 *Id*. at 1305 (citing Julian Morris, *Defining the Precautionary Principle*, *in* RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE 1 (Julian Morris ed., 2000); Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996)); John D. Graham, Admin., Office of Info. & Regulatory Affairs, THE ROLE OF PRECAUTION IN RISK ASSESSMENT AND MANAGEMENT: AN AMERICAN'S VIEW, ADDRESS AT THE US, EUROPE, PRECAUTION AND RISK MANAGEMENT: A COMPARATIVE CASE STUDY ANALYSIS OF THE MANAGEMENT OF RISK IN A COMPLEX WORLD (Jan. 11–12, 2002).

117 *Id*.

Court decisions from several decades ago. One such decision is *Industrial Union Department v. American Petroleum Institute* (commonly referred to as *Benzene*),[118] which took a rather narrow view of objective criteria in risk management, including cost-beneficiality and technological feasibility. Other agencies, however, appear to be reaching beyond these narrow views, are more open to these objective criteria, and are attempting to improve consistency within their risk management processes and accompanying regulatory frameworks. This Section focuses on the recent risk management practices of four of the leading agencies in the area of risk assessment: the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health (NIOSH), the Nuclear Regulatory Commission (U.S. NRC or Commission), and the Environmental Protection Agency.

A. *Occupational Safety and Health Administration*

1. *Risk Management at OSHA*

OSHA's risk management practices are largely based on the requirements of its enabling statute, the Occupational Safety and Health Act (OSH Act), and numerous court interpretations of the OSH Act.[119] OSHA's interpretation of its authority to promulgate workplace standards under these statutes is based chiefly on the Supreme Court's *Benzene* decision.[120] Specifically, in terms of determining the significance of any particular risk in setting new health standards, OSHA relies on the example provided by the Supreme Court in *Benzene*:

> If . . . the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate

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118 Indus. Union Dep't, AFL–CIO v. Am. Petroleum Inst., 448 U.S. 607 (1980).

119 *See, e.g.*, Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1,494 (Jan. 10, 1997); Occupational Exposure to Respirable Crystalline Silica, 81 Fed. Reg. 16,286 (Mar. 25, 2016). *See infra* Section IV.A.1.

120 *See* Indus. Union Dep't, AFL–CIO v. Am. Petroleum Inst., 448 U.S. 607 (1980) (plurality opinion). *See* 81 Fed. Reg. at 16,289–94 (noting pertinent legal authority for promulgating the crystalline silica rule).

steps to decrease or eliminate it.[121]

The Supreme Court thus recognized that what constitutes "'significant risk'" is "not a mathematical straitjacket,"[122] and "will be based largely on policy considerations."[123]

Following *Benzene*, OSHA has, in many of its health standards, considered the one-in-a-thousand metric when determining whether a significant risk exists.[124] In addition, because courts have interpreted the OSH Act as requiring OSHA to set the standard that eliminates or reduces risk to the lowest feasible level, OSHA notes that "the limits of technological[125] and economic[126] feasibility usually determine where the new standard is set."[127] Moreover, despite the consideration of economic feasibility, OSHA is not permitted to use cost-benefit analysis when setting regulatory standards.[128]

2. *Case Study: Crystalline Silica Rule*

In 2016, OSHA applied these risk management practices

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121 Indus. Union Dep't, AFL–CIO v. Am. Petroleum Inst., 448 U.S. 607, 655 (1980); Occupational Exposure to Respirable Crystalline Silica, 81 Fed. Reg. at 16,290.

122 *Id*. at 655.

123 *Id*. at 655 n.62.

124 *See, e.g*., Occupational Exposure to Methylene Chloride, 62 Fed. Reg. at 1,494; Occupational Exposure to Respirable Crystalline Silica, 81 Fed. Reg. at 16,286; Occupational Exposure to 1,3-Butadiene, 61 Fed. Reg. 56,746, 56,790–91 (Nov. 4, 1996) ("[A] risk of 1/1000 (10^{-3}) is clearly significant. It represents the uppermost end of the million-fold range suggested by the [*Benzene*] Court, somewhere below which the boundary of acceptable versus unacceptable risk must fall.").

125 A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 513 (1981); American Iron and Steel Institute v. OSHA, 939 F.2d 975, 980 (D.C. Cir. 1991).

126 A standard is economically feasible if industry can absorb or pass on the cost of compliance without threatening its long-term profitability or competitive structure. *See* Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 513, 530 n.55 (1981); American Iron and Steel Institute v. OSHA, 939 F.2d 975, 980 (D.C. Cir. 1991).

127 *See* 81 Fed. Reg. at 16,291 (citing UAW v. Pendergrass, 878 F.2d 389, 390 (D.C. Cir. 1989)).

128 *See* 81 Fed. Reg. at 16,293 (citing Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 513, 509 (1981)). OSHA also notes that "while OSHA estimates the costs and benefits of its proposed and final rules, these calculations do not form the basis for the Agency's regulatory decisions." *Id*.

when promulgating a rule amending its existing standards for occupational exposure to respirable crystalline silica.[129] Specifically, the rule established a new permissible exposure limit (PEL) of 50 micrograms of crystalline silica per cubic meter of air (50 $\mu g/m^3$) for an eight hour average in all covered industries.[130]

After carefully reviewing a risk assessment, stakeholder comments, and new information provided to the rulemaking record, OSHA found there to be a clearly significant risk at the previous PELs for crystalline silica.[131] Therefore, OSHA concluded that these results represented a risk of material health impairment that is significant within the context of the *Benzene* decision.[132]

OSHA determined that, at the revised PEL of 50 $\mu g/m^3$ respirable crystalline silica, the estimated risks were substantially reduced as compared to the previous PELs. Specifically, lowering the PEL to 50 $\mu g/m^3$ would "reduce the lifetime excess risk of death per 1000 workers to between 5 and 23 deaths from lung cancer, 7 deaths from silicosis, 44 deaths from non-malignant respiratory disease, and 32 deaths from renal disease."[133] Despite this substantial decrease in risk, OSHA concluded that the risk under the PEL of 50 $\mu g/m^3$ was still significant.[134] Nevertheless, OSHA did not adopt a PEL below the revised 50 μg/m3 limit because of technological and economic feasibility considerations of the standard in determining exposure limits.[135] Therefore,

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129 *See id*. at 16,286 (noting that the purpose of the new rule was to curb lung cancer and other diseases in workers by limiting their exposure to crystalline silica).

130 *See id*. The new rule also establishes a new action level of 25 $\mu g/m^3$, at which concentration an exposure assessment and medical surveillance would be required. *Id*. at 16,707. The prior PELs were set at approximately 100 $\mu g/m^3$ for general industry and between 250 and 500 $\mu g/m^3$ for construction and shipyards. *Id*. at 16,300.

131 OSHA's quantitative risk assessment indicated that a 45-year (working lifetime) exposure "to respirable crystalline silica at the preceding general industry PEL would lead to between 11 and 54 excess deaths from lung cancer, 11 deaths from silicosis, 85 deaths from all forms of non-malignant respiratory disease[], and 39 deaths from renal disease per 1000 workers. Exposures at the preceding construction and shipyard PEL would result in even higher levels of risk." *Id*. at 16,755.

132 *Id*.

133 *Id*.

134 *See id*. at 16,399.

135 *See id*. at 16,381 (noting that the revised PEL of 50 mg/m^3 is technologically and economically feasible in most operations in the affected

OSHA concluded that it reduced significant risk to the extent feasible by establishing a PEL of 50 $\mu g/m^3$.[136]

B. *The National Institute for Occupational Safety and Health*

1. *Risk Management at NIOSH*

NIOSH works closely with OSHA and other Federal agencies to protect workers and miners from injury and illness.[137] Like OSHA, NIOSH's risk management practices are statutorily driven by the OSH Act. Under the OSH Act, NIOSH is mandated to

> develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience.[138]

NIOSH undertakes its mandate by conducting "an independent analysis of the scientific evidence on a chemical's carcinogenicity, evaluating how and where the chemical may be used in the workplace, and quantitatively estimating the risk to workers at various exposure levels."[139]

2. *Case Study: NIOSH's Cancer Policy*

In 2016, NIOSH revised its 1995 Chemical Carcinogen Policy.[140] The revised policy, among other things, governs

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general industrial and maritime sectors and in the construction industry but that a lower PEL of 25 mg/m^3 is not technologically feasible for most of these operations). *See also id*. at 16,461–62.

136 *See id*. at 16,381.

137 *See* NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, PUBL'N NO. 2013-140, NIOSH FACTSHEET 1 (2015), https://www.cdc.gov/niosh/docs/2013-140/pdfs/2013-140.pdf. NIOSH is part of the U.S. Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services.

138 29 U.S.C. § 669(a)(3) (2012). *See also* 30 U.S.C. § 811(a)(1) (2012) and 30 U.S.C. § 811(a)(6)(B) (2012) pertaining to NIOSH's statutory requirements with respect to mining.

139 NIOSH, *Current Intelligence Bulletin 68: Chemical Carcinogen Policy*, at 1 (2016) [hereinafter NIOSH, *Cancer Policy*]. NIOSH seeks public comment on these comprehensive analyses and recommendations, submits them for peer review, and publishes an authoritative document containing the recommendations and supporting analyses. *Id*.

140 *See generally id*. NIOSH issued a draft document, which was available for public comment until February 13, 2014. Draft Current Intelligence Bulletin: Update of NIOSH Carcinogen Classification and Target Risk Level Policy for

NIOSH's classification of chemicals as occupational carcinogens and sets risk management limits for workers exposed to carcinogens.[141] Under its revised policy, NIOSH will determine whether a chemical is an occupational carcinogen by using one of three methods:

> (1) evaluation of chemical carcinogen hazard assessments developed by the U.S. Department of Health and Human Services (HHS) National Toxicology Program (NTP), the EPA Integrated Risk Information System (IRIS), and/or the World Health Organization International Agency for Research on Cancer (IARC); (2) nomination by NIOSH for Classification by NTP; or (3) classification by NIOSH.[142]

NIOSH's revised policy explains that each of the scientific approaches used by NTP, the EPA, and IARC in developing carcinogen classifications employs a systematic methodology "for critically assessing and interpreting a body of scientific information."[143] Thus, NIOSH believes that relying on the preexisting hazard assessments and cancer classifications developed by these agencies will allow it to "focus its resources on assessing occupational risks" and develop workplace risk management recommendations to reduce those risks.[144] NIOSH anticipates that evaluating hazard assessments from NTP, IARC, or the EPA, will "increase the number of cancer assessments it can complete without sacrificing the scientific quality of those assessments."[145]

If NIOSH determines that a chemical is an occupational carcinogen, it will assess whether a quantitative risk assessment

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Chemical Hazards in the Workplace, 78 Fed. Reg. 68,849 (Nov. 15, 2013).

141 *See* NIOSH, *Cancer Policy*, *supra* note 139, at 1.

142 *Id*. at 15, 23. NIOSH states that it "views the assessments produced by NTP, IARC, and EPA to be of the highest scientific quality, subject to extensive peer review or prepared by acknowledged experts in the field in a consensus building process." *Id*. at 8.

143 *Id*. at 7 (noting that each of these agencies "employ a thorough, systematic analysis of the body of evidence or evaluation of the strength of evidence using a transparent protocol and integration of evidence across studies. . . .").

144 *Id*.

145 *Id*. at 15. "NIOSH may nominate a chemical for review by NTP when NIOSH has determined that the chemical has the potential for worker exposure and (a) there is no prior carcinogen classification by NTP, EPA, or IARC or (b) information in the occupational relevance evaluation indicates the need for reconsideration of the evidence. If the chemical is of particular concern to NIOSH, NIOSH may develop its own hazard assessment of the chemical." *Id*. at 17–18.

(QRA) is necessary.[146] NIOSH will then undertake a QRA to determine a range of risk estimates and set a risk management limit.[147] Prior to issuing its revised policy, NIOSH "issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime."[148] NIOSH's prior recommendations were based on its interpretation of the *Benzene* decision as establishing that a 1 in a 1,000 lifetime excess risk of fatality is significant.[149] However, in its revised policy, NIOSH notes that "in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level."[150]

Thus, in keeping with these advances, NIOSH's revised policy sets a "'risk management limit for a carcinogen' or an 'RML-CA,'[151] at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible."[152] If measurement of the carcinogen "at the

146 *See id*. at 18 (noting that "NIOSH will perform the QRA based on the best available data.").

147 *See id*. at 20, 24.

148 *Id*. at 20.

149 *See* NIOSH, *Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace*, at 30–33 (Nov. 5, 2013) [hereinafter NIOSH, *Draft Carcinogen Policy*] (noting that although *Benzene* does not pertain specifically to NIOSH, it will continue to use the *Benzene* decision as guidance).

150 NIOSH, *Cancer Policy* at 20.

151 *Id*. at 20, 25. NIOSH defines an RML-CA as the maximum 8-hour time-weighted average concentration of an occupational carcinogen above which a worker should not be exposed. NIOSH established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no known safe level of exposure to carcinogens. *Id*. at 20.

152 *Id*. at 20, 25. NIOSH notes that several public commenters "urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000." Many of these commenters suggested that NIOSH should not recommend one specific exposure level and should leave such a policy decision to OSHA. Commenters also observed that "NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility." In response, NIOSH stated that it "agrees that it should provide information on the exposure levels that correspond to various levels of risk; however, NIOSH indicated that it will continue to provide a health-based RML-

RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ)" of the analytical method for that occupational carcinogen.[153] NIOSH, in diverging from the risk significance determination in *Benzene*, notes that underlying its revised policy is the recognition that there is no known safe level of exposure to a carcinogen and that therefore reducing worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer.[154]

C. *Nuclear Regulatory Commission*

1. *Safety Goals Policy Statement*

In 1975, the U.S. Nuclear Regulatory Commission published its Reactor Safety Study (WASH-1400) "to try to reach some meaningful conclusions about the risk of nuclear accidents."[155] Although it was deemed a major step forward in the development and refinement of accident risk quantification, WASH-1400 did not directly address the question of what level of risk from nuclear accidents is acceptable.[156] To address this question, in 1986, the U.S. NRC issued its Policy Statement on "Safety Goals for the Operations of Nuclear Power Plants" (Safety Goals Policy Statement), focusing on the risks to the public from nuclear power plant operation.[157] The objective of the policy statement was "to establish goals that broadly define an acceptable level of radiological risk" from the operation of commercial nuclear power plants.[158]

The policy statement established two qualitative safety

CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers." *Id*. at 20.

153 *Id*. at 20, 25.

154 *See id*. at iii, v, 18, 20, 24 (noting that the change in terminology from REL to RML-CA also acknowledges that there is no known safe level for exposure to carcinogens and the RML-CA is a reasonable starting place for controlling exposures).

155 WASH-1400, *supra* note 32.

156 *See* Safety Goals for the Operations of Nuclear Power Plants, 51 Fed. Reg. 30,028, 30,030 (Aug. 21, 1986).

157 *Id*. at 30,029 (noting that these risks are from release of radioactive materials from the reactor to the environment from normal operations as well as from accidents).

158 *Id*. at 30,028.

goals,[159] and adopted two quantitative objectives concerning mortality risks to be used in determining achievement of the qualitative safety goals. The first quantitative objective is that "[t]he risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed."[160] The second quantitative objective is that "[t]he risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes."[161] The Commission also issued guidance for determining whether changes to the level of safety at a nuclear power plant are consistent with its policy statement. Specifically, the guidance provides quantitative risk acceptance guidelines that are used to determine whether a proposed change in risk is "small" and therefore consistent with the Commission's Safety Goals Policy Statement.[162]

The U.S. NRC uses its Reactor Oversight Process (ROP) "to inspect, measure, and assess the safety and security performance of operating commercial nuclear power plants and to respond to any decline in their performance."[163] Specifically, the ROP uses a significance determination process (SDP), "to determine the safety

159 *See id*. The first qualitative safety goal is that "individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health." *Id*. at 30,030 (noting that the Commission's intent is to require a level of safety that individuals living or working near a nuclear plant should be able to go about their daily lives without concern by virtue of their proximity to the plant). The second qualitative goal was that "societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks. *Id*.

160 *Id*. (acknowledging the general risk of fatality associated with accidents from activities such as driving, swimming, flying, or generating electricity from coal).

161 *Id*.

162 NUCLEAR REGULATORY COMMISSION, REGULATORY GUIDE 1.174, AN APPROACH FOR USING PROBABILISTIC RISK ASSESSMENT IN RISK-INFORMED DECISIONS ON PLANT SPECIFIC CHANGES TO THE LICENSING BASIS 15–17 (2011).

163 *See* https://www.nrc.gov/reactors/operating/oversight.html (last visited Oct. 5, 2017) (defining Reactor Oversight Process).

or security significance of inspection findings."[164] This involves assessing whether and how much the inspection findings affect the risk of a nuclear plant accident.[165] Inspection findings are assigned severity levels, derived from the Commission's Safety Goals Policy Statement, representing the safety or security significance of the finding.[166]

2. *Risk-Informed Regulations*

In addition to the risk management principles underlying its safety goals, the U.S. NRC also employs risk management insights in promulgating regulations. Section 182(a) of the Atomic Energy Act (AEA) requires the Commission to ensure that "the utilization or production of special nuclear material will . . . provide adequate protection to the health and safety of the public."[167] The U.S. NRC refers to this provision as the *adequate protection* standard or the *undue risk* standard.[168] Courts, such as the D.C. Circuit, have interpreted this standard, not as a "zero risk" standard, but as one that permits some level of risk.[169] Thus, the courts have acknowledged that adequate protection is not "absolute protection," and that "even when the standard is satisfied, safety improvements will be possible."[170] Notably, the court also declined to allow the U.S. NRC to consider costs in defining what constitutes "adequate protection" under the AEA.[171]

In consideration of its policy statement and adequate protection standard, the U.S. NRC has promulgated numerous regulations that utilize risk insights.[172] For example, in 1988, the

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164 *See Reactor Oversight Process (ROP),* U.S. NUCLEAR REGULATORY COMM'N, https://www.nrc.gov/reactors/operating/oversight/rop-description.html (last visited Oct. 5, 2017).

165 *See generally* NUCLEAR REGULATORY COMMISSION, NRC INSPECTION MANUAL CHAPTER 0609, SIGNIFICANCE DETERMINATION PROCESS 1 (2015) [hereinafter IMC 0609].

166 *See id.* at 3–4 (noting four levels of increasing safety or security significance).

167 42 U.S.C. § 2232(a) (2012).

168 *See, e.g.*, Union of Concerned Scientists v. U.S. Nuclear Regulatory Comm'n, 824 F.2d 108, 109 (D.C. Cir. 1987).

169 *See id.* at 118.

170 *Id.* at 114.

171 *Id.*

172 In 1998, the U.S. NRC approved the issuance of a white paper defining the terms and the Commission's expectations for risk-informed and performance-based regulation. NUCLEAR REGULATORY COMMISSION, STAFF REQUIREMENTS –

U.S. NRC promulgated its "station blackout" rule, which requires plants to be able to withstand for a specified duration, and recover from, a "total loss of alternating current (ac) electrical power" or station blackout.[173] As another example, in 1991, the U.S. NRC issued its "maintenance rule" for nuclear power reactors.[174] The maintenance rule requires licensees to monitor the performance of the defined safety systems and components against licensee-established goals, which are established based on safety significance and operating experience, and to take corrective action when the goals are not met.[175] The U.S. NRC amended its maintenance rule in 1999 to require that licensees assess and manage the increase in risk that might result from proposed maintenance activities (for example, taking components out of service).[176]

Risk Management Task Force

The U.S. NRC also formed a Risk Management Task Force (RMTF) "to evaluate how the agency should be regulating 10 to 15 years in the future."[177] In 2012 the RMTF published its report,

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SECY-98-144 – WHITE PAPER ON RISK-INFORMED AND PERFORMANCE-BASED REGULATION 1 (1999).

173 Station Blackout, 53 Fed. Reg. 23,203, 23,203 (June 21, 1988). The U.S. NRC notes that the "objective of the rule is to reduce the risk of severe accidents resulting from station blackout maintaining highly reliable ac electric power systems and, as additional defense-in-depth, assuring that plants can cope with a station blackout for some period of time." *Id*. at 23,204.

174 *See generally* Monitoring the Effectiveness of Maintenance at Nuclear Power Plants, 56 Fed. Reg. 31,306 (July 10, 1991). "The [U.S.] NRC's maintenance team inspections of all nuclear power plant licensees in the late 1980s found the lack of consideration of plant risk in prioritizing, planning, and scheduling maintenance activities to be a common weakness." Monitoring the Effectiveness of Maintenance at Nuclear Power Plants, 64 Fed. Reg. 38,551, 38,551 (July 19, 1999). The maintenance rule was promulgated to address that weakness. *See id*.

175 *See* 10 C.F.R. § 50.65 (1999).

176 *See generally* 64 Fed. Reg. at 38,551. After promulgation of the original maintenance rule in 1991, "[d]uring plant visits in mid-1994, several U.S. NRC senior managers expressed concerns that licensees were increasing both the amount and frequency of maintenance performed during power operation without adequately evaluating safety when planning and scheduling these maintenance activities." *Id*. Thus, the U.S. NRC amended the maintenance rule "to require licensees to understand their options with respect to risk and to manage their maintenance activities according to their best judgment, considering insights from operating experience and deterministic and probabilistic analyses." *Id*. at 38,553.

177 Evaluation of a Proposed Risk Management Regulatory Framework, 80 Fed. Reg. 27,191, 27,192 (May 12, 2015) ("[T]he RMTF was chartered 'to

NUREG-2150, which concluded that the U.S. NRC's programs "do not require radical or revolutionary changes," but could benefit from a risk management regulatory framework.[178] The RMTF envisioned that this proposed framework would use a "disciplined risk management process to identify and evaluate issues and make decisions on appropriate protections for various radiological hazards."[179] Notably, in making its recommendations, the RMTF considered and evaluated numerous risk management frameworks implemented at other agencies such as the EPA, the U.S. National Aeronautics and Space Administration (NASA), the U.S. Coast Guard, and the Department of Homeland Security (DHS).[180]

The RMTF found that the proposed framework would yield several important benefits including: (1) "[u]pdated knowledge from contemporary studies . . . would be incorporated into regulations and guidance;" (2) "[i]mplementation of a systematic approach would foster a consistent regulatory decision-making process throughout the agency and improve resource allocation;" (3) "[c]onsistency in language and communication would be improved across the agency and externally;" and (4) "[s]upport of issue resolution would be achieved in a systematic, consistent, and efficient manner."[181] The RMTF recognized that the proposed framework would pose a number of challenges, including the need to develop additional guidance and metrics and increase understanding of the value of risk concepts and risk management language both within the agency and externally.[182] Nonetheless,

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develop a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material.'").

178 NUCLEAR REGULATORY COMMISSION, NUREG-2150, A PROPOSED RISK MANAGEMENT REGULATORY FRAMEWORK xxviii (2012) [hereinafter NUREG-2150].

179 *Id*. at xxviii–xxix. "The risk-informed and performance-based defense-in-depth protections provide sufficient barriers, controls, and personnel to prevent, contain, and mitigate the exposure of workers or the public to radioactive materials. The appropriate barriers, controls, and personnel are based on the hazards present, the relevant scenarios leading to possible exposures, and the associated uncertainties to ensure that the risks resulting from the failure of some or all of the established barriers are maintained acceptably low." *Id*. at xxix.

180 *See id*. at A3–A15.

181 *Id*. at xvi.

182 *See id*. (noting that a long-term commitment from the Commission and senior agency management would be necessary to implement the proposed framework).

the RMTF recommended that the U.S. NRC "formally adopt the proposed Risk Management Regulatory Framework through a Commission Policy Statement."[183] The RMTF also noted specific changes that could be made in the next several years to support implementation of the risk management framework.[184]

In 2015, the U.S. NRC staff issued for public comment a draft white paper identifying options and making recommendations based on NUREG-2150.[185] The white paper identifies options for enhancing the risk management approach used to ensure nuclear power safety,[186] re-evaluates improvement activities from the Near Term Task Force established in response to the accident at the Fukushima Dai-ichi site in Japan, and provides a draft example of an agency-wide policy statement on using the risk management approach to ensure safety and security.[187]

D. *Environmental Protection Agency*

1. *Risk Management at EPA*

The mission of the EPA is simple, yet complex: "to protect human health and the environment."[188] To accomplish its goal, the EPA, among other things, develops and enforces regulations, studies environmental issues, and educates the public about the

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183 *Id*. at xv.

184 *See id*. at xiii. Specifically, the RMTF developed findings and recommendations in a number of different program areas including power reactors, nonpower reactors, nuclear materials, low-level waste, high-level waste, uranium recovery, fuel cycle, spent nuclear fuel storage, and transportation. These program area findings and recommendations focus on what changes would be needed to ensure that the proposed risk management framework would be implemented in 10 to 15 years. *Id*.

185 *See* 80 Fed. Reg. at 27,192.

186 *See* NUCLEAR REGULATORY COMMISSION, NRC STAFF WHITE PAPER ON OPTIONS FOR RESPONDING TO THE JUNE 14, 2012 CHAIRMAN'S TASKING MEMORANDUM ON "EVALUATING OPTIONS PROPOSED FOR A MORE HOLISTIC RISK-INFORMED, PERFORMANCE-BASED REGULATORY APPROACH" 3 (2015) (2015 Draft White Paper) (noting that the U.S. NRC's existing policy statements on PRA and Safety Goals, in concert with increasing experience with risk-informed regulation and integrated risk-informed decision making processes, have already established a *de facto* Risk Management Regulatory Framework).

187 *See generally id*.

188 U.S. ENVTL. PROT. AGENCY, OUR MISSION AND WHAT WE DO, https://www.epa.gov/aboutepa/our-mission-and-what-we-do (last visited Mar. 9, 2017).

environment.[189] In December 2000, the EPA published a "Risk Characterization Handbook," to provide risk assessors, risk managers, and other decision-makers at the EPA with an understanding of the goals and principles of risk characterization.[190] Additionally, the Handbook outlines the importance of planning and scoping for a risk assessment, the essential elements to address in a risk characterization, the factors that are considered in decision making by risk managers, and the forms that risk characterization takes for different audiences.[191] This Section describes the EPA's approach to risk management for some of the actions with which it deals.[192]

2. *CERCLA Superfund Remedial Cleanup*

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as Superfund, was enacted in 1980 and provides broad authority to the federal government to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment.[193] CERCLA sections 121(a) through 121(d) provide general rules for the selection of remedial actions, provide for periodic review of remedial actions, and describe requirements for the degree of cleanup.[194] In 1990, the EPA promulgated regulations implementing the remedy section process prescribed by section 121.[195] The purpose of this process "is to implement remedies that

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189 *See id*.

190 *See* ENVIRONMENTAL PROTECTION AGENCY, *supra* note 39, at 1. To help inform its regulatory decision making, the EPA evaluates environmental risks through an assessment process that "involves a substantial body of scientific data and analysis with much judgment and uncertainty." *Id*. at 5.

191 *See id*. at 1.

192 EPA's website provides a number of examples of risk management actions it deals with including: "deciding how much of a substance a company may discharge into a river; deciding which substances may be stored at a hazardous waste disposal facility; deciding to what extent a hazardous waste site must be cleaned up; setting permit levels for discharge, storage, or transport [of hazardous materials]; establishing national ambient air quality standards; and determining allowable levels of contamination in drinking water." EPA's website describes risk management as "the process which evaluates how to protect public health." U.S. ENVTL. PROT. AGENCY, *supra* note 17.

193 *See* 42 U.S.C. § 9601 *et seq*.

194 *See* 42 U.S.C. § 9621.

195 *See* National Oil and Hazardous Substances Pollution Contingency Plan, 55 Fed. Reg. 8,666 (Mar. 8, 1990) [hereinafter National Oil] (to be codified at 40 C.F.R. pt. 300).

eliminate, reduce, or control risks to human health and the environment."[196] EPA's approach relies on a process that examines site characteristics and alternative approaches for remediating site problems and uses risk management judgments to make these decisions.

Specifically, the remedy selection process guides the EPA's risk management decision by evaluating alternatives with nine criteria based on CERCLA's mandate "to determine advantages and disadvantages of the alternatives, thus identifying site-specific trade-offs between options."[197] These criteria are as follows: (1) protection of human health and the environment; (2) compliance with applicable or relevant and appropriate requirements (ARARs); (3) long-term effectiveness and permanence; (4) reduction of toxicity, mobility, or volume; (5) short-term effectiveness; (6) implementability; (7) cost; (8) state acceptance; and (9) community acceptance.[198] EPA states that these trade-offs "are balanced in a risk management judgment as to which alternative provides the most appropriate solution for the site problem."[199]

EPA's regulations also set boundaries of "the acceptable risk range for Superfund cleanups to 10^{-4} to 10^{-6} but allow for cleanups more stringent than 10^{-6} when warranted by exceptional circumstances."[200] In setting this range, EPA notes that while "CERCLA does not require the complete elimination of risk or of all known or anticipated" adverse effects, section 121 directs "that remedies protect human health and the environment, be permanent to the maximum extent practicable, and be cost-effective."[201] The EPA states that its "risk range of 10^{-4} to 10^{-6} represents EPA's opinion on what are generally acceptable [risk] levels."[202]

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196 40 C.F.R. § 300.430(a)(1) (2011).

197 National Oil, *supra* note 195, at 8,700.

198 *See id*. at 8,712. These nine criteria encompass statutory requirements specifically the long-term effectiveness factors that must be assessed under CERCLA section 121(b)(1)(A-G) and include other technical and policy considerations that have proven to be important for selecting among remedial alternatives. *Id*. at 8,701.

199 *Id*. at 8,700.

200 *Id*. at 8,716.

201 *Id*. at 8,752.

202 *Id*. at 8,716–17, 8,752 (explaining that to be consistent with the accepted *de minimis* level used by other EPA programs, e.g., the drinking water program, the lower boundary of the risk range has been changed from 10^{-7} in the proposed

However, as noted below, to the extent that many regulators may continue to feel restricted by the Court in *Benzene*, the EPA's range of acceptable levels may ultimately be based on little more than the Justices' stated preferences for risk in that opinion.

Finally, the Superfund program establishes remediation goals by means of a two-step approach. Specifically, EPA's preliminary remediation goals for carcinogens "are set at a 10^{-6} excess cancer risk as a point of departure, but may be revised to a different risk level within the acceptable risk range based on the consideration of appropriate factors including, but not limited to, the following: exposure factors,[203] uncertainty factors,[204] and technical factors."[205] EPA's final selection of the appropriate risk level "is made when the remedy is selected based on the balancing of criteria."[206]

3. *Water Quality Standards*

In 2000 the EPA announced the availability of final revisions to its *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*,[207] published pursuant to section 304(a)(1) of the Clean Water Act (CWA). Section 304(a)(1) requires that the EPA periodically revise water quality criteria "to accurately reflect the latest scientific knowledge on the kind and extent of all identifiable" health effects that might be expected from "the presence of pollutants in any body of water, including ground water."[208] EPA also determined that the revisions

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rule to 10^{-6} in the final rule). EPA also notes that other federal agencies generally do not reduce individual lifetime risk levels below 10^{-6}. *Id*. at 8,717 n.9.

203 *Id*. at 8,717 (including exposure factors such as the cumulative effect of multiple contaminants, the potential for human exposure from other pathways at the site, population sensitivities, potential impacts on environmental receptors, and cross media impacts of alternatives).

204 *Id*. (including uncertainty factors such as the reliability of alternatives, the weight of scientific evidence concerning exposures and individual and cumulative health effects, and the reliability of exposure data).

205 *Id*. (including technical factors such as detection/quantification limits for contaminants, technical limitations to remediation, the ability to monitor and control movement of contaminants, and background levels of contaminants).

206 *Id*.

207 *See* Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), 65 Fed. Reg. 66,444 (Nov. 3, 2000).

208 *Id*. (noting that the EPA's revisions were prompted by "many significant scientific advances that have occurred during the past 20 years in key areas such as cancer and noncancer risk assessments, exposure assessments, and bioaccumulation assessments.").

were necessary to address differences in its risk assessment and risk management approaches to set human health ambient water quality criteria (AWQC) under the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA).[209]

One of these differences, as EPA notes, is that it had historically treated Group C chemicals (possible human carcinogens under the EPA's cancer classification scheme) differently under the CWA and the SDWA,[210] with respect to cancer risk ranges for its drinking water and ambient surface water programs.[211] Specifically, EPA's surface water program under the CWA "derived AWQC for carcinogens that generally corresponded to lifetime excess cancer risk levels of 10^{-7} to 10^{-5}."[212] On the other hand, the EPA's drinking water program under the SDWA set MCLGs "based on a slightly less stringent risk range of 10^{-6} to 10^{-5}."[213] To achieve consistency between its water standards, the EPA notes that it intends to publish its national 304(a) water quality criteria under the CWA at a 10^{-6} risk level, which the EPA "consider[s] to be appropriate for the general population."[214]

The EPA also notes that under the drinking water program, MCLGs for chemicals with strong evidence of carcinogenicity are set at zero.[215] For those substances having an MCLG of zero, "enforceable Maximum Contaminant Levels (MCLs) have generally been promulgated to correspond with cancer risk levels ranging from 10^{-6} to 10^{-4}."[216] Unlike AWQC and MCLGs, which the EPA notes "are strictly health-based criteria," the EPA develops MCLs giving consideration "to the costs and technological feasibility of reducing contaminant levels in water to meet those standards."[217]

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209 *See id*. at 66,445.

210 *See id*. (noting that the 1980 AWQC National Guidelines for setting AWQC under the CWA predated EPA's carcinogen classification system, which was proposed in 1984 and finalized in 1986).

211 *See id*. at 66,447.

212 *Id*.

213 *Id*.

214 *Id*.

215 *See id*. (describing chemicals with strong evidence of carcinogenicity as being classified as Group A (known) or B (probable) human carcinogens).

216 *Id*.

217 *Id*.

E. *Conclusions*

A survey of risk management practices at federal agencies reveals one thing for certain: risk management is essential to agencies charged with protecting public health and safety. These agencies have been implementing and honing their risk management practices for decades. Some of these practices have been heavily influenced by court interpretations in case law. For example, OSHA has promulgated numerous workplace safety and health regulations incorporating risk management practices that are largely, if not entirely, based on the requirements of its enabling statute as well as numerous court interpretations of that statute.[218] Similarly, the EPA has attempted to ensure that its interpretations of various statutes such as the CWA are in accordance with case law. However, as discussed below, the courts in general, and the Supreme Court in particular, appear to be embracing an evolving view of risk management. While Court decisions from several decades ago, such as *Benzene*, took a very narrow view of objective criteria in risk management, such as cost-beneficiality and technological feasibility, recent cases appear much more open to these concepts and some even suggest that they are necessary.

Agencies also appear to be concerned with consistency in risk management to ensure they fulfill their respective missions to protect health and safety. For example, the EPA has proactively sought to maintain consistency amongst its own regulatory programs with respect to risk management approaches by modifying the risk ranges for water criteria under the CWA and SDWA. Similarly, the U.S. NRC has been assessing the risks of nuclear accidents for decades, has developed numerous agency-wide policy statements involving risk, and has utilized a risk management task force to further "risk-inform" its regulatory processes. Moreover, rather than employ cost-benefit analysis, technological feasibility, or absolute safety to set meaningful safety goals, the U.S. NRC sought to ensure that nuclear energy

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218 *See, e.g.*, Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1,494, 1,561 (Jan. 10, 1997) (explaining that OSHA's approach to regulating occupational exposure to certain substances is consistent with recent court decisions interpreting the OSH Act); Crystalline Silica, 81 Fed. Reg. at 16,287 (stating that "the final rule is based on the requirements of the [OSH Act] and court interpretations of the Act); Occupational Exposure to 1,3-Butadiene, 61 Fed. Reg. 56,746, 56,791 (Nov. 4, 1996) ("OSHA's overall analytic approach to regulating occupational exposure to particular substances . . . [is] consistent with judicial interpretations of the OSHA Act, such as the Benzene Decision . . . .").

would pose no greater risk to the public than comparable industries. These safety goals have had a pervasive impact at the U.S. NRC, and the agency continues to explore ways to enhance the use of quantitative risk assessment in its regulatory activities.

To some extent, agencies have also looked to other agencies to ensure consistency in managing risk. NIOSH's revised cancer policy statement demonstrates that it intends to classify carcinogens based on hazard assessments completed by other agencies including the EPA. Additionally, the U.S. NRC analyzed the risk management frameworks of several other federal agencies in making recommendations on how to implement a new framework of its own. Finally, the impetus to improve agencies' risk management approaches stems not just from federal agencies but from the legislative branch as well. For example, the EPA's Superfund program was created pursuant to new legislation.

In sum, over the past few decades, agencies have heavily invested time and resources in enhancing their risk management. In improving consistency within their risk management processes and accompanying regulatory frameworks, agencies also frequently rely exclusively on case law and statutory interpretations. However, as explained below, agencies may want to exercise caution in relying too heavily on case law, particularly case law that predates the significant shift in the Court's attitude toward risk management.

IV. RISK MANAGEMENT CASES: EVOLVING TOWARD OBJECTIVITY

Over the years, the Supreme Court and lower courts have considered a variety of challenges to agency risk-management decisions. Typically, these challenges assert that agencies inappropriately considered costs, technological feasibility, or measures to provide an absolute assurance of safety.[219] The allure

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219 In a sense, technological feasibility is something of a variant to cost. *See infra* note 232 (defining technological feasibility). After all, to meet technologically infeasible requirements, industries must expend significant resources to develop new technologies. *See infra* note 292. Thus, a consideration of technological feasibility often boils down to whether the costs of a measure would be excessive. Consequently, this Article treats the concepts as being somewhat interchangeable, at least to the extent that the courts' later insistence that agencies can, and sometimes should, consider cost when promulgating regulations under ambiguous statutory language is a repudiation of earlier holdings that agencies may not consider technological feasibility in such circumstances.

of such approaches to risk management is self-evident: they are much less subjective than risk management approaches directed at eliminating risks that are "significant" or providing a margin of safety that is "adequate." Indeed, the core of Justice Breyer's complaint is that a variety of subjective approaches to risk management created the striking inefficiencies he observed, in which the nation spends millions of dollars to prevent some deaths while foregoing the opportunity to spend a few thousand to spare others.[220]

Nonetheless, early risk-management opinions were extremely inhospitable toward agency interpretations of authorizing statutes that allowed for an objective consideration of costs. Rather, as discussed below, these cases generally found that agencies could only consider costs or technological feasibility when explicitly required to by the underlying enabling statute. This approach to risk management left agencies grappling with nebulous terms like "significance," with relatively little guidance from Congress or the courts as to what that means.[221]

However, recent years have seen an enormous shift in risk management jurisprudence; since 2009, the Supreme Court has consistently found that agencies can, and should, consider costs in risk management decisions unless expressly forbidden to do so by statute.[222] Neither the courts nor academics have successfully explained this shift, or even acknowledged it. But it does not appear that the advent of the *Chevron* doctrine or the underlying statutory language alone are sufficient to account for this shift. Under *Chevron*, the Court defers to an agency's interpretation of an ambiguous statute unless it is arbitrary or capricious. [223] As shown below, in recent years the Supreme Court has both relied on *Chevron* to defer to agency considerations of cost and found that an agency's failure to consider costs was not entitled to *Chevron* deference.[224] A close look at these cases reveals that this change

220 *See* Breyer, *supra* note 9, at 11–13, 19, 22–23.

221 *See supra* notes 62–68 and accompanying text.

222 *See* Michigan v. E.P.A., 135 S.Ct. 2699, 2707 (2015); E.P.A. v. HME Homer City Generation, 134 S.Ct. 1584, 1607 (2014); Entergy Corp. v. Riverkeeper, Inc., 556 U.S. 208, 208 (2009).

223 *See* Chevron v. Nat. Res. Defense Council, 467 U.S. 837, 843 (1984).

224 *Compare HME Homer City Generation*, 134 S.Ct. at 1603, 1606 (allowing *Chevron* deference to agency decision to determine what emissions "significantly" contribute to nonattainment based, in part, on cost) *with* Michigan v. E.P.A., 135 S.Ct. 2699, 2707 (2015) ("EPA strayed far beyond" the bounds of

evolved from a vigorous dialogue on the Court that has recognized the unusual significance of risk management, as well as the soundness of taking a rigorous and objective approach that considers costs to risk management questions.

A. *Traditional Risk Management Cases: Boundaries on Agency Discretion?*

1. Benzene*, Done That*

The richest traditional judicial discussion of risk management is likely the Supreme Court's multiple opinions in *Benzene*.[225] In *Benzene*, a plurality of the Court, including Justices Stevens, Powell, Stewart, and Chief Justice Berger rejected an OSHA standard for benzene. The plurality, with Justice Rehnquist concurring in the result, remanded the workplace airborne safety standard of one part per million (ppm) for benzene on the ground, on the grounds that OSHA had not found that the standard was necessary to address a "significant" health problem.[226] The previous standard for benzene was slightly higher at ten ppm,[227] but OSHA decided to consider changing it upon receiving a report from its research division that the ten ppm standard might be insufficient to protect against leukemia.[228] OSHA also studied whether such a reduction would be economically feasible and concluded that it would be because the costs imposed by the reduction would not impair the economic viability of affected industries.[229]

Chevron when it determined that "it could ignore cost when deciding whether to regulate power plants.").

225 *See* Indus. Union Dep't, AFL–CIO v. Am. Petroleum Inst., 448 U.S. 607 (1980).

226 *See id*. at 623–25, 656.

227 *See id*. at 617. The American National Standards Institute adopted this consensus standard in 1969, and OSHA adopted it in 1971. *Id*.; *see also* 29 U.S.C. § 655(a) (2012) (requiring OSHA to adopt then–effective national consensus standards unless it found adoption would not improve workplace health or safety).

228 Indus. Union Dep't, AFL–CIO v. Am. Petroleum Inst., 448 U.S. 607, 618–20 (1980). OSHA's research arm, NIOSH, noted that studies of high exposures to benzene suggested a "distinct possibility that benzene caused leukemia" and called for additional studies. *Id*. at 619 (internal quotations omitted). After reviewing the results of those studies, NIOSH "recommended that the exposure limit be set as low as possible." *Id*. at 620. NIOSH followed up with a further recommendation that the limit be set at 1 ppm. *Id*. at 621.

229 *See id*. at 613, 627. Nonetheless, OSHA's study revealed that the

In reviewing the benzene standard, the plurality noted that two provisions of OSHA's enabling statute, the OSH Act, guided OSHA's risk assessment. First, section 3(8) of the OSH Act defined a health and safety standard as one "reasonably necessary and appropriate to provide safe or healthful employment."[230] For health and safety standards for toxic material, such as benzene, section 6(b)(5) further required OSHA to "set the standard which most adequately assures, to the extent feasible . . . that no employee will suffer material impairment of health or functional capacity."[231] The government argued that the second standard was controlling. Therefore, according to OSHA, it had to set the level for benzene exposure at either a level that assured absolute safety or at the lowest level feasible, defining feasible as a level that was technologically attainable without imposing crippling costs on the regulated industry.[232]

The Court rejected this reasoning. The plurality found that the two provisions should be read in harmony, and that by defining a health and safety standard as one necessary to provide safe employment, Congress implied that before promulgating a standard, OSHA must find that a workplace is not safe.[233] But, the plurality further reasoned, "'safe' is not the equivalent of 'risk-free'" because "[t]here are many activities that we engage in every day—such as driving a car or even breathing city air—that entail some risk[;] nevertheless few people would consider these activities 'unsafe.'"[234] Consequently, according to the plurality, "a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm."[235] Thus, before promulgating a health or safety standard, the plurality determined that OSHA "is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices."[236] In supporting this conclusion the plurality noted that,

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regulation would lead to significant economic costs—approximately $266 million in engineering controls, $187 million to $205 million in first-year costs, and $34 million in annual costs in 1980 dollars. *Id.* at 628.

230 *Id.* at 639 (internal quotations omitted).

231 *Id.* (internal quotations omitted).

232 *See id.*

233 *See id.* at 642.

234 *Id.*

235 *Id.*

236 *Id.*

during floor debates, Congress amended the OSH Act to avoid suggesting that OSHA should assume the Herculean task of eliminating all workplace harms, both significant and insignificant.[237] Thus, because OSHA never addressed this threshold finding of significance, the Court remanded the proceedings back to the agency.[238]

While Justice Rehnquist agreed with the plurality that the revised benzene standard was invalid, he travelled a very different path to that destination. Justice Rehnquist grounded his argument on John Locke's famous observation that because legislatures derive their authority from the public, "'the legislative [branch] can have no power to transfer their authority of making laws and place it into other hands.'"[239] In this vein, Justice Rehnquist noted that the Court had previously recognized that "'Congress cannot delegate legislative power to the President . . . .'"[240] He further recalled that the Court had relied on this non-delegation doctrine, along with a potentially cramped reading of the Commerce Clause and notions of substantive Due Process, to invalidate a number of laws in a string of decisions before and during the New Deal.[241] He conceded that the doctrine "fell under a cloud," as later Courts overturned these decisions.[242] Nonetheless, Justice Rehnquist concluded that the Court's non-delegation jurisprudence "suffer[s] from none of the excesses of judicial policymaking that plagued some of the other decisions of that era."[243] Thus, he concluded that the non-delegation principle remained viable and that the statute at

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237 *See id*. at 646–49. The Court noted that the initial version of the bill read that OSHA "'shall set the standard which adequately and feasibly assures . . . that no employee will suffer *any* impairment of health or functional capacity.'" *Id*. at 647 (quoting S. 2193, 91st Cong., 2d Sess. 39 (1970) (emphasis added)). The latter version of the bill replaced "any impairment" with "material" impairment. *Id*. at 648. Senator Dominick called the initial standard "unrealistic" because it suggested that Congress meant for OSHA to provide absolute protection to workers and noted that such a result was not intended by the sponsors of the bill, who agreed. *Id*. at 648–49 (quoting 116 CONG. REC. at 37662–63).

238 *See id*. at 658, 662.

239 *Id*. at 672–73 (Rehnquist, J., concurring) (quoting J. Locke, *Second Treatise of Civil Government*, *in* THE TRADITION OF FREEDOM 244 (M. Mayer ed., 1957)).

240 *Id*. (quoting Field v. Clark, 143 U.S. 649, 692 (1892)).

241 *See id*. at 674 (citing ROBERT HOUGHWOUT JACKSON, THE STRUGGLE FOR JUDICIAL SUPREMACY: A STUDY OF A CRISIS IN AMERICAN POWER POLITICS 48–123 (1949)).

242 *Id*. at 675.

243 *Id*.

issue in this case, which empowered OSHA to set workplace safety standards, was potentially incompatible with that principle.[244]

In evaluating whether section 6(b)(5) violated the non-delegation principle, Justice Rehnquist stated that the non-delegation principle served three important functions: (1) it ensures that Congress itself makes "important choices of social policy," (2) it provides the recipient of authority with an "intelligible principle" for exercising the delegated authority, and (3) the "intelligible principle" aides judicial review.[245] Justice Rehnquist concluded that the statutory provisions in *Benzene* satisfied none of these requirements; he found that the "decision whether the law of diminishing returns should have any place in the regulation of toxic substances" was essentially legislative. Likewise, he found that evidence in the record regarding OSHA's confusion implementing the standard suggested that "feasibility" was not an "intelligible principle" for the agency or the Court to follow.[246] Thus, he concluded that section 6(b)(5) was invalid under the non-delegation doctrine.

The dissenters, Justices Marshall, Brennan, White, and Blackmun argued that the plurality's approach to statutory interpretation "may charitably be described as obscure."[247] They claimed that the plurality failed to demonstrate how its "significance" test could be "plausibly derived from the 'reasonably necessary or appropriate' clause."[248] Thus, they would have upheld OSHA's benzene standard and concluded with the expectation that future Courts would reject the plurality and that "the representative branches of government will once again be allowed to determine the level of safety and health protection to be accorded to the American worker."[249]

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244 *See id*.

245 *Id*. at 685–86.

246 *Id*. Judge Silberman of the D.C. Circuit viewed Justice Rehnquist's argument as nearly heroic and urged his colleagues to follow his reasoning in reviewing grant of authority. American Trucking Associations v. EPA, 195 F.3d 4, 14 (1999) (Silberman, J., dissenting).

247 *Benzene*, 448 U.S. at 708 (Marshall, J., dissenting).

248 *Id*.

249 *Id*. at 724.

2. *The* Benzene *Blueprint*

The Court's discourse in *Benzene* is notable in a number of respects, which consistently appear in later risk management cases. Most importantly, the plurality's approach to evaluating risk management was carefully grounded on a thorough parsing of the underlying statute (although the dissent might call it an over-parsing).[250] In this exacting reading, the plurality invalidated OSHA's technological feasibility test, which had some basis in the underlying statute, in favor of a far more amorphous significance test, which found less grounding in the statute (although perhaps it was more in line with the legislative history).[251] Many earlier risk management cases employed a similar close reading of the text to invalidate agency approaches based on cost or technological feasibility, and later cases issued after 2007 would typically not engage in such exacting readings.

The plurality's approach to risk management also looked extensively at the legislative history underlying the relevant statutory language. For example, the *Benzene* plurality emphasized that the legislative history underlying the OSH Act demonstrated that Congress did not intend for OSHA to make workplaces absolutely safe by eliminating all risk in the workplace.[252] The plurality highlighted individual legislators' statements that such a task was likely impossible and would impose crippling costs on the economy.[253] The plurality also pointed to changes in the wording of the Act that suggested these legislators were able to convince their counterparts that such costs were unacceptable.[254] Many future cases would emphasize similar legislative records.[255]

3. Cotton Dust*: Risk Management Reconsidered*

A year later, the Court again heard a challenge to an OSHA regulation implemented under section 6(b)(5) of the OSH Act in *American Textile Manufacturers Institute v. Donovan* (commonly known as *Cotton Dust*).[256] That case arose from challenges by the

250 *See id.* at 642.
251 *See id.*
252 *See id.* at 646–49, 651–52.
253 *See id.*
254 *See id.*
255 *See* Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 513, 514–521 (1981).
256 *See id.*

cotton industry to an OSHA standard that limited occupational exposure to cotton dust, a harmful particle generated in cotton manufacture and production.[257] Building on the previous term's decision, the industry argued that the OSH Act required OSHA to find that the standard addressed a "significant" risk, as the plurality held in *Benzene*. The industry also went further and argued that the act also required OSHA to find that the reduction in risk was warranted in light of the associated costs.[258]

The Court concluded that the plain meaning of the statute contradicted the industry's reading because the statute did not use the phrase "cost-benefit."[259] The Court observed that Congress had used this term or similar terms elsewhere and the absence of such a phrase suggested Congress did not intend for OSHA to consider costs and benefits.[260] Instead section 6(b)(5) explicitly used the word "feasible," suggesting that the agency should set the standard at the lowest level possible—which did not imply a cost-benefit analysis. In that sense, the Court noted that "Congress itself defined the basic relationship between costs and benefits, by placing the 'benefit' of worker health above all other considerations save those making the attainment of this 'benefit' unachievable."[261]

Next, the Court considered the industry's claim that section 6(b)(5) contained a cost-benefit requirement because the definition of an occupational safety and health standard provided for those means "reasonably necessary or appropriate to provide safe or healthful employment."[262] Again, the Court rejected the industry's argument. The Justices reasoned that regardless of whether the phrase "reasonably necessary or appropriate" contained a requirement to consider costs and benefits, Congress could not have intended for that requirement to apply to section 6(b)(5). Imposing that requirement would render section 6(b)(5)'s

257 *See id*. at 494–96. The Court noted that inhalation of cotton dust could lead to byssinosis, also called "brown lung" disease, which could produce symptoms ranging from coughing and wheezing to potential death from heart failure. *Id*. at 496.

258 *See id*. at 506.

259 *See id*. at 509.

260 *See id*. at 510–11 (citing the Flood Control Act of 1936, 33 U.S.C. § 701(a) and the Outer Continental Shelf Lands Act Amendments of 1978, 43 U.S.C. § 1347(b)).

261 *Id*. 508–09.

262 *Id*. at 512.

feasibility test superfluous. The agency would always be required to set the health and safety standard at the more lenient level between the cost-beneficial or lowest-feasible standard, which would, by definition, be the cost-beneficial level. To give effect to all parts of the statute, the Court concluded that even if section 3(8) did contain a requirement to consider costs and benefits, that requirement would not apply to a standard promulgated under section 6(b)(5).[263] Lastly, the Court once again reviewed the legislative history behind the Act and found that it generally supported OSHA's position because it did not indicate a position on the role of costs and benefits.[264]

4. *Sweeping up* Cotton Dust

Cotton Dust is notable for a number of reasons. First, despite the dissent's expectation in *Benzene*, the majority of the Court appeared to confirm the plurality opinion from that case. The industry group assumed that the plurality's readings of section 3(8) and (6)(b)(5) were correct, and the Court did not object to that assumption.[265] Thus, after *Cotton Dust*, it appears that the plurality opinion in *Benzene* was affirmed as the defining Supreme Court statement on risk management, at least in the context of OSHA. Again, in *Cotton Dust,* the Supreme Court rejected a proposal to tether risk management to a fixed or objective standard, cost-beneficiality in this case, because it was not clearly stated in the statutory text. Instead, the Court reaffirmed the significance test from *Benzene*, and found that, once this test was met, an agency must set the safety standard at the lowest level feasible.[266]

5. Lead Industries Ass'n v. EPA*: Breathe Lead*

The Courts of Appeals generally took a similar approach to that adopted by the Supreme Court in reviewing agency risk management decisions. In an early and frequently-cited decision regarding the Clean Air Act (CAA), *Lead Industries Ass'n v.*

263 *See id*. at 512–13.

264 *See id*. at 514–21. Consistent with the prior opinion, Justice Rehnquist again dissented on the grounds that the Act violated the non-delegation doctrine, although this time, Chief Justice Berger appears to have reversed his prior position and joined Justice Rehnquist. *Id*. at 543 (Rehnquist, J., dissenting).

265 *See id*. at 506.

266 *See id*.

EPA,[267] the D.C. Circuit rejected an industry claim that the EPA should have considered costs in setting air quality criteria for lead under section 108 of the CAA and air quality standards under section 109 of the CAA.[268] The court explained that despite the name, air quality criteria are not guidelines, but instead contain air quality standards that each state must meet through a plan, submitted to the EPA for approval, that will "contain emission limitations and all other measures necessary" to meet the standard "'as expeditiously as practicable.'"[269] In *Lead Industries*, the EPA set the air quality standard for lead at 1.5 micrograms of lead per meter cubed averaged over a three month period primarily to protect children's health.[270]

The industry challenged the standard on a number of procedural, technical, and statutory grounds, one of which was the claim that, in setting the air quality standard for lead, the EPA should have considered economic cost and technological feasibility.[271] It claimed that the CAA's requirement that the EPA must allow an "adequate margin of safety" suggested that the EPA should consider cost and feasibility in setting air quality standards.[272] The court found the argument to be "totally without merit" and noted that the petitioner was "unable to point to anything in either the language of the [CAA] or its legislative history" to support its claim.[273] The D.C. Circuit reasoned that since Congress had clearly stated that the EPA should consider economic and technological feasibility in other sections of the CAA, it clearly did not intend for the EPA to entertain such

267 *See* Lead Industries Ass'n v. EPA, 647 F.2d 1130 (1980).

268 *See Lead Industries*, 647 F.2d at 1136–37, 1148–49. The D.C. Circuit reached a similar result in the landmark decision *Union of Concerned Scientists v. U.S. Nuclear Regulatory Comm'n*, 824 F.2d 108, 119–120 (1987), in which the court refused to allow the U.S. NRC to consider costs in defining what constitutes "adequate protection" under the Atomic Energy Act. *See also* Natural Resources Defense Council, Inc. v. EPA, 824 F.2d 1146, 1163–64 (D.C. Cir. 1987) (invalidating an agency consideration of cost in setting emissions for chloride vinyl when the statute required the agency to provide an "ample margin of safety . . . .").

269 *Lead Industries*, 647 F.2d at 1137 (quoting 42 U.S.C. § 7410(a)(2)(A)-(B)).

270 *See id.* at 1144–45.

271 *See id.* at 1148.

272 *Id.*

273 *Id.*

considerations in setting air quality standards under section 109.[274] Moreover, the judges found many examples within the legislative history of the Act where members of Congress expressed a clear desire that sources of air pollution either meet appropriate standards or shut down.[275] In something of a coup de grace, the court even noted that the Senate Report for the Clean Air Act explicitly addressed the "adequate margin of safety language," upon which the petitioners rested their case, and explained that rather than direct the agency to consider pragmatic considerations like cost or feasibility, the language was meant to protect against unidentified hazards.[276]

Thus, the D.C. Circuit in *Lead Industries*, following the Supreme Court's lead, narrowly construed a statute to limit an agency's ability to employ an objective approach to risk management, in part based on legislative history. Instead, *Lead Industries* directed the agency to engage in the far more amorphous task of determining what level of safety constituted an "adequate margin."[277]

6. American Trucking Associations*: Breathe More Lead (the Sequel)*

Finally, in *Whitman v. American Trucking Associations*,[278] the Supreme Court returned to the Clean Air Act air quality standards by considering a variety of challenges to the D.C. Circuit's *Lead Industries* precedent. In *Whitman*, several petitioners, including industry as well as the states of Michigan, Ohio, and West Virginia, challenged the EPA's air quality standard for particulate matter and ozone.[279] Petitioners presented a variety of arguments

274 *See id*. at 1148–49 (citing 42 U.S.C. § 7411 (directing the EPA to consider economic and technological considerations in developing performance standards for new stationary air pollution sources)).

275 *See id*. at 1149 (citing S. REP. NO. 91-1196, at 2–3 (1970)).

276 *Id*. at 1150 (citing S. REP. NO. 91-116, at 10).

277 *Id*. at 1153. In arguing this case, the EPA Administrator artfully summed up some of the difficulties facing a regulator in these circumstances: "protecting the public from harmful effects requires decisions about exactly what those harms are . . . the task of making these decisions is complicated by the absence of any clear thresholds above which there are adverse effects and below which there are none. Rather, as scientific knowledge expands and analytical techniques are improved, new information is uncovered which indicates that pollution levels that were once considered harmless are not in fact harmless." *Id*. at 1152.

278 *See* Whitman v. American Trucking Associations, 531 U.S. 457 (2001).

279 *See id*. at 463.

explaining why the Court should overturn *Lead Industries* and find that the CAA permitted the EPA Administrator to consider costs and feasibility in setting air quality standards.[280] Justice Scalia, writing for the majority, rejected petitioners' strained efforts to read a consideration of costs into section 109 of the CAA. Those efforts included the following: relying on secondary definitions of "public health" in the CAA,[281] noting the potential harm that economic costs of regulation may inflict on the public,[282] interpreting the phrase "adequate margin" to include a consideration of costs,[283] observing that the text of the statute did not preclude such considerations,[284] and referring to several other parts of the act that directed the EPA to consider cost.[285] Thus, once the particulate matter settled, *Lead Industries* remained unscathed.

Next, Justice Scalia turned to the lower court's intriguing finding that section 109(b)(1) of the Clean Air Act as interpreted by the EPA violated the non-delegation doctrine. Perhaps following Justice Rehnquist's lead in *Industrial Union*, the D.C. Circuit determined that EPA's ozone regulations were unconstitutional because they lacked "any determinate criterion for drawing lines. [The EPA] has failed to state intelligibly how much is too much."[286] The Court determined that the D.C. Circuit's test

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280 *See id*. at 464–65.

281 *See id*. at 465 (finding meritless a claim that interpreting the phrase "public health" to mean the "art and science dealing with the protection and improvement of community health" suggested that the EPA could consider cost in setting air quality standards "requisite to protect the public health" under section 109 of the Clean Air Act).

282 *See id*. at 466 (responding to this claim by noting that Congress in fact considered this possibility and provided waiver provisions to address it).

283 *See id*. at 468 ("Congress . . . does not . . . one might say, hide elephants in mouseholes.").

284 *See id*. at 469 (responding that economic cost "is *both* so indirectly related to public health *and* so full of potential for cancelling the conclusions drawn from direct health effects that it would surely have been expressly mentioned in §§ 108 and 109 had Congress meant it to be considered.").

285 *See id*. at 470–71 (noting that these cost benefit provisions assist the states in effecting point source regulations and other methods to meet the air quality standards).

286 American Trucking Associations v. EPA, 175 F.3d 1027, 1034 (1999). As noted above, the D.C. Circuit's own prior jurisprudence specifically forbade the EPA from developing such intelligible principles like cost-beneficiality or technological feasibility in this context. As a result, the holding was roughly the judicial equivalent of an older child grabbing a younger child's wrists, pummeling the younger child with his or her own hands, and demanding to know

of whether the statute, as interpreted by the agency, failed to provide an intelligible principle, was itself unintelligible and noted that "[t]he idea that an agency can cure an unconstitutionally standardless delegation of power by declining to exercise some of that power seems to us internally contradictory."[287] Instead, the Court examined section 109 in light of other statutes and determined that it contained similar standards for exercising delegated power.[288] Thus, the Court determined that the EPA's ozone standards rested on a valid delegation of power from Congress.

As could be expected given his earlier scholarly work, Justice Breyer filed a thoughtful concurrence that appears to have had a profound influence on future opinions in this area. Justice Breyer disagreed with the majority view that an authority to consider costs in setting safety standards "must flow from a textual commitment that is clear."[289] Instead, he reasoned that to better "achieve regulatory goals—for example, to allocate resources so that they save more lives or produce a cleaner environment—regulators must often take account of all of a proposed regulation's adverse effects."[290] Thus, he found that "other things being equal, we should read silences or ambiguities in the language of regulatory statutes as permitting, not forbidding, this type of rational regulation."[291] However, Justice Breyer also determined that "other things are not equal" with respect to section 109 because the Act's structure and legislative history clearly indicated that Congress did not intend for the EPA to consider costs under section 109.[292]

In many ways, *Whitman* marks a cross-over point in the courts' risk management jurisprudence. True to its many predecessors, *Whitman* held firm to the principle that agencies should not consider feasibility or cost in setting safety standards unless explicitly directed by statute. However, Justice Breyer

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"why are you hitting yourself?"

287 *Whitman*, 531 U.S. at 473.

288 *See id*. at 473–75.

289 *Id*. at 490 (Breyer, J., dissenting) (internal quotations omitted).

290 *Id*.

291 *Id*.

292 *Id*. at 491 (citing 116 CONG. REC. 32901–02 (1970)) (noting that the primary sponsor for the amendments explicitly stated that the purpose of the act was to protect health and safety regardless of cost, even if "industries will be asked to do what seems to be impossible at the present time" (internal quotations omitted) (emphasis removed)).

observed that such a result, while perhaps appropriate in *Whitman*, hardly produced a rational system of risk regulation. Indeed, as noted above, Justice Breyer convincingly revealed in his scholarly work the contradictions in a government-wide system of regulation that effectively placed dramatically different values on human life.[293] Finally, the Court conclusively rejected a jurisprudence that borrowed heavily from Rehnquist's dissent in *Benzene*. The Court applied the non-delegation doctrine, but found that section 109 of the CAA, which is a relatively vague standard, provided a sufficiently intelligible principle to survive judicial review. As a result, *Whitman* likely dispelled then-Justice Rehnquist's efforts to reanimate the non-delegation doctrine, at least in the field of risk management.[294] However, as discussed below, his concern that Congress had delegated too much power to administrative agencies in this field could be one explanation for the increasing judicial willingness to entertain more objective approaches to risk management.

B. *Recent Risk Management Decisions: Economics Strikes Back*

Since 2009, the Supreme Court has issued a string of opinions that suggest a softened stance toward a consideration of technological feasibility and economic costs in risk management. Generally, these cases respond to challenges to agencies' consideration of cost in setting safety standards under statutes that do not explicitly provide for such a consideration. Although earlier cases would suggest that the agency could not consider costs in such situations, in three high-profile cases, the Supreme Court concluded that a consideration of costs was appropriate or even required.[295] Thus, the rule regarding consideration of cost and technological feasibility in risk management appears to have significantly shifted from allowing that consideration only when expressly provided for by statute to permitting that consideration

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293 *See id*. *See* BREYER, *supra* note 9.

294 Interestingly, Chief Justice Rehnquist joined the entire opinion in *Whitman*. Perhaps he reconsidered the non-delegation doctrine in the intervening years, chose to respect *stare decisis*, or found the delegation in section 109 of the CAA to be more intelligible than the delegations in the OSH Act at issue in *Benzene*. Given the similarities between the two acts, one of the first two explanations appears more plausible.

295 *See generally* Entergy v. Riverkeeper, 556 U.S. 208 (2009); Michigan v. E.P.A., 135 S.Ct. 2699 (2015). *See HME Homer City Generation*, 134 S.Ct. at 1584.

unless expressly forbidden by statute. As a result, agencies grappling with risk management questions may now rely on a far greater, and potentially more reliable, set of considerations in most instances.

1. Entergy v. Riverkeeper*: Consistency Being the Hobgoblin of a Small Jurisprudence*

The first case to herald a new era of risk management jurisprudence on the Court was the high-stakes litigation in *Entergy v. Riverkeeper*.[296] Although not a health and safety case, the opinion dealt with a classic risk management-type decision: how much of an environmental impact on aquatic life is acceptable? Justice Scalia, writing for the majority, considered the EPA's regulations under the Clean Water Act for cooling water intake structures for existing power plants, which accounted for over 50 percent of the United States' electric power market.[297] These regulations required all power plants to reduce impingement ("squashing against intake screens") of fish and shellfish by 80 to 95 percent and entrainment ("suction into the cooling system") for those species by 60 to 90 percent at a "subset" of power plants.[298] In setting this standard, the EPA declined to require existing facilities to adopt closed-cycle cooling systems, or an equivalent technology, which could reduce impingement by 98 percent, even though it had required new facilities to meet such standards.[299] The EPA decided not to require closed-cooling systems because of the "generally high costs," approximately $3.5 billion, such measures would impose on the industry without a commensurate benefit.[300] Riverkeeper and other parties challenged the EPA's consideration of costs in setting standards for intake structures.[301]

As expected, the Court began its analysis with the precise terms of the statute. Section 1326(b) of the Clean Water Act required regulations for cooling water intake structures to reflect

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296 *See Riverkeeper*, 556 U.S. 208 (2009).

297 *See id.* at 215.

298 *Id.* at 213, 215 (citing 40 C.F.R. §§ 125.93, 125.94(b)(1)(2)).

299 *See id.* at 215–16 (citing National Pollutant Discharge Elimination System—Final Regulations to Establish Requirements for Cooling Water Intake Structures at Phase II Existing Facilities, 69 Fed. Reg. 41,576, 41, 601–66 (July 9, 2004)).

300 *Id.*

301 *See id.* at 217.

"the best technology available for minimizing adverse environmental impact."[302] The Court pondered the meaning of the word "best"; while the word "best" in the statute could mean the technology that most completely prevented environmental harm, it could also mean the technology that most efficiently minimized such impacts.[303] The Court found the latter definition to be the more persuasive.[304] The non-governmental organization challenging the regulation argued that because the phrase "for minimizing adverse environmental impact" immediately followed "best technology available," the text most clearly suggested that the word "best" meant the most complete elimination of environmental harms. Focusing on the word "minimize," the majority found that the term "admits of degree" and therefore did not necessarily connote the greatest possible reduction.[305] Interestingly, unlike previous risk management cases, the Court did not deeply parse the legislative history. Rather, to support its finding, the Court carefully considered other provisions of the Act and noted that other sections much more clearly conveyed an intent to eliminate environmental impacts without consideration of costs.[306] Thus, the Court concluded that the silence on economic costs in section 1326(b) afforded the EPA with discretion to consider such factors in setting standards for intake structures.[307]

The dissenting Justices viewed the majority's holding as a repudiation of *American Trucking* and *Cotton Dust*. The dissent began with the observation that cost-benefit analysis can be especially "controversial in the environmental context in which a regulation's financial costs are often more obvious and easier to quantify than its environmental benefits."[308] Indeed, the dissent noted that the EPA had struggled to appropriately quantify the

302 *Id*. at 218 (internal quotations omitted).

303 *See id*.

304 *See id*.

305 *Id*.

306 *See id*. at 219 (noting that section 1311(b) required "'*elimination* of discharges of all pollutants'" and section 1316(a)(1) required a standard "'permitting *no discharge* of pollutants.'"). As described by Justice Breyer, that legislative history, while not necessarily fatal to the majority's position, was hardly completely favorable. Senator Muskie, the act's sponsor, described the "best available technology" standard to require "'evaluat[ing] . . . what needs to be done . . . without regard to cost.'" *Id*. at 232 (Breyer, J., dissenting) (alterations in original) (quoting 118 CONG. REC. 33693 (1972)).

307 *See id*. at 219.

308 *Id*. at 237 (Stevens, J., dissenting).

benefits of averted harm to aquatic species.[309] The dissent concluded that the Court's previous holdings in *American Trucking* rested on the fundamentally sound insight that if Congress intended for agencies to consider cost it would explicitly direct them to do so.[310] Finally, the dissent noted that the legislative history supported this view and explicitly stated that the best available technology standard was "'not subject to any . . . form of cost/benefit analysis.'"[311] Justice Breyer ultimately agreed with the majority, but did acknowledge that some parts of the legislative history supported the dissent's reading. For example, the Act's sponsor described the "best available technology" standard to require "'evaluat[ing] . . . what needs to be done . . . without regard to cost.'"[312]

Writing on behalf of the majority, Justice Scalia disavowed any attempt to overturn *American Trucking* or *Cotton Dust*. Justice Scalia noted that unlike the statutory scheme at issue in *Riverkeeper*, the statute in *American Trucking* was silent on the question of cost while other sections expressly directed the EPA to consider cost, which suggested a Congressional intent for the agency not to consider costs in *American Trucking*.[313] By contrast, the statute in *Riverkeeper* did not mention cost while other provisions in the statute explicitly forbid the consideration of cost, which indicated that Congress did not intend such a prohibition in *Riverkeeper*.[314] Likewise, the majority concluded that *American Trucking* only stood for the proposition that the agency was not required to engage in a cost-benefit analysis under the terms of the underlying statute but could choose to do so.[315]

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309 *See id*. at 238. *See also id*. (noting that the EPA concluded that the benefit of the regulation could be as high as $735 million if it considered all species but only would be $83 million when if it just considered commercially harvested species (about 1.8% of the total)) (citing 69 Fed. Reg. at 41,660–66).

310 *See id*. at 239.

311 *Id*. at 243 (citing 3 Legislative History of the Clean Water Act of 1977: A continuation of the Legislative History of the Federal Water Pollution Control Act (Committee Print compiled for the Senate Committee on Environmental and Public Works by the Library of Congress), Ser. No. 95-14, p. 427 (1978)).

312 *Id*. at 232 (Breyer, J., dissenting) (alterations in original) (quoting Senator Muskie's statements at118 Cong. Rec. 33693 (1972)).

313 *See id*. at 223.

314 As described below, a majority of the Court would reject this approach in *Michigan v. EPA*. *See infra* at Section III.B.4.

315 *See id*.

2. *Unsticking* Riverkeeper

The majority holding in *Riverkeeper* was surprising in many respects. Most obviously, the majority went to considerable lengths, similar to those of the plurality in *Benzene*, to find the EPA's interpretation acceptable. The interpretation that "best" meant "most efficiently" seems as obscure as the conclusion in *Benzene* that the phrase "necessary and appropriate" also included a buried requirement that OSHA find a hazard "significant" before regulating. Second, unlike previous risk management opinions, the majority almost completely ignored legislative history. In that sense, the Court's flexible interpretation of the statute appears far less justified than previous cases, which took expansive readings of statutory phrases to match a perceived Congressional intent. Indeed, the dissent's and concurrence's treatment of the legislative history suggested that the majority's reading would have been inconsistent with Congress's intent.

3. HME Homer City Generation*: Risky Neighbors*

The Court continued this trend in *EPA v. HME Homer City Generation*.[316] In that CAA case, the Court considered the complicated issue of how to regulate air pollutants that originate in one state and lead to another state's inability to meet air quality attainment standards promulgated pursuant to the CAA.[317] To address this problem, Congress amended the "Good Neighbor Provision" of the CAA in 1990 to require that state plans for complying with attainment standards "contain adequate provisions . . . prohibiting any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will . . . contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any" attainment standard.[318] To implement this law, the EPA conducted a series of advanced models to determine which sources would be sufficiently cost-beneficial to eliminate for states that were responsible for more than *de minimis* downwind pollution.[319]

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316 *See* EPA v. HME Homer City Generation, 134 S.Ct. 1584 (2014).

317 *See id*. at 1594 ("'The wind bloweth where it listeth, and thou hearest the sound thereof, but canst not tell whence it cometh, and whither it goeth.'" (quoting *John* 3:8 (King James))).

318 *Id*. at 1587.

319 *See id*. at 1596–97. The EPA effectively ran a series of models that considered the effects of implementing all mitigation measures that could

The Court touted the benefits of the EPA's reasonable approach and found it to be (1) efficient because it was based on cost, and (2) equitable because it penalized more heavily those states that had made less progress in reducing air pollution.[320] Moreover, in an increasingly familiar approach to risk management review, the Court noted that "nothing in text of the Good Neighbor Provision precludes that choice."[321] Notably, the Court applied the more deferential standard of review in *Chevron* to the agency's risk management analysis.[322] The majority concluded that the statute clearly required the EPA to set standards to eliminate downwind pollution from upwind polluters, but did not indicate how the EPA was to allocate the reductions among upwind polluters.[323] Thus, it found the EPA's cost-benefit approach was reasonable.[324] Finally, the Court also concluded the EPA's approach was reasonable because an alternative approach, based on proportional contributions, could potentially prove impossible in light of the complexities in tracing back pollutants to their original sources.[325]

Somewhat surprisingly, given his opinion in *Riverkeeper*, Justice Scalia filed a spirited dissent. Echoing then-Justice Rehnquist's comments in *Industrial Union*, Scalia began by noting that "[t]oo many important decisions of the Federal Government are made nowadays by unelected agency officials . . . rather than by the people's representatives in Congress."[326] Justice Scalia argued that the majority employed a "Look Ma, no hands!" approach to judicial review by failing to meaningfully engage with the actual text of the statute.[327] Indeed, Justice Scalia noted that the statute itself did not mention costs or efficiency but instead

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eliminate one ton of pollutants for $500 or less, and then the EPA re-ran the models at additional $500 thresholds to determine what measures were cost effective. *Id*. The EPA then used the results of these estimates to identify thresholds at which "noticeable change occurred in downwind air quality." *Id*. (quoting Federal Implementation Plans: Interstate Transport of fine Particulate Matter and Ozone and Correction of SIP Approvals, 76 Fed. Reg. 48,208, 48,249–51 (Aug. 8, 2011)).

320 *See id*. at 1607.

321 *Id*.

322 *See id*. at 1603.

323 *See EME Homer City Generation*, 134 S.Ct. at 1603–04.

324 *See id*. at 1604.

325 *See id*. at 1607.

326 *Id*. at 1610 (Scalia, J., dissenting).

327 *Id*.

directed that states eliminate pollutants that "contribute significantly to nonattainment" in downwind states and that the majority entirely failed to explain how the EPA's approach found support in the text of the statute.[328] Thus, Justice Scalia found the majority's approach lacking because it did not appear to have any relation to the statutory text, which did not clearly direct a consideration of costs and benefits in setting upwind standards. In his view, the statute plainly directed the EPA to eliminate those pollutants that significantly contributed to nonattainment regardless of cost. Likewise, Justice Scalia did not concur with the majority's impossibility argument; he noted that under well-established judicial principle, sometimes if a statute is impossible to execute as clearly worded, then it must fail.[329]

Thus, the unifying theme in Justice Scalia's dissent, whether fair or not, appeared to be that the majority's approach to risk management unduly usurped Congressional authority by unhinging the inquiry into the adequacy of the agency's risk management analysis from the terms of the statute for reasons that were ultimately unpersuasive—impossibility. In that sense, the dissent does highlight the dramatic extent to which this line of cases continued to depart from the careful and searching textual inquiries of the earlier risk management cases toward a far more deferential approach to agency risk management decisions. That trend has continued until the most recent terms.

4. Michigan v. EPA*: The Cost of Regulating*

Finally, the Court returned to risk management in 2015, in *Michigan v. EPA*,[330] with Justice Scalia once again writing the majority opinion. Again, the Court considered a complex portion of the CAA: this time the National Emissions Standards for Hazardous Air Pollutants Program, which "targets for regulation stationary-source emissions" of over 180 pollutants.[331] When it enacted that provision, Congress provided a special procedure to

328 *Id*. (quoting 42 U.S.C. § 7410(a)(2)(D)(i)(I)). This distinction perhaps forms the basis for reconciling Justice Scalia's opinion in *Riverkeeper* with his dissent in *EME Homer City Generation*—at least in *Riverkeeper* he was able to articulate a nexus, albeit one that required some quick footwork, between the consideration of costs and the text of the statute.

329 *See id*. at 1613 (*quoting* ROSCOE POUND, JURISPRUDENCE 493 (1959)).

330 *See* Michigan v. EPA, 135 S.Ct. 2699 (2015).

331 *Id*. at 2704 (citing 42 U.S.C. § 7412).

determine its applicability to fossil fueled power plants; Congress directed the EPA to study the potential results of regulating such facilities under the program and do so if "regulation is appropriate and necessary."[332] The EPA found such regulation was "'appropriate and necessary'" but explicitly declined to consider costs in making that determination.[333] A number of petitioners challenged the EPA's refusal to consider costs in deciding to regulate fossil fueled plants.

Although the Court applied the deferential *Chevron* test to the agency's decision, it nonetheless found that the EPA "strayed far beyond [reasonable] bounds" by ignoring cost.[334] The Court concluded, "[r]ead naturally in the present context, the phrase 'appropriate and necessary' requires at least some attention to cost. One would not say that it is even rational, never mind 'appropriate,' to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits."[335] The EPA argued that, as the Court itself reasoned in *American Trucking,* because other provisions in the Clean Air Act explicitly mention cost, the phrase "appropriate and necessary" did not require such a consideration.[336] But, the Court surprisingly distinguished *American Trucking* on the grounds that the "appropriate and necessary" language at issue was far more expansive than the narrower criteria at issue in *American Trucking*, "requisite to protect the public health."[337] Finally, the EPA argued that because it adequately considered costs at later points in its regulatory process, such a consideration at the "necessary and appropriate" stage was unnecessary.[338] The majority rejected this reasoning by observing that the adequacy of later stages of the regulatory process was not an issue before it and moreover by "EPA's logic, someone could decide whether it is 'appropriate' to buy a Ferrari without thinking about the cost, because he plans to think about cost later when deciding whether to upgrade the sound

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332 *Id*. at 2707.

333 *Id*. at 2706.

334 *Id*. at 2707 (citing Chevron v. Nat. Res. Defense Council, 467 U.S. 837, 842–43 (1984)).

335 *Id*.

336 *See id*. at 2709 (citing *American Trucking*, 531 U.S. at 467).

337 *Id*.

338 *Id*. at 2709.

system."[339]

Interestingly, the dissent, written by Justice Kagan, did not challenge the majority's central point that the EPA must consider costs in regulating fossil fuel power plants under the program: "I agree with the majority—let there be no doubt about this—that EPA's power plant regulation would be unreasonable if the Agency gave cost no thought *at all*."[340] But instead, the dissent determined that the EPA gave adequate consideration to cost at a later stage in the process, and therefore its declination to do so at the first step of its process was reasonable.[341]

Consequently, *Michigan v. EPA* fits firmly into the Court's recent risk management tradition: once again the Court interpreted a relatively vague statute in a way that not only permitted consideration of costs, but required it. Moreover, by this point, the importance of cost consideration as a key element to informed decision making was so ingrained in Court precedent, perhaps thanks to the efforts of Justice Breyer—but also Justice Rehnquist, who recognized the implications of fully unconstrained agency decision making—that the dissent did not dispute that the agency must consider costs in deciding to regulate, but only when it must do so.

C. *Explaining the Court's Evolution*

As the above discussion illustrates, the Courts' approach to risk management has undergone a fundamental shift in recent years. Whereas in decades past courts strongly rejected attempts to read cost-beneficiality or technological feasibility into phrases like "reasonably necessary and appropriate"[342] or "adequate margin of safety,"[343] after 2009, the Court was willing to find such requirements in similarly vague words like "contribute significantly"[344] or "appropriate and necessary."[345] Additionally,

339 *Id*.

340 *Id*. at 2714 (Kagan, J., dissenting) (internal quotations omitted).

341 *See id*. Judge Kavanaugh of the D.C. Circuit relied on the majority and dissenting opinions in *Michigan v. EPA* to distill a general rule, albeit in a dissent, that "the costs of an agency's action are a relevant factor that the agency must consider before deciding whether to act." Mingo Logan Coal Co. v. EPA, 829 F.3d 710, 731 (2016) (Kavanaugh, J., dissenting).

342 *Benzene*, 448 U.S. at 637–40 (internal quotations omitted).

343 *Lead Industries*, 647 F.2d at 1148 (internal quotations omitted).

344 *HME Homer City Generation*, 134 S.Ct. at 1611 (Scalia, J., dissenting) (internal quotations omitted).

Justice Scalia suggested that the difference between the two approaches could be grounded in surrounding provisions of an act and whether those terms expressly allowed or forbade cost consideration.[346] However, he later appeared to abandon this distinction, or at least neglected to provide a compelling defense for it, in *Michigan v. EPA*.[347] Thus, the difference in the judicial consideration of risk management does not appear to be grounded in the statutory text under consideration. Nor does it appear to arise from the advent of *Chevron*; while *HME Homer City Generation* relied on *Chevron* to defer to an agency's use of costs, *Michigan* found that an agency's failure to consider costs was not entitled to deference under that standard.[348] Finally, although the complexity and accuracy of cost-benefit analyses have increased significantly as a result of advances in computer modelling from the 1970s to the present day, the Court does not appear to have relied heavily on this trend in its opinions.

This shift appears to be best understood as part of a growing understanding on the Court of both the colossal significance of risk management determinations and the extent to which objective standards can promote regularity in these determinations. Perhaps Justice Rehnquist most vividly described the significance of risk management determinations in his separate opinion in *Benzene*, which has continued to resonate with jurists. Likewise, Justice Breyer's famous description of the role that concrete standards, such as cost-beneficiality and, to an extent, technological feasibility, can play in bringing some regularity to those decisions has also appeared to have shaped subsequent Courts' thinking. Indeed, while earlier decisions treated these notions as suspect, by the time of *Michigan v. EPA*, both the majority and dissent acknowledged that consideration of costs was so inherent to effective regulation that the agency's regulations would be invalid without such a consideration at some point in the process.

345 Michigan v. E.P.A., 135 S.Ct. 2699, 2707 (2015) (internal quotations omitted).

346 *See* Entergy v. Riverkeeper, 556 U.S 208, 223 (2009).

347 *See Michigan*, 135 S.Ct. at 2709.

348 *Compare HME Homer City Generation*, 134 S.Ct. at 1603–04, *with Michigan*, 135 S.Ct. at 2707.

V. THOUGHTS FOR PRACTITIONERS

In light of this evolution, agency practitioners should feel more enabled to consider objective criteria like cost or feasibility in their risk-management decisions. As discussed in the previous sections, many agencies' current practices appear to have been informed by the past, inhospitable precedent toward such approaches. However, in setting new standards, agencies should feel more confident to rely on these objective criteria. Moreover, in revisiting previously established standards, safety regulators may find that the door to cost-effective regulation in previously forbidden areas now only *appears* to be locked. Agencies would certainly benefit from these new perspectives in risk management decision making.

Ultimately, it may be the public who benefits the most if such a change leads to a more consistent and efficient use of societal resources to protect health and safety both by shunning standards that are unduly expensive and by identifying measures that offer a large safety return on modest investment.

Given the wealth of knowledge and experience in various risk management approaches, agencies would greatly benefit from reaching out to other agencies and learning about their risk management practices. Federal agencies would be in a much better position to protect public health and safety and enhance their risk management approaches by learning from other agencies that have been looking at these same issues for decades.

CONCLUSION

While expert technical agencies may be very adept at performing risk assessments, the ultimate goal of achieving a meaningful consistency in risk management remains elusive—and perhaps always will be. The pursuit of a happy and full life is a universal goal, especially given the certainty that it will all come to an end and that we must face some struggle along the way (in the form of illnesses, injuries, taxes, etc.). To accomplish that goal, it would help to know of and be protected from the true risks of the air we breathe, the food we eat, the activities we do, and the reasons behind the rules that govern our life. However, there is no consensus about which risk-management approach actually leads to the "right answer." And the "right answer" in and of itself is a murky concept. Some say the "right answer" is to eliminate risk

altogether while others seek to reduce the risk or shift the burden to the industry to prove something is "safe."

Through risk management, expert agencies must essentially approve a one-size-fits-all approach to safety for everyone. Given the subjectivity inherent to questions of risk management, objective approaches like cost-beneficiality or technological feasibility are alluring. Whether a regulation is in fact cost-beneficial or imposes requirements that can be met with existing technology is far less debatable than how many deaths are acceptable and more clearly tied to a logical basis. Yet many courts, especially the Supreme Court, have treated such approaches as suspect in prior years. Fortunately, recent case law suggests that this precedent is ceding ground in favor of judicial opinions that are supportive of, or even require, consideration of objective criteria in the field of risk management.

Given these changes, regulatory agencies would be well advised to take an increasingly holistic look at questions of risk management, and utilize a framework that incorporates objective as well as subjective criteria. In doing so, agencies may find the practices of fellow agencies instructive, and may be able to achieve greater consistency within their regulatory frameworks. Moreover, such efforts may ultimately lead to greater consistency across the government, and while the United States may never fully realize Justice Breyer's vision of a perfectly consistent approach to risk management, greater consistency would, in the Authors' view, provide substantial benefits to all stakeholders.