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SHIFTING SANDS: THE LIMITS OF SCIENCE IN SETTING RISK STANDARDS

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INTRODUCTION

Administrative law aspires to bring reason to agency policymaking.[1] The Administrative Procedure Act[2] requires agencies to specify the basis for the rules they promulgate,[3] and in exercising their review

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[1] *See, e.g.*, CASS R. SUNSTEIN, ONE CASE AT A TIME: JUDICIAL MINIMALISM ON THE SUPREME COURT 31 (1999) ("Much of administrative law consists of an effort to ensure reason-giving by regulatory agencies . . . . The agency . . . must generate a convincing explanation . . . ."); Lisa Schultz Bressman, *Disciplining Delegation After* Whitman v. American Trucking Ass'ns, 87 CORNELL L. REV. 452, 485 (2002) ("[Administrative law principles] require agencies in general to articulate a basis for their policy determinations and, in particular, to articulate the standards for those determinations."); Jerry L. Mashaw, *Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State*, 70 FORDHAM L. REV. 17, 20 (2001) (arguing that the demand for reason is stronger in administrative law than even in judicial decision making).

[2] 5 U.S.C. §§ 551–559, 701–706 (2000).

[3] *Id.* § 553(c).

of agency action under the arbitrary and capricious standard,[4] courts have repeatedly demanded that agencies justify their decisions with careful reasoning.[5] In striving to meet administrative law's demands and aspirations, agencies have applied their expertise to gather facts and to invest in sustained scientific research. For regulatory decision makers, science provides a systematic basis for understanding policy problems and the potential consequences of different policy options, and therefore, scientific evidence must play a key role in agency decision making.[6] But even though science is valuable for what it can tell administrators about policy problems and their possible solutions, science alone cannot provide a complete rationale for a policy decision

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[4] *Id.* § 706(2)(a).

[5] *See, e.g.*, Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 48 (1983) (referring to the "strict and demanding" requirement that "an agency must cogently explain why it has exercised its discretion in a given manner"); *see also* AT&T Corp. v. FCC, 236 F.3d 729, 736 (D.C. Cir. 2001) (invalidating an FCC rule because the agency "ha[d] considered this question on several occasions, each time applying a test different from that applied here"); Pearson v. Shalala, 164 F.3d 650, 660-61 (D.C. Cir. 1999) (holding that an agency cannot "refuse to define the criteria it is applying," and that "it must be possible for the regulated class to perceive the principles which are guiding agency action"); Am. Lung Ass'n v. EPA, 134 F.3d 388, 392-93 (D.C. Cir. 1998) ("[U]nless [the Administrator] describes the standard under which she has arrived at this conclusion, . . . we have no basis for exercising our responsibility to determine whether her decision is 'arbitrary [or] capricious . . . .'" (citation omitted)); Hall v. McLaughlin, 864 F.2d 868, 872 (D.C. Cir. 1989) ("Reasoned decisionmaking requires treating like cases alike; an agency may not casually ignore its own past decisions. Divergence from agency precedent demands an explanation." (footnote omitted)); Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 525 (D.C. Cir. 1983) ("By EPA's logic, adverse health effects would permit it to justify any lead standard at all, without explaining why it chose the level it did. We cannot accept such incomplete reasoning."); Greater Boston Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir. 1970) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute." (footnotes omitted)).

[6] *See, e.g.*, COMM. ON RESEARCH AND PEER REVIEW IN EPA, NAT'L RESEARCH COUNCIL, STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY: RESEARCH-MANAGEMENT AND PEER-REVIEW PRACTICES 24 (2000) ("In the absence of sound scientific information, high-risk problems might not be adequately addressed, while high-profile but lower-risk problems might be targeted wastefully."), *available at* http://www.nap.edu/openbook/0309071275/html/24.html; CHRISTOPHER F. EDLEY, JR., ADMINISTRATIVE LAW: RETHINKING JUDICIAL CONTROL OF BUREAUCRACY 13-14 (1990) (highlighting science as one of the three central aspects of administrative decision making); Alon Rosenthal et al., *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269, 270 (1992) ("Scientific information about the human health risks of exposure to toxic chemicals is critical to making sound regulatory decisions.").

because it does not address the normative aspects of administrative policymaking.[7] To fulfill administrative law's aspiration of reason, agencies need to explain their decisions by reference not only to scientific evidence but also to policy principles that speak to the value choices inherent in their decision making.

In this Article, we examine the role and limitations of science in the important policy domain of environmental risk management. In particular, we offer a detailed account of the use—and misuse—of science by the Environmental Protection Agency (EPA) in its efforts to justify recent changes to its national ambient air quality standards (NAAQS) for ozone[8] and particulate matter (PM).[9] Environmental risk management is an area of public policy where science plays a vital role in revealing the health effects associated with human exposure to different substances.[10] It is also an area, however, where agencies have often exaggerated the role of science and thus have escaped their responsibility to give careful reasons for the value judgments implicit in their decision making.[11]

EPA's recent revisions to its air quality standards hold profound implications for both public health and the economy.[12] Not surprisingly, these revisions generated substantial political controversy[13] and led to several rounds of litigation.[14] In the first case to come before the D.C. Circuit, the majority rejected EPA's revised standards,

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[7] *See infra* notes 34-36 and accompanying text (showing how EPA's exclusive reliance on science in its ozone and particulate matter rulemakings was fundamentally mistaken).

[8] National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856 (July 18, 1997) (codified as amended at 40 C.F.R. §§ 50.9–.10) [hereinafter EPA, Ozone Final Rule].

[9] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652 (July 18, 1997) (codified as amended at 40 C.F.R. §§ 50.6–.7) [hereinafter EPA, PM Final Rule].

[10] *See infra* notes 34, 413 and accompanying text (noting the role of scientific analysis in EPA decision making).

[11] *See* Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1617 (1995) ("[A]gencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions.").

[12] *See infra* notes 369-70 and accompanying text (detailing estimated costs of the revisions).

[13] *See, e.g.*, *infra* note 70 and accompanying text (describing the congressional hearings on the standards).

[14] The standards were the subject of multiple decisions in the D.C. Circuit in addition to a major decision in the U.S. Supreme Court. For a discussion of the litigation, see *infra* notes 15-20, 408-12 and accompanying text.

holding that the Agency's application of the Clean Air Act violated the constitutional nondelegation doctrine.[15] Congress delegated authority to EPA to set air quality standards that "'protect the public health' with an 'adequate margin of safety,'"[16] language that the majority held could pass constitutional muster only if EPA applied an "intelligible principle" to cabin its discretion in setting air quality standards.[17] The D.C. Circuit's novel constitutional ruling generated considerable attention and seemed potentially to cast other regulatory statutes into some doubt.[18] On appeal, in the much-heralded case of *Whitman v. American Trucking Ass'ns*,[19] the Supreme Court rejected the D.C. Circuit's constitutional analysis, holding that the Clean Air Act did not violate the nondelegation doctrine.[20]

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[15] Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1038-40 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

[16] *Id.* at 1034 (quoting 42 U.S.C. § 7409(b)(1) (2000)).

[17] *Id.* at 1038-40.

[18] The constitutional issues presented in *American Trucking* received extensive academic and legal analysis. For examples of such analysis, see Cary Coglianese, *The Constitution and the Costs of Clean Air*, 42 ENV'T 32 (2000); Ernest Gellhorn, *The Proper Role of the Nondelegation Doctrine*, 31 Envtl. L. Rep. (Envtl. L. Inst.) 10,232 (Feb. 2001); C. Boyden Gray, *The Search for an Intelligible Principle: Cost-Benefit Analysis and the Nondelegation Doctrine*, 5 TEX. REV. L. & POL. 1 (2000); Lisa Heinzerling, *The Clean Air Act and the Constitution*, 20 ST. LOUIS U. PUB. L. REV. 121 (2001); Thomas O. McGarity, *The Clean Air Act at a Crossroads: Statutory Interpretation and Longstanding Administrative Practice in the Shadow of the Delegation Doctrine*, 9 N.Y.U. ENVTL. L.J. 1 (2000); Craig N. Oren, *Run Over by* American Trucking *Part I: Can EPA Revive Its Air Quality Standards?*, 29 Envtl. L. Rep. (Envtl. L. Inst.) 10,653 (Nov. 1999); Richard J. Pierce, Jr., *The Inherent Limits on Judicial Control of Agency Discretion: The D.C. Circuit and the Nondelegation Doctrine*, 52 ADMIN. L. REV. 63 (2000); Cass R. Sunstein, *Is the Clean Air Act Unconstitutional?*, 98 MICH. L. REV. 303 (1999).

[19] 531 U.S. 457 (2001).

[20] *Id.* at 475-76; *see also* Cass R. Sunstein, *Regulating Risks After* ATA, 2001 SUP. CT. REV. 1, 3 ("[*Whitman*] reestablish[es] long-settled law allowing Congress to delegate broad discretionary authority to regulatory agencies."). *But cf.* Bressman, *supra* note 1, at 469-70 ("[*Whitman*] denie[s] agencies the power to cure deficiencies in delegating statutes."). The Supreme Court also rejected industry's statutory argument that EPA can consider costs in setting air quality standards, affirming a string of D.C. Circuit decisions holding likewise. *Whitman*, 531 U.S. at 464-71 (citing Am. Lung Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998); Natural Res. Def. Council v. Adm'r., EPA, 902 F.2d 962, 973 (D.C. Cir. 1990); Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1185 (D.C. Cir. 1981); Lead Indus. v. EPA, 647 F.2d 1130, 1148 (D.C. Cir. 1980)). The Supreme Court did leave open the possibility for separate consideration of EPA's decision under the arbitrary and capricious standard on remand to the D.C. Circuit. *Id.* at 476. Given the Supreme Court's affirmation of the adequacy of EPA's decision making on constitutional grounds, it came as little surprise that the D.C. Circuit subsequently (although not necessarily correctly) found EPA's decision making to withstand the arbitrary and capricious test. Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 358 (D.C. Cir. 2002).

The Supreme Court's decision to uphold the Act—and by implication EPA's revised standards—against constitutional challenge resolved what had become one of the most significant and controversial issues in environmental, health, and safety regulation to emerge in recent years. Nevertheless, although the constitutional issues raised by the case have been settled, the revised ozone and particulate standards remain one of EPA's most significant environmental policy decisions. Not only will the standards have important impacts on public health, but these two standards alone are expected to impose more costs on the economy than all other air pollution regulations combined.[21] The policy significance of these standards makes all the more salient another vital issue raised by this case, one that was not explicitly addressed by the Supreme Court and that has also escaped much scrutiny in the academic commentary on the case.[22] The unaddressed issue is the question of the appropriate role of science in setting risk standards.

Agencies like EPA must rely on science to make well-informed and effective policy decisions, such as where air quality standards should be set, but they cannot rely on science exclusively to justify these decisions.[23] This Article explains how EPA's invocation of science in defense of its new air quality standards contributed to, or at least deflected attention from, a remarkable series of inconsistencies in EPA's positions. Given the way EPA and the courts have interpreted the Clean Air Act, the Agency has been able to, if not been forced to, cloak its policy judgments under the guise of scientific objectivity, with the consequence that the Agency has evaded accountability for a shifting set of policy positions having major implications for public health and the economy.[24] In short, EPA's use of a science-based rhetoric enabled it to avoid responsibility for providing any clear, consistent reasons for its policy choices in setting air quality standards.[25] The Agency's shifting and incoherent approach to its NAAQS decisions

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[21] *See infra* note 370 and accompanying text (detailing the amount of money spent on compliance with the Clean Air Act).

[22] The academic literature has focused predominantly on the constitutional issues raised in *Whitman*. *See* sources cited *supra* notes 18, 20.

[23] *See infra* Part I.B (defining the appropriate role of science in decision making while pointing out common uses of it).

[24] *See infra* Part II (discussing EPA's invocation of science instead of reliance on reasoned policy judgments).

[25] *Infra* Part II.

ultimately failed to live up to the aspiration for reasoned decision making that undergirds contemporary administrative law.[26]

In Part I of this Article, we show how EPA invoked science to justify its NAAQS revisions, and we explain why such an approach misconceived the role of science in regulatory decision making. Drawing on the conventional distinction between risk assessment and risk management, we show how EPA's retreat behind the cloak of science mistook the normative nature of risk management decisions, such as those involved in setting air quality standards. We also show how policy choices enter into standard setting even more starkly for nonthreshold pollutants (such as ozone and particulate matter), where it appears there is no level of exposure that is free from all health effects.

In Part II, we demonstrate that EPA's positions on various aspects of its NAAQS decision making have shifted over time, even during the course of its most recent rulemakings on ozone and particulate matter. When agencies like EPA rely on science as a justification for how they set risk standards, they neglect to offer a principled justification for their policy decisions.[27] In fact, EPA has quite explicitly argued that it should be able to approach each NAAQS rulemaking in an ad hoc manner.[28] With such an ad hoc approach to risk management, inconsistencies are to be expected as an inevitable result, as we show in the incoherent positions EPA adopted in its recent revisions to its air quality standards.

Finally, in Part III we review several alternative principles for justifying risk standards, showing what direction EPA and other regulatory agencies need to take in order to develop more principled approaches to risk management. We conclude that in order to bring greater clarity and coherence to air quality standard setting, Congress will need to step in and direct EPA to use clear policy principles in justifying its decisions. This will almost certainly require a repudiation of the fundamental fiction, endorsed by both EPA and the Supreme Court in *Whitman*, that risk standards can be set without consideration for the

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[26] On administrative law's aspirations for reason, see *supra* notes 1, 5 and *infra* notes 398-402.

[27] By "principled justification," we simply mean an explicit reason or explanation for why, given what is known about the world, a standard should be set at a particular level, such that in situations with similar conditions a similar result should follow.

[28] *See infra* notes 188-89 and accompanying text (presenting the Agency's claim that it cannot be constrained by any "generalized paradigm").

costs or feasibility of complying with them.[29] By amending the underlying statute, Congress can enable and encourage the Agency to live up to the aspirations for reason embedded within contemporary administrative law.

I. SCIENCE AND SETTING RISK STANDARDS

Throughout its recent ozone and particulate matter rulemakings, EPA attempted to justify its selection of its air quality standards based on scientific evidence, namely evidence of the health effects of such pollution.[30] In the early stages of the rulemaking, EPA's emphasis on science was more restrained, and Agency documents sometimes noted obliquely that there was some room for policy inputs in risk management.[31] As the Agency's rulemaking proceedings progressed, however, and as the amount of controversy surrounding them increased, EPA's reliance on science to justify and defend its standards became more pronounced.

EPA initially emphasized its scientific evidence partly in response to a campaign by opponents who questioned the soundness of the science underlying EPA's standards.[32] EPA understandably responded to these attacks by attempting to defend the validity of its scientific findings. Yet, in addition to defending the Agency's scientific research on its own merits, EPA soon came to inflate the role of science,

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[29] *See supra* Part III.B (arguing that the Agency did, in fact, take cost into consideration).

[30] Throughout this Article, we use the terms "science" or "scientific evidence" to refer to the natural sciences, though our discussion would in theory apply to positive social science as well. In addition, while we refer to the "EPA" repeatedly in this Article in its capacity as a legal entity, we recognize that government organizations are not unitary actors, but instead are comprised of many individuals with views that may or may not be in agreement with an agency's official rulemaking documents and court briefs.

[31] *See infra* note 164 and accompanying text (citing the Agency's brief acknowledgment of a policy choice in its *Federal Register* notice).

[32] *See, e.g., Air Quality Standards: Science-Driven Ozone, PM Proposals Will Be Finished by July 19, EPA Says*, 27 Env't Rep. (BNA) 2068 (Feb. 14, 1997) ("Industry officials . . . continued to hammer EPA proposals as lacking a sound scientific basis . . . ."); Allan Freedman, *Latest Fight on Clean Air Rules Centers on Scientific Data*, CONG. Q., Mar. 1, 1997, at 530 (pointing out the tendency of opponents to say that the regulations were based on flimsy science); Joby Warrick, *Panel Seeks Cease-Fire on Air Quality but Gets a War*, WASH. POST, Feb. 6, 1997, at A21 (describing opponents of EPA air quality standards carrying placards reading "EPA—Show me the science").

using science in an attempt to justify its standards in order to provide greater support for its position in the political arena and the courts.[33]

In this Part, we show how EPA appealed to a science-based rhetoric in its ozone and particulate matter rulemakings, and we explain why such an exclusive reliance on science is fundamentally mistaken. Science does properly play a vital role in environmental regulatory decisions, and regulatory agencies do need to develop credible and relevant scientific analysis of environmental risks.[34] Yet regulatory agencies have too often invoked science in order to answer questions that science is not designed to answer.[35] By purporting to rely on science to justify normative policy decisions, agencies succumb to a category mistake, since science speaks to what *is*, rather than to what *should be*.[36] Relying exclusively on science, as EPA has done in its

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[33] A telling anecdote of this shift in EPA's emphasis can be found in Professor Craig Oren's contrasting of two statements by EPA Administrator Carol Browner. Oren, *supra* note 18, at 10,653. In November 1996, at the time the ozone and fine PM standards were first proposed, the EPA Administrator was quoted as stating that "[t]he question is not one of science, the real question is one of judgment." *Air Pollution: Agency Announces Proposals to Toughen Regulations for Ozone, Particulate Matter*, 27 Env't Rep. (BNA) 1571 (Nov. 29, 1996). Four months later, at the height of heated public, congressional, and regulatory debate on the standards, Administrator Browner made a 180-degree reversal, stating that "I think it is not a question of judgment, I think it is a question of science." *Air Quality Standards: Science-Driven Ozone, PM Proposals Will Be Finished by July 19, EPA Says*, *supra* note 32, at 2068. As we outline below in Part I.A, EPA never emerged from its retreat behind the cloak of science and indeed only hid itself further behind its apparent shield. Of course, this is not the first time that EPA has made an about-face on the role of science and policy in its decision making. *See* Sheila Jasanoff, *The Problem of Rationality in American Health and Safety Regulation*, *in* EXPERT EVIDENCE: INTERPRETING SCIENCE IN THE LAW 151, 168-69 (Roger Smith & Brian Wynne eds., 1989) (describing EPA's contradictory characterization of its cancer principles in the context of proceedings involving the pesticides heptachlor and chlordane in the 1970s).

[34] *See* EXPERT PANEL ON THE ROLE OF SCI. AT EPA, EPA, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS 2 (1992) ("Scientific knowledge has assumed an increasingly critical role as the environmental issues faced by the nation and the world grow in complexity and cut across all environmental media."); *see also id.* at 15 ("Strong science provides the foundation for credible environmental decision-making."); MARK R. POWELL, SCIENCE AT EPA: INFORMATION IN THE REGULATORY PROCESS 8 (1999) (noting that science plays "an important part in environmental regulatory decisionmaking"); Administrator Christine Todd Whitman, Remarks at the EPA Science Forum (May 1, 2002) ("Sound science is the foundation of EPA's work."), *available at* http://yosemite.epa.gov/administrator/speeches.nsf.

[35] Wagner, *supra* note 11, at 1617 (arguing that agencies have often used science to "camouflag[e] controversial policy decisions").

[36] This is not to say, of course, that normative judgments cannot affect the way that questions of scientific research are framed or how scientific research is interpreted. On the contrary, especially with policy-relevant research, the ways in which normative judgments enter into the research process can themselves be "disguised in the cloak of

ozone and particulate rulemakings, is as misguided as it would be to disregard relevant scientific information altogether.[37]

A. *"Listen to the Science:" EPA's Use of Science as a Policy Rationale*

Science has considerable rhetorical appeal when it comes to defending regulatory decisions, as it is often described and perceived as being "objective."[38] Because of its perceived objectivity, as well as the extensive advancements in science and technology that have emerged over the past century, science is viewed by the public as highly credible if not even infallible.[39] Politicians and advocates regularly call for government to use "sound science" in making regulatory decisions.[40] For

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objectivity." Peter Brown, *Ethics and Policy Research*, 2 POL'Y ANALYSIS 325, 340 (1976); *see also infra* notes 107-08 and accompanying text (discussing the difficulties in completely separating science and policy when making decisions).

[37] For an argument that agencies sometimes disregard scientific evidence, see James W. Conrad, Jr., *The Reverse Science Charade*, 33 Envtl. L. Rep. (Envtl. L. Inst.) 10,306 (Apr. 2003).

[38] Whether the "objectivity" of science even makes sense as a philosophical or sociological matter is certainly subject to debate. *See* SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 207 (1995) ("There is no way for the law to access a domain of facts untouched by values or social interests."); *see also* SCIENCE WARS (Andrew Ross ed., 1996) (collecting essays critical of the notion of a value-free science); AFTER THE SCIENCE WARS (Keith M. Ashman & Philip S. Baringer eds., 2001) (exploring the debate over the extent to which science is objective versus socially constructed). Regardless of where one stands on this issue, the fact that science is perceived by many people to be "objective" does lend persuasive strength to scientific claims when they are made in political and legal fora. *See, e.g.*, Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1059 (D.C. Cir. 1999) (asserting that because members of EPA's Clean Air Science Advisory Committee (CASAC) bring "scientific methods to their evaluation of the Agency's Criteria Document and Staff Paper, CASAC provides an objective justification for the pollution standards the Agency selects.") (Tatel, J., dissenting); James D. Wilson & J.W. Anderson, *What the Science Says: How We Use It and Abuse It to Make Health and Environmental Policy*, RESOURCES, Summer 1997, at 5, 6 ("To many laymen, certainty and precision is [sic] the essence of science: as they understand it, a scientific question can have only one right answer.").

[39] *See, e.g.*, NAT'L SCI. BD., NAT'L SCI. FOUND., SCIENCE AND ENGINEERING: INDICATORS 2000, at 8-1, 8-13 (2001) (describing public trust in scientists and medical researchers), *available at* http://www.nsf.gov/sbe/srs/seind00/; Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 569-75 (1992) (discussing the "allure of science" in environmental decision making); Samuel J. McNaughton, *What Is Good Science?*, NAT. RESOURCES & ENV'T, Spring 1999, at 513, 519 ("[S]cience in our society has come to have a quality of infallibility attached to it.").

[40] *See, e.g.*, *The Regulatory Flexibility Act: Are Federal Agencies Using "Good Science" in Their Rule Making?: Joint Hearing Before the Subcomm. on Gov't Programs and Oversight and the Subcomm. on Regulation Reform and Paperwork Reduction of the House Comm. on Small Bus.*, 105th Cong. 115 (1997) (prepared statement of James M. Harless, Techna Corp.)

regulators, invoking science to defend a regulatory decision can be an effective and expedient political strategy.[41] Given the political appeal of science, regulatory decision makers have an incentive to exaggerate the determinacy of science in an effort to mask contested policy choices and escape scrutiny.[42] Professor Wendy Wagner has dubbed this practice the "science charade."[43]

("A common refrain today among all stakeholders in the regulatory process is 'use good science.'"), *available at* 1997 WL 10569570.

[41] *See* KAREN T. LITFIN, OZONE DISCOURSES: SCIENCE AND POLITICS IN GLOBAL ENVIRONMENTAL COOPERATION 4 (1994) (observing that science is a "key source of legitimation"); POWELL, *supra* note 34, at 6 (remarking that science "is a favorite weapon in political battles over environmental policy"); Elizabeth Fisher, *Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration*, 20 OXFORD J. LEGAL STUD. 109, 130 (2000) (noting the tendency for increased reliance on science in standard setting because of its perceived objectivity and legitimacy). Not only can policymakers use science to defend decisions to issue new regulatory standards, as EPA did in the case of its revised NAAQS, but they can also use science to defend decisions to defer issuing new standards. For an argument that science has been used as a political defense for regulatory inaction over food safety, see MARION NESTLE, SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM 46 (2003) (noting "the invocation of 'science' as an obstructive measure" thwarting the development of regulations on the use of antibiotics in animal feed).

[42] *See, e.g.*, RICHARD N.L. ANDREWS, MANAGING THE ENVIRONMENT, MANAGING OURSELVES: A HISTORY OF AMERICAN ENVIRONMENTAL POLICY 269 (1999) (asserting that EPA risk-based decisions "in effect used scientific language to mask fundamentally political decisions, and to allow policy to be controlled by an EPA subgovernment rather than by a broader political process"); JASANOFF, *supra* note 38, at 207 (noting "the law's desire to cloak morally difficult judgments with the 'objective' authority of experts and instruments"); LITFIN, *supra* note 41, at 4 ("[T]he cultural role of science as a key source of legitimation means that political debates are framed in scientific terms; questions of value become reframed as questions of fact, with each confrontation leading to the search for further scientific justification."); NAT'L ENVTL. POLICY INST., ENHANCING SCIENCE IN THE REGULATORY PROCESS 5 (1999) (observing that policymakers can blame science "instead of acknowledging social, political, or economic bases for policy decisions and taking responsibility for including those factors in their decisions"); David L. Bazelon, *Risk and Responsibility*, 205 SCIENCE 277, 278 (1979) ("[S]cientists are tempted to disguise controversial value decisions in the cloak of scientific objectivity, obscuring those decisions from political accountability."); Giandomenico Majone, *Science and Trans-Science in Standard Setting*, 9 SCI., TECH., & HUM. VALUES, Winter 1984, at 15, 15 ("Traditionally, government regulators have sought legitimacy for their decisions by wrapping them in a cloak of scientific respectability."); Mark E. Rushefsky, *The Misuse of Science in Governmental Decisionmaking*, 9 SCI., TECH., & HUM. VALUES, Summer 1984, at 47, 47 ("Some policymakers have attempted also to legitimize decisions by clothing them with the 'respectable neutrality' of science."); Andrew D. Siegel, *The Aftermath of* Baltimore Gas & Electric Co. v. NRDC*: A Broader Notion of Judicial Deference to Agency Expertise*, 11 HARV. ENVTL. L. REV. 331, 377 (1987) ("One possible result of the deference [to scientific findings] rule is that agencies will strain to characterize their policy decisions, especially if they are controversial, as resting on technical or scientific judgments."); Eugene B. Skolnikoff, *The Role of Science in Policy*, ENV'T, June 1999, at 17, 19 ("[I]f the level of uncertainty is high enough, science

Perhaps no agency has so mistakenly and prominently advanced science as a justification for its policy decisions as did EPA in defending its recent revisions to air quality standards for ozone and particulate matter. In its rulemaking documents, in the courts, in Congress, and before the general public, EPA invoked science as its exclusive justification for revising its air quality standards.[44] The EPA Administrator repeatedly argued that she simply "listened to the science" in establishing new air quality standards.[45] The Agency generally avoided describing its decisions as policy judgments that required the articulation of a principled explanation for why the standards should be lowered to the chosen level. Instead, EPA defended its decisions as determined exclusively by scientific evidence.[46]

The Clean Air Act specifies the steps EPA must take in setting or revising its air quality standards.[47] The Act provides, in section 108,

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may become the principal lever that all sides use to justify positions reached primarily on other grounds.").

[43] Wagner, *supra* note 11, at 1617.

[44] EPA and other regulatory agencies have had a long history of invoking science as a policy rationale under both Democratic and Republican Administrations. *See generally* Wagner, *supra* note 11 (discussing the exaggeration of science in agency decision making). For example, former Administrator William Reilly, working in the first Bush Administration, called generally for more "science-based regulation," arguing that "EPA must and will continue to rely on a rational, science-based process for determining when to take risk management actions." William Reilly, *Taking Aim Toward 2000: Rethinking the Nation's Environmental Agenda*, 21 ENVTL. L. 1359, 1364 (1991). Since EPA's decisions to revise the ozone and particulate standards were some of the most costly and controversial risk management decisions in the Agency's history, the extent to which EPA used science as a shield was particularly problematic in this instance.

[45] *See infra* notes 71-87 and accompanying text (detailing Administrator Browner's statements that she based the new standards on science).

[46] The science-based rationale deployed by EPA was not merely an example of political rhetoric, as serious legal scholars have also argued for a similar normative justification for environmental standard setting. For example, Dan Tarlock has suggested, with few qualifications, that "environmental law and management should derive their primary political power and legitimacy from science, not ethics." A. Dan Tarlock, *Environmental Law: Ethics or Science?*, 7 DUKE ENVTL. L. & POL'Y F. 193, 194 (1996); *see also* Susan Buck, *Science as a Substitute for Moral Principle*, *in* THE MORAL AUSTERITY OF ENVIRONMENTAL DECISION MAKING 25, 27-30 (John Martin Gillroy & Joe Bowersox eds., 2002) (arguing that most decisions made by environmental regulators are properly based on "scientific and technical information" rather than on "moral principle"). For additional examples, see *infra* notes 117-18 and accompanying text.

[47] 42 U.S.C. §§ 7401-7601 (2000). The Act directs EPA to issue both primary and secondary standards. *Id.* § 7409(a). Primary standards aim at protecting human health, while secondary standards address nonhuman biological and physical effects. *Id.* § 7409(b). Although this Article focuses on EPA's decisions to revise its primary standards for ozone and particulate matter, our discussion of the limits of science also applies to secondary standards.

that the first step in promulgating a new or revised NAAQS is for the Agency to prepare a "criteria document" for the relevant pollutant.[48] The criteria document is required to report "the latest scientific knowledge" on "all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air."[49] Section 109 of the Act then directs the EPA Administrator to use her "judgment" to select a primary NAAQS that is "requisite to protect the public health" based on the criteria document and allowing for "an adequate margin of safety."[50]

In July 1997, EPA promulgated revised primary NAAQS for ozone and particular matter. The Agency revised the previous one-hour, 0.12 ppm, average primary ozone standard to an eight-hour, 0.08 ppm, average standard.[51] It also added two new fine particulate matter standards—a 15 $\mu g/m^3$ annual standard and a 65 $\mu g/m^3$ daily standard for $PM_{2.5}$[52]—while retaining the existing PM_{10} standard with only minor technical changes.[53] In explaining its decision, EPA stressed

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[48] *Id.* § 7408(a).

[49] *Id.* § 7408(a)(2). The criteria documents for the most recent revisions of the ozone and particulate matter standards were voluminous, spanning over 1500 and 2400 pages respectively. Although the stage of preparing these criteria documents can be thought of as akin to the stage of risk assessment discussed below in Part I.B, it is interesting to note that, on its face, the language of the Clean Air Act seems to acknowledge that certain policy considerations need to enter into the Administrator's decision making, even in the process of listing criteria pollutants and developing the criteria documents. Section 7408(a) directs the Administrator (a) to add to the criteria list those air pollutants "which, *in his judgment*, cause or contribute to air pollution which may *reasonably* be anticipated to *endanger* public health or welfare;" (b) to ensure that the criteria documents "*reflect*" the useful and current scientific knowledge (though arguably not necessarily be based solely on such knowledge); and (c) to include in these documents information about the impact of atmospheric patterns, interactions with other pollutants, and any possible impacts on welfare—but only "to the extent *practicable*." *Id.* § 7408(a) (emphases added).

[50] *Id.* § 7409(b)(1).

[51] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857. Compliance with this averaging standard is measured in several steps. First, the mean ozone concentration over every period of eight consecutive hours is continuously measured at a given site. Second, the fourth highest eight-hour average ozone concentration over the entire year is determined. Finally, the three-year average of the annual fourth-highest daily maximum eight-hour ozone concentrations is calculated. If the three-year average is at or below 0.08 ppm, the site is in attainment with the new ozone standard. If it is above 0.08 ppm., it is in nonattainment.

[52] $PM_{2.5}$, or fine particulate matter, refers to particles that are equal to or smaller than 2.5 micrometers in diameter. The term "$\mu g/m^3$" means "micrograms per cubic meter."

[53] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,652. PM_{10} refers to particles that are equal to or smaller than 10 micrometers in diameter.

the sources of information on which it based its decision, principally the risk assessments conducted by the Agency's staff and the advice given by the Agency's Clean Air Science Advisory Committee (CASAC), a panel dedicated to providing EPA with scientific input on air pollution issues.[54] Yet a statement of information sources is not a statement of principles, and nothing in any of these information sources explicated a policy justification for the revised standards.[55]

After EPA promulgated its revised ozone and particulate matter standards, industry groups and three States filed petitions seeking judicial review of the standards in the United States Court of Appeals for the District of Columbia Circuit. In the initial round of this litigation, EPA argued that the Agency's "scientific review" led it "to the inescapable conclusion" that the existing NAAQS were not protecting the public health with an adequate margin of safety.[56] After a panel of the Court of Appeals rejected EPA's decisions on nondelegation grounds, finding that the Agency failed to articulate an intelligible principle to guide its NAAQS selection, EPA appealed to the United States Supreme Court. The Agency argued before the Supreme Court that its decision under the Clean Air Act did not offend the nondelegation doctrine because the Agency had been constrained by three types of factors that together effectively constituted an "intelligible principle."[57] The three factors were the Agency's criteria documents reflecting "the latest scientific knowledge," the advice from CASAC, and the rulemaking requirements of section 307(d) of the Clean Air Act.[58] The first two factors—the criteria documents and CASAC advice—emphasized scientific inputs exclusively.[59] Since the last of these factors was merely a procedural limitation, EPA in effect argued that

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[54] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859; EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,655-56.

[55] For a further discussion of the Agency's science-based argument in the rulemaking process, see *infra* Part II.A.

[56] Brief for Respondent at 3-4, Am. Trucking Ass'ns v. EPA, 195 F.3d 4 (D.C. Cir. 1999) (No. 97-1440) [hereinafter EPA, D.C. Cir. PM Brief].

[57] Brief for Petitioners at 22-24, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257) [hereinafter EPA, Supreme Court Petitioners' Brief].

[58] *Id.* at 23-24.

[59] *Supra* notes 49, 54 and accompanying text. Section 109(d)(2)(C)(iv) required CASAC to provide advice on other issues that go beyond scientific matters, but EPA took the position that "neither CASAC's recommendations nor EPA's decisions on NAAQS revisions may be influenced by § 109(d)(2)(C)(iv) factors." Brief of Respondent at 53, Am. Trucking Ass'ns v. EPA, 195 F.3d 4 (D.C. Cir. 1999) (No. 97-1441) [hereinafter EPA, D.C. Cir. Ozone Brief]. Thus, under EPA's interpretation of the statute, CASAC's advice in NAAQS proceedings was limited to scientific matters.

science alone provided the Agency with its substantive principle for how it selected its NAAQS standards.

EPA offered other statements in its briefs to the Supreme Court that claimed or suggested that its revised standards could be justified on the basis of science alone. For example, it argued that "Congress has unambiguously indicated its intent that NAAQS should be based on scientific evidence regarding the health and welfare effects of ambient pollution."[60] In addition, the Agency argued "that Congress made a policy choice to cabin EPA's discretion by requiring the Agency to set NAAQS on the basis of a specific body of information: the latest scientific knowledge on the public health and welfare effects caused by the presence of criteria pollutants in the ambient air."[61] In its opening brief to the Supreme Court, EPA repeatedly referred to scientific evidence as the basis for its NAAQS standards:

- "EPA revised the PM standards based on new scientific studies that had emerged since EPA's last PM review . . . ."[62]
- "To select the levels requisite to protect public health, with an adequate margin of safety, the Administrator relied chiefly on epidemiological studies that employed direct measures of fine particles . . . ."[63]
- "The scientific evidence convinced the Administrator that she should revise both the averaging time and the concentration level of the 1979 one-hour ozone standard."[64]
- "EPA must consider the factors that the [Clean Air] Act prescribes and provide a reasoned explanation, based on scientific evidence, for its decision."[65]

EPA even suggested that the Supreme Court should be highly deferential to the Agency under the Court's *Baltimore Gas*[66] decision precisely because the selection of NAAQS standards was, it argued, a "scientific determination."[67]

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[60] Brief for the Federal Respondents at 18, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1426) [hereinafter EPA, Supreme Court Respondents Brief].

[61] Reply Brief for Petitioners at 9, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257) [hereinafter EPA, Supreme Court Reply Brief].

[62] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 9.

[63] *Id.* at 10.

[64] *Id.* at 12.

[65] *Id.* at 30.

[66] Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, 462 U.S. 87 (1983).

[67] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 27 ("'When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing

After the Supreme Court upheld EPA's decision on constitutional and statutory grounds, the litigation returned to the D.C. Circuit Court of Appeals for consideration of challenges to the rule under the arbitrary and capricious standard. Again, EPA stressed the scientific basis for the standards. The Agency argued that it had "revised the PM standards based primarily on scientific studies that had emerged since the EPA's last review, including an extensive body of epidemiological studies on exposure to PM pollution."[68] Similarly, in defending its ozone decision, EPA repeatedly invoked scientific factors for its decision, emphasizing in particular that "[s]ignificant new clinical studies provided 'conclusive evidence'" in support of the Agency's action.[69]

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court must generally be at its most deferential.'" (quoting *Baltimore Gas*, 462 U.S. at 103)). The type of "scientific determination" that the Supreme Court referred to in *Baltimore Gas* appears to have been much closer to a science-based prediction than to a more obviously policy-based judgment such as selecting an air quality standard. In that case, the Nuclear Regulatory Commission estimated that the long-term environmental impact of nuclear waste disposal was zero, an action that the Supreme Court characterized as "making predictions, within its area of special expertise, at the frontiers of science." *Baltimore Gas*, 462 U.S. at 103. In its reply brief filed with the Supreme Court, EPA responded to various amici briefs, including one we wrote on behalf of twenty law professors and scientists that argued that EPA had mistakenly claimed that science, by itself, could justify its standard-setting decisions. Brief of Amici Curiae Gary E. Marchant et al., Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257). EPA asserted that "[t]hose amici simply ignore the rulemaking record," but, tellingly, the government cited no policy justification for its decision in the *Federal Register* or elsewhere to support its assertion that the Agency had indeed recognized a need to make a policy rather than a scientific determination. EPA, Supreme Court Reply Brief, *supra* note 61, at 6 n.10. Instead, the Agency only cited two supporting EPA staff papers, neither of which provided any policy justification for the Agency's decisions. *Id.* at 6-7 n.10 ("For example, EPA prepared a detailed 'Policy Assessment of Scientific and Technical Information' in each rulemaking 'to evaluate the policy implications of the key studies and scientific information contained in [the Criteria Document].'" (citation omitted)). It speaks volumes that EPA cited only these supplementary documents, which simply identify a range of possible standards potentially consistent with the scientific evidence and statutory requirements, without identifying any factors or rationales that the Administrator would subsequently rely on to select a particular standard from within this range. Moreover, these documents are neither part of the Administrator's actual decision published in the *Federal Register* nor defended in the Agency's extensive briefs filed with the D.C. Circuit and Supreme Court.

[68] Brief for Respondent at 4, Am. Trucking Ass'ns v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (No. 97-1440) [hereinafter EPA, 2001 D.C. Cir. PM Brief]; *see also id.* at 2 ("In developing the $PM_{2.5}$ standards, EPA relied primarily on studies . . . ."); *id.* at 5 ("To select the levels requisite to protect public health, with an adequate margin of safety, the Administrator relied chiefly on epidemiological studies . . . .").

[69] Brief for Respondent at 8, Am. Trucking Ass'ns, Inc. v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (No. 97-1441) [hereinafter EPA, 2001 D.C. Cir. Ozone Brief]; *see also id.* at 2 (asserting that EPA relied on scientific criteria as the basis for its decision); *id.* at 6 (characterizing the Administrator's decision as "[b]ased on the extensive new science").

EPA also took its science-based rhetoric into the halls of Congress, where the Agency faced intense opposition to its proposed revisions to the ozone and particulate matter standards.[70] At a legislative hearing in February 1997, Administrator Browner testified that "[c]learly, the science calls for action."[71] "In a most compelling way," she continued, "the science leads us to the new, stronger standards that EPA has proposed for smog and soot."[72] She argued that "[s]cience now tell[s] us that our air pollution standards are not adequate to protect the public's health. Let us listen to science."[73]

At another hearing held a few months later, following completion of the public comment period but before announcement of the final standards, Administrator Browner testified to Congress that, "[a]s you can see from the description of the process I went through to choose proposed levels on ozone and particulate matter, the focus has been entirely on health, risk, exposure and damage to the environment."[74] On questioning at the same hearing, the Administrator claimed that "[t]he proposal that we take comment on is based on 250 peer-reviewed, published scientific studies" and that "the best available current science . . . forms the proposal we have made to the American people."[75] When urged by one member of Congress to keep an open mind on the multiple alternatives that might meet the statutory requirements, the Administrator replied succinctly: "We will go where the science takes us."[76]

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[70] Steven P. Croley, *Public Interested Regulation*, 28 FLA. ST. U. L. REV. 7, 63-65 (2000) (describing the intense congressional hearings as "no picnic, for Browner especially"); Wilson & Anderson, *supra* note 38, at 6 ("In congressional hearing after hearing, EPA's Administrator, Carol Browner, defended her proposed standards as merely reflecting 'the science.'"). Again, this strategy may have also helped defend against critics who attacked the credibility of EPA's scientific analysis. *See supra* notes 38, 41 and accompanying text (noting the reliance on science based on its supposed objectivity).

[71] *Clean Air Act: Ozone and Particulate Matter Standards: Hearing Before the Subcomm. on Clean Air, Wetlands, Private Property and Nuclear Safety of the Senate Comm. on Env't and Pub. Works*, 105th Cong. (1997) (testimony of Carol M. Browner, Administrator, EPA).

[72] *Id.*

[73] *Id.*

[74] *EPA's Particulate Matter and Ozone Rulemaking: Is EPA Above the Law?: Hearings Before the Subcomm. on Nat'l Econ. Growth, Nat. Res., and Regulatory Affairs of the House Comm. on Gov't Reform and Oversight*, 105th Cong. 360, 380 (1997) (statement of Carol M. Browner, Administrator, EPA) [hereinafter April 23, 1997 Hearing].

[75] *Id.* at 396-97.

[76] *Id.* at 409; *see also Joint Hearing Before Subcomms. on Health & Env't and Oversight & Investigations of the House Commerce Comm.*, 105th Cong. 265 (1997) (testimony of Carol A. Browner, Administrator, EPA) [hereinafter Browner, May 15, 1997 Hearing] (stating that "we should go where the science takes us").

Shortly after finalizing the ozone and PM standards, Administrator Browner appeared before Congress to explain her decision. But in that setting, she identified only scientific factors in her decision making:

> Clearly, the best available science shows that the previous standards were not adequately protecting Americans from the hazards of breathing polluted air.
>
> . . . .
>
> These updated standards are based on more than 250 of the latest, best scientific studies on ozone and PM—all of them published, peer-reviewed, fully-debated and thoroughly analyzed by the independent scientific committee, CASAC. We're talking literally peer review of peer review of peer review.
>
> It is good science. It is solid science.[77]

At other legislative hearings, Administrator Browner stated that the science "determined" or "warranted" the new standards.[78]

EPA continued to invoke science in public speeches, media interviews, and press releases.[79] For example, when EPA proposed the revised ozone and PM standards, its press release claimed that Congress required the proposed standards to be "based solely upon the best current scientific opinion on public health effects"[80] and that accordingly the Agency "will use the very best science to do what is necessary to protect public health in common-sense, cost-effective ways."[81] The

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[77] *Clean Air Act Implementation: Joint Hearing Before Subcomms. on Health & Env't and Oversight & Investigations of the House Commerce Comm.*, 105th Cong. (1997) (testimony of Carol A. Browner, Administrator, EPA).

[78] *E.g.*, Browner, May 15, 1997 Hearing, *supra* note 76, at 263 (arguing that EPA's regulatory process is designed "to achieve the goals set forth in the Clean Air Act that every American breathe clean, healthy air as determined by the latest and best scientific information."); *id.* ("[I]f the science warrants a revision to the standards, the law sets forth a reasonable and rational procedure for implementation . . . ."); *Hearing Before the Subcomm. on Energy & Env't of the House Comm. on Sci.*, 105th Cong. (May 21, 1997) (testimony of Carol A. Browner, Administrator, EPA) (repeating that the law prescribes the implementation process "if the science warrants a revision in the standards").

[79] The Administrator was not the only EPA official to invoke science as the Agency's justification for its NAAQS revisions. In an interview, EPA's General Counsel was likewise quoted as saying: "'Even without the consideration of cost, there are sound scientific reasons for setting the standards at a particular level.'" David Rubenstein, *Legions of Business Groups Take on the Clean Air Act*, CORP. LEGAL TIMES, Oct. 2000, at 96 (quoting EPA General Counsel Gary S. Guzy).

[80] Press Release, EPA, EPA Proposes Air Standards for Particulate Matter & Ozone (Nov. 27, 1996), http://yosemite.epa.gov/opa/admpress.nsf.

[81] *Id.* (quoting EPA Administrator Carol M. Browner).

Agency's press release also quoted Administrator Browner as stating that "'EPA has based its proposal on a thorough review of the best available science.'"[82]

In defending her selection of the proposed standards to the public, the Administrator told reporters at an Agency briefing that "I think it is not a question of judgment, I think it is a question of science."[83] In Philadelphia, she told the local Chamber of Commerce that "[t]he Clean Air Act clearly requires levels of smog and soot to be based solely on health, risk, exposure and damage to the environment, as determined by the best available science."[84] The Administrator continued by stating that "[t]he current best science must prevail in determining the level of protection the public will be guaranteed. Nothing else can take precedence."[85] In a speech to the American Enterprise Institute on the proposed air quality standards, Administrator Browner stated that "[t]he science is clear and compelling . . . . We have to go where the best available science leads us."[86] Claiming that science determined the adequacy of the Agency's revised standards, Administrator Browner typically ended her speeches on the ozone and PM NAAQS with the admonition: "Let us listen to the science."[87]

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[82] *Id.*

[83] *Science-Driven Ozone, PM Proposals Will Be Finished by July 19, EPA Says*, 27 Env't Rep. (BNA) 2068 (Feb. 14, 1997).

[84] Administrator Carol M. Browner, Remarks Before the Greater Philadelphia Chamber of Commerce (May 12, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf.

[85] *Id.* The Administrator repeated this statement in other speeches. For an example of such a speech, see Administrator Carol M. Browner, Remarks Before the Society of Environmental Journalists (May 17, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf.

[86] Administrator Carol M. Browner, Remarks at the American Enterprise Institute Conference: Clearing the Air: An Examination of EPA's Proposed Regulations for Particulate Matter and Ozone (Feb. 10, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf. In a speech to the City Club of Cleveland, the Administrator stated that EPA was being "truthful" to the American people by telling them that science dictated the new standards. Administrator Carol M. Browner, Remarks Before the City Club of Cleveland (Mar. 25, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf [hereinafter Browner, Cleveland Speech] (claiming that "[s]cience now tells us that our air pollution standards are not adequate to protect the public's health" and arguing that EPA needed to "tighten those standards in order to ensure that we are being truthful with the American people about the quality of the air they are breathing and what it is doing to them").

[87] Browner, Cleveland Speech, *supra* note 86; *see also* Browner, *supra* note 84; Browner, *supra* note 85; John H. Cushman, Jr., *On Clean Air, Environmental Chief Fought Doggedly, and Won*, N.Y. TIMES, July 5, 1997, at A8 (quoting Administrator Browner as stating that "[w]hat we have done is follow the science").

B. *Standard Setting, Science, and the Management of Risk*

Although EPA invoked science as its core defense for its NAAQS revisions, doing so mistook the ability of science to serve as a principle for setting environmental policy standards. Science describes; it does not prescribe. Scientific claims are empirical rather than normative. Science seeks to supply verifiable descriptions of—and explanations and inferences about—what *is*, rather than imposing judgments about what *should be*.[88] While science provides valuable information needed for regulatory decisions, science cannot *on its own* dictate the appropriate decision about where to set environmental standards.[89]

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[88] *See, e.g.*, Lee Epstein & Gary King, *The Rules of Inference*, 69 U. CHI. L. REV. 1, 19-20 (2002) ("[A]ll empirical research seeks to accomplish one of three ends, or more typically some combination thereof: *amassing data* for use by the researcher or others; *summarizing data* so they are easier to comprehend; and *making descriptive or causal inferences* . . . ."); Marcia R. Gelpe & A. Dan Tarlock, *The Uses of Scientific Information in Environmental Decisionmaking*, 48 S. CAL. L. REV. 371, 385 (1974) ("Science is concerned with describing physical relationships and thus with drawing inferences from observed to unobserved behavior."); Lee Loevinger, *The Distinctive Functions of Science and Law*, 24 INTERDISC. SCI. REV. 87, 87 (1999) ("The function of science is to enlarge our knowledge and understanding of both the natural and cultural environments in which we live . . . . Thus, the role of science is to learn, to report, and to teach—but only facts."); Peter H. Schuck, *Multi-Culturalism Redux: Science, Law, and Politics*, 11 YALE L. & POL'Y REV. 1, 4 (1993) ("Science appeals to the capacity of technical rationality and specialized expertise to generate and test empirically falsifiable propositions."); *see also* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590 (1993) (noting that science is "'a *process* for proposing and refining theoretical explanations about the world'" (quoting Brief for the American Association for the Advancement of Science et al. as Amici Curiae at 7-8, *Daubert* (No. 92-102))).

[89] *See, e.g.*, JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 218 (1988) (observing that "science cannot answer the ultimate regulatory questions"); NAT'L ACAD. OF PUB. ADMIN., SETTING PRIORITIES, GETTING RESULTS: A NEW DIRECTION FOR EPA 61 (1995) ("Technical information can inform EPA's decisions, but the decisions remain policy judgments with political and ethical components."); John S. Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decision-Making*, 63 U. CIN. L. REV. 1643, 1645 (1995) ("Risk is appropriately the starting point of much standard setting and priority setting for health-based environmental regulation, but other factors must have equal weight . . . . [I]t is the business of public policy, not of science, to decide how these problems should be handled."); Paul Fischbeck et al., *The Challenge of Improving Regulation*, *in* IMPROVING REGULATION: CASES IN ENVIRONMENT, HEALTH, AND SAFETY 1, 4 (Paul Fischbeck & R. Scott Farrow eds., 2001) ("Even in the best of worlds, good science is rarely sufficient for informed regulatory decisionmaking."). To say that science alone is insufficient is not to say that science is not helpful, or even essential, for setting regulatory policy. Setting regulatory standards requires both ethical or policy analysis as well as scientific information. *See* ROBERT A. DAHL, DEMOCRACY AND ITS CRITICS 69 (1989) (acknowledging that, although "both moral understanding and instrumental knowledge are always necessary for policy judgments, neither alone can ever be sufficient").

To clarify the role of science in setting environmental policy, we distinguish in this Section between two aspects of the standard-setting process: "risk assessment" and "risk management." The National Research Council of the National Academy of Sciences (NAS/NRC) recognized this distinction between risk assessment and risk management in its influential 1983 report known as the *Red Book*,[90] which established a framework for risk-based decision making that regulatory agencies continue to follow today. The *Red Book* defined risk assessment as "the characterization of the potential adverse health effects of human exposures to environmental hazards."[91] Risk assessment is based extensively on scientific information, supplemented with what have been termed "risk assessment policy" judgments to bridge gaps and uncertainties in the scientific evidence.[92] Risk assessment is therefore considered to be predominantly—though not exclusively[93]—based on scientific evidence and analysis.[94]

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[90] NAT'L RESEARCH COUNCIL, NAT'L ACAD. OF SCI., RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter NAS/NRC RED BOOK]; *see also* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 9 (1993) (recognizing that risk regulation "has two basic parts, a technical part, called 'risk assessment,' designed to measure the risk associated with the substance, and a more policy-oriented part, called 'risk management'").

[91] NAS/NRC RED BOOK, *supra* note 90, at 18; *see also* 2 THE PRESIDENTIAL/CONGRESSIONAL COMM'N ON RISK ASSESSMENT AND RISK MGMT., FINAL REPORT: RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION-MAKING 2 (1997) [hereinafter RISK COMM'N] ("Risk assessment is the systematic, scientific characterization of potential adverse effects of human or ecological exposures to hazardous agents or activities."), *available at* http://www.epa.gov/ncea/pdfs/riskcom/riskcom2.pdf.

[92] NAS/NRC RED BOOK, *supra* note 90, at 37. Such risk assessment policy judgments include factors such as which health effects to consider and group together, the type of models and assumptions to use in the risk assessment, how to extrapolate data from one small segment of a population to the entire population, and how to compute, present, and account for uncertainties. *Id.* at 29-33; *see also* REGULATORY IMPACT ANALYSIS PROJECT, INC., CHOICES IN RISK ASSESSMENT: THE ROLE OF SCIENCE POLICY IN THE ENVIRONMENTAL RISK MANAGEMENT PROCESS, at xi (1994) (acknowledging that there are "gaps and uncertainties in scientific knowledge, data, and methodology that arise in the assessment of risks to human health and the environment associated with exposure to substances, conditions, activities, and sites"), *available at* http://www.library.ucsf.edu/tobacco/batco/html/600/687/otherpages/7.html; Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 732-47 (1979) (discussing a range of science policy issues that arise in risk regulation including the sufficiency of data and varying scientific interpretations of data).

[93] *See* DANIEL M. BYRD III & C. RICHARD COTHERN, INTRODUCTION TO RISK ANALYSIS: A SYSTEMATIC APPROACH TO SCIENCE-BASED DECISION MAKING 6-8, 330-34 (2000) (noting that risk assessment inherently and inevitably involves some judgment); Sheila Jasanoff, *Contested Boundaries in Policy-Relevant Science*, 17 SOC. STUD. SCI. 195, 211 (1987) (observing that analysts have "agreed that very little in a typical risk

Risk management, on the other hand, is "an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard."[95] It "necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control."[96] As a subsequent National Research Council report reiterated, "science alone can never be an adequate basis for a risk decision" because "[r]isk decisions are, ultimately, public policy choices."[97] The U.S. Supreme Court has likewise recognized that the risk management decision of selecting the level at which to set health and

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assessment could be labeled as pure science"); Mark E. Rushefsky, *Assuming the Conclusions: Risk Assessment in the Development of Cancer Policy*, 4 POL. & LIFE SCI. 31, 31 (1985) (arguing that "[i]n reality facts and values in policy making are hopelessly mixed"). Even the NRC, in its "1983 report and accompanying working papers[,] acknowledged that risk assessment unavoidably combined elements of both science and policy." Sheila Jasanoff, *Science, Politics, and the Renegotiation of Expertise at EPA*, 7 OSIRIS 194, 209 (1992) [hereinafter Jasanoff, *Science, Politics, and the Renegotiation of Expertise*]; *see also infra* note 108 and accompanying text (recognizing the roles that both science and policy play in risk assessments).

[94] *See* GAIL CHARNLEY, DEMOCRATIC SCIENCE: ENHANCING THE ROLE OF SCIENCE IN STAKEHOLDER-BASED RISK MANAGEMENT DECISION-MAKING (2000) ("[R]isk assessment generally constitutes the vehicle for including science in risk management decision-making . . . . [R]isk assessment is based on science to the extent possible and on judgment when necessary."), *available at* http://www.epa.gov/sab/pdf/eccm01006appne.pdf; Frank Cross, *The Public Role in Risk Control*, 24 ENVTL. L. 887, 889-90, 90 n.5 (1994) ("[Even though] purely scientific judgments contain underlying values[,] [i]n the case of risk assessment . . . the overriding value is accuracy [in determining] . . . the objective probability of an event's occurrence. Value judgments are largely irrelevant to the probabilistic determination of scientific risk." (footnote omitted)).

[95] NAS/NRC RED BOOK, *supra* note 90, at 18-19; *see also* NAT'L ACAD. OF PUB. ADMIN., *supra* note 89, at 37 ("[Risk management] includes a wide array of actions such as writing and enforcing regulations, providing information and technical assistance, and establishing market incentives for risk reduction."); RISK COMM'N, *supra* note 91, at 2 (finding that "risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems" for the purpose of adopting "scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations").

[96] NAS/NRC RED BOOK, *supra* note 90, at 19; *see also* Oren, *supra* note 18, at 10,660 ("[T]he decision of who should be protected, and what effects they should be protected against, is an ethical decision, not a scientific one.").

[97] NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 26 (1996).

environmental standards is primarily a policy, rather than a scientific, undertaking.[98]

While risk assessment is thus conventionally understood to be predominantly (but not exclusively) a scientific undertaking, risk management decisions, including the selection of regulatory standards, require making value judgments that extend beyond the scope of science.[99] The *Red Book* recommended that regulatory agencies "maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies."[100]

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[98] In the Court's 1980 review of the Occupational Safety and Health Act's (OSHA) benzene occupational exposure standard, Justice Marshall's dissenting opinion stated:

> [W]hen the question involves determination of the acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of the facts.

Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 706 (1980) (Marshall, J., dissenting). The plurality opinion responded directly to Justice Marshall's policy argument: "We agree. Thus, while the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." *Id.* at 656 n.62 (plurality opinion); *see also* EDLEY, *supra* note 6, at 75 (noting that in setting new OSHA standards "[s]cience alone . . . cannot determine what to do with [the] uncertainties" and that "[t]he science is inseparable from the value choices which are the familiar grist of political decision making").

[99] *See* WILLIAM W. LOWRANCE, OF ACCEPTABLE RISK 75-76 (1976) ("Determining safety, then, involves two extremely different kinds of activities . . . . Measuring risk—measuring the probability and severity of harm—is an empirical, scientific activity; Judging safety—judging the acceptability of risks—is a normative, political activity."); Fisher, *supra* note 41, at 130 ("[Risk] standards are normative prescriptions which require the balancing of different social and political factors and the consideration of scientific and other specialist information in the context of scientific uncertainty."); *see also* Jocelyn Kaiser, *Showdown over Clean Air Science*, 277 SCIENCE 466, 469 (1997) ("Deciding whether to set a stringent standard . . . 'becomes a value judgment. It's not a scientific question.'" (quoting environmental health scientist Arthur Upton)).

[100] NAS/NRC RED BOOK, *supra* note 90, at 7. Even though the authors of the *Red Book* argued for conceptual clarity in distinguishing between risk assessment and risk management, this does not mean that they did not acknowledge that policy considerations entered into the risk assessment process. *See id.* (noting "the scientific findings and policy judgments embodied in risk assessments"); *see also* Jasanoff, *supra* note 33, at 171 (arguing that the *Red Book* "definitively established that most of the determinations made in the process of carcinogenic risk assessment involve a mixture of science and policy").

In other contexts, EPA has endorsed and relied on the NAS/NRC's distinction between risk assessment and risk management.[101] For example, in a recent EPA guidance document on conducting risk analysis, EPA directed Agency staff to separate risk assessment from risk management, with risk assessment involving the selection, evaluation, and presentation of "scientific information," but not "decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks."[102] In contrast, EPA noted that risk management decisions should be based on, to the extent

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[101] EPA describes the "risk assessment/risk management paradigm" as an "important Agency organizing principle." Office of Research and Development, EPA, *Risk Assessment*, *at* http://www.epa.gov/ord/htm/risk.htm (last visited Feb. 10, 2004); *accord* William D. Ruckelshaus, *Risk, Science, and Democracy*, ISSUES SCI. & TECH., Spring 1985, at 19, 28 (representing a former two-time EPA Administrator's view that there should be a "strict distinction" between risk assessment and risk management "in all statutes seeking to deal with risk"); *see also* Announcement of Preliminary Determinations for Priority Contaminants on the Drinking Water Contaminant List, 67 Fed. Reg. 38,222, 38,225 (June 3, 2002) (noting that EPA's overall approach to research on drinking water contaminants "is closely aligned with the 1983 National Research Council (NRC) risk assessment/risk management paradigm").

> Risk assessment . . . defines the potential adverse health consequences of exposure to a toxic agent. The other component, risk management, combines risk assessment with . . . socioeconomic, technical, political, and other considerations, in order to decide whether to control future exposure to the suspected toxic agent and, if so, the nature and level of control.

Guidelines for Neurotoxicity Risk Assessment, 63 Fed. Reg. 26,926, 26,928 (May 14, 1998).

> [R]isk assessment and risk management are two distinct activities. The former involves the evaluation of the likelihood of adverse effects, while the latter involves the selection of a course of action in response to an identified risk that is based on many factors (e.g., social, legal, political, or economic) in addition to the risk assessment results.

Guidelines for Ecological Risk Assessment, 63 Fed. Reg. 26,846, 26,852 (May 14, 1998); *see also* Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,960 (Apr. 23, 1996) (citing NAS/NRC report as recommending risk assessment guidelines "to ensure that the risk assessment process was maintained as a scientific effort separate from risk management"); Guidelines for Developmental Toxicity Risk Assessment, 56 Fed. Reg. 63,798, 63,800 (Dec. 5, 1991) ("Risk assessment . . . defines the potential adverse health consequences of exposure to a toxic agent," while risk management "combines risk assessment with . . . socioeconomic, technical, political, and other considerations."); Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,992-93 (Sept. 24, 1986) (stipulating that risk assessment should "use the most scientifically appropriate interpretation" and "be carried out independently from considerations of the consequences of regulatory action"); Sci. Pol'y Council, EPA, *Guidance for Risk Characterization*, *at* http://www.epa.gov/OSP/spc/rcguide.htm (Feb. 1995) ("In 1984, EPA endorsed these [NAS/NRC] distinctions between risk assessment and risk management for Agency use, and later relied on them in developing risk assessment guidelines." (endnotes omitted)).

[102] Sci. Pol'y Council, *supra* note 101.

permissible, a consideration of "technical feasibility (e.g., treatability and detection limits), economic, social, political, and legal factors," in addition to the output of the risk assessment process.[103] According to the EPA guidance document, "risk assessors and managers should understand that the regulatory decision is usually not determined solely by the outcome of the risk assessment."[104] In order to make risk assessments "transparent," EPA has further stated that it is important "that the conclusions drawn from the science are identified separately from policy judgments."[105] Risk management, the Agency has acknowledged, "goes beyond scientific considerations alone."[106]

Of course, in practice the distinction between risk assessment and risk management is surely not as clear cut as the distinction made in the *Red Book* might suggest.[107] This is because policy considerations almost invariably underlie, and may even dominate, many of the choices made in conducting a risk assessment, just as they inherently must pervade risk management determinations.[108] For this reason, a

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[103] *Id.*; *see also* EPA, SCIENCE POLICY COUNCIL HANDBOOK: RISK CHARACTERIZATION 51 (2000) ("The scientific risk assessment and its peer review provide the sound scientific underpinnings for a decision. However, it is only one of the many factors that a decision maker considers in arriving at a final environmental decision.").

[104] Sci. Pol'y Council, *supra* note 101.

[105] Draft Water Quality Criteria Methodology Revisions: Human Health, 63 Fed. Reg. 43,756, 43,769 (Aug. 14, 1998).

[106] Guidelines for Neurotoxicity Risk Assessment, *supra* note 101, 63 Fed. Reg. at 26,928.

[107] *See* Jasanoff, *Science, Politics, and the Renegotiation of Expertise*, *supra* note 93, at 209 (noting the "impracticability of cleanly separating science from policy").

[108] *See* CARNEGIE COMM'N ON SCI., TECH., & GOV'T, RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING 69 (1993) ("The lines between science, science policy, and policy are fuzzy and wavering."); MARC K. LANDY ET AL., ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS 186 (2d ed. 1994) ("[T]here is no way to make a simple separation between the 'scientific' and the 'policy' aspects of labeling a compound 'carcinogenic.'"); Mary R. English, *Can Risk Assessment and Risk Prioritization Be Extricated from Risk Management?*, *in* RISK ASSESSMENT IN SETTING NATIONAL PRIORITIES 495, 496 (James J. Bonin & Donald E. Stevenson eds., 1989) (arguing that many risk assessments require policy considerations); Sheila Jasanoff, *Bridging the Two Cultures of Risk Analysis*, 13 RISK ANALYSIS 123, 129 (1993) ("[T]he principles by which we organize the 'facts' of risk have to derive, at least in part, from underlying concerns of public policy . . . ."); Sheila Jasanoff, *Relating Risk Assessment and Risk Management: Complete Separation of the Two Processes is a Misconception*, 19 EPA J. 35, 35 ("Risk assessment . . . requires the exercise of subjective judgment . . . [which] must remain sensitive to the policy context."); Howard Kunreuther & Paul Slovic, *Science, Values, and Risk*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 116, 119 (1996) (discussing "the subjective and value-laden nature of risk assessment"); Paul Slovic, *Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield*, 1997 U. CHI. LEGAL F. 59, 95 (1997) ("Risk assessment is inherently subjective

subsequent National Research Council report has cautioned against making a strict separation in practice between the conceptually distinct aspects of risk assessment and risk management because nonscientific considerations, including policy concerns and deliberation, are relevant to risk assessment.[109] That said, agencies and commentators continue to maintain that, notwithstanding the unavoidable intrusion of certain policy considerations, the process of risk assessment remains primarily a scientific undertaking that should be treated as largely distinct from the policy-dominated domain of risk management.[110]

For the purposes of this Article, the debate over how sharply to distinguish risk assessment from risk management is not crucial because it is a debate that focuses on how to characterize the risk assessment enterprise.[111] Those who reject a strict dichotomy between risk assessment and risk management do so because they conclude

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and represents a blending of science and judgment with important psychological, social, cultural, and political factors.").

[109] NAT'L RESEARCH COUNCIL, *supra* note 97, at 34.

[110] *See, e.g.*, International Standard-Setting Activities, 67 Fed. Reg. 37,760, 37,770-71 (May 30, 2002) (defining risk assessment as a "scientifically based process" and risk management as a "process, distinct from risk assessment, of weighing policy alternatives . . . and, if needed, selecting appropriate prevention and control options"); Guidelines for Neurotoxicity Risk Assessment, *supra* note 101, 63 Fed. Reg. at 26,950 (distinguishing risk characterization (assessment) from risk management and noting that "[t]he risk manager uses the results of the risk characterization along with other technological, social, and economic considerations in reaching a regulatory decision"); Bernard D. Goldstein, *If Risk Management Is Broke, Why Fix Risk Assessment?*, 19 EPA J. 37, 37 ("[R]isk management is contextual, with the best decision being related to time and place, while risk assessment inherently embraces the concept that there is a single right assessment for all time."); Howard Raiffa, *Science and Policy: Their Separation and Integration in Risk Analysis*, *in* THE RISK ANALYSIS CONTROVERSY: AN INSTITUTIONAL PERSPECTIVE 27, 28 (Howard C. Kunreuther & Eryl V. Ley eds., 1982) (distinguishing between risk "assessment" and risk "evaluation"); Ruckelshaus, *supra* note 101, at 28 ("It is impossible to evaluate the merits of these positions without first drawing a distinction between the assessment of risk and the process of deciding what to do about it, which is 'risk management.'"); *see also* GRAHAM ET AL., *supra* note 89, at 218 (calling for a "neoseparationist" approach which would entail "a good-faith attempt by regulatory institutions to address separately and explicitly the extent of risks from chemical exposures and the acceptability of such risks").

[111] *See, e.g.*, CARNEGIE COMM'N ON SCI., TECH., & GOV'T, *supra* note 108, at 78 (acknowledging that risk assessment can be "assumption- and value-laden"); LANDY ET AL., *supra* note 108, at 200 ("Risk assessment is an enterprise that is neither wholly scientific nor wholly independent of science."); Terry Davies, *Risk Assessment in Environmental Policy*, EARTH MATTERS 8 (Mar. 1999) (noting that "the practice of risk assessment has, from the beginning, been a hybrid mixture of science and non-science"), *available at* http://www.earthinstitute.columbia.edu/library/earthmatters/march99/Pages/page8.html.

that social values inevitably enter into (or should enter into) risk assessment judgments, not because they believe risk management decisions can be based solely on science.[112] In the debate over the separation of risk assessment and risk management, neither side disputes that risk management decisions are normative.[113]

We have highlighted the distinction between risk assessment and risk management here because a decision about where to set an air quality standard falls squarely in the domain of risk management.[114]

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[112] *See, e.g.*, Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 90 (1988) (challenging the conventional separation between risk assessment and risk management by arguing that "social policy considerations must play as prominent a role in the choice of risk estimates [i.e., risk assessment] as in the ultimate determination of which predicted risks should be deemed unacceptable [i.e., risk management]"). In part, this criticism emerges because the conventional separation between risk assessment and risk management serves to draw a boundary that may make it appear as if risk assessment is a purely scientific enterprise. *See, e.g.*, BYRD & COTHERN, *supra* note 93, at 335 (noting that risk assessors at times "attempt to disguise . . . values and ethics in some decisions with scientific or technical labels"). Of course, demarcating where science ends and policy begins, sometimes referred to as "boundary work," is seldom easy or uncontestable. *See generally* THOMAS F. GIERYN, CULTURAL BOUNDARIES OF SCIENCE: CREDIBILITY ON THE LINE 66 (1999) ("Boundary work gets especially interesting when it happens in places of power, for the demarcation games played out there often have large consequences for the symbolic and material conditions of scientific work."); Thomas F. Gieryn, *Boundaries of Science, in* HANDBOOK OF SCIENCE & TECHNOLOGY STUDIES 393, 393 (Sheila Jasanoff et al. eds., rev. ed. 1995) (focusing on "the "boundary problem" in science and technology studies: Where does science leave off, and society—or technology—begin? Where is the border between science and non-science?").

[113] *See generally* Ralph L. Keeney, *The Role of Values in Risk Management*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 126, 134 (concluding that "values are crucial to risk management").

[114] The development of a regulatory standard is the quintessential risk management decision. *See* NAT'L ACAD. OF PUB. ADMIN, *supra* note 89, at 37 (noting that risk management includes "writing and enforcing regulations"); RISK COMM'N, *supra* note 91, at 2 (describing the "traditional definition" as referring "to the process of evaluating alternative regulatory actions and selecting among them," though arguing for a still broader conception of risk management to include voluntary, private sector initiatives), *available at* http://www.epa.gov/ncea/pdfs/riskcom/riskcom1.pdf; Fisher, *supra* note 41, at 113 (arguing that "risk regulation standards are *regulative* and thus *normative* prescriptions"). EPA has frequently characterized air quality standard setting as a risk management process. *See, e.g.*, National Emission Standards for Hazardous Air Pollutants: Pesticide Active Ingredient Production, 64 Fed. Reg. 33,550, 33,553 (to be codified at 40 C.F.R. pts. 9, 63) (June 23, 1999) (noting that "[t]he EPA's risk management strategy could include the development of risk based emission standards under the [Clean Air Act]"); National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,668 (to be codified at 40 C.F.R. pt. 50) (July 18, 1997) (referring to the risk management for a "short-term . . . standard"); National Ambient Air Quality Standards for Ozone and Particulate Matter, 61 Fed. Reg. 29,719, 29,723 (to be codified at 40 C.F.R. pt. 50) (June 12, 1996) (describing EPA's decision as one

EPA's national ambient air quality standards represent the core risk management objectives for the nation, with significant regulatory ramifications depending on the levels at which these standards are set. Areas of the country that do not attain a level of air quality meeting NAAQS are subject to more stringent regulatory controls, such as standards for reformulated gasoline, automobile inspection and maintenance programs, and tighter federal standards for the development of new sources of pollution.[115] In setting NAAQS, or any other regulatory standard, EPA officials need to draw upon the available scientific evidence on the health effects of different pollutants, but ultimately they must make a decision based on factors other than just the science. Standing alone, scientific data on ozone and particulate matter do not, and cannot, provide a principled justification for the level at which the respective air quality standards are set.[116]

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of "selecting a suite of standards that would focus risk management approaches"); Proposed Requirements for Designation of Reference and Equivalent Methods for $PM_{2.5}$ and Ambient Air Quality Surveillance for Particulate Matter, 61 Fed. Reg. 65,780, 65,793 (Dec. 13, 1996) (to be codified at 40 C.F.R. pts. 53, 58) (referring to "the risk management approach of the proposed new $PM_{2.5}$ NAAQS"); Revised Requirements for Designation of Reference and Equivalent Methods for $PM_{2.5}$ and Ambient Air Quality Surveillance for Particulate Matter, 62 Fed. Reg. 38,764, 38,780 (to be codified at 40 C.F.R. pts. 53, 58) (July 18, 1997) (noting EPA's "risk management approach" in setting NAAQS); NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors, 64 Fed. Reg. 52,828, 52,841 (to be codified at 40 C.F.R. pts. 60, 63, 260, 261, 264, 265, 266, 270, 271) (Sept. 30, 1999) (characterizing decisions about "the protectiveness of the MACT standards" as "national risk management decisions"); National Emission Standards For Hazardous Air Pollutants: Standards for Inorganic Arsenic, 51 Fed. Reg. 27,956, 27,957 (to be codified at 40 C.F.R. pt. 61) (Aug. 4, 1986) (describing EPA's "Risk Management Approach" to selecting standards); National Emission Standards For Hazardous Air Pollutants: Regulation of Radionuclides, 49 Fed. Reg. 43,906, 43,909 (Oct. 31, 1984) (to be codified at 40 C.F.R. pt. 61) ("[T]he individual facts, calculational operations, scientific judgments, and estimates of uncertainty [are] documented and integrated in a clear and logical manner to provide a risk assessment that can be used as a scientific basis for risk management purposes, i.e., standard-setting.").

[115] *See* 42 U.S.C. § 7503(a), (c) (2000) (permit requirements); *id.* § 7507 (new motor vehicle emissions standards); *id.* § 7511a (state submission requirements); *id.* § 7512(a) (classification and attainment dates for nonattainment areas); *id.* § 7513 (additional classification and attainment dates); *id.* § 7545 (fuel regulation).

[116] *See* Lead Indus. v. EPA, 647 F.2d 1130, 1146 (D.C. Cir. 1980) (recognizing that the selection of a NAAQS "presents complex questions of science, law, and social policy under the Act"); *Reauthorization of the Clean Air Act Reauthorization: Hearing Before the Senate Subcomm. on Clean Air, Wetlands, Private Property and Nuclear Safety of the Comm. on Env't & Pub. Works*, 106th Cong. (1999) (statement of John D. Graham, former Director of the Harvard Center for Risk Analysis) [hereinafter Graham Testimony] ("[S]cientific information (alone) does not typically provide an intelligible basis for the setting of safe (yet non-zero) amounts of air pollution."); Morton Lippmann, *Role of Science Advisory Groups in Establishing Standards for Ambient Air Pollutants*, 6 AEROSOL

C. *The Clean Air Act and the Problem of Non-Threshold Pollutants*

Given the way the Clean Air Act has been written and interpreted, scholars have sometimes suggested that EPA not only can, but legally must, base its NAAQS decisions solely on science. For example, Professor Lisa Heinzerling has argued that EPA properly revised its standards "based on mounting scientific evidence of the harmfulness of these pollutants at levels allowed by the existing standards."[117] Similarly, Professor Robert Percival has argued that the "EPA's determination of what levels of air pollution harm health has consistently been understood to require a judgment based on science, not economics."[118] It is true that the Clean Air Act specifies the steps EPA must take in setting or revising its air quality standards,[119] and that these steps have been interpreted to preclude the consideration of costs.[120] But even though the statute may constrain EPA in certain ways, it remains inherently necessary to make risk management policy judgments when setting air quality standards.

As noted earlier, the Clean Air Act provides that in promulgating a new or revised NAAQS, EPA must draw upon a "criteria document"

SCI. & TECH. 93, 114 (1987) (suggesting that with respect to setting NAAQS standards, "[s]cience and scientists cannot solve all of the EPA's problems"); Oren, *supra* note 18, at 10,660 (arguing that "the decision of who should be protected, and what effects they should be protected against, is an ethical decision, not a scientific one"). For a discussion of policy principles applicable to setting air quality standards, see *infra* Part III.A.

[117] Lisa Heinzerling, *The Clean Air Act and the Constitution*, 20 ST. LOUIS U. PUB. L. REV. 121, 122 (2001). Heinzerling also has claimed that EPA's "standards [were] promulgated based on this body of scientific evidence." *Id.*; *see also* David M. Driesen, *Sustainable Development and Air Quality: The Need to Replace Basic Technologies with Cleaner Alternatives*, 32 Envtl. L. Rep. (Envtl. L. Inst.) 10,277, 10,282 (Mar. 2002) (noting that "[t]he revised standards reflect new health data"); Thomas O. McGarity, *The Clean Air Act at a Crossroads: Statutory Interpretation and Longstanding Administrative Practice in the Shadow of the Delegation Doctrine*, 9 N.Y.U. ENVTL. L.J. 1, 2 (2000) (stating that each time EPA has established or revised a NAAQS "the Agency based its decision on one or more air quality criteria documents that set out in considerable detail the available scientific information on the adverse health effects of the relevant pollutants"). To be sure, science could demonstrate that health effects occurred at levels of exposure below current standards, but this scientific evidence by itself cannot be used to justify a decision about where a standard should be set. *Supra* note 89 and accompanying text.

[118] Robert V. Percival, *Joint Center Amici Brief Misses the Mark* (AEI-Brookings Joint Ctr. for Regulatory Studies, Policy Matters No. 00-11, 1990), *available at* http://www.aei.brookings.org/policy/page.php?id=55.

[119] *Supra* notes 47-50 and accompanying text.

[120] *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 464-70 (2001) (finding that Congress' instructions to EPA to set air quality standards do not allow consideration of "the costs of achieving such a standard"); *Lead Indus.*, 647 F.2d at 1148 (stating that "economic considerations play no part in the promulgation of ambient air quality standards").

that reflects "the latest scientific knowledge" of the health effects of the relevant pollutant.[121] Then, under section 109 of the Act, EPA is to set a standard that is "requisite to protect the public health" with "an adequate margin of safety."[122] The legislative history of the Clean Air Act provides some additional guidance for construing the brief statutory language. In 1970, when the current language of section 109 was enacted, the Senate Report stated that the objective of air quality standards was to ensure "an absence of adverse effects on the health of a statistically related sample of persons in sensitive groups."[123] NAAQS were intended to protect susceptible groups such as "bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment."[124] Based on this language, EPA and the courts have construed section 109 to require air quality standards to "be set at a level at which there is 'an absence of adverse effect' on . . . sensitive individuals."[125]

Moreover, NAAQS must provide a "margin of safety" to ensure that "'a reasonable degree of protection is to be provided against hazards which research has not yet identified.'"[126] Thus, at least as reflected in the 1970 Senate Report, EPA was required to set NAAQS at a level that would ensure no detectable adverse health effects in even susceptible subgroups of the population, and then to add an additional margin of safety to protect against unknown health risks that may be discovered in the future. In short, the NAAQS were apparently intended to provide near-absolute protection against adverse health effects.

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[121] 42 U.S.C. § 7408(a)(2) (2000).

[122] *Id.* § 7409(b)(1).

[123] S. REP. NO. 91-1196, at 10 (1970). The Senate explained that an adequate sample is "the number of persons necessary to test in order to detect a deviation in the health of any person within such sensitive group which is attributable to the condition of the ambient air." *Id.*

[124] *Id.*

[125] *Lead Indus.*, 647 F.2d at 1153; *see also Whitman*, 531 U.S. at 464-65 (agreeing with the approach taken by the D.C. Circuit in *Lead Industries*).

[126] *Lead Indus.*, 647 F.2d at 1150 (quoting S. REP. NO. 91-1196, at 2-3 (1970)); *see also id.* at 1154 (observing that the margin of safety requirement was intended to protect against health effects "which have not yet been uncovered by research"). According to EPA:

> The margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below

The statutory provisions for adopting NAAQS, initially enacted in their present form in 1970, are based on the assumption that pollutants have thresholds for which it is possible to set a "safe" level.[127] Such a "threshold pollutant" causes adverse effects only above a certain exposure level, designated as the threshold level. In contrast, a "non-threshold" pollutant is one that may cause adverse effects at any level above zero exposure.[128]

For threshold pollutants, it would appear as if science alone might be sufficient to determine the level at which an air quality standard should be set. If a pollutant shows a clear threshold, the science would presumably provide the basis for using this threshold as a "safe" point below which the regulator could be assured the complete protection of public health. Yet even with threshold pollutants, some judgments would still be required on the part of the Administrator.[129] Moreover, even when the standard is set below the threshold level, the Administrator must make a clear policy judgment in selecting an

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those at which human health effects can be said to occur with reasonable scientific certainty.

EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857; *see also* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,653 (same).

[127] *See Clean Air Act Amendments of 1977: Hearing Before the Subcomm. on Envtl. Pollution of the Senate Comm. on Env't & Pub. Works*, 95th Cong., 1st Sess., pt. 3, at 8 (1977) (statement of Sen. Edmund Muskie, Member, Senate Subcomm. on Envtl. Pollution) ("The Clean Air Act is based on the assumption, although we knew at the time it was inaccurate, that there is a threshold."); Joseph M. Feller, *Non-Threshold Pollutants and Air Quality Standards*, 24 ENVTL. L. 821, 823 (1994) ("A critical . . . assumption underlies . . . the structure of the Clean Air Act . . . . The assumption is that, for each pollutant of concern, there is a threshold concentration, represented by the NAAQS, above which the pollutant is a threat to health or welfare and below which it is not."); William K. Reilly, *Foreword* to ROBERT D. FRIEDMAN, SENSITIVE POPULATIONS AND ENVIRONMENTAL STANDARDS, at vii, vii (1981) ("The Clean Air Act incorporates the notion of threshold values of pollutants, levels below which there are presumed to be no adverse health effects, and requires that standards be set on the basis of the threshold, with a margin of safety.").

[128] *See* Natural Res. Def. Council v. EPA, 824 F.2d 1146, 1148 (D.C. Cir. 1987) (defining a "non-threshold" pollutant as one that "appears to create a risk to health at all non-zero levels of emission"). A non-threshold pollutant is always defined provisionally, because it is "impossible to scientifically prove the absence of a threshold, as one can never prove a negative." David L. Eaton & Curtis D. Klaassen, *Principles of Toxicology*, *in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 11, 21 (Curtis D. Klaassen ed., 6th ed. 2001).

[129] Judgment would be needed in (1) evaluating the scientific evidence indicating that a threshold exists, (2) determining that the threshold has been adequately specified, and (3) defining what counts as an "adverse effect" covered by the threshold. Judgment would also be needed to determine whether the threshold protected susceptible groups and accounted for interindividual variability in response to the pollutant in question.

"adequate margin of safety" to protect against uncertain or unknown health effects at lower exposure levels.[130]

The need for making a policy judgment is still clearer for non-threshold pollutants. Unlike with threshold pollutants, where a standard can be set at a level below the threshold to provide complete health protection, the only way to protect against the entire continuum of adverse health effects from a non-threshold pollutant would be to set a standard at the level of zero.[131] As a result, when regulators set standards for non-threshold pollutants at levels above zero, they must, at least implicitly, do so based on some criteria other than the science, since the science indicates that health effects likely occur at levels below the standard selected by the regulators.

It turns out that few, if any, criteria pollutants regulated under the Clean Air Act exhibit a clear threshold.[132] The scientific data for ozone and fine PM indicate a continuum of health effects down to background (or natural) concentrations of the pollutants in the air, at which point the health effects associated with the pollutants cannot be distinguished from effects caused by other factors.[133] In other words, there is no identifiable threshold below which a standard for ozone or particulate matter could be set to avoid all health effects.[134]

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[130] 42 U.S.C. § 7409(b)(1) (2000).

[131] *See* Sunstein, *supra* note 18, at 315 (noting that the apparent continuum of biological responses to ozone "means that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an 'adequate margin of safety' is not possible").

[132] According to one report:

> In no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at or above some level of pollution, but no effects at all below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, and with no sharp lower limit.

NAT'L ACAD. OF SCI. & NAT'L ACAD. OF ENG'G, AIR QUALITY AND AUTOMOTIVE EMISSION CONTROL, S. DOC. NO. 93-24, at 17 (1974) [hereinafter NAS/NAE].

[133] *See, e.g.*, EPA, *EPA's Updated Clean Air Standards: A Common Sense Primer, at* http://www.epa.gov/oar/primer/science.htm (Sept. 1997) (stating that "[t]he scientific community, EPA, Congress and the courts have long recognized there is no health threshold for ozone and other air pollutants—in other words, no specific-level at which all people can be fully-protected"); Heinzerling, *supra* note 117, at 122 (acknowledging that, at the time of EPA's decision, "the existing evidence seemed to point to the possibility that there is no level at which ozone exerts no effect whatsoever on the human body"); *see also infra* notes 146-50 and accompanying text (describing Congress' acknowledgment of the absence of thresholds).

[134] Lisa Heinzerling has sought to downplay the inherent policy judgment called for in NAAQS decision making by arguing that EPA never definitively determined that

EPA acknowledged this point in its rulemaking. With respect to ozone, EPA stated that ozone "may elicit a continuum of biological responses down to background concentrations" and that "in the absence of any discernable threshold, it is not possible to . . . identify a level at which it can be concluded with confidence that no 'adverse' effects are likely to occur."[135] Moreover, the Agency specifically rejected industry arguments that the health evidence for ozone indicated the existence of a threshold, responding that the available evidence suggested "a linear relationship down to a background level of 0.04 ppm."[136] For fine PM, EPA speculated that a threshold might exist, but acknowledged that "the level or even existence of population thresholds below which no effects occur cannot be reliably determined by an examination of the results from the available studies."[137]

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ozone and particulate matter had adverse health effects down to zero. She has written:

> EPA's observation that particulate matter and ozone may be "nonthreshold" pollutants was nothing more than an admission that the agency had not proven the existence of a level at which these pollutants had no effects on human health. . . . It was also not a claim that the agency would regard all such effects on health, if detected, to be sufficiently "adverse" to warrant a regulatory response. Nor was it a claim that the agency would regard all such effects to be effects on *public* health within the meaning of the Clean Air Act.

Heinzerling, *supra* note 117, at 126 (footnotes omitted). This argument misses the point. Even though the Agency did not definitively demonstrate health effects all the way to zero, its own analyses indicated that there were health effects below the levels at which it chose to set its standards, including in the case of PM, a substantial number of premature deaths every year, which certainly must be considered "adverse." Moreover, EPA most certainly did need to make a policy judgment in deciding that some effects were not "sufficiently 'adverse'" to warrant protection. The Agency knew that there would be many individuals who would suffer health effects at levels of exposure permitted by EPA's standards, and it strongly suspected that there would always be such individuals so long as there was some level of ozone or particulate matter in the air. *Infra* Part II.B–C. Choosing to disregard these effects in setting its regulatory standard may well have been reasonable and even justified, but it was a clear policy choice that EPA failed to acknowledge openly and explain adequately. For further criticism of Heinzerling's argument, see Richard J. Pierce, Jr., *The Appropriate Role of Costs in Environmental Regulation*, 54 ADMIN. L. REV. 1237, 1261-65 (2002).

[135] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863 (citation omitted). EPA further acknowledged that "no standard within the range of levels and forms considered in this review, including the selected standard, is risk free, due to the continuum of risk likely posed by exposures to ambient O_3 [ozone] potentially down to background levels." *Id.* at 38,873.

[136] EPA, RESPONSES TO SIGNIFICANT COMMENTS ON THE 1996 PROPOSED RULE ON THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE 81 (Docket No. A-95-58, 1997) [hereinafter EPA, OZONE RESPONSE TO COMMENTS]; *see also id.* at 84 ("There is clear evidence from hospital admission studies that effects continue down to background.").

[137] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,670; *see also* Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1034 (D.C. Cir. 1999) ("EPA regards ozone definitely,

CASAC, the advisory committee that must review the scientific basis of EPA's criteria document and NAAQS standards,[138] concurred with EPA that "the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations."[139] Rather, "it appears that ozone may elicit a continuum of biological responses down to background concentrations."[140] Likewise, in its review of particulate matter, CASAC concluded that "[a]s with ozone, there appears to be no apparent threshold for biological responses to PM exposures."[141] According to CASAC, the absence of a demonstrated threshold implies "that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an 'adequate margin of safety' is no longer possible."[142] For ozone, CASAC also concluded that "there is no 'bright line' that distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of health" and thus "the selection of a specific level and number of allowable exceedences is a policy judgment."[143] In testimony to Congress, the Chair of CASAC reiterated that "the decisions to select a given level or number of allowable exceedences within [EPA's] proposed ranges cannot be based on science;"[144] rather, the selection of a particular standard was "strictly a policy judgment."[145]

The absence of clear thresholds for these pollutants was a well-known fact to members of Congress during deliberations over the 1977 amendments to the Clean Air Act, if not earlier.[146] Senator

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and PM likely, as non-threshold pollutants, i.e., ones that have some possibility of some adverse health impact (however slight) at any exposure level above zero.").

[138] 42 U.S.C. § 7409(d)(2) (2000).

[139] Letter from Dr. George T. Wolff, Chair, Clean Air Scientific Advisory Committee, to Administrator Carol M. Browner 2 (Nov. 30, 1995), *available at* http://www.epa.gov/sab/pdf/casac02.pdf.

[140] *Id.*

[141] Letter from Dr. George T. Wolff, Chair, Clean Air Scientific Advisory Committee, to Administrator Carol M. Browner 3 (Jan. 5, 1996), *available at* http://www.epa.gov/sab/pdf/casac03.pdf.

[142] Wolff, *supra* note 139, at 2.

[143] *Id.* at 2-3.

[144] *EPA Proposed Clean Air Regulations: Hearing Before the House Subcomm. on Health & Env't and House Subcomm. on Oversight & Investigations,* 105th Cong. 2 (1997) (statement of George T. Wolff, Chair, EPA's Clean Air Scientific Advisory Committee's Panels on Ozone and PM), *available at* 1997 WL 10569483.

[145] *Id.* at 1.

[146] Congress was strongly influenced by a 1974 report prepared for the Senate by the National Academy of Sciences and National Academy of Engineering which

Muskie, the primary Senate sponsor of the amendments, observed that for nearly all criteria pollutants, "[t]here is no threshold health effect which can be used to say that above this threshold there is danger to health and below it there is not."[147] The House likewise acknowledged in 1977 that the "safe threshold" concept underlying section 109 was "at best, a necessary myth"[148] since "no safe thresholds can be established."[149] Accordingly, the House noted that air quality standards set by EPA at the time had failed to satisfy either of "the two main safeguards which have been recognized as necessary in the protection of public health: proof of a safe threshold level of exposure and a fully adequate margin of safety beyond harm levels which have already been proved."[150]

In setting air quality standards at any level above zero, the EPA Administrator is compelled to rely upon some criterion other than the absolute protection against health effects. As Senator Muskie recognized in 1977:

> I wish it were possible for the Administrator to set national primary and secondary standards that fully implement the statutory language . . . . The fact is, as testimony and documents disclose, the standards do not fully protect in accordance with the statutory language which gives the Administrator authority to provide for additional protection. He has had to make a pragmatic judgment in the face of the fact that he found

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concluded that, contrary to the assumption underlying the 1970 Act, there were no thresholds for criteria pollutants. NAS/NAE, *supra* note 132, at 17-18.

[147] STAFF OF SENATE COMM. ON ENV'T & PUB. WORKS, 95TH CONG., LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1977 (Comm. Print 1978), *reprinted in* 3 COMM. ON ENV'T & PUB. WORKS, 95TH CONG., LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1977, at 781 (1978) (remarks of Sen. Edmund Muskie). Senator Muskie likewise stated:

> [T]estimony on the health question over the last 7 years over and over again has made the point that there is no such thing as a threshold for health effects. Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.

123 CONG. REC. 18,460 (1977) (statement of Sen. Edmund Muskie).

[148] H.R. REP. NO. 95-294, at 111 (1977).

[149] *Id.* at 127. The House Report also quoted the National Academy of Sciences in support of this understanding:

> "[I]n no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at and above some level of pollution, but no effects at all below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, with no sharp lower limit."

Id. at 110 (quoting NAS/NAE, *supra* note 132, at 17).

[150] *Id.* at 111-12.

> there is no threshold on health effects, which makes it very difficult then to apply absolute health protection, and he has not been able to do that.[151]

The House recognized that some limits were necessary to prevent the kind of zero-risk standards that would follow from strict application of the Clean Air Act to non-threshold pollutants: "Some have suggested that since the standards are to protect against all known or anticipated effects and since no safe thresholds can be established, the ambient standards should [b]e set at zero or background levels. Obviously, this no-risk philosophy ignores all economic and social consequences and is impractical."[152] Nevertheless, Congress did not amend the statutory language of section 109 to reflect this recognition. Nor did it provide any further guidance to EPA on how to justify a nonzero standard for a non-threshold pollutant in a way that would satisfy the Clean Air Act's requirement to "protect the public health" with an "adequate margin of safety."[153]

The House's recognition that a zero-risk approach would "ignore all economic and social consequences," however, implicitly demonstrated the inevitable need to incorporate factors other than scientific evidence about health effects in justifying where standards are set for non-threshold pollutants. Any nonzero standard for a non-threshold pollutant must inherently take into account economic and social considerations in addition to the scientific evidence of health effects, since a science-only approach that seeks to prevent all "adverse effects" with an "adequate margin of safety" can only be set at zero, which everyone agrees would be nonsensical.

II. THE ABANDONMENT OF REASON IN EPA'S AIR QUALITY STANDARD SETTING

The selection of a NAAQS standard, especially for a non-threshold pollutant, is a quintessential risk-management decision that, while drawing on scientific evidence, ultimately turns on social, political, and economic choices.[154] While science provides relevant information describing the frequency and severity of adverse effects at various

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[151] 123 CONG. REC. 18,463 (1977) (statement of Sen. Edmund Muskie).

[152] H.R. REP. NO. 95-294, at 127 (1977).

[153] 42 U.S.C. § 7409(b)(1) (2000).

[154] Reilly, *supra* note 127, at viii ("In the absence of a scientifically definable threshold, the decision makers responsible for establishing a standard are inescapably forced to make social, not scientific, judgments.") (statement of former Administrator Reilly before he assumed his position as head of EPA).

pollutant levels, this information, by itself, fails to identify the level at which to set the standard. As we have detailed, EPA has attempted to justify its recent NAAQS decisions (as it has earlier ones) based exclusively on science, when the selection of such a standard necessarily requires policy judgments.[155] EPA's most recent revisions to its ozone and fine PM NAAQS not only provide yet another case study of the so-called science charade, but, more importantly, they reveal the consequences of a regulatory regime that permits, and even encourages, agencies to cloak their policy decisions in science. When EPA or any other agency invokes science to justify its regulatory decisions, it fails to provide the public with a transparent and principled justification for its regulatory decisions.[156]

In the recent ozone and particulate matter rulemakings, EPA took a series of inconsistent positions that remained largely hidden behind the Agency's repeated invocation of science as the basis for its decisions. Throughout its rulemakings and subsequent rounds of litigation, EPA's policy positions resembled shifting sands. For example, even though the Agency claimed to justify its standards based on a singular concern for evidence of health risks, it explicitly rejected options that, according to its own analysis, would have provided greater protection to the public from such risks.[157] In this Part, we present some of the most significant inconsistencies that emerged in EPA's rulemaking documents and its arguments in court. EPA's use of science as a rhetorical defense helped to mask the absence of a coherent, principled account for why the Agency revised its ozone and particulate matter standards as it did.[158]

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[155] *See* R. SHEP MELNICK, REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT 261 (1983) ("There is, in short, no simple answer to the question of how the EPA sets air quality standards. Medical evidence cannot offer definitive guidance. . . . The EPA itself has refused to deal with the problem in a forthright manner, hiding its policy choices behind its interpretation of scientific evidence."); Kevin D. Hill, *Smog, Science & the EPA*, 25 N. KY. L. REV. 1, 27 (1997) ("Decisions as costly and important as the ozone standard should not hide behind a charade of science but should be part of the public debate."); Pierce, *supra* note 18, at 73 ("The *ATA* case is laced with symptoms of the science charade."); Wagner, *supra* note 11, at 1640-44 (arguing that EPA's reliance on scientific and medical evidence alone to justify its previous ozone NAAQS is a "vivid illustration" of an "intentional science charade").

[156] *See* Nicholas A. Ashford et al., *A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking*, 7 HARV. ENVTL. L. REV. 297, 311 (1983) (noting that "[s]uch an approach frustrates any effort to measure agency decisions against the reasoned decisionmaking standard.").

[157] *Infra* Part II.B–C.

[158] This is not to say that no consistent set of reasons could have been offered to justify EPA's decisions. An agency's decision making may be reasonable, even if

A. *Science and EPA's Ad Hoc Policymaking*

EPA's reliance on science as a rationale made it easier for the Agency to claim that it could make ad hoc policy judgments without the need to provide a consistent set of principles to guide its NAAQS decision making. In the ozone and particulate matter rulemakings, EPA explicitly asserted that it could rely on scientific inputs and therefore, did not need to provide any consistent set of policy principles to explain its decisions.[159]

EPA's revision of the ozone and PM NAAQS began with the preparation of a Criteria Document and then a Staff Paper for each pollutant. As required by the statute, the Criteria Document provided a review of "the latest scientific knowledge" on "all identifiable effects on public health or welfare" that may result from ambient levels of a pollutant.[160] As EPA and its amici argued to the Supreme Court, the Criteria Document was thus a "descriptive" document that was "limited" to scientific information.[161] Although the Staff Paper was intended to "help bridge the gap between the scientific review contained in the Criteria Document and the judgments required of the Administrator in setting ambient standards," it too emphasized "conclusions and uncertainties in the available scientific literature" to be considered in setting the standards.[162] Neither the Criteria Document

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inadequately reasoned. That said, given the wide disparity in health benefits achieved between the ozone and PM decisions, we have our doubts about whether EPA's decisions across these rulemakings could ever have been adequately justified. *Infra* Part II.D.

[159] *See infra* notes 164, 188-90, 202-03 and accompanying text (elaborating on the Agency's reluctance to establish a framework for its decision making).

[160] 42 U.S.C. § 7408(a)(2) (2000); *see also supra* note 49 and accompanying text (discussing the preparation of criteria documents).

[161] As EPA indicated in its subsequent Supreme Court brief defending its ozone and PM standards, section 108(a)(2) "limits the kind of information to be included in the 'criteria' to 'the latest scientific knowledge.'" EPA, Supreme Court Respondents Brief, *supra* note 60, at 19. Indeed, the criteria documents are intended to be "descriptive." *See* Brief for Respondents Massachusetts and New Jersey at 18-19, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1426) [hereinafter Massachusetts and New Jersey Brief] (citing statements from early criteria documents that such documents are "descriptive" summaries of "scientific knowledge," and noting that Congress ratified this understanding of the purpose and content of the criteria documents in the 1970 Clean Air Act); *see also* S. REP. NO. 90-403, at 26-27 (1967) ("Air quality criteria are an expression of the scientific knowledge of the relationship between various concentrations of pollutants in the air and their adverse effects on man, animals, vegetation, materials, visibility and so on." (citation omitted)).

[162] OFFICE OF AIR QUALITY PLANNING & STANDARDS, EPA, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER: POLICY

nor the Staff Papers purported to recommend or justify any specific regulatory standard, but instead they identified a range of possible standards that the staff believed would protect public health with some margin of safety.[163]

The EPA Administrator is supposed to select specific standards only after considering the information from the Criteria Document and Staff Paper, along with public comments that had been filed during the rulemaking process. In explaining the Administrator's decisions on ozone and particulate matter, EPA began by making two brief and uncontroversial assertions. First, EPA acknowledged briefly in the *Federal Register* that the Administrator's decision was a "policy choice," though one the Agency asserted was "left specifically to the Administrator's judgment."[164] This latter language seemed to imply that the exercise of the Administrator's judgment did not need to be explained with any meaningful policy justification. Second, EPA reaffirmed statements in the 1977 legislative history of the Clean Air Act that the Agency was not required to set a zero-risk standard for a non-threshold pollutant.[165] Of course, no major participant in environmental policymaking has ever seriously argued that a zero-risk standard is required, given that a zero-risk standard for a non-threshold pollutant would result, at a minimum, in the end of the industrialized

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ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION, at I-1 (1996) [hereinafter PM STAFF PAPER], *available at* http://www.epa.gov/ttn/oarpg/t1sp.html.

[163] OFFICE OF RESEARCH AND DEVELOPMENT, EPA, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS (1996) [hereinafter CRITERIA DOCUMENT]; OFFICE OF AIR QUALITY PLANNING & STANDARDS, EPA, REVIEW OF NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE: ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION 213-14 (1996) [hereinafter OZONE STAFF PAPER] (recommending a primary eight-hour ozone standard in the range of 0.07 to 0.09 ppm); PM STAFF PAPER, *supra* note 162, at VII-47 ("Staff recommends that the Administrator consider selecting the level of a new 24-hour $PM_{2.5}$ standard from the range of 20 $\mu g/m^3$ to approximately 65 $\mu g/m^3$, and the level of a new annual $PM_{2.5}$ standard from the range of 12.5 $\mu g/m^3$ to approximately 20 $\mu g/m^3$.").

[164] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857; EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,653.

[165] *E.g.*, EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857 ("The Act does not require the Administrator to establish a primary NAAQS at a zero-risk level but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety."); *id.* at 38,863 ("[A] zero-risk standard is neither possible nor required by the Act."); *id.* at 38,867 ("Clearly, for pollutants, such as O_3, that have no discernible thresholds for health effects, no standard can be risk-free."). EPA made identical statements in the preamble to the final PM standard. EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,653, 38,656.

economy as we know it.[166] But as we will see, this position has put the Agency in an especially difficult, if not impossible, position when it comes to providing a consistent justification for its standards.[167]

What EPA failed to address in its rulemaking was the critical question of what risk management principle or criterion justified the Administrator's "policy choice" in selecting nonzero standards along the continuum of predicted health risks for ozone and fine PM.[168] Instead, EPA identified only scientific factors to defend its choices, arguing that risk assessments played a "central role in identifying an appropriate level."[169] In the preamble for the final ozone standard, EPA summarized its basis for its decision by identifying the information which it gathered in the rulemaking process: (1) the Criteria Document, (2) the Staff Paper, (3) CASAC's advice, and (4) public comments.[170] Of course, a simple bibliography is not the same as a meaningful explanation, but more importantly these various sources of information do not themselves contain any principled justification for the revised standards. As noted earlier, the Criteria Document is limited to a description of scientific information,[171] and the Staff Paper was intended to "bridge" the scientific evidence and the Agency's policy determination but did not itself recommend or develop a

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[166] *See, e.g.*, Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1038 (D.C. Cir. 1999) ("No party here appears to advocate this [zero-risk policy], and EPA appears to show no inclination to adopt it."); Paul R. Portney, *EPA and the Evolution of Federal Regulation*, *in* PUBLIC POLICIES FOR ENVIRONMENTAL PROTECTION 11, 17 (Paul R. Portney & Robert N. Stavins eds., 2000) ("[I]t is impossible to eliminate all traces of environmental pollution without simultaneously shutting down all economic activity, an outcome which neither Congress nor the public would abide.").

[167] *Infra* notes 364-67 and accompanying text.

[168] CASS R. SUNSTEIN, THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION 112 (2002) ("The basic problem is that the agency did not explain, in concrete terms, why it chose one level of regulation rather than another."). For a discussion of risk management principles, see *infra* Part III.A.

[169] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863 (citation omitted). Later, in a brief defending the PM rule, EPA claimed that the Agency's full risk assessment played only a "limited role," but that the standards "were based primarily on EPA's analysis of the epidemiological studies in the record," also a clearly scientific consideration. EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, at 51.

[170] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859. Although we focus in this part of the text primarily on the justification EPA offered for its revisions to the ozone standard, EPA provided a similar account in its preamble to the final rule revising the particulate matter standards. *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,655 ("These decisions are based on a thorough review, in the Criteria Document, of the latest scientific information on known and potential human health effects associated with exposure to PM at levels typically found in the ambient air.").

[171] *Supra* notes 49, 160 and accompanying text.

justification for specific policy determinations.[172] The Staff Paper expressly acknowledged that setting a NAAQS standard was "a policy choice left specifically to the Administrator's judgment."[173] As with the staff materials, CASAC's input was similarly limited, almost by definition, to scientific advice.[174] Finally, while public comments may raise policy arguments in addition to scientific conclusions, they reflect the opinions of interested individuals and organizations, not the judgment of the Administrator. Even though some of these comments undoubtedly discussed policy issues and not merely scientific evidence of health effects, EPA did not (and could not) rely on these comments to offer the justification that the Agency itself is required to provide in exercising its governmental authority.[175]

Based solely on these sources of information contained in the rulemaking record, EPA claimed to have determined that a revision to its current standards was "appropriate."[176] Once it made this determination, EPA needed to decide the specific level at which the revised standards should be set. In its final rule, EPA stated that a revised ozone primary standard set at 0.08 ppm based on an eight-hour average was likewise "appropriate."[177] It offered as its purported "rationale"

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[172] *Supra* text accompanying note 162.

[173] OZONE STAFF PAPER, *supra* note 163, at 3 (citation omitted); *id.* at 213 ("In making recommendations, staff notes that the decision ultimately made by the Administrator regarding level of the primary O_3 NAAQS will be based on a policy judgment as to the degree of risk reduction that is necessary to protect public health with an adequate margin of safety.").

[174] *Supra* note 59 and accompanying text.

[175] *See, e.g.*, Brief of Amici Curiae Environmental Defense et al. at 21, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1426) ("[T]here is no plausible scenario under which the requirement that the agency consider comments could modify the standards defined in the statute for the setting of the NAAQS."); Massachusetts and New Jersey Brief, *supra* note 161, at 34 (describing as "fantastical" the argument that "the Administrator must consider anything submitted in the public record as relevant to her decision setting the NAAQS" because "[s]uch a process would allow public commenters to determine the scope and content of EPA's obligations in setting the NAAQS"). Indeed, there is no indication in the rulemaking record that EPA adopted any policy criteria for setting NAAQS suggested by a public commentator.

[176] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859. EPA took a similar approach in its final rule on particulate matter:

> Based on the rationale and recommendations contained in the Staff Paper and the advice of CASAC, and taking into account public comments, the Administrator concludes that it is appropriate at this time to revise the current PM standards to increase the public health protection provided against the known and potential effects of PM identified in the air quality criteria.

EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,666.

[177] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859.

for this decision the Agency's "consideration of" health effects information, human exposure, and risk assessments: "[s]pecific conclusions . . . that, taken together, would be *appropriate* to protect public health with an adequate margin of safety."[178] Of course, it is far from clear what the Agency meant by basing its decision on "consideration of" scientific information or, more significantly, what made its judgment "appropriate." The Agency was simply begging the question.

In the preamble to the final ozone rule, EPA stated that CASAC recognized that "the selection of specific standards requires that the Administrator make public health policy judgments in addition to determinations of a strictly scientific nature."[179] But what did such judgments entail and what was EPA's reasoned basis for making them as it did? EPA claimed that its public health policy judgment was "framed by" the scientific information and its view that the standards should be set at some "appropriate level."[180] It also stated that its public health policy judgment was "informed by" various "key observations and conclusions,"[181] including the results of various health studies, the types of health effects identified in those studies, the levels of human exposure, the results of EPA's risk assessment, and the advice from CASAC.[182] Again, these types of data are relevant scientific inputs for any risk management decision, but even taken together they categorically differ from a policy reason that justifies setting risk standards at one level rather than another.[183] EPA concluded in its preamble that these factors, in particular the fact that no CASAC member endorsed a standard below 0.08 ppm, led the Agency to focus on the alternative

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[178] *Id.* (emphasis added). The Agency also stated that it examined "[a]lternative views of the significance of the effects and factors to be considered in policy judgments about the *appropriate* elements of the standard." *Id.* (emphasis added).

[179] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863.

[180] *Id.*

[181] *Id.*

[182] *Id.* at 38,863-65. The only type of public health "policy judgments" that EPA identified were "the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed." *Id.* at 38,883. These factors are an integral part of characterizing risks, the final step in risk assessment, but they do not provide any policy principles that would justify a risk management decision. NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 27 (1994) (noting that such "science-policy" factors "are distinct from the policy choices associated with ultimate decision-making").

[183] *See, e.g.*, LANDY ET AL., *supra* note 108, at 56 ("[T]erms like sensitive group, health, and adequate margin of safety are not self-defining. The science of the situation could not, by itself, produce a decision." (emphasis omitted)).

levels of 0.08 ppm and 0.09 ppm.[184] The remainder of EPA's explanation for its selected standard consisted of a list of factors that simply supported the obvious descriptive point that an 0.08 ppm standard provides more health protection than does an 0.09 ppm standard.[185]

Other statements that EPA made in the preambles to its final rules likewise reflected a reliance on scientific factors to justify its decisions and failed to specify any risk management criterion. For example, EPA summarized its approach for establishing a "margin of safety" (clearly a policy decision) almost entirely in terms of scientific information. According to the Agency, its task was "to select an approach that best takes into account the health effects and other information assessed in the air quality criteria for the pollutant in question and to apply appropriate and reasoned analysis to ensure that the scientific uncertainties are taken into account in an appropriate manner."[186] However, this itself is not an explanation of why the Agency arrived at its revised standards. No one can deny that the Administrator should make an "appropriate" decision, but the Administrator's underlying rationale for these decisions was never stated, nor was any principle offered that could explain these decisions as well as similar decisions made by any other Administrator in the past or future. The factors invoked by EPA speak to how the risk is characterized, not to how that risk should be managed.[187] After discussing the scientific data and associated uncertainties, EPA basically stopped and pronounced the standards it had selected, explaining its decisions simply by asserting that they were "appropriate."

The lack of any policy justification was all the more striking because the one issue where EPA most clearly should have explained its risk management judgment would have been in setting the margin of safety. Yet, the Agency failed to articulate any clear or consistent policy principles for establishing a margin of safety, instead arguing

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[184] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,864-65.

[185] *Id.* at 38,865, 38,867-68. Of course, this observation is obvious only if ground-level ozone provides no countervailing health benefits. *See infra* notes 312-13 and accompanying text (indicating that there may be potential health benefits of ozone).

[186] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883. EPA's preamble to the revised particulate matter standard contains virtually the same language. *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688-89 ("[T]he task of the Administrator is to select an approach that best takes into account the nature of the health effects . . . and to apply appropriate and reasoned analysis to ensure that scientific uncertainties are taken into account in an appropriate manner.").

[187] For the distinction between risk characterization and risk management, see *supra* notes 91-95 and accompanying text.

against the need to provide a principle at all. The Agency claimed that "no generalized paradigm . . . can substitute for the Administrator's careful and reasoned assessment of all relevant health factors in reaching . . . a judgment."[188] Moreover, because the Agency's determination is "largely judgmental in nature," it "may not be amenable to quantification in terms of what risk is 'acceptable' *or any other metric*."[189] EPA even argued that it can change its approach for setting NAAQS on a case-by-case basis, stating that "the Administrator is not limited to any single approach to determining an adequate margin of safety and, in the exercise of her judgment, may choose an integrative approach, a two-step approach, or perhaps some other approach, depending on the particular circumstances confronting her in a given NAAQS review."[190] In effect, EPA argued that it possessed complete discretion to set standards in any way it desired, without the need to offer any consistent, reasoned explanation for its decision.

It is not surprising, then, that EPA has been inconsistent in how it sets the margin of safety required by the Clean Air Act. In particular, the Agency has shifted its position on whether the margin of safety provision requires the Agency to set primary standards below the lowest probable adverse effects identified by scientific studies. In the recently revised ozone standard, EPA set the primary standard at 0.08 ppm, the level at which it claimed that adverse health effects were directly observed in clinical studies.[191] In past rulemakings, however, EPA has taken the position that the margin of safety requirement

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[188] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883; EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688.

[189] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883 (emphasis added); EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688 (emphasis added).

[190] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688; *see also* EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883 (providing an almost identical statement).

[191] *See, e.g.*, EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 15 ("[N]ew clinical studies provided 'conclusive evidence' that prolonged ozone exposure decreases lung function and causes respiratory symptoms at ozone concentrations down to 0.08 ppm."); EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863-64 (noting "clear evidence from human clinical studies . . . of the following statistically significant responses at 6- to 8-hour exposures to the lowest concentration evaluated, 0.08 ppm O_3, at moderate exertion: lung function decrements, respiratory symptoms . . . , nonspecific bronchial responsiveness, and biochemical indicators of pulmonary inflammation" and admitting that these effects in some individuals are "sufficiently severe and extended in duration to be considered adverse"); EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 13-14 ("The Agency's decision . . . is that the O_3 primary standard should be set with an 8-hour averaging period and at 0.08 ppm, a level at which numerous controlled-exposure human studies have reported health effects such as lung function decrements, respiratory symptoms, and indicators of inflammation.").

directs the Agency to set the standards below those at which adverse health effects are found or expected in sensitive groups.[192] EPA had earlier argued that "[t]he intent of the margin of safety requirement was to direct the Administrator to set air quality standards at pollution levels below those at which adverse health effects have been found or might be expected to occur in sensitive groups."[193] EPA even acknowledged before the Supreme Court its view that air quality "standards must be 'preventative or precautionary,' reflecting an emphasis on the 'predominant value of protection of public health'"[194] and that EPA should be sure to "err on the side of caution."[195]

Accordingly, EPA previously claimed to have set the primary standard substantially below the lowest level of demonstrated adverse effects in order to ensure an adequate margin of safety. For example, in the previous revision of the ozone standard in 1979, EPA concluded that "the probable level for adverse effects in sensitive persons . . . is in the range of 0.15-0.25 ppm."[196] Nevertheless, EPA set the standard at 0.12 ppm, well below the probable effects level, because, based on its statutory interpretation, it was required to make a "[j]udgment of a standard level *below* the probable effect level that provides an

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[192] *See* National Ambient Air Quality Standards for Ozone-Final Decision, 58 Fed. Reg. 13008, 13,009 (Mar. 9, 1993) [hereinafter EPA, 1993 Ozone Decision] ("[T]he 'margin of safety' requirement by definition only comes into play where no conclusive showing of adverse effects exists."); National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46,246, 46,247 (Oct. 5, 1978) ("It is clear from section 109 that [EPA] should not attempt to place the standard at a level estimated to be at the threshold for adverse health effects but should set the standard at a lower level in order to provide a margin of safety."); *see also supra* notes 50, 122, 127 and accompanying text. *See generally* William F. Pederson, *Costs Matter: Effective Air Quality Regulation in a Risky World*, 20 ST. LOUIS U. PUB. L. REV. 153, 159 (2001) ("A standard that incorporates a 'margin of safety' is one that goes beyond addressing provable harms.").

[193] Revisions to the National Ambient Air Quality Standards for Particulate Matter, 52 Fed. Reg. 24,634, 24,641 (July 1, 1987) [hereinafter EPA, 1987 PM Rule]; *see also* Lead Indus. v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980) (remarking that Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement").

[194] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 24 (citing *Lead Indus.*, 647 F.2d at 1152 (quoting H.R. REP. NO. 294, 95th Cong. 49 (1977))).

[195] *Id.* (citing *Lead Indus.*, 647 F.2d at 1155).

[196] Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202, 8216 (Feb. 8, 1979) [hereinafter EPA, 1979 Ozone Rule]. EPA explained that it "uses the terminology 'probable effects level' to refer to the level that in its best judgment is most likely to be the adverse health effect threshold concentration." *Id.* at 8203.

adequate margin of safety."[197] As EPA subsequently explained its 1979 decision, it set the ozone standard at 0.12 ppm because of "the *possibility* of adverse effects occurring below 0.15 ppm O_3."[198] When EPA next revisited the ozone standard in 1993, it concluded that the controlled human studies failed to show any "adverse effects" below 0.15 ppm and thus retained the existing ozone NAAQS set significantly below that level at 0.12 ppm.[199] Likewise, EPA set the annual PM_{10} standard at 50 $\mu g/m^3$ in 1987 to provide a "reasonable margin of safety" based on evidence showing that long-term degradation in lung function was "likely" at 80-90 $\mu g/m^3$ and possible at concentrations above 60 to 65 $\mu g/m^3$.[200]

Thus, when it came to its recent ozone and PM revisions, EPA abandoned its earlier approach. It even argued in court that it was not "required to follow any particular paradigm of decision making"[201] and that "nothing in the statute requires [the Administrator] to make any specific 'findings' or to structure her decision making in any particular way."[202] EPA's inconsistent application of the margin of safety concept, combined with its assertions that it did not even need to try to be consistent, revealed an agency intentionally or unintentionally dodging its responsibility to give the public a principled justification for its preferred policy outcome.

B. *EPA's Incoherent Disregard of the Health Effects from Particulate Matter*

EPA could not help but struggle to apply its preventative notion of a margin of safety coherently, given that the Agency predicted that adverse health effects would persist at levels below the Agency's new

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[197] *Id.* at 8213 (emphasis added). EPA further stated:

> [A]t levels in the range of 0.15–0.25 ppm, adverse health effects will almost certainly be experienced by significant numbers of sensitive persons. Unless the standard is set somewhat below that level, the Agency would not be exercising the degree of prudence called for by the 'adequate margin of safety' requirement of the Clean Air Act.

Id. at 8217.

[198] National Ambient Air Quality Standards for Ozone; Proposed Decision, 57 Fed. Reg. 35,542, 35,547 (Aug. 10, 1992) (emphasis added) [hereinafter EPA, 1992 Ozone Proposal].

[199] EPA, 1993 Ozone Decision, *supra* note 192, 58 Fed. Reg. at 13,011.

[200] EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,645.

[201] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 29.

[202] *Id.* at 43. After losing in the D.C. Circuit, EPA changed its tune in its argument to the Supreme Court, claiming that the Clean Air Act severely constrained its discretion. EPA, Supreme Court Reply Brief, *supra* note 61, at 8.

standards. Although EPA purported to act to protect the public health and err on the side of safety, the Agency actually disregarded a range of public health effects in both the ozone and particulate matter rulemakings. While the Agency might well have had good cause for treating some level of health risk as tolerable, it never provided any coherent account for why it turned its back on what were, at times, quite substantial health effects.[203]

In its rulemaking on particulate matter, EPA set two standards for fine PM—an annual standard set at 15 $\mu g/m^3$ and a daily (i.e., twenty-four-hour average) standard set at 65 $\mu g/m^3$ (after initially proposing a daily standard of 50 $\mu g/m^3$).[204] The daily standard effectively acts as a constraint on the variation around the average annual level of fine PM in any given area, and in this way provides its own health protection.[205] Assuming the validity of EPA's interpretation of the scientific data on the health effects of fine PM,[206] EPA could have saved hundreds, if not thousands, of additional lives per year by setting a more stringent daily standard than the one it did.[207] Indeed, some public health advocacy groups claimed that EPA's PM standard left tens of millions of Americans at risk for serious health effects.[208]

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[203] As noted in one recent review of the PM standard:

> [O]ne must recognize the arbitrariness of the limits set by U.S. EPA. There is little, genuine, data-based or risk-based justification for the specific values chosen by the Agency: one might as easily have set a $PM_{2.5}$ annual standard set at either 10 or 20 $\mu g/m^3$, rather than the 15 $\mu g/m^3$ chosen.

Laura C. Green et al., *What's Wrong with the National Ambient Air Quality Standard (NAAQS) for Fine Particulate Matter ($PM_{2.5}$)?*, 35 REG. TOXICOLOGY & PHARMACOLOGY 327, 334 (2002).

[204] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,679.

[205] The annual standard could be met by averaging together periods of higher concentrations with periods during which wind or climate patterns, or fluctuations in industrial or transportation activity, significantly reduced the concentration of air pollutants. The daily standard therefore creates an upper bound on those periods of higher concentration.

[206] We assume the validity of EPA's risk assessment only for the purpose of our discussion here. Many commentators disagreed with EPA's conclusion that the available data sufficiently demonstrated mortality health risks from $PM_{2.5}$, leading them to advocate less stringent standards than those ultimately adopted by EPA. In the words of EPA's CASAC Chairman, "[i]f all of the [CASAC] panel members were convinced that the reported $PM_{2.5}$/mortality relationship was causal, I believe we would have come to consensus on PM standards at the low end of the EPA's recommended range." George T. Wolff, *In Response to the PM Debate*, REGULATION, Winter 1997, at 9; *see also* Green et al., *supra* note 203, at 327 (summarizing concerns with EPA's fine PM analysis).

[207] *See infra* notes 212, 214 and accompanying text.

[208] The American Lung Association, for example, advocated a 24-hour standard set at 18 $\mu g/m^3$, claiming that EPA's proposed standard set at 50 $\mu g/m^3$ would fail to protect the health of 89 million people. *See* ALA Calls for Tighter Fine PM Standard,

EPA's risk assessment document reported the Agency's estimates of the consequences of alternative standards for fine PM in two cities: Philadelphia and Los Angeles.[209] In Philadelphia, EPA estimated that the incidence of mortality associated with short-term exposure to fine PM would be reduced by 60 deaths per year, from 370 deaths per year under the existing standards to 310 deaths per year under EPA's new fine PM standard set at 15 $\mu g/m^3$ annually, 65 $\mu g/m^3$ daily.[210] Yet if EPA had reduced the daily standard even further to 25 $\mu g/m^3$, without changing the annual standard, premature mortality from short-term exposure would have been reduced to 110 deaths per year, or a reduction of 200 deaths per year above and beyond the 60 lives predicted to be saved by the standard EPA adopted.[211] For mortality from long term exposure to fine PM in Philadelphia, EPA's new standard would reduce mortality from 920 deaths per year under the existing standards to 660 deaths per year, for a net reduction of 260 deaths per year.[212] Had the Agency's sole focus been on protecting the public health, presumably it should have adopted the more stringent alternative standard it considered, namely a standard set at 15

Says EPA Proposal Leaves Millions at Risk, Env't Rep. (BNA), Jan. 14, 1997, at A-6. A more stringent annual PM standard would also likely result in additional health protection, but EPA did not evaluate a more stringent alternative than the 15 $\mu g/m^3$ standard it ultimately adopted. *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,676 (admitting that "the possibility of effects at lower annual concentrations cannot be excluded").

[209] In the rulemaking, EPA claimed that it relied on the risk assessment "as an aid to the Administrator in judging which alternative PM NAAQS would reduce risks sufficiently to protect public health with an adequate margin of safety . . . ." EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656. While acknowledging uncertainty in the quantitative estimates of health effects in the two-city study, EPA stated that "they do represent reasonable estimates as to the possible extent of risk for these effects given the available information." *Id.* Moreover, the Agency relied on its risk assessment to argue that "the risk remaining after attaining the current PM_{10} standards was on the order of hundreds of premature deaths each year, hundreds to thousands of respiratory-related hospital admissions, and tens of thousands of additional respiratory related symptoms in children." *Id.* Subsequently, in litigation, EPA emphasized that the Agency's risk assessment played only a "limited role" in EPA's decision making. EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, at 51.

[210] PM STAFF PAPER, *supra* note 162, at VI-49.

[211] *Id.*

[212] *Id.* EPA later revised its estimates of the mortality effects from long term exposure "to reflect the actual statistics used in the study upon which they were based," noting that these revisions "cumulatively reduce estimates of mortality associated with long-term exposures by 20 to 35%." EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656. The Agency stated that these revisions had "no effect on risk estimates for mortality associated with short-term exposures or the estimates for any other effects." *Id.*

$\mu g/m^3$ annually and 25 $\mu g/m^3$ daily. This more stringent standard would have reduced mortality in a city of this size to zero, securing an additional reduction of 660 deaths per year.[213]

In total, the standard that EPA adopted was expected to reduce mortality in Philadelphia by 320 deaths per year, while the more stringent alternative rejected by EPA would have resulted in an additional reduction in overall mortality of 860 deaths per year, or over two and a half times the mortality benefits than EPA's chosen standard. Similarly, EPA's risk assessment indicated that in Los Angeles the Agency could have prevented an additional 1080 deaths annually by adopting a more stringent standard. If EPA could claim it needed to revise its PM standard to prevent 1620 premature deaths per year in Los Angeles (as the Agency predicted it would achieve under the less stringent standard), it is hard to understand why the Agency saw no need to lower the standard still further to prevent an additional 1080 premature deaths each year in Los Angeles (or an annual total of 2700 premature deaths avoided under the more stringent alternative).[214]

In both Philadelphia and Los Angeles, the marginal reductions in nonmortality effects (such as respiratory and cardiac health effects) associated with the more stringent alternative were greater than the selected standard for every health endpoint evaluated by EPA.[215] EPA's own analysis showed that the Agency could have achieved substantially greater health benefits by further reducing the twenty-four-hour fine PM standard from the 65 $\mu g/m^3$ standard selected by EPA to the more stringent 25 $\mu g/m^3$ daily alternative.[216] As EPA's PM Staff

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[213] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656. Even if these mortality effects are overstated by twenty to thirty-five percent (as the Agency has subsequently claimed), this would still mean preventing 430 to 530 cases of premature mortality.

[214] PM STAFF PAPER, *supra* note 162, at VI-51. EPA explained that the greater absolute and relative differences between Los Angeles and Philadelphia are based largely on differences in current air quality levels: "As expected, the estimated health risk reductions are larger for Los Angeles County than Philadelphia County due to the higher PM air quality levels associated with meeting the current PM_{10} standards (i.e., baseline air quality in Philadelphia is below the level required to meet the current standards)." *Id.* at VI-54.

[215] *Id.* at VI-49, -51.

[216] As the EPA PM Staff Paper stated:

> Based on the limited risk analyses for two example cities, using base case assumptions, a 24-hour $PM_{2.5}$ standard of 25 $\mu g/m^3$ is estimated to reduce PM-related risks associated with short-term exposures for the effects considered by roughly 70%–85%, relative to risks associated with attaining the current standards. Alternatively, at a 24-hour $PM_{2.5}$ level of 65 $\mu g/m^3$, risks are estimated

Paper concluded, "rough estimates of incidences are *appreciably lower,* but not eliminated in going from a $PM_{2.5}$ standard of 65 to 25 $\mu g/m^3$."[217]

What stopped EPA from further tightening its daily fine PM standard to the more stringent level and thereby saving thousands of additional lives? The answer certainly cannot be based exclusively on a concern for protecting the public from health risks. The record demonstrated that, according to EPA's interpretation of the data, statistically significant increases in premature mortality and significant morbidity effects occurred at levels far below EPA's selected twenty-four-hour standard of 65 $\mu g/m^3$ for fine PM. As EPA's own PM Staff Paper acknowledged, "[e]pidemiological studies reporting statistically significant associations were conducted in areas in which the mean twenty-four-hour $PM_{2.5}$ concentrations ranged from approximately 16 to 30 $\mu g/m^3$ for mortality studies, with hospital admissions and respiratory symptoms studies falling within this range."[218] The Staff Paper continued by noting that "[s]everal epidemiological studies reporting statistically significant effects include ranges of air quality that may approach estimates of background levels in some locations."[219] It also stated that "mortality studies show significant associations even when the observed means of twenty-four-hour $PM_{2.5}$ concentrations in each of the study locations are approximately at or below 20 $\mu g/m^3$."[220] Furthermore, the EPA Staff Paper noted that the results from the Agency's quantitative risk assessment "suggest a pattern of a continuum of decreasing risk with lower levels of alternative $PM_{2.5}$ standards, extending over and likely below the range of 65 to 25 $\mu g/m^3$ $PM_{2.5}$ included in the risk analyses."[221] EPA, in defending its selection of its final daily fine PM standards set at 65 $\mu g/m^3$, observed that short-term exposures appeared to offer the most compelling evidence of a health problem[222] and agreed with the Staff Paper that short-term exposures

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to be reduced by roughly 10% and 40% for the Philadelphia and Los Angeles study areas, respectively.

Id. at VII-28.

[217] *Id.* at VII-29 (emphasis added).

[218] *Id.* at VII-26.

[219] *Id.* at VII-30.

[220] *Id.*

[221] *Id.* at VII-28.

[222] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,676 ("In accordance with EPA staff and CASAC views on the relative strengths of the epidemiological studies, the Administrator has placed greater emphasis on the short-term exposure studies in selecting the level of the annual standard.").

in the range of 16–21 $\mu g/m^3$ resulted in statistically significant health effects.[223]

EPA made an attempt to justify its decision not to set a more stringent twenty-four-hour fine PM standard. The Agency argued that "the risk associated with infrequent peak 24-hour exposures in otherwise clean areas [that is, those meeting the annual standard] is not well enough understood at this time to provide a basis for selecting the more restrictive levels . . . [below] 65 $\mu g/m^3$."[224] This claim, though, is inconsistent with other EPA conclusions. EPA's own analysis indicated that it was not merely occasional "peak" concentrations that presumably should have been of concern under a 24-hour standard, but more frequent days with below-peak concentrations as well. EPA's examination of the available health data concluded that "most of the aggregate risk associated with short-term exposures likely results from the large number of days during which the 24-hour average concentrations are in the low- to-mid-range, below peak 24-hour concentrations."[225] Moreover, if residual levels of fine PM remaining under EPA's new standard would still result in hundreds, if not thousands, of additional premature deaths, it is hard to see how EPA could properly claim that areas meeting the annual standard were "otherwise clean" and that there was no basis for adopting the lower standard.[226]

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[223] *Id.*

[224] *Id.* at 38,677. EPA also argued that an annual standard can "provide the requisite reduction in risk associated with both annual and 24-hour averaging times in most areas of the United States" and that a 24-hour standard "would be intended to provide supplemental protection against extreme peak fine particle levels that may occur in some localized situations or in areas with distinct variations in seasonal fine particle levels." *Id.* at 38,674. Yet, as the textual discussion suggests, EPA's own analysis showed that major reductions in premature mortality would be achieved with a more stringent 24-hour standard than that which was adopted by EPA, even under EPA's selected annual standard.

[225] National Ambient Air Quality Standards for Particulate Matter; Proposed Decision, 61 Fed. Reg. 65,638, 65,652 (Dec. 13, 1996).

[226] Even after a few rounds of litigation, EPA apparently still could not explain why it was acceptable, as a policy matter, to turn its back on the remaining mortalities it predicted under the PM levels allowed under the revised standards. EPA responded to arguments that it should have adopted more stringent PM standards by noting that it revised its risk assessment in a way that "resulted in a substantial reduction in the number of deaths predicted" from exposure to levels permitted under the standard. EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, at 54. Acknowledging that even under the revised risk assessment the "values of estimated risk are not zero" (that is, the Agency still predicted premature deaths under the new standard), the Agency simply dismissed its own risk assessment as "not sufficiently reliable." *Id.* Without saying anything more, EPA then retreated to its science-based rhetoric claiming that it based its new PM standards on the "analysis of the epidemiological studies themselves." *Id.*

Science by itself certainly could not explain why EPA did not adopt a more stringent daily standard for fine PM, nor could a precautionary approach based solely on a concern for avoiding significant health effects. After all, the scientific analysis relied upon by EPA indicated that the Agency could have reduced both mortality and morbidity effects still further than it did. EPA's action was inconsistent with its frequently recited position that it must "err on the side of caution" by setting a margin of safety that will protect against "not just known adverse effects, but those of scientific uncertainty or that 'research has not yet uncovered.'"[227] EPA's own analysis, which the Agency used to defend its decision to tighten the PM standard, predicted that at least hundreds of cases of premature mortality nationwide would result from fine PM exposure even if all regions in the country were to meet EPA's new standards.[228]

Throughout the PM rulemaking, EPA invoked uncertainty as a wild card in an effort to defend its regulatory decisions. The Agency dismissed the sometimes large uncertainties in the estimates it used to support its regulatory actions, but it then cited uncertainty as a barrier to adopting regulations that it was not otherwise inclined to adopt. For example, EPA relied on results from "key" epidemiology studies showing significant mortality risks from fine PM, but did so only for the results at concentrations at and above the standard level EPA selected, dismissing similar results for lower concentrations in the same studies as too uncertain to support the standards.[229] Yet the underlying studies reported no distinctions between the concentration ranges in terms of magnitude of effect, statistical significance, or methodological approach.[230] For EPA, it was as if the same studies could be

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[227] EPA, D.C. Cir. PM Brief, *supra* note 56, at 49 (quoting Lead Indus. v. EPA, 647 F.2d 1130, 1153 (1980)).

[228] *See* Sunstein, *supra* note 18, at 329-30 (asserting that EPA's own figures suggested that more deaths could be prevented by more stringent regulations); *see also* Pierce, *supra* note 18, at 74 ("Even if every area of the country were in compliance with the new primary standards the court struck down in *ATA*, the best scientific evidence available suggests that ozone and particulates would continue to kill several thousand people per year.").

[229] *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,675 ("While placing substantial weight on the results of the key health studies in the higher range of concentrations observed, EPA is persuaded that the inherent scientific uncertainties are too great to support standards based on the lowest concentrations measured in such studies . . . .").

[230] *See, e.g.*, Douglas W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENG. J. MED. 1753, 1753 (1993) (concluding that "these results suggest that fine-particulate air pollution, or a more complex pollution mixture associated with fine particulate matter, contributes to excess mortality in certain U.S.

reliable or unreliable depending simply on what was more expedient for the Agency.[231] The uncertainty inherent in setting air quality standards—and any other risk standards—creates the potential for opportunism by any agency that decides to engage in post hoc rationalization of its decisions. Without a principled basis explaining how it treats uncertainty, EPA's claim that uncertainty prevented it from taking action to lower the PM standard only further served to illustrate the kind of unbounded discretion that the Agency effectively claimed for itself.[232]

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cities"); Joel Schwartz et al., *Acute Effects of Summer Air Pollution on Respiratory Symptom Reporting in Children*, 150 AM. J. RESPIRATORY & CRITICAL CARE MED. 1234, 1240-41 (1994) (discussing study results that did not indicate that concentration ranges affected the results); Joel Schwartz et al., *Is Daily Mortality Associated Specifically with Fine Particles?*, 46 J. AIR & WASTE MGMT. ASS'N 927 (1996). These studies found that each 10 $\mu g/m^3$ elevation in fine PM levels was associated with a significant (six to four percent, depending on the study) increase in all-cause mortality, with no apparent threshold. *See generally* Kenneth A. Colburn & Philip R.S. Johnson, *Air Pollution Concerns Not Changed by S-PLUS Flaw*, 299 SCIENCE 665, 665-66 (2003) (summarizing studies relied on by EPA). Subsequent to EPA's rulemaking, one of the authors upon whom EPA relied published an analysis showing that the mortality effects from fine PM decreased in a linear fashion over the range from 35 to 0 $\mu g/m^3$, supporting the existence of significant mortality at levels permitted by the new standard selected by EPA. Joel Schwartz et al., *The Concentration-Response Relation Between $PM_{2.5}$ and Daily Deaths*, 110 ENVTL. HEALTH PERSP. 1025 (2002).

[231] EPA's treatment of statistical significance has also, on occasion, appeared to be opportunistic. In the PM rulemaking, EPA claimed to have placed "greatest weight on those studies that were clearly statistically significant . . . ." EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,676; *see also* EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, 62 Fed. Reg. at 49 (arguing that "EPA's conclusion [on an annual standard] is supported by the fact that epidemiological studies performed in areas with annual mean concentrations below 15.7 $\mu g/m^3$ did not find a statistically significant relationship between daily fine particle concentration and adverse health effects"). Yet, in 1992, when EPA set the ozone standard at 0.12 ppm, the "key study" on which EPA relied to find an "adverse effect" at 0.15 ppm did not contain statistically significant findings. *See* EPA, 1992 Ozone Proposal, *supra* note 198, 57 Fed. Reg. at 35,546 ("The key study . . . by DeLucia and Adams (1977) . . . reported symptoms of discomfort and small but statistically-nonsignificant lung function decrements . . . at concentrations as low as 0.15 ppm O_3."); EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207 ("EPA acknowledges that Delucia and Adams failed to demonstrate any statistically significant decrements in pulmonary function resulting from exposure to 0.15 ppm for one hour.").

[232] As the D.C. Circuit stated, "the increasing-uncertainty argument is helpful only if some principle reveals how much uncertainty is too much." Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1036 (D.C. Cir. 1999). For a review of systematic ways to account for uncertainty in regulatory decision making, see GRANGER MORGAN & M. HENRION, UNCERTAINTY: A GUIDE TO DEALING WITH UNCERTAINTY IN RISK AND POLICY ANALYSIS (1990); Jonathan P. Caulkins, *Using Models that Incorporate Uncertainty*, 21 J. POL'Y ANALYSIS & MGMT. 486 (2002) (discussing models used in policy analyses and ways of addressing the inherent uncertainty that comes with using them).

C. *EPA's Incoherent Disregard of the Health Effects from Ozone*

EPA's decision making in the ozone rulemaking resulted in still more incoherence. Even though the Agency claimed to set its standards based on a precautionary approach to protecting the public health,[233] EPA nevertheless disregarded a range of adverse health effects and failed to provide an adequate explanation for why one level of risk was acceptable while another level was not. Indeed, over the course of the ozone rulemaking, EPA actually shifted the level of remaining risk it found acceptable.

When EPA proposed its new eight-hour, 0.08 ppm standard in 1996, it did so knowing that the new standard still would leave the public exposed to risk. According to EPA's risk estimates at the time, the proposed standard still would result in 1 million occurrences of moderate decreases in lung function and 74,000 cases of moderate-to-severe cough in outdoor children.[234] Presumably EPA viewed this residual risk as acceptable, as it did not propose the still lower option of 0.07 ppm. As it turned out, by the time EPA issued its final standard in 1997, its risk estimates had changed and the level of risk under the old standard, the one EPA tightened, was actually lower than what it had previously predicted would remain under the proposed 0.08 ppm standard.[235] According to EPA's revised risk assessment, the old standard resulted in only 931,000 cases of moderate decreases in lung function and 58,000 cases of moderate-to-severe cough.[236] If 1 million cases of decreased lung function could be tolerated by EPA in its

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[233] In defending its decision to lower the standard to 0.08 ppm, EPA argued in court that "EPA must 'err on the side of caution' to protect public health with an adequate margin of safety" and, therefore, that the Agency "considered suspected, but not yet demonstrated, chronic effects." EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 27 (quoting Lead Indus. v. EPA, 647 F.2d 1130, 1153 (1980)).

[234] Memorandum from Harvey M. Richmond, Risk and Exposure Assessment Group, to Karen Martin, Group Leader, Health Effects and Standards Group 10 tbl.3 (Feb. 11, 1997) (on file with author).

[235] The only relevant change in the Agency's risk assessment from the proposed rule to the final rule came from "several technical changes" that were "based on insights gained from the initial analyses." EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,861.

[236] Memorandum from Harvey M. Richmond, *supra* note 234, at 10 tbl.3. For the two other health endpoints EPA evaluated (decreased lung function at a greater forced expiratory volume and moderate-to-severe chest pain), the 0.08 ppm standard resulted in only a somewhat lower number of occurrences than the 0.12 ppm standard. In considering all four endpoints together, the combined residual health effects for the 0.12 ppm standard, which EPA found unacceptable in response to its final risk assessment, were not clearly higher than the residual effects under the proposed 0.08 ppm standard, which EPA found acceptable after its initial risk assessment. *Id.*

proposed rule, why in the final rulemaking did it need to revise the old standard that resulted in only 931,000 similar cases? If 74,000 cases of cough were acceptable in the proposed rule, why were 58,000 cases of cough not acceptable in the final rule? The Agency offered no explanation.

In a brief filed in the D.C. Circuit in 1998, EPA essentially admitted that it had shifted its position on the level of acceptable risk, but it argued that this was irrelevant because "[t]he relative differences are of greater import than the absolute numbers for purposes of comparing alternative standards."[237] In effect, EPA's brief acknowledged that agency decision makers had simply made up their minds to adopt a lower standard, rather than establish any particular level of acceptable health protection. Such an approach is inconsistent with the conventional understanding of the Clean Air Act, which calls for setting a standard that protects the public health with an adequate margin of safety, rather than setting a standard that is simply more stringent than the existing standard—a point EPA has acknowledged in other contexts.[238]

More significantly, EPA failed to provide any adequate explanation for why it turned its back on harms that some citizens would continue to suffer even under the Agency's new standards. EPA's own findings indicated that further reduction of the ozone standard from 0.08 ppm to 0.07 ppm would have provided additional incremental health benefits that, in at least some cases, were even more substantial than the benefits of the 0.08 ppm standard that EPA selected.[239] In its rulemaking, EPA did not directly dispute those commentators "who argue[d] that similarly large improvements in public health protection would result from a standard set at 0.07 ppm as compared to the proposed standard, such that, based on the same reasoning, the evidence warrants a standard set at 0.07 ppm."[240] For example, EPA estimated that the incremental risk reduction to children would be greater if an 0.07 ppm standard was adopted:

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[237] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 37 n.34.

[238] EPA rejected industry's argument that the implementation of the current ozone standard would have resulted in cleaner air, stating that such a factor "is irrelevant to the issue here, *i.e.*, what the level *should* be to protect public health with an adequate margin of safety." EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 48; *see also* EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,652 ("The overriding consideration in selecting a standard is how well it protects public health, not its relative stringency as compared to the previous standard.").

[239] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868.

[240] *Id.*

> [T]he median percent of outdoor children estimated to experience FEV_1 decrements greater than 15 percent is reduced from about 7.7 percent for a 0.09 ppm, 8-hr standard to about 6.8 percent for a 0.08 ppm, 8-hr standard. Attaining a 0.07 ppm, 8-hr standard results in a further reduction to about 3.0 percent of outdoor children estimated to experience this effect.[241]

In other words, EPA's own 0.08 ppm standard would reduce the median percentage of children experiencing lung function decrements by less than 1% (0.9%) relative to an 0.09 ppm standard (which is roughly equivalent to the preexisting one-hour, 0.12 ppm, standard).[242] In contrast, an 0.07 ppm standard would reduce this same health endpoint by an additional 3.8% or would provide more than *four times* the health benefits of the 0.08 ppm standard. If reducing this endpoint by 0.9% is "requisite to protect the public health,"[243] then consistency should have dictated that reducing the same endpoint by 3.8% would also be "requisite."

EPA's attempt to justify its decision to reject the lower 0.07 ppm standard marked a departure from the past interpretations that EPA and the courts had given to section 109 of the Clean Air Act. NAAQS traditionally have been understood not only to protect healthy persons, but also to protect the health of sensitive subgroups.[244] EPA identified several ozone sensitive groups, including children playing outdoors on hot summer days and children suffering from asthma and other respiratory illnesses. Moreover, even among healthy individuals, there is substantial variability in the response to

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[241] OZONE STAFF PAPER, *supra* note 163, at 203. FEV_1 refers to "forced expiratory volume," which is the volume of air that can be expired in one second by a subject and a frequently used measure of lung function. In the proposed rule, EPA states that the 0.08 ppm standard will reduce the median percent of outdoor children experiencing 15% FEV_1 decrements to 5.1%, rather than the 6.8% figure cited in the Staff Paper, while the figures for the 0.09 and 0.07 ppm standards remain the same in the two documents (7.7% and 3.0%, respectively). National Ambient Air Quality Standards for Ozone, 61 Fed. Reg. 65,716, 65,725 (Proposed Dec. 13, 1996) (to be codified at 40 C.F.R. pt. 50) [hereinafter EPA, Ozone Proposed Rule]. No explanation is given by EPA for this discrepancy. Even if the figure cited in the proposed rule is the correct one, it means that the benefit of reducing the standard from 0.09 ppm to 0.08 ppm is a 2.6% (7.7% minus 5.1%) reduction in children with such lung decrements, whereas to reduce the standard to 0.07 ppm would produce a further 2.1% (5.1% minus 3.0%) reduction in this health effect. *Id.* EPA would be hard-pressed to justify why a 2.6% percent reduction in this health effect is important while a further 2.1% reduction is not, and EPA did not attempt to provide any such justification.

[242] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,858.

[243] 42 U.S.C. § 7409(b)(1) (2000).

[244] *Supra* notes 193-97 and accompanying text.

ozone.[245] The existence of susceptible subgroups and the variability of responses makes it impossible to identify an ozone exposure level at which no significant adverse health effects would ever occur.

EPA purported to justify its selection of an 0.08 ppm ozone standard based on its claim that "an estimated 40-65% more children would experience health effects that could limit their activity and in some cases require medical treatment" at an 0.09 ppm ozone standard.[246] The Agency noted that "[t]hese effects would occur an estimated 70-120% more times per year—a significant consideration given concerns about repeated exposures."[247] EPA relied on scientific evidence showing that under the 0.09 ppm standard (which approximated the preexisting standard) an estimated 41,000 children in the nine cities studied would suffer moderate-to-severe pain upon deep breathing at least once per year.[248] The Agency estimated a reduction in this number to 27,000 children under the 0.08 standard it selected.[249] However, at the 0.07 ppm standard rejected by EPA, only about 9000 children would experience moderate or severe pain from breathing.[250] EPA's estimates were similar for large decreases in lung function (i.e., decreases of at least 20%). At the 0.09 ppm level, 97,000 children in the nine cities studied would suffer these large decreases in lung function, while only 58,000 cases were predicted at the 0.08 ppm level chosen by EPA.[251] Yet, at the rejected 0.07 ppm level,

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[245] *E.g.*, EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 15-16 ("[A]pproximately 5–20% of healthy individuals appear to be unusually sensitive to ozone. For these 'hyper-responders,' even low ozone exposures may trigger responses that interfere with normal activity." (citations omitted)); CRITERIA DOCUMENT, *supra* note 163, at 9-4 ("There is a large range of physiological responses among humans, with at least a 10-fold difference between the most and least responsive individuals."); OZONE STAFF PAPER, *supra* note 163, at 69 ("[T]here is wide variability in the severity of response to O_3 among both healthy individuals and those with impaired respiratory systems.").

[246] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 23 (citing Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38865, 38868).

[247] *Id.* at 23-24 (citation omitted).

[248] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,865; EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,725; *see also* Brief of Amici Curiae Senator Orrin Hatch and Representative Tom Bliley in Support of Respondents at 28-29, Browner v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257) (citing this evidence to exemplify EPA's arbitrary line drawing).

[249] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,865.

[250] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,725 tbl.1 (0.3% of 3.1 million outdoor children in the nine urban areas).

[251] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,865.

only about 12,000 children would suffer similar effects.[252] EPA never offered the public any reason for why it believed it needed to lower the standard to protect 14,000 children from moderate-to-severe pain from breathing but at the same time it could reject an even lower standard that would have protected still 18,000 more children from the same effects. Nor did it explain why protecting an additional 39,000 children from decreases in lung function justified lowering the standard but protecting still 46,000 more children did not.

As the Agency proceeded through several rounds of litigation over the ozone revisions, a purported explanation for EPA's choice of an 0.08 ppm standard did appear to emerge. In the initial round of review, a panel of the Court of Appeals for the District of Columbia held that EPA failed to articulate an "intelligible principle" to constrain its discretion.[253] Dissenting from that panel's holding, Judge David Tatel articulated a science-based argument that EPA would refine and advance in subsequent rounds of litigation.[254] He argued that the scientific evidence and advice on ozone did indeed provide a clear basis for EPA's choice of a new NAAQS standard. Judge Tatel argued that "different types of health effects [are] observed above and below [0].08 ppm," the level selected by EPA.[255] Specifically, he opined that the health effects below 0.08 ppm were qualitatively different in that they were "transient and reversible."[256] He also claimed that the scientific evidence indicated that normal background levels of ozone sometimes occur at 0.07 ppm but not at 0.08 ppm.[257]

In petitioning the D.C. Circuit for a rehearing and advancing arguments on further appeal, EPA resurrected Judge Tatel's arguments

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[252] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,725 tbl. 1 (0.4% of 3.1 million outdoor children in the nine urban areas).

[253] Am. Trucking Ass'ns v. EPA, 175 F.3d. 1027, 1034 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) The court stated that "EPA's explanations for its decisions amount to assertions that a less stringent standard would allow the relevant pollutant to inflict a greater quantum of harm on public health, and that a more stringent standard would result in less harm," and fails to set a specific "requisite" pollution level to "protect the public health." *Id.* at 1035.

[254] *Id.* at 1057-62 (Tatel, J., dissenting); *see* Pierce, *supra* note 18, at 75 (Judge Tatel's "dissenting opinion in *ATA* . . . contains a typical symptom of the science charade.").

[255] *Am. Trucking*, 175 F.3d at 1059 (Tatel, J., dissenting).

[256] *Id.*

[257] *Id.* at 1059-60. Not surprisingly, Judge Tatel accepted these same arguments in the final round of litigation, authoring the panel opinion that upheld EPA's actions under the "arbitrary and capricious" standard of review. Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 358 (D.C. Cir. 2002).

in defending its air quality standards.[258] EPA came to argue that it "sets primary NAAQS at levels that provide protection from medically significant risks and *not* at levels that protect against any and all risks, or any and all effects."[259] EPA also asserted that the standards should be set at the lowest level at which studies indicated a statistically significant increase in "adverse effects," which the Agency redefined as health effects that are not "transient and reversible."[260] EPA thus argued to the court that the scientific evidence on ozone indicated a break point at 0.08 ppm, even though EPA also acknowledged, and the record showed, that there was no known threshold for health effects from ozone.[261]

EPA purported to identify "important and meaningful differences in the character of the scientific evidence regarding risks—including the estimated frequency and duration of adverse health effects—associated with levels above and below 0.08 ppm."[262] For example, EPA argued to the Supreme Court that the scientific evidence did not support setting an ozone standard below 0.08 ppm:

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[258] Petition for Rehearing and Petition for Rehearing En Banc for the United States Environmental Protection Agency at 15-17, Am. Trucking Ass'ns v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (Nos. 97-1440, 97-1441) [hereinafter EPA, Petition for Rehearing]; *see also*, EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 28-30 (stating the EPA's argument on which Judge Tatel relied in his dissenting opinion in *American Trucking Ass'ns*).

[259] EPA, Supreme Court Respondents' Brief, *supra* note 60, at 33; *see also id.* at 36 ("Section 109(b)(2) [of the Clean Air Act] clearly directs that EPA must set NAAQS at levels requisite to protect the general population, or identifiable groups within communities, from medically significant effects.").

[260] EPA, Petition for Rehearing, *supra* note 258, at 16.

[261] *Id.* at 13.

[262] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 33; *see also* EPA, Petition for Rehearing, *supra* note 258, at 17 ("[T]he character of the scientific evidence differed for levels above and below 0.08 ppm, and supported the selection of the 0.08 ppm level as 'requisite' to protect public health."). This argument was not made in this form in the proceedings below. In the rulemaking itself, and in the original D.C. Circuit litigation, EPA summarily dismissed an 0.07 ppm alternative with the simple assertion that "[b]ecause health impacts below 0.08 ppm were less certain and likely to be less serious, the Administrator focused on the 0.08 and 0.09 ppm alternatives." EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 23 (citing EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863, 38,868). As with the PM rulemaking, EPA again invoked uncertainty as a wild card. Even though uncertainty was ostensibly a barrier to the adoption of the 0.07 ppm standard, it did not keep EPA from defending its decision to lower the standard to 0.08 ppm based on "suspected, but not yet demonstrated, chronic effects" and an obligation to "err on the side of caution." EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 27 (quoting Lead Indus. v. EPA, 647 F.2d 1130, 1153 (1980)).

> [T]he record showed that average responses caused by exposures even at 0.08 ppm were "typically small or mild in nature." The Administrator recognized that repeated exposures at the 0.08 ppm level could potentially produce adverse effects for some unusually sensitive individuals, but the record indicated that the "most certain" ozone-related effects at and below that level, even when adverse, are "transient and reversible." Moreover, the quantitative exposure and risk assessments showed that a standard set at 0.08 ppm would significantly reduce the number of such exposures. As for more serious health effects, EPA lacked clinical data indicating the existence of an exposure-response relationship at ozone levels below 0.08 ppm.[263]

While rejection of an 0.07 ppm standard may have been sound or even compelling on policy grounds, the "character of the scientific evidence" alone did not, nor could not, justify rejection of a standard lower than 0.08 ppm.[264]

After all, according to EPA, there was no scientifically established threshold at which no "adverse effects" occurred. In promulgating its final ozone standard, EPA stated that it did not "seem possible, in the Administrator's judgment, to identify a level at which it can be concluded with confidence that no 'adverse' effects are likely to occur."[265] EPA's own brief in the Supreme Court acknowledged that "[t]he evidence showed a continuum of risk within the range considered [i.e., 0.07 to 0.09 ppm], with statistically significant decreases in risk and corresponding increases in public health protection for successively more stringent eight-hour ozone standards."[266] Similarly, in the preamble to the proposed ozone standard, EPA concluded that "[w]ithin any given urban area, statistically significant reductions in exposure and risk associated with functional and symptomatic effects result from alternative 8-hour standards as the level changes from 0.09 ppm to 0.08 ppm to 0.07 ppm."[267] EPA acknowledged that the science showed "no break point or bright line that differentiates between acceptable and unacceptable risks within this range."[268]

In rejecting industry arguments that there appeared to be a threshold for respiratory effects at 0.08 ppm, EPA argued that there were moderate decrements in lung function (FEV_1) in a significant

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[263] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 14 (citations omitted).

[264] For purpose of the following analysis, we assume the validity of EPA's conclusions on the results and meaning of the scientific evidence.

[265] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863.

[266] EPA, Supreme Court Respondents' Brief, *supra* note 60, at 12.

[267] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,728.

[268] *Id.*

percentage of the population at 0.08 ppm and that, moreover, "the response rates at 0.07 ppm are only slightly less than these values."[269] EPA also found "clear evidence from hospital admission studies that effects may continue down to background [0.04 ppm]."[270] Indeed, although the relationship between ozone levels and hospital admissions appeared somewhat less certain at lower levels, the Agency concluded that there was "a consistency between studies which supports the associations at all levels studied" (that is, down to background levels of 0.04 ppm).[271] Thus, for the very health effects on which EPA based its selection of the 0.08 ppm ozone standard, namely respiratory effects and hospital admissions, EPA's own findings in the record demonstrated that such effects occur at ozone levels well below 0.08 ppm.

Moreover, while the record showed a continuum in the frequency and severity of respiratory effects at successively lower ozone levels, it did not show a discernible discontinuum at 0.08 ppm between those effects that were transient and reversible and those that were more permanent, as Judge Tatel and EPA argued.[272] The majority of the respiratory effects on which EPA relied to lower the primary ozone standard down to 0.08 ppm were also transient and reversible.[273] Most significantly, by invoking a distinction between effects that were transient and reversible and those that were not, EPA again shifted its position without offering any justifications. When EPA last revised the ozone standard in 1979, it relied on the same types of transient respiratory health effects to support its standard, expressly finding that such effects were of concern and "adverse," "[e]ven when reversible" and "even though transitory."[274] Similarly, when the Agency previously

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[269] EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 82.

[270] *Id.* at 84.

[271] *Id.* Moreover, even if the effects at the lower levels may have appeared less certain, EPA was supposed to adopt a margin of safety to protect against less certain, or even unknown, risks. For our previous extensive discussion on EPA's ad hoc approach to the margin of safety requirement under the Clean Air Act, see *supra* notes 186-90 and accompanying text.

[272] *See* Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1059 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (Tatel, J., dissenting) (arguing that health effects below 0.08 ppm were qualitatively different in that they were "transient and reversible").

[273] As the majority opinion in the D.C. Circuit noted, "it is far from apparent that any health effects existing above the [0.08 ppm] level are permanent or irreversible." *Id.* at 1035.

[274] EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207. One of the key studies relied upon by EPA in 1979 found that subjects were uncomfortable when exercising while exposed to higher levels of ozone, but that "[t]he discomfort disappeared shortly after the termination of the experiment." *See* LESTER B. LAVE, THE

revised the PM standard in 1987, it set the standard "in the lower portion of the range where sensitive, *reversible* physiological responses of *uncertain health significance* are *possibly*, but not definitely, observed in children."[275] EPA's attempt to construct a scientific demarcation based on whether effects are transient and reversible was therefore neither supported by the record nor consistent with its own past decisions.

EPA has treated health effects as relevant when they could justify the standard that EPA preferred, but then discounted these same health effects in explaining why it did not adopt a more stringent alternative. For example, in its 1993 decision not to revise the 0.12 ppm ozone standard, EPA determined that lung function decrements in the range of ten to twenty percent, even "when accompanied by symptoms," were not "adverse effects."[276] Yet, in revising the same standard in 1997, EPA shifted its position concluding that a moderate lung decrement in the range of ten to twenty percent was indeed an "adverse effect."[277] In defending its most recent ozone standard against industry attacks that it was based on nonserious and reversible lung effects, EPA accused industry of "seek[ing] to trivialize lung function

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STRATEGY OF SOCIAL REGULATION: DECISION FRAMEWORKS FOR POLICY 104 (1981) (describing the DeLucia and Adams study relied upon by EPA in the 1979 revision of the ozone standard).

[275] EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,643 (emphases added).

[276] EPA, 1992 Ozone Proposal, *supra* note 198, 57 Fed. Reg. at 35,549. The proposal also states:

> [I]ndividuals exposed to lower levels of O_3 (e.g., 0.12 to 0.15 ppm) typically experience only mild and transient functional decrements [anywhere from a –9 to –16 percent decline in FEV_1, *id.* at 35,548.] . . . [This] may be accompanied by symptoms such as cough, chest tightness, pain on deep inspiration, and throat irritation . . . .
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> . . . Although there is a difference of opinion among the EPA's scientific advisors as to the significance of decrements in lung function in the range of 10 to 20 percent when accompanied by symptoms, it is the Administrator's judgment that the lesser effects associated with exposure to O_3 in the range of 0.12 ppm to 0.15 ppm observed in the controlled human studies do not constitute adverse effects for purposes of section 109 of the Act.

Id.

[277] *See* EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 17 (noting that EPA "concluded that 'moderate' effects . . . experienced by asthmatics [defined as 10 to 20 percent FEV_1 decrements] would likely be adverse because they could interfere with normal activity."). Likewise, in its 1979 revision of the ozone standard, EPA concluded that lung function decrements in the range of 5 to 15% were adverse effects. *See* EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207 ("[T]he experts' judgments varied as to the point at which adverse effects would begin, but fell within the range of a 5 to 15 percent decrease.").

decrements and respiratory symptoms, . . . [when] these effects can be sufficiently severe to disrupt the normal activity of both healthy individuals and asthmatics."[278] Similarly, when EPA revised its ozone standard in 1979, it concluded that physical discomfort and pulmonary function changes, "[e]ven when reversible" and "even though transitory," were "adverse effects" that needed to be taken into account "in selecting the level of the primary standard."[279] Yet, in defending its 1997 revision to the ozone standard, EPA argued that it was justified in disregarding the health effects that occur at levels below 0.08 ppm since "these effects (*e.g.*, lung function decreases and coughs) are less serious because they are 'transient and reversible.'"[280] The same kind of health effects seemed relevant when they supported EPA's decision to lower standards, but irrelevant when EPA needed to defend its decision not to lower standards still further.

EPA also justified its rejection of the 0.07 ppm standard by stating that the lower standard "would be closer to peak background levels that infrequently occur in some areas due to nonanthropogenic sources of O_3 precursors, and thus more likely to be inappropriately targeted in some areas on such sources."[281] Of course, it bears noting initially that any argument about setting standards to avoid naturally occurring background levels departs from a purely health-focused justification for a risk standard. It speaks to the standard's feasibility, a factor that EPA has otherwise claimed is impermissible to use in setting air quality standards.[282] Indeed, in previous NAAQS rulemakings, EPA specifically rejected industry arguments that EPA should consider the feasibility problems created by setting air quality standards too

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[278] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 33 (citation omitted).

[279] EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207. Likewise, in its 1987 revision to the PM standards, EPA set the standard at a level where "reversible" effects of "uncertain health significance" may "possibly, but not definitely" occur. EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,643.

[280] EPA, Petition for Rehearing, *supra* note 258, at 16. Elsewhere in the litigation over its NAAQS revisions, EPA emphasized the transient and reversible nature of health effects observed at lower levels in defending its decision to reject a more stringent standard. *See* EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 28-30 (arguing that while a 0.08 ppm standard may lead to adverse effects, they are transient and reversible and, therefore, "less serious").

[281] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868.

[282] *See, e.g.*, EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,683 ("For more than a quarter of a century, EPA has interpreted section 109 of the [Clean Air] Act as precluding consideration of the economic costs or technical feasibility of implementing NAAQS in setting them.").

close to the background levels.[283] If health is the only permissible consideration under the Clean Air Act, as EPA has argued and the courts have affirmed, then it should not matter whether a standard is set near or even below background levels.[284]

Even if background levels were considered to be relevant, EPA's concern about an 0.07 ppm standard approaching background levels was not supported by the Agency's own estimates in the rulemaking record. In conducting its risk assessment, and again in making its argument to the D.C. Circuit, EPA assumed a background level of 0.04 ppm—not 0.07 ppm.[285] The Agency's Staff Paper indicated that "it is reasonable to estimate that the 8-hour daily maximum O_3 during the summer is also in the range of 0.03 to 0.05 ppm."[286] Moreover, EPA specifically rejected arguments made by industry during rulemaking that background levels may approach 0.08 ppm.[287] In doing so, EPA stated that:

> While background concentrations of O_3 can be as high as 0.05 ppm, unless O_3 concentrations are affected by anthropogenic VOC and/or NOx emissions, 8-hr O_3 background concentrations will typically be much lower than 0.05 ppm. A reasonable estimate of the 8-hr daily maximum O_3 background during the summer season is 0.03-0.05 ppm.[288]

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[283] *See, e.g.*, Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1190 (D.C. Cir. 1981) (upholding EPA's refusal even to docket evidence submitted by industry claiming that attainment of an ozone standard would be precluded by background ozone areas in many parts of the country because "the EPA position that attainability is not central to a rulemaking of this type is correct").

[284] In other regulatory programs, EPA has sought to reduce pollutants to below background levels. For example, EPA's recently promulgated standard for arsenic levels in drinking water primarily controls naturally occurring levels of arsenic. *See* EPA, National Primary Drinking Water Regulations: Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976 (Jan. 22, 2001) (to be codified at 40 C.F.R. pts. 9, 141, 142) (establishing "a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero"). EPA has also taken steps to address radon, another naturally occurring pollutant. *See generally* EPA, *Indoor Air-Radon (Rn)*, http://www.epa.gov/iaq/radon/index.html (last updated Feb. 10, 2004) (describing EPA activities in addressing radon). In any case, EPA added a new provision into 40 C.F.R. pt. 50 app. I, that created a compliance exemption for peak ozone concentrations if they are associated with forest fires, stratospheric ozone intrusion, or "other natural events." *See* EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 95 (setting forth the justifications for adding the compliance exemption). The existence of an exemption such as this one undercuts the claim that EPA could not set the standard lower than 0.08 ppm because of background ozone levels.

[285] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 20 n.19, 47 (footnote omitted).

[286] OZONE STAFF PAPER, *supra* note 163, at 23.

[287] EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 86.

[288] *Id.; see also id.* at 93-94 (arguing that background levels will be below 0.05 ppm unless affected by anthropogenic emissions).

EPA did acknowledge that "at remote or rural sites O_3 concentrations can exceed 0.07 ppm," but dismissed the relevance of this finding because most of these concentrations were, in the Agency's view, caused by human activities.[289] EPA's claim that it could not adopt an 0.07 ppm standard because it was too close to background level did not comport with past positions taken by the Agency, nor with the Agency's own positions adopted earlier in the rulemaking.[290]

In its rulemaking and subsequent rounds of litigation, EPA offered one remaining defense of its decision to reject the lower 0.07 ppm standard. The Agency claimed it was justified in its decision not to set a NAAQS below 0.08 ppm based on the fact that no member of EPA's CASAC supported a standard below 0.08 ppm.[291] Of course, the statute delegates the authority to select a standard to the EPA Administrator, not to CASAC.[292] In its subsequent brief before the Supreme Court, EPA acknowledged that CASAC "did not relieve the Administrator of her duty to reach decisions on specific NAAQS

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[289] *Id.* at 86; *see also id.* at 94 (asserting that it is "clear that the component consisting of natural background O_3 is only a fraction of rural O_3 concentrations, which are clearly increased by human activities throughout the U.S.").

[290] *See* Oren, *supra* note 18, at 10,659 (arguing that the Agency's reasoning in adopting its ozone standard was flawed because it failed to explain why the background level was relevant).

[291] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 14 (noting that "none of the CASAC advisors recommended setting the revised NAAQS at a level below 0.08 ppm"). Judge Tatel had advanced this point in his dissent in *American Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1059 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001), and used it again in the panel opinion in the D.C. Circuit's second round of review in the case. *See* Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 379 (D.C. Cir. 2002) ("EPA is entitled to give 'significant weight' to the fact that no committee member advocated a level of 0.07 ppm." (quoting EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868)); *see also* Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1188 (D.C. Cir. 1981) (stating that EPA is required "to submit the criteria document and standard to the SAB [Science Advisory Board] for comment, but it was not obligated to obtain SAB approval of either before promulgation of a final standard"). This decision was made under the same statutory provision that provides CASAC authority, but before the relevant subcommittee of SAB was renamed CASAC. H.R. REP. NO. 95-722, at 16 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3293, 3295 (stating that the SAB's review of EPA's air quality standards and criteria documents "is intended to be advisory only").

[292] *Whitman*, 531 U.S. at 462-63 (2001) ("Once a NAAQS has been promulgated, the Administrator must review the standard (and the criteria on which it is based) 'at five-year intervals' and make 'such revisions . . . as may be appropriate.'" (quoting 42 U.S.C. § 7409(d)(1) (2000))); *see also Am. Trucking Ass'ns*, 283 F.3d at 358 (describing CASAC as an advisory committee).

levels."[293] The function of CASAC is to provide scientific advice, not to make the risk management choices necessary for selecting a standard.[294]

Admittedly, some members of CASAC did express their "personal preferences" for specific levels for the revised standards.[295] As EPA has recognized elsewhere, however, the individual preferences of CASAC members are distinct from the collective findings of the entire committee, which comprise the official advice that EPA must consider.[296] CASAC as a whole expressly concluded that the selection of the ozone standard was a policy choice for the Administrator, rather than a scientific determination within the expertise of the committee.[297] Even though the individual views of CASAC members provided neither a legal basis for, nor a limitation on, the Administrator's decisions, it is interesting to note that more than half of those members who expressed a view actually supported a level higher than 0.08 ppm.[298] In the end, EPA effectively claimed that it was entitled to give

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[293] EPA, Supreme Court Respondents' Brief, *supra* note 60, at 11. EPA acknowledged that the official CASAC consensus view was limited to providing scientific advice, not advising on the ultimate selection of a regulatory standard: "Once the Administrator had concluded that the NAAQS required revision, she—unlike CASAC—had to resolve the uncertainties associated with those decisions." *Id.*

[294] *See* EPA, No. A-95-54, RESPONSES TO SIGNIFICANT COMMENTS ON THE 1996 PROPOSED RULE ON THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER 26-27 (1997) [hereinafter EPA, PM RESPONSE TO COMMENTS] (rejecting comments that CASAC's failure to reach consensus on the Agency's chosen standards undermines the basis for those standards because such arguments "appear to rest on questionable assumptions about the role and purposes of CASAC review," which is to provide scientific advice that the Administrator must consider "but is not bound" by).

[295] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 37 (describing the views of individual CASAC members as "personal preferences"); *see also Am. Trucking Ass'ns*, 283 F.3d at 379 (noting that ten CASAC members expressed opinions about where the revised standard should be set).

[296] April 23, 1997 Hearing, *supra* note 74, at 370 ("While ten of the 16 CASAC members who reviewed the ozone staff paper expressed their preferences as to the level of the standard, all believe it is ultimately a policy decision for EPA to make."); EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 37 ("CASAC recognized that these views were just that—'personal preferences'—and distinguished them from the committee's consensus view that the selection of a standard was a 'policy judgment' for the Administrator."); EPA, PM RESPONSE TO COMMENTS, *supra* note 294, at 29 ("[I]t is important to separate the personal opinions that individual members might express on particular policy choices such as standard levels from their scientific conclusions on the range of options that is supported by the science and should be considered by the Administrator.").

[297] *Supra* notes 143-45, 179 and accompanying text.

[298] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,729 (noting that "while some CASAC members supported the choice of the proposed 0.08 ppm, fully

significant weight to individual views of CASAC members when it bolstered the Agency's decision not to lower the standard to 0.07 ppm, but that it did not need to give them this same weight when it was less supportive of the Agency's position.

In sum, EPA's attempt in litigation to argue that science compelled it to reject any ozone standard below 0.08 ppm was inconsistent with numerous other Agency positions. The Agency disregarded the health effects from exposures below 0.08 ppm, abandoning the position it took in previous NAAQS rulemakings that transient and reversible effects warranted regulatory protection. EPA's position on background levels in litigation was inconsistent with its analysis of background levels in the rulemaking record and with its previous dismissal of industry concerns about background levels. Finally, EPA's position was inconsistent with its purported health-only construction of the Clean Air Act, as presumably would have been any decision to set a standard other than zero for a non-threshold pollutant. Rejecting an 0.07 ppm ozone standard may well have been an appropriate decision, but it could only be defended on public policy grounds, not based on scientific evidence or expertise. EPA identified no such policy reason to justify why it effectively turned its back on the adverse effects that some citizens will continue to experience even if all parts of the country come into compliance with the Agency's new standards.

D. *Comparing the Health Benefits of the Ozone and Particulate Matter Standards*

One of the most striking examples of regulatory incoherence in EPA's NAAQS revisions lies in the disparity between the health benefits from the revised ozone standards and the revised particulate matter standard.[299] In refusing a more stringent alternative for the PM

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half or more of the CASAC panel members expressing views on a specific level supported a specific level or range of levels that include 0.09 ppm"). Furthermore, EPA did not defer in the same way to the views of CASAC members when it came to setting the level of its revised PM standard. Of the twenty-two members of the CASAC panel, only four expressed a preference for the more stringent PM alternatives in EPA's proposal. Robert W. Crandall, *The Costly Pursuit of the Impossible*, BROOKINGS REV., Summer 1997, at 41, 45.

[299] *See, e.g.*, Lester B. Lave, *Clean Air Sense*, BROOKINGS REV., Summer 1997, at 41, 43 (noting that EPA estimated its ozone standard would provide at most $1.5 billion annually in health benefits, while its particulate standard would offer as much as $110 billion in health benefits). EPA's starkly disparate responses to health benefits across the two standards is an example of comparative incoherence. *See* Cary Coglianese, *Bounded Evaluation: Cognition, Incoherence, and Regulatory Policy*, 54 STAN. L. REV. 1217, 1223 (2002) (noting that comparative incoherence arises when one regulation "turns

standard, EPA rejected an option that would have achieved a much greater gain in health benefits than the gain EPA anticipated from its revision of the ozone standard. If protecting the public health with an adequate margin of safety did not require the Agency to lower the PM standard still further, then it is far from clear why the Agency was justified in revising its ozone standard at all.

Based on staff analysis, and consistent with CASAC's advice, the Agency assumed that the new ozone standard would not achieve any reduction in mortality.[300] In quantifying the nonmortality health benefits of the new ozone standard, EPA estimated the total monetized value to be $0.06 billion.[301] In contrast, EPA estimated that lowering the daily $PM_{2.5}$ standard from the selected 65 $\mu g/m^3$ level to 50 $\mu g/m^3$ would produce an additional $1.64 billion in *nonmortality*

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out to be inconsistent with other regulations of either the same general type or other types altogether").

[300] In setting the ozone standard, EPA found that there was insufficient evidence of any association between ozone exposure and mortality, and therefore it did not rely on any reduction in mortality to justify its new ozone standard. *See, e.g.*, OZONE STAFF PAPER, *supra* note 163, at 71 (concluding that "only limited, suggestive evidence" exists that "[a]n increase in daily mortality [is] associated with O_3 exposure"); *id.* at 72 (noting that "associations between O_3 exposure and chronic health impacts have not been sufficiently demonstrated in humans"). EPA identified and used some recent scientific studies identifying a mortality risk from ozone in its Regulatory Impact Analysis, which had the effect of substantially increasing the Agency's estimate of the benefits of the revised ozone standard while making clear that "this evidence was not used in the NAAQS standard setting process." EPA, REGULATORY IMPACT ANALYSES FOR THE PARTICULATE MATTER AND OZONE NATIONAL AMBIENT AIR QUALITY STANDARDS AND PROPOSED REGIONAL HAZARD 2-9 (1997), [hereinafter RIA] *available at* http://www.epa.gov/ttn/oarpg/naaqsfin/ria.html. The EPA's response to ozone comments stated:

> [P]remature mortality associated with O_3 was not given substantial consideration during this review of the O_3 primary NAAQS. Because some of the new studies were considered in the Regulatory Impact Analysis, some commenters may have believed mistakenly that they were considered in review of the NAAQS . . . . EPA did not give significant weight to that mortality evidence.

EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 48-49.

[301] RIA, *supra* note 300, at 12-70 tbl.12-19 (estimating health benefits of the new standard using an assumption of a constant annual PM standard of 15 $\mu g/m^3$). In the RIA, EPA claimed that some new studies not reviewed by CASAC strengthened the evidence for some reduced mortality benefits from the ozone standard. Although the RIA made clear that EPA did not rely on reduced mortality in selecting the ozone standard, *id.* at 12-15, 12-19, it included an estimate of potential mortality reduction benefits to produce a "high-end" ozone benefits estimate. *Id.* at 12-20 to 12-21. The estimated reduced mortality would increase the health benefits of the ozone standard from $0.06 to $1.76 billion. *Id.* at 12-70 tbl.12-19. Even this latter figure, however, is smaller than the incremental benefits of the revisions to the $PM_{2.5}$ standard previously discussed.

health benefits.[302] EPA's analysis did not permit a direct comparison of the mortality benefits of the two $PM_{2.5}$ alternatives, but given that most of the health benefits from the $PM_{2.5}$ standards are from reduced mortality, the total marginal health benefits of reducing the $PM_{2.5}$ standard from 65 to 50 $\mu g/m^3$ would likely have been much larger than $1.7 billion. The incremental benefits of reducing the daily PM standard still further to 25 $\mu g/m^3$ would have been even larger, but they were not calculated by EPA.

EPA's analysis clearly indicates that the health benefits foregone by EPA's decision not to tighten the $PM_{2.5}$ daily standard below the 65 $\mu g/m^3$ level dwarfed the total health benefits of the ozone standard (by a factor of approximately 50).[303] EPA claimed that its ozone revision was necessary in order to protect public health with an adequate margin of safety, but it also argued that a further tightening of the PM standard to achieve significantly greater health benefits was *not* necessary to protect public health with an adequate margin of safety. EPA offered no explanation for why its treatment of health risks should vary markedly from one pollutant to another.[304]

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[302] RIA, *supra* note 300, at 12-44 tbl.12.5 (listing high-end estimated monetized health benefits for partial attainment of each of the two $PM_{2.5}$ standards). EPA calculated the mortality benefits of the two standards using slightly different methodologies, so a direct apples-to-apples comparison is not possible, although the monetized mortality health benefits of the 50 $\mu g/m^3$ standards appear, as expected, to be larger than the benefits for the 65 $\mu g/m^3$ standard.

[303] Furthermore, this inconsistency cannot be explained based on the uncertainty contained in any risk analysis. Both the ozone and PM risk assessments involve substantial uncertainty, as EPA acknowledges. EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,860 (indicating that "the Administrator and CASAC recognized that there are many uncertainties inherent in such [risk assessment] analyses" of ozone exposure); EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656 (noting that the "quantitative risk estimates include significant uncertainty"). Moreover, the PM_{25} risk estimates for the regulatory increments not adopted by EPA come from the same studies and data sets that EPA used to justify the $PM_{2.5}$ standard it did select. Given that there is no qualitative break point in the extent of uncertainty in those data, EPA cannot on one hand say that the data above its selected standard is sufficiently certain to support regulation, but the data, produced with the same method and in the same studies, below its standard is too uncertain to be treated as credible. *See also supra* notes 229-32 and accompanying text (discussing EPA's use of uncertainty as claim for disregarding data that did not support its policies).

[304] *See* Sunstein, *supra* note 18, at 330 ("EPA's own calculations showed that a tighter particulates standard would have produced far greater health benefits than the ozone standard; this leaves a serious unexplained anomaly in the two standards taken together."); Sunstein, *supra* note 20, at 6 ("[T]ighter regulation of particulates, going well beyond the EPA's rule, would appear to do a great deal more to protect public health than would the new regulation of ozone.").

III. TOWARD MORE PRINCIPLED RISK MANAGEMENT

EPA's effort to rely exclusively on science may have effectively conveyed the impression to its overseers that the Agency had a sound basis for revising its standards, but in fact, by relying on science-based rhetoric, the Agency had only disguised a series of ad hoc and incoherent decisions. Positions adopted in previous rulemakings, or at previous points in the same rulemaking, shifted in the course of the Agency's defense of the new standards. Findings or assumptions made in the rulemaking record were set aside in order to support the Agency's positions in litigation. Nowhere during the entire rulemaking and litigation process did EPA articulate a clear policy rationale to justify how the NAAQS standards should be set, other than to assert that they were set at the "appropriate" level.[305]

Given the way that section 109 of the Clean Air Act has been construed over the years, the Agency has found itself navigating untenable conceptual terrain. Following the dictates of the Clean Air Act, EPA has claimed to select standards that protect the public health with an adequate margin of safety and, hence, has proceeded to defend revisions of its standards by marshaling scientific evidence of health effects at levels below its previously set standards.[306] Yet, similar evidence considered by the Agency demonstrated that health effects would still persist even at levels below the revised standards.[307] Indeed, with non-threshold pollutants, these effects will by definition persist at any level above zero.[308] The Agency has admitted that it need not, even cannot, set its standards at zero, but it has never provided any consistent and meaningful set of reasons that justify its decision to lower its standards to protect against one increment of adverse effects but not to lower them further to protect against another increment of adverse effects.

In this final Part, we highlight what needs to be done if air quality standard setting is to proceed in the future with more coherent justification. We present four principled approaches to standard setting in the Section that follows, with the aim of showing what has been missing from EPA's decision making as well as pointing toward better ways

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[305] *See* Sunstein, *supra* note 18, at 327 ("EPA's presentation of all the relevant data shows reason for concern about adverse health effects at current levels, but leaves many doubts about why EPA chose the particular standards it did, rather than standards somewhat higher or somewhat lower.").

[306] *Supra* Parts I.A, II.A.

[307] *Supra* Part II.B–C.

[308] *Supra* Part I.C.

of setting air quality standards in the future. Unfortunately, some of the most promising of these approaches are no longer permissible under EPA's, and now the Supreme Court's, interpretation of the Clean Air Act and therefore raise important implications for future legal developments. In this Part, we show how achieving a more candid and coherent policy justification for environmental decisions will require a significant change in EPA's existing approach toward setting NAAQS standards, including an abandonment of the fundamental fiction that costs do not and should not enter into the Agency's decision making. Of course, given the Supreme Court's affirmation of this fiction,[309] moving toward principled standard setting will now require legislative change, not only to overcome the restrictive interpretation EPA and the courts have given to section 109 of the Clean Air Act, but also to direct EPA to develop a set of general policy guidelines for use in making future decisions about its air quality standards.

A. *Risk Management Principles*

Regulatory decisions, such as the selection of air quality standards, involve enormous stakes in terms of both health consequences and economic burdens. How can EPA provide a more coherent justification for these significant decisions than it offered in its most recent NAAQS revisions? A regulatory agency such as EPA has four basic approaches available that it can use to provide a consistent justification for making risk management decisions such as setting ambient standards: (1) eliminate all risks (or all nonnaturally occurring risks); (2) avoid unacceptable risks; (3) avoid unacceptable costs (sometimes described as the feasibility approach); and (4) balance costs and benefits.[310] Although these approaches are not all equally

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[309] *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 465 (2001) (affirming that EPA is not permitted by statute to consider costs in setting ambient air quality standards).

[310] For a similar taxonomy of approaches, see FRANK CROSS, ENVIRONMENTALLY INDUCED CANCER AND THE LAW 69-95 (1989). While the four approaches we outline represent the major justification strategies available to risk regulators, they do not represent an exhaustive list of all possible principled approaches. Another principled approach would be to eliminate all costs of regulation, but this would be as misguided as eliminating all risks. Some level of government intervention is needed to address environmental risk and thereby impose an appropriate level of costs on those actors that have not fully internalized all the social costs of their action. For discussions of the rationales for governmental regulation, see NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 3-7 (1994); CASS R. SUNSTEIN, AFTER THE RIGHTS REVOLUTION 45-46 (1990); V. KIP VISCUSI ET AL., ECONOMICS OF REGULATION AND ANTITRUST 2-3 (2000). Other principled approaches

sound strategies—nor are they all currently permissible under the Supreme Court's interpretation of the Clean Air Act—they do illustrate the range of possible ways to provide a consistent explanation for risk management decision making.[311]

1. Eliminate All Risks

The first approach is conceptually straightforward: eliminate all risks. This principle could be consistently applied if EPA set its standards at levels at which it believed there would be absolutely no health risks. The Agency also could take a consistent risk management approach if it chose to minimize risk by setting standards at background levels, thereby opting to eliminate all risks except those that are naturally occurring (a zero *additive* risk approach).

More generally, the EPA could decide to follow an approach aimed at minimizing all risk. A minimize risk approach could in some cases lead to a *nonzero* risk level if a pollutant provides some beneficial health effects that countervail its adverse health effects. For example, commentators in the ozone rulemaking alleged that, despite the adverse pulmonary effects of ground level ozone, concentrations of the pollutant also screen out harmful ultraviolet radiation.[312] If a

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take into account issues of distributional equity—deploying a consistent strategy to promote fairness and equality in the distribution of costs and benefits across different individuals and groups within society. *See* NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 40 (1996) (noting that in some cases "managing environmental risks has become a question of fairness, moral responsibility, and distributional equity"); K.S. SHRADER-FRECHETTE, RISK AND RATIONALITY: PHILOSOPHICAL FOUNDATIONS FOR POPULIST REFORMS 183 (1991) (arguing for weighing "egalitarian values, social obligations, and rights" as a part of risk management decision making).

[311] Our focus here is on developing consistent general approaches to risk management decision making, not on all the choices that enter into risk decision making, such as the treatment of uncertainty. Much has been written about the development of principled approaches to risk assessment, and government agencies have issued guidelines for assessing and characterizing risk with the aim of increasing consistency. *See, e.g.*, EPA, DRAFT GUIDELINES FOR CARCINOGEN RISK ASSESSMENT 1 (1999) (offering guidance to EPA staff and decision makers on how to develop and use risk assessments), *available at* http://www.epa.gov/ncea/raf/pdfs/cancer_gls.pdf. Our aim, in contrast, is to focus on the core principles needed to justify the central risk management question that science by itself simply is unable to answer, namely the level at which ambient risk standards should be set.

[312] *See, e.g.*, Randall Lutter & Howard Gruenspecht, *Assessing Benefits of Ground-Level Ozone: What Role for Science in Setting National Air Quality Standards*, 15 TUL. ENVTL. L.J. 85, 87 (2001) (arguing that in setting its 1997 ozone standard EPA focused only on the ozone's harmful effects without taking into account its potential benefits). The D.C. Circuit, in the first round of litigation over EPA's ozone revision, directed the Agency

reduction of the pollutant would create offsetting risks, such as an increase in skin cancer, then a standard that minimizes health risks would be set above zero.[313] In cases with such so-called risk-risk tradeoffs, EPA could opt for a standard set at a level that achieves the lowest possible adverse health effects, namely the level at which the marginal adverse health effects equal the marginal beneficial health effects.[314]

Minimizing risk would appear to resonate with the conventional interpretation of the Clean Air Act, with its emphasis on a preventative approach to health protection through a margin of safety.[315] As the D.C. Circuit Court directed in *Lead Industries*, EPA should set its NAAQS standards in a way that ensured "an absence of adverse effect"

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to take these possible beneficial health effects of ozone into consideration. Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1051-53 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

[313] This assumes that the dose-response curves of the health benefits and health risks of the pollutants have different shapes. If the two dose-response curves are parallel, it may be that the health risks or the health benefits dominate the other at all dose levels as they both decrease in step with exposure. In this case, the standard that maximizes net health benefits would be set at zero (if health risks are greater than health benefits at all exposure levels) or no standard should be set (if health benefits are greater than health risks at all exposure levels).

[314] *Cf. Whitman*, 531 U.S. at 495 (Breyer, J., concurring) ("A rule likely to cause more harm to health than it prevents is not a rule that is 'requisite to protect the public health.'"). *See* LAVE, *supra* note 274, at 15-17 (outlining methods for weighing the risks of exposure to a carcinogen versus the risks of eliminating it); John D. Graham & Jonathan Baert Wiener, *Confronting Risk Tradeoffs*, *in* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT 1-4 (John D. Graham & Jonathan Baert Wiener eds., 1995) (advocating a "more rigorous framework for analyzing risk tradeoffs" that arise when countervailing risks emerge from attempts to reduce target risks); Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533, 1535-38 (1996) (arguing that individuals and regulators suffer from "selective attention" that allows them to overlook ancillary risks and, therefore, advocating that policymakers act to minimize net risks). There are obvious affinities between such an approach and one that balances all benefits and costs of a risk standard, but because the "maximize risk reduction" approach focuses only on costs and benefits as measured in health effects, it should be distinguished from an approach that aims to maximize net social benefits. In those cases where the existence of some amount of a pollutant offers no offsetting health benefits whatsoever, the "maximize risk reduction" approach equates with the "zero risk" approach.

[315] *See supra* notes 194-95 and accompanying text (noting EPA's claim that the protection of public health is the predominant goal of its air quality standards). The language in the Clean Water Act that commands the elimination of all discharges into the nation's waterways also exemplifies this approach. *See* 33 U.S.C. § 1251(a) (2000) (stating that the national goal underlying the prevention of water pollution is to protect the use of water by individuals and fish and wildlife). The regulation of food additives under the Delaney Clause also followed this approach for many years. *See* Pub. Citizen v. Young, 831 F.2d 1108, 1109 (D.C. Cir. 1987) (finding that the Delaney Clause, which prohibits use of color food additives "found . . . to induce cancer in man or animal," does not contain a de minimus exception).

on members of the public.[316] Of course, for non-threshold pollutants that lack countervailing health benefits, the minimize risk principle can only be applied consistently if EPA sets its standards at a zero or background concentration level, something that would effectively call for the elimination of all economic activities.[317] Quite sensibly, the Agency has expressly disavowed any intention of adopting a zero-risk approach, and the Supreme Court has also recognized the folly of such an approach.[318] Moreover, while EPA has raised concerns about background levels (when it would appear expedient), it has neither adopted nor applied consistently any principle of eliminating all human-created pollution.[319] It has also so far rejected calls for making health-health tradeoffs in setting NAAQS standards under a minimize risk principle.[320] Consequently, if EPA is to make its risk management decision making more coherent, it will almost certainly need to choose a principle other than eliminating all risk.

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[316] Lead Indus. v. EPA, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

[317] *See* W. KIP VISCUSI, RISK BY CHOICE: REGULATING HEALTH AND SAFETY IN THE WORKPLACE 136-38 (1983) (using EPA's lead standard requiring that 99.5% of the most sensitive group be exposed to levels below a zero-risk threshold as an example of the economic inefficiencies that result from the exclusion of cost-benefit tradeoffs in risk management decision making); *see also supra* Part I.C (arguing that eliminating pollution entirely would have the universally undesirable effect of prohibiting economic activity).

[318] *See supra* notes 164-65 and accompanying text (stating that neither EPA nor any other major participant in environmental policymaking has ever argued for a zero-risk standard, as it would call for the elimination of the industrialized economy); *see also Whitman*, 531 U.S. at 494 (Breyer, J., concurring) (noting that the Clean Air Act should not be construed as requiring "a world that is free of all risk—an impossible and undesirable objective"); Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 642 (1980) (noting that "safe" does not necessarily mean "risk-free").

[319] *See supra* notes 282-91 and accompanying text (showing the inconsistencies in EPA's argument that it set the standard at a level approximating "naturally occurring background levels").

[320] National Ambient Air Quality Standards for Ozone: Final Response to Remand, 68 Fed. Reg. 614, 618 (Jan. 6, 2003) (to be codified at 40 C.F.R. pt. 50) (noting that any increase in risks associated with reductions in ground-level ozone levels, such as from increased exposure to ultraviolet radiation, is "too uncertain at this time to warrant any relaxation in the level of public health protection previously determined to be requisite to protect against the demonstrated adverse respiratory effects of direct inhalation exposure to O_3 in the ambient air").

2. Avoid Unacceptable Risks

A second approach would be for the Agency to establish a level of acceptable risk for its air quality standards.[321] Rather than minimizing all risks, the Agency would only reduce risks to a consistent and tolerable level. As with the minimize risk principle, the acceptable risk approach focuses exclusively on the benefits to be reaped from a risk standard.[322] It does not try to maximize those benefits, but simply to deliver a desirable level of health benefits.

The acceptable risk approach has been used in other regulatory contexts. For example, in setting standards for hazardous air pollutants, EPA has presumptively defined "acceptable risk" to mean a maximum individual mortality risk of no greater than one in ten thousand.[323] The Agency has similarly set acceptable risk targets in other contexts, including the regulation of water quality, hazardous wastes, and pesticides.[324] The Occupational Safety and Health Administration (OSHA) follows a similar approach, using a benchmark mortality risk of one in one thousand as the level of "significant risk"

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[321] *See* Baruch Fischhoff, *Acceptable Risk: A Conceptual Proposal*, 5 RISK 1, 4-8 (1994) (proposing an analytical procedure for determining and implementing an acceptable risk approach); Gary E. Marchant & Dawn P. Danzeisen, *'Acceptable' Risk for Hazardous Air Pollutants*, 13 HARV. ENVTL. L. REV. 535, 540-42 (1989) (summarizing the four approaches proposed by EPA to develop a level of acceptable risk on which to base emissions standards for hazardous air pollutants).

[322] *See* Cass R. Sunstein, *Cost-Benefit Default Principles*, 99 MICH. L. REV. 1651, 1664 (2001) (describing the acceptable risk approach as "entirely benefits-based" (emphasis omitted)).

[323] National Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants, 54 Fed. Reg. 38,044, 38,045 (Sept. 14, 1989) (codified at 40 C.F.R. pt. 61) [hereinafter National Emission Standards]. This risk level slides down towards one in one million as the size of the exposed population increases. *Id.* at 38,044-45. In addition, the Clean Air Act now authorizes EPA to remove categories of sources of hazardous air pollutants from the list of regulated sources whenever it finds "that no source in the category . . . emits such hazardous air pollutants in quantities which may cause a lifetime risk of cancer greater than one in one million to the individual in the population who is most exposed to emissions of such pollutants from the source." 42 U.S.C. § 7412(c)(9)(B)(i) (2000).

[324] *See* March Sadowitz & John D. Graham, *A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy*, 6 RISK 17, 25-30 (1995) (outlining the risk standards that EPA has created with respect to water quality and hazardous wastes). The legislative history of the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, stipulates that EPA should apply an acceptable risk level of one in one million for certain pesticide residues. H.R. REP. NO. 104-669, pt. 2, at 41 (1996).

on which it bases its occupational health standards.[325] If EPA adopted a similar, approach, it could then use an acceptable risk criterion to select a set of consistent air quality standards.

Extending an acceptable risk approach to NAAQS decision making would not be easy, however, since criteria pollutants such as ozone and PM cause varied types of health effects other than mortality. Most acceptable risk benchmarks established by EPA under other regulatory programs focus exclusively, or at least primarily, on cancer mortality.[326] Mortality is a binary effect, but many of the health effects of pollutants, like ozone, involve continuous health effects (e.g., respiratory irritation) that vary in intensity from a minor nuisance to a serious illness. It is generally harder to define an acceptable risk level for such continuous effects because it is necessary to address both the frequency and the severity of the disease.[327] Moreover, a common metric for morbidity is needed to compare alternative standards, each of which may vary along multiple dimensions of predicted health effects (such as if exposure contributed to circulatory as well as to pulmonary problems).[328]

Another issue raised by the acceptable risk approach is whether to focus on the risks to individuals, to the population, or to both.[329] EPA has yet to adopt a clear and consistent position on whether to base its NAAQS decisions on maximum individual or population risk.[330] In its

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[325] *E.g.*, Occupational Exposure to Formaldehyde, 52 Fed. Reg. 46,168, 46,230 (Dec. 4, 1987) (codified at 29 C.F.R. pts. 1910, 1926); Occupational Exposure to Ethylene Oxide, 49 Fed. Reg. 25,734, 25,764 (June 22, 1984) (codified at 29 C.F.R. pt. 1910); Occupational Exposure to Inorganic Arsenic, 48 Fed. Reg. 1864, 1902 (Jan. 14, 1983) (codified at 29 C.F.R. pt. 1910); *see also* Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 655 (1980) (determining that OSHA should use a mortality risk of one in one thousand as a benchmark for significant risk); Int'l Union v. OSHA, 37 F.3d 665, 670-71 (D.C. Cir. 1994) (upholding OSHA's decision to use a single risk standard applicable to all general industry employers, rather than to disaggregate industries).

[326] *See, e.g.*, Sadowitz & Graham, *supra* note 324, at 19-21 (discussing EPA's analysis of risk based on cancer rates).

[327] *See* Reilly, *supra* note 44, at 1365-66 ("The search for the Holy Grail of risk management—the so called 'bright line' that would let policy makers determine, under any and all circumstances, whether a particular level of risk is 'acceptable' or not—seems doomed to failure.").

[328] *See infra* notes 338-40 and accompanying text (analyzing EPA's comparative analysis of continuous health effects).

[329] *See* Sunstein, *supra* note 20, at 9 ("[I]t is not clear if the agency should focus on the probability of harm faced by each individual, or instead on some statistical measure of aggregate harms, faced by the population as a whole.").

[330] In the late 1980s, EPA defined "acceptable risk" for exposure to hazardous air pollutants under section 112 of the Clean Air Act by considering only maximum

recent ozone revision, EPA appeared in some ways to accept a population risk approach.[331] Yet, in a previous NAAQS rulemaking, EPA explicitly indicated that the number of people exposed was not relevant, since "[s]tandards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect with given concentration levels."[332] The problem with relying only on levels of risk to individuals, of course, is that it overlooks the number of people exposed to the risk, something that clearly affects overall health benefits.

If EPA were to measure and compare the overall benefits of different regulatory alternatives, it would need to use consistent methods to quantify all the benefits that it predicted from each proposed standard and its alternatives. Such a careful "benefits analysis," as Professor Cass Sunstein has called it, would enable the Agency to determine whether any given regulatory option can be expected to achieve an acceptable level of risk.[333] A benefits analysis would detail all the health effects associated with different levels of exposure as well as report the predicted incidence of these effects on all exposed individuals, including those in any sensitive subgroups within the overall population.[334] Such a benefits analysis would contain EPA's best range (or point) of estimates for the number of people likely to be exposed to the pollutant under an alternative standard, the probabilities that they will suffer various health effects, and the severity of those effects.[335] These benefits could be monetized using willingness-to-pay (WTP) measures, a standard way of aggregating different kinds of environmental health effects across an entire population.[336]

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individual risk or only total population risk before ultimately selecting a hybrid approach that considered both measures. National Emission Standards, *supra* note 323, 68 Fed. Reg. at 38,045.

[331] EPA justified its selection of the 0.08 ppm ozone standard over the 0.09 ppm standard based largely on the argument that greater numbers of people would be exposed to unhealthy air quality under the 0.09 ppm standard than under the 0.08 ppm standard. EPA argued that under the 0.08 ppm standard "an estimated 40–65% more children would experience health effects that could limit their activity and in some cases require medical treatment." EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 23-24 (citing EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868).

[332] EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8210.

[333] Sunstein, *supra* note 18, at 363-65.

[334] *Id.*

[335] CASS R. SUNSTEIN, RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT 245 (2002).

[336] For a recent discussion of WTP measures, see James K. Hammitt, *QALYs Versus WTP*, 22 RISK ANALYSIS 985 (2002); Cass R. Sunstein, *Lives, Life Years, and Willingness to Pay*, 104 COLUM. L. REV. 205 (2004). EPA used willingness to pay metrics to estimate

Alternatively, EPA could consider using other metrics for aggregation such as quality adjusted life years (QALY)—a measure used more commonly in health care analyses.[337] Whatever their relative merits, measures like WTP and QALY serve as a common basis for measuring the total health benefits associated with different regulatory standards.[338]

By using a common measure, EPA could improve the consistency of outcomes across different standards. For example, more explicit and detailed attention to benefits analysis might have made EPA decision makers—as well as the American public—more aware that the Agency was passing up an opportunity to secure greater health gains, through increased tightening of the particulate matter standard, than it reaped altogether from its revisions to the ozone standard.[339] In this way, a benefits-based approach could help ensure that different standards reduce risks to comparable (and acceptable) levels, achieving comparable (and desirable) levels of health benefits.[340]

While a benefits-based approach may help in identifying inconsistencies across rules, by itself such an approach still skirts the underlying question: What makes a particular level of risk "acceptable" (or a particular level of benefits "desirable")? An acceptable risk approach

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the health benefits of its recent ozone and PM standards in its Regulatory Impact Analysis for its rulemaking, although it was not permitted to consider these estimates in making its regulatory decision. RIA, *supra* note 300, at 12-34 to 12-37. For example, EPA calculated that the value of a life saved was $4.8 million, a case of chronic bronchitis prevented was $260,000, and a case of shortness of breath prevented was $5.30. *Id.* at 12-40.

[337] In its decision in *American Trucking*, the D.C. Circuit suggested that another possible way to aggregate health effects would be to define a generic unit of harm, such as through QALY. Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1039-40 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001). For a discussion of the QALY measure in the context of EPA's air pollution policy, see BRYAN J. HUBBELL, ENVIRONMENTAL PROTECTION AGENCY, IMPLEMENTING QALYS IN THE ANALYSIS OF AIR POLLUTION REGULATIONS (Innovative Strategies and Econ. Group, EPA, Working Paper May 2002), *available at* http://www.epa.gov/ttn/ecas/workingpapers/ereqaly.pdf; SUNSTEIN, *supra* note 335, at 246-47; *see also* Richard J. Zeckhauser & Donald Shepard, *Where Now for Saving Lives?*, LAW & CONTEMP. PROBS., Autumn 1976, at 5, 11 (providing the original treatment of the QALY metric).

[338] For comparative assessments of these measures, see Hammitt, *supra* note 336; Janice Clair Wright, Investments that Save Lives: The Norms of Environmental and Medical Decision Making 2-1 to 2-59 (1997) (unpublished Ph.D. dissertation, Harvard University) (on file with author).

[339] *Supra* Part II.D.

[340] *See* SUNSTEIN, *supra* note 335, at 245 ("A chief advantage of this approach is that it should ensure interregulation consistency . . . .").

seems to envision that government makes risk management decisions in individual proceedings according to some predetermined level of acceptable risk. A benefits analysis can reveal whether a particular standard meets this predetermined level. It does not, however, provide a basis for determining what that level should be. After all, any detailed benefits analysis, such as the kind that Professor Sunstein proposes, is really just a highly professional risk assessment and not the risk management judgment called for in standard setting.[341] Selecting an acceptable risk level still requires making a reasoned judgment about the optimal appropriate level.[342]

The acceptable risk approach suffers from another notable limitation: it directs that standards be set based solely on the level of benefits to be gained—regardless of the costs of meeting those standards.[343] To follow this approach would require that EPA set standards based on benefits even when the costs of compliance were disproportionately high.[344] Moreover, the consistent application of this approach

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[341] *See id.* (noting the "inevitable judgment of value" involved in setting standards).

[342] *See id.* (proposing not only careful benefits analysis, but also that EPA "explain why one set of savings . . . justifies regulation, whereas other sets of savings do not"). Justice Stephen Breyer has suggested that one approach would be for the Agency to base an acceptable level on "the public's ordinary tolerance" of similar health risks. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 494 (2001) (Breyer, J., concurring). Comparative risk analysis can be used to provide information about other benchmark risks. *See* M. Granger Morgan et al., *A Proposal for Ranking Risk Within Federal Agencies*, *in* COMPARING ENVIRONMENTAL RISKS 112-15 (J. Clarence Davies ed., 1996) (noting that ranking risks reveals society's priorities about which risks are of immediate concern). For a discussion of some of the difficulties in defining an "acceptable" level of risk, see Adam Babich, *Too Much Science in Environmental Law*, 28 COLUM. J. ENVTL. L. 119, 146-57 (2003); Sanford E. Gaines, *Science, Politics, and the Management of Toxic Risks Through Law*, 30 JURIMETRICS 271, 283 (1990); Marchant & Danzeisen, *supra* note 321, at 548-57.

[343] For a discussion of the weight given to the level of benefits, see Feller, *supra* note 127, at 873-74:

> [R]elatively large risks may be tolerated if they yield comparably large benefits. With respect to air quality, the benefit of tolerating a certain level of air pollution is the pollution control expense saved by foregoing reductions in pollution below that level. . . . [A] rational selection of an acceptable level of air quality requires consideration of the costs required to attain various levels.

Id.

[344] *Cf.* Roy E. Albert, *Carcinogen Risk Assessment in the U.S. Environmental Protection Agency*, 24 CRITICAL REV. TOXICOLOGY 75, 84 (1994) ("[T]here is no acceptable risk in the absence of benefits. Risks at virtually any level can be ignored, depending on circumstances.").

would also lead the Agency to reject risk reductions below the "acceptable level" even when the costs of achieving them were trivial.[345]

Of course, however desirable or undesirable an acceptable risk approach may be, EPA has so far not even tried to use it in setting or revising any of its NAAQS standards. The Agency has so far eschewed responsibility for offering a consistent account of its decisions, claiming that the range of health effects associated with criteria pollutants makes it too difficult to follow any "generalized paradigm" in explaining its NAAQS decisions.[346] As a result, it is hardly surprising that the recently revised ozone and PM standards will achieve markedly disparate levels of health benefits.[347]

3. Avoid Unacceptable Costs

A third approach to consistent risk management is the mirror image of the acceptable risk approach. Instead of focusing exclusively on benefits, the cost of a regulation should be the key factor. In other words, EPA could set its standards as low as possible while keeping the costs of compliance below an acceptable level.

This approach typically has been couched in terms of feasibility—what can be achieved without high costs or severe economic disruptions.[348] Saying that a standard is feasible implies that its costs are acceptable. For example, OSHA is charged by statute with developing regulations to protect workers from exposure to toxic substances "to the extent feasible."[349] Of course, just stating that a regulatory standard is "feasible" or "infeasible" is rather imprecise.[350] However, just as agencies have defined the concept of acceptable risk by setting

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[345] *See* Sunstein, *supra* note 18, at 377 (suggesting that when a nontrivial risk reduction "would be a trivial expense, surely it should be required"); *see also* Int'l Union v. OSHA, 938 F.2d 1310, 1322 (D.C. Cir. 1991) ("[E]ven a slight risk might be considered significant if it could be reduced or eliminated at a cost (including costs of enforcement and compliance) less than the resulting benefits.").

[346] *See* EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883 (arguing against a "generalized paradigm" and for a case-by-case approach to setting NAAQS); *see also supra* Part II.A (describing EPA's ad hoc approach to decision making).

[347] *Supra* Part II.D.

[348] *See, e.g.*, Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729, 744 (arguing that "society may choose to limit its protection of workers only at the point where the protection would cause industry substantial economic dislocation"); Wendy E. Wagner, *The Triumph of Technology-Based Standards*, 2000 U. ILL. L. REV. 83, 93-94 (defending a standard-setting approach that is based on the use of feasible technology).

[349] 29 U.S.C. § 655(b)(5) (2000).

[350] Sunstein, *supra* note 322, at 1691, 1703.

specific risk targets, they could similarly develop precise standards establishing acceptable levels of costs and then reduce risk to the point at which compliance costs reached the specified level.[351]

Such an approach, it should be noted, would disregard the benefits of risk standards. If a standard with exceedingly high costs (or that would cause severe economic disruption) would also save thousands of lives, then society almost certainly would be better off even if the costs might seem unacceptably high.[352] For example, government regulations eliminating lead from gasoline resulted in hundreds of millions of dollars in annual costs and appeared to threaten not only layoffs in the industrial firms that produced lead additives but also gasoline shortages during the transition to unleaded fuels.[353] Nevertheless, these regulations also resulted in dramatic health benefits that substantially dwarfed the costs.[354] If regulatory agencies had adhered to an approach that avoided all regulations that imposed costs exceeding a specified level or threatened economic dislocation, without any

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[351] Regulators already use a cost ceiling as a trigger for certain legal requirements. For example, when a proposed regulation is expected to impose $100 million or more in annual costs, agencies are required to conduct formal regulatory impact analyses. 2 U.S.C. § 1532(a)(2) (2000); *see also* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, § 6, at 51,740-43 (Sept. 30, 1993) (outlining the cost-benefit analysis required for agency regulatory action). Professor Sunstein has suggested that agencies could define feasibility in terms of a specific number of bankruptcies, business closures, or job losses. Sunstein, *supra* note 322, at 1703.

[352] *See* Sunstein, *supra* note 322, at 1701-02 (noting that regulations that are not "feasible" still can result in enormous social benefits). A ban on tobacco sales, for example, might be one such case where a seemingly infeasible governmental intervention arguably could be justified. *See* DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY 392 (2001) ("[T]he solution to the smoking problem rests with the bottom line, prohibiting the tobacco companies from continuing to profit from the sale of a deadly, addictive drug.").

[353] Albert L. Nichols, *Lead in Gasoline, in* ECONOMIC ANALYSES AT EPA: ASSESSING REGULATORY IMPACT 49, 56-57, 59, 74 (Richard D. Morgenstern ed., 1997).

[354] In its final RIA, EPA estimated that the benefits of the lead phase-down rule would be over ten times greater than the costs. RIA, *supra* note 300, at 7-1, 12-1. In a retrospective study conducted by EPA in the mid-1990s, the Agency's average monetized estimate of health benefits from the elimination of lead emissions amounted to about two trillion dollars, with ninety-four percent of the reductions in lead emissions attributed to the phase-out of lead in gasoline. OFFICE OF AIR & RADIATION, EPA, NO. 410-R-97-002, FINAL REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF THE CLEAN AIR ACT, 1970 TO 1990, at 17, 52 (1997) [hereinafter EPA, FINAL REPORT TO CONGRESS], *available at* http://www.epa.gov/air/sect812/chptr1_7.pdf. These benefits exceeded, by approximately four times, the estimated costs of *all* the regulations EPA issued under the Clean Air Act between 1970 and 1990 ($0.5 trillion), not just the costs of the lead phase-out. *Id.* at 8.

concern for the level of corresponding benefits, they may well have delayed or avoided phasing out lead additives in gasoline.[355]

When regulatory agencies justify their risk management decisions based only on either costs or benefits, they can achieve consistent, principled decision making simply by using the same level of acceptable costs or risks across different rulemakings. Nevertheless, all the approaches we have discussed so far truncate the range of risk management criteria and may therefore lead regulatory agencies, in some cases, to make decisions that make little sense, even though they are consistent.[356] Under the acceptable risk approach, however, agencies can affirm standards that impose significant costs without proportional health protection gains. Under the acceptable cost approach, agencies can reject opportunities to achieve significant net social benefits simply because costs are high.

4. Balance Costs and Benefits

With precisely these kinds of perverse outcomes in mind, a fourth approach for risk management would take both benefits and costs into consideration and seek to achieve a consistent balance of the two.[357] By considering both costs and benefits, regulators could set

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[355] The use of cost-benefit analysis in developing the lead phase-down rule has been credited with hastening the elimination of lead emissions:

> Without quantitative analysis, it would not have been possible to make a compelling case for the accelerated phase down because it would not have been possible to show how much more important lead in gasoline was relative to the vast majority of other rules competing for attention, many of which involved congressional or court-imposed deadlines, in contrast to lead.

Nichols, *supra* note 353, at 78. The lead phase-down rule also took advantage of a market-like trading program designed to make the phase-down more cost-effective. Robert W. Hahn & Robert N. Stavins, *Incentive-Based Environmental Regulation: A New Era from an Old Idea?*, 18 ECOLOGY L.Q. 1, 17 (1991).

[356] *See* Coglianese, *supra* note 299, at 1223 (distinguishing between instrumental and comparative coherence and the need to consider multiple dimensions of regulatory policies).

[357] *See* William H. Rodgers, Jr., *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191, 214, 226 (1980) (evaluating the role for cost-benefit analysis in setting risk standards); Sunstein, *supra* note 322, at 1691 (arguing that a reasonable approach to risk regulation involves a comparison of costs against benefits); Edward W. Warren & Gary E. Marchant, *"More Good than Harm": A First Principle for Environmental Agencies and Reviewing Courts*, 20 ECOLOGY L.Q. 379, 419-25 (1993) (describing how courts have interpreted the reasoned decision making requirement in the Administrative Procedure Act to include at least a loose balancing of costs and benefits).

risk management standards to maximize net benefits.[358] Several environmental statutes other than the Clean Air Act actually require agencies to balance benefits and costs when they are setting risk standards.[359] Indeed, absent statutory prohibitions to the contrary (such as now in the Clean Air Act), regulatory agencies are directed by Executive Order 12,866 to assess both costs and benefits of significant proposed regulations and to "propose or adopt a [new] regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."[360]

Of course, in practice, there will be important issues regarding measurement, valuation, and discount rates that must be treated consistently.[361] But this is true for any other approach to risk management

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[358] For a general discussion of the use of cost-benefit analysis, see COST-BENEFIT ANALYSIS: LEGAL, ECONOMIC, AND PHILOSOPHICAL PERSPECTIVES (Matthew D. Adler & Eric A. Posner eds., 2001); RISKS, COSTS, AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION (Robert W. Hahn ed., 1996); Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489 (2002).

[359] *See, e.g.*, 7 U.S.C. § 136a(c)(2) (2000) (requiring the EPA administrator to consider both the costs and benefits prior to adoption of regulations on pesticides); 15 U.S.C. § 2605(c) (2000) (requiring EPA administrator to consider both costs and benefits in promulgating rules with respect to the regulation of hazardous chemicals); 42 U.S.C. § 300g-1(b)(3)(C)(i) (2000) (requiring EPA administrator to seek public comment on the costs and benefits of a proposed maximum contaminant level for national drinking water regulation). Even when the statute calls for balancing costs and benefits, the Agency possesses considerable discretion in how the balancing actually takes place, which may still permit the Agency to make incoherent, inconsistent, or costly decisions. *See* George Van Houtven & Maureen L. Cropper, *When is a Life Too Costly to Save? The Evidence from U.S. Environmental Regulations*, 30 J. ENVTL. ECON. & MGMT. 348, 367 (1996) (noting that even though "Congress may require that the costs of a regulation be balanced against the benefits, . . . as long as EPA has discretion in the weights it assigns to costs and benefits, regulations issued under balancing statutes may still be very costly").

[360] Exec. Order No. 12,866, § 1(b)(6), 58 Fed. Reg. 51,735, 51,736 (Sept. 30, 1993); *see also id.* § 6(a)(3)(C), 58 Fed. Reg. at 51,741 (detailing the required assessments of costs and benefits). The Unfunded Mandates Reform Act also requires agencies to prepare statements of costs and benefits of significant proposed rules. 2 U.S.C. § 1532 (2000). The Act generally directs agencies in these rulemakings to adopt the "least costly, most cost-effective or least burdensome" alternative that achieves the regulatory objective. *Id.* § 1535(a).

[361] *See generally* RAYMOND J. KOPP ET AL., COST-BENEFIT ANALYSIS AND REGULATORY REFORM: AN ASSESSMENT OF THE SCIENCE AND THE ART 14-31 (Research for the Future, Discussion Paper No. 97-19, 1997) (reviewing the state of the art in cost-benefit methodology); Steve P. Calandrillo, *Responsible Regulation: A Sensible Cost-Benefit, Risk Versus Risk Approach to Federal Health and Safety Regulation*, 81 B.U. L. REV. 957, 986-1007 (2001) (discussing some of the challenges of using cost-benefit analysis). For a discussion of the issue of the discount rate in particular, see Richard L. Revesz, *Environmental*

decision making, and regulators have developed guidelines for approaching these operational issues in consistent ways.[362] When conducted responsibly, cost-benefit analysis can prove quite valuable in explaining regulatory agencies' decision making.[363] It offers a consistent and systematic approach to risk management.

What is most striking is that EPA has not only rejected a cost-benefit approach but also all of the other general policy principles for risk management. It has explicitly ruled out zero-risk and acceptable-risk approaches, and it has successfully argued that the Clean Air Act precludes it from adopting a feasibility or cost-benefit balancing approach.[364] Instead, EPA has taken an explicitly ad hoc approach.[365]

Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives, 99 COLUM. L. REV. 941 (1999).

[362] *See* EPA, NO. 240-R-00-003, GUIDELINES FOR PREPARING ECONOMIC ANALYSES, FACT SHEET 1 (2000) (providing "a sound scientific framework for performing economic analyses of environmental regulations and policies"), *available at* http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/guidelines.html/file/FactSheet.pdf; Memorandum from Jacob J. Lew, Director, Office of Management and Budget, to the Heads of Departments and Agencies, Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements 3-16 (Mar. 22, 2000) (providing guidelines for the preparation of cost-benefit analyses), *available at* http://www.whitehouse.gov/omb/memoranda/m00-08.pdf; *see also* KOPP ET AL., *supra* note 361, at 14-31 (discussing the methodological issues surrounding cost-benefit analysis).

[363] *See* SUNSTEIN, *supra* note 168, at 65 (noting that "any reasonable judgment will ordinarily be based on some kind of weighing of costs and benefits"); Kenneth J. Arrow et al., *Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?*, 272 SCIENCE 221, 221-22 (1996) (explaining the appropriate use of cost-benefit analysis). This does not mean that a formal cost-benefit analysis will by itself determine where to set a standard in any strict algorithmic sense, for there will be uncertainties associated with it as with any other kind of analysis. EPA has mistakenly accused critics of its ad hoc approach to NAAQS rulemakings as advocating "a determinate formula" that would "straightjacket" its discretion. EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 70, at 17-26. Reliance on a cost-benefit principle provides a coherent guide for agency discretion and a consistent basis for justifying its air quality standards. Such an approach "could improve both the regulatory decisionmaking process by making it more transparent and the regulatory decision by allowing all relevant information to be considered explicitly." Brief of Amici Curiae AEI-Brookings Joint Center for Regulatory Studies et al. at 12, Am. Trucking Ass'ns v. Browner, 530 U.S. 1202 (2000) (No. 99-1426).

[364] *See supra* notes 165-66, 282 and accompanying text (noting that EPA has interpreted the Clean Air Act to preclude consideration of economic costs or technical feasibility but not to require a zero-risk standard).

[365] *See supra* Part II.A (highlighting EPA's reliance on its ad hoc judgments rather than a consistent set of principles to guide its NAAQS decision making).

Given this predicament, it is by no means surprising that the EPA's account of its recent NAAQS decisions has been so inconsistent.[366] At the core of EPA's position lies a fundamental inconsistency: The Agency rejects any need to achieve a level of zero risk, but the reason to reject a zero-risk approach is its complete infeasibility.[367] Thus, an important step toward achieving a more principled and consistent account of EPA's air quality standard would be to free the Agency from its conceptual straightjacket. As we show in the next

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[366] *See* SHRADER-FRECHETTE, *supra* note 310, at 182 (arguing that any stance that rejects "systematic risk decisions . . . leaves room for arbitrary, dishonest, purely political, or irrational hazard assessment").

[367] *See* John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 275 (1991) (noting the "difficulty of determining an appropriate nonabsolute level of safety in the absence of cost considerations"); Christopher H. Schroeder, *In the Regulation of Manmade Carcinogens, If Feasibility Analysis is the Answer, What is the Question?*, 88 MICH. L. REV. 1483, 1493 (1990) ("Any regulation short of the zero-risk paradigm depends upon there being some countervailing value, one that conflicts with pure [risk] prevention, that merits a role in policy formation."); Sunstein, *supra* note 18, at 378 ("[I]t is impossible to assess 'safety' in a cost vacuum."); *cf.* LON L. FULLER, THE MORALITY OF LAW 179 (1964) ("[P]roblems of weighing costs run throughout our legal and political life."). Even the decision to pursue an acceptable risk approach and to set that level at something above zero would seem implicitly to recognize the need to balance health protection with economic costs or other considerations. Of course, as Justice Breyer has pointed out, a concern for infeasibility need not be entirely unrelated to a concern for public health. Breyer conceded that eliminating all risk would be "impossible," but suggested that EPA could defend its rejection of a zero-risk approach on health considerations since "[p]reindustrial society was not a very healthy society . . . [and therefore] a standard demanding the return of the Stone Age would not prove 'requisite to protect the public health.'" Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 494, 496 (2001) (Breyer, J., concurring). EPA has not taken seriously the "minimize risk" approach suggested by Justice Breyer, *supra* note 320 and accompanying text, since adhering to such an approach would necessitate that EPA take into account the possible health effects associated with the costs its regulations impose on the economy. Since the Agency's position is that it does not take costs into consideration at all in setting air quality standards, then it cannot consider the possibility that "the economic cost of implementing a very stringent standard might produce health losses sufficient to offset the health gains achieved in cleaning the air." *Whitman*, 531 U.S. at 466. For discussions of the estimated health effects associated with the costs of regulation, see ROBERT W. HAHN ET AL., DO FEDERAL REGULATIONS REDUCE MORTALITY? 12-22 (2000); Frank B. Cross, *When Environmental Regulations Kill: The Role of Health/Health Analysis*, 22 ECOLOGY L.Q. 729, 772-84 (1995); Ralph L. Keeney, *Mortality Risks Induced by the Costs of Regulations*, 8 J. RISK & UNCERTAINTY 95, 97-109 (1994); Randall Lutter et al., *The Cost-Per-Life-Saved Cutoff for Safety-Enhancing Regulations*, 37 ECON. INQUIRY 599 (1999); Paul R. Portney & Robert N. Stavins, *Regulatory Review of Environmental Policy: The Potential Role of Health-Health Analysis*, 8 J. RISK & UNCERTAINTY 111, 115-19 (1994); W. Kip Viscusi, *Risk-Risk Analysis*, 8 J. RISK & UNCERTAINTY 5, 9-12 (1994); Ralph L. Keeney & Kenneth Green, Estimating Fatalities Induced by Economic Impacts of Ozone and Particulate Standards 6-11 (June 1997) (unpublished manuscript, on file with author), *available at* http://www.rppi.org/environment/ps225.html.

Section, EPA most certainly does consider feasibility and costs when setting its air quality standards, even though it claims otherwise. By acknowledging the fiction that its risk management decisions are made regardless of cost considerations, EPA could pave the way for a clear, systematic justification for its NAAQS decision making.[368]

B. *Abandoning the Fiction of Ignoring Costs*

The estimated costs of the recently revised ozone and particulate matter standards make them among the most expensive federal regulations ever promulgated in the history of the United States. EPA estimated that by 2010 the standards would impose incremental costs exceeding forty-five billion dollars per year[369]—an amount larger than the combined annual cost of all the other Clean Air Act regulations in

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[368] *See* Pierce, *supra* note 134, at 1255 ("I do not believe it is possible to make many regulatory decisions in a rational manner without considering costs in some way.").

[369] EPA estimated that the costs of full attainment of its revised ozone and particulate matter NAAQS would be about $47 billion per year ($9.6 billion for ozone and $37 billion for PM) by 2010. RIA, *supra* note 300, at 9-1. EPA was only able to identify technologies that could partially attain the ozone and PM standards; thus, it simply assumed that new technologies will be developed in the future that will enable full attainment of the two standards at a cost of $10,000 per ton. *Id.* at ES-9. Other cost estimates that relaxed this assumption and addressed technological change empirically were substantially higher. For example, the President's Council of Economic Advisors estimated that the costs of the ozone standard alone could approach $60 billion per year. *See* Peter Passell, *The Air Standards Are Set, but How Clean Is Clean Enough?*, N.Y. TIMES, July 3, 1997, at D2 (citing an estimate that meeting the ozone standard could cost $11 to $60 billion per year); *see also* RANDALL LUTTER, IS EPA'S OZONE STANDARD FEASIBLE? 11 (AEI-Brookings Joint Ctr. for Regulatory Studies, Regulatory Analysis 99-6 1999) (finding that compliance with EPA's ozone standard would be seven-fold more expensive than EPA estimated for most cities, and would be infeasible for one city), *available at* http://www.aei.brookings.org/admin/authorpdfs/page.php?id=93; ANNE E. SMITH ET AL., COSTS, ECONOMIC IMPACTS, AND BENEFITS OF EPA'S OZONE AND PARTICULATE STANDARDS 2 (Reason Pub. Pol'y Inst., Policy Study No. 226, 1997) (estimating that compliance costs will range from $20 billion to $60 billion per year for the ozone standard and $70 to $150 billion per year for the $PM_{2.5}$ standard), *available at* http://www.rppi.org/environment/ps226.html; Darrell A. Winner & Glen R. Cass, *Effect of Emissions Control on the Long-Term Frequency Distribution of Regional Ozone Concentrations*, 34 ENVTL. SCI. & TECH. 2612, 2617 (2000) (deducing that compliance with the new 0.08 ppm ozone standard would be physically impossible even with the most stringent emissions controls). Of course, some have hypothesized that as a general matter ex ante estimates of regulatory compliance costs may tend to be overstated to some extent. For a discussion of research on the accuracy of compliance cost predictions, see Cary Coglianese, *Empirical Analysis and Administrative Law*, 2002 ILL. L. REV. 1111, 1121-22; Richard B. Stewart, *A New Generation of Environmental Regulation?*, 29 CAP. U. L. REV. 21, 45-48 (2001).

effect at the time.[370] The high costs of the air quality standards might appear to support EPA's claim that it did not consider costs in setting the standards.[371] Yet, these high costs notwithstanding, it is widely acknowledged that the EPA does, and indeed must, consider costs when deciding where to set air quality standards.[372]

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[370] EPA has estimated annual costs of $19 billion (1990 dollars) resulting from all of the Clean Air Act's requirements during the period from 1990 to 2000, an analysis that excluded the costs of the recent ozone and particulate matter NAAQS revisions. EPA, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT 1990 TO 2010, at iii (1999), *available at* http://www.epa.gov/oar/sect812. In its retrospective study of the costs and benefits of the Clean Air Act from 1970 to 1990, EPA estimated the annual compliance costs associated with all its air pollution regulations ranged from $19.0 to $25.7 billion. EPA, FINAL REPORT TO CONGRESS *supra* note 354, at A-15.

[371] EPA, Supreme Court Respondents Brief, *supra* note 60, at 44 (asserting in a heading that "The Administrator Did Not Base Her NAAQS Decisions On Consideration Of Compliance Costs.").

[372] *See, e.g.*, Graham Testimony, *supra* note 116 ("When multi-billion dollar rulemaking decisions are made, it is inevitable that regulators will consider the consequences of their actions as well as the reasonableness of the relationship between risks, benefits and costs."); DAVID L. FAIGMAN, LEGAL ALCHEMY: THE USE AND MISUSE OF SCIENCE IN THE LAW 183 (1999) ("In practice, therefore, despite the legal technicality limiting EPA to promulgating regulations solely to promote health, costs are an integral part of the policy-making process at EPA."); LANDY ET AL., *supra* note 108, at 238 ("[I]n the absence of any threshold for risk, some balancing between costs and benefits had to be implicit in the standard setting decision—a reality EPA neither acknowledged nor forced the Congress to confront."); THOMAS O. MCGARITY, REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY 253 (1991) ("[EPA] has considered costs and benefits, and the advice that the Administrator receives orally from subordinates reflects those considerations."); MELNICK, *supra* note 155, at 297 ("Regulators inevitably consider cost [in setting air quality standards]. But presently they cannot explain how they do so."); David W. Barnes, *Back Door Cost-Benefit Analysis Under a Safety-First Clean Air Act*, 23 NAT. RES. J. 827, 856 (1983) (criticizing the "subterfuge of back door cost-benefit analysis" in setting clean air standards); George Eads, *The Confusion of Goals and Instruments: The Explicit Consideration of Cost in Setting National Ambient Air Quality Standards, in* TO BREATHE FREELY: RISK, CONSENT, AND AIR 222, 229 (Mary Gibson ed., 1985) (noting that it is a "policy fiction" that costs are not considered in setting NAAQS); Feller, *supra* note 127, at 833 ("If all costs were truly ignored, then no risk would be acceptable."); Barbara A. Finamore & Elizabeth E. Simpson, *Ambient Air Standards for Lead and Ozone: Scientific Problems and Economic Pressures*, 3 HARV. ENVTL. L. REV. 261, 274 (1979) ("[E]conomic pressures were obviously present and arguably influential in the formulation of the new ozone [1979] and lead [1978] standards."); C. Boyden Gray, *The Clean Air Act Under Regulatory Reform*, 11 TUL. ENVTL. L.J. 235, 235 (1998) ("The plain fact is that the EPA has for a long time considered costs and benefits in setting ambient standards—only it has done so behind closed doors . . . ."); James E. Krier, *On the Topology of Uniform Environmental Standards in a Federal System—and Why it Matters*, 54 MD. L. REV. 1226, 1231 n.12 (1995) ("Congress has nominally insisted that costs be ignored in setting most environmental standards . . . even though everyone knows this is a fiction."); Howard Latin, *Regulatory Failure, Administrative Incentives, and the New Clean Air Act*, 21 ENVTL. L. 1647, 1658 (1991) (observing "EPA's great reluctance to cause serious social dislocation, even if

EPA has certainly acknowledged the significant economic impacts of its NAAQS decisions.[373] Even the amicus briefs filed in favor of EPA in the recent NAAQS litigation admitted that the EPA Administrator "will naturally have before her information on the implementation of standards even as she sets them."[374] This awareness of the costs appears to have influenced the Agency's decision making by creating a reluctance to make standards too stringent, even when doing so would provide still greater public health protection.[375] After all, as Professor

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that result appears clearly mandated by the statute"); Gary E. Marchant, *Turning Two Blind Eyes: The EPA's Failure to Consider Costs and Health Disbenefits in Revising the Ozone Standard*, 11 TUL. ENVTL. L.J. 261, 268 (1998) (stating that EPA failed "to 'come clean' about the true nature of its decision-making"); Oren, *supra* note 18, at 10,662 ("EPA inevitably must therefore consider costs in standard-setting to help decide how stringent to make the standards."); Pierce, *supra* note 134, at 1239 ("[A]ll participants in this decision making process know [that] the EPA Administrator always considers costs when making decisions pursuant to [the Clean Air Act] section 109."); Pierce, *supra* note 18, at 85 ("I am confident that the EPA did, in fact, consider its CBA [cost-benefit analysis] of the ozone and particulate rules, notwithstanding its claims to the contrary."); Sunstein, *supra* note 18, at 308 ("There is reason to think that at least in some cases, an understanding of costs has affected EPA's decision about appropriate standards—but that the cost-benefit balancing has been left implicit and free from public scrutiny and review."); Sunstein, *supra* note 20, at 11 (noting "the apparent fact, urged by credible observers, that the EPA had in fact considered costs, although tacitly and without public supervision"); ALAN J. KRUPNICK & DEIRDRE FARRELL, SIX STEPS TO A HEALTHIER OZONE POLICY 6 (Resources for the Future, Discussion Paper 96-13, 1996) ("[C]osts must implicitly be playing a role."), *available at* http://www.rff.org/rff/Documents/RFF-DP-96-13.pdf. Without confronting either the academic record or the logical necessity of EPA at least implicitly considering costs in setting NAAQS, the Supreme Court dismissed the argument that EPA was "secretly considering the costs of attainment without telling anyone" as mere speculation. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 471 n.4 (2001).

[373] *See, e.g.*, EPA, 1993 Ozone Decision, *supra* note 192, at 13,013 (noting that "implementation of the NAAQS can have profound economic and social as well as environmental consequences"); EPA, 1979 Ozone Rule, *supra* note 196, 52 Fed. Reg. at 8213 (admitting that "controlling ozone to very low levels is a task that will have significant impact on economic and social activities"); Oren, *supra* note 18, at 10,662 (stating that "EPA decisionmakers have admitted that they examine cost data when deciding on the levels of the standards."). The estimated costs of the air quality standards have been included in the *Federal Register* notice signed by the Administrator. *See, e.g.*, EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,746 (showing estimates of NAAQS benefits and costs).

[374] Massachusetts and New Jersey Brief, *supra* note 161, at 44; *see also* MCGARITY, *supra* note 372, at 162 (noting that "[t]he artificiality of [EPA's] attempt to shield the decisionmaking process from analysis is apparent"); EPA, Douglas M. Costle: Oral History Interview, *at* http://www.epa.gov/history/publications/print/costle.htm (last updated June 10, 2002) (acknowledging that the former EPA Administrator considered costs in his decision-making process over the 1979 ozone NAAQS revisions).

[375] *See supra* Part II.B–C (indicating that EPA could have saved thousands of additional lives per year by setting more stringent standards).

Joseph Feller, a former EPA attorney, has noted, "[i]f all costs were truly ignored, then no risk would be acceptable."[376]

Even if the Administrator did not explicitly consider the cost estimates that EPA analysts had gone to great lengths to prepare, she and her staff could not have been unaware that the regulations EPA promulgated were among the most expensive ever adopted.[377] After all, an implicit recognition of cost considerations would seem to be the only way to explain EPA's new standard for fine PM.[378] The only apparent reason why EPA would accept thousands of additional predicted deaths per year was because of concern about the costs of tightening the standards even further,[379] which would have imposed unacceptable economic burdens on society.[380]

In explaining its decision to reject the tougher PM standard, EPA asserted that setting more stringent standards "*might* result in regulatory programs that go beyond those that are *needed* to effectively reduce risks to public health."[381] But under a precautionary approach that is supposed to "err on the side of safety," the mere possibility that

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[376] Feller, *supra* note 127, at 833; *see also* Eads, *supra* note 372, at 228 ("*No* level of ambient exposure above zero could be ruled out if consideration was given just to health effects.").

[377] Furthermore, the intensity of industry lobbying efforts undoubtedly signaled to EPA the economic impact at stake in its decisions. *See* Jason Scott Johnston, *A Game Theoretic Analysis of Alternative Institutions for Regulatory Cost-Benefit Analysis*, 150 U. PA. L. REV. 1343, 1353 (2002) (deploying a game-theoretic model to show that even where agency is precluded from taking costs into account, "the agency generally will internalize some of the compliance costs its regulation will impose" through the political process of rulemaking).

[378] *Supra* Part II.B.

[379] *See* Sunstein, *supra* note 18, at 317 n.51 ("EPA's failure to require more stringent regulation of particulates provides some evidence of cost consideration. On EPA's own numbers, more stringent regulation might have provided $4 billion in increased benefits . . . . If these benefits were possible, why did EPA not require greater stringency, if not because of some cost consciousness?").

[380] A recent New England Journal of Medicine editorial, which accompanied a review generally supportive of EPA's scientific analysis of $PM_{2.5}$, stated that significant further reductions in the 24-hour $PM_{2.5}$ standard would have been particularly burdensome, if not impossible. James H. Ware, *Particulate Air Pollution and Mortality—Clearing the Air*, 343 NEW ENG. J. MED. 1798 (2000). The article states that:

> The epidemiologic evidence suggests that the association between fine-particle concentrations and mortality is linear across the entire range of current concentrations. Although substantial reductions can be achieved at a reasonable cost, a reduction in 24-hour exposures to levels consistently below the current range would be prohibitively costly, if not impossible, in the foreseeable future.

Id. at 1799.

[381] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,675 (emphasis added).

a standard "might" exceed the level of health protection "needed" should not prevent the Agency from adopting it.[382] Indeed, by definition, erring on the side of safety would require going beyond what might appear to be needed.

EPA advanced a similar argument in its petition for rehearing in the D.C. Circuit, stating that section 109 requires that a NAAQS standard be set at a level "*necessary* for public health protection: neither *more* nor *less* stringent than necessary, but 'requisite.'"[383] Given that particulate matter appears to present a continuum of risk down to background levels (or at least to levels well below EPA's selected standard), it is far from clear how the Agency can show that its selected standard was neither more nor less stringent than necessary. Each increment of additional stringency will protect against some additional unit of risk (some perhaps unknown or uncertain). In the case of fine PM, additional stringency would have protected against additional human mortality predicted by the Agency's own risk assessment.[384] If standards are supposed to be set solely to protect public health, and if the Agency is supposed to be precautionary by erring on the side of safety, then it is not possible under EPA's risk model to have a PM standard that was too stringent.[385] Indeed, a more stringent standard would have been "necessary" to prevent the loss of thousands of additional lives, according to the Agency's own analysis.[386] When this evidence is taken into consideration, there is no escaping the conclusion that there must have been some other factor—presumably cost—that kept EPA from lowering the standard even further.[387]

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[382] *See supra* notes 194-95 and accompanying text (citing EPA's Supreme Court brief, which stated that the predominant purpose of its standards was to be preventative and precautionary).

[383] EPA, Petition for Rehearing, *supra* note 258, at 8.

[384] *Supra* Part II.B.

[385] In the case of non-threshold pollutants, where discernible harm to human health is believed to occur down to levels just above zero, then by definition no level can be said to be completely "safe," thus eliminating any room for erring on the side of safety. *See* Pierce, *supra* note 18, at 74 (describing non-threshold pollutants as having "no level at which [they] do not kill some people"); *supra* notes 128, 131-34 and accompanying text (discussing the policy implications of regulating non-threshold air pollutants).

[386] *See supra* text accompanying notes 209-17 (discussing how up to 860 additional lives in Philadelphia and 1080 lives in Los Angeles would have been saved with more stringent standards).

[387] As the National Academy of Sciences and National Academy of Engineering concluded in a 1974 report to Congress, in setting air quality standards "[t]here is no escape from a reasoned judgment, containing an unavoidable subjective element, as to the level at which the possible benefits from reducing pollution further no longer

Given that EPA almost certainly considers costs implicitly when determining the level of its standards, the question arises whether society would be better served if the Agency began to consider cost estimates explicitly.[388] Express consideration of cost data may provide important information that can be used to set standards that are more cost-effective without sacrificing health protection. This is because costs and benefits from air quality standards, like other regulatory standards, may exhibit discontinuities and nonlinearities that can only be discerned through careful analysis of cost functions. For example, EPA's draft Regulatory Impact Analysis (RIA) for ozone, published at the time of the Agency's proposed rule, indicated that an eight-hour ozone standard set at 0.08 ppm based on the fifth rather than the fourth highest annual concentration would provide roughly equivalent health protection but at approximately twenty percent lower cost.[389] This analysis suggests that there is a disconnect in the cost-effectiveness of tightening the standard from the fifth to the fourth highest annual concentration. Had EPA been able to consider this evidence openly and explicitly, the Administrator could have based the standard on the fifth highest annual concentration and saved the nation over $1 billion per year without sacrificing health protection.[390]

Such an open consideration of costs would not only likely ensure more cost-effective policy decisions, it would also better serve some of

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justify the high probable costs of bringing about such further reduction." NAS/NAE, *supra* note 132, at 18.

[388] *See* Barnes, *supra* note 372, at 857 ("Given the presence of a cost-minded administration, society might be better off with explicit cost-benefit analysis in setting the air quality standards from the start and abandoning as giving an inferior result the safety-first approach.").

[389] Partial attainment costs would decrease from $1.10 to $0.89 billion per year. RIA, *supra* note 300, at 7-12. EPA's analysis also indicates that there would be little, if any, health decrement in basing the standard on the fifth highest annual concentration. EPA calculated that total monetized health benefits would actually increase if the standard was based on the fifth rather than the fourth highest annual concentration under one method of controlling for $PM_{2.5}$ benefits, while slightly decreasing under an alternative method. *Id.* at 12-46; *see also* OZONE STAFF PAPER, *supra* note 163, at 212 ("Risk analyses . . . indicate that for most of the health endpoints analyzed there is little difference in health risk, at a given level of the standard, within the ranges of 1- to 5-expected-exceedances and the second to the fifth highest 8-hr daily maximum concentration forms of the O_3 primary standard.").

[390] EPA's RIA calculated the cost savings of a standard based on the fifth rather than the fourth highest annual concentration for partial attainment of the ozone standard, but not full attainment. But given that EPA estimated that the fifth highest concentration would save $0.2 billion of the $1.1 billion attainment costs, it would almost certainly save over $1 billion of EPA's estimated $9.6 billion full compliance estimates. RIA, *supra* note 300.

the core principles that undergird administrative law.[391] As John Graham has noted, EPA's "legal fiction" of not considering costs when setting NAAQS "reduces political accountability for value judgments and political choices, [and] hides from public scrutiny claims that are made about risks, benefits and costs (since such claims are driven 'underground' in the course of regulatory deliberations)."[392] Put more simply, as Professor David Faigman has recently argued, the "real loser in the PM/ozone drama was candor."[393] By framing the standard-setting decision as one for which costs cannot be taken into consideration, EPA, Congress, and the courts have endorsed a misleading and ultimately fictional basis for setting air quality standards.[394]

In testimony to Congress on the revised ozone and PM standards, EPA Administrator Carol Browner argued that "to allow costs and related factors to influence the determination of what levels protect public health would be to mislead the American public in a very

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[391] *See supra* notes 1, 5 and accompanying text (describing the fundamental principle of administrative law as reasoned decision making).

[392] Graham, *supra* note 116. Graham also writes that:

> Although regulators might prefer to pass the buck by hiding behind a cloak of quantitative risk assessment, it is important for a representative democracy to deliberate explicitly about the political aspects of chemical regulation. If regulators are not compelled to be explicit about the nature of their policy judgments, then it is unlikely that an informed public discussion of ethics and values will occur.

GRAHAM ET AL., *supra* note 89, at 198; *see also* Barton H. Thompson, Jr., *People or Prairie Chickens: The Uncertain Search for Optimal Biodiversity*, 51 STAN. L. REV. 1127, 1156 (1999) (concluding, in a related context, that "no one can argue that our current system of covert, indirect consideration of costs is better than open and direct consideration").

[393] FAIGMAN, *supra* note 372, at 187; *see also id.* ("The debate was phrased almost entirely in terms of science when the science played a decidedly minor role in the actual decision . . . . Science should not be used to hide what are essentially the true bases for decision.").

[394] *See* J. CLARENCE DAVIES & JAN MAZUREK, POLLUTION CONTROL IN THE UNITED STATES: EVALUATING THE SYSTEM 30 (1998) ("Statutory prohibitions of considering costs in setting environmental standards encourage dishonest, pseudoscientific debates that are really about policy choices (that is, who will we protect, and from what)."); LANDY ET AL., *supra* note 108, at 316 (lamenting that EPA has "sought refuge" in "the Clean Air Act's prohibition against using cost considerations to decide on standards" and that "[a]s a result the public often has an unrealistic picture of environmental uncertainty"); Eads, *supra* note 372, at 231 (noting that EPA's refusal to consider costs explicitly means that the public sees "only the shadow, not the substance" of EPA's decisions); Portney, *supra* note 166, at 77, 117 ("[I]t seems disingenuous to have a law that has been interpreted to prohibit costs from being considered in setting the NAAQSs when, in fact, virtually everyone knows that costs do—and should—get factored into decisionmaking anyway.").

fundamental way."[395] Yet, as we have indicated, when EPA considers costs at least implicitly in setting air quality standards, and then denies that it is doing so, it is actually the Agency's refusal or inability to reveal the full basis for its decision making that "misleads the American public."[396]

C. *Reforming EPA's Air Quality Risk Management*

What steps can be taken that might lead EPA to adopt a more candid and coherent account of its risk management decision making? One possible option would be to look to the courts, while another would be to encourage greater awareness of the limits of science in risk management by Agency scientists, policy advisors, and decision makers. As we discuss below, however, each of these options is unlikely to result in any real improvements in the foreseeable future given the prevailing construction of the Clean Air Act. Under the Supreme Court's interpretation of the Act, the Agency is essentially locked into an ad hoc approach to its standard setting.[397] We conclude that if the aspiration of well-reasoned agency decision making is

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[395] *Clean Air Act: Ozone and Particulate Matter Standards: Hearings Before the Subcomm. on Clean Air, Wetlands, Private Prop., and Nuclear Safety of the Senate Env't and Pub. Works Comm.*, 105th Cong. 282 (1997) (statement of Carol M. Browner, Administrator, EPA).

[396] It is not enough simply to say that EPA can always take costs into account when the states develop implementation plans seeking to bring their air quality into compliance with the national standards. *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 470 (2001) (suggesting that, by statute, the appropriate place to consider costs and feasibility is in the state implementation process). While there is nothing wrong with taking costs into account during implementation, the fact that costs can potentially be considered later does not resolve the core question of how EPA should set the national standards that the states must implement. Consideration of costs during implementation cannot provide a principled explanation for how EPA sets those standards, any more than the justice of a law imposing the death penalty for parking tickets can be established by pointing to the potential for jury nullification. Moreover, even if costs were considered during state implementation, this would at best only partially address the economic impacts of the standards, for the Clean Air Act requires the automatic application of certain regulatory requirements in nonattainment areas and states have no authority to grant exemptions from these requirements. *See supra* note 115 and accompanying text (noting that areas of the country failing to attain air quality standards are subject to more stringent regulations).

[397] Admittedly, even under the existing interpretation of the Clean Air Act, EPA could have improved the comparative coherence of its recent NAAQS revisions by opting to aim for a consistent level of residual risk (or a consistent level of health benefits). In other words, adhering to a predetermined level of risk could have reduced the incoherence between the ozone and PM standards. *Supra* Part II.D. This still would leave unanswered, however, how to justify the predetermined risk level (as opposed to other levels), a decision that would essentially remain ad hoc if costs or feasibility are not considered.

to become a reality for risk management of non-threshold air pollutants, Congress will need to step in to authorize and encourage EPA to break free from its current, incoherent approach. The Clean Air Act itself will need amendment if EPA is ever to pursue a principled approach to air quality standard setting.

Judicial review once would have been considered an option for encouraging EPA to adopt a more candid and consistent justification for its decision making. The availability of judicial review long has been viewed as a mechanism for ensuring that regulatory agencies provide reasoned explanations for their actions.[398] In judging agency decisions under the arbitrary and capricious standard of the Administrative Procedure Act,[399] courts are expected to make a "searching and careful" review of the agency record and to dismiss "post hoc rationalizations" offered by the agency.[400] The prevailing doctrine imposes a "strict and demanding requirement" on an administrative agency that it "must cogently explain why it has exercised its discretion in a given manner."[401] Moreover, even though many judges may lack the expertise to scrutinize scientific research, they should be able to determine where an agency's science ends and its policy reasoning needs to

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[398] *See, e.g.*, Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (applying the "arbitrary and capricious" standard and holding that the agency must "articulate a satisfactory explanation for its action"); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415-17 (1971) (subjecting administrative action to "a thorough, probing in-depth review" to ensure it is not arbitrary or capricious); Air Transp. Ass'n of Can. v. FAA, 254 F.3d 271, 279 (D.C. Cir. 2001) ("[W]ith its delicate balance of thorough record scrutiny and deference to agency expertise, judicial review can occur only when agencies explain their decisions with precision."); Am. Petroleum Inst. v. EPA, 216 F.3d 50, 58 (D.C. Cir. 2000) (holding that an EPA decision was arbitrary and capricious "because the agency failed to provide a rational explanation for its decision"); *see also* JERRY L. MASHAW, BUREAUCRATIC JUSTICE: MANAGING SOCIAL SECURITY DISABILITY CLAIMS 50 (1983) (observing that most of "administrative law has to do with judicial oversight of administrative rationality").

[399] 5 U.S.C. § 706(2)(A) (2000) ("The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . .").

[400] *Overton Park*, 401 U.S. at 416, 419.

[401] *State Farm*, 463 U.S. at 48; *see also* SEC. OF ADMIN. L. & REG. PRAC., AM. BAR ASS'N, THE ADMINISTRATIVE PROCEDURE ACT PROJECT: FINAL BLACK LETTER STATEMENT 23 (2001) (noting that courts may reverse an agency action when it "is unsupported by any explanation or rests upon reasoning that is seriously flawed" or where "[t]he action is, without legitimate reason and adequate explanation, inconsistent with prior agency policies or precedents") [hereinafter ABA, BLACK LETTER STATEMENT], *available at* http://www/abanet.org/adminlaw/apa/home.html.

begin, and, thus, compel the agency to justify its risk management choices with coherent reasoning.[402]

Although an entrenched doctrinal tradition in American administrative law requires agencies to give reasoned explanations,[403] there also exists an equally substantial tradition of judicial deference to agency action.[404] Notwithstanding widely held claims that judicial review under the arbitrary and capricious standard has ossified the rulemaking process, judges actually only review a small fraction of agency rules and, typically, defer to administrative agencies in conducting such review.[405] Moreover, even though the courts have

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[402] *See* ABA, BLACK LETTER STATEMENT, *supra* note 401, at 20 (noting that courts commonly "review agency findings that may be termed factual but actually embody a degree of normative judgment"); Bazelon, *supra* note 42, at 279 ("[A]t the interface of fact and value, courts can help ensure that the value component of decisions is explicitly acknowledged, not hidden in quasi-scientific jargon."). Wendy Wagner suggested an amendment to the Administrative Procedure Act requiring regulatory agencies to clearly demark scientific from policy judgments. *See* Wagner, *supra* note 11, at 1711 (suggesting that such an amendment would "correct the courts' current inclination to interpret the APA to require more, rather than less, quantitative and technical justifications"). While such an amendment might be helpful, it does not seem necessary, since a reviewing court presumably should be able to strike down a regulation as arbitrary and capricious if the agency misrepresents a policy decision as a scientific determination.

[403] This general administrative law tradition has been reflected in judicial decisions reviewing air quality standards. *See supra* note 5.

[404] *See, e.g.*, Natural Res. Def. Council v. EPA, 902 F.2d 962, 968, 973 (D.C. Cir. 1990) (stating that the court must "defer to the agency's interpretation of equivocal evidence, so long as it is reasonable," when reviewing predictions that are within the agency's area of expertise and at the frontiers of science); Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir. 1976) (characterizing the arbitrary and capricious standard of review as "a highly deferential one" that "presumes agency action to be valid").

[405] *See* Coglianese, *supra* note 369, at 1129 ("[I]t appears that judicial review blocks the EPA from taking action in only about 0.5% of all its rulemakings."). Overall, the D.C. Circuit upholds EPA rulemakings in their entirety almost as often as it finds even a single reason to remand the rule to the agency. *See* Cary Coglianese, *Assessing Consensus: The Promise and Performance of Negotiated Rulemaking*, 46 DUKE L.J. 1255, 1308-09 n.249 (1997) (noting that, from 1979 to 1990, EPA rules were affirmed in their entirety in fifty-one percent of the cases decided by the D.C. Circuit); Patricia M. Wald, *Regulation at Risk: Are Courts Part of the Solution or Most of the Problem?*, 67 S. CAL. L. REV. 621, 636-39 (1994) (reporting that agency rules were upheld in their entirety in over fifty percent of the cases decided by the D.C. Circuit during the 1992–1993 term). Moreover, these judicial remands do not appear to be too demanding, as EPA is usually able to take some action to see that its original decision is carried out. *See* William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393, 422-24 (2000) (finding that EPA was able to overcome twenty-seven of thirty-nine remands from the D.C. Circuit from 1985 to 1995 and concluding that judicial review causes "relatively little interference with agency attempts to achieve regulatory goals").

required agencies to give reasons for their regulatory actions, in practice this does not necessarily compel agencies to give sound or consistent reasons, even where judges purport to give them a "hard look."[406]

As the litigation over EPA's recent NAAQS revisions demonstrates, when it comes to reviewing decisions purportedly based on highly specialized scientific analysis, judges tend to give agencies a deferential pass. Particularly in rulemakings that generate a large volume of scientific analysis, agencies can readily appeal to the authority of scientific studies and can look for (and usually find) some pattern in the scientific evidence that appears to rationalize their decision. This rationalization holds even if in the next, similar rulemaking the pattern of the same kind of evidence aligns differently. By practicing this "science charade," agencies can escape the need to provide a consistent, reasoned account of the core policy issues imbedded in risk management.[407]

That is what happened, in the end, with EPA. Of course, in the initial round of litigation, Judge Stephen Williams recognized that EPA's emperor had no clothes. Despite a voluminous record of scientific analysis, all of which was reviewed by the Clean Air Science Advisory Committee, Judge Williams concluded that EPA had provided "no intelligible principle by which to identify a stopping point" for its air quality standards.[408] Unfortunately, Judge Williams's insight came accompanied with a novel constitutional argument that the Supreme Court quickly rejected, and that may have made the significance of his core observation easier to discount.

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[406] Offering "a reason" is not necessarily the same as offering "a good reason." For example, Frederick Schauer explains:

> [A] judge who says she has decided for the plaintiff because it is raining in Calcutta offers a reason . . . even though the reason, unconnected to any sound basis for decision, is a bad one. . . . [A]lthough it is a bad reason, it still exhibits the feature . . . of offering a justification or explanation for the result reached.

Frederick Schauer, *Giving Reasons*, 47 STAN. L. REV. 633, 636 (1995). EPA prepared lengthy documents that purported to offer a justification or explanation for its NAAQS, but because it has not adopted any principle with respect to the core policy issues, and because science by itself cannot address these issues, the agency's proffered explanation is akin to the judge deciding for the plaintiff "because it is raining in Calcutta."

[407] *See* Wagner, *supra* note 11, at 1664 (noting "the tendency of many courts to defer to the agency as expert when the issue is framed as scientific in nature").

[408] Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1037 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

The Supreme Court, in an opinion by Justice Antonin Scalia, interpreted the Clean Air Act in such a way as to preclude the administrator from considering costs.[409] The Court concluded that the Act directed EPA to use "information about health effects . . . to identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an 'adequate' margin of safety, and set the standard at that level."[410] The Court held that this prosaic understanding of the statute provided adequate guidance to sustain the constitutionality of the Clean Air Act. Dismissing concerns about the inability to take a principled health-only approach for non-threshold pollutants, the Court declared that it was simply "not conclusive for delegation purposes" that ozone and PM were non-threshold pollutants with health effects occurring at levels below EPA's promulgated standards.[411] With the Supreme Court effectively affirming the incoherent approach embedded in the longstanding interpretation of the Clean Air Act, it was not surprising that the D.C. Circuit, on remand, upheld EPA's revised standards under the arbitrary and capricious test and deferred ultimately to the agency's "expert judgment."[412] In the end, EPA prevailed and secured judicial approval for its explicitly ad hoc decision making.

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[409] *See Whitman*, 531 U.S. at 471 ("The text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the [Clean Air Act] as a whole, unambiguously bars cost considerations from the NAAQS-setting process . . . ."). In his concurrence, Justice Breyer drew extensively on the legislative history of the Clean Air Act to conclude that EPA may not consider technological or economic feasibility in setting NAAQS:

> [T]he legislative history shows that Congress intended the statute to be "technology forcing." Senator Edmund Muskie, the primary sponsor of the 1970 amendments to the Act, introduced them by saying that Congress' primary responsibility in drafting the Act was not "to be limited by what is or appears to be technologically or economically feasible," but "to establish what the public interest requires to protect the health of persons," even if that means that "*industries will be asked to do what seems to be impossible at the present time.*"

Id. at 490-91 (Breyer, J., concurring) (quoting 116 CONG. REC. 32, 901-02 (1970) (statement of Sen. Muskie))

[410] *Id.* at 465. Interestingly, this language by the Court indicates that EPA must take a "two-step" approach according to the statute in setting its air quality standards, first identifying a "safe" level and then adding an adequate margin of safety. In the past, EPA has expressly rejected any need to follow this "two-step" or any other consistent approach in setting its air quality standards. *See supra* text accompanying notes 186-90 (noting that EPA has continually refused to offer a policy justification in setting the margin of safety and instead has claimed that the administrator has sole discretion in determining how it is addressed).

[411] *Whitman*, 531 U.S. at 475.

[412] Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 373 (D.C. Cir. 2002). For a careful analysis of the Supreme Court's approach to statutory interpretation in *Whitman*, see

If judicial review no longer ensures coherent reasoning by EPA, another possible option would be for EPA professionals to commit themselves to candor about the role and limits of science in making risk management decisions. The Agency has, after all, recently initiated several efforts to improve its scientific analysis.[413] In particular, EPA has made reliance on "sound science" one of its agency-wide strategic goals,[414] creating an office of science advisor[415] and taking steps to ensure that its analysis meets the standards for reliable scientific evidence provided in the Information Quality Act.[416] These efforts to improve the quality of agency science are certainly important in their own right, but by themselves are insufficient to prevent future attempts to stretch the limits of what science can bear.[417] Indeed, calls for a "science-based" approach to risk regulation, however warranted, may mistakenly reinforce the tendency of EPA and other agencies to cloak their policy decisions in scientific terms.[418] What the Agency

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Pierce, *supra* note 134, at 1251 ("[T]he Court seemed to announce and to apply a new canon that is inherently inconsistent with all of the pre-existing law applicable to interpretation of agency-administered regulatory statutes.").

[413] For a discussion of the need to improve scientific analysis and its role within EPA decision making, see E. Donald Elliott et al., *Science, Agencies, and the Courts: Is Three a Crowd?*, 31 Envtl. L. Rep. (Envtl. L. Inst.) 10,125, 10,125-128 (Jan. 2001).

[414] EPA, FY 2003 ANNUAL PERFORMANCE PLAN, at VIII-1 (2002), *at* http://www.epa.gov/ocfo/budget/2003/2003ap/2003ap.htm.

[415] *See* Press Release, EPA, Whitman Appoints Gilman Science Advisor (June 2002) (quoting Administrator Whitman as directing the EPA Science Advisor to "ensure that the highest quality science is better integrated into the Agency's programs, policies and decisions"), *available at* http://www.epa.gov/ord/htm/sci-advi.htm.

[416] Pub. L. No. 106-554, § 515, 114 Stat. 2763A-154 (2001); *see also* OFFICE OF ENVTL. INFO., EPA, NO. EPA/260R-02-008, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY 4 (2002) ("Our Guidelines reflect EPA's best effort to present our goals and commitments for ensuring and maximizing the quality of information we disseminate. . . . EPA's intention is to fully implement these Guidelines in order to achieve the purposes of Section 515."), *available at* http://www.epa.gov/oei/qualityguidelines/EPA-OEI-IQG-FINAL-10.2.pdf.

[417] That said, one recent proposal for improving the use of science at EPA would encourage science advisors to make explicit policy recommendations, under the theory that allowing scientists to express policy advice openly might discourage disingenuousness. E. Donald Elliott, *Strengthening Science's Voice at EPA*, 66 LAW & CONTEMP. PROBS. 45 (2003). Elliott argues that "[i]f told that it is improper to make policy recommendations, scientific groups are much more likely to smuggle in their policy predilections covertly, either consciously or unconsciously." *Id.* at 58. He believes "[w]e would be far better advised to invite scientific advisory bodies to *separate* their scientific conclusions from their policy recommendations, and to empower them to address both." *Id.*

[418] *See, e.g.*, Press Release, Office of Management and Budget, OMB Announces Science-Based Regulatory Review Framework (Sept. 25, 2001) (calling for "high-quality

needs is not only "sound science," but also sound policy reasoning regarding its risk management decisions.[419] Part of the mandate of the new science advisor should include a duty to notify the Administrator when the Agency is overemphasizing the role of science in justifying its policy recommendations.

Even with better and more circumspect scientific advice, however, the Agency still may shirk from providing consistent reasons for its risk management decisions. After all, EPA already had the benefit of science advisors who explained that the choice of where to set its new air quality standards was not a question that science could answer.[420] CASAC clearly explained to the Administrator that the decision about what alternative NAAQS standard it selected was a "policy judgment."[421] In other recent regulatory proceedings, EPA's science advisory committees have pointed out the limitations of science within regulatory decision making, specifically warning EPA when it was overrelying on science.[422] Notwithstanding the sound advice it has

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cost-benefit analyses, science-based risk assessments, peer review, consultation with state and local governments, and specific consideration of the welfare of small businesses"), *available at* http://www.whitehouse.gov/omb/pubpress/2001-38.html. Even though those who call for a "science-based" approach to regulation generally mean to increase the rigor and reliability of scientific research that forms the basis of agency risk assessments (surely a noteworthy aim), such calls may unintentionally increase the incentives for couching policy decisions in terms of "listening to the science." *See supra* Part I.A (describing the rhetorical use of science to hide arbitrary policy decisions); *see also* Kunreuther & Slovic, *supra* note 108, at 123 ("[T]echnical analysis is vital for making risk decisions better informed, more consistent, and more accountable. However, value conflicts and pervasive distrust in risk management cannot be reduced by technical analysis. Trying to address risk controversies with more science, in fact, is likely to exacerbate conflict.").

[419] *See supra* Part III.A (detailing a more principled approach to justifying risk management decisions). In setting environmental standards, "[v]alue judgments must be made about how much health protection is feasible and affordable and who should pay the costs of cleanup." John D. Graham, *Science and Environmental Regulation, in* HARNESSING SCIENCE FOR ENVIRONMENTAL REGULATION 1, 2 (John D. Graham ed., 1991). Making these judgments requires hard thinking about risk management principles, even more than perfecting scientific techniques. Obviously, the Agency needs to invest in both.

[420] *See supra* notes 143-45, 179, 297 and accompanying text (detailing CASAC's repeated statements that the setting of the NAAQS standards was a policy judgment rather than a scientific determination).

[421] Wolff, *supra* note 139, at 2.

[422] For example, in commenting on EPA's proposed methodology for setting "residual risk" standards for hazardous air pollutants, the Interim Chair of EPA's Scientific Advisory Board (SAB) advised the Administrator on behalf of the SAB Executive Committee that "while we certainly endorse the concept of science-based decisionmaking at the Agency, we also recognize that no one is well served by asking science to take on an impossible task." Letter from Dr. Morton Lippmann, Interim Chairman, EPA

received about the limits of science, EPA has continued to use science as a fig leaf for its policy choices.[423]

If neither science advisors nor judicial overseers can ensure that EPA will strive for principled, risk management decision making, perhaps we should simply accept that EPA will set its standards in an ad hoc manner and take steps to enhance the democratic basis for the policy choices embedded in the Agency's risk management.[424] After all, even if it makes sense to delegate to agencies on issues requiring scientific expertise, it is much harder to claim that agencies like EPA possess comparable expertise in making social policy judgments, such as determining an acceptable level of risk. Consequently, even if agency expertise is needed to assess and characterize risks, the policy judgments embedded within any risk management decision arguably should be made by a more democratically accountable decision maker or through more direct democratic means.[425] Dean Elena Kagan, for example, has argued that the President should play a greater role in regulatory decision making because agencies do not possess any special expertise to make value judgments and the President is more directly accountable to the citizenry.[426]

While there is much to the idea of holding regulatory agencies more accountable to elected officials, that position only makes it more

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Science Advisory Board, to Carol M. Browner, Administrator, EPA 2 (July 25, 2000), *available at* http://www.epa.gov/sab/pdf/eccm005.pdf.

[423] Wagner, *supra* note 11, at 1617 ("[A]gencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions.").

[424] *See, e.g.*, Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1698 (1975) (theorizing that a major thrust of contemporary administrative law in the United States has been to foster a more pluralistic and transparent process by which agencies develop regulations).

[425] For the standard exposition of this general argument, see THEODORE J. LOWI, THE END OF LIBERALISM: THE SECOND REPUBLIC OF THE UNITED STATES (2d ed. 1979). *But see* Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 95-99 (1985) (arguing that executive branch agencies should be given more power in deference to the electorate's choice in electing the president).

[426] *See* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2353 (2001) ("[A]gency experts have neither democratic warrant nor special competence to make the value judgments—the essentially political choices—that underlie most administrative policymaking."). Reliance on political intervention as a reason for administrative policymaking would represent a shift in the traditional direction of administrative law, which has generally favored independent reasoning by agency decision makers. *See* Mashaw, *supra* note 1, at 21 ("[A] retreat to political will or intuition is almost always unavailable to modern American administrative decisionmakers. The electoral connection is generally unavailable as a justification for administrative action.").

important that agencies respect the limits of science in setting risk standards. After all, even those who favor greater involvement by the President or Congress in regulatory decision making acknowledge a need for relying on agency expertise, particularly on scientific questions.[427] As Dean Kagan writes, "there is no good reason for a President to displace or ignore purely scientific determinations" because "[t]he exercise of presidential power in this context would threaten a kind of impartiality and objectivity in decisionmaking that conduces to both the effectiveness and the legitimacy of the administrative process."[428] As a result, rather than curing the problems with how EPA set its recent air quality standards, any argument for improving the democratic basis for the policy choices in risk management actually makes it all the more imperative that regulatory agencies openly acknowledge science's limits.[429] Using science to justify nonscientific decisions only serves to shield agency decision making from the political institutions that oversee the agency.[430]

Given how EPA has proceeded in its NAAQS rulemakings, citizens are left with a fundamental question unanswered: What justifies the revisions of the ozone and PM standards?[431] Those who will continue

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[427] *See* Kagan, *supra* note 426, at 2353 ("However much political judgment pervades administration and however much political actors should take the lead as to these questions, an important place for substantive expertise remains in generating sound regulatory decisions.").

[428] *Id.* at 2357.

[429] *See id.* at 2332 ("[T]he need for transparency, as an aid to holding governmental decisionmakers to account, here reaches its apex."); *see also* GRAHAM ET AL., *supra* note 89, at 218 ("[S]cience cannot answer the ultimate regulatory questions . . . . Only by recognizing the limited role of science as resolver of conflict can [the policy considerations underlying regulatory decisions] be addressed explicitly and democratically.").

[430] *See* Wagner, *supra* note 11, at 1617 ("Although camouflaging controversial policy decisions as science assists the agency in evading various political, legal, and institutional forces, doing so ultimately delays and distorts the standard-setting mission, leaving in its wake a dysfunctional regulatory program.").

[431] *See* SUNSTEIN, *supra* note 335, at 240-41 ("The EPA's own public justification was . . . in important respects vague and conclusory . . . . Hence any reader is likely to be puzzled about exactly why EPA chose the particular regulations it did—about why it did not regulate either somewhat more or somewhat less."). Dean Kagan argues that sometimes presidential intervention should count as an answer to a question such as this one. Kagan, *supra* note 426, at 2382. In the case of EPA's NAAQS revisions, even that answer was not offered and instead the Agency sought to shield itself within the cloak of science. *Supra* Part I.A. It is not clear, furthermore, whether the President would have intervened to make the critical policy decision. *See* Kagan, *supra* note 426, at 2356-57 (noting President Clinton's "frequent practice of sidestepping involvement" in cases where regulators would "confront the question, which science alone cannot

to suffer from environmentally induced respiratory problems or whose family members will die prematurely due to the levels of pollution permitted under EPA's standards are entitled to a coherent reason why the Agency did not set lower standards in the face of evidence of remaining health effects.[432] Similarly, those who lose out on jobs or forego an increased standard of living as the result of the high costs of the revised standards can also reasonably demand a clear and candid explanation.[433] Yet right now, EPA cannot say anything sensible to those who will be affected by its air quality standards. The Agency is locked into a fictional framework that presumes that pollutants have clear threshold health effects (which they do not) and that costs can be ignored (which they cannot).[434] The law now prohibits the Agency from clearly explaining why it draws the line where it does.

How can EPA achieve greater candor and consistency in its NAAQS rulemakings? Given the prevailing legal structure as well as the incentives agencies have to hide behind the perceived objectivity of science, it seems unlikely that improvements will result from anything other than legislative change.[435] Since EPA does not have a strong incentive to abandon its scientific rhetoric and articulate policy principles, legislative change must do more than simply reject the current interpretation of section 109. It seems unlikely that EPA would take up such an initiative on its own accord, so legislative amendments are needed to spur meaningful change. Such amendments must either provide EPA with a preferred policy approach, such

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answer, of how to make determinate judgments regarding the protection of health and safety in the face both of scientific uncertainty and competing political interests").

[432] *See* Daniel A. Farber, *Risk Regulation in Perspective:* Reserve Mining *Revisited*, 21 ENVTL. L. 1321, 1340 (1991) ("When the decision is being made by an administrator or a judge, we would like to have a little more guidance than simply the decision maker's gut reaction. Too many different kinds of people get jobs as administrators and judges for us to simply trust their intuitions.").

[433] SUNSTEIN, *supra* note 335, at 7-8 ("When the costs of regulation are high, real people will be hurt, through increased prices, decreased wages, and even greater unemployment . . . . [T]he costs should be placed 'on-screen,' so that if they are to be incurred, it is with knowledge and approval rather than ignorance and wishful thinking.").

[434] *See supra* notes 133-36, 166, 368 and accompanying text and Part III.B (discussing the lack of threshold levels in the health effects of pollutants to air and the necessity of considering costs when setting air quality standards).

[435] *See* Wagner, *supra* note 11, at 1651 (arguing that without some external mandate "no rational agency or administrative official acting in her own self-interest would expose the underlying policy choices when faced with the numerous benefits of engaging in the science charade and the high price to be paid for proceeding any other way").

as by directing the Agency to balance benefits and costs, or by imposing a mandate on the Agency to articulate a principle to explain its NAAQS decision making.

Legislative change will not come easily, to be sure, but it may become more viable when the absurdity of the Clean Air Act's outmoded legislative model becomes still clearer to those across the political spectrum. This was the case with the Delaney Clause, which Congress amended after many years, once the Act was interpreted to require the elimination of all cancer risks from pesticide residues in food.[436] If the Clean Air Act follows a course similar to that taken with the Delaney Clause, then ever-advancing knowledge about the adverse effects from still lower levels of air pollutants may force EPA and Congress to confront the absurdity of the current interpretation of the Clean Air Act. For example, the recent identification of genetic susceptibilities to pollutants such as particulate matter and ozone may well heighten the demand under the existing statutory framework to set even more

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[436] The Delaney Clause, adopted in the late 1950s, required agencies to prohibit all carcinogens in food additives. Food Additives Amendment of 1958, 21 U.S.C. § 348(c)(3)(A) (2000). For decades, EPA and the Food and Drug Administration attempted to evade the harsh and unrealistic absolutism of the Delaney Clause by applying various exceptions and limitations. *See* Edward Dunkelberger & Richard A. Merrill, *The Delaney Paradox Reexamined: Regulating Pesticides in Processed Foods*, 48 FOOD & DRUG L.J. 411, 416-18 (1993) (describing EPA's efforts to ameliorate the extreme effects of a strict interpretation of the Delaney Clause, including a short-lived effort to establish a de minimus exception); Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 YALE J. ON REG. 1, 21-41 (1988) (describing how, by circumscribing and reinterpreting the statute in a number of instances, the "FDA chipped away at the edges of the Delaney Clause"). Once the courts confirmed that the Delaney Clause would require zero-risk standards that would impose unacceptable burdens on society, Congress stepped in to amend the food safety laws. *See, e.g.*, Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (legislating additive and pesticide levels in food and applying a "reasonable certainty" standard instead of the Delaney Clause's zero tolerance policy); Les v. Reilly, 968 F.2d 985, 990 (9th Cir. 1992) (rejecting the Agency's interpretation of the Delaney Clause intended "to bring about a more sensible application of the regulatory scheme" because "[r]evising the existing statutory scheme . . . is neither our function nor the function of the EPA"); James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENVTL. L.J. 273, 289-333 (1998) (detailing the repeated congressional attempts to legislate around the strict prohibitions of the Delaney Clause, culminating with the passage of the Food Quality Protection Act in 1996). *But see* James S. Turner, *Delaney Lives! Reports of Delaney's Death Are Greatly Exaggerated*, 28 Envtl. L. Rep. (Envtl. L. Inst.) 10,003, 10,004 (Jan. 1998) (arguing that the Food Quality Protection Act of 1996 "neither removes the protections provided by the Delaney Clause prohibition against adding cancer-causing substances to food nor reflects a public policy rationale or political consensus to do so").

stringent standards.[437] As scientific research continues to document the public health effects that EPA already acknowledges still exist under its revised standards, the pressures to lower air quality standards ever closer to zero will persist and likely increase over time, as will, of course, the costs for complying with more stringent standards. Perhaps fortunately, at least for those who value reason and candor in governmental policymaking, this dynamic will most likely result, eventually, in a broader recognition of the need for statutory reform. If this is correct, then perhaps it is only a matter of time before Congress steps in and adopts a more realistic legislative approach that will bring clarity to this important domain of risk management.

CONCLUSION

The recent revisions to the ozone and PM standards confirm what has been widely known since at least the mid-1970s, namely that section 109 of the Clean Air Act is unrealistic.[438] As scientific knowledge has expanded, health risks have been identified at decreasing levels of exposure. In light of this evolving evidence, it is no longer possible to

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[437] *See generally* GEORGE D. LEIKAUF ET AL., HEALTH EFFECT INST., RESEARCH REPORT NO. 105, PATHOGENOMIC MECHANISMS FOR PARTICULATE MATTER INDUCTION OF ACUTE LUNG INJURY AND INFLAMMATION IN MICE (2001) (reporting that genetic factors contributed to the response of mice to inhaled nickel particles); Enrico Bergamaschi et al., *Polymorphism of Quinone-metabolizing Enzymes and Susceptibility to Ozone-induced Acute Effects*, 163 AM. J. RESPIRATORY CRITICAL CARE MED. 1426 (2001) (demonstrating a link between human genotype and lung function after ozone exposure); Steven R. Kleeberger et al., *Linkage Analysis of Susceptibility to Ozone-Induced Lung Inflammation in Inbred Mice*, 17 NATURE GENETICS 475 (1997) (finding a genetic factor that increased susceptibility to lung damage brought on by ozone exposure); William F. McDonnell, *Individual Variability in Human Lung Function Responses to Ozone Exposure*, 2 ENVTL. TOXICOLOGY PHARMACOLOGY 171, 175 (1996) (finding widespread interindividual variation in response to ozone exposure and speculating that genetic factors may explain some of this variation); Yoshinori Ohtsuka et al., *Genetic Linkage Analysis of Susceptibility to Particle Exposure in Mice*, 22 AM. J. RESPIRATORY CELL & MOLECULAR BIOLOGY 574 (2000) (identifying a genetic trait in mice linked with increased susceptibility to immune dysfunction induced by particulate exposure). As the susceptible subgroups carrying these genetic variants become better characterized, EPA will likely be confronted with an even clearer choice to either set more stringent standards to protect such sensitive subgroups, perhaps even adopting standards approaching zero, or to recognize that other factors such as cost need to be taken into consideration in providing a rationale for decisions about standards set at levels above zero. Gary E. Marchant, *Genomics and Toxic Substances: Part II—Genetic Susceptibility to Environmental Agents*, 33 Envtl. L. Reptr. (Envtl. L. Inst.) 10641, 10656 (Sept. 2003).

[438] *See supra* notes 147-52 and accompanying text (noting that even members of Congress have acknowledged the disingenuousness of the Clean Air Act's framework during past deliberations over legislative amendments).

select a standard that protects the public health, with an adequate margin of safety, from all the adverse effects of non-threshold pollutants, at least not without imposing dire economic costs on the nation.[439] As a practical matter, EPA has had little choice but to disregard evidence about substantial adverse effects on a public whose health the Agency is directed by law to protect.

But EPA has been neither candid nor consistent about the policy choices it has made in revising the nation's air quality standards. The Agency has so far succeeded in shielding its policy decisions behind the language of science and expertise, but it has done so at the expense of consistent and principled public management. These consequences are the less widely acknowledged, but no less significant, lessons to be drawn from EPA's recent experience in revising its air quality standards. Although these rulemakings will likely be remembered for the vigorous arguments that they engendered about the nondelegation doctrine,[440] the more enduring and significant lesson for administrative law concerns the limitations of science in justifying risk management decisions. When agencies rely on science to explain the policy decisions they make, they not only escape their duty to provide a principled account of their decision making, but they also can find themselves submitting to expediency and post hoc rationalization in their efforts to defend their actions.

Examination of the ozone and particulate matter rulemakings reveals that EPA's invocation of science enabled it to ignore numerous inconsistent positions and incoherent results. The same kind of scientific evidence that EPA relied on to tighten its standards also indicated that significant adverse effects—including, in the case of fine PM, substantial mortality—would persist even at the levels of exposure permitted by the revised standards.[441] EPA failed to offer any meaningful rationale to justify both the enormous costs of these rules and the significant adverse effects that they still permit. Without any justification, EPA adopted positions in these rulemakings that shifted from

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[439] *See supra* notes 166, 317 and accompanying text (illustrating the impossibility of eliminating all risks associated with exposure to non-threshold pollutants, short of setting a standard at zero).

[440] *See, e.g.*, Coglianese, *supra* note 18, at 33-35 (noting the tendency of courts and commentators to focus on the constitutional issues raised in the litigation over EPA's revised standards).

[441] *Supra* Part II.B-C.

earlier positions the Agency had taken—both in other NAAQS rulemakings as well as even earlier in these same proceedings.[442]

We have argued that the courts' acceptance of a dysfunctional legislative framework means that to achieve greater consistency in setting air quality standards, Congress must compel EPA to come clean about what science can and cannot say and about what policy principles justify its standards. The Agency cannot simply "listen to the science" to tell it how to make policy choices about how many adverse health effects or how much regulatory cost should be tolerated in society. Risk management calls for value judgments about which it is both possible and desirable for public officials to defend through policy analysis and normative reasoning.[443]

It will probably take new legislation before EPA will begin to adopt a more principled approach to setting air quality standards, but the lessons from the recent experience need not await future legislation to be applied in other contexts. Whenever policymakers find themselves tempted to "listen to the science," they should be careful to consider what science really can and cannot tell them. Embedded within any bare claim that a policy decision is "based on" science, or that science "leads to" a particular policy choice, will be some underlying normative position.[444] If the core normative dimension to any policy decision is camouflaged in science, the resulting policy outcomes, as well as any explanations or rationalizations offered in their defense, will likely be inconsistent if not unreasonable. To be sure, high-quality scientific analysis is vitally needed to inform decision makers about policy problems and to predict the consequences of different solutions, but appeals to science are no substitute for clear and careful reasoning about the normative choices inherent in public policymaking.

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[442] *See supra* Part II (exposing EPA's "veil of science" in its decision making).

[443] *See* Brown, *supra* note 36, at 338 ("The attempt to expunge values is not only doomed to failure or partiality but is harmful to the objectivity and usefulness of the resulting endeavor."); Mashaw, *supra* note 1, at 26 ("'Expertise is no longer a protective shield to be worn like a sacred vestment. It is a competence to be demonstrated by cogent reason-giving.").

[444] *See* Mashaw, *supra* note 1, at 32-33 ("Administrators by and large claim not to be making value judgments . . . . But we know this administrative claim to be hollow.").