Science and Policy in Setting National Ambient Air Quality Standards: Resolving the Ozone Enigma

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I. Introduction

The elusive interaction between science and policy has dominated risk-based standard setting since the dawn of the environmental era. This is attributable in part to the fact that the regulatory agencies operate on the frontiers of scientific knowledge and in part to Congress's choice of vague language to describe the level of expected protection. This interaction is especially apparent in the Environmental Protection Agency's (EPA's) efforts to promulgate and revise national ambient air quality standards (NAAQS) under § 109 of the Clean Air Act—where the EPA has navigated the boundaries between science and policy in ways that sometimes appear arbitrary or inconsistent to outside observers. The history of the EPA's most recent revision and attempted rerevision of the primary NAAQS for photochemical oxidants (ozone), in which two EPA Administrators from different political parties reached different conclusions on the same administrative record, offers a unique perspective on the roles of science and policy in environmental decision making.

Drawing on the ozone "rulemakings" as a case study, this Article will explore how science and policy interact in promulgating NAAQS. After providing an introduction to the NAAQS standard-setting process in Part II, Parts III and IV describe the EPA's 2008 revision to the ozone NAAQS and its reconsideration of the 2008 standard in 2009 through 2011. Part V then draws on the case study and the relevant academic literature to explore the roles of science and policy in environmental decision making. Part VI examines the critical question of what policy should guide the EPA's resolution of science–policy questions in NAAQS standard setting. Part VI also addresses arguments that the EPA's approach to NAAQS standard setting is incoherent because it does not provide a rational approach to determining how much risk is too much in the context of nonthreshold pollutants like ozone. This Article concludes that the EPA's traditional approach to NAAQS standard setting is neither incoherent nor irrational, and it is easily adaptable to nonthreshold pollutants.

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II. Promulgating and Revising Ambient Air Quality Standards Under the Clean Air Act

The Clean Air Act requires the EPA to promulgate and periodically revise national primary and secondary ambient air quality standards for "criteria" pollutants that may reasonably be anticipated to endanger public health or welfare and that derive from numerous or diverse mobile or stationary sources.[1] For each of the criteria pollutants, the Agency must first prepare a "criteria document" (now called an "integrated science assessment" (ISA)) that "accurately reflect[s] the latest scientific knowledge" on the health effects of the pollutant.[2] It then establishes "primary" NAAQS for each pollutant at a level that is "requisite to protect the public health" while "allowing an adequate margin of safety."[3] The legislative history of the statute makes it clear that the goal of the primary standards is to ensure "an absence of adverse effect on the health of a statistically related sample of persons in sensitive groups . . . ."[4] The statute directs the Agency to conduct a "thorough review" of the existing criteria document every five years and, if necessary, revise the document and the corresponding standards to reflect scientific information that has become available since the last revision.[5] To assist the Administrator in her assessment of the scientific evidence, the statute creates an independent seven-member Clean Air Scientific Advisory Committee (CASAC).[6]

The Supreme Court elaborated on the roles of cost, risk, and uncertainty when it reviewed the 1997 revisions of the ozone and particulate-matter standards in the seminal case of *Whitman v. American Trucking Assn's*.[7] The Court carefully interpreted that section's operative phrases, "requisite to protect the public health" and "adequate margin of safety," to conclude that the statute "unambiguously bars cost considerations from the NAAQS-setting process . . . ."[8] In particular, the words "requisite" and

1. 42 U.S.C. § 7408(a) (2012). This Article will focus exclusively on the primary NAAQS for ozone. Similar science–policy issues attend the EPA's promulgation and revision of the secondary NAAQS for ozone and the NAAQS for other criteria pollutants.

2. *Id.* § 7408(a)(2). *See also* U.S. ENVTL. PROT. AGENCY, REVIEW OF THE PROCESS FOR SETTING NATIONAL AMBIENT AIR QUALITY STANDARDS, at E-1 (2006) (referring to the EPA's science-assessment documents for NAAQS review as "[c]riteria [d]ocuments").

3. § 7409(b)(1).

4. SENATE COMM. ON PUB. WORKS, NATIONAL AIR QUALITY STANDARDS ACT OF 1970, S. REP. NO. 91-1196, at 10 (1970). *See also* Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 524–25 (D.C. Cir. 2009) (per curiam) (quoting Am. Lung Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998)) (discussing the legislatively imposed requirement that the EPA consider how the primary standard affects "sensitive citizens" in addition to "healthy individuals").

5. § 7409(d)(1).

6. § 7409(d)(2); U.S. ENVTL. PROT. AGENCY, CHARTER OF THE CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE (2013).

7. 531 U.S. 457, 466 (2001).

8. *Id.* at 471–72.

"adequate margin" did not "leave room to pad health effects with cost concerns."[9] The Court accepted the Solicitor General's definition of "requisite" as "sufficient, but not more than necessary."[10] Thus, the EPA had to establish NAAQS at a level that was "not lower or higher than is necessary—to protect the public health with an adequate margin of safety . . . ."[11]

III. The George W. Bush Administration Ozone NAAQS Revision

The EPA revised the primary NAAQS for ozone in late 1997 by changing the averaging period from the original one hour to eight hours, and it lowered the level from 0.12 parts per million (ppm) to 0.08 ppm.[12] The standard was still in limbo at the end of the Clinton Administration, however, because of pending legal challenges.[13] Since the agency had a statutory duty to revisit the standard every five years, it was already in the process of revising the 1997 standard before it went into effect.[14]

A. The Criteria Document

The criteria document that the EPA published in February 2006 summarized and evaluated the relevant scientific information that had become available since 1996.[15] The document concluded that controlled human studies (often called clinical studies) and animal studies provided "clear evidence of causality" for associations "between [acute ozone] exposure and relatively small, but statistically significant *declines in lung function* observed in numerous recent epidemiologic studies."[16] Two very recent clinical studies, conducted by Dr. William Adams of the University of California at Davis, found significant lung-function decrement in human subjects exposed to 0.080 ppm but no significant differences between exposed and unexposed subjects at 0.040 ppm and 0.060 ppm.[17] Other controlled human studies demonstrated that healthy young adults exposed to 0.080 ppm for six to eight hours during moderate exercise experienced

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9. *Id.* at 468.

10. *Id.* at 473.

11. *Id.* at 475–76.

12. National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856 (July 18, 1997) (to be codified at 40 C.F.R. pt. 50). The form for the standard was also changed to employ an eight-hour averaging period. *Id.* at 38,885.

13. *Am. Trucking Ass'ns*, 531 U.S. at 486.

14. 42 U.S.C. § 7409(d)(1) (2012).

15. 1 U.S. ENVTL. PROT. AGENCY, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS I–iii (2006).

16. *Id.* at E-13 (emphasis added).

17. *Id.* at 6-10; U.S. ENVTL. PROT. AGENCY, RESPONSES TO SIGNIFICANT COMMENTS ON THE 2007 PROPOSED RULE ON THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE 97 (2008) [hereinafter RESPONSES TO SIGNIFICANT COMMENTS].

the *respiratory symptoms* of coughing and acute pain when breathing deeply.[18] This was consistent with epidemiological studies demonstrating significant associations between exposure to ambient ozone and a variety of respiratory symptoms.[19] Although *airway hyperresponsiveness* had not been widely studied in epidemiological investigations, the controlled human studies and animal studies "clearly indicat[ed]" that ozone exposure could induce that symptom.[20] Many recent epidemiological studies supported the conclusion that ozone exposure was associated with respiratory *hospitalizations and emergency department visits* during the warm season (April through October) when ozone levels were typically the highest, but not necessarily during the cool season.[21]

The most controversial issue was whether short-term ozone exposure was associated with *increased mortality* rates. A number of mortality studies had appeared in the literature since 1996,[22] and most of them showed positive associations between ozone exposure and increased mortality.[23] A few studies, like Professor Michelle L. Bell's 2004 study of ninety-five communities, specifically concluded that ozone exposure increased mortality risk.[24] Finding that "uncertainties remain in some areas," the criteria document concluded that "robust associations have been identified between various measures of daily [ozone] concentrations and increased risk of mortality."[25]

The criteria document concluded that "no clear conclusion can now be reached regarding possible threshold levels for [ozone-induced] effects."[26] One reason for this was the great variability in responsiveness among healthy subjects in controlled human-exposure studies.[27] Another was the limited capacity of epidemiological studies to discern thresholds.[28] The document concluded that if a threshold existed it was "likely near the lower limit of ambient [ozone] concentrations in the United States."[29]

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18. U.S. ENVTL. PROT. AGENCY, *supra* note 15, at E-13.
19. *Id.*
20. *Id.* at E-15.
21. *Id.* at 7-83.
22. *Id.* at 7-84.
23. *Id.* at 7-85, 7-86 fig.7-14.
24. *Id.* at 7-86 fig.7-14; Michelle L. Bell et al., *Ozone and Short-Term Mortality in 95 US Urban Communities, 1987-2000*, 292 JAMA 2372, 2376 (2004).
25. U.S. ENVTL. PROT. AGENCY, *supra* note 15, at 7-110.
26. *Id.* at 8-44.
27. *Id.*
28. *Id.*
29. *Id.*

B. The Staff Paper

As the EPA's Office of Research and Development was putting the final touches on the criteria document, the Office of Air Quality Planning and Standards (OAQPS) published a staff paper containing an evaluation of the "policy implications of the key studies and scientific information" contained in the criteria document, an exposure assessment, and several quantitative-risk assessments.[30] It also offered advice to the Administrator about the "appropriate response to the range of uncertainties . . . inherent in the scientific evidence and analyses."[31] The staff recommended that the Administrator consider setting a new eight-hour primary standard in the 0.064 ppm to 0.084 ppm range with a primary focus on 0.070 ppm.[32]

In its review of the staff paper, the CASAC concluded that there was "no scientific justification for retaining" the current eight-hour primary standard.[33] In particular, the Adams study showed "[s]tatistically-significant decrements in lung function" at the 0.080 ppm exposure level, and "adverse lung function effects were also observed in some individuals at 0.06 ppm."[34] The committee noted that scientific uncertainty existed "with regard to the low[est] level of ozone exposure that would be fully-protective of human health."[35] Indeed, it was "possible that there [was] no threshold for an ozone-induced impact on human health," a development that greatly complicated the process of determining an adequate margin of safety.[36]

Although it relied on the reports described in the criteria document for most of its technical descriptions, the final version of the staff paper presented the staff's own detailed reanalysis of the data from the Adams studies. At the CASAC's suggestion, the staff extended the lower limit of its recommended range for the primary standard to 0.060 ppm and dropped its preference for 0.070 ppm.[37] At the same time, the paper noted that "uncertainty in the epidemiological findings [increased] at the low end of the range[] of concentrations . . . because of . . . poor correlations between

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30. U.S. ENVTL. PROT. AGENCY, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE: POLICY ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION 1-1 (2007) [hereinafter OZONE STAFF PAPER]. The contents of the staff paper are now contained in a risk and exposure report and a policy assessment. U.S. ENVTL. PROT. AGENCY, *supra* note 2, at 9.

31. OZONE STAFF PAPER, *supra* note 30, at 6-1.

32. Letter from Clean Air Scientific Advisory Comm. to Stephen L. Johnson, Administrator, U.S. Envtl. Prot. Agency (Oct. 24, 2006), *in* ENVTL. PROT. AGENCY, OZONE STAFF PAPER, *supra* note 30, attach. A at 1; *EPA Staff Narrows Recommendations For Ways to Tighten Ozone Standard*, 37 ENV'T REP. (BNA) 1502, 1502 (2006).

33. Letter from Clean Air Scientific Advisory Comm. to Stephen L. Johnson, *supra* note 32, attach. A at 4–5.

34. *Id.* at 3.

35. *Id.* at 5.

36. *Id.*

37. OZONE STAFF PAPER, *supra* note 30, at 6-49.

ambient concentrations and personal exposure" and "questions of plausibility that are more salient at relatively low concentrations."[38]

C. The Notice of Proposed Rulemaking

The notice of proposed rulemaking that the agency published in July 2007 proposed to lower the primary standard from 0.084 ppm to somewhere between 0.070 ppm and 0.075 ppm, using an eight-hour averaging period.[39] The Agency also solicited comments on whether it should set the standard at a level within a range of 0.060 ppm to 0.070 ppm or within a range above 0.075 ppm up to the existing standard.[40]

In discussing lung-function decrement and other respiratory symptoms, the preamble noted that one of the two Adams studies found that some sensitive subjects had experienced adverse effects at 0.060 ppm.[41] The EPA staff's reanalysis of the Adams data showed a statistically significant difference in lung-function decrement at 0.060 ppm.[42] These results were fully consistent with a "relatively large number" of recent epidemiological studies.[43] The preamble also cited "numerous" epidemiological studies that had "consistently" found a statistically significant relationship between ambient ozone in the summer months and "increased incidence of emergency department visits and hospital admissions for respiratory causes . . . ."[44] Several clinical studies had detected increased hyperresponsiveness in asthmatics exposed to ozone.[45] Furthermore, many studies demonstrated that a number of sensitive subpopulations—including children, older adults, people with preexisting pulmonary disease, and other genetically predisposed people—were especially susceptible to ozone exposure.[46] Vulnerable subpopulations included joggers, outdoor workers, and children who spent a lot of time outdoors.[47] Addressing mortality risk, the preamble highlighted Professor Bell's 2004 study of populations in ninety-five U.S. cities.[48] Many single-city studies had also reported statistically significant associations between mortality and short-term ozone

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38. *Id.* at 6-48.

39. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. 37,818, 37,818 (July 11, 2007) (to be codified at 40 C.F.R. pt. 50).

40. *Id.* at 37,878.

41. *Id.* at 37,828; OZONE STAFF PAPER, *supra* note 30, at 3-81 (noting that in Adams's 2006 study, 7% of participants exposed to 0.060 ppm had greater than 10% FEV1 decrement). FEV1 refers to "forced expiratory volume in one second," a measure of lung health based on the amount of air that a person can exhale in a forced breath in one second. *Id.* at 3-4.

42. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,828.

43. *Id.*

44. *Id.* at 37,832.

45. *Id.* at 37,830, 37,847.

46. *Id.* at 37,825.

47. *Id.* at 37,825–26.

48. *Id.* at 37,835; Bell et al., *supra* note 24, at 2376.

exposure during the ozone season.[49] Integrating the new epidemiological studies with the preexisting studies, the preamble found the association between ozone exposure and mortality to be strong, robust, and consistent.[50]

The preamble recognized that there was "no sharp breakpoint within the continuum ranging from at and above 0.080 ppm down to 0.060 ppm."[51] Thus, the existing studies neither supported nor refuted the existence of a threshold.[52] In any event, it would be "difficult to detect" a threshold below which "no individual would experience a given effect," given the fact that some people are "unusually sensitive even down to very low concentrations."[53] It was therefore important to "*balance concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower [ozone] levels*."[54]

The preamble relied heavily on mathematical models employed by the staff to estimate both exposures to ozone in the ambient air and the risks to humans at various levels of exposure.[55] To estimate population exposure, the staff employed the highly complex Air Pollutants Exposure model that "simulate[d] the movement of individuals through time and space and estimate[d] their exposure to . . . [the] pollutant in indoor, outdoor, and in-vehicle [environments]."[56] The model produced two types of exposure estimates: counts of the estimated number of people exposed to specified "benchmark" concentration levels (called exposures of concern) and counts of the number of times those people would be exposed to the benchmark level (expressed as person-occurrences) during any given time period.[57] While noting "significant improvements" in exposure and risk-assessment models since 1996, the preamble cautioned that the models were laden with uncertainties and still relied heavily on contestable assumptions.[58]

Based on monitoring data from 2002 (a bad ozone year), the model predicted that the current 0.084 ppm standard would leave 700,000 children and 110,000 asthmatic children exposed to the 0.080 ppm benchmark—where a number of clinical studies had concluded that children were at risk for serious respiratory morbidity and cardiopulmonary mortality—and that asthmatic children were at risk for serious adverse responses due to lung

49. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,828.
50. *Id.* at 37,837–40.
51. *Id.* at 37,824.
52. *Id.* at 37,840.
53. *Id.*
54. *Id.* at 37,824 (emphasis added).
55. *Id.* at 37,851.
56. OZONE STAFF PAPER, *supra* note 30, at 4-6 to -11.
57. *Id.* at 4-13.
58. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,851.

inflammation.[59] A standard set at 0.074 ppm would allow only 60,000 children and 10,000 asthmatic children to be exposed to concentrations above 0.080 ppm, but would allow 770,000 children and 120,000 asthmatic children to be exposed to the 0.070 ppm benchmark,[60] where the Adams studies (as interpreted by the EPA staff) and many epidemiological studies suggested that children would be at risk for lung-function decrement and asthmatic children would be at risk for lung inflammation.[61] A standard set at 0.074 ppm would also allow 4,550,000 children and 700,000 asthmatic children to be exposed to the 0.060 ppm benchmark, where the Adams studies (as interpreted by the staff) and several epidemiological studies indicated that children would be at some risk for lung-function deficit.[62] Finally, a standard set at 0.064 ppm would leave no children exposed to levels of 0.080 ppm, but would leave 30,000 children and 10,000 asthmatic children exposed to the 0.070 ppm benchmark and 950,000 children and 150,000 asthmatic children exposed to the 0.060 ppm benchmark.[63]

The preamble also summarized the staff's quantitative risk assessments to provide "additional insights" into the public health implications associated with meeting specified standards.[64] The risk assessments were, however, limited to the health effects for which the staff had sufficient information of adequate quality to develop quantitative estimates.[65] A risk assessment based on data from controlled human studies focused on lung-function decrement and relied exclusively on the Adams studies for exposure–response relationships at ozone exposure levels below 0.080 ppm.[66] Using the 2002 exposure data, the risk assessment estimated that at the current level of 0.084 ppm, 610,000 children and 130,000 asthmatic children would suffer lung-function deficits, while 340,000 children and 90,000 asthmatic children would suffer lung-function deficits if the standard were set at 0.074 ppm.[67] If the EPA promulgated a stringent standard of 0.064 ppm, only 180,000 children and 50,000 asthmatic children would suffer lung-function deficit.[68]

Another risk assessment relying exclusively on epidemiological data included separate estimates for health end points related to respiratory

59. *Id.* at 37,854–55.

60. *Id.* at 37,855 tbl.1.

61. *Id.* at 37,828–29.

62. *Id.* at 37,828, 37,855 tbl.1.

63. *Id.* at 37,855 tbl.1.

64. *Id.* at 37,856.

65. OZONE STAFF PAPER, *supra* note 30, at 5-1. The risk assessment did not include airway hyperresponsiveness, inflammation, immune system effects, increased medication usage in asthmatics, increased doctor visits and emergency department visits, or increased school absences. *Id.* at 5-1, 5-4, 5-8.

66. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,828.

67. *Id.* at 37,860 tbl.2.

68. *Id.*

symptoms in moderately to severely asthmatic children, hospital admissions, and premature mortality.[69] Using the 2002 monitoring data, the staff estimated that reducing the standard from 0.084 ppm to 0.064 ppm would bring about an 11% drop in the incidence of chest tightness in asthmatic children.[70] Lowering the standard from 0.084 ppm to 0.064 ppm would decrease the incidence of hospital visits from 6.4 cases per 100,000 to 4.6 cases per 100,000.[71] The assessment of premature mortality relied primarily on the Bell ninety-five-city study to predict that the incidence of ozone-caused mortality would decrease by 40% if the agency reduced the primary standard from 0.084 ppm to 0.064 ppm.[72]

Among the many sources of uncertainty in the estimates was the uncertainty as to whether the associations reported in the epidemiological studies were in fact cause-and-effect relationships and would fit the concentration–response curves of the models that the staff had selected.[73] Drawing on the criteria document and the CASAC review of the studies, the staff had concluded that the associations were sufficiently robust and biologically plausible that this source of uncertainty was not likely to be very large.[74] Uncertainties also arose in determining the shape of the concentration–response curve and, in particular, in determining whether a threshold existed.[75] The staff paper had concluded that there was "insufficient evidence to support use of potential threshold levels in the quantitative risk assessment," but there was "increasing uncertainty about the concentration-response relationship at lower concentrations."[76]

Based on the foregoing analyses, Administrator Johnson found that the current eight-hour standard did not protect public health with an adequate margin of safety and should therefore be revised.[77] The newly available evidence increased the Administrator's confidence that "respiratory morbidity effects such as lung function decrements and respiratory symptoms" were causally related to ozone exposures, as were indicators of respiratory morbidity such as emergency department visits.[78] The evidence was "highly suggestive" that ozone exposures during the warm season contributed to premature mortality.[79] Finally, important new evidence demonstrated that ozone exposures below the existing standard were

69. *Id.* at 37,858; OZONE STAFF PAPER, *supra* note 30, at 5-29.
70. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,861.
71. *Id.*
72. *Id.*
73. *Id.* at 37,856.
74. OZONE STAFF PAPER, *supra* note 30, at 5-42.
75. *Id.*
76. *Id.* at 5-45.
77. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,869.
78. *Id.*
79. *Id.*

"associated with a broad array of adverse health effects, especially in at-risk populations."[80]

The Administrator recognized that there was "no evidence-based bright line that indicate[d] a single appropriate level" for the standard.[81] The choice of the appropriate level was therefore a "public health policy judgment" that he was required to make after "considering the strengths and limitations of the evidence, and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments."[82] The Administrator concluded that a standard within the range of 0.070 ppm to 0.075 ppm "would reduce the risk of a variety of health effects" and was therefore "requisite to protect public health, including the health of at-risk groups, with an adequate margin of safety."[83]

Acknowledging that the CASAC had unanimously recommended a range of 0.060 ppm to 0.070 ppm,[84] the Administrator nevertheless concluded that the "very limited new evidence" from controlled human experiments of lung-function decrements and respiratory symptoms at the 0.060 ppm exposure level was "too limited to support a primary focus at this level."[85] The epidemiological studies did suggest adverse effects at levels far below 0.080 ppm, but they were "not themselves direct evidence of a causal link" between exposure to ozone and adverse health effects.[86] The Administrator concluded that "the increasing uncertainty of the existence and magnitude of additional public health protection that standards below 0.070 ppm might provide" suggested that a lower level would "likely be below what is necessary to protect public health with an adequate margin of safety."[87]

D. The Final Rule

After considering the comments from the public and participating in a vigorous debate within the Bush Administration, Administrator Johnson selected a level of 0.075 ppm averaged over eight hours for the primary standard.[88] That level, he explained, was "appreciably below 0.080 ppm, the level in controlled human exposure studies at which adverse effects ha[d] been demonstrated."[89] Referring to the exposures-of-concern

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80. *Id.*
81. *Id.* at 37,879.
82. *Id.*
83. *Id.*
84. *Id.* at 37,880.
85. *Id.* at 37,878.
86. *Id.* at 37,879.
87. *Id.* at 37,880.
88. National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,436, 16,436 (Mar. 27, 2008) (to be codified at 40 C.F.R. pts. 50, 58).
89. *Id.* at 16,483.

analysis, the Administrator noted that a level of 0.075 ppm would "essentially eliminate[]" exposures above the 0.080 ppm benchmark and "substantially reduce[] or eliminate[]" exposures above the 0.070 ppm benchmark for "the vast majority of people in at-risk groups."[90] He concluded that because of the uncertainties in the available data at low exposure levels, "the likelihood of obtaining benefits to public health with a standard set below 0.075 ppm . . . decreases, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increases."[91] That being the case, the Administrator concluded that "the appropriate balance to be drawn, based on the entire body of evidence and information available in this review, is a standard set at 0.075."[92]

E. Judicial Review and an Election

A large number of states, public-health and environmental groups, and industry trade associations challenged the standard in the D.C. Circuit Court of Appeals.[93] While the appeals were pending, the 2008 elections put both houses of Congress and the White House under the control of the Democratic Party. In March 2009, the EPA asked the court to give the agency 180 days to decide whether to withdraw and revise the standard.[94] The court granted the stay.[95]

IV. The Obama Administration Ozone NAAQS Proposal

Although new clinical studies indicating that short-term exposure to ozone caused serious adverse respiratory effects at levels of 0.070 ppm and 0.060 ppm had been published since the rulemaking record had closed,[96] newly appointed EPA Administrator Lisa Jackson concluded that the withdrawal and any reproposal had to be based on the information that was summarized in the February 2008 criteria document.[97] This exercise provided a unique opportunity to observe how two administrators with

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90. *Id.*

91. *Id.*

92. *Id.*

93. Andrew Childers, *Lawsuit Alleges EPA Violated Air Act, Seeks Tougher Standards for Ozone*, 39 ENV'T REP. (BNA) 1046, 1046–47 (2008); Steven D. Cook, *EPA Asks Appeals Court for 180 Days to Review Ozone Air Quality Standard*, 40 ENV'T REP. (BNA) 533, 533 (2009).

94. Cook, *supra* note 93, at 533.

95. Mississippi v. EPA, 744 F.3d 1334, 1341 (D.C. Cir. 2013).

96. Andrew Childers, *Researchers Find Ozone Exposure at Levels Below EPA Standards Reduces Lung Function*, 40 ENV'T REP. (BNA) 1817, 1817 (2009); Andrew Childers, *Study Links Low Levels of Ozone Exposure to Reduced Lung Function, Inflammation*, 42 ENV'T REP. (BNA) 53, 53–54 (2011).

97. Andrew Childers, *EPA Review Plan Outlines Process Used to Reconsider Ozone Standards*, 40 ENV'T REP. (BNA) 2440, 2440 (2009).

different policy perspectives resolved difficult science–policy questions based on the same underlying scientific information.

A. The Notice of Proposed Rulemaking

In January 2010 the EPA published a notice of proposed rulemaking announcing that Administrator Jackson had "serious cause for concern" that the 2008 standards did not meet the Clean Air Act's requirements.[98] The preamble's detailed description of the available scientific information tracked almost word-for-word the July 2007 preamble's description.[99] Thus, any difference in ultimate outcome reflected a different view of the statutory policies guiding the agency's discretion. In a departure from the earlier preamble, the 2010 preamble announced that Administrator Jackson was adopting a precautionary approach toward her re-evaluation of the evidence under which the agency was obliged to prevent ozone exposures at "levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree."[100]

The staff's reanalysis of the data from the Adams studies played a prominent role in Administrator Jackson's choice of the range of possible levels for the standard.[101] Unlike the 2007 preamble, the 2010 preamble noted that in the other controlled human studies showing adverse inflammatory responses and indications of lung injury at the 0.080 ppm exposure level, that was the lowest level tested.[102] The fact that many of those studies reported significant interindividual variability suggested that "some portion of the population would likely experience such effects at exposure levels extending well below 0.080 ppm."[103] The 2010 preamble also expressed greater concern for the effects of ozone on sensitive and vulnerable subpopulations.[104] It noted that because the vast majority of the existing studies focused on healthy adults, they most likely underestimated the effects of ozone on those subpopulations.[105]

The preamble concluded that the existing epidemiological studies showed "significant associations" between ozone exposures and "a wide array of respiratory symptoms," especially during the warm season.[106] In addition, many epidemiological studies found "positive associations"

98. National Ambient Air Quality Standards for Ozone, 75 Fed. Reg. 2938, 2943 (Jan. 19, 2010) (to be codified at 40 C.F.R. pts. 50, 58).

99. *Compare id.* at 2946–74, *with* National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. 37,818, 37,824–51 (July 11, 2007) (to be codified at 40 C.F.R. pts. 50).

100. National Ambient Air Quality Standards for Ozone, 75 Fed. Reg. at 2944, 2997.

101. *Id.* at 2985–86, 2993.

102. *Id.* at 2986.

103. *Id.*

104. *Id.* at 2987.

105. *Id.* at 2994.

106. *Id.* at 2993.

between ambient ozone concentrations and cardiopulmonary mortality.[107] In both cases the associations extended well below the current standard of 0.084 ppm and as far down as at least 0.050 ppm.[108] Studies like the Bell study that limited the observations to days on which ambient ozone levels were lower than 0.084 ppm also reported statistically significant associations between ozone exposure and increased mortality all the way down to 0.061 ppm.[109]

Although Administrator Jackson relied heavily on the staff paper's exposure and risk assessments, she was "mindful of the important uncertainties and limitations" associated with those analyses.[110] Despite the fact that 0.064 ppm was the lowest standard examined in the staff paper, Administrator Jackson predicted that additional reductions in exposures below the selected benchmark levels would occur at the 0.060 ppm level.[111]

Like Administrator Johnson, Administrator Jackson believed that determining the level that was requisite to protect public health with an adequate margin of safety was a "public health policy judgment" that called for balancing threatened harm against uncertainty.[112] Because "important and significant risks to public health" were likely to occur at the 0.075 ppm level, a standard of 0.075 ppm would not, in her judgment, be sufficient to protect public health with an adequate margin of safety.[113] She therefore invited public comment on a primary standard in the range of 0.060 ppm to 0.070 ppm.[114]

B. The EPA Withdraws the Proposal

On July 11, 2011, the EPA sent a draft final rule to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget that set the level of the primary standard at 0.065 ppm.[115] As word of this got out, the affected industries put on a full-court press to force the agency to withdraw the proposal.[116] After a series of meetings between

107. *Id.* at 2986.
108. *Id.* at 2987.
109. *Id.* at 2987, 2994.
110. *Id.* at 2994.
111. *Id.*
112. *Id.* at 2996.
113. *Id.*
114. *Id.* at 2998.
115. Jessica Coomes, *EPA Sends Reconsidered Ozone Standards to White House OMB for Regulatory Review*, 42 ENV'T REP. (BNA) 1569, 1569 (2011); John M. Broder, *Re-election Strategy is Tied to a Shift on Smog*, N.Y. TIMES, Nov. 16, 2011, http://www.nytimes.com/2011/11/17/science/earth/policy-and-politics-collide-as-obama-enters-campaign-mode.html?pagewanted=all&pagewanted=print, *archived at* http://perma.cc/CP3N-EU96.
116. Broder, *supra* note 115.

high-level White House officials and industry and environmental groups,[117] President Obama ordered Administrator Jackson to withdraw the proposal and continue ahead with the Agency's already-initiated five-year revision of the new criteria document (or, in current parlance, ISA).[118] When five public-health and environmental groups challenged the withdrawal in the D.C. Circuit, the court agreed with the EPA that the action was not judicially reviewable as a final agency action because the EPA had merely deferred action on the ozone standard until the next NAAQS revision cycle.[119]

C. Judicial Review of the 2008 Standard

In July 2013 the D.C. Circuit in *Mississippi v. EPA*[120] upheld the 2008 primary standard.[121] Quoting the Supreme Court's "malleable" definition of "requisite" as "sufficient, but not more than necessary," the court rejected the industry's contention that "only one standard at any given time can be 'requisite' because . . . that standard is neither higher nor lower than necessary."[122] That argument "presuppose[d] scientific certainty in an area actually governed by policy-driven approaches to uncertain science."[123] The EPA was not required to explain why a 0.080 ppm standard was no longer requisite to protect public health, so long as it adequately explained why a 0.075 ppm standard was requisite.[124]

The court also rejected the industry challenges to the evidentiary support for the EPA's decision.[125] The court noted that the record contained "epidemiological studies linking health effects to exposure to ozone levels below 0.08 ppm and clinical human exposure studies finding a causal relationship between health effects and exposure to ozone levels at and below 0.08 ppm . . . ."[126] The court dismissed the industry's claim that the EPA's reliance on the staff's reinterpretation of the Adams studies violated the Clean Air Act.[127] It noted that "nothing in the Clean Air Act . . . prohibits EPA from independently analyzing the science" underlying a cited study.[128]

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117. Jessica Coomes, *White House Chief of Staff Hears Arguments by Industry, Advocacy Groups on Ozone Rule*, 42 ENV'T REP. (BNA) 1919, 1919 (2011).

118. Broder, *supra* note 115.

119. Am. Lung Ass'n v. EPA, No. 11-1396, slip-op at 2 (D.C. Cir. Feb. 17, 2012).

120. 744 F.3d 1334 (D.C. Cir. 2013).

121. *Id.* at 1339, 1362.

122. *Id.* at 1342–43.

123. *Id.* at 1343.

124. *Id.*

125. *Id.*

126. *Id.* at 1345.

127. *Id.* at 1346–47.

128. *Id.* at 1347.

In rejecting the public-health groups' challenges, the court accepted the EPA's explanation that the greater uncertainty that attended the conclusions of epidemiological studies at exposure levels below 0.080 ppm outweighed the threat of harm suggested by those conclusions.[129] With respect to the Adams studies, the court was unwilling to disturb EPA's conclusion that the data at the 0.060 ppm exposure level were "too limited to support a reduction in the NAAQS to that level."[130] It recognized that the Adams data indicated "some degree of risk that some number of individuals might continue to experience health effects at and below 0.075 ppm," but it stressed "the impossibility of eliminating all risk of health effects from 'non-threshold' pollutants like ozone."[131] The EPA was apparently permitted to ignore trivial risks.

The court also rejected the environmental groups' contention that the EPA had failed to provide an "adequate margin of safety."[132] Observing that previous judicial opinions had "left EPA with a wide berth when it comes to deciding how best to account for an adequate margin of safety," the court accepted the EPA's conclusion that a level of 0.075 ppm was "appreciably below" 0.080 ppm, "the lowest level at which EPA expressed confidence that ozone causes adverse health effects in healthy individuals."[133] This explanation did not explain how a level of 0.075 ppm provided an adequate margin of safety for sensitive and vulnerable subpopulations, but it may have reflected a legal conclusion that those populations were not entitled to a margin of safety of their own.[134]

The court concluded that "[t]he task of determining what standard is 'requisite' to protect the qualitative value of public health or what margin of safety is 'adequate' to protect sensitive subpopulations necessarily requires the exercise of policy judgment."[135] The EPA had appropriately struck a "balance between 'the increasing uncertainty associated with [its] understanding of the likelihood of such effects at lower [ozone] exposure levels' and 'concern about the potential for health effects and their severity.'"[136]

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129. *Id.* at 1349–51.

130. *Id.* at 1350.

131. *Id.* at 1350–51.

132. *Id.* at 1353.

133. *Id.*

134. *See supra* subpart III(D).

135. *Mississippi v. EPA*, 744 F.3d at 1358.

136. *Id.* (first alteration in original) (quoting National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,436, 16,477 (Mar. 27, 2008) (to be codified at 40 C.F.R. pts. 50, 58)).

V. Resolving Science–Policy Questions Under Conditions of Scientific Uncertainty

The foregoing description of the EPA's efforts to revise the NAAQS for ozone should make it clear that scientific considerations alone rarely dictate the level of ambient air quality standards because the available scientific evidence is usually clouded by large uncertainties. When the agency staff encounters scientific uncertainty in the data, it has to choose from among several scientifically plausible interpretations.[137] These choices turn on a mixture of scientific judgment, policy considerations, intuition, and even the personal values of the scientists making the choices.[138] Likewise, the models that the staff employs in exposure and risk assessments are driven by assumptions that are based on a combination of scientific and policy judgment.[139] The policy judgment is so deeply embedded in the scientific assessment, however, that it is often very difficult for outside observers to know what policies the agency is advancing.

A. Science and Policy in Assessing the Reliability and Relevance of Scientific Evidence

The first point at which policy considerations enter the picture is when the EPA's Office of Research and Development staff chooses the studies for inclusion in the criteria document after an evaluation of the objectivity (or reliability) and usefulness (or relevance) of each potentially relevant study.[140] To accomplish this task, the staff has traditionally employed a broadly inclusive "weight-of-the-evidence" approach under which it weighs the strengths and weaknesses of less-than-perfect studies in deciding the extent to which it will rely on them.[141] This represents a policy judgment that the agency is willing to accept the risk that one or more of the studies upon which it relies do not reflect scientific reality and that conclusions based on those studies may be wrong from a scientific perspective.[142]

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137. NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 42 (2009).

138. *Id.* at 42–43.

139. Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255, 1279 (2004).

140. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002) (providing guidelines from the Office of Management and Budget for agencies to review and substantiate the quality of information prior to dissemination, in order to comply with the Information Quality Act). *See supra* notes 2–5 and accompanying text.

141. Thomas O. McGarity, *On The Prospect of "Daubertizing" Judicial Review of Risk Assessment*, LAW & CONTEMP. PROBS., Autumn 2003, at 155, 166–67.

142. Initial Brief for Respondent at 49, Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir. 2013) (No. 08-1200).

One of the industries' prime targets in the ozone rulemaking was the agency's heavy reliance on time-series epidemiological studies, such as the Bell ninety-five-city study, that employed fixed air-quality monitors instead of expensive personal monitors to measure exposure.[143] They argued that fixed monitors did not provide sufficiently reliable approximations of personal exposure because they were often located far away from most exposed people and did not take into account human activity patterns.[144] The Agency recognized that fixed monitors did not always provide an accurate measure of individual exposures,[145] but it cited many studies finding that daily averaged ozone exposures as measured by personal monitors tended to be well-correlated with ozone concentrations as measured by fixed monitors.[146] Given the gravity of the increased mortality risk documented in the admittedly imperfect time-series studies, Administrators Johnson and Jackson both made the policy judgment that they were entitled to substantial weight in the decision-making process.

B. Science and Policy in Interpreting and Drawing Inferences from the Data

Scientists frequently disagree about the proper interpretations and inferences to draw from a study or group of studies. In such cases, policy may properly play a role in the agency's choice among conflicting interpretations and inferences.[147] The disagreements over the proper interpretation of the Adams clinical studies provide an excellent example. Both of those studies demonstrated "notable interindividual variability" at all three levels of exposure, an indication of higher risk for persons in sensitive and vulnerable subpopulations.[148] The authors of the 2006 study, which was sponsored by the American Petroleum Institute, concluded that there was no statistically significant relationship between ozone exposure and lung-function decrements at ozone levels below 0.080 ppm.[149] The

143. Joint Opening Brief of Petitioner State of Mississippi and Industry Petitioners at 54–57, Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir. 2013) (No. 08-1200); OZONE STAFF PAPER, *supra* note 30, at 5-43 to -44.

144. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. 37,818, 37,881 (July 11, 2007) (to be codified at 40 C.F.R. pt. 50); *EPA's Proposal to Revise the National Ambient Air Quality Standards for Ozone: Hearing at Philadelphia, Pa.*, U.S. Envtl. Prot. Agency, No. EPA-HQ-OAR-2005-0172 (Aug. 30, 2007) (statement of Edison Elec. Inst.).

145. Initial Brief for Respondent at 85, Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir. 2013) (No. 08-1200).

146. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,838.

147. 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, 741–47 (1979).

148. OZONE STAFF PAPER, *supra* note 30, at 3-81.

149. William C. Adams, *Comparison of Chamber 6.6-h Exposures to 0.04–0.08 PPM Ozone via Square-Wave and Triangular Profiles on Pulmonary Responses*, 18 INHALATION TOXICOLOGY 127, 135 (2006).

EPA staff's reinterpretation of the Adams data, however, concluded that there was a statistically significant difference in lung-function decrement at 0.060 ppm.[150] The staff's reanalysis also squared with a number of recent epidemiological studies.[151]

Noting that Dr. Adams disagreed with the staff's interpretation of his data,[152] industry groups argued that the reanalysis did not apply an appropriate statistical test and that it demonstrated systemic bias on the part of the EPA staff.[153] The EPA staff responded that Adams and his coauthors had employed a multiple-comparison statistical technique to avoid type I error (erroneously finding a statistically significant difference) that may also have increased type II error (erroneously concluding that there was no statistically significant difference).[154] In other words, the authors of the study apparently adopted a policy of erring on the side of concluding that no statistically significant relationship between ozone exposure and adverse effects existed.

To Administrator Johnson, the staff reanalysis of the Adams studies provided "evidence that some healthy individuals will experience lung function decrements and respiratory symptoms" down to the 0.060 ppm level, but that evidence was "too limited to support a primary focus at this level."[155] He was unwilling to infer from the reanalysis of the Adams studies that ozone exposures at levels below 0.075 ppm endangered public health.[156]

Administrator Jackson concluded that the reanalyzed Adams studies provided "limited but important evidence" that added to "the overall body of evidence" supporting a standard in the range of 0.060 ppm to 0.070 ppm.[157] Adopting a more precautionary policy than Administrator Johnson, Administrator Jackson placed greater emphasis on the evidence of interindividual variability in the controlled human studies and on the fact that most of those studies employed healthy adults as subjects and therefore likely underestimated the risk to sensitive and vulnerable subpopulations.[158]

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150. OZONE STAFF PAPER, *supra* note 30, at 3-81.

151. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. at 37,828.

152. Joint Opening Brief of Petitioner State of Mississippi and Industry Petitioners at 31, Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir. 2013) (No. 08-1200).

153. National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,436, 16,454 (Mar. 27, 2008) (to be codified at 40 C.F.R. pts. 50, 58).

154. OZONE STAFF PAPER, *supra* note 30, at 3-8.

155. National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. at 16,478.

156. *Id.* at 16,481.

157. National Ambient Air Quality Standards for Ozone, 75 Fed. Reg. 2938, 2993 (proposed Jan. 19, 2010) (to be codified at 40 C.F.R. pts. 50, 58).

158. *Id.* at 2986–87, 2994.

C. Science and Policy in Assessing Risk

The role of policy in risk assessment is quite apparent in the ways that Administrators Johnson and Jackson relied on the staff-prepared risk assessment. Administrator Johnson stated that he was "fully mindful" of the limitations of the risk assessment when he cited it as "additional support" for his judgment that the 0.084 ppm standard did not adequately protect public health with an adequate margin of safety.[159] He concluded that the risk estimates were useful at exposures above 0.075 ppm because the scientific data were more robust at that level, but the predictions were not as accurate at levels below 0.075 ppm (where the scientific data were clouded by greater uncertainty).[160] In determining where along the proposed range to set the standard, he therefore gave little weight to the risk assessment's estimates of damage at the lower levels.[161]

Administrator Jackson, by contrast, was willing to rely more heavily on the risk assessment's estimates at low concentrations in concluding that the standard should be set at a level of 0.065 ppm.[162] Unlike Administrator Johnson, she stressed the risk assessment's tendency to underestimate risk.[163] She alluded to a "much broader array" of health effects that were not susceptible to quantitative evaluation and therefore not captured in the risk assessment.[164] Less troubled than Administrator Johnson by the greater uncertainties in the risk assessment at low levels, she concluded that "[t]he magnitudes of exposure and risk reductions estimated to occur in going from a 0.074 ppm standard to a 0.064 ppm standard are as large as those estimated to occur in going from the then current 0.084 ppm standard to a 0.074 ppm standard."[165] In electing to rely on the risk assessment despite its potentially erroneous assumptions, Administrator Jackson was adopting a protective policy of erring on the side of safety.

D. Science and Policy in Applying the Margin of Safety

The EPA has consistently taken the position that the margin-of-safety requirement for primary NAAQS "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."[166] In

159. RESPONSES TO SIGNIFICANT COMMENTS, *supra* note 17, at 74.

160. Initial Brief for Respondent at 104, Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir. 2013) (No. 08-1200).

161. National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. at 16,481.

162. National Ambient Air Quality Standards for Ozone, 75 Fed. Reg. at 2993–94.

163. *Id.* at 2994.

164. *Id.* at 2995.

165. *Id.*

166. National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856, 38,857 (July 18, 1997) (to be codified at 40 C.F.R. pt. 50).

determining the margin of safety, the Agency "considers such factors as the nature and severity of the health effects involved, the size of the population(s) at risk, and the kind and degree of the uncertainties that must be addressed."[167] The ozone rulemaking provides an unusual opportunity to observe how two administrators with two very different policy perspectives resolved the tension between the requirement, inherent in the term "margin of safety," that the Agency err on the side of safety and the requirement, implicit in the word "requisite," that the standard not be more stringent than necessary in an uncertainty-laden scientific setting.

The public-health groups complained that Administrator Johnson's explanation for setting the primary standard at 0.075 ppm was devoid of any analysis of the margin-of-safety requirement.[168] The agency responded that Administrator Johnson's reasoning "at many points addressed the need to protect against uncertain risks that is at the heart of the margin-of-safety requirement."[169] "[I]nstead of setting the standard just below 0.080 ppm," the level at which he was confident that healthy individuals were adversely affected, "the Administrator set it 'appreciably below' that level [at 0.075 ppm] to account for risks to individuals with asthma."[170] Implicit in this explanation is the contestable legal conclusion that sensitive and vulnerable subpopulations are not entitled to their own margin of safety.[171] Whether a margin of 0.005 ppm was adequate to protect sensitive and vulnerable subpopulations was a policy judgment with respect to which the preamble provided no further amplification.

In applying the margin of safety to healthy individuals, Administrator Johnson reasoned that setting the standard at a level below 0.075 ppm "would only result in significant further public health protection" if there was a "continuum of health risks" for healthy individuals down to concentrations "well below" 0.080 ppm and only "if the reported associations observed in epidemiological studies [were], in fact, causally related to [ozone exposures] at those lower levels."[172] He was "not prepared to make [those] assumptions" for the purpose of establishing a margin of safety.[173]

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167. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. 37,818, 37,820 (July 11, 2007) (to be codified at 40 C.F.R. pt. 50).

168. Proof Brief for Environmental Petitioners at 34, Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir. 2013) (No. 08-1200).

169. Initial Brief for Respondent at 105, Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir. 2013) (No. 08-1200).

170. *Id.* at 107.

171. *See supra* notes 130–32 and accompanying text.

172. National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,436, 16,483 (Mar. 27, 2008) (to be codified at 40 C.F.R. pts. 50, 58).

173. *Id.*

Administrator Jackson, by contrast, was willing to consider "how effectively alternative standard levels would serve to limit exposures of concern relative to the 0.060 ppm benchmark level as well as to the 0.070 ppm benchmark level," despite the uncertainties in the data at the 0.060 ppm level.[174] She observed that a standard set at the 0.074 ppm level would allow "approximately 27% of asthmatic school age children and 25% of all school age children . . . to experience one or more exposures of concern over the 0.060 ppm benchmark level . . . ."[175] Explicitly invoking the margin-of-safety requirement, she concluded that "important and significant risks to public health" were likely to occur at the 0.075 ppm level and that a standard of 0.075 ppm would therefore not be "sufficient to provide protection with an adequate margin of safety."[176] Although she was unable to make a final selection (because President Obama ordered her to withdraw the proposal), the draft final rule that she sent to OIRA would have set the primary standard at 0.065 ppm.[177]

VI. The Policy that Drives Decision Making

The Clean Air Act is a precautionary statute. Its purpose is to protect public health and welfare from anticipated harms, not necessarily from proven harms. The statute is also aspirational. Congress set high protective goals and it expected the EPA and the states to strive to attain those goals even if attainment appeared impossible at any given point in time.[178] Nowhere in § 109 of the statute is there any indication that Congress meant for the EPA to temper its protective goals with concerns for the economic cost of attaining the standards.[179] The policies that drive the EPA's resolution of science–policy issues in setting the NAAQS are therefore the precautionary policies of the statute and not extrastatutory concerns for economic efficiency, industrial expansion, or job growth.

A. Balancing Risk and Uncertainty in Setting NAAQS

When Congress wrote § 109 of the Clean Air Act in 1970, it may have assumed that all of the criteria pollutants would exhibit "threshold" exposures below which no harm to public health or welfare would result.[180] In the context of threshold pollutants, the level that is requisite is a level sufficiently below the highest level at which no adverse effects are likely to

174. National Ambient Air Quality Standards for Ozone, 75 Fed. Reg. 2938, 2996 (Jan. 19, 2010) (to be codified at 40 C.F.R. pts. 50, 58).

175. *Id.*

176. *Id.*

177. *Id.* at 2998; Broder, *supra* note 115.

178. Coglianese & Marchant, *supra* note 139, at 1283.

179. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 490 (2001) (Breyer, J., concurring).

180. Coglianese & Marchant, *supra* note 139, at 1285; Joseph M. Feller, *Non-Threshold Pollutants and Air Quality Standards*, 24 ENVTL. L. 821, 823–24 (1994).

occur to represent an adequate margin of safety.[181] For nonthreshold pollutants, determining the ambient concentration that is requisite to protect public health is not a simple matter because the science alone yields no obvious benchmark for how much is too much.[182] The Supreme Court in *American Trucking* held that Congress did not have to "provide a 'determinate criterion' for saying 'how much . . . is too much'"[183] and that the statute properly vested "[a] certain degree of discretion" in the agency.[184]

In situations in which no clear threshold exists, the EPA has interpreted the statute to allow it to balance the scientific uncertainty encountered in assessing hazard, exposure, and risk at low concentrations against the threatened harm (or risk) to public health posed by exposure to the pollutant.[185] Thus, the preamble to the 2008 revision of the ozone standard stressed the importance of "balanc[ing] concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower [ozone] levels."[186] The court in *Mississippi v. EPA* concluded that the EPA had struck a proper "balance between 'the increasing uncertainty associated with [its] understanding of the likelihood of such effects at lower [ozone] exposure levels' and 'concern about the potential for health effects and their severity.'"[187]

B. Is Balancing Unprincipled?

In their comprehensive critique of the 1997 ozone and particulates NAAQS proceedings, Professors Coglianese and Marchant accuse the EPA of using science to mask the absence of a "coherent, principled account for why the Agency" chooses the levels that it deems requisite to protect public health with an adequate margin of safety.[188] In particular, the EPA has failed to identify the "principle or criterion [that] justified the

181. *Am. Trucking Ass'ns*, 531 U.S. at 465.

182. Feller, *supra* note 180, at 825.

183. *Am. Trucking Ass'ns*, 531 U.S. at 475.

184. *Id.* (alteration in original) (quoting Mistretta v. United States, 488 U.S. 361, 417 (1989) (Scalia, J., dissenting)) (internal quotation marks omitted).

185. 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, 9–14 (2000).

186. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. 37,818, 37,824 (July 11, 2007) (to be codified at 40 C.F.R. pt. 50). The preamble for the 2010 notice of proposed rulemaking contains the same language. National Ambient Air Quality Standards for Ozone, 75 Fed. Reg. 2938, 2994–95 (proposed Jan. 19, 2010) (to be codified at 40 C.F.R. pts. 50, 58).

187. Mississippi v. EPA, 744 F.3d 1334, 1358 (D.C. Cir. 2013) (quoting National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,436, 16,477 (Mar. 27, 2008) (to be codified at 40 C.F.R. pts. 50, 58).

188. Coglianese & Marchant, *supra* note 139, at 1269, 1291.

Administrator's 'policy choice' in selecting nonzero standards along the continuum of predicted health risks . . . ."[189] Curiously, they do not mention the balancing approach that the EPA has repeatedly applied in addressing nonthreshold criteria pollutants nor do they attempt to demonstrate that it is irrational.

Throughout their critique, Coglianese and Marchant rely heavily on point estimates in the staff-prepared risk assessments.[190] For example, they point to the EPA's estimate that the eight-hour 0.080 ppm level "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."[191] They presume that the Agency viewed this risk as acceptable because it did not propose to set the standard at 0.070 ppm.[192] In a footnote, they note that when the EPA issued its final standard, the risk assessment had changed so dramatically that the risk estimated to accompany the existing one-hour standard was actually lower (at 931,000 cases of moderate decreases in lung function and 58,000 cases of moderate to severe cough) than the previously estimated risk for the proposed 0.080 ppm eight-hour standard.[193] For them, this raises the following questions:

> If 1 million cases of decreased lung function could be tolerated by EPA in its 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?[194]

For those less enamored with quantitative risk assessment, the example might raise the question why the EPA would rely heavily on such highly uncertain point estimates in the first place. The fact that the risk assessment changed so dramatically between the proposed and final rule suggests that point estimates derived from quantitative risk assessments are not especially reliable tools for setting NAAQS. Yet Coglianese and Marchant show little respect for the large uncertainties inherent in the point estimates upon which they rely to support their contention that the EPA was acting in an unprincipled fashion.

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189. *Id.* at 1294.

190. *Id.* at 1302–03, 1306 (referring to point estimates of deaths per year attributable to exposure to fine particulate matter at various levels); *id.* at 1308–09 (referring to point estimates of cough and lung-function decrement attributable to exposure to ozone at various levels); *id.* at 1310 (referring to point estimates of FEV1 decrements in outdoor children); *id.* at 1311–12 (referring to point estimates of moderate to severe pain and decrements in lung function in children).

191. *Id.* at 1308.

192. *Id.*

193. *Id.* at 1308 n.236.

194. *Id.* at 1308–09.

In fact, as we have seen, the EPA did not yield to the temptation to rely on point estimates in choosing the 0.080 ppm level over the 0.090 ppm and 0.070 ppm levels. It balanced the uncertainties inherent in determining the effects on children of exposure to ozone against the threat of harm attributable to ozone exposures.[195] The D.C. Circuit upheld the 0.080 ppm standard over the industry's similar objection.[196] To the industry contention that the EPA had failed to articulate a standard for determining how much ozone pollution was too much, the court responded that the Agency had "no obligation either to identify an accurate 'safe level' of a pollutant or to quantify precisely the pollutant's risks prior to setting primary NAAQS."[197] Instead, the EPA was required to "err on the side of caution . . . taking into account both the available evidence and the inevitable scientific uncertainties."[198]

Professors Coglianese and Marchant are especially critical of the EPA's application of the margin-of-safety concept to nonthreshold pollutants.[199] If the purpose of the margin-of-safety language is to ensure that the Agency errs on the side of safety, they ask, how can the Agency accept any level of risk that is greater than zero for such pollutants?[200] In the EPA's view, the stopping point is inherent in the term "requisite," which conveys the notion of needed but not unnecessary.[201] When large uncertainties make it impossible to determine the precise level at which exposure to a pollutant no longer causes harm, the Agency must err on the side of safety in choosing, interpreting, and drawing inferences from the scientific studies, and employ conservative assumptions in conducting modeling exercises.[202]

C. Justice Breyer's Qualitative Trivial-Risk Approach

Justice Breyer's concurring opinion in *American Trucking* suggests an approach to setting primary NAAQS for nonthreshold pollutants by reference to the concept of "trivial" risk.[203] Like the EPA, Justice Breyer concluded that the terms "requisite" and "adequate margin of safety" did not "describe a world that is free of all risk—an impossible and undesirable

195. *See supra* note 54 and accompanying text.

196. Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 379–80 (D.C. Cir. 2002).

197. *Id.* at 378.

198. *Id. See also* Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 527 (D.C. Cir. 2009) (per curiam) (finding that the EPA was not arbitrary and capricious in declining to rely on point estimates in risk assessment).

199. Coglianese & Marchant, *supra* note 139, at 1309.

200. *Id.* at 1321.

201. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. 37,818, 37,879 (July 11, 2007) (to be codified at 40 C.F.R. pt. 50).

202. *See supra* subpart VI(A).

203. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 496 (2001) (Breyer, J., concurring).

objective," nor were they "to be understood independent of context."[204] In his view, "what counts as 'requisite' to protecting the public health will . . . vary with background circumstances, such as the public's ordinary tolerance of the particular health risk in the particular context at issue."[205] The statute thus granted the Administrator "considerable discretion" to "take account of context when determining the acceptability of small risks to health."[206] The Administrator had discretion to "avoid regulating risks that it reasonably conclude[d] [were] *trivial in context*."[207]

Although Justice Breyer's trivial-in-context approach may beg the question of how little risk is trivial, it does offer as a reference point risks that are within the "public's ordinary tolerance" for risks imposed by others in similar contexts.[208] The Agency could adopt a trivial-risk approach that is consistent with its current approach of balancing uncertainty against threatened harm if it focused more heavily on health end points than on the probabilities of reaching those end points in determining triviality. It may be hard for the Agency to characterize a credible risk of premature death as trivial, even if the probability of any exposed individual dying is very low. When multiplied by the number of people exposed to the criteria pollutants, even a low probability like one in one million will yield estimates of hundreds of deaths per year, which may be hard to characterize as trivial. It will be much easier for the Agency to characterize additional coughs and wheezes as trivial, even if the probability is quite high, because they are less serious end points, tend to be transient and reversible, afflict all of us at one time or another, and are generally regarded as minor inconveniences.

D. A Modest Role for Cost?

The Supreme Court in *American Trucking* held that the EPA may not consider costs in setting the NAAQS.[209] Thoughtful critics of the EPA's balancing approach maintain, however, that if cost considerations are irrelevant to NAAQS standard setting for nonthreshold pollutants, then there is no discernable stopping place along the continuum of exposures other than zero.[210] The fact that the EPA always stops short of zero suggests that some consideration other than science is at least implicitly

204. *Id.* at 494.
205. *Id.*
206. *Id.* at 495.
207. *Id.* at 496 (emphasis added).
208. *Id.* at 494, 496.
209. *Id.* at 471.
210. Coglianese & Marchant, *supra* note 139, at 1284.

operating as a brake against stringency.[211] And that consideration must be cost.[212]

In his *American Trucking* concurring opinion, Justice Breyer argued that Congress did not "require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of 'hurtling' industry over 'the brink of ruin,' or even forcing 'deindustrialization.'"[213] He therefore concluded that the statute gave the Administrator "sufficient flexibility to avoid setting ambient air quality standards ruinous to industry."[214] The EPA seized on the quoted language in the preamble to the 2007 ozone rule in elaborating on the meaning of "requisite" in the statute.[215]

This "calamitous-cost" approach to limiting the stringency of the NAAQS has the considerable advantage of recognizing political reality. The EPA will never write a NAAQS that would bring an important segment of American industry to the brink of ruin. It also recognizes that society has values other than protecting public health and welfare. At the same time, economic considerations are not allowed to dominate the analysis. They become relevant not at the margins but only at the extremes.

The problem with the calamitous-cost approach from a legal standpoint is its exclusive focus on cost. Allowing cost considerations to enter the picture, even at the extremes, may send the Agency down a slippery slope that ends with costs being the dominant consideration. The Agency will face a difficult line-drawing problem in deciding how much economic disruption is too much. And powerful political actors will pressure the Agency to avoid the risk of economic disruption by setting lenient standards. The calamitous-cost approach is thus inconsistent with the protective policies that motivated Congress to exclude cost from the considerations that the EPA may rely upon in setting the NAAQS.

Cost might have an indirect role to play under Justice Breyer's trivial-risk approach, which focuses on "the public's ordinary tolerance of the particular health risk in the particular context at issue."[216] What the public regards as trivial in any particular context may well depend on the cost or inconvenience of reducing or eliminating the risk. We face a risk of contracting a cold or even influenza when we shake hands with one another,

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211. *Id.* at 1286.

212. *Id.* at 1341 n.372 (citing nineteen academic sources concluding that the EPA considered costs in setting NAAQS).

213. *Am. Trucking Ass'ns*, 531 U.S. at 494 (Breyer, J., concurring) (quoting Am. Trucking Ass'ns v. EPA, 174 F.3d 1027, 1037, 1038 n.4 (D.C. Cir. 1999)).

214. *Id.*

215. National Ambient Air Quality Standards for Ozone, 72 Fed. Reg. 37,818, 37,820 (July 11, 2007) (to be codified at 40 C.F.R. pt. 50) (quoting *Am. Trucking Ass'ns*, 531 U.S. at 494–96 (Breyer, J., concurring)).

216. *Am. Trucking Ass'ns*, 531 U.S. at 494 (Breyer, J., concurring).

but most regard that risk as trivial, not only because the probability of contracting a cold is usually small, but also because the consequences are low and the social stigma (i.e., cost) associated with refusing an offered hand is high. To the extent, then, that cost plays this modest indirect role in setting the benchmark for triviality, cost considerations may be lawful under the Clean Air Act.

VII. Conclusions

To the chagrin of many observers, the EPA has never allowed cost to play a prominent role in setting NAAQS. Although the EPA's approach of balancing uncertainty against threatened harm may not be the most intellectually satisfying approach to determining the level of exposure that is requisite to protect public health, the critics have not demonstrated that it is an irrational approach in situations in which uncertainty prevents the Agency from determining a threshold exposure that presents no risk to the public. As scientific studies continue to probe the effects of the criteria pollutants at low exposure levels, the day may come when the EPA can confidently state that there is no threshold level for a given pollutant above the background exposure level. Uncertainty will no doubt still surround the shape of the concentration–response curve at low exposure levels. In contexts in which the uncertainty side of the balance diminishes, smaller risks on the threatened-harm side of the balance will warrant the EPA's attention. At that point, Justice Breyer's trivial-risk approach could become the dominant decision-making approach to setting NAAQS.

Though far from perfect, the EPA's balancing approach has the virtue of advancing a precautionary approach to air pollution control against powerful economic forces intent on avoiding the cost of further controls. In the end, that approach has brought about a remarkable reduction in emissions of the criteria pollutants and their precursors at a cost that, despite apocalyptic predictions to the contrary, has proved far from catastrophic.[217]

217. *Id.* at 492.