

TO LIMIT AIR POLLUTION’S RISKS: A LAW/SCIENCE  
SUCCESS STORY

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INTRODUCTION .....	114
I. A CLEAN AIR STATUTORY EVOLUTION .....	120
II. THE SCIENTIFIC EVOLUTION .....	127
<i>A. A Scientific Challenge</i> .....	129
<i>B. Linearity in Extrapolation: A Dichotomy Grows</i> .....	135
III. THE LEGAL EVOLUTION .....	139
<i>A. The Emergence of ‘Sufficient ≤ Necessary’</i> .....	140
<i>B. Incomplete Information as Weight of the Evidence</i> .....	149
IV. LESSONS & CONCLUSIONS.....	157
APPENDIX: NAAQS ACTIONS, 1970–2022 .....	162

INTRODUCTION

Retired Supreme Court Justice Stephen Breyer once complained that public perceptions of risk, followed by congressional responses thereto and regulatory responses to Congress, routinely created a “vicious circle” in which relatively small risks were over-studied and over-regulated.<sup>1</sup> Examples can be found. Excluded from Breyer’s “circle,” though, was the possibility that an inquiry pursued in response to the public’s risk perceptions could yield astounding progress, discoveries of important new knowledge, and the certainty needed to regulate in the public interest. His so-called ‘last 10 percent’ risks were the catalysts of legalistic irrationality, not scientific or public health triumphs.<sup>2</sup> Seldom has the skeptic been shown up by our risk-regulatory state. From the case study that follows, however, Breyer’s circle is an allegory to

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<sup>1</sup> See STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 10–29, 50–51 (1993) (arguing that “tunnel vision,” “random agenda selection,” and “inconsistency” all resulted from the circularity of public attention to uncertain risks). Breyer was not alone. See, e.g., CASS R. SUNSTEIN, RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT 28–52 (2002).

<sup>2</sup> See BREYER, *supra* note 1, at 11 (“Removing that last little bit [of risk] can involve limited technological choice, high cost, devotion of considerable agency resources, large legal fees, and endless argument.”) (footnotes omitted).

beware. Laws surely have shaped and guided the science of our risk assessments (and risk management). Many are the objects of blistering critiques.<sup>3</sup> From what follows here, though, the question should be: how might legal form be the difference between success and failure?

Laws make some facts relevant and thus can exert a kind of demand-pull on scientists. Putting aside for a moment whether we can measure the strength of such an effect, all things equal, a fact with real consequences turning on its discovery is a fact with more to motivate its study. Now consider what that relationship would be if it had continued to unfold for over five decades. Many students of the policymaking process have held that the supply-demand dynamic between law and fact is straightforward, obvious even, some going to great lengths to measure or to isolate it for study.<sup>4</sup> To grasp any dynamic, however, we must first grasp the relevant state space well enough to distinguish univariate change from multivariate interaction. And it is at least unclear that our understanding of the state spaces of law and science has reached such heights. Without knowing the potential variations in a state space, multivariate interactions are at best difficult to understand and at worst undetectable.

From many examinations of this dynamic to date, it is clear that some “science” is produced for the sole purpose of aiding litigants in present cases and controversies.<sup>5</sup> Thus, our judges have long experimented with

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<sup>3</sup> At least as many of these critiques, however, are of laws that have not regulated stringently enough. See, e.g., Valerie J. Watnick, *The Lautenberg Chemical Safety Act of 2016: Cancer, Industry Pressure, and a Proactive Approach*, 43 HARV. ENV'T L. REV. 373, 375–88 (2019); Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2322–44 (2017); CARL F. CRANOR, TRAGIC FAILURES: HOW AND WHY WE ARE HARMED BY TOXIC CHEMICALS 6–7, 44–45 (2017); FREDERICK ROWE DAVIS, BANNED: A HISTORY OF PESTICIDES AND THE SCIENCE OF TOXICOLOGY 214–20 (2014); Valerie J. Watnick, *Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point*, 4 UTAH L. REV. 1305, 1310–16 (2004).

<sup>4</sup> See, e.g., WILLIAM ASCHER ET AL., KNOWLEDGE AND ENVIRONMENTAL POLICY: RE-IMAGINING THE BOUNDARIES OF SCIENCE AND POLITICS 9–14 (2010); SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 41 (1990) [hereinafter JASANOFF, THE FIFTH BRANCH]; SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 8–11, 24–25, 42–43 (1995) [hereinafter JASANOFF, SCIENCE AT THE BAR].

<sup>5</sup> See, e.g., Edith Beerdsen, *Litigation Science After the Knowledge Crisis*, 106 CORNELL L. REV. 529, 536 (2021); Noah Smith-Drelich, *Performative Causation*, 93 S. CAL. L. REV. 379, 385–96 (2020); Nora Freeman Engstrom, *The Lessons of Lone Pine*, 129 YALE L.J. 2, 21, 47–50 (2019); Gary Edmond et al., *Forensic Science Evidence and the Limits of Cross-Examination*, 42 MELBOURNE U. L. REV. 858, 876–94 (2019); Erin Murphy, *No Room for Error: Clear-Eyed Justice in Forensic Science Oversight*, 130 HARV. L. REV. F. 145, 147 (2017); Erin Murphy, *Neuroscience and the Civil/Criminal Daubert Divide*, 85 FORDHAM L. REV. 619, 621–27 (2016); Edward K. Cheng, *Reconceptualizing the Burden of Proof*, 122 YALE L.J. 1254, 1269–71 (2013); Joëlle Anne Moreno, *Beyond the Polemic Against Junk Science: Navigating the Oceans that Divide Science and Law with Justice Breyer at the Helm*, 81 B.U. L. REV. 1033, 1074–81 (2001).

the means of testing claims to scientific fact.<sup>6</sup> “Deliberate co-production”<sup>7</sup> of factual claims and the legal demands for them now has ensued and now factors into the judicial tests for admissibility in court.<sup>8</sup> Indeed, for every claimed success in the narrative of this form of co-production, there seem to be expanding domains of ‘scientific’ fact as to which much of the public—novices and experts alike—has become resolutely suspect.<sup>9</sup> For many, evidently, such deliberate *production* of facts does not sit well.<sup>10</sup> Facts that are denied by as many as accept them rarely settle disputes, though.<sup>11</sup> As Robert Adler has explained, there are many alternative models to characterize the multivariate interactions that are obviously afoot in any overlapping law/science state space.<sup>12</sup>

For as much as law and science have occupied contemporary political discourse, it would be easy to complain that one or both of them have lately been diminished. The vehement, often baseless attacks in our politics on both seem to be ubiquitous.<sup>13</sup> Our adversarial justice

Finally, some putative experts’ testimony surely is of dubious quality. See Brandon L. Garrett & Gregory Mitchell, *The Proficiency of Experts*, 166 U. PA. L. REV. 901, 903–10 (2018).

<sup>6</sup> Some careful works have analyzed their efforts, see, e.g., DAVID H. KAYE, *THE DOUBLE HELIX AND THE LAW OF EVIDENCE* (2010), as well as the strategic responses thereto. See, e.g., THOMAS O. MCGARITY & WENDY E. WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* (2008).

<sup>7</sup> See Alison M. Meadow et al., *Moving Toward the Deliberate Coproduction of Climate Science Knowledge*, 7 WEATHER, CLIMATE, & SOC’Y 179, 179 (2015) (arguing that “[c]oproduction of knowledge is the process of producing usable, or actionable, science through collaboration between scientists and those who use science to make policy and management decisions.”); see also Ida Nadia S. Djenontin & Alison M. Meadow, *The Art of Co-Production of Knowledge in Environmental Sciences and Management: Lessons from International Practice*, 61 ENV’T MGMT. 885 (2018); Maria Carmen Lemos & Barbara J. Morehouse, *The Co-Production of Science and Policy in Integrated Climate Assessments*, 15 GLOB. ENV’T CHANGE 57 (2005). Professor Jasanoff was among the first to advance a theory of this co-production. See STATES OF KNOWLEDGE: THE CO-PRODUCTION OF SCIENCE AND SOCIAL ORDER (Sheila Jasanoff ed., 2004).

<sup>8</sup> Cf. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589–90 (1993) (asserting that “arguably, there are no certainties in science,” only hypotheses that can be falsified, construing Federal Rule of Evidence 702); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 138, 150–51 (1999) (holding that trial court could exclude expert testimony by an engineer where the engineer’s methods were neither generally accepted nor testable).

<sup>9</sup> See Philip Kitcher, *Public Knowledge and Its Discontents*, 9 THEORY & RSCH. EDUC. 103, 121 (2011).

<sup>10</sup> See Wendy E. Wagner, *No One Solution to the “New Demarcation Problem”?: A View from the Trenches*, 92 STUD. HIST. & PHIL. SCI. 177, 177–78 (2022).

<sup>11</sup> See, e.g., JAMES LAWRENCE POWELL, *THE INQUISITION OF CLIMATE SCIENCE* 3–5 (2011).

<sup>12</sup> See Robert W. Adler, *Coevolution of Law and Science: A Clean Water Act Case Study*, 44 COLUM. J. ENV’T. L. 1, 2–9 (2019).

<sup>13</sup> No doubt our contemporary media and communications environments have amplified these attacks to new heights. See generally JONATHAN RAUCH, *KINDLY INQUISITORS: THE NEW ATTACKS ON FREE THOUGHT* (expanded ed. 2013); LEE MCINTYRE, *THE SCIENTIFIC ATTITUDE: DEFENDING SCIENCE FROM DENIAL, FRAUD, AND PSEUDOSCIENCE* (2019); MICHAEL STREVEN, *THE KNOWLEDGE MACHINE: HOW IRRATIONALITY CREATED MODERN SCIENCE* (2020);

system's tendency to devolve into 'our science versus junk science' no less so.<sup>14</sup> What follows is no such complaint, though. The role of science in a democratic society must remain permanently open to testing. No less is true of law: how the law should constrain administrators (or not) is a foundational yet frustratingly unresolved debate.<sup>15</sup> Though our politics seem to suffer from all the degrading influences lately, if we have any faith in collective action to facilitate the scientific breakthroughs that we need, this study assuredly should inform science and scientists as well as judges and other legal actors.<sup>16</sup>

There is no shortage of literature on the reception of science in U.S. courts.<sup>17</sup> Less prevalent if not much so are the accounts of probability

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JONATHAN RAUCH, *THE CONSTITUTION OF KNOWLEDGE: A DEFENSE OF TRUTH* (2021); John Copeland Nagle, *Humility, Climate Change, and the Pursuit of Scientific Truth*, 97 NOTRE DAME L. REV. REFLECTION 125 (2022); see also RICHARD H. FALLON, JR., *LAW AND LEGITIMACY IN THE SUPREME COURT* (2018).

<sup>14</sup> See, e.g., Wes E. Henricksen, *Scientific Knowledge Fraud*, 97 OR. L. REV. 307, 319–23 (2019); CRANOR, *supra* note 3, at 41–42, 52, 55, 138; Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 KAN. L. REV. 897, 900–01 (2004).

<sup>15</sup> See generally PHILIP HAMBURGER, *IS ADMINISTRATIVE LAW UNLAWFUL?* (2014); ADRIAN VERMEULE, *LAW'S ABNEGATION: FROM LAW'S EMPIRE TO THE ADMINISTRATIVE STATE* (2016).

<sup>16</sup> Cf. MCGARITY & WAGNER, *supra* note 6, at 60–96 (reviewing different efforts at “shaping” science).

<sup>17</sup> See generally James R. Dillon, *Expertise on Trial*, 19 COLUM. SCI. & TECH. L. REV. 247 (2018); Barbara Pfeffer Billauer, *Admissibility of Scientific Evidence Under Daubert: The Fatal Flaws of 'Falsifiability' and 'Falsification'*, 22 B.U. J. SCI. & TECH. L. 21 (2016); Michael Traynor, *Communicating Scientific Uncertainty: A Lawyer's Perspective*, 45 ENV'T L. REP. 10159 (2015); Deborah M. Hussey Freeland, *Law & Science: Toward a Unified Field*, 47 CONN. L. REV. 529 (2014); Deborah M. Hussey Freeland, *Speaking Science to Law*, 25 GEO. INT'L ENV'T L. REV. 289 (2013); Emily Hammond Meazell, *Deference and Dialogue in Administrative Law*, 111 COLUM. L. REV. 1722 (2011); Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733 (2011) [hereinafter Meazell, *Super Deference*]; Stephanie Tai, *Uncertainty About Uncertainty: The Impact of Judicial Decisions on Assessing Scientific Uncertainty*, 11 J. CONST. L. 671 (2009); Sara A. Clark, *Taking a Hard Look at Agency Science: Can the Courts Ever Succeed?*, 36 ECOLOGY L.Q. 317 (2009); ROBIN FELDMAN, *THE ROLE OF SCIENCE IN LAW* (2009); John S. Applegate & Robert L. Fischman, *Foreword: Missing Information: The Scientific Data Gap in Conservation and Chemical Regulation*, 83 IND. L.J. 399 (2008); ERICA BEECHER-MONAS, *EVALUATING SCIENTIFIC EVIDENCE: AN INTERDISCIPLINARY FRAMEWORK FOR INTELLECTUAL DUE PROCESS* (2007); David L. Faigman, *Judges as "Amateur Scientists"*, 86 B.U. L. REV. 1207 (2006); Carla Mattix & Kathleen Becker, *Scientific Uncertainty Under the National Environmental Policy Act*, 54 ADMIN. L. REV. 1125 (2002); DAVID L. FAIGMAN, *LEGAL ALCHEMY: THE USE AND MISUSE OF SCIENCE IN THE LAW* (1999); KENNETH R. FOSTER & PETER W. HUBER, *JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS* (1999); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995); Kenneth S. Abraham & Richard A. Merrill, *Scientific Uncertainty in the Courts*, 2 ISSUES SCI. & TECH. 93 (1986).

and hypothesis testing in court.<sup>18</sup> Hypothesis testing is a shopworn element of many scientific traditions. Its basic relevance and epistemic foundations, however, both remain unsettled. Moreover, advocates in the legal process have shown great talent for distorting those in the eyes of novice jurors and generalist judges. This has impacted the practice of risk assessment repeatedly.<sup>19</sup> We will approach the involvement of courts in probabilities and hypothesis testing indirectly, largely because the law in focus is administered by an agency and only comes to court within strict parameters. This affords us a detailed case study grounded in especially deep legal and scientific records. Climate change has kept the roles of hypothesis uncertainty and burdens of proof in civil adjudication under the microscope for years now.<sup>20</sup> Many have been the claims about law and science emanating from that crucible. None of them, however, can be assessed over a half-century of legal and scientific development. That length of time foregrounds the key relationships: iterations of gathering and weighing evidence numerous enough to detect the reciprocal influences.<sup>21</sup> Certainly the judiciary's

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<sup>18</sup> See generally Erica Beecher-Monas, *Lost in Translation: Statistical Inference in Court*, 46 ARIZ. STATE L.J. 1057 (2014); Sander Greenland & Charles Poole, *Problems in Common Interpretations of Statistics in Scientific Articles, Expert Reports, and Testimony*, 51 JURIMETRICS J. 113 (2011); Sander Greenland, *The Need for Critical Appraisal of Expert Witnesses in Epidemiology and Statistics*, 39 WAKE FOREST L. REV. 291 (2004); David E. Adelman, *Scientific Activism and Restraint: The Interplay of Statistics, Judgment, and Procedure in Environmental Law*, 79 NOTRE DAME L. REV. 497 (2004); William Meadow & Cass R. Sunstein, *Statistics, Not Experts*, 51 DUKE L.J. 629 (2001); STATISTICAL SCIENCE IN THE COURTROOM (Joseph L. Gastwirth ed., 2000); D.H. Kaye, *Is Proof of Statistical Significance Relevant?*, 61 WASH. L. REV. 1333 (1986).

<sup>19</sup> See NAT'L RSCH. COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 26–57 (2009) [hereinafter NRC, SCIENCE AND DECISIONS]; NAT'L RSCH. COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 3, 29–42 (1994).

<sup>20</sup> See, e.g., Daniel Kim et al., *Judicial Review of Scientific Uncertainty in Climate Change Lawsuits: Deferential and Nondeferential Evaluation of Agency Factual and Policy Determinations*, 46 HARV. ENV'T L. REV. 367, 367, 372–77, 430–33 (2022); Cass R. Sunstein, *Arbitrariness Review and Climate Change*, 170 U. PA. L. REV. 991, 1019–22 (2022) [hereinafter Sunstein, *Arbitrariness Review*]; Michael Burger et al., *The Law and Science of Climate Change Attribution*, 45 COLUM. J. ENV'T L. 57, 147–50, 191–94 (2020); Fred K. Morrison et al., *Climate Change Science and the Daubert Standard*, 44 WM. & MARY ENV'T L. & POL'Y REV. 391, 391–92, 417–19 (2020); Kirsten Engel & Jonathan Overpeck, *Adaptation and the Courtroom: Judging Climate Science*, 3 MICH. J. ENV'T & ADMIN. L. 1, 4–7, 23–25 (2013); Eric Biber, *Which Science? Whose Science? How Scientific Disciplines Can Shape Environmental Law*, 79 U. CHI. L. REV. 471, 471–72, 480–81 (2012); Jill Jaffe, *Scientific Uncertainty and the Regulation of Greenhouse Gases Under the Clean Air Act*, 37 ECOLOGY L.Q. 765, 767–771 (2010).

<sup>21</sup> See, e.g., Wendy Wagner, *It isn't Easy Being a Bureaucratic Expert: Celebrating the EPA's Innovations*, 70 CASE W. RESV. L. REV. 1093, 1094–97 (2020) [hereinafter Wagner, *EPA's Innovations*]; Adler, *supra* note 12, at 64 (“Scientific advances often stimulate a legal response, and vice versa.”); cf. Edward K. Cheng, *Changing Scientific Evidence*, 88 MINN. L. REV. 315, 322 (2003) (“Whenever litigation occurs before the scientific community has developed a

decisional record and posture(s) can register a range of impacts within any given field of inquiry persisting over time. Whether it or any other legal actor can do so deliberately or effectively, however, is the better question.<sup>22</sup>

This examination of the setting of the Clean Air Act's ("CAA") national ambient air quality standards ("NAAQS") traces a court/agency interface of high stakes and deep uncertainties. *Law's* role in any such model must be distinguished from that of *policy* and policymaking. Policy is immanently mutable in ways that law is not. Lawmaking entails costs ("frictions") that policymaking may not. That is its typifying feature. Fixity distinguishes legal norms from other, similar norms, at least to the extent that law makes a practical difference. Law, in this much, *inhibits* policy change and denies policymakers full(er) autonomy.<sup>23</sup> This inhibition of policy change may even be a key to why law can help a science advance more deliberately, rapidly, or beneficially. For, as well-intentioned as policymakers may be, they can also be ill-informed, ill-timed, biased, and worse.<sup>24</sup>

Our courts were well past the point of regarding science as a "charter of certainty"<sup>25</sup> when this tale began. In its best light, science was seen as advanced inquiry that might one day force us to reevaluate our deepest beliefs about logic, value, truth, and meaning.<sup>26</sup> It had become abundantly clear that bureaucratic organizations were prototypically superior to generalist judges and their adversarial adjudications in martialing, weighing, and grasping the rhythms of scientific research.<sup>27</sup> But Breyer's critical hypothesis was decades away, and skeptical resistance to science and bureaucratic attacks on risks still rare. Part I traces the statutory developments leading to the CAA we know. Parts II

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substantial literature on the harmful effects of a substance, there is a significant probability that fact finders will reach ultimately inaccurate conclusions.").

<sup>22</sup> See, e.g., Kim et al., *supra* note 20, at 422 (identifying four forms of arbitrariness in agency judgments that have drawn heightened scrutiny from reviewing courts). *But see* Tai, *supra* note 17, at 708 ("[I]n the context of determining whether the existence of scientific uncertainties warrants judicial deference, judges have even fewer traditional constraints on their ability to reach ends-oriented judgments."); Jamison E. Colburn, *Reasons as Experiments: Judgment and Justification in the "Hard Look"*, 9 CONTEMP. PRAGMATISM 205, 205–209 (2012).

<sup>23</sup> See FREDERICK SCHAUER, *PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISION-MAKING IN LAW AND IN LIFE* 167–74 (1991); JOSEPH RAZ, *PRACTICAL REASON AND NORMS* 149–53 (1975).

<sup>24</sup> See, e.g., JASON BRENNAN, *AGAINST DEMOCRACY* 141–43 (2016).

<sup>25</sup> JEROME FRANK, *LAW AND THE MODERN MIND* 285 (1930) (calling this notion naïve, unsophisticated, and unscientific).

<sup>26</sup> See JOHN DEWEY, *LOGIC: THE THEORY OF INQUIRY* 6, 14 (1938).

<sup>27</sup> See HENRY M. HART, JR. & ALBERT M. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW* cxiii–cxxv (William N. Eskridge, Jr. & Philip P. Frickey eds., 1994).

and III describe the scientific and legal evolutions that ensued from within that compound scheme. Part IV collects the lessons learned since and proposes three firm conclusions.

#### I. A CLEAN AIR STATUTORY EVOLUTION

In 1963, Congress directed its agent—then the Secretary of Health, Education, and Welfare, later the Administrator of the Environmental Protection Agency (“EPA”)—to “compile and publish criteria reflecting accurately the latest scientific knowledge useful in indicating the kind and extent of [effects harmful to the health or welfare of persons] which may be expected from the presence of . . . air pollution . . . in the air in varying quantities.”<sup>28</sup> These air quality criteria were informational. States were to use them as needed in their own bids to reduce air pollution.<sup>29</sup> Congress required that they be updated “whenever necessary to reflect accurately developing scientific knowledge.”<sup>30</sup> The 88th Congress also initiated the federal government’s commitment to a “national research and development program” to include “research, investigations, experiments, training, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, and control of air pollution.”<sup>31</sup>

By amendments in 1967, the 90th Congress required that the air quality criteria be issued “after consultation with appropriate advisory committees and Federal department and agencies,” and were to be prepared “from time to time, but as soon as practicable” as “in [the Secretary’s] judgment may be *requisite for the protection of the public health and welfare*.”<sup>32</sup> That would become a key facet of the scheme: the linking of the term “requisite” with “the protection of public health and welfare.”

In 1970, the 91st Congress reworked this scheme a third time.<sup>33</sup> The federal pollution control statutes of the time were notorious for their

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<sup>28</sup> Clean Air Act of 1963, Pub. L. No. 88-206, § 3(c)(2), 77 Stat. 392, 395 (current version at 42 U.S.C. § 7408).

<sup>29</sup> *See id.* (“Any such criteria shall be published for informational purposes and made available to municipal, State, and interstate air pollution control agencies.”). Some states, California especially, pioneered the air quality improvement efforts that were eventually federalized by these statutes. *See generally* JAMES E. KRIER & EDMUND URSIN, POLLUTION AND POLICY: A CASE ESSAY ON CALIFORNIA AND FEDERAL EXPERIENCE WITH MOTOR VEHICLE AIR POLLUTION, 1940–1975 (1977).

<sup>30</sup> Clean Air Act of 1963, Pub. L. No. 88-206, § 3(c)(2), 77 Stat. 392, 395 (current version at 42 U.S.C. § 7408).

<sup>31</sup> *Id.* § 3(a).

<sup>32</sup> *See* Air Quality Act of 1967, Pub. L. No. 90-148, § 107(b)(1), 81 Stat. 485, 491 (emphasis added).

<sup>33</sup> *See* Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676.

tactical embrace of a “best available technology” approach. Sources of pollution were required to control emissions based on the best technology available, regardless of their causation of or contribution to public health or welfare problems. The most prominent exception would become the national ambient air quality standards or “NAAQS,” which were instead informed by public health impacts.<sup>34</sup> The 1970 amendments reiterated that “[a]ir quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.”<sup>35</sup> But those criteria were now to become the basis of federal ambient environmental quality minima—the NAAQS. Congress required that these NAAQS be set at levels “requisite” to protect “public health,” “allowing an adequate margin of safety.”<sup>36</sup> That term, “requisite,” the courts would later agree, was a deliberate choice, one with considerable significance given the other facets of the scheme.<sup>37</sup> With the ensemble of steps and outputs leading to the NAAQS—criteria, criterial reviews, independent consultations, and federal minima *requisite* to protect the public health—courts would also hold (repeatedly) that the statute precluded EPA from any consideration of costs or technical feasibility.<sup>38</sup> Indeed, that interpretation of the Act was binding precedent as of 1980.<sup>39</sup>

These standards, the NAAQS, were to be the “cornerstone” of the Act.<sup>40</sup> The Senate Report, still quoted by courts and EPA to interpret the CAA, dubbed the Senate bill the “National Air Quality Standards Act of 1970.”<sup>41</sup> States were to “provide[] for implementation, maintenance, and enforcement of such primary standard[s] in each air quality control

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<sup>34</sup> See Joseph M. Feller, *Non-Threshold Pollutants and Air Quality Standards*, 24 ENV'T L. 821, 827–38 (1994).

<sup>35</sup> Clean Air Amendments, sec. 4(a), § 108(a)(2) (current version at 42 U.S.C. § 7408(a)(2)).

<sup>36</sup> Clean Air Amendments, sec. 4(a), § 109(b)(1) (current version at 42 U.S.C. § 7409(b)(1)).

<sup>37</sup> *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 473 (2001); see also *Nat'l Env't Dev. Ass'n v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012); *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1146–50 (D.C. Cir. 1980) (quoting S. REP. NO. 91-1196 (1970)).

<sup>38</sup> See, e.g., *Lead Indus. Ass'n*, 647 F.2d at 1148–49; *Nat. Res. Def. Council, Inc. v. EPA (NRDC)*, 902 F.2d 962, 973 (D.C. Cir. 1990); *Am. Trucking Ass'ns v. EPA (Am. Trucking I)*, 175 F.3d 1027, 1038–40 (D.C. Cir. 1999), *rev'd in part sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. at 464–72. See *infra* Part III.

<sup>39</sup> See *Am. Petrol. Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981) (“API’s argument that the Administrator erred in not considering the attainability and cost justifications for the ozone standards was specifically rejected in the *Lead Industries* case.” (citing *Lead Indus. Ass'n*, 647 F.2d at 1148)).

<sup>40</sup> R. SHEP MELNICK, *REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT* 239 (1983).

<sup>41</sup> See S. REP. NO. 91-1196 (1970).



region” within their boundaries.<sup>42</sup> States would claim the discretion therein to decide which sources of the pollutants to control the strictest, and also the responsibility for doing so.<sup>43</sup> Other, “secondary” NAAQS were to be set at levels “requisite to protect the *public welfare* from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.”<sup>44</sup> Only later would these secondary standards make much practical difference and, to date, no court has yet made much of the distinct terminology guiding the secondary NAAQS.<sup>45</sup> Thus, as twin ambient environmental quality minima, they set nationwide goals of “clean” air for all.

Yet, when the 91st Congress transitioned the air quality criteria into the substrate of the NAAQS, our understanding of air pollution as a threat to public health was still quite rudimentary compared to what we know today. For example, the best available scientific knowledge of that day took air *pollutants* singly, divisibly, as agents unto themselves. Today, the science is much more mixed about that agenda, much of it demonstrating that air pollutants intermix, interact, and are contributory causes of illness and death.<sup>46</sup> The 91st Congress also appropriated EPA a considerable budget for EPA’s own research, some 1,900 scientists and engineers in-house, and had extensive plans for the agency to learn. Their statutory amendments had required EPA to “give special emphasis to research on the short- and long-term effects of air pollutants on public health and welfare,” and demanded an “accelerated research program” “to improve knowledge” on a list of pollution sources.<sup>47</sup> And accelerate the research on air pollutants it did.<sup>48</sup>

Finally, in 1977, Congress added novel facets to the scheme for a fourth time. First, it directed EPA to create and maintain a science advisory body, what would become known as the Clean Air Scientific

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<sup>42</sup> Clean Air Amendments of 1970, Pub. L. No. 91-604, sec. 4(a), § 110(a)(1), 84 Stat. 1676, 1680 (current version at 42 U.S.C. § 7410(a)(1)).

<sup>43</sup> See *Union Elec. Co. v. EPA*, 427 U.S. 246, 255–65 (1976).

<sup>44</sup> Clean Air Amendments, sec. 4(a), § 109(b)(2) (current version at 42 U.S.C. § 7409(b)(2)) (emphasis added). The Act defined public “welfare” to include “effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.” *Id.* sec. 15(a)(1), § 302(h) (current version at 42 U.S.C. § 7602(h)).

<sup>45</sup> Clean Air Amendments, sec. 4(a), § 109(b)(2) (current version at 42 U.S.C. § 7409(b)(2)).

<sup>46</sup> See Knudsen, *supra* note 3, at 2314–21.

<sup>47</sup> Clean Air Amendments, sec. 2(a), § 103(f)(1) (amended 1990).

<sup>48</sup> “By 1977, EPA’s energy research budget [alone] was equivalent to over \$500 million in 2019 dollars, most of it to support research by experts in industry and academic institutions.” Charles Andrew Miller, *Fifty Years of EPA Science for Air Quality Management and Control*, 67 ENV’T MGMT. 1017, 1019 (2021) (citation omitted).

Advisory Committee (“CASAC”).<sup>49</sup> This CASAC was to be “composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.”<sup>50</sup> EPA was, by “January 1, 1980, and at five-year intervals thereafter,” to “complete a review of the criteria [and the NAAQS] and . . . recommend to the Administrator any new [NAAQS] and revisions of existing criteria and standards as may be appropriate.”<sup>51</sup> In those instances, the Administrator, “at the time any proposed criteria document, standard, limitation, or regulation . . . is provided to any other Federal agency for formal review and comment,” was to “make available to the [CASAC] such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information” in EPA’s possession “on which the proposed action is based.”<sup>52</sup>

The CASAC, in turn, was directed to “make available to the Administrator . . . its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitations, or regulation, together with any pertinent information in the Board’s possession.”<sup>53</sup> For any rulemaking, EPA was to include in its basis and purpose statement an “explanation of the reasons” for any “important” differences between its finished rule and any of the CASAC’s “pertinent findings, recommendations, and comments.”<sup>54</sup> Lastly, CASAC was to “advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised [NAAQS]” and “describe the research efforts necessary to provide the required information,” among other things.<sup>55</sup>

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<sup>49</sup> See Clean Air Act Amendments of 1977, Pub. L. No. 95-95, sec. 106(a), § 109(d)(2), 91 Stat. 685, 691 (current version at 42 U.S.C. § 7409(d)(2)). EPA had already taken it upon itself in 1974 to create a “Science Advisory Board” (“SAB”) in connection with the criteria and NAAQS. See *Am. Petrol. Inst. v. Costle*, 665 F.2d 1176, 1182 (D.C. Cir. 1981). The SAB was later endorsed by Congress, see Environmental Research, Development, and Demonstration Authorization Act of 1978, Pub. L. No. 95-155, § 8(a), 91 Stat. 1257, 1260 (1977), and the CASAC later rendered a subpart thereof. See *About the Science Advisory Board (SAB) and the SAB Staff Office*, U.S. EPA, <https://www.epa.gov/aboutepa/about-science-advisory-board-sab-and-sab-staff-office> (last updated May 15, 2023).

<sup>50</sup> Clean Air Act Amendments, sec. 106(a), § 109(d)(2) (current version at 42 U.S.C. § 7409(d)(2)).

<sup>51</sup> *Id.*

<sup>52</sup> Environmental Research, Development, and Demonstration Authorization Act § 8(e)(1).

<sup>53</sup> *Id.* § 8(e)(2).

<sup>54</sup> Clean Air Act Amendments, sec. 305(a), § 307(d)(3) (current version at 42 U.S.C. § 7607(d)(3)).

<sup>55</sup> *Id.* sec. 106(a), § 109(d)(2) (current version at 42 U.S.C. § 7409(d)(2)). CASAC was also to advise EPA “on the relative contribution to air pollution concentrations of natural as well as

A final facet of the scheme, mostly an accident of timing, is worth mentioning. The 91st Congress also (fatefully) required that NAAQS be set *within four months* of its amendments' enactment (December 31, 1970) for the pollutants for which criteria had been developed. That included carbon monoxide ("CO"), hydrocarbons, photochemical oxidants, oxides of sulfur (commonly known as "SO<sub>x</sub>"), total suspended particulates (TSP), and EPA's later-added oxides of nitrogen (commonly known as "NO<sub>x</sub>").<sup>56</sup> In this, Congress decided six of the eventual seven "criteria pollutants" and ensuing NAAQS.<sup>57</sup> (The last, lead, would be added in 1976 in response to a court order.<sup>58</sup>) EPA's scientists and others would pursue these pollutants and their traceable effects in what has now been about a half century of directed inquiry. There is no knowing what further study or deliberation might have revealed about *other* pollutants worthy of inclusion in or treatment by this scheme. The lock-in effect on these pollutants, though perhaps considerable,<sup>59</sup> is of unknown strength. One entry, hydrocarbons, *was* removed from the original list and its NAAQS revoked. It had been set in 1971 as an auxiliary to photochemical oxidants, a major constituent of what was already known as *smog*. Following removal, hydrocarbons were thereafter swept into that standard's ambit.<sup>60</sup> Indeed,

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anthropogenic activity" and on "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies" for attaining the NAAQS. *Id.*

<sup>56</sup> See National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 1502, 1502 (proposed Jan. 30, 1971). This rush to standards no doubt distorted the list as several other pollutants could easily have been included after further study. See John Bachmann, *Will the Circle Be Unbroken: A History of the U.S. National Ambient Air Quality Standards*, 57 J. AIR & WASTE MGMT. ASS'N 652, 671–74 (2007). The emitted pollutants closely tracked what was then being controlled from auto emissions. See Delbert S. Barth, *Federal Motor Vehicle Emission Goals for CO, HC, and NO<sub>x</sub> Based on Desired Air Quality Levels*, 20 J. AIR POLLUTION CONTROL ASS'N 519, 519 (1970). Krier and Ursin quoted an assistant EPA administrator of the time to the effect that the Act was "interpreted to require that emissions be controlled to a point at which . . . the sickest emphysema victim on the second worst inversion day of the year should be able to spend eight hours at the busiest street corner of the most polluted city without suffering any ill effects." KRIER & URSIN, *supra* note 29, at 208.

<sup>57</sup> See National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 8186, 8186 (Apr. 30, 1971).

<sup>58</sup> See National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46246, 46246 (Oct. 5, 1978) (discussing Nat. Res. Def. Council v. Train, 411 F. Supp. 864 (S.D.N.Y. 1976), *aff'd*, 545 F.2d 320 (2d Cir. 1976)).

<sup>59</sup> Cf. E. Donald Elliott, *A Critical Assessment of the EPA's Air Program at Fifty and a Suggestion for How It Might Do Even Better*, 70 CASE W. RESV. L. REV. 895, 896, 904–15 (2020) (arguing that EPA's air quality program has been fixed on a short list of pollutants to its detriment).

<sup>60</sup> See National Primary and Secondary Ambient Air Quality Standards, 48 Fed. Reg. 628 (Jan. 5, 1983). EPA revoked the NAAQS with the CASAC's approval after concluding that hydrocarbons were not then a threat to public health or welfare at ambient levels and because "the

photochemical oxidants themselves would soon be replaced by the indicator ozone (“O<sub>3</sub>”) as the chief measurable constituent thereof.<sup>61</sup>

Importantly, each of the original 1971 NAAQS consisted of the same four components or *elements* that would later define the NAAQS as legal norms: (1) an indicator, (2) a level, (3) an averaging period, and (4) a form. Although the original rulemaking notice did not state that its pollutant descriptions were merely indicators nor that the statistics being used were specific choices, these elements have jointly defined the standards as laws since. The “indicator” is the species of chemical, element, or agent being measured. (Since 1971, with the exceptions of lead and carbon monoxide (CO), the indicators were or became surrogates for multiple agents that the NAAQS control in place.<sup>62</sup>) The “level” is the acceptable quantity or concentration of that indicator in ambient air. The averaging period is the timespan or interval in which measures are taken and then aggregated. And the specific form is the air quality statistic relating the level(s) measured to the intervals. So, for example, a standard for sulfur oxides in the ambient air set at 1,300 µg/M<sup>3</sup> (or 0.5 parts per million (ppm) at standard temperature and pressure) averaged over three-hour periods with no more than one exceedance per year<sup>63</sup> prohibits sulfur dioxide (“SO<sub>2</sub>”) from comprising—more than once annually—more than that mass-fraction of a cubic meter of ambient air (or its equivalent volumetric fraction) measured in three-hour intervals.<sup>64</sup>

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original basis for the NAAQS for hydrocarbons c[ould] no longer . . . justify retaining them as a guide for attainment of the ozone standards.” *Id.* at 628.

<sup>61</sup> See Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202, 8210 (Feb. 8, 1979).

<sup>62</sup> For example, photochemical oxidants, a group of elements (like O) and compounds (like O<sub>3</sub>) which cause oxidative stress in lung tissues, form from the combination of shortwave ultraviolet radiation and various chemical precursors, including hydrocarbons and NO<sub>2</sub>. The indicator for photochemical oxidants was later changed to O<sub>3</sub> (ozone), *see id.* at 8210, in part to reflect the “chemical species (ozone) that has always been measured by the reference method used to estimate ambient oxidant levels and determine compliance with the standard.” Ozone has been the principal constituent but has presented unique challenges for its interrelationship with other criteria pollutants (like the nitrogen oxides).

<sup>63</sup> This was part of the original secondary standard for sulfur oxides, *see* National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 8186, 8187 (Apr. 30, 1971) (codified at 42 C.F.R. pt. 410), and has been retained in full in two subsequent reviews. *See* Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Sulfur, 77 Fed. Reg. 20218, 20219–20 (Apr. 3, 2012). The specific form permitting no more than one (or two, three, four, *etc.*) exceedances annually as opposed to an arithmetic average (or mean) can make immense practical differences for control strategies.

<sup>64</sup> Although Congress has never intervened in the settling of a NAAQS level, the 1977 amendment did direct EPA to decide about a short-term, *i.e.*, a three-hour, averaging period for NO<sub>2</sub>. *See* Clean Air Act Amendments of 1977, Pub. L. No. 95-95, sec. 104(b), § 108(c), 91 Stat. 685, 689 (current version at 42 U.S.C. § 7408(c)). EPA made no determination on a short-term

These elements reflect air pollution as risk. The risk is in the exposure and exposures vary tremendously. Originally, for example, the primary NAAQS for nitrogen dioxide (“NO<sub>2</sub>”) had been proposed with a daily averaging period but was changed in the final rule in 1971 to an annual averaging period because “[n]o adverse effects on public health or welfare ha[d] been associated with *short-term exposure* to nitrogen dioxide at levels which have been observed to occur in the ambient air.”<sup>65</sup> Understandings of the risks from exposure evolve, too. By 2010, the evidentiary picture of NO<sub>2</sub> had changed and a short-term (one-hour) aspect of the standard was adopted.<sup>66</sup>

What of other pollutants and the evidence adduced supporting a NAAQS for them? That is less a tale of science and more one of the statute’s structure and timing: the control of most other pollutants went elsewhere.<sup>67</sup> Indeed, the NAAQS have been shaped considerably by that origin in 1971. Much of the political impetus for the constitution of CASAC and the periodic reviews that would regularly actuate it stemmed from complaints about the original standards and EPA’s mistakes (or alleged mistakes) therein.<sup>68</sup> Congress’s response during a period of intense political foment over air pollution and its control was to tightly structure the gathering of the ‘latest scientific knowledge’ by employing an external reviewer EPA’s exchanges with whom would be recorded and docketed for judicial review.

In total, as of November 1977, the statutory scheme required that: (1) EPA propose the NAAQS based on criteria “accurately reflect[ing] the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects . . . which may be expected from the presence of such pollutant in the ambient air,”<sup>69</sup> (2) EPA provide CASAC with its criteria documents (“CDs”) forming the basis of any NAAQS or its revision; (3) the “primary” NAAQS be “requisite” to protect “public health”<sup>70</sup> allowing an “adequate margin of safety” while any

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NO<sub>2</sub> standard until 1985 and then decided to retain the NAAQS unchanged. *See* Retention of the National Ambient Air Quality Standards for Nitrogen Dioxide, 50 Fed. Reg. 25532 (June 19, 1985).

<sup>65</sup> National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 8186, 8186 (Apr. 30, 1971) (emphasis added).

<sup>66</sup> *See* Primary National Ambient Air Quality Standards for Nitrogen Dioxide, 75 Fed. Reg. 6474, 6474 (Feb. 9, 2010). The 2010 addition to the primary standard was 100 parts per billion (ppb), 1-hour average at the 98th percentile of 1-hour daily maximum concentrations in the yearly distributions, averaged over three years. Practically, that permits about 7 exceedances per year.

<sup>67</sup> *See* Bachmann, *supra* note 56, at 674 (noting that EPA utilized a variety of authorities elsewhere in the statute to control other pollutants outside the criterial route).

<sup>68</sup> *See* MELNICK, *supra* note 40, at 281–94; Bachmann, *supra* note 56, at 676–79.

<sup>69</sup> 42 U.S.C. § 7408(a)(2) (1982).

<sup>70</sup> *Id.* § 7409(b)(1).

“secondary” NAAQS be so for “public welfare”<sup>71</sup> following comments from CASAC and the public; (4) EPA explain any *important* differences between its rules and the CASAC’s findings or recommendations; (5) EPA review each NAAQS by 1980 and at least once every five years;<sup>72</sup> (6) the CASAC be formed and conduct reviews of criteria and NAAQS at least once every five years;<sup>73</sup> and (7) CASAC identify any knowledge not yet possessed that could aid the foregoing. This compound scheme—and several critical details following below—resulted in a highly visible and coordinated investigative scientific program that would go on to push immense social, economic, and legal change.

The contents of that first rulemaking in 1971 reveal the sweep of the evolution since. For, although the information available on the pollutants’ risks was slim, the statute demanded action all the same.<sup>74</sup> The only suit the 1971 rulemaking prompted—which ended in a remand to EPA to create a fuller administrative record—itself prompted EPA’s reconsideration and revocation of part of its secondary NAAQS for sulfur oxides.<sup>75</sup> The NAAQS-setting exercises would quickly evolve scientifically and legally, creating a deep record of reciprocal influences. Part II tracks the scientific developments.

## II. THE SCIENTIFIC EVOLUTION

A statute requiring the “latest scientific knowledge useful” in indicating “all identifiable effects” of pollutants demands a continuing inquiry into causation, pollutant by pollutant, and how the discriminable effects thereof register.<sup>76</sup> That search for cause and effect has now been ongoing for a half century.<sup>77</sup> The statute’s identification of that approach with the pursuit of “safety” has irritated critics (including Breyer<sup>78</sup>). The

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<sup>71</sup> *Id.* § 7409(b)(1)–(2).

<sup>72</sup> *Id.* § 7409(d)(1).

<sup>73</sup> *Id.* § 7409(d)(2).

<sup>74</sup> See National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 8186, 8186 (Apr. 30, 1971) (“[T]he need for increased knowledge of the health and welfare effects of air pollution cannot justify failure to take action based on knowledge presently available.”).

<sup>75</sup> See National Primary and Secondary Ambient Air Quality Standards: Sulfur Oxides, 38 Fed. Reg. 25678, 25679 (Sept. 14, 1973). (“[T]he Administrator has concluded that there still is not adequate information on which to base any long-term secondary standard for sulfur dioxide.”).

<sup>76</sup> “Effects” had demanded legal “causes” long before the CAA. See H.L.A. HART & TONY HONORÉ, CAUSATION IN THE LAW 28–61 (2d ed. 1985).

<sup>77</sup> See Bachmann, *supra* note 56, at 692.

<sup>78</sup> See, e.g., Whitman v. Am. Trucking Assns, 531 U.S. 457, 494 (2001) (Breyer, J., concurring) (“The statute, by its express terms, does not compel the elimination of *all* risk; and it grants the Administrator sufficient flexibility to avoid setting [NAAQS] ruinous to industry.”).

courts, however, have emphatically and repeatedly endorsed the search and the resulting *ratchet* put in EPA's hands. A ratchet is a tool locked to drive in one direction and passively reset in the opposite direction. In thirty-two final actions on thirteen distinct NAAQS from the original 1971 rulemaking to the present, EPA has only once determined that a standard was set to a level that was *too* stringent (which it later changed back<sup>79</sup> and then lowered further<sup>80</sup>), and no court has ever held that EPA's chosen NAAQS level was too stringent.<sup>81</sup> Indeed, even now, as some of the NAAQS butt up against natural background levels of their pollutants, there is still pressure to lower them to be more stringent.<sup>82</sup> Although many have questioned the speed at which EPA operated this ratchet,<sup>83</sup> as a rule, the levels of pollution allowed by the NAAQS have changed only in decrements and as trailing indicators of the toxicological and epidemiological inquiries studying them. The five-year reviews became the reset. As the means of detecting and measuring effects from those pollutants have sharpened, this tool has driven a truly colossal air pollution control curve.<sup>84</sup> More recently, the ratchet has

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<sup>79</sup> When the original NAAQS for photochemical oxidants was reviewed in 1978, EPA changed the indicator to O<sub>3</sub> (ozone) and increased the level slightly from 0.08 parts per million (ppm) hourly average not to be exceeded more than once per year to 0.12 ppm hourly average not to be exceeded more than once annually. *See Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants*, 44 Fed. Reg. 8202, 8202 (Feb. 8, 1979). In the 2008 review, however, the level was revised back to 0.075 ppm. *See National Ambient Air Quality Standards for Ozone*, 73 Fed. Reg. 16436, 16511 (Mar. 27, 2008) (codified at 40 C.F.R. pts. 50, 58).

<sup>80</sup> *See National Ambient Air Quality Standards for Ozone*, 80 Fed. Reg. 65292, 65452 (Oct. 26, 2015).

<sup>81</sup> In only six instances has any petitioner prevailed in any way and, in all six, it was with a remand to the agency for an improved administrative record, *see Kennecott Copper Corp. v. EPA*, 462 F.2d 846, 850–51 (D.C. Cir. 1972); *Am. Petrol. Inst. v. Costle*, 609 F.2d 20, 21 (D.C. Cir. 1979), or for a clearer explanation of the choices made, *see Nat. Res. Def. Council, Inc. v. EPA (NRDC)*, 902 F.2d 962, 980 (D.C. Cir. 1990); *Am. Trucking Ass'ns v. EPA (Am. Trucking I)*, 175 F.3d 1027, 1033 (D.C. Cir. 1999), *rev'd in part sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001); *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 392–93 (D.C. Cir. 1998); *Murray Energy Corp. v. EPA*, 936 F.3d 597, 616–20 (D.C. Cir. 2019).

By contrast, industry petitions arguing the standard(s) set were set too stringently have been denied in full at least ten times. *See Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1184 (D.C. Cir. 1980); *Am. Petrol. Inst. v. Costle*, 665 F.2d 1176, 1181, 1192 (D.C. Cir. 1981); *NRDC*, 902 F.2d at 970–79; *Am. Trucking Ass'ns v. EPA (Am. Trucking III)*, 283 F.3d 355, 364–72 (D.C. Cir. 2002); *Mississippi v. EPA*, 744 F.3d 1344, 1339 (D.C. Cir. 2013); *Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 624–25 (D.C. Cir. 2010); *Nat'l Env't Dev. Ass'n v. EPA*, 686 F.3d 803, 809–13 (D.C. Cir. 2012); *Am. Petrol. Inst. v. EPA*, 684 F.3d 1342, 1347–53 (D.C. Cir. 2012); *Nat'l Ass'n of Mfrs. v. EPA* 750 F.3d 921, 924–27 (D.C. Cir. 2014); *Murray Energy Corp.*, 936 F.3d at 611–12.

<sup>82</sup> *See infra* note 254 and accompanying text.

<sup>83</sup> *See Elliott*, *supra* note 59, at 904–08.

<sup>84</sup> *Compare Elliott*, *supra* note 59, at 900–01 (showing significant reductions of ambient concentrations of the criteria pollutants from 1980–2005, including a 96% reduction in ambient

reached the secondary NAAQS, too, as more studies and insights into the pollutants' effects on nonhuman biota have accumulated.<sup>85</sup> Section A introduces the challenge that has defined the science, and Section B describes how it has divided the scientists working the problem.

#### A. A Scientific Challenge

The challenge facing the scientists studying the health risks from ambient air pollution has been remarkably stable over time. Our knowledge of the pollutants has improved considerably since we first started linking sickness and disease to exposures to pollution, as have our capabilities for measurement.<sup>86</sup> These are important and welcome developments. Yet the challenge has persisted and is roughly this: How to find assurances that we have detected *all* the significantly adverse effects from pollution across the immense variability of human physiology, anatomy, demography, and geography—whatever our knowledge of *certain* effects may be? The statute obliges EPA to identify a level of *pollutedness* (or freedom from pollution) that does *not* degrade “public health.” Public health was an outcome or endpoint the statute left undefined and for which a vast range of accounts can be given. Degradations of public health are at least as numerous and diverse as the definitions of public health. However, the Act also expected that the science would change and progress,<sup>87</sup> and that a level that once provided some such assurances could in time prove insufficient.<sup>88</sup> Thus, the challenge is as much epistemic as it has been empirical. Distinguishing the evidence of absence (of adversity to public health) from a lack of evidence (ignorance thereof) has defined the inquiries pursued, credited, discounted, and relegated. That distinction is

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lead (Pb) concentrations, while U.S. population increased 59%, vehicle miles travelled increased 189%, and gross domestic product increased 262%), with Janet Currie & Reed Walker, *What Do Economists Have to Say About the Clean Air Act 50 Years After the Establishment of the Environmental Protection Agency?*, 33 J. ECON. PERSPS. 3, 4, 22 (2019) (reviewing economists' research on the costs and benefits of the CAA over its history and finding a broad range of estimates of both, but with benefits vastly outweighing costs almost without exception).

<sup>85</sup> See *infra* notes 189–94 and accompanying text.

<sup>86</sup> See NAT'L RSCH. COUNCIL, SCIENCE FOR ENVIRONMENTAL PROTECTION: THE ROAD AHEAD 57–95 (2012) (tracking the range of scientific and technological advances for detecting and measuring environmental change by media, phase, and spatial and temporal scales).

<sup>87</sup> Cf. 42 U.S.C. § 7408(a)(2) (requiring EPA to identify air quality criteria that “accurately reflect the *latest* scientific knowledge useful”) (emphasis added).

<sup>88</sup> Cf. 42 U.S.C. § 7409(d)(1) (requiring review and potential revision of air quality criteria and NAAQS “at five-year intervals”).



never a finished product, though, never known to a certainty.<sup>89</sup> This epistemic dilemma has remained current for each of the pollutants, but it has been more problematic for some than others. For two criteria pollutants, O<sub>3</sub> and particulate matter (“PM”), it has erupted and simmered through fits of controversy, made no easier by the complex atmospheric chemistry that determines their presence in ambient air.<sup>90</sup>

When the original six NAAQS were adopted in 1971, the final notice announcing them disclosed almost nothing about the data or observational record EPA had compiled or considered.<sup>91</sup> What little was said included the following disclaimer: “[w]here the validity of available research data has been questioned, but not wholly refuted, the Administrator has in each case promulgated a national primary standard which includes a margin of safety adequate to protect the public health from adverse effects suggested by the available data.”<sup>92</sup> This is remarkable for its contrast with the review process and outputs later required by the 1977 amendments. After that, EPA invariably found itself publicly crediting some studies while discounting others and having to explain why.<sup>93</sup> The explanations would beget more questions.

In its first review of nitrogen oxides, EPA dismissed a study experimenting with controlled chamber exposures of asthmatics to NO<sub>2</sub> as proof of need for a short-term standard.<sup>94</sup> As the studies and data mounted, and as EPA and CASAC reviews were repeated, it became evident that subpopulations of the public who were most sensitive to the

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<sup>89</sup> It has remained, as Dewey argued, deeply contextual. *See* DEWEY, *supra* note 26, at 6–14 (arguing that all knowledge is contextual and that inquiry and action necessarily interrelate, reciprocally influencing one another).

<sup>90</sup> *See* S. Trivikrama Rao et al., *Understanding the Spatio-Temporal Variability in Air Pollution Concentrations*, J. AIR & WASTE MGMT. ASS’N 42 (2011).

<sup>91</sup> The preamble totaled a mere eight (8) paragraphs of explanation for eight unique standards (six primary NAAQS and distinct secondary NAAQS for total suspended particulates (TSP) and SO<sub>2</sub>), mentioning only four of them (carbon monoxide, photochemical oxidants, hydrocarbons, and oxides of nitrogen). *See* National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 8186, 8186 (Apr. 30, 1971). In what could only be termed a colossal understatement, the agency acknowledged that “[c]urrent scientific knowledge of the health and welfare hazards of these air pollutants is imperfect.” *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> Section 307(d) required that a final NAAQS be based solely on “information or data” disclosed to a public docket for comment and that EPA respond “to each of the significant comments, criticisms, and new data submitted” in the rulemaking proceeding. *See* 42 U.S.C. § 7607(d)(6).

<sup>94</sup> *See* Retention of the National Ambient Air Quality Standards for Nitrogen Dioxide, 50 Fed. Reg. 25532, 25534 (June 19, 1985) (calling the observed effects “subtle” and “of uncertain health significance” and noting CASAC’s agreement).

pollutants were framing the focal cause-to-effect dynamics.<sup>95</sup> For some of the pollutants, this meant those with cardiac or cardiopulmonary diseases and ailments; for others, it was children or older adults.<sup>96</sup> It meant a range of exposures down to very low levels and a range of health-related effects from the mild and reversible to mortality, spread unevenly over different subpopulations.

The first review of photochemical oxidants from 1977 to 1979 showed how things had changed. EPA was compelled by interested parties and by its own Science Advisory Board to sort and compare several disparate studies and to arrive at a transparent synthesis for its conclusions on the NAAQS.<sup>97</sup> Industry objections to the studies discussed in the CD were, even then, familiar: alleged deficits of statistical significance or power, replicability, or proper controls, the existence of contrary findings of *no* adverse effects at exposures above EPA's proposed levels, etc.<sup>98</sup> There were objections to the methods and integrity of the science being weighed, objections the D.C. Circuit in particular had heard before.<sup>99</sup> Just as contentious was defining which effects, assuming they were the result of air pollution, were harmful

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<sup>95</sup> See Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202, 8215–16 (Feb. 8, 1979) (discussing “sensitive citizens” as a subpopulation, smaller subsets of that subpopulation, and the challenges of defining “adverse” effects therein).

<sup>96</sup> See Bachmann, *supra* note 56, at 677–78; JASANOFF, THE FIFTH BRANCH, *supra* note 4, at 113–16; MELNICK, *supra* note 40, at 269–94; KRIER & URSIN, *supra* note 29, at 208–09. For lead and ozone, for example, children clearly comprised the sensitive subpopulation. For lead (Pb), more specifically, it is children whose ingestion of Pb elevates their blood-Pb levels as much or more as their inhalation of Pb from the ambient air. See Review of the National Ambient Air Quality Standards for Lead, 81 Fed. Reg. 71906, 71916 (Oct. 18, 2016). Children's blood-Pb burdens became the focus of the 1977–78 proceeding creating the NAAQS for Pb, see National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46246, 46252–53 (Oct. 5, 1978), featured in the petitions for review thereof, see *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1157–62 (D.C. Cir. 1980), and have remained the focus since. See National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66964, 66983–67007 (Nov. 12, 2008); *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 615–17 (D.C. Cir. 2010). In the third review of O<sub>3</sub>, children's exposures began to show the greatest sensitivities in clinical and cohort studies. See National Ambient Air Quality Standards for Ozone, 61 Fed. Reg. 65716, 65723 (proposed Dec. 13, 1996).

<sup>97</sup> See Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. at 8207–10.

<sup>98</sup> See *id.* at 8207–15. Objections of the kind were raised in the lead rulemaking, see National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. at 46248–56, where the D.C. Circuit Court of Appeals first encountered and rejected them. See *Lead Indus. Ass'n*, 647 F.2d at 1162–72.

<sup>99</sup> By the time *Lead Industries* was heard, the D.C. Circuit had already decided several early landmarks of agency risk assessment, including several involving toxic pollutants like lead. See *Hercules Inc. v. EPA*, 598 F.2d 91 (D.C. Cir. 1978) (toxaphene and endrin); *Env't Def. Fund v. EPA*, 598 F.2d 62 (D.C. Cir. 1978) (PCBs); *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (lead); *Indus. Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974) (asbestos); *Amoco Oil Co. v. EPA*, 501 F.2d 722 (D.C. Cir. 1974) (lead).

enough. EPA found itself having to interview doctors for their opinions on what constituted a degradation of health.<sup>100</sup>

Confronted with claims requiring it to review an expert agency's sorting and weighing of the best available science, and the agency's estimation of the significance of that science, the court had unequivocally held that the standard to be met was a "rational basis,"<sup>101</sup> a forgiving standard. The difference would become the specificity, sequencing, and repetition of the required decisions, together with the procedural steps to which EPA is subject under Section 307(d) and several related provisions.

At its best, toxicological research, typically in controlled experiments with exposures to human or other subjects, can reveal the mechanism by which an agent causes morbidity or mortality.<sup>102</sup> In contrast, epidemiological research, typically from statistical work linking mortality/morbidity to the suspected "risk factors," reveals correlative associations at most.<sup>103</sup> Each approach is limited in how it evinces causal influences from pollutant to polluted.<sup>104</sup> We might say that the former works inductively and the latter deductively.<sup>105</sup> Whether about mechanisms or associations, though, and no matter how express EPA or CASAC have become in their deliberations, toxicological and epidemiological inferences cannot be synthesized objectively, *i.e.*, free of subjectivity. Each draws inferences from its own forms of data and context. Combining them compounds the inferences, but whose synthetic judgments are these to make?

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<sup>100</sup> See Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. at 8215-16; Joseph Padgett & Harvey Richmond, *The Process of Establishing and Revising National Ambient Air Quality Standards*, 33 J. AIR POLLUTION CONTROL ASS'N 13, 15 (1983) ("[A]t the margin where effects are often subtle and reasonable scientists disagree about their importance, the Administrator must ultimately judge which effects should be regarded as 'adverse' for standard-setting purposes.").

<sup>101</sup> *Ethyl Corp.*, 541 F.2d at 37. Oddly enough, that court also opined at length about the likely validity of decisions involving scientific uncertainty. See *id.* at 37-38 ("[T]he Administrator's decision may be fully supportable if it is based . . . on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative: the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion.").

<sup>102</sup> JOHN HARTE ET AL., *TOXICS A TO Z: A GUIDE TO EVERYDAY POLLUTION HAZARDS*, 27-30 (1991).

<sup>103</sup> *Id.*

<sup>104</sup> See Sander Greenland et al., *The Value of Risk-Factor ("Black Box") Epidemiology*, 15 EPIDEMIOLOGY 529, 532 (2004) [hereinafter Greenland et al., *The Value of Risk-Factor*]; Kenneth J. Rothman & Sander Greenland, *Causation and Causal Inference in Epidemiology*, 95 AM. J. PUB. HEALTH S144 (Supp. 2005) [hereinafter Rothman & Greenland, *Causation and Causal Inference*].

<sup>105</sup> The two arguably lack any common idiom given this tactical (and logical) differentiation. See JUDEA PEARL, *CAUSALITY: MODELS, REASONING, AND INFERENCE* 283 (2d ed. 2009).

As the information diversified and deepened, which types of evidence and which tokens of each type to credit more (or less) defined the deliberations.<sup>106</sup> Still, combining domain experts' views, absent resort to contentious philosophical commitments,<sup>107</sup> is changed for being part of a repeating sequence.<sup>108</sup> For every such judgment can inform future inquirers and, thus, the way they pursue their inquiries and the deliverables thereof. In its first review of the oxidants NAAQS, EPA identified about eighteen unique studies suggesting a specific level at which O<sub>3</sub> exposures caused or correlated with adverse health effects.<sup>109</sup> This was a vast improvement from 1971. But the levels and persistence of exposures varied from 0.01 parts per million (ppm) to 0.37 ppm as measured in hourly, multi-hourly, and daily averages.<sup>110</sup> With growth in the research came diversity. EPA's relaxation of the level, the only time it has ever slackened the level in a NAAQS, was upheld against a challenge by the Natural Resources Defense Council precisely because EPA was "required to take into account all the relevant studies revealed in the record," not just a partisan's preferred few.<sup>111</sup>

The later the review, the more contextualized became the judgments. The first review of the NO<sub>2</sub> NAAQS referenced over thirty studies of health effects ranging in method from surveys, controlled exposures, and cohort comparisons to clinical diagnoses.<sup>112</sup> By the second review of the O<sub>3</sub> NAAQS, the universe of relevant studies had ballooned to over

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<sup>106</sup> For PM (as for O<sub>3</sub>), the challenge became one of synthesizing a tremendous volume of scientific studies and distinguishing those with the greatest power from those with less. See Daniel S. Greenbaum et al., *Particulate Air Pollution Standards and Morbidity and Mortality: Case Study*, 154 AM. J. EPIDEMIOLOGY S78, S82–S83 (Supp. 2001).

<sup>107</sup> In an early encounter with lead's toxicological and epidemiological profiles, the D.C. Circuit included a footnote hinting that science itself was without foundations. See *Ethyl Corp. v. EPA*, 541 F.2d 1, 25 n.52 (D.C. Cir. 1976) ("Even scientific 'facts' are not certain, but only theories with high probabilities of validity." (citing THOMAS KUHN, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS* (1961))).

<sup>108</sup> Cf. Rothman & Greenland, *Causation and Causal Inference*, *supra* note 104, at S150 (arguing that causal inferences can never attain the certainty of logical deductions, much as the potential for error can never be eliminated from actual science, but that evaluations that quantify the uncertainties associated with either will incentivize continuous improvement).

<sup>109</sup> See Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202, 8214 (Feb. 8, 1979). The change of indicator from photochemical oxidants to O<sub>3</sub> was made because O<sub>3</sub> had in fact all along been the principal component of the former and the component air pollution control agencies had all elected to monitor. *Id.* at 8210.

<sup>110</sup> See *id.* at 8214.

<sup>111</sup> *Am. Petrol. Inst. v. Costle*, 665 F.2d 1176, 1187 (D.C. Cir. 1981).

<sup>112</sup> See Retention of the National Ambient Air Quality Standards for Nitrogen Dioxide, 50 Fed. Reg. 25532, 25543–44 (June 19, 1985).

1,000,<sup>113</sup> some of it stimulated by the review episodes themselves.<sup>114</sup> Responsiveness to exposures varied greatly among individuals,<sup>115</sup> but new studies that emerged after the EPA/CASAC CD deliberations had also begun to signal a range of adverse effects at lower exposures over periods longer than an hour.<sup>116</sup> With obvious consternation, EPA committed in the final notice to commencing the next review immediately.<sup>117</sup>

What those O<sub>3</sub> reviews accentuated was that a dichotomous choice awaited anyone who had to synthesize growing bodies of scientific inquiry from the disparate methodological traditions. As many have written about,<sup>118</sup> the lead standards hinted as much well before the third O<sub>3</sub> review. The choice was the same. Detectable health effects typically trail off in prevalence, severity, or both. They signal, in the words of one famous epidemiological account, a *biological gradient*<sup>119</sup> and that signal itself permits the inference that the influences being measured are in some way(s) causal.<sup>120</sup> (It *permits* the inference; it does not command or assure the accuracy thereof.)

Yet health effects do not necessarily vanish below some “threshold” of exposure(s). They may simply afflict other subjects or become undetectable. The choice, thus, is this: Should the inquirer or one synthesizing inquiries presume that health (or environmental) effects trail off linearly, even at extremely low exposures, or, instead, presume that below some minimum exposure, no real (health) effects occur?<sup>121</sup>

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<sup>113</sup> See National Ambient Air Quality Standards for Ozone; Proposed Decision, 57 Fed. Reg. 35542, 35546 (Aug. 10, 1992). This review, begun in 1982, proved exceptionally difficult to complete. *Id.* at 35545.

<sup>114</sup> See Bachmann, *supra* note 56, at 682; Greenbaum et al., *supra* note 106, at S82–S83.

<sup>115</sup> National Ambient Air Quality Standards for Ozone; Proposed Decision, 57 Fed. Reg. at 35548.

<sup>116</sup> See *id.* at 35547.

<sup>117</sup> See National Ambient Air Quality Standards for Ozone—Final Decision, 58 Fed. Reg. 13008, 13016 (Mar. 9, 1993). “The Agency continues to believe that a rigorous assessment of the new studies is necessary to assure a sound decision. Because of the extraordinary importance of this public health issue, however, the Administrator intends to move the process ahead as quickly as possible . . .” *Id.*

<sup>118</sup> See Feller, *supra* note 34, at 854–64; MELNICK, *supra* note 40, at 269–81.

<sup>119</sup> A.B. Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC’Y MED. 295, 298 (1965).

<sup>120</sup> Hill’s notion, which he called a *biological gradient*, was one of nine distinct means of assessing epidemiological associations, each to be used in conjunction with the others, to test the verity of the association. Their complementarity was intended to improve the probative value of each. Cf. Greenland et al., *The Value of Risk-Factor*, *supra* note 104, at 529–30 (arguing that the tendency toward overinterpreting observed associations as causal can be moderated by hypothesis and data precision and replication tracing variations more exactly, often revealing a gradient).

<sup>121</sup> This dichotomization became more manifest years later. See, e.g., Ronald H. White et al., *State-of-the-Science Workshop Report: Issues and Approaches in Low-Dose-Response*

More than any other, this question of linearizing inferences about the unobserved has divided scientists studying criteria pollutants.

### *B. Linearity in Extrapolation: A Dichotomy Grows*

EPA continues to weigh and compare individual studies and to disqualify some for outright errors.<sup>122</sup> Its perspective has lengthened considerably as the totality of information for each indicator at precise levels, intervals, and forms has accumulated.<sup>123</sup> Some of that stemmed directly from EPA through its funded and in-house research efforts.<sup>124</sup> A major influence coordinated (partly mandated) by EPA was the rise of reliable, nationwide sampling technology able to measure air quality and particular pollutants in place.<sup>125</sup> But some of it stemmed from innovations by the research community, with the fashioning of new time-series and prospective cohort methods, improved reanalysis, and

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*Extrapolation for Environmental Health Risk Assessment*, 117 ENV'T HEALTH PERSPS. 283 (2009); Lorenz R. Rhomberg et al., *Linear Low-Dose Extrapolation for Noncancer Health Effects Is the Exception, Not the Rule*, 41 CRITICAL REV. TOXICOLOGY 1 (2011). But the dichotomy was evident in the 1997 reviews of O<sub>3</sub> and particulate matter (PM), both of which were highly contentious. See Roger O. McClellan, *Role of Science and Judgment in Setting National Ambient Air Quality Standards: How Low is Low Enough?*, 5 AIR QUALITY, ATMOSPHERE & HEALTH 243, 247 (2012); MCGARITY & WAGNER, *supra* note 6, at 263–69.

<sup>122</sup> One such episode charged the 1997 review and revision of the particulate matter (PM) standards, published the same day as the O<sub>3</sub> revisions. See National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38652, 38662 (July 18, 1997). The dispute garnered significant attention in the legal challenges to those standards. See *American Trucking Ass'n v. EPA (Am. Trucking I)*, 175 F.3d 1027, 1060–61 (D.C. Cir. 1999) (Tatel, J., dissenting).

<sup>123</sup> The 1997 review and revision of the PM standards, the second thereof, resulted in a splitting of the indicators between PM of 10 microns or less in nominal mean aerodynamic diameter (PM<sub>10</sub>) and PM of 2.5 microns or less (PM<sub>2.5</sub>). See National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. at 38652. By then, the epidemiological studies of PM exposures and human morbidity/mortality trends had grown into a much fuller research record. *Id.* at 38655–66.

<sup>124</sup> See Miller, *supra* note 48, at 1018. EPA's own in-house scientific program suffered severe setbacks in the 1970s stemming from both poor research designs and an excess of external scrutiny and attack in Congress. See Greenbaum et al., *supra* note 106, at S81.

<sup>125</sup> Miller, *supra* note 48, at 1020 (“Among the less well recognized accomplishments of EPA's scientific achievements is the development of the technical infrastructure required to reliably, repeatably, and accurately measure air pollutants.”). In the latest review of the ozone NAAQS, EPA noted the central importance of having 1,300 monitors active nationally constantly measuring O<sub>3</sub> concentrations in the ambient air. See Review of the Ozone National Ambient Air Quality Standards, 85 Fed. Reg. 87256, 87263 (Dec. 31, 2020). Much of the PM<sub>2.5</sub> research that has been conducted over the past two decades has been based on in-place PM concentration monitoring data gathered under EPA supervision and reference methods, correlated to health- and health-related outcome data. See Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82684, 82687, 82704 (Dec. 18, 2020). Congress played a leading role in the rapid growth of PM<sub>2.5</sub> monitoring data. See Transportation Equity Act for the 21st Century, Pub. L. No. 105-178, §§ 6101–6102, 112 Stat. 107, 463 (1998) (codified at 42 U.S.C. § 7407 note) (authorizing and directing PM<sub>2.5</sub> monitoring program).

the refinement of relative risk as a metric.<sup>126</sup> The epidemiology, especially for PM and NO<sub>2</sub>, eventually outpaced the toxicology—so much so that some toxicologists were dubious of the statistical associations emerging.<sup>127</sup>

A turning point came when EPA, siding with the epidemiologists, overhauled the PM primary standards to control both coarse and fine particulates, each over daily and annual intervals.<sup>128</sup> That same day, EPA also overhauled the O<sub>3</sub> primary standards with a new level, averaging period, and form—largely on the basis of clinical (toxicological) exposure studies with human subjects.<sup>129</sup> The group of epidemiologists doing the PM work was small.<sup>130</sup> The group doing the O<sub>3</sub> work was larger and more diverse in its views.<sup>131</sup> Both coarse and fine PM standards' levels would soon be ratcheted downward further still.<sup>132</sup> But, in time, as the epidemiological work on PM accumulated in

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<sup>126</sup> See Daniel S. Greenbaum, *A Historical Perspective on the Regulation of Particles*, 66 J. TOXICOLOGY & ENV'T HEALTH 1493, 1495 (2003); Greenbaum et al., *supra* note 106, at S83–S87; Douglas W. Dockery, *Health Effects of Particulate Air Pollution*, 19 ANNALS EPIDEMIOLOGY 257 (2009); Douglas W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENG. J. MED. 1753 (1993) [hereinafter Dockery et al., *Six U.S. Cities*].

<sup>127</sup> See Rhomberg et al., *supra* note 121, at 6 (“In our view, a presumption that a little more chemical leads to a little more probability of effect is not self evident and needs careful consideration.”). Low-dose linear extrapolations were and have remained current in toxicology for carcinogenic agents. Noncancer linear models, however, remain contentious. See *id.* (“Unlike mutations, where the change of state is a single molecular event at a single locus, the generation of noncancer toxicity is a complex process of interacting forces acting throughout the tissue and the organism. This toxicity reflects an emergent property of control networks—or rather of the failure of those control networks—that, instead of dissipating and ameliorating perturbations, come at a certain level to amplify them.”).

<sup>128</sup> See National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. at 38679. EPA retained the level (150 µg/M<sup>3</sup>) but amended the form of the primary and secondary NAAQS for daily PM<sub>10</sub> to the 99th percentile of daily averages over a three-year period while adding a new annual component of 50 µg/M<sup>3</sup> annual arithmetic mean over a three-year period. *Id.* For PM<sub>2.5</sub>, EPA set the primary daily NAAQS level of 65 µg/M<sup>3</sup> to the 98th percentile averaged over three-year periods and the primary annual level of 15 µg/M<sup>3</sup> annual arithmetic mean averaged over three-year periods. *Id.* The so-called ‘Harvard Six Cities’ study comparing mortality statistics from differently polluted cities was instrumental in the decision. See MCGARITY & WAGNER, *supra* note 6, at 263; Dockery et al., *Six U.S. Cities*, *supra* note 126.

<sup>129</sup> National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38856, 38872–73 (July 18, 1997). The primary and secondary standards were both set to 0.08 ppm annual fourth-highest daily maximum eight-hour concentration, averaged over 3 years. *Id.* at 38856. This replacement of a one-hour with an eight-hour period and a form allowing no more than four expected exceedances in three years reflected a judgment balancing perceived risks against on-going attainment challenges nationally. *Id.* at 38868–70.

<sup>130</sup> See Greenbaum et al., *supra* note 106, at S87.

<sup>131</sup> Bachmann, *supra* note 56, at 688.

<sup>132</sup> In 2013, EPA revised the PM standards as follows. The primary NAAQS for PM<sub>2.5</sub> had an annual level of 12 µg/M<sup>3</sup> by arithmetic mean averaged over three years and a 24-hour level of 35 µg/M<sup>3</sup> by the 98th percentile averaged over three years. The secondary NAAQS for PM<sub>2.5</sub> had an

the wake of the 1997 shift, the linearity of its revealed results became its most unsettling property.<sup>133</sup> The epidemiologists' statistical techniques revealed lower and lower levels and shorter exposures "associated with" mortality or morbidity.<sup>134</sup> Here, again, the epistemic challenge invades, questioning the verity of statistical associations beyond mere coincidence.

Even barring accusations of research fraud, such linearities are curious if not suspect.<sup>135</sup> They may result from publication biases, selective reporting, measurement imprecision, etc.<sup>136</sup> No authoritative or final resolution of the divide between the toxicological and the epidemiological has been achieved, not by EPA, the National Academy of Sciences, or by independent researchers.<sup>137</sup> The questions that remain

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annual level of 15  $\mu\text{g}/\text{M}^3$  by arithmetic mean averaged over three years and a 24-hour level of 35  $\mu\text{g}/\text{M}^3$  by the 98th percentile averaged over three years. The primary and secondary NAAQS for  $\text{PM}_{10}$ 's 24-hour level of 150  $\mu\text{g}/\text{M}^3$  not to be exceeded more than once per year on average over a three-year period was retained from the 2006 review and revision. See National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086, 3277 (Jan. 15, 2013) (codified at 40 C.F.R. pts. 50–53, 58). A Trump Administration review ended with a retention of the 2013 standards, which drew petitions for judicial review from the Sierra Club and others as well as a Biden Administration commitment to review the previous review. See Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 88 Fed. Reg. 5558, 5566–67 (proposed Jan. 27, 2023) (to be codified at 40 C.F.R. pts. 50, 53, 58).

<sup>133</sup> See McClellan, *supra* note 121, at 251. Later, a systematic review of the published epidemiological studies on PM yielded some troubling conclusions about this linearity. See Robyn L. Prueitt et al., *Systematic Review of the Association Between Long-Term Exposure to Fine Particulate Matter and Mortality*, 32 INT'L J. ENV'T HEALTH RSCH. 1647, 1666–68 (2022). Chiefly, Prueitt and others noted that none of the studies examined had adjusted for all of the key potential confounding influences. *Id.* at 1665. Very few had adjusted for major confounders like relative humidity, other chemical exposures, medication use, or diet. *Id.*

<sup>134</sup> See Rhomberg et al., *supra* note 121, at 3. For the 2008 lead (Pb) review, the epidemiological studies moved EPA to cut the allowable level of ambient air Pb by 90% over the 1978 standards. See National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66964, 66977–86 (Nov. 12, 2008). The trend in the epidemiology continued into the 2013 Integrated Science Assessment but EPA elected to retain the 2008 NAAQS. See Review of the National Ambient Air Quality Standards for Lead, 81 Fed. Reg. 71906, 71914–35 (Oct. 18, 2016).

<sup>135</sup> See NICOLAS CHEVASSUS-AU-LOUIS, FRAUD IN THE LAB: THE HIGH STAKES OF SCIENTIFIC RESEARCH 42–51 (Nicholas Elliott trans., 2019). At the very least, they cannot be interpreted without "caution" given the statistical properties of the underlying work and the alternative explanations that it cannot rule out. See Prueitt et al., *supra* note 133, at 1667–69. EPA seems to agree, stating (again) in its 2015  $\text{O}_3$  review that it places the most weight on controlled human exposure studies and on quantitative analyses based on such studies. See National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65292, 65341 (Oct. 26, 2015).

<sup>136</sup> See Julie E. Goodman et al., *Evaluation of the Causal Framework Used for Setting National Ambient Air Quality Standards*, 43 CRITICAL REVS. TOXICOLOGY 829, 839 (2013) [hereinafter Goodman et al., *Evaluation of the Causal Framework*].

<sup>137</sup> See NAT'L RSCH. COUNCIL, ADVANCING THE FRAMEWORK FOR ASSESSING CAUSALITY OF HEALTH AND WELFARE EFFECTS TO INFORM NATIONAL AMBIENT AIR QUALITY STANDARD REVIEWS 28–34 (2022) [hereinafter NRC REPORT]; Anne E. Smith, *Setting Air Quality Standards for  $\text{PM}_{2.5}$ : A Role for Subjective Uncertainty in NAAQS Quantitative Risk Assessments?*, 38 RISK ANALYSIS 2318, 2319 (2018).



are serious: are these associations spurious,<sup>138</sup> or are the pollutants even worse than we have found?<sup>139</sup> Building the NAAQS from them was a stark reversal from where EPA and CASAC had begun a decade before, when they refused to engage in the same extrapolations.<sup>140</sup> They were not, however, alone.<sup>141</sup> By 2020, following NAAQS reviews for O<sub>3</sub>, NO<sub>2</sub>, and PM,<sup>142</sup> some of those who had served in prior administrations' EPA and CASACs—not long after being dismissed by the Trump EPA—announced their conviction that the PM standards should be reduced still further to about an eighth of where they were set in 1997.<sup>143</sup>

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<sup>138</sup> See Rhomberg et al., *supra* note 121, at 8–10. “[T]he core assertion of the additivity-to-background argument [behind linear extrapolations to zero] . . . is that the distribution of individual thresholds (or equivalently, the distribution of internal states vis-à-vis a fixed threshold) goes all the way down to zero thresholds and zero tolerance for further alteration for some part of the population.” *Id.* at 8. Such an assumption was part of any inference attributing causality below exposures proven to be causally effective. Not everyone agreed it was justified, though. “The fact that we do indeed recognize distinct modes of acute and chronic toxicity, and that agents cause different outcomes from short and prolonged exposures, argues against the generality of the needed assumptions for additivity to background.” *Id.* at 9.

<sup>139</sup> In May 2022, the chair of CASAC announced a “pause” in its review of the O<sub>3</sub> standards, aiming to double back on prior work and reconsider its predecessor’s decisions to retain the O<sub>3</sub> NAAQS. See Jennifer Hijazi, *Clean Air Panel Takes ‘Unprecedented’ Pause for Science Review*, BLOOMBERG L. NEWS (June 24, 2022), <https://news.bloomberglaw.com/environment-and-energy/clean-air-panel-takes-unprecedented-pause-for-science-review>.

<sup>140</sup> The 1987 review and revision changed the indicator from TSP to PM<sub>10</sub>, and the levels and forms to 150 µg/M<sup>3</sup> 24-hour with no more than one exceedance annually, with an annual of 50 µg/M<sup>3</sup> annual arithmetic mean over three-year periods. EPA confronted a record devoid of any “threshold” beneath which the adverse effects of PM were provably absent. See Revisions to the National Ambient Air Quality Standards for Particulate Matter, 52 Fed. Reg. 24634, 24641–42 (July 1, 1987). It set the levels and forms it did over the objections of some who insisted no “margin of safety” had been found. See Mark R. Powell, *The 1987 Revision of the NAAQS for Particulate Matter and the 1993 Decision Not to Revise the NAAQS for Ozone: Two Case Studies in EPA’s Use of Science* 15–17 (Res. for the Future, Discussion Paper No. 97-07, 1997), <https://media.rff.org/documents/RFF-DP-97-07.pdf>.

The 1997 review of the PM NAAQS retained the 1987 primary/secondary NAAQS for annual PM<sub>10</sub> unchanged (at 50 µg/M<sup>3</sup> annual arithmetic mean averaged over three-year periods). It retained the 24-hour standard’s *level* of 150 µg/M<sup>3</sup> while amending the *form* to the 99th percentile of 24-hour maximum averages over a three-year period. It also added both 24-hour and annual PM<sub>2.5</sub> standards set at 65 µg/M<sup>3</sup> for the 98th percentile of 24-hour maximum averages over three years and a 15 µg/M<sup>3</sup> annual arithmetic mean averaged over three years, respectively. See National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38652, 38652, 38711–12 (July 18, 1997) (adopting 40 C.F.R. § 50.7, primary and secondary NAAQS for PM<sub>10</sub> and PM<sub>2.5</sub>).

<sup>141</sup> By 2009, the National Academy of Sciences’ National Research Council had concluded that EPA ordinarily should adopt a presumption in favor of linearity in low-exposure (or “dose”) extrapolations for PM<sub>2.5</sub>. See NRC, SCIENCE AND DECISIONS, *supra* note 19, at 151–56.

<sup>142</sup> See Review of the Ozone National Ambient Air Quality Standards, 85 Fed. Reg. 87256 (Dec. 31, 2020); Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82684 (Dec. 18, 2020); Review of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen, 83 Fed. Reg. 17226 (Apr. 18, 2018).

<sup>143</sup> See H. Christopher Frey et al., *The Need for a Tighter Particulate-Matter Air-Quality Standard*, 383 NEW ENG. J. MED. 680, 680–81 (2020).

EPA's failure to do so, they urged, would be the cause of tens of thousands of unnecessary deaths and illnesses.<sup>144</sup> Matters have improved little since given the serious attacks on the underlying epidemiological methods that have, to a surprising extent, gone unanswered.<sup>145</sup> Let us now turn to the legal evolution that has coincided with the scientific before attempting a reckoning of the two.

### III. THE LEGAL EVOLUTION

It all began with the role of regulatory *costs* in the NAAQS. Three of the first four judicial opinions adjudicating petitions for review of final NAAQS held unequivocally that costs and technological feasibility could play no role in the setting of a primary NAAQS.<sup>146</sup> The same three flatly refused to constrain EPA's discretion in choosing levels of the pollutants that were "requisite" to protect public health.<sup>147</sup> Because of the Act's special venue and jurisdiction provision, all of these cases were heard and decided by one court—the D.C. Circuit Court of Appeals.<sup>148</sup> Through that one move, Congress ensured an accumulation of precedent that later adjudications would be forced to confront.<sup>149</sup> Against such a jurisdictional landscape, those opinions and judgments established early on that the judiciary was in no way to re-weigh the

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<sup>144</sup> *Id.* at 681.

<sup>145</sup> See, e.g., Susan Haack, *An Epistemologist Among the Epidemiologists*, 15 EPIDEMIOLOGY 521, 522 (2004); George Davey Smith, *Reflections on the Limitations to Epidemiology*, 54 J. CLINICAL EPIDEMIOLOGY 325 (2001); Petr Skrabanek, *The Emptiness of the Black Box*, 5 EPIDEMIOLOGY 553 (1994); Petr Skrabanek, *The Poverty of Epidemiology*, 35 PERSPS. BIOLOGY & MED. 182 (1992). Professor Greenland and colleagues' reply to Skrabanek and others prefaced its defense by acknowledging that a "genuine problem of risk-factor epidemiology is over-interpretation of observed associations as causal." Greenland et al., *The Value of Risk-Factor*, *supra* note 104, at 529.

<sup>146</sup> See *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1150 (D.C. Cir. 1980); *Am. Petrol. Inst. v. EPA*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *Nat. Res. Def. Council, Inc. v. EPA (NRDC)*, 902 F.2d 962, 973 (1990) ("Consideration of costs . . . would be flatly inconsistent with the statute, legislative history and case law on this point."). The very first opinion adjudicated a petition to review the 1971 *secondary* NAAQS for sulfur oxides and, thus, had nothing to do with this argument. See *Kennecott Copper v. Costle*, 462 F.2d 846, 847 (D.C. Cir. 1972).

<sup>147</sup> See *NRDC*, 902 F.2d at 973–74; *Am. Petrol.*, 665 F.2d at 1186; *Lead Indus.*, 647 F.2d at 1161–62.

<sup>148</sup> Section 307(b)(1) directs all petitions for the review of any "national primary or secondary ambient air quality standard" to the "United States Court of Appeals for the District of Columbia." See 42 U.S.C. § 7607(b)(1). Reviewing courts regard this as both a venue statute, see, e.g., *Sierra Club v. EPA*, 47 F.4th 738, 744 (D.C. Cir. 2022), and a jurisdictional statute. See *Env't Def. Fund v. Thomas*, 870 F.2d 892, 896–98 (2d Cir. 1989).

<sup>149</sup> Although this rule is not without subtleties, see, e.g., Henry J. Dickman, Note, *Conflict of Precedent*, 106 VA. L. REV. 1345 (2020), lower federal courts are known to follow "circuit precedent" unless and until overruled *en banc* or by the Supreme Court. See Joseph W. Mead, *Stare Decisis in the Inferior Courts of the United States*, 12 NEV. L.J. 787, 798 (2012).

relevant evidence in reviewing the NAAQS.<sup>150</sup> Yet those early precedents, which between them had denied eighteen of the nineteen petitions for review and remanded one for a clarification of EPA's basis for decision citing *SEC v. Chenery Corp.*,<sup>151</sup> were but a prelude.

The rapid evolution began in a challenge to the SO<sub>2</sub> NAAQS and the 1996 review and retention.<sup>152</sup> The court fixed upon EPA's failure to explain precisely and fully why asthmatics' bronchoconstriction events from levels of SO<sub>2</sub> permitted by the existing NAAQS were *not* reason enough to tighten the SO<sub>2</sub> standards.<sup>153</sup> The Agency's reasons to defer ratcheting down of SO<sub>2</sub> standards, the panel held, were central to the decision's validity.<sup>154</sup> Soon enough, that demand would flourish under the circumstances set by the CAA's scheme and the nature of the scientific inquiries animating it. Section A traces the emergence of a defining legal interpretation, and Section B explains how it has affected the science.

#### A. The Emergence of 'Sufficient $\leq$ Necessary'

From 1971 to 1997, there were only four adjudications of a NAAQS standard.<sup>155</sup> There had only been a dozen reviews and other actions since the original standards' adoption in 1971. Things accelerated in 1989 when the Second Circuit held that, although EPA had no duty<sup>156</sup> to *revise* the NAAQS at least once every five years, it did have a duty to *review* each of them that often.<sup>157</sup> After that, EPA faced legal jeopardy if

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<sup>150</sup> See *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 391–92 (D.C. Cir. 1998); *NRDC*, 902 F.2d at 967–76; *Lead Indus.*, 647 F.2d at 1145–48.

<sup>151</sup> See *Kennecott Copper*, 462 F.2d at 849 (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943)).

<sup>152</sup> In the 1996 review and retention, EPA had concluded that the existing standard would permit short-term "pulses" of SO<sub>2</sub> that could, in turn, trigger some asthmatics to suffer bronchial distress but that revisions of the standards were, nevertheless, not appropriate. See National Ambient Air Quality Standards for Sulfur Oxides (Sulfur Dioxide)—Final Decision, 61 Fed. Reg. 25566, 25570–76 (May 22, 1996).

<sup>153</sup> See *Am. Lung Ass'n*, 134 F.3d at 391–93.

<sup>154</sup> *Id.* at 392 ("[J]udicial review can occur only when agencies explain their decisions with precision, for '[i]t will not do for a court to be compelled to guess at the theory underlying the agency's action . . .'" (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196–97 (1947)).

<sup>155</sup> See *Kennecott Copper*, 462 F.2d at 846; *Lead Indus.*, 647 F.2d at 1135; *Am. Petrol. Inst. v. EPA*, 665 F.2d 1176 (D.C. Cir. 1981); *NRDC*, 902 F.2d at 965.

<sup>156</sup> Under the Act's citizen suit provision, Section 304(a), the district courts are granted jurisdiction to compel the Administrator "to perform any act or duty under [the Act] which is not discretionary with the Administrator." 42 U.S.C. § 7604(a)(2). This, then, permits suits in a district court of the challenger's choosing seeking to compel the finalization of any action that the Act mandates be taken by the Administrator. See *Env't Def. Fund v. Thomas*, 870 F.2d 892, 896–900 (2d Cir. 1989).

<sup>157</sup> See *Env't Def. Fund*, 870 F.2d at 899–900.

it failed to review each NAAQS on schedule,<sup>158</sup> and, given the stakes, almost as certain legal jeopardy if the reviews it conducted were in any way flawed or unexplained.<sup>159</sup> Following the SO<sub>2</sub> review ordered by the Second Circuit and the fate it met in the D.C. Circuit,<sup>160</sup> the reviews piled up. EPA's capacities to complete them were limited.<sup>161</sup> Another subtle but important development was the D.C. Circuit's rejection of industry arguments that EPA owed the public access to any underlying data in the studies on which it had relied.<sup>162</sup> Finally, the overall scheme had, by the late '90s, consolidated a deep base of opposition. Well-funded critics and enemies were loudly denouncing the scheme and EPA's administration of it.<sup>163</sup>

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<sup>158</sup> Several reviews that ensued were carried out under court-ordered timing. National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38652, 38654 n.3 (July 18, 1997); National Ambient Air Quality Standard for Ozone, 58 Fed. Reg. 13008, 13010 (Mar. 9, 1993); National Ambient Air Quality Standards for Nitrogen Dioxide—Final Decision, 61 Fed. Reg. 52852, 52853 (Oct. 8, 1996); National Ambient Air Quality Standards for Sulfur Oxides (Sulfur Dioxide)—Reproposal, 59 Fed. Reg. 58958, 58962 (proposed Nov. 15, 1994); National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66964, 66968 (Nov. 12, 2008).

<sup>159</sup> See *Am. Lung Ass'n*, 134 F.3d at 393. *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), has also featured in the Administrative Procedure Act reviews of agency rulemaking, see, e.g., *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34, 50 (1983) (quoting *Chenery*, 318 U.S. at 95), which have, in turn, featured in the reviews of CAA rulemakings pursuant to its special statutory review provision, Section 307(d)(9). See *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1064 (D.C. Cir. 1995). “The *Chenery* decisions . . . make clear that it matters both *who* articulates the legally sufficient basis to sustain the agency's ultimate decision and *when* the justification comes. The agency itself, not its counsel or . . . lawyers defending the action, must state reasons sufficient to justify the agency's action, and that statement must accompany the action itself, not follow later.” Kevin M. Stack, *The Constitutional Foundations of Chenery*, 116 YALE L.J. 952, 961 (2007) (emphasis added).

<sup>160</sup> See *Env't Def. Fund*, 870 F.2d 896; *Am. Lung Ass'n*, 134 F.3d 388.

<sup>161</sup> See Bachmann, *supra* note 56, at 686–89.

<sup>162</sup> See Greenbaum et al., *supra* note 106, at S82. This argument would later motivate a Trump Administration rule limiting the use of toxicological or epidemiological research where the underlying identities of affected persons and/or their medical records were not made available to the public in rulemakings like a NAAQS review. See *Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information*, 86 Fed. Reg. 469 (Jan. 6, 2021) (codified at 40 C.F.R. pt. 30). The Biden Administration then summarily withdrew the rule four months later following a partial summary judgment in the district court. See *Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information; Implementation of Vacatur*, 86 Fed. Reg. 29515 (June 2, 2021) (codified at 40 C.F.R. pt. 30).

<sup>163</sup> See Craig N. Oren, Whitman v. American Trucking Associations—*The Ghost of Delegation Revived . . . and Exorcised*, in *ADMINISTRATIVE LAW STORIES* 7, 26–30 (Peter L. Strauss ed., 2006); Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1 (1995); MELNICK, *supra* note 40, at 239–98. The NAAQS-setting process, specifically its exclusion of cost-benefit balancing, soon featured in Professor Sunstein's 2002 paean to monetized cost-benefit analysis—after the Supreme Court had rejected it in *Whitman*! See SUNSTEIN, *supra* note 1, at 230–46. Sunstein expressed doubts that the NAAQS should even exist. See *id.* at 231 (“[I]n light of the extraordinary diversity of the fifty states, it is not clear that the idea of national standards can be rationally defended.”).

The panel of the D.C. Circuit to hear the consolidated fifty-one petitions for review of the 1997 O<sub>3</sub> and PM NAAQS even thought it had found an Achilles heel—the debate over low-exposure linear extrapolations and EPA’s inability to determine an assuredly “safe” level of exposure for either of them.<sup>164</sup> Desperate to obstruct the ratchet and EPA, three states (Michigan, Ohio, and West Virginia) and a slew of industry groups among others argued that the whole scheme was a perversion of the separation of powers.<sup>165</sup> What followed from the case, however, became a tectonic shift in the law, accelerating the NAAQS’ development and further focusing the scientific inquiries backing them.

Before the D.C. Circuit panel, two judges, Stephen Williams and Douglas Ginsburg writing *per curiam*, began by announcing that “the only concentration for ozone and PM that is utterly risk-free, in the sense of direct health impacts, is zero.”<sup>166</sup> They then inferred that “[f]or EPA to pick any non-zero level it must explain the degree of imperfection permitted.”<sup>167</sup> Yet without cost or technological feasibility, they asserted, EPA lacked “any determinate criterion for drawing lines.”<sup>168</sup> That meant, to this duo at least, that the CAA had unconstitutionally delegated “legislative” power to EPA—unless EPA could somehow constrain its *own* discretion to set the NAAQS.<sup>169</sup> In a dissenting judge’s view, and in the Supreme Court, this reasoning was easily refuted.<sup>170</sup> Congress had done plenty to guide EPA’s setting of the

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<sup>164</sup> See *Am. Trucking Ass’ns, v. EPA (Am. Trucking I)*, 175 F.3d 1027, 1034 (D.C. Cir. 1999) (“The single most important factor influencing the uncertainty associated with the risk estimates is whether or not a threshold concentration exists below which PM-associated health risks are not likely to occur.” (quoting National Ambient Air Quality Standards for Particulate Matter, 61 Fed. Reg. 65637, 65651 (proposed Dec. 13, 1996))), *rev’d*, *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457 (2001).

<sup>165</sup> See *Oren, supra* note 163, at 18–30 (cataloguing opposition to Clinton Administration’s O<sub>3</sub> and PM NAAQS in small business, industry, Capitol Hill, and within the Administration). Long a hobbyhorse to opponents of risk regulation by administrative agencies, this attack on health-based interpretations of the Act never fully ended and now seems to be ascendant again. See, e.g., *West Virginia v. EPA*, 142 S. Ct. 2587, 2607–16 (2022); *Michigan v. EPA*, 576 U.S. 743, 750–60 (2015).

<sup>166</sup> *Am. Trucking I*, 175 F.3d at 1034.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* The *per curiam* opinion rejected EPA’s claim that “‘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’” were the criteria informing the term “requisite.” *Id.* at 1034–35 (quoting National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38856, 38883 (July 18, 1997)).

<sup>169</sup> *Id.* at 1035–40.

<sup>170</sup> See *id.* at 1057–60 (Tatel, J., dissenting). The Supreme Court announced its reversal in *Whitman* less than four months after the case was argued—where the respondents’ counsel had faced a blistering attack from most of the bench. *Oren, supra* note 163, at 38–39. Justice Scalia’s opinion for the Court was unanimous, although it drew three separate concurrences for four

NAAQS, not least in the complexity of the scheme itself—from criteria documents to proposals to CASAC reviews and *ex post* explanations—and by requiring that the standards be “requisite” to protect public health and welfare with an adequate margin of safety.<sup>171</sup> Public health, moreover, did not demand the eradication of risk. Thus, what was “requisite,” the Supreme Court unanimously held (quoting the Solicitor General), meant “sufficient, *but not more than necessary*” for the protection of public health.<sup>172</sup> Congress intended that EPA set NAAQS sufficient to protect the public from air pollution’s ill effects but that any resulting standards be *no more* stringent than necessary to that end.<sup>173</sup>

In scuttling that duo’s brazen attempt on the Act, the Court fixed the posture of the one lower court tasked with hearing challenges to the “latest scientific knowledge” underlying the NAAQS. Following the showdown in *Whitman*, the legal standard was explicitly Goldilocksian<sup>174</sup> (“sufficient  $\leq$  necessary”) and anything *but* too loosely defined. Indeed, with each NAAQS having an indicator, level, averaging period, and form, Goldilocks could be four dimensional and no more: costs and feasibility would not “contaminate” these determinations.<sup>175</sup> In determining what was sufficient but not more than necessary, EPA would consider the nature and severity of the health effects involved, the size of the sensitive subpopulation(s) at risk, the types of health information gathered, and the kind or degree of uncertainties that remained.<sup>176</sup> It would, in a word, focus on the *causality* revealed by relevant toxicological and/or epidemiological research and determine the assurances that work provided (or denied) on alternative formulations of the NAAQS.<sup>177</sup>

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justices—including Justice Breyer’s unique interpretation of the NAAQS-setting decisions. See *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 490–96 (2001) (Breyer, J., concurring).

<sup>171</sup> See *Whitman*, 531 U.S. at 464–71 (quoting 42 U.S.C. §§ 7408–7409).

<sup>172</sup> *Id.* at 473 (emphasis added) (quoting Transcript of Oral Argument at 7, *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457 (2001) (No. 99-1257)).

<sup>173</sup> *Id.* at 466.

<sup>174</sup> Cf. *Mississippi v. EPA*, 744 F.3d 1334, 1338 (D.C. Cir. 2013) (“EPA finds itself in a situation reminiscent of *Goldilocks and the Three Bears*.”).

<sup>175</sup> Cf. Natalie Jacewicz, *Risk Assessment & Cost Contamination*, 44 HARV. ENV’T. L. REV. 417, 425–34 (2020) (characterizing the analytical separation of risk assessments from risk management in environmental and natural resources law as the former’s protection from “contamination” by the latter).

<sup>176</sup> See *Am. Trucking Ass’ns v. EPA (Am. Trucking III)*, 283 F.3d 355, 364–80 (D.C. Cir. 2002).

<sup>177</sup> *Whitman* decided nothing at all about the specific scientific or philosophical conception(s) of causation EPA should or should not adopt. Then, as now, there remained considerable variation therein. See M. Parascandola & D.L. Weed, *Causation in Epidemiology*, 55 J. EPIDEMIOLOGY & CMTY. HEALTH 905, 905–06 (2001).

Petitions challenging the review and revision of NAAQS rolled in unabated. Some thirty-four petitions for review of thirteen NAAQS final actions have been adjudicated since *Whitman*.<sup>178</sup> In all but one, petitions challenging action on a primary NAAQS have been rejected in full.<sup>179</sup> In only three instances did petitions for review of actions on a secondary NAAQS result in a remand to the agency.<sup>180</sup> In the aggregate, though, these challenges have drawn panels of the D.C. Circuit deep into the debates about causation in the administrative proceedings. In responding to detailed challenges to the change of indicator and revision of the primary PM NAAQS level and form in 1987, the court had flatly stated that “the Administrator must ‘take into account all the relevant studies revealed in the record,’ and ‘make an informed judgment based on available evidence. The record shows that the Administrator did so.’”<sup>181</sup> Following the Supreme Court’s remand, the panel in *American Trucking III* painstakingly verified that the Administrator had taken “all the relevant studies revealed” on PM and O<sub>3</sub> into account.<sup>182</sup> Almost every subsequent judicial opinion adopted their telescoped approach.

Where the notice announcing the 1971 standards was so devoid of detail or explanation that the only petition filed challenging them was a demand for more information,<sup>183</sup> the ensuing procedural norms EPA helped to fashion have enabled—even invited—an exacting form of scrutiny of the agency’s judgments about what is cause, what is effect,

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<sup>178</sup> See, e.g., *Am. Farm Bureau Fed’n v. EPA*, 559 F.3d 512 (D.C. Cir. 2009) (5); *Mississippi v. EPA*, 744 F.3d 1344 (5); *Coal. of Battery Recyclers v. EPA*, 604 F.3d 613 (D.C. Cir. 2010) (2); *Am. Petrol. Inst. v. EPA*, 684 F.3d 1342 (D.C. Cir. 2012) (2); *Nat’l Env’t Dev. Ass’n v. EPA*, 686 F.3d 803 (D.C. Cir. 2012) (11); *Cmtys. for a Better Env’t v. EPA*, 748 F.3d 333 (D.C. Cir. 2014) (1); *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079 (D.C. Cir. 2014) (2014) (1); *Nat’l Ass’n of Mfrs. v. EPA*, 750 F.3d 921 (D.C. Cir. 2014) (2); *Murray Energy Corp. v. EPA*, 936 F.3d 597 (D.C. Cir. 2019) (5).

<sup>179</sup> See *Murray Energy*, 936 F.3d at 608–12; *Nat’l Ass’n of Mfrs.*, 750 F.3d at 922–27; *Cmtys. for a Better Env’t.*, 748 F.3d at 337; *Am. Petrol. Inst.*, 684 F.3d at 1354; *Nat’l Env’t Dev. Ass’n*, 686 F.3d at 809–13; *Battery Recyclers*, 604 F.3d at 621–25; *Mississippi*, 744 F.3d at 1348. The lone exception was a remand of the annual aspect of the primary NAAQS for PM<sub>2.5</sub> following the 2006 revisions. See *Am. Farm Bureau*, 559 F.3d at 520.

<sup>180</sup> See *Murray Energy*, 936 F.3d at 614–20; *Mississippi*, 744 F.3d at 1362; *Am. Farm Bureau Fed’n*, 559 F.3d at 531. In each instance, the remand demanded only a clearer explanation from EPA for its decisions. All challenges to actions on secondary NAAQS were rejected in full in *Ctr. for Biological Diversity*, 749 F.3d at 1088–89, and *Cmtys. for a Better Env’t*, 748 F.3d at 337–38.

<sup>181</sup> *Nat. Res. Def. Council, Inc. v. EPA (NRDC)*, 902 F.2d 962, 971 (D.C. Cir. 1990) (quoting *Am. Petrol. Inst. v. Costle*, 665 F.2d 1176, 1187 (D.C. Cir. 1981)).

<sup>182</sup> *Id.*; see also *Am. Trucking Ass’ns v. EPA (Am. Trucking III)*, 283 F.3d 355, 364–80 (D.C. Cir. 2002).

<sup>183</sup> See *Kennecott Copper Corp. v. EPA*, 462 F.2d 846, 848 (D.C. Cir. 1972) (“No contention is made that [the criteria] were not adequate to serve the function contemplated of criteria under the 1970 law . . . . The complaint is that there is no adequate indication of the basis of the 1971 standard[.]”).

and to whom or what the ties reach. The methodological integrity and power of studies credited in the statements of basis and purpose have regularly featured in the opinions.<sup>184</sup> This has put the court squarely between contending factions of scientists and their interpreters.

The court has long declared that the standards' values need not “spring from the bounty of definitive research as the clear and sole appropriate” values.<sup>185</sup> In most cases since *Whitman*, though, the net result of the judicial review examining EPA's gathering and weighing of the scientific evidence—enabled by the CASAC's reviews and commentary thereon—has been exacting verification of the scientific keys to the ratchet.<sup>186</sup> The court has, in short, adapted to Congress's integral scheme in checking the work of its regulator.

Arguably the lone exception, Judge Tatel, Judge Brown, and then-Judge Kavanaugh's denial of petitions by the National Association of Manufacturers and the American Lung Association against the 2013 revisions of the PM<sub>2.5</sub> NAAQS,<sup>187</sup> was adjudicated against a baseline of fourteen circuit precedents fourteen years after *Whitman*.<sup>188</sup> It may be

<sup>184</sup> See *Lead Indus., Inc. v. EPA*, 647 F.2d 1130, 1156–67 (D.C. Cir. 1980); *Am. Petrol. Inst. v. Costle*, 665 F.2d 1176, 1186–87 (D.C. Cir. 1981); *NRDC*, 902 F.2d at 970; *Am. Farm Bureau Fed'n*, 559 F.3d at 524–25; *Battery Recyclers*, 604 F.3d at 622–23; *Am. Petrol. Inst.*, 684 F.3d at 1346–53 (D.C. Cir. 2012); *Cmtys. for a Better Env't*, 748 F.3d at 335–37 (D.C. Cir. 2014); *Ctr. for Biological Diversity*, 749 F.3d at 1088–89; *Murray Energy*, 936 F.3d at 611–12, 615–20.

<sup>185</sup> *NRDC*, 902 F.2d at 972.

<sup>186</sup> See, e.g., *Murray Energy*, 936 F.3d at 613–14 (judging EPA's use of W126 exposure index); *Ctr. for Biological Diversity*, 749 F.3d at 1087–89 (judging EPA's interpretation of an aquatic acidification index); *Mississippi v. EPA*, 744 F.3d 1344, 1347 (D.C. Cir. 2013) (judging EPA's consideration of study by Brown et al. (2007)); *Battery Recyclers*, 604 F.3d at 617–24 (judging EPA's consideration and weighing of studies by Lanphear, Bellinger, Needleman, and Téllez-Rojo, among others).

In one light, such opinions follow from Judge Bazelon's solution to the D.C. Circuit's dilemma in reviewing the work of EPA and its experts. See David L. Bazelon, *Coping with Technology Through the Legal Process*, 62 CORNELL L. REV. 817, 823 (1977) (“What courts and judges can do . . . and do well when conscious of their role and limitations—is scrutinize and monitor the decisionmaking process to make sure that it is thorough, complete, and rational; that all relevant information has been considered; and that insofar as possible, those who will be affected by a decision have had an opportunity to participate in it.”).

In a less flattering light, however, and especially as EPA has adapted to the court's approvals of its weighting of scientific evidence, see, e.g., National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65292, 65334 n.94 (Dec. 28, 2015) (noting court's approval of EPA's interpretation of Brown et al. (2007) in *Mississippi*, 744 F.3d at 1347), the agency is increasingly empowered to clothe unbridled discretion in the trappings of scientific deliberations properly conducted. See Julie E. Goodman et al., *Systematically Evaluating and Integrating Evidence in National Ambient Air Quality Standards Review*, 2 GLOB. EPIDEMIOLOGY, Feb. 2020, at 7–9.

<sup>187</sup> See *Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921 (D.C. Cir. 2014). A panel of Judges Sentelle, Kavanaugh, and Douglas Ginsburg also turned down petitioners' invitation to judge EPA's assessment of several studies' statistical significance in *Nat'l Env. Dev. Ass'n v. EPA*, 686 F.3d 803, 811–13 (D.C. Cir. 2013).

<sup>188</sup> See *infra* Appendix, Table 1 (listing the fourteen decisions since 2001).



the exception that proves the rule. Then-Judge Kavanaugh's opinion stands out for its brevity and terse denials of both petitioners' claims—both of whom were among the most seasoned NAAQS litigants in the country.<sup>189</sup> Keying their rejection of the attacks on EPA's weighing of the scientific evidence to a Safe Drinking Water Act precedent,<sup>190</sup> the panel stated flatly: "EPA offered reasoned explanations for how it approached and weighed the evidence . . ."<sup>191</sup> Their apparent disenchantment with dissecting *Federal Register* notices running to the hundreds of pages, though, did little to alter that court's norm.

Hearing challenges to the 2015 O<sub>3</sub> revisions, Judges Griffith, Pillard, and Wilkins—on five petitions, including another from the American Lung Association—returned the court to form shortly thereafter. After patiently describing and refuting each attack on EPA's weighing of specific scientific studies underlying a revision of the primary standards and retention of the secondary,<sup>192</sup> the panel turned to CASAC's contributions on the key issues. It carefully distinguished CASAC's treatment of the science from its expressed policy leanings.<sup>193</sup> Then it turned to the secondary standards and O<sub>3</sub>'s proven harms to vegetation.<sup>194</sup> The court had once before opined that the 'sufficient ≤ necessary' construction of "requisite" applied to the Act's secondary standards as well.<sup>195</sup> Piecing together CASAC's views, the panel

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<sup>189</sup> The American Lung Association also petitioned or intervened in challenges to the 2015 O<sub>3</sub> revision, *Murray Energy*, 936 F.2d 597, the 2010 SO<sub>2</sub> revision, *Nat'l Env't Dev. Ass'n*, 686 F.3d 803, the 2008 O<sub>3</sub> revision, *Mississippi*, 744 F.3d 1334, the 2006 PM revision, *Am. Farm Bureau Fed'n*, 559 F.3d 512, the 1997 PM and O<sub>3</sub> revisions, *Am. Trucking Ass'ns v. EPA (Am. Trucking I)*, 175 F.3d 1027 (D.C. Cir. 1999), and the 1996 SO<sub>2</sub> retention, *Am. Lung Ass'n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998). The National Association of Manufacturers exists in large part to coordinate industry challenges to government. See JENNIFER A. DELTON, *THE INDUSTRIALISTS: HOW THE NATIONAL ASSOCIATION OF MANUFACTURERS SHAPED AMERICAN CAPITALISM* 237–313 (2020).

<sup>190</sup> In *City of Waukesha v. EPA*, 320 F.3d 228 (D.C. Cir. 2003), from the Safe Drinking Water Act's mandate that EPA, in setting allowable contaminant levels for drinking water, employ "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices[.]" *id.* at 247 (quoting 42 U.S.C. § 300g-1(b)(3)(A)), the court denied challenges to EPA's setting of limits for radionuclides in public water systems. See *id.* at 247–58. After stating that the court "will give an extreme degree of deference to the agency when it 'is evaluating scientific data within its technical expertise[.]'" *id.* at 247, it still followed up with a detailed examination of EPA's use of a complex model and that model's "rational relationship to the characteristics of the data to which it is applied." *Id.* at 248 (quoting *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 565 (D.C. Cir. 2002)).

<sup>191</sup> *Nat'l Ass'n of Mfrs.*, 750 F.3d at 924 (citing *City of Waukesha*, 320 F.3d at 247). This was well short of the norm. See *Murray Energy*, 936 F.3d at 608–24.

<sup>192</sup> See *Murray Energy*, 936 F.3d 597.

<sup>193</sup> See *id.* at 609–12.

<sup>194</sup> *Id.* at 613–14.

<sup>195</sup> This has not been lost on the court. See *Mississippi v. EPA*, 744 F.3d 1334, 1360–61 (D.C. Cir. 2013) ("[I]t is insufficient for EPA merely to compare the level of protection afforded by the

questioned EPA's use of an annual compositing index for quantifying O<sub>3</sub>'s harms.<sup>196</sup> It held that EPA had not adequately explained its decision to use three-year averaging of an annualized index.<sup>197</sup> Much of that involved comparing EPA's past judgments with those under review, a comparison that highlighted some discrepancies.<sup>198</sup> So convinced was the panel that EPA had failed fully to take into account the true welfare losses from O<sub>3</sub> pollution, however, that it remanded EPA's retention of the secondary standard from its own head-on assessment of the evidence backing that standard's form.<sup>199</sup> In short, the panel demonstrated a striking confidence and fluency in the uses (and potential abuses) of averaging in the NAAQS.

Both the volume and precision of scientific studies of the criteria pollutants have grown tremendously since 1971. As the science has accumulated, it has regularly enabled inferences linking measured effects from the pollutants to smaller and smaller exposures. The *weight* of the evidence overall corroborates inferences of causality—or fails to.<sup>200</sup> This, importantly, puts review of any such association onto an increasingly routine footing with a progressively deepening foundation

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primary standard to possible secondary standards and find the two roughly equivalent. EPA must expressly 'determine what level of . . . protection is requisite to protect the public welfare' and explain why this is so." (quoting *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 530 (D.C. Cir. 2009))).

<sup>196</sup> See *Murray Energy*, 936 F.3d at 613–14.

<sup>197</sup> But for the esoteric context in which this *Chenery* ("failure to explain") remand appeared, it could easily be mistaken for routine arbitrariness review. See *id.* at 619 (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983)). The difference was that EPA's supposed failure to explain its use of the index was entirely dependent upon highly technical judgments about what had not been explained. In the actual notice, EPA reasoned that the index was prone to wide annual variations, that the weight of the evidence suggested the worst effects of O<sub>3</sub> on vegetation were from exposures persisting over years, and that the instability that would result from on-again, off-again nonattainment designations without the triennial averaging would be counterproductive. See *National Ambient Air Quality Standards for Ozone*, 80 Fed. Reg. 65292, 65398 (Oct. 26, 2015).

<sup>198</sup> See *Murray Energy*, 936 F.3d at 613–20. If anything has proven consistently to embolden courts to set aside agency technical judgments as arbitrary, the agency's own apparent inconsistency over time has been it. See Sunstein, *Arbitrariness Review*, *supra* note 20, at 1005–10.

<sup>199</sup> See *Murray Energy*, 936 F.3d at 619. This involved parsing experiments with tree growth loss, CASAC's assessment of that data (and the imprecision therein), and past reviews' treatments of similar data. *Id.* at 615–16. In the waning days of the Trump Administration, EPA's review ended in a retention of the 2015 primary and secondary NAAQS for O<sub>3</sub>. See *Review of the Ozone National Ambient Air Quality Standards*, 85 Fed. Reg. 87256 (Dec. 31, 2020). *Murray Energy* marked the fifth time a *secondary* NAAQS was remanded to EPA in any part. See also *Kennecott Copper Corp. v. EPA*, 462 F.2d 846 (D.C. Cir. 1973); *Am. Lung Ass'n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998); *Am. Farm Bureau Fed'n*, 559 F.3d at 531; *Mississippi*, 744 F.3d at 1339.

<sup>200</sup> See Elizabeth Oesterling Owens et al., *Framework for Assessing Causality of Air Pollution-Related Health Effects for Reviews of the National Ambient Air Quality Standards*, 88 *REGUL. TOXICOLOGY & PHARMACOLOGY* 332 (2017).

of precedent.<sup>201</sup> It has, thus, routinized the often-polarizing struggle over causation and causal sufficiency in a way few legal fields have.<sup>202</sup>

However one captures the law/fact dynamics at this interface, it would be anything but “super deference.”<sup>203</sup> Indeed, the attempted capture itself might be suspect, the context of each evaluation being so unique.<sup>204</sup> Furthermore, it is hard to imagine much else for a reviewing court adjudicating claims that an agency has erred where the legal norm (‘sufficient  $\leq$  necessary’) is so logically unforgiving and yet so factually context-sensitive. It puts EPA to having to quantify every but only those effects of pollutants on polluted and respond to those that are contrary to public health or welfare and the court to verifying that EPA did so and just so. The key has become the weighing and integration of suggestive but inconclusive science tending to prove or to fail to prove causality. Novices reviewing the work of experts have limited means to their end.<sup>205</sup> The D.C. Circuit had confronted that dilemma long before the CAA’s Section 109(b) took on its Goldilocksian construction.<sup>206</sup> It has grown immensely more familiar since. Indeed, the court may have inadvertently pioneered an approach worth broad emulation.

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<sup>201</sup> This has not been lost on the courts. *Cf. Mississippi*, 744 F.2d at 1343–44 (“[W]e note, first, that the NAAQS review process includes EPA’s public health policy judgments as well as its analysis of scientifically certain fact, and, second, that as the contours and texture of scientific knowledge change, the epistemological posture of EPA’s NAAQS review necessarily changes as well; additional certainty about what was merely a thesis might very well support a determination that the line marked by the term “requisite” has shifted.”).

<sup>202</sup> *See* NRC REPORT, *supra* note 137, at 55–56; *cf. PEARL*, *supra* note 105, at 283–85 (noting the continuing disagreement over “necessary” and “sufficient” causes and epidemiology’s treatment thereof). To epidemiologists, an *association* is no more than a statistical dependence between two or more events or variables and bears no necessary relationship to causation or causal relations. But it does constitute for them a good reason for further inquiry where it perhaps might not for others. *See* Greenland et al., *The Value of Risk-Factor*, *supra* note 104, at 530.

<sup>203</sup> *Cf. Hammond Meazell*, *Super Deference*, *supra* note 17, at 756–78 (arguing that judicial attention to scientific debates and unresolved matters of scientific methodology has grown less superficial and more searching over time).

<sup>204</sup> *Cf. Stephen Breyer*, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 373 (1986) (arguing that blanket rules about the court/agency interface can be “seriously overbroad, counterproductive, and sometimes senseless”).

<sup>205</sup> *See* Alvin I. Goldman, *Experts: Which Ones Should You Trust?*, 63 PHIL. & PHENOMENOLOGICAL RSCH. 85 (2001).

<sup>206</sup> *See, e.g., Merrick Garland*, *Deregulation and Judicial Review*, 98 HARV. L. REV. 505 (1985); David L. Bazelon, *The Impact of the Courts on Public Administration*, 52 IND. L.J. 101 (1976); Harold Leventhal, *Environmental Decisionmaking and the Role of the Courts*, 122 U. PA. L. REV. 509 (1974); Skelly Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 CORNELL L. REV. 375 (1974); *see also* Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1978); Hercules, Inc. v. EPA, 598 F.2d 91 (D.C. Cir. 1978); Env’t Def. Fund v. EPA, 598 F.2d 62 (D.C. Cir. 1978); Env’t Def. Fund v. EPA, 489 F.2d 1247 (D.C. Cir. 1973).

### B. Incomplete Information as Weight of the Evidence

What to infer from suggestive but inconclusive evidence is as much a *legal* matter as anything is. Evidence, after all, is admitted into and decides a proceeding. Yet it is also an epistemic question, one that logicians and philosophers own as much as toxicologists and epidemiologists can. The divide over linearity in extrapolation to very low exposures has occupied evidence scholars for as long as it has administrative law and CAA aficionados.<sup>207</sup> For as long as EPA and CASAC personnel have been dividing over the issue, they have understood that the NAAQS themselves are probably the single most focal object in the evolving science.<sup>208</sup> As the standards have been ratcheted downward, scientists have been assured that questions with a progressively tightening focus will be decisive in the struggle for “clean” air.<sup>209</sup> The dynamics, thus, now little resemble the more questionable models of “regulatory peer review.”<sup>210</sup> The standards’ four dimensions have organized the inquiries being pursued in parallel,<sup>211</sup> as the D.C. Circuit no doubt understands,<sup>212</sup> and as has become clear from the PM, O<sub>3</sub>, NO<sub>2</sub>, and SO<sub>2</sub> reviews of the last decade.<sup>213</sup>

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<sup>207</sup> Compare BEECHER-MONAS, *supra* note 17, at 68–82 (arguing that linearity of exposure-response as a default assumption in the absence of evidence should turn on the totality of available evidence), with Feller, *supra* note 34, at 854 (arguing that the CAA creates an “incentive for EPA to discount the veracity of data that suggest that there is no [“safe”] level and to rely disproportionately on data suggesting the existence of a health effects threshold”).

<sup>208</sup> See McClellan, *supra* note 121, at 251 (recollecting from personal experience that, when EPA was deciding whether to introduce the PM<sub>2.5</sub> indicator, some argued that that move was justified at least in part because the NAAQS indicator would then mandate the monitoring necessary to its implementation and that the resulting monitoring data could be used to inform later reviews).

<sup>209</sup> Cf. Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 88 Fed. Reg. 5558, 5575–5606 (proposed Jan. 27, 2023) (reviewing the history of PM<sub>2.5</sub> research and its use in the setting of PM NAAQS from 1970s to the present).

<sup>210</sup> See, e.g., Ian Fein, *Reassessing the Role of the National Research Council: Peer Review, Political Tool, or Science Court?*, 99 CALIF. L. REV. 465 (2011).

<sup>211</sup> See Miller, *supra* note 48, at 1020–23 (reviewing the path from EPA funding of in-house and independent researchers to the targeting of specific questions and key uncertainties in NAAQS); McClellan, *supra* note 121, at 249 (observing that, as they have matured, both EPA and CASACs have focused more attention on amended forms and averaging periods and less on lowered levels).

<sup>212</sup> See *Am. Farm Bureau Fed’n v. EPA*, 559 F.3d 512, 516 (D.C. Cir. 2009) (recognizing that every NAAQS must have each of the four elements); *Murray Energy Corp. v. EPA*, 936 F.3d 596, 611–12 (D.C. Cir. 2019) (concluding that EPA could reasonably discount studies showing reversible loss of lung function from exposures possible under extant NAAQS by amending its definition of adversity to health used in the review and ignoring CASAC’s disagreement because to do so was a “policy” judgment and not one for scientists).

<sup>213</sup> See NRC REPORT, *supra* note 137, at 55 (noting that science assessments since 2015 have introduced “study quality criteria tables” and criterial judgments about study quality that are independent of study outcomes).

In the beginning, CDs were “encyclopedic” collections of the ‘latest scientific knowledge.’<sup>214</sup> The CASAC has almost as long served as their external reviewer extraordinaire.<sup>215</sup> The 1977 amendments resolved one of that era’s major debates about informal rulemaking: the scope of the record for a NAAQS rulemaking, its inclusivity, exclusivity, and availability.<sup>216</sup> Thereafter, the exchanges with CASAC evolved to become tightly timed, issue-driven, routinized, and public.<sup>217</sup> Instead of an exhaustive compendium jammed into an overstuffed record, the science was gathered into an “Integrated Science Assessment” held separate from a “Policy Assessment” and a “Risk and Exposure Assessment.”<sup>218</sup> Today, the reviews routinely begin shortly after the prior iteration concludes, focusing on the research published since and the lingering questions of causality at realistic (but declining) exposures.<sup>219</sup> In Professor Wagner’s estimate, the political pressures felt within and around the reviews combined with the threat of judicial review to create powerful incentives toward excellence in the process and in these outputs.<sup>220</sup>

Inferences from missing information, however, are the most divisive of all, and we often deliberately exclude information, even in bureaucratic settings, because we are unprepared to judge its veracity. Toxicology and epidemiology each have their own models with which to draw inferences from missing information in the low-exposure

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<sup>214</sup> Wagner, *EPA’s Innovations*, *supra* note 21, at 1112.

<sup>215</sup> See JASANOFF, *THE FIFTH BRANCH*, *supra* note 4, at 101–22. These reviews have often included scrutiny of multiple draft CDs, scrutiny of related documents such as the Office of Air Quality Planning and Standards’ Staff Papers, and other outputs, as detailed in Table 1 in the Appendix.

<sup>216</sup> See William F. Pedersen, *Formal Records and Informal Rulemaking*, 85 *YALE L.J.* 38 (1975). Section 307(d), added in the 1977 amendments, required the establishment of a proper “docket,” the docketing of “all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period,” as well as other protections of the rulemaking record suggested in Pedersen’s article. See 42 U.S.C. §§ 7607(d)(2)–(5); see also H.R. REP. NO. 95-294, at 319 (1977) (“By and large, this section [Section 307(d)] represents a legislative adoption of the suggestions for a rulemaking record set forth in a law review article dealing with EPA.” (citing Pedersen *supra*, then with EPA’s Office of General Counsel)).

<sup>217</sup> Wagner, *EPA’s Innovations*, *supra* note 21, at 1112–16.

<sup>218</sup> See Bachmann, *supra* note 56, at 689 (describing the transition to Integrated Science Assessments and other outputs). ISAs and RAs took the place of CDs after the reviews became more regular and routine, updating the pollutant’s “latest scientific knowledge” and not cataloguing it anew.

<sup>219</sup> See, e.g., Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 88 Fed. Reg. 5558, 5564–67 (proposed Jan. 27, 2023); Review of the Ozone National Ambient Air Quality Standards, 85 Fed. Reg. 87256, 87259–62 (Dec. 31, 2020).

<sup>220</sup> See Wagner, *EPA’s Innovations*, *supra* note 21, at 1117; see also JASANOFF, *THE FIFTH BRANCH*, *supra* note 4, at 104–22.

extrapolation debate.<sup>221</sup> In today's climate, there may be no avoiding the partisan political undertones in such divides, even if they appear before a bench striving to tame these influences in the name of impartiality.<sup>222</sup> The admission of expert testimony in court comes down to a judge making a call very similar in structure to this one<sup>223</sup> and, ever since it was mandated, having judges make choices of this kind has been controversial to say the least.<sup>224</sup>

Still, most of the science judges rule inadmissible is excluded not because the judge knows it should not be evidence, but because s/he does *not* know whether it should be evidence and is ill-prepared to learn.<sup>225</sup> At EPA, decisions about particular scientific studies in NAAQS reviews have been ad hoc and criticized as uneven.<sup>226</sup> In 2015, EPA installed a common framework by which studies could be evaluated but resolved little more than a laundry list of considerations to weigh.<sup>227</sup> This has drawn petitioners into arguments over EPA's reliability—and

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<sup>221</sup> Compare Rhomberg et al., *supra* note 121, at 10 (“It is a fundamental property of living systems that they have extensive means to buffer their internal physiological state against the effects of changes the environment might tend to have on them.”), with Greenland et al., *The Value of Risk-Factor*, *supra* note 104, at 530 (“[T]he incoherence or implausibility of observations in light of current theory should never be a deterrent to publication; a field that appears to be nothing more than an incoherent jumble of haphazard or implausible observations could be rapidly transformed by the introduction of a new and unifying theory.”).

<sup>222</sup> See Harry T. Edwards, *The Effects of Collegiality on Judicial Decision Making*, 151 U. PA. L. REV. 1639, 1648–52 (2003) (observing that, from about 1979 when he joined the D.C. Circuit to about 2003, the court had changed from one of “ideological ‘camps’” to a more collegial body where judges help each other articulate their own, sometimes contrary views); cf. Adelman, *supra* note 18, at 563–82 (reviewing the challenges of integrating scientific studies and data from methodologically different models and noting the partisan undertones).

<sup>223</sup> See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 585–97 (1993).

<sup>224</sup> Chief Justice Rehnquist, dissenting in *Daubert*, insisted that he deferred to no one in his “confidence in federal judges,” but that he was “at a loss to know what is meant when it is said that the scientific status of a theory depends on its ‘falsifiability,’” and that he “suspect[ed] some of them will be, too.” *Id.* at 600 (Rehnquist, C.J., concurring and dissenting in part). Rehnquist’s concerns were immediately echoed by Judge Kozinski on remand. See *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (“Our responsibility, then, unless we badly misread the Supreme Court’s opinion, is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not ‘good science,’ and occasionally to reject such expert testimony because it was not ‘derived by the scientific method.’ Mindful of our position in the hierarchy of the federal judiciary, we take a deep breath and proceed with this heady task.”).

<sup>225</sup> See BEECHER-MONAS, *supra* note 17, at 65.

<sup>226</sup> See NRC REPORT, *supra* note 137, at 35–46; Owens et al., *supra* note 200, at 333 (“For any given causal determination, the evidence base is not required to comprise studies of a defined level of quality.”). Smith ably tracks the changing assessments of uncertainty about linearity in extrapolation across three of the four PM NAAQS reviews since *Whitman*. See Smith, *supra* note 137, at 2328–32.

<sup>227</sup> See NAT’L CTR. FOR ENV’T ASSESSMENT–RTP DIVISION, U.S. EPA, PREAMBLE TO THE INTEGRATED SCIENCE ASSESSMENTS 6 (2015).

the D.C. Circuit into judging as much from missing information and/or information that EPA discounts significantly while deciding.<sup>228</sup>

Deliberately chosen defaults have long been the solution to such conundrums.<sup>229</sup> A default assumption about the linearity of effects at very low exposures extrapolated from greater or longer exposures might facilitate consistency over time, especially if information grows scarcer.<sup>230</sup> But crediting some information over other, contrary information is the only way to overcome such a default once set. The default itself may therefore become the cause of error or information scarcity.<sup>231</sup> Allocating uncertainty's burdens in this nexus impels one with the authority to decide how choices ought to be made to make an all-in judgment, including the weighing of potential outcomes. The reasons for and against setting any such default, thus, are entangled with its consequences,<sup>232</sup> more so where the decisions will influence the pace or direction of inquiry pursued thereafter.<sup>233</sup> To its credit, the D.C. Circuit has (so far) refused to set any such default, but so has EPA—a refusal that has manifested itself most directly in the agency's flexible approach to the “margin of safety” that Section 109(b)(1) of the CAA requires.<sup>234</sup>

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<sup>228</sup> See Feller, *supra* note 34, at 840–54 (tracing EPA's treatment of studies leading to its eventual embrace of epidemiological approach to PM).

<sup>229</sup> See NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) (proposing a series of defaults for risk assessments where information is lacking).

<sup>230</sup> See NRC, SCIENCE AND DECISIONS, *supra* note 19, at 134–35.

<sup>231</sup> Cf. Haack, *supra* note 145, at 522 (arguing that “[t]he structure of evidence is not linear, like a mathematical proof, but ramifies like a crossword puzzle”).

<sup>232</sup> Cf. NRC, SCIENCE AND DECISIONS, *supra* note 19, at 127–54 (proposing a “unified framework” for assessing exposure responses and acknowledging a diversity of “conceptual models” that could serve as defaults but for tremendous variabilities that remain intractable beyond discrete assessments under set conditions).

<sup>233</sup> Cf. McClellan, *supra* note 121, at 250 (arguing that defaults inform inquirers of the terms that they must discover or prove to affect choices of level, averaging period, or form in a NAAQS); NRC REPORT, *supra* note 137, at 101–02 (tracking the emergence of precision monitoring in association with the NAAQS and finding that “[a]dvances in techniques to measure . . . and analyze exposure data with high temporal and spatial resolutions are revolutionizing exposure assessment and resultant air pollution-related studies for both health and welfare effects”).

<sup>234</sup> 42 U.S.C. § 7409(b)(1) (primary NAAQS to be based on the criteria of § 108(a)(2) and “allowing an adequate margin of safety,” the attainment and maintenance of which “in the judgment of the Administrator . . . is requisite to protect public health”). The court has several times affirmed EPA's interpretation of this margin as addressing “uncertainties associated with inconclusive scientific and technical information” and, alternatively, as necessitating a “reasonable degree of protection against hazards that research has not yet identified.” See *Lead Indus., Inc. v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *Am. Petrol. Inst. v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981); *Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013).

Confronting a pattern in toxicological studies showing uncertain evidence of adverse health effects below exposures to 60 parts per billion (ppb) but highly probative evidence of such effects following multiple exposures at that concentration, EPA could just as readily judge that it justified a NAAQS with a form permitting periodic but not routine exceedances as it could that ratcheting the level downward was necessary.<sup>235</sup> Linear extrapolation could easily decide between the two, but so could an ad hoc interpretation of the “margin of safety.”<sup>236</sup> Taking the evidence on its face, the choice between adjustments would be distributive: who and how many shall be at risk for adverse health effects? Because of the averaging, level adjustments can require achievements well *below* the target to offset those above it within a compliance period, varying the effects of the level and form adjustments distributively. Accepting as true what there is reason to doubt, however, is contrary to why we inquire at all.<sup>237</sup> Could one choice advantage further inquiry into the causal forcings afoot?

Unlike the PM and O<sub>3</sub> standards, EPA never did ratchet down the CO NAAQS. It has been retained three times since 1971,<sup>238</sup> and EPA revoked its secondary NAAQS for CO in 1985.<sup>239</sup> In its most recent review and retention, EPA confronted epidemiological evidence suggesting that exposures at or around the NAAQS levels were causing

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<sup>235</sup> See National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65292, 65351–66 (Oct. 26, 2015); Review of the Ozone National Ambient Air Quality Standards, 85 Fed. Reg. 87256, 87283 (Dec. 31, 2020).

<sup>236</sup> See, e.g., National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16436, 16476–77 (Mar. 27, 2008); *Mississippi*, 744 F.3d at 1354–57. In the O<sub>3</sub> review completed in 2015, EPA retained the form allowing three exceedances of 8-hour maximum concentrations annually averaged over three years in part because it elected instead to ratchet down the level (from 75 to 70 parts per billion). See National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. at 65352. And it did that in part because the level adjustment was said to offer a better “margin of safety” than the form adjustment. *Id.* at 65362.

<sup>237</sup> Dewey’s signature insights for the reconstruction of inquiry on pragmatic bases stemmed from his recognition of all inquiries’ place between the “objects” or stimuli of thought and judgment—with the contrivances of logic and other tools as mere means to its ends. Judgments, in Dewey’s estimation, were transformations of an inquirer’s context or “situation,” what his readers have understood to be the fruits of adequate inquiry. See Patrick Suppes, *Nagel’s Lectures on Dewey’s Logic*, in *PHILOSOPHY, SCIENCE AND METHOD: ESSAYS IN HONOR OF ERNEST NAGEL* 2, 13–14 (Sidney Morgenbesser et al., eds., 1969). Reasons to doubt, thus, should forestall pragmatic judgments.

<sup>238</sup> See Review of the National Ambient Air Quality Standards for Carbon Monoxide, 50 Fed. Reg. 37484, 37494 (Sept. 13, 1985); National Ambient Air Quality Standards for Carbon Monoxide—Final Decision, 59 Fed. Reg. 38906, 38914 (Aug. 1, 1994); Review of National Ambient Air Quality Standards for Carbon Monoxide, 76 Fed. Reg. 54294, 54304 (Aug. 31, 2011).

<sup>239</sup> See Review of the National Ambient Air Quality Standards for Carbon Monoxide, 50 Fed. Reg. at 37494.



adverse health effects in some segments of the population.<sup>240</sup> Nevertheless, EPA found the extant standards adequate, dismissing the studies to the contrary as insufficiently indicative of causality.<sup>241</sup> Later reviews of both O<sub>3</sub> and PM turned up considerably more research than did that CO review, but similar issues emerged, the doubts about causality persisting.<sup>242</sup>

As the questions about PM<sub>2.5</sub> and O<sub>3</sub> sharpened and the disciplinary variations differentiating inquiries' outputs became focal, consistency across studies became a deciding factor.<sup>243</sup> (Exclusion of studies may too, by derivation.<sup>244</sup>) But so has the possibility that the epidemiological signals being detected reflect a mix of pollutants (O<sub>3</sub>, PM, SO<sub>2</sub>, NO<sub>2</sub>) and not any one of them.<sup>245</sup> Defining the "public" in which the effects of those pollutants will be decisive can constrain the causal questions even being asked. Indeed, choices in NAAQS reviews between level and form adjustments, paradoxically enough, can do just that: determine whether and where people may be exposed to the pollutants and at what concentrations and, thus, the epidemiological signals and/or corroborating evidence that may emerge thereafter.<sup>246</sup>

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<sup>240</sup> See Review of National Ambient Air Quality Standards for Carbon Monoxide, 76 Fed. Reg. at 54304.

<sup>241</sup> See *id.* at 54305–08 (finding that the studies in question took insufficient account of co-pollutant confounding effects and that most were conducted in areas where CO levels were frequently above the NAAQS).

<sup>242</sup> See National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65292, 65324, 65335, 65341, 65347–65 (Oct. 26, 2015); National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086, 3103–21, 3133–35 figs. 3 & 4 (Jan. 15, 2013).

<sup>243</sup> See, e.g., Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82684, 82721 (Dec. 18, 2020) (noting continued inconsistencies of studies showing health effects from long-term PM<sub>10</sub> exposures); National Ambient Air Quality Standards for Particulate Matter, 71 Fed. Reg. 61144, 61198–99 (Oct. 17, 2006) (revoking annual component of primary NAAQS for PM<sub>10</sub> because available toxicological and epidemiological evidence was mixed and inconsistent in its findings of health effects from long-term exposure to coarse particulates in amounts greater than the averaged 24-hour standard would permit).

<sup>244</sup> See NAT'L CTR. FOR ENV'T ASSESSMENT–RTP DIVISION, *supra* note 227, at 6; Prueitt et al., *supra* note 133, at 1680–81; Goodman et al., *Evaluation of the Causal Framework*, *supra* note 136, at 839.

<sup>245</sup> The chemistries of O<sub>3</sub>, PM, and oxides of nitrogen and sulfur are interrelated, as are their sources. Nitrogen oxides, for example, are an O<sub>3</sub> precursor and sometime constituent of PM, stem from fossil fuel combustion like the other three, and cause health effects similar to the other three. While all of that has long been known, see HARTE ET AL., *supra* note 102, at 365–67, in the 2010 NO<sub>2</sub> review which instituted a 1-hour standard, the "co-pollutant" confounding effects were the most serious issue in the proceeding. See Primary National Ambient Air Quality Standards for Nitrogen Oxide, 75 Fed. Reg. 6474, 6485 (Feb. 9, 2010). That would soon become a theme in the Integrated Science Assessments for each of the pollutants. See NRC REPORT, *supra* note 137, at 48–51, 55.

<sup>246</sup> See Bryan Hubbell & Daniel Greenbaum, *Counterpoint: Moving from Potential-Outcomes Thinking to Doing—Changing Research Planning to Enable Successful Health Outcomes Research*, 180 AM. J. EPIDEMIOLOGY 1141, 1141–42 (2014).

Congress never has decided what percentage, number, or identity of persons experiencing some detected effect(s) of pollution's causes (or which environmental harm) is contrary to *public* health (or welfare). EPA first argued that that choice had been made in a House Report on the 1970 amendments during the original lead rulemaking in 1978.<sup>247</sup> Almost a half-century later, though, the question has been through endless permutations at EPA.<sup>248</sup> It still blends imperceptibly into the uncertainties attending “identifiable” effects,<sup>249</sup> reflecting perhaps the oldest confusion in such pursuits: populational versus personal risks.<sup>250</sup> With the PM<sub>2.5</sub> and O<sub>3</sub> standards especially, this question has now repeatedly highlighted the importance of EPA and CASAC personnel and what they think of the disparate lines of evidence being weighed.<sup>251</sup>

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<sup>247</sup> See *Lead Indus., Inc. v. EPA*, 647 F.2d 1130, 1152–55 (D.C. Cir. 1980). The Senate Report on the 1970 amendments is also indicative, reporting that the NAAQS should be set to “the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” See S. REP. NO. 91-1196, at 10 (1970). Committee reports, however, are no substitute for bill text voted up by both chambers and signed by the president.

<sup>248</sup> See Smith, *supra* note 137, at 2321–32. The ongoing re-leveling of the PM<sub>2.5</sub> standards downward follows five prior reviews, the most recent of which in 2020 was put up for “reconsideration” months later by a new Administrator. See Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 88 Fed. Reg. 5558, 5564–67 (proposed Jan. 27, 2023). A major question raised by the epidemiological work being interpreted is the city-to-city variations in the mortality associations with short-term PM<sub>2.5</sub> exposures. *Id.* at 5583–85. Once co-pollutants and other confounders were controlled, the heterogeneity of associations suggested some other characteristic(s) differentiating the populations, the pollutant(s), or both. *Id.* In general, older adults (65+) appear more susceptible than average, *id.* at 5591, as do children, *id.*, but Blacks and Hispanics suffered considerably worse exposures on average. *Id.* at 5592. Effect modifications, in short, challenged the integration of the epidemiological data with the toxicology.

<sup>249</sup> See NRC REPORT, *supra* note 137, at 4–5; Smith, *supra* note 137, at 2333 (“Lacking any ability to balance health risk estimates against compliance costs, subjective judgments about uncertainty in the health effects have become the legally accepted route for drawing a line for the NAAQS level somewhere above zero.”); Davey Smith, *supra* note 145, at 327–28 (“The problems of chance . . . are exacerbated when the exposure-disease associations are weak. However, since a small risk applied to a large proportion of the population can have important public health implications, investigating these associations could be of potential importance.”).

<sup>250</sup> See ALEX BROADBENT, PHILOSOPHY OF EPIDEMIOLOGY 10–25 (2013); Parascandola & Weed, *supra* note 177, at 910–11. Having a *definition* of causation is not necessarily to have a satisfactory *model* thereof. *Id.* Thus, because many diseases and ill effects result from several contributing causes which differ in strengths across persons and (sub)populations, it is easy to mistake a model of one for that of the other even after careful expositions of the meaning of “cause” and “causation.”

<sup>251</sup> See NRC REPORT, *supra* note 137, at 34 (discussing the rise of “accountability” studies). More recently, even these questions have crept into court. *Cf.* *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 638 (D.C. Cir. 2020) (challenge to EPA’s rule disqualifying grant recipients from certain roles and posts); see also Stuart Parker, *Former CASAC Chair Says Panel Dismissals Will Weaken NAAQS’ Legality*, 25 INSIDE EPA’S RISK POL’Y REP. 1, 1, 11–12 (Oct. 16, 2018). It has also long accentuated the identities of the judges (and their perceived biases).

Quantifications of impartiality aside,<sup>252</sup> some accounts of this dynamic maintain that Republican administrators (and judges) have been reliably in favor of rescinding, easing, or retaining existing NAAQS while only Democrats aim to crank the ratchet.<sup>253</sup> It is often treated as a given that the former's hostility toward "regulatory science"<sup>254</sup> is somehow afoot whenever administrators (or judges) differ over the epidemiological evidence.<sup>255</sup> Against the full measure of experience, however, this obscures more than it clarifies. Indeed, even if it were true, the revolving control of EPA between the parties since 1977 has surely signaled to those pursuing the epidemiological inquiries that they will face a range of interpreters at EPA and CASAC and perhaps even the occasional request for their underlying data.<sup>256</sup>

With the NAAQS' four dimensions (indicator, level, averaging period, and form), there is some likelihood that each Administrator will sum the inquiries and arrive at a unique judgment, or at least at a judgment different from those of their predecessors. The surprise may be that there is much agreement at all. In that light, it is important that the Trump EPA's reviews of the O<sub>3</sub> and PM<sub>2.5</sub> NAAQS, like the Obama EPA's (which also tracked its predecessors'), were all focused on exposures at or near those currently experienced by some in the U.S. population.<sup>257</sup> Both deemed the same indicators, levels, averaging periods, and forms "requisite" to protect public health and welfare.<sup>258</sup> That stands out in a transition painfully short on such agreements.<sup>259</sup>

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That much, however, is hardly unique to the NAAQS experience. See JASANOFF, *SCIENCE AT THE BAR*, *supra* note 4, at 78–83.

<sup>252</sup> Cf. Harry T. Edwards & Michael A. Livermore, *Pitfalls of Empirical Studies that Attempt to Understand the Factors that Affect Appellate Decisionmaking*, 58 DUKE L.J. 1895, 1913–30 (2009) (cataloguing the challenges of empirical studies of judicial decision-making that employ "attitudinal" models of decisionmakers).

<sup>253</sup> See, e.g., Shi-Ling Hsu, *Anti-Science Ideology*, 75 U. MIA. L. REV. 405, 421–22 (2021); Albert C. Lin, *President Trump's War on Regulatory Science*, 43 HARV. ENV'T L. REV. 247, 264–66 (2019); Sidney A. Shapiro, "Political" Science: *Regulatory Science After the Bush Administration*, 4 DUKE J. CONST. L. & PUB. POL'Y 31 (2009); Richard L. Revesz, *Environmental Regulation, Ideology, and the D.C. Circuit*, 83 VA. L. REV. 1717, 1727–38 (1997) (describing hypotheses); JASANOFF, *FIFTH BRANCH*, *supra* note 4, at 84–100.

<sup>254</sup> Professor Jasanoff popularized the distinction between "regulatory" and "research" science by claiming that the former was more concerned with knowledge synthesis and prediction. See JASANOFF, *FIFTH BRANCH*, *supra* note 4, at 76–79.

<sup>255</sup> Cf. Lin, *supra* note 253, at 295 ("One can easily get lost in the frequent skirmishes, multiple fronts, and wide range of legal doctrines that characterize the war on regulatory science.").

<sup>256</sup> See, e.g., National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086, 3154 (Jan. 15, 2013); MCGARITY & WAGNER, *supra* note 6, at 263–65.

<sup>257</sup> See NRC REPORT, *supra* note 137, at 47–56.

<sup>258</sup> In three instances the Trump EPA found that the standards set by its predecessor were *requisite*, retaining each in full. See Review of the Primary National Ambient Air Quality

Judicial impartiality, or at least the approximations thereof, have played a considerable role in this evolution. Judge Harry Edwards's spirited and sustained defense of his D.C. Circuit's collegiality and deliberative process<sup>260</sup> comes to us today behind a further twenty years' experience with the NAAQS and accumulated precedent.<sup>261</sup> Table 1 pairs each of the twenty-six reviews across seven presidencies and their revision/retentions with the twenty-one reported opinions disposing of 106 petitions (seventy-eight of them on O<sub>3</sub> or PM) since 1971. Party of the appointing president and party in power are denominated in bold or underline, but the decisive factors must lie elsewhere.<sup>262</sup> There is a noticeable lack of fit between base attitudinal models and any significant patterning in this sample. Far more prominent is the direction of change since 1963 when Congress began from the ideal of clean air criteria set by science. Part IV collects the lessons of this past half century that support at least three conclusions about a long-term law/science interface and its reciprocal influences.

#### IV. LESSONS & CONCLUSIONS

As early as the 1950s, historians had indicted the New Deal's shift of policymaking initiative toward bureaucratic settings, finding it contrary

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Standards for Oxides of Nitrogen, 83 Fed. Reg. 17226, 17226 (Apr. 18, 2018); Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82684, 82684 (Dec. 18, 2020); Review of the Ozone National Ambient Air Quality Standards, 85 Fed. Reg. 87256, 87256 (Dec. 31, 2020).

<sup>259</sup> The Biden EPA's "reconsideration" of the 2020 PM review, only the second time a transition has made such a move, proposed in early 2023 to ratchet down the level of the annual PM<sub>2.5</sub> standard. See Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 88 Fed. Reg. 5558, 5567, 5567–69 (proposed Jan. 27, 2023) (proposing to reduce level of annual PM<sub>2.5</sub> primary NAAQS from 12.0 µg/M<sup>3</sup> to between 9.0 and 10.0 µg/M<sup>3</sup>). Finding from its quantitative risk analysis (including a mass of epidemiological data) that the current annual PM<sub>2.5</sub> primary standard had been associated with tens of thousands of all-cause mortalities among the most vulnerable subpopulations annually, *id.* at 5615, EPA sorted alternative possible levels according to lines of evidence, latent uncertainties therein, and the distributive consequences. *Id.* at 5607–29. Finally, it prefaced the whole reconsideration with the acknowledgment that wildfires in some Western communities were contributing enough daily PM<sub>2.5</sub> emissions to themselves violate the NAAQS, especially were the NAAQS to be lowered. *Id.* at 5569–70.

<sup>260</sup> See Revesz, *supra* note 253, at 1718 n.4 (collecting sources); Edwards, *supra* note 222, at 1650, 1654–55.

<sup>261</sup> See *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1087–88 (D.C. Cir. 2014) (setting out selected quotes from a "sample of circuit law" from NAAQS review challenges of the past).

<sup>262</sup> This Article foregoes the empty gesture of converting so interdependent a universe of actions and judgments into some covering statistic(s). Readers are trusted to draw their own inferences from the tabulation.

to a distinctly American legal tradition.<sup>263</sup> Legal scholars' opinions were more mixed, but some of them took to denouncing what they perceived to be overreactions to risk by Congress and its agencies. Just before joining the Supreme Court, Breyer's "vicious circle" made no room for the possibility that public campaigns against pollution's risks could provoke vast scientific progress, new knowledge, and the consensus to regulate in the public interest. The NAAQS experience has clearly broken that circle, though, leaving the question: what difference can the law's forms make between failure and success?

One lesson is that Congress *can* build a scheme of statutory constraints (which itself took fourteen years to assemble) for achieving national standards with periodic reviews bound to the "latest scientific knowledge" and an extra-agency accounting of that work, as well as a special venue provision tapping a lone appeals court for any challenges thereto, that yields a robust, self-editing, continuously improving system. The scheme as a whole answered the fears of Breyer and others that standards of the sort, by excluding costs and feasibility, would amount to perennial overreaction. Experience has been to the opposite effect. The NAAQS' four dimensions led to a telescoping of the scientific inquiries and permitted a variety of adjustments for the causal pathways that were found or suggested to a convincing likelihood.

Another lesson straddles the divide of epidemiological from toxicological and other experimental sciences and the continued "associations" of less and less exposure with disease and illness. Here it is fair to say that no "scientific" consensus has yet emerged.<sup>264</sup> We still have serious questions about causality at these lower-end exposures. Today, the debate has enlarged to reach welfare effects and secondary NAAQS. Yet, this lack of consensus has hardly been an existential threat to the standards. Combining the outputs of these different scientific disciplines is incorrigibly subjective. Reviewing judges have evidently understood that, though, electing rather to judge EPA's efforts through CASAC. In this light, the further lesson from ambient air pollution science of the last fifty years is that long-persisting epistemic debates need not stop us from acquiring new, useful, and often definitive facts about pollution's harms—facts that enable better (if not perfectly) informed decisions.

A third lesson comes from what is included and excluded from the reviews of the NAAQS, as reinforced by available judicial review and

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<sup>263</sup> See, e.g., RICHARD HOFSTADTER, *THE AGE OF REFORM: FROM BRYAN TO F.D.R.* 302–16 (1955).

<sup>264</sup> See, e.g., NRC REPORT, *supra* note 137, at 59–66.

the accumulated precedents of the D.C. Circuit. The text and structure of the statute, which excluded costs, feasibility, political favor, etc., from the policymaking, left EPA and its partners to a pragmatic inquiry into cause and effect, pollutant by pollutant, as they sought out all “identifiable effects” thereof and set standards to protect the public from harm, to do what was “requisite to protect public health.”<sup>265</sup> The law left EPA to cause and effect, and left the states and others to achieve the emissions reductions. In that legislated role scheme, EPA discovered that its own four-dimensional expressions of the standards could determine later-studied exposures as spread across varied populations, revealing a subtle but potentially important choice factor.

Finally, it is evident that the judges of the D.C. Circuit have learned and grown savvy from repeat experiences with the NAAQS petitions, especially following *Whitman*. The latest adjudication, reported in the *Murray Energy* opinion,<sup>266</sup> showed considerable finesse in deciding claims about EPA’s uses of averaging in the setting of a secondary (welfare-based) NAAQS. Without impinging on EPA’s role in the subjective assembly of the extant research, that panel questioned the agency’s explanation of its math. Yet these judges and the judgments they have registered within the scheme have excelled at avoiding partisan rancor, reputations for partiality, or sub-par justifications for their decisions. Although some nation-states have achieved lower ambient concentrations of the criteria pollutants over the same period, none has reduced them so much, so consistently, and with so diversified, immense, and mature an economy as ours. Taken together, the foregoing suggests at least three conclusions, each important to the law/science state space and its deliberate improvement.

First, high-stakes pursuits of specific causalities (causal sufficiency) may accentuate science’s disciplinary boundaries and the ensuing disagreements. One way to moderate this effect—routinized periods of study, public review, and rolling syntheses—will form the stages in which major uncertainties persist and come to define the applicable legal standards. American philosopher John Dewey argued that inquiry, properly pursued, is transformative of values, reasons, plans, actions, and more.<sup>267</sup> The pragmatic response to divisions and uncertainties like those in the NAAQS, thus, are provisional actions that sustain continued inquiry and help it to run its course in full. For environmental threats especially, the “latest scientific knowledge” may reveal causal

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<sup>265</sup> 42 U.S.C. §§ 7408(a)(2), 7409(b)(1).

<sup>266</sup> See *Murray Energy Corp. v. EPA*, 936 F.3d 596 (D.C. Cir. 2019).

<sup>267</sup> See DEWEY, *supra* note 26, at 104–05.

mechanisms that, though unalarming at first estimate, in fact jeopardize those who can least afford it.

Second, scientific inquiry and the outputs that it yields can be used in policy and lawmaking processes in many ways. Sometimes what is most important is how these outputs are *not* used; specifically, that they not be used to support inferences broader in scope than the output warrants. Chance alone explains too much of what scientists find to invest much faith in any single study, no matter how impressive. Contemporary epidemiology has underscored this fact repeatedly with findings that fail to withstand scrutiny. Before long, explicit weighting schemes and critical judgments about study quality become decisive because they differentiate the science that supports inferences from the science that does not. Entanglement of relevant variables means that separating signal from noise can require assembling scores of outputs in irreducibly subjective judgments. Part of what is needed to sustain inquiry in the wake of such assemblies are the assurances that it can still make a practical difference. Precisely because the scientific endeavor, to be sustained for so long, is a vast collective action, such assurances can be the difference between failure and (eventual) success.

Third, and finally, it was the law's fixity that guided much of the above—law's exclusion of ad hoc editing that has channeled and focused the kinetic elements of this scheme for a half century—in our NAAQS scheme. This is perhaps easiest to observe where the law was *not* a constraint: the defining of "public" health and welfare effects where they diminish in both prevalence and severity. The fixity that followed from the Goldilocks construction of Sections 108 and 109 of the CAA never did harden EPA's "margin of safety," nor did pertinent legislative history ever amount to much of a constraint on EPA at that exact decisional nexus. In retrospect, the genius of that construction of "requisite to protect public health" was the congruence of scientific practice and legal rule it spurred. The law's demand for scientific guidance was correctly shaped and sized to what the science could conceivably offer. The resulting demand-pull on epidemiologists, toxicologists, and others concerned with the criteria pollutants impelled them all to devise whatever means they could to reveal causal sufficiency from pollutant to polluted. That congruence between science and law is what legal actors must strive for more broadly.

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Given the many complexities afflicting the law/science interface and its deliberate improvement, there are few exemplars that give more

reason for optimism than the CAA NAAQS. They have intertwined legal and scientific evolutions with considerable subtleties and noticeably reciprocal influences. How this scheme will continue to evolve, though, is uncertain. Clearly, a vital element thereof—legal rules constraining opportunistic policymakers—has impacted how and by whom the information gathered is synthesized and deployed. The proper functioning of such limiting legal rules is not assured, however, and it is easily obscured by the many other kinetic parts and processes within the scheme. The National Research Council and others have long advocated a turn away from single-agent risk/exposure research and toward more integrative and cumulative risk assessment.<sup>268</sup> Should that become the focus of NAAQS reforms at EPA or CASAC, new chapters will have to be added to this story, most likely some of them by Congress. We would all do well in that event to keep the successes to date in mind.

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<sup>268</sup> See Knudsen, *supra* note 3; NAT'L RSCH. COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 9–11 (1993).



## APPENDIX

**Table 1: NAAQS Actions, 1970–2022**

INDICATOR	ACTION	SAB/ CASAC	PETITION(S) ADJUDICATED	JUDGES	OUTCOME
CO, Oxidants, Hydro- carbons	<b>35 FR 4768 (1970) (CDs announced)</b>	N/A	N/A		
TSP	<b>36 FR 8186 (1971) (NAAQS final P/S)</b>	N/A	N/A		
SO <sub>2</sub>	<b>36 FR 8186 (1971) (NAAQS final P/S)</b>	N/A	<i>Kennecott Copper</i> , 462 F.2d 846 [1]	<u>Leventhal</u> <u>Tamm</u> <u>Wright</u>	Remanded
Oxidants/O <sub>3</sub>	<b>36 FR 8186 (1971) (NAAQS final P/S)</b>	N/A	N/A		
CO	<b>36 FR 8186 (1971) (NAAQS final P/S)</b>	N/A	N/A		
Hydro- carbons	<b>36 FR 8186 (1971) (NAAQS final P/S)</b>	N/A	N/A		
NO <sub>2</sub>	<b>36 FR 8186 (1971) (NAAQS final P/S)</b>	N/A	N/A		
SO <sub>2</sub>	<b>38 FR 25678 (1973) (secondary 3-hour NAAQS retained; secondary annual NAAQS rescinded)</b>	NAQAC reviewed draft and final CD			
Pb	<u>43 FR 46246 (1978) (NAAQS final P/S)</u>	SAB reviewed CD and proposed NAAQS, rejecting both	<i>Lead Indus.</i> , 647 F.2d 1130 [2]	<u>Wright</u> <u>Robinson</u> <b>MacKinnon</b>	Denied
Oxidants/O <sub>3</sub>	<u>44 FR 8202 (1979) (NAAQS P/S revisions)</u>	SAB reviewed three draft CDs but not final or NAAQS	<i>Am. Petrol. Inst.</i> , 665 F.2d 1176 [10]	<b>Robb</b> <u>Wald</u> <u>Mikva</u>	Denied
Hydro- carbons	<b>48 FR 628 (1983) (NAAQS rescinded)</b>	CASAC approved rescinding NAAQS	N/A		
CO	<b>50 FR 37484 (1985) (primary NAAQS retained, secondary NAAQS rescinded)</b>	CASAC approved CD; approved rescinding secondary NAAQS	N/A		

NO <sub>2</sub>	<b>50 FR 25532 (1985)</b> <b>(P/S NAAQS retained)</b>	CASAC approved draft and final SPs and CDs	N/A		
PM <sub>10</sub>	<b>52 FR 24634 (1987)</b> <b>(NAAQS indicator change + final P/S)</b>	CASAC approved CD	<i>NRDC</i> , 902 F.2d 962 [6]	<u>Wald</u> <u>Edwards</u> <b>Silberman</b>	Denied
O <sub>3</sub>	<u>58 FR 13008 (1993)</u> <u>(primary NAAQS retained)</u>	CASAC approved CD	N/A		
SO <sub>2</sub>	<u>58 FR 21351 (1993)</u> <u>(secondary NAAQS retained)</u>	CASAC approved CD	N/A		
CO	<u>59 FR 38906 (1994)</u> <u>(primary NAAQS retained)</u>	CASAC approved CD	N/A		
SO <sub>2</sub>	<u>61 FR 25566 (1996)</u> <u>(primary NAAQS retained)</u>	CASAC approved CD	<i>Am. Lung Ass'n</i> , 134 F.3d 388 [2]	<u>Edwards</u> <b>D. Ginsburg</b> <u>Tatel</u>	Remanded
PM	<u>62 FR 38652 (1997)</u> <u>(P/S NAAQS revised)</u>	CASAC reviewed drafts of SP, CD, issued closure letter on final CD	<i>Am. Trucking I</i> , 175 F.3d 1027 [51]  <i>Am. Trucking II</i> , 195 F.3d 4  <i>Whitman</i> , 531 U.S. 457  <i>Am. Trucking III</i> , 283 F.3d 355	<b>Williams</b> <b>D. Ginsburg</b> <u>Tatel</u>  -----	Remanded  EPA reh'g petition granted in part/denied in part  Reversed  Denied in part, granted in part
O <sub>3</sub>	<u>62 FR 38856 (1997)</u> <u>(P/S NAAQS revised)</u>	CASAC reviewed drafts of SP, CD, issued closure letter on final CD	(Petitions consolidated with PM petitions)		
PM	<b>71 FR 61144 (2006)</b> <b>(primary NAAQS for PM<sub>2.5</sub> revised; primary NAAQS for PM<sub>10</sub> revised; annual NAAQS for PM<sub>10</sub> revoked)</b>	CASAC approved CD, disapproved of revised secondary NAAQS	<i>Am. Farm Bureau Fed'n</i> , 559 F.3d 512 [5]	<b>D. Ginsburg</b> <u>Garland</u> <b>Griffith</b>	Granted in part on primary PM <sub>2.5</sub> , remanded  Granted in full on secondary

					PM <sub>2.5</sub> , remanded  Denied on primary PM <sub>10</sub> daily
O <sub>3</sub>	<b>73 FR 16436 (2008)</b> <b>(P/S NAAQS revised)</b>	CASAC disapproved CD, disapproved of final secondary NAAQS form/level	<i>Mississippi</i> , 744 F.3d 1344 ( <i>Mississippi</i> , 723 F.3d 246) [5]	<u>Tatel</u> <b>Brown</b> <b>Griffith</b>	Denied on primary, remanded secondary
Pb	<b>73 FR 66964 (2008)</b> <b>(P/S NAAQS revised)</b>	CASAC reviewed draft CD	<i>Battery Recyclers</i> , 604 F.3d 613 [2]	<u>Sentelle</u> <u>Garland</u> <u>Rogers</u>	Denied
SO <sub>2</sub>	<u>75 FR 35520 (2010)</u> <u>(primary NAAQS revised)</u>	CASAC rejected draft ISA and REA; EPA revised both	<i>Nat'l Env't Dev. Ass'n.</i> , 686 F.3d 803 [11]	<b>Sentelle</b> <b>D. Ginsburg</b> <b>Kavanaugh</b>	Denied
NO <sub>2</sub>	<u>75 FR 6474 (2010)</u> <u>(primary NAAQS revised)</u>	CASAC reviewed drafts and approved final REA and ISA	<i>Am. Petrol. Inst.</i> , 684 F.3d 1342 [2]	<u>Edwards</u> <b>D. Ginsburg</b> <u>Rogers</u>	Denied
CO	<u>76 FR 54294 (2011)</u> <u>(primary NAAQS retained)</u>	CASAC reviewed draft REA and PA; approved final REA	<i>Cmtys. for a Better Env't</i> , 748 F.3d 333 [1]	<b>Williams</b> <b>Brown</b> <b>Kavanaugh</b>	Denied
NO <sub>x</sub> + SO <sub>x</sub>	<u>77 FR 20218 (2012)</u> <u>(secondary NAAQS retained)</u>	CASAC reviewed draft PA, REA, and ISA, final ISA, REA	<i>Ctr. for Biological Diversity</i> , 749 F.3d 1079 [1]	<b>Sentelle</b> <b>Randolph</b> <b>Kavanaugh</b>	Denied
PM	<u>78 FR 3086 (2013)</u> <u>(primary NAAQS revised for PM<sub>2.5</sub>; retained for PM<sub>10</sub>, both secondaries retained)</u>	CASAC reviewed draft ISA, RA, and two draft PAs	<i>Nat'l Ass'n of Mfrs.</i> , 750 F.3d 921 [2]	<u>Tatel</u> <b>Brown</b> <b>Kavanaugh</b>	Denied
O <sub>3</sub>	<u>80 FR 65292 (2015)</u> <u>(primary NAAQS revised)</u>	CASAC reviewed draft SP, REA, ISA, proposed NAAQS	<i>Murray Energy Corp.</i> , 936 F.3d 597 [5]	<b>Griffith</b> <u>Wilkins</u> <u>Pillard</u>	Denied on primary, remanded secondary

Pb	<u>81 FR 71906 (2016)</u> (existing P/S NAAQS retained)	CASAC reviewed drafts of SP, RA, CD	N/A		
NO <sub>x</sub>	<b>83 FR 17226 (2018)</b> (existing primary NAAQS retained)	CASAC reviewed draft ISA, PA, REA Plan, concurred in final decision	N/A		
O <sub>3</sub>	<b>85 FR 87256 (2020)</b> (existing P/S NAAQS retained)	CASAC reviewed draft ISA, PA, concurred in final decision	N/A		
PM	<b>85 FR 82684 (2020)</b> (existing P/S NAAQS retained)	CASAC reviewed draft IRP and two draft ISAs	N/A		

CASAC – Clean Air Scientific Advisory Committee

CD – Criteria Document

ISA – Integrated Science Assessment

NAQAC – National Air Quality Advisory Committee

PA – Policy Assessment

REA – Risk and Exposure Assessment

SAB – Science Advisory Board

SP – Staff Paper

**Bold = Republican Administration/Appointing President**

Underline = Democratic Administration/Appointing President