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Environmental Standards, Thresholds, and the Next Battleground of Climate Change Regulations

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Article

**Environmental Standards, Thresholds,
and the Next Battleground of Climate
Change Regulations**

Kimberly M. Castle[†] and Richard L. Revesz^{††}

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INTRODUCTION

In its landmark decision *Michigan v. EPA*, the Supreme Court held that the Environmental Protection Agency (EPA) is required to consider costs before deciding to regulate the hazardous air pollutant emissions of power plants through its Mercury and Air Toxics Standards,¹ which were promulgated during the Obama Administration.² The Court, however, did not decide how benefits should be taken into account, and identified, but left open, a significant question: how to address the benefits from reductions in particulate matter beyond the levels already required under the Clean Air Act's National Ambient Air Quality Standards (NAAQS).³ Reductions of hazardous air pollutant emissions are the direct benefits of the Mercury and Air Toxics Standards, whereas particulate reductions are the indirect benefits, also referred to as co-benefits or ancillary benefits,⁴ which result from the actions that power plants are expected to take in order to comply with these standards.⁵

Courts may soon have the opportunity to address the question of how to treat particulate matter co-benefits as a result of President Trump's efforts to undo the most significant environmental regulations of the Obama Administration. In particular, a top priority of the Trump Administration is repealing the Clean Power Plan,⁶ which would regulate the greenhouse gas

1. *Michigan v. EPA*, 135 S. Ct. 2699, 2712 (2015).

2. See National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units, 77 Fed. Reg. 9304, 9304 (Feb. 16, 2012) (to be codified at 40 C.F.R. pts. 60 and 63) [hereinafter MATS Rule].

3. *Michigan*, 135 S. Ct. at 2711 (“Even if the Agency *could* have considered ancillary benefits when deciding whether regulation is appropriate and necessary—a point we need not address—it plainly did not do so here.”).

4. See Samuel J. Rascoff & Richard L. Revesz, *The Biases of Risk Tradeoff Analysis: Towards Parity in Environmental and Health-and-Safety Regulation*, 69 U. CHI. L. REV. 1763, 1766 (2002) (discussing the difference between direct and ancillary benefits). Throughout the literature, co-benefits are alternatively referred to as ancillary benefits, secondary benefits, or indirect benefits. See David Pearce, *Policy Frameworks for the Ancillary Benefits of Climate Change Policies*, in ANCILLARY BENEFITS AND COSTS OF GREENHOUSE GAS MITIGATION 518 (2000). For simplicity, this Article uses the term “co-benefits.”

5. MATS Rule, *supra* note 2.

6. *Trump Moves to Let States Regulate Coal Plant Emissions*, NPR (Aug.

emissions of power plants.⁷ A proposed rule to that effect has already been published.⁸ Attacking the consideration of co-benefits is an important strategy in this quest. Indeed, it is only by completely disregarding the Clean Power Plan's principal co-benefits—particulate reductions under the level of the NAAQS—that the Trump Administration is able to conclude that the cost savings from repealing the rule exceed the forgone benefits.⁹ The

21, 2018), <https://www.npr.org/2018/08/21/639396683/trump-moves-to-let-states-regulate-coal-plant-emissions> (detailing President Trump's targeting of the Plan for repeal).

7. See Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units, 80 Fed. Reg. 64,662, 64,663 (Oct. 23, 2015) (to be codified at 40 C.F.R. pt. 60) [hereinafter Clean Power Plan].

8. See Repeal of Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units, 82 Fed. Reg. 48,035 (proposed Oct. 16, 2017) (to be codified at 40 C.F.R. pt. 60) [hereinafter Clean Power Plan Proposed Repeal].

Instead of finalizing that repeal, as this Article was going to press, the EPA proposed a significant roll-back of the Clean Power Plan. See Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units, 83 Fed. Reg. 44,746 (Aug. 31, 2018). As in the case of the proposed repeal, see *infra* note 9, the forgone benefits are higher than the cost savings except where all PM_{2.5} benefits below the NAAQS are ignored. See U.S. ENVTL. PROT. AGENCY, EPA-452/R-18-006, REGULATORY IMPACT ANALYSIS FOR THE PROPOSED EMISSION GUIDELINES FOR GREENHOUSE GAS EMISSIONS FROM EXISTING ELECTRIC UTILITY GENERATING UNITS; REVISIONS TO EMISSION GUIDELINE IMPLEMENTING REGULATIONS; REVISIONS TO NEW SOURCE REVIEW PROGRAM, at 6-16 tbl.6-14 (2018), https://www.epa.gov/sites/production/files/2018-08/documents/utilities_ria_proposed_ace_2018-08.pdf. Even then, the proposed replacement appears net beneficial only under one of the three illustrative compliance scenarios modeled by the EPA. *Id.*

9. See Clean Power Plan Proposed Repeal, *supra* note 8, at 48,045–46. The EPA presents the net benefits of repeal under different scenarios: rate-based and mass-based implementation. At a 3% discount rate, net benefits of the repeal are negative in the year 2030—meaning that the forgone benefits from the Clean Power Plan (or, put differently, the costs of repeal) are higher than the benefits of repeal in every scenario, except where all PM_{2.5} benefits below the NAAQS are ignored.

The EPA also presents calculations of benefits at a 7% discount rate, but that figure is out of line with economists' practice. See Richard G. Newell, *Unpacking the Administration's Revised Social Cost of Carbon*, RESOURCES FOR THE FUTURE (Oct. 10, 2017), <http://www.rff.org/blog/2017/unpacking-administration-s-revised-social-cost-carbon> ("It is clearly inappropriate . . . to use such modeling results with OMB's 7 percent discount rate, which is intended to represent the historical before-tax return on private capital. . . . Practically speaking, the use of such a high discount rate means that the effects of our actions on future generations are largely unaccounted for in the new analysis. This is incompatible with the long-lived nature of greenhouse gas emissions in the atmosphere, and the fact that damages from emissions today will continue to be felt for generations to come.").

In order to justify the repeal, the EPA also needs to significantly downplay

validity of co-benefits will certainly be at issue in the inevitable ensuing litigation.¹⁰

Further, on remand from the Supreme Court in the Mercury and Air Toxics Standards litigation, the EPA evaluated the reasonableness of the rule's costs under multiple metrics and put forward two approaches to demonstrate that the rule is cost-benefit justified in a Supplemental Finding; one of which includes a discussion of co-benefits.¹¹ However, because this method is the EPA's alternative approach, the D.C. Circuit would need to rule on the validity of including co-benefits only if it does not uphold the rule under the EPA's preferred approach. The case is now being held in abeyance¹² while the Trump Administration considers whether to modify the Supplemental Finding.¹³ However, if the Trump Administration reverses itself on the inclusion of

the direct benefits of carbon dioxide reductions. *Cf.* Niina Heikkinen, *EPA Revises the Social Cost of a Potent Greenhouse Gas*, SCI. AM. (Nov. 20, 2017), <https://www.scientificamerican.com/article/epa-revises-the-social-cost-of-a-potent-greenhouse-gas> (reporting on the Trump Administration's plans to reduce the "social cost of methane" measure and suggesting that the Administration could use this change to support deregulation on the grounds that compliance costs would outweigh the value of any methane reductions).

10. Cheryl Hogue, *Trump Administration Is Considering Reweighing Costs and Benefits of EPA Regulations*, CHEMICAL & ENGINEERING NEWS (Aug. 5, 2018), <https://cen.acs.org/policy/regulation/Trump-administration-considering-reweighing-costs/96/i32> (arguing "[a] lawsuit challenging [the] repeal is inevitable" and co-benefits will factor strongly into the lawsuit).

11. See Supplemental Finding that It Is Appropriate and Necessary To Regulate Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units, 81 Fed. Reg. 24,420, 24,423–24 (Apr. 25, 2016) (to be codified at 40 C.F.R. pt. 63) [hereinafter Supplemental Finding]. The EPA's preferred approach weighed the costs of compliance against the volumetric reduction in hazardous air pollutants. *Id.* at 24,426. In turn, the Agency's alternative approach compared the costs against the quantified benefits, including co-benefits and unquantified benefits. See *id.* at 24,427, 24,437–42.

12. See *Murray Energy Corp. v. EPA*, No. 16-1127 (D.C. Cir. Apr. 27, 2017) (per curiam) (order granted to continue oral argument).

13. See Respondent EPA's Motion to Continue Oral Argument at 6, *Murray Energy Corp. v. EPA*, No. 16-1127 (D.C. Cir. Apr. 18, 2017). It seems highly likely that the Trump Administration will reverse the EPA's position on the use of co-benefits: in an early iteration of this litigation, former EPA Administrator Scott Pruitt, then the Attorney General of Oklahoma, filed a brief, together with a number of other state attorneys general and industry groups, strongly arguing that the particulate reduction co-benefits were not cognizable for the purposes of evaluating the permissibility of the EPA's decision to regulate hazardous air pollutant emissions of power plants. See Opening Brief of State and Industry Petitioners at 41–55, *Murray Energy Corp. v. EPA*, No. 16-1127 (D.C. Cir. Nov. 18, 2016).

co-benefits, environmental groups would likely challenge the decision, bringing the question before a federal court.¹⁴

How courts ultimately respond to challenges of the reliance on co-benefits of particulate reductions below the NAAQS will have far reaching consequences for climate change regulations, as well as for public health rules more generally. Co-benefits of particulate reductions under the NAAQS are a substantial portion of the total benefits from regulating the emissions from stationary sources and, strikingly, a substantial portion of the benefits of all federal regulation. The NAAQS standards are not intended to eliminate all risks from pollutant exposure, so reductions beyond the standards have significant health benefits.

Indeed, EPA rules accounted for 61% to 80% of the monetized benefits from *all* major federal regulations over the past ten years, and 98% to 99% of those monetized benefits come from air quality rules.¹⁵ And, the large estimated benefits of air quality rules “are mostly attributable to the reduction in public exposure to fine particulate matter.”¹⁶ Furthermore, as the Mercury and Air Toxics Standards and the Clean Power Plan illustrate, a highly significant proportion of these reductions come from the co-benefits of particulate reductions.¹⁷ The Mercury and Air Toxics Standards, in particular, have the second-highest quantified benefits of all of the EPA’s twenty-two clean air rules of the past decade.¹⁸ The EPA estimated \$4 to \$6 million in direct quantified benefits under the Mercury and Air Toxics Standards from the target hazardous pollutants,¹⁹ in addition to significant unquantified benefits,²⁰ but quantified benefits of \$37 to \$90 billion in health co-benefits from particulate reductions.²¹ For the Clean

14. See Hogue, *supra* note 10 (predicting a challenge to the repeal of the Clean Power Plan).

15. OFFICE OF MGMT. & BUDGET, 2016 DRAFT REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT 2, 7–8, 11–12 (2016), https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/legislative_reports/draft_2016_cost_benefit_report_12_14_2016_2.pdf.

16. *Id.* at 12.

17. *Id.*

18. *Id.*

19. Brief for the Federal Respondents at 55, *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (No. 14-46).

20. See *id.* (“[V]irtually all of the direct benefits from reducing emissions of hazardous air pollutants are unquantifiable.”).

21. *Id.* at 54; U.S. ENVTL. PROT. AGENCY, EPA-452/R-11-011, REGULATORY IMPACT ANALYSIS FOR THE FINAL MERCURY AND AIR TOXICS STANDARDS, at 5-1 (2011) [hereinafter MATS RIA], <https://www3.epa.gov/ttnecas1/regdata/RIAs/>

Power Plan, the EPA under President Obama calculated \$20 billion in climate benefits, and an additional \$13 to \$31 billion from particulate reduction co-benefits.²²

The bulk of these particulate co-benefits come from reductions below the NAAQS.²³ For example, in the case of the Mercury and Air Toxics Standards, the EPA notes that a small percentage of the co-benefits come from reductions in particulate matter above the NAAQS, as the regulation would help to bring out-of-compliance areas into compliance, but that “[a] large fraction of the . . . related benefits . . . occur below the level of the National Ambient Air Quality Standard (NAAQS).”²⁴

The preceding analysis reveals how much is at stake in the controversy over the permissibility of relying on the co-benefits of particulate reductions below the NAAQS. Ignoring these benefits will threaten significant regulatory initiatives and adversely affect populations such as the elderly and asthmatic children, who are particularly sensitive to the adverse health effects caused by particulate matter at levels below the NAAQS.²⁵

matsriafinal.pdf. These numbers were calculated using a 3% discount rate. *Id.*

22. See U.S. ENVTL. PROT. AGENCY, EPA-452/R-15-003, REGULATORY IMPACT ANALYSIS FOR THE CLEAN POWER PLAN FINAL RULE, at ES-23, 4-27 (2015) [hereinafter CLEAN POWER PLAN RIA], https://www3.epa.gov/ttnecas1/docs/ria/utilities_ria_final-clean-power-plan-existing-units_2015-08.pdf. This estimate includes reductions in SO₂, which is both a precursor to the formation of PM_{2.5} as well as a component of PM_{2.5} (since SO₂ itself is often present as a fine particle). *Id.* at 4-11. Notably, the Clean Power Plan rule is cost-benefit justified without these additional health benefits; the EPA estimated that the regulation would cost between \$5.1 and \$8.4 billion in 2030, a range dwarfed by the total estimated benefits of between \$34 and \$54 billion. See *id.* at ES-20, ES-22, ES-23. Moreover, recent analyses of Clean Power Plan compliance costs suggest that the cost of complying with the Plan has fallen since 2015, when the EPA’s analysis was released. See DENISE A. GRAB & JACK LIENKE, INST. FOR POLICY INTEGRITY, THE FALLING COST OF CLEAN POWER PLAN COMPLIANCE 1 (2017), https://policyintegrity.org/files/publications/Falling_Cost_of_CPP_Compliance.pdf. These compliance costs fell due to declines in the cost of renewable energy, declines in the forecast price of natural gas, extensions of federal tax credits for renewable energy, and expansions of state programs supporting the adoption of clean energy. See generally *id.* (collecting and analyzing reports of independent groups calculating the updated costs of compliance with the Clean Power Plan).

23. MATS RIA, *supra* note 21, at ES-4.

24. *Id.*

25. In a 2017 study of Medicare recipients, discussed further in Part III, researchers observed a rising risk of death in association with PM_{2.5} exposure beginning at levels significantly below the NAAQS for PM_{2.5}. Qian Di et al., *Air Pollution and Mortality in the Medicare Population*, 376 NEW ENG. J. MED. 2513, 2513 (2017). In a study of inner-city children with asthma, short-term

Opponents of these regulations employ a few key arguments to suggest that these benefits should not be cognizable in evaluating EPA regulations. In this Article, we address each of these arguments in turn. Relying on scientific evidence, EPA practice, and judicial decisions, we show that these arguments are unfounded.

Critics argue first that the benefits from particulate matter reduction do not exist.²⁶ They do so by assuming that particulate matter is a threshold pollutant.²⁷ By implication, these critics make the same assumption for all “criteria pollutants,” which are pollutants regulated by NAAQS pursuant to § 108 of the Clean Air Act: ground level ozone, particulate matter, carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide.²⁸ A threshold is the level below which there are no quantifiable health effects from pollutant exposure,²⁹ and threshold pollutants are those pollutants for which a threshold can be identified. The Clean Air Act requires that NAAQS levels allow an “adequate

increases in PM_{2.5} concentrations below the NAAQS were associated with adverse respiratory health effects. George T. O'Connor et al., *Acute Respiratory Health Effects of Air Pollution on Children with Asthma in US Inner Cities*, 121 J. ALLERGY & CLINICAL IMMUNOLOGY 1133, 1135 (2008).

26. See *infra* notes 286–90 and accompanying text; see also JONATHAN A. LESSER, MISSING BENEFITS, HIDDEN COSTS: THE CLOUDY NUMBERS IN THE EPA'S PROPOSED CLEAN POWER PLAN 5 (2016), <https://www.manhattan-institute.org/download/8988/article.pdf> (“The EPA’s estimates of co-benefits from future air-pollution reductions also suffer from significant uncertainty and modeling errors . . . [including the] use of epidemiological models that assume that there are no threshold air-pollution concentration levels below which additional health benefits cannot be obtained, even though under the Clean Air Act, the EPA is required to establish exposure levels that are supposed to incorporate an adequate margin of safety to protect the public health . . .”); *id.* at 18–19 (“But because the magnitude of CO₂ reductions under the [Clean Power Plan] is below the threshold level (assumed to be the level where there are measurable climate impacts), the [Plan]’s actual CO₂ reduction benefits are effectively zero.”); C. Boyden Gray, *EPA’s Use of Co-Benefits*, FEDERALIST SOC’Y (2015), <https://fedsoc.org/commentary/publications/epa-s-use-of-co-benefits> (“As a former Chairman of the Texas Commission on Environmental Quality has explained, ‘[i]f reducing particulate matter had the enormous benefits that EPA’s analysis claims, it has a legal responsibility to lower the national ambient standard to a level that is actually protective of human health. The fact that it has not done so suggests that the EPA does not really believe its own numbers.’ . . . [Agencies should not] be allowed to count reductions of pollutants in areas where they appear below the national standard EPA has already set for those pollutants.”).

27. See *infra* notes 286–93 and accompanying text.

28. See Clean Air Act, 42 U.S.C. § 7408 (2012).

29. Al McGartland et al., *Estimating the Health Benefits of Environmental Regulations*, 357 SCI. 457, 458 (2017).

margin of safety . . . requisite to protect the public health.”³⁰ The logic of critics who claim criteria pollutants have a threshold is that NAAQS are set with reference to the threshold, plus an adequate margin of safety.³¹ Thus, they argue, there should be no adverse health effects below the threshold, and therefore, no benefits from lowering pollution levels below the NAAQS.³²

The Trump Administration has embraced these criticisms despite their lack of empirical foundation. In its proposed rule to repeal the Clean Power Plan, announced in October 2017, the Trump EPA presents radically different estimates of the costs and benefits than those presented in the original plan.³³ The proposed rule includes three estimates of health benefits, the first of which closely mirrors the estimates in the original rule promulgated during the Obama Administration and includes the full range of particulate matter benefits.³⁴ The middle estimate assumes—without scientific basis—that the benefits of particulate matter reductions fall to zero below the “lowest measured level” or LML, which is the lowest level of exposure studied.³⁵ There is no scientific support for the proposition that risks are nonexistent below this level, though there is greater uncertainty about the magnitude of risk below this level.³⁶ Finally, the lowest estimate of benefits incorporates the assumption that NAAQS represent a threshold for particulate matter.³⁷ This estimate completely eliminates all particulate matter benefits below the NAAQS,³⁸ essentially ignoring a bulk of the benefits of the rule

30. 42 U.S.C. § 7409(b)(1). According to the EPA, the margin of safety component is “intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting . . . [and] to prevent lower pollutant levels that [the Administrator] finds pose an unacceptable risk of harm, even if that risk is not precisely identified as to nature or degree.” Revisions to the National Ambient Air Quality Standards for Particulate Matter, 52 Fed. Reg. 24,634, 24,634–35 (July 1, 1987) (to be codified at 40 C.F.R. pt. 50) [hereinafter 1987 Revisions to NAAQS].

31. See *infra* note 161 and accompanying text.

32. See *supra* note 26 and accompanying text.

33. Compare Clean Power Plan Proposed Repeal, *supra* note 8, at 48,044–47, with Clean Power Plan, *supra* note 7, at 64,928–29, 64,934–35.

34. See Clean Power Plan Proposed Repeal, *supra* note 8, at 48,044–47.

35. *Id.* at 48,044.

36. See *infra* notes 409–25 and accompanying text.

37. See Clean Power Plan Proposed Repeal, *supra* note 8, at 48,044 (setting the threshold at the model-predicted air quality annual average).

38. See *id.* at 48,045–46 (calculating that there are fewer benefits associated with this measurement, while using the full range of ambient concentrations does not favor repeal due to the large amount of benefits).

in order to more easily justify its repeal.³⁹ Even with the significant changes made to other cost and benefits estimates throughout the proposed rule, only this last estimate makes the repeal cost-benefit justified.⁴⁰ The issue of how particulate matter benefits are calculated will thus be of central importance in the inevitable slew of litigation challenging the repeal.⁴¹

The EPA's own early treatment of criteria pollutants potentially contributed to confusion over whether these pollutants have a threshold, as some early analyses arguably implied that criteria pollutants had thresholds.⁴² However, the EPA has subsequently adjusted its practices in ways that make clear the Agency views particulate matter and most criteria pollutants as non-threshold.⁴³

As a general matter, the EPA currently assumes that carcinogenic pollutants do not have a threshold and that non-criteria noncarcinogenic pollutants do have a threshold.⁴⁴ In its earliest analyses in the late 1970s, the EPA treated criteria pollutants similarly to other noncarcinogens.⁴⁵ For example, the Agency used language that suggested thresholds when setting

39. See *id.* at 48,043 (“[T]his analysis increases transparency of the 2015 [Clean Power Plan] analysis by presenting the energy efficiency cost savings as a benefit rather than a cost reduction and provides a bridge to future analyses that the agency is committed to performing. The current analysis also provides alternative approaches for examining the forgone benefits, including more clearly distinguishing the direct benefits from the co-benefits and exploring alternative ways to illustrate the impacts on the total net benefits of the uncertainty in health co-benefits at various PM_{2.5} cutpoints. This approach shifts the focus to the domestic (rather than global) social cost of carbon, and employs both 3 percent and 7 percent discount rates. Finally, we consider how changing market conditions and technologies may have affected future actions that may have been undertaken by states to comply with the [Clean Power Plan] and how these changes may affect the potential benefits and costs of the [Plan’s] repeal.”).

40. See *supra* note 9 and accompanying text.

41. See Caroline Cecot & W. Kip Viscusi, *Judicial Review of Agency Benefit-Cost Analysis*, 22 GEO. MASON L. REV. 575, 578 (2015) (noting that “[a]s agencies rely more on [cost-benefit analyses] in their decision making, challenges to [cost-benefit analyses] will rise, and judicial review of [cost-benefit analyses] will become increasingly important”).

42. See *infra* note 182.

43. See *infra* Part II.C.

44. See NAT’L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 8 (2009) [hereinafter SCIENCE AND DECISIONS].

45. See *infra* note 182.

allowable pollutant levels, such as the “critical populations, critical effects” model.⁴⁶ However, as scientific research accumulated showing adverse health effects at lower concentrations, the EPA quickly departed from this approach, and the Agency has not treated criteria pollutants as threshold pollutants for several decades under administrations of both parties.⁴⁷ First, the EPA has explicitly acknowledged in many NAAQS rulemakings that there is no evidence to support the view that specific criteria pollutants have a threshold.⁴⁸ Further, the EPA has stopped using the “critical effects” language when setting NAAQS.⁴⁹ Additionally, the EPA has calculated benefits for reducing criteria pollutants below NAAQS levels—a practice that is inconsistent with the notion of a threshold.⁵⁰ The EPA’s modern treatment of the NAAQS moved the Agency in line with current science on this question, which supports a non-threshold model.⁵¹

Critics next argue that the EPA “double counts” benefits by claiming benefits already implemented through other regulations.⁵² For example, Senator John Barrasso asserted in an Environmental and Public Works Committee hearing in 2015 that

46. See *infra* notes 185–95 and accompanying text. The “critical populations, critical effects” model refers to a way of setting the NAAQS with reference to a sensitive population and key early health effects of the pollutant. *Id.*

47. See *infra* Part III.B.

48. See *infra* Part II.C.

49. See *infra* notes 207–08 and accompanying text.

50. See *infra* Part II.C.

51. See *infra* Part II.C.

52. See Michael Bastach, *Critics Accuse EPA of Fudging the Math on Its Global Warming Rule*, DAILY CALLER (Oct. 1, 2015), <http://dailycaller.com/2015/10/01/critics-accuse-epa-of-fudging-the-math-on-its-global-warming-rule> (“Former Sen. John Kyl, an Arizona Republican, also criticized the EPA over double-counting PM_{2.5} reduction benefits in its [Mercury and Air Toxics Standards] rule. In 2012, Kyl took to the Senate floor to lambast the EPA for double-counting the benefits of reducing particulates.”); Jude Clemente, *The Clean Power Plan Is Irrelevant*, FORBES (Oct. 29, 2017), <https://www.forbes.com/sites/judeclemente/2017/10/29/the-clean-power-plan-is-irrelevant> (“And there seems to be some serious ‘double counting’ going on under the promoted [Clean Power Plan] benefits. That’s mostly because the emissions of criteria pollutants NO_x, SO₂, and PM have been regulated for decades, but they are erroneously counted in the claimed benefits of the [Plan].”); Diana Furchtgott-Roth, *Ten Problems with EPA’s Clean Power Plan Analysis*, MANHATTAN INST. (Mar. 20, 2017), <https://economics21.org/html/ten-problems-epa’s-clean-power-plan-analysis-2275.html> (“If reductions in particulates can be counted as a health benefit of reducing mercury, the first of three major rules put in place by EPA, the agency cannot then count these same reductions as a benefit from reducing ozone and carbon dioxide.”); Gray, *supra* note 26 (“[W]henver EPA counts PM_{2.5} or ozone reductions in its cost-benefit analysis for other rules, it is double-counting reductions already mandated by the NAAQS.”).

multiple EPA rules were using “the same reductions in particulate matter [to] claim the same health benefits,” including the Clean Power Plan.⁵³ Other opponents of the Clean Power Plan likewise contend that “not only are [the Agency’s] estimates of co-benefits highly subjective and uncertain, but the EPA has almost surely double-counted some of those estimates.”⁵⁴ These critics also allege that the Agency achieves the same end by failing to properly calibrate its baseline levels from which to measure costs and benefits.⁵⁵ In fact, the EPA’s longstanding guidelines on baselines state that it is the Agency’s practice “to assume full compliance with regulatory requirements,” including newly enacted regulations that are not yet implemented.⁵⁶ Moreover, the EPA expressly discusses the methods by which it accounts for benefits previously achieved under the NAAQS regime and other rules, which include an explanation of how the Agency accounted for existing regulations of particulate matter.⁵⁷

Finally, critics suggest that, even if these benefits are real and not “double-counted,” they should not be considered in cost-benefit analyses because they are “co-benefits” instead of direct benefits.⁵⁸ For example, while the Mercury and Air Toxics Standards primarily target mercury pollution⁵⁹ and the Clean Power Plan directly regulates carbon dioxide emissions,⁶⁰ both rules

53. *Economy-Wide Implication of President Obama’s Air Agenda: Hearing Before the Comm. on Env’t & Pub. Works*, 114th Cong. 82 (2015) (statement of Sen. John Barrasso) (“Yet when you take a look at the EPA’s own documents, you [s]tate that you are counting co-benefits of reducing the same PM 2.5 in other rules before [the] 111(d) rule for existing power plants was even released.”).

54. LESSER, *supra* note 26, at 19.

55. *See id.* at 5.

56. U.S. ENVTL. PROT. AGENCY, GUIDELINES FOR PREPARING ECONOMIC ANALYSES, at 5-3 (2010) [hereinafter GUIDELINES FOR PREPARING ECONOMIC ANALYSES].

57. *See infra* notes 431–40.

58. *See* Michael Bastach, *Trump’s Executive Order to Repeal Regulations Puts EPA in the Crosshairs*, DAILY CALLER (Jan. 13, 2017), <http://dailycaller.com/2017/01/31/trumps-executive-order-to-repeal-regulations-puts-epa-in-the-crosshairs> (“Republicans have long criticized EPA for counting ‘co-benefits’ of regulation towards its cost effectiveness.”); Furchtgott-Roth, *supra* note 52 (“If EPA believes that their levels of other substances should be reduced, it should issue rules to lower them, with their own comment periods and cost-benefit analysis.”); *infra* notes 455–65 and accompanying text.

59. MATS Rule, *supra* note 2, at 9305.

60. Clean Power Plan, *supra* note 7, at 64,663, 64,710.

would reduce particulate matter as well.⁶¹ Opponents claim that accounting for co-benefits skews cost-benefit analyses in favor of regulation⁶² and exceeds the statutory bounds of the EPA's power to regulate these pollutants under the Clean Air Act.⁶³ The Trump Administration, a key critic of these rules, decries these benefits and asserts that their inclusion “essentially hid[es] the true net cost” of rules like the Clean Power Plan.⁶⁴

This view, however, conflicts with four decades of EPA practice under administrations of both parties: the EPA during that time has taken co-benefits under consideration when evaluating air pollution regulations.⁶⁵ Further, Office of Management and Budget (OMB) Circular A-4, issued during the George W. Bush Administration, instructs agencies like the EPA to look at and consider co-benefits and their mirror image: indirect costs.⁶⁶ Indirect costs are consistently calculated for Clean Air Act and

61. *Id.* at 64,670, 64,679; MATS Rule, *supra* note 2, at 9305. Some of these rules would also have the co-benefit of reducing other criteria pollutants. *See, e.g.*, MATS Rule, *supra* note 2, at 9305, 9380 (noting incidental reductions in sulfur dioxide pollution). While this Article focuses primarily on particulate matter because of the scope of those benefits and the clarity of the scientific evidence that particulate matter lacks a threshold, there is likewise no reason to exclude co-benefits of reductions of other NAAQS pollutants where sufficient evidence shows that such pollutants also lack a threshold.

62. *See* Kyle Feldscher, *Senate Republicans Take Aim at Cost of EPA Regs*, WASH. EXAMINER (Oct. 21, 2015), <http://www.washingtonexaminer.com/senate-republicans-take-aim-at-cost-of-epa-regs> (quoting Senator Mike Rounds' statement that “[b]ecause of [its] exorbitant regulations, the EPA attempts to justify . . . the costs by identifying ancillary benefits, which the EPA refers to as co-benefits, to help outweigh the cost of regulations”).

63. *See* Gray, *supra* note 26 (“EPA is treating the Clean Air Act as a completely open-ended grant of power, precisely as the Supreme Court forbids. . . . The costs of complying with a given regulation should be compared against the social goods that that regulation is authorized to achieve—not incidental co-benefits . . .”); *infra* notes 445–54 and accompanying text.

64. *News Releases: EPA Takes Another Step To Advance President Trump's America First Strategy, Proposes Repeal of “Clean Power Plan,”* U.S. ENVTL. PROTECTION AGENCY (Oct. 10, 2017), <https://www.epa.gov/newsreleases/epa-takes-another-step-advance-president-trumps-america-first-strategy-proposes-repeal>.

65. *See infra* Part IV.B.

66. *See* OFFICE OF MGMT. & BUDGET, CIRCULAR A-4: REGULATORY ANALYSIS 26 (2003) [hereinafter CIRCULAR A-4: REGULATORY ANALYSIS], <https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf> (articulating that agencies should “look beyond the direct benefits and direct costs . . . and consider any important ancillary benefits and countervailing risks”). Just as there are various terms for “co-benefits,” there are likewise multiple names for “indirect costs,” including countervailing risks. This Article primarily uses the term “indirect costs” but occasionally employs “countervailing risks” as well.

other EPA regulations,⁶⁷ and it would be inconsistent to consider the negative indirect effects of regulations without similarly considering the positive indirect effects.⁶⁸ The benefits from reducing particulate matter below the levels of the NAAQS in terms of avoided health harms and premature mortality are scientifically well established and have been acknowledged by the EPA for decades.⁶⁹ There is thus no reason to exclude them from analyses of air pollution regulations.

Courts likewise have long held that when a rule's justification includes economic analyses, agencies may not ignore important costs or benefits, whether the effect is direct or ancillary.⁷⁰ For example, the D.C. Circuit, the most important court of appeals for federal environmental regulation,⁷¹ has held that the EPA must consider indirect effects in its rulemakings.⁷² In 1999, the court remanded a revision to the NAAQS for ozone and particulate matter because the Agency had failed to consider the potential indirect health costs from strengthening the regulatory standards.⁷³ Likewise, in *American Trucking Ass'ns v. EPA*, the court held that the Agency must consider incidental countervailing risks.⁷⁴ More recently, in *Sugar Corp. v. EPA* the court upheld an EPA regulation that relied on co-benefits in its analysis

67. See Rascoff & Revesz, *supra* note 4, at 1786 (discussing the number of bills that have been passed that discuss health risk tradeoffs); *infra* Part IV.B.

68. See generally *id.* (making the argument that ancillary benefits should be considered, given the rise in consideration of risk tradeoffs).

69. See *infra* Part III.

70. *E.g.*, *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1036–37 (D.C. Cir. 1999), *rev'd on other grounds sub nom.* *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

71. Richard J. Lazarus, *Senator Edmund Muskie's Enduring Legacy in the Courts*, 67 ME. L. REV. 239, 242 (2015) (“[T]he D.C. Circuit of course is the nation’s most important court for federal environmental law because it has original jurisdiction to hear challenges to EPA rules promulgated under a host of federal environmental laws, including the Clean Air and Clean Water Acts, and exclusive jurisdiction to consider some of those challenges.”).

72. *E.g.*, *id.*

73. See *Am. Trucking Ass'ns*, 175 F.3d at 1036–37.

74. *Id.* at 1051–53; *cf.* Michael A. Livermore & Richard L. Revesz, *Rethinking Health-Based Environmental Standards*, 89 N.Y.U. L. REV. 1184, 1250 (2014) (“In a portion of its *American Trucking* opinion not reviewed by the Supreme Court, the D.C. Circuit stated that at least certain types of secondary effects must be considered by the agency when setting the NAAQS. . . . The court noted that it ‘seems bizarre that a statute intended to improve human health would . . . lock the agency into looking at only one half of a substance’s health effects in determining the maximum level for that substance.’ Thus, the D.C. Circuit required the agency to account for the negative secondary consequences of regulation—the countervailing risks.” (quoting *Am. Trucking Ass'ns*,

of the effects of reducing hazardous air pollutants from boilers, process heaters, and incinerators.⁷⁵ The labels “benefit” and “cost” merely serve as useful shorthand for positive effects versus negative effects. In the context of cost-benefit analysis, neither possesses any inherent quality warranting different weight or analytical treatment from the other.⁷⁶

Because the frontal attack on the co-benefits of particulate reductions below the NAAQS arose so recently, there is no existing academic literature in this area. Neither is there sustained discussion on the evolution in the understanding of thresholds for criteria pollutants following the enactment of the Clean Air Act in 1970 or on how this understanding developed alongside different approaches used for carcinogens and noncarcinogens other than criteria pollutants. And there is no historical, scientific, and practical analysis of the question of how the competing arguments on thresholds interact with cost-benefit analysis.

This Article fills these voids. Part I discusses the EPA’s approaches for assessing the risks of carcinogenic and noncarcinogenic pollutants other than criteria pollutants. The EPA has consistently treated carcinogens as non-threshold pollutants, whereas for noncarcinogen, non-criteria pollutants, the EPA’s approach has lagged behind the scientific evidence and assumes that there is a no-harm threshold. Part II turns to criteria pollutants. It examines Congress’s growing doubts about the existence of NAAQS thresholds, which resulted in a significant conceptual change in the understanding of criteria pollutant reflected in the 1977 amendments to the Clean Air Act. It also shows how the EPA’s approach has evolved, from embracing threshold models in the 1970s to consistently rejecting them since the 1980s. Part III addresses the critics’ first two arguments: that benefits from particulate matter reductions below the NAAQS do not exist, and that the EPA erroneously “double counts” benefits by failing to adjust its estimation baselines to account for prior regulation of particulate matter. We explain the scientific basis for calculating particulate matter benefits below the NAAQS, as well as the EPA’s longstanding practice of measuring and quantifying these benefits. We also examine how the

175 F.3d at 1051–52)).

75. *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 591, 625 (D.C. Cir. 2016).

76. See INST. FOR POLICY INTEGRITY, THE IMPORTANCE OF EVALUATING REGULATORY “CO-BENEFITS” 2 (2017), https://policyintegrity.org/files/media/Co-Benefits_Factsheet.pdf (arguing that there is no “logical reason for agencies to treat indirect benefits differently than indirect costs”).

Agency deals with uncertainty and sets its baselines when revising the NAAQS. Part IV assesses the final assertion of the critics: that even if real, these benefits should not be included in cost-benefit analyses when they are co-benefits as opposed to direct benefits. We discuss the treatment of co-benefits in a range of contexts over the past four decades by academics, the EPA, and the judiciary, and argue that there is no plausible justification for excluding them from cost-benefit analyses.

I. TRADITIONAL RISK ASSESSMENT MODELS

The EPA currently uses different risk assessment approaches for carcinogens, noncarcinogens, and NAAQS criteria pollutants, respectively. This Part analyzes the Agency's current models for evaluating the health and environmental risks posed by carcinogens and by noncarcinogens other than criteria pollutants.

A. CARCINOGENS

The EPA assumes that carcinogens have no thresholds unless sufficient pollutant-specific data leads the Agency to conclude that a particular carcinogen has a threshold.⁷⁷ Under this approach, the EPA first attempts to discern a "mode of action" for carcinogens,⁷⁸ which describes the sequence of key events and

77. See SCIENCE AND DECISIONS, *supra* note 44, at 127. The EPA will adjust its model to include a threshold where there is such evidence. For example, the EPA treats chloroform as a threshold carcinogen. See U.S. ENVTL. PROT. AGENCY, CASRN 67-66-3, INTEGRATED RISK INFORMATION SYSTEM: CHLOROFORM CHEMICAL ASSESSMENT SUMMARY 1-2, 10 (2001), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0025_summary.pdf. However, the EPA has not identified many exceptions to its general rule that carcinogens should be treated as non-threshold and noncarcinogens should be treated as having a threshold. See Wendy Wagner et al., *Misunderstanding Models in Environmental and Public Health Regulation*, 18 N.Y.U. ENVTL. L.J. 293, 335 (2010) (discussing the EPA's assumption that carcinogens have no threshold of effect and noting that the EPA has identified threshold carcinogens, including chloroform, and has struggled with accommodating such exceptions). In 2000, the D.C. Circuit spurred the Agency to action on chloroform, finding that the EPA's use of an assumption of linearity for chloroform violated the Safe Drinking Water Act of 1974, 42 U.S.C. §§ 300f to 300j-24 (2012), because it "openly overrode the best available scientific evidence, which suggested that chloroform is a threshold carcinogen." *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290 (D.C. Cir. 2000) (internal quotation omitted).

78. U.S. ENVTL. PROT. AGENCY, EPA/630/P-03/001F, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, at 1-10 (2005) [hereinafter GUIDELINES FOR CARCINOGEN RISK ASSESSMENT], https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

processes resulting in cancer formation.⁷⁹ When the EPA can determine the mode of action, it will model the risk-exposure relationship based on that mode of action.⁸⁰ If the mode suggests a linear, non-threshold relationship, the EPA will so model the relationship; if, in contrast, the mode suggests a threshold, the EPA will model the threshold. Where the EPA does not have sufficient data to determine the mode of action, the Agency assumes that pollutants that cause tumors in animals are harmful to humans,⁸¹ that cancer risks of these pollutants do not have a threshold,⁸² and that the effects can be modeled by low dose linearity,⁸³ which describes a relationship between exposure and risk under which additional exposure will result in additional risk at a constant rate.⁸⁴

Next, the Agency reviews the evidence available from scientific studies and produces a “weight of evidence narrative,” which is intended to assess the health impacts of a pollutant and the

79. *Id.* at 1-10 n.2 (defining “mode of action”).

80. *See id.* at 1-11, 1-11 n.3 (discussing the relationship between mode of action and risk exposure).

81. *Id.* at 1-10 to -11.

82. *See id.* at 1-11, 1-11 n.3 (stating that “cancer risks are assumed to conform with low dose linearity” and that such models are necessarily non-threshold); SCIENCE AND DECISIONS, *supra* note 44, at 8 (“For cancer, it is generally assumed that there is no dose threshold of effect . . .”).

83. *See* GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, *supra* note 78, at 1-11.

84. *See id.* at 1-11 n.3 (“A low-dose-linear model is one whose slope [comparing dosage to risk] is greater than zero at a dose of zero. A low-dose-linear model approximates a straight line only at very low doses; at higher doses . . . [it] can display curvature.”). This approach comports with cancer policies of other federal agencies. For example, the EPA, the FDA, and OSHA “all . . . employ a linear mathematical model for low-dose extrapolation” of carcinogenic risk assessment. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-01-810, CHEMICAL RISK ASSESSMENT: SELECTED FEDERAL AGENCIES’ PROCEDURES, ASSUMPTIONS, AND POLICIES 40, 173, 197 (2001), <https://www.gao.gov/assets/240/232303.pdf> (noting the FDA’s assumption of a “linear, no-threshold approach” for low dose cancer estimation, as well as OSHA’s acceptance of the “overwhelming scientific consensus . . . that genotoxins follow low-dose linear functions”); *cf.* NAT’L INST. FOR OCCUPATIONAL SAFETY & HEALTH, DEPT. OF HEALTH & HUMAN SERVS., CURRENT INTELLIGENCE BULLETIN 68, NIOSH CHEMICAL CARCINOGEN POLICY 19 (2017) [hereinafter NIOSH CHEMICAL CARCINOGEN POLICY], <https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf?id=10.26616/NIOSH PUB2017100revised> (“For carcinogen risk assessment, the NIOSH generally treats exposure-response as low-dose linear unless a non-linear mode of action has been clearly established, in which case the NIOSH will adopt a modeling approach defined by the data (including non-linear approaches when appropriate). In general, whether the model forms are linear or non-linear, any nonzero exposure to a carcinogen is expected to yield some excess risk of cancer.”).

strength of the evidence of those effects.⁸⁵ The EPA considers factors such as whether tumors were found in humans or animals, the agent's chemical and physical properties, and studies addressing its mode of action.⁸⁶ The Agency uses standard descriptors to express the weight of the evidence: "Carcinogenic to Humans, Likely to Be Carcinogenic to Humans, Suggestive Evidence of Carcinogenic Potential, Inadequate Information to Assess Carcinogenic Potential, and Not Likely to Be Carcinogenic."⁸⁷

Dose response assessments, the next phase of the EPA's analysis of risk from carcinogens, are generally completed for pollutants labeled "Carcinogenic to Humans" and "Likely to Be Carcinogenic to Humans."⁸⁸ Dose response assessments aim to measure health effects at different exposure levels.⁸⁹ These assessments are performed by first assessing data to determine a "point of departure,"⁹⁰ which "marks the beginning of extrapolation to lower doses" based on experimental data.⁹¹ Above the point of departure, the EPA attempts to develop a tailored model of dose-response pattern.⁹² Where the EPA lacks sufficient data to develop one, the Agency states that "an appropriate policy choice" is to use a standard curve-fitting model, which is a standardized mathematical function for drawing a trend line among data points.⁹³ Below the point of departure, the EPA assumes that risk is related to exposure in a linear pattern.⁹⁴

The EPA's cancer guidelines emphasize that "a critical analysis of all of the [relevant] available information . . . [is] the starting point from which a default option *may* be invoked *if needed* to address uncertainty or the absence of critical information."⁹⁵

85. GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, *supra* note 78, at 1-11.

86. *Id.*

87. *Id.* at 1-12 (internal quotations omitted).

88. *Id.* at 3-2.

89. *Id.* at 1-12.

90. *Id.* at 1-13.

91. *Id.* at 1-13 n.4.

92. *See id.* at 1-14 ("The first step of dose-response assessment is evaluation within the range of observation.").

93. *Id.* at 1-9 to -10.

94. *See* SCIENCE AND DECISIONS, *supra* note 44, at 127 ("After adjustment for animal-human differences in the dose metric, risk is assumed to decrease linearly with doses below the [point of departure] for carcinogens . . .").

95. GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, *supra* note 78, at 1-7 (emphasis added).

Thus, if evidence emerges that a particular carcinogenic pollutant does in fact have a threshold, or is non-linear at low levels or all levels (for example if data instead suggests a logarithmic relationship), the EPA may depart from the default no-threshold, linear model.⁹⁶

Other agencies have taken similar approaches to regulating carcinogens. The Occupational Safety and Health Administration (OSHA), under its guidance for regulating potential carcinogens,⁹⁷ has not standardized its classification and regulation of carcinogens to the degree that the EPA has. Rather than identifying default models that will be used when data is insufficient to tailor a model, as the EPA has done, OSHA will evaluate arguments for a “threshold” effect in an individual rulemaking, but only if there is sufficient evidence to suggest there may be levels of exposure below which no health effects are observed.⁹⁸ Further, OSHA guidance has been affected by the landmark *Benzene Case* in which the Supreme Court struck down OSHA’s standard for exposure to benzene.⁹⁹ The Labor Secretary had set that standard at one ppm (one part benzene per million parts air) after concluding that, because benzene was a carcinogen, no level of exposure to this substance was safe.¹⁰⁰ The Court faulted the Secretary for not quantifying the reduction in risks that resulted from tightening the prior standard of ten ppm.¹⁰¹ In order to satisfy the requirements of the *Benzene Case*, OSHA now estimates “the risk to workers subject to a lifetime of exposure at various possible exposure levels.”¹⁰² It is more difficult to discern what

96. A linear model is not synonymous with a non-threshold model. *See id.* at 1-11 n.3. A non-threshold model may be non-linear, so long as it includes health effects even at very low levels. *Id.*

97. *See* 29 C.F.R. § 1990.101–.152 (2017) (providing guidance for the identification, classification, and regulation of carcinogens).

98. *See id.* § 1990.143. The scientific evidence for a threshold, below which adverse health effects do not occur, must comport with certain research requirements such as the length of time of the study and size of the population group studied. *See id.* § 1990.144 (providing “criteria for consideration of arguments on certain issues,” including threshold status); *id.* § 1990.145 (providing criteria for “consideration of substantial new issues or substantial new evidence”).

99. *Indus. Union Dep’t, AFL–CIO v. Am. Petroleum Inst. (Benzene Case)*, 448 U.S. 607, 662 (1980).

100. *Id.* at 613.

101. *See id.* at 630–34 (finding that though a ten ppm standard was reasonable, the Agency lacked sufficient support for a further reduction to one ppm).

102. Chemical Management and Permissible Exposure Limits (PELs), 79 Fed. Reg. 61,384, 61,387 (proposed Oct. 10, 2014) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, and 1926).

OSHA's specific models are for evaluating risks posed by carcinogens. However, OSHA carcinogen guidance makes clear that the Agency treats carcinogens as non-threshold pollutants.¹⁰³ The Agency develops models for risk that "best fit the existing data and are consistent with available information on mode of action," but also notes that there is "a reasonable body of scientific evidence that genotoxic carcinogens, and perhaps other carcinogenic modes of action, display linear, non-threshold behavior at very low dose levels."¹⁰⁴

The National Institute for Occupational Safety and Health (NIOSH), established under the same legislation as OSHA¹⁰⁵ and empowered to "develop and establish recommended occupational safety and health standards,"¹⁰⁶ recently released a revised chemical carcinogen policy.¹⁰⁷ NIOSH, like the EPA, generally treats the exposure response relationship as linear at low doses, which implies a non-threshold model.¹⁰⁸ Also like the EPA, NIOSH will depart from this model where a non-linear

103. See 29 C.F.R. § 1990.143(h) ("No determination will be made that a 'threshold' or 'no-effect' level of exposure can be established for a human population exposed to carcinogens in general, or to any specific substance.").

104. Chemical Management and Permissible Exposure Limits (PELs), 79 Fed. Reg. at 61,391.

105. Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (codified as amended at 29 U.S.C. §§ 651–75, 677–78 (2012), 42 U.S.C. § 3142-1 (2012)). The section creating NIOSH is found at 29 U.S.C. § 671 (2012).

106. 29 U.S.C. § 671(c)(1). NIOSH was originally conceived as the research arm of a coordinated federal effort to regulate workplace safety, and OSHA was to be the standard-setting agency. See *About NIOSH*, CENTERS FOR DISEASE CONTROL & PREVENTION (Aug. 6, 2018), <https://www.cdc.gov/niosh/about/default.html> ("The Occupational Safety and Health Act of 1970 established NIOSH as a research agency focused on the study of worker safety and health."); *All About OSHA*, OCCUPATIONAL SAFETY & HEALTH ADMIN. (2006), <https://www.osha.gov/Publications/about-osha/3302-06N-2006-English.html> ("The OSH Act established the National Institute for Occupational Safety and Health in the Department of HHS as the research agency for occupational safety and health. NIOSH conducts research on various safety and health problems, provides technical assistance to OSHA, and recommends standards for OSHA's consideration.").

107. See NIOSH CHEMICAL CARCINOGEN POLICY, *supra* note 84. NIOSH's 2017 guidance on carcinogens post-dates OSHA's guidance, which was published in 1980. Compare *id.*, with 29 C.F.R. § 1990 (1980). As such, it is not entirely clear how extensively OSHA relies on NIOSH data to set regulations on carcinogens in the workplace. OSHA guidance does, however, reference consulting with the Director of the NIOSH. See 29 C.F.R. §§ 1990.104, 1990.106 (2017).

108. See NIOSH CHEMICAL CARCINOGEN POLICY, *supra* note 84.

mode of action has been clearly established.¹⁰⁹ Further, NIOSH explicitly notes that even where there is evidence of a non-linear relationship between risk and exposure at low doses, “it is highly unlikely that one can demonstrate empirically that a threshold exists.”¹¹⁰

In summary, the EPA, OSHA, and NIOSH all treat carcinogens as non-threshold contaminants, and make this determination based on the relevant scientific evidence. Further, the EPA and NIOSH both assume linearity at low doses, unless the data strongly suggests a different relationship between exposure and risk to health. The assumption of non-threshold low dose linearity presumes health impacts even at very low levels of exposure.¹¹¹ Because health effects can be estimated at low doses under this model, the agencies can include these health benefits in cost-benefit analyses used to support allowable standards for carcinogenic pollutants. Considering these benefits of pollution regulation allows agencies to more accurately weigh the effects of regulations at different stringencies, facilitating more informed decision-making.

Accounting for adverse health impacts from very low levels of pollution does not mean that the EPA or other agencies must or will require the elimination of that pollutant.¹¹² For example,

109. *See id.* (“For carcinogen risk assessment, NIOSH generally treats exposure-response as low-dose linear unless a non-linear mode of action has been clearly established, in which case NIOSH will adopt a modeling approach defined by the data (including non-linear approaches when appropriate).”).

110. *Id.*

111. *Id.*

112. Commentators have suggested that the non-threshold approach to carcinogens was responsible for the EPA’s reluctance to list carcinogenic pollutants during the 1970s and much of the 1980s. *See, e.g.,* Matthew D. Adler, *Against “Individual Risk”: A Sympathetic Critique of Risk Assessment*, 153 U. PA. L. REV. 1121, 1150 (2005) (“Thus EPA faced the dilemma of either banning all emissions of carcinogenic pollutants (with huge economic costs) or allowing some emissions and therewith a nonzero probability of some deaths, in apparent violation of the ‘ample margin of safety’ language of section 112.”); John P. Dwyer, *The Pathology of Symbolic Legislation*, 17 ECOLOGY L.Q. 233, 251–52 (1990) (discussing the EPA’s use of “cumbersome” regulatory processes to avoid making tough choices); Bradford C. Mank, *What Comes After Technology: Using an “Exceptions Process” to Improve Residual Risk Regulation of Hazardous Air Pollutants*, 13 STAN. ENVTL. L.J. 263, 268 (1994) (“The ‘ample margin of safety’ language proved counterproductive because the EPA was reluctant to effectively shut down entire industries by listing pollutants, where such listing would require zero emission standards.”); Deanna Schmitt, Note, *North Carolina Air Toxics Regulations*, 69 N.C. L. REV. 1579, 1581–82 (1991) (“To avoid such dire consequences and in response to pressure from industry, the EPA instead chose only to regulate a few pollutants.”). Originally, § 112 of the Clean

under the Safe Drinking Water Act (SDWA),¹¹³ the EPA is required to set maximum contaminant level goals (MCLG), which is the maximum level of a contaminant in drinking water at which no known or anticipated health effects would occur.¹¹⁴ When the EPA regulates carcinogens under the SDWA, the Agency sets the MCLG at zero where there is evidence that the chemical may cause cancer, and there is no dose below which the chemical is considered safe.¹¹⁵ However, the MCLG is *not* an enforceable standard. Rather, the enforceable standard, known as the maximum contaminant level, is set as close to the MCLG as

Air Act required an “ample margin of safety” for “hazardous air pollutants.” 42 U.S.C. § 7412(b)(1)(B) (1988), *amended by* Pub. L. No. 101-549, § 301, 104 Stat. 2399, 2531 (1990). Because carcinogens have no threshold below which they are safe, EPA officials feared listing a pollutant as a carcinogen might forbid emitting the pollutant at all, shuttering entire industries. *See* Adler, *supra*; Dwyer, *supra*, at 251; Mank, *supra*; Schmitt, *supra*, at 1581. However, the U.S. Supreme Court determined that zero tolerance for carcinogens was not an appropriate approach, at least with regard to OSHA regulations. In the *Benzene Case*, Justice Stevens relied heavily on statutory language mandating that OSHA only regulate standards for toxic materials “to the extent feasible,” and determined that before the Agency enact more stringent standards, OSHA had to determine the regulated chemical exposure posed “significant risks of harm.” *Indus. Union Dep’t, AFL-CIO v. Am. Petroleum Inst. (Benzene Case)*, 448 U.S. 607, 612, 641 (1980). Eventually the EPA linked safety to “best available technology” standards: after identifying the lowest level of emissions possible with the best available technology, the EPA would decide whether to set emissions at an even lower level by weighing the reduction in health risks against the costs of setting the lower standard. *Nat’l Res. Def. Council, Inc. v. EPA*, 824 F.2d 1146, 1163–64 (D.C. Cir. 1987). In 1987, the D.C. Circuit rejected this approach, favoring instead a two-step process in which the EPA first determined what would be an “acceptable” risk to health without any consideration of cost or technological capability, and in a second step, determined the ample margin of safety, incorporating feasibility considerations. *Id.* at 1164–65. The EPA then settled on this approach for regulating carcinogenic air pollutants: the EPA would set standards so that the maximally exposed individual had a risk of one in ten-thousand or less, and if economically feasible, further regulate the pollutant to minimize the number of people with a risk greater than one in one million. *See* National Emission Standards for Hazardous Air Pollutants, 54 Fed. Reg. 38,044, 38,044–45 (Sept. 14, 1989) (40 C.F.R. pt. 61); Adler, *supra*, at 1151.

113. 42 U.S.C. §§ 300f to 300j-24 (2012).

114. *Id.* § 300g-1(b)(4)(A) (“Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.”).

115. *See How EPA Regulates Drinking Water Contaminants*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/dwregdev/how-epa-regulates-drinking-water-contaminants#develop> (last updated June 6, 2018) (“For chemical contaminants that are carcinogens, EPA sets the MCLG at zero if . . . there is evidence that a chemical may cause cancer [and] there is no dose below which the chemical is considered safe.”).

feasible, taking into consideration costs and available technology.¹¹⁶ In short, even where the EPA recognizes that a carcinogen is unsafe at any level, the Agency can, and does, set standards above zero. Including health costs from low level exposure to carcinogenic pollutants does not force the EPA to ban the pollutant; it merely facilitates more informed decisions about how to regulate these pollutants.

A proposed rule released April 30, 2018 would move the EPA away from its longstanding use of a default linear dose response model, purportedly because “there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects.”¹¹⁷ The proposed rule would encourage the EPA to incorporate a variety of “competing” models on low dose risk assessment, including linear but also threshold, U-shaped, J-shaped, and bell-shaped models.¹¹⁸ Yet the EPA cites no studies in support of the assertion that there is empirical evidence of non-linearity, nor does it mention any pollutants in particular as justification of the rule.¹¹⁹ The proposed rule also does not mention its current cancer guidelines or the guidelines’ default assumption of low-dose linearity in the absence of evidence to the contrary.¹²⁰ However, the proposed rule could dramatically impact the default assumptions used by the Agency in regulating carcinogenic pollutants. It would apply to all significant regulatory actions¹²¹ and specifically refers to the “dose re-

116. 42 U.S.C. § 300g-1(b)(4)(B)–(D).

117. Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,770 (proposed Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30) [hereinafter Strengthening Transparency].

118. *Id.*

119. *See id.*

120. *Id.*; see also Maria Hegstad, *Draft Science Rule Targets EPA’s Use of Strict Default Linear ‘Dose’ Models*, INSIDE EPA (May 2, 2018), <https://insideepa.com/daily-news/draft-science-rule-targets-epas-use-strict-default-linear-dose-models> (discussing the responses of both critics and supporters of the proposed rule and the potential result of less stringent regulations).

121. The regulation incorporates the definition of “significant regulatory actions” included in Executive Order 12,866. *See* Strengthening Transparency, *supra* note 117, at 18,771. Executive Order 12,866 defines “significant regulatory actions” as:

any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned

sponse data and models that underlie . . . ‘pivotal regulatory science.’”¹²² There is nothing in the proposed rule to suggest that it does not encompass carcinogenic pollutants. The EPA’s posture in this proposed rule suggests a drastic departure in the Agency’s treatment of carcinogens and other pollutants for which there is strong evidence of linearity of health effects.

B. NONCARCINOGENS OTHER THAN CRITERIA POLLUTANTS

In contrast to carcinogens, the EPA treats noncarcinogens other than criteria pollutants as threshold pollutants. The EPA assumes that there is a threshold below which such pollutants do not have adverse health impacts,¹²³ despite the fact that this assumption is inconsistent with modern scientific understanding.¹²⁴ This Section analyzes the EPA’s current practice and then criticizes its continued reliance upon this assumption.

The EPA assessments for noncarcinogens focus on finding a “reference dose,” which is the quantity “likely to be without an appreciable risk of deleterious effects.”¹²⁵ The reference dose is derived from the point of departure, which is the point from which the EPA extrapolates the risk-exposure relationship.¹²⁶

by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.

Exec. Order No. 12,866, 3 C.F.R. §§ 638, 641–42 (1994).

122. Strengthening Transparency, *supra* note 117, at 18,770 (defining “pivotal regulatory science” as the “studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based”).

123. See SCIENCE AND DECISIONS, *supra* note 44, at 128 (“For noncancer end points, it is assumed that homeostatic and defense mechanisms lead to a dose threshold (that is, there is low-dose nonlinearity) below which effects do not occur or are extremely unlikely.”); LOUIS THEODORE & R. RYAN DUPONT, ENVIRONMENTAL HEALTH AND HAZARD RISK ASSESSMENT: PRINCIPLES AND CALCULATIONS 289 (2012) (“The noncancer hazard quotient assumes that there is a level of exposure . . . below which it is unlikely for even sensitive populations to experience adverse health effects . . .”).

124. See SCIENCE AND DECISIONS, *supra* note 44 (“Noncancer effects do not necessarily have a threshold, or low-dose nonlinearity . . .”).

125. *Id.* at 128 (quoting U.S. ENVTL. PROT. AGENCY, A REVIEW OF THE REFERENCE DOSE AND REFERENCE CONCENTRATION PROCESSES, at 4-4 (2002), <https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf>).

126. See *id.* (“As in cancer dose-response assessment, the [reference dose] is also derived from a [point of departure], which could be a no-observed-adverse-

For non-cancer pollutants, this point of departure is generally the no-observed-adverse-effect level (NOAEL),¹²⁷ which is “the highest exposure level at which no statistically or biologically significant increases are seen in the frequency or severity of adverse effect[s],”¹²⁸ or the lowest-observed-adverse-effect level (LOAEL), which is “[t]he lowest dose in a study in which there was an observed toxic or adverse effect.”¹²⁹ The reference dose might also be derived based on the “benchmark dose,” which is calculated using “a predetermined change in the response rate of an adverse effect.”¹³⁰ Once the EPA determines the NOAEL, LOAEL, or benchmark dose, the Agency divides that dose by the “uncertainty factor,” a margin of safety intended in part to reflect the possible differences between human and animal responses.¹³¹ The resulting number is the reference dose.¹³² This model presumes a threshold at the reference dose: below this exposure level, the health risk from exposure to noncarcinogenic pollutants is considered to be effectively zero.¹³³

Modern scientific studies have challenged the accuracy of the EPA’s threshold approach for noncarcinogens, and suggest that many of these pollutants do not have a population threshold.¹³⁴ Epidemiological studies now provide information about the health impacts of pollutants across a range of human exposures, including at very low levels.¹³⁵ Most significantly, a 2009

effect level (NOAEL) or a benchmark dose (BMD).”).

127. *See id.*

128. *Conducting a Human Health Risk Assessment: Dose-Response*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/risk/conducting-human-health-risk-assessment#tab-3> (last updated June 20, 2017) [hereinafter *Conducting Human Health Risk Assessment*].

129. ToxTutor, *Glossary*, NAT’L INSTITUTES HEALTH, <https://tox.tutor.nlm.nih.gov/glossary.html> (last visited Nov. 19, 2018); *see Conducting Human Health Risk Assessment*, *supra* note 128 (stating that the EPA uses LOAEL “in cases in which a NOAEL has not been demonstrated experimentally”).

130. *Conducting Human Health Risk Assessment*, *supra* note 128.

131. *See id.* (“These uncertainty factors take into account the variability and uncertainty that are reflected in possible differences between test animals and humans (generally 10-fold or 10x) and variability within the human population (generally another 10x) . . .”).

132. *See id.* (“Thus, the RfD is determined by use of the following equation: RfD = NOAEL (or LOAEL or BMDL)/UFs.”).

133. *See SCIENCE AND DECISIONS*, *supra* note 44, at 128.

134. *See id.* at 8.

135. *See* McGartland et al., *supra* note 29 (“Epidemiological studies of criteria air pollutants provide dose-response relationships applicable across a range of human exposures. These dose-response functions allow for quantifying and monetizing the benefits of reducing exposures at every level of exposure.”).

report of the National Research Council of the National Academy of Sciences¹³⁶—an independent organization comprised of distinguished scholars in science and engineering,¹³⁷ dedicated to the use of science and technology to improve the general welfare, and created by an act of Congress with a mandate to provide independent and objective advice to the federal government¹³⁸—explained that the EPA’s current threshold assumption model for noncarcinogens is based on outdated approaches developed between the 1950s and the 1980s.¹³⁹ The report observed that noncarcinogenic pollutants do not necessarily have a threshold,¹⁴⁰ and recommended that the EPA evaluate all noncarcinogens without assuming that they have a threshold.¹⁴¹ According to the report, the current model yields end products “inadequate for benefit-cost analyses or for comparative risk analyses,”¹⁴² and instead “creates an inconsistent approach for bringing toxicology and risk science into the decision-making process.”¹⁴³ The EPA has largely ignored this particular recommendation from the 2009 report and has not changed its model for assessing noncarcinogens.¹⁴⁴

136. See generally SCIENCE AND DECISIONS, *supra* note 44.

137. NAS was chartered by the Senate in 1863 with the purpose to, “when-ever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art.” Steve Olson, *The National Academy of Sciences at 150*, PNAS EARLY EDITION 1, 1 (2014), http://www.pnas.org/content/111/Supplement_2/9327.full. The organization is “a private agency with the public role of advising the government on policy-related technical issues.” *Id.* The National Research Council is the “principal operating agency” of the National Academies. *Articles of Organization of the National Research Council*, NAT’L ACADEMIES SCI., ENGINEERING & MED. (June 1, 2015), http://www.nationalacademies.org/nasem/na_070358.html.

138. The National Research Council was established in 1916 at the request of President Wilson to recruit specialists to participate in the National Academy of Sciences’ advisory work for the government. See *History*, NAT’L ACAD. SCI., <http://www.nasonline.org/about-nas/history> (last visited Nov. 19, 2018).

139. See McGartland et al., *supra* note 29. The report concluded that the EPA’s approach is no longer scientifically supportable, as it “does not make the best possible use of available scientific evidence.” SCIENCE AND DECISIONS, *supra* note 44, at 177.

140. SCIENCE AND DECISIONS, *supra* note 44.

141. See *id.* at 132 (“There are multiple toxicants . . . for which low-dose linear concentration-response functions rather than thresholds have been derived for noncancer end points . . . for critical end points driving the risk characterization at low doses, such cases may be common, and a new framework and practice are needed.”).

142. *Id.* at 133.

143. *Id.*

144. It is interesting to note that Dr. Thomas Burke, who chaired the NAS committee that wrote SCIENCE AND DECISIONS, served as the Deputy Assistant

Even if there were a threshold for an individual of average sensitivity, that level would, by definition, be lower for more sensitive individuals. Especially sensitive individuals would have an even lower threshold. And for the most sensitive individuals in a population, there might be no threshold at all.¹⁴⁵ While there might be individual thresholds for average people, there would be no population threshold—the level at which a population experiences no negative health effects.¹⁴⁶ Thus, deciding to treat one individual’s threshold as a population threshold is necessarily a decision to leave some individuals—those with lower thresholds—unprotected. For example, very young children, pregnant women, or the elderly might have harm thresholds for certain pollutants that are much lower than the average population threshold.¹⁴⁷ By assuming a threshold for a typical person, the EPA overlooks sensitive individuals who may experience negative health impacts at exposure levels lower than the regulatory standard. The question of how many people to leave unprotected is ultimately a policy question. An accurate accounting

Administrator of the EPA’s Office of Research and Development during the Obama Administration and did not, during that time, usher in implementation of the SCIENCE AND DECISIONS recommendation to eschew the threshold assumption for noncarcinogens. *See About the Deputy Assistant Administrator of EPA’s Office of Research and Development, and EPA’s Science Advisor*, U.S. ENVTL. PROTECTION AGENCY (Jan. 19, 2017), https://19january2017snapshot.epa.gov/aboutepa/about-deputy-assistant-administrator-epas-office-research-and-development-and-epas-science_.html.

145. *See* SCIENCE AND DECISIONS, *supra* note 44, at 153 (“[A study on individual thresholds] provides good physiologic plausibility of low-dose linearity on a population basis, given ubiquitous exposures that imply that a substantial number of people will be found to be at least as sensitive as the 99.9th percentile individual.”).

146. *See* U.S. ENVTL. PROT. AGENCY, SUMMARY OF EXPERT OPINIONS ON THE EXISTENCE OF A THRESHOLD IN THE CONCENTRATION-RESPONSE FUNCTION FOR PM_{2.5}-RELATED MORTALITY 16 (2010), <https://www3.epa.gov/ttnecas1/regdata/Benefits/thresholdstd.pdf> (defining a population threshold as “the concentration below which no member of the study population would experience an increased risk of death”).

147. *See, e.g.*, National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086, 3104 (Jan. 15, 2013) (to be codified at 40 C.F.R. pts. 50, 51, 52, 53, and 58) [hereinafter NAAQS Particulate Matter] (“There is emerging, though still limited, evidence for additional potentially at-risk populations, such as those with diabetes, people who are obese, pregnant women, and the developing fetus.”); Bingheng Chen & Haidong Kan, *Air Pollution and Population Health: A Global Challenge*, 13 ENVTL. HEALTH & PREVENTIVE MED. 94, 96 (2008) (noting that for “[a]dverse health effects associated with exposure to air pollution . . . [h]igh-risk subgroups include young children, the elderly, persons with predisposed diseases, and persons with low socioeconomic status (SES)”).

of the effects of these pollutants on sensitive people does not necessitate draconian regulations to completely eliminate all risks; rather this information facilitates more informed decision-making that accurately accounts for the impacts on all members of the population.

The current threshold model also ignores all scientific evidence of health effects that lacks a high level of confidence. This problem is built in to the EPA's process for determining the limits for these pollutants: when the EPA determines standards, it performs a benefits analysis that includes evidence of different health impacts of the pollutant.¹⁴⁸ It classifies evidence as "likely" or "known" if there is a "high degree of confidence in the association between exposure and a health outcome," or as "suggestive" where there is lesser confidence in the link.¹⁴⁹ "Suggestive" evidence is generally excluded from the potential health risks assessed by the EPA in its primary benefits analysis for noncarcinogenic effects.¹⁵⁰ As a result, the EPA essentially gives no weight to health effects that have not been conclusively demonstrated when determining the benefits of a regulation. In effect, the EPA imposes a sharp discontinuity in the level of risk depending on how the Agency classifies the evidence: the Agency assumes there is a risk associated with "known" and "likely" evidence, the specific level of which is based on data, but assumes a zero percent probability of risk when evidence is "suggestive." But the probability of an adverse impact is not zero.¹⁵¹ "Suggestive" evidence, instead, presents some other positive level of risk which is arbitrarily ignored.

Economics has a way of addressing uncertainty without ignoring it completely. Using the concept of expected value, economists can incorporate the level of uncertainty into the calculation of overall risk.¹⁵² In the example of noncarcinogenic pollutants, if the EPA employed this concept, the expected value

148. McGartland et al., *supra* note 29, at 457 ("EPA risk assessments for cancer and 'criteria' air pollutants . . . use standard terms to summarize the strength of evidence regarding a health effect.").

149. *Id.*

150. *Id.*

151. *See id.* at 457–58 ("This practice implicitly assumes that exposed populations have zero [adverse impacts] for reduced exposure when there is some evidence of an adverse health effect but that evidence is not unambiguous. This assumption . . . is contradicted by findings.").

152. *See* INST. OF MED. OF THE NAT'L ACADS., ENVIRONMENTAL DECISIONS IN THE FACE OF UNCERTAINTY 167–69 (2013) (discussing the applications of value-of-information analysis, which attempts to quantify uncertainty and the value of additional information).

of the health risk posed by exposure to these pollutants would incorporate both the best estimates for overall harm from exposure and the level of uncertainty. The fact of uncertainty would lower the estimated potential risk, but some level of risk would still be calculated from exposure at low levels.

Another way to better account for this risk would be to look at the willingness of individuals to pay to avoid risks from low level exposures. The “willingness to pay” measure can be calculated by directly asking people what they would hypothetically pay to avoid a risk, or by comparing wages from similar jobs that are more or less risky.¹⁵³ Workers who take riskier jobs receive higher wages to compensate for that risk.¹⁵⁴ By measuring this difference, it is possible to calculate the risk premium, or willingness to pay for the additional risk posed by the job.¹⁵⁵ By assuming there is zero risk below the threshold, the EPA has presumed that there is zero willingness to pay to avoid low level exposure. There is evidence to suggest, however, that individuals actually display a greater willingness to pay when risk is ambiguous than they do for unambiguous risks with the same expected value.¹⁵⁶ A willingness to pay or expected value model would better account for the magnitude and the certainty of these risks.

The EPA’s failure to update its noncarcinogen model to account for more recent scientific evidence, sensitive populations, and scientific uncertainties has important policy implications. Because the EPA ignores risks below the threshold, the Agency is unable to fully incorporate data on health effects at low levels of exposure. The EPA cannot calculate what percentage of the population or how many additional people would be protected by reductions in pollution below the reference dose. Further, when the EPA regulates these pollutants it does not include any health benefits from reducing pollution below the reference dose, thus

153. See John Bronsteen et al., *Well-Being Analysis vs. Cost-Benefit Analysis*, 62 DUKE L.J. 1603, 1645–46 (2013) (discussing two measures of willingness-to-pay: revealed preferences and surveys of hypothetical willingness to pay for a given benefit).

154. *Id.* at 1646.

155. *Id.*

156. See Paul A. Kivi & Jason F. Shogren, *Second-Order Ambiguity in Very Low Probability Risks: Food Safety Valuation*, 35 J. AGRIC. & RESOURCE ECON. 443, 454 (2010) (finding in the context of food safety that “people prefer unambiguous food safety choices over ambiguous ones with the same expected value,” asserting that “[a]mbiguity premiums—how much more people are willing to pay to avoid an ambiguous situation than an equivalent unambiguous one—are positive” for scenarios the authors tested, and noting that the findings are consistent with previous studies).

undercounting potential benefits of regulation. The resulting standards therefore do not reflect any potential harm from lower-level exposure. If the EPA instead modeled the marginal risk of reductions or increases in dose exposure at every level using a tool like willingness to pay or expected value, the Agency would be able to calculate with greater accuracy the overall costs and benefits of different levels of regulation, which would facilitate more informed decision-making.

II. TREATMENT OF CRITERIA POLLUTANTS

The previous Part analyzed the EPA's risk assessment models of carcinogens and noncarcinogens other than criteria pollutants. That discussion provides a useful foundation upon which to examine NAAQS criteria pollutants. The EPA's understanding of criteria pollutants has evolved over five decades of implementing the Clean Air Act, shifting from a model that resembled the one used for other noncarcinogens, which are treated as threshold contaminants, to one that more closely approximates its handling of carcinogens, which are treated as non-threshold contaminants. Under multiple presidential administrations of both parties, the Agency has calculated benefits from reducing criteria pollutants below the NAAQS, thereby acting inconsistently with the existence of thresholds. Further, recent EPA rules have explicitly stated that there is no evidence of thresholds for certain criteria pollutants.

This Part first explores Congress's understanding of criteria pollutants, and describes how even by the mid-1970s, Congress had already recognized that criteria pollutants likely do not have thresholds. It then presents the EPA's revision of lead NAAQS in 1978 and 2008 as a case study demonstrating the EPA's shift away from threshold language in its promulgation of criteria pollutant standards. The Part concludes with a survey of the EPA's rejection of thresholds, both in its rulemaking language and in its calculation of benefits, for the remaining criteria pollutants excepting particulate matter, which receives an in-depth examination in Part III.

A. CLEAN AIR ACT AMENDMENTS OF 1977

The NAAQS criteria pollutants are six air pollutants for which there are clearly established public health concerns at historic ambient levels.¹⁵⁷ The Clean Air Act governs the “establishment, review, and revision” of the NAAQS to “provide protection for the nation’s public health and the environment.”¹⁵⁸ Health-based standards have been developed for each pollutant, and the standards are periodically reviewed based on human exposure assessments, health risk assessments, and ecological risk assessments.¹⁵⁹

Critics of clean air regulations have asserted that the NAAQS levels are adequate to fully address criteria pollutant risks, and that reductions in these pollutants below the level of the standard are not beneficial.¹⁶⁰ Even though the statute does not refer to thresholds, some of these critics argue that thresholds are implied by the statutory requirement commanding the EPA to set the NAAQS at levels that, “allowing an adequate margin of safety, are requisite to protect the public health.”¹⁶¹ This argument requires the significant leap of equating “requisite to protect the public health” with a no-risk standard.

An examination of the legislative history of the 1977 Clean Air Act Amendments reveals that in the years following the 1970 Act, Congress developed a more nuanced understanding of the

157. SCIENCE AND DECISIONS, *supra* note 44, at 368.

158. *Criteria Air Pollutants: Process of Reviewing the National Ambient Air Quality Standards*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards> (last updated July 10, 2018); *see also* Clean Air Act, 42 U.S.C. § 7401(b)(1) (2012) (“The purposes of this subchapter are—(1) to protect and enhance the quality of the Nation’s air resources so as to promote the public health and welfare and the productive capacity of its population.”).

159. *See* 42 U.S.C. § 7409(d)(1) (mandating periodic review of NAAQS every five years); SCIENCE AND DECISIONS, *supra* note 44, at 369 (“Human exposure and/or health risk assessments and ecological risk assessments are performed during the periodic reviews of these standards.”).

160. *See supra* note 26 (providing examples of criticism).

161. Clean Air Amendments of 1970, Pub. L. No. 91–604, § 109(b)(1), 84 Stat. 1676, 1680 (current version at 42 U.S.C. § 7409(b)(1) (2012)).

relationship between air pollution at low concentrations and adverse health effects¹⁶²—so much so that by the mid-1970s, Congress expressly rejected the view that criteria pollutants have thresholds.¹⁶³

Congress's understanding of thresholds by the time of the 1977 amendments was influenced by the National Academy of Sciences' (NAS) evaluation of the implementation of the 1970 Clean Air Act,¹⁶⁴ which had been requested by the Senate Public Works Committee.¹⁶⁵ The report addressed in part the question of whether the NAAQS were based on "threshold levels" and what evidence there was of a threshold for NAAQS pollutants.¹⁶⁶ The NAS conducted a review of existing studies on air pollutants, including several it had completed for both the Committee

162. Congress's early acknowledgement of the threshold concept's inapplicability to air pollutants has been discussed extensively in literature about the Clean Air Act. *See, e.g.*, Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255, 1288–90 (2004) ("The absence of clear thresholds for these pollutants was a well-known fact to members of Congress during deliberations over the 1977 amendments to the Clean Air Act, if not earlier."); Christopher T. Giovinazzo, *Defending Overstatement: The Symbolic Clean Air Act and Carbon Dioxide*, 30 HARV. ENVTL. L. REV. 99, 112 (2006) ("By 1977, when Congress undertook major revisions to the [Clean Air Act], it was perfectly clear that most pollutants had no clear thresholds, and that it would therefore be impossible to set NAAQS 'requisite to protect the public health' without considering cost. Yet Congress chose to maintain the fiction that thresholds exist . . ."); Craig N. Oren, *Prevention of Significant Deterioration: Control-Compelling Versus Site-Shifting*, 74 IOWA L. REV. 1, 71 (1988) ("Judging from its frequency of citation, the apparent lack of thresholds was considered by PSD supporters to be a powerful argument for the program.").

163. *See, e.g.*, Giovinazzo, *supra* note 162 (noting Congress's recognition that pollutants had no clear thresholds).

164. *See* Coglianese & Marchant, *supra* note 162, at 1288–89 n.146 ("Congress was strongly influenced by a 1974 report prepared for the Senate by the National Academy of Sciences and National Academy of Engineering which concluded that, contrary to the assumption underlying the 1970 Act, there were no thresholds for criteria pollutants.").

165. COORDINATING COMM. ON AIR QUALITY STUDIES, NAT'L ACAD. OF SCIS., AIR QUALITY AND AUTOMOBILE EMISSION CONTROL: A REPORT 22 (1974) [hereinafter 1974 NAS REPORT] (prepared for the Senate Public Works Committee) (reviewing the Committee's charge to NAS). According to the Committee, "[t]he Academy was chosen as the body most likely to provide an independent and objective study of issues relating to health effects of air pollution at a time when the Committee found it increasingly difficult to obtain sufficient independent and objective information through its own limited staff investigative capacity." *Id.*

166. *Id.* at 23. The Senate Public Works Committee asked NAS to specifically examine "(1) the adverse health effects of air pollutants, (2) the relation of [automobile] emissions to ambient air quality, and (3) the costs and benefits associated with control of automobile emissions." *Id.* at 4.

and for the EPA.¹⁶⁷ The result of that effort was the NAS's 1974 "Air Quality and Automobile Emission Control" report, which embraced a non-threshold view of NAAQS pollutants:

The present standards were derived on the assumption that such thresholds do exist. . . . However, in no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at and above some level of pollution, but no effects at all below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, with no sharp lower limit.¹⁶⁸

The NAS's guidance for the Committee was clear: "[A]t any concentration, no matter how small, health effects may occur, the importance of which depends on the gravity of the effect."¹⁶⁹

Similarly, the House Committee report for the 1977 amendments emphasized that there was "neither empirical evidence nor a theoretical basis for a threshold phenomenon" for any of the NAAQS pollutants.¹⁷⁰ The report, analyzing the limitations of the NAAQS in 1976, also stated as one of its key findings: "The national primary standards are based on the assumption that a no-effects threshold level exists and can be proved: in fact, this assumption of a safe threshold appears to be false."¹⁷¹ The report likewise discounted the utility of a threshold's "margin of safety":

From the fact that the "safe threshold" concept is, at best, a necessary myth to permit the setting of some standards, it necessarily follows that the margin of safety concept is also an illusion. . . . [T]he supposed existence of even a modest (two or threefold) margin of safety is hardly reassuring.¹⁷²

167. *See id.* at 4 (previewing the sources used in the report).

168. *Id.* at 17.

169. *Id.* at 18. The report further noted that "[o]ther considerations also argue against accepting a threshold model of health effects literally. Even if there were sharp threshold levels for individual persons, the levels would certainly not be the same for different persons, or even for the same person in different states of health." *Id.* at 17. Moreover, thresholds fail to account for "synergistic effects" of combining several pollutants, both in the human body and in the atmosphere. *See id.* at 18–19 (explaining the possible outcomes from the presence of multiple pollutants). The D.C. Circuit cited NAS's discussion of NAAQS thresholds in its *Lead Industries Ass'n v. EPA* decision, one of the early legal challenges to the 1977 amendments. *See Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 n.43 (D.C. Cir. 1980) (quoting the NAS report as countering "the assumption that there is a discoverable no-effects threshold").

170. COMM. ON INTERSTATE & FOREIGN COMMERCE, CLEAN AIR ACT AMENDMENTS OF 1977, H.R. REP. NO. 95-294, at 110 (1977).

171. COMM. ON INTERSTATE & FOREIGN COMMERCE, CLEAN AIR ACT AMENDMENTS OF 1976, H.R. REP. NO. 94-1175, at 89 (1976).

172. *Id.* at 91.

The House Committee report endorsed verbatim the NAS's assertion that "it is impossible at this time to establish an ambient air concentration for any pollutant—other than zero—below which it is certain that no human beings will be adversely affected."¹⁷³ Even by 1976, "[t]he idea that the national primary standards are adequate to protect the health of the public ha[d] been belied."¹⁷⁴

In the floor debates leading up to 1977 Clean Air Act Amendments, various members of both chambers endorsed a non-threshold view of NAAQS contaminants.¹⁷⁵ The bill's chief author, Senator Edmund Muskie, emphasized a consistent theme throughout the deliberations: "There is no threshold health effect which can be used to say that above this threshold there is danger to health and below it there is not. The testimony before the committee is replete over 14 years to that effect."¹⁷⁶ Only

173. *Id.* (citing NAT'L ACAD. OF SCI., SUMMARY OF PROCEEDINGS: CONFERENCE ON HEALTH EFFECTS OF AIR POLLUTION 7 (1973)).

174. *Id.*

175. Senators Muskie and Brooke, as well as Representatives Waxman, Rogers, Preyer, Maguire, and Stagers, all contested the assumption of a "safe" threshold. *See generally* ENVTL. POLICY DIV., CONG. RESEARCH SERV., A LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1977: A CONTINUATION OF THE CLEAN AIR ACT AMENDMENTS OF 1970 (1979), <https://catalog.hathitrust.org/Record/002947778> (collecting six volumes of congressional reports, floor debates, and testimony for the 1977 amendments).

176. 123 CONG. REC. 18,043 (1977) (statement of Sen. Muskie). Senator Muskie was emphatic on this point, stressing that:

Long-term, low-level exposure to pollutants produce health effects which are not guarded against by national primary standards. We would have to get down to zero pollution in order to eliminate all health effects. At any level between zero pollution and the pollution permitted by national primary standards, there are health effects.

Let us not disabuse ourselves on that score.

Id. at 18,460. Senator Muskie's views on environmental legislation have held particularly strong sway in the federal courts. As Professor Richard Lazarus concluded:

Congressional intent in the context of federal environmental law may be fairly equated with the intent of Senator Ed Muskie of Maine. Federal courts in their opinions have cited to the views of Senator Muskie in the enactment of federal environmental statutes in at least 293 separate cases. That is an enormous number of cases. The United States Court of Appeals for the District of Columbia has itself cited to Muskie's views in fifty-four cases. . . .

Looking just to the United States Supreme Court, the statistics are even more striking. The Justices have cited to Muskie in twenty-two different cases. They include eight Clean Air Act cases, and eleven Clean Water Act cases. For each of those laws, that number constitutes a large percentage of Clean Air and Clean Water Act cases decided by the Court.

The Senator, moreover, was cited most often by the Court majority

seven years into the Clean Air Act regime, Senator Muskie was unequivocal, stating that “there is no such thing as a threshold for health effects. Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.”¹⁷⁷ There was evidence suggesting these pollutants were non-threshold before the 1970 Clean Air Act was passed, and at least some members of Congress were aware of that issue.¹⁷⁸ But whatever Congress believed in 1970, by 1977 Congress had determined that a non-threshold approach was well-supported.

Importantly, the core element of the Prevention of Significant Deterioration (PSD) program is inconsistent with the notion that criteria pollutants have thresholds. The PSD program constrains the degradation of ambient air quality in areas that have air quality that is better than the NAAQS.¹⁷⁹ If criteria pollutants had thresholds and if the NAAQS were set at these thresholds, then there would be no reason for Congress to attempt to provide such protection. A program of this sort would have costs but no benefits. Quite to the contrary, in establishing the PSD program, Congress rejected the argument now being made by opponents of the Obama Administration’s environmental regulations: that there can be no benefits from particulate reductions below the NAAQS.¹⁸⁰

In sum, a broad collection of evidence—advisory group reports, committee reports, floor debates, and the structure of the legislation itself—all indicate that by 1977, Congress had rejected the threshold model for criteria pollutants. Only a few

in those cases, meaning that his views literally influenced the reasoning underlying the Court’s ruling. Seventeen different majority opinions cited to Muskie. . . . The Justices referred to the Senator as “the principal Senate sponsor” and the “primary author” of federal environmental legislation.

Lazarus, *supra* note 71, at 239, 242–43 (citations omitted).

177. 123 CONG. REC. 18,460 (1977) (statement of Sen. Muskie).

178. In fact, Muskie asserted that Congress was aware of this issue when it passed the original Act: “The [1970] Clean Air Act is based on the assumption, although we knew at the time it was inaccurate, that there is a threshold.” *Clean Air Act Amendments of 1977: Hearing on S. 251, S. 252 and S. 253 Before the Subcomm. on Envtl. Pollution of the S. Comm. on Env’t & Pub. Works*, 95th Cong. 8 (1977) (statement of Sen. Muskie); *see also* Coglianese & Marchant, *supra* note 162 (asserting that the Senate knew there was no threshold when it passed the 1977 amendments, if not earlier).

179. Clean Air Act, 42 U.S.C. § 7473(b) (2012).

180. *See supra* notes 26–30 and accompanying text; *infra* notes 285–302 and accompanying text (providing an overview of opposing views toward particulate reduction regulations).

years after the setting of the first standards for criteria pollutants, Congress equated “[t]he concept of a ‘no-effect’ concentration” with “a chimera.”¹⁸¹

B. SHIFT IN THE EPA’S APPROACH: A CASE STUDY OF LEAD

Some early EPA practices, before the 1977 amendments, were consistent with a threshold model. However, the Agency subsequently rejected this approach as a result of advances in scientific understanding. In this Section, we illustrate the EPA’s shift through a comparison of how the EPA set the NAAQS levels for one pollutant—lead—for the first time in 1978 and how the EPA revised these levels in 2008.

When the EPA first developed standards for criteria pollutants, the Agency treated these contaminants similarly to the way in which it treats other noncarcinogens, using language suggesting criteria pollutants had thresholds.¹⁸² The first model developed by the EPA was used during the promulgation of the 1978 lead standard,¹⁸³ which focused on finding the “safe level of total lead exposure.”¹⁸⁴ To find this level, the EPA employed the “critical population, critical effects” model: identify a “critical population” and “critical effect,” analyze the relationship between environmental exposure and the critical effect, and determine an averaging period.¹⁸⁵ The first step of this model was to

181. COMM. ON INTERSTATE & FOREIGN COMMERCE, CLEAN AIR ACT AMENDMENTS OF 1977, H.R. REP. NO. 95-294, at 111 (1977) (quoting 1974 NAS REPORT, *supra* note 165, at 57). The report further quotes NAS’s findings that it had “been unable to . . . prove[] that a threshold for nitrogen dioxide-induced injury exists” and that “ozone is a compound like carbon monoxide for which no safe threshold exists.” *Id.* (quoting 1974 NAS REPORT, *supra* note 165, at 41, 50).

182. *See* Livermore & Revesz, *supra* note 74, at 1202, 1203 n.111, 1206, 1227–28 (discussing the EPA’s use of threshold language for its earliest NAAQS). It is worth noting that even by the 1978 Lead Rule, which as discussed in this section included language suggestive of a threshold of health effects for lead, the EPA acknowledged that a threshold may not, in fact, exist. “It is also true that the absence of statistical correlation of EP levels with blood lead levels below 15 µg Pb/dL does not necessarily mean that these lower blood lead levels are known to be without risk.” Lead: Proposed National Primary and Secondary Ambient Air Quality Standards, 42 Fed. Reg. 63,076, 63,079 (proposed Dec. 14, 1977) (to be codified at 40 C.F.R. pt. 50) [hereinafter 1977 Lead Proposed Rule].

183. *See* Livermore & Revesz, *supra* note 74, at 1211.

184. 1977 Lead Proposed Rule, *supra* note 182. A “safe level” assumes that there is a threshold; by definition, a threshold is a level below which there are no health effects. *See supra* note 29 and accompanying text. For a more detailed discussion of how the EPA set the 1978 lead standard, see Livermore & Revesz, *supra* note 74, at 1202–06.

185. *See* Livermore & Revesz, *supra* note 74, at 1211 (explaining the “critical-population-critical-effect” framework as applied to lead).

identify the critical population, a particularly vulnerable segment of the population that differed depending on the pollutant and the type of harm posed.¹⁸⁶ The EPA chose young children ages one to five as the critical population for lead, both because young children are more susceptible to adverse health effects at lower exposure levels than adults, and because children are at higher risk of exposure to lead through dirt and soil.¹⁸⁷ The EPA noted that children are at greater risk because of higher intake of lead per unit of body weight, greater absorption and retention of ingested lead, physiologic stresses due to rapid growth and dietary habits, incomplete development of metabolic defense mechanisms, and greater sensitivity of developing systems.¹⁸⁸ The EPA acknowledged that there were other potential critical populations, notably pregnant women and fetuses, but stated that there was no available evidence to indicate that this population would require more stringent standards than small children.¹⁸⁹

The critical effect is defined by the EPA as “the first adverse effect, or its known precursor” which occurs in the critical population.¹⁹⁰ The EPA identified lead-induced elevation of erythrocyte protoporphyrin (EP) elevation as the critical effect.¹⁹¹ EP elevation is limited iron absorption in red blood cells that can be caused by exposure to lead.¹⁹² The EPA noted that EP elevation causes impairment of cell functions which should not, in the Agency’s view, be permitted to persist as a chronic condition.¹⁹³

In 1978, the EPA reasoned that if the most sensitive population was protected, everyone else would be protected as well.¹⁹⁴

186. *See id.*

187. *See* 1977 Lead Proposed Rule, *supra* note 182, at 63,077–78 (“EPA believes that young children (ages 1–5 years) should be regarded as the foremost critically sensitive population for setting the lead standard.”).

188. *Id.* at 63,078.

189. *Id.*

190. *Risk Assessment for Other Effects*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/fera/risk-assessment-other-effects> (last updated Jan. 31, 2017).

191. *See* 1977 Lead Proposed Rule, *supra* note 182, at 63,078 (“EPA is proposing that lead-induced elevation in children of EP should be accepted as the pivotal adverse effect of lead.”).

192. *Id.*

193. *Id.*

194. *See* National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46,246, 46,250, 46,252, 46,254 (Oct. 5, 1978) (to be codified at 40 C.F.R. pt. 50) [hereinafter 1978 Lead Final Rule] (reasoning that the proposed standard will protect adults in part because “children are known to

Moreover, if the critical population was protected against the critical effect, then everyone would be protected against every effect of the pollutant.¹⁹⁵ After making these two determinations, the EPA established a relationship between environmental exposure and the critical effect of EP elevation. The Agency first determined the blood lead level at which children ages one to five would experience EP elevation. The EPA selected 30 µg/dL as the “maximum safe blood level for an individual child.”¹⁹⁶ This was the individual threshold of risk for children established by the Center for Disease Control (CDC) at that time.¹⁹⁷ The EPA then selected 15 µg/dL as the average blood level target, reasoning that at that level 99.5% of the population of children would have blood levels below the 30 µg/dL level.¹⁹⁸

The EPA then attempted to account for non-air sources of lead, which are much more significant than airborne lead pollution and include lead paint, which may be ingested by small children.¹⁹⁹ Studies examined by the EPA suggested non-air pollution to be from 10.2 µg/dL to as much as 14.4 µg/dL,²⁰⁰ from which the Agency estimated a contribution of 12 µg/dL.²⁰¹ The EPA then subtracted the non-air contributions from its target average blood level of 15 µg/dL, leading to a permissible air contribution of 3 µg/dL.²⁰²

have greater net absorption and retention of lead than adults”); *see also* Livermore & Revesz, *supra* note 74, at 1203.

195. Livermore & Revesz, *supra* note 74, at 1203.

196. 1978 Lead Final Rule, *supra* note 194, at 46,253.

197. 1977 Lead Proposed Rule, *supra* note 182, at 63,079 (“[I]n 1975 the Center for Disease Control established as a guideline for undue or increased lead absorption in children a blood lead level of 30 µg Pb/dL or EP levels of 60 µg/dL.”).

198. *See id.* Despite its use of a threshold model, the EPA effectively opted to leave more than 20,000 children unprotected and likely subjected to lead levels above 30 µg/dL in their blood. *See* Livermore & Revesz, *supra* note 74, at 1207 (citing to 1978 Lead Final Rule, *supra* note 194, at 46,255). Thus, even when the Agency tried to set a threshold standard, it knowingly failed to set that standard at a level below which no adverse health effects occurred.

199. *See* 1978 Lead Final Rule, *supra* note 194, at 46,253–54 (discussing the rulemaking approach for non-air sources of lead exposure).

200. *Id.*

201. *Id.* at 46,254. One consequence of selecting the 12 µg/dL estimate for contribution was that individuals living in areas of the country in which non-air contribution exceeded 12 µg/dL were left unprotected by the threshold that the EPA ultimately chose. Livermore & Revesz, *supra* note 74, at 1207–08.

202. *See* 1978 Lead Final Rule, *supra* note 194, at 46,254; 1977 Lead Proposed Rule, *supra* note 182, at 63,081 (showing the EPA calculations).

The EPA then needed to translate the target level of lead in blood into a limitation on lead in air, which is what the NAAQS regulate. To do so, the EPA estimated the ratio of lead in air to lead in blood. Finally, the Agency divided the air-to-blood ratio it had selected by two.²⁰³ The final standard set was a maximum allowable concentration of lead in the air of 1.5 $\mu\text{g}/\text{m}^3$.²⁰⁴

In 2008, the EPA under President George W. Bush revisited its 1978 lead NAAQS determination and revised the standard from 1.5 $\mu\text{g}/\text{m}^3$ to one tenth that amount; 0.15 $\mu\text{g}/\text{m}^3$.²⁰⁵ New epidemiological research on the effects of even very low blood lead levels on intelligence quotient (IQ) convinced EPA officials to lower NAAQS for lead.²⁰⁶ By 2008, there was broad consensus in the scientific community that these effects were among the most sensitive of lead's harms and of the greatest public concern.²⁰⁷ Though the EPA focused on loss of IQ points, the EPA eliminated the "critical effect" language.²⁰⁸

In evaluating potential lead limits, the EPA focused on measurements of lead in urban areas²⁰⁹ where lead pollution and lead exposure is generally higher.²¹⁰ The EPA chose three urban case studies: Cleveland, Chicago, and Los Angeles to measure ambient air quality.²¹¹ The EPA also included a "general urban

203. See 1978 Lead Final Rule, *supra* note 194, at 46,252, 46,254 ("On the basis of an estimated relationship of air lead to blood lead of 1 to 2, EPA concludes that the ambient air standard should be 1.5 $\mu\text{g}/\text{m}^3$."); 1977 Lead Proposed Rule, *supra* note 182, at 63,081.

204. 1978 Lead Final Rule, *supra* note 194, at 46,246 ("EPA is setting a national ambient air quality standard for lead at a level of 1.5 micrograms lead per cubic meter of air ($\mu\text{g Pb}/\text{m}^3$), averaged over a calendar quarter.").

205. See 2008 Final Rule National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66,964, 66,966 (Nov. 12, 2008) (to be codified at 40 C.F.R. pts. 50, 51, 53, and 58) [hereinafter 2008 Lead Final Rule].

206. See GERALD MARKOWITZ & DAVID ROSNER, LEAD WARS: THE POLITICS OF SCIENCE AND THE FATE OF AMERICA'S CHILDREN 96–121 (2013) (tracking the emergence and acceptance of research showing negative impacts on IQ at low lead blood levels despite lead industry interference).

207. See National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 29,184, 29,198 (proposed May 20, 2008) (to be codified at 40 C.F.R. pts. 50, 51, 53, and 58) [hereinafter 2008 Lead Proposed Rule] (referring to neurological effects as being "currently clearly of greatest public health concern").

208. See *id.* at 29,198–207.

209. See *id.* at 29,208 ("EPA . . . focused on characterizing risk for residential populations in three specific urban locations.").

210. Ronnie Levin et al., *Lead Exposures in U.S. Children, 2008: Implications for Prevention*, 116 ENVTL. HEALTH PERSP. 1285, 1289 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2569084/pdf/ehp-116-1285.pdf> ("Lead contamination typically is greater in urban versus rural areas.").

211. 2008 Lead Proposed Rule, *supra* note 207, at 29,210.

case study,” not based on a specific geographic area, but using simplifications to represent exposure of children in small residential areas near the current NAAQS.²¹² Finally, the EPA included a “primary Pb smelter case study,” based on a specific area not currently in compliance with NAAQS.²¹³ The Agency analyzed each of these cases under alternative NAAQS, including the current standard, and calculated the median blood level associated with each scenario.²¹⁴ To convert each ambient air standard into a distribution of blood levels in children, the EPA used two models that incorporated air, soil, and indoor dust estimations for each case study and separated sources of blood level into non-air related, “recent air,” including ingesting ambient air and dust recently carried into the home, and “past air,” including sources less immediately affected by a standard change, like ingesting outdoor soil and dust.²¹⁵ For each blood level estimated as a result of a particular NAAQS scenario, the EPA attempted to estimate what percentage of the blood level was attributable to air sources, with the lower bound of the estimate including only recent air sources and the upper bound including recent and past air sources.²¹⁶

The EPA then needed to translate blood levels into lost IQ points. The EPA noted that “the slope for effects on IQ is steeper at lower blood lead levels,”²¹⁷ meaning that one additional unit of exposure at low levels has a greater health effect than one additional unit at higher levels. The EPA suggested that one possible reason for this is that lead at low exposures might interfere with different biological mechanisms than lead at higher exposures, and the mechanisms affected at lower levels might be more easily saturated.²¹⁸

Across the case study locations, at the then-current standard of $1.5 \mu\text{g}/\text{m}^3$, the model showed a median loss of more than

212. *Id.* at 29,209.

213. *Id.* at 29,209–10.

214. *See id.* at 29,216–17, 29,217 tbl.3 (summarizing the results of simulations with different NAAQS levels).

215. *Id.* at 29,210–11.

216. *See id.* at 29,215 tbl.2 (summarizing the air-related percentage of lead in blood levels across different potential NAAQS levels).

217. *Id.* at 29,201.

218. *See* NAT'L CTR. FOR ENVTL. ASSESSMENT RTP DIV., U.S. ENVTL. PROT. AGENCY, EPA/600/R-5/144aF, AIR QUALITY CRITERIA FOR LEAD, at 8-66 (2006), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=459555 (“It is conceivable that . . . lower Pb levels may be disrupting different biological mechanisms than the more severe levels of high exposures . . .”).

two IQ points, and an upper bound of four or more IQ points lost.²¹⁹ This is not a small risk: because this figure measures a *median* loss, the actual loss for certain individuals at the high end of the distribution could be much greater.²²⁰ The EPA also estimated the number of children in Cleveland, Chicago, and Los Angeles likely to lose between one and seven IQ points under the 1978 NAAQS regime, still in place at the time.²²¹ One model predicted 395,528 children in Chicago, 13,857 in Cleveland, and 284,945 in Los Angeles would lose more than one IQ point.²²² According to the same model, in Chicago, 100,159 children were estimated to lose more than seven IQ points; in Cleveland, 1858 children would suffer such losses; as would 57,834 children in Los Angeles.²²³ As a result of the existing studies and risk assessment, the Administrator determined the current standard did not protect public health with an adequate margin of safety.²²⁴

Reviewing this data, a panel of the Clean Air Scientific Advisory Committee (CASAC), a non-partisan entity tasked with providing independent scientific advice to the EPA,²²⁵ advised

219. 2008 Lead Proposed Rule, *supra* note 207, at 29,217.

220. *See id.* at 29,195 (“While levels in the U.S. general population, including geometric mean levels in children aged 1–5, have declined significantly, levels have been found to vary among children of different socioeconomic status . . . and other demographic characteristics. . . . For example, while the 2001–2004 median blood level for children aged 1–5 of all races and ethnic groups is 1.6 µg/dL, the median for the subset living below the poverty level is 2.3 µg/dL and 90th percentile values for these two groups are 4.0 µg/dL and 5.4 µg/dL, respectively. Similarly, the 2001–2004 median blood level for black, non-Hispanic children aged 1–5 is 2.5 µg/dL, while the median level for the subset of that group living below the poverty level is 2.9 µg/dL and the median level for the subset living in more well-off households (i.e., with income more than 200% of the poverty level) is 1.9 µg/dL. Associated 90th percentile values for 2001–2004 are 6.4 µg/dL (for black, non-Hispanic children aged 1–5), 7.7 µg/dL (for the subset of that group living below the poverty level) and 4.1 µg/dL (for the subset living in a household with income more than 200% of the poverty level).”).

221. *Id.* at 29,219–20 tbls.4, 5 & 6.

222. *Id.* at 29,219–20 tbl.5 (employing a log-linear model).

223. *Id.* at 29,220 tbl.6.

224. *Id.* at 29,229.

225. CASAC was established as part of the 1977 amendments “to review the criteria and standards promulgated [by the EPA], and provide other related scientific and technical advice.” *EPA Clean Air Scientific Advisory Committee (CASAC): Charter*, U.S. ENVTL. PROTECTION AGENCY (June 5, 2015), <https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/currentcharter?OpenDocument>.

By statute, CASAC is composed of seven members appointed by the EPA Administrator, “including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.” Clean Air Act, 42 U.S.C. § 7409(d)(2)(A) (2012).

the EPA that a population IQ loss of one to two points represented a “highly significant” public health loss²²⁶ and advised a standard “no higher than 0.2 $\mu\text{g}/\text{m}^3$.”²²⁷ Using the air-to-blood ratio and the concentration-response function, the Administrator determined in the final rule that 0.15 $\mu\text{g}/\text{m}^3$ would result in a mean IQ loss within the subset population below two points.²²⁸

Between 1978 and 2008, the EPA’s analysis shifted significantly with regard to the issue of thresholds.²²⁹ In 1978, the EPA adopted the CDC’s threshold of 30 $\mu\text{g}/\text{dL}$ as the “maximum safe blood lead level.”²³⁰ The Agency’s next steps were all premised on the assumption that so long as a child’s blood level remained below this limit, adverse health effects would be avoided. In the EPA’s 2008 revision for lead, this premise was no longer valid as a result of new epidemiological studies about lead’s effects at low doses.²³¹ The proposed rule explicitly stated that “the Administrator recognizes that [lead] can be considered a non-threshold pollutant.”²³² Moreover, the EPA noted in 2008 that the CDC recognized that no “safe” threshold for blood lead has been identified,²³³ and stated that “[t]hreshold levels, in terms of blood [lead] levels in individual children, for neurological effects cannot be discerned from the currently available studies.”²³⁴ The Agency acknowledged that there are effects from lead at very low

226. 2008 Lead Proposed Rule, *supra* note 207, at 29,226.

227. *Id.* at 29,241.

228. 2008 Lead Final Rule, *supra* note 205, at 67,005–06. Note that the proposed rule modeled the median loss of IQ points, whereas the final rule modeled the mean loss of IQ points. Compare 2008 Lead Final Rule, *supra* note 205, at 67,005 tbl.4 (showing mean IQ loss), with 2008 Lead Proposed Rule, *supra* note 207, at 29,218 tbl.4 (showing median IQ loss).

229. Though the 2008 method represents a significant shift, there are still concerns about this analysis. For a brief overview, see Livermore & Revesz, *supra* note 74, at 1214. The most significant issue is that the population IQ loss of one to two points is rather arbitrary. *Id.*

230. 1978 Lead Final Rule, *supra* note 194, at 46,253.

231. See MARKOWITZ & ROSNER, *supra* note 206, at 111–20.

232. 2008 Lead Proposed Rule, *supra* note 207, at 29,244. This claim is reiterated in the final rule, albeit qualified by the possibility that thresholds may still exist “at levels distinctly lower than the lowest exposures examined in these epidemiological studies.” 2008 Lead Final Rule, *supra* note 205, at 66,984.

233. 2008 Lead Final Rule, *supra* note 205, at 66,972.

234. *Id.* at 66,975.

levels,²³⁵ and even asserted that the slope for effects on IQ is actually steeper at lower blood lead levels.²³⁶ Further, though the EPA based the final steps of its analysis around the significant health effect of loss of one to two IQ points, the Agency did not claim that this was a level below which there are no health risks.²³⁷ The Administrator even acknowledged that standards would ideally be set so that no children would lose IQ points due to lead pollution.²³⁸ The rule's Regulatory Impact Analysis (RIA), which examines the "the potential social benefits and social costs of a regulation,"²³⁹ effectively reaffirmed these conclusions: while the EPA ultimately adopted an updated standard of 0.15 $\mu\text{g}/\text{m}^3$, it had also analyzed the costs and benefits of a more stringent standard of 0.10 $\mu\text{g}/\text{m}^3$,²⁴⁰ and found additional total benefits from moving to a 0.15 $\mu\text{g}/\text{m}^3$ level to a 0.10 $\mu\text{g}/\text{m}^3$ level to be between \$1.1 billion and \$1.7 billion.²⁴¹ These are benefits that would not exist below a true threshold. The EPA acknowledged that the decision was ultimately a "public health policy judgment" because there is no "evidence- or risk-based bright line that indicates a single appropriate level."²⁴² Overall, this 2008

235. *Id.* at 66,992 n.68. The EPA "recognizes today that 'there is no level of [lead] exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects.'" *Id.* (quoting 2006 Criteria Document, at 8-63).

236. *Id.* at 66,987.

237. *See id.* at 66,998; 2008 Lead Proposed Rule, *supra* note 207, at 29,243.

238. *Id.* at 29,242.

239. *Regulatory Impact Analyses for Air Pollution Regulations*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/regulatory-impact-analyses-air-pollution> (last updated Sept. 11, 2018). The Agency's RIAs include descriptions of social costs and benefits "that cannot be quantified in monetary terms and a determination of the potential net benefits of the rule[,] including an evaluation of the effects that are not monetarily quantified." *Id.*

240. *See* U.S. ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSIS OF THE PROPOSED REVISIONS TO THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR LEAD, at ES-1 to -7 (2008), https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-lead_ria_final_2008-10.pdf.

241. *Id.* at 5-2. This number is the difference between the low estimate for the 0.10 $\mu\text{g}/\text{m}^3$ level and the 0.15 $\mu\text{g}/\text{m}^3$ level and the difference between the high estimates at those levels. Both estimates are calculated using a 3% discount rate, though the EPA also calculates benefits and costs using a 7% discount rate. *Id.* However, economists generally find the 7% rate to be unrealistically high for air pollution estimates. *See* Newell, *supra* note 9. The benefits discussed in this section were all calculated using the 3% discount rate unless otherwise noted.

242. 2008 Lead Final Rule, *supra* note 205, at 67,006.

rulemaking reflected an important shift in how the EPA regulates NAAQS pollutants: from assuming that there is a threshold below which no health effects will occur to acknowledging that the decision is ultimately a policy judgment because there is no exposure level where all risks can be avoided.²⁴³

C. REJECTING THRESHOLDS AND CALCULATING BENEFITS BELOW THE NAAQS

The EPA's rejection of thresholds for lead is not atypical. Across the range of criteria pollutants, the EPA has moved toward a non-threshold model. For many criteria pollutants, the EPA has explicitly acknowledged—in some cases for decades—where it has evidence to suggest that NAAQS pollutants lack a threshold. Further, for all but one of the criteria pollutants,²⁴⁴ the Agency has calculated benefits from alternatives more stringent than what the EPA ultimately selected as its standard, and

243. In 2016, the EPA again reviewed the lead NAAQS and declined to adjust the standard, leaving in place the 0.15 $\mu\text{g}/\text{m}^3$ level. The Agency noted that newly available evidence “reaffirms conclusions” from the 2008 NAAQS and stated that the “currently available evidence is generally consistent with the evidence available in the last review.” Review of the National Ambient Air Quality Standards for Lead, 81 Fed. Reg. 71,906, 71,907 (Oct. 18, 2016) (to be codified at 40 C.F.R. pt. 50). The Agency also reiterated that the NAAQS were not a no-risk threshold. *Id.* at 71,929. In reviewing the 2008 standard, the EPA “recogniz[ed] the continued lack of a discernible threshold of exposure associated with neurocognitive effects.” *Id.* Moreover, the Administrator, responding to comments that there is no safe level of lead exposure, instead noted that she was not required by the Clean Air Act to establish a NAAQS with zero risk. *Id.* at 71,928; see also Joseph M. Feller, *Non-Threshold Pollutants and Air Quality Standards*, 24 ENVTL. L. 821, 824–25, 837 (1994) (“The absence of health or welfare thresholds is well-known not only to scientists but also to Congress, EPA, and the courts, which are often called on to oversee EPA’s implementation of the Act. Nonetheless, attempts to deal rationally with the problems of air pollution are frustrated because the threshold assumption is built into the structure of the Act. . . . While recognizing that health-effects thresholds may not exist for some pollutants, EPA has nonetheless generally structured its NAAQS rulemakings as if they do.”(citations omitted)).

244. The EPA found benefits for every criteria pollutant for which it has performed an RIA in recent times. The sole exception is carbon monoxide: the Agency reviewed the carbon monoxide NAAQS in 2011, but did not conduct an RIA. See Review of National Ambient Air Quality Standards for Carbon Monoxide, 76 Fed. Reg. 54,294 (Aug. 31, 2011) (to be codified at 40 C.F.R. pts. 50, 53, and 58) [hereinafter 2011 Carbon Monoxide Review]. The most recent RIA for carbon monoxide was conducted in 1985. See U.S. ENVTL. PROT. AGENCY, EPA-450/5-85-007, REGULATORY IMPACT ANALYSIS OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR CARBON MONOXIDE (1985), <http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=2000NK80.TXT>.

it has done so under presidents from both parties.²⁴⁵ That the EPA finds additional benefits for levels more stringent than the NAAQS is inconsistent with the existence of a threshold for these pollutants: below a threshold there should be no additional benefits from reductions. This section surveys the EPA's historical practices for ozone, carbon monoxide, nitrogen dioxide, and sulfur dioxide,²⁴⁶ revealing the Agency's consistent calculations of benefits below NAAQS levels and its more explicit finding on the lack of evidence of thresholds. A similar analysis for particulates follows in Part III.

As early as 1979, the EPA began to acknowledge the difficulty of identifying thresholds for criteria pollutants. In its revision for ozone, the Carter EPA noted that the rule's "criteria document supports the contention that a clear threshold of adverse health effects cannot be identified with certainty for ozone."²⁴⁷ In revising that standard, the George H.W. Bush EPA concluded that "[t]here appears to be no threshold level below which materials damage will not occur; exposure of sensitive materials to any non-zero concentration of O₃ (including natural background levels) can produce effects if the exposure duration is sufficiently long."²⁴⁸ In its 1997 review for ozone, the Clinton EPA went even further. The Agency recognized "O₃ may elicit a continuum of biological responses down to background concentrations."²⁴⁹ In stark terms, the Agency noted that, "in the absence of any discernible threshold, it is not possible to select a level below which

245. These calculations are part of the EPA's efforts to comply with Executive Order 12,866, issued during the Clinton Administration, and OMB Circular A-4, issued during the George W. Bush Administration. See U.S. ENVTL. PROT. AGENCY, FINAL REGULATORY IMPACT ANALYSIS (RIA) FOR THE NO₂ NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS), at ES-2 (2010), https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-no2_ria_final_2010-01.pdf (discussing these documents as presenting "guidelines for EPA to assess the benefits and costs of the selected regulatory option, as well as one less stringent and one more stringent option").

246. The additional benefits for more stringent lead standards were discussed as part of the case study *supra* Part II.B, while the benefits for additional particulate matter reductions are discussed in depth *infra* Part III.

247. Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202, 8213 (Feb. 8, 1979) ("Rather, there is a continuum consisting of ozone levels at which health effects are certain, through levels at which scientists can generally agree that health effects have been clearly demonstrated, and down to levels at which the indications of health effects are less certain and harder to identify.").

248. Proposed Rule for National Ambient Air Quality Standards for Ozone, 57 Fed. Reg. 35,542, 35,553 (Aug. 10, 1992) (to be codified at 40 C.F.R. pt. 50).

249. National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856, 38,863 (July 18, 1997) (to be codified at 40 C.F.R. pt. 50).

absolutely no effects are likely to occur . . . [or] to identify a level at which it can be concluded with confidence that no ‘adverse’ effects are likely to occur.”²⁵⁰ In 2008, the George W. Bush EPA’s final rule for ozone repeatedly confirmed that “the underlying scientific evidence is [not] certain enough to support a focus on any single bright-line benchmark level.”²⁵¹ The rule’s RIA explicitly noted that “ozone is a non-threshold pollutant.”²⁵² In 2015, the EPA under President Obama noted in its final rule for ozone that “[f]rom the inception of the NAAQS standard-setting process, the EPA and the courts have acknowledged that scientific uncertainties in general, and the lack of clear thresholds in pollutant effects in particular, preclude any [] definitive determinations [of zero risk standards].”²⁵³ Similarly, the rule’s Integrated Science Assessment stated more explicitly the Agency’s “overall conclusion[] that the epidemiologic studies . . . indicated a generally linear [concentration-response] function with no indication of a threshold”²⁵⁴

The EPA in 2008 also included benefits calculations for levels below the standard set by the regulation. While the EPA selected a standard of 0.075 ppm, the Agency also analyzed a more stringent standard of 0.070 ppm—the level later selected by the Obama Administration in 2015—as well as an even more stringent 0.065 ppm standard.²⁵⁵ The Agency provided third-party estimates of benefits for its chosen standard of 0.075 ppm which ranged from \$2 billion to \$19 billion in 2020.²⁵⁶ For a more stringent standard of 0.070 ppm, the Agency estimated benefits of

250. *Id.*

251. National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,436, 16,465, 16,471, 16,476–77, 16,481–82 (Mar. 27, 2008) (to be codified at 40 C.F.R. pts. 50 and 58). Moreover, the rule noted that, in light of the continuum of effects associated with varying levels of exposure to ozone, adverse health effects are “related to the actual magnitude of the O₃ concentration, not just whether the concentration is above a specified level.” *Id.* at 16,475. The Administrator recognized “that exposures of concern must be considered in the context of a continuum of the potential for health effects of concern, and their severity, with increasing uncertainty associated with the likelihood of such effects at lower O₃ exposure levels.” *Id.* at 16,465–66.

252. U.S. ENVTL. PROT. AGENCY, FINAL OZONE NAAQS REGULATORY IMPACT ANALYSIS, at 6-30 (2008) [hereinafter 2008 FINAL OZONE RIA], https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-o3_ria_final_2008-03.pdf.

253. National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65,292, 65,355 (Oct. 26, 2015) (to be codified at 40 C.F.R. pts. 50, 51, 52, 53, and 58).

254. *Id.* at 65,309.

255. 2008 FINAL OZONE RIA, *supra* note 252, at ES-1.

256. *Id.* at 7-3 tbl.7.1a.

\$3.5 billion to \$36 billion.²⁵⁷ For the most stringent standard of 0.065 ppm, the EPA included estimates of benefits ranging from \$5.5 billion to \$58 billion in 2020.²⁵⁸

In its 2015 RIA, the EPA again calculated benefits for reductions in ozone below its chosen NAAQS level. In the RIA analyzing a revision of the secondary standard for ozone from 75 to 70 parts per billion (ppb),²⁵⁹ the EPA provided an analysis of the benefits of a 70 ppb standard and an alternative of 65 ppb.²⁶⁰ The Agency estimated the benefits of the 70 ppb level to be between \$2.9 and \$5.9 billion in 2025, and the benefits of a 65 ppb level to be between \$15 and \$30 billion over the same period.²⁶¹ Further, the Agency found that in 2025, the 70 ppb standard would prevent between 96 and 160 ozone-related premature deaths and 220 to 500 particulate matter-related premature deaths.²⁶² However, the 65 ppb level would prevent between 490 and 820 ozone-related deaths and between 1100 and 2500 particulate matter-related deaths.²⁶³

In its 1985 revision for nitrogen dioxide, the Reagan EPA asserted a qualified rejection of NO₂ thresholds, stating that “none of the evidence presented in the Criteria Document shows a clear threshold of adverse health effects for NO₂.”²⁶⁴ As it had done six years earlier with ozone, the Agency described adverse health effects from nitrogen dioxide exposure as occupying “a continuum, ranging from NO₂ levels at which health effects are undisputed, through levels at which many, but not all scientists generally agree that health effects have been convincingly shown, down to levels at which the indications of health effects

257. *Id.* at 7-3 tbl.7.1c.

258. *Id.* at 7-4 tbl.7.1d.

259. U.S. ENVTL. PROT. AGENCY, EPA-452/R-15-007, REGULATORY IMPACT ANALYSIS OF THE FINAL REVISIONS TO THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR GROUND-LEVEL OZONE, at 1-1 (2015), https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-o3_ria_final_2015-09.pdf. The standard was set with an averaging time of eight hours and the form of annual fourth-highest daily maximum averaged over three years. *Id.*

260. *Id.* at ES-2.

261. *Id.* at ES-15 tbl.ES-5. These figures were calculated at a 7% discount rate as the EPA only summarized benefits at the 7% discount rate. *Id.*

262. *Id.* at ES-16 tbl.ES-6.

263. *Id.* at ES-16 tbl.ES-6.

264. Retention of the National Ambient Air Quality Standards for Nitrogen Dioxide, 50 Fed. Reg. 25,532, 25,537 (June 19, 1985) (to be codified at 40 C.F.R. pt. 50).

are less certain and more difficult to identify.”²⁶⁵ In the 2010 update to that standard, the Obama EPA noted that “[t]his meta-analysis does not provide any evidence of a threshold below which effects do not occur.”²⁶⁶ The revision’s Integrated Science Assessment also “concluded that NO₂ epidemiologic studies provide ‘little evidence of any effect threshold’” and that “concentration-response relationships . . . appear linear.”²⁶⁷ That 2010 review prompted the EPA to set a new short-term NO₂ standard of 100 ppb, based on the three-year average of the 98th percentile of one-hour daily maximum concentrations.²⁶⁸

The Agency in 2010 also found additional benefits for reductions in nitrogen dioxide below NAAQS levels. In addition to its 100 ppb standard, the EPA also analyzed a lower, more stringent level of 80 ppb.²⁶⁹ At and above 100 ppb, according to the controlled human exposure studies, increased airway responsiveness was observed in “a large percentage of asthmatics.”²⁷⁰ However, the EPA acknowledged that people with more severe asthma would be expected to experience symptoms at concentrations below the 100 ppb standard.²⁷¹ The Agency calculated that an 80 ppb standard would have an additional \$3.2 to \$8.6 million in benefits in 2020 over the 100 ppb standard that the EPA chose.²⁷²

The primary sulfur dioxide NAAQS standard was most recently revised under the Obama Administration in 2010. The final rule recognized that “the available health effects evidence reflects a continuum consisting of ambient levels of SO₂ at which

265. *Id.* The Agency went on to note that there was uncertainty, acknowledging that based on evidence available at the time, “[t]his does not necessarily mean that there is no threshold, other than zero, for NO₂ related health effects; it simply means no precise threshold can be identified with certainty based on existing medical evidence.” *Id.*

266. Primary National Ambient Air Quality Standards for Nitrogen Dioxide, 75 Fed. Reg. 6474, 6500 (Feb. 9, 2010) (to be codified at 40 C.F.R. pts. 50 and 58).

267. *Id.* at 6480. For further discussion of the EPA’s acknowledgment of scientific “uncertainty” of thresholds, see *infra* Part III.C.

268. U.S. ENVTL. PROT. AGENCY, FINAL REGULATORY IMPACT ANALYSIS (RIA) FOR THE NO₂ NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS), at ES-1 (2010) [hereinafter 2010 FINAL NO₂ RIA], https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-no2_ria_final_2010-01.pdf.

269. *Id.*

270. Livermore & Revesz, *supra* note 74, at 1218.

271. *Id.*

272. 2010 FINAL NO₂ RIA, *supra* note 268, at ES-6 tbl.ES-1, ES-7 tbl.ES-2. This is at the 65% gradient, which was the level the EPA chose in its final regulation. *Id.*

scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.”²⁷³

As part of these regulations, the EPA set a new standard of 75 ppb, based on the three-year average of the 99th percentile of one-hour daily maximum concentrations,²⁷⁴ but also analyzed alternative primary standards of 50 ppb.²⁷⁵ At the 75 ppb level, the EPA found \$2.2 million in benefits, including 260 fewer emergency room visits for respiratory symptoms.²⁷⁶ At the lower 50 ppb level, the EPA calculated \$8.5 million in benefits, including 930 fewer such emergency room visits.²⁷⁷ The Agency also calculated that a 50 ppb standard could have yielded as much as \$46 billion in additional PM_{2.5} co-benefits compared to the 75 ppb standard.²⁷⁸

In its 2011 revision for carbon monoxide, the Obama EPA recognized carbon monoxide pollution as similarly exhibiting a “continuum” of adverse health effects with varying degrees of certainty.²⁷⁹ The Agency highlighted two studies that were unable to discern a threshold for cardiovascular effects from carbon monoxide exposure.²⁸⁰ The rule’s Integrated Science Assessment

273. Primary National Ambient Air Quality Standard for Sulfur Dioxide, 75 Fed. Reg. 35,520, 35,529 (June 22, 2010) (to be codified at 40 C.F.R. pts. 50, 53, and 58).

274. *Id.* at 35,524.

275. U.S. ENVTL. PROT. AGENCY, FINAL REGULATORY IMPACT ANALYSIS (RIA) FOR THE SO₂ NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS), at ES-1 (2010), https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-so2_ria_final_2010-06.pdf.

276. *Id.* at 5-20, 5-21 tbl.5.5 (showing figures that represent “the incidences of health effects and monetized benefits of attaining the alternative standard levels by health endpoint. Because all health effects from SO₂ exposure are expected to occur within the analysis year, the monetized benefits for SO₂ [for these figures] do not need to be discounted. Please note that these benefits do not include any of the benefits listed as ‘unquantified’ . . . nor do they include the PM co-benefits . . .”).

277. *Id.*

278. *Id.* at 5-31 (comparing estimates in particulate matter co-benefits calculated in the Laden study, using a 3% discount rate).

279. 2011 Carbon Monoxide Review, *supra* note 244, at 54,308 (“These judgments are informed by the recognition that the available health effects evidence generally reflects a continuum, consisting of ambient levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.”).

280. *Id.* at 54,300 (“Among the controlled human exposure studies, the ISA places principal emphasis on the study of CAD patients by Allred *et al.* (1989a, 1989b, 1991) (which was also considered in the previous review) for the follow-

concluded that “[e]pidemiologic analyses investigating the exposure-response relationship for mortality and cardiovascular morbidity did not find evidence for a departure from linearity or a threshold for CO effects.”²⁸¹

In short, the EPA has moved away from the “critical effect” language it originally developed for NAAQS pollutants in 1978 and which might have suggested a threshold,²⁸² and since the late 1970s has openly rejected the threshold assumption for criteria pollutants on the basis of advances in the scientific understanding. The EPA also calculates benefits for criteria pollutant reductions below the levels the Agency chose for each of the most recent NAAQS.²⁸³ All of this is flatly inconsistent with the notion, advanced by the Trump Administration and by other opponents of Obama-era regulations in litigation,²⁸⁴ that the NAAQS represent a no-harm threshold for criteria pollutants, and that Obama-era rules inflated benefits in ways inconsistent with historical EPA practices.

III. CALCULATING HEALTH BENEFITS FROM PARTICULATE MATTER REDUCTIONS BELOW THE NAAQS

Critics of climate change regulations argue that particulate reduction benefits do not exist below the NAAQS, which they characterize as a no-harm threshold.²⁸⁵ According to adherents of this view, “[b]oth theory and data suggest that thresholds exist below which further reductions in exposure to PM_{2.5} do not yield changes in mortality response and that one should expect

ing reasons: (1) Dose-response relationships were observed; (2) effects were observed at the lowest COHb levels tested (mean of 2–2.4% COHb following experimental CO exposure), with no evidence of a threshold.” (citations omitted). The EPA later in the same section on “Cardiovascular Effects” notes that “an important finding of the multilaboratory study was the dose-response relationship observed between COHb and the markers of myocardial ischemia, with effects observed at the lowest increases in COHb tested, without evidence of a measurable threshold effect.” *Id.*

281. U.S. ENVTL. PROT. AGENCY, EPA/600/R-09/019F, INTEGRATED SCIENCE ASSESSMENT FOR CARBON MONOXIDE, at 2-16 (2010), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=494432.

282. *See supra* notes 185–95 and accompanying text; *supra* notes 207–08 and accompanying text.

283. Note that the EPA did not calculate benefits for carbon monoxide, the lone exception to this pattern, as the EPA did not produce a new RIA. *See supra* note 139.

284. *See supra* notes 30–38. Moreover, this argument is not supported for particulate matter. *See infra* notes 409–25 and accompanying text.

285. *See supra* note 26.

diminishing returns as exposures are reduced to lower and lower levels.”²⁸⁶ Similarly, the Heartland Institute, which bills itself as “the world’s most prominent think tank supporting skepticism about man-made climate change,”²⁸⁷ advocates that there is a “widely held belief among scientists and health experts, supported by ample research, that some threshold must exist below which pollution has no health impact. That belief is often summarized as ‘[t]he dose makes the poison.’”²⁸⁸ More recently, it has deemed PM_{2.5} a “favorite new bogeyman” of the EPA, calling it a “fabricate[d] . . . disease entity . . . [of] post-modern pseudo-science.”²⁸⁹ The National Mining Association advances the same line of reasoning in *Michigan v. EPA* in its challenge to the Mercury and Air Toxics Standards:

EPA concedes that most of these benefits supposedly result from reducing [particulate matter] concentrations to below the level that EPA set in its PM_{2.5} NAAQS But EPA set the [particulate matter] NAAQS, as it set all of the NAAQS, at a level that is “requisite to protect the public health” with a margin of safety and without considering compliance costs.²⁹⁰

286. Susan E. Dudley, *OMB’s Reported Benefits of Regulation: Too Good To Be True?*, 36 REG. 26, 28 (2013), <http://www.cato.org/sites/cato.org/files/serials/files/regulation/2013/6/regulation-v36n2-4.pdf>.

287. *Arthur B. Robinson Center on Climate and Environmental Policy: About*, HEARTLAND INST., <https://www.heartland.org/Center-Climate-Environment/About/index.html> (last visited Nov. 19, 2018).

288. Jay Lehr, *Warning: New HEI Report on PM10 Easy to Misinterpret*, HEARTLAND INST. (June 17, 2004), <https://www.heartland.org/news-opinion/news/warning-new-hei-report-on-pm10-easy-to-misinterpret?source=policybot>; see also Paul Driessen, *EPA’s Dangerous Regulatory Pollution*, HEARTLAND INST. (Sept. 6, 2016), <https://www.heartland.org/news-opinion/news/epas-dangerous-regulatory-pollution> (“How can it be that PM_{2.5} particulates are dangerous or lethal for Americans in general, every time they step outside—but harmless to human guinea pigs [in EPA experiments] who were intentionally administered pollution dozens of times worse than what they would encounter outdoors? How can it be, as EPA-funded researchers now assert, that ‘acute, transient responses seen in clinical studies cannot necessarily be used to predict health effects of chronic or repeated exposure’—when that is precisely what EPA claims they can and do show?”). The Heartland Institute now asserts that the EPA’s PM_{2.5} science constitutes “an attempted takeover of absolutely all industry in the United States,” despite “[t]he best scientific research show[ing] these particles are ubiquitous and, contrary to EPA’s claims, . . . harmless.” H. Sterling Burnett, *EPA Air Quality Research, Regulations Flawed, Study Finds*, HEARTLAND INST. (Aug. 23, 2017), <https://www.heartland.org/news-opinion/news/epa-air-quality-research-regulations-flawed-study-finds>.

289. Charles Battig, *Driving Policies Through Fraud and Fear-Mongering*, HEARTLAND INST. (July 10, 2015), <https://www.heartland.org/news-opinion/news/driving-policies-through-fraud-and-fear-mongering?source=policybot>.

290. Opening Brief of Petitioner the National Mining Ass’n at 41 n.19, *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (No. 14-46) (citations omitted) (quoting 42

In other words, the National Mining Association asserts that if the EPA followed its mandate to regulate particulate matter to the extent required under the NAAQS regime, then there would be no benefits below the NAAQS standard because the NAAQS standard would be set at the point at which benefits would not accrue below it.²⁹¹ Either, it claims, the EPA has not appropriately set the particulate matter NAAQS standard with the requisite margin of safety, or the asserted co-benefits of particulate matter reduction are nonexistent.²⁹²

Opponents also challenge the science underlying the EPA's calculation of additional benefits from pollution reduction below the NAAQS. The EPA's use of a linear, non-threshold approach for low-level particulate matter concentrations²⁹³ has been criticized as "highly imprecise" and guilty of "cherry-picking" epidemiology studies en route to a "biased assessment of the available data."²⁹⁴ Moreover, the EPA's assertion of benefits from particulate matter have been deemed "[i]llusory";²⁹⁵ based on "empty generalities and speculative claims";²⁹⁶ "based on questionable assumptions and . . . likely overstated";²⁹⁷ "specious";²⁹⁸ and "employ[ing] a methodology that places a thumb on the scale at every step of its benefit calculations and that regularly eschews real data in place of unrealistic assumptions and wild speculations."²⁹⁹ These purported benefits are allegedly "vague[,] unmonetized,"³⁰⁰ and "too speculative,"³⁰¹ with the implication that if benefits are too uncertain to be quantified, they are too uncer-

U.S.C. § 7409(b)(1) (2012)).

291. *See id.*

292. *See id.* at 41 (asserting that the EPA cannot prove co-benefits exist).

293. *See* NAAQS Particulate Matter, *supra* note 147, at 3119; *infra* notes 399–400 and accompanying text.

294. Brief for the Cato Institute as Amicus Curiae in Support of Petitioners at 25 n.21, *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (No. 14-46).

295. Opening Brief of State and Industry Petitioners, *supra* note 13, at 51.

296. *Id.* at 56.

297. Brief of the Chamber of Commerce of the United States of America, the National Ass'n of Manufacturers, the National Federation of Independent Business, & the National Ass'n of Home Builders as Amici Curiae in Support of Petitioners at 22 n.15, *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (Nos. 14-46, 14-47, 14-49).

298. Brief of Amicus Curiae Cato Institute in Support of Petitioners at 3, *Murray Energy Corp. v. EPA*, No. 16-1127 (D.C. Cir. Nov. 18, 2016).

299. *Id.*

300. Opening Brief of State and Industry Petitioners, *supra* note 13, at 55.

301. *Id.* at 56.

tain to be contemplated at all. The Agency simply “cannot quantify them [because] they are not supported by the scientific literature.”³⁰²

Benefits from particulate matter reductions are thus a key battleground in the fight over major Obama-era Clean Air Act rules and will almost certainly be a point of contention in future climate change regulations. Because of the size of these benefits, both in absolute terms and in comparison with other regulatory effects, there is a substantial incentive for both sides to misrepresent them, and a critical need to get these estimates right. The following section describes the robust scientific basis for the determination that particulate matter lacks a threshold below which adverse health effects occur.

A. SCIENTIFIC BASIS

Particulate matter (PM) is a mixture of very small particles and liquid droplets that are found in the air.³⁰³ Some particles are large enough to be visible, such as dust, dirt, soot, and smoke, while others are too small to be seen with the naked eye.³⁰⁴ Exposure to particulate matter can have negative effects on lung and heart health, including coughing or difficulty breathing, aggravating asthma and decreased lung function, as well as heart attacks and irregular heartbeat.³⁰⁵ Exposure can be deadly, particularly for people with heart or lung disease.³⁰⁶

The EPA regulates particulate matter under two standards, which are based on the size of the particulate matter particles.³⁰⁷ Extremely small particles, those measuring 2.5 micrometers or less, are regulated under the PM_{2.5} standards, while larger particles measuring between 2.5 and 10 micrometers are regulated under the PM₁₀ standards.³⁰⁸ The current standards for particulate matter set limits on PM_{2.5} of 35 µg/m³ averaged over 24

302. *Id.*

303. *Particulate Matter (PM) Basics*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/pm-pollution/particulate-matter-pm-basics#PM> (last updated Sept. 10, 2018).

304. *Id.*

305. *Health and Environmental Effects of Particulate Matter (PM)*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/pm-pollution/health-and-environmental-effects-particulate-matter-pm> (last updated June 20, 2018) (listing the health effects linked to exposure to particulate matter).

306. *See id.*

307. *See* NAAQS Particulate Matter, *supra* note 147, at 3086 (explaining the standards for fine particles).

308. *Id.*

hours and of 12 $\mu\text{g}/\text{m}^3$ averaged annually.³⁰⁹ The PM_{10} standard is a 24-hour average of 150 $\mu\text{g}/\text{m}^3$, and there is no annual standard.³¹⁰

These standards do not represent the level at which there are no health effects from particulate matter exposure.³¹¹ The science on benefits from reductions in particulate matter below the NAAQS, some of which is summarized in this section, is robust.³¹² In general, the evidence suggests there is no threshold for particulate matter, which means that risk from particulate matter exists at every level of exposure.³¹³

For example, in 2006, the EPA solicited a report of judgments from experts on the concentration response relationship between small particulate matter particles ($\text{PM}_{2.5}$) and mortality.³¹⁴ The twelve experts who participated in the report were selected through a peer-nomination process and included experts in epidemiology, toxicology, and medicine.³¹⁵ As part of this study, the experts were asked about their views on the concentration-response function, which measures health effects at different levels of exposure.³¹⁶ While all experts believed that individuals may exhibit thresholds for PM-related mortality, eleven of the twelve rejected the idea of a population threshold, stating

309. *Id.*

310. *Id.* at 3089.

311. *See, e.g.*, Jonathan O. Anderson et al., *Clearing the Air: A Review of the Effects of Particulate Matter Air Pollution on Human Health*, 8 J. MED. TOXICOLOGY 166, 172 tbl.5 (2012) (showing that “[u]nusually sensitive people” can experience adverse effects and are recommended to avoid heavy exertion even when the particulate matter exposure is below the current standards).

312. For extensive examples of research on the benefits particulate matter reductions below the current NAAQS, *see infra* notes 314–69 and accompanying text.

313. *See infra* notes 314–69. It is well beyond the scope of this Article to comprehensively review and independently evaluate all of the scientific research on the relationship between particulate matter exposure and negative health outcomes. The research presented here thus focuses primarily on aggregated reports written by scientists, doctors, and other experts on the effects of particulate matter on human health. In doing so, the authors defer to the expertise of these writers and their judgments in aggregating and analyzing evidence on the health effects of particulate matter.

314. *See* INDUS. ECON., EXPANDED EXPERT JUDGMENT ASSESSMENT OF THE CONCENTRATION-RESPONSE RELATIONSHIP BETWEEN $\text{PM}_{2.5}$ EXPOSURE AND MORTALITY, at i–ii (2006), https://www3.epa.gov/ttnecas1/regdata/Uncertainty/pm_ee_report.pdf (documenting “expert judgments concerning the impact of a one $\mu\text{g}/\text{m}^3$ change in ambient, annual average $\text{PM}_{2.5}$ on annual, adult, all-cause mortality in the U.S.”).

315. *See id.* at ii.

316. *Id.* at iv.

that there was insufficient evidence to support such a threshold.³¹⁷ Seven experts noted that a population threshold was unlikely due to variations in susceptibility as a result of genetic, environmental, and socioeconomic factors.³¹⁸ The single expert who believed it was possible to make a conceptual argument for a population threshold noted that he did not believe such a threshold was detectable in currently available epidemiologic studies.³¹⁹ This expert also stated that he was 50% certain a population threshold existed, and that if there were a threshold, he thought there was an 80% chance the threshold would be less than 5 $\mu\text{g}/\text{m}^3$, and a 20% chance that it would fall between 5 and 10 $\mu\text{g}/\text{m}^3$.³²⁰ Both levels cited by the expert are lower than the current NAAQS levels for $\text{PM}_{2.5}$ of 12 $\mu\text{g}/\text{m}^3$.³²¹

A 2010 scientific report from the American Heart Association reached similar conclusions.³²² The authors of that report included specialists in a wide range of disciplines: “cardiovascular and environmental epidemiology and statistics, atmospheric sciences, cardiovascular and pulmonary medicine, basic science research, and public policy.”³²³ The report comprehensively reviewed studies, published between 2004 and 2009, on the relationship between particulate matter and heart health.³²⁴ The report concluded that “there appeared to be no lower-limit threshold below which PM_{10} was not associated with excess [cardiovascular] mortality.”³²⁵ With regard to $\text{PM}_{2.5}$, the report stated that there appeared to be a linear concentration-response relationship between the small particles and mortality risk without a discernible safe threshold.³²⁶ The report suggested that an area for future research was determining whether there is any safe PM threshold that protects both healthy and susceptible in-

317. *Id.* at 3-25. For a discussion of the difference between individual and population thresholds, see *supra* notes 145–47 and accompanying text.

318. *INDUS. ECON.*, *supra* note 314, at 3-25.

319. *Id.* at 3-25 to -26.

320. *Id.* at 3-26.

321. See NAAQS Particulate Matter, *supra* note 147, at 3157.

322. See Robert D. Brook et al., *Particulate Matter Air Pollution and Cardiovascular Disease: An Update to the Scientific Statement from the American Heart Association*, 121 *CIRCULATION* 2331, 2338 (2010) (finding there is an increased mortality rate for PM levels lower than the current NAAQS threshold).

323. *Id.* at 2332.

324. See generally *id.*

325. *Id.* at 2338.

326. *Id.* at 2350–51.

dividuals, but noted that current evidence supports the conclusion that there is no safe threshold.³²⁷

The American Thoracic Society (ATS), in a 2016 article, likewise reported adverse health effects below the NAAQS.³²⁸ The ATS recommended an annual standard for PM_{2.5} of 11 µg/m³, which is lower than the current NAAQS requirements.³²⁹ The report estimated the health impacts from PM exposure in places that violated the ATS's annual standard, including places in compliance with the EPA's requirements.³³⁰ The report found that relative to current particulate matter levels across the country,³³¹ an estimated 2913 deaths and 5543 instances of morbidity would be avoided if the 11 µg/m³ were met.³³² The report also noted that "this approach does not imply that further health benefits would not be achieved by still further reductions in pollution levels," relying in part on the EPA's own statement that there is no epidemiological evidence of a threshold for PM.³³³

The Harvard School of Public Health Six Cities Study³³⁴ and an American Cancer Society study³³⁵ are two key studies in the evaluation of particulate matter exposure health impacts, and both have been extensively relied upon by the EPA in its particulate matter NAAQS rulemakings.³³⁶ Both studies include follow up research; the Six Cities Study was originally published in

327. *See id.* at 2365–66.

328. *See* Kevin R. Cromar et al., *American Thoracic Society and Marron Institute Report Estimated Excess Morbidity and Mortality Caused by Air Pollution Above American Thoracic Society-Recommended Standards, 2011–2013*, 13 ANNALS AM. THORACIC SOC'Y 1195, 1201 (2016) ("The ATS recommendations for . . . PM_{2.5}. . . are more stringent than the current NAAQS determined by the EPA.").

329. *Id.* at 1195.

330. *Id.* at 1197 (finding annually approximately 6408 deaths can be attributed to pollution concentrations higher than ATS's recommendation).

331. Note that many parts of the United States violate the current NAAQS levels. *See id.* at 1197 fig.1. As such, these estimates reflect cumulative effects of current violations of the NAAQS plus the benefits of lowering the PM_{2.5} from the current 12 µg/m³ to 11 µg/m³, as recommended by the American Thoracic Society. *See id.* at 1196–97.

332. *Id.* at 1198 fig.3.

333. *Id.* at 1201.

334. Douglas W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENG. J. MED. 1753, 1753 (1993).

335. C. Arden Pope III et al., *Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults*, 151 AM. J. RESPIRATORY & CRITICAL CARE MED. 669 (1995).

336. *See* U.S. ENVTL. PROT. AGENCY, EPA-452/R-12-005, REGULATORY IMPACT ANALYSES FOR THE FINAL REVISIONS TO THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER, at 1-12 (2012) [hereinafter

1993, with follow up research released in 2006 and again in 2012;³³⁷ the American Cancer Society Study was released in 1995 and updated in 2002 and 2004.³³⁸ These studies were cited by the Bush Administration EPA in the 2006 particulate matter NAAQS,³³⁹ by all experts solicited in the 2006 EPA expert solicitation,³⁴⁰ and were also relied upon by the Obama Administration in the 2016 particulate matter NAAQS,³⁴¹ the Mercury and Air Toxics Standards report,³⁴² the Clean Power Plan report,³⁴³ and the Cross Border Air Pollution Rule report.³⁴⁴ The Bush EPA noted that “these studies have found consistent relationships between fine particle indicators and premature mortality across

2012 PM RIA], https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-pm_ria_final_2012-12.pdf (“Since the proposed rule, the EPA has incorporated an array of policy and technical updates to the benefits analysis approach applied in this RIA, including incorporation of the most recent follow-up to the Harvard Six Cities cohort study (Lepeule et al., 2012).”); *see also* U.S. ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSES FOR THE REVIEW OF PARTICULATE MATTER NATIONAL AMBIENT AIR QUALITY STANDARDS, at 5-27 (2006) [hereinafter 2006 PM RIA], https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-pm_ria_final_2006-10.pdf (“The most extensive analyses have been based on data from two prospective cohort groups, often referred to as the Harvard ‘Six-Cities Study’ . . . and the ‘American Cancer Society or ACS study’ . . .”).

337. *See* 2012 PM RIA, *supra* note 336, at 5-7 (citing the Six Cities Study updates from 2006 and 2012); 2006 PM RIA, *supra* note 336, at 5-27 (citing the Harvard Six Cities Study history from 1993 and 2006).

338. *See* 2006 PM RIA, *supra* note 336, at 5-27 (citing the American Cancer Society study’s versions from 1995, 2002, and 2004).

339. *Id.* (citing the Six Cities Study and the American Cancer Society study).

340. *See* INDUS. ECON., *supra* note 314, at viii (“Experts relied upon a core set of cohort epidemiology studies to derive their quantitative estimates, mainly those associated with the ACS and Six Cities cohort.”).

341. 2012 PM RIA, *supra* note 336, at 1-12 (stating that the EPA relied on the Six Cities Study for its report).

342. MATS RIA, *supra* note 21, at 5-27 (relying on the analyses from the Six Cities Study and the American Cancer Society study).

343. CLEAN POWER PLAN RIA, *supra* note 22, at 4-16 to -17 (stating that the EPA used the American Cancer Society report and the Six Cities Study to help determine “PM-related mortality”).

344. U.S. ENVTL. PROT. AGENCY, EPA-452/R-16-004, REGULATORY IMPACT ANALYSIS OF THE CROSS-STATE AIR POLLUTION RULE (CSAPR) UPDATE FOR THE 2008 NATIONAL AMBIENT AIR QUALITY STANDARDS FOR GROUND-LEVEL OZONE, at 5-11 to -13 (2016) [hereinafter CSAPR RIA], https://www3.epa.gov/ttn/ecas/docs/ria/transport_ria_final-csapr-update_2016-09.pdf (citing findings from the Six Cities Study and the American Cancer Society study); U.S. ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSIS FOR THE FEDERAL IMPLEMENTATION PLANS TO REDUCE INTERSTATE TRANSPORT OF FINE PARTICULATE MATTER AND OZONE IN 27 STATES; CORRECTION OF SIP APPROVALS FOR 22 STATES, at 5-27 (2011), https://www3.epa.gov/ttn/ecas/docs/ria/transport_ria_final-csapr_2011-06.pdf (citing findings from the Six Cities Study and ACS study).

multiple locations in the United States.”³⁴⁵ The EPA summarized in the Cross Border Air Pollution Rule report that the authors of the 2012 Six Cities Study follow-up “found significant associations between PM_{2.5} exposure and increased risk of premature all-cause, cardiovascular and lung cancer mortality,” and “concluded that the [concentration-response] relationship was linear down to PM_{2.5} concentrations of 8 µg/m³.”³⁴⁶ This level is substantially lower than 12 µg/m³, the current NAAQS annual standard for particulate matter.³⁴⁷

Experts outside of the EPA have also relied on the findings of the Six Cities Study and the American Cancer Society study to support their determination that particulate matter is a no threshold pollutant.³⁴⁸ In 2002, relying on the American Cancer Society study, the National Research Council’s Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations³⁴⁹ concluded that “there is no evidence for any . . . indication of a threshold” for particulate matter.³⁵⁰ Additionally, the Health Effects Subcommittee (HES) of the Advisory Council on Clean Air Compliance Analysis relied on both the Six Cities Study and the American Cancer Society study to conclude that it “fully supports EPA’s use of a no-threshold model to estimate the mortality reductions associated with reduced PM exposure.”³⁵¹ It reasoned that the EPA’s “decision is

345. 2006 PM RIA, *supra* note 336, at 5-27.

346. CSAPR RIA, *supra* note 344, at 5-12 to -13.

347. See NAAQS Particulate Matter, *supra* note 147, at 3086 (stating that the current NAAQS levels for PM_{2.5} is 12 µg/m³).

348. For an example of how experts have relied on these studies see *infra* notes 349–54 and accompanying text.

349. In 2000, due to congressional concerns about the EPA’s method of estimating health benefits from air pollution reduction, the Senate appropriated funds to the EPA and directed the Agency to request a study from the National Academy of Sciences on the EPA’s methodologies. The National Academy of Science arranged for the National Research Council’s Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations to prepare a report in 2002, which reviewed and critiqued the EPA’s benefit analysis. See COMM. ON ESTIMATING THE HEALTH-RISK-REDUCTION BENEFITS OF PROPOSED AIR POLLUTION REGULATIONS, NAT’L RESEARCH COUNCIL, ESTIMATING THE PUBLIC HEALTH BENEFITS OF PROPOSED AIR POLLUTION REGULATIONS 1–2 (2002) [hereinafter HEALTH-RISK-REDUCTION COMMITTEE].

350. *Id.* at 109. The committee went on to recommend that if the EPA plans to base its benefit analysis on the assumption that a threshold exists, which is not proven in any scientific study, the EPA should make its assumptions and reasoning clear. *Id.* at 111.

351. U.S. ENVTL. PROT. AGENCY ADVISORY COUNCIL ON CLEAN AIR COMPLIANCE ANALYSIS HEALTH EFFECTS SUBCOMM., REVIEW OF EPA’S DRAFT HEALTH BENEFITS OF THE SECOND SECTION 812 PROSPECTIVE STUDY OF THE CLEAN AIR

supported by the data, which are quite consistent in showing effects down to the lowest measured levels.”³⁵² Also, a 2008 follow-up to the Harvard Six Cities Study found that there was an 86% probability that PM_{2.5} followed a linear no-threshold model.³⁵³ This report explained that “[a] key finding of this study is that there is little evidence for a threshold in the association between exposure to fine particles and the risk of death on follow-up.”³⁵⁴ Instead of reducing PM concentration by relying on “an arbitrary standard,” such as a threshold model, the study recommended “reduc[ing] particle concentration everywhere, at all times, to the extent feasible and affordable.”³⁵⁵ Another 2012 follow-up to the Harvard Six Cities Study provided additional data suggesting the health effects from PM exposure do not have a threshold and follow a linear model at low doses.³⁵⁶

The World Health Organization (WHO), a specialized agency of the United Nations,³⁵⁷ in a report cataloguing the global impact of particulate matter pollution, noted that this pollution represents one of the world’s biggest environmental health risks, killing around three million people annually worldwide.³⁵⁸ The report explains that this “pollution has health impacts even at very low concentrations—indeed no threshold has been identified below which no damage to health is observed.”³⁵⁹ WHO recommends that countries set standards at the lowest concentrations possible, and has set guideline values for PM_{2.5} at

ACT 2 (2010) [hereinafter REVIEW OF EPA’S DRAFT], [https://yosemite.epa.gov/sab/sabproduct.nsf/0/72D4EFA39E48CDB28525774500738776/\\$File/EPA-COUNCIL-10-001-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/72D4EFA39E48CDB28525774500738776/$File/EPA-COUNCIL-10-001-unsigned.pdf). Similarly to the National Research Council’s Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations, see HEALTH-RISK-REDUCTION COMMITTEE, *supra* note 349, the HES was tasked with drafting a report in order to provide the EPA with guidance on how it estimates benefits and uncertainties for particulate matter and ozone. *See id.*

352. *Id.* at 13.

353. Joel Schwartz et al., *The Effect of Dose and Timing of Dose on the Association Between Airborne Particles and Survival*, 116 ENVTL. HEALTH PERSP. 64, 67 (2008).

354. *Id.*

355. *Id.* at 68.

356. Johanna Lepeule et al., *Chronic Exposure to Fine Particles and Mortality: An Extended Follow-up of the Harvard Six Cities Study from 1974 to 2009*, 120 ENVTL. HEALTH PERSP. 965, 967 (2012) (finding results “indicating a linear relationship with PM_{2.5}”).

357. World Health Org. [WHO] Const. pmb. (1946).

358. WORLD HEALTH ORG., AMBIENT AIR POLLUTION: A GLOBAL ASSESSMENT OF EXPOSURE AND BURDEN OF DISEASE 11 (2016), <http://apps.who.int/iris/bitstream/10665/250141/1/9789241511353-eng.pdf?ua=1>.

359. *Id.* at 21.

10 $\mu\text{g}/\text{m}^3$ annual mean and 25 $\mu\text{g}/\text{m}^3$ 24-hour mean,³⁶⁰ which is well below the current NAAQS of 12 $\mu\text{g}/\text{m}^3$ annual mean and 35 $\mu\text{g}/\text{m}^3$ 24-hour mean.³⁶¹

A recent study from the Harvard School of Public Health confirms these findings and strengthens the evidence of health effects from particulate matter exposure below the current NAAQS. The 2017 study, which included a cohort of all Medicare beneficiaries (approximately 60 million people) throughout the United States, focused specifically on measuring health effects below the current particulate matter and ozone NAAQS.³⁶² The researchers measured health effects for people residing in places where $\text{PM}_{2.5}$ concentrations ranged from 6.21 to 15.64 $\mu\text{g}/\text{m}^3$.³⁶³ The study reported “a relationship between $\text{PM}_{2.5}$, ozone, and all-cause mortality that was almost linear, with no signal of [a] threshold down to 5 $\mu\text{g}/\text{m}^3$ ” in annual exposure.³⁶⁴ Moreover, the authors found that “[t]here was a significant association between $\text{PM}_{2.5}$ exposure and mortality when the analysis was restricted to concentrations below 12 μg per cubic meter [the current NAAQS], with a steeper slope below that level.”³⁶⁵ This study, which contains a very large sample size representing a geographically and socioeconomically diverse cross section of the country,³⁶⁶ concludes that in the entire population studied “there was significant evidence of adverse effects related to exposure to $\text{PM}_{2.5}$. . . concentrations below current national standards.”³⁶⁷ The study “found no evidence of a threshold value—the concentration at which $\text{PM}_{2.5}$ exposure does not affect mortality—at concentrations as low as approximately 5 μg per cubic meter,”³⁶⁸ confirming a finding similar to those of other studies.³⁶⁹

360. *Id.*

361. *See* NAAQS Particulate Matter, *supra* note 147, at 3086 (stating the current NAAQS).

362. *See* Di et al., *supra* note 25, at 2514 (explaining the method of the nationwide study).

363. *Id.* at 2515.

364. *Id.* at 2518.

365. *Id.* at 2520. A steeper slope at low levels indicates that the marginal health risk from additional exposure at low levels is actually higher than the marginal risk at higher levels of exposure. *See id.*

366. *See id.* at 2515 tbl.1 (providing information of the large cohort’s characteristics).

367. *Id.* at 2513.

368. *Id.* at 2520.

369. *See id.*

The Trump Administration has attacked the validity of these studies in a rulemaking announced in April 2018.³⁷⁰ The proposed rule on “Strengthening Transparency in Regulatory Science” targets the use of most primary scientific literature currently available on the health impacts of particulate matter.³⁷¹ Specifically, the rulemaking would prohibit the EPA from using “data and models underlying the science” unless that data “is publicly available in a manner sufficient for validation and analysis.”³⁷² Though a rule requiring transparency in scientific data may seem innocuous, in practice the regulation would severely hamstring the EPA. Individual medical data used in scientific studies generally cannot be made fully public,³⁷³ in order to protect the confidential medical information of study participants.³⁷⁴ Under this proposed rule it would no longer be permissible for the EPA to use any of these studies when performing cost benefit analyses on particulate matter or other public health regulations. Even the Medicare data used in the 2017 Harvard School of Public Health study is confidential and protected from general public access, though it may be requested by scientists or industry to conduct their own independent analysis.³⁷⁵ The

370. See generally Strengthening Transparency, *supra* note 117 (explaining the EPA’s proposed rule under the Trump Administration).

371. Cf. *id.* at 18,769 (stating that the purpose of the rule is to “[e]nhanc[e] the transparency and validity of the scientific information relied upon by EPA”).

372. *Id.* There is a provision which would allow the Administrator to:

exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB’s Information Quality Bulletin for Peer Review provides for an exemption (Section IX).

Id. at 18,772. Of course, aggressive utilization of this provision would blunt the effects of this regulation, but because the provision is entirely discretionary, it is also possible that this provision would provide no relief at all from the impacts of this proposed rule.

373. See Jennifer Lu & Abby Smith, *EPA Plan to Limit Science Use May Undercut Air, Climate Programs*, BLOOMBERG ENV’T (Apr. 25, 2018), <https://bna.news.bna.com/environment-and-energy/epa-plan-to-limit-science-use-may-undercut-air-climate-programs> (“The studies use individual medical data that can’t be made public, and that would be prohibited from agency use under the EPA’s new plans.”).

374. See *id.* (stating researchers are required to keep private medical data confidential).

375. See Lu & Smith, *supra* note 373 (stating the Harvard Six Cities Study contains private individuals’ medical information that cannot be shared publicly).

proposed rule, if finalized, would have the effect of dramatically reducing estimates of the negative health effects of particulate matter and other air pollutants. This, in turn, would lower the estimated benefits from regulating these pollutants, and thus could be used to justify less stringent regulations.

B. REGULATORY TREATMENT

The EPA has consistently found over three decades, and under administrations of both parties, that there are health effects from particulate matter exposure at low levels, below the NAAQS. The Agency has done so at different times by explicitly stating that there is no evidence of a threshold, by calculating benefits for reductions in particulate matter below the level of the NAAQS, or both.

As early as 1984, the EPA under President Reagan explicitly stated that there is no evidence of a threshold for particulate matter.³⁷⁶ Specifically, the Agency's 1984 Regulatory Impact Analysis stated that "the data do not . . . show evidence of a clear threshold in exposed populations. Instead they suggest a continuum of response with both the likelihood (risk) of effects occurring and the magnitude of any potential effect decreasing with concentration."³⁷⁷ This language was reiterated verbatim in the 1987 final rule.³⁷⁸

In 1997, the Clinton EPA determined that "the available epidemiological studies provide strong evidence suggesting that

376. U.S. ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSIS ON THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER, at VI-15 to -17 (1984) [hereinafter 1984 PM RIA], <http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=9101HEPX.TXT> (explaining research in a staff paper that concluded there was no evidence to show "a clear threshold").

377. *Id.* at VI-15. The 1984 RIA was also the first time the EPA calculated the economic benefits for ambient air standards, and the Agency also analyzed benefits from particulate matter at different levels. *See id.* at VI-1. While the EPA did not analyze an alternative that was equally or more stringent for both the annual average and 24-hour standard, it did analyze an annual standard lower than the one it ultimately selected, paired with a 24-hour limit higher than what it chose. *See id.* at VI-15. In the 1987 NAAQS, the EPA selected a PM₁₀ annual average limit of 50 µg/m³ and a 24-hour limit of 150 µg/m³. 1987 Revisions to NAAQS, *supra* note 30, at 24,634. However, in its RIA, the EPA reviewed benefits from a PM₁₀ annual limit of 48 µg/m³ paired with a 24-hour limit of 183 µg/m³. 1984 PM RIA, *supra* note 376, at VI-38 tbl.VI.G.2. While the EPA did not conduct an analysis of benefits at the level it ultimately selected, *see id.* at VI-40, making it impossible to directly compare the two options, the EPA did find benefits at the 48 µg/m³ annual limit scenario. *See id.* at VI-37 to -40.

378. 1987 Revisions to NAAQS, *supra* note 30, at 24,642.

PM causes or contributes to health effects at levels below the current standards”³⁷⁹ and that “the level or even existence of population thresholds below which no effects occur cannot be reliably determined.”³⁸⁰ The Agency also calculated benefits for reducing particulate matter below the level it ultimately selected.³⁸¹ In the 1997 NAAQS revision, the EPA set the annual average standard for PM_{2.5} at 15µg/m³, and the 24-hour limit at 65 µg/m³.³⁸² In the accompanying RIA, the EPA analyzed the costs and benefits of the level it chose along with a more stringent standard. The more stringent standard the EPA reviewed was an annual standard set at 15µg/m³, in combination with a lower 24-hour standard set at 50 µg/m³.³⁸³ At the level the EPA eventually selected for the NAAQS standard, the Agency found annual benefits from partial attainment³⁸⁴ to be between \$19 billion (low estimate) and \$104 billion (high estimate).³⁸⁵ However, the EPA found greater benefits, a high estimate of \$107 billion, under this more stringent level.³⁸⁶

379. National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,670 (July 18, 1997) (to be codified at 40 C.F.R. pt. 50) [hereinafter 1997 PM NAAQS].

380. *Id.*

381. Compare *id.* at 38,652 (setting the 24-hour PM_{2.5} limit at 65 µg/m³), with U.S. ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSES FOR THE PARTICULATE MATTER AND OZONE NATIONAL AMBIENT AIR QUALITY STANDARDS AND PROPOSED REGIONAL HAZE RULE, at EΣ-23 tbl.ES-3 (1997) [hereinafter 1997 PM RIA], https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-o3-pm_ria_proposal_1997-07.pdf (reviewing a lower 24-hour standard for PM_{2.5} at 50 µg/m³).

382. 1997 PM NAAQS, *supra* note 379, at 38,652.

383. 1997 PM RIA, *supra* note 381 (comparing the annual costs and benefits alternatives for 2010, including one at the low rate of a 15µg/m³ annual standard with a 50 µg/m³ 24-hour standard).

384. The 1997 RIA refers to “partial attainment” rather than full attainment because the analysis “does not attempt to force its models to project full attainment of the new standard in areas not predicted to achieve attainment by 2010,” the year selected for the baseline. *Id.* at EΣ-13. Instead, the RIA attempts to account for the probability “that counties with PM_{2.5} levels above the standard will likely need more time beyond 2010; new control strategies (e.g., regional controls or economic incentive programs); and/or new technologies in order to attain the standard.” *Id.* at EΣ-12. Additionally, “[f]or the PM analysis [in the RIA], a \$1 billion/µg/m³ cut-off is used to limit the adoption of control measures. Control measures providing air quality improvements are less than \$1 billion/µg/m³ are adopted where the air quality model and cost analysis identify control measures as being necessary.” *Id.*

385. *Id.* at EΣ-19. These are annual gross benefits. See *id.* EΣ-14 to -15. “There are benefits from PM control that could not be monetized in the benefits analysis[.] . . . The effect . . . leads to an underestimation of the monetized benefits presented.” *Id.* at EΣ-19.

386. *Id.* at EΣ-23 tbl.ES-3. The RIA does not provide a low estimate of annual benefits or annual costs for the more stringent 15µg/m³ standard. See *id.*

In 2006, the EPA under George W. Bush found that “effect thresholds can neither be discerned nor determined not to exist.”³⁸⁷ The Agency also noted that “several new studies available in [its] review have used different methods to examine [particulate matter concentration-response relationships], and most have been unable to detect threshold levels in time-series mortality studies.”³⁸⁸ The EPA again calculated benefits at a particulate matter standard more stringent than the one it ultimately chose for the NAAQS. The 2006 final rule established a PM_{2.5} 24-hour standard of 35 µg/m³ and retained the annual standard of 15 µg/m³.³⁸⁹ The RIA also included an analysis of benefits from a more stringent annual standard of 14 µg/m³ paired with the same 35 µg/m³ 24-hour limit.³⁹⁰ Again, the EPA found higher benefits for the more stringent standard.³⁹¹ Using a 3% discount rate,³⁹² the EPA found \$17 billion in benefits at the 15 µg/m³ standard, but \$30 billion in benefits under the more stringent 14 µg/m³ standard.³⁹³ Again using a 3% discount rate, the EPA also calculated benefits using a different methodology and found between \$9 billion and \$76 billion in benefits from the 15 µg/m³ standard, but \$17 billion to \$140 billion in benefits for the 14 µg/m³ standard.³⁹⁴

Further, the Bush EPA calculated additional health and welfare benefits under the more stringent standard. Under multiple valuation methods, the EPA found that approximately twice as many deaths would be avoided under the 14 µg/m³ standard compared with the 15 µg/m³ standard it ultimately selected.³⁹⁵ The EPA found that chronic bronchitis effects would be

at ES-14 to -23.

387. National Ambient Air Quality Standards for Particulate Matter, 71 Fed. Reg. 61,144, 61,152 (Oct. 17, 2006) (to be codified at 40 C.F.R. pt. 50).

388. *Id.* at 61,158.

389. *Id.* at 61,144.

390. 2006 PM RIA, *supra* note 336, at ES-1 to -2.

391. *Id.* at ES-7 tbl.ES-1 (showing the estimated benefits for the more stringent standards versus the 1997 revised standards).

392. As noted above, the 3% discount rate presents a more realistic figure for calculating the present value of benefits from reduction of future air pollution. *See* Newell, *supra* note 9.

393. 2006 PM RIA, *supra* note 336, at ES-7 tbl.ES-1 (comparing full attainment benefits with social costs through incremental attainment of the 1997 standards).

394. *Id.*

395. *Id.* at ES-8 tbl.ES-2 (estimating the reduction of adverse health and welfare effects associated with incremental attainment of alternative standards).

reduced by 4600 cases under a more stringent standard but by 2600 under the standard it selected.³⁹⁶ Hospital admissions for respiratory events would be reduced by 980 under the stricter level but by 530 under EPA's standard, and hospital admissions for cardiovascular events for people over the age of seventeen would decrease by 2100 under the stricter level but by only 1100 under the standard selected.³⁹⁷

In the most recent revision of particulate matter NAAQS under the Obama Administration, the EPA expressed its clearest rejection of thresholds for particulate matter. The Agency noted in the Final Rule updating the NAAQS in 2013 that, because "there is no discernible population-level threshold below which effects would not occur, . . . it is reasonable to consider that health effects may occur over the full range of concentrations observed in the epidemiological studies, including the lower concentrations in the latter years."³⁹⁸ The EPA also explicitly addressed comments from the American Petroleum Institute and the American Chemistry Council asserting that "there is a threshold in the PM-health effect relationship and that the log-linear model is not biologically plausible."³⁹⁹ The Agency countered that:

The EPA disagrees with this assertion due to the number of studies evaluated in the Integrated Science Assessment that continue to support the use of a no-threshold, log-linear model to most appropriately represent the PM concentration-response relationship. . . . [EPA's Clean Air Science Advisory Committee] likewise advised that "[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold."⁴⁰⁰

As in previous administrations, the EPA again found additional benefits from a standard more stringent than the NAAQS. The

396. *Id.*

397. *Id.*

398. NAAQS Particulate Matter, *supra* note 147, at 3148.

399. *Id.* at 3119.

400. *Id.* Further, when the EPA acknowledged in its Integrated Review Plan for the 2016 PM NAAQS rulemaking that particulate matter lacks a threshold of effects, the Clean Air Science Advisory Committee affirmed that conclusion. See Memorandum from Dr. Ana V. Diez Roux, Chair, Clean Air Sci. Advisory Comm., to Gina McCarthy, Adm'r, Env'tl. Prot. Agency, CASAC Review of the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft - April 2016) (Aug. 31, 2016), [https://yosemite.epa.gov/sab/sabproduct.nsf/0/9920C7E70022CCF98525802000702022/\\$File/EPA-CASAC+2016-003+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/9920C7E70022CCF98525802000702022/$File/EPA-CASAC+2016-003+unsigned.pdf) (noting that "[t]he approach in the last review to setting an annual standard when there is 'no discernible population level threshold' for health effects is clearly explained" and appropriate).

2012 RIA presents the benefits for the NAAQS levels the EPA chose, a PM_{2.5} 24-hour standard of 35 µg/m³ and an annual average standard of 12 µg/m³.⁴⁰¹ The Agency also calculated benefits from an 11µg/m³ annual standard.⁴⁰² At a 3% discount rate, the EPA found between \$3.7 and \$9 billion in benefits for the 12 µg/m³ standard, but \$11 to \$29 billion in benefits at the more stringent 11 µg/m³ level.⁴⁰³

C. ADDRESSING UNCERTAINTY

The preceding discussion should not be read to suggest that there is no uncertainty about the health effects of particulate matter at low levels of exposure. Exposure studies generally do not examine populations exposed to ambient levels down to zero. Rather, studies generally have a lowest measured level (LML), which is the lowest level of exposure studied.⁴⁰⁴ The EPA is tasked with the difficult job of extrapolating a dose-response relationship below these levels, and it has acknowledged that uncertainty remains about the shape of that relationship.⁴⁰⁵

One tactic of regulatory critics is to conflate this uncertainty with the existence of a threshold. For example, state and industry challengers to the Clean Power Plan emphasized the EPA's admission that there is uncertainty about the scale of particulate matter health effects at very low exposure levels.⁴⁰⁶ These challengers asserted that NAAQS are “precautionary and preventative’ in nature . . . and intended to protect the most sensitive subgroups in the population, [yet] EPA did not have confidence that

401. See 2012 PM RIA, *supra* note 336, at ES-2.

402. *Id.*

403. *Id.* at ES-14 to -15 tbl.ES-2 (showing total monetized benefits, costs, and net benefits for full attainment by 2020).

404. For example, the RIA for the proposed repeal of the Clean Power Plan states that:

[e]stimates were calculated assuming that the number of PM_{2.5}-attributable premature deaths falls to zero at PM_{2.5} levels at or below the Lowest Measured Level of each of two [long-term] epidemiological studies used to quantify PM_{2.5}-related risk of death (Krewski et al. 2009, LML = 5.8 µg/m³; Lepeule et al. 2012; LML = 8 µg/m³).

ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSIS FOR THE REVIEW OF THE CLEAN POWER PLAN: PROPOSAL 10 (2017), https://www.epa.gov/sites/production/files/2017-10/documents/ria_proposed-cpp-repeal_2017-10_0.pdf.

The EPA routinely deals with this issue for carcinogens as well. See GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, *supra* note 78, at 1-14, 3-16 to -17 (describing the use of the “point of departure” method).

405. GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, *supra* note 78, at 3-16 to -17.

406. Opening Brief of State and Industry Petitioners, *supra* note 13, at 53.

a level below 12 $\mu\text{g}/\text{m}^3$ was needed to provide the rigorous protections the Act requires.”⁴⁰⁷ The group further asserted that if the EPA, in its 2013 NAAQS review of particulate matter, determined that the health benefits of reductions were “so uncertain that it [was] not appropriate to include exposures below 12 $\mu\text{g}/\text{m}^3$ within the ‘adequate margin of safety’ provided by the NAAQS,” the EPA should not later be able to claim that reductions below that same level will yield billions of dollars in benefits.⁴⁰⁸

However, over the course of several decades, the EPA has consistently considered and incorporated uncertainty into its assessments of the NAAQS on the basis of the relevant scientific research. In its 1997 Regulatory Impact Analysis for particulate matter, the EPA noted that “one significant source of uncertainty is the possible existence of a threshold concentration below which no adverse health effects occur.”⁴⁰⁹ The EPA addressed this uncertainty in its benefits calculations, providing a “high end” estimate, which assumed that health benefits from reductions in particulate matter occur “all the way down to background levels” for certain health effects.⁴¹⁰ The EPA also provided a “low end” estimate which assumed that health benefits from particulate matter reductions occur “only down to the level of the standard.”⁴¹¹

In 2006, the EPA acknowledged that there was a debate as to whether a threshold exists for particulate matter,⁴¹² and addressed the uncertainty by assuming that the particulate matter concentration-response function was linear within the concentrations “under consideration,” which the EPA defined to be above an assumed threshold of 10 $\mu\text{g}/\text{m}^3$.⁴¹³ The Agency also

407. *Id.*

408. *Id.* “EPA cannot justify its decision to regulate EGU HAPs under § 112 based on asserted public health benefits it only recently concluded did not justify regulation of those non-HAPs.” *Id.* at 51.

409. 1997 PM RIA, *supra* note 381, at 12-14.

410. *Id.*

411. *Id.*

412. 2006 PM RIA, *supra* note 336, at 5-20.

413. *Id.* at 5-7 (“The C-R function for fine particles is approximately linear within the range of ambient concentrations under consideration (above the assumed threshold of 10 $\mu\text{g}/\text{m}^3$). Thus, we assume that the [C-R] functions are applicable to estimates of health benefits associated with reducing fine particles in areas with varied concentrations of PM, including both regions that are in attainment with PM_{2.5} standards and those that do not meet the standards.”). However, the EPA also examined several alternative thresholds in a sensitivity analysis. *See id.* at 5-44 (“Five cutpoints (including the base case assumption) were included in this sensitivity analysis: (a) 14 $\mu\text{g}/\text{m}^3$ (assumes no impacts be-

noted that its Science Advisory Board, which provides advice to the EPA on benefits analysis methods, “model[ed] premature mortality associated with PM exposure as a non-threshold effect, that is, with harmful effects to exposed populations regardless of the absolute level of ambient PM concentrations.”⁴¹⁴

By 2012, a much larger number of studies had produced evidence of the health effects of particulate matter exposure at low levels. The EPA acknowledged that there was still uncertainty in the 2012 RIA, but both the language used by the Agency and the assumptions it makes reflect the growing body of evidence that particulate matter has health effects at low levels. Specifically, the EPA stated that it was “more confident in the magnitude of the risks we [estimated] from simulated PM_{2.5} concentrations that coincide with the bulk of observed PM concentrations.”⁴¹⁵ The EPA further acknowledged that it was “less confident in the risk we estimate from simulated PM_{2.5} concentrations that fall below the bulk of the observed data in these studies.”⁴¹⁶

The EPA likewise discussed uncertainties in developing the Mercury and Air Toxics Standards. The EPA calculated particulate matter reduction benefits for the Mercury and Air Toxics Standards using studies measuring health impacts below the

low the alternative annual NAAQS), (b) 12 $\mu\text{g}/\text{m}^3$ (c) 10 $\mu\text{g}/\text{m}^3$ (reflects comments from CASAC - 2005), (d) 7.5 $\mu\text{g}/\text{m}^3$ (reflects recommendations from SAB-HES to consider estimating mortality benefits down to the lowest exposure levels considered in the Pope 2002 study used as the basis for modeling chronic mortality) and (e) background or 3 $\mu\text{g}/\text{m}^3$ (reflects NRC recommendation to consider effects all the way to background).”) For the more stringent 7.5 $\mu\text{g}/\text{m}^3$ and 3 $\mu\text{g}/\text{m}^3$ threshold cutpoints, the sensitivity analyses estimated increased benefits relative to the assumed 10 $\mu\text{g}/\text{m}^3$ threshold, albeit with increasing uncertainty at lower concentrations. *See id.* at 5-81 to -84 (estimating greater reductions in mortality incidence and greater monetized benefits from reduced mortality risk for lower threshold cutpoints).

The 2008 RIA for PM reiterated the Science Advisory Board’s discussion of PM exposure as a non-threshold effect and endorsed the use of a non-threshold model at low concentrations. *See* 2008 FINAL OZONE RIA, *supra* note 252, at 6c-5 n.2 (“For the studies of long-term exposure, . . . the most careful work on this issue . . . report[s] that the associations between PM_{2.5} and both all-cause and cardiopulmonary mortality were near linear within the relevant ranges, with no apparent threshold. Graphical analyses of these studies . . . also suggest a continuum of effects down to lower levels. Therefore, it is reasonable for EPA to assume a no threshold model down to, at least, the low end of the concentrations reported in the studies.”).

414. 2006 PM RIA, *supra* note 336, at 5-20.

415. 2012 PM RIA, *supra* note 336, at 5-81.

416. *Id.*

NAAQS levels, but above the zero exposure level.⁴¹⁷ The LML of these studies helped inform EPA's analysis.⁴¹⁸ The EPA calculated the benefits at LMLs of major PM studies and found that 11% of the estimated benefits from avoided premature deaths occur at or above an annual mean PM_{2.5} level of 10 µg/m³,⁴¹⁹ and 73% of the benefits occur at or above 7.5 µg/m³.⁴²⁰ The EPA modeled benefits below the LML, in line with the Agency's acknowledgement that particulate matter is not a threshold pollutant, but noted that the Agency has lower confidence in the exact value of those estimates.⁴²¹ The EPA also noted that it addressed uncertainties in the magnitude of effects by following the same approach used by the Bush EPA in the 2006 particulate matter NAAQS RIA.⁴²²

However, the fact that uncertainty remains does not mean there is evidence to conclude that particulate matter causes no health effects below a certain level. As the EPA noted in the 2012 RIA, "[i]t is important to emphasize that 'less confidence' does not mean 'no confidence.' . . . [W]e still have high confidence that PM_{2.5} is causally associated with risk at those lower air quality concentrations."⁴²³ The EPA went on to note that although it uses benchmarks as part of its analysis, including the LML, this does not mean that the EPA views "these concentration benchmarks as a concentration threshold below which we would not quantify health benefits of air quality improvements."⁴²⁴ In short, the EPA has consistently acknowledged scientific uncertainty and accounts for it at various times, but this does not prevent the Agency from modeling health effects at low levels of exposure.⁴²⁵ And the EPA has found adverse health effects below

417. MATS RIA, *supra* note 21, at 5-98, 5-100.

418. *See id.*

419. *Id.* at 5-100. For the Laden et al. study, a major 2006 study and a follow up to the Harvard Six Cities study, 10 µg/m³ was the LML. *Id.* (citing Francine Laden et al., *Reduction in Fine Particulate Air Pollution and Mortality: Extended Follow-up of the Harvard Six Cities Study*, 173 AM. J. RESPIRATORY & CRITICAL CARE MED. 667 (2006)).

420. MATS RIA, *supra* note 21, at 5-100. For the Pope et al. study of 2002, another prominent study, 7.5 µg/m³ was the LML. *Id.* (citing C. Arden Pope III et al., *Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution*, 287 J. AM. MED. ASS'N 1132 (2002)).

421. MATS RIA, *supra* note 21, at 5-100.

422. *Id.* at 5-17.

423. 2012 PM RIA, *supra* note 336, at 5-81 to -82.

424. *Id.* at 5-82.

425. *See, e.g., id.* at ES-1; 2006 PM RIA, *supra* note 336, at ES-1; 1997 PM RIA, *supra* note 381, at ES-23 tbl.ES-3; 1984 PM RIA, *supra* note 376, at VI-

the NAAQS nearly every time the Agency has studied exposure effects below those levels.⁴²⁶

D. ADJUSTING BASELINES

In addition to asserting that particulate matter reductions below the NAAQS yield no health benefits, critics of regulations also attack the methods the EPA uses to measure these effects. Specifically, critics claim that the EPA has not adjusted the baseline to account for prior regulation of particulate matter, effectively “double counting” particulate matter benefits.⁴²⁷ This section addresses those criticisms, showing that the EPA practice has consistently accounted for emission reductions resulting from prior regulations in setting its basis of comparison.

A baseline is the status quo that would exist without a new regulation, and it is necessary to measure the benefits of the regulation. OMB Circular A-4 instructs agencies to “[i]dentify a baseline” so as to “evaluate properly the benefits and costs of regulations and their alternatives.”⁴²⁸ Baselines are straightforward in theory but quite complex in practice. For example, think of a rule that has already been promulgated but is not scheduled to go into effect immediately and will be rolled out over many years—or consider that the earlier rule may never be fully implemented if a later administration decides to repeal it. How should the EPA measure that earlier rule? Should the Agency include it in the baseline for a new regulation? The EPA has developed standard methods for handling such questions to promote uniformity across regulations, which are discussed in this section.

Opponents argue that the EPA is “double counting;” that is, inflating a regulation’s purported benefits by failing to account for existing regulations that will achieve the same reduction of the pollutant. According to one critic, the Agency “regularly flouts [a] basic principle of sound regulation by ignoring the PM_{2.5} and ozone reductions it has already mandated, and counting those reductions again as benefits in new rules. The same ton of pollutant thus serves to justify multiple rules, even though the pollution can only be prevented once.”⁴²⁹ Tellingly, former

15.

426. See *supra* Part III.B (cataloging the EPA’s consistent finding over three decades of adverse health effects from particulate matter below NAAQS levels).

427. See LESSER, *supra* note 26.

428. CIRCULAR A-4: REGULATORY ANALYSIS, *supra* note 66, at 2.

429. Gray, *supra* note 26.

Trump EPA Administrator Scott Pruitt expressed a commitment to ensuring that his Agency would not “double count” benefits from existing regulations; he asserted that the EPA “shouldn’t take pollutants that we regulate under our [NAAQS] program and then count that as a benefit when we’re already achieving that with other regulation and contribute it to . . . the Clean Power Plan cost-benefit analysis. And [the Obama Administration] did that because the costs were so extraordinary.”⁴³⁰

These claims ignore the reality that the EPA has maintained clear standards designed to prevent double counting. The EPA’s guidance on baselines states that it is the Agency’s common practice “to assume full compliance with regulatory requirements,”⁴³¹ which includes newly enacted but not yet implemented regulations.⁴³² This means that benefits from prior rules are accounted for in the baseline—these benefits are not ignored and then used again for a later regulation.⁴³³ The Agency specifically notes that this general rule allows the EPA to focus on incremental economic effects of the new rule “without double counting benefits and costs captured by analyses performed for other rules.”⁴³⁴

The EPA also explicitly discusses the ways in which it accounts for prior benefits achieved under the NAAQS. For the Mercury and Air Toxics Standards, the EPA notes that its baseline accounts for “the emissions reductions of SO_x, NO_x, directly emitted PM, and CO₂ . . . consistent with application of federal rules, state rules and statutes, and other binding, enforceable commitments in place by December 2010,”⁴³⁵ as well as the Cross-State Air Pollution Rule (CSAPR) as finalized in July 2011.⁴³⁶ Likewise, in the Clean Power Plan, the EPA states that it included in its baseline all state and federal air regulations either in effect or enacted and clearly delineated at the time.⁴³⁷

430. Justin Worland, *EPA Head Scott Pruitt Says Oil and Coal Companies He Met with Aren't 'Polluters,'* TIME (Oct. 20, 2017), <http://time.com/4990060/scott-pruitt-interview-epa-schedule-meetings> (showing Scott Pruitt’s interview with TIME).

431. GUIDELINES FOR PREPARING ECONOMIC ANALYSES, *supra* note 56, at 5-3.

432. *Id.* at 5-9.

433. *Id.*

434. *Id.*

435. MATS RIA, *supra* note 21, at 1-11.

436. *See id.*

437. *See* CLEAN POWER PLAN RIA, *supra* note 22, at 1-5 (“Base Case v.5.15 includes the Cross-State Air Pollution Rule (CSAPR), the Mercury and Air Toxics Rule (MATS), the proposed Carbon Pollution Standards for New Power

The EPA also notes in its Base Case, which documents the Agency's calculations of the baseline used to measure the benefits and costs of new regulations, that the baseline includes "NAAQS to the extent that state regulations . . . contain measures to bring non-attainment areas into attainment."⁴³⁸ The EPA further notes that "[a]part from these state regulations, individual permits issued by states in response to [NAAQS] are only captured [to the extent they are reported to EPA]."⁴³⁹ Thus, the EPA includes benefits from NAAQS requirements to the extent they are implemented by states. Such treatment makes sense in light of the regulatory structure created by the Clean Air Act. Under the Act, the EPA sets the NAAQS, which are a national standard for allowable air pollution levels. However, the NAAQS are implemented by the states through State Implementation Plans (SIPs). States have a great deal of discretion in determining how to work toward achieving the NAAQS. As a result of this structure, when the EPA promulgates the NAAQS and attempts to estimate the costs and benefits of these standards, the Agency must make a number of assumptions about how states will ultimately choose to regulate pollution. The SIPs provide a much clearer picture of the actual costs and benefits of the NAAQS. Further, it is the SIPs, and not the NAAQS, which are actually enforceable. The EPA used the SIPs as its baseline for the Mercury and Air Toxics Standards and the Clean Power Plan, which were promulgated to bring areas into attainment with the NAAQS.

Plants, the Cooling Water Intakes (316(b)) Rule, the Combustion Residuals from Electric Utilities (CCR), and other state and Federal regulations to the extent that they contain measures, permits, or other air-related limitations or requirements.").

438. U.S. ENVTL. PROT. AGENCY, EPA BASE CASE V.5.14 USING IPM: INCREMENTAL DOCUMENTATION 1 (2015), https://www.epa.gov/sites/production/files/2015-08/documents/epa_base_case_v514_incremental_documentation.pdf. The Base Case in place when the Mercury and Air Toxics Standards rule was promulgated in 2011 similarly included "ozone and particulate matter standards to the extent that some of the state regulations . . . contain measures to bring non-attainment areas into attainment." U.S. ENVTL. PROT. AGENCY, DOCUMENTATION FOR EPA BASE CASE V.4.10 USING THE INTEGRATED PLANNING MODEL, at 1-1 (2010) [hereinafter BASE CASE 4.10], <https://nepis.epa.gov/Exe/ZyPDF.cgi/P100CF8G.PDF?Dockey=P100CF8G.PDF>.

439. BASE CASE 4.10, *supra* note 438 (regarding which permits are included, the EPA specifically notes that "to the extent that they are reflected in the NOx rates reported to EPA under [CSAPR], Title IV and the NOx Budget Program which are incorporated in the base case and . . . to the extent that SO₂ permit limits are used in the base case to define the choice of coal sulfur grades that are available to specific power plants").

The EPA likewise accounts for rules that have the co-benefit of reducing NAAQS pollutants in its baseline for future NAAQS. Particulate matter is regulated directly under the NAAQS but is also affected indirectly by rules like the Mercury and Air Toxics Standards and the Clean Power Plan that directly target other pollutants. In a subsequent update of the NAAQS for particulate matter, the EPA stated that it included the Mercury and Air Toxics Standards in that baseline as well, noting that “[e]mission reductions achieved under rules that require specific actions from sources—such as [Mercury and Air Toxics Standards]—are in the baseline of this NAAQS analysis, as are emission reductions needed to meet the current NAAQS.”⁴⁴⁰

In its draft repeal of the Clean Power Plan, the Trump Administration also raises the issue of baselines. However, the Agency takes a different approach than other critics of these regulations. Rather than arguing that the EPA’s 2015 Regulatory Impact Analysis for the Clean Power Plan double counts particulate matter benefits, the proposed rule points out that particulate matter could be regulated in other ways. This is, of course, the case; particulate matter is regulated directly under the National Ambient Air Quality Standards. From this fact, the Trump EPA presents the following hypothetical:

“[H]ad those SO₂ and NO_x [particulate matter] reductions been achieved through other means, then they would have been represented in the baseline for this proposed repeal (as well as for the 2015 Final [Clean Power Plan]), which would have affected the estimated costs and benefits of controlling CO₂ emissions alone.”⁴⁴¹

The Agency then presents calculations of the forgone benefits of repealing the Clean Power Plan, with all of the SO₂ and NO_x benefits removed.⁴⁴² The logic seems to be that because these benefits *could* be achieved through other regulations, the Agency need not calculate the benefits of reducing the pollution through this regulation; rather, it can just assume the benefits have already been achieved through another regulation. Of course, such a regulation does not exist. The EPA cannot wish away benefits by pretending we live in a world where the benefits have already been achieved, and courts tasked with overseeing the EPA should not stand idly by while the Agency attempts to do so. Not only does the Trump Administration’s approach deviate from the

440. 2012 PM RIA, *supra* note 336, at ES-18.

441. Clean Power Plan Proposed Repeal, *supra* note 8, at 48,044 n.24.

442. *Id.* at 48,044–45.

EPA's longstanding methodology for determining baselines, but its benefits calculations also depart from reality.

IV. CONSIDERING CO-BENEFITS

Particulate matter reductions are often co-benefits, or ancillary benefits, from rules targeting other types of pollution.⁴⁴³ For example, the Mercury and Air Toxics Standards directly limit mercury emissions from power plants but would likewise have the effect of reducing particulate matter emissions. Similarly, the Clean Power Plan directly regulates carbon dioxide emissions from power plants because these well-known greenhouse gases contribute to global climate change.⁴⁴⁴ However, because the rule requires energy generators to internalize the cost of emissions, thus raising the cost of polluting, the rule would likely cause a shift in sources of energy production away from sources that produce large quantities of greenhouse gases, notably coal, to cleaner forms of energy. This shift would additionally have the effect of reducing particulate matter because coal-fired power plants are also significant sources of particulate pollution.

Critics of regulations argue that cost-benefit analyses for specific pollutants should not include co-benefits from reductions in non-targeted pollutants. They contend that only direct and quantifiable benefits resulting from the reduction of the specific pollutant at issue should be included in a rule's calculus. In their view, the consideration of co-benefits extends beyond the scope of the problems Congress intended to address, and instead is a "sleight of hand" to "circumvent the[] statutory limitations on [the EPA's] authority."⁴⁴⁵ According to regulation opponents, "[p]ermitting EPA to use such illusory and statutorily irrelevant co-benefits to justify the Rule would . . . amount to an unconstitutional delegation of legislative power."⁴⁴⁶

443. Of course, for the NAAQS regulating particulate matter, benefits from PM reduction are the target benefits.

444. See, e.g., INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, CLIMATE CHANGE 2013—THE PHYSICAL SCIENCE BASIS: WORKING GROUP I CONTRIBUTION TO THE FIFTH ASSESSMENT REPORT OF THE INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE 467 (Thomas F. Stocker et al. eds., 2014); NAT'L RESEARCH COUNCIL, CLIMATE STABILIZATION TARGETS: EMISSIONS, CONCENTRATIONS, AND IMPACTS OVER DECADES TO MILLENNIA 3–4 (2011); *Climate Change Science: Causes of Climate Change*, U.S. ENVTL. PROTECTION AGENCY, <https://19january2017snapshot.epa.gov/climate-change-science/causes-climate-change.html> (last updated Dec. 27, 2016).

445. Brief for the Cato Institute as Amicus Curiae in Support of Petitioners, *supra* note 294, at 4.

446. Brief of 166 State and Local Business Ass'ns as Amici Curiae in Support

This theme arose prominently in the litigation leading to *Michigan v. EPA*, where co-benefits were attacked as a means of impermissibly enabl[ing the EPA] to expand its authority to conduct additional PM_{2.5} regulation without following the proper procedures of imposing such restrictions upon the country.⁴⁴⁷ Critics argued that the Agency “routinely takes credit for reductions of PM_{2.5} caused by rules that address harms from other pollutants” as a “power grab” in order to regulate “outside the specific [statutory] authority under which they are acting”⁴⁴⁸ and to obligate further PM_{2.5} reductions beyond those required under other Clean Air Act programs.⁴⁴⁹ Mercury, the pollutant directly regulated by the Mercury and Air Toxics Standards, was deemed “a Trojan horse used to justify regulation under Section 112, when EPA’s real focus was particulate-matter emissions by power plants, which the agency has targeted across numerous rulemakings in recent years.”⁴⁵⁰ Because they are not targeted by the section of the statute upon which the rule is based, critics argue that including co-benefits circumvents the Clean Air Act by additionally reducing pollutants that are directly regulated by other sections of the Act,⁴⁵¹ so as to “indirectly require further reductions in PM_{2.5} emissions from power plants that EPA would be unable to require directly.”⁴⁵² At oral argument in the *Michigan* case, Chief Justice John Roberts suggested that indirect benefits merely served as “an end run” around statutory restrictions.⁴⁵³ Chief Justice Roberts also noted that he believed it was a “good thing if your regulation also benefits in other ways.

of Petitioners at 26, *West Virginia v. EPA*, Nos. 15-1363 et al. (D.C. Cir. Feb. 23, 2016).

447. Motion for Leave to File Amicus Curiae Brief and Brief of the Chamber of Commerce of the United States of America as Amicus Curiae in Support of Petitioners at 1–4, *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (Nos. 14-46, 14-47, 14-49).

448. *Id.* at 16–17.

449. *Id.* at 23.

450. Brief for the Cato Institute as Amicus Curiae in Support of Petitioners, *supra* note 294, at 22.

451. *See* Opening Brief of State and Industry Petitioners, *supra* note 13, at 47.

452. Brief of the Chamber of Commerce of the United States of America, the National Ass’n of Manufacturers, the National Federation of Independent Bus., and the National Ass’n of Home Builders as Amici Curiae in Support of Petitioners, *supra* note 297, at 16.

453. *See* Opening Brief of State and Industry Petitioners, *supra* note 13, at 47 (internal citations omitted) (noting that at oral argument in *Michigan*, Chief Justice Roberts described relying on co-benefits as “an end run” around § 109’s restrictions and as an issue that “raises the red flag”).

But when it's such a disproportion, you begin to wonder whether it's an illegitimate way of avoiding the different—quite different limitations on EPA that apply in the criteria program.”⁴⁵⁴

Opponents contend that even if a rule yields co-benefits, those effects are essentially “irrelevant”⁴⁵⁵ or mere “regulatory externalities”⁴⁵⁶ that should play no part in a cost-benefit analysis. Critics of co-benefits have called their use a “well-worn accounting trick”⁴⁵⁷ and “a controversial and legally dubious accounting method.”⁴⁵⁸ Petitioners in *Michigan v. EPA* argued that “ancillary co-benefits from lower PM_{2.5} emissions are not *relevant* benefits for the purpose of deciding whether it is appropriate to regulate [hazardous air pollutant] emissions from electric utilities. Congress required EPA to determine whether reducing emissions of hazardous air pollutants (not PM_{2.5}) is ‘appropriate.’”⁴⁵⁹ Put differently:

Even if Congress intended that EPA may consider co-benefits—a concept found nowhere in the statute—in setting technology-based standards, Congress certainly did not dictate that the purported co-benefits may force regulation of [hazardous air pollutants] under Section 112(n)(1)(A) where the reductions of the [hazardous air pollutants] themselves provide no relative benefits in comparison to the substantial costs of regulation.⁴⁶⁰

Others have called co-benefits “inflated”⁴⁶¹ and “unlawful[,] . . . obscur[ing] the impact of the rule on the targeted pollutant (CO₂) and creates deliberate confusion regarding the Rule’s costs and benefits.”⁴⁶²

454. Clean Power Plan Proposed Repeal, *supra* note 8, at 48,044 n.23 (quoting Chief Justice Roberts at oral argument in *Michigan v. EPA*).

455. Brief for the Cato Institute as Amicus Curiae in Support of Petitioners, *supra* note 294, at 3; Opening Brief of State and Industry Petitioners, *supra* note 13, at 49.

456. Brief of Amicus Curiae Cato Institute in Support of Petitioners, *supra* note 298, at 4.

457. Brief of 166 State and Local Business Associations as Amici Curiae in Support of Petitioners, *supra* note 446.

458. Brief of the Chamber of Commerce of the United States of America, the National Ass’n of Manufacturers, the National Federation of Independent Business, and the National Ass’n of Home Builders as Amici Curiae in Support of Petitioners, *supra* note 297, at 3.

459. Brief for Petitioners State of Michigan, et al. at 48, *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (Nos. 14-46, 14-47, 14-49) (emphasis in original).

460. Brief of the Chamber of Commerce of the United States of America, the National Ass’n of Manufacturers, the National Federation of Independent Business, and the National Ass’n of Home Builders as Amici Curiae in Support of Petitioners, *supra* note 297, at 22.

461. Gray, *supra* note 26.

462. Brief of 166 State and Local Business Ass’ns as Amici Curiae in Support

In the case of the Clean Power Plan, critics argue that “[w]ithout the artificial consideration of these purported co-benefits, the Rule’s benefits would be seen for what they are: vastly exceeded by its costs.”⁴⁶³ The Trump EPA echoed this claim when, in announcing the repeal of the Clean Power Plan, it decried co-benefits as “essentially hiding” the plan’s true cost.⁴⁶⁴ The Trump Administration EPA also described the Obama Administration’s inclusion of co-benefits in the Plan as an area of “controversy and/or uncertainty,”⁴⁶⁵ suggesting that the incorporation of these benefits is outside common EPA practice.

The arguments against considering co-benefits ring hollow, however, when looked at in context. The EPA has consistently and over multiple presidential administrations considered both co-benefits and their mirror image, indirect costs, in evaluating the consequences of regulation. Removing co-benefits would mean systematically considering a narrower range of benefits than costs, because it would leave intact the EPA’s current practice of measuring indirect costs while ignoring co-benefits.⁴⁶⁶ Were this not the case, critics would potentially have a valid point. Were it true that the EPA only considers indirect effects that are benefits, then the EPA arguably would be inflating benefits, as critics accuse.⁴⁶⁷ However, because the EPA does consider both indirect costs and benefits, what critics really want is to put a thumb on the scale against regulation by forcing the EPA to ignore some indirect effects while embracing others. This Part examines the well-established use of co-benefits in cost-benefit analyses by presidential administrations, the EPA, and the courts, as well as their endorsement in the academic literature.

A. CO-BENEFITS AND INDIRECT COSTS

The question of how to measure indirect costs and benefits arises in the context of cost-benefit analyses. Federal agencies have been required to perform these analyses since 1981, when President Reagan issued Executive Order 12,291.⁴⁶⁸ Previous

of Petitioners, *supra* note 446, at 27.

463. *Id.*

464. See *EPA Takes Another Step to Advance President Trump’s America First Strategy*, *supra* note 64.

465. See *id.*

466. For a more detailed discussion of co-benefits as the “mirror image” of indirect costs, see Rascoff & Revesz, *supra* note 4.

467. See Gray, *supra* note 26.

468. Exec. Order No. 12,291, 46 Fed. Reg. 13,193, 13,193–94 (Feb. 19, 1981).

presidents had required some assessment of the impacts of proposed regulatory actions,⁴⁶⁹ but the Reagan Administration was the first to formalize this requirement.⁴⁷⁰ The EPA's early cost-benefit analyses focused only on the direct costs and benefits of regulations.⁴⁷¹ However, substantial academic, administrative, and judicial attention turned to the consideration of countervailing risks in the 1990s with the publication of *Risk Versus Risk* by John D. Graham and Jonathan Baert Wiener.⁴⁷² The book outlined the leading framework for considering indirect costs, also known as countervailing risks: risk-risk analysis.⁴⁷³ The guiding principal of risk-risk analysis, as conceived by Graham and Wiener, is that regulations intended to minimize or eliminate certain health or environmental risks can have the perverse effect of promoting other risks, and thus a more comprehensive and accurate accounting of regulatory effects would consider these countervailing risks.⁴⁷⁴

469. See, e.g., Exec. Order No. 12,044, 43 Fed. Reg. 12,661, 12,662–63 (Mar. 24, 1978) (requiring agencies to consider “the direct and indirect effects of the regulation” and report a “Regulatory Analysis” that contains “an analysis of the economic consequences of . . . [regulatory] alternatives”). See generally Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 11, 13 (1995) (tracing the President’s control over the regulatory state to “Theodore Roosevelt’s creation, in 1903, of a commission designed to study the scientific work done by government agencies” and the “Nixon Administration’s system of ‘Quality of Life’ reviews” in which “agencies were required to submit significant rules to [the] OMB in advance of publication in the Federal Register”).

470. Exec. Order No. 12,291 was later revoked and replaced by President Clinton under Executive Order 12,866, which remains in effect today. See Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993). President Obama reinforced the continued viability of this order and expanded it modestly under Executive Order 13,563, which moderately increased the scope of cost-benefit analyses to permit consideration of “values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.” Exec. Order No. 13,563, 76 Fed. Reg. 3821, 3821 (Jan. 21, 2011).

471. See, e.g., Exec. Order 12,291, 46 Fed. Reg. at 13,194 (only requiring agencies to provide a “description of the potential benefits [and costs] of the rule”).

472. RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (John D. Graham & Jonathan Baert Wiener eds., 1995).

473. Graham and Wiener coined the term “risk tradeoff analysis.” John D. Graham & Jonathan Baert Wiener, *Confronting Risk Tradeoffs*, in RISK VERSUS RISK, *supra* note 472, at 1, 4.

474. RISK VERSUS RISK, *supra* note 472, at 270. For example, Graham examines Corporate Average Fuel Economy (CAFE) standards, a Department of Transportation regulation intended to improve automobile fuel standards and reduce attendant environmental and health harms, as potentially promoting countervailing risks in the economic, energy, and national security sectors. John D. Graham, *Saving Gasoline and Lives*, in RISK VERSUS RISK, *supra* note 472,

Risk-risk analysis picked up traction among academics specializing in administrative law. In addition to Graham and Wiener, Professor Cass Sunstein, a prominent administrative law scholar and the head of the Office of Information and Regulatory Affairs (OIRA) under President Obama, advocated at that time for broad application of risk-risk analysis.⁴⁷⁵ W. Kip Viscusi, a prominent economist and leading proponent of cost-benefit analysis, also endorsed risk tradeoff analysis in the regulatory process.⁴⁷⁶

Judges at this time began to embrace risk-risk analysis as well. Justice Breyer, concurring in *Whitman v. American Trucking Ass'ns*, agreed with the Court's unanimous ruling that the Clean Air Act prohibits the consideration of costs in setting the NAAQS but wrote separately to argue that the "statute . . . permits the Administrator to take account of comparative health risks."⁴⁷⁷ Judge Stephen Williams of the D.C. Circuit was also a notable proponent of risk-risk analysis. For example, in a concurrence in *International Union, United Automobile, Aerospace & Agricultural Implement Workers v. OSHA*, Judge Williams used risk-risk analysis to challenge what he viewed as the "casual assumption that more stringent regulation will always save lives."⁴⁷⁸ He argued that the health-wealth connection⁴⁷⁹ required consideration of negative economic effects of regulation

at 87–103. In a separate article, Wiener discusses how risk-risk analysis reveals a "bewildering array of countervailing risks that face efforts to prevent global warming." Jonathan Baert Wiener, *Protecting the Global Environment, in RISK VERSUS RISK*, *supra* note 472, at 193–225.

475. See, e.g., Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533, 1537 (1996); see also Rascoff & Revesz, *supra* note 4, at 1764–65.

476. See, e.g., W. Kip Viscusi, *Regulating the Regulators*, 63 U. CHI. L. REV. 1423, 1455 (1996) (arguing that "regulatory agencies should be concerned with this broader effect [ancillary costs] of regulatory policy since their mandate is to improve the health and welfare of citizens generally"); see also Rascoff & Revesz, *supra* note 4, at 1792.

477. 531 U.S. 457, 495 (2001) (Breyer, J., concurring). The D.C. Circuit opinion in that case examined a different countervailing risk: less protection from harmful ultraviolet radiation as a result of reducing ozone pollution. *Am. Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1036–37 (D.C. Cir. 1999), *rev'd on other grounds sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

478. 938 F.2d 1310, 1326 (D.C. Cir. 1991) (Williams, J., concurring).

479. There is much evidence to suggest that the "health-wealth" effect, which asserts that less wealth causes worse health outcomes, is fallacious. For a detailed discussion of this criticism, see RICHARD L. REVESZ & MICHAEL A. LIVERMORE, *RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH* 67–76 (2008), which questions the "health-wealth" effect and offers alternative explanations for both

and their purported effect on health: “More regulation means some combination of reduced value of firms, higher product prices, fewer jobs in the regulated industry, and lower cash wages. All the latter three stretch workers’ budgets tighter. . . . And larger incomes enable people to lead safer lives.”⁴⁸⁰

The growing focus on examining the broader range of regulatory effects ultimately led to Office of Management and Budget Circular A-4, which was promulgated when John D. Graham served as Administrator of OIRA.⁴⁸¹ OIRA, which resides with the Office of Management and Budget, is responsible for overseeing regulatory efforts of administrative agencies and has the power to issue guidance which they must follow.⁴⁸² Circular A-4 guides federal agencies in the cost-benefit regulatory analyses required under Executive Order 12,866,⁴⁸³ “standardizing the way benefits and costs of Federal regulatory actions are measured and reported.”⁴⁸⁴ As part of this standardization, Circular A-4 explicitly requires the consideration of countervailing risks, enshrining the analysis of the type of risks Graham and Weiner identified.⁴⁸⁵ However, Circular A-4 goes a step further by likewise requiring consideration of ancillary benefits.⁴⁸⁶ The Circular instructs agencies to “look beyond the direct benefits and direct costs” to “consider any important ancillary benefits and countervailing risks.”⁴⁸⁷ Further, it states that “[t]he same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks.”⁴⁸⁸

B. THE EPA’S PRACTICE

The EPA has long acknowledged the relevance of co-benefits, and specifically has done so for regulations promulgated under the Clean Air Act. First, the EPA’s current guidelines for

health and wealth—notably, education—as well as the potential for reverse causation (i.e., that worse health causes lower wealth).

480. 938 F.2d at 1326.

481. CIRCULAR A-4: REGULATORY ANALYSIS, *supra* note 66, at 1.

482. See The Paperwork Reduction Act of 1980, 44 U.S.C. §§ 3501–21 (1980) (establishing the Federal Office of Information and Regulatory Affairs (OIRA)).

483. CIRCULAR A-4: REGULATORY ANALYSIS, *supra* note 66, at 1.

484. *Id.*

485. See RISK VERSUS RISK, *supra* note 472.

486. CIRCULAR A-4: REGULATORY ANALYSIS, *supra* note 66, at 26.

487. *Id.*

488. *Id.*

cost-benefit analyses, which were adopted in 2010 after extensive peer review, instruct the Agency to assess “all identifiable costs and benefits,”⁴⁸⁹ and state that an economic analysis of regulations should include both “directly intended effects . . . as well as ancillary (or co-) benefits and costs.”⁴⁹⁰ The aim of these analyses is to “inform decision making” and allow meaningful comparisons between policy alternatives.⁴⁹¹

These guidelines build on principles applied in previous administrations. For example, the George W. Bush EPA used similar language in its 2008 draft “Guidelines for Preparing Economic Analyses,” declaring that “[a]n economic analysis of regulatory or policy options should present all identifiable costs and benefits that are incremental to the regulation or policy under consideration. These should include directly intended effects and associated costs, as well as ancillary (or co-) benefits and costs.”⁴⁹² The proposed George W. Bush guidelines also stated that “[f]or a regulation that is expected to have substantial indirect effects beyond the regulated sector, it is important to choose a model that can capture those effects.”⁴⁹³

Likewise, the Clinton EPA’s guidelines for conducting cost-benefit analyses endorsed the importance of considering indirect costs and benefits.⁴⁹⁴ Issued in 2000, the Clinton guidelines included indirect costs as a component of its calculations for health and social costs.⁴⁹⁵ Emphasizing that “[a] complete benefits analysis is also useful because it makes explicit the assumptions about the value of benefits embedded in different policy choices,”⁴⁹⁶ the guidelines determined that indirect benefits are cognizable, focusing on indirect ecological benefits.⁴⁹⁷ Moreover,

489. U.S. ENVTL. PROT. AGENCY, GUIDELINES FOR PREPARING ECONOMIC ANALYSES, at 11-2 (2010) [hereinafter OBAMA EPA GUIDELINES], <https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf>.

490. *Id.*

491. *Id.* at 7-1.

492. U.S. ENVTL. PROT. AGENCY, GUIDELINES FOR PREPARING ECONOMIC ANALYSES (EXTERNAL REVIEW DRAFT), at 10-4 (2008) (on file with author).

493. *Id.* at 8-17.

494. U.S. ENVTL. PROT. AGENCY, GUIDELINES FOR PREPARING ECONOMIC ANALYSES 67, 70, 81 (2000), <https://www.epa.gov/sites/production/files/2017-09/documents/ee-0228c-07.pdf>.

495. *Id.* at 82–83, 94, 114–15.

496. *Id.* at 59.

497. *Id.* at 70 (noting that “[e]cosystem services that do not directly provide some good or opportunity to individuals may be valued because they support off-site ecological resources or maintain the biological and biochemical processes required for life support”).

the guidelines noted that “immediately following a net benefit calculation, there should be a presentation and evaluation of all benefits and costs that can only be quantified but not valued, as well as all benefits and costs that can be only qualitatively described.”⁴⁹⁸ The implication is that, even for effects that cannot be monetized, informed decision-making requires consideration of all benefits and costs, not just direct ones. In short, all three iterations of guidelines authored by the EPA—the 2000 guidelines, the 2008 draft guidelines, and the 2010 guidelines—called for the use of co-benefits in cost-benefit analyses.

The EPA’s cost-benefit analyses for clean air rules have also long included co-benefits.⁴⁹⁹ The EPA began acknowledging these benefits in Clear Air Act rules all the way back in the 1980s. In 1985, the EPA under President Ronald Reagan conducted an extensive analysis of co-benefits from reductions of non-target pollutants in its landmark 1985 regulation reducing lead in gasoline, including an analysis of benefits from reductions in ozone, nitrogen oxides, and hydrocarbons.⁵⁰⁰ As part of this analysis, the EPA found monetized co-benefits from reducing hydrocarbons, nitrogen oxides, and carbon monoxide, benzene, and other non-targeted pollutants to be worth an estimated \$222 million over just a one-year period.⁵⁰¹ The Reagan-era EPA also proposed developing New Source Performance Standards for municipal waste combustors.⁵⁰² As part of this proposal, the EPA discussed the importance of considering “indirect benefits” from its regulation of toxic emissions from municipal waste combustors.⁵⁰³ The EPA explained that it would include “indirect

498. *Id.* at 177.

499. The Senate Report accompanying the 1990 Clean Air Act amendments indicated that the EPA could take co-benefits into account when setting standards for hazardous air pollutants. S. REP. NO. 101-228, at 172 (1989) (“When establishing technology-based standards under this subsection, the Administrator may consider the benefits which result from the control of air pollutants that are not listed but the emissions of which are, nevertheless, reduced by control technologies or practices necessary to meet the prescribed limitation.”).

500. U.S. ENVTL. PROT. AGENCY, EPA-230-05-85-006, COSTS AND BENEFITS OF REDUCING LEAD IN GASOLINE: FINAL REGULATORY IMPACT ANALYSIS, at VI-1 to -74 (1985), <https://yosemite.epa.gov/ee/epa/erm.nsf/vwan/ee-0034-1.pdf/%24file/ee-0034-1.pdf>.

501. *Id.* at E-8.

502. *See* Assessment of Municipal Waste Combustor Emissions Under the Clean Air Act, 52 Fed. Reg. 25,399 (July 7, 1987) (codified at 40 C.F.R. pt. 60).

503. *Id.* at 25,406.

benefits accruing from concomitant reductions in other regulated pollutants.”⁵⁰⁴

Under President George H.W. Bush, the EPA in 1991 justified performance standards in a proposed rule for landfill gases in part on “the ancillary benefit of reducing global loadings of methane.”⁵⁰⁵ Further, the EPA examined countervailing climate change risks. The Agency noted that carbon dioxide emissions under the proposed standard would increase, but justified regulation in part because of the climate change benefits from methane emission reductions.⁵⁰⁶ The EPA took into consideration both the ancillary benefits of methane reductions in reducing greenhouse gas pollution as well as the countervailing risk of increasing carbon dioxide emissions.⁵⁰⁷ The EPA’s judgment on how to regulate was guided by the full scope of effects.

The EPA under President Bill Clinton in a 1998 rule establishing standards for hazardous air pollutant emissions from pulp and paper producers analyzed indirect effects, both co-benefits from reductions in emissions and indirect costs from increases in emissions, for NAAQS criteria pollutants.⁵⁰⁸ Though hazardous air pollutants were directly targeted by the rule, the EPA nonetheless analyzed the effects of its regulation on other air pollutants, including the criteria pollutants.⁵⁰⁹ For the “Best Available Technology” standards which govern existing plants,⁵¹⁰ the EPA estimated small increases in emissions of carbon monoxide, nitrogen oxides, and sulfur dioxides from the rule, but a significant decrease in particulate matter.⁵¹¹ For the New Source Performance Standards, which govern new sources of emissions, the EPA concluded that in addition to decreasing hazardous air pollutants, the rule would also decrease many criteria pollutant emissions including particulate matter.⁵¹² Rather than

504. *Id.*

505. Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills, 56 Fed. Reg. 24,468, 24,469 (May 30, 1991) (codified at 40 C.F.R. pts. 51, 52, and 60).

506. *Id.* at 24,472.

507. *Id.*

508. See National Emission Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Pulp, Paper, and Paperboard Category, 63 Fed. Reg. 18,504, 18,504, 18,576 (Apr. 15, 1998) (codified at 40 C.F.R. pts. 63, 261, and 430).

509. *Id.* at 18,576–77.

510. See *id.* at 18,508.

511. *Id.* at 18,576.

512. *Id.* at 18,579.

ignoring some or all of these effects because they did not derive from the target pollutants, the EPA estimated these effects and analyzed them as part of its rule-making process.

In 2005, the EPA under George W. Bush noted that its Clean Air Interstate Rule, which targeted particulate matter and ozone emissions, would also reduce mercury emissions,⁵¹³ and included the benefits from mercury reductions in its cost-benefit analysis for the rule.⁵¹⁴ The Bush EPA also discussed co-benefits as part of a regulation governing hazardous air pollutants from mobile sources (primarily cars).⁵¹⁵ The Agency noted that though the rule dealt with control of air toxics and not criteria pollutants including particulate matter and ozone, “this co-benefit . . . is significant.”⁵¹⁶ The EPA calculated that the standards would reduce exhaust emissions of direct particulate matter by over 19,000 tons in 2030 nationwide.⁵¹⁷ The Agency also analyzed the effects of the rule on ozone emissions, concluding that overall ozone emissions reductions would be small, but some areas would have “non-negligible improvements in projected eight-hour ozone.”⁵¹⁸ The EPA further noted that it viewed “these improvements as useful in meeting the eight-hour ozone NAAQS.”⁵¹⁹

In sum, the EPA has consistently examined a full range of effects from regulations. Rather than arbitrarily ignoring certain effects because they are ancillary or indirect, the EPA discusses and analyzes indirect costs and co-benefits. The Agency has done so through multiple presidential administrations of different parties, and in a wide range of clean air regulations. These practices have been standard since the Reagan Administration. Two of its OIRA administrators, Christopher DeMuth and Judge Douglas Ginsburg, noted that: “the EPA and other agencies frequently include ancillary benefits in their benefits estimates.”⁵²⁰

513. Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NOx SIP Call, 70 Fed. Reg. 25,162, 25,170 (May 12, 2005) (codified at 40 C.F.R. pts. 51, 72, 73, 74, 77, 78, and 96).

514. *Id.* at 25,312.

515. Control of Hazardous Air Pollutants from Mobile Sources, 72 Fed. Reg. 8428, 8430, 8461 (Feb. 26, 2007) (codified at 40 C.F.R. pts. 59, 80, 85, and 86).

516. *Id.* at 8461.

517. *Id.* at 8453.

518. *Id.* at 8458.

519. *Id.*

520. Christopher C. DeMuth & Douglas H. Ginsburg, *Rationalism in Regulation*, 108 MICH. L. REV. 877, 887 (2010) (reviewing REVESZ & LIVERMORE, *supra* note 479).

They also observed that “OIRA itself recommends that agencies account for ancillary benefits as well as countervailing risks.”⁵²¹ Similarly, high-profile Obama-era EPA regulations like the Mercury and Air Toxics Standards and the Clean Power Plan reflect the requirement of OMB Circular A-4 that the Agency consider co-benefits, and the requirement of the EPA’s own guidelines to consider “all identifiable costs and benefits.”⁵²² The inclusion of co-benefits in these regulations is well in line with the longstanding practice of the EPA to include co-benefits and countervailing risks in its assessment of clean air regulations.

C. JUDICIAL RECOGNITION

Courts are often asked to review the adequacy of an agency’s cost-benefit analysis, and in this context they have addressed the issue of indirect benefits and costs.⁵²³ Reviewing courts have frequently required agencies to include ancillary impacts.⁵²⁴ This Section first discusses judicial decisions requiring the consideration of indirect risks, and then turns to the nascent case law on co-benefits.

In 1991, the Fifth Circuit rejected the EPA’s attempt to ban asbestos-based brakes under the Toxic Substances Control Act.⁵²⁵ A central part of the court’s holding was its finding that the EPA needed to consider the indirect safety effects of other potential, non-asbestos options for car breaks.⁵²⁶ The court determined that under the Toxic Substances Control Act, the EPA “was required to consider both alternatives to a ban and the costs of any proposed actions and to ‘carry out [the Act] in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.’”⁵²⁷ The court noted with disapproval that the Agency had not evaluated the harm from increased use of substitute products.⁵²⁸ Because the EPA did not

521. *Id.*

522. OBAMA EPA GUIDELINES, *supra* note 489.

523. *See generally* Cecot & Viscusi, *supra* note 41 (collecting and analyzing cases where courts reviewed agencies’ cost-benefit analyses).

524. *See, e.g.*, Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin., 956 F.2d 321, 323–25 (D.C. Cir. 1992); Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1229–30 (5th Cir. 1991).

525. *Corrosion Proof Fittings*, 947 F.2d at 1229–30.

526. *Id.* at 1225.

527. *Id.* at 1215 (quoting Toxic Substances Control Act, 15 U.S.C. § 2601(c) (1988)).

528. *Id.* at 1220–21.

account for “the dangers posed by the substitutes, including cancer deaths from the other fibers used and highway deaths occasioned by less effective, non-asbestos brakes,” the Agency’s “failure to examine the likely consequence of the EPA’s regulation render[ed] the ban of asbestos friction products unreasonable.”⁵²⁹ In short, the EPA’s cost-benefit analysis did not, in the court’s view, adequately address indirect costs and was therefore unsupported by “substantial evidence” as required under the statute.⁵³⁰

A year later the D.C. Circuit also struck down a regulation, this time promulgated by the National Highway Traffic Safety Administration (NHTSA), for failing to consider indirect costs.⁵³¹ NHTSA had attempted to increase fuel efficiency standards for cars.⁵³² The Agency failed to consider the potential increased safety risks because smaller, more fuel efficient cars might be less protective in a crash.⁵³³ The court admonished the Agency and required NHTSA to “reconsider the matter and provide a genuine explanation for whatever choice it ultimately makes.”⁵³⁴ Without calculating these indirect costs, the court found that the Agency had not met the requirement of reasoned decision-making.⁵³⁵

Other circuit court decisions have likewise addressed the issue of indirect costs and have rejected cost-benefit analyses that lacked an estimate of these effects. In 1993, the Seventh Circuit partially vacated an OSHA regulation putting standards in place to limit the transmission of communicable diseases.⁵³⁶ The Agency failed to consider the indirect health effects that might result if the rule increased health care costs and thus limited

529. *Id.* at 1224.

530. *Id.* at 1207.

531. *Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin.*, 956 F.2d 321, 323–25 (D.C. Cir. 1992).

532. *Id.* at 322–23.

533. *Id.* at 326–27.

534. *Id.* at 327.

535. *Id.* (“When the government regulates in a way that prices many of its citizens out of access to large-car safety, it owes them reasonable candor. If it provides that, the affected citizens at least know that the government has faced up to the meaning of its choice. The requirement of reasoned decision-making ensures this result and prevents officials from cowering behind bureaucratic mumbo-jumbo. Accordingly, we order NHTSA to reconsider the matter and provide a genuine explanation for whatever choice it ultimately makes.”).

536. *Am. Dental Ass’n v. Martin*, 984 F.2d 823, 823–27, 830–31 (7th Cir. 1993).

access to care.⁵³⁷ OSHA's "consideration of the indirect costs of the rule is thus incomplete."⁵³⁸ Similarly, the D.C. Circuit also rebuffed an EPA regulation revising the NAAQS for ozone and particulate matter in 1999 because in the court's view, the Agency failed to consider the potential health detriments from lowering pollution.⁵³⁹ Specifically, the EPA failed to consider whether "ground-level (tropospheric) ozone—the subject of th[e] rule—has [an ultraviolet radiation]-screening function independent of the ozone higher in the atmosphere"⁵⁴⁰ with indirect health benefits, such as reducing incidences of cataracts and skin cancers.⁵⁴¹ The court asserted that by ignoring these consequences, the EPA looked only at "half of a substance's health effects."⁵⁴² As a result, the Agency's interpretation of Title VI of the Clean Air Act⁵⁴³ failed under the reasonableness standard laid out in *Chevron U.S.A. Inc. v. Natural Resource Defense Council, Inc.*⁵⁴⁴ In 2002, the D.C. Circuit also overturned two Federal Communications Commission rules for the Agency's failure to consider the rules' indirect costs⁵⁴⁵ in contravention of the language and objectives of the Telecommunication Act.⁵⁴⁶

537. *Id.* at 826 ("OSHA also exaggerated the number of lives likely to be saved by the rule by ignoring lives likely to be sacrificed by it, since the increased cost of medical care, to the extent passed on to consumers, will reduce the demand for medical care, and some people may lose their lives as a result.").

538. *Id.* (citing a comparison to *Competitive Enter. Inst.*, 956 F.2d 321).

539. *Am. Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1036–37 (D.C. Cir. 1999), *rev'd on other grounds sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

540. *Id.* at 1052.

541. *Id.* at 1051.

542. *Id.* at 1052.

543. Clean Air Act, 42 U.S.C. §§ 7671–7671q (2012).

544. *Am. Trucking Ass'ns*, 175 F.3d at 1052 (citing *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984)).

545. *U.S. Telecom Ass'n v. FCC*, 290 F.3d 415, 424–25 (D.C. Cir. 2002). One rule required incumbent local exchange carriers to lease "unbundled network elements" to competitive local exchange carriers (CLECs), while the other rule unbundled the spectrum of local copper loops such that the CLECs would be positioned to offer competitive internet access. *Id.* at 417. However, the court found that the Commission "loftily abstracted away all specific markets" and did not take into account indirect cost differentials in different competitive markets. *Id.* at 423. Moreover, the Agency "completely failed to consider the relevance of competition in broadband services coming from cable" and satellite companies, another crucial indirect cost. *Id.* at 428.

546. *Id.* at 427–29 (noting that the FCC "must 'apply some limiting standard, rationally related to the goals of the Act,' . . . [and] 'cannot, consistent with the statute, blind itself to the availability of elements outside the incumbent's network.'" (quoting *AT&T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 388–89 (1999))).

Futhermore, the D.C. Circuit has explicitly addressed the “mirror image” of indirect costs: co-benefits.⁵⁴⁷ In 2016, the court’s decision in *United States Sugar Corp. v. EPA* upheld the EPA’s consideration of co-benefits in regulating the effects of reducing hazardous air pollutants from boilers, process heaters, and incinerators.⁵⁴⁸ Specifically, the EPA decided not to adopt more lenient hydrogen chloride emission standards, reasoning that it could weigh additional factors such as the “cumulative adverse health effects due to concurrent exposure to other [hazardous air pollutants] or emissions from other nearby sources” and the “potential impacts of increased emissions on ecosystems.”⁵⁴⁹ Industry challengers argued that the EPA’s consideration of these co-benefits in its decision to maintain the more stringent emissions standard rendered the Agency’s decision arbitrary and capricious under the Administrative Procedure Act.⁵⁵⁰ The EPA asserted that “its consideration of these co-benefits was not a regulation of other pollutants; rather, it was simply choosing not to ignore the purpose of the [Clean Air Act]—to reduce the negative health and environmental effects of [hazardous air pollutant] emissions—when exercising its discretionary authority under the Act.”⁵⁵¹ The D.C. Circuit held that the EPA acted within its legal authority when it considered not only the direct benefits of reducing hydrogen chloride, but also the co-benefits from that reduction—namely, indirect reductions of other hazardous air pollutants.⁵⁵² The court agreed that the use of co-benefits conforms with the Clean Air Act’s purpose, finding that “[t]he EPA was . . . free to consider potential co-benefits that might be achieved” from enforcing the more stringent standard.⁵⁵³

Courts that have examined cost-benefit analyses have acknowledged the logic of evaluating the indirect effects of regulations and using this information to guide the rule-making process. While there have been more cases concerning indirect costs, modern cases have addressed indirect benefits as well and no court has said there is any reason to treat them differently. Courts are correct to do so; these terms are merely descriptors

547. See Rascoff & Revesz, *supra* note 4, at 1793 (noting that indirect costs and indirect benefits “are simply mirror images of each other”).

548. 830 F.3d 579, 591, 625 (D.C. Cir. 2016).

549. *Id.* at 624.

550. *Id.* at 625.

551. *Id.*

552. *Id.* at 624–25.

553. *Id.* at 625.

that helpfully depict whether effects are positive or negative and they provide no justification for focusing on some effects while ignoring others.⁵⁵⁴ Further, as DeMuth and Ginsburg note, “[t]here appear to be no legal, political, or intellectual . . . impediments to treating ancillary benefits and countervailing risks equally in cost-benefit analysis and regulatory design.”⁵⁵⁵ It would therefore be incoherent to consider the negative indirect effects of regulations without also considering the positive indirect effects.

CONCLUSION

Considering co-benefits from reductions in particulate matter and other criteria pollutants below the NAAQS is clearly supported by science and long-standing EPA precedent. It is also necessary in order to give the public an accurate understanding of the effects of regulation and deregulation. Critics of regulation seek to paint benefits below the NAAQS as illusory and suggest their inclusion in rules targeting other pollutants is overreach by an overzealous regulator. In this Article, we have shown that this narrative rings hollow. Through multiple presidential administrations, the EPA has calculated benefits from criteria pollutant reductions below the NAAQS, following established science. The health and mortality reduction benefits are also exceptionally well documented for particulate matter reductions, and account for the bulk of the criteria pollutant benefits in the Mercury and Air Toxics Standards, Clean Power Plan, and likely in any future regulation of greenhouse gases. The EPA has consistently acknowledged there is no evidence supporting a threshold for particulate matter over the past thirty years and has calculated benefits from reductions below particulate matter NAAQS levels for two decades. The science on these benefits clearly indicates that no threshold can be identified and shows that reducing this pollution at levels well below the current NAAQS will yield dramatic health benefits.

The Trump Administration has embraced an anti-regulatory stance in its efforts to repeal the Clean Power Plan. The Administration, and other regulation opponents, suggest that their approach is a logical way to account for effects, arguing that including these benefits artificially inflates the positive effects of

554. See Rascoff & Revesz, *supra* note 4, at 1793 (“Risk tradeoffs and ancillary benefits are simply mirror images of each other. There is no justification for privileging the former and ignoring the latter.”).

555. DeMuth & Ginsburg, *supra* note 520, at 888.

regulating. But what they advocate is a dishonest attempt to obscure the actual effects of regulations from the public.

Ideological differences about the appropriate role for government to play in the control of pollution are a natural part of democratic debate. But public participation is a key attribute of a vibrant democracy, and such participation is meaningful only if the public is given accurate information about the effects of different proposals. Hiding these substantial benefits obscures the real-world effects of deregulation. We encourage policy makers and the courts that oversee them to embrace well-accepted science and economics, and to require transparent and accurate accounting of the benefits of air pollution regulations.