DESTABILIZING ENVIRONMENTAL REGULATION: THE TRUMP ADMINISTRATION'S CONCERTED ATTACK ON REGULATORY ANALYSIS

Richard L. Revesz*

ABSTRACT

Occasionally during his presidency, Trump has suggested that he cares deeply about clean air and water. But the specifics of Trump's deregulatory approach tell a different story. The Trump administration has undertaken a series of regulatory moves to weaken the analytical foundation for clean air and water regulations, thereby seeking to eliminate or undercut precisely those regulations that bring the biggest health benefits. The clean air regulations under the Clean Air Act, which account for the overwhelming majority of all quantified and monetized benefits of all federal regulation, are under particular threat.

Four specific analytical moves demand focus: first, shifting focus to costs and ignoring benefits of regulation; second, erasing public health science; third, reviving discredited scientific models; and fourth, eliminating indirect benefits from regulatory impact analysis. Individually, each of these four strategies, if fully enacted, would significantly harm the health and welfare of Americans. Together, they threaten a truly monumental reshaping of environmental and public health protection in the United States. These four moves—manifested in rules currently proposed or already passed by the EPA and other agencies—represent a concerted attack on rational economic analysis of regulation which has received little comprehensive discussion in the academy to date. When put together, these disparate deregulatory thrusts paint a picture of a deeply committed assault on rational policy-making.

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* Lawrence King Professor of Law and Dean Emeritus, New York University School of Law. The generous financial support of the Filomen D'Agostino and Max E. Greenberg Fund at NYU Law School is grateful acknowledged.

INTRODUCTION

It is common knowledge that the Trump administration has waged a highly public campaign against climate change regulation. Two major accomplishments of the Obama administration—an international climate change agreement, the Paris Climate Agreement, and Environmental Protection Agency (EPA) regulations of coal-fired power plants, the Clean Power Plan—have both been in Trump's crosshairs. For both the Paris Climate Agreement[1] and the Clean Power Plan,[2] the Trump administration has reversed course from the approach taken by the Obama administration. Trump has been unabashed in expressing his doubts about the scientific basis for climate change. When his own administration released the fourth congressionally mandated National Climate Assessment in 2018, highlighting the dire consequences climate change would have on the U.S. economy, Trump famously responded "I don't believe it."[3] At the 2020 World Economic Forum in Davos, Trump dramatically warned, "We must reject the perennial prophets of doom and their predictions of the apocalypse."[4]

Occasionally during his presidency, however, Trump has also suggested that he cares deeply about the environment. He has described himself as an environmentalist and professed his love for clean air and water. Trump assures us that: "I've done many environmental impact statements in my life, and I believe very strongly in very, very crystal clear clean water and clean air."[5] He claims he wants "the cleanest water on the planet" and "the cleanest air anywhere."[6] In 2019, when the EPA let California know that it would move to eliminate the state's backlog of California State Implementation Plans (SIPs) under the Clean Air Act, EPA Administrator Andrew Wheeler declared, "EPA stands ready to work with California to meet the Trump Administration's goal of clean, healthy air for all Americans."[7]

This rhetorical split—between criticism of climate change regulation on the one hand and praise for clean air and clean water regulation on the other—seems to position Trump as a part of a generational transition from the world of the Clean Air Act of 1970—a bipartisan bill that targeted the public health consequences of air pollution—to the more diffuse, existential threat of climate change. Trump claims to support old fashioned clean air and water rules, but not the modern consensus on climate change.

But the specifics of Trump's broader deregulatory approach tell a different story. The Trump administration has undertaken a series of regulatory moves to weaken the analytical foundation for clean air and water regulations, thereby seeking to eliminate or undercut precisely those regulations that bring the biggest health benefits. The clean air regulations under the Clean Air Act, which account for the overwhelming majority of all quantified and monetized benefits of all federal regulation, are under particular threat. Four specific analytical moves demand focus: first, shifting focus to costs and ignoring benefits of regulation; second, erasing public

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[1] *See* Lisa Friedman, *Trump Serves Notice to Quit Paris Climate Agreement*, N.Y. TIMES (Nov. 4, 2019), https://www.nytimes.com/2019/11/04/climate/trump-paris-agreement-climate.html.

[2] *See* Lisa Friedman, *E.P.A. Finalizes Its Plan to Replace Obama-Era Climate Rules*, N.Y. TIMES (June 19, 2019), https://www.nytimes.com/2019/06/19/climate/epa-coal-emissions.html.

[3] Timothy Cama, *Trump on Dire Warnings in Climate Report: 'I Don't Believe It,'* HILL (Nov. 26, 2019), https://thehill.com/policy/energy-environment/418289-trump-on-dire-warnings-in-climate-report-i-dont-believe-it.

[4] Helier Cheung, *What Does Trump Actually Believe on Climate Change?*, BBC (Jan. 23, 2020), https://www.bbc.com/news/world-us-canada-51213003.

[5] *Id.*

[6] *Id.*

[7] News Release, U.S. Envtl. Prot. Agency, EPA Takes Action to Ensure California Meets Nation's Air Quality Standards (Sept. 24, 2019), https://www.epa.gov/newsreleases/epa-takes-action-ensure-california-meets-nations-air-quality-standards.

health science; third, reviving discredited scientific models; and fourth, eliminating indirect benefits from regulatory impact analysis. Individually, each of these four strategies, if fully enacted, would significantly harm the health and welfare of Americans. Together, they threaten a truly monumental reshaping of environmental and public health protection in the United States. These four moves—manifested in rules currently proposed or already passed by the EPA and other agencies—represent a concerted attack on rational economic analysis of regulation which has received little comprehensive discussion in the academy to date.

Though the four strategies highlighted in this Article represent four urgent threats to the core of how regulatory impact analysis is done, they shed light on a broader threat to the scientific basis of regulation more generally, whether protective of the environment and public health or otherwise. The Trump administration has certainly taken other actions to sideline science and economic analysis in environmental regulation other than those described here, including disbanding scientific advisory committees at the EPA[8] and restricting academic scientists from serving on advisory boards to the agency.[9] And the precise contours of these specific attacks depends on how proposed rules are finalized, how final rules are implemented, and whether courts will be able to rein in the worst perversions of regulatory analysis. When put together, these disparate deregulatory thrusts paint a picture of a deeply committed assault on rational policy-making.

I. THE ILLUSION OF COSTS WITHOUT BENEFITS

The core of the Trump administration's regulatory agenda is to focus exclusively on the costs of regulations while ignoring, trivializing, and mischaracterizing their benefits. This agenda is most visibly embodied in Executive Order 13,771, titled *Reducing Regulation and Controlling Regulatory Costs*, which the president issued during his second week in office.[10] The order explicitly leaves in place Executive Order 12,866, which requires that regulatory actions—regardless of whether they impose new requirements or repeal existing requirements—be justified by cost benefit analysis,[11] Nonetheless, the Trump order focuses exclusively on regulatory costs and makes no reference at all to regulatory benefits.[12]

This one-sided approach is also reflected in significant regulatory efforts to delay or repeal important initiatives of the Obama administration designed to protect public health and the environment. In some of these proceedings, the Trump administration has ignored the benefits of this rule altogether, justifying its actions solely on the cost savings to regulated industry. In others, it has taken into account a rule's quantified benefits but has wholly ignored the benefits that could not be quantified because appropriate techniques for doing so have not yet been developed.

The Trump administration's approach makes a mockery of the notion of cost-benefit analysis. In our daily lives, we might decide that it is not worth spending $50 to prevent a broken toe nail. But we are likely to feel quite differently, if, instead the effect is the loss of a limb. To say that our goal is to save the $50, no matter what the consequences might be, is obviously foolish.

The central tenet of cost-benefit analysis involves comparing the costs and benefits of an action, and choosing the alternative that maximizes net benefits, which is the difference between benefits and costs. Evaluating the cost savings of a deregulatory action without reference to what benefits society might thereby forgo is not an inquiry that cost-benefit analysis can entertain. Saving regulatory cost would be very attractive if the associated foregone benefits are far lower and very unattractive if, instead, they are far higher.

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[8] *See, e.g.*, Lisa Friedman, *EPA to Disband a Key Scientific Review Panel on Air Pollution*, N.Y. TIMES (Oct. 11, 2018), https://www.nytimes.com/2018/10/11/climate/epa-disbands-pollution-science-panel.html.

[9] *See* Pamela King, *Judge Tosses EPA Policy That Barred Agency Grantees from Serving as Science Advisors*, SCIENCE (Feb. 11, 2020), https://www.sciencemag.org/news/2020/02/judge-tosses-epa-policy-barred-agency-grantees-serving-science-advisers.

[10] Reducing Regulation and Controlling Regulatory Costs, Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

[11] Regulatory Planning and Review, Exec. Order No. 12,866, § 1(b)(6), 58 Fed. Reg. 51,735, 51,736 (Oct. 4, 1993).

[12] *See* Exec. Order No. 13,771, 82 Fed. Reg. at 9339.

Moreover, the Trump administration's approach does more than mock rationality and cost benefit analysis. If it succeeds, the effects would be significant and pernicious for public health and the environment. Fortunately, so far the courts have systematically struck down the administration's efforts to roll back regulations through the one sided consideration of cost savings and the erasure of the associated regulatory benefits.

A. Trump's One-Sided Executive Order

Executive Order 13,771 has two components. First, agencies must repeal two existing rules for each new rule the promulgate.[13] We have already shown why the requirement makes little sense. The second component is a regulatory budget, which caps new regulatory costs at zero for fiscal year 2017 and at a level set by the Director of the Office of Management and Budget (OMB) for each agency in the following years.[14] To meet the 2017 zero cost budget, agencies needed to offset any costs associated with a new rule by delaying, suspending, or repealing other rules with equivalent costs.[15]

The cost cap for fiscal year 2017, which ran through September 30, 2017, roughly eight months into the new administration, could be seen as a moratorium on regulations during that period, since one way to meet it would be by not promulgating any new rules. There are antecedents for moratoria of various kinds at the beginning of a new administration, though they were for shorter periods of time. For example, on taking office, President Reagan asked federal agencies to postpone the effective date of pending final rules for 60 days and to refrain from proposing any new regulations for the same two-month period.[16] Presidents Clinton,[17] George W. Bush,[18] and Obama[19] placed more flexible moratoria by prohibiting agencies from submitting final or proposed rules to the Federal Register, and withdrawing any rules that had not yet been published, until those rules could be approved by an agency head appointed by the new president.[20]

The Trump administration's approach differs primarily from prior moratoria in that a cap on regulatory costs continues indefinitely.[21] And, while the Executive Order leaves open the possibility that agencies could impose net costs on the regulated entities following fiscal year 2017,[22] they in fact have shown no inclination to do so. For fiscal year 2018, the respective agencies indicated that their regulatory actions would lead to net costs costs of zero or to net cost savings, with no major agency showing an increase in costs.[23] Similary, for fiscal year 2019, no major agencies proposed imposing net costs through their regulatory initiatives.[24]

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[13] *See* Exec. Order No. 13,771, §2(a), 82 Fed. Reg. at 9339.

[14] *See* Exec. Order No. 13,771, §2(b), §3(d), 82 Fed. Reg. at 9340. For a critical discussion of this requirement, see Richard J. Pierce, Jr., *Is a Ceiling on Regulatory Costs Reasonable*, REG. REV. (Sept. 30, 2019), https://www.theregreview.org/2019/09/30/pierce-ceiling-regulatory-costs/?

[15] *See id.*, §2(c), 82 Fed. Reg. at 9339.

[16] Administrative Conference of the United States, Midnight Rules Appendix, Reagan Memorandum, https://www.acus.gov/sites/default/files/documents/Midnight-Rules-Appendix-2-8-12.pdf.

[17] *Id.*

[18] Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7701 (Jan. 24, 2001).

[19] Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 4435 (Jan. 26, 2009).

[20] *See* Kathryn A. Watts, *Regulatory Moratoria*, 61 DUKE L.J. 1883, 1891-93 (2012).

[21] Exec. Order No. 13,771, §3, 82 Fed. Reg. at 9339-40.

[22] *See* Exec. Order No. 13,771, §3(d), 82 Fed. Reg. at 9340.

[23] OFFICE OF INFORMATION AND REGULATORY AFFAIRS, REGULATORY REFORM UNDER EXECUTIVE ORDER 13771: FINAL ACCOUNTING FOR FISCAL YEAR 2018, *available at* https://www.reginfo.gov/public/pdf/eo13771/EO_13771_Final_Accounting_for_Fiscal_Year_2018.pdf.

[24] OFFICE OF INFORMATION AND REGULATORY AFFAIRS, REGULATORY REFORM: REGULATORY BUDGET FOR FISCAL YEAR 2019, *available at*

As with the text of the Executive Order itself, statements by senior administration officials, celebrated these cost caps and paid almost no attention at all to what societal benefits might thereby be foregone.[25] Most significant are the statements by Neomi Rao, Director of the Office of Information and Regulatory Affairs (OIRA) from 2017 to 2019, because that institution is charged with ensuring that regulatory initiatives are consistent with the precepts of cost-benefit analysis.[26] Rao celebrated the "cost-savings" associated with the administration's deregulatory actions, gleefully tallying a $23 billion dollar reduction in "burdensome regulations" by the end of fiscal year 2018.[27] She claimed that these reductions were "unleashing the freedom of American workers, innovators and businesses,"[28] and justified the regulatory budgets as "an important backstop to make sure deregulatory actions are not just paper revisions and repeals, but actions that generate real regulatory cost savings for the American public."[29] And, Rao insisted that "the benefits of deregulation are felt far and wide" and gave the Trump Administration's deregulatory agenda credit for the nation's low unemployment rate and GDP growth.[30]

Each of the empirical claims about the virtues of the Trump administration's approach—the cost savings, and the effects on economic growth and unemployment have been the subject of significant criticism.[31] But, more importantly for the purposes of this discussion, what is missing from this self-congratulatory narrative is an accounting for the forgone benefits and new risks the public faces as a result of the deregulatory actions. Even if cost savings were high, how do we know that the public's risk of premature death, heart disease, and asthma, among other serious negative consequences, are not even higher?[32]

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https://www.reginfo.gov/public/pdf/eo13771/EO_13771_Regulatory_Budget_for_Fiscal_Year_2019.pdf.

[25] *See, e.g.,* Neomi Rao, *The Trump Administration's Deregulation Efforts Are Saving Billions of Dollars,* WASH. POST, Oct. 17, 2018 [hereinafter Rao Editorial]; *Reviewing the Office of Information and Regulatory Affairs: Hearing Before the Subcomm. on Regulatory Affairs and Federal Mgmt. of the S, Comm. on Homeland Security and Gov't,* 115th Cong. (2018) (testimony of Neomi Rao, Administrator of OIRA) [hereinafter Rao Testimony]; Neomi Rao, What's Next for Trump's Regulatory Agenda: A Conversation with OIRA Administrator Neomi Rao, Remarks at The Brookings Institution (Jan. 26, 2018) [hereinafter Rao Remarks]; Mick Mulvaney (@MickMulvaneyOMB), TWITTER (Oct. 17, 2018), https://twitter.com/mickmulvaneyomb/status/1052617874668437504 (celebrating the Administration's reduction in regulatory costs during fiscal year 2018 with an infographic with statistics from the Unified Agenda); Mick Mulvaney (@MickMulvaneyOMB), TWITTER (Dec. 14, 2017, 4:12 PM), https://twitter.com/MickMulvaneyOMB/status/941400558220578816 (discussing the Trump administration's approach to regulation in a video to his followers).

[26] Exec. Order No. 12,866, § 2(b), 58 Fed. Reg. at 51,737.

[27] *See, e.g.,* Rao Editorial, *supra* note 25; Rao Testimony, *supra* note 25; Rao Remarks, *supra* note 25.

[28] Rao Editorial, *supra* note 25.

[29] Rao Testimony, *supra* note 25.

[30] Rao Editorial, *supra* note 25.

[31] *See, e.g.*, Danny Vinik, *Trump's War on Regulations Is Real. But Is it Working?*, POLITICO (Jan. 20, 2018), https://www.politico.com/agenda/story/2018/01/20/trumps-regulatory-experiment-year-one-000620 (explaining that the vast majority of Trump's touted cost savings came from the repeal of a single federal contract rule, as opposed to a dramatic decrease in the number of regulations as he has claimed, while much of that deregulation was accomplished by Congress repealing Obama-era rules under the Congressional Review Act early in his term); James Pethokoukis, *What's Been the Economic Impact of Trump's Deregulation Push?*, AM. ENTERPRISE INST. (Feb. 12, 2018), http://www.aei.org/publication/whats-been-the-economic-impact-of-trumps-deregulation-push/ (highlighting a Goldman Sachs report that found that deregulation has been overshadowed by tax reform in impact on economic decisionmaking and that there was no evidence that employment grew in sectors with higher regulatory burdens).

[32] Richard L. Revesz, *Trump Rollbacks Causing Premature Deaths Should not Be Celebrated*, THE HILL (Oct. 25, 2018), https://thehill.com/opinion/energy-environment/413157-trump-rollbacks-causing-premature-deaths-should-not-be-celebrated#bottom-s.

Rao does not even attempt to answer that question. Not doing so is expedient for her purposes, though a serious abdication of the responsibilities of her office. One does not need to search far for the reason. As explained in part in the following subsections and throughout this book, the regulatory initiatives that the Trump administration is trying to dismantle had benefits that far exceeded their costs. Repealing or rolling them back will therefore make the American people substantially worse off. Instead of celebrating the cost savings, we should be mourning the far more economically significant consequences of additional deaths and serious illnesses.[33]

To the extent that the Trump administration is treating the Executive Orders as imposing a budget constraint under which no new net costs can be imposed on regulated industry, not only for fiscal year 2017 but subsequently as well, the negative consequences fall into two discrete categories. First, this constraint might stand in the way of promulgating regulations that produce net benefits to society.[34] And second, it might lead to the repeal of other net beneficial regulations. On both scores, the impacts are pernicious.[35]

Properly designed, regulatory budgets could be socially beneficial, increasing net benefits to society.[36] To do so, however, agencies would necessarily need to consider benefits in setting the budget's caps. In fact, early proponents of regulatory budgets, including Chris DeMuth, OIRA's head during the Reagan administration and subsequently president of the conservative American Enterprise Institute, acknowledged explicitly that benefits should be taken into account in allocating regulatory budgets to particular agencies.[37] Similarly, John Graham, the OIRA head during the George W. Bush administration explained that "programs with a strong benefit justification should receive more generous treatment under a regulatory budget [than other programs]."[38]

This type of nuanced approach is technically possible under the Executive Order for fiscal years beyond 2017, during which the director of OMB is required to designate a regulatory budget for each agency after considering the agency's regulatory plan.[39] But, in fact, the Trump administration has done nothing of sort, focusing only on costs and entirely ignoring the associated benefits.

Any respected economist would cringe at this one-sidedness. It is simply absurd for the economic analysis of policy to ignore the deaths averted, the reduced number of hospitalizations, the morbidity reductions, and other significant impacts on the well-being of Americans.[40]

B. Ignoring Benefits Loses in the Courts

The Trump Administration has justified a number of its efforts to delay, stay, or suspend Obama Administration regulations by reference only to the cost savings to regulated industries, without looking at the

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[33] *Id.*

[34] Caroline Cecot & Michael A. Livermore, "The One-In, Two-Out Executive Order Is a Zero," 166 *University of Pennsylvania Law Review Online* 1, 5 (2017); *see, e.g.*, Richard J. Pierce, Jr., *The Regulatory Budget Debate*, 19 N.Y.U. J. LEGIS. & PUB. POL'Y 249, 251-52 (2016) ("[I]t would be irrational. Any regulatory process that ignores either costs or benefits would cause great harm to society."); Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 ADMIN. L. REV. 1, 33-34 (1994) (calling the imposition of an arbitrary binding constraint on an agency incoherent).

[35] Cecot & Livermore, *supra* note 34, at 9-10.

[36] Cecot & Livermore, *supra* note 34, at 7.

[37] *See* Christopher C. DeMuth, *Constraining Regulatory Costs Part Two: The Regulatory Budget*, 4 AEI J. ON GOV'T & SOC'Y 29, 32 (1980) ("[B]enefits would indeed be taken into account- but early in the process, when the President and Congress determined the *size* of each agency's budget.").

[38] *See* John D. Graham et al., *Managing the Regulatory State: The Experience of the Bush Administration*, 33 FORDHAM URB. L.J. 101, 132 (2005).

[39] Exec. Order No. 13,771, §3(d), 82 Fed. Reg. at 9340.

[40] Richard Revesz, *E.O. 12866: 25th Anniversary Remarks*, GEO. WASH. UNIV. REG. STUD. CTR. (Oct. 9, 2018), https://regulatorystudies.columbian.gwu.edu/eo-12866-25th-anniversary-remarks.

forgone benefits to the regulatory beneficiaries.[41] Not surprisingly, the courts have set aside a significant number of these misguided initiatives.[42]

For example, in March 2019 the Department of Health and Human Services (HHS) proposed a "gag rule" that would end an existing requirement that organizations receiving Title X funding counsel women about abortion.[43] In its analysis of the rule, HHS fails to take into account the negative impact on women who receive incomplete information about their options, instead focusing instead on the impact on providers with conscience conflicts.[44] While HHS does mention that comments addressed the issue that "proposed changes could reduce access to services, especially for the most vulnerable populations," in response the agency does not consider the specific forgone benefits resulting from the loss of healthcare options but merely insists that "these final rules will contribute to more clients being served, gaps in service being closed, and improved client care that better focuses on the family planning mission of the Title X program."[45]

Groups like the American Medical Association and Planned Parenthood challenged the rule in federal court.[46] So far, three federal district courts have enjoined the rule, which preserves the current state of affairs by not allowing this new rule to be implemented. A judge in the Eastern District of Washington wrote that the plaintiffs presented facts showing that "the Final Rule is arbitrary and capricious because it reverses long-standing positions of the Department without proper consideration of sound medical opinions and the economic and non-economic consequences."[47] Similarly, a judge in the District of Oregon found the plaintiff's likely to prevail on the merits of their arbitrary and capricious claim, because HHS did not attempt to justify its conclusion that women would not be harmed by the rule or adequately respond to comments asserting the opposite.[48] And in the Northern District of California, a judge ruled against the agency because it had not explained its departure from its prior position, which had repealed a prior version of the "gag rule" on the grounds that not providing information about women's reproductive choices "endangers women's lives and health by preventing them from receiving complete and accurate medical information."[49] The government has obtained a stay of the preliminary injunctions pending review by the United States Court of Appeals for the Ninth Circuit, which has scheduled oral argument for September 2019.[50]

In another example, in June 2017 the Bureau of Land Management attempted to suspend the Methane Waste Prevention Rule,[51] originally promulgated by the Obama administration in 2016, which reduces the loss of natural gas from leaks during the extraction of oil and natural gas.[52] The rule was expected to generate $204 million in net benefits over ten years through reduced production of hazardous air pollutants and greenhouse gases, cost savings from the sale of natural gas, with ancillary benefits like improvements in quality of life for

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[41] *Id.*

[42] *Id.*

[43] *Id.*; *see* Compliance With Statutory Program Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019).

[44] *Id.* at 7718-19.

[45] *Id.* at 7722-23.

[46] Complaint, Am. Med. Ass'n v. Azar, 2019 WL 1897475 (D. Or. Apr. 29, 2019) (No. 6:19-cv-318), available at https://www.ama-assn.org/system/files/2019-03/oregon-titlex-suit.pdf.

[47] Washington v. Azar, 376 F. Supp. 3d 1119, 1131 (E.D. Wash. 2019).

[48] Oregon v. Azar, 389 F. Supp. 3d 898, 918-19 (D. Or. 2019).

[49] State v. Azar, 385 F. Supp. 3d 960, 1012 (N.D. Cal. 2019) (internal citations omitted).

[50] *Title X Cases*, U.S. COURTS FOR THE NINTH CIR., https://www.ca9.uscourts.gov/content/view.php?pk_id=0000000994 (last visited Aug. 14, 2019).

[51] Waste Prevention, Production Subject to Royalties, and Resource Conservation; Postponement of Certain Compliance Dates, 82 Fed. Reg. 27,430 (Jun, 15, 2017).

[52] Waste Prevention, Production Subject to Royalties, and Resource Conservation, 81 Fed. Reg. 83,008 (Nov. 18, 2016).

nearby residents.[53] The agency justified its decision to suspend the rule based on the "substantial cost" that industry would incur to comply with the rule, but it did not consider the $204 million dollars in foregone benefits resulting from the suspension.[54] When this deregulatory action was challenged, the U.S. District Court for the Northern District of California struck down the rule, finding that the administration had "entirely failed to consider the benefits of the Rule, such as decreased resource waste, air pollution, and enhanced public revenues."[55] The government initially appealed to the United States Court of Appeals for the Ninth Circuit, but subsequently agreed to have its appeal dismissed, thus letting the lower court decision stand and signaling the death knell of the Waste Prevention Rule's suspension.[56]

Similarly, in its December 2017 delay of the publication of training materials for farmers exposed to pesticides,[57] required by a regulation promulgated in 2015 by the Obama administration,[58] the Environmental Protection Agency (EPA), did not consider the resulting harms to farmworkers and their families.[59] Instead, the agency focused exclusively on the savings to the regulated community, explaining that its objective was to "prevent extra work and costs to developers of the training materials and EPA reviewers."[60] When challenged in court, the agency responded by publishing the training documents instead of presenting a reasoned explanation for the delay,[61] presumably realizing that it was likely to lose for failing to consider the forgone benefits of delaying the publication of the training materials.

In June 2017, the EPA also attempted to postpone compliance deadlines for the Chemical Disaster Rule,[62] promulgated five months earlier by the Obama administration to reduce the frequency and magnitude of chemical accidents, resulting in savings in damages and other, unquanitifed benefits.[63] Commenters complained that the action would cause harm by failing to prevent or mitigate chemical accidents during the period of the delay and that the agency had not explained why it was appropriate to forgo such benefits during this period.[64] The EPA's response was that because the rule had not yet gone into effect, a delay of the compliance dates would simply maintain the status quo and therefore not cause any harms.[65] The United States Court of Appeals for the D.C. Circuit roundly rejected this argument, determining that the agency had not provided any good

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[53] *Id.* at 83,013-14.

[54] Waste Prevention, Production Subject to Royalties, and Resource Conservation; Postponement of Certain Compliance Dates, 82 Fed. Reg. at 27,431.

[55] California v. U.S. Bureau of Land Mgmt, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017) (vacating the delay of the rule); *see* California v. U.S. Bureau of Land Mgmt*,* 286 F. Supp. 3d 1054 (N.D. Cal. 2018) (enjoining Interior's second attempt to delay the rule).

[56] California v. U.S. Bureau of Land Mgmt., 2018 WL 2735410, at *1 (Mar. 15, 2018).

[57] Pesticides; Agricultural Worker Protection Standard; Reconsideration of Several Requirements and Notice About Compliance Dates, 82 Fed. Reg. 60,576 (Dec. 12, 2017).

[58] Pesticides; Agricultural Worker Protection Standard Revisions, 80 Fed. Reg. 67,495 (Nov. 2, 2015).

[59] BETHANY DAVIS NOLL & ALEC DAWSON, INSTITUTE FOR POLICY INTEGRITY, DEREGULATION RUN AMOK: TRUMP-ERA REGULATORY SUSPENSIONS AND THE RULE OF LAW 9 (2018).

[60] Pesticides; Agricultural Worker Protection Standard; Reconsideration of Several Requirements and Notice About Compliance Dates, 82 Fed. Reg. at 60,577.

[61] DAVIS NOLL & DAWSON, *supra* note 59, at 9.

[62] Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Further Delay of Effective Date, 82 Fed. Reg. 27,133, 27,138-39 (June 14, 2017).

[63] Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, 82 Fed. Reg. 4,594, 4,597 (Jan. 13, 2017).

[64] Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Further Delay of Effective Date, 82 Fed. Reg. at 27,138-39.

[65] *Id.*

explanation "for delaying provisions that EPA previously determined would help keep first responders safe and informed about emergency-response planning."[66]

The D.C. Circuit explicitly rejected the agency's argument that the delay would impose no costs because it simply maintained the status quo. The court reasoned that "the baseline for measuring the impact of a change or rescission of a final rule is the requirements of the rule itself, not the world as it would have been had the rule never been promulgated."[67] And, the court noted the inconsistency in the agency position: that the rule would not lead to forgone benefits because it had not yet gone into effect but that, nonetheless, it would produce cost savings to regulated industry. It concluded that "EPA cannot have it both ways."[68]

The Trump administration also relied on the same irrationally flawed logic when, in May 2017, the Food and Drug Administration postponed compliance deadlines of a 2014 Obama administration nutritional labeling rule.[69] Here, too, the agency justified the delay based on "the reduction in costs to covered establishments," which averaged $4 million per year over twenty years.[70] It acknowledged, however, that the forgone benefits of the delay, suffered by consumers, averaged $10 million, annualized over the same period, but did not take them into account as an argument against the postponement.[71] Despite the command to maximize net benefits in Executive Order 12,866, which the Trump Administration claims is still "the primary governing EO regarding regulatory planning and review,"[72] the agency acknowledged that, as a result of the delay, "average annualized net benefits decrease by $5 million,"[73] but did not find this outcome troubling. Following a court challenge,[74] the agency agreed to enforce the rule,[75] probably recognizing that its failure to take the forgone benefits into account was untenable.

C. Equating Unquantified Benefits with Nonexistent Benefits

In addition to illegally ignoring benefits altogether, the Trump administration has also attempted to justify some of its deregulatory actions by removing unquantified benefits from consideration in its cost-benefit analyses. To justify this approach, it has equated unquantified benefits with speculative, insignificant, and uncertain benefits.

In contrast, the executive orders and guidance governing regulatory analysis instruct agencies to give due consideration to all important unquantified costs and benefits. Executive Order 12,866 requires agencies to assess "qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to

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[66] Air All. Houston v. EPA, 906 F.3d 1049, 1069 (D.C. Cir. 2018).

[67] *Id.* at 1068.

[68] *Id.*

[69] Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825 (May 4, 2017).

[70] *Id.* at 20,828.

[71] *Id. See also* FOOD AND DRUG ADMIN., *Interim Final Regulatory Impact Analysis for the Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date and Request for Comments* 6 (2017), *available at* https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm557203.htm.

[72] DOMINIC J. MANCINI, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, M-17-21, GUIDANCE IMPLEMENTING EXEC. ORDER 13,771, TITLED "REDUCING REGULATION AND CONTROLLING REGULATORY COSTS," 2, 13 (2017).

[73] *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. at 20,828.

[74] Peter Lehner, *Counting Calories? New Lawsuit Will Make Restaurants Show You the Stats*, EARTHJUSTICE (Feb. 6, 2018), https://earthjustice.org/blog/2017-june/new-lawsuit-seeks-end-to-calorie-secrecy.

[75] *FDA Agrees to Enforce Menu Labeling Rule in May 2018*, EARTHJUSTICE (Sept. 27, 2017), https://earthjustice.org/news/press/2017/fda-agrees-to-enforce-menu-labeling-rule-in-may-2018.

consider."[76] The Office of Management and Budget's Circular A-4 guidance on regulatory analysis cautions agencies against ignoring the potential magnitude of unquantified benefits, because the most efficient rule may not have the "largest quantified and monetized . . . estimate."[77] The economic literature has widely recognized that cost-benefit analysis requires proper consideration of effects that "defy quantification but are thought to be important."[78]

Uncertainty about an effect does not mean the effect is worthless. Quite to the contrary, unquantified benefits can explicitly be brought to bear in a cost-benefit calculation. For example, breakeven analysis seeks to determine the minimum value of an unquantifiable benefit that would give a regulation net positive benefits.[79] In fact, Circular A-4 contemplates the use of breakeven analysis when it asks how small those nonquantified benefits would need to be for the rule to yield zero net benefits.[80]

Recognizing that unquantified benefits can sometimes be substantial has been a longstanding practice for agencies under administrations of both political parties. For example, in April 1982—just months after President Reagan signed Executive Order 12,291,[81] which, like its successor Executive Order 12,866, required agencies to conduct regulatory impact analyses—the Bureau of Land Management (BLM) prepared an analysis of oil and gas leasing in Alaska's National Petroleum Reserve.[82] BLM explained that, "[b]ecause of information gaps and scientific uncertainty," the "social costs" of allowing oil and gas drilling in sensitive Alaskan land "cannot be quantitatively predicted."[83] BLM noted, however, that drilling operations could entail the "risk of significant environmental harm,"[84] and particularly insisted that sociocultural, nutritional, and economic effects to the subsistence activities of Native communities, while unquantifiable, were "real and very important."[85] Ultimately, in BLM's 1982 regulatory impact analysis, the agency concluded that "[t]hese costs must, therefore, be analyzed in terms of the potential risks (or cost) posed to environmental values in relation to the perceived benefits to accrue through oil and gas development."[86]

Similarly, under the Clinton administration BLM developed new regulations for hardrock mining and determined that while the benefits are "difficult to quantify" due to information gaps, the the net economic benefits could be "substantial" and the "environmental benefits of protecting even a small number of unique resources over time could easily offset the costs."[87] Even when BLM later repealed portions of those hardrock

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[76] Exec. Order No. 12,866, § 1(a), 58 Fed. Reg. at 51,735.

[77] OFFICE OF MGMT. & BUDGET, CIRCULAR A-4: REGULATORY ANALYSIS 2 (2003) [hereinafter CIRCULAR A-4].

[78] KENNETH J. ARROW ET AL., BENEFIT-COST ANALYSIS IN ENVIRONMENTAL, HEALTH, AND SAFETY REGULATION: A STATEMENT OF PRINCIPLES 8 (1996).

[79] *See* Richard L. Revesz, *Quantifying Regulatory Benefits*, 102 CALIF. L. REV. 1423, 1424 (2014).

[80] CIRCULAR A-4, *supra* note 77, at 2.

[81] Exec. Order No. 12,291, § 2(b), 46 Fed. Reg. 13,193, 13,194 (Feb. 19. 1981).

[82] BUREAU OF LAND MGMT., *Final Regulatory Impact Analysis for Regulations Governing Competitive Oil and Gas Leasing in the National Petroleum Reserve in Alaska* (1982), *available at* https://books.google.com/books?id=5g4xAQAAMAAJ [hereinafter *Alaska RIA*]. Courts may look beyond the administrative record and take judicial notice of agencies' own records. *Dent v. Holder*, 627 F.3d 365, 371 (9th Cir. 2010).

[83] *Alaska RIA*, *supra* note 82, at 33.

[84] *Id.*

[85] *Id.* at 31-32.

[86] *Id.* at 33.

[87] Mining Claims Under the General Mining Laws; Surface Management, 65 Fed. Reg. 69,998, 70,100-02 (Nov. 21, 2000).

mining regulations during the George W. Bush administration, the agency noted that certain effects could be "substantial" even though uncertainty prevented quantification.[88]

Departing from the well-accepted approaches to considering unquantified benefits and the consistent regulatory practices and judicial determinations, the Trump administration has pretended that unquantified benefits do not exist. A few examples illustrate how the administration has engaged in this conduct that flouts both the law and the economic consensus.

The EPA ignored unquantified benefits in delaying the Chemical Disaster Rule,[89] discussed above.[90] When the EPA, during the Obama administration, initially promulgated this rule, it engaged in a thorough analysis of the costs and benefits.[91] The agency found that the rule would result in extensive, but unquantified, benefits.[92] The EPA said that though it was "unable to quantify what specific reductions may occur as a result of the[] revisions, [it was] able to present data on the total damages that currently occur at …facilities each year,"[93] which would be reduced by some amount by the rule, and pointed to other unquantified benefits, such as avoiding catastrophes, lost productivity, significant emergency response costs, transaction costs caused by accidents, property value impacts in nearby neighborhoods, and environmental damages.[94] The agency determined that annualized costs would be just over $130 million.[95] It estimated that monetized accident damages for facilities covered by the rule were $274.7 million per year and "some portion of [these] future damages would be prevented through implementation of [the] final rule."[96] The Chemical Disaster Rule would lead to a "reduction of the frequency and magnitude of damages from releases,"[97] and thus these damage costs would be reduced—though the exact amount of the decrease was impossible to predict.[98] The EPA concluded that "[w]hen considering the rule's likely benefits that are due to avoiding some portion of the monetized accident impacts, as well as the additional non-monetized benefits…EPA believes the costs of the rule are reasonable in comparison to its benefits."[99]

In delaying the effective date of the Chemical Disaster Rule, the Trump EPA ignored its own prior findings about the benefits of the rule. EPA dismissed the forgone benefits caused by the delay of the rule as "speculative at best," [100] because of the "lack of a quantification of benefits in the final rule regulatory impact analysis."[101]

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[88] Mining Claims Under the General Mining Laws; Surface Management, 66 Fed. Reg. 54,834, 54,844 (Oct. 30, 2001).

[89] Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Further Delay of Effective Date, 82 Fed. Reg. at 27,133.

[90] Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, 82 Fed. Reg. at 4594, 4597.

[91] *Id.* at 4596-98.

[92] *Id.* at 4597-98.

[93] *Id.* at 4597.

[94] *Id.* at 4598.

[95] *Id.* at 4596-97.

[96] Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, 82 Fed. Reg. at 4597.

[97] *Id.*

[98] *Id.*

[99] *Id.* at 4598.

[100] Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Further Delay of Effective Date, 82 Fed. Reg. at 27,139.

[101] *Id.*

This conclusion is unsupportable. While insufficient data may render a particular benefit unquantifiable, that does not mean the benefit is "speculative." The term "speculative" (defined as "theoretical rather than demonstrable"),[102] suggests that there may be no benefit at all, whereas an unquantified benefit is an expected benefit that cannot currently be quantified because of the lack of analytical techniques for doing so. Agencies cannot rationally ignore benefits just because they are unquantified. As the D.C. Circuit has held, "[t]he mere fact that the magnitude of [an effect] is *uncertain* is no justification for *disregarding* the effect entirely."[103] Or, as it had stated in an earlier case, agencies have no license to ignore the effects of its decisions just because they are "difficult, if not impossible, to quantify reliably."[104] In vacating the delay, the D.C. Circuit took issue with the fact that EPA did not "explain why the detailed factual findings regarding the harm that would be prevented upon implementation of the Chemical Disaster Rule are now only 'speculative.'"[105]

In another example, in October 2018, the Trump administration attempted to extend various compliance deadlines for the Landfill Rule,[106] promulgated by the Obama administration in 2016, which was designed to reduce the emissions of greenhouse gases and other pollutants from landfills.[107] The rule was estimated to deliver significant monetized benefits—$440 million in the year 2025 alone— reducing methane and carbon dioxide emissions, which contribute to climate change, and by capturing otherwise wasted landfill gas and redirecting it to productive use to generate electricity.[108] The EPA estimated that the corresponding annualized costs would be just $54 million, in the form of equipment installation, testing, and monitoring.[109] The rule could therefore be justified on the basis of the monetized costs and benefits alone.[110] The Landfill Rule also reduced emissions of volatile organic compounds, which are precursors to particulate matter and ozone, and reduced some organic hazardous air pollutants.[111] The agency found that reducing all of these pollutants would improve air quality and related health effects associated with exposure.[112] However, these benefits, unlike those resulting from methane and carbon dioxide reductions, could not be readily quantified.[113] The Obama administration made clear that the fact that it was difficult to model the direct and indirect impacts of the reductions in emissions with the data available at that time did not mean that benefits from such reductions did not exist.[114] In contrast, when justifying the delay the Trump administration largely ignored the impact of forgone emissions reduction benefits, quantified or not.[115] It merely said "although the costs and benefits of harmonizing the

[102] *Speculative*, MERRIAM-WEBSTER.COM (2017).

[103] Public Citizen v. Fed. Motor Carrier Safety Admin., 374 F.3d 1209, 1219 (D.C. Cir. 2004).

[104] Am. Trucking Assocs. v. E.P.A., 175 F.3d 1027, 1052 (D.C. Cir. 1999), *rev'd on other grounds sub. nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

[105] Air All. Houston v. EPA, 906 F.3d 1049, 1067 (D.C. Cir. 2018).

[106] Proposal to Delay the Timing of State and Federal Plans to Implement the Emission Guidelines for Municipal Solid Waste Landfills 83 Fed. Reg. 54,527 (Oct. 30, 2018).

[107] Emissions Guidelines and Compliance Times for Municipal Solid Waste Landfills, 81 Fed. Reg. 59,276 (Aug. 29, 2016).

[108] *Id.* at 59,280.

[109] *Id.* at 59,279.

[110] *Id.* at 59,280.

[111] *Id.*

[112] *Id.*

[113] I*d.* at 59,280.

[114] *Id.*

[115] Emissions Guidelines and Compliance Times for Municipal Solid Waste Landfills, 83 Fed. Reg. at 54,531.

timing requirements of state plans cannot be quantified due to inherent uncertainties, the EPA believes that they will be minimal."[116]

But the mere fact that a benefit cannot currently be quantified also does not mean that the benefit is "minimal." That an agency presently lacks the necessary data to quantify a given benefit has no relationship with the magnitude of the benefit, or the certainty that the benefit exists. In fact, some of the most substantial categories of monetized benefits of environmental regulation were at one time considered to be unquantifiable.[117] Mortality risks, for example, were once ignored by agencies due to unsatisfactory methods for assigning a value to a regulation's expected lifesaving effects.[118] The development of the "willingness-to-pay" methodology allowed economists to determine how much people, on average, were willing to spend on reductions in risk.[119] This information could then be aggregated to determine the "value of statistical life."[120] The integration of the value of life in agency cost-benefit analysis has become standard practice, and has been instrumental in supporting regulations with life- saving benefits that justify their cost.[121]

Not surprisingly, the Trump administration's effort to delay the Landfill Rule was unsuccessful. A judge in the United States District Court for the Northern District of California ordered EPA to implement and enforce the requirements within a specific timeframe.[122] The states bringing the action and the EPA agreed that EPA had a mandatory duty to so. While the court noted the harmful impact of the types of pollution produced in landfill gas,[123] due to the parties' stipulation it did not analyze whether EPA adequately considered the forgone benefits caused by delaying the rule, but rather proceeded to determine a feasible timeline under which the EPA must implement the rule.[124]

Another example of the Trump administration's failure to take unquantified benefits into account involves BLM's repeal in December 2017 of the Fracking Rule,[125] promulgated by the Obama administration in 2015 in order to address the extraction of natural resources for the purpose of producing natural gas.[126] The rule sought to "ensure wellbore integrity, protect water quality, and enhance public disclosure of chemicals and other details of hydraulic fracturing operations."[127] At the time of its promulgation, BLM had stated that "the primary challenge in monetizing benefits lies in the quantification of a baseline risk associated with specific operating practices and in the measurement of the change in that risk that the BLM can attribute to the rule's requirements."[128] For example, the agency indicated that while data is not clear about the exact difference between risk of spills using storage tanks or pits, there is widespread agreement that tanks are the less risky

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[116] *Id.*

[117] Revesz, *supra* note 79, at 1436.

[118] *Id.*

[119] *Id.* at 1437.

[120] *Id.*

[121] *Id.* at 1438-39.

[122] California v. EPA, 385 F. Supp. 3d 903, 916 (N.D. Cal. 2019).

[123] *Id.* at 906-07.

[124] *Id.* at 908-09.

[125] Oil and Gas; Hydraulic Fracturing on Federal and Indian Lands; Recission of a 2015 Rule, 82 Fed. Reg. 61,924 (Dec. 29, 2017).

[126] Oil and Gas; Hydraulic Fracturing on Federal and Indian Lands, 80 Fed. Reg. 16,127, 16,128 (Mar. 26, 2015).

[127] *Id.* at 16,129.

[128] *Id.* at 16,204.

option.[129] Quantifying the benefits would require understanding this incremental risk reduction.[130] However, BLM made clear that this lack of quantification did not mean that the rule is without benefits, [131] and expressed confidence that the overall risk reductions would be significant,[132] and concluded that the standards were "prudent," "necessary," and "common-sense,"[133] and that "potential benefits of the rule are *significant*."[134]

In repealing the Fracking Rule, the Trump administration repeatedly assumed that forgone benefits must be small or nonexistent because they were unquantified, improperly equating quantification with significance. The repeal, for example, concluded that "[a]ny *marginal benefits* provided by the 2015 rule *do not outweigh* the rule's costs, even if those costs are a small percentage of the cost of a well. *In fact, benefits were largely unquantified* in the 2015 rule."[135]

The clear implication was that *because* the Fracking Rule's benefits were unquantified, they must have been "marginal" and would therefore be outweighed by its the costs. Along similar lines, the agency also indicated in the repeal that "[t]here were *no monetary estimates of any incremental benefit* that the 2015 rule provides" and concluded that "[s]uch incremental benefits, however, are *likely to be too small* . . . to justify compliance *costs that are both monetized and certain to exist*."[136] BLM thus implied that forgone benefits were not "certain to exist" because they were not monetized, and so assumed that in no case could non-monetized benefits possibly be large enough to justify a rule's monetized costs. A corollary to this analysis is that unquantified benefits, no matter how significant, could never justify the expenditure of any monetized costs, no matter how small. This position defies logic and is inconsistent with long-accepted and judicially approved approaches for dealing with unquantified benefits. A challenge to the repeal is currently pending in the U.S. District Court for the Northern District of California.

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In a variety of ways discussed in this Part, the Trump administration has shown how it privileges regulatory costs over benefits, leading to one-sided analyses of regulatory policies that contravene the most basic tenet of cost-benefit analysis: that costs and benefits should be compared on an equal footing. Right out of the gate, the administration issued Executive Order 13,771, a one-sided policy that pays lip service to cost-benefit analysis while totally losing sight that its goal is to maximize net benefits to society, not to reduce regulatory costs. While cost-benefit analysis would mourn a reduction of regulatory costs that is associated with a larger reduction of benefits, the Trump administration celebrates cost-reducing measures regardless of the magnitude of the foregone benefits. And it is is particularly galling that it conducted this celebration in the Office of Information and Regulatory Affairs—the institution charged with protecting the integrity of cost-benefit analysis—and that the main cheerleader for this affront was Neomi Rao, the office's head before her appointment to the D.C. Circuit.

Sometimes Executive Orders are written to please political constituencies and have little substantive significance.[137] That has not been the case here. The order was followed with significant regulatory actions

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[129] *Id.*

[130] *Id.* at 16,188.

[131] *Id.*

[132] Oil and Gas; Hydraulic Fracturing on Federal and Indian Lands, 80 Fed. Reg., at 16,203.

[133] *Id.*at 16,188-89.

[134] *Id.* at 16,203.

[135] Oil and Gas; Hydraulic Fracturing on Federal and Indian Lands; Recission of a 2015 Rule, 82 Fed. Reg. at 61,939 (emphasis added).

[136] *Id.* at 61,942.

[137] For example, a review of President Trump's executive orders found that "many were geared toward favored political constituencies…[and] few moved policy significantly." Noah Bierman, *Must Reads: What's Behind all those Executive Orders Trump Loves to Sign? Not Much*, L.A. TIMES (Mar. 27, 2019), https://www.latimes.com/politics/la-na-pol-trump-executive-

seeking to delay or repeal signature initiatives of the Obama administration, focusing exclusively on the cost savings to industry and totally ignoring the forgone benefits to regulatory beneficiaries. And, in other cases in which the Trump administration actually acknowledged a rule's benefits, it did so only in a partial way, crediting the quantified benefits but ignoring the benefits that could not be quantified. Moreover, unquantified benefits are not the only category of benefits that the administration is trying to erase. Indirect benefits, or co-benefits, which are examined in in a subsequent Part, are another such category.

The Trump administration's one-sided approach to considering regulatory costs and ignoring the associated benefits has suffered a near-total rout in the courts, which, not surprisingly, have found this approach to be arbitrary and capricious. Similarly, the administration's treatment of unquantified benefits as speculative, insignificant, and uncertain, and therefore not worthy of attention, has also been met with successful court challenges because the law requires that agencies give due consideration to all benefits, regardless of whether they can be quantified.

These losses, however, do not make the affront on cost-benefit analysis any less pernicious, in part because the Trump administration is getting its way until a court can set aside its illegal action—a process that is often lengthy. More significantly, unless this frontal attack on rationality is brought to light, these practices might be taken up by future administration, particularly if over time the judiciary becomes less vigilant after repeated exposure to bad practices.

orders-ineffective-20190327-story.html. Political scientist Kenneth Mayer, who studies presidential power, found in an empirical study that of 1000 executive orders, only between 15 and 25 percent had substantive importance. Andrew Prokop, *Why Counting Executive Orders Is an Awful Way to Measure Presidential Power*, VOX (Nov. 22, 2014), https://www.vox.com/xpress/2014/11/22/7260059/president-executive-orders-chart.

II. ERASING PUBLIC HEALTH SCIENCE

In addition to acting as if deregulatory measures could be justified without regard to the foregone benefits, the Trump administration is also undertaking more targeted but similarly unsupportable strategies. The prior Part analyzed the effort to assume away benefits entirely, justifying deregulatory actions solely on the basis of cost savings. In addition, the administration has adopted a more targeted attack by calling into question the scientific studies supporting the most significant health benefits of environmental regulation. By erasing validly conducted peer-reviewed studies that meet the standards of the scientific community, the Trump administration is not just placing a light thumb on the scale against regulation—it is pressing down hard.

In this connection, in April 2018, the EPA, then headed by Administrator Scott Pruitt, proposed the Strengthening Transparency in Regulatory Science (STRS) rule.[1] The EPA claimed that the proposal was "intended to strengthen the transparency of EPA regulatory science,"[2] and would "help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand."[3] Pruitt himself stated that the STRS proposed rule signified that "[t]he era of secret science at EPA is coming to an end," adding that "[t]he ability to test, authenticate, and reproduce scientific findings is vital for the integrity of [the] rulemaking process" and "Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives."[4]

The STRS proposed rule, if finalized and implemented, would constitute a serious attack on the EPA's ability to rely on peer reviewed epidemiological studies—which present the most direct and persuasive evidence of the adverse health effects of pollutants—and undermine the agency's ability to protect public health and the environment. Epidemiological studies are one of the two main types of studies of the adverse consequences of pollution to health (toxicological studies being the other). Some of the most serious risks posed by pollution could go unregulated if the Trump administration has its way. This effort is part of an overarching strategy by the Trump administration to attempt to erase the significant benefits of regulation in general and environmental regulation in particular.

A. The Historical Roots of the STRS Proposed Rule

On first impression, the STRS proposed rule might look like a beneficial attempt to improve the quality of scientific evidence on which the EPA relies in its regulatory efforts. The rule states that "for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis."[5] The STRS proposed rule is also intended to ensure that decision-making is marked by "reproducibility."[6] The EPA explained that "information is considered 'publicly available in a manner sufficient for validation and analysis' when it includes the information necessary for the public to understand, assess, and replicate findings."[7] According to the EPA, the STRS proposed rule is "informed by the policies recently adopted by some major scientific journals,"[8] including *Science*, *Nature*, and *Public Library of Science (PLoS)*,[9] and "is consistent with . . . the focus on transparency in OMB's *Guidelines for*

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

[2] *Id.* at 18,768.

[3] *Id.* at 18,769.

[4] *EPA Administrator Pruitt Proposes Rule to Strengthen Science Used in EPA Regulations*, EPA (Apr. 24, 2018), https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations.

[5] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. at 18,769.

[6] *Id.*

[7] *Id.* at 18,773–74.

[8] *Id.* at 18,770.

[9] *Id.* at 18,770 n.11.

Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies."[10] And although the STRS proposed rule "includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable,"[11] the document gives virtually no guidance on when that might happen, and the statements by the EPA leadership and the proposed rule's proponents strongly suggest that the Trump administration's goal is to give this exemption a very narrow meaning, if any at all.

One does not need to scratch much below the surface to understand that the STRS proposed rule would exclude a myriad of vital scientific studies from EPA consideration. Instead of a beneficial, "good government" measure, it is an effort to sacrifice, at the altar of deregulation, the leading peer reviewed epidemiological studies of the past and to make it virtually impossible for such studies to be conducted in the future. Barring the EPA from considering any scientific studies for which the underlying data cannot be made publicly available or reproduced does not increase the credibility of the EPA's decisions. On the contrary, the provisions of the STRS proposed rule threaten to restrict the pool of peer reviewed scientific studies that the EPA may rely on, which would be detrimental to public health and the environment.

The STRS proposed rule is the newest incarnation of past failed attempts to undermine the role of science in regulatory decision-making. Prior to Pruitt's proposed STRS rule, congressional Republicans had attempted to pass the Secret Science Reform Act of 2014,[12] the Secret Science Reform Act of 2015,[13] and the Honest and Open New EPA Science Treatment (HONEST) Act of 2017.[14] These past bills were similar to the STRS proposed rule and all of them would have prohibited the EPA from acting on scientific research without making data publicly available.[15]

Most recently, the HONEST Act was introduced by Republican Representative Lamar Smith of Texas, chairman of the House Science, Space and Technology Committee, and passed in the House in March 2017 without any amendments or much clarification on how it would achieve transparency and respect privacy. The HONEST Act would have prohibited the EPA from proposing, finalizing, or disseminating "a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance" unless "all scientific and technical information relied on" was the "best available science" and was made "publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of research results."[16] After the HONEST Act failed in the Senate, Representative Smith met with Pruitt to pitch a new plan to discuss how the EPA could unilaterally implement the policies found in the HONEST Act.[17] In March 2018, during a closed-door meeting at the Heritage Foundation, Pruitt announced

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[10] *Id.* at 18,769.

[11] *Id.* at 18,772.

[12] H.R. 4012, 113th Cong. (2014). This Act passed in the House and failed in the Senate.

[13] H.R. 1030, 114th Cong. (2015). This Act passed in the House and failed in the Senate.

[14] H.R. 1430, 115th Cong. (2017). This Act passed in the House and failed in the Senate.

[15] *Id.* § 2.

[16] *Id.* The HONEST Act does identify exceptions to this rule for "personally identifiable information, trade secrets, or commercial or financial information obtained from a person and privileged or confidential." The Act states: "The Administrator shall not propose, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action is— (a) the best available science; (b) specifically identified; (c) publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of research results, except that any personally identifiable information, trade secrets, or commercial or financial information obtained from a person and privileged or confidential, shall be redacted prior to public availability." *Id.*

[17] *See* Scott Waldman & Niina Heikkinen, *Trump's EPA Wants to Stamp Out 'Secret Science.' Internal Emails Show It Is Harder than Expected*, SCIENCE (Apr. 20, 2018), https://www.sciencemag.org/news/2018/04/trump-s-epa-wants-stamp-out-secret-science-internal-emails-show-it-harder-expected. EPA congressional affairs staffer Aaron Ringel wrote in an email to colleagues at the EPA: "All, see below follow up from Chairman Smith's meeting with the administrator . . . . [T]his is in regards to his pitch that EPA internally implement the HONEST Act (no regulation can go into effect unless the

his intention to move forward with internally implementing a rule that would have the same effect as the HONEST Act.[18] One month later, the EPA rolled out its STRS proposal.

By the time the comment period ended in August 2018, the EPA had received almost 600,000 comments from a wide range of parties, including individual citizens, environmental and health organizations like Natural Resources Defense Council and Physicians for Social Responsibility, and large chemical and gas groups like the American Chemistry Council and the American Petroleum Institute.[19] Pruitt's resignation in July 2018 called the future of the rule into question. Nevertheless, his successor, Andrew Wheeler, has now repeatedly affirmed his commitment to seeing the rule through.[20]

The STRS proposed rule would make it very difficult, in many cases downright impossible, for the EPA to rely on epidemiological studies—studies of the impact of pollutants on human populations—because of the confidentiality agreements necessary to obtain personal health data. Epidemiological studies on humans and toxicological studies on laboratory animals are the two predominant sources of evidence on the adverse health effects of environmental contaminants. Undermining the first source will become more difficult and, in some cases impossible, to regulate harmful substances that cause tens of thousands of premature deaths each year. And, in fact, the Trump administration has now indicated that it wants to undermine the second source—toxicological studies on laboratory animals—as well. The E.P.A. has proposed to reduce its requests for, and funding of, mammal studies by 30 percent by 2025 and to eliminate them altogether by 2035, though some may still be approved on a case-by-case basis.[21] The new policy appears to have been a direct response to pleas by the chemical industry, which sees this move as protecting it against regulation of the harmful effects of their products.

The full extent of the impact of the STRS proposed rule would extend beyond epidemiological studies as well. Many of the quantified benefits from environmental regulations derive from large numbers of premature deaths prevented by the regulations. To monetize the benefit of these reductions in premature deaths, economists have developed estimates for the Value of a Statistical Life (VSL). The widely used, best VSL estimates are based on the Census of Fatal Occupational Injuries (CFOI) fatality data.[22] The CFOI data, which are confidential and never reported in journals that require data posting, could be just as vulnerable under the STRS proposed rule as epidemiological studies. (Interestingly, the reasons for confidentiality for the CFOI data has less to do with protecting personally sensitive information of the deceased in the studies, than with the fear that the data will be used to identify firms that are part of the studies.)

These studies, which enjoy the support of the scientific community, provide the main justification—in some cases the only possible justification—for some of our most important environmental protections, which have significantly improved the lives of the American people. The EPA's claim that the STRS proposed rule would make the science it relies on more credible and reliable do not withstand scrutiny. The EPA wrongly asserts that its proposal is consistent with the data sharing policies of the leading scientific journals and with the replication standards of the Office of Management and Budget. Neither assertion is true. The EPA also asserts

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scientific data is publicly available for review)." *Id.*

[18] *See* Scott Waldman & Robin Bravendar, *Pruitt Is Expected to Restrict Science. Here's What It Means*, CLIMATEWIRE (Mar. 16, 2018), https://www.eenews.net/climatewire/stories/1060076559/.

[19] *See* Rebecca Beitsch, *Battle over Science Roils EPA*, HILL (June 9, 2019), https://thehill.com/policy/energy-environment/447520-battle-over-science-roils-epa.

[20] Michael Bastasch, *Andrew Wheeler Says He Will Implement Rule to Keep 'Secret Science' Out of EPA*, DAILY CALLER (Mar. 5, 2019), https://dailycaller.com/2019/03/05/ANDREW-WHEELER-SECRET-SCIENCE-EPA/.

[21] Richard L. Revesz, *Trump's EPA Chooses Rodents Over People*, N.Y. TIMES (Sept. 26, 2019), https://www.nytimes.com/2019/09/26/opinion/epa-animal-testing.html.

[22] *See* W. KIP VISCUSI, PRICING LIVES: GUIDEPOSTS FOR A SAFER SOCIETY (2018).

that the confidentiality of health data can be protected through data anonymization. The leading researchers in the area compelling show that not to be the case. And, the EPA's proposal is inconsistent with standard precepts of decision theory and with the goal of acting consistently with cost-benefit principles. The STRS proposed rule would cripple the ability to conduct future epidemiological studies and, if applied retroactively, would threaten to remove from consideration the leading research demonstrating the link between airborne pollutants and devastating public health consequences.

B. Attacking Epidemiological Studies

The STRS proposed rule could bar the agency from relying on epidemiological studies in the rulemaking process. Such studies typically collect years' worth of extensive sensitive data on medical history, personal habits, and socioeconomic status from thousands of individuals. Data of this sort is generally protected by confidentiality agreements that bar researchers from sharing it in a manner that would allow an individual to be identified. Without such confidentiality protections, individuals typically would not agree to participate in studies requiring personal information.[23]

Many experts have expressed their concern about the impact that the STRS proposed rule would have on the use of scientific data to inform EPA regulations, especially epidemiological studies. Nearly seventy public health, medical, academic, and scientific organizations wrote a joint letter to Pruitt explaining that while they support transparency in the scientific process, they strongly opposed the approach taken by the STRS proposed rule.[24] The signatories explained that excluding studies simply because the raw data cannot be made publicly available would result in inadequately informed regulatory decisions that could subject people to real harm: "The result would be decisions affecting millions based on inadequate information that fails to include well-supported studies by expert scientists. These efforts are misguided and will not improve the quality of science used by EPA nor allow the agency to fulfill its mandate of protecting human health and the environment."[25]

For example, there are many studies for which the underlying data cannot be made publicly available because doing so would be infeasible, counterproductive, or dangerous.[26] In particular, epidemiological studies would be especially vulnerable to exclusion.[27] Environmental epidemiologist Douglas Dockery, director of Harvard's Center for Environmental Health and a coauthor of the Harvard Six Cities study, discussed later in this Part, stated that the STRS proposed rule would undermine how scientists track the effects of pollution and chemical exposure on public health, concluding that the STRS proposed rule is "a direct assault on epidemiology."[28]

Indeed, under the STRS proposed rule, many epidemiological studies that are pertinent to the EPA's work could not be considered during the rulemaking process due to data confidentiality obligations. For example, in a study published in the *American Journal of Respiratory and Critical Care Medicine* in June 2018, researchers found, for the first time, that fine particulate matter exposure was more strongly associated with respiratory emergency hospital visits for children than for adults, while ozone exposure was more strongly associated with respiratory

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[23] *See* Warren Cornwall, *New Rule Could Force EPA to Ignore Major Human Health Studies*, SCIENCE (Apr. 25, 2018), https://www.sciencemag.org/news/2018/04/new-rule-could-force-epa-ignore-major-human-health-studies.

[24] *Public Health, Medical, Academic, and Scientific Groups, Oppose EPA Transparency Rule*, MICHAEL J. FOX. FOUNDATION (July 16, 2018), https://www.michaeljfox.org/publication/public-health-medical-academic-and-scientific-groups-oppose-epa-transparency-rule?category=7&id=663.

[25] *Id.*

[26] Michael J. Fox Foundation, Comment Letter on Proposed Rule for Strengthening Transparency in Regulatory Science 1 (Aug. 16, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4878.

[27] Marianna Lavelle, *Science, Health Leaders Lay Out Evidence Against EPA's 'Secret Science' Rule*, INSIDE CLIMATE NEWS (Aug. 15, 2018), https://insideclimatenews.org/news/15082018/epa-secret-science-rule-opposition-health-environmental-data-public-comments.

[28] Carolyn Kormann, *Scott Pruitt's Crusade Against "Secret Science" Could Be Disastrous for Public Health*, NEW YORKER (Apr. 26, 2018), https://www.newyorker.com/science/elements/scott-pruitts-crusade-against-secret-science-could-be-disastrous-for-public-health.

emergency hospital visits for adults than for children. The researchers concluded that in light of this finding, relying on Medicare data and other studies that restrict their analysis to populations over age sixty-five "could underestimate population respiratory health impacts of $PM_{2.5}$ or ozone."[29] However, because the study was based on confidential emergency room visit records aggregated by state agencies to protect the patients' privacy, the STRS proposed rule would bar the EPA from considering it.[30]

In addition to excluding studies that have already been conducted, the rule will have a devastating effect on future research. Most obviously, absent confidentiality agreements, it would be very difficult to recruit subjects for epidemiological studies. Few people want their most private habits—that they engage in risky activities, for example—or detailed information about their health disclosed publicly for everyone to see. Peter Thorne, a toxicologist at the University of Iowa and former chair of the EPA's science advisory board, said that, with the STRS proposed rule in place, researchers might have more trouble recruiting participants for epidemiological studies in the future because of a fear that their personal information would ultimately be shared with the government.[31]

Some scientists have considered alternative approaches to study design to improve transparency while satisfying confidentiality obligations, but these efforts are unlikely to satisfy the STRS proposed rule. For example, Joel Kaufman, an epidemiologist at the University of Washington, is currently conducting a study for which he is attempting to create a "limited" dataset that could be shared with other researchers consistent with confidentiality restrictions under which he obtained the data, but believes that reasonable efforts to protect confidentiality while allowing transparency will not satisfy the rule.[32]

The STRS proposed rule is likely to have particularly pernicious effects for studies using data from low probability but high impact events, including natural disasters, environmental catastrophes, wars, or terrorist attacks This is because replication standard could be interpreted as barring the EPA from considering any study for which the underlying data cannot be replicated in an experimental setting. Obvious examples include studies using data of human exposure to pollution or toxins resulting from natural disasters, including oil spills, such as the 2009 BP Deepwater Horizon catastrophe in the Gulf of Mexico; events like the nuclear plant failures in Chernobyl or the Fukushima; fallout from deployment of nuclear weapons in Hiroshima and Nagasaki; or the long-term health effects for first responders to the September 11, 2001 terrorist attacks. In its own data guidelines developed during the George W. Bush Administration, the Office of Management and Budget explicitly identified this problem, noting that "it may not be feasible to replicate the radiation exposures studied after the Chernobyl accident."[33]

Focusing on studies of this sort, a group of nearly one thousand scientists from across the United States sent a letter to Pruitt explaining that the proposed rule would exclude critically important public health studies because their underlying data cannot be replicated.[34] And, at the STRS proposed rule's public hearing, the American

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[29] Heather M. Strosnider et al., *Age-Specific Associations of Ozone and Fine Particulate Matter with Respiratory Emergency Department Visits in the United States*, 199 AM. J. RESPIRATORY & CRITICAL CARE MED. 882, 887 (2018).

[30] Paul English & John Balmes, *Associations between Ozone and Fine Particulate Matter and Respiratory Illness Found to Vary between Children and Adults. Implications for U.S. Air Quality Policy*, 199 AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE 817, 818 (2019).

[31] Cornwall, *supra* note 23.

[32] *Id.*

[33] Office of Mgmt. & Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8456 (2002).

[34] Letter from 985 scientists to Scott Pruitt, Administrator, U.S. Envtl. Prot. Agency (Apr. 23, 2018), https://s3.amazonaws.com/ucs-documents/science-and-democracy/secret-science-letter-4-23-2018.pdf.

Pediatric Association, the American Lung Association, and former government employees with regulatory experience in the EPA and OSHA all raised these concerns as well.[35]

C. Meta-Analysis and Decision Theory

The STRS proposed rule could also cast a pall over meta-analyses, another significant category of studies linking exposure to contaminants and adverse health effects. Meta-analyses, which aggregate the results of large numbers of studies, including epidemiological studies, have become increasingly prevalent and are an important, standard tool in the field of public health.[36] Because the purpose of a meta-analysis is to aggregate the data from existing studies, the researcher conducting the meta-analysis will often be unable to make the underlying data public, even if she desired to do so. Excluding credible, peer-reviewed meta-analyses from the EPA's rulemaking process simply because they might incorporate some studies for which the data is not publicly available prevents the agency from using an effective tool for increasing the oversight and credibility of the underlying studies included in the meta-analyses.

A different problem arises if, as a result of the STRS proposed rule, researchers begin to exclude from their meta-analyses studies for which the underlying data is not publicly available in order to meet the requirements of the STRS proposed rule. Excluding these studies risks introducing systemic bias into the meta-analyses, undercutting their ultimate quality. For an optimal meta-analysis, researchers first select studies based on how relevant they are to answering the question of interest. In aggregating the relevant pool of studies, researchers would weigh each study based on that study's evidentiary value. As long as a study has any evidentiary value whatsoever, researchers would not exclude it because doing so would result in a less precise aggregate estimate. Thus, the STRS proposed rule would force researchers to violate the best practices, endorsed in the scientific community, for how meta-analysis should be conducted if they want their meta-analysis to be eligible for EPA consideration.[37]

Designating a study as having no evidentiary value simply because the underlying data cannot be made publicly available is arbitrary, and would result in a less accurate average estimate.[38] Moreover, it would reduce the sample size of a meta-analysis, making it more difficult to draw legitimate statistical conclusions.[39] Additionally, excluding studies based on criteria that are unrelated to their evidentiary value, such as whether the data is publicly disclosed, may result in biased estimates if the estimates in studies for which the data is not publicly disclosed differ from the estimates in other studies.[40] Moreover, doing so is inconsistent with the EPA's own guidance for conducting meta-analyses, which states that studies should be weighted according to their sample size or standard error.[41]

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[35] U.S. ENVTL. PROT. AGENCY, PUBLIC HEARING ON STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE 200, 282, 372 (2018), https://yosemite.epa.gov/sab/sabproduct.nsf/C8DC97CD16CBF8808525840B0068C228/$File/Public+comments+from+Earthjustice.pdf (attachment 2)

[36] *See* Jessica Gurevitch et al., Review, *Meta-Analysis and the Science of Research Synthesis*, 555 NATURE 175 (2018).

[37] Madison Condon, Michael Livermore & Jeffrey Shrader, *The Costs and Benefits of "Strengthening Transparency in Regulatory Science,"* _ REV. ENVTL. ECON. & POL'Y (forthcoming 2020).

[38] *See, e.g.*, PETER HOWARD, INST. FOR POLICY INTEGRITY, AN EVALUATION OF THE REVISED DEFINITION OF "WATERS OF THE UNITED STATES" 7 (Apr. 11, 2019), https://policyintegrity.org/documents/Shrader_Howard_Expert_Report_FINAL.pdf.

[39] MADISON CONDON, INST. FOR POLICY INTEGRITY, ORAL COMMENTS TO EPA'S SCIENCE ADVISORY BOARD ON PLANNED ACTIONS AND THEIR SUPPORTING SCIENCE 2–3 (June 5, 2019), https://policyintegrity.org/documents/EPA_SAB_Comments_on_Science_Transparency.pdf.

[40] HOWARD, *supra* note 38, at 6–7 (citing MICHAEL BORENSTEIN ET AL, INTRODUCTION TO META-ANALYSIS 280 (2009)). *See also* Condon, Livermore & Shrader, *supra* note 37, at 2.

[41] U.S. ENVTL. PROT. AGENCY, EE-0494, REPORT OF THE EPA WORK GROUP ON VSL META-ANALYSES (2006), https://www.epa.gov/sites/production/files/2018-02/documents/ee-0494-01.pdf.

Even if epidemiological studies in the future are conducted in a manner that complies with the STRS proposed rule, past studies still could not be included in meta-analyses. The entire purpose of a meta-analysis is to aggregate large numbers of scientific studies that span generations and incorporate different datasets and research methods. The STRS proposed rule would make it impossible for scientists to conduct scientifically appropriate meta-analyses that would meet the requirements of the STRS proposed rule.

The STRS proposed rule's all-or-nothing approach, in which scientific evidence is credited if it meets its data transparency requirements and must be ignored if it does not, is also inconsistent with key precepts of decision theory. In particular, outright exclusion of scientific studies based on arbitrary criteria, such as whether a study's underlying data is publicly available, will result in the exclusion of relevant, valid peer-reviewed science from EPA consideration.

In a recent article, Madison Condon, Michael Livermore, and Jeffrey Shrader evaluated the reasoning underlying the STRS proposed rule's approach.[42] In particular, the authors take issue with the EPA's claim that "the benefits of this proposed rule justify the costs,"[43] because the agency neglected to consider how the exclusion of relevant studies will adversely affect decisionmaking processes. Given accepted approaches to decision theory, the agency should take account of all available evidence and update its assessments in light of new evidence. Under this approach, the agency would use all studies that include potentially valuable information to inform its belief about the costs and benefits of regulation. And it would place weight on each study in proportion to that study's evidentiary value.

This framework sheds significant light on the question of whether the agency should exclude studies based on the public availability of underlying data. If the agency had a defensible reason to believe that studies have higher evidentiary value if their data is publicly available, then, other things being equal, it should place a higher weight on those studies. But there is no justification for treating the availability of information as more important than any other consideration by altogether ignoring studies that do not have publicly available data. Indeed, data availability is not the only factor that could plausibly affect the weight accorded to a particular study. Other factors include the size of the sample, the age of the study, the publication in a peer-reviewed journal, and the transparency of the estimation technique.

Taken to its logical conclusion, the EPA's approach could lead to a nihilistic situation in which all scientific data is excluded. As anyone who submits articles to peer reviewed journals can attest, referees almost always subject articles to criticism. If every departure from perfection, which is necessary given data or methodological limitations, were a reason to ignore a study's conclusions, we might end up in a world in which no scientific studies could be used for regulatory purposes. In such a world, of course, deadly harms would go unregulated. For this reason, the scientific community uses peer review and widely accepted disciplinary norms, as opposed to perfection, as the standard for crediting scientific work. And, as indicated above, the peer review practices of the leading journals do not require the data disclosure straitjacket of the EPA's proposed rule.

D. False Claims About the Scientific Consensus

The EPA's justifications for this radical proposal, which would allow dangerous pollutants to be inadequately regulated or unregulated altogether, are based on false claims and do not withstand serious scrutiny. For example, in its proposal, the EPA wrote that the STRS proposed rule is "informed by the policies recently adopted by some major scientific journals,"[44] including *Science*, *Nature*, and *Public Library of Science (PLoS)*.[45] The head editors of those journals published a joint statement in response to the STRS proposed rule, emphasizing that while they require that all data be made available to other researchers for the purposes of reproducing or

[42] Condon, Livermore & Shrader, *supra* note 37. This paragraph and the next one rely heavily on that piece.

[43] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,772 (proposed Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30).

[44] 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).

[45] *Id.* at 18,770 n.11.

extending the analysis of a study, the data need not be made publicly available.[46] Moreover, the editors stress that "[e]xceptional circumstances, where data cannot be shared openly with all, include data sets featuring personal identifiers," thus recognizing that full transparency is not appropriate for epidemiological studies.[47] And, they explain that "the merits of studies relying on data that cannot be made publicly available can still be judged" because "[r]eviewers can have confidential access to key data and as a core skill, scientists are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results."[48] The editors conclude by stressing the importance that public policies rely on "the full suite of relevant science vetted through peer review" and that "[e]xcluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."[49]

More generally, these leading journals, along with over one thousand other journals, have adopted the 2015 Transparency and Openness Promotion (TOP) standards.[50] Unlike the STRS proposed rule, the TOP standards are effective for producing reliable science while allowing for flexibility in situations where data cannot be made publicly available. The TOP standards recognize that researchers' ability to share data differs across scientific disciplines, and that not all of the standards are applicable to every journal.

Science, *Nature*, and *PLoS* have all incorporated the TOP standards in their research data sharing policies, allowing them to encourage data transparency while understanding that public data disclosure is not feasible in studies where researchers must protect the confidentiality of personal information. Unlike the STRS proposed rule, the policies of these journals encourage data transparency, but do not strictly require that the data underlying scientific studies be made publicly available in order to evaluate the credibility of a study.

Prominent scientists similarly took issue with the EPA's approach. For example, John P.A. Ioannidis, Chair in Disease Prevention at the Stanford University School of Medicine, published an article criticizing the STRS proposed rule.[51] Although Ioannidis believes that direct access to data is an indicator of transparency,[52] and making data widely available is an "exciting, worthy aspiration,"[53] he explained that the STRS proposed rule would be harmful to EPA decisionmaking because "most of the raw data from past studies are not publicly available."[54] Ioannidis pointed out that in a random sample of 268 biomedical papers published from 2000-2014, none of them provided access to all of their raw data, and "the proportion of studies that have had their raw data independently re-analyzed is probably less than one in a thousand."[55] Thus, he concluded that the STRS proposed rule would lead the EPA to exclude so much relevant research that it would practically eliminate science from the decisionmaking process, leaving regulations to be designed "on opinion and whim."[56]

E. Inconsistency with Established Government Practices

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[46] Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, 360 SCIENCE (May 4, 2018), http://science.sciencemag.org/content/360/6388/eaau0116.

[47] *Id.*

[48] *Id.*

[49] *Id.*

[50] *Implementing TOP*, CENTER FOR OPEN SCIENCE, https://cos.io/top/ (last visited Aug. 2, 2019).

[51] John P.A. Ioannidis, Editorial, *All Science Should Inform Policy and Regulation*, 15 PLOS MED., at 1 (May 3, 2018), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.

[52] Shareen A. Iqbal et al., *Reproducible Research Practices and Transparency Across the Biomedical Literature*, 14 PLOS BIOLOGY (Jan. 4, 2016), https://journals.plos.org/plosbiology/article/file?id=10.1371/journal.pbio.1002333&type=printable.

[53] Ioannidis, *supra* note 51.

[54] *Id.*

[55] *Id.* (citing Iqbal et al., *supra* note 52).

[56] *Id.* at 2.

In another false assertion seeking to claim support for its misguided policy proposal, the EPA suggested that the STRS proposed rule is consistent with the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies.*[57] Unlike the STRS proposed rule, the OMB Guidelines do not try to strictly link data transparency to scientific credibility. Instead of the one-size-fits-all approach of the EPA proposal, the OMB Guidelines contemplate a broader scope for the requirement of reproducibility. In particular, they urge caution, particularly in the case of epidemiological studies, "because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data."[58] And the guidelines ask "that agencies consider, in developing their own guidelines, which categories of original and supporting data should be subject to the reproducibility standard and which should not."[59] The guidelines recognize that "[e]ven in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard."[60] For example, they note that the results could be replicated by "a qualified party, operating under the same confidentiality protections as the original analysts."[61] The STRS proposed rule misleadingly cites the OMB Guidelines without acknowledging any of these essential distinctions.

Neither the scientific practices of the leading journals nor the OMB Guidelines do anything remotely similar to what the EPA proposal attributes to them. Instead of the EPA's wooden inflexible approach, which is at odds with the way in which science is conducted, the scientific journals and the OMB Guidelines explicitly tailor the data disclosure requirements to the needs of particular types of research and recognize that, for epidemiological studies, there are serious limits on what data can be disclosed.

F. Data Anonymization

In its proposal, the EPA acknowledges that a significant amount of raw data cannot be made entirely publicly available for legal and ethical reasons. However, the EPA suggested that these concerns can be addressed with "simple" techniques such as data masking, coding, and de-identification measures.[62] Along these lines, some of the most prominent trade associations representing regulated entities closely aligned with the deregulatory policies of the Trump administration, including the National Association of Manufacturers, American Chemistry Council, and American Petroleum Institute encouraged the EPA to implement or develop de-identification strategies and protected data sharing mechanisms, arguing that this would be sufficient for maintaining anonymity and protecting individuals' privacy.[63] Going further, the Fertilizer Institute stated that arguments that confidentially protected data is a barrier to implementing the STRS proposed rule are "red herrings."[64]

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[57] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,769–70 (proposed Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30).

[58] Office of Mgmt. & Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8456 (Feb. 22, 2002).

[59] *Id.* at 8455.

[60] *Id.* at 8456.

[61] *Id.*

[62] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. at 18,771.

[63] *See, e.g.*, National Association of Manufacturers, Comment Letter on Proposed Rule for Strengthening Transparency in Regulatory Science 2 (Aug. 9, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6102.

[64] The Fertilizer Institute, Comment Letter on Proposed Rule for Strengthening Transparency in Regulatory Science 3 (Aug. 16, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6148. The Fertilizer Institute wrote that "[s]ome opponents of the use of transparent data claim that use of non-public or confidentially protected data is a barrier to implementing the practices described in the proposed rule," but "arguments for using non-publically available data are red herrings." *Id.* TFI went on to say that "[m]any tools and methodologies exist to mask personal information that may be sensitive." *Id.* TFI also wrote, however, that they recognize "that in some circumstances full transparency may

The EPA and the trade associations supporting its position have vastly oversimplified the nature of confidentiality problem. Indeed, measures like data de-identification and masking are widely known to be ineffectual because anonymized datasets can be combined with additional publicly available information in order to uniquely identify individuals. Latanya Sweeney, a professor of government and technology at Harvard University and one of the leading scholars in the field of data privacy, used data from the 1990 census to determine that eighty-seven percent of Americans are uniquely identified by the combination of their zip code, birthdate, and gender.[65] And it is especially easy to re-identify individuals living in small rural communities.[66]

Sweeney powerfully illustrated this phenomenon while she was still in graduate school, with respect to an instance in which a government agency released an anonymous dataset containing every state employee's hospital visits. William Weld, the governor of Massachusetts at the time, had assured the public that patient privacy had been protected because the dataset excluded obvious individual identifiers, such as name, address, and social security number. However, the dataset still contained the zip code, birthdate, and gender of every individual. To prove how easy it was to re-identify the individuals using this information, Sweeney used publicly available voter roll information—which included the name, address, ZIP code, birthdate, and gender of every voter—and cross-referenced it with the health data. By combining these datasets, Sweeney was able to uniquely identify Governor Weld's health data, which she sent to his office.[67] As a result, Paul Ohm, a professor at Georgetown University Law Center and a prominent expert in information privacy and computer crime law, argues that "[d]ata can be either useful or perfectly anonymous but never both."[68]

Similarly, a group of Belgian scientists recently published an article in *Nature Communications* setting forth a method that can accurately estimate the likelihood of a specific person being re-identified from a de-identified dataset.[69] Using their model, the scientists found that 99.98% of Americans would be re-identified in any dataset using 15 demographic attributes. The scientists concluded by explaining that "even heavily sampled anonymized datasets are unlikely to satisfy the modern standards for anonymization set forth by [the European General Data Protection Regulation] and seriously challenge the technical and legal adequacy of the de-identification release-and-forget model."[70]

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not be achievable." *Id.* For example, "some data submissions by trade groups or TFI members is protected as confidential business information (CBI) and may present transparency challenges to the agency;" in those cases, "it may have to be considered whether to exclude such data from the analysis or determine whether a generic format may be adequate to conceal site or company-specific proprietary information." *Id.*

[65] Latanya Sweeney, *Simple Demographics Often Identify People Uniquely* 2 (Carnegie Melon Univ., Data Privacy Working Paper No. 3, 2000). *See also* LATANYA SWEENEY, AKUA ABU & JULIA WINN, IDENTIFYING PARTICIPANTS IN THE PERSONAL GENOME PROJECT BY NAME 1 (2013), https://dataprivacylab.org/projects/pgp/1021-1.pdf ("We linked names and contact information to publicly available profiles in the Personal Genome Project. These profiles contain medical and genomic information, including details about medications, procedures and diseases, and demographic information, such as date of birth, gender, and postal code. By linking demographics to public records such as voter lists, and mining for names hidden in attached documents, we correctly identified 84 to 97 percent of the profiles for which we provided names.").

[66] *See* Alessandra Potenza & Rachel Becker, *Scott Pruitt's New 'Secret Science' Proposal Is the Wrong Way to Increase Transparency*, VERGE (May 1, 2018), https://www.theverge.com/2018/5/1/17304298/epa-science-transparency-rule-scott-pruitt-data-sharing.

[67] *Id.* at 1719–20.

[68] Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701, 1704 (2010).

[69] Luc Rocher et al., *Estimating the Success of Re-identifications in Incomplete Datasets Using Generative Models*, 10 NATURE COMM. (2019).

[70] *Id.* at 1.

At the same time, when datasets are stripped of so much useful identifying information, like age, gender, and occupation, they become less useful for epidemiological research. For example, in a dataset that contains individuals' names, gender, birthdate, zip code, and health conditions, a researcher may want to redact the names, gender, and birthdate of the individuals to protect anonymity before sharing the dataset with other researchers. However, with this new dataset, future researchers would be able to only correlate health issues with zip code, without taking into account potentially confounding variables like age and gender. A new, redacted dataset of this sort would certainly not be as valuable as the original in reproducing results or conducting further analysis.

Instead of redaction, researchers' standard protocol is to protect anonymity by aggregating the data. Speaking to this point, Peter Thorne, director of the Environmental Health Sciences Research Center at the University of Iowa College of Public Health and former chairman of the EPA's Science Advisory Board, said that if he had to redact a dataset, "it would have far less value than it has when [he] aggregate[s] it," because he would have to "redact so much of it, there would be nothing left."[71] Thorne explained that "when researchers disclose their datasets, they don't black out personal health information; instead, they group the results."[72] Thorne offered an example, explaining that "if [he] enrolled 100 people in a specific zip code, and 70 developed asthma and 30 didn't [he would] disclose data on those groups rather than individuals [to] protect people's privacy."[73] But this aggregation procedure, though more scientifically appropriate, would run afoul of the STRS proposed rule's commands.

G. Retroactive Application of the STRS Proposed Rule

A particularly pernicious consequence would follow if the EPA applied the STRS proposed rule retroactively to historical studies. The initial proposal did not take a position on this enormously important issue, instead soliciting comments on whether the STRS proposed rule should apply to scientific studies that were completed before the rule's effective date.[74] A subsequent draft of the rule, which suggested the EPA was considering having the rule apply retroactively, was later leaked in the press.[75]

If the STRS proposed rule only applies to future studies and rules—that is, if it applies solely prospectively—researchers and scientists may be able to start adapting the design of some studies to meet the requirements of the STRS proposed rule, though as discussed above, it may be impossible to adapt other studies to satisfy the rigid requirements of the rule. However, if the STRS proposed rule applies retroactively to studies that have already been completed, then the EPA could not rely on these studies, even if they were published in the leading peer reviewed journals, in setting regulations to protect public health and the environment. Some of the most important environmental regulations, which save tens of thousands of lives each year, would be deprived of their scientific support, on which administrations of both parties relied for decades.

Even if the substantive provisions of the STRS proposed rule were justified, targeting historical studies because they do not comport with contemporary methodological innovations is not consistent with well-established scientific research practices. Not surprisingly, the EPA received numerous comments saying as much. In particular, the major scientific organizations vigorously opposed the retroactive application of the STRS proposed rule. For example, the American Association for the Advancement of Science urged that all prior

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[71] Potenza & Becker, *supra* note 66.

[72] *Id.*

[73] *Id.*

[74] *Id.* at 18,772.

[75] *See* Lisa Friedman, *E.P.A. to Limit Science Used to Write Public Health Rules*, N.Y. TIMES (Nov. 11, 2019), www.nytimes.com/2019/11/11/climate/epa-science-trump.html. In response to the leaked document, the EPA claimed that the document was merely a draft and that the final rule would not apply retroactively. *See* News Release, U.S. Envtl. Prot. Agency, The New York Times' Several Glaring Inaccuracies 'That's Fit to Print' (Nov. 12, 2019), www.epa.gov/newsreleases/new-york-times-several-glaring-inaccuracies-thats-fit-print.

studies be exempt from the STRS proposed rule.[76] And the EPA's own Science Advisory Board, even after Pruitt purged it of many of the academic scientists and filled the positions with employees of regulated entities,[77] called the wisdom of retroactive application into question. It indicated that "[i]t might be easier to accomplish the rule's objectives if the focus were on future studies rather than on studies that are already designed and published with terms that make complete transparency difficult or impossible to accomplish."[78] Editors of major peer-reviewed scientific journals, in addition to submitting comments for the proposed rule, subsequently released a joint statement strongly reiterating their opposition to the retroactive application of the proposed rule to existing studies and regulations.[79] Disregarding historical scientific studies simply because accepted methodologies have changed is flatly inconsistent with how scientific research is actually done.

The regulated community was divided on the question. The American Chemistry Council, a prominent trade association representing chemical companied that generally opposes regulation, took issue with the retroactive application of the STRS proposed rule. It indicated that "[r]etrospective application of any regulation (and its underlying scientific evaluations) is rife with complication, confusion, and significant ambiguity for EPA and stakeholders alike."[80] Using the National Ambient Air Quality Standards (NAAQS) under the Clean Air Act (CAA) as an example, it explained that "each NAAQs review under the CAA is based on a substantial amount of scientific and policy information" and "[t]he retroactive application of this proposal to those administrative records would only serve to confuse, distress, and impede a NAAQS review process that is already severely overburdened."[81]

In contrast, the American Petroleum Institute, a prominent trade association representing oil companies, which normally is aligned with the American Chemistry Council, parted ways with its usual ally on this matter. It argued that the STRS proposed rule should apply retroactively to studies that the EPA has previously relied on in promulgating regulations.[82]

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[76] *See* American Association for the Advancement of Science, Comment Letter on Proposed Rule for Strengthening Transparency in Regulatory Science 3 (July 16, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4595 ("Regarding prospective and retrospective application, while the proposed rule states that it will be prospectively applied to future regulations and policies, it acknowledges it will capture scientific data and models that were developed prior to this current proposal. AAAS believes that all prior studies should be exempt from this rule, as many foundational studies regarding air quality and asthma and exposure to mercury and lead were conducted decades ago. Thus, it will be difficult or impossible to make all the underlying data fully accessible.").

[77] *See* Lisa Friedman, *E.P.A. Broke Rules in Shake-Up of Science Panels, Federal Watchdog Says*, N.Y. TIMES (July 15, 2019), www.nytimes.com/2019/07/15/climate/epa-advisory-panels-gao-report.html.

[78] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, to Members of the Chartered SAB and SAB 3 (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[79] *See* H. Holden Thorp et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data (2019)*, 366 SCIENCE (Dec. 6, 2019), https://science.sciencemag.org/content/366/6470/eaba3197.full.

[80] American Chemistry Council, Comment Letter on Proposed Rule for Strengthening Transparency in Regulatory Science 20 (Aug. 16, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6946.

[81] *Id.*

[82] *See* American Petroleum Institute, Comment Letter on Proposed Rule for Strengthening Transparency in Regulatory Science 9 (Aug. 16, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6375 ("Regarding retrospective application, if EPA does not ensure that data and models from past dose-response studies are made publicly available when reviewing a previously finalized rule or creating a new rule, EPA could be giving the same weight to studies that may not have the same level of quality or veracity. This could bias the rulemaking decisions toward results which do not represent the best available science.").

The most significant consequence of the STRS proposed rule is the potential exclusion of the Harvard Six Cities study, a large-scale epidemiological study published in 1993,[83] and a subsequent epidemiological study from the American Cancer Society published in 1995,[84] which are widely regarded as the leading studies of the adverse health consequences of particulate matter in the ambient air and were foundational to the EPA's subsequent strengthening of the NAAQS for particulate matter.[85]

The reason that so much is at stake is that reductions in particulate matter avoid such a large number of premature deaths. According to a 2016 OMB report, 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.[86] Moreover, the estimated benefits of air quality rules "are mostly attributable to the reduction in public exposure to fine particulate matter."[87] Reductions in exposure to fine particulate matter under the Clean Air Act have yielded myriad health benefits, including preventing, annually, nearly 230,000 premature deaths, 180,000 cases of acute bronchitis, 200,000 heart attacks, and 2.4 million cases of asthma exacerbation.[88] As a result, the consequences of not considering the Harvard Six Cities study and American Cancer Society study in future revisions of the particulate matter standards could be extremely serious, needlessly placing at risk the lives of large numbers of Americans. And, contrary to the stated goals of the STRS proposed rule, excluding the two studies would mean that the EPA was no longer using the "best available science" in setting the National Ambient Air Quality Standards.[89]

This is not the first time that anti-regulatory figures have attempted to cast doubt on the Harvard Six Cities study and American Cancer Society in an effort to undermine EPA regulations. In 2013, Republican Representative Lamar Smith, then the chairman of the Committee on Science, Space, and Technology, subpoenaed the raw data of the two studies, arguing that "[r]egulations based on secret data have no place in a democracy."[90] He was ultimately unsuccessful in his quest, as the studies' research teams refused to turn over the data, explaining that they had to protect the participants' confidentiality.

These complaints are being leveled even though both the Harvard Six Cities study and the American Cancer Society study have been the subject of independent verification. When the findings of the Harvard Six Cities

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

[84] 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).

[85] *See* Paul English & John Balmes, *Associations Between Ozone and Fine Particulate Matter and Respiratory Illness Found to Vary Between Children and Adults. Implications for U.S. Air Quality Policy*, 199 AM. J. RESPIRATORY & CRITICAL CARE MED. 817, 818 (2019) ("If this rule is approved, then it is possible that these study findings might not be taken into consideration for any changes in the NAAQS on fine particulate matter or ozone, as they are based on personal patient data."); Renee N. Salas et al., *The U.S. Environmental Protection Agency's Proposed Transparency Rule Threatens Health*, 170 ANNALS OF INTERNAL MEDICINE 197, 197 (2019) ("[The Harvard Six Cities study] was fundamental to the EPA's implementation of the Clean Air Act . . . . Although the Six Cities Study has been heralded as transparent, high-quality science, the proposed rule would have excluded it from the EPA's consideration.").

[86] 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.

[87] *Id.* at 12.

[88] *See* U.S. ENVTL. PROT. AGENCY, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT FROM 1990 TO 2020: SUMMARY REPORT 14 exhibit 8 (2011). The estimates above were predicted to be achieved, annually, by the year 2020. *Id.*

[89] *See* English & Balmes, *supra* note 85, at 818.

[90] Christopher Rowland, *House GOP Demands Harvard Study Data*, BOS. GLOBE (Sept. 6, 2013), https://www.bostonglobe.com/news/nation/2013/09/06/landmark-harvard-study-health-effects-air-pollution-target-house-gop-subpoena/2K0jhfbJsZcfXqcQHc4jzL/story.html.

study were first published, industry groups attacked the research, primarily by publicizing that it contained "secret science."[91] The reason for the complaint was that, in the original publication of the study, the researchers provided the participant data only in an aggregated format because the data for each individual could not be made publicly available due to the patient confidentiality agreements under which the information was obtained.[92] For each city, the researchers provided summary statistics for twenty-one metrics such as the percentage of males and females, the percentage of smokers, and the average age.[93]

In July 2000, in response to the industry complaints, the researchers asked the Health Effects Institute (HEI), an organization co-funded by the EPA and the automobile industry, to determine whether the study's conclusions were correct.[94] To do so, the HEI was given access to the individual-level data. Like the original researchers, it had to sign strict confidentiality agreements.[95]

The HEI's Reanalysis Team performed a quality assurance audit of a sample of the original data of both the Harvard Six Cities study and the American Cancer Society study, which "revealed the data to be of generally high quality with a few exceptions" due to a small number of coding errors.[96] Correcting these errors did not materially change the original results. The work the Reanalysis Team were then "intensively and independently peer reviewed by a Special Panel of the HEI Health Review Committee."[97] The Reanalysis Team tested the robustness of the original results with alternative models. For example, it controlled for more variables and added interactions between variables that the original studies had not included. The HEI concluded that "the Reanalysis Team identified relatively robust associations of mortality with fine particles, sulfate, and sulfur dioxide, and they tested these associations in nearly every possible manner within the limitations of the datasets."[98]

Opposing the STRS proposed rule, George Thurston, a scientist at the New York University School of Medicine who worked on the HEI's Reanalysis team, explained that the EPA already has the ability to independently verify scientific studies through organizations like the HEI. Thurston wrote that instead of requiring that data be made publicly available through the STRS proposed rule, the EPA should "fund HEI to do such independent assessments, without risking private research data." [99]

And, ironically, the OMB Guidelines, on which, as discussed above, the EPA relies for support of its proposed rule, use the HEI's reanalysis of the Harvard Six Cities study and American Cancer Society study as an example of how to comply with a reproducibility standard for scientific studies without violating the confidentiality agreements necessary to obtain the data on which the studies are based.[100]

In proposing the STRS proposed rule, the EPA completely ignored the fact that the Harvard Six Cities study and American Cancer Society study have been successfully replicated and verified by and independent, unbiased third-party. If the EPA truly cared about increasing transparency, credibility, and reliability, it would at least

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[91] *See* Kormann, *supra* note 28.

[92] *See* Salas et al., *supra* note 85.

[93] Dockery et al., *supra* note 83, at 1755 tbl.1.

[94] HEALTH EFFECTS INST., REANALYSIS OF THE HARVARD SIX CITIES STUDY AND THE AMERICAN CANCER SOCIETY STUDY OF PARTICULATE AIR POLLUTION AND MORTALITY (2000), https://www.healtheffects.org/system/files/HEI-Reanalysis-2000.pdf.

[95] *Id.* at 42.

[96] *Id.* at ii.

[97] *Id.*

[98] *Id.* at iv.

[99] George Thurston, *The Perils Posed by the US Environmental Protection Agency's Transparency Rule*, 6 LANCET 40 (2018).

[100] *See* Office of Mgmt. & Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8456 (Feb. 22, 2002).

consider expanding the role of unbiased third-party organizations to perform independent analyses of the scientific studies the EPA relies on. Instead, the EPA has chosen to propose a rule that would make it impossible for the agency to rely on a vast literature of important epidemiological studies and would completely throw out some of the most important public health science we have to date. The EPA has tried to mask the STRS proposed rule as a policy that would increase scientific credibility and reliability. In reality, the STRS proposed rule is a thinly-veiled attempt at excluding science from the EPA's rulemaking process, particularly the Harvard Six Cities study and American Cancer Society study.

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The STRS proposed rule attempts to undermine EPA's ability to set effective public health and environmental protections. Epidemiological studies, which are especially vulnerable to exclusion, have been instrumental in determining the benefits of EPA regulations that protect public health and the environment. Promoting transparency is clearly desirable, but the EPA's blunt, one-size fits-all approach, as opposed to the contextually sensitive approaches of the scientific community, threatens to erase the conclusions of well-conducted, peer-reviewed, and appropriately replicated studies, cutting the legs from under regulations that have brought enormous benefits to the American people in the form of large numbers of avoided deaths, heart attacks, strokes, and serious respiratory problems. And there is good reason to suspect, given the longstanding efforts of congressional Republicans and of the Trump Administration's interest group allies, that behind this seemingly general proposal is the very specific objective of, once again, casting doubt on the Harvard Six Cities study and American Cancer Society study.

The Harvard Six Cities study and American Cancer Society study are largely responsible for providing the scientific support for the air quality rules that constitute a majority of all the monetized benefits of federal regulations. Ignoring studies such as these based will significantly worsen the quality of the regulatory outcomes. If the EPA's genuine aim is to improve the scientific integrity of its rulemaking processes, there are good-faith alternatives that, unlike the STRS proposed rule, enjoy the support of the scientific community. That it has chosen not to do so is an indication that the rule's purported goal of transparency is merely a means to the true end of erasing the scientific basis for major environmental protections.

III. RESURRECTING DISCREDITED MODELS

The prior two Parts analyzed alternative strategies used by the Trump administration to provide a veneer of rationality to its deregulatory agenda. First, inconsistently with the core precept of cost-benefit analysis, which is based on a comparison of costs and benefits, the Trump administration is trying to justify deregulation by looking exclusively at cost savings to regulated industry and ignoring the forgone public health and environmental benefits. Second, disregarding the consensus of the scientific community and consistent regulatory practices by administrations of both parties over decades, the Trump administration has called into question the validity of epidemiological studies, which are one of the two main categories of studies of the adverse health effects of contaminants. So, if the first approach fails and the administration cannot deregulate without considering the forgone benefits, it can eliminate the most important public health benefits by striking at that their scientific underpinnings.

This Part focuses on an additional backup plan in the campaign to undermine cost-benefit analysis. In case both tactics criticized in the prior two Parts failed, the Trump administration is pushing another argument, also flatly inconsistent with the scientific consensus: that the most prevalent air pollutants, in general, and that particulate matter, in particular, have thresholds below which they produce no adverse health effects. In doing so, it can eliminate an important proportion of the health benefits of regulation.

When first confronted with the potential for pollutants to cause serious health effects, scientists needed to identify the relationship between exposure to these substances and damage to the body. The common refrain that "the dose makes the poison" had been the mantra of medical experts for generations.[1] It evoked the idea that exposures are harmless until some threshold is reached; only once subjected to a high enough amount would people experience any negative health consequences.

But, as scientists began studying pollutants like radiation and particulate matter in greater detail, they concluded that while there are certain substances that do cause harm only above an exposure threshold, many dangerous chemicals do not have a threshold below which no harm occurs. Instead, any amount of exposure causes damage to the human body, though the effects are more severe at higher concentrations.[2] As a result of these more modern scientific understandings, for more than four decades, under administrations of both parties, federal agencies have treated two important classes of pollutants as non-threshold contaminants: carcinogens, and the six so-called "criteria" pollutants regulated by the Clean Air Act: ground level ozone, particulate matter, carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide.

The Trump administration is now trying to undermine the scientific consensus and, without any plausible justification, depart from settled administrative practices. As with its attack on epidemiological studies discussed in the prior Part, it is focusing its ire on particulate matter, which is enormously pernicious to pubic health. If it can make some of the benefits of particulate reductions go away, the administration would have an easier task in providing a cost-benefit justification for its deregulatory actions.[3]

The Trump administration is engaged in this effort with the support of junk science advocates, who have discredited themselves repeatedly over more than half a century by attacking the scientific consensus behind government regulation of tobacco, acid rain, and other threats to health and the environment.[4] In contrast, its

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[1] *See* Claas Kirchhelle, *Toxic Tales—Recent Histories of Pollution, Poisoning, and Pesticides (ca. 1800–2010)*, 26 N.T.M. 213, 215 (2018).

[2] The discussion throughout this Part draws heavily from Kimberly M. Castle & Richard L. Revesz, *Environmental Standards, Thresholds, and the Next Battleground of Climate Change Regulations*, 103 MINN. L. REV. 101 (2018).

[3] *See* Nina Heikkinen, *To Kill Climate Rule, Trump's EPA Wants to Redefine Danger of Soot*, E&E NEWS (Aug. 6, 2018), https://www.eenews.net/climatewire/2018/08/06/stories/1060092763 (discussing how changes in benefit calculations for particulate matter helped justify the Clean Power Plan repeal).

[4] *See* NAOMI ORESKES & ERIK M. CONWAY, MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING (2010); RACHEL ROTHSHILD, POISONOUS SKIES: ACID RAIN AND THE GLOBALIZATION OF POLLUTION (2019).

efforts are opposed, as was the case with its attack on epidemiological studies, by the leadership of the scientific community and by the EPA's own science advisors.

A. Emergence of a Non-Threshold Consensus

The earliest studies demonstrating that pollution could cause harm even at very low doses concerned carcinogenic pollutants. Research into how carcinogens damage the body expanded dramatically following the development of nuclear technology and increasing concerns about the release of radioactive isotopes through atomic testing.[5] This work led to the realization that there was no threshold below which cells showed no damage once exposed to radiation.[6]

Over many decades, the EPA built off this insight to model the relationship between many different types of carcinogens and human health impacts. For example, the EPA has assumed in its cancer policy that a carcinogen does not have a safe threshold unless there is sufficient pollutant-specific data suggesting such a threshold exists for that pollutant. Other federal regulatory agencies like the Occupational Safety and Health Administration (OSHA) and Food and Drug Administration (FDA) have similarly taken the position that, presumptively, carcinogens have no thresholds.

The basic approach taken by the EPA and other federal agencies, consistent with modern understandings, involves first identifying the "mode of action" for carcinogens, which describes the sequence of key events and processes resulting in cancer formation. The mode of action can help scientists discern whether there is a threshold for the substance as well as whether the association between exposure and harm is linear in nature. A linear relationship means that negative effects increase proportionally as the amount of exposure rises. Non-linear associations can show different patterns. For example, an additional unit of concentration might produce more negative health impacts at higher concentrations than at lower ones. Once the EPA determines the mode of action, it models how exposure relates to risk of harm based on that mode of action. As one would expect, if the mode suggests a linear, non-threshold relationship, the EPA will so model the relationship; if, in contrast, the mode suggests a non-linear relationship or a threshold, the EPA will model that as well. In situations where the EPA does not have enough data to model the mode of action for carcinogens, it adopts a linear, non-threshold model as a default.[7]

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[5] *See generally* ELOF AXEL CARLSON, GENES, RADIATION AND SOCIETY: THE LIFE AND WORK OF H.J. MULLER (1981) (discussing H.J. Muller's pioneering research into how radiation causes cancer). *But see* NANCY LANGSTON, TOXIC BODIES: HORMONE DISRUPTORS AND THE LEGACY OF DES 17 (2010) (noting that early toxicological frameworks had been based on "a set of assumptions about thresholds, impermeable bodies, and purity that worked reasonably well in addressing the effects of acute poisoning" but failed to account for chronic exposures).

[6] Toshihiro Higuchi, *Atmospheric Nuclear Weapons Testing and the Debate on Risk Knowledge in Cold War America, 1945-1963*, *in* ENVIRONMENTAL HISTORIES OF THE COLD WAR 307 (J.R. McNeill & Corinna R. Unger, eds., 2010) (examining how the 1954 "Lucky Dragon" accident in the Bikini atoll led geneticists to publicly dispute the idea that exposure to radiation below a certain threshold "would not pose a threat to human health.").

[7] *See* U.S. ENVTL. PROT. AGENCY, EPA/630/P-03/001F, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, at 1-10 to -11 (2005) [hereinafter GUIDELINES FOR CARCINOGEN RISK ASSESSMENT], https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf (stating that "cancer risks are assumed to conform with low dose linearity" and that such models are necessarily non-threshold); NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 8 (2009) [hereinafter SCIENCE AND DECISIONS] ("For cancer, it is generally assumed that there is no dose threshold of effect . . . ."). 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/NIOSHPUB2017100revised ("For carcinogen risk assessment, the NIOSH generally treats exposure-response as low-

Research into noncarcinogenic chemicals eventually revealed that many of them, such as carbon monoxide and ozone, also did not appear to have a threshold below which no injuries occurred. In its earliest analyses in the 1970s, the EPA, in formulating regulations for the criteria pollutants—ground level ozone, particulate matter, carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide—used language suggesting threshold models for these pollutants.[8]

By 1977, only a few years after the federal government began formulating these regulatory standards, studies of air pollutants had provided sufficiently strong evidence of a non-threshold relationship between exposure and harm that Congress equated the idea that there was a "'no-effect' concentration" with a "chimera."[9] As a result, in the 1977 amendments of the Clean Air Act, it adopted a regulatory program called Prevention of Significant Deterioration, which constrains the degradation of ambient air quality in areas that have air quality that is better than the National Ambient Air Quality Standards.[10] If criteria pollutants had thresholds and if the standards were set at these thresholds, then there would be no reason for Congress to attempt to provide additional protection. Thus, in the 1977 amendments to the Clean Air Act, Congress rejected the threshold argument now being made by the Trump administration

Also in the late 1970's, the emerging scientific consensus led the EPA to adopt linear, non-threshold modeling for all but one of the six criteria pollutants: ozone, particulate matter, lead, sulfur dioxide, and nitrogen dioxide. Following this decision, the agency has consistently treated criteria pollutants as non-threshold pollutants under administrations of both parties, in line with the scientific consensus, an enormous body of literature, and the practice of other federal agencies.

There is also growing evidence that the EPA should stop using the threshold concept for other noncarcinogenic substances, not just those classified as criteria pollutants under the Clean Air Act. Unlike its approach to modeling risk for carcinogens and criteria pollutants, for other compounds the EPA does assume that there is a threshold below which exposure will not lead to adverse health impacts. However, epidemiological studies have documented human health impacts at lower and lower levels of exposure to a variety of chemicals. These findings led the National Research Council of the National Academy of Sciences to conclude in an influential 2009 report, *Science and Decisions*, that the threshold assumption model for most noncarcinogens currently used by the EPA is based on an outdated scientific understanding developed between the 1950s and the 1980s and "does not make the best possible use of available scientific evidence."[11] For these substances, instead of assuming a threshold model as the default and a non-threshold model as the exception, the better approach would be the opposite: a non-threshold model as the default and a threshold model as the exception, only where specific evidence for a given pollutant suggests it would be appropriate.[12] Though the EPA has consistently applied, for decades, the non-threshold assumption for carcinogens and criteria pollutants, the agency has not yet attempted to follow the 2009 recommendation to do away with using thresholds for

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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.").

[8] *See* Michael A. Livermore & Richard L. Revesz, *Rethinking Health-Based Environmental Standards*, 89 N.Y.U. L. REV. 1184, 1200–06, 1213–28 (2014) (discussing the EPA's use of threshold language for its earliest NAAQS).

[9] COMM. ON INTERSTATE & FOREIGN COMMERCE, CLEAN AIR ACT AMENDMENTS OF 1977, H.R. REP. NO. 95-294, at 111 (1977). The report cites findings from the National Academy of Sciences 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.*

[10] 42 U.S.C. § 7473(b).

[11] SCIENCE AND DECISIONS, *supra* note 7, at 177.

[12] *See* Al McGartland et al., *Estimating the Health Benefits of Environmental Regulations*, 357 SCIENCE 457 (2017).

evaluating the health impacts of other chemicals.[13] The European Commission, however, has signaled that, in at least some contexts, it may be moving more broadly towards using non-threshold models.[14]

Moreover, non-threshold models are generally more appropriate for analyzing population-level risk, which is what environmental standards are designed to reduce, because of the differential sensitivity that individuals exhibit towards contaminants. Each individual person has their own unique sensitivity to pollution exposures, and scientific studies have provided evidence that certain segments of the population are particularly susceptible to harm.[15] For example, very young children, pregnant women, or the elderly frequently will be more sensitive to toxins when exposed at the same level as the average population.[16] As a result, even if there were a threshold for person of average sensitivity, the threshold for an exceptionally sensitive person would necessarily be lower. And the threshold would be lower still, or even non-existant, for the most sensitive individuals in the population. In other words, even if individual toxicity thresholds existed, population-level toxicity would still be best modeled with non-threshold models. If an agency instead modeled the health risks of pollutants according to a toxicity threshold for the average person, it would be leaving more sensitive people unprotected.[17]

B. Particulate Matter and Public Health

As mentioned above, the EPA has long relied on a linear, non-threshold model for particulate matter (PM), a criteria pollutant that is especially dangerous to human health. Particulate matter is a mixture of very small particles and liquid droplets that are found in the air. Some particles, such as dust, dirt, soot, and smoke, are large enough to be visible, while others are too small to be seen with the naked eye. The EPA regulates particulate matter differently depending on the size of the particles because of variations in risk; smaller particles pose more of a danger because they penetrate further into the lungs. Exposure to particulate matter can have negative effects on lung and heart health, causing coughing or difficulty breathing, aggravating asthma, decreasing lung function, and contributing to heart attacks and irregular heartbeat. Exposure can be deadly, particularly for people with heart or lung disease.[18]

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[13] It is interesting to note that Dr. Thomas Burke, who chaired the NAS committee that wrote SCIENCE AND DECISIONS, *supra* note 7, served as the Deputy Assistant 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.

[14] *See Towards a Comprehensive European Union Framework on Endocrine Disruptors*, at 3, COM (2018) 734 final (July 11, 2018) (noting that "[a] share of scientists is of the view that a safe threshold cannot be established for endocrine disruptors.").

[15] *See* McGartland et al., *supra* note 12.

[16] *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)").

[17] *See* SCIENCE AND DECISIONS, *supra* note 7, 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.").

[18] *See 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); *Health and Environmental Effects of Particulate Matter (PM)*, U.S. ENVT'L PROTECTION AGENCY, https://www.epa.gov/pm-pollution/health-and-environmental-effects-particulate-matter-pm (last visited May 23, 2019) (listing the health effects linked to exposure to particulate matter).

Two studies have provided the most important evidence on the adverse health effects of particulate matter: the Harvard Six Cities study[19] and an American Cancer Society study.[20] Published in the 1990s based on data collected over decades, they present robust evidence on the negative effects of particulate matter from exposures at very low concentrations.[21] More recent follow-up research has confirmed the original findings of the two studies,[22] and the EPA has continued to rely on their assessments in formulating air quality standards for particulate matter,[23] as well as other emission controls that affect particulate levels.[24]

Experts outside of the EPA widely agree that the findings of the Harvard Six Cities study and the American Cancer Society study demonstrate that particulate matter is a non-threshold pollutant. 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 Regulations[25] concluded that "there is no evidence for any . . . indication of a threshold" for particulate matter.[26] 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 particulate matter exposure."[27] It reasoned that the EPA's

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[19] 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).

[20] 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).

[21] 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.

[22] *See id.* (citing the American Cancer Society's study versions from 1995, 2002, and 2004). *See also* 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 5-7 (2012) [hereinafter 2012 PM RIA], (citing the Six Cities Study updates from 2006 and 2012), https://www3.epa.gov/ttn/ecas/docs/ria/naaqs-pm_ria_final_2012-12.pdf.

[23] *See* 2012 PM RIA, *supra* note 22, at 1-12 (stating that the EPA relied on the Six Cities Study for its report).

[24] For instance, these studies were cited to support the Mercury Air Toxic Standards and the Clean Power Plan. *See* U.S. ENVTL. PROT. AGENCY, EPA-452/R-11-011, REGULATORY IMPACT ANALYSIS FOR THE FINAL MERCURY AND AIR TOXICS STANDARDS, at 5-27 (2011) [hereinafter MATS RIA], (relying on the analyses from the Six Cities Study and the American Cancer Society study), https://www3.epa.gov/ttnecas1/regdata/RIAs/matsriafinal.pdf. *See also* U.S. ENVTL. PROT. AGENCY, EPA-452/R-15-003, REGULATORY IMPACT ANALYSIS FOR THE CLEAN POWER PLAN FINAL RULE, at 4-16 to -17 (2015) [hereinafter CLEAN POWER PLAN RIA], https://www3.epa.gov/ttnecas1/docs/ria/utilities_ria_final-clean-power-plan-existing-units_2015-08.pdf, 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").

[25] 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 Heath-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].

[26] *Id.* at 109.

[27] 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 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.

"decision is supported by the data, which are quite consistent in showing effects down to the lowest measured levels."[28]

The findings have also been corroborated by additional research conducted separately from the follow up work to the two studies. For instance, the American Thoracic Society has found adverse health effects even in areas meeting current air quality standards for particulate matter set through the NAAQS.[29] A separate investigation by the Harvard School of Public Health produced similar results, and concluded that there is no evidence to suggest a threshold exists for particulate matter risks.[30] Global data compiled by the World Health Organization, a specialized agency of the United Nations, also supports the absence of a threshold for particulate matter; research throughout the world has found damage even at very low concentrations below current U.S. standards.[31]

The body of scientific evidence overwhelmingly supports the conclusion that particulate matter causes negative health effects at even the lowest levels of exposure, meaning there is no safe threshold below which risks would be eliminated for all individuals in a population. In 2006, the EPA solicited a report from experts in epidemiology, toxicology, and medicine to offer their expert opinions on the scientific evidence regarding the concentration-response relationship between small particulate matter particles and mortality.[32] All the contributors agreed that there was no epidemiological evidence to support the existence of a threshold.[33] The consensus of the group was that using a threshold model would also be inappropriate for determining potential harm from particulate matter, given that variations in genetic, environmental, and socioeconomic factors can make certain people experience negative effects at even small exposure levels.[34] A 2010 scientific report by the American Heart Association reached similar conclusions.[35] The report comprehensively reviewed studies on the relationship between particulate matter and heart health that had been published in the preceding five years.[36] It concluded that there was no safe threshold of exposure for particulate matter.[37]

C. A Consistent Regulatory Approach

As a result of the plethora of evidence on the absence of a threshold for particulate matter, the EPA has set air quality standards for particulate matter using non-threshold models for decades, regardless of which political party oversaw the agency. The EPA has incorporated the models in its Regulatory Impact Analyses, which

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[28] *Id.* at 13.

[29] *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.").

[30] The study indicated that the marginal health risk from additional exposure at low levels is actually higher than the risk at higher levels of exposure. *See* Qian Di et al., *Air Pollution and Mortality in the Medicare Population*, 376 NEW ENG. J. MED. 2513, 2515-18 (2017).

[31] 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.

[32] *See* INDUS. ECON., INC., EXPANDED EXPERT JUDGMENT ASSESSMENT OF THE CONCENTRATION-RESPONSE RELATIONSHIP BETWEEN $PM_{2.5}$ EXPOSURE AND MORTALITY, at i–ii (2006), https://www3.epa.gov/ttn/ecas/regdata/Uncertainty/pm_ee_report.pdf.

[33] *See id.* at 3-26.

[34] *See id.* at i-ii, iv, 3-25.

[35] *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).

[36] *See id.*

[37] *See id.* at 2338, 2350-51.

calculate the costs and benefits of pollution restrictions. In these evaluations, the EPA assumes that there will be benefits to reducing particulate matter all the way to zero in order to account for the harm caused by even the lowest levels of the pollutant.

Beginning with the Reagan administration, the EPA stated that no evidence supported the use of a threshold for particulate matter and used a linear model to determine the likely risk of effects at varying concentrations of the pollutant.[38] Likewise, the Clinton EPA issued NAAQS for particulate matter using linear, non-threshold modeling, noting that "the level or even existence of population thresholds below which no effects occur cannot be reliably determined."[39] It initiated the practice of calculating benefits for reducing particulate matter at levels below the standards it ultimately chose to implement. This analysis revealed that further reductions beyond the standards the agency promulgated would actually be cost-benefit justified.[40] The George W. Bush EPA, after analyzing recent new studies on particulate matter, found that no threshold could be found for the pollutant and maintained the Clinton administration's practice of calculating benefits below the standards it set through the NAAQS.[41] Again, the agency found that even stricter restrictions on particulate matter emissions would have additional net benefits because of the enormous health improvements from lower levels of the pollutant.[42] For example, twice as many deaths would be avoided by just a small reduction in emissions.[43]

The Obama EPA continued the use of linear, non-threshold modeling for particulate matter. For example, in the EPA's most recent revision of particulate matter standards, the agency stated that because "there was 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."[44] Again, as it had done in earlier administrations, the EPA analyzed the costs and benefits of controls assuming negative health effects at the lowest levels of exposure and found net benefits would actually be greater below the standards it chose to implement.[45] While acknowledging that all extrapolations of effects contain some degree of uncertainty, the agency noted that recent research had continued to find damage from very levels of exposure.[46]

D. Threshold Models and Junk Science

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[38] 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." 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.

[39] 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].

[40] The calculations showed that there would be greater overall benefits from reductions below the level of particulate matter ultimately chosen by the agency. *See* 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 ES−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.

[41] 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).

[42] 2006 PM RIA, *supra* note 21, at ES-7 tbl.ES-1 (comparing full attainment benefits with social costs through incremental attainment of the 1997 standards).

[43] *See id.* at ES-8 tbl.ES-2 (estimating the reduction of adverse health and welfare effects associated with incremental attainment of alternative standards).

[44] National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086, 3148 (Jan. 15, 2013) (to be codified at 40 C.F.R. pts. 50, 51, 52, 53, and 58) [hereinafter NAAQS Particulate Matter 2013].

[45] *See* 2012 PM RIA, *supra* note 22, at ES-2.

[46] *See id.* at 5-81.

During the Obama administration, the use of non-threshold modeling for particulate matter and other pollutants began to prompt a backlash from industry, as the EPA tightened regulatory controls.[47] Organizations like the American Chemistry Council and American Petroleum Industry, two trade groups representing regulated entities, advocated for using thresholds in modeling health effects despite the enormity of scientific research against the existence of a threshold for a vast array of chemicals.[48] Industry representatives seized on greater uncertainties in modeling effects at these lower levels of pollution to try to argue that the agency should not attempt to calculate possible benefits from further reductions below the current air quality standards.[49]

The Trump administration's EPA, prompted by industry lobbying for less regulation, is considering reinstating the use of thresholds for carcinogens, criteria pollutants, and other chemicals.[50] Yet the agency has not done the work required under the law to justify departing from prior EPA modeling. And such work could not be done because it would fly in the face of established, well-developed science.

In particular, the Trump EPA has called the non-threshold treatment of particulate matter into question in three important policies: the Strengthening Transparency in Regulatory Science (STRS) proposed rule, and the repeal of the Clean Power Plan coupled with the Affordable Clean Energy rule. If the EPA were to follow the course of action on which it is embarking, the absence of any reasonable explanation for its adoption of thresholds will leave the agency vulnerable to multiple legal challenges under the Administrative Procedure Act, including that its regulations are arbitrary and capricious and have not complied with notice and comment requirements.

In the STRS proposed rule, the EPA suggested it intended to reconsider non-threshold modeling for pollutants by challenging the studies on which these models are based. Buried in the proposed regulation is a short paragraph stating that the agency is seeking to "increase transparency of the assumptions underlying dose response models" by considering approaches other than linear, non-threshold models.[51] According to the EPA, "there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects," requiring a reevaluation of whether thresholds are a better approach.[52] The EPA cites absolutely no scientific studies to support these statements, or any other research that would explain its departure from longstanding agency practice on evaluating the health effects of pollution. Without details about the research the agency is relying on to support incorporating threshold models, outside experts and the public are unable to adequately assess and comment on the proposed rule.[53]

The Trump administration's EPA has also also proposed threshold modeling for the harmful effects from particulate matter to justify it proposal to repeal the Clean Power Plan—an important Obama administration initiative to control the greenhouse gas emissions of existing power plants. In calculating whether deaths would

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[47] For an early example of this opposition, the American Chemistry Council's comments on the use of no threshold modeling for the Obama EPA's HAPS standards for the cement industry are particularly revelatory. *See* The American Chemistry Council, Comment Letter on Proposed Rule for National Emissions Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry (Sept. 9, 2009).

[48] NAAQS Particulate Matter 2013, *supra* note 44, at 3119.

[49] 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. Opening Brief of State and Industry Petitioners at 53, Murray Energy Corp. v. EPA, No. 16-1127 (D.C. Cir. Nov. 18, 2016).

[50] *See* Susanne Rust, *Scientist Says Some Pollution Is Good for You — A Disputed Claim Trump's EPA Has Embraced*, L.A. TIMES (Feb. 19, 2019), https://www.latimes.com/local/california/la-me-secret-science-20190219-story.html.

[51] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768, 18770 (Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30).

[52] *See id.*

[53] Instead, scientists in the field have responded by pointing to the plethora of research on the harmful effects of pollutants at all levels of exposure. *See, e.g.*, Comment from Susan Mandel, President of the Endocrine Society, on Proposed Rule Strengthening Transparency in Regulatory Science (May 21, 2018) (citing to SCIENCE AND DECISIONS, *supra* note 7).

be prevented from reductions in particulate matter, an indirect benefit, or co-beneift of the Clean Power Plan, the EPA, consistent with its established practice spanning decades, first applied a linear, non-threshold model to calculate the potential for harm at all levels of exposure. The proposed repeal, however, includes modeling estimates that assume that no individual would suffer a health impact from reducing particulate matter pollution below a certain population threshold level.[54] The agency chose to examine two different potential thresholds: first, the level set by the NAAQS, and second, the lowest measurable level detected in epidemiological studies, which is below the limit set by the NAAQS.[55] The regulatory impact analysis accompanying the proposed repeal acknowledged that prior scientific studies have supported a finding that particulate matter does harm to human health below these two thresholds.[56] But the agency then emphasized the supposed uncertainties surrounding extrapolations below pollutant concentrations that can be measured in epidemiological studies.[57] It was particularly critical of the fact that models of non-observable effects assume that the relationship between exposure and harm occurs in a linear fashion, suggesting that it was unwise to place much confidence in the "shape and magnitude" of the curve.[58] It relied on these supposed uncertainties to analyze the two threshold models, though it provided no justification to support the use of either of these models, or of any other threshold model.

The EPA eventually abandoned an outright repeal of the Clean Power Plan. Instead, Administrator Andrew Wheeler announced that the agency would promulgate the Affordable Clean Energy rule, which would regulate the greenhouse gas emissions of existing power plants, but significantly less stringently than had been the case under the Clean Power Plan.[59] But, in switching course on the proposed repeal, the EPA did not abandon its effort to change the modeling of particulate matter's health effects.

As it did with the proposed Clean Power Plan repeal, the EPA introduced a threshold concept into its calculations of health effects from reducing particulate matter emissions.[60] In the proposal for the Affordable Clean Energy rule, the agency asserted that it was "less confident" in risk estimates from exposures that are extrapolated to lower doses through modeling rather than directly observed in observational studies.[61] This uncertainty, it claimed, underscored the need to calculate benefits from particulate matter reductions using a threshold, or what the agency surreptitiously called "concentration benchmark analyses."[62] While acknowledging that its own scientists endorsed a non-threshold, linear approach, the EPA nevertheless

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[54] Repeal of Carbon Pollution Emission, Guidelines for Existing Stationary Sources: Electric Utility Generating, 82 Fed. Reg. 48035, 48044 (Oct. 16, 2017) (to be codified at 40 CFR Part 60).

[55] *See id.*

[56] *See id.* at 2-25-2-26 (noting that the Integrated Science Assessment for Particulate Matter, used to set the most recent NAAQS level in 2012, concluded there was "little evidence was observed to suggest that a threshold exists").

[57] *See* U.S. ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSIS FOR THE REVIEW OF THE CLEAN POWER PLAN: PROPOSAL, at 50 (Oct. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ria_proposed-cpp-repeal_2017-10_0.pdf.

[58] *Id.*

[59] Jessica Wentz, *6 Important Points About the "Affordable Clean Energy Rule"*, STATE OF THE PLANET BLOG (Aug. 22, 2018), https://blogs.ei.columbia.edu/2018/08/22/affordable-clean-energy-rule/.

[60] *See* Lisa Friedman, *E.P.A. Plans to Get Thousands of Pollution Deaths Off the Books by Changing Its Math*, N.Y. TIMES (May 24, 2019), https://www.nytimes.com/2019/05/20/climate/epa-air-pollution-deaths.html.

[61] Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units, 83 Fed. Reg. 44760, 44790 (Aug. 31, 2018) (to be codified at 40 CFR Parts 51, 52, and 60) https://www.govinfo.gov/content/pkg/FR-2018-08-31/pdf/2018-18755.pdf

[62] *See* U.S. ENVTL. PROT. AGENCY, REGULATORY IMPACT ANALYSIS FOR THE PROPOSED EMISSION GUIDELINES FOR GREENHOUSE GAS EMISSIONS FROM EXISTING ELECTRIC UTILITY GENERATING UNITS, at 4-20-4-31 (Aug. 2018), https://www.epa.gov/sites/production/files/2018-08/documents/utilities_ria_proposed_ace_2018-08.pdf.

contended that inserting these alternative calculations would give the government and the public a better appreciation for the rule's costs and benefits.

The EPA's attempted shift from non-threshold to threshold modeling appears to be based on work by scientists with extensive ties to industry. Industry groups have attempted to cast doubt on non-threshold models as part of their deregulatory toolkit.[63] For example, shortly before the Trump administration took office, an industry funded think tank called the Heartland Institute began attacking the Clean Power Plan's use of non-threshold modeling, claiming that it was biased and based in fearmongering about risks to children.[64] Their strategy was soon adopted by other groups like the Competitive Enterprise Institute, a think tank with extensive ties to the tobacco, chemical, and fossil fuel industries; it has asserted that "[t]he Obama EPA's linear-no-threshold (LNT) assumption that PM2.5 [particulate matter] kills at any concentration above zero is non-validated, contrary to considerable evidence, and a license for regulatory excess."[65]

Yet the vast majority of scientific experts have been extremely critical of these claims and the suggestion that the use of threshold modeling is better supported by the scientific evidence than non-threshold modeling.[66] In a recent Senate hearing on the STRS proposed rule, Rush D. Holt, Chief Executive Officer of the American Association for the Advancement of Science, stated: "Those who want to overturn the EPA procedures with this rule provide no good evidence that there is any deficiency in the scientific research that has been used up until now. Excluding the kinds of peer reviewed research that has been used is not justified. To put it bluntly, the initiative you consider today is not about transparency or sound science; it apparently is about reducing regulations. We know this because the architects and proponents present their proposals as part of a deregulatory agenda."[67]

At a subsequent EPA hearing on the Clean Power Plan repeal, outside scientific experts on lung diseases agreed that the Trump EPA's use of particulate matter thresholds is contrary to the latest research on effects from low levels of exposures and underestimates the health benefits from reductions below current air quality standards.[68] As groups like the Union of Concerned Scientists have noted, these changes are likely to particularly harm children and others who are sensitive to low levels of pollution.[69]

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[63] *See* Dana Nuccitelli, *Pruitt Promised Polluters EPA Will Value Their Profits over American Lives*, GUARDIAN (Apr. 23, 2018), https://www.theguardian.com/environment/climate-consensus-97-per-cent/2018/apr/23/pruitt-promised-polluters-epa-will-value-their-profits-over-american-lives. *See also* Dino Grandoni, *The Energy 202: The Other Scientific Consensus the EPA is Bucking*, WASH. POST (Oct. 11, 2017), https://www.washingtonpost.com/news/powerpost/paloma/the-energy-202/2017/10/11/the-energy-202-the-other-scientific-consensus-the-epa-is-bucking/59dcff9230fb0468cea81e52/?utm_term=.9ee98b4984f9.

[64] Charles Battig, *Driving Policies through Fraud and Fear-mongering*, CFACT INSIGHTS (July 10, 2015), https://www.heartland.org/news-opinion/news/driving-policies-through-fraud-and-fear-mongering?source=policybot (summarizing remarks at a Heartland Institute meeting on climate change in 2015).

[65] Marlo Lewis, Jr., *Free Market Groups Call for Repeal of Clean Power Plan*, COMPETITIVE ENTERPRISE INSTITUTE (Apr. 26, 2018), https://cei.org/blog/free-market-groups-call-repeal-clean-power-plan.

[66] Comments from Charles T. Discoll, PhD, et al, on the Proposal to Repeal the Carbon Pollution Emission Guidelines for Existing Stationary Sources (Apr. 26, 2018), *available at* https://science-policy-exchange.org/sites/default/files/documents/CPP_Repeal_Comments_Final.pdf (noting there is no evidence for a threshold of harm from particulate matter in comments to the Clean Power Plan repeal)

[67] *See* Testimony of Rush D. Holt, CEO of the American Association for the Advancement of Science, Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation, Hearing before the S. Subcomm. on Superfund, Waste Management, and Regulatory Oversight, 115th Cong. 31 (2008).

[68] Press Release, ATS Testifies in Opposition to Clean Power Plan Repeal (Dec. 5, 2017), *available at* https://news.thoracic.org/washington-letter/2017/ats-testifies-in-opposition-to-clean-power-plan-repeal1.php

[69] Comments from the Union of Concerned Scientists on Proposed Repeal of the Carbon Pollution Emission Guidelines for Existing Stationary Sources (Apr. 26, 2018), *available at* https://s3.amazonaws.com/ucs-documents/clean-

Even the EPA's own scientific advisory board opposed the use of thresholds in evaluating the risk of harm from the repeal of the Clean Power Plan.[70] And it did so even after the Trump administration purged it of many of its academic scientists and replaced them with scientists employed by regulated industry, as discussed in the prior Part.

The industry assault on non-threshold models for particulate matter continued after the proposal of the Affordable Clean Energy rule, which, as the EPA's own analysis revealed, would lead to an additional 1400 deaths per year under linear, non-threshold modeling.[71] In response, groups like the Institute for Energy Research, an industry funded non-profit with ties to the Koch brothers, claimed the media was wrongly focusing on only "one estimate" from the EPA's analysis and that linear, non-threshold modeling should be done away with because it inaccurately represents health impacts from particulate matter.[72] The argument was picked up by conservative outlets like *The Daily Caller*, which asserted that "EPA is just estimating premature deaths based on current epidemiological studies that are still the subject of debate."[73] Industry creation of a manufactured scientific debate, despite a clear consensus to the contrary, is a well-trod path to attempt to avoid regulation.[74] And it is a path that the Trump is exploring with enthusiasm.

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The efforts to reinstate threshold modeling for environmental regulation is a blatant attempt to undermine cost-benefit justified regulation to benefit industry at the cost of public health. Where epidemiological studies have not demonstrated a threshold toxicity level for a pollutant, the best current scientific evidence suggests that a linear, non-threshold model is the best assumption for predicting the toxicity for the pollutant at a population level. Most importantly, with respect to particulate matter, the pollutant that produces the largest number of premature deaths and hospitalizations for serious injuries, the overwhelming scientific consensus is that a linear, non-threshold model is most appropriate for modeling the pollutant's toxicity. In contrast, arguments for threshold modeling for particulate matter, which the Trump administration is embracing in important regulatory proceedings, have virtually no support in the modern scientific literature and would rewind over thirty years of scientific progress.

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energy/UCS-CPP-Proposed-Repeal-Comments.pdf.

[70] Memorandum from Alison Cullen, Chair, Scientific Advisory Board, to Members of the Chartered Scientific Advisory Board (May 18, 2018), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/9263940BB05B89A885258291006AC017/$File/WG_Memo_Fall17_RegRevAttsABC.pdf

[71] Lisa Friedman, *Cost of New E.P.A. Coal Rules: Up to 1,400 More Deaths a Year*, N.Y. TIMES (Aug. 22, 2018), https://www.nytimes.com/2018/08/21/climate/epa-coal-pollution-deaths.html.

[72] Institute for Energy Research, *EPA Proposes Rule to Replace Obama's Clean Power* Plan, IER COMMENTARY (Aug. 24, 2018), https://www.instituteforenergyresearch.org/fossil-fuels/coal/epa-proposes-rule-to-replace-obamas-clean-power-plan/.

[73] Michael Bastasch, *NYT Left Some Key Details Out of Its Claim That Ditching Obama-Era Rules Could Kill 1,400 People*, THE DAILY CALLER (Aug. 21, 2018), https://dailycaller.com/2018/08/21/new-york-times-energy-laws-obama/.

[74] *See* DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH (2008).

IV. IGNORING INDIRECT BENEFITS

Another component of the cost-benefit charade carried out by the Trump administration concerns its treatment of the indirect consequences of regulation. Established and well-accepted practices for conducting cost-benefit analysis require the consideration of not only the direct consequences of a regulation but also its indirect consequences. And they require not only the consideration of the indirect negative consequences, its indirect costs, but also the indirect positive consequences, its indirect benefits. These precepts have been embodied in the guidance documents under which federal agencies operate, in the regulations promulgated by these agencies, and in decisions of the federal courts reviewing these regulations.

In its zeal to repeal or severely roll back enormously beneficial environmental regulations, the Trump administration has assumed away, for some important regulations, tens of billions of dollars in yearly benefits from a large number of averted premature deaths, strokes, heart attacks, and severe respiratory problems. The pseudo-logic to support this assumption was that these effects were "indirect" effects on "non-target" pollutants and therefore should not be considered in cost-benefit analysis. But, at the same time that the agency willfully ignored massive co-benefits for some rules, it is willing to embrace them for others when they happened to help justify deregulation. The frank inconsistency cleanly demonstrates that there is no principle at play in the treatment of indirect effects, other than the expediency of creating an illusion of rationality for actions that will have severe negative consequences for the American public.

A. Development of the Administrative Practice of Counting Indirect Consequences of Regulation

The question of how to account for the indirect consequences of regulation, first received sustained attention in the 1990s with the publication of *Risk Versus Risk* by John Graham, who later became the head of the Office of Information and Regulatory Affairs (OIRA) in the George W. Bush administration, and Jonathan Wiener.[1] That book took issue with prior administrative practices of looking only at the direct consequences of regulation and argued that the direct benefits of regulation were sometimes coupled with indirect negative consequences. In particular, Graham and Wiener focused on the fact that regulations seeking to reduce certain risk can increase other risks, which they referred to as "countervailing risks,"[2] which are a form of indirect costs. They maintained that an accurate accounting of regulatory effects would consider these countervailing risks through what they termed risk-tradeoff analysis,[3] or risk-risk analysis.[4]

Risk-risk analysis picked up traction among academics specializing in administrative law. In addition to Graham and Wiener, Professor Cass Sunstein, later the Obama administration's OIRA head, advocated at that time for broad application of risk-risk analysis.[5] W. Kip Viscusi, a prominent economist and leading proponent of cost-benefit analysis, also endorsed the use of risk tradeoff analysis in the regulatory process.[6]

Judges who had been prominent administrative law scholars before joining the bench embraced risk-risk analysis as well. Justice Breyer concurred in *Whitman v. American Trucking Ass'ns*, agreeing with the Court's unanimous ruling that the Clean Air Act prohibits the consideration of costs in setting the National Ambient Air Quality Standards. But he wrote separately to argue that the "statute . . . permits the Administrator to take

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

[2] *Id.* at 22-25.

[3] *Id.* at 270.

[4] This subsection and the next two rely heavily on Kim M. Castle & Richard L. Revesz, *Environmental Standards, Thresholds, and the Next Battleground of Climate Change Regulations*, 103 *MINN. L. REV.* 1349 (2019).

[5] *See* Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533, 1537 (1996).

[6] *See* 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").

account of comparative health risks."[7] Under Breyer's approach, the countervailing risks of the regulation could be taken into account, particularly if they exceeded the direct benefits.[8]

Judge Stephen Williams of the United States Court of Appeals for 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."[9] He argued that the health-wealth connection required consideration of negative economic effects of regulation 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."[10] And while the health-wealth tradeoff has been largely discredited, Judge Williams' embrace of risk-risk analysis is independent of the theoretical or empirical support for the health-wealth relationship.[11]

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.[12] In its effort to "standardiz[e] the way benefits and costs of Federal regulatory actions are measured and reported,"[13] Circular A-4 explicitly requires the consideration of countervailing risks,[14] enshrining the analysis of the type of risks Graham and Weiner identified. However, Circular A-4 goes a step further by likewise requiring consideration of ancillary benefits.[15] The circular instructs agencies to "look beyond the direct benefits and direct costs" to "consider any important ancillary benefits and countervailing risks."[16] 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."[17]

B. Consistent Approach for Indirect Costs and Benefits

The EPA, the agency most in the cross hairs of the Trump administration unwarranted attack on co-benefits, has long taken co-benefits into account in its economic analyses of environmental rules, and specifically has done so for regulations promulgated under the Clean Air Act, which are the ones for which the Trump administration has reserved particular ire. First, the EPA's current guidelines for cost-benefit analyses, which

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[7] 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).

[8] *See* 531 U.S. at 495.

[9] 938 F.2d 1310, 1326 (D.C. Cir. 1991) (Williams, J., concurring).

[10] 938 F.2d at 1326.

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

[12] OFFICE OF MANAGEMENT AND BUDGET, CIRCULAR A-4: REGULATORY ANALYSIS at 1 (2003) [hereinafter CIRCULAR A-4].

[13] *Id.*

[14] *See id.* at 26 .

[15] *See id.*

[16] *Id.*

[17] *Id.*

were adopted in 2010 after extensive peer review, instruct the Agency to assess "all identifiable costs and benefits,"[18] and state that an economic analysis of regulations should include both "directly intended effects . . . as well as ancillary (or co-) benefits and costs."[19] The aim of these analyses is to "inform decision making" and allow meaningful comparisons between policy alternatives.[20]

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."[21] 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."[22]

Likewise, the Clinton EPA's guidelines for conducting cost-benefit analyses endorsed the importance of considering indirect costs and benefits.[23] Issued in 2000, the Clinton guidelines included indirect costs as a component of its calculations for health and social costs.[24] 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,"[25] focusing on an ecological example, the guidelines explained that indirect benefits are cognizable as well.[26] Moreover, 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."[27] 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.[28] The agency 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

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[18] 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.

[19] *Id.*

[20] *Id.* at 7-1.

[21] U.S. ENVTL. PROT. AGENCY, GUIDELINES FOR PREPARING ECONOMIC ANALYSES (EXTERNAL REVIEW DRAFT) at 10-4 (2008).

[22] *Id.* at 8-17.

[23] 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.

[24] *Id.* at 82–83, 94, 114–15.

[25] *Id.* at 59.

[26] *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").

[27] *Id.* at 177.

[28] 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.").

pollutants in its landmark 1985 regulation reducing lead in gasoline, including an analysis of benefits from reductions in ozone, nitrogen oxides, and hydrocarbons.[29] 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.[30] Also, in its proposal for developing New Source Performance Standards for municipal waste combustors, the Reagan-era EPA discussed the importance of considering "indirect benefits" from its regulation of toxic emissions from municipal waste combustors and explained that its analysis would include "indirect benefits accruing from concomitant reductions in other regulated pollutants." [31]

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."[32] 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.[33] 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.[34] The EPA's judgment on how to regulate was thus guided by the full scope of the regulatory 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 criteria pollutants regulated by the NAAQS.[35] With respect to the standards for existing sources, the agency estimated small increases in emissions of carbon monoxide, nitrogen oxides, and sulfur dioxides from the rule, but a significant decrease in particulate matter emissions.[36] And, with respect to the standards for new sources, the EPA concluded that, in addition to decreasing hazardous air pollutants, the rule would also decrease the emissions of several other criteria pollutants, including particulate matter.[37] Thus, the agency relied on co-benefits in justifying the rules for both new and existing standards.

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,[38] and included the co-benefits from mercury reductions in its cost-benefit analysis for the rule.[39] The Bush EPA also discussed co-benefits as part of a

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[29] 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/eerm.nsf/vwan/ee-0034-1.pdf/%24file/ee-0034-1.pdf.

[30] *Id.* at E-8.

[31] *See* Assessment of Municipal Waste Combustor Emissions Under the Clean Air Act, 52 Fed. Reg. 25,399, 25,406 (July 7, 1987) (codified at 40 C.F.R. pt. 60).

[32] *See* 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).

[33] *See id.* at 24,472.

[34] *See id.*

[35] *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).

[36] *See id.* at 18,576.

[37] *See id.* at 18,579.

[38] *See* Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X 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).

[39] *See id.* at 25,312.

regulation governing hazardous air pollutants from mobile sources, primarily cars.[40] The agency noted that though the rule was designed to control of air toxics, it also reduced particulate matter and ozone and "this co-benefit . . . is significant."[41] The EPA calculated that the standards would reduce exhaust emissions of direct particulate matter by over 19,000 tons in 2030 nationwide.[42] The agency also analyzed the effects of the rule on ozone emissions, concluding that some areas would have "non-negligible improvements in projected eight-hour ozone."[43]

Similarly, high-profile Obama-era EPA regulations like the Mercury and Air Toxics Standards and the Clean Power Plan, discussed below, 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." 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.

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.

C. Judicial Treatment of Indirect Costs

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.[44] Reviewing courts have frequently required agencies to include ancillary impacts in their economic analyses of regulatory actions.[45]

In 1991, the United States Court of Appeals for the Fifth Circuit rejected the EPA's attempt to ban asbestos-based brakes under the Toxic Substances Control Act.[46] 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.[47] 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.'"[48] The court noted with disapproval that the agency had not evaluated the harm from increased use of substitute products.[49] Because the EPA did not 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."[50] In short, the EPA's cost-benefit analysis did not, in the court's view,

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[40] *See* 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).

[41] *Id.* at 8461.

[42] *See id.* at 8453.

[43] *Id.* at 8458.

[44] *See* Caroline Cecot & W. Kip Viscusi, *Judicial Review of Agency Benefit- Cost Analysis*, 22 GEO. MASON L. REV. 575, 578 (2015) (collecting and analyzing cases where courts reviewed agencies' cost-benefit analyses).

[45] *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).

[46] *Corrosion Proof Fittings*, 947 F.2d at 1229–30.

[47] *Id.* at 1225.

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

[49] *Id.* at 1220–21.

[50] *Id.* at 1224.

adequately address indirect costs and was therefore unsupported by "substantial evidence" as required under the statute.[51]

A year later, the D.C. Circuit struck down a promulgated by the National Highway Traffic Safety Administration (NHTSA), for failing to consider indirect costs.[52] In a rule designed to NHTSA had attempted to increase fuel efficiency standards for cars, the agency did not consider the potential increased safety risks because smaller, more fuel efficient cars might be less protective in a crash.[53] The court found that the agency had not met the requirement of reasoned explanation and required that NHTSA "reconsider the matter and provide a genuine explanation for whatever choice it ultimately makes."[54]

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 United States Court of Appeals for the Seventh Circuit partially vacated an OSHA regulation putting standards in place to limit the transmission of communicable diseases.[55] The agency failed to consider the indirect health effects that might result if the rule increased health care costs and thus limited access to care.[56] The court found that OSHA's analysis "is thus incomplete."[57]

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.[58] 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"[59] with indirect health benefits, such as reducing incidences of cataracts and skin cancers.[60] The court asserted that by ignoring these consequences, the EPA looked only at "half of a substance's health effects."[61] Similarly, in 2002, the D.C. Circuit overturned two Federal Communications Commission rules for the Agency's failure to consider the rules' indirect costs in contravention of the language and objectives of the Telecommunication Act.[62]

Furthermore, the D.C. Circuit has explicitly addressed the "mirror image" of indirect costs: co-benefits.[63] 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.[64] 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

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[51] *Id.* at 1207.

[52] Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin., 956 F.2d 321, 323–25 (D.C. Cir. 1992).

[53] *See id.* at 326–27.

[54] *Id.* at 327.

[55] Am. Dental Ass'n v. Martin, 984 F.2d 823, 823–27, 830–31 (7th Cir. 1993).

[56] *See id.* at 826.

[57] *Id.*

[58] 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).

[59] *Id.* at 1052.

[60] *See id.* at 1051.

[61] *Id.* at 1052.

[62] *See* U.S. Telecom Ass'n v. FCC, 290 F.3d 415, 423–29 (D.C. Cir. 2002).

[63] *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, 1793 (2002).

[64] 830 F.3d 579, 591, 625 (D.C. Cir. 2016).

other [hazardous air pollutants] or emissions from other nearby sources" and the "potential impacts of increased emissions on ecosystems."[65] Industry groups argued that the EPA's consideration of these co-benefits invalidated the agency's decision.[66] In response, 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."[67] 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.[68] 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.[69]

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 that helpfully depict whether effects are positive or negative and they provide no justification for focusing on some effects while ignoring others.[70]

Underscoring this important point, Christopher DeMuth and Judge Douglas Ginsburg, both of whom led OIRA during the Reagan administration, noted that "OIRA … recommends that agencies account for ancillary benefits as well as countervailing risks,"[71] and that "[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."[72] Indeed, it would be incoherent to consider indirect consequences of regulation if they are negative but ignore them if they are positive.

D. Ignoring Economic Reality

The attack on this longstanding consensus, supported by economic theory, logic, and a consistent administrative practice by administrations of both parties over decades first reared its head in June 2018, the EPA published an Advance Notice of Proposed Rulemaking inviting comments on "perceived inconsistency and lack of transparency in how the Agency considers costs and benefits in rulemaking."[73] The document, issued by Administrator Scott Pruitt one month before his resignation, asked the following question with respect to co-benefits: "[T]o what extent should EPA develop a general rule on how the Agency will weigh the benefits from reductions in pollutants that were not directly regulated (often called 'co-benefits' or 'ancillary benefits') … ?"[74]

Tellingly, the EPA did not raise similar questions about the consideration of indirect costs. In any event, such questions would have been futile given the extensive case law requiring that agencies take them into account. Thus, an effect of this EPA publication was to open the doors for the possible irrational outcome, discussed

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[65] *Id.* at 624.

[66] *See id.* at 625.

[67] *See id.*

[68] *See id.* at 624–25.

[69] *Id.* at 625.

[70] *See* Rascoff & Revesz, *supra* note 63, at 1793.

[71] Christopher C. DeMuth & Douglas H. Ginsburg, *Rationalism in Regulation*, 108 MICH. L. REV. 877, 887 (2010)

[72] *Id.* at 888.

[73] Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process, 83 Fed. Reg. 27,524, 27,527 (June 13, 2018).

[74] *Id.*

above, under which the indirect consequences of regulation are taken into account if they are negative but ignored if they are positive.[75]

In the advance notice, EPA did not attempt to answer the question on how co-benefits should it be treated, but it telegraphed its thinking in several ways. First, in April 2018, two months before the advance notice's publication, when, in all likelihood it was being draft, in a speech to the Heritage Foundation, Pruitt said that "EPA will soon stop relying on "co-benefits" in crafting new regulations."[76] In light of this statement, the advanced notice should be seen as the opening gambit in an effort to upend the accepted practice.

Second, industry and conservative and allied with the Trump administration had been railing the use of co-benefits to justify environmental regulations prior to the publication of the advance notice.[77] For example, the U.S. Chamber of Commerce termed the consideration of co-benefits "a controversial and legally dubious accounting method" and the Cato Institute termed relying on them a "sleight of hand."[78] In light of this confluence of evidence, it is not credible to think that, in seeking comments on co-benefits, the EPA was merely asking an open-ended question as opposed to taking a first step to sacrifice uncontroversial analysis at the altar of deregulation.

Pruitt's advance notice was never finalized. His successor, Andrew Wheeler, indicated in May 2019 that the EPA would not attempt to fashion an across-the-board methodology and would instead develop media-specific approaches to the consideration of costs and benefits, applying, for example, to air, water, and hazardous substances—steps that have not yet taken place.[79]

Nonetheless, by now any questions about the EPA's true intentions with respect to these proceedings have been dispelled. Indeed, in February 2019, the agency, under Wheeler's leadership, proposed to reverse the Obama administration's finding that the regulations of the hazardous air pollutant emissions of power plants is "appropriate and necessary," which the threshold finding undergirding the MATS rule.

In order to regulate hazardous air pollutant emissions from power plants, the Clean Air Act, in section 122(n), requires the EPA to first determine whether it is "appropriate and necessary" to do so.[80] The agency made this determination in 2012, and, at the same time, it promulgated the MATS rule, setting forth the emissions limitations that would apply to power plants.[81] Subsequently, in *Michigan v. EPA*, the Supreme Court remanded the "appropriate and necessary" finding on the grounds that the EPA had failed to consider costs before making

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[75] This subsection relies heavily on Inst. for Pol'l Integrity, Comments to EPA on Reconsideration of Mercury and Air Toxics Standards (Apr. 17, 2019), https://policyintegrity.org/projects/update/comments-to-epa-on-reconsideration-of-mercury-and-air-toxics-standards.

[76] Michael Bastasch, *Sources: Pruitt to End a Tactic Obama Used to Justify Massive EPA Rules*, DAILY CALLER (Apr. 12, 2018), https://dailycaller.com/2018/04/12/sources-pruitt-epa-obama-tactics/

[77] *See id.*

[78] Brief for the Cato Institute as Amicus Curiae in Support of Petitioners, Michigan v. EPA, 135 S. Ct. 2699 at 4 (2015) (Nos. 14-46, 14-47, 14-49).

[79] *See* Memorandum of Andrew R. Wheeler to Assistant Administrators, Increasing Consistency and Transparency in Considering Benefits and Costs in the Rulemaking Process (May 13, 2019), https://www.epa.gov/sites/production/files/2019-05/documents/memorandum_05_13_2019_increasing_consistency_and_transparency_in_considering_benefits_and_costs_in_rulemaking_process.pdf.

[80] 42 U.S.C. § 7412(n)(1)(A) (2012).

[81] *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. 9303 (Feb. 16, 2012).

it.[82] EPA had, in fact, conducted a formal cost- benefit analysis for MATS, but the agency had not relied on this analysis as a basis for the threshold appropriate-and-necessary finding; this analysis, therefore, did not satisfy the Court's requirement.[83]

The Supreme Court left it "up to the Agency to decide [on remand] (as always, within the limits of *reasonable* interpretation) how to account for cost."[84] In 2016, EPA, under the Obama administration, reaffirmed its 2012 appropriate-and-necessary finding after taking costs into account in two different ways.[85] In its "preferred approach," EPA analyzed the cost reasonableness of MATS by (1) evaluating "the cost of MATS compliance in comparison to the power sector's revenues from retail sales of electricity"; (2) comparing "annual capital expenditures due to MATS compliance to the power sector's annual capital expenditures between 2000 and 2011"; and (3) comparing "the impact of MATS on the retail price of electricity to historical fluctuations of the average retail price of electricity."[86] EPA determined that each of these metrics "support[ed] a conclusion that the cost of MATS is reasonable."[87]

As an alternative basis for the 2016 finding, EPA relied on the conclusions of the formal cost-benefit analysis contained in the Regulatory Impact Analysis justifying the actual emission limitations in MATS.[88] That analysis projected that MATS would impose $9.6 billion per year in compliance costs but yield between $37 and $90 billion per year in quantifiable benefits, in addition to many other positive health and environmental effects that could not be quantified.[89] The "great majority" of these quantified benefits were "attributable to co-benefits from reductions in [particulate matter]-related mortality."[90] These particulate matter reductions would occur as a direct consequence of the steps that the EPA assumed that power plants would take to reduce their emissions of hazardous air pollutants. Consistently with prior practices, the agency referred to particulate matter reductions as "co-benefits" because they were "not the primary objective" of MATS and took them into account in its analysis.[91] Because EPA's formal cost-benefit analysis showed that MATS's benefits would "exceed the costs by 3 to 9 times," the agency found that it "provide[d] an independent basis to support the finding that a consideration of cost does not cause the agency to alter its [2012 appropriate-and-necessary] determination."[92]

Now, under the Trump administration, EPA proposes to reverse the agency's prior "appropriate and necessary" determination by rejecting both its cost-reasonableness analysis and its formal cost-benefit analysis as inconsistent with the requirements of section 112(n).[93] Alternatively, EPA argues that its refusal to consider co-benefits is a "reasonable approach . . . to considering costs in response to *Michigan*."[94] In other words, according to EPA, even if section 112(n) does not unambiguously preclude the full consideration of co-benefits, the

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[82] *Michigan*, 135 S. Ct. 2699, 2712 (2015).

[83] *Id.* at 2711.

[84] *Id.* (emphasis added).

[85] 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, 24,420 (Apr. 25, 2016).

[86] *Id.* at 24,425.

[87] *Id.* at 24,427.

[88] *Id.*

[89] *Id.* at 24,425.

[90] 77 Fed. Reg. at 9305.

[91] *Id.*

[92] 81 Fed. Reg. at 24,428.

[93] 84 Fed. Reg. at 2676.

[94] *Id.*

agency has discretion to fully or partially disregard such benefits. In alleged accordance with this new interpretation of section 112(n), EPA, ignoring the vast co-benefits at stake, then "proposes to conclude that it is not appropriate and necessary to regulate HAP from EGUs . . . because the costs of such regulation grossly outweigh the [direct] HAP benefits."[95]

There is no support for the EPA's claim that section 122(n) precludes it from considering co-benefits because that section does not contain the words "costs" or "benefits" and the operative words, which are "appropriate and necessary" are certainly subject to a capacious, rather than a restrictive interpretation. But the resolution of this question of statutory interpretation is not relevant to an understanding of the EPA's approach to co-benefits, and therefore to an evaluation of the agency's rationality. That is because the agency made the alternative argument that, even if the statute did not preclude the consideration of co-benefits, it would exercise its discretion to ignore co-benefits nonetheless. Here, too, the agency attempts to diffuse its responsibility by saying through its reference to *Michigan v. EPA*. But in that case, the Supreme Court said explicitly that it would be "up to [EPA] to decide (as always, within the limits of reasonable interpretation) how to account for cost."[96] In making that pronouncement, the Court expressly declined to address the issue of co-benefits and whether and how they should be weighed against costs.[97] The Court held *only* that it was unreasonable for EPA to have deemed costs entirely irrelevant to its "appropriate and necessary" determination.[98]

While ignoring co-benefits is by itself illogical enough, in reversing the "appropriate and necessary finding, the EPA went even further. Even though EPA ignored the co-benefits of the rule, it did consider the indirect costs of the MATS rule. EPA acknowledged that its $9.6 billion annual cost estimate included costs "beyond [those] borne by owners of coal- and oil-fired units regulated by MATS."[99] In other words, EPA's cost estimate included indirect costs—"those incurred in related markets or experienced by consumers or government agencies not under the direct scope of regulation"[100]—in addition to the direct costs to the power sector of complying with the rule. In other words, the EPA relied on a cost estimate that includes indirect costs but declined to give equal consideration to co-benefits, thereby engaging in a lopsided, opportunistically framed economic analysis to justify the reversal of its prior finding that the MATS rule was massively net beneficial for society. It was only by ignoring the MATS rule's co-benefits through this irrational path that the EPA was able to justify finding that it was not appropriate and necessary to issue a regulation that, in fact, bestowed tens of billions of dollars of benefits on society each year.

E. Selective Embrace of Co-benefits

The Trump administration's affront on rationality with respect to its treatment of co-benefits is compounded by its failure to have a consistent position on the issue. Indeed, when co-benefits stand in the way of its deregulatory zeal, it cavalierly calls them into question, as discussed above. But, in other cases, where co-benefits would further its deregulatory agenda, the administration embraces them with great enthusiasm. Two recent examples of highly significant rules illustrate the point.

The Trump administration relied heavily on co-benefits to support its Affordable Clean Energy (ACE) rule, which is a toothless replacement for the Clean Power Plan, a signature climate initiative of the Obama Administration that sought to substantially reduce reliance on aging coal plants and boost the use of non-

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[95] *Id.*

[96] *Michigan*, 135 S. Ct. at 2711.

[97] *See id.*

[98] *See id.* at 2712.

[99] 81 Fed. Reg. at 24,440.

[100] OBAMA EPA GUIDELINES, *supra* note 18, at 8-7 to 8-8.

emitting alternatives like wind farms and solar arrays.[101] ACE, by contrast, requires at most modest efficiency gains at coal plants—a strategy that perversely runs the risk of *raising* emissions from such plants by increasing their cost-competitiveness and, in turn, the frequency with which they are dispatched. The EPA's economic justification proceeded in two steps. First, the agency evaluated an outright repeal of the CPP and, for reasons unrelated to the treatment of co-benefits, concluded, wholly implausibly, that this repeal would have no costs and no benefits.

Then, the EPA compared the ACE rule to a baseline with no CPP. The agency's cost-benefit analysis considered three elements: direct benefits, which resulted from greenhouse gas reductions; co-benefits, which resulted from reductions in particulate emissions; and costs. Under every scenario that the agency analyzed, the costs were higher, by a considerable amount, than the direct benefits. It was only by relying on co-benefits that the agency was able to justify the rule. For example, the impact of the rule in 2030, at a 3% discount rate, was as follows: direct benefits of $52 million, co-benefits of $320 to $780 million, and costs of $180 million. Thus, the rule would have negative net benefits of $128 million if the co-benefits are not taken into account. But it had positive net benefits of $192 to $652 million when co-benefits are accounted for.[102]

Similarly, in proposing an enormously consequential rollback of emission and fuel economy standards for cars and light trucks, which had been one of the Obama administration's signature achievements to combat climate change, the Trump administration relies heavily on co-benefits for both its rhetoric and its economic analysis.[103] The proposal, authored jointly by the EPA and the National Highway Safety Transportation Administration (NHTSA), claims that the increases in pollution and fuel costs resulting from the rollback are justified by supposed safety benefits. It assumes that stricter efficiency standards raise the price of vehicles. Standard economic theory predicts that people would then buy fewer cars because each car would be more expensive. But instead, the administration's faulty analysis leads it, wholly implausibly, to the opposite conclusion: that people will buy more cars, and therefore drive more miles and have more accidents.

This truly bizarre claim does not turn on the treatment of co-benefits and is therefore not relevant to this discussion. But what is relevant is that the Trump administration justifies its action in large part on the basis of the safety benefits that it attributes to the rule. For example, EPA Administrator Andrew Wheeler conceded that, as a result of the rollback, "more oil will be consumed."[104] And, because burning of a gallon of gas produces a fixed amount of greenhouse gases, a necessary corollary of the consumption of more oil is the emission of more greenhouse gases. But Wheeler was quick to justify these uncontroversially bad effects: "But it will also save 12,000 lives."[105] Along the same lines, Heidi King, NHTSA's deputy administrator, stated: "Most importantly, this rule promises to save lives.[106] In fact, the name of the rule was chosen so that its acronym,

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[101] This paragraph relies heavily on Jack Lienke & Richard L. Revesz, *EPA Will Say Anything to Avoid Addressing Climate Change*, REG. REV. (July 29, 2019), https://www.theregreview.org/2019/07/29/revesz-lienke-epa-avoid-addressing-climate-change/?utm_source=The+Regulatory+Review+newsletter+and+alert+subscribers&utm_campaign=9e69c9e4c8-EMAIL_CAMPAIGN_4_21_2019_15_21_COPY_01&utm_medium=email&utm_term=0_d70039d0ef-9e69c9e4c8-711774509.

[102] *See* U.S. Envt'l Prot. Agency, Regulatory Impact Analysis, Repeal of the Clean Power Plan; Emission Guidelines for Greenhouse Gas Emissions From Existing Electric Utility Generating Units; Revisions to Emission Guidelines Implementing Regulations, Docket No. EPA-HQ-OAR-2017-0355 at 6-6 (2019).

[103] This paragraph relies heavily on Richard L. Revesz, *On Climate, the Facts and the Law Are Against Trump*, N.Y. TIMES (Dec. 4, 2018), https://www.nytimes.com/2018/12/04/opinion/climate-report-trump.html?action=click&module=Opinion&pgtype=Homepage.

[104] Timothy Cama & Miranda Green, *Trump Moves to Roll Back Obama Emission Standards*, THE HILL (Aug. 2, 2018), https://thehill.com/policy/energy-environment/400036-trump-submits-rule-to-weaken-iconic-obama-car-efficiency-standards.

[105] *Id.*

[106] *Id.*

which appears in the rule's official title, could telegraph this message: The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks.[107] Furthermore, the economic analysis of the rule reveals that more than half of its benefits were attributable to the asserted safety benefits.[108]

From EPA's perspective, the direct benefits of the rule are the reduction of greenhouse gases: that is the objective of the section of the Clean Air Act under which it has the authority to promulgate the rule.[109] And, NHTSA's authority for the rule stems from the Corporate Average Fuel Economy (CAFÉ) program, which dates back to the energy crisis of the 1970s and is designed to conserve fuel.[110] As a result, from the perspective of both agencies, any safety benefits are co-benefits, not direct benefits.

It is true that, as its name implies, NHTSA, unlike the EPA, has the statutory authority to promote vehicle safety. But its safety mandate lies in other provisions of its governing statute, not in the statutory provision providing the authority for the CAFÉ standards. Thus, NHTSA is in the same position that the EPA was with respect to the Mercury and Air Toxics Standards. The EPA had clear statutory authority to regulate particulate matter, but the benefits from such reduction were deemed co-benefits as opposed to direct benefits because, as explained earlier in this Part, the MATS rule was promulgated under a section of the Clean Air Act dealing with hazardous air pollutants, not with particulate matter. Because it would help it undo the Obama administration's MATS determination, the EPA was eager to call go benefits into question there. But here, in contrast, it is willing to embrace co-benefits to help it undo the Obama administration's vehicle standards.

So, as the discussion shows, the EPA is trying to have it both ways. On the one hand, it appears to be engaged in a broad effort to discredit reliance on co-benefits to justify regulatory actions. But, on the other hand, it is eager to embrace them when doing so furthers its deregulatory objectives.

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The Trump administration's actions on co-benefits are an affront to settled economic theory and the precepts of rationality; fly in the face of clear, longstanding guidance from the Executive branch on how cost-benefit analysis should be conducted; and are inconsistent with the regulatory practices of administrations of both parties over several decades.

The intellectual dishonesty of this approach is compounded by two further features of the Trump administration's actions. First, while the Trump administration decries the use of co-benefits, it embraces with enthusiasm the use of indirect costs. Thus, it takes the wholly implausible position that the indirect consequences of regulation should be taken into account if they are negative but should be ignored if they are positive. And, second, the Trump administration's sleight of hand to hide co-benefits is deployed only when it furthers the administration's deregulatory agenda. In contrast, when invoking co-benefits is expedient to support deregulation, the administration celebrates them with zeal.

CONCLUSION

Put together, these four deregulatory moves—focusing on costs and ignoring benefits, erasing public health science, reviving discredited models, and eliminating indirect benefits—reveal a broader attack on cost-benefit analysis and a rational approach to regulatory policy setting. They demonstrate a concerted effort to defang analytical tools used to set regulatory policy and to eliminate possible justifications that can be offered in support of environmental and public health regulation.

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[107] 83 Fed. Reg. 42,986 (proposed Aug. 24, 2018).

[108] *See* Nat'l Highway Transp. Admin. & Envt'l Prot. Agency, Preliminary Regulatory Impact Analysis: The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks, Docket No. NHTSA–2018–0067, at 1467-68 (2018).

[109] 42 U.S.C. § 202.

[110] *See* 49 U.S.C. § 32,902.

Importantly, the main target of the Trump administration's attacks on regulation will be precisely the clean air and water rules that he superficially claims to support. Specifically, these attacks are designed to wipe out benefits that are credited to reductions in air pollution, such as due to reductions in particulate matter in the air, thereby undercutting not just new regulatory efforts, but potentially retroactively threatening established regulation that has already proven to save thousands of lives annually. By placing senseless roadblocks in the way of clean air and water regulation, this administration threatens to dismantle the regularization of regulatory analysis. If implemented fully, these would make it harder for an agency to justify imposing costs on regulated industries where the justification to do so would be based on health and other benefits that come from cleaner air and water.