Dear Mr. Armitage,

I would also like to ask that these written comments also be included with the meeting materials for consideration by SAB members.

Thank you,
Hayden Hashimoto

CLEAN AIR
TASK FORCE

Hayden Hashimoto

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process, 85 Fed. Reg. 35,612 (June 11, 2020)	**Docket ID No. EPA-HQ-OAR-2020-00044** *Submitted via Regulations.gov* *August 3, 2020*

COMMENTS OF PUBLIC HEALTH AND ENVIRONMENTAL ORGANIZATIONS

Environmental and public health organizations[1] Chesapeake Bay Foundation, Clean Air Task Force, Environmental Defense Fund, Environmental Law & Policy Center, Environmental Protection Network, Natural Resources Defense Council, and Union of Concerned Scientists hereby submit the following comments on the U.S. Environmental Protection Agency's proposed rule "Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process," 85 Fed. Reg. 35,612 (June 11, 2020).

[1] Questions about this submission may be addressed to Ben Levitan at (202) 572-3318 or blevitan@edf.org.

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I. INTRODUCTION

Over the past half-century, the Clean Air Act ("CAA" or the "Act") has established the United States as a global leader in improving air quality. Under the Act, the benefits of pollution reduction have included hundreds of thousands of avoided premature deaths, improved respiratory and cardiovascular health, reduced incidence of cancer, more opportunities for children to play safely outdoors, and preservation of national parks and natural ecosystems. Multiple studies have demonstrated that the monetized benefits of the Act exceed the costs of pollution control many times over, even without considering the significant unmonetized benefits. Economically, these benefits have had a profound impact: cleaner air has led to fewer missed school and work days, reduced medical expenses, and more tourism and recreational activities. The U.S. economy has experienced phenomenal growth since Congress passed the Act, and clean-air technologies developed in America have opened up business opportunities around the world. Through its implementation by the Environmental Protection Agency ("EPA" or the "agency"), the Act has significantly advanced Congress's intent "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population."[2]

At the same time, there is more work to be done. Communities of color and low-income communities continue to suffer disproportionately from poor air quality—disparities that EPA has an urgent obligation to address. Climate change is already harming our nation and world, and failure to take action today forebodes even greater suffering in the decades to come. EPA must advance stronger Clean Air Act protections to comprehensively fulfill its obligations under the statute, not backtrack from the progress it has already made.

Yet this Proposal[3] appears completely oblivious to the monumental benefits that the Act has delivered for our nation—and utterly indifferent to the harm that the Act seeks to alleviate. Most strikingly, the agency has refused to evaluate the impacts that this rulemaking would have on environmental justice communities. In fact, the agency has failed to illustrate or discuss the public health and environmental consequences of its Proposal at all.

As we explain in these comments, EPA lacks the authority to issue this Proposal, which is based on an unsupported and inaccurate premise that the agency has previously overestimated the benefits of Clean Air Act protections. Section 301 of the Clean Air Act, the sole basis for authority that the agency has invoked, applies only to rules that are "necessary" for the Administrator to implement the statute.[4] Yet this Proposal sharply *conflicts* with the agency's statutory obligations. Its blanket requirement to conduct benefit-cost analyses ("BCAs") for all significant rulemakings disregards the varied ways that the Act directs EPA to consider costs, including provisions that outright preclude such consideration. It would twist one of our nation's most important public health statutes into a servant of rigid and one-sided BCAs.

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[2] 42 U.S.C. § 7401(b)(1).

[3] Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process, 85 Fed. Reg. 35,612 (June 11, 2020) ("Proposal").

[4] 42 U.S.C. § 7601(a)(1).

Far from being "necessary," EPA has identified no problem that this action would solve. The Proposal is premised largely on the agency's vague references to public comments alleging that previous rulemakings have overestimated benefits. EPA apparently takes these false claims at face value without pointing to a single example to substantiate them. Nor can the agency refute the existing analyses—produced by both EPA and external experts—showing that benefits of the Act's protections have vastly exceeded costs. And nowhere does the agency consider the possibility that it has historically underestimated benefits and overestimated costs, despite significant evidence to that effect.

When assessing costs and benefits of public health and environmental protections, EPA has historically utilized guidance developed in-house and by the Office of Management and Budget ("OMB") that is more adaptable and recognizes the range of obligations that the agency fulfills. The Proposal's binding mandate to utilize a particular approach to assessing costs and benefits for all significant Clean Air Act rulemakings is unlawful, arbitrary, and unworkable—and ignores that there are other and varied methods of cost assessment that may be appropriate in different circumstances. Moreover, the agency's guidance has been developed through a public process and peer-reviewed, in stark contrast to the inscrutable nature of this Proposal. The existing guidance genuinely provides the consistency and transparency that this Proposal falsely advertises.

The sole driver of this incoherent and opaque Proposal is the agency's desire to downplay benefits, exaggerate costs, and generally thwart Clean Air Act protections. For example:

- The requirement to disaggregate and exclude co-benefits from presentations of the costs and benefits of a rulemaking would make it easier to ignore the human suffering that Clean Air Act protections prevent. This requirement could advance the Administrator's dangerous intention to ignore these crucial public health benefits altogether when determining the stringency of public health protections.
- The Proposal is replete with arbitrary requirements that would make the establishment of Clean Air Act protections more onerous and resource-intensive—and increase the vulnerability of final rules to litigation—for reasons that are totally disconnected from the agency's statutory obligations.
- The Proposal takes an arbitrarily inconsistent approach to assessing costs and benefits, setting a higher standard of evidence to demonstrate benefits than costs.
- The Proposal would manipulate the scientific data and other inputs that inform cost-benefit analyses—and potentially the underlying rulemakings—in violation of the agency's obligation to utilize the best available science.

EPA's faithful implementation of the Clean Air Act over most of the Act's first fifty years has been a great American success story. By any legitimate metric, the benefits of clean air protections have consistently and overwhelmingly exceeded the costs, which may account for the unprecedented and one-sided tactics to which this Proposal resorts. With so much on the line—from threats to public health amidst a pandemic, to the generational challenge of climate change—we cannot afford to dismiss the benefits that the Act promises. Doing so would violate the law and inflict devastating health and environmental consequences upon the nation. We strongly urge the agency to withdraw this unnecessary and unlawful Proposal.

II. EPA'S PROPOSAL FAILS TO ACKNOWLEDGE THAT CLEAN AIR PROTECTIONS HAVE CONSISTENTLY BEEN FOUND TO HAVE OVERWHELMING NET BENEFITS.

The Proposal's unsupported assertion that EPA's prior analyses of Clean Air Act protections "overestimate" benefits and "underestimate" costs ignores a vast body of rigorous analyses concluding that clean air protections yield overwhelming net benefits for society, both in qualitative and quantitative terms. Further, the Proposal ignores clear evidence showing that past assessments of Clean Air Act protections have excluded or undervalued important categories of benefits and overestimated costs of compliance—meaning that, if anything, EPA has *underestimated* the net benefits associated with clean air protections. Lastly, the Proposal arbitrarily fails to address distributional impacts, contrary to the directive in Executive Order 12,898.

A) Clean Air Protections Have Clear and Overwhelming Net Benefits.

Since 1970, EPA safeguards promulgated under the Clean Air Act have saved lives, improved health, and elevated quality of life nationwide by reducing harmful pollution that contaminates the air we breathe and the places where we live, work, and recreate. Thanks to these safeguards, our air quality has markedly improved over the past five decades—while our population, gross domestic product, and other indicators of economic activity have dramatically increased. Moreover, the United States has become an international leader in pollution control industries, spurring innovation and job creation.

As discussed in section III of these comments, the various provisions and programs in the Clean Air Act in some cases carefully delineate whether and how EPA may consider costs and benefits when undertaking rulemakings. Nevertheless, for decades EPA has undertaken rigorous analyses of the benefits and costs of Clean Air Act protections through Regulatory Impact Analyses ("RIAs") prepared under Executive Order 12,866 and related executive orders, as well as through comprehensive assessments required under Section 812 of the Act. These analyses are prepared according to longstanding EPA and OMB guidelines, are developed in a transparent manner with opportunities for public comment, and are subject to interagency review or peer review to ensure a high standard of rigor.[5]

These analyses, as well as independent analyses, have consistently found that clean air protections yield benefits far in excess of costs. For example:

- OMB regularly submits reports to Congress assessing the costs and benefits of major federal regulations, including Clean Air Act rules issued by EPA. The most recent

[5] EPA's most recent Section 812 analysis was subject to external expert review led by the Science Advisory Board's Advisory Council on Clean Air Compliance Analysis, as well as three technical subcommittees of the Advisory Council. EPA, Benefits and Costs of the Clean Air Act From 1990 to 2020: Summary Report 1 (2011). Moreover, intermediate analyses leading up to the final report were made available to the public for review and comment. EPA, *Benefits and Costs of the Clean Air Act 1990-2020: Revised Analytical Plan for EPA's Second Prospective Analysis* 10-1 (2003). Likewise, EPA's Regulatory Impact Analyses for individual rulemakings are made available for public comment and are sometimes subject to review by the Science Advisory Board.

report prepared by OMB, which was finalized in December 2019, reported that major rules issued by the Office of Air and Radiation between October 1, 2006 and September 30, 2016 yielded a cumulative total of $180.5 billion to $665.4 billion in *annual* benefits; when joint fuel economy and vehicle greenhouse gas standards issued by the Department of Transportation and EPA are included, the total benefits increase to $225.1 billion to $743.2 billion each year. These benefits are between 4.3 and 10.6 times higher than the annual compliance costs associated with these rules.[6]

- EPA's most recent analysis of the costs and benefits of the Clean Air Act projects that the benefits of the 1990 Clean Air Act Amendments will exceed the costs of compliance by a factor of 30 to 1 over the period of 1990 to 2020.[7] The study identified benefits valued at $2 trillion in 2020 alone, including 230,000 avoided deaths, 200,000 avoided heart attacks, over 250,000 avoided hospitalizations and emergency room visits, 2.4 million avoided asthma attacks, and 22.4 million lost work and school days avoided.[8] Required by Section 812 of the Clean Air Act, this comprehensive analysis rests on a vast body of peer-reviewed literature and numerous technical reports, and was reviewed by an Advisory Council of the agency's Science Advisory Board ("SAB") and three separate technical subcommittees.

- A more recent independent analysis of the costs and benefits of the Clean Air Act, prepared by Industrial Economics, Inc. for the Natural Resources Defense Council, used a methodology similar to that of EPA's own study but with updated health and valuation assumptions drawn from more recent RIAs. This study concluded that the benefits of Clean Air Act protections range from nearly $2 trillion to nearly $3.9 trillion in 2020, with projected benefits of $2.5 trillion to $5.0 trillion in 2030.[9] The 2030 benefits identified in the study include between 229,000 and 457,000 avoided deaths; nearly 55,000 avoided heart attacks; over 250,000 cardiac and respiratory hospital admissions; over 67 million avoided asthma attacks; and over 36 million lost school and work days avoided.[10]

These analyses reflect EPA's extensive track record of implementing the Clean Air Act to achieve dramatic reductions in air pollution in a cost-effective way. For example, EPA estimates that power plant mercury emissions have decreased by 86% from 2006 to 2016, due in no small part to EPA's Mercury and Air Toxics Standards ("MATS"), with further reductions

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[6] OMB, *2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act* 9, Table 1-2 (2019), https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf.

[7] EPA, *The Benefits and Costs of the Clean Air Act from 1990-2020* 7-1 (Apr. 2011), https://www.epa.gov/sites/production/files/2015-07/documents/fullreport_rev_a.pdf. ("EPA 2011 Study")

[8] *Id.* at 5-25, Table 5-6.

[9] Industrial Economics, Inc., *The Benefits and Costs of U.S. Air Pollution Regulations* 25 (May 2020), https://www.nrdc.org/sites/default/files/iec-benefits-costs-us-air-pollution-regulations-report.pdf ("IEc/NRDC 2020 Study").

[10] *Id.* at 32, Table 11.

expected from the sector.[11] Power plant emissions of pollutants that cause acid rain, haze and smog have fallen dramatically as well—94% for sulfur dioxide and 86% for oxides of nitrogen, from 1990 to 2019.[12] Since the early 1990s, average visibility in Class I protected areas like Great Smoky Mountains National Park has improved by 20 miles with significant reductions in sulfur dioxide and ozone pollution from Clean Air Act requirements.[13]

These reductions in pollution have not only resulted in massive improvements in public health, but as the studies above have found, they have also resulted in a variety of other improvements in economic well-being and quality of life. Improved air quality in our nation's protected areas, for example, has resulted in increased tourism at national parks, [14] as visitors highly value clean air. That in turn generates significant revenue for local economies.[15] Protections adopted under the Clean Air Act over the last few decades have also led to a dramatic decrease in acid rain,[16] and sharply reduced levels of neurotoxic lead pollution in the air.[17]

These benefits have occurred as America has achieved robust economic growth. By 2017, the combined emissions of the six most common air pollutants fell 73%, compared to 1970.[18] During this time, gross domestic product grew 246% and population grew by more than 50%.[19] EPA standards themselves can drive innovation and progress, establishing the United States as a leader. For example, the Clean Air Act's Significant New Alternatives Policy has helped drive American innovations in alternative products that are less harmful to the ozone layer, while providing new markets to American manufacturers.[20]

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[11] EPA, *Comparing Industry Sectors, in 2016 TRI National Analysis* 31 (Jan 2018), https://www.epa.gov/sites/production/files/2018-01/documents/comparing_industry_sectors.pdf.

[12] EPA, *Clean Air Markets: Power Plant Emission Trends Data*, https://www.epa.gov/airmarkets/power-plant-emission-trends#:~:text=From%201990%2D2019%2C%20annual%20emissions,94%20percent%2C%20from%201990%20levels.

[13] National Parks Conservation Association, *Polluted Parks: How Dirty Air is Harming America's National Parks*, (Sept. 2015), https://www.npca.org/resources/3137-polluted-parks-how-dirty-air-is-harming-america-s-national-parks.

[14] David Keiser et al., *Air pollution and visitation at U.S. national parks*, Science Advances (July 18, 2018), http://advances.sciencemag.org/content/4/7/eaat1613.

[15] *See* National Parks Service, *2019 National Park Visitor Spending Effects Economic Contributions to Local Communities, States, and the Nation* (2020), https://www.nps.gov/subjects/socialscience/vse.htm.

[16] National Acid Precipitation Assessment Program, *Report to Congress 2011* at ES-2, ES-3 (Dec. 28, 2011) (noting that the health benefits in 2010 alone resulting from the Acid Rain Program are estimated at $170 billion to $430 billion, and that wet sulfate deposition has decreased 42-44% since the program was enacted).

[17] *See* EPA, *Lead Trends*, *https://www.epa.gov/air-trends/lead-trends* (showing mean concentrations of lead in the air have declined 98%).

[18] EPA, *Progress Cleaning the Air and Improving People's Health*, https://www.epa.gov/clean-air-act-overview/progress-cleaning-air-and-improving-peoples-health.

[19] *Id.*; *See* U.S. Population by Year, http://www.multpl.com/united-states-population/table.

[20] *See, e.g.*, Honeywell, *Performance Materials and Technologies: Reducing the impact on climate change*, https://www.honeywell-refrigerants.com/europe/wp-content/uploads/2013/03/honeywell-lgwp_hfo-environmental_brochure.pdf ("[T]he Company has been at the forefront of the industry's drive to develop these safer, non-ozone depleting alternatives to the older technology (CFC and HCFC refrigerants), in compliance with global legislation for their phase-out.").

The Proposal presents absolutely no evidence indicating that these assessments of Clean Air Act benefits are in error. And the sheer scale of the benefits associated with clean air protections means that Clean Air Act programs would still yield benefits far in excess of costs *even assuming* significant uncertainty as to both benefits and costs. EPA's most recent Section 812 study, for example, carefully evaluated the uncertainty associated with each element of its assessment and concluded that:

> the very wide margin between estimated benefits and costs, and the results of the uncertainty analysis, suggest that it is extremely unlikely that the monetized benefits of the CAA [Amendments] over the 1990 to 2020 period reasonably could be less than its costs, under any alternative set of assumptions we can conceive.[21]

B) Assessments of Clean Air Protections Underestimate Key Benefits and Overestimate Costs.

Contrary to EPA's suggestion that prior analyses "overestimated benefits,"[22] efforts to quantify and monetize the tremendous benefits provided by EPA safeguards have long been recognized to capture only a portion of their value, due to the difficulty of quantifying and monetizing many of their beneficial impacts. For example, EPA's 2011 analysis of the benefits of the Clean Air Act evaluated both the uncertainty associated with the quantification and monetization of different air pollution benefits as well as categories of benefits that are excluded from benefit-cost analyses. Among other things, the analysis observed that:

- EPA has "high confidence" that estimates of the impacts of particulate matter on health are subject to "potentially major" *underestimates*, given that actual human exposure to particulate matter is likely to be much greater than ambient air monitor data would indicate.[23]
- EPA does not quantify many health effects of hazardous air pollutants such as mercury[24]—a potentially major omission in light of recent research concluding that reductions in power plant emissions of mercury alone could yield cumulative health benefits (primarily cardiovascular) valued at between $43 billion and $147 billion by 2050.[25]
- EPA does not quantify a range of potential ecological effects associated with air pollution, including eutrophication of estuaries, acidification of soils, and bioaccumulation of mercury and dioxins in the food chain—effects that EPA

[21] EPA 2011 Study at 7-8.

[22] 85 Fed. Reg. at 35,617.

[23] EPA 2011 Study at 5-41; Daniel M. Sullivan & Alan Krupnick, *Using Satellite Data to Fill the Gaps in the US Air Pollution Monitoring Network*, at 1, Resources for the Future Working Paper (Sept. 2018) (finding that over 24 million Americans live in areas misclassified as in attainment for fine particulate matter), https://www.rff.org/documents/1823/RFF20WP-18-21_0.pdf.

[24] EPA 2011 Study at 5-48.

[25] A. Giang & N.E. Selin, *Benefits of Mercury Controls for the United States*, 113 Proc. Nat'l Acad. Sci. 286, at S11-S12 (2016).

characterized as "widespread and significant," resulting in "potentially major" underestimates of the net benefits of Clean Air Act programs.[26]

Overall, EPA determined that its assessment of the costs and benefits of Clean Air Act programs is "more likely to understate net benefits than overstate them" in light of the relatively large number of major sources of uncertainty that would result in an underestimate of benefits (and the much smaller number of uncertainties that could lead to an overestimate of benefits).[27]

Importantly, EPA's 2011 conclusion that benefits of Clean Air Act programs are likely underestimated has been echoed in other studies. The Industrial Economics study referenced above, for example, noted that its assessment of the benefits of Clean Air Act protections—even though it was substantially higher than EPA's estimate—*excluded* multiple major categories of criteria air pollutant benefits, including "improved productivity for agricultural crops and commercial timber, visibility improvements in recreational and residential areas, avoided degradation of buildings constructed with acid-sensitive materials, and reduced acid deposition."[28] Likewise, the Industrial Economics study (like EPA) excluded health benefits of reductions in organic aerosols—despite scientific literature indicating that these reductions avoided 180,000 premature deaths between 1990 and 2012 alone.[29] And the Industrial Economics study, like EPA, also assigned no quantitative value to reductions in air toxics such as mercury, arsenic and lead.[30]

That these benefits may be difficult to quantify and monetize, of course, does not "make them any less real" or diminish their value and relevance in policymaking.[31] OMB's longstanding guidance for regulatory assessments, entitled Circular A-4, has recognized since 2003 that "[i]t will not always be possible to express in monetary units all the important benefits and costs."[32] Circular A-4 also instructs agencies to present unquantifiable or unmonetized benefits alongside quantified estimates of other benefits,[33] and advises that where there are significant unquantified benefits "the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate."[34] This guidance, which has been in place for nearly seventeen years and followed under administrations of both parties, affirms the importance of considering unquantified benefits on an equal footing with quantified and monetized benefits when conducting regulatory assessments.

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[26] EPA 2011 Study at 6-43.
[27] *Id.* at 7-11.
[28] IEc/NRDC 2020 Study at 38.
[29] *Id.* at 39 (citing Ridley, D.A., Heald, C. L., Ridley, K.J., and Kroll, J.H. 2018. Causes and consequences of decreasing atmospheric organic aerosol in the United States. PNAS. 115(2)).
[30] *Id.*
[31] J. Scott Halladay, Valuing the Clean Air Act: How Do We Know How Much Clean Air is Worth? 14 (Institute for Policy Integrity, 2011).
[32] OMB, Circular A-4: Regulatory Analysis 2 (Sept. 17, 2003), https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.
[33] *Id.* at 27.
[34] *Id.* at 2.

At the same time that benefits of clean air protections are routinely underestimated, the costs of clean air protections are often grossly exaggerated by industry—and actual costs have often been markedly lower than initially estimated by EPA. In 1990, for example, American Electric Power told the Boston Globe that bipartisan solutions to address acid rain could lead to "the potential destruction of the Midwest economy."[35] Power companies predicted that reducing sulfur dioxide pollution would cost $1,000-$1,500 per ton and electricity prices would increase up to 10% in many states.[36] In fact, the actual pollution reduction cost has been between $100 and $200 per ton for both phases of the acid rain program, and electricity prices fell in most states.[37] Acid rain has been dramatically reduced and the limits on sulfur dioxide pollution were met faster and at a strikingly lower price than anyone expected in 1990.[38] Similarly, despite initial industry protestations about the costs of compliance with MATS, actual implementation costs have been lower than EPA's projections by hundreds of millions—even billions—of dollars.[39]

Assessments of regulatory analyses conducted by EPA and other agencies have confirmed that such overestimates of costs are frequent—undermining the Proposal's unsubstantiated suggestion that costs of EPA rules tend to be "underestimated."[40] A 2014 study by EPA's own National Center for Environmental Economics ("NCEE") contained an extensive literature review of studies conducted by independent researchers, the Office of Management and Budget, the National Research Council, and the former Office of Technology Assessment. The vast majority of the studies reviewed by NCEE found that official estimates of the costs of environmental regulations were overestimated far more frequently than they were underestimated.[41] One frequently cited study by researchers at Resources for the Future, for example, examined 28 environmental regulations and found that 14 of the rules overestimated costs and that only 3 of the rules underestimated costs. The researchers concluded that "EPA and other regulatory agencies tend to overestimate the total costs of regulations" because they fail to

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[35] Michael Kranish, *A clean air revival*, Boston Globe (Oct. 17, 2010), http://archive.boston.com/news/science/articles/2010/10/17/washing_away_of_acid_rain_offers_lesson/.

[36] U.S. House of Representatives Committee on Energy and Commerce, *Industry Claims about the Costs of the Clean Air Act* (2009).

[37] *Id.*

[38] EDF, *There They Go Again: AEP Seeks Delay in Health Protections for Children and Elderly*, http://www.edf.org/sites/default/files/AEP%20-%20There%20They%20Go%20Again.pdf; *see also* Sam Napolitano et al., *The U.S. Acid Rain Program: Key Insights from the Design, Operation, and Assessment of a Cap-and-Trade Program*, 20 Elsevier 47 (Aug./Sept. 2007), https://www.epa.gov/sites/production/files/2016-03/documents/us_acid_rain_program_elec_journal_aug_2007.pdf ("Since its inception in 1995, the U.S. Acid Rain Program (ARP) has earned widespread acclaim due to dramatic sulfur dioxide (SO2) and nitrogen oxides (NOX) emission reductions, far-ranging environmental and human health benefits, and far lower-than expected compliance costs.").

[39] EDF, *Power Companies' Declining Estimates of the Compliance Costs of Mercury & Air Toxics Standards (MATS)*, http://blogs.edf.org/climate411/files/2014/05/Declining-costs-of-MATS-compliance.pdf?_ga=1.64911789.383468789.1454952534.

[40] 85 Fed. Reg. at 35,617.

[41] National Center for Environmental Economics, *Retrospective Study of the Costs of EPA Regulations: A Report of Four Case Studies* 4-5, Table 1.1 (2014).

account for future technological innovations that reduce the cost of compliance, or rely on industry estimates of costs that (as noted above) are themselves exaggerated.[42]

C) The Proposal Unlawfully Ignores Distributional Impacts of Clean Air Protections.

While the Proposal dwells on completely unsubstantiated speculation that the net benefits of clean air protections are overstated, it completely overlooks the very real impacts that clean air protections have on health and quality of life in communities that are disproportionately exposed to air pollution, including low-income communities and communities of color who are most likely to live in close proximity to industrial facilities and other sources of pollution. Protecting those communities, tribal communities, and persons more vulnerable to air pollution due to preexisting health conditions or age (the very young and the elderly) should be central to EPA's implementation of the Clean Air Act, and in fact are central tenets of the Act as written. Indeed, EPA's Office of Inspector General recently identified considering environmental justice and demonstrating leadership on environmental justice as a top management challenge for EPA.[43] The Proposal's failure to consider these environmental justice and equity impacts—and the ramifications that its new requirements might have on clean air protections that affect overburdened communities—runs afoul of the Act's purposes by emphasizing cost to industry over public health goals. For those and other reasons, the Proposal is arbitrary, contrary to good practices in economic analysis, and in conflict with the directives of Executive Order 12,898, which requires agencies to identify and address such impacts.

As described below, this Proposal is riddled with arbitrary and burdensome requirements that threaten to make it more difficult for EPA to develop and justify clean air protections—including requirements that create higher evidentiary hurdles for benefits than for costs; requirements that would limit and distort EPA's consideration of public health studies; and disclosure requirements that could limit EPA's consideration of proprietary or older data. There is no question that this Proposal's effects on clean air protections would fall disproportionately on communities that are most exposed to air pollution—including communities with large numbers of low-income and minority residents. A recent meta-analysis of economic research on clean air protections, for example, highlights evidence that the 1990 Clean Air Act Amendments have led to significant air quality improvements in neighborhoods near particulate matter monitors—with benefits that are particularly great for low-income communities.[44] Similarly,

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[42] Winston Harrington, Richard Morgenstern, and Peter Nelson, *How Accurate Are Regulatory Cost Estimates?*, at 1 (Resources for the Future, 2010) (describing research reflected in Winston Harrington, Richard D. Morgenstern, and Peter Nelson, *On the accuracy of regulatory cost estimates*, 19 Journal of Policy Analysis and Management, 297–322 (2000)).

[43] EPA Office of Inspector General, *FYs 2020-2021 U.S. Environmental Protection Agency Top Management Challenges* (Report No. 20-N-0231, July 21, 2020), https://www.epa.gov/sites/production/files/2020-07/documents/_epaoig_20200721-20-n-0231_0.pdf.

[44] Janet Currie & Reed Walker, *What Do Economists Have to Say About the Clean Air Act 50 Years After the Establishment of the Environmental Protection Agency?*, 33 Journal of Economic Perspectives 20 (2019) (citing Antonio Bento, Matthew Freedman, and Corey Lang, *Who Benefits from Environmental Regulation? Evidence from the Clean Air Act Amendments*, 97 Review of Economics and Statistics 610–22 (2015)).

Clean Air Act protections phasing out lead in gasoline and targeting reductions in particulate matter have been shown to have particularly significant benefits for minority communities.[45]

By altering benefit-cost analyses for Clean Air Act protections in a way that might make the benefits of these protections more difficult to demonstrate—as well as creating new administrative and litigation-related hurdles to these protections—the Proposal puts at risk these vital protections and the progress they have yielded in overburdened communities. Furthermore, the proposed requirements themselves say absolutely nothing about analyzing the distributional impacts of clean air protections as part of future benefit-cost analyses. In this regard the Proposal "entirely fails to consider an important aspect of the problem" it is purporting to address,[46] a hallmark of arbitrary and capricious rulemaking. Further underscoring the arbitrary nature of the Proposal, EPA's failure to consider the distributional impacts of the Proposal or to consider distributional equity in the benefit-cost requirements in the Proposal is contrary to accepted practices in regulatory analysis. Circular A-4 itself recommends that agencies "provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision-makers can properly consider them along with the effects on economic efficiency."[47]

These omissions in the Proposal also run afoul of Executive Order 12,898. The Proposal incorrectly asserts that "this proposed action is not subject to Executive Order 12898 . . . because it does not establish an environmental health or safety standard."[48] Executive Order 12,898, however, is not so limited. By its terms, Executive Order 12,898 directs each federal agency, including EPA, to make environmental justice part of its mission "to the greatest extent practicable" and requires each agency to "identify[] and address[]" the "disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States."[49] This obligation holds regardless of whether those programs, policies, and activities are substantive or procedural in nature, and clearly applies to this Proposal—which would substantially affect clean air protections that are important to the health and well-being of overburdened communities.

III. THRESHOLD LEGAL OBJECTIONS

EPA fails to identify any problem solved by finalizing the Proposal. That in and of itself contravenes the fundamental administrative law principle that an agency action must identify both authority to take the action, and a problem it addresses. Moreover, it indicates a substantive legal issue: the Proposal is fundamentally unnecessary for implementation of the CAA, which means EPA is precluded from relying upon CAA Section 301(a)(1). Section 301(a)(1) authorizes only regulations necessary to carry out the CAA. Far from being necessary, this Proposal

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[45] *Id.* at 21 (citing Anna Aizer, Janet Currie, Peter Simon, and Patrick Vivier, *Do Low Levels of Blood Lead Reduce Children's Future Test Scores?*, 10 American Economic Journal: Applied Economics 307–41 (2018)).

[46] *Motor Vehicle Mfrs Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) ("*State Farm*").

[47] Circular A-4 at 14. *See also id.* ("You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups.").

[48] 85 Fed. Reg. at 35,625.

[49] E.O. 12,898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, Section 1-101 (Feb. 11, 1994) ("E.O. 12,898").

undermines EPA's capacity to carry out the CAA's purpose to protect public health and welfare and violates statutory duties under the Act, as discussed below.[50] As a result, EPA has identified no statutory authority under the CAA to properly issue the rule.

Additionally, the Proposal exceeds the scope of EPA's authority to issue rules of agency organization, procedure, and practice because it will have a binding effect on the agency and effect sweeping impacts on public health. Accordingly, the Proposal is a substantive rule requiring EPA to consider comments submitted through notice-and-comment rulemaking and to provide a new opportunity for public comment on any aspects of a final rule that are not logical outgrowths of the Proposal, and prohibiting EPA from relying on any authorities to issue the Proposal that extend only to internal or procedural practices. Neither has EPA provided any reason to issue a binding regulation or to arbitrarily depart from decades of practice under its existing guidelines, which are developed through a more robust peer-review process and better suited to flexibly adapt to methodological innovations and unique regulatory and statutory circumstances. Lastly, the rule risks an unnecessary increase in litigation for no reason.

A) EPA Identifies No Legitimate Source of Legal Authority Under the Clean Air Act for the Proposal.

EPA cites no legitimate source of legal authority under the CAA for enacting the Proposal. The agency inappropriately relies on only 42 U.S.C. § 7601(a)(1) (also referred to as Section 301(a)(1) of the CAA), which grants the Administrator authority "to prescribe such regulations as are necessary to carry out his functions" under the CAA. Yet courts have "consistently held that EPA's authority to issue ancillary regulations is not open-ended," and its "gap-filling authority" is designed only "to supplement the CAA's provisions."[51] Section 7601(a)(1) "does not give EPA carte blanche authority to promulgate any rules, on any matter relating to the CAA, in any manner that the Administrator wishes."[52] If the agency wishes to invoke the Administrator's "gap-filling" authority, it must identify a gap that requires filling, which the agency has failed to do.

Moreover, there is no gap to identify. As discussed elsewhere in this comment, the Proposal is entirely unnecessary, duplicating and confusing the role of guidance that has no need to be made binding and fulfilling no obligation under the Clean Air Act. This puts the Proposal beyond the proper scope of Section 7601(a)(1), which only authorizes the Administrator to issue regulations "necessary to carry out his functions" under the statute. As the D.C. Circuit pointed out the same month that the Proposal was published, "a 'necessary or appropriate' provision in an agency's authorizing statute does not necessarily empower the agency to pursue rulemaking

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[50] *See infra* sections V, VI, VII, IX, XI.

[51] *NRDC v. EPA*, 749 F.3d 1055, 1063, 1064 (D.C. Cir. 2014).

[52] *Citizens to Save Spencer County v. U.S. E.P.A.*, 600 2d. 844, 873 (D.C. Cir. 1979) ("*Spencer County*"). *See also American Petroleum Institute v. U.S. E.P.A.*, 52 F.3d 1113, 1117 (D.C. Cir. 1995); *Merck & Co., Inc. v. U. S. H.H.S.*, 962 F.3d 531 (D.C. Cir. 2020) ("Although the Secretary's regulatory authority is broad, it does not allow him to move the goalposts to wherever he kicks the ball.").

that is not otherwise authorized."[53] As such, the Proposal is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and in excess of statutory authority.

Reflecting its limited authority under 42 U.S.C. § 7601(a)(1), EPA has typically issued regulations under this provision in tandem with another statutory grant of authority. As recently as 2018, when issuing proposed regulations setting the requirements for non-attainment state implementation plans for the 2015 National Ambient Air Quality Standards ("NAAQS") for ozone, the agency relied on its statutory authority under 42 U.S.C. § 7601(a)(1) *and* 42 U.S.C. §§ 7409-7410, 7502, 7511(a)-7511(d), and 7661(2)(B).[54] Similarly, in its proposed rule regarding good neighbor obligations for the 2015 Ozone NAAQS, the agency cited its authority under both 42 U.S.C. § 7601(a)(1) *and* § 7410.[55] As the Seventh Circuit has observed, where "the U.S. EPA relie[s] solely upon the provisions of § 301," as it does here, "its authority to promulgate . . . regulations might be questionable."[56]

In contrast to the Proposal, the Administrator may rely on 42 U.S.C. § 7601(a)(1), for example, to reconcile previous regulations that "contain[] certain provisions that are inconsistent with more recent actions and rulemakings promulgated by the EPA."[57] Similarly, the Administrator may find it necessary to issue regulations, relying on 42 U.S.C. §7601(a)(1), where there are seemingly contradictory statutory provisions and it is necessary to issue regulations that "accommodate reasonably the purpose and concerns behind the two contradictory provisions."[58] In both of those instances, the statute could not be implemented without additional regulations, clarifying inconsistencies across regulations or within the language of the statute itself. Neither of these scenarios pertains to the Proposal. The Proposal resolves no inconsistencies in the statute or regulations, nor resolves any obstacles to the agency's ability to implement the statute. Indeed, the Proposal seeks to fill the role already effectively fulfilled by existing guidance documents.[59]

Furthermore, the agency has also failed to provide an explanation for why the rule is "necessary"—likely because this Proposal fulfills no requirement of the Clean Air Act and in fact would interfere with EPA's performance of its statutory duties, as discussed below.[60] As the agency has previously recognized, when enacting regulations under 42 U.S.C. § 7601(a)(1), the Administrator must provide a reasoned explanation as to why the proposed regulation is

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[53] *N.Y. Stock Exch. LLC v. SEC*, slip op. at 25; s*ee also Michigan v. EPA*, 135 S. Ct. 2699, 2706-07 (2015) ("*Michigan v. EPA*").

[54] Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements, 83 Fed. Reg. 62,998, 63,031 (Dec. 6, 2018).

[55] Determination Regarding Good Neighbor Obligations for the 2008 Ozone National Ambient Air Quality Standard, 83 Fed. Reg. 65,878, 65,882 (Dec. 21, 2018).

[56] *Illinois E.P.A. v. U.S. E.P.A.*, 947 F.2d 283, 291 (7th Cir. 1991).

[57] Revisions to the Source-Specific Federal Implementation Plan for the Four Corners Power Plant, Navajo Nation, 81 Fed. Reg. 86,988, 86,990-86,991 (Dec. 2, 2016) (proposed rule).

[58] NAAQS for Particulate Matter, 78 Fed. Reg. 3086, 3254 (Jan. 15, 2013) (quoting 45 Fed. Reg. 52,676, 52,683); *see also Spencer County*, 600 F.2d at 873 (where two statutory provisions are in direct conflict with each other "it was clearly 'necessary' for the Administrator in order to 'carry out his functions' in administering the [Act] . . . to employ the rulemaking authority provided in [42 U.S.C. §7601(a)(1)]").

[59] *See infra* section III.D.

[60] *See infra* sections V, VI, VII, IX, XI.

necessary.[61] Yet, here, the agency fails to identify any specific statutory provision that renders the proposed regulation necessary. In failing to explain why the rule is necessary to implement the Clean Air Act, the agency confirms the underlying weakness of the Proposal: it serves no statutory purpose.

Since the Proposal serves no purpose under the CAA, EPA lacks statutory authority to issue the rule under 42 U.S.C. §7601(a)(1). The agency improperly seeks to stretch out a gap-filling authority to side-step the statute and issue a regulation that is not necessary to implement any provision of the CAA.

B) EPA Unlawfully Fails to Identify Any Problem That Justifies the Issuance of a Binding Regulation.

EPA's Proposal is patently unnecessary. EPA has not demonstrated any problem for this rule to solve. This failure violates a basic principle of administrative law. An agency action is arbitrary and capricious where it fails to identify a problem that it must address.[62] EPA offers no explanation for why it now requires this binding regulation after decades of successfully conducting economic analyses under its own guidance, which is better suited to the task. EPA attempts to bolster its case for the Proposal by noting that courts have read certain provisions of the CAA to require some consideration of cost, but the Act does not mandate BCA across all of its provisions. In fact, certain provisions of the Act prohibit cost considerations altogether when setting standards,[63] and the other sections provide a range of approaches for how to consider costs when setting standards.[64] The agency thus requires a flexible framework to apply its analyses across the Act, which is more readily implemented through guidelines.[65]

EPA next tries to cobble together support for the Proposal by pointing to statutes and executive orders "in place for decades formally requiring the preparation of BCA in the development of major Federal regulations."[66] But rather than demonstrate a need for the Proposal, they prove precisely the opposite. For decades, EPA has fulfilled these requirements by following its own guidance, including the *Guidelines for Preparing Economic Analyses* ("*Guidelines*").[67] EPA has additionally followed the direction of OMB's Circular A–4 since its

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[61] *See, e.g.*, Oil and Natural Gas Sector: Emissions Standards for New, Reconstructed, and Modified Sources, 82 Fed. Reg. 51,788, 51,790 (Nov. 8, 2017) ("The Agency's determination that [a] regulation [is] necessary" is entitled to *Chevron* deference "as long as it provide[s] a reasoned explanation.").

[62] *See, e.g.*, *Nat'l Ass'n of Fed. Employees v. Vilsack*, 681 F. 3d 483, 485-86 (D.C. Cir. 2012) (concluding that identifying a legitimate governmental interest without foundation that the problem exists is "a solution in search of a problem" and arbitrary).

[63] *See Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 486 (2001) ("*American Trucking*"); 42 U.S.C. § 108(a)(1)(A), (B).

[64] Congressional Research Service, *Cost and Benefit Considerations in Clean Air Act Regulations* (May 5, 2017) at 2-9, https://crsreports.congress.gov/product/pdf/R/R44840/4.

[65] *See infra* section III.D.

[66] 85 Fed. Reg. at 35,614.

[67] EPA, Office of Policy, National Center for Environmental Economics, *Guidelines for Preparing Economic Analyses* (2010), https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses ("*Guidelines*"). *See also*, 85 Fed. Reg. at 35,615; website for *Guidelines*. The *Guidelines* were published in 2010, updated in 2014, and are currently being reviewed. The first *Guidelines* built upon related guidance first issued in

release in 2003. Both of these documents remain in effect today. As EPA summarizes, these two policies complement one another to direct EPA in how to increase transparency and "conduct BCA and other types of economic analyses" to enhance compliance with existing laws.[68] EPA identifies no gap left by these two policies for the Proposal to fill.

As EPA acknowledges, the agency is currently reviewing its *Guidelines*,[69] which provide a more appropriate mechanism to direct the agency in its BCAs.[70] The Proposal offers no compelling rationale for why the agency must now promulgate a regulation on the same topic when it has successfully utilized its *Guidelines* for decades and could issue any appropriate changes through the pending review process. While making reference to unidentified commenters' recommendations for a binding rule and concerns over an alleged inadequate adherence to the *Guidelines*,[71] nowhere does the Proposal identify any existing problem or substantiate how a binding regulation would add value. The Proposal fails to identify any instance of alleged inconsistencies, overestimated or double-counted benefits, inaccurate baselines, underestimated costs, or any other issue. Moreover, even if any of these issues had occurred, the Proposal offers no explanation of how it would change anything from current practice to fix these particular issues—to the extent that a rule even could.

The Proposal appears to implicitly adopt an assumption that the agency has historically underestimated costs or overestimated benefits. But as discussed in section II of this comment, such an assumption contradicts the evidence: the benefits of the CAA protections are routinely underestimated, while the costs have been less than anticipated. Despite these well-documented tendencies to undercount the net benefits of clean air protections, the benefits of the Clean Air Act have been found to exceed costs many times over. During the Obama Administration, EPA estimated that the CAA's benefits between 1990-2020 would exceed its costs by a factor of 30 to 1 and possibly much more.[72] EPA found similar results after conducting benefit-cost analyses of individual regulations. In its review of the 55 economically significant CAA regulations promulgated from 2001 to 2016, EPA found only two in which it estimated costs exceeded benefits.[73]

By contrast, the Proposal arbitrarily and unlawfully fails to consider the possibility that EPA may be underestimating benefits or overestimating costs. The Proposal displays an unexplained, one-sided focus on reducing estimated benefits and increasing estimated costs of clean air protections, entirely failing to assess ways that EPA has historically underestimated benefits and overestimated costs. Nor does the agency consider whether systematic changes are needed in order to fully account for benefits. To the extent that EPA attempts to manufacture a

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December of 1983 as the *Guidelines for Performing Regulatory Impact Analysis* and later revised in the late 1990s. In September of 2000, EPA issued its first *Guidelines for Preparing Economic Analyses*, which it has continued to periodically revise. *See Guidelines* at 1-1.

[68] 85 Fed. Reg. at 35,615.

[69] 85 Fed. Reg. at 35,615 n.13.

[70] *See infra* section III.D.

[71] 85 Fed. Reg. at 35,617.

[72] EPA 2011 Study at 7-8.

[73] Congressional Research Service, *Clean Air Act: A Summary of the Act and Its Major Requirements*, (Feb. 25, 2020), https://fas.org/sgp/crs/misc/RL30853.pdf at 11-12 (CRS table based on OMB data).

problem to solve, it has reviewed that "problem" unlawfully. It is arbitrary and capricious to "'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate."[74]

Given the lack of evidence of any harm that this Proposal could ameliorate, the Proposal presents a classic instance of an arbitrary "solution in search of a problem."[75] As the D.C. Circuit noted the same month that the Proposal was issued, "Normally . . . an agency regulation must be designed to address identified problems. Rules are not adopted in search of regulatory problems to solve."[76]

C) The Proposal Is a Substantive Rule Subject to Notice-and-Comment Rulemaking Requirements and Cannot Be Authorized by a Law Governing Procedural Rules.

EPA's claim that its authority under CAA Section 301 "extends to internal agency procedures" is irrelevant to this rulemaking.[77] The agency's description of the Proposal as a rule of "internal agency procedure"[78] is meritless in light of the evidence that the Proposal easily meets the criteria for a substantive rule: it would have a binding effect on the agency that would jeopardize the rights and interests of the public by affecting the stringency of clean air and public health protections under the Clean Air Act. Accordingly, EPA must abide by all notice and comment requirements under the Administrative Procedure Act ("APA"), including the obligation to consider and respond to all comments received.[79] Further, EPA is prohibited from relying on the Federal Housekeeping Act or any other authority that pertains only to internal rules of agency organization, procedure, or practice.

A "substantive rule" is not defined in the APA, but in distinguishing between "substantive rules" and "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice," courts have described "substantive rules" as those "affecting individual rights and obligations," a quality which helps identify which rules are "binding" or "have the force of law."[80] Conversely, agency actions which meet the requirements for a rule of agency organization, procedure, or practice for purposes of the APA are the opposite of substantive rules: they are those "that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints

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[74] *Michigan v. EPA*, 135 S. Ct. at 2707 (quoting *State Farm*, 463 U.S. at 43).

[75] *Nat'l Ass'n of Fed. Employees*, 681 F.3d at 485-86; *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 840-41 (D.C. Cir. 2006) ("Professing that an order ameliorates a real industry problem but then citing no evidence demonstrating that there is in fact an industry problem is not reasoned decisionmaking."); *Sorenson Commc'ns v. FCC*, 755 F.3d 702, 709-10 (D.C. Cir. 2011) (similar).

[76] *N.Y. Stock Exch. LLC v. SEC*, 962 F.3d 541, No 19-1042, slip op. at 27 (D.C. Cir. 2020) (internal citations omitted).

[77] 85 Fed. Reg. 35,613.

[78] *Id.*

[79] *See* 5 U.S.C. § 553(b)(A).

[80] *Chrysler Corp. v. Brown*, 441 U.S. 281, 301-02 (1979) (quoting *Morton* v. *Ruiz*, 415 U.S. 199, 232, 235-36 (1974)).

to the agency."[81] The Proposal is a substantive rule, meeting the criteria for a binding nature that alters the rights and interests of parties beyond EPA.

Courts have found rules to be binding if they prescribe practices for weighing data and limit agency consideration of data that the public might otherwise legally submit and have weighed in the rulemaking process. For example, in *CropLife America v. EPA*, the D.C. Circuit Court of Appeals considered whether an EPA press release, which stated that the agency would not consider third-party-controlled human exposure studies for purposes of pesticide registration subject to case-by-case consideration of individual studies, was a substantive rule. Even though it was only a press release, the court held that it bound both EPA and registrants during pesticide registrations and so was a binding "substantive rule."[82] In reaching its decision, the court considered two established case law formulations for determining whether an agency action constitutes a substantive regulation.[83] Consistent with *Chrysler Corporation*, the two analyses overlap in recognizing that a substantive action "binds private parties or the agency itself with the 'force of law.'"[84] In *CropLife*, the court determined: "EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply 'will not consider' human studies."[85]

Similarly to *CropLife*, EPA would bind itself through the Proposal to follow the particular practices it has designated to evaluate health studies, conduct economic analyses, and consider the benefits of CAA rules. Additionally, EPA proposes to bind the public, including organizations such as those submitting this comment, who can no longer receive the benefit of EPA's consideration, in BCA, of valid studies and data (for example, certain concentration-response studies) that they submit to the agency as part of an administrative record for an agency action, but that the agency deems noncompliant with this rule. Under Clean Air Act Section 307(d)(4)(B)(i), as well as general principles of administrative law, such comments and data are required to become part of the record that must be considered as part of the rulemaking process. Moreover, this Proposal is even more clearly a substantive rule than the proposal in *CropLife* because it was published according to notice and comment procedures in the Federal Register, unlike the EPA action evaluated in *CropLife*. Courts have considered whether the agency used full public notice and comment procedures, which an agency need not use when promulgating a

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[81] *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

[82] *CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003) ("*CropLife*").

[83] *See Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting *Am. Bus Ass'n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980)) (considering whether the agency action (1) "impose[s] any rights and obligations," or (2) "genuinely leaves the agency and its decisionmakers free to exercise discretion"); s*ee also Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) (stating that the court considers "(1) the Agency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency").

[84] *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382 (D.C. Cir. 2002); *see also NRDC v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020) ("A legislative rule is one that has legal effect or, alternately, one that an agency promulgates with the intent to exercise its delegated legislative power by speaking with the force of law. . . . Here, the 2018 Rule has independent legal effect beyond that compelled by *Mexichem* and reflects EPA's intent to exercise its delegated legislative power." (internal citation and quotation marks omitted)).

[85] *CropLife*, 329 F.3d at 881.

rule of agency procedure, as an indicator of a substantive rule.[86] While courts consider an agency's own characterization of its action, they disregard claims that conflict with the record. EPA's weak attempts to whitewash the Proposal by declaring it procedural make no difference.[87] "The agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the 'force of law,' but the record indicates otherwise."[88]

The Proposal must also be considered a substantive rule because it would affect private rights and interests. An agency action that "trenches on substantial private rights and interests" cannot be a rule of agency organization, procedure, or practice.[89] By restricting the methodologies and data on which EPA may base final significant regulatory actions, EPA severely limits parties from relying on excluded studies and public health benefit considerations in advocating for particular safeguards, or petitioning the agency to take a specific action, as the statute authorizes them to do. Since the rule would substantively impact agency conclusions and regulations, it impacts private rights and interests for both the regulated community as well as for regulatory beneficiaries and public health. EPA's proposed action "encodes a substantive value judgment [and] puts a stamp of approval or disapproval on a given type of behavior" by requiring regulatory actions to be supported only by certain scientific and economic information deemed acceptable by the Proposal.[90]

Moreover, to the extent that this Proposal would advance Administrator Wheeler's intention[91] to preclude consideration of health and climate co-benefits, the effects on the American public would be enormous, clearly rendering this a substantive rule.[92] For example, in 2016, when reaffirming that regulation of power plants under Section 112 was appropriate, EPA correctly considered tens of billions of dollars of what the agency declared were health "co-benefits" of air toxics regulation (although some were actually the direct benefit of controlling the regulated pollution).[93] The disastrous impacts of an unlawful co-benefit preclusion were on

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[86] *See, e.g.*, *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 172–73 (2007); *see also* 5 U.S.C. § 553(b)(3)(A); *Molycorp*, 197 F.3d at 545.

[87] 85 Fed. Reg. at 35,613.

[88] *CropLife*, 329 F.3d at 883 (citing *Gen. Elec. Co.*, 290 F.3d at 383-85); *see also, e.g.*, *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 95-96 (D.C. Cir. 2002).

[89] *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980).

[90] *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987); *see also Pharm. Mfrs. Ass'n v. Finch*, 307 F. Supp. 858, 865 (D. Del. 1970) (finding that a regulation promulgating new criteria for clinical investigations that will meet the standards of evidence necessary to demonstrate the effectiveness of drug products, and excluding certain kinds of clinical investigations, was not merely a procedural rule, because it "did effect a material narrowing of the range of evidence which previously had been considered relevant in evaluating a drug's efficacy" "[b]ecause of the important clarification of acceptable testing standards effected by the . . . regulations," and "because of the substantial impact of the[] regulations on the drug industry. . . . ").

[91] The New York Times reported that Administrator Wheeler told reporters that the economic value of co-benefits would be calculated but no longer used to defend rules, explaining that "[c]o-benefits would not be used to justify the rule[.]" Coral Davenport & Lisa Friedman, *Trump, Citing Pandemic, Moves to Weaken Two Key Environmental Protections*, N.Y. Times (June 4, 2020), https://www.nytimes.com/2020/06/04/climate/trump-environment-coronavirus.html.

[92] See *infra* section IV for further discussion of co-benefits and why the Proposal cannot require the agency to ignore or subordinate consideration of co-benefits.

[93] EPA, *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, 24,438 (Apr. 25, 2016).

full display earlier this year when EPA reversed this legal finding by dismissing public health benefits valued at $37 billion to $90 billion each year, including the annual avoidance of 11,000 premature deaths, 4,700 heart attacks, 130,000 asthma attacks, and 540,000 lost work days.[94]

If EPA now were to finalize a *generalized* framework that ignores or devalues the importance of such co-benefits, it would significantly affect the agency's conclusions about issuing new protections and changing existing rules, significantly infringing on the public's interest in health protections under the CAA. As discussed above, OMB estimates that major rules issued by the Office of Air and Radiation between October 1, 2006 and September 30, 2016 cumulatively yield hundreds of billions of dollars in benefits for the American public including avoided deaths, heart attacks, and hospitalizations. This is a *conservative* approach to regulation—counting all of the benefits and costs of controlling air pollution. By contrast, the new methodologies laid out in the Proposal would fail to account for significant health and environmental benefits of the agency's actions—clearly in service of further intended rollbacks of existing CAA protections. Additional rollbacks, or artificial cost-related limits on the implementation of new required Clean Air Act protections, harm the health and well-being of hundreds of thousands of Americans.

If finalized, this Proposal would also establish a substantive rule because it would bind EPA to a certain method of BCA. That in turn would have direct legal consequences on the agency and significant impacts on the public by affecting EPA's ability to justify setting substantive clean air protections that safeguard public health.[95] Further, if this rule would effect a change in policy, then it by definition is a substantive rule—fundamental changes to agency policy have been consistently characterized by the courts as substantive.[96]

For the reasons laid out above, the Proposal is a substantive rule subject to the requirements of notice-and-comment rulemaking, and EPA is bound to consider the comments submitted to the record. Conversely, even if EPA's claim that the rule is procedural is somehow correct, then there would be no reason that the agency must implement these changes through regulations rather than through the *Guidelines* which, as discussed in section III.D, are better tailored to the task. Moreover, since the Proposal is a substantive rule, EPA's claim that CAA Section 301 authorizes the agency to issue procedural rules is irrelevant. By the same logic, the Proposal cannot be authorized by the Federal Housekeeping Act. Courts have consistently found that the Federal Housekeeping Act authorizes only rules of agency procedure, organization, or practice.[97] Moreover, EPA is not even one of the listed "executive departments" with

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[94] EPA, *Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards*, EPA-452/R-11-011, ES-3, ES-5—ES-6, Tables ES-3, ES-4 (Dec. 2011), https://www.epa.gov/sites/production/files/2015-11/documents/matsriafinal.pdf.

[95] *See NRDC v. Wheeler*, 955 F.3d at 90 (stating that a rule is final when it has "an immediate and practical" impact on rights and obligations).

[96] *See, e.g., Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (a substantive regulation "supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy"); *Rocky Mountain Helicopters, Inc. v. F.A.A.*, 971 F.2d 544, 546 (10th Cir. 1992) (a rule that "changes existing law, policy, or practice" is substantive).

[97] 5 U.S.C. § 301; *Chrysler Corp.*, 441 U.S. at 309-10; *City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1023 (N.D. Cal. 2019) (vacating regulations from the Department of Health and Human Services and explaining that defendants "mistakenly rely on their 'housekeeping authority' to support their authority to promulgate the rule" but

housekeeping authorities under this statute.[98] Regardless, authorities under the Housekeeping Act would not excuse EPA from any violation of environmental statutes like the CAA.

D) EPA's Proposal Is Arbitrary and Unnecessary in Light of EPA's Longstanding *Guidelines*, and Because It Risks Decreasing the Quality of EPA's Benefit-Cost Analysis.

EPA's Proposal to codify and constrain aspects of its benefit-cost analysis process is arbitrary and patently unnecessary in light of existing guidelines, risks stifling the agency's ability to adapt to future changes in BCA methodology and to flexibly apply its analysis to meet unique statutory and regulatory contexts, and could reduce the rigor with which BCA is conducted. As EPA notes, the agency is currently reviewing its *Guidelines for Performing Economic Analyses*,[99] and EPA acknowledges that for many years these *Guidelines* have complemented OMB's directions in Circular A-4 to provide the agency with "more detailed peer-reviewed guidance on how to conduct BCA and other types of economic analyses" to enhance compliance with existing law.[100] EPA has not identified any need to further describe or explain the BCA process through regulation, which is at best superfluous to the current *Guidelines* review process.

1. EPA's longstanding *Guidelines* support a better-tailored approach to BCA that can more easily adapt to reflect improvements in methodology and practice and offers more flexibility across diverse statutory and regulatory contexts.

EPA should withdraw this Proposal because it will severely limit the agency's ability to flexibly adapt to scientific changes in the methodology and best practice surrounding risk assessment and economic analysis. A 2017 study on federal agency guidance found that senior officials across federal agencies prefer to use guidance as opposed to legislative rules in "matters that involve uncertainty, either because the general matter being regulated . . . is likely to change rapidly, or because it is difficult to anticipate particulars that might arise in individual proceedings that would justify an ad hoc adjustment."[101] In the past, EPA has declined to promulgate regulations defining how certain analyses must be conducted for exactly this reason. For example, under the Hazardous Waste Permit Program, EPA authorizes a site-specific risk assessment as part of the permitting process, and the agency has explicitly declined to

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"[n]one of the statutes cited by defendants provide HHS with the authority to promulgate substantive rules," including the Housekeeping Act); *United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1255 (8th Cir. 1998) ("In recent years, several agencies have unsuccessfully attempted to find statutory authority for substantive regulations in the Housekeeping Statute."); *In re Bankers Trust Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (holding regulation requiring subpoenaed party to refuse production of confidential information was not authorized by the Housekeeping Statute and "exceeded the congressional delegation of authority"); *Exxon Shipping Co. v. U.S. Dep't of Interior*, 34 F.3d 774, 776-78 (9th Cir. 1994) (holding that the Housekeeping Act did not authorize regulations allowing agency to withhold deposition testimony of federal employees).

[98] 5 U.S.C. § 101.

[99] 85 Fed. Reg. at 35,615 n.13.

[100] 85 Fed. Reg. at 35,615.

[101] Nicholas Parrillo, *Federal Agency Guidance: An Institutional Perspective*, Administrative Conference of the United States, at 30 (Oct. 12, 2017).

promulgate regulations defining how those assessments must be conducted.[102] The agency explained that "risk assessment—especially multi-pathway, indirect exposure assessment—is a highly evolving field" and that "any regulatory approach it might codify in this area is likely to become outdated, or at least artificially constraining, shortly after promulgation in ways that it cannot anticipate now."[103]

EPA explains in the Proposal that "risk assessments often provide key inputs to the development of EPA's health benefit estimates in a BCA," meaning benefit-cost analysis could be frequently influenced by the "highly evolving" nature of risk assessment.[104] As best practice methodology for BCA evolves to reflect scientific progress, EPA will be less able to adapt under the constraints of a binding and fixed rule. Past and planned updates demonstrate such evolution of frameworks for conducting BCA is standard matter of course that will continue. In just the last ten years, EPA's *Guidelines* have been updated multiple times, and the agency is reviewing the *Guidelines* even now.[105] Should EPA's substantive rule be finalized and conflict with future changes to the *Guidelines*' process, the agency would have to undergo a lengthy notice and comment process to make updates to its rule, as opposed to just updating the *Guidelines* already in existence. This could seriously delay its ability to adapt to changes in best practices and could hinder the promulgation of public health and environmental protections.

Additionally, guidance provides a better tool to tailor analyses to the diverse statutory and regulatory circumstances encompassed by the CAA. The Act's protections encompass a wide range of pollutants, program structures, and requirements for compliance that include a variety of different approaches to cost consideration. To protect the public health and welfare through the CAA, Congress directed the EPA Administrator to, among other things, set NAAQS; set emission standards for both stationary and mobile sources of air pollution; reduce emissions of 187 hazardous air pollutants that Congress itself listed in the statute; protect air quality in relatively pristine areas from significant deterioration; regulate fuels and fuel additives, both to protect public health and welfare and to prevent the impairment of emission control devices; require the use of renewable transportation fuels; control acid deposition; protect the stratospheric ozone layer by requiring the phase-out of ozone-depleting substances; issue permits and enforce the Act's emission limits; and develop and enforce Federal Implementation Plans in states that fail to implement the Act's requirements.[106] The Administrator's authority to carry out these tasks spans dozens of different sections and subsections of the CAA and varies from broad authority to protect public health with an adequate margin of safety to detailed requirements that specify numerical emission limits.

How the Administrator should, or should not, consider cost in accomplishing the myriad tasks and responsibilities of the Clean Air Act varies significantly across the programs.[107] While

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[102] *See Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 211 (D.C. Cir. 2007).
[103] *Id.* at 214 (quoting 70 Fed. Reg. 59,402, 59,512 (Oct. 12, 2005)).
[104] 85 Fed. Reg. at 35, 618.
[105] *See Guidelines* website, https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses#howproduced (last visited July 17, 2020); *see also* 85 Fed. Reg. at 35,615 n.13.
[106] Congressional Research Service, *Cost and Benefit Considerations in Clean Air Act Regulations* at 2 (May 5, 2017), https://crsreports.congress.gov/product/pdf/R/R44840/4.
[107] *Id*. at 2-9.

many provisions of the Act specifically mention cost or economic considerations, others only imply it (e.g., where it requires a standard that is "practicable" or "reasonably achievable").[108] Many more do not mention or imply cost,[109] including those that require the NAAQS, which must be designed to protect public health with an adequate margin of safety and which the Supreme Court has read to prohibit cost considerations.[110] Guidance documents are better suited to flexibly accommodate the range of circumstances regulated under the CAA and the Act's diverse requirements for cost considerations.

Earlier this year, EPA proposed an additional rule on administrative procedures for issuing guidance that included a provision requiring that "significant guidance documents" as defined in Executive Order 13,891 go through notice and comment procedures.[111] EPA has cited no legitimate authority to issue the proposal on EPA Guidance and Administrative Procedures for Issuance of Public Petitions ("Guidance Proposal"). EPA claims authority to issue the Guidance Proposal under the Federal Housekeeping Act, but, as noted above, that statute does not include EPA in the list of Executive Offices granted housekeeping powers. Moreover, the Federal Housekeeping Act only grants authority for executive departments to issue rules of agency organization, procedure, or practice.[112] The Guidance Proposal is a substantive rule that exceeds the authorities of the Housekeeping Act. Accordingly, the Guidance Proposal is unlawful and should not affect the flexibility with which EPA can amend the *Guidelines* concerning analysis of costs and benefits.

EPA should continue to rely on its existing *Guidelines* to ensure the latest expertise is always incorporated into its analyses given the constantly changing and improving nature of this field. The agency is not only unauthorized to, but also has no need to issue an additional binding rule establishing further requirements for BCA, and EPA has not stated a compelling rationale for this Proposal to do so. The use of a binding legislative rule is unnecessary and patently undermines the goals of benefit-cost analysis under the CAA by creating barriers that could constrain adaptation to future improvements in methodology and practice.

2. EPA is already reviewing its longstanding *Guidelines* developed through a peer-reviewed process significantly more rigorous than the Proposal.

As EPA acknowledges, the agency is currently reviewing its existing *Guidelines* which already "establish a scientific framework for analyzing the benefits, costs, and other economic impacts of regulations and policies."[113] This is exactly what the Proposal posits to do. The Proposal acknowledges—and even praises—the thoroughness and accuracy of the current sources of guidance for conducting BCA and fails to provide any rationale as to why this rule is needed in addition to those credible resources. EPA's *Guidelines* are developed and updated by the agency's National Center for Environmental Economics, and all chapters undergo peer

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[108] *Id*. at 3-5 & Table 1.

[109] *Id*. at 5-8 & Table 2.

[110] *See American Trucking*, 531 U.S. at 486.

[111] EPA, *EPA Guidance; Administrative Procedures for Issuance and Public Petitions*, 85 Fed. Reg. 31,104, 31,106-07 (May 22, 2020).

[112] 5 U.S.C. § 101.

[113] 85 Fed. Reg. at 35,615.

review from EPA's Science Advisory Board, a panel of experts from outside the agency.[114] This comprehensive set of guidance first released in 2010 is over 400 pages in length and compiles research in environmental economics from hundreds of scholars[115] to guide EPA in producing evidence-based policy decisions that are not swayed by politically motivated outcomes.[116]

Further, EPA's current practice reflects OMB's Circular A-4, which provides guidance to agencies on the development of regulatory analysis under Executive Order 12,866.[117] The Proposal makes repeated reference to the methodologies laid out in EPA's *Guidelines* and Circular A-4 with frequent instruction to the reader to see those documents for best practices on establishing baselines, estimating costs and benefits, conducting uncertainty analysis, and other elements of BCA.[118] Specifically, OMB's Circular A-4 instructs agencies not to use only one formula for BCA and sets out a broader objective for agencies to achieve analytical consistency in estimating benefits and costs across regulations. Both requirements create potential points of contention with the Proposal, in which EPA puts forth formulaic criteria and imposes constraints on BCA under the CAA.[119]

3. EPA's Proposal is arbitrary and capricious in its departure from existing practice without a reasoned explanation, and it further undermines the role of science and economics in agency decision-making.

EPA does not provide a sufficient rationale to justify its harmful new restrictions on BCA under the CAA, especially given its veiled attempts to constrain the scope of literature review in assessing health endpoints and limit analysis of co-benefits.[120] Falling far short of that sufficiency threshold, EPA provided only a vague rationale for promulgating this rule: a purported aim to increase consistency and transparency in the BCA process in response to ANPR comments claiming an inadequate adherence to existing EPA *Guidelines* and OMB guidance.[121] However, EPA provides no specific facts or examples as to how the current BCA process lacks consistency and/or transparency. The D.C. Circuit maintains that an "Agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed" and an "Agency may not gloss over or swerve from prior precedents without discussion."[122] Given the clear credibility and reliability of the peer-reviewed and longstanding methodologies—as acknowledged by EPA itself throughout the Proposal—it is arbitrary and capricious for EPA to constrain its methodologies and depart from previous practice without providing a fact-based and reasoned analysis.

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[114] *See Guidelines* website, https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses#howproduced.

[115] *See generally Guidelines*.

[116] *See* Kevin Boyle & Matthew Kotchen, *Retreat on Economics at the EPA*, 361(6404) Science 729 (Aug. 24, 2018), https://science.sciencemag.org/content/361/6404/729.

[117] 85 Fed. Reg. at 35,615.

[118] *Id.* at 35,618-35,621.

[119] *Id.* at 35,620-21.

[120] *See, e.g.*, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) ("[O]ne of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions.").

[121] 85 Fed. Reg. at 35,617.

[122] *Greater Bos. Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970).

This Proposal appears to be the latest in a series of actions to diminish the role of science in EPA's regulatory analyses. In 2018, EPA eliminated the Environmental Economics Advisory Committee of the Science Advisory Board, which had previously taken a leading role in peer reviewing analytical approaches to quantifying costs and benefits.[123] Also in 2018, the agency first proposed to restrict the scientific data and models on which it could rely in developing regulations—and then early this year issued a supplemental notice furthering this idea.[124] EPA has also adopted an opaque and non-scientific approach to distort the social cost of carbon identified by an inter-agency working group, enabling the agency to severely underestimate the environmental and public health impacts of climate change.[125] This Proposal is just EPA's latest effort to constrain the process of establishing public health and environmental protections. EPA is undermining the rigorous independent peer review that informs its current *Guidelines* and continuing its recent pattern of threatening the scientific basis of the agency's regulatory decision-making.

4. The Proposal arbitrarily restricts EPA's cost analyses, decreasing the quality of regulatory analyses and conflicting with statutory requirements.

Moreover, BCA is only one of a number of cost metrics available to fulfill requirements for robust regulatory analysis. Both OMB and EPA have recognized other metrics as potentially more effective and appropriate under certain circumstances. For example, in issuing the Mercury and Air Toxics Standards 2016 "Supplemental Finding That It Is Appropriate and Necessary To Regulate Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units," EPA utilized several different cost metrics to evaluate whether compliance with MATS is reasonable for the power sector.[126] There, EPA considered annual compliance costs as a percent of power sector sales, annual compliance capital expenditures compared to the power sector's annual capital expenditures, impacts on the retail price of electricity, and impacts on power sector resource capacity.

OMB also provides guidance on different viable tools to evaluate costs and benefits as part of rigorous regulatory analyses in Circular A-4. Circular A-4 acknowledges that there are important costs and benefits that cannot be monetized. In this guidance, OMB recognizes cost-effectiveness as an acceptable alternative for BCA in regulatory analyses—and that it may be the only possible method under certain circumstances. In particular, OMB notes the importance of the cost-effectiveness metric for public health and safety rulemakings. By the nature of its statutory purpose to protect the public health and welfare, many CAA rulemakings fall under this category. The *Guidelines*, and guidance more broadly, provide a much more flexible framework

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[123] *See* Kevin & Kotchen, *Retreat on Economics at the EPA*.

[124] EPA, *Strengthening Transparency in Regulatory Science*, 85 Fed. Reg. 15,396 (Mar. 18, 2020); 83 Fed. Reg. 18,768 (Apr. 30, 2018) (collectively, "Restricted Science proposal").

[125] Chris Mooney, *New EPA document reveals sharply lower estimate of the cost of climate change*, Wash. Post (Oct. 11, 2017), https://www.washingtonpost.com/news/energy-environment/wp/2017/10/11/new-epa-document-reveals-sharply-lower-estimate-of-the-cost-of-climate-change/.

[126] EPA, *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, 24,438 (Apr. 25, 2016).

that can guide EPA in conducting robust analyses through a toolbox of cost metrics that can be tailored to meet a variety of circumstances.

The Proposal's requirement that "future significant proposed and final regulations promulgated under the Clean Air Act be accompanied by a BCA" would arbitrarily restrict EPA from fully utilizing the range of cost metrics necessary to complete robust public health and safety rulemaking. Such restrictions would hobble EPA from pursuing rulemakings ill-suited to BCA, diminishing the quality of regulatory analyses and health-based standards, and ultimately compromising the CAA's statutory purpose to protect public health and welfare. Additionally, it would also arbitrarily depart from prior practice.

E) EPA's Proposal Would Arbitrarily Incur an Unnecessary Risk of Increased Litigation.

If finalized, EPA's Proposal would likely subject the agency to future lawsuits, not only over the rule itself but also because the new methods required would impose an additional layer of analytical tasks divorced from the statutory mandate under which the agency is acting—tasks that could themselves be subject to separate claims. Regulatory deterrence, delays, and costs resulting from this litigation risk do not further—and indeed frustrate—the agency's mandates under the CAA and its mission to protect public health and the environment. Yet EPA has provided no analysis of the costs of such litigation risk. EPA cannot finalize its Proposal without fully examining this important aspect of the problem and explaining its reasoning for accepting this unnecessary litigation risk.[127]

Any final rule similar to the Proposal would likely lead to litigation that would not otherwise occur. These additional requirements are not innocuous boxes to check: even where the governing statute does not require EPA to conduct a BCA, "when an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable."[128] Thus, although EPA claims that its rule is merely procedural,[129] failure to comply with its requirements could subject future rules to challenge on those grounds. Courts would ordinarily review a BCA deferentially,[130] upholding a rule even where the agency "did not intend to conduct a rigorous societal cost-benefit analysis" but instead compared costs and benefits "in broad strokes."[131] Under the Proposal, however, EPA would strip itself of discretion to compare costs and benefits as it sees fit for particular regulatory scenarios. Rather, noncompliance with the Proposal's convoluted requirements could amount to reversible error, compromising future rulemaking efforts. And even the threat of litigation presents a formidable deterrent to timely and efficient rulemaking and imposes its own costs.

Such litigation could lead to absurd outcomes that blatantly contradict the requirements of the Act. For instance, opponents of a NAAQS could try to sue the agency, alleging that EPA's

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[127] *See State Farm*, 463 U.S. at 43.
[128] *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012).
[129] 85 Fed. Reg. at 35,613.
[130] *Nat'l Ass'n of Home Builders*, 682 F.3d at 1040.
[131] *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 507-08 (D.C. Cir. 2019).

BCA does not fully comply with this rule—even though the CAA prohibits consideration of costs when setting the NAAQS. Thus, parties could attempt to block or delay a vital public health protection based on violations of a rule that is not required by the Act and that pertains to analysis the agency could not legally consider.

Unnecessary litigation risk stemming from this rule would inflict significant costs on EPA. Staff development of regulations and accompanying RIAs would become more time- and resource-intensive, such as by requiring entirely new, burdensome, and unnecessary tasks like assessing whether staff can disseminate data and models on which they relied.[132] Once a rule and its RIA are prepared, interagency review would be protracted as the agencies seek to establish, through multiple rounds of comment and transmittals, that the rule complies with the Proposal's numerous requirements. Such a future rule would also need to undergo close scrutiny by EPA's Office of General Counsel to ensure its defensibility under the Proposal's requirements. Then, once final, the agency would need to defend the rule against inevitable attacks on these grounds and, in all likelihood, re-propose and re-promulgate rules that courts hold invalid for noncompliance—a process that would entail the same needless burdens and delays. Thus, the costs to the agency from unnecessary litigation risk and lawsuits resulting from the Proposal would be manifold and substantial.

Costs to the public and regulatory beneficiaries would likely prove even greater, although EPA has offered no estimate of these costs in its Proposal. As an initial matter, the costs to the agency discussed above could rightly be viewed as public costs because the public funds the agency. Setting these costs aside, however, regulatory beneficiaries would experience significant losses in benefits from fewer, delayed, or invalidated regulations. Again, these losses would be attributable entirely to alleged violations of a rule that in no way enhances the quality of public health or environmental protections. It is arbitrary for the agency not to consider the full range of costs from unnecessary litigation risk associated with its Proposal, and EPA cannot finalize this Proposal or a similar rule until it does so.[133]

Moreover, EPA fails to explain why the additional litigation risk and additional lawsuits might be warranted. The CAA provides for judicial review of rules promulgated under that statute,[134] which the court may reverse if it finds them to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[135] As noted above, this standard applies to the economic analyses EPA prepares to support its rules,[136] so the public already has a recourse if a rule relies on arbitrary economic analysis. There is no reason to believe that additional scrutiny beyond that which Congress provided for other components of a rule—which would be the effect of the Proposal's rigid requirements—is appropriate for EPA's assessment of costs and

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[132] *See* 85 Fed. Reg. at 35,627 (proposed 40 C.F.R. § 83.3(a)(12)). EPA's Restricted Science proposal makes clear that it would not require the agency to make available to the public all data and models underlying "pivotal regulatory science" and "pivotal science." *See* 85 Fed. Reg. 15,396, 15,402 (Mar. 18, 2020). The present Proposal, however, does appear to contemplate—and require—that EPA itself disseminate the data and models. *See* 85 Fed. Reg. at 35,627 (proposed 40 C.F.R. § 83.3(a)(12)).

[133] *State Farm*, 463 U.S. at 43.

[134] 42 U.S.C. § 7607(b).

[135] *Id.* § 7607(d)(9)(A)

[136] *Nat'l Ass'n of Home Builders*, 682 F.3d at 1040.

benefits. If there were some conceivable purpose for this rule, EPA could plausibly argue that an added level of review would be warranted. But this Proposal lacks any cogent purpose that would justify additional judicial review for compliance with its requirements.[137]

Given the agency's silence on this matter, it seems more likely that EPA is inviting litigation in order to impede or deter future regulation. It is also reasonable to expect that those with vested interests and ample resources to expend on litigation would be most successful in enforcing the Proposal's provisions—leading to an anti-regulatory bias in its application. These objectives are not valid grounds for rulemaking under the CAA, and in fact run directly contrary to the CAA's purposes and EPA's mission. EPA must abandon the Proposal.

IV. EPA IS NOT AUTHORIZED TO FINALIZE ANY RULE REQUIRING THE AGENCY TO IGNORE OR SUBORDINATE CONSIDERATION OF CO-BENEFITS, AND DOING SO WOULD BE CONTRARY TO LONGSTANDING PRACTICE AND EXISTING GUIDANCE, AND WOULD BE ARBITRARY AND CAPRICIOUS.

The agency is not authorized to finalize any rule *requiring* it to ignore or devalue the ancillary benefits (also known as "co-benefits" or "indirect benefits") of its Clean Air Act regulations. Not only is there no authority in the Act for it to do so, but that outcome would also arbitrarily depart from longstanding guidelines and policies maintained by EPA and the Office of Management and Budget, and furthermore would be arbitrary and capricious, as it would fail to take account of an important aspect of Clean Air Act regulation.

Moreover, any such requirement would not be a logical outgrowth of the Proposal. Despite the Administrator's statements suggesting that the Proposal is intended to preclude consideration of co-benefits, the published document contains no specific provisions that expressly disqualify or discredit co-benefits. Since EPA has not proposed any changes to how it accounts for co-benefits, finalizing any such changes would be unlawful. Nevertheless, these comments address the general need to properly account for co-benefits in a BCA in light of the Proposal's "presentational" requirement about co-benefits and because the agency's Proposal solicits comments on "how the Agency could take into consideration the results of a BCA in future rulemakings under specific provisions of the CAA" and "approaches for how the results of the BCA could be weighted in future CAA regulatory decisions."[138]

A) Statutory Language and Legal Precedent Regarding the Clean Air Act Support Consideration of Co-Benefits and Their Inclusion in Economic Analyses.

EPA's longstanding practice has been to evaluate and consider the co-benefits of its regulations. That approach is supported by D.C. Circuit and Supreme Court precedent. In *United States Sugar Corp. v. EPA*, the U.S. Court of Appeals for the D.C. Circuit upheld EPA's consideration of co-benefits in regulating the effects of reducing hazardous air pollutants

[137] *See supra* section III.B.
[138] 85 Fed. Reg. at 35,623.

("HAPs") from boilers, process heaters, and incinerators.[139] Specifically, the court held that EPA properly considered not only the direct benefits of reducing hydrogen chloride, but also the co-benefits of reducing other HAPs.[140] The court reasoned that the use of co-benefits conformed with the Clean Air Act's purpose, finding that "EPA was . . . free to consider potential co-benefits that might be achieved" from enforcing the more stringent standard.[141]

In *Michigan v. EPA*, Justice Scalia's opinion for the Court highlighted the importance of conducting a balanced regulatory analysis when deciding whether to regulate power plants under Section 112 of the Act.[142] In holding that EPA must consider costs when determining whether regulation was appropriate and necessary, the Court reasoned that "[c]onsideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions."[143] The Court's opinion offered a hypothetical in which regulation under Section 112, while serving to control HAP emissions, would have the collateral effect of causing new health harms—a factor that, according to the Court, EPA would necessarily have to consider in deciding whether regulation is "appropriate."[144]

The language of Section 112(n)(1)(A) itself also suggests Congress *expected* there to be significant co-benefits from co-pollutant reductions for various other Clean Air Act programs as well. The Administrator is required to perform a study of hazards from HAP emissions for power plants "after imposition of the requirements of this chapter."[145] This requirement clearly recognizes and anticipates the potential for co-benefit HAP emissions reductions from the implementation of other provisions of the Clean Air Act at electric generating units (for example, the acid rain requirements), that are not specifically targeted at HAP emissions reductions.

Section 111 of the Clean Air Act also shows Congress contemplated that EPA would consider co-benefits when promulgating Clean Air Act rules. Under Section 111, EPA rules set standards of performance which reflect "the degree of emission limitation achievable through the application of the best system of emission reduction which (taking into account the cost of achieving such reduction and any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated."[146] EPA "must exercise its discretion to choose an achievable emission level which represents the best balance of economic, environmental, and energy considerations."[147] The statutory language and precedent indicate that EPA must consider indirect effects of regulation, including co-benefits.

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[139] 830 F.3d 591, 625 (D.C. Cir. 2016).
[140] *Id.* at 624-25.
[141] *Id.* at 625.
[142] *Michigan v. EPA*, 135 S. Ct. at 2707.
[143] *Id.*
[144] *See id.*
[145] 42 U.S.C. § 7412(n)(1)(A).
[146] *Id.* § 7411(a)(1).
[147] *Sierra Club v. Costle*, 657 F.2d 298, 330 (D.C. Cir. 1981).

Congress designed Section 111 to control new plants "to the greatest degree practicable" to achieve the "national goal of a cleaner environment."[148] Indeed, the current administration has also relied on co-benefits in its rules, including under Section 111. Though EPA's recent Affordable Clean Energy rule is targeted at CO_2 emissions from power plants, the rule's preamble also includes ancillary health impacts from concomitant variation in emissions of other pollutants.[149] Indeed, in ACE, ancillary impacts are key to EPA's determination that benefits exceed costs, given the minimal reductions in carbon pollution that the rule is expected to achieve.[150]

B) Accounting for Indirect Effects, Including Co-Benefits, Is an Established Principle of Economic Analysis.

Indirect effects, including ancillary or co-benefits and indirect costs, must be taken into account in comprehensive economic analyses, including EPA's regulatory impact analyses. Failing to account for co-benefits would be inconsistent with best practices for economic analysis. As the External Environmental Economics Advisory Committee ("E-EEAC")—which reconstituted in external form after EPA disbanded it as an SAB advisory committee—noted in its report on the Mercury and Air Toxics Standards, "When determining whether a policy promotes economic efficiency, properly estimated direct benefits and co-benefits (or costs) should count on an equal footing when making benefit-cost calculations."[151] The E-EEAC also noted that "statements in EPA and OMB documents on including ancillary benefits in the assessment of the benefits and costs of regulations build on an extensive academic literature that is unambiguous on this point."[152]

And EPA's own Science Advisory Board in its report on the MATS appropriateness finding withdrawal proposal noted that the agency's approach of categorically excluding co-benefits "departs from the Agency's longstanding practice and is contrary to both the Agency's guidance document on economic analysis (U.S. EPA 2014) and to the recommendations of the Office of Management and Budget (U.S. OMB 2003). As the agency's guidance has been previously reviewed by the SAB, excluding co-benefits is a departure from the Board's recommended practice."[153] The SAB Economic Guidelines Review Panel, which, as discussed above, is currently reviewing EPA's *Guidelines*, recently published a draft report recommending "explicit, consistent text throughout the report on the importance of accounting for all benefits

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[148] *Essex Chem. Corp. v. Ruckelshaus*, 486 F.2d 427, 434 n.14 (D.C. Cir. 1973) (citing S. Rep. No. 1196, 91st Cong., 2d Sess. 16 (1970)).
[149] 84 Fed. Reg. 32,520, 32,562, 32,572 (July 8, 2019).
[150] *Id.*
[151] External Environmental Economics Advisory Committee, *Report on the Proposed Changes to the Federal Mercury and Air Toxics Standards* (Dec. 2019), https://www.e-eeac.org/mats-report.
[152] *Id.*
[153] EPA Science Advisory Board, Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review (Apr. 9, 2020), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4908A62FD4C0DE2285258549005B8797/$File/EPA-SAB-20-004+.pdf (citations omitted).

associated with a regulation or policy, regardless of whether any given benefit was the intended target of the regulation."[154]

C) Presidential Administrations of Both Parties Have Followed Recognized Economic Principles and Practices by Requiring Analysis of Co-Benefits.

The longstanding and (until now) uncontroversial practice of administrations of both parties has been to ensure that regulatory analyses focus on the overall societal costs and benefits (including indirect benefits and costs) expected to result from regulatory action.[155] In 1971, President Nixon initiated the first effort to establish comprehensive and centralized regulatory review, called the "Quality of Life Program."[156] This program established a process for agency consideration of information on environmental quality and public health and safety.[157] In 1974, President Ford issued Executive Order 11,821,[158] which directed detailed economic impact analyses for proposed regulations.[159]

President Carter would expand this comprehensive economic impact analysis with Executive Order 12,044,[160] and also signed the Paperwork Reduction Act, which established the Office of Information and Regulatory Affairs within the Office of Management and Budget.[161] In 1981, President Reagan signed Executive Order 12,291, which directed agencies, to the extent permitted by law, to refrain from regulatory action unless potential benefits to society outweigh potential costs and to set regulatory priorities with the aim of maximizing aggregate net benefits to society.[162]

President Clinton rescinded Executive Order 12,291 and issued Executive Order 12,866, which remains in effect and created the foundation for the current regulatory review process.[163] Executive Order 12,866 highlights the need for agencies to "assess *all* costs and benefits of

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[154] EPA Science Advisory Board, Draft SAB Peer Review of EPA's Revised Guidelines for Preparing Economic Analyses (June 2, 2020), https://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/40f2adc8d6e4bb868525857b007234d5/$FILE/6.2.20%20draft%20report.pdf.

[155] Kimberly M. Castle & Richard L. Revesz, *Environmental Standards, Thresholds, and the Next Battleground of Climate Change Regulations*, 103 Minn. L. Rev. 1349, 1424 (2019) (noting "EPA has consistently and over multiple presidential administrations considered both co-benefits and their mirror image, indirect costs, in evaluating the consequences of regulation").

[156] John D. Graham, Paul R. Noe, & Elizabeth L. Branch, *Managing the Regulatory State: The Experience of the Bush Administration*, 33 Fordham Urb. L.J. 953, 956 (2006).

[157] *Id.*

[158] Exec. Order No. 11,821, 39 Fed. Reg. 41,501 (Nov. 27, 1974), https://www.govinfo.gov/content/pkg/FR-1974-11-29/pdf/FR-1974-11-29.pdf.

[159] Graham et al., *Managing the Regulatory State* at 957.

[160] Exec. Order No. 12,044, 43 Fed. Reg. 12,661 (Mar. 23, 1978), https://www.foreffectivegov.org/sites/default/files/regs/library/eo12044.pdf.

[161] Paperwork Reduction Act of 1980, 44 U.S.C. §§ 3501–3521.

[162] Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 17, 1981), https://www.archives.gov/federal-register/codification/executive-order/12291.html.

[163] Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf.

available regulatory alternatives, including the alternative of not regulating" and to consider non-quantifiable effects including potential economic, environmental, public health, and safety benefits.[164] Executive Order 12,866 also recognizes that as "some costs and benefits are difficult to quantify, [each agency shall] propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs," to the extent permitted by law and where applicable.[165] Therefore, while quantified benefits do not have to outweigh costs under this Executive Order, an agency must consider all regulatory benefits in deciding whether regulation is justified. President Obama's Executive Order 13,563 reaffirmed the principles of Executive Order 12,866, and directs agencies to "select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."[166]

The George W. Bush Administration supported the full accounting of societal effects of regulation by issuing the most formal, and still governing, guidance for agency RIAs in OMB Circular A-4, which details what the Office of Information and Regulatory Affairs ("OIRA") expects in a regulatory analysis for its purposes. Circular A-4 specifically notes that agencies should "look beyond the direct benefits and direct costs of [a] rulemaking and consider any important ancillary and countervailing risks."[167] Circular A-4 also states that agencies should "subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost."[168]

Circular A-4 emphasizes the need for agencies to account for co-benefits that could change the outcome of a regulatory analysis. In particular, Circular A-4 states that "[a]nalytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis."[169] Circular A-4 goes on to note that "[i]n some cases the mere consideration of these secondary effects may help in the generation of a superior regulatory alternative with strong ancillary benefits and fewer countervailing risks."[170] Nothing in Circular A-4 suggests that co-benefits should not be given equal consideration with costs or that benefits falling outside of the intended scope of regulation are not appropriate to consider. Instead, Circular A-4 directs agencies to consider all effects of regulatory action. Failing to adequately consider all consequences of regulatory action would result in an inaccurate and unreasonable assessment of the overall impacts of a regulation.

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[164] *Id.* at 51,735 (emphasis added).
[165] *Id.*
[166] *Id.*
[167] Circular A-4 at 26. Indeed, the George W. Bush EPA made multi-pollutant strategies an organizing principle of its legislative objectives, including the Clear Skies bill, and also its implementation of the Clean Air Act. *See, e.g.*, EPA, *The Multipollutant Report: Technical Concepts & Examples* (2008), https://archive.epa.gov/airquality/aqmp/web/pdf/20080702_multipoll.pdf (promoting the idea that it is more efficient and cost-effective to implement regulatory strategies that address multiple pollutants at the same time).
[168] *Id.* at 12.
[169] *Id.* at 26.
[170] *Id.*

More recently, OMB weighed in on this issue in its *2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act*, noting "OMB encourages agencies to include in their analyses all reasonably foreseeable and reasonably expected ancillary effects, both benefits and costs."[171]

EPA's own economic analysis guidelines, adopted after extensive peer review, also instruct the agency to assess "all identifiable costs and benefits," including both direct effects "as well as ancillary benefits and costs."[172] The assessment of both direct and indirect effects is needed to "inform decision-making" and allow meaningful comparisons between policy alternatives."[173]

Accordingly, under multiple presidential administrations of both parties, EPA has consistently taken indirect benefits into account when evaluating regulations,[174] and recognized that ancillary effects such as reducing or increasing emissions of other pollutants are part of any proper benefit-cost analysis.

D) A Final Rule that Disqualifies These Benefits from Consideration or Treats Them Differently from Indirect Costs in Regulatory Decision-Making Would Be Arbitrary and Capricious.

When promulgating regulations, federal agencies may not "entirely fail[] to consider an important aspect of the problem"[175] and must provide a "reasoned explanation" for their departure from "facts and circumstances that underlay or were engendered by the prior policy."[176] Failure to satisfy these requirements renders agency action arbitrary and capricious, and therefore unlawful under the APA.[177] The Clean Air Act was enacted to "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare."[178] Any rule that would require EPA to ignore or hinder the agency's ability to consider the co-benefits of regulations would be inconsistent with the Act's purpose of promoting public

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[171] The Report can be accessed at https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf.

[172] *Guidelines* at 11-2.

[173] Id. at 7-1.

[174] *See e.g.*, 52 Fed. Reg. 25,399, 25,406 (July 7, 1987) (in issuing advance notice for new source performance standards for municipal waste combustors, noting intent to "consider the full spectrum of the potential impacts of regulation," including "indirect benefits accruing from concomitant reductions in other regulated pollutants"); 56 Fed. Reg. 24,468, 24,469 (May 30, 1991) (in proposing performance standards and emission guideline for landfill gases, justifying the regulation partly on "the ancillary benefit of reducing global loadings of methane"); 63 Fed. Reg. 18,504, 18,585-86 (Apr. 15, 1998) (analyzing the indirect benefits of reducing co-pollutants like volatile organic compounds, particulate matter, and carbon monoxide from emissions standards addressing HAP emissions from pulp and paper producers); 72 Fed. Reg. 8428, 8430 (Feb. 26, 2007) ("Although ozone and PM2.5 are considered criteria pollutants rather than 'air toxics,' reductions in ozone and PM2.5 are nevertheless important co-benefits of this proposal."); 75 Fed. Reg. 51,570, 51,578 (Aug. 20, 2010) (considering indirect benefits of regulating HAP emissions from combustion engines).

[175] *State Farm*, 463 U.S. at 43.

[176] *FCC v. Fox Television Stations*, 556 U.S. 502, 516 (2009).

[177] 5 U.S.C. § 706.

[178] 42 U.S.C. § 7401(b)(1).

health and welfare and could require the agency to ignore important effects of its rulemakings. Any such rule would be arbitrary and unlawful.

Furthermore, when public health and environmental protections are being rescinded, the agency must consider the indirect costs of foregone co-benefits. Co-benefits and indirect costs must be treated similarly because they are opposite sides of the same coin,[179] as the same environmental, public health, or economic impacts can be considered co-benefits or indirect costs depending on whether a rule imposes regulatory requirements or rescinds existing requirements.[180] As discussed above, equal treatment and inclusion of co-benefits and countervailing risks is consistent with OMB Circular A-4, and EPA's Proposal provides no explanation to support changing this longstanding policy.

The logic of the Court in *Michigan* also rules out an arbitrarily selective approach to benefit-cost analysis. In explaining the flaws in EPA's interpretation that cost is "irrelevant" in determining appropriateness, the Court considered a hypothetical scenario in which pollution controls for HAP emissions from power plants reduce HAP emissions but have the unfortunate side effect of harming human health. The Court said:

> The Government conceded that if the Agency were to find that emissions from power plants do damage to human health, but that the technologies needed to eliminate those emissions do even more damage to human health, it would still deem regulation appropriate. See Tr. of Oral Arg. 70. No regulation is 'appropriate' if it does significantly more harm than good.[181]

Under the logic of *Michigan*, the effects of a government action on life and health are an important component of whether such action is "appropriate." The Court's hypothetical was clearly describing a regulation that would reduce HAP emissions but, in doing so, cause collateral harm to human health, which would be considered an indirect cost or countervailing risk. Those costs are logically indistinguishable from the indirect benefits to public health associated with reductions in co-pollutants.

As discussed above, it has been longstanding agency practice to include co-benefits in economic analyses of EPA's Clean Air Act regulations, and even the Proposal acknowledges that "BCA requires a comparison of total social benefits and total social costs."[182] Any new requirements to ignore or devalue these benefits would be inconsistent with established practice, existing OMB guidance, and EPA guidelines, and the agency would need to acknowledge and

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[179] Dan Farber, *The Case for Co-Benefits: Ignoring Co-Benefits Violates Well-Established Legal Principles*, Legal Planet (Sept. 24, 2018), https://legal-planet.org/2018/09/24/the-case-for-co-benefits/.

[180] Castle & Revesz, *supra* n.155, at 1435-36 (2019) (noting indirect benefits and costs 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").

[181] 135 S. Ct. at 2707.

[182] 85 Fed. Reg. at 35,622.

"provide a reasoned explanation for the change."[183] EPA's Proposal provides no such explanation and cannot require the agency to ignore an important aspect of a problem, so to the extent this effort would result in inconsistent treatment of indirect costs and benefits by devaluing or ignoring co-benefits, it would be arbitrary and unlawful.

E) EPA Should Retain Discretion to Present Information About Costs and Benefits as Appropriate Depending on the Context, Rather than Creating Prescriptive Requirements That May Be Less Helpful or Transparent than Past Practice.

EPA's proposed new requirement that the preambles of CAA rules must include an additional presentation of results that excludes co-benefits is not supported by the agency's longstanding practice, and has no basis in mainstream economic understanding. Nor is such an alternative presentation mentioned in OMB Circular A-4 or EPA's *Guidelines*. Those guidance documents direct that when promulgating Clean Air Act regulations, EPA must identify the full range of benefits expected to result and the pollutants they are associated with, in preparing the regulatory impact analyses accompanying Clean Air Act rules. While the current Proposal does not include a requirement to entirely exclude co-benefits from the agency's analysis, the presentational requirement is both arbitrary and unnecessary. It is unclear why EPA would even consider creating rigid new prescriptive requirements that would impair its own ability to continue the transparent presentation of costs and benefits.

Furthermore, EPA's Proposal fails to grapple with the reality that the distinction between benefits that are supposedly "targeted" and those that are not is not always clear, and attempting to disaggregate these benefits can be difficult or confusing. For example, for the 2012 MATS rule, EPA evaluated benefits from reducing HAPs as direct benefits of the rule, while benefits from reducing fine particulate matter were considered co-benefits. But in fact, certain metallic HAPs are emitted as particulate matter, so limiting them as HAPs due to their hazardous properties necessarily yields benefits for ambient particulate matter concentrations. Furthermore, while Section 112 deals with HAPs, the 2012 MATS rule actually targets fine particulate matter and SO_2 as surrogates for HAPs, providing power plants alternative means of compliance. In other words, the pollutants that are primarily targeted by the statute are not necessarily the only harmful pollutants that may properly be controlled by the regulation in pursuit of those statutory objectives.[184]

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[183] *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). *See also Physicians for Social Responsibility v. Wheeler*, 956 F.3d 634, 644 (D.C. Cir. 2020) (noting that APA requirement for a reasoned explanation is especially important when "an agency changes course").

[184] The CAA legislative history shows that Congress intended for EPA to consider co-benefits when setting standards under Section 112: "When establishing technology-based standards under this subsection, the Administrator may consider the benefits which result from 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. For instance, control technologies that reduce the emission of volatile organic compounds which are listed pursuant to this subsection may also have the effect of limiting other VOC emissions. These other compounds, although not listed, would be precursors of ozone pollution and control, even in attainment areas, may produce substantial health and environment benefits." Sen. Rep. 101-228 (reporting S.1630, the Senate version of the CAA Amendments), 101st Cong. (Dec. 20, 1989).

F) Despite the Administrator's Statements Strongly Suggesting that His Intention Is to Finalize a Rule Discounting or Not Counting Co-Benefits at All, in Fact No Such Provision Was Proposed and No Rationale Provided, Thereby Denying the Public the Opportunity to Comment.

The text of the Proposal contains no specific requirements regarding EPA's consideration of co-benefits, despite Administrator Wheeler's public comments that under the Proposal "[c]o-benefits would not be used to justify [a] rule."[185] Administrator Wheeler has also referred to the established economic practice of calculating and including co-benefits as "playing a shell game,"[186] and has claimed that the Proposal corrects a supposedly dishonest accounting method the previous administration used to justify costly, ineffective regulations. These statements are contradicted by the text of the preamble, which clearly states that the agency "is not proposing to specify how or whether the results of the BCA should inform significant CAA regulatory decisions."[187]

Despite the Administrator's statements, EPA's Proposal provides no indication of a change to the agency's longstanding and required reliance on all benefits, including co-benefits, to justify its regulations under the Clean Air Act. Therefore, no new provisions backing away from that approach can be included in any final rule without a supplemental notice detailing statutory authority and an explanation of the basis and purpose for such a change—and what specifically the agency proposes to do—and providing additional opportunity for public comment.[188]

V. EPA'S PROPOSED REQUIREMENTS FOR CONSIDERATION OF CONCENTRATION-RESPONSE STUDIES—AND HEALTH ENDPOINTS GENERALLY—ARE ARBITRARY.

As EPA acknowledges, the rigor of any given BCA is a product of the mechanisms by which the analysis is conducted as well as the quality and integrity of the data used to inform that analysis. With its proposed requirements for quantifying health endpoints to be included in a BCA, including the treatment and use of concentration-response studies, the agency would arbitrarily and irreparably damage the quality of the analysis and misrepresent the evidence on which it relies. As a result, such manipulation of input data would undermine and invalidate the integrity of any ensuing analysis. These proposed requirements are all the more concerning given that they would affect a core endpoint considered in Clean Air Act rulemakings: human health. Despite the magnitude of the consequences of these proposed requirements, however, EPA did not adhere to best practices in their development. Instead, it is evident that these proposed requirements, which would manipulate and constrain the health endpoints included in CAA BCAs to potentially devastating public health effect, are arbitrary, following neither economic best practices, nor established scientific methods, nor any sound practice at all.

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[185] Coral Davenport & Lisa Friedman, *Trump, Citing Pandemic, Moves to Weaken Two Key Environmental Protections*, N.Y. Times (June 4, 2020), https://www.nytimes.com/2020/06/04/climate/trump-environment-coronavirus.html.

[186] *Id.*

[187] 85 Fed. Reg. at 35,623.

[188] 5 U.S.C. § 553; 42 U.S.C. § 7607(d).

A) Consideration of Outcome in Choice of Model Fundamentally Contradicts the Scientific Method.

Selection of scientifically valid concentration-response functions should depend on the strength of the available scientific evidence informing the relationship between the pollutant and response. However, the EPA Proposal indicates that "[d]ecisions should also consider the sensitivity of net benefits to the choice of concentration-response function."[189] This statement is ambiguous and appears to directly contradict other language guiding the agency's choice of concentration-response models. To the extent EPA intends for this to mean sensitivity of net benefits should influence choice of model, this approach would run counter to the scientific method and would incentivize choice of models that provide a more politically desirable answer in the benefit-cost analysis, raising scientific integrity questions. Because the Proposal indicates the agency will choose models based only on scientific quality, it is unclear how such an arbitrary and inconsistent provision facilitates a scientific assessment and indeed creates risks to the contrary. In addition to contradicting broader scientific norms, this provision also ignores longstanding accepted principles in the fields of risk assessment and environmental health, which have well-established methods for assessing the strength and breadth of scientific evidence in assessing risk from environmental contaminants.[190] As EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* explicitly notes, "the Framework does not allow for the manipulation of the risk assessment to support predetermined policy or management choices. As articulated by the [National Research Council] in the *Silver Book*, '[T]he conduct of risk assessments used to evaluate the risk-management options [is] in no way to be influenced by the preferences of risk managers.'"[191]

B) Restrictions on Data Sources, Location, and Population Are Unsupported by Scientific Norms and Arbitrarily Exclude Valid Research.

To determine the appropriate concentration-response functions to be applied, consideration of the best available scientific evidence is necessary; yet, the Proposal arbitrarily restricts the ability of the agency to fully consider all available data sources. The Proposal asserts that epidemiological studies considered in EPA analysis must meet the following criteria, among others: "(b) the study location must be appropriately matched to the analysis; and (c) the study population characteristics must be sufficiently similar to those of the analysis."[192]

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[189] 85 Fed. Reg. at 35621.

[190] National Academies, *Science and Decisions: Advancing Risk Assessment* (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment (relevant portions incorporated into the record by reference); EPA, Preamble to the Integrated Science Assessments (ISA), EPA/600/R-15/067, 2015; Richard E. Peltier and Gretchen T. Goldman, *It's not about transparency: politics is intruding into USEPA science and it could cost the public's health*, 30(4) Journal of Exposure Science & Environmental Epidemiology 594-95 (May 2020); Gretchen T. Goldman & Francesca Dominici, *Don't abandon evidence and process on air pollution policy*, 363(6434) Science 1398-1400 (Mar. 2019), http://science.sciencemag.org/cgi/content/full/science.aaw9460.

[191] EPA, *Framework for Human Health Risk Assessment to Inform Decision Making*, EPA/100/R-14/001 (2014) (citing National Academies (2009) at 244) (relevant portions incorporated into the record by reference).

[192] 85 Fed. Reg. at 35,621.

Such requirements are arbitrary and unscientific. The Proposal fails to consider that, for certain pollutants and in certain regulatory contexts, the best available science may consist of studies conducted in different locations and focused on different populations. Such studies may still provide strong evidence as to the health impacts of pollution, and should not be discarded based on the arbitrary criteria in the Proposal.[193] In addition, the agency fails to adequately define "appropriately matched" and "sufficiently similar" and such vague language risks rejection of scientifically valid studies due to a narrow interpretation of alignment between the study and the EPA proposal being analyzed.

Similarly, the proposed requirement to consider the "age of the air quality data,"[194] as opposed to the *quality* of the air quality data, again threatens to rule out scientifically valid studies for arbitrary, ambiguous, and unscientific reasons. Such an outcome runs counter to the longstanding, science-backed EPA process of assessing all relevant reliable scientific studies, inclusive of studies conducted in different locations and on different populations.[195] Further, existing EPA scientific literature review processes already account for excluding studies when they fail to meet quality standards; these added restrictions, therefore, would not serve to address any identified gaps in processes, but rather arbitrarily hinder the agency's ability to develop science-based standards.[196] Further, it is unclear whether the agency has considered the use of multi-pollutant concentration-response functions and the Proposal fails to account for how such functions would be treated under this rule.

C) Pooling of Concentration-Response Functions and Forced Consideration of Alternative Models Are Scientifically Questionable and Arbitrary.

The draft rulemaking includes several provisions that would force arbitrary and unscientific inclusion of alternative models and lower-quality studies in determining concentration-response functions. The Proposal asserts that the agency "would quantify risks using separate concentration-response relationships and, if appropriate, pool, or combine, the results (e.g. in a meta-analysis) as means of providing a broader representation of the effects estimate" and that "EPA would characterize multiple concentration-response functions reflecting the full set of studies as a means of providing a broader representation of the effects estimate, including high quality studies that do not find a significant concentration-response relationship."[197]

These proposed requirements present an end-run around the informed judgment of EPA experts. Historically, a broad range of models have been considered in risk assessment and EPA experts have had deference to assess the body of evidence from animal and human studies to determine the appropriate model. The National Academies of Sciences, Engineering, and Medicine in 2009 published a report concluding the importance of EPA's ability to assess

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[193] For example, the National Academies' 2009 report *Science and Decisions* underscored that probative information on the health impacts of some pollutants may derive from in vitro studies or animal studies. *See Science and Decisions*, p. 156-57.

[194] 85 Fed. Reg. at 35,621.

[195] Peltier & Goldman, *It's not about transparency* at 594-595.

[196] EPA, Preamble To The Integrated Science Assessments.

[197] 85 Fed. Reg. at 35,621.

available evidence and make appropriate decisions.[198] Now, the agency is proposing requirements that would undermine that ability.

However, these strictures are not just arbitrary—they threaten to corrupt the quantification of health endpoints included in Clean Air Act BCAs. It is simply not scientifically justified to arbitrarily force pooling results from different studies, nor to blend concentration-response functions from different studies. The agency fails to define when such "pooling" would be appropriate, a critical distinction given that universal application is not supported by established scientific methods and could lead to misrepresentations of the available evidence. In particular, inappropriate pooling across studies could dilute observed effects in high quality studies that should be given greater weight, rather than pooled with studies that found little or no effect. For example, there is increasing evidence that many pollutants of primary interest to EPA, such as particulate matter and ozone, follow a linear or near linear non-threshold concentration-response function, even at low levels. This Proposal would preclude the agency from appropriately reflecting this increasing evidence because it would require blending of potentially divergent studies and alternative concentration-response functions regardless of their scientific rigor. Arbitrarily advanced and arbitrarily enforced, this effort would not lead to increased transparency—as the Proposal asserts is its aim—but rather confuse and distort understanding of pollutant effects. Instead, EPA's specific emphasis on ensuring the inclusion of studies that "do not find a significant concentration-response relationship"[199] reveals its clear intent: to override scientific expertise and bias results in favor of weaker pollution protections.

Concerningly, scientifically unjustified weight given to alternative models and pooling and blending of scientific assessments between pollutants and health outcomes is likely to disproportionately affect the sensitive populations that EPA is charged with protecting. Under the NAAQS, for example, EPA is required to set standards requisite to protect public health with an adequate margin of safety. The margin of safety must protect sensitive subpopulations, for whom adverse health effects are observed at lower concentrations.[200] For ozone and particulate matter, for example, evidence suggests that health effects (including mortality, cardiovascular effects, and respiratory effects) below the current NAAQS are more pronounced for the elderly, children, low-income individuals, and African Americans.[201] As a result, any pooling and blending of models and concentration-response functions will dilute or eliminate observed effects in sensitive subpopulations, inhibiting the ability of the agency to protect these groups, despite its mandate. Thus, assessment of costs and benefits of EPA actions under this Proposal is likely to disproportionately harm these sensitive populations.

Additionally, the Proposal forces EPA to consider alternative concentration-response functions for each endpoint, as well as "demonstrate the sensitivity of the choice of the concentration-response function on the magnitude and the uncertainty associated with air

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[198] National Academies, *Science and Decisions*.

[199] 85 Fed. Reg. at 35,621.

[200] *See, e.g.*, *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 525-26 (D.C. Cir. 2009).

[201] Di Qian et al., *Air Pollution and Mortality in the Medicare Population*, 376 New England Journal of Medicine 2513 (2017), https://www.nejm.org/doi/full/10.1056/NEJMoa1702747; EPA, Integrated Science Assessment for Ozone and Related Photochemical Oxidants (2020), https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=348522.

pollution-attributable effects."[202] Specifically, the Proposal demands that the agency characterize "[t]he variability in the concentration-response functions across studies and models, including plausible alternatives."[203] Such requirements are arbitrary, undefined, and may inhibit the agency's ability to conduct benefit-cost analyses effectively. Furthermore, the litany of characterization requirements the Proposal would impose on EPA analyses threaten to burden the agency so greatly as to paralyze its ability to make forward progress. Again, then, instead of benefitting the benefit-cost analysis process, these requirements could irreparably derail them—and for no scientific or public health gain.

EPA must be able to consider a range of models when choosing appropriate concentration-response functions and rely on weight of evidence and the advice of experts to choose appropriate models that protect public health including the health of sensitive subpopulations, rather than the mandate of an arbitrary rule. Similar to EPA's Restricted Science proposal,[204] this Proposal exploits scientific uncertainties in ways that tend toward less pronounced concentration-response functions.[205] The threatened effect is one of manipulated findings and distorted evidence pointing to rules that ignore the scientific evidence.

D) Extending the Proposal's Risk Assessment Requirements to All Significant Clean Air Act Rulemakings Would Be Arbitrary and Capricious, as Well as a Setback for Human Health, Contrary to the Very Purposes for Which the Clean Air Act Was Enacted.

In Section V.B. of the Proposal, *Other Areas of Solicitation for Public Comment,* the agency returns to the topic of quantifying health endpoints and conducting risk assessments, asking whether the Proposal's requirements should be expanded to apply "to all risk assessments used in CAA significant rulemakings."[206] Given the topic's treatment in the Proposal—requiring multiple departures from science and best practice, placing significant analytical burdens on a resource-constrained agency, and repeatedly attempting to bias risk assessment results in favor of lessened pollutant impacts—the related proposed requirements should not be advanced in the present pursuit, let alone expanded to apply to CAA significant rulemakings more broadly. Beyond the disastrous consequences these draft requirements would have on the agency's ability to fully engage with its mission to protect human health and the environment, it would also be nonsensical and contrary to the CAA's requirements to use the best available science[207] to apply changes advanced under the cover of BCA processes to risk assessments more broadly, once more suggesting bad-faith motivations driving this effort. It is profoundly unreasonable for the agency to advance requirements that would be so fundamentally contrary to the core purpose of the Clean Air Act. We adamantly oppose any action that would expand the scope of these requirements to all CAA significant rulemakings.

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[202] 85 Fed. Reg. at 35,621.
[203] *Id.*
[204] *See supra* n.124.
[205] Peltier & Goldman, *It's not about transparency*.
[206] 85 Fed. Reg. at 35,623.
[207] See, e.g., 42 U.S.C. § 7408(a)(2) ("Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.").

To EPA's specific inquiries, first, the agency should *not* codify into regulation "the proposed selection criteria for selecting among studies characterizing concentration-response relationships."[208] These selection criteria do not advance the already robust risk analysis decision making framework and associated literature; instead, by failing to elevate those studies advancing the best available science, these criteria would present a major setback. Similarly, we oppose any move to incorporate *additional* requirements on this front. The proposed requirements represent a dramatic departure from best practice, scuttling expert opinion in the face of arbitrary mandates. Additional requirements in line with such harmful proposed methods to date would be all the more damaging to the agency's continued ability to issue defensible, health-protective work.

We also oppose EPA's consideration of codifying into regulation the proposed requirement for "synthesizing evidence across the literature."[209] As detailed above, this proposed practice threatens to distort risk analyses and weaken protections, with no upside for scientific understanding or protection of public health. The agency would be forcing an arbitrary practice without technical or logical merit.

Finally, we are alarmed by, and opposed to, EPA's consideration of imposing requirements both for "any weight-of-evidence (WOE) frameworks that the Agency uses in the developments of CAA significant rulemakings" as well as surrounding the "assessment of bias and uncertainty in risk analyses." [210] Each of these considerations threatens to undermine the agency's ability to conduct robust scientific assessment and implement health-protective standards.[211] They would also have far-reaching implications, weighing the agency down with arbitrary and unnecessary burdens, while at the same time deploying obstacles in the face of valid and informative studies.

VI. THE PROPOSAL ARBITRARILY IMPOSES A MORE DEMANDING STANDARD FOR ESTIMATING BENEFITS THAN COSTS.

It is well-established that an agency acts arbitrarily and capriciously when it fails to consider an important aspect of the problem it is addressing.[212] It follows that agencies must properly weigh both costs and benefits when considering regulatory action.[213] Nor may an agency "put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards."[214] Reliance on a flawed benefit-cost analysis can doom an agency's rule.[215] Executive Order 12,866, which has been continuously effective since 1993 through

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[208] 85 Fed. Reg. at 35,623.
[209] *Id.*
[210] *Id.*
[211] Goldman & Dominici, *Don't abandon evidence and process on air pollution policy*; EPA, Preamble to the Integrated Science Assessments.
[212] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).
[213] *See California v. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017) ("Without considering both the costs *and* the benefits of [its action], the [agency's] decision failed to take this 'important aspect' of the problem into account and was therefore arbitrary." (emphasis in original)).
[214] *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008).
[215] *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012).

administrations of both political parties, directs agencies to "assess both the costs and the benefits of the intended regulation."[216]

As explained above, this Proposal seems animated by unsupported and false allegations that EPA has historically overvalued benefits and undervalued costs. Because these allegations are baseless, increasing the emphasis on costs would skew the agency's analyses such that benefits are arbitrarily undervalued. Yet the Proposal contains at least two measures that would bias the agency's consideration of costs and benefits. Any requirement that future rulemakings utilize these measures would render this rule arbitrary, capricious, and an abuse of the agency's discretion.

A) Applying a "Fitness for Purpose" Test to Benefits, but Not Costs, Would Be Arbitrary and Unlawful.

The agency suggests that it will utilize a "fitness for purpose" test, "whereby information anticipated to have a higher impact must be held to higher standards of quality."[217] Yet the agency discusses this requirement only in the context of benefits, not costs. This suggests that the benefits of a potentially costly public health or environmental protection would be subject to greater scrutiny and a heightened standard of evidence. But apparently, information about costs that might lead the agency to reduce the stringency of a regulation would face no heightened standard. EPA's arbitrary approach is on full display in the current Proposal, in which EPA is accepting vague and unsupported allegations about costs essentially on faith, and using them as the basis to commit all future Clean Air Act rulemakings to a deeply flawed method of benefit-cost analysis.

Moreover, the sources that EPA cites for the "fitness for purpose" test do not support the agency's approach. EPA explains that the "fitness for purpose" concept is discussed in OMB M-19-15, which, as EPA notes, in turn refers to OMB's 2002 Guidelines. Although OMB's Guidelines do not use the term "fitness for purpose," they apply this principle to "influential" information, "mean[ing] that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."[218] EPA now raises the "fitness for purpose" test only in the context of scientific information, but OMB deliberately and expressly included "financial" information among the types of potentially influential information.[219] Therefore, if scientific information about benefits is "influential" or otherwise subject to the "fitness for purpose" test, so too is financial information about costs. The Proposal's asymmetrical consideration of costs and benefits is arbitrary, capricious, and an abuse of the agency's discretion.

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[216] Exec. Order 12,866, 58 Fed. Reg. 51,735 (published Oct. 4, 1993).
[217] 85 Fed. Reg. at 35,620.
[218] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002).
[219] *See id.* (defining influential); *id.* at 8455 ("In response to a public comment, we added an explicit reference to 'financial' information as consistent with our original intent."); *see also* OMB M 19-15 at 3 (retaining the reference to influential scientific information).

B) The Proposed Clear Causal Relationship Requirement Is Arbitrary and Unlawful.

Similarly, EPA proposes imposing additional requirements for inclusion of benefit endpoints based on evidence of a "clear causal" or "likely causal" relationship between pollutant exposure and effect.[220] The agency has a long history of applying a weight of evidence approach to causality determinations, rightly recognizing and valuing the strength of the approach's incorporation of multiple disciplines and lines of evidence.[221] In its 2008 *Integrated Science Assessment for Oxides of Nitrogen and Sulfur – Ecological Criteria*, EPA lays out a causality framework to support assessing causality.[222] In Table 1-2 of that report, the agency provides a five-step weight of evidence framework for assessing causal determination, including causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and suggestive of no causal relationship.[223] With these new proposed requirements, EPA is contradicting its own established methods for assessing causality, which have been endorsed by the scientific community and EPA science advisors.[224] The changes would rule out consideration of endpoints "suggestive of a causal relationship," an action that would arbitrarily and inappropriately undermine the judgment of scientists and other contributing experts in applying a full weight of evidence approach.

EPA also solicits comment on an alternative requirement in place of the above: solely including benefit endpoints "for which there is a positive [willingness-to-pay] conditional on the available scientific literature."[225] We strongly oppose this unscientific and inappropriately restrictive requirement. Multiple critical endpoints cannot be translated into willingness to pay estimates, including as detailed in the *Guidelines for Preparing Economic Analyses.* This screening requirement would do nothing to aid in better-informing benefit-cost analyses, but rather arbitrarily and inappropriately constrain efforts to conduct a full and detailed analysis.

VII. EPA'S PROPOSED REQUIREMENTS CONTAIN ANALYTICAL LIMITATIONS THAT ARBITRARILY BURDEN BENEFITS ESTIMATES.

A) EPA's Proposed Requirements for Quantification and Monetization Are Inappropriate.

EPA proposes to bind itself to a formal benefit-cost analysis, comparing quantified and monetized costs and benefits "to the extent supported by scientific literature as well as practicable in a given rulemaking."[226] A separate duplicative proposed provision would require EPA to "quantify effects for endpoints which scientific evidence is robust enough to support

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[220] 85 Fed. Reg. at 35,620.

[221] EPA, Preamble to the Integrated Science Assessments; Goldman & Dominici, *Don't abandon evidence and process on air pollution policy*.

[222] EPA, Integrated Science Assessment for Oxides of Nitrogen and Sulfur – Ecological Criteria, EPA/600/R-08/082F (2008).

[223] *Id.* at 1-8.

[224] Goldman and Dominici, *Don't abandon evidence and process on air pollution policy*.

[225] 85 Fed. Reg. at 35,620.

[226] *Id.* at 35,626 (proposed § 83.3(a)(8)).

such quantification."[227] Both requirements would sometimes require EPA to engage in burdensome and unnecessary analysis, and should be rejected.

Both proposed requirements unnecessarily cabin EPA's discretion. As described in section III, as with other proposed requirements, there is no legal or rational basis for the agency to bind itself to conduct BCAs in any particular manner, considering the multiple options that the agency usually has for reasonably assessing costs and benefits. The Proposal would, in many situations, mandate unnecessary or inappropriate approaches to such analysis. Many factors influence the wisdom of attempting to quantify and/or monetize various costs and benefits of regulatory action. EPA already has ample ability to exercise appropriate judgment in deciding how and whether to quantify or monetize effects of a regulation.

The proposed standard for when to require quantification and monetization of regulatory effects is inconsistent with existing guidance and executive orders. Executive Order 12,866 only directs quantification of costs and benefits "to the extent feasible."[228] Similarly, Circular A-4 advises agencies to quantify and monetize costs and benefits "where feasible." Feasibility is a more appropriate standard because it furthers the agency's discretion to consider the particulars of the factual circumstances before it.

The Proposal also fails to recognize situations in which quantification and/or monetization of benefits may be inappropriate. The analyses necessary to quantify and monetize costs and benefits impose administrative burdens. The burdens associated with performing such analysis exist on a continuum; additional analysis may result in quantification of additional cost or benefit categories, or may reduce associated uncertainty. EPA should retain discretion as to where to fall on that continuum.

There are at least two types of situations where a requirement to quantify or monetize costs and benefits would be inappropriate. First, a qualitative assessment might be sufficient for the agency to conclude with high confidence that a rule's benefits exceed its costs. In these circumstances, significant expenditures to quantify or monetize the rule's benefits and costs would not necessarily be useful. Second, many provisions under the CAA prohibit consideration of costs or prescribe a limited role for the consideration of costs,[229] and the quantification of costs or benefits, to the extent it is permitted by law at all, could cause unjustifiable delays or other hurdles to statutorily guaranteed protections.

Additionally, EPA fails to identify measures to ensure that unquantified and unmonetized benefits and costs are given equal weight. There are many instances where environmental costs and benefits are not easily or feasibly represented in dollars and cents. For example, suppose a BCA estimated that a regulation had net positive quantified benefits, but that the quantified costs fall upon environmental justice communities. In such a case, that disproportionate impact would be an unquantified cost of the regulation. Conducted properly, the BCA would fully account for

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[227] *Id.* at 35,626 (proposed § 83.3(a)(7)(ii)).
[228] Exec. Order 12,866 § 6(a)(3)(C)(i).
[229] Congressional Research Service, *Cost and Benefit Considerations in Clean Air Act Regulations* (2017), https://crsreports.congress.gov/product/pdf/R/R44840/4.

the unquantified distributional cost. However, EPA has failed to propose or solicit comment on any aspect of distributional analysis.

B) EPA Should Not Require Separate Reporting of Domestic and Non-Domestic Effects.

EPA requests comment "as to whether non-domestic benefits and costs of regulations, when examined, should be reported separately from domestic benefits and costs of such regulations."[230] Such a requirement would be unnecessary and counterproductive.

Certain classes of effects cannot be meaningfully disaggregated into their domestic and non-domestic components. For example, a federal district court recently rejected the use of domestic-only social costs of greenhouse gases, finding that such estimates are "soundly rejected by economists as improper and unsupported by science."[231] In 2015, the Interagency Working Group on the Social Cost of Carbon concluded that "good methodologies for estimating domestic damages do not currently exist."[232] Likewise, in 2017, the National Academies found that the calculation of a domestic social cost of methane cannot be credibly done using current models, as they ignore important spillover effects given the global nature of climate change.[233] Other leading experts agree.[234] Thus, a blanket requirement to require separate reporting of domestic and non-domestic benefits and costs would be arbitrary and capricious.

The same issues may also apply to disaggregation of other domestic and non-domestic costs and benefits of EPA regulations. For example, emissions of ozone and ozone precursors in the United States may affect ozone levels in neighboring countries, and vice versa.[235] The costs of regulatory action may also be difficult to disentangle, for example, when those costs are borne by companies that operate in the United States but which also have foreign shareholders, employees, or other non-U.S. interests. Additionally, to the extent these analytical difficulties arise predominantly with respect to disaggregating the benefits associated with additional pollution controls, the proposed requirement would inappropriately bias results of BCAs away from such regulations.

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[230] 85 Fed. Reg. at 35,623.

[231] *California v. Bernhardt*, No. 18-5712 (N.D. Cal. July 15, 2020).

[232] Interagency Working Group on the Social Cost of Carbon, *Response to Comments: Social Cost of Carbon for Regulatory Impact Analysis under Executive Order 12,866*, at 36 (July 2015).

[233] National Academies of Sciences, Engineering, and Medicine, *Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide* 53 (2017).

[234] *See, e.g.*, William D. Nordhaus, *Revisiting the Social Cost of Carbon*, 114 Proc. Nat'l Acad. Sci. 1518 (2017) (concluding that "regional damage estimates are both incomplete and poorly understood" and that "there is little agreement on the distribution of the SCC by region").

[235] *See Clean Wisconsin v. EPA*, No. 18-1203, 2020 U.S. App. LEXIS 21428, at*24 (D.C. Cir. July 10, 2020) (noting EPA's conclusion that "[o]zone and ozone precursors can be transported to an area from sources in nearby areas or from sources located hundreds of miles away").

C) Any Proposed Requirement Regarding Technological Change and Learning Effects Should Address Overestimation of Costs.

EPA solicits comment on "whether this rulemaking should specify best practices related to assumptions about technological change and/or learning effects in BCA."[236] As with other aspects of the proposed regulations, guidance documents already describe how EPA should consider these factors in estimating costs of regulatory compliance,[237] such that imposing this as a regulatory requirement is unnecessary.

However, if EPA insists on codifying best practices for these topics, EPA should address these and other factors that regularly lead to overestimation of costs. As described in section II.B, the tremendous benefits provided by EPA safeguards are regularly underestimated due to the difficulty of quantifying and monetizing many regulatory benefits. Likewise, the cost of compliance with those safeguards is regularly overestimated, likely due to conservative assumptions regarding pollution control innovations and learning effects.[238] For example, EPA overestimated compliance costs for the Mercury and Air Toxics Standards to be $9.6 billion per year, while ex post estimates of actual costs range from $3 to $4.5 billion, less than half of EPA's original estimate.[239] Major sections of the Clean Air Act are premised on likely innovation and learning in response to pollution control requirements,[240] and these dynamics should not be ignored.

VIII. FINALIZING A REQUIREMENT FOR BENEFITS TO EXCEED COSTS IN FUTURE RULEMAKINGS WOULD BE UNLAWFUL.

EPA "solicits comment on whether and under what circumstances the EPA could determine that a future significant CAA regulation be promulgated only when monetized benefits exceed the costs of the action."[241] However, EPA has not issued any proposal on this topic, and any final rule requiring rules to pass a cost-benefit test would fail the logical outgrowth test and thus be unlawful.[242]

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[236] 85 Fed. Reg. at 35,623.

[237] *See* EPA, *Guidelines* 8-10 to 8-12 (section 8.3.1.4).

[238] R. David Simpson, *Do regulators overestimate the costs of regulation?*, 5 J. Benefit-Cost Analysis 315 (2014); Winston Harrington, Richard D. Morgenstern, & Peter Nelson, *On the accuracy of regulatory cost estimates*, 19 J. Policy Analysis & Mgmt. 297 (2000).

[239] 77 Fed. Reg. 9304, 9425 (Feb. 16, 2012) (MATS rule containing projected annual compliance cost of $9.6 billion); M.J. Bradley & Associates, MJB&A Issue Brief, *Status of the MATS Rule* (Nov. 16, 2017) (estimating $4.45 billion in actual compliance costs from December 2014 to April 2016); Letter from Edison Electric Institute, et al., to William Wehrum, EPA Assistant Administrator, Office of Air and Radiation (July 10, 2018), http://src.bna.com/Ajk (industry letter estimating the total cost of MATS compliance from 2012 to 2018 as "more than $18 billion," or roughly $3 billion per year).

[240] David Gerard & Lester B. Lave, *Implementing Technology-Forcing Policies: The 1970 Clean Air Act Amendments and the Introduction of Advanced Automotive Emissions Controls in the United States*, 72 Technological Forecasting & Soc. Change 761, 763 (2005).

[241] 85 Fed. Reg. at 35,623.

[242] *See, e.g.*, *Sierra Club v. Costle*, 657 F.2d 298, 352 (D.C. Cir. 1981) (imposing the "logical outgrowth" in the context of the Clean Air Act). *See also* 42 U.S.C. § 7607(d)(3); 5 U.S.C. § 553(b). EPA's statement that this Proposal is "a rule of Agency procedure . . . [and] exempt from the notice and comment requirements," 85 Fed. Reg.

EPA cannot satisfy the notice requirement through "general notice that it might make unspecified changes. . . . Agency notice must describe the range of alternatives being considered with reasonable specificity."[243] Agency notice must take "a concrete and focused form so as to make criticism or formulation of alternatives possible."[244] Commenters "cannot be expected to divine the EPA's unspoken thoughts."[245] Adequate notice serves "three distinct purposes," none of which EPA has satisfied: "ensuring that agency regulations will be tested by exposure to diverse public comment"; enabling "fairness to affected parties"; and "giving affected parties an opportunity to develop evidence in the record to support their objections to a rule…enhanc[ing] the quality of judicial review."[246]

EPA's solicitation of comment on this topic leaves profound questions as to what the agency is actually considering. Notably, EPA has not even defined what it means by "monetized benefits" or "costs" in this context. For instance, elsewhere in the Proposal, EPA acknowledges that not all benefits and costs can be monetized but proposes to "exercise its subject matter expertise" in assessing the importance of those benefits and costs.[247] Commenters have no signal of whether imposing a requirement that monetized benefits exceed costs would complement EPA's Proposal, displace it, relegate it to irrelevance, or something else. Commenters are also left to guess whether EPA means that monetized benefits would need to exceed only monetized costs, or *all* costs that the agency decided to consider (a possibility raised by the literal wording of the solicitation for comment). In addition, the Proposal describes "three broad frameworks for estimating social cost—compliance cost, partial equilibrium, and general equilibrium."[248] Commenters are left to guess which of those cost frameworks would be used as the benchmark for monetized costs, or whether EPA would select its preferred framework on a rulemaking-specific basis, leading to an outcome that present commenters could not possibly anticipate.

Nor has EPA specified which monetized benefits it would include in this analysis. In several places, EPA suggests that the presentation of benefits should be sliced and diced into various categories (even though the agency already has a longstanding practice of clearly delineating the components of its benefits estimates). For example, the Proposal would require EPA to disaggregate co-benefits in the presentation of BCA results.[249] But EPA's solicitation of comment does not specify whether the monetized benefits in this context would include *all* monetized benefits, or only those that the agency deems not "ancillary." Additionally, the Proposal raises the possibility that "domestic" benefits and costs should be reported separately from those that are "non-domestic."[250] But EPA's solicitation of comment does not specify whether the cost-monetized benefit test would be limited to a domestic scope. And as discussed

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at 35,613, is factually inadequate and legally flawed. But it is particularly inapt here, where EPA considers explicitly establishing a new substantive factor affecting the stringency of future health and environmental protections.

[243] *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983).

[244] *Home Box Office, Inc. v. Fed. Commc'ns Comm'n*, 567 F.2d 9, 36 (D.C. Cir. 1977).

[245] *Shell Oil Co. v. EPA*, 950 F.2d 741, 751 (D.C. Cir. 1991).

[246] *Small Refiner*, 705 F.2d at 547.

[247] 85 Fed. Reg. at 35,618.

[248] *Id.* at 35,619.

[249] *Id.* at 35,622.

[250] *Id.* at 35,623.

in other contexts, there are instances where dividing benefits into "domestic" and "non-domestic" is analytically unsound, which further confuses this issue.[251]

Furthermore, the various sections of the Clean Air Act contain distinct requirements for how EPA may consider costs. In certain provisions, EPA is prohibited from considering cost at all.[252] Other sections enumerate cost as one of several factors that the agency must consider.[253] And elsewhere, EPA is already required to conduct a benefit-cost analysis.[254] The agency's solicitation of comment has vastly different implications for different sections of the Clean Air Act, ranging from introducing a prohibited element into the analysis, to unlawfully elevating the consideration of costs above other statutory concerns, to awkwardly and unpredictably clashing with the agency's existing practices.

Considering the various ways that EPA could attempt to impose a benefit-cost test upon future significant regulations, it is currently infeasible to provide informed comments. Accounting for the different methods of accounting for costs and benefits and the multiple sections of the Clean Air Act that could be affected, there are at least several dozen permutations that EPA's idea could take. It would be infeasible to meaningfully address all of the possibilities under any circumstances, but especially here, given the brevity of the comment period.[255] And it is unlikely that *any* single methodology could be rationally applied to the full range of CAA rulemakings.

IX. EPA'S PROPOSED TRANSPARENCY REQUIREMENTS ARE ARBITRARY, IMPRACTICABLE, AND AMBIGUOUS.

The elements of this Proposal pertaining to the public availability of data and models bear a disturbing resemblance to EPA's separate, unlawful proposal restricting the scientific information upon which the agency relies when setting public health and environmental protections. Several of the undersigned organizations also commented on that proposed rule and supplemental notice of proposed rulemaking, and many of those comments are attached.[256] We

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[251] *See, e.g.*, Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis* 17 (Aug. 2016).

[252] *See* 42 U.S.C. § 7409(b); *American Trucking*, 531 U.S. at 471 (2001).

[253] *See* 42 U.S.C. § 7411(a)(1); *id.* § 7412(d)(2); *id.* § 7521(a)(2).

[254] *See id.* § 7545(c)(2)(B).

[255] *See* Environmental Defense Fund, Clean Air Task Force, Earthjustice, Environmental Law & Policy Center, Environmental Protection Network, National Parks Conservation Association, Sierra Club, *Request to Immediately Halt and Withdraw EPA's Clean Air Act Cost-Benefit Rulemaking Action, and Extend Deadline for Public Comments on EPA's Notice of Proposed Rulemaking*, Docket ID EPA-HQ-OAR-2020-0044-0052 (June 26, 2020); Union of Concerned Scientists, *Request for an Extension on Comment Period for EPA's Notice of Proposed Rulemaking, "Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process,"* Docket ID EPA-HQ-OAR-2020-0044-0053 (June 29, 2020).

[256] *See* Comment of the Environmental Defense Fund on the Environmental Protection Agency's Proposed Rule: Strengthening Transparency in Regulatory Science, Docket ID EPA-HQ-OA-2018-0259-9227 (Aug. 16, 2018); Comment of Andrew A. Rosenberg, Union of Concerned Scientists, Docket ID EPA-HQ-OA-2018-0259-6144 (Aug. 16, 2018); Comments of Clean Air Task Force on the Proposed Rule "Strengthening Transparency in Regulatory Science," Docket ID EPA-HQ-OA-2018-0259-6916 (Aug. 16, 2018); Comment of Environmental Law & Policy Center, et al., Docket ID EPA-HQ-OA-2018-0259-6174 (Aug. 16, 2018); Comments of Natural Resources Defense Council on "Strengthening Transparency in Regulatory Science," Docket ID EPA-HQ-OA-2018-0259-

incorporate all of those comments by reference here. While recognizing the value of transparency, as we extensively discussed in those comments and reiterate here, we also recognize that the promulgation of scientifically robust protections may require EPA to rely on rigorous data and models that cannot feasibly or lawfully be released publicly.

A) EPA Must Explain How This Proposal Relates to Its Proposal to Restrict the Use of Scientific Information.

As an initial matter, EPA should clearly explain the relationship between this Proposal and its Restricted Science proposal. Given that the proposals bear key similarities,[257] it is unclear whether EPA would expect the rules to operate independently, or if restrictions on using scientific information would affect (directly or indirectly) which information the agency can consider in BCAs. More generally, it is unclear whether the two proposals would impact the same information or would expand upon each other. This is largely the result of the problematic vagueness of both proposals, including EPA's total failure to illustrate how either proposal would function in practice. Without explaining how the proposals relate—and more generally what they are intended to do—EPA has not provided the public with adequate notice to make informed comments.

The similarities between the two proposals are especially perplexing because the proposals appear in some respects to have different areas of focus. For example, the Restricted Science proposal repeatedly speaks of "independent validation" of data and models—a theme that is reflected in its definition of "data":

> [T]he set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party.[258]

The current Proposal never mentions validation of data and models but inexplicably uses the same definition of "data."[259] Such duplication would be unremarkable if the definition were standard, but this definition is highly idiosyncratic and tied directly to the purported aims of the other proposal.[260] EPA should explain whether the current Proposal is an effort to implement

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8283 (Aug. 15, 2018); Comments of Environmental Defense Fund on EPA's Supplemental Notice of Proposed Rulemaking: "Strengthening Transparency in Regulatory Science," Docket ID EPA-HQ-OA-2018-0259-12727 (May 18, 2020); Comment of Andrew A. Rosenberg and Genna Reed, Union of Concerned Scientists, Docket ID EPA-HQ-OA-2018-0259-11479 (May 15, 2020); Comments of Clean Air Task Force on the Supplemental Notice of Proposed Rulemaking on "Strengthening Transparency in Regulatory Science," Docket ID EPA-HQ-OA-2018-0259-13788 (May 18, 2020); Comments of Natural Resources Defense Council on "Strengthening Transparency in Regulatory Science (Supplemental notice of proposed rulemaking)," Docket ID EPA-HQ-OA-2018-0259-12720 (May 18, 2020).

[257] In addition to requiring that certain information be made publicly available, the two proposals utilize identical definitions of "data," "model," and "publicly available."

[258] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[259] 85 Fed. Reg. at 35,625 (proposed 40 C.F.R. § 83.1).

[260] *See, e.g.*, EDF Comments, Docket ID EPA-HQ-OA-2018-0259-12727, at 72-73.

some of the objectives of the Restricted Science proposal, or—if not—what other purpose is being served by replicating elements of that proposal.

These similarities are especially troubling because the proposal to restrict the use of scientific studies garnered criticism from several leading scientific experts, whose objections are also relevant here. For example, in November 2019, the editors of the nation's leading science journals issued a statement underscoring that the notion of discounting studies based on the availability of underlying data is contrary to good scientific practice and would be a "catastrophe" for public health:

> As leaders of peer-reviewed journals, we support open sharing of research data, but we also recognize the validity of scientific studies that, for confidentiality reasons, cannot indiscriminately share absolutely all data. . . . *Discounting evidence from the decision-making process on the basis that some data are confidential runs counter to the EPA stated mission "to reduce environmental risks . . . based on the best available scientific information."* . . . We urge the EPA to continue to adopt an approach that ensures the data used in decision-making are the best available, which will at times require consideration of peer-reviewed scientific data, not all of which may be open to all members of the public. The most relevant science, vetted through peer review, should inform public policy. Anything less will harm decision-making that claims to protect our health.[261]

Likewise, EPA's Science Advisory Board questioned the very basis for the Restricted Science proposal in light of the alternative methods available to validate scientific studies:

> The SAB notes that there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share "data" - including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data. The EPA, the U.S. Office of Management and Budget, and scientific institutions have recognized these legitimate concerns, and recognized that such constraints on availability of data do not prevent studies from being verified in other ways - or preclude those studies from being considered in regulatory decisions.[262]

Considering this damning commentary from the scientific community—to which EPA still has not provided an answer—finalizing a rule that would impose some of the same counterproductive measures is arbitrary, capricious, and an abuse of the agency's discretion.

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[261] H. Holden Thorp et al., *Joint Statement On EPA Proposed Rule and Public Availability of Data*, Science (Dec. 6, 2019), https://science.sciencemag.org/content/366/6470/eaba3197 (emphasis added).

[262] *Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled* Strengthening Transparency in Regulatory Science, at 17 (Apr. 24, 2020), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf.

B) EPA's Failure to Consider or Explain How It Would "Ensure" the Public Availability of Data and Models Is Arbitrary and Capricious.

EPA's proposed regulatory language would require the agency to "ensure that all information (including data and models) used in the development of the BCA is publicly available."[263] Although the Proposal allows some exceptions for confidential business information and personally identifiable information, it does not contemplate the other reasons that data or models may not be publicly available. Some data and models may be infeasible to release due to technical or practical constraints. EPA's Proposal targets all potential "data and models" to be considered by the agency, without consideration that they have likely been developed by a wide breadth of entities inside and outside government, and are highly variable including in terms of how they are generated, collected, curated, and stored. In the context of the Restricted Science proposal, the SAB observed:

> Some individual data (i.e., data associated with individuals in a sample) used in epidemiological studies are held by federal agencies such as the Centers for Disease Control and Prevention or the Department of Health and Human Services (Medicare data), while other data have been developed by state, local or tribal governments, academic institutions or private organizations, among others. Some federal agencies have efficiently developed methods for making data available to the public (e.g., Census Bureau, CDC). *Currently, no comparable system exists for datasets that are owned by non-federal governments (e.g., states, tribes), and/or owned by private societies/organizations or academic institutions, which are themselves protected by strong privacy and confidentiality requirements through their Institutional Review Boards (IRBs). . . .*
>
> The proposed regulation should clearly address the issue of obtaining public access to datasets while maintaining the privacy of the participants and confidentiality of the data.[264]

EPA's proposed regulatory text also provides:

> If the data and models are proprietary, the Agency must make available, to the extent permitted by law, the underlying inputs and assumptions used, equations, and methodologies used by EPA, while continuing to provide appropriate protection for information claimed as confidential business information (CBI), personally identifiable information (PII), and other privileged, non-exempt information.[265]

Nowhere does EPA explain what it means by "appropriate protection," much less how this protection would be assured. The Proposal offers no information on where the raw data collected would reside, how the resources to manage the data would be obtained, or how EPA would deal with legally and ethically protecting confidential or sensitive data. Ensuring all this

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[263] 85 Fed. Reg. at 35,627 (proposed 40 C.F.R. § 83.3(a)(12)).
[264] Science Advisory Board 2020, at 3 (emphasis added).
[265] 85 Fed. Reg. at 35,627 (proposed 40 C.F.R. § 83.3(a)(12)).

extra information is received, stored, and made publicly accessible would be no small task. Especially at a time when EPA's budget and capacity are under strain,[266] it is unreasonable for the agency to initiate such an undertaking.

EPA does not seriously consider the issues involved with redacting data, such as the fact that simply redacting a name or a few pieces of information will not adequately protect an individual's identity. A simple anonymization process is at odds with the legal and ethical frameworks developed to protect human participants in scientific studies. For instance, the Health Insurance Portability and Accountability Act ("HIPAA") requires that medical information be protected by a set of administrative, physical, and technical safeguards.[267] Furthermore, the release of underlying human health data may include participants who cannot consent to such a process, like those who have died or cannot be located, and it may discourage people to sign up for future research studies. In a rare joint statement on the proposed rule about scientific studies, the editors of six prominent scientific journals wrote that some data "cannot be shared openly; even anonymized personal data can be subject to re-identification, and it has been a longstanding practice for agencies and journals to acknowledge the value of data privacy adjustments."[268]

A mere anonymization process is inadequate to protect personal data. Simple steps like an Internet search or database query search can re-identify research participants.[269] Research using 1990 census data found that around 87% of Americans can be identified with just three data points: their zip code, gender, and date of birth.[270] One paper found that with just 15 characteristics (like age, gender, and marital status), a machine learning program could re-identify 99.98% of Americans from an anonymized database.[271] Another paper found that a research participant's region of residence could be deduced from prominent environmental studies with 80% to 98% accuracy.[272] Data that include genetic information could reveal sensitive information about the relatives of the research participants, including those who have not yet been born.

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[266] Chris Sellers et al., Environmental Data & Governance Initiative, *An Embattled Landscape Series, Part 2b: The Declining Capacity of Federal Environmental Science* (May 4, 2020), https://envirodatagov.org/embattled-landscape-series-part-2b-the-declining-capacity-of-federal-environmental-science/.

[267] HHS Office for Civil Rights, *Security Rule Guidance Material* (2019), https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html.

[268] H. Holden Thorp. et al., *Joint statement on EPA proposed rule and public availability of data*, 366(6470) Science 25368-25368, https://www.pnas.org/content/116/51/25368.

[269] Erica Check Hayden, *Privacy protections: The genome hacker*, 497(7448) Nature 172 (2013), https://www.nature.com/news/privacy-protections-the-genome-hacker-1.12940; Richard Chirgwin, *No hack needed: Anonymisation beaten with a dash of SQL*, The Register (Dec. 18, 2017), https://www.theregister.co.uk/2017/12/18/no_hack_needed_anonymisation_beaten_with_a_dash_of_sql/.

[270] Latanya Sweeney, *Simple demographics often identify people uniquely*, Carnegie Mellon University, Data Privacy Working Paper (1999).

[271] Luc Rocher et al., *Estimating the success of re-identifications in incomplete datasets using generative models*, 10 Nature Communications 3069 (2019), https://www.nature.com/articles/s41467-019-10933-3.

[272] Katherine Boronow et al., *Privacy Risks of Sharing Data from Environmental Health Studies*, 128 Environmental Health Perspectives 1 (Jan. 2020), https://ehp.niehs.nih.gov/doi/full/10.1289/EHP4817.

Redacting data and protecting privacy is difficult and time-consuming. It can also strip data of their value, as when completely public data is de-identified to such an extent that the information garnered becomes useless. For example, when it comes to understanding the impacts of pollution on health, information like age and location is vital to understanding the health impact of the contaminant. Furthermore, EPA is statutorily responsible for characterizing pollutant exposure to at-risk subpopulations, such as the elderly, young people, Indigenous people, and people of color. If subjected to the rigid transparency requirements outlined by the Proposal about scientific studies, many studies of at-risk groups would have raw data that could not be made available because it would too easy to identify individuals, even with redactions of some personal information. Cohort studies, which can rely on small populations with unique characteristics, would be particularly affected.

EPA did not ask commenters how it might be able to manage privacy protections of patient health data, but if it had, the answer would be clear: it would be nearly impossible for EPA to strike an appropriate balance between redacting data to protect privacy and maintaining its utility.

Finally, EPA has not explained how it would pay to make all of the data and models publicly available. For many of the reasons discussed above, this can be a complex and technical undertaking. The Congressional Budget Office estimated that legislation similar to EPA's Restricted Science proposal would impose costs of hundreds of millions of dollars per year.[273] Due to the ambiguities of the current Proposal, it is difficult to predict the price tag of compliance, but it will almost certainly be significant. The Proposal is silent on what would happen if neither the agency nor the researchers have the resources to make data and models publicly available—and specifically, what impact that would have on the agency's benefit-cost analyses or other scientific and public health determinations.

EPA's general failure to consider how this Proposal could be implemented—particularly in light of the many foreseeable obstacles—is arbitrary, capricious, an abuse of the agency's discretion, and otherwise contrary to law.

C) Requiring Third Parties to Make Their Models Publicly Available Is Arbitrary and Infeasible.

EPA calls for comment on:

> whether this rule should allow the Agency to use models offered by a third party only where the third party makes its models and assumptions publicly available (or allows the EPA to do so) to the extent permitted by law.[274]

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[273] *See* Susanne S. Mehlman et al., Cong. Budget Office, *Cost Estimate for H.R. 1030: Secret Science Reform Act of 2015* at 2-3 (Mar. 11, 2015) ("CBO expects that EPA . . . would base its future work on fewer scientific studies . . . . CBO expects that the agency would probably cut the number of studies it relies on by about one-half . . . ."); Susanne S. Mehlman et al., Cong. Budget Office, *Cost Estimate for S. 544, Secret Science Reform Act of 2015* (June 5, 2015) (estimating that another similar congressional proposal would cost up to $250 million per year).
[274] 85 Fed. Reg. at 35,624.

While we support and encourage the public availability of models whenever feasible, there may be circumstances when third parties face legitimate restrictions that prevent public release of their models. It would be inconsistent with EPA's obligation to use the best available information for the agency to knowingly use a less rigorous or robust model—or no model at all—on that basis. In addition, there are other measures short of public release that can reassure and inform the public about the validity of a model and EPA's use thereof.[275] There is no indication that EPA considered these alternatives. It would be arbitrary, capricious, and unlawful for EPA to impose an across-the-board requirement for the release of third-party models used by the agency without assessing (i) the constraints this requirement could place on the agency's use of the best available information, (ii) the various reasons that the release of third-party models may be unauthorized or impracticable, and (iii) the options short of public release that may be available in certain circumstances.

Third parties may have valid concerns about making their underlying models publicly available, including that they may incorporate valuable proprietary information, or they may make it easier to personally identify participants in a study. Even when a model could conceivably be released publicly in a safe manner, a researcher may not have the resources to do so, and she may have legitimate concerns about "allow[ing]" EPA to release it. For example, EPA might not implement all of the safeguards that the researcher deems necessary. If EPA releases the model in a manner that exposes CBI or PII, however inadvertently, the researcher might worry that she or the agency could be held liable. The Proposal does not indicate whether EPA would indemnify a researcher who "allows" the agency to release a model.

Moreover, a researcher might not be authorized to release a model or even to "allow" EPA to release it. Researchers may be governed by Institutional Review Boards that must approve the disclosure of potentially sensitive information. For studies involving multiple authors, it may be necessary to obtain unanimous authorization, even though they may be governed by Boards around the world and subject to a wide variety of privacy laws.[276]

EPA should also clarify whether it is required to release a model if a researcher allows it to do so. If EPA neglects or declines to release a model for whatever reason—such as because it is too cumbersome or costly to issue in a publicly accessible format, or it is too difficult to guarantee that sensitive information will be protected—EPA should indicate whether the model could still be utilized in its BCA, or whether the BCA would have to exclude consideration of the model. EPA's failure to consider these questions and propose a process for addressing them is arbitrary and capricious.

D) EPA's Failure to Explain Key Terms Is Arbitrary and Capricious.

In several contexts—including in its proposed regulatory language—EPA indicates that the disclosure requirements would apply "to the extent permitted by law."[277] However, EPA has

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[275] *See, e.g.*, EPA, *Response to the Peer Review Report EPA Base Case Version 5.13 Using IPM* (2016), https://www.epa.gov/sites/production/files/2018-05/documents/response_and_peer_review_120516.pdf.
[276] *See, e.g.*, EDF Comments, Docket ID EPA-HQ-OA-2018-0259-12727, at 17 (describing statements of EPA Science Advisory Board member Bernard Goldstein).
[277] 85 Fed. Reg. at 35,622, 35,624, 35,627 (proposed 40 C.F.R. § 80.3(a)(12)).

not revealed which laws it expects to apply. Commenters are left to guess whether EPA is referring to the Clean Air Act, other laws that EPA implements, or entirely unrelated federal laws. EPA also has failed to indicate whether it will respect state laws governing the release of information. There may be situations in which a researcher and EPA both have access to a model, and the researcher is prohibited from releasing it under state law. It is unclear whether EPA would release the model, or what obligations the researcher would have to try to prevent that outcome.

EPA also indicates that it will protect "information claimed as confidential business information (CBI), personally identifiable information (PII), and other privileged, non-exempt information."[278] As an initial matter, this is grammatically ambiguous. It is unclear whether "claimed as" applies only to CBI, or to all elements in the series. If only to CBI, it is unclear who can "claim[]" that information is CBI, and whether that claim is dispositive. Either way, it is unclear who determines that information is PII—can anyone potentially affected by the release of information make such a claim, and is that claim dispositive? In addition, EPA has provided no definition of "privileged, non-exempt information." The agency must clarify how this category will be determined. It is unclear which privileges EPA is contemplating, and what the information may or may not be exempt from. EPA's failure to explain the meaning of terms that are central to the function of the Proposal is arbitrary and deprives the public of an opportunity to comment on what the Proposal would actually do. EPA cannot finalize any disclosure requirement until it provides notice adequate for public comment.

X. EPA HAS NOT EXPLAINED OR JUSTIFIED A RETROSPECTIVE ANALYSIS REQUIREMENT, AND CANNOT ADOPT ONE ON THE CURRENT VAGUE PROPOSAL.

EPA requests comments "on whether EPA should include a requirement for conducting retrospective analysis of significant CAA rulemakings."[279] The Proposal does not provide sufficient detail on the nature and effects of such a program to adequately notify the public of the agency's plans and allow for meaningful public comment. Therefore, because EPA has not made a sufficiently concrete proposal, it cannot adopt retrospective analysis requirements in its final rule. Additionally, EPA should not include such a requirement because it has not explained why existing processes for retrospective review of regulations are insufficient.

A) EPA Has Not Proposed a Retrospective Review Requirement with Enough Specificity to Allow for Meaningful Comment.

EPA's Proposal provides more questions than answers and thus leaves any potential position on retrospective analysis hopelessly vague and insufficiently noticed. Beyond asking for comments on "whether" the agency should adopt a retrospective review analysis, the agency does not propose any specifics. The agency merely notes that some comments on the advance notice of proposed rulemaking suggested adopting a retrospective review analysis, then "requests more specific comments on this issue" and poses a short series of questions:

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[278] *Id.* at 35,622, 35,627 (proposed 40 C.F.R. § 80.3(a)(12)).
[279] 85 Fed. Reg. at 35,624.

> In particular, what form should a requirement take in the case of CAA regulations? For example, should the requirement pertain to analysis of an individual rule or a review of the cumulative burden of a set of rules regulating the same or related entities? Should it be applicable to all parts of CAA or just some provisions? What are the advantages and disadvantages of such a requirement? How can the Agency overcome the challenges conducting retrospective analysis in cases where the EPA's ability to collect information about the costs of compliance is limited or otherwise influenced by other statutes?[280]

The public cannot comment on "the advantages and disadvantages of . . . a requirement" that remains completely undefined. Particularly troubling is the fact that EPA has not specified whether, if it does decide to implement a retrospective review requirement, there will be further opportunities for public participation in the creation of the review process, the selection of which rules to review, or in the reviews of individual rules. The chance to comment on this vague, undefined Proposal cannot be the public's only opportunity to give the agency feedback on a potential retrospective analysis requirement.

As described above in section VIII, an agency provides adequate notice to the public of a final rule only if that final rule is a "logical outgrowth" of the proposed rule.[281] The notice requirements of the Administrative Procedure Act are designed: "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."[282] An agency may not "issue broad [notices of proposed rulemaking] 'only to justify any final rule it might be able to devise by whimsically picking and choosing within the four corners of a lengthy "notice"'" because doing so "would hardly promote the purposes of the APA's notice requirement."[283] "The 'logical outgrowth' doctrine does not extend to a final rule that finds no roots in the agency's proposal because '[s]omething is not a logical outgrowth of nothing' . . . nor does it apply where interested parties would have had to "divine [the agency's] unspoken thoughts."[284] A final rule is not a logical outgrowth of the proposal if a new round of notice and comment would "provide commenters with 'their first occasion to offer new and different criticisms which the agency might find convincing.'"[285] Such a vague Proposal as EPA has put forth here—essentially providing no details other than the broad concept of "retrospective

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[280] *Id.*

[281] *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin*., 407 F.3d 1250, 1259 (D.C. Cir. 2005).

[282] *Id.*

[283] *CSX Transp., Inc. v. Surface Transp. Bd*., 584 F.3d 1076, 1082 (D.C. Cir. 2009) (*quoting Envtl. Integrity Project v. EPA*, 425 F.3d 992, 998 (D.C. Cir. 2005)).

[284] *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (internal citations omitted) (*quoting Kooritzky v. Reich*, 17 F.3d 1509,1513 (D.C. Cir. 1994); *Arizona Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000)).

[285] *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1311 (D.C. Cir. 1991) (*quoting United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1225 (D.C. Cir. 1980)).

analysis"—cannot provide sufficient notice as is required by the Administrative Procedure Act or Clean Air Act.

EPA asks for comments on how to do the review—without providing *any* details on how it proposes to do that review—but has not proposed, and does not ask for comments on, what the purpose or effect of such a review would be. A retrospective review could potentially serve a number of purposes. For example, in one of its reviews completed under Executive Order 13,563 (discussed *infra*), EPA used retrospective analyses to examine whether estimates of compliance costs differed from actual compliance costs, and whether any systematic bias existed in EPA's ex ante cost estimates.[286] Executive Order 13,563 said that retrospective analysis should be done for regulations "that may be outmoded, ineffective, insufficient, or excessively burdensome," and that the agency should "modify, streamline, expand, or repeal them" as appropriate after review.[287] The public cannot adequately comment without knowing whether the proposed retrospective analysis would be used to improve EPA's BCA and decision-making moving forward, or would be used as a basis to modify or eliminate regulations that are reviewed.

The agency also does not propose how it would select which regulations to review, or at which frequency, instead only asking for comment on whether all or only some CAA regulations should be reviewed, and whether regulations should be reviewed as a bundle (of regulations addressing the same pollutant or same industry sector) or individually. The lack of detail in the Proposal is striking when contrasted with the level of detail that was asked for in agencies' Executive Order 13,563 retrospective review plans and that EPA provided in its draft and final plan. A memorandum from OMB on the process through which agencies' preliminary review plans under Executive Order 13,563 would be finalized required agencies to "specify factors that the agency will consider and the process that the agency will use in setting priorities and selecting rules for review."[288] EPA drafted a preliminary plan and, in compliance with OMB guidance, took public comment on the preliminary plan before creating a final draft. In fact, the agency took two rounds of public comment on the draft plan, and held twenty public meetings.[289] EPA's review plan provided details on a four-step process for each five-year review cycle, which consisted of: soliciting nominations of regulations for review, selecting regulations for review,

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[286] EPA, *Improving Our Regulations: Final Plan for Period Retrospective Reviews of Existing Regulations*, at 30–31 (Aug. 2011), https://19january2017snapshot.epa.gov/sites/production/files/2015-09/documents/eparetroreviewplan-aug2011_0.pdf ("Final Plan for Periodic Retrospective Reviews"); EPA, National Center for Environmental Economics, *Retrospective Study of the Costs of EPA Regulations: A Report of Four Case Studies* (Aug. 2014), https://www.epa.gov/sites/production/files/2017-09/documents/ee-0575_0.pdf. This study followed an early 2012 case study of five regulations which "d[id] not aim to estimate ex post costs of these EPA actions," but sought to "examine key drivers of compliance costs to see if informed judgments (weighing the evidence) can be made about whether ex post costs are higher or lower than the estimates of ex ante costs." EPA, National Center for Environmental Economics, *Retrospective Study of the Costs of EPA Regulations: An Interim Report of Five Case Studies*, at 7 (Mar. 2012), https://www.epa.gov/sites/production/files/2014-04/documents/retro-cost-3-30-12.pdf.

[287] Exec. Order 13,563 § 6.

[288] Memorandum from Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs at 5 (Feb. 2, 2011), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2011/m11-10.pdf.

[289] *Final Plan for Periodic Retrospective Reviews* at 48–49.

conducting retrospective reviews, and making necessary modifications to the reviewed regulations.[290]

Any final rule that EPA may issue on retrospective analysis could not be a logical outgrowth of such a vague and amorphous proposal as has been put forth here. If EPA does intend to move forward with instituting a retrospective analysis requirement for Clean Air Act rules, the agency should: (1) establish a separate docket for that proposal; (2) develop a concrete proposed rule or set of alternative proposed rules for public comment, including: details on the purpose and intended effect of the review; the need to establish a new, Clean Air Act-specific retrospective review process; the selection criteria for rules to be reviewed; and public participation opportunities within the selection and analysis process; and (3) take public comment on the concrete proposal.

To the extent EPA implies that it might be appropriate to assess the "cumulative burden of a set of rules" on an industry,[291] it would also be necessary—at the very least—to evaluate the cumulative benefits achieved by reducing air pollution from that industry under the same rules. A sector-by-sector analysis, however, could obscure wider social net benefits that would justify a rule and confirm its ongoing value and validity. For example, although economic impacts could be spread unevenly among industries, a rule might nonetheless have substantial net benefits when viewed as a whole.[292] In its solicitation of comment on this point, EPA offers no reason why a retrospective analysis focusing exclusively on one class of regulated entities would be useful in examining the benefits and costs of a rule or set of rules. Without an adequate explanation, any policy on retrospective analysis that exclusively examines the costs, or costs and benefits, of regulating a single industry would be arbitrary.[293]

B) EPA Has Not Explained Why Existing Retrospective Review Processes Are Insufficient.

EPA does not acknowledge that the agency has already been conducting retrospective reviews both under Executive Order 13,563—which directs the preparation of retrospective review plans from all agencies—and under the Clean Air Act. Nor does EPA explain either why the existing processes are inadequate or why a new process specific to the Clean Air Act is needed. EPA merely notes:

> As discussed in the [advance notice of proposed rulemaking], many previous administrations have periodically undertaken programs of retrospective review or issued executive orders urging agencies to reassess existing regulations and to eliminate, modify, or strengthen those regulations that have become outmoded in light of changed circumstances. But for the most part retrospective review has not become institutionalized practice as has prospective review (such

[290] *Id.* at 51–52.
[291] 85 Fed. Reg. at 35,624.
[292] *See, e.g.*, EPA, Regulatory Impact Analysis: National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters at 4-3 to 4-4 & Figure 4-2, 8-1 to 8-2 & Table 8-1 (Feb. 2011).
[293] *State Farm*, 463 U.S. at 43.

> as ex ante benefit-cost analysis conducted under Executive Order 12866) within EPA.[294]

The Proposal therefore briefly acknowledges that there have been previous efforts to establish retrospective review, without specifically naming or citing any of these efforts, or indicating how a new retrospective review process would be different from or superior to these existing processes.

Executive Order 13,563 in 2011 directed a program of retrospective reviews:

> *Retrospective Analyses of Existing Rules*. (a) To facilitate the periodic review of existing significant regulations, agencies shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.
> (b) Within 120 days of the date of this order, each agency shall develop and submit to the Office of Information and Regulatory Affairs a preliminary plan, consistent with law and its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.[295]

A 2012 executive order expanded on Executive Order 13,563 by requiring agencies to solicit public feedback on which regulations are priorities for retrospective review and directing agencies to prioritize review of regulations that may be imposing unjustified burdens on small businesses.[296] It also added a requirement that agencies regularly report to OIRA on the status of their reviews.[297]

EPA complied with Executive Order 13,563 by creating a review plan and following through on it. EPA drafted a preliminary review plan, held two public comment periods and twenty public meetings, then issued its final review plan in 2012.[298] The final review plan identified 35 regulations that were priorities for retrospective review over the next five years, and stated an intention to start a new review cycle each five years after that.[299] EPA continued to provide semi-annual progress reports on its retrospective reviews through July 2016.[300] While

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[294] 85 Fed. Reg. at 35,624.

[295] Exec. Order 13,563, "Improving Regulation and Regulatory Review," January 18, 2011.

[296] Exec. Order 13,610, "Identifying and Reducing Regulatory Burdens," May 10, 2012.

[297] *Id.*

[298] *Final Plan for Periodic Retrospective Reviews* at 48–49.

[299] *Id.* at 56.

[300] EPA, *Retrospective Review History*, https://19january2017snapshot.epa.gov/laws-regulations/retrospective-review-history_.html. In that final report, EPA noted that 20 reviews were "completed" and 24 were "ongoing." EPA, *Progress Report, July 2016 – Final Plan for Periodic Retrospective Review of Existing Regulations*,

the retrospective review directed by Executive Order 13,563 was not *only* a cost-benefit review, EPA's Executive Order 13,563 Review Plan stated that "EPA intends to answer a general question such as 'Are there benefit and cost estimates related to this regulation that warrant review at this time?' If yes, then during Step 3, the Agency intends to conduct a benefit-cost analysis to understand if the benefits of continuing the regulation still justify its costs."[301] This BCA component was rooted in one of several principles from Executive Order 12,866 that were reiterated in Executive Order 13,563.[302]

EPA also has done retrospective reviews outside of the framework of Executive Order 13,563. EPA's Final Review Plan noted that "[o]f the approximately 200 active actions that are listed in EPA's *Spring 2011 Semiannual Regulatory Agenda*, roughly 60% are reviews of existing regulations."[303] EPA further explained that, "[w]hile some of these regulatory reviews are required by statute, many others are being examined by EPA as a discretionary measure. EPA intends to apply the principles and directives of EO 13563 to these ongoing reviews."[304]

EPA also has not explained why, even if the agency's current retrospective review of regulations overall is lacking, a new process *that is specific to the Clean Air Act* is needed. For similar reasons to those discussed *supra* in section III, EPA has not explained why a statute-specific process would be preferable to an agency-wide process of retrospective review. EPA has also not explained why its existing review process for the Clean Air Act is insufficient. Section 812 of the Clean Air Act Amendments of 1990 (Public Law 101-549) requires EPA to periodically assess the effect of the Clean Air Act on the "public health, economy, and environment of the United States," and to report the findings and results of its assessments to Congress. In 1997, EPA undertook a retrospective study of the Clean Air Act Amendments of 1970 and 1977 that concluded that the benefits of the statute and regulations issued pursuant to it exceeded the costs, with a benefit/cost ratio of at least 10.7, to as high as 94.5.[305] EPA did two studies in 1999 and 2011 of the benefits of the Clean Air Act Amendments of 1990 (CAAA).[306] Although these studies were labeled "prospective" and sought to project future benefits, they were in fact also *retrospective* because they sought to calculate the incremental costs and benefits of the CAAA that had accrued since 1990.[307]

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https://19january2017snapshot.epa.gov/sites/production/files/2016-09/documents/eparetroreviewprogressrpt-july2016.pdf.

[301] *Final Plan for Periodic Retrospective Reviews* at 53.

[302] Memorandum from Cass R. Sunstein, at 1 ("Section 1 of Executive Order 13563 specifically reiterates five principles from Executive Order 12866. These principles generally involve consideration of benefits, costs, and burdens."); Exec. Order 13,563 § 1 (stating that our regulatory system "must take into account benefits and costs, both quantitative and qualitative").

[303] *Final Plan for Periodic Retrospective Reviews* at 14.

[304] *Id.* at 50.

[305] EPA, *The Benefits and Costs of the Clean Air Act, 1970 to 1990* (Oct. 1997), at second unnumbered page of abstract, https://www.epa.gov/sites/production/files/2015-06/documents/contsetc.pdf.

[306] EPA, *The Benefits and Costs of the Clean Air Act 1990 to 2010*, EPA-410-R-99-001 (Nov. 1999), https://www.epa.gov/sites/production/files/2015-07/documents/fullrept.pdf; EPA 2011 Study.

[307] The 1999 Study examined benefits for 1990 through 2010, and the 2011 study examined benefits for 1990 through 2020.

EPA does not explain why these previous efforts at retrospective review were unsatisfactory, other than noting merely that retrospective analysis "has not become institutionalized practice as has prospective review (. . . under Executive Order 12866) within EPA."[308] The agency also does not explain why, if an Executive Order was sufficient to "institutionalize" the process of prospective BCA, an agency rulemaking is needed to institutionalize the process of retrospective review. Without clearly understanding the problem the agency seeks to solve, the public cannot adequately comment on whether this amorphous Proposal would solve it. Additionally, as previously discussed, adopting a rule that fails to solve any identifiable problem is arbitrary and capricious.[309]

XI. EPA HAS FAILED TO CONSIDER COSTS AND BENEFITS OF THIS PROPOSAL.

Ironically, EPA has entirely failed to assess the likely costs of this Proposal, which is purportedly intended to increase transparency surrounding the benefits and costs of rulemakings under the CAA. It is apparent, however, that the Proposal would impose substantial costs on both the agency and the public. EPA cannot finalize its rule unless it fully examines the costs of overlaying a set of detailed requirements on its existing rulemaking processes and considers the implications of the rule for its duty under the CAA to protect public health and welfare.[310]

First, and most critically, EPA has not analyzed the impacts of its Proposal on environmental justice communities, as required.[311] The agency simply concludes: "The EPA believes that this proposed action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard."[312] Executive Order 12,898, however, plainly applies to all agency "programs, policies, and activities."[313] EPA cannot disclaim its responsibility to analyze all of the costs described above through an equity lens before it can finalize any rule similar to the Proposal.

Regarding the costs of the Proposal more generally, because EPA has not specified what need the Proposal would fulfill, it is difficult to predict whether its requirements will add to the work that the agency already does in developing rules under the CAA. Although we maintain that the rule is unnecessary given the agency's existing practices, which have long involved rigorous evaluation of costs and benefits and produced clean air regulations with benefits far exceeding costs,[314] there would presumably be some instances in which the Proposal would require additional, superfluous steps before the agency could issue a regulation. EPA must delineate its Proposal's effects on the established rulemaking process, noting which efforts

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[308] 85 Fed. Reg. at 35,624.

[309] *N.Y. Stock Exch. LLC v. SEC*, 962 F.3d 541 (D.C. Cir. 2020); *Sorenson Commc'ns v. FCC*, 755 F.3d 702, 709-10 (D.C. Cir. 2011).

[310] *See Physicians for Social Responsibility v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020).

[311] *See* Exec. Order No. 12,898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, 59 Fed. Reg. 7629 (Feb. 16, 1994).

[312] 85 Fed. Reg. at 35,625.

[313] Exec. Order No. 12,898 § 2-2.

[314] EPA, *The Benefits and Costs of the Clean Air Act from 1990 to 2020: Summary Report*, at 2 & Exhibit 1 (2011).

would be additional and in what types of rulemakings those additional requirements would apply, and assess the costs to the agency of carrying out the extra steps.

For example, EPA proposes to require that every rulemaking in which there is a "continuum of options" assess the benefits and costs of at least three regulatory options, with one more stringent and one less stringent than the proposed or finalized option.[315] Alternatively, the agency may "explain why it is not appropriate to analyze more options."[316] There may be instances in which it would be appropriate to select the most or least stringent regulatory option as the preferred alternative. EPA does not offer any reason why additional explanation is required where the agency decides, at proposal or upon finalization, that its preferred regulatory option is the most or least stringent option it analyzed.[317] This requirement could deter EPA from selecting the most stringent regulatory option available when a rule is ready for proposal or finalization, as the agency could need to add and analyze a more-stringent option, possibly through a supplemental proposal with subsequent notice and comment. It could also impose costs on the agency of carrying out an unnecessary analysis of a weaker option, even where the agency has determined that any lesser level of protection is unlawful or otherwise unacceptable. The additional analysis that the Proposal would require, which is entirely unmoored from any statutory directives that govern the agency's decision-making, could entail significant cost. EPA cannot finalize the Proposal unless it examines the costs to the agency and the public of conducting superfluous analysis, or selecting less stringent regulatory options.

The proposed requirements for selecting benefit endpoints and quantifying health benefits—which, as discussed above, are themselves arbitrary[318]—would impose significant unanalyzed costs. The Proposal stipulates that:

> The Agency must select benefit endpoints that the scientific evidence indicates there is [*sic*]:
> (i) A clear causal or likely causal relationship between pollutant exposure and effect, and subsequently [*sic*]; and
> (ii) An anticipated change in that effect in response to changes in environmental quality or exposures expected as a result of the regulation under analysis. The Agency must quantify effects for endpoints which scientific evidence is robust enough to support such quantification.[319]

This proposed requirement is incomprehensible, with key terms (*e.g.*, "robust enough to support . . . quantification") undefined, and it therefore provides inadequate notice to commenters as to the agency's intentions.[320]

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[315] 85 Fed. Reg. at 35,626 (proposed 40 C.F.R. § 83.3(a)(3)).
[316] *Id.*
[317] *See* 85 Fed. Reg. at 35,618.
[318] *See supra* section V.
[319] *Id.* at 35,626 (proposed 40 C.F.R. § 83.3(a)(7)).
[320] *See Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983) ("Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."); *see also*

In any event, the provision could entail significant costs. The terms "causal relationship" and "likely to be causal relationship" are defined in EPA's Preamble to the Integrated Science Assessments.[321] There, the agency explains that it finds such relationships to exist after a "weight-of-evidence evaluation . . . based on the integration of findings from various lines of evidence from across health and environmental effect disciplines that are integrated into a qualitative statement about the overall weight of the evidence and causality."[322] If no such weight-of-evidence evaluation is available for any given pollutant exposure, the Proposal could block EPA from estimating benefits from pollutant reductions that it reasonably believes would improve public health. Furthermore, EPA offers no criteria for "scientific evidence [that] is robust enough to support . . . quantification."[323] This nebulous requirement could deter EPA from estimating some benefits, or it could induce the agency to confirm scientific evidence that would already suffice for purposes of quantifying benefits. EPA must assess the costs to the agency and the public of failing to regulate pollution that it is statutorily charged with addressing, or conducting superfluous analysis, under this provision as well.

Compounding its demands for unnecessary analysis, the Proposal would impose numerous new and amorphous criteria on EPA's use of concentration-response functions in selecting the health endpoints to quantify in its benefits analyses—without any demonstration that these criteria will improve the agency's ability to fulfill its statutory mandates.[324] Regarding concentration-response functions in epidemiological studies, these specific criteria would apply: "that the study must assess the influence of confounders, that the study location must be appropriately matched to the analysis, and that the study population characteristics must be sufficiently similar to those of the analysis."[325] The Proposal does not define any of these terms, leaving agency staff to guess at which studies would be "appropriately matched" in location or "sufficiently similar" in population characteristics.[326]

If multiple studies satisfy the criteria, EPA must "characterize multiple concentration-response functions."[327] Then:

> (v) The Agency must base decisions about the choice of the number of alternative concentration-response functions quantified for each endpoint on the extent to which it is technically feasible to quantify alternative concentration-response relationships given the available data and resources.
> (vi) The Agency must select and clearly identify concentration-response functions with the strongest scientific evidence, as well as evidence necessary to demonstrate

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id. ("This is doubly true under Clean Air Act § 307(d)(3), which requires EPA to issue a specific 'proposed rule' as a focus for comments.").

[321] EPA, Office of Research and Development, Preamble to the Integrated Science Assessments 22-23 (2015).

[322] *Id.* at 22.

[323] *See* 85 Fed. Reg. at 35,620.

[324] *Id.* at 35,626 (proposed 40 C.F.R. § 83.3(a)(9)).

[325] *Id.* (proposed 40 C.F.R. § 83.3(a)(9)(iii)(D)).

[326] *See id.* at 35,621.

[327] *Id.* at 35,626 (proposed 40 C.F.R. § 83.3(a)(9)(iv)).

> the sensitivity of the choice of the concentration-response function on the magnitude and the uncertainty associated with air pollution-attributable effects.[328]

Determining whether it is "technically feasible" to quantify alternative concentration-response relationships would add a step to EPA's assessment of the scientific evidence. Even more unnecessary (and improper), staff would have to ascertain which concentration-response function would have the greatest effect on benefits, an exercise that appears to be designed to enable manipulation of the benefits analysis. EPA cannot finalize the rule without considering the costs to the agency of running this gauntlet of analytical requirements, as well as the likely effect of the new requirements on public-health protections.

Perhaps most onerous of all, the Proposal would require EPA to disclose all data and models used in the analysis of benefits and costs:

> (12) To the extent permitted by law, the Agency must ensure that all information (including data and models) used in the development of the BCA is publicly available. If the data and models are proprietary, the Agency must make available, to the extent permitted by law, the underlying inputs and assumptions used, equations, and methodologies used by EPA, while continuing to provide appropriate protection for information claimed as confidential business information (CBI), personally identifiable information (PII), and other privileged, non-exempt information.[329]

This provision contemplates that EPA will be responsible for disseminating all of the data and models underlying scientific studies that it relies upon in assessing benefits and costs. EPA must also provide "appropriate protection" for proprietary or personal information—still another undefined term with which agency staff must grapple. And, under this provision, the Office of General Counsel would likely need to make numerous determinations that disclosure is permitted by law.

As commenters have thoroughly explained in opposing EPA's ill-advised Restricted Science proposal, there is no reason that all underlying data and models need to be available to the public in order for valid science to support EPA's regulations.[330] That proposal, at least, makes clear that it would not require the agency to make available to the public all data and models underlying "pivotal regulatory science" and "pivotal science."[331] The present Proposal, however, *does* appear to contemplate—and require—EPA to disseminate the data and models itself.[332] EPA must examine the enormous costs of this requirement to the agency[333]—as well as

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[328] *Id.* at 35,626 (proposed 40 C.F.R. § 83.3(a)(9)(v), (vi)).

[329] *Id.* at 35,627 (proposed 40 C.F.R. § 83.3(a)(12)).

[330] *See supra* n.256.

[331] *See* 85 Fed. Reg. 15,396, 15,402 (Mar. 18, 2020).

[332] *See* 85 Fed. Reg. at 35,627 (proposed 40 C.F.R. § 83.3(a)(12)).

[333] *See* EDF Comments, Docket ID EPA-HQ-OA-2018-0259-12727, at 75-83 (discussing the potential—though unexamined—costs of limiting the scientific information available to the agency to that for which underlying data and models are publicly available).

its implications for public health and environmental protections—if it truly intends to impose them here.

All of these costs are unnecessary under the CAA and would hinder the agency's fulfillment of its statutory mandates. The CAA does not demand a definitively established causal or likely causal relationship between pollution exposure and health impacts. Nor does it require EPA to confine itself to concentration-response functions that satisfy certain criteria, or to seek out concentration-response functions that are not supported by the best available science. Instead, the CAA frequently instructs EPA to regulate where, in the agency's "judgment," the subject of regulation contributes to air pollution that "may reasonably be anticipated to endanger public health or welfare."[334] And EPA has acknowledged that the "best available science must serve as the foundation of EPA's regulatory actions,"[335] a directive with which the proposed disclosure requirements could interfere if it is not feasible for EPA to make underlying data and models public. Thus, the Proposal would interfere with the agency's duties under the CAA by requiring extraneous analysis and disclosure—and by limiting the information available to the agency where it is unable to satisfy the Proposal's numerous, murky, and unjustified requirements. EPA cannot finalize the rule unless it examines the costs to the public of failing to secure the health and environmental protections that the CAA requires.

Aside from additional requirements in conducting benefit-cost analyses, the Proposal would also entail costs associated with EPA's compliance activities, rulemaking decisions, and defense of its rules from attacks stemming from the Proposal.[336] EPA must carefully consider the full range of these likely costs before it can finalize any rule along these lines.

In sum, EPA has completely disregarded the numerous and substantial costs that its rule would likely impose on the agency and the public. The agency has thus ignored an important aspect of the problem, and any action on its Proposal without such analysis—short of withdrawal—would be arbitrary and unlawful.[337]

XII. EPA MUST ALLOW ADDITIONAL OPPORTUNITY FOR PUBLIC COMMENT.

The Administrative Procedure Act "requires that the public have a meaningful opportunity to submit data and written analysis regarding a proposed rulemaking."[338] The purposes of the APA's notice and comment requirements are "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected

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[334] *See* 42 U.S.C. §§ 7408(a)(1)(A), 7411(b)(1)(A), 7521(a)(1), 7545(c)(1), 7571(a)(2)(A); *see also Coal. for Responsible Regulation v. EPA*, 684 F.3d 102, 122 (D.C. Cir. 2012) ("This language requires a precautionary, forward-looking scientific judgment about the risks of a particular air pollutant, consistent with the CAA's precautionary and preventive orientation." (internal quotation marks and citation omitted)), *rev'd on other grounds sub nom. Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302 (2014).

[335] 83 Fed. Reg. 18,768, 18,769 (Apr. 30, 2018) (citing Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011)).

[336] *See supra* section III.E.

[337] *State Farm*, 463 U.S. at 43.

[338] *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011) (citing 5 U.S.C. § 553(c)); *see also Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009) ("The opportunity for comment must be a meaningful opportunity.").

parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."[339] The Clean Air Act likewise requires that the public be permitted to meaningfully comment on EPA's proposed rulemakings.[340]

Many of the undersigned organizations requested that EPA extend the comment period for this Proposal. These requesters noted the "novel and complex issues raised in the proposed rule" and "far-reaching and significant impacts this proposal would have on EPA's obligation to protect public health and the environment."[341] They explained that "[t]he proposed rule is especially consequential and requires careful scrutiny because it has implications for multiple Clean Air Act standards."[342] On July 22, EPA denied these requests without addressing the arguments for extension.[343]

In a notice published July 23, 2020, the EPA "Science Advisory Board (SAB) staff office announce[d] two public teleconferences of the chartered SAB to review the scientific and technical basis of [this] proposed rule."[344] These meetings are scheduled for August 11, 2020, and September 15, 2020.[345] Particularly in light of the opaque and technical nature of the Proposal, the SAB's discussion will likely provide the public with informative perspectives on the design and possible impacts of this rulemaking. Information from the SAB meetings could significantly enhance the public's ability to comment on this Proposal.

It is indefensible for EPA to retain its comment deadline of August 3, 2020, when the public is likely to become much more informed about the Proposal shortly thereafter. The current

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[339] *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005); *United States v. Reynolds*, 710 F.3d 498, 519-20 (3d Cir. 2013) ("[T]he essential purpose of according § 553 notice and comment opportunities is to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." (alteration in original) (quoting *Dia Nav. Co., Ltd. v. Pomeroy*, 34 F.3d 1255, 1265 (3d Cir. 1994)); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1404 (9th Cir. 1995) ("The purpose of the notice and comment requirement is to provide for meaningful public participation in the rule-making process."). "[T]hese policy goals of maximum participation and full information" are of "obvious importance." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987).

[340] 42 U.S.C. § 7607(d); *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 518-19, 550 ("[T]he additional notice requirements in § 307(d)(3) suggest that Congress intended agency notice under the Clean Air Act to be more, not less, extensive than under the APA."); *Sierra Club v. Costle*, 657 F.2d at 398 (D.C. Cir. 1981) (public must be able to meaningfully comment on proposed Clean Air Act rule).

[341] Letter from Environmental Defense Fund, Clean Air Task Force, Earthjustice, Environmental Law & Policy Center, Environmental Protection Network, National Parks Conservation Association, and Sierra Club to EPA Administrator Andrew R. Wheeler re: Request to Immediately Halt and Withdraw EPA's Clean Air Act Cost-Benefit Rulemaking Action, and Extend Deadline for Public Comments on EPA's Notice of Proposed Rulemaking, Docket ID No. EPA-HQ-OAR-2020-0044-0052 (June 26, 2020).

[342] Letter from Gretchen Goldman and Rachel Cleetus, Union of Concerned Scientists, to Administrator Andrew Wheeler, Docket ID No. EPA-HQ-OAR-2020-0044-0053 (June 29, 2020).

[343] *See* Letter from Principal Deputy Assistant Administrator Anne L. Austin to Stakeholders, re: Request to immediately halt and withdraw EPA's Clean Air Act Cost-Benefit Rulemaking Action, and extend deadline for public comments on EPA's Notice of Proposed Rulemaking (July 22, 2020).

[344] EPA, Notification of Two Public Teleconferences of the Chartered Science Advisory Board, 85 Fed. Reg. 44,535 (July 23, 2020).

[345] *Id.* at 44,536.

deadline is in tension with all three of the above-listed purposes of public comments. First, it limits the Proposal's exposure to diverse public comment by requiring the public to engage from a position of relatively little information. Second, it is unfair to the affected parties. The SAB meetings will likely clarify how the public will be affected—and, more fundamentally, who the affected parties are, since EPA provides no explanation of how this Proposal would affect the public. And third, the current deadline limits the evidence in the record, as the SAB meetings will likely present new impacts, critiques, and other considerations for commenters to react to. Further, the SAB's statements on the Proposal should themselves be part of the rulemaking record and record for judicial review, and the agency must extend the public comment period to allow interested parties to collect and submit this vital information.

As noted elsewhere in these comments, the Proposal does not solve any problem or mitigate any threat to public health or the environment that the agency has articulated. No harm would arise from the modest extension necessary to allow the public to hear and react to the SAB's discussions, but refusing to allow additional comments after those discussions would further tarnish this deeply flawed rulemaking.

Submitted by:

CHESAPEAKE BAY FOUNDATION
CLEAN AIR TASK FORCE
ENVIRONMENTAL DEFENSE FUND
ENVIRONMENTAL LAW & POLICY CENTER
ENVIRONMENTAL PROTECTION NETWORK
NATURAL RESOURCES DEFENSE COUNCIL
UNION OF CONCERNED SCIENTISTS