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Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

To Whom It May Concern:

The National Association of Clean Air Agencies (NACAA) offers the following comments on the U.S. Environmental Protection Agency's (EPA's) proposed action, "Review of the National Ambient Air Quality Standards for Particulate Matter," which was published in the *Federal Register* on April 30, 2020 (85 Fed. Reg. 24,094).¹ NACAA is the national, nonpartisan, non-profit association of air pollution control agencies in 41 states, including 115 local air agencies, the District of Columbia and four territories. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the U.S. These comments are based upon that experience. The views expressed in these comments do not represent the positions of every state and local air pollution control agency in the country.

Based on EPA's recent review of the air quality criteria and National Ambient Air Quality Standards (NAAQS) for particulate matter (PM), EPA Administrator Andrew Wheeler has proposed his decision to retain the current primary NAAQS (to protect public health) for fine PM (PM_{2.5}) and coarse PM (PM₁₀) and secondary NAAQS (to protect public welfare) for PM_{2.5} and PM₁₀, without revision. As we explain below, after closely tracking EPA's PM NAAQS Review since it was initiated in December 2014, NACAA concludes that this review process was flawed; that it resulted in a flawed proposed decision by the EPA Administrator, particularly with respect to the primary PM_{2.5} standards; that the Administrator's proposed action should be withdrawn; and that a revised review process should be undertaken.

I. The PM NAAQS Review Process Was Profoundly and Irreparably Flawed

In 2018, EPA leadership took several decisive steps that changed the course of the PM NAAQS review: Then-Administrator Scott Pruitt issued a memorandum setting out principles for future NAAQS reviews and Administrator Wheeler announced the appointment of five new members of the seven-member Clean Air Scientific Advisory Committee (CASAC) and disbanded the PM NAAQS Review Panel.

¹ 85 Fed. Reg. 24,094 (April 30, 2020) – <https://www.govinfo.gov/content/pkg/FR-2020-04-30/pdf/2020-08143.pdf>

A. Then-Administrator Pruitt's "Back-to-Basics Process for Reviewing NAAQS" Set the Stage for a Rush to Judgment

Then-Administrator Pruitt's May 9, 2018 "Back-to-Basics Process for Reviewing National Ambient Air Quality Standards" memorandum² set out principles for EPA to follow in future NAAQS reviews, including meeting all statutory deadlines and streamlining and standardizing the process for developing and reviewing key policy-relevant information. With respect to meeting statutory deadlines, Pruitt stated that "EPA and CASAC shall look for efficiencies and opportunities to streamline the NAAQS review process to ensure that they finish within a five-year interval" as required by the Clean Air Act (CAA). Although Administrator Pruitt focused this statement on the then-forthcoming review of the ozone NAAQS he also stated that "EPA intends to conduct the already initiated review of the particulate matter NAAQS in such a manner as to ensure that any necessary revisions to that NAAQS are finalized by December 2020."

In its April 11, 2019 review of the EPA staff's "Integrated Science Assessment [ISA] for Particulate Matter (External Review Draft – October 2018)"³ CASAC reported its finding that the "Draft ISA does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to particulate matter" and recommended that EPA staff develop a second draft for the Committee's review. Administrator Wheeler responded to CASAC on July 25, 2019,⁴ acknowledging that CASAC had "raised a number of important issues" with the draft ISA but dismissing the recommendation for a second draft, suggesting that a memo written by his predecessor precluded him from allowing it: "The process outlined in the May 9, 2018, 'Back-to-Basics' memo directs the agency to ensure that NAAQS reviews are completed in a timely, efficient and transparent manner, consistent with the Clean Air Act. The five-year review cycle for each NAAQS is challenging in light of the continuous development of new and relevant science, challenges compounded by the EPA practice of facilitating CASAC and public engagement throughout the process." The Administrator went on to advise CASAC that, "with this in mind," he had directed his staff to complete the review of the PM NAAQS by the end of 2020; to the extent possible, incorporate CASAC's comments and recommendations into the final ISA; and "for the comments and recommendations that are more significant or cross-cutting, and which cannot be fully addressed in this timeframe, develop a plan to incorporate these changes in future PM ISAs as well as ISAs for other criteria pollutants."

Thus, the "Back-to-Basics" memo resulted in a truncated process that sacrificed thoroughness, deliberation and scientific integrity for the sake of expediency. In pursuit of "efficiency," the PM NAAQS review process fell victim to a compressed schedule that eliminated the preparation and review of key documents. The Integrated Review Plan (IRP) finalized in December 2016⁵ not only called for two review drafts of the ISA, but also two review drafts of the Risk and Exposure Assessment (REA) and two review drafts of the Policy Assessment (PA). These sequential documents are intended to build on one another to

² *Back-to-Basics Process for Reviewing National Ambient Air Quality Standards*, Memorandum from E. Scott Pruitt, U.S. Environmental Protection Agency (May 9, 2018) – <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

³ *CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)*, Clean Air Scientific Advisory Committee (April 11, 2019) –

[https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)

⁴ Letter from EPA Administrator Andrew R. Wheeler to CASAC Chair Louis Anthony Cox, Jr., Ph.D. (July 25, 2019) –

[https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf)

⁵ *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter*, U.S. Environmental Protection Agency (December 2016) – <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf>

inform NAAQS reviews, as reflected in the schedule for the preparation and review of these documents established in the IRP, culminating in a proposed decision in 2021 and a final decision in 2022. However, this complete, orderly and typical plan was discarded and replaced with a deficient offering that consisted of only one review draft each of the ISA and PA and no REA at all (with a risk assessment folded into the PA). This approach also comingled development and review of science, risk and policy. As a result, EPA introduced policy issues for consideration before issues related to science and risk were resolved. Further, the schedule was accelerated from that in the December 2016 IRP by well over a year and a new, immovable deadline of December 2020 was established.

Further, the rush to the finish line precluded adequate time for in-depth discussions, public input and transparency. Not only were fewer meetings of CASAC held, opportunities for public review and comment were shortchanged.

B. CASAC Lacked the Expertise Needed to Conduct the PM NAAQS Review and the Administrator's Dismissal of the PM Review Panel Seriously Exacerbated this Deficit

In October 2018, Administrator Wheeler appointed five new members to the chartered seven-member CASAC;⁶ the remaining two members had been appointed within the previous year. These appointments were based on the principles established by then-Administrator Pruitt in an October 31, 2017 memorandum, "Strengthening and Improving Membership on EPA Federal Advisory Committees"⁷: 1) strengthen member independence, 2) increase state, tribal and local government participation, 3) enhance geographic diversity and 4) promote fresh perspectives. Administrator Wheeler also announced that this new seven-member CASAC would directly review key science assessments for the ongoing review of the PM NAAQS, which was to be completed by late 2020. The following day, the Administrator disbanded the 24-member advisory panel of experts that was currently reviewing the PM standards with CASAC. Panel members were advised by email that the "PM Review Panel will no longer be involved with the Agency's PM NAAQS review and your service on the panel has concluded." These actions damaged the scientific rigor and integrity of the review.

First, then-Administrator Pruitt's principles for establishing federal advisory committees focused on appointing more state, tribal and local government members, increasing geographic diversity and bringing new faces to the table. While all are certainly laudable goals, they should not supersede criteria that consider breadth and depth of expertise and experience, a balance of scientific perspectives and continuity of knowledge and an understanding of EPA's mission and environmental programs. In addition, excluding from eligibility any non-governmental researcher in receipt of an EPA grant eliminated from consideration many extremely qualified experts who do not have the luxury of private funding.

Second, CASAC is a seven-member body. Members select the NAAQS reviews in which they will participate; six members of the current CASAC participated in the PM NAAQS review. The Committee includes members who are experts in toxicology, medicine, engineering, atmospheric science and ecology; however, although epidemiology is a discipline that is essential to analyzing the distribution and determinants of health impacts of exposure in populations associated with PM_{2.5}, CASAC does not include an

⁶ *Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee*, Press Release, U.S. Environmental Protection Agency (October 10, 2018) – <https://archive.epa.gov/epa/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee.html>

⁷ *Strengthening and Improving Membership on EPA Federal Advisory Committees*, Memorandum from E. Scott Pruitt, U.S. Environmental Protection Agency (October 31, 2017) – http://www.4cleanair.org/sites/default/files/Documents/FAC_Directive-10-31-2017.pdf

epidemiologist. No matter who sits on CASAC, the small Committee simply cannot provide the variety of expertise necessary to conduct a credible review of any NAAQS: disciplines such as epidemiology, toxicology, medical specialties, risk assessment, atmospheric sciences and exposure assessment from both the modeling and measurement sides, controlled human studies and more. Moreover, several experts are needed in each area of expertise to provide diverse perspectives. In the mid-1980s, CASAC has been assisted by pollutant-specific review panels to provide that breadth and depth of expertise and perspectives. With respect to PM, the first review panel was appointed in 1994 and continued until the most recent 20-member panel was dismissed in 2018. Without this panel, a virtually brand new CASAC was left lacking in crucial expertise and without the expert review and analysis of EPA staff drafts by panel members, without additional colleagues with whom to freely deliberate and without additional points of view to enrich and inform the discussions and recommendations.

CASAC understood the gravity of this loss and in its April 2019 review of the draft ISA appealed to EPA not only “to reappoint the previous CASAC PM panel (or appoint a panel with similar expertise)” but also to expand it with numerous additional areas of expertise. CASAC requested that the panel be reappointed “in time for the review of the Second Draft ISA.” But, as with CASAC’s request for a second draft ISA, Administrator Wheeler refused the recommendation to reappoint the PM Review Panel. In his July 2019 response to CASAC’s review of the draft ISA, the Administrator told Committee Chair Anthony Cox that he had directed his staff to “create a pool of subject matter expert consultants that the seven-person chartered CASAC, through the chair, will draw from as needed to support its PM and ozone reviews. The consultants will make themselves available as requested to provide feedback on the scientific and technical aspects of science and policy assessments and related documents. ... Requests for feedback from these consultants should be submitted in writing through you, the CASAC’s chair, and the CASAC’s designated federal official.” This no-direct-contact arrangement offering only responses to questions posed is a far cry from the highly synergistic relationship CASAC enjoyed with the PM Review Panel, which benefitted the review process and, moreover, the outcome.

C. EPA and CASAC Did Not Consider the Latest Science

Section 108(a)(2) of the Clean Air Act mandates, “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.” (emphasis added) However, EPA staff and CASAC did not assess the latest scientific knowledge for the PM NAAQS review. Numerous robust, relevant studies were either overlooked or published after EPA staff drafted the ISA (a list of “Recent Causal Particulate Matter Mortality Studies” is attached). Together, these studies create a body of evidence strongly supporting the causal relationship between exposure to PM at levels below the current primary standards and mortality. There are numerous additional studies – causal and epidemiological – demonstrating the severe impact of PM_{2.5} on morbidity. Had EPA staff not faced such an abbreviated timeframe these studies could have been considered in a second draft ISA and allowed for better-informed recommendations by CASAC. At a minimum, as has occurred in the past, the Administrator could have committed in his proposed decision to a review and assessment of these and any other recent studies with findings presented in a “Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure” to inform his final decision.

Notwithstanding this, however, in the final ISA and PA EPA staff still provided substantial, solid evidence of the serious adverse health impacts that occur – including premature death – at levels of PM_{2.5} that are below the current annual and 24-hour primary standards.

D. CASAC's Approach to Making a Causal Determination of Mortality Due to PM_{2.5} Exposure Demanded an Unreasonable and Unnecessary Burden of Proof

Sections 108(a)(2)(C) and 109(b)(1) of the Clean Air Act require consideration by EPA of “any known or anticipated adverse effects on welfare” (emphasis added) to set the primary NAAQS at a level necessary to protect public health “allowing an adequate margin of safety.” Nonetheless, CASAC increased the burden of proof required for making causal associations to an unreasonable and unnecessary level in instances where there was any uncertainty over adverse effects, ignoring the CAA's requirements for the consideration of *anticipated* adverse effects and allowance of an adequate margin of safety..

In its April 2019 review of the draft ISA CASAC stated that it “did not reach consensus on the causality determination of mortality from PM_{2.5} exposure. Some members of the CASAC think that the EPA must better justify their determination that short-term or long-term exposure to PM_{2.5} causes mortality.” These members advised EPA staff to address a number of “considerations” – such as the biological action of PM, heterogeneity, concentration concordance and concentration-response functions and thresholds – in specific detail and also raised the specter of doubt over the use of epidemiological studies as the basis for NAAQS determinations.

However, CASAC also stated in its review of the draft ISA that “[o]ther members of the CASAC are of the opinion that, although uncertainties remain, the evidence supporting the causal relationship between PM_{2.5} exposure and mortality is robust, diverse, and convincing. The epidemiological observations have been reproduced around the world in communities with widely varying exposures. The findings of many of the largest studies have been repeatedly reanalyzed, with confirmation of the original findings. The EPA's causality determination, rather than considering the epidemiological evidence ‘in isolation,’ includes a wide range of evidence from a variety of sources, including human clinical exposure and animal toxicology studies that have provided rational biological plausibility and potential mechanisms. This causality determination was first clearly promulgated in the 2009 ISA, with full CASAC support. It is widely accepted by the scientific community and many public health organizations, including the World Health Organization. There is no credible or convincing new evidence since 2009 to question or refute this determination. Indeed, there is new evidence from epidemiological studies supporting the relationship between PM_{2.5} and mortality, and new toxicology studies informing the mechanisms involved and supporting their plausibility. The evidence supporting a causal relationship between PM_{2.5} and mortality is even more robust now than it was in 2009. Uncertainties clearly remain: for example, the specific PM characteristics responsible for health effects, dose-response relationships at low ambient concentrations (the threshold issue), explanations for the observed heterogeneity in effect sizes across geographical locations, and whether (or to what degree) particle translocation away from the lung mediates health effects. These uncertainties have been for the most part thoroughly discussed in the draft ISA, as well as in previous PM ISAs. The fact that there is uncertainty with regard to specific issues does not negate the overwhelming evidence that PM_{2.5} exposure increases mortality.”

In the end, a majority of CASAC (four of the six participating members) reached the conclusion that doing nothing on the annual primary PM_{2.5} standard was the proper response to uncertainty and all six members concluded the same with respect to the 24-hour primary PM_{2.5} standard. CASAC stated the

following in its December 16, 2019 review of the draft PM PA⁸: “The Draft PM PA depends on a Draft Particulate Matter (PM) Integrated Science Assessment (ISA) that, as noted in the April 11, 2019, CASAC Report on the Draft PM ISA, does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to PM, due largely to a lack of a comprehensive, systematic review of relevant scientific literature; inadequate evidence and rationale for altered causal determinations; and a need for clearer discussion of causality and causal biological mechanisms and pathways. Given these limitations in the underlying science basis for policy recommendations, and diverse opinions about what quantitative uncertainty analysis and further analysis of all relevant data using the best available scientific methods would show, some CASAC members conclude that the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current 2012 PM_{2.5} annual standard. Other members of CASAC conclude that the weight of the evidence, particularly reflecting recent epidemiology studies showing positive associations between PM_{2.5} and health effects at estimated annual average PM_{2.5} concentrations below the current standard, does reasonably call into question the adequacy of the 2012 annual PM_{2.5} National Ambient Air Quality Standards (NAAQS) to protect public health with an adequate margin of safety. The CASAC also finds, in agreement with the EPA, that the available evidence does not reasonably call into question the adequacy of the current 24-hour PM_{2.5} standard, PM₁₀ standard, or secondary PM standards and concurs that they should be retained.”

The high degree of certainty sought by CASAC with respect to the causal relationship between PM_{2.5} exposure at low levels and mortality is not required by the Clean Air Act, violates the CAA Section 109(b)(1) directive that primary NAAQS “shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect public health” and could set a dangerous precedent under which epidemiological studies are no longer an acceptable basis for future NAAQS reviews.

II. The Flawed Process Led to a Flawed Proposed Decision by the EPA Administrator to Retain the Current Primary PM_{2.5} NAAQS Without Revision

Any one of the aforementioned failings, on its own, would have undermined the PM NAAQS Review, but all of them combined resulted in a process that was profoundly and irreparably flawed, which, in turn, led to a deeply flawed proposal.

In proposing to retain the current PM NAAQS without revision, the Administrator ignores the advice of his own staff as provided in the final PA and instead stokes doubt about the preponderance of clear scientific evidence in the final ISA and PA that supports strengthening the primary PM_{2.5} standards, particularly epidemiologic studies. The Administrator places significant weight on studies that demonstrate a causal relationship and notes the absence of evidence from experimental studies – an issue that could have been resolved had EPA staff and CASAC had time to consider the latest scientific literature – which “leave important questions unanswered.” The Administrator also “judges that there is considerable uncertainty in the potential for increased public health protection from further reductions in ambient PM_{2.5} concentrations.” For reasons such as these, the Administrator proposes to conclude that the available scientific evidence and technical information continue to support the current annual and 24-hour primary

⁸ CASAC Review of the EPA’s Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019), Clean Air Scientific Advisory Committee (December 16, 2019) – [https://yosemite.epa.gov/sab/sabproduct.nsf/0/E2F6C71737201612852584D20069DFB1/\\$File/EPA-CASAC-20-001.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf)

PM_{2.5} NAAQS, noting that “this proposed conclusion reflects the fact that important limitations in the evidence remain.”

Completely unaddressed by the Administrator’s proposed decision are at-risk populations and issues of environmental justice. In the ISA, EPA staff cite “strong evidence demonstrating that black and Hispanic populations, in particular, have higher PM_{2.5} exposures than non-Hispanics white populations” and “consistent evidence across multiple studies demonstrating an increase in risk for non-white populations.” In one of the studies from which this information is drawn – “Air pollution and mortality in the Medicare population,”⁹ published in the *New England Journal of Medicine* in 2017 – researchers concluded, “In the entire Medicare population, there was significant evidence of adverse effects related to exposure to PM_{2.5} and ozone at concentrations below current national standards. This effect was most pronounced among self-identified racial minorities and people with low income.” The researchers further concluded that “men; black, Asian, and Hispanic persons; and persons who were eligible for Medicaid (i.e., those who had low socioeconomic status) had a higher estimated risk of death from any cause in association with PM_{2.5} exposure than the general population....Among black persons, the effect estimate for PM_{2.5} was three times as high as that for the overall population.” In another study – “Environmental Inequality in Exposures to Airborne Particulate Matter Components in the United States,”¹⁰ published in *Environmental Health Perspectives* in 2012 – researchers concluded, “Exposures to PM_{2.5} components differed by race/ethnicity, age, and SES [socioeconomic status]. If some components are more toxic than others, certain populations are likely to suffer higher health burdens. Demographics differed between populations covered and not covered by monitors.”

Also not addressed by the proposal is the increased, or possibly increased, risk of PM_{2.5}-related adverse health impacts among various populations, including older adults; those with pre-existing cardiovascular or respiratory disease; and populations that are overweight or obese, have particular genetic variants, are of low socioeconomic status or are current or former smokers.

III. Highly Credible Parties Find That the Scientific Evidence Supports Strengthening the Primary PM_{2.5} Standards

A. CASAC Members Were Split on the Adequacy of the Annual Primary PM_{2.5} Standard

The six participating members of CASAC lacked support from the PM Review Panel, whose members had the expertise necessary to inform this review, but nonetheless concluded that “the available evidence does not reasonably call into question the adequacy of the current 24-hour [primary] PM_{2.5} standard” of 35 µg/m³. However, only four of the six came to the same conclusion for the current annual primary PM_{2.5} standard of 12 µg/m³, with the remaining two concluding that “the weight of evidence ... does reasonably call into question the adequacy of the 2012 annual PM_{2.5} National Ambient Air Quality Standards (NAAQS) to protect public health with an adequate margin of safety.”

⁹ *Air Pollution and Mortality in the Medicare Population*, *New England Journal of Medicine* (June 29, 2017) – <https://www.nejm.org/doi/full/10.1056/NEJMoa1702747>

¹⁰ *Environmental Inequality in Exposures to Airborne Particulate Matter Components in the United States*, *Environmental Health Perspectives* (December 2012) – <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1205201>

B. EPA Staff, in Their Final Policy Assessment, Concluded That Available Information Suggests That Tighter Annual and 24-Hour Primary Standards Are Supported

In their January 2020 final PA,¹¹ after summarizing their findings regarding whether available scientific evidence and risk-based information support or call into question the adequacy of the public health protection provided by the current annual and 24-hour primary PM_{2.5} standards, EPA staff stated, “When taken together, we reach the conclusion that the available scientific evidence, air quality analyses, and the risk assessment, as summarized above, can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the combination of the current annual and 24-hour primary PM_{2.5} standards.” The staff concluded that an annual primary PM_{2.5} standard at a level below 10 µg/m³ and potentially as low as 8 µg/m³ (versus the current standard of 12 µg/m³) could be supported and a 24-hour primary PM_{2.5} standard as low as 30 µg/m³ (versus the current standard of 35 µg/m³) could be supported.

C. Twenty Members of the Disbanded CASAC PM Review Panel Reconvened as the Independent PM Review Panel and Recommended Revisions to the Annual and 24-Hour Primary PM_{2.5} Standards

On October 10 and 11, 2019, 20 members of the disbanded CASAC PM Review Panel convened as the Independent PM Review Panel (IPMRP) to discuss the draft PM PA. Following the same process and procedures that they followed as the CASAC PM Review Panel, members of the IPMRP developed a letter to the EPA Administrator with consensus responses to the charge questions EPA posed to CASAC. In an October 22, 2019 letter,¹² the IPMRP advises, among other things, that, “Based on scientific evidence, as detailed in Attachment B, the Panel finds that the current suite of primary fine particle (PM_{2.5}) annual and 24-hour standards are not protective of public health. Both of these standards should be revised to new levels, while retaining their current indicators, averaging times, and forms. The annual standard should be revised to a range of 10 µg/m³ to 8 µg/m³. The 24-hour standard should be revised to a range of 30 µg/m³ to 25 µg/m³. These scientific findings are based on consistent epidemiological evidence from multiple multi-city studies, augmented with evidence from single-city studies, at policy-relevant ambient concentrations in areas with design values at and below the levels of the current standards, and are supported by research from experimental models in animals and humans and by accountability studies.”

IV. NACAA Recommends That the Administrator Withdraw This Proposal, Reconvene the PM Review Panel and Follow a Review Process that Corrects the Aforementioned Failures

NACAA’s mission is to protect clean air and public health and improve the capability and effectiveness of state and local air agencies as we work tirelessly to fulfill our responsibility under the Clean Air Act to prevent and control air pollution so that our constituents will breathe clean, healthful air. We cannot succeed unless EPA – our federal regulatory partner – makes well-informed, thoughtfully considered policy decisions. In the case of NAAQS, these policy decisions must be guided by a thorough review of the latest available science by, and sound advice from, highly qualified experts from a wide array of disciplines and with a diversity of perspectives. The PM NAAQS review fell short in every way.

¹¹ *Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter*, U.S. Environmental Protection Agency (January 2020) – https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf

¹² *Advice from the Independent Particulate Matter Review Panel (formerly EPA CASAC Particulate Matter Review Panel) on EPA’s Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)*, IPMRP (October 22, 2019) – <https://ucs-documents.s3.amazonaws.com/science-and-democracy/IPMRP-FINAL-LETTER-ON-DRAFT-PA-191022.pdf>

The stakes are too high for EPA leadership to finalize its ill-advised proposed decision. Public health hangs in the balance.

In a June 11, 2020 email to all EPA staff, Administrator Wheeler closed with this quote from Nelson Mandela: "If our expectations, if our fondest prayers and dreams are not realized, we should bear in mind that the greatest glory of living lies not in never falling, but in rising every time you fall."¹³ Administrator Wheeler should withdraw the proposed PM NAAQS decision; reconvene CASAC; reappoint the former PM NAAQS Review Panel to its full stature and former role; provide CASAC with any other resources it requests to effectively complete its review; and charge the collective group and EPA staff with reviewing the latest available science, engaging in meaningful discourse and deliberation, developing and reviewing second drafts of the ISA and PA and issuing new final work products – all with an appropriate allotment of time. Finally, the Administrator must give serious consideration to new information to ensure a PM NAAQS proposal that is truly consistent with the Clean Air Act and protective of public health with an adequate margin of safety.

On behalf of NACAA, we thank you for this opportunity to comment on this extremely important issue. If you have questions or would like further information, please contact either of us or Nancy Kruger, Deputy Director of NACAA.

Sincerely,



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George S. (Tad) Aburn, Jr.
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¹³ *Message from the Administrator* (to EPA Employees), Andrew Wheeler, U.S. Environmental Protection Agency (June 11, 2020) – http://www.4cleanair.org/sites/default/files/Documents/EPA_Administrator-email_to_staff-061120.pdf

Recent Causal Particulate Matter Mortality Studies¹⁴

(Full articles have been submitted to the docket separately by the Northeast States for Coordinated Air Use Management and others.)

Recent causality studies not included in the Integrated Science Assessment (ISA) and Policy Assessment (PA)

Abu Awad Y, Q Di, Y Wang, X Choirat, B Coull, A Zanobetti, J Schwartz. 2019. Change in PM_{2.5} exposure and mortality among Medicare recipients. *Environmental Epidemiology* 3:e054. doi: 10.1097/EE9.0000000000000054.

https://journals.lww.com/environepidem/Fulltext/2019/08000/Change_in_PM2_5_exposure_and_mortality_among.2.aspx

We consider the sub-population of Medicare enrollees who moved residence from one ZIP Code to another from 2000 to 2012. We used Cox proportional hazards models stratified on original ZIP Code with inverse probability weights (IPW) to control for individual and ecological confounders at the new ZIP Code. The distribution of covariates appeared to be randomized by change in exposure at the new locations as standardized differences were mostly near zero. Using IPW, per 10 µg/m³ increase in PM_{2.5}, the hazard ratio was 1.21 (95% confidence interval [CI] = 1.20, 1.22) among whites and 1.12 (95% CI = 1.08, 1.15) among blacks. This study provides evidence of likely causal effects at concentrations below current limits of PM_{2.5}.

Bennett JE, H Tamura-Wicks H, RM Parks, RT Burnett, CA Pope 3rd, MJ Bechle, et al. 2019. Particulate matter air pollution and national and county life expectancy loss in the USA: A spatiotemporal analysis. *PLoS Med* 16(7):

e1002856 <https://doi.org/10.1371/journal.pmed.1002856>

We used four Bayesian spatiotemporal models, with different adjustments for other determinants of mortality, to directly estimate mortality and life expectancy loss due to current PM_{2.5} pollution and the benefits of reductions since 1999, nationally and by county.

Carone M, F Dominici, L Sheppard. 2020. In Pursuit of Evidence in Air Pollution Epidemiology, *Epidemiology*: 31(1): 1-6. doi: 10.1097/EDE.0000000000001090.

https://journals.lww.com/epidem/Fulltext/2020/01000/In_Pursuit_of_Evidence_in_Air_Pollution.1.aspx

In our view, causal inference methods should not be used as another opportunity to weaponize science against itself. Policymakers cannot wait for the data, study designs, and analytic tools that will ensure unarguable causal inferences: stalling until perfect evidence arises is irresponsible and does not protect public health.

¹⁴ List compiled by the Northeast States for Coordinated Air Use Management (June 29, 2020)

Corrigan AE, MM Becker, LM Neas, WE Cascio, AG Rappold. 2018. Fine particulate matters: the impact of air quality standards on cardiovascular mortality. *Environ Res* 161:364–69.

<https://doi.org/10.1016/j.envres.2017.11.025>

We examined the change in cardiovascular (CV) mortality rate and the association between change in PM_{2.5} and change in CV-mortality rate before (2000–2004) and after implementation of the 1997 annual PM_{2.5} NAAQS (2005–2010) among U.S. counties. We further examined how the association varied with respect to two factors related to NAAQS compliance: attainment status and design values (DV). We used difference-in-differences and linear regression models, adjusted for sociodemographic confounders.

Danesh Yazdi M, Y Wang, Q Di, A Zanobetti, J Schwartz. 2019. Long-term exposure to PM_{2.5} and ozone and hospital admissions of Medicare participants in the southeast USA. *Environ Int* 130:104879. <https://doi.org/10.1016/j.envint.2019.05.073>

We examined the association between average annual fine particulate matter (PM_{2.5}) and ozone and first hospital admissions of Medicare participants for stroke, chronic obstructive pulmonary disease (COPD), pneumonia, myocardial infarction (MI), lung cancer, and heart failure (HF). Annual average PM_{2.5} and ozone levels were estimated using high-resolution spatio-temporal models. We fit a marginal structural Cox proportional hazards model, using stabilized inverse probability weights (IPWs) to account for the competing risk of death and confounding. Analyses were then repeated after restricting to exposure levels below the current U.S. standards. The results showed that PM_{2.5} was significantly associated with an increased hazard of admissions for all studied outcomes; the highest observed being a 6.1% (95% CI: 5.9%–6.2%) increase in the hazard of admissions with pneumonia for each µg/m³ increase in particulate levels. The hazard of pneumonia increased by 3.0% (95% CI: 2.9%–3.1%) for each ppb increase in the ozone level. Our results reveal a need to regulate long-term ozone exposure, and that associations persist below current PM_{2.5} standards.

Dominici F, C Zigler. 2017. Best practices for gauging evidence of causality in air pollution epidemiology. *American Journal of Epidemiology* 186(12): 1303–1309,

<https://doi.org/10.1093/aje/kwx307>

Using 3 prominent air pollution studies as examples, we review good practices for how to critically evaluate the extent to which an air pollution study provides evidence of causality. We argue that evidence of causality should be gauged by a critical evaluation of design decisions such as 1) what actions or exposure levels are being compared, 2) whether an adequate comparison group was constructed, and 3) how closely these design decisions approximate an idealized randomized study.

Henneman LRF, C Choirat, C Zigler, M Corwin. 2019. Accountability Assessment of Health Improvements in the United States Associated with Reduced Coal Emissions Between 2005 and 2012, *Epidemiology*: July 2019 - Volume 30 - Issue 4 - p 477-485 doi: 10.1097/EDE.0000000000001024,

https://journals.lww.com/epidem/Abstract/2019/07000/Accountability_Assessment_of_Health_Improvements.3.aspx

We associate changes in 10 health outcome rates among approximately 30 million US Medicare beneficiaries with exposure changes between 2005 and 2012 using two difference-in-difference regression approaches designed to mitigate observed and unobserved confounding. Rates per 10,000 person-years of six cardiac and respiratory health outcomes—all cardiovascular disease, chronic obstructive pulmonary disorder, cardiovascular stroke, heart failure, ischemic heart disease, and respiratory tract infections—decreased by between 7.89 and 1.95 per $\mu\text{g}/\text{m}^3$ decrease in $\text{PM}_{2.5}$, with comparable decreases in coal exposure leading to slightly larger rate decreases.

Higbee JD, JS Lefler, RT Burnett, M Ezzati, JD Marshall, S-Y Kim, M Bechle, AL Robinson, CA Pope 3rd. 2020. Estimating long-term pollution exposure effects through inverse probability weighting methods with Cox proportional hazards models. *Environmental Epidemiology* 4(2): e085. doi: 10.1097/EE9.0000000000000085.

https://journals.lww.com/environepidem/FullText/2020/04000/Estimating_long_term_pollution_exposure_effects.5.aspx

Twenty-nine years of data from the National Health Interview Survey was compiled and linked to modeled annual average outdoor $\text{PM}_{2.5}$ concentration and restricted-use mortality data. A series of Cox proportional hazards models, adjusted using inverse probability weights, yielded causal risk estimates of long-term exposure to ambient $\text{PM}_{2.5}$ on all-cause and cardiopulmonary mortality.

Liu C, Chen R, F Sera, AM Vicedo-Cabrera, Y Guo, S Tong, et al. 2019. Ambient particulate air pollution and daily mortality in 652 cities. *New Engl J Med* 381:705-715.

<https://www.nejm.org/doi/10.1056/NEJMoa1817364>

We evaluated the associations of inhalable particulate matter (PM) with an aerodynamic diameter of $10\ \mu\text{m}$ or less (PM_{10}) and fine PM with an aerodynamic diameter of $2.5\ \mu\text{m}$ or less ($\text{PM}_{2.5}$) with daily all-cause, cardiovascular, and respiratory mortality across multiple countries or regions. The pooled concentration-response curves showed a consistent increase in daily mortality with increasing PM concentration, with steeper slopes at lower PM concentrations.

Miles CH, J Schwartz, EJ Tchetgen Tchetgen. 2018. A class of semiparametric tests of treatment effect robust to confounder classical measurement error. *Statistics in Medicine*, 37(24):3403-3416. doi: 10.1002/sim.7852. Epub 2018 Jun 25.

<https://onlinelibrary.wiley.com/doi/abs/10.1002/sim.7852>

We develop a large class of semiparametric test statistics of an exposure causal effect which are completely robust to additive unbiased measurement error of a subset of confounders.

Pope, A, JS Lefler, M Ezzati, JD Higbee, JD Marshall, S-Y Kim, M Bechle, et al. 2019. Mortality risk and fine particulate air pollution in a large, representative cohort of U.S. adults. *Environmental Health Perspectives* 127(7): 077007.

<https://ehp.niehs.nih.gov/doi/10.1289/ehp4438>

Cox proportional hazards models were used to estimate PM_{2.5}–mortality hazard ratios for all-cause and specific causes of death while controlling for individual risk factors and regional and urban versus rural differences. In general, PM_{2.5}–mortality associations were consistently positive for all-cause and cardiopulmonary mortality across key modeling choices and across subgroups of sex, age, race-ethnicity, income, education levels, and geographic regions.

Qiu X, Y Wei, Y Wang, Q Di, T Sofer, J Schwartz. 2020. Inverse probability weighted distributed lag effects of short-term exposure to PM_{2.5} and ozone on CVD hospitalizations in New England Medicare participants - exploring the causal effects. *Environ Research* 182:109095. <https://doi.org/10.1016/j.envres.2019.109095>

Application of causal distributed lag modeling showed harmful effects of short-term PM_{2.5} exposure on CVD hospitalizations in a causal way among elderly population. Each 10 µg/m³ increase in lag0-lag5 cumulative PM_{2.5} exposure on average increased the AMI, CHF, IS hospital admission rate by 4.3%, 3.9% and 2.6% among New England Medicare participants.

Sanders NJ, AI Barreca. MJ Neidell. 2020. Estimating causal effects of particulate matter regulation on mortality. *Epidemiology* 31(2):160-167. doi: 10.1097/EDE.0000000000001153. https://journals.lww.com/epidem/Abstract/2020/03000/Estimating_Causal_Effects_of_Particiate_Matter.2.aspx

Based on estimates from log-linear difference-in-differences models, our results indicate after the CAAA designation for PM_{2.5} in 2005, PM_{2.5} levels decreased 1.59 µg/m³ (95% CI = 1.39, 1.80) and mortality rates among those 65 and older decreased by 0.93% (95% CI = 0.10%, 1.77%) in nonattainment counties, relative to attainment ones. Results are robust to a series of alternate models, including nearest-neighbor matching based on propensity score estimates.

Schwartz JD, Y Wang, I Kloog, M Yitshak-Sade, F Dominici, A Zanobetti. 2018. Estimating the effects of PM 2.5 on life expectancy using causal modeling methods. *Environmental Health Perspectives* 126(12): 127002. <https://ehp.niehs.nih.gov/doi/10.1289/EHP3130>

We derived nonparametric estimates of the distribution of life expectancy as a function of PM_{2.5} using data from 16,965,154 Medicare beneficiaries in the Northeastern and mid-Atlantic region states (129,341,959 person-years of follow-up and 6,334,905 deaths). The estimated mean age at death for a population with an annual average PM_{2.5} exposure of 12 µg/m³ (the 2012 National Ambient Air Quality Standard) was 0.89 years less (95% CI: 0.88, 0.91) than estimated for a counterfactual PM_{2.5} exposure of 7.5 µg/m³.

Schwartz J, K Fong, A Zanobetti. 2018. A national multicity analysis of the causal effect of local pollution, NO₂, and PM_{2.5} on mortality. *Environmental Health Perspectives* 126, (8): 087004. <https://ehp.niehs.nih.gov/doi/10.1289/EHP2732>

We used three methods which, under different assumptions, provide causal marginal estimates of effect: a marginal structural model, an instrumental variable analysis, and a negative exposure control. Causal-modeling techniques, each subject to different assumptions, demonstrated causal effects of locally generated pollutants on daily deaths with effects at concentrations below the current EPA daily PM_{2.5} standard.

Vodonas A, Y Abu Awad, J Schwartz. 2018. The concentration-response between long-term PM_{2.5} exposure and mortality; A meta-regression approach. *Environmental Research* 166:677-689. <https://doi.org/10.1016/j.envres.2018.06.021>

We systematically searched all published cohort studies examining the association between long term exposure to PM_{2.5} and mortality. We applied multivariate linear random effects meta-analysis with random effects for cohort, and study within cohort. Meta-regression techniques were used to test whether study population or analytic characteristics modify the PM_{2.5} mortality association and to estimate the shape of the concentration-response curve.

Ward-Caviness C, AM Weaver, M Buranosky, ER Pfaff, LM Neas, RB Devlin, J Schwartz, Q Di, WE Cascio, D Diaz-Sanchez. 2020. Associations Between Long-Term Fine Particulate Matter Exposure and Mortality in Heart Failure Patients. *Journal of the American Heart Association*. 2020;9. <https://www.ahajournals.org/doi/10.1161/JAHA.119.012517>

We used Cox proportional hazards models to evaluate the association of annual average fine particulate matter (PM_{2.5}) exposure at the time of initial heart failure diagnosis with all-cause mortality, adjusted for age, race, sex, distance to the nearest air pollution monitor, and socioeconomic status indicators. Elevated PM_{2.5} exposures result in substantial years of life lost even at concentrations below current national standards.

Wei Y, Y Wang, X Wu, Q Di, L Shi, P Koutrakis, et al. 2020. Causal effects of air pollution in Massachusetts. *Am J Epidemiol* kwaa098, <https://doi.org/10.1093/aje/kwaa098>

Implementing a generalized propensity score adjustment approach with 3.8 billion person-days of follow-up, we simultaneously assessed causal associations of long- (one-year moving average) and short-term (two-day moving average) PM_{2.5}, O₃, and NO₂ exposures with all-cause mortality on additive scale among Medicare beneficiaries in Massachusetts, 2000–2012. We found long- and short-term PM_{2.5}, O₃, and NO₂ were all associated with increased mortality risk. Mortality associated with long-term PM_{2.5} and O₃ increased substantially at low levels. The findings suggest air pollution was causally associated with mortality, even at levels below national standards.

Wu X, D Braun, MA Kioumourtzoglou, C Choirat, Q Di, F Dominici. 2019. Causal inference in the context of an error prone exposure: air pollution and mortality. *Ann Appl Stat* 13:520-547. doi: 10.1214/18-AOAS1206. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6812524/>
We propose a new approach for estimating causal effects when the exposure is measured with error and confounding adjustment is performed via a generalized propensity score (GPS). Using validation data, we propose a regression calibration (RC)-based adjustment for a continuous error-prone exposure combined with GPS to adjust for confounding (RC-GPS). Under assumptions of noninterference and weak unconfoundedness, using matching we found that exposure to moderate levels of PM_{2.5} ($8 < PM_{2.5} \leq 10 \mu\text{g}/\text{m}^3$) causes a 2.8% (95% CI: 0.6%, 3.6%) increase in all-cause mortality compared to low exposure ($PM_{2.5} \leq 8 \mu\text{g}/\text{m}^3$).

Wu X, D Braun, J Schwartz, MA Kioumourtzoglou, F Dominici. 2020. Evaluating the impact of long-term exposure to fine particulate matter on mortality among the elderly. *Science Advances* 26 Jun 2020: eaba5692. DOI: 10.1126/sciadv.aba5692.
<https://advances.sciencemag.org/content/early/2020/06/26/sciadv.aba5692>
Leveraging 16 years of data—68.5 million Medicare enrollees and 570 million observations—provide strong evidence of the causal link between long-term PM_{2.5} exposure and mortality under a set of assumptions necessary for causal inference. Using five distinct statistical approaches, we found that a decrease of $10 \mu\text{g}/\text{m}^3$ PM_{2.5} leads to a statistically significant 6%–7% decrease in mortality risk. Based on these models, lowering the air quality standard to $10 \mu\text{g}/\text{m}^3$ would save 143,257 lives (95% confidence interval 115,581–170,645) in one decade.

Yitshak-Sade M, R Nethery, Y Abu Awad, F Mealli, F Dominici, I Kloog, et al. 2020. Lowering air pollution levels in Massachusetts may prevent cardiovascular hospital admissions. *J Am Coll Cardiol* 75:2642-2644.
<https://www.sciencedirect.com/science/article/abs/pii/S0735109720347495>
We estimated the number of cause-specific CVD hospital admissions—all CVD, myocardial infarction, ischemic stroke, and congestive heart failure—attributable to high levels of 2-day exposure to PM_{2.5} using a causal modeling approach. We found significant numbers of CVD admissions among the elderly population in Massachusetts that were attributable to short-term exposure to PM_{2.5}.

Yitshak-Sade M, I Kloog, A Zanobetti, JD Schwartz. 2019. Estimating the causal effect of annual PM_{2.5} exposure on mortality rates in the Northeastern and mid-Atlantic states. *Environmental Epidemiology* 3(4): e052.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6693936/>
We obtained records of Medicare beneficiaries 65 years of age or more who reside in the Northeastern or mid-Atlantic states from 2000 to 2013 and followed each participant from the year of enrollment to the last year of follow-up. We estimated the causal effect of annual PM_{2.5} exposure on mortality rates using the difference-in-differences approach in the Poisson survival analysis. We controlled for individual confounders, for spatial differences using dummy variables for each ZIP code and for time trends using a penalized spline of year. The interquartile range (IQR) of the annual PM_{2.5} concentration was $3 \mu\text{g}/\text{m}^3$, and the mean annual PM_{2.5} concentration ranged between 6.5 and $14.5 \mu\text{g}/\text{m}^3$ during the study period. An IQR

incremental increase in PM_{2.5} was associated with a 4.04% increase (95% CI = 3.49%, 4.59%) in mortality rates.

Zigler CM, C Choir, F Dominici. 2018. Impact of National Ambient Air Quality Standards nonattainment designations on particulate pollution and health. *Epidemiology* 29(2):165-172. doi: 10.1097/EE9.0000000000000052.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5792368/>

We employ causal inference methods and a spatial hierarchical regression model to characterize the extent to which a designation of “nonattainment” with the 1997 National Ambient Air Quality Standard for ambient fine particulate matter (PM_{2.5}) in 2005 causally affected ambient PM_{2.5} and health outcomes among over 10 million Medicare beneficiaries in the Eastern US in 2009–2012.

Causality study cited in the ISA, but not in PA

Makar M, J Antonelli, Q Di, D Cutler, J Schwartz, F Dominici. 2017. Estimating the causal effect of fine particulate matter levels on death and hospitalization: are levels below the safety standards harmful? *Epidemiology* 28(5): 627-634. doi: 10.1097/EDE.0000000000000690

[.https://journals.lww.com/epidem/Abstract/2017/09000/Estimating_the_Causal_Effect_of_Low_Levels_of_Fine.1.aspx](https://journals.lww.com/epidem/Abstract/2017/09000/Estimating_the_Causal_Effect_of_Low_Levels_of_Fine.1.aspx)

We constructed a cohort of 32,119 Medicare beneficiaries residing in 5138 US ZIP codes who were interviewed as part of the Medicare Current Beneficiary Survey (MCBS) between 2002 and 2010 and had 1 year of follow-up. We found that increasing exposure to PM_{2.5} from levels lower than 12 µg/m³ to levels higher than 12 µg/m³ is associated with increases in all-cause admission rates of 7% (95% CI = 3%, 10%) and in circulatory admission hazard rates of 6% (95% CI = 2%, 9%). When we restricted analysis to enrollees with exposure always lower than 12 µg/m³, we found that increasing exposure from levels lower than 8 µg/m³ to levels higher than 8 µg/m³ increased all-cause admission hazard rates by 15% (95% CI = 8%, 23%), circulatory by 18% (95% CI = 10%, 27%), and respiratory by 21% (95% CI = 9%, 34%).

Recent causality studies referenced in the final ISA and PA

Schwartz J, M-A Bind, P Koutrakis. 2017. Estimating causal effects of local air pollution on daily deaths: effect of low levels. *Environmental Health Perspectives* 125(1): 23-29.

<https://ehp.niehs.nih.gov/doi/full/10.1289/EHP232>

Using an instrumental variable approach, we developed an instrument for variations in local pollution concentrations that is unlikely to be correlated with other causes of death, and examined its association with daily deaths in the Boston, Massachusetts, area. We also used Granger causality to assess whether omitted variable confounding existed.

Schwartz J, E Austin, M-A Bind, A Zanobetti, P Koutrakis. 2015. Estimating causal associations of fine particles with daily deaths in Boston. *American Journal of Epidemiology* 182(7): 644-650. <https://doi.org/10.1093/aje/kwv101>

Author's response to comments: Schwartz J, P Koutrakis, M-A Bind. 2016. Three authors reply. *American Journal of Epidemiology* 183(6):595-596. <https://doi.org/10.1093/aje/kww024>

We used an instrumental variable approach, including back trajectories as instruments for variations in PM_{2.5} uncorrelated with other predictors of death. We also used propensity score as an alternative causal modeling analysis. We found a causal association of PM_{2.5} with mortality, with a 0.53% (95% confidence interval: 0.09, 0.97) and a 0.50% (95% confidence interval: 0.20, 0.80) increase in daily deaths using the instrumental variable and the propensity score, respectively.

Wang Y, I Kloog, BA Coull, A Kosheleva, Aa Zanobetti, JD Schwartz. 2016. Estimating causal effects of long-term PM_{2.5} exposure on mortality in New Jersey. *Environmental Health Perspectives* 124(8): 1182-1188. <https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.1409671>

We applied a variant of the difference-in-differences approach, which serves to approximate random assignment of exposure across the population and hence estimate a causal effect. Under the assumption of the difference-in-differences approach, we identified a causal effect of long-term PM_{2.5} exposure on mortality that was modified by seasonal temperatures and ecological socioeconomic status.

Wang Y, M Lee, P Liu, L Shi, Z Yu, Y Abu Awad, A Zanobetti, JD Schwartz. (2017). Doubly Robust Additive Hazards Models to Estimate Effects of a Continuous Exposure on Survival. *Epidemiology (Cambridge, Mass.)*, 28(6), 771–779. <https://doi.org/10.1097/EDE.0000000000000742>

The proposed approaches improve the robustness of the additive hazards model and produce a novel additive causal estimate of PM_{2.5} on survival and several additive effect modifications, including social inequality.

