April 6, 2018

Neomi Rao
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Room 9235
725 17th Street NW
Washington, DC 20503

Comments submitted via Regulations.gov

RE: Draft 2017 Report to Congress on the Benefits and Costs of Federal Regulation and Agency Compliance with the Unfunded Mandates Reform Act

Docket ID OMB-OMB-2018-0001

Dear Administrator Rao:

The undersigned public health and medical organizations appreciate the opportunity to comment on the Office of Management and Budget's draft 2017 Report to Congress on the Benefits and Costs of Federal Regulation and Agency Compliance with the Unfunded Mandates Reform Act.

Our organizations support the draft report's clear conclusion that the benefits of air pollution protections greatly outweigh the costs. We call on OMB to continue the current practice of considering all benefits of healthy air protections, including the co-benefits of reducing air pollution, in calculations of the benefits and costs of the rules; we also call on OMB to include benefits from all reductions in particulate matter based on the clear evidence that no threshold exists for harm from exposure to this pollutant.

OMB must continue to consider health benefits from reductions in all pollutants, including co-pollutants, when calculating the benefits and costs of clean air protections.

As the draft report acknowledges, "The consideration of co-benefits, including the co-benefits associated with reduction of particulate matter, is consistent with standard accounting practices and has long been required under OMB Circular A-4." Agencies must assess *all* benefits, direct and indirect, to be achieved by a major regulation.[1]

The Clean Air Act is, at its core, a public health law. To adequately assess whether the law is fulfilling its purpose of achieving healthy air for all to breathe, OMB (and EPA) must continue to calculate as complete a picture as possible of benefits of rules. In the draft report, OMB includes an extended discussion of the various aspects of costs of regulations and how to account for them. Co-benefits, including from reductions in particulate matter (PM), are as critical a component to the analysis as any of these types of costs.

Particulate matter is deadly.

Breathing particulate matter day in and day out can be deadly, as landmark studies in the 1990s conclusively showed[2] and as other studies confirmed.[3] Recent research has confirmed that long-term

exposure to particulate matter still kills, even with the declining levels in the U.S. since 2000 [4] and even in areas, such as New England, that currently meet the national ambient standards for annual particulate matter.[5]

There is no threshold of harm for particulate matter.

In the draft report, OMB suggests that six assumptions about particulate matter inject uncertainty into measuring the benefits and costs of clean air protections. Included on this list are questions about whether and to what extent PM is causally associated with premature death at lower concentrations. Our organizations find no safe threshold for PM based on the scientific evidence, and strongly oppose methods of calculation that would assume a safe level of PM exposure.

For example, in its proposed repeal of the Clean Power Plan, EPA indicated that it may ignore any health benefits that would accrue at places where prevailing levels now meet the annual national ambient air quality standard (NAAQS) for $PM_{2.5}$.[6] This approach would disregard more recent scientific evidence showing effects at exposures below those benchmarks.[7, 8, 9] These studies cited above indicate a benefit to health from reductions in $PM_{2.5}$ down to very low air pollution levels. EPA's own scientific assessments have demonstrated that significant health benefits can be gained by achieving ambient levels below the NAAQS.[10]

The World Health Organization has stated that "[s]mall particulate pollution have [sic] health impacts even at very low concentrations – indeed no threshold has been identified below which no damage to health is observed."[11]

Other independent reviews have also found that no threshold exists. In 2010, the American Heart Association updated its Scientific Statement on Particulate Matter Air Pollution and Cardiovascular Disease to state that the evidence supported measures to reduce PM because of the presence of no threshold of harm:

> "[W]e agree with the concept and continue to support measures based on scientific evidence, such as the US EPA NAAQS, that seek to control PM levels to protect the public health. Because the evidence reviewed supports that there is no safe threshold, it appears that public health benefits would accrue from lowering PM2.5 concentrations even below present day annual (15 µg/m3) and 24-hour (35 µg/m3) NAAQS, if feasible, to optimally protect the most susceptible populations."[12]

The Health Effects Subcommittee (HES) of the EPA's independent Scientific Advisory Board reviewed this issue in 2010 when EPA was assessing the benefits and costs of the Clean Air Act as required under Section 182. This panel also concluded that the evidence supported modeling that included no threshold:

> "The HES fully supports EPA's decision to use a no-threshold model to estimate mortality reductions. This decision is supported by the data, which are quite consistent in showing effects down to the lowest measured levels. Analyses of cohorts using data from more recent years, during which time PM concentrations have fallen, continue to report strong associations with mortality. Therefore, there is no evidence to support a truncation of the CRF [Concentration Response Function]." [13]

There is no scientific justification to include a threshold to discount the benefits from the implementation of the Clean Air Act. OMB must continue to follow the science when counting the benefits of reduced PM exposure.

Health benefits of air pollution rules are likely undercounted.

The draft report rightly points out that benefits are not always quantifiable, including in the case of reductions in hazardous air pollutants such as mercury. The result is that health benefits of air pollution reductions are likely greater than quantifiable estimates. EPA's use of established BenMAP modeling means that its predictions focus on findings from certain studies looking at specific outcomes. The BenMAP model cannot estimate the impact on other, also demonstrated, benefits. For example, although the World Health Organization has determined that particulate matter causes lung cancer, the model currently lacks appropriate capacity to estimate how many fewer cases of lung cancer would occur in 2030 with the reductions in particulate matter.[14]

The Administration's stated focus on deregulation fails to prioritize Americans' health.

Our organizations are deeply concerned by the potential impacts of Executive Orders 13771 and 13777 and the overall emphasis on deregulation indicated in the draft report. EO 13771 establishes an arbitrary requirement that for every new regulation issued, the agency must identify two to be repealed. This directive could put EPA and other agencies in the absurd position of having to sacrifice existing public health protections before being able to set a new one.

Further, EO 13771 directed agencies to ensure that the total incremental *cost* of all new regulations in 2017 equaled zero, without consideration for the total *benefits.* Directing agencies to ignore benefits essentially ensures that no new clean air protections will be promulgated, regardless of the urgent need to reduce pollution and the tremendous benefits that can be achieved by doing so.

The nation has made great progress toward ensuring healthy air to breathe for all Americans by implementing and enforcing protections under the Clean Air Act. However, more work remains to ensure that everyone, including at-risk populations like children and people with lung disease, is protected from suffering asthma attacks, hospitalizations, or premature deaths due to air pollution. Arbitrarily encouraging or requiring federal agencies to repeal existing rules and avoid setting new health-based protections threatens to halt or even reverse the progress the nation has made.

Sincerely,

Allergy & Asthma Network
Alliance of Nurses for Healthy Environments
American Lung Association
American Public Health Association
American Thoracic Society
Children's Environmental Health Network
Health Care Without Harm
National Environmental Health Association
Trust for America's Health

[1] E.O. No. 13,563 §1, 76 Fed. Reg. 3821 (Jan. 21, 2011); E.O. No. 12,866 6(a)(3)(C), 58 Fed. Reg. 541,735, 51,741 (Oct. 4, 1993); O.M.B. Circular A-4 at 26 (2003).

[2] Dockery DW, Pope CA III, Xu X, Spengler JD, Ware JH, Fay ME, Ferris BG, Speizer FE. An association between air pollution and mortality in six U.S. cities. *N Engl J Med.* 1993; 329: 1753-1759. Pope CA, Thun MJ, Namboodiri MM, Dockery DW, Evans JS, Speizer FE, Heath CW. Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. *Am J Respir Crit Care Med.* 1995; 151: 669-674.

[3] Zanobetti A, Schwartz J. The effect of fine and coarse particulate air pollution on mortality: A national analysis. *Environ Health Perspect*. 2009; 117: 1-40 2009; Krewski D; Jerrett M; Burnett RT; Ma R; Hughes E; Shi Y; Turner MC; Pope AC III; Thurston G; Calle EE; Thun MJ. *Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality.* Report Nr. 140 (Cambridge, MA: Health Effects Institute, 2009); Franklin M, Zeka A, Schwartz J. Association between $PM_{2.5}$ and all-cause and specific cause mortality in 27 U.S. communities. *J Expo Sci Environ Epidemiol*. 2007; 18: 1005-1011; Lepeule et al, 2012; Pope CA III, Burnett RT, Thun MJ, Calle EE, Krewski D, Ito K, Thurston GD. Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. *JAMA.* 2002; 287(9): 1132-1141.

[4] Thurston GD, Ahn J, Cromar KR, Shao Y, Reynolds H, et al. Ambient particulate matter air pollution exposure and mortality in the NIH-AARP Diet and Health Cohort. *Environ Health Perspect*. 2015 Advanced Publication; Lepeule J, Laden F, Douglas Dockery D, and Schwartz J. Chronic exposure to fine particles and mortality: An extended follow-up of the Harvard Six Cities Study from 1974 to 2009. *Environ Health Perspect*. 2012; 120: 965–970.

[5] Shi, et al., 2016.

[6] U.S. EPA. RIA, 2017, Table 1-7 and Table 1-8.

[7] Thurston GD, Ahn J, Cromar K, Shao Y, Reynolds H, Jerrett M, Lim C, Shanley R, Park Y, Hayes RB. (2016) Ambient Particulate Matter Air Pollution Exposure and Mortality in the NIH-AARP Diet and Health Cohort. *Environ Health Perspect*. 2016 Apr;124(4):484-90.

[8] Crouse DL, Peters PA, van Donkelaar A, Goldberg MS, Villeneuve PJ, Brion O, Khan S, Atari DO, Jerrett M, Pope CA, Brauer M, Brook JR, Martin RV, Stieb D, Burnett RT. (2012). Risk of Nonaccidental and Cardiovascular Mortality in Relation to Long-term Exposure to Low Concentrations of Fine Particulate Matter: A Canadian National Level Cohort Study. *Environ Health Perspect*. 2012 May;120(5):708-14.

[9] Di Q, Wang Y, Zanobetti A, Wang Y, Koutrakis P, Choirat C, Dominici F, Schwartz JD. Air Pollution and Mortality in the Medicare Population. *N Engl J Med*. 2017 Jun 29;376(26):2513-2522.

[10] 2012 PM NAAQS RIA at ES-14.

[11] World Health Organization (WHO). 2016. Ambient (Outdoor) Air Quality and Health. WHO Fact Sheet. Geneva, Switzerland. .**http://www.who.int/mediacentre/factsheets/fs313/en/**

[12] Brook RD, Rajagopalan S, Pope CA 3rd, Brook JR, et al; on behalf of the American Heart Association Council on Epidemiology and Prevention, Council on the Kidney in Cardiovascular Disease, and Council on Nutrition, Physical Activity and Metabolism. 2010. "Particulate matter air pollution and cardiovascular disease: an update to the scientific statement from the American Heart Association." *Circulation*. 121: 2331-2378.

[13] U.S. Environmental Protection Agency - Science Advisory Board (U.S. EPA-SAB). 2010. Review of EPA's DRAFT Health Benefits of the Second Section 812 Prospective Study of the Clean Air Act. EPA-COUNCIL-10-001. June. Accessed at https://yosemite.epa.gov/sab/sabproduct.nsf/f697818d4467059f8525724100810c37/72D4EFA39E48CDB28525774500738776/$File/EPA-COUNCIL-10-001-unsigned.pdf.

[14] World Health Organization International Agency for Research on Cancer. *IARC Monograph on the Evaluation of Carcinogenic Risks to Humans.* Volume 109, Outdoor Air Pollution. Lyon: IARC (in Press).