Congress of the United States
Washington, DC 20515

March 4, 2013

The Honorable Gina McCarthy
Assistant Administrator, Office of Air and Radiation
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Assistant Administrator McCarthy:

As the Administration pushes to propose and finalize a litany of costly new air quality rules in the coming months, we write to highlight serious concerns regarding scientific integrity and transparency at the Environmental Protection Agency (EPA). EPA has continually refused to make public the basic scientific data underlying virtually all of the Agency's claimed benefits from new Clean Air Act (CAA) rules. Everyone agrees on the importance of clean air, but EPA needs to release the secret data they use in formulating new rules. We also write regarding the lack of openness for critical elements of EPA's upcoming review of National Ambient Air Quality Standards (NAAQS) for ozone.

As outlined below, you and other high-ranking Administration officials have repeatedly backtracked and reneged on promises to Members of Congress to make the scientific information that underpins the Agency's basic associations between air quality and mortality available to the public and independent scientists over the last year and a half. Not only do these assumed relationships provide the scientific building blocks for virtually all air quality regulations that you have pursued during your tenure at the Office of Air and Radiation, they also provide a disproportionately significant role in claimed regulatory benefits across the federal government. This troubling reliance on secret data belies the oft-repeated claims that this is the most transparent Administration in history and that you will restore scientific integrity in government decision making. This disconnect is even more clear in light of last week's White House memorandum reiterating that "[t]he Administration is committed to ensuring that… the direct results of federally funded scientific research are made available to and useful for the public, industry, and the scientific community."[1]

As has been noted in multiple communications from Congress, federally-funded analyses of two well-known data sets – the "Cancer Prevention Study" and the "Harvard Six Cities Study" – are the basis for nearly all health and benefit claims from CAA rulemaking in this Administration. Beyond EPA's reliance on these data sets, this science also provides a disproportionate share of overall federal regulatory benefit claims. As the White House Office of Information and Regulatory Affairs (OIRA) noted in their most recent report to Congress, nearly all of EPA's claimed benefits – which represent between 60 and 81 percent of the

[1] http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

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estimated benefits for the whole federal government - are attributable to fine particulate matter ($PM_{2.5}$) – health associations derived from these two data sets.[2]

In other words, this secret data is the lynchpin for a majority of the regulatory benefit claims made by this Administration for the entire federal regulatory enterprise. When you and the Agency make the claim that the CAA will generate $2.0 trillion in benefits through 2020 and that CAA benefits exceed costs by a ratio of 30-to-1, these undisclosed data are the origin of 85 percent these benefits.[3] The recently-finalized NAAQS for $PM_{2.5}$ depended on this secret data for more than 90 percent (final rule)[4] and 98 percent (proposed rule)[5] of the total monetized benefits.

Despite the obvious importance, you and other Administration officials have repeatedly failed to respond to Congressional requests to make the underlying data publicly available. When any information has been provided, it contains significant gaps that make full replication and validation of the studies' original results impossible (not to mention independent re-analysis).[6] In September of 2011, you committed to providing all underlying $PM_{2.5}$-mortality data in order for it to be independently reviewed[7] and on November 30, 2011, you pledged in a letter to take action "...as soon as possible to provide you with any data and analysis produced with EPA funds...."[8] The head of OIRA[9] and the President's Science Advisor[10] made similar promises. Despite these pledges for public access to this critical information and specific Congressional demands prior to your Agency finalizing the Mercury and Air Toxics Standards in December 2011[11] and the final $PM_{2.5}$ NAAQS in December 2012,[12] no meaningful underlying data has been released. This is unacceptable.

The need for data availability in this important area of regulatory science has been underlined by recent developments in EPA's forthcoming review of ozone NAAQS.[13] On

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[2] OIRA, *Draft 2012 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, March 2012, http://www.whitehouse.gov/sites/default/files/omb/oira/draft_2012_cost_benefit_report.pdf, pg. 15.

[3] EPA, *The Benefits and Costs of the Clean Air Act from 1990 to 2020*, March 2011, http://www.epa.gov/oar/sect812/feb11/fullreport.pdf, 7-3 to 7-5.

[4] http://www.epa.gov/ttnecas1/regdata/RIAs/finalria.pdf.

[5] http://www.epa.gov/ttnecas1/regdata/RIAs/PMRIACombinedFile_Bookmarked.pdf.

[6] Information provided by EPA in June of 2012 has been determined by air quality experts to be inadequate for re-analysis. See http://science.house.gov/letters-niss-and-tceq-chairman-harris.

[7] *Out of Thin Air: EPA's Cross-State Air Pollution Rule*, Hearing before the Committee on Science, Space, and Technology, September 15, 2011, http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg70585/pdf/CHRG-112hhrg70585.pdf, pg. 58-60.

[8] http://science.house.gov/epa-assistant-adminitrator-mccarthy-chairman-harris.

[9] http://science.house.gov/letter-cass-sunstein-chairman-harris.

[10] *An Overview of the Administration's Federal Research and Development Budget for Fiscal Year 2013*, Hearing before the Committee on Science, Space, and Technology, February 17, 2012, http://science.house.gov/hearing/full-committee-hearing-overview-administration%E2%80%99s-federal-research-and-development-budget.

[11] http://science.house.gov/letter/letter-administrator-sunstein.

[12] http://science.house.gov/letter/science-committee-letter-jackson-holdren-and-bershteyn.

[13] *See* Letter from Senator David Vitter and Senator James Inhofe to Hon. Lisa Jackson, Adm'r, Envtl. Prot. Agency (June 30, 2011); *See also* Statement from President Barack Obama, *Statement by the President on the Ozone National Ambient Air Quality Standards* (Sept. 2, 2011) *available at*

Friday, February 15, 2013, EPA released its final Integrated Science Assessment (ISA) that evaluates and synthesizes "the most policy-relevant science" on ozone to support EPA's upcoming review of NAAQS for ozone. The 1200- page document includes an important new finding that long-term exposure to ozone is "suggestive" of a causal relationship with mortality. This conclusion differs significantly from the 2006 review where EPA and CASAC concluded that the evidence supporting mortality was not "suggestive."

The new "suggestive" conclusion will allow EPA to develop highly theoretical benefit estimates for reducing ozone that will dwarf the Agency's previous estimates. With this new finding, EPA may be able to claim that the benefits of further reductions in ozone will exceed the $90 billion per year in costs that EPA estimates could result from further regulation. Given the significant costs associated with the ozone standard, it is very important that the Agency's benefit estimates are well-grounded in the science.

We were surprised after further investigation to find that the basis for EPA's decision to change its conclusion to "suggestive" of a causal relationship was one new long-term cohort study, Jerrett 2009.[14] In relying primarily on this one long-term cohort study, EPA seemingly ignored 11 other studies[15] involving seven different cohorts that show no significant association. In fact, close scrutiny of the Jerrett 2009 study shows that EPA relies on only a single positive result *within* the study and ignores four other results within the study that either fail to show a positive association or show a statistically negative association. Furthermore, in evaluating this one positive result from Jerrett 2009, EPA ignores the unexplained lack of a statistically significant association reported in four of seven regions examined (representing over two-thirds of the U.S. population), including regions with very high ozone levels. Instead, EPA states in its draft *Risk and Exposure Assessment for Ozone* that it plans to rely on this single "U.S. national" result that, in essence, averages the results of the seven regions to quantify respiratory mortality, despite its uncertainty and questionable validity. Thus, not only is EPA selectively relying on the one positive study among many other non-positive long-term cohort studies, but the Agency is also selectively picking the result *within* the study that best supports the most extreme case of the potential effect of long-term exposure to ozone.

Heightening our concern over this lack of an objective review of the data is the fact that the Jerrett 2009 study again relies on one of the same secret databases used for decades by EPA to support the mortality $PM_{2.5}$ benefit estimates. This is particularly egregious, as the Director of

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http://www.whitehouse.gov/the-press-office/2011/09/02/statement-president-ozone-national-ambient-air-quality-standards

[14] Michael Jerrett et al., "Long-Term Ozone Exposure and Mortality," *New England Journal of Medicine*, 360 (2009). The study was funded in part by the National Institute of Environmental Health Sciences (grant number ES00260 to the New York University School of Medicine.) While EPA references a second study (Zanobetti and Schwartz 2011) that reports a positive association, the study fails to control for the confounding role of other cardiovascular risk factors, such as smoking or diet, and other possible air pollutants, such as exposure to PM. The study results also raise questions because they appear to mimic regional differences in cardiovascular death rates.

[15] Three previous analyses with ACS cohort were inconclusive (Pope 1995 and 2002, Krewski 2000); a study with the Harvard Six Cities Study cohort reports no association (Dockery et al. 1993); 3 updates with the AHSMOG cohort were negative (Beeson 1998, Abbey 1999, Chen 2005); a study using the Women's Health Initiative cohort reports no association (Miller 2007) ; the latest update with the Veterans Affairs cohort reports no association (Lipfert 2006); a new study in a Brisbane Australia cohort reports no association (Wang 2009); a study in Los Angeles reports no association (Jerrett 2005) .

the National Center for Environmental Assessment, which develops the ISA, recommended in 2009 that "[s]tudies used in the formulation of regulation should be subject to data access requirements equivalent under the Data Access Act (Shelby Amendment) and its implementing circular regardless of who funded the study."[16] In choosing to rely on this study, EPA also ignores the clear admonition from the National Research Council in 2004 that further follow-ups of these cohorts studies, such as Jerrett 2009, "will have little use for decisionmaking" due to the fact the "cohorts were established decades ago, and some critical data items, including residence history and potential confounding and modifying factors, have not been comprehensively updated."[17] The Jerrett 2009 study fails to update any of the key ecological or individual risk factors obtained from the 1980 U.S. census data and 1982 individual surveys. The idea that these factors have not changed significantly in 30 years defies common sense.

We request that you take immediate steps to obtain and release the Jerrett 2009 data before EPA proposes the ozone NAAQS so the public will have its rightful opportunity to comment. We also request that you refrain from relying on the Jerrett 2009 study in reviewing the ozone NAAQS unless the full data set is released and the authors have updated the cohort related data in accordance with the NRC's 2004 recommendation.

In this same vein and reiterating previous Congressional requests for the underlying data supporting the $PM_{2.5}$ mortality estimates, we again ask that you take action to obtain and release the data supporting the most recent $PM_{2.5}$ long-term cohort studies that EPA cited in the December 14, 2012, final NAAQS for $PM_{2.5}$. These include:

- The following long-term cohort studies relying on the Cancer Prevention Study data: (1) Daniel Krewski et al., "Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality," Health Effects Institute Research Report, 140 (2009); (2) C. Arden Pope et al., "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution," *Journal of the American Medical Association*, 287, no. 9 (2002), (funded by the National Institute of Environmental Health Sciences (NIEHS)); and (3) Pope et al., "Fine-Particulate Air Pollution and Life Expectancy in the United States," *New England Journal of Medicine*, 360 (2009), (funded by EPA, NIEHS, and Centers for Disease Control and Prevention); and

- The following long-term cohort studies that rely on the Harvard Six Cities study: (1) Krewski et al., "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, Special Report to the Health Effects Institute (2000); (2) Francine Laden et al., "Reduction in Fine Particulate Air Pollution and Mortality," *American Journal of Respiratory and Critical Care Medicine*, 173 (2006), (funded by NIEHS); (3) Johanna Lepeule et al., "Chronic Exposure to Fine Particles and Mortality: An Extended Follow-up of the Harvard Six Cities Study from 1974 to 2009," *Environmental Health Perspectives* (in press), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404667/pdf/ehp.1104660.pdf (funded by

[16] Bipartisan Policy Center Science for Policy Project, Improving the Use of Science in Regulatory Policy, August 5, 2009, http://bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf.
[17] National Research Council, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress* (2004), Board on Environmental Studies and Toxicology (BEST), pg. 135.

EPA and NIEHS), which has 11 additional years of follow-up of the Harvard Six Cities study.

The EPA's new CAA regulations are expected to be some of the most costly rules the federal government has ever issued. Relying on secret data to support these rules is not acceptable. The public and outside scientists must be able to independently verify the EPA's claims, especially when the results are contradicted by so many other studies.

We thank you for your prompt attention to this important issue and we look forward to your response by March 18, 2013. Please contact Clint Woods with the Committee on Science, Space, and Technology at 202.226.2179 and Margaret Caravelli with the Committee on Environment and Public Works at 202.224.6176 if you have any further questions concerning this request.

Sincerely,

David Vitter
Ranking Member
Environment and Public Works

Lamar Smith
Chairman
Science, Space, and Technology

cc: Rep. Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology
Mr. Bob Perciasepe, Acting EPA Administrator
Dr. Glenn Paulson, Science Advisor to the EPA Administrator
Dr. Ken Olden, NCEA Director
Dr. John Holdren, Director, OSTP
Mr. Boris Bershteyn, Acting Administrator, OIRA

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