

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371

www.science.house.gov

July 22, 2013

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Administrator McCarthy,

The House Committee on Science, Space and Technology has repeatedly requested from the Environmental Protection Agency (EPA) the research data that supports the health benefit claims that justify virtually every Clean Air Act regulation proposed and finalized by the Obama Administration. Despite a commitment you made in testimony before this Committee more than 20 months ago, and multiple requests since that time, EPA has failed to provide the information in a manner that would allow for independent scientific verification.

Given the central role of these publically-funded analyses in providing justification for major, costly EPA regulations, it is imperative that this information be open and transparent. As one example, EPA's proposed limits on ozone are expected to be some of the most costly regulations the federal government has ever issued. In the Agency's first assessment to support these regulations, EPA cited studies based upon these hidden data sets more than a thousand times. The American people are going to be forced to foot the bill. They have a right to know whether EPA's new rules are based on sound science or a partisan agenda.

Recent claims by the Agency that it is working to obtain the data from certain academic institutions ring hollow, given the years of delay and excuses. With regard to data produced from federal grants or awards, EPA's actions are in direct conflict with Administration policy. White House guidelines¹ clearly state: "The Federal Government has the right to... Obtain, reproduce, publish or otherwise use" data from taxpayer-funded analyses, especially those used to justify regulations.

¹ OMB Circular A-110.36(c)

The Agency's failure to comply with repeated Congressional requests shows a blatant disregard for Administration policy and President Obama's promise of transparency. The EPA's actions – or inactions – obstruct the ability of Congress to provide effective oversight of costly regulations on behalf of the American people.

If EPA has nothing to hide, why not provide this information to Congress and the American people? We are concerned that EPA's reluctance to respond to Congressional requests or to obtain and assess the data to assure the legitimacy of claimed benefits may reflect weaknesses in the studies. This concern is accentuated by the fact that these analyses are inconsistent with studies based on more recent information.

The National Academy of Sciences has stated that these analyses have "little use for decisionmaking." However, EPA continues to rely on these 30-year-old studies, ignoring years of changes that impact the health of the surveyed population. This practice borders on scientific misconduct. The need for independent review and verification is even more apparent considering Agency claims that the benefits of its clean air rules outweigh the costs by a ratio of 30-to-1.² The fact that the White House uses these studies to justify up to 80 percent of the benefits of regulations promulgated across the entire federal government³ strains credulity and reflects a weakness at the core of how your Agency conducts and oversees scientific inquiry.

The Committee has been more than patient in its request. Your September 15, 2011, commitment was followed by a letter from this Committee dated September 22, 2011. When the Agency failed to live up to its commitment, subsequent requests for the information were sent to EPA and other Administration officials including: November 15, 2011, and December 12, 2011 letters to White House Office of Information and Regulatory Affairs (OIRA) Director Cass Sunstein; a December 13, 2012, letter to EPA Administrator Lisa Jackson, the President's Science Advisor, John Holdren, and Acting OIRA Director Boris Bershteyn; a March 4, 2013, letter to Assistant Administrator McCarthy; and, a June 12, 2013, letter to Acting Administrator Bob Perciasepe (see enclosures).

Several of these letters also included requests that the Administration respond to this Committee's concerns before finalizing its costly regulations. These requests were ignored. The Committee also recently invited the Agency to testify at a hearing on these matters. That request was denied.

In our June 12, 2013, letter, the Committee made two requests of EPA: 1) stop relying upon and citing this 30-year-old undisclosed data in its rulemaking process; and 2) obtain and release the data. EPA has not complied with either request.

In light of EPA's steadfast refusal to cooperate, we are writing to inform you that failure to provide the requested documents will result in a subpoena to ensure disclosure.

² EPA, *The Benefits and Costs of the Clean Air Act from 1990 to 2020*, March, 2011

³ OIRA, *Draft 2013 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, April 2013.

Please provide all original data and analysis that has been requested and commit to refrain from further using this data to justify regulations until it has been made accessible in a manner sufficient for independent re-analysis. This information must be provided by 10:00 am on July 31, 2013 to avoid formal Committee action.

Thank you for your prompt attention to this matter. If you have any questions, please contact Todd Johnston or Clint Woods of my staff at (202) 225-6371.



Rep. Lamar Smith
Chairman
Committee on Science, Space, and Technology



Rep. Chris Stewart
Chairman
Subcommittee on Environment

cc: Rep. Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology
Mr. Bob Perciasepe, Deputy EPA Administrator
Dr. Glenn Paulson, Science Advisor to the EPA Administrator
Dr. John Holdren, Director, OSTP
Mr. Howard Shelanski, Administrator, OIRA

Enclosures: Committee Correspondence

Congress of the United States House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

June 12, 2013

The Honorable Robert Perciasepe
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Acting Administrator Perciasepe:

On March 4, 2013, a letter was sent from this Committee to Gina McCarthy, Assistant Administrator for the Office of Air and Radiation at the Environmental Protection Agency (EPA), requesting that EPA take immediate steps in accordance with current law and Administration policy to obtain and release the underlying research data from specific PM_{2.5} studies that EPA has relied on to support multiple rulemakings. In this same letter, we also requested that EPA obtain and immediately release the underlying data supporting a critical ozone study (Jerrett 2009) that relies on these same datasets and that EPA has referenced 18 times in its Integrated Scientific Assessment (ISA) in preparation for the upcoming ozone rulemaking.

The Agency's April 10, 2013, response to that letter acknowledges that the previously released information is "not sufficient" to allow replication of the study results. In the three months that have passed since our most recent request, we have yet to receive any commitment from the Agency that, in the case of Jerrett 2009, it will discontinue the use of this data or in the case of the most recent PM_{2.5} long term cohort studies, immediately obtain and release that data. In May, EPA proposed new Tier III Vehicle Emission and Fuel Standards that depend on these same datasets to provide a majority of the claimed benefits. EPA's response also shows a general lack of understanding of Administration policy and the nature of the requested data:

- While EPA is correct in noting that the responses to the personal interview questionnaires collected 30 years ago include confidential information, the electronic input and output files used in the actual analysis for these studies are unlikely to contain confidential data. This was confirmed by Health Effects Institute (HEI) in 2000 when it conducted a reanalysis of the studies.¹

¹ Krewski et al. 2000, *Part I: Replication and Validation*; (p 42). The HEI Report confirms that an electronic data file ("Mort6C.file") containing a copy of the Harvard Six cities database "did not contain any information that could be used to identify the individual study participants."

- EPA's proffered excuse for not obtaining the data because the studies "received funding from a number of different sources, including the EPA, other federal agencies, and non-federal sources" conflicts with OMB policy which clearly states that funding Agencies retain the right to obtain all data developed from mixed funding sources.²
- EPA's response also incorrectly states that NDI data cannot be released, ignoring the fact referenced in its own attachment on page 3 that Harvard University had released (and EPA transmitted) coded NDI data in 2011.

We also remain deeply concerned that EPA continues to rely on this data, even while the National Research Council has cautioned against using them in its 2004 report.³ In that report, the NRC concluded that updates of these two cohorts alone would be of "little use for decisionmaking" due to the outdated nature of the information and dwindling relevance to today's population and risk profile. The full NRC discussion on this point is attached for review. For example, since the time the data were initially collected, smoking rates have declined from 40 to 20 percent, while education levels (used as a surrogate for socioeconomic status in air pollution studies) have increased. A number of other factors affecting the surveyed population's health status have also changed, including improved treatments for hypertension and cholesterol that have contributed to reductions in the cardiovascular mortality rates in the U.S. Because the American Cancer Society and Harvard Six City cohorts have not been updated, there is a clear concern that the health benefits attributed to reduced PM_{2.5} and ozone levels over the past 30 years could in fact be incorrect due to other changes affecting the health status of the surveyed individuals that may have a much greater bearing.

EPA's recent clarification about which studies it relies upon fails to acknowledge this central point. Indeed, the fact that EPA has chosen not to rely on two studies using this outdated cohort information (Pope 2002 and Laden 2006) in the Regulatory Impact Assessment for the Tier III rulemaking but instead to use Krewski 2009 and Lepeule 2012 does not address this weakness but rather exacerbates the problem since both of these more recent studies use more recent and lower air pollution data but continue to rely on the same outdated cohort information.

Throughout this process, EPA has responded to our questions in a cavalier manner, hoping perhaps we were not reading the NRC reports carefully or were simply unaware of the law or guidance governing data access. The opposite is true. Our examination has underscored two central points:

- EPA must immediately refrain from relying on and citing studies that continue to use 30-year old cohort data. This includes all PM_{2.5} and ozone studies that rely on the American Cancer Society and the Harvard Six Cities cohorts. The NRC's main criticism in 2004 is even more relevant today, nine years later.

² *Federal Register*, Vol. 64, No. 195 (Friday, October 8, 1999). See section G: Projects Funded From Multiple Sources.

³ National Research Council, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress* (2004), Board on Environmental Studies and Toxicology (BEST), p 135.


- EPA must immediately obtain all of the underlying research data supporting the previously requested PM_{2.5} and ozone studies, and release all non-confidential data in accordance with current law and Administration guidance. EPA must also take steps to determine whether confidential data sets can be de-identified to help ensure transparency in its decision making.

Current law and OMB guidance are clear in requiring EPA to obtain and release the data. To confirm there are no confidential data in the electronic input and output files and whether de-identification procedures can be applied, EPA must first obtain the data – which it openly admits to not having. The EPA's continued refusal to comply with this Committee's oversight request undermines the credibility of its regulations.

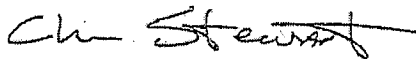
EPA officials should justify their agenda through an open and transparent process that is based on good science, if they can. EPA has projected that its upcoming ozone standard will be the most costly environmental regulation in U.S. history. Working families will bear these costs. They have a right to know what scientific data supports EPA's claims.

EPA must respect the law and the public's right to this information. In order to avoid formal action by this Committee to obtain the requested information, we urge you to comply with our request by July 8, 2013.

Sincerely,



Lamar Smith
Chairman
House Science, Space and Technology



Chris Stewart
Chairman
Environment Subcommittee

cc: Rep. Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology
Ms. Gina McCarthy, Assistant EPA Administrator
Dr. Glenn Paulson, Science Advisor to the EPA Administrator
Dr. Ken Olden, NCEA Director
Dr. John Holdren, Director, OSTP
Ms. Sylvia Mathews Burwell, Director, Office of Management and Budget

References

- Jerrett et al. "Spatial analysis of air pollution and mortality in Los Angeles." *Epidemiology* 16(2005): 727-736.
- Jerrett et al. "Long-term ozone exposure and mortality." *N Engl Med* 360 (2009): 1085-1095
- 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, Cambridge MA. (2000) <http://pubs.healtheffects.org/getfile.php?u=274>
- Krewski et al. "Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality." *HEI Research Report, 140*, Health Effects Institute, (2009) Boston, MA
- Laden et al. "Reduction in Fine Particulate Air Pollution and Mortality." *American Journal of Respiratory and Critical Care Medicine*. 173 (2006): 667-672
- Lipfert et al. "PM_{2.5} constituents and related air quality variables as predictors of survival in a cohort of U.S. military veterans." *Inhal. Toxicol.* 18 (2006): 41-72.
- Lepeule et al. "Chronic Exposure to Fine Particles and Mortality; An Extended Follow-Up of the Harvard Six Cities Study from 1974 to 2009." *Environ Health Perspect.* Jul; 120(7) (2012): 965-70
- Pope et al. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution." *Journal of the American Medical Association* 287 (2002): 1132-1141.
- Pope et al. "Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults." *Am. J. Respir. Crit. Care Med* 151 (1995): 669-674.

Attachment A:

Excerpt from the National Research Council's 2004 report, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress*

INVESTIGATING THE HEALTH EFFECTS OF LONG-TERM EXPOSURE TO AIR POLLUTION

Epidemiological Approaches

The striking findings of the Harvard Six Cities Study (Dockery et al. 1993), which linked chronic exposure to increased mortality, provided a strong impetus for reevaluating the PM NAAQS, particularly after their confirmation in the 1995 publication based in the American Cancer Society's Cancer Prevention Study 2 (CPS 2) (Pope et al. 1995). The findings on increased mortality associated with longer-term exposures to higher concentrations of particles suggested that the associations observed in the time-series studies did not reflect only a slight advancement of the timing of death for frail individuals. The findings of the two studies were confirmed with an extensive reanalysis (Krewski et al. 2000) and on further follow-up of the CPS 2 cohort (Pope et al. 2002). Findings from several other cohort studies have also been reported (Abbey et al. 1999; Lipfert et al. 2000; Hoek et al. 2002). Although these cohorts have provided critical evidence for long-term effects, evidence from further follow-up of these two U.S. cohorts alone will have little use for decisionmaking. 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. Consequently, an increasing degree of exposure misclassification can be anticipated as the participants move from their original residences. And, most important, characterization of current air quality cannot recreate the complex air environments in which the individuals and populations lived and worked in the many years for which data are not available. Long-term studies are likely to remain central, however, in assessing the public health burden caused by air pollution. For quantitative risk assessment and cost-benefit analysis, estimates of the disease burden associated with exposure to particles are needed. These estimates could come from a new generation of studies with more complete information on short- and long-term exposures to PM, its components, and exposures to other pollutants.

Recognizing both the limitations of these studies and the need for ongoing information on long-term exposure to air pollution and health, the committee recommends that research approaches continue to be developed on the basis of existing and new cohorts. Mechanisms are needed for enrollment and tracking of cohorts over time to provide an ongoing characterization of any impact on health of long-term exposure to air pollution. Without substantial commitment of personnel and funds, studies, such as the Six Cities Study and the CPS 2 cohorts, cannot be readily and feasibly undertaken. Rather, such studies might be based on cohorts routinely enrolled for other purposes, for example, investigating cardiovascular diseases (Atherosclerosis Risk in Communities [ARIC 2004] and the Cardiovascular Health Study [CHS 2003]), Medicare participants, and cohorts assembled by the National Center for Health Statistics. However, even such studies will require substantial funding, and their value must be compared with data collection specifically designed as long-term studies of health effects of air pollution. Medicare has a large cohort under follow-up that is maintained with replacement sampling. The Veterans'

Administration also has a large cohort under follow-up. In addition, there might be other opportunities for adding a component related to air pollution and health; the anticipated National Children's Study (2004) is one example. That study might provide insights into air pollution and childhood asthma or lung development, for example. New cohort studies of persons having informative patterns of exposure or heightened susceptibility may also be warranted.

Studies of effects of long-term exposure to PM, based on residence location and other information, need to include large numbers of participants and to incorporate exposure estimates. With information on residence location, the EPA's monitoring data, captured in the Air Quality System (AQS) database (EPA 2004), could be used to estimate exposures. However, these data might not be optimal for health studies, and additional data collection or model data would be needed to better capture population exposure (see Chapter 6). For example, the spatial detail within communities might be better captured with focused monitoring and use of population exposure models. As the AQS data are increased from the new speciation sites and other data-collection efforts, it should become possible to develop estimates for exposures beyond particle mass alone. It is critically important that future monitoring strategies go beyond currently regulated pollutants to allow the testing of a broader range of epidemiological hypotheses.

An additional concern in any cohort study is the availability of information on potential confounding and modifying factors. Life styles and the associated frequency of chronic diseases, particularly heart and lung diseases, are variable across the country. There is a potential for a varying profile of susceptibility to PM across the country and for confounding as well. Some approaches based on population-level data can be identified that might be used to characterize potential confounding and modifying factors. Population-level data are available on tobacco sales, although they are a poor surrogate for actual smoking rates within the cohorts; available data on prevalence of tobacco use and mortality provide an index of the underlying rates of chronic heart and lung disease, particularly coronary heart disease and chronic obstructive pulmonary disease. Population sampling might be done to augment those data resources. However, such population-level data are inherently imperfect measures of individual-level exposures. Some health-system-based cohorts, such as Medicare, include information on diagnoses leading to outpatient visits and hospitalizations. Those data could be used to identify susceptible groups.

The development of new approaches to carrying out these cohort studies will be challenging and time-consuming and should be supported by EPA or other agencies. In 2001 and again in 2003, EPA sought new cohorts for studies of long-term effects through its Science to Achieve Results (STAR) grant mechanism, but it should also support an ongoing planning effort. Although a request has been initiated by EPA to establish a long term cohort to follow up cardiovascular events, it is important for EPA to recognize the need for continued and substantial financial support necessary for these types of studies. At the same time, it will be important for EPA to continue to support additional alternative approaches. The spectrum of human health effects has expanded over the past several years (see Table 5-1). Because each of these effects has the potential to result in substantial economic and social consequences, as well as significant health impairment, it is important that continued work be undertaken to quantify as much as possible the degree to which PM contributes to these conditions.

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.

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 reviewed⁷ 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 OIRA⁹ and the President's Science Advisor¹⁰ 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 2011¹¹ 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

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-112/hrhg70585/pdf/CHRG-112/hrhg70585.pdf>, pg. 58-60.

⁸ <http://science.house.gov/epa-assistant-administrator-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-bershsteyn>.

¹³ See Letter from Senator David Vitter and Senator James Inhofe to Hon. Lisa Jackson, Adm'r, Env'tl. 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 studies¹⁵ 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

<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%20final.pdf>.

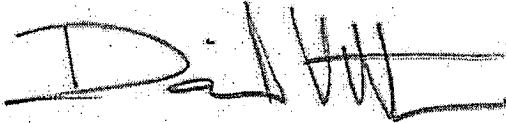
¹⁷ National Research Council, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress* (2004), Board on Environmental Studies and Toxicology (BEST), pg. 135.

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

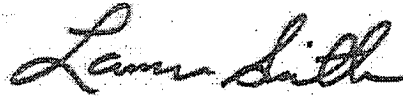
The EPA's new CAA regulations are expected to be some of the most costly rules the federal government has ever issued. Relying on secret data to support these rules is not acceptable. The public and outside scientists must be able to independently verify the EPA's claims, especially when the results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

References

- Abbey et al. "Long-term inhalable particles and other air pollutants related to mortality in nonsmokers." *Am. J. Rep. Crit. Care Med.* 159 (1999): 373-382.
- Beeson et al. "Long-term concentrations of ambient air pollutants and incident lung cancer in California adults: results from the ASHMOG study." *Environ. Health Perspect.* 106 (1998): 813-823.
- Chen et al. "The association between fatal coronary heart disease and ambient particulate air pollution: Are females at greater risk?" *Environ Health Perspect* 113 (2005): 1723-1729.
- Dockery et al. "An association between air pollution and mortality in six US cities." *N. Engl. J. Med* 329 (1993): 1753-1759.
- Jerrett et al. "Spatial analysis of air pollution and mortality in Los Angeles." *Epidemiology* 16(2005): 727-736.
- Lipfert et al. "PM2.5 constituents and related air quality variables as predictors of survival in a cohort of U.S. military veterans." *Inhal. Toxicol.* 18 (2006): 41-72.
- Miller et al. "Long-term exposure to air pollution and incidence of cardiovascular events in women." *New England Journal of Medicine* 356, 5, (2007): 447-513. Supplementary information.
- Pope et al. "Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults." *Am. J. Respir. Crit. Care Med* 151 (1995): 669-674.
- Wang X.Y. et al. "Long-term exposure to gaseous air pollutants and cardio-respiratory mortality in Brisbane, Australia." *Geospat Health* 3 (2009): 257-263.
- Zanobetti and Schwartz "Ozone and survival in four cohorts with potentially predisposing diseases." *Amer. J. Resp. Crit. Care Med.* 184 (2011): 837-841.

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
www.science.house.gov

December 13, 2012

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 6101A
Washington, D.C. 20460

The Honorable John P. Holdren
Director
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Mr. Boris Bershteyn
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, N.W.
Washington, DC 20403

Dear Administrator Jackson, Dr. Holdren, and Acting Administrator Bershteyn,

As the White House and the Environmental Protection Agency (EPA) aim to respond to a court-imposed December 14th deadline for release of the final National Ambient Air Quality Standards (NAAQS) for fine particulate matter (PM_{2.5}), we write to reiterate concerns that this important rule is being hastily considered and is based on scientific processes and data that have not been made available for public review. As you know, Members of the Science, Space, and Technology Committee have repeatedly requested release of the scientific data that EPA uses to justify alleged benefits of this rule (as well as the majority of EPA's Clean Air Act benefit claims for non-PM_{2.5} rules). Multiple senior Obama Administration officials have promised to ensure release of this data but have yet to fulfill such commitments, raising further questions regarding the President's pledge of openness and transparency.

Prior to finalizing NAAQS for PM_{2.5}, which could destroy countless jobs and subject large portions of the country to nonattainment status under the Clean Air Act, it is essential that EPA and the White House make the underlying data linking PM_{2.5} and mortality publicly available in a manner sufficient for analysis by independent scientists and researchers. This is especially important as EPA's action will subject taxpayers who funded this research to costly regulatory consequences without having permitted public review or scrutiny of the data and information.

Federally-funded analyses of two well-known data sets – the “Cancer Prevention Study” and the “Harvard Six Cities Study” – provide the lynchpin to virtually all of EPA's Clean Air Act claims. For example:

- Nearly all of the rules adopted by EPA to implement the Clean Air Act since 2003, even those that do not directly regulate fine particulate matter, have been justified on the basis of estimated monetized benefits from reducing ambient PM_{2.5}.¹
- The Regulatory Impact Analysis that accompanied the proposed PM_{2.5} NAAQS in June acknowledged that **98 percent** of the total of these claimed monetized benefits of lowering the standard is derived from these two data sets.²
- An analysis of these two data sets is the only source for EPA claims of \$1.7 trillion, or 85 percent, of the \$2.0 trillion in total benefits from the Clean Air Act between 1990 to 2020.³ These undisclosed data are also the origin of EPA's frequent claim that Clean Air Act benefits exceed the costs by a 30-to-1 ratio.
- Not only does EPA rely on these data sets for its Clean Air Act claims, this science also provides the basis for a disproportionate share of overall federal regulatory benefit claims. In its *Draft 2012 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, the White House Office of Information and Regulatory Affairs (OIRA) notes that EPA rules represent 60 to 81 percent of the estimated benefits for all regulations across the entire federal government. The report further emphasizes that 97 to 98 percent of EPA's claimed benefits come from air quality rules, and that “the large estimated benefits of EPA rules are mostly attributable to the reduction in public exposure to a single air pollutant: fine particulate matter.”⁴ Put succinctly, **it is likely that a majority of the benefits claimed from all federal regulations are grounded in data sets that have never been made available to the public.**

¹ <http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/Sunstein%20Letter.pdf>

² EPA, *Regulatory Impact Analysis for the Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter*, June 2012, http://www.epa.gov/ttnecas1/regdata/RIAs/PMRIACombinedFile_Bookmarked.pdf, ES-9.

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 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.

For more than a year, EPA and the White House have declined repeated requests from Science, Space, and Technology Committee members to make the underlying data from these analyses publicly-available at a level sufficient for independent re-analysis⁵:

- In a September 2011 hearing on the Cross-State Air Pollution Rule, EPA Assistant Administrator for Air and Radiation Gina McCarthy committed to provide all of the underlying PM_{2.5} death and injury data in order to be independently reviewed.⁶
- In follow-up correspondence on November 30, 2011, Ms. McCarthy stated that she would take action "...as soon as possible to provide you with any data and analysis produced with EPA funds..."⁷
- On December 22, 2011, in response to a request to make this data available, OIRA Administrator Cass Sunstein wrote that "OIRA takes... Executive Order [13563] very seriously and strives to make such information available whenever possible."⁸
- During a February 2012 budget hearing, the President's Science Advisor and Director of the White House Office of Science and Technology Policy, Dr. Holdren committed to providing this information and stated that he would "start working on it immediately."⁹

Similarly, Administration officials have repeatedly supported making data relied upon for regulatory decisions publicly-available:

- When asked about this specific Clean Air Act example, Dr. Holdren stated that "...absolutely the data on which regulatory decisions and other decisions are based should be made available to the Committee and should be made public..." during a June 20, 2012 hearing.¹⁰
- The then-Chair of EPA's Science Advisory Board (SAB), Dr. Deborah Swackhamer, agreed in February 2012 testimony that "data used to justify regulation should be made publicly available" without any restrictions and that "all data that goes into making conclusions in a scientific study should be made available." Similarly, in follow-up questions for the record, Dr. Swackhamer said: "The SAB recommends that literature and data used by EPA be peer-reviewed and made available to the public."¹¹

⁵ Information provided by EPA in June of 2012 has been determined by air quality experts to be inadequate for re-analysis.

⁶ *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.

⁷ <http://science.house.gov/epa-assistant-administrator-mccarthy-chairman-harris>.

⁸ <http://science.house.gov/letter-cass-sunstein-chairman-harris>.

⁹ *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>.

¹⁰ *The Office of Science and Technology Policy: Examining Priorities and Effectiveness of the Nation's Science Policies*, Hearing before the Committee on Science, Space, and Technology, <http://science.house.gov/hearing/full-committee-hearing-examining-priorities-and-effectiveness-nation%E2%80%99s-science-policies>.

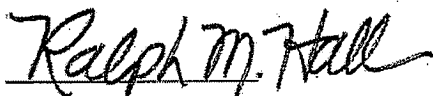
¹¹ *Fostering Quality Science at EPA: Perspectives on Common Sense Reform – Day II*, Hearing before the Subcommittee on Energy & Environment, February 3, 2012, <http://science.house.gov/hearing/energy-and-environment-subcommittee-hearing-fostering-quality-science-epa-perspectives-0>.

- Dr. Kenneth Olden, the Director of EPA's National Center for Environmental Assessment, which develops the science for NAAQS decisions, was a member of the Bipartisan Policy Center's Science for Policy Project, which recommended in 2009 that: "Studies 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."¹²

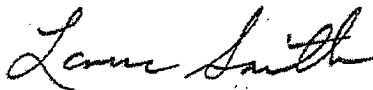
The refusal by EPA and the White House to provide this underlying data in a manner sufficient for independent re-analysis is clearly at odds with the President's rhetoric about transparency, as well as the transparency provisions contained in EPA's Scientific Integrity Policy, Public Law 105-277, and Executive Order 13563. As EPA's *Peer Review Handbook* recognizes, public access and transparency are essential to peer review and credible scientific conclusions. Accordingly, and in light of the importance of these data sets to EPA's final PM_{2.5} NAAQS as well as to the credibility of the broader federal regulatory enterprise, we call on EPA and the White House to immediately work to make these data sets publicly-available, and ensure that future federal regulatory decisions are based on transparent and publicly-available scientific data.

If you have any questions about this request, please contact Mr. Clint Woods of the Subcommittee on Energy and Environment Staff at 202-225-8844.

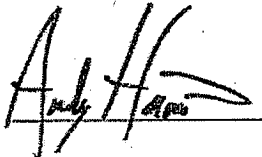
Sincerely,



Rep. Ralph Hall
Chairman
Committee on Science, Space,
and Technology



Rep. Lamar Smith
Committee on Science, Space,
and Technology



Rep. Andy Harris M.D.
Chairman
Subcommittee on Energy
& Environment

¹² 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%20final.pdf>.

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
www.science.house.gov

December 12, 2011

The Honorable Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, N.W.
Washington, DC 20403

Dear Administrator Sunstein:

As the Office of Management and Budget reviews the Environmental Protection Agency's (EPA) Mercury and Air Toxics Standards for Utilities (Utility MACT) with an expectation of a finalized rule in the next week, we are concerned that EPA and your office have failed to respond to a variety of specific questions raised by members of the Science, Space, and Technology Committee about this rule over the last several months. Through questions for the record on related hearings and letters to the Administration, Committee members have highlighted a variety of scientific and procedural issues with the Agency's pursuit of unmanageable and costly Utility MACT requirements.

Before the Office of Management and Budget approves any form of the Utility MACT, we expect that the Office of Information and Regulatory Affairs and EPA will provide specific and responsive answers to these questions. More than 30 questions by Committee members have been posed and remain unanswered that are directly relevant to this Administration's consideration of Utility MACT. These questions came from:

- Questions for the record for EPA Assistant Administrator Gina McCarthy following the September 15, 2011 hearing, *Out of Thin Air: EPA's Cross-State Air Pollution Rule*;
- September 22 letter to Gina McCarthy on data transparency from Energy and Environment Subcommittee Chairman Andy Harris;
- November 15 letter to you from Investigations and Oversight Subcommittee Chairman Paul Broun and Energy and Environment Chairman Andy Harris.

For your review and response, enclosed are the relevant questions from these communications. Enclosed also is a November 4th letter sent by nine members of the Committee asking EPA to adhere to its promises on transparency and to respond to past due questions, letters, and requests. As this letter explained, "As the authorizing Committee for scientific activities at EPA, we require such information to examine the scientific foundations of EPA regulations and inform our decision making in regard to the Agency's work and resources."


These questions are particularly important in light of the Court of Appeals for the D.C. Circuit's decision last Friday on EPA's rulemaking for emissions from cement kilns (*Portland Cement Association v. EPA*). Stating that "EPA has put the cart before the horse, and there is no justification, least of all an agency's own timing choices, for such a cavalier and unscientific attitude," the Court emphasized that "reasoned

decisionmaking is not a dispensable part of the administrative machine that can be blithely discarded even in pursuit of a laudable regulatory goal."

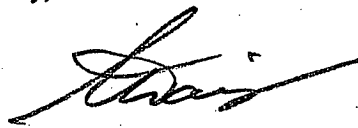
As you know, EPA estimates that the Utility MACT will cost the American economy approximately \$11 billion annually; other estimates are far higher. It is incumbent upon you and the Administration to ensure that a costly regulation of this magnitude be based on transparent and robust scientific and economic justifications. Accordingly, we suggest a delay of any formal actions or decisions on Utility MACT until answers to the aforementioned questions are provided. Continued inaction and lack of response from this Administration will compel our Committee to exercise more rigorous oversight.

If you have any questions regarding this request please contact Ms. Tara Rothschild or Mr. Clint Woods with the Subcommittee on Energy and Environment at (202) 225-8844.

Sincerely,



Ralph M. Hall
Chairman
Committee on Science, Space, and Technology



Andy Harris, MD
Chairman
Subcommittee on Energy and Environment



Paul Broun, MD
Chairman
Subcommittee on Investigations and Oversight

Enclosure

Enclosure

Questions for the Record from Chairman Ralph Hall to EPA Assistant Administrator Gina McCarthy following September 15, 2011 hearing, Out of Thin Air: EPA's Cross-State Air Pollution Rule:¹

7. In the past, you and EPA Administrator Lisa Jackson have claimed that CSAPR and related rules have included an analysis of electric reliability, as well as consultations with FERC. However, when FERC Chairman Jon Wellinghoff testified in front of Congress, he emphasized that their informal assessment "in no way should be used for planning," and that the only relevant assessments are conducted by planning authorities like ERCOT. How has ERCOT's breakdown of the massive reliability concerns – including rotating outages- been included in EPA's CSAPR decision-making?

8. The State of South Carolina has asked the Federal Energy Regulatory Commission to convene a state-federal panel- called a section 209 panel- to resolve specific reliability problems likely to result in that state because of the new EPA power-sector rules. Federal law allows for this type of dialogue in order to ensure adequate planning has occurred in advance of federal policy developments. Are you aware of this? Will EPA delay the implementation of CSAPR and related rules UNTIL this dialogue is complete?

Questions from September 22, 2011 letter from Chairman Andy Harris to EPA Assistant Administrator Gina McCarthy (response requested by October 3, 2011):²

I also questioned you about how the number of avoided premature deaths EPA found to justify the CSAPR rule compared with the avoided premature deaths EPA used to justify the ozone reconsideration that was recently pulled back by the White House. Please provide the number of avoided premature deaths attributable to each proposed or finalized Clean Air Act rule issued since January 20, 2009 and a description of the changes from a proposed rule to a finalized rule if the number of avoided premature deaths attributable to the proposed rule changed in the finalized version. Make sure to include the proposed rules since January 20, 2009 that have not yet been finalized. Please distinguish how many of the projected avoided premature deaths result from reductions in each rule's target pollutant and how many resulted from co-benefits from reductions in fine particulate matter. Furthermore, please detail the degree to which each rule contributed to the same avoided premature deaths that would have occurred in the rule's absence.³

Lastly, I questioned you about the availability of the data that support the death and injury benefits and you assured me that all such data is publicly available and you were willing to provide it. In light of the pivotal role of this publically-funded research in providing a justification for major EPA regulations, it is imperative that associated data and analysis be open and transparent to allow for sufficient scientific and technical review. Accordingly, in the spirit and letter of Public Law 105-277, Executive Order 13563 (which explicitly states that regulations "must be based on the best available science"), EPA's *Peer*

¹ Questions sent October 6, 2011, with a response required by October 20, 2011. As of December 7, 2011, no response has been received by any Member of the Committee.

² <http://science.house.gov/sites/republicans.science.house.gov/files/9-22-2011%20Harris%20to%20McCarthy.pdf>. Response was received on November 30, 2011.

³ Instead of responding to these questions directly, EPA's response on November 30 (almost two months after the deadline) merely included a "summary table...with links to the Regulatory Impact Analysis (RIA) of all Clean Air Act Rules issued since January 20, 2009."

Review Handbook, and recently-released Scientific Integrity Policy Draft, please provide all original data and analysis for the following studies that were used in EPA analysis:

1. The Cancer Prevention Study I compiled by the American Cancer Society.
2. The Cancer Prevention Study II compiled by the American Cancer Society.
3. The Harvard Six Cities Study.
4. The Nurses' Health Study and Nurses' Health Study II.⁴

Questions from November 15, 2011 letter from Chairman Andy Harris and Chairman Paul Broun to Administrator Cass R. Sunstein (response requested by December 6):⁵

Repeated Double-Counting of Health Benefits

1. Do you believe it is appropriate, accurate, or intellectually defensible to assert economic benefits already claimed in concurrent and prior rulemakings to justify the economics of an individual regulation?
2. How does relying on coincidental PM_{2.5} co-benefits for non-PM_{2.5} rules meet Executive Order (E.O.) 12866's requirement that each "agency shall avoid regulations that are...duplicative with its other regulations"?
3. When the PM_{2.5} benefits are removed from the Utility MACT RIA, EPA is asking the American people to pay \$3,600 to \$4.36 million for every one dollar of benefit. Absent benefits derived from PM_{2.5} reductions, does OIRA believe that the cost-benefit ratio for achieving the Utility MACT's stated purpose – that is, reducing hazardous air pollutants and not fine particulates – satisfies the E.O. 13563 directive to narrowly tailor regulations such that the benefits justify the cost?
4. In 1999, you stated that "If – as seems clear – the risks prevented by the new ozone regulation are far smaller than the risks that would be prevented by more stringent regulation of particulates, EPA should explain the apparent anomaly in terms of statutorily relevant factors. A chief advantage of this approach is that it should ensure inter-regulation consistency, in such a way as to combat, simultaneously, interest-group power, public torpor, and public over-reaction with respect to certain pollutants." You also stated that "The question is whether EPA can defend apparent interregulation inconsistency in statutorily relevant terms.... If it cannot, it has acted unlawfully."

How does relying on coincidental PM_{2.5} co-benefits for dozens of non-PM_{2.5} rules achieve inter-regulation consistency as you have defined it?

⁴ EPA's November 30 response did not provide any of this information. It instead stated that: "In response to the new request in your letter regarding the availability of data and analyses from five epidemiological studies (two American Cancer Society studies, the Harvard Six Cities Study, and two Nurses Health studies), we will take action under 2 CFR 215.36 as soon as possible to provide you with any data and analyses produced with EPA funds to the extent that this information remains available."

⁵ Full letter available at:

<http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/Sunstein%20Letter.pdf>

Footnotes and other information excluded from this reproduction of questions.

5. The draft OIRA Report to Congress for 2011 discussed revisions to prevent the double-counting of PM_{2.5} benefits, stating that "...to prevent double-counting, the estimates for the PM_{2.5} NAAQS will be adjusted, and estimates associated with the implementing rules promulgated in subsequent years will be used appropriately. The benefit and cost estimates for lead NAAQS and SO₂ NAAQS may also be adjusted in future reports to avoid double-counting...."
 - a. Why was this language and other references to revising EPA estimates to prevent PM_{2.5} benefit double-counting deleted from the final OIRA Report to Congress?
 - b. Please outline all steps that OIRA has taken to prevent the double-counting of PM_{2.5} benefits for individual CAA rules listed in Appendix A.
 - c. Please also outline the steps that will be taken by OIRA to prevent EPA from taking credit for already-counted PM_{2.5} benefits in upcoming PM_{2.5} NAAQS from the Agency.
6. For the Utility MACT and CSAPR, please quantify the aggregate costs and benefits without double-counting (i.e. ensure that both benefits and costs are unique).
 7. You have also stated in the past that "[a] projection of benefits must depend on a baseline about what would have happened without regulation."

Please provide a list of all examples for EPA CAA RIAs in which the Agency has clearly removed PM_{2.5} benefits that were already counted in providing a baseline for new rules.

8. As noted above, an accounting change in 2009 allowed EPA to inflate health benefit estimates associated with PM_{2.5} reductions by counting benefits down to the lowest measurable level with no change in the underlying science.
 - a. Did OIRA approve this change in benefits calculation?
 - b. Has EPA used this same public health benefit assumption in any of the risk analyses regarding its current review of the PM_{2.5} NAAQS? If not, please explain the different treatment of the same air pollutant and why EPA's approach is not the same.

A. Understating Compliance Costs

How is EPA's practice of estimating single-year compliance costs instead of net present value consistent with OMB Circular A-94? Why has OIRA approved RIAs and agency communications that do not use net present value? What steps has OIRA taken to revise EPA's approach to compliance costs?

B. Ignoring Negative Health Impacts of Regulatory Economic Burdens

1. If, as you have stated, "expensive regulation can have adverse effects on life and health," why have none of the EPA CAA RIAs listed in Appendix A included a single dollar of cost associated with the health effects from regulatory expenditures and accompanying economic outcomes?
2. Please provide a list of all health disbenefits identified by EPA in the RIAs for the ozone NAAQS reconsideration, the Utility MACT, or CSAPR.

3. In the context of the Utility MACT, please explain how the estimated \$10.9 billion estimate in compliance costs and subsequent increases in electricity rates will not affect the health of a single American.

C. *Failing to Analyze and Communicate Uncertainties*

1. Why did OMB approve EPA Assistant Administrator Gina McCarthy's September 15, 2011 testimony before the Committee on Science, Space, and Technology in which she stated that CSAPR would avoid "Up to 34,000 premature deaths; 15,000 heart attacks; 400,000 cases of aggravated asthma; 19,000 cases of acute bronchitis; 19,000 hospital and emergency room visits"?
 - a. Is this treatment of uncertainty consistent with OMB Circular A-94?
 - b. What steps does OMB take to ensure that EPA's characterizations of RIAs are consistent with the guidelines for these analyses?
2. Former OIRA Administrator John Graham wrote in a December 2001 letter to then-EPA Administrator Christine Todd Whitman that "it is clear that we need to understand better which sources of PM in our economy are responsible for the PM-related health effects." Similarly, you have stated that upon finding the need to lower ambient PM_{2.5} levels, "...EPA will have to decide what, exactly, to regulate; and to do this, it will have to decide what fine particulates consist of."

Does OIRA continue to hold this view about PM speciation? If so, why has OIRA approved several regulations that are being justified from associations based on PM mass alone?

3. The OIRA Report to Congress indicates that "[t]he wide range of benefits estimates for particle control does not capture the full extent of the scientific uncertainty in measuring the health effects associated with exposure to fine particulate matter and its constituent elements." The Report further identifies six key assumptions that demonstrate the significant uncertainty in making these associations in RIAs.

Please explain how EPA's CAA RIAs incorporate an uncertainty analysis that incorporates these six key assumptions.

4. There were also significant changes made to the section on PM_{2.5} uncertainties between the draft and final OIRA Report to Congress for 2011:

The draft reported stated that: "Although biological mechanisms for this effect have **not been established definitively** yet, the weight of the available epidemiological evidence supports an **assumption of causality**." (emphasis added)

In the final report, this passage was changed to: "The weight of available epidemiological evidence supports a **determination of causality**. Biological mechanisms for this effect, while not completely understood, are **supportive of this determination**." (emphasis added)

Why did OIRA alter this section to reflect more certainty in this association? What was the scientific basis for making this change?

5: EPA has acknowledged that its RIAs assume a causal association between $PM_{2.5}$ exposure and premature mortality and that “[i]f the PM/mortality relationship is not causal, it would lead to a significant overestimation of net benefits.”

- a. What steps have been taken by EPA in RIAs to reflect uncertainty in making this assumption of causality?
- b. EPA typically relies on only two studies to extrapolate $PM_{2.5}$ -mortality associations, ignoring a large body of peer-review literature that indicates different results. Is this practice consistent with the President’s requirement to develop regulations based on the best available science? In reviewing EPA assertions regarding $PM_{2.5}$ and mortality, does OIRA consider the best available peer-reviewed science? If not, why not? If so, what is this body of science and what does it conclude regarding $PM_{2.5}$ and mortality?
- c. What is the appropriate threshold for an assumption of causality between a pollutant and an individual health outcome?

D. Questionable “Value of a Statistical Life” Assumptions

1. Is EPA’s VSL identical to the figure used by other federal agencies? If not, how is it different, and why?
2. As commentators on the CSAPR rule noted: “EPA’s estimate for the value of a reduction in the risk of premature mortality was developed in the 1990s based on... literature available circa 1990.” You characterized the proposed reconsideration of the 2008 ozone NAAQS as being “based on evidence that is no longer the most current” in violation of E.O. 13563. Is EPA’s calculation subject to your interpretation of “evidence that is no longer the most current” in violation of E.O. 13563?
3. EPA’s VSL has not been updated or discounted in light of our ongoing economic problems. As you noted in 2003, “[w]illingness to pay is dependent on ability to pay,” suggesting that economic issues could substantially diminish EPA’s estimated health-based benefits. Has OIRA recommended that EPA or other agencies evaluate VSL in light of economic conditions? If not, why not?
4. You have stated that “it makes a great deal of sense to focus on statistical life-years rather than statistical lives.” In spite of the fact that most mortality associated with $PM_{2.5}$ happens in the population over 65 years of age, EPA puts the same value on mortality for all ages. In your view, is this practice appropriate?

A. Lack of Transparency

RIAs for EPA’s proposed ozone reconsideration, Utility MACT, CSAPR, and other major CAA rules have relied heavily on two studies to find a correlation between $PM_{2.5}$ and premature death. In turn, these analyses, which were funded by EPA and the National Institute of Environmental Health Scientists, rely exclusively on data sets that are not transparent and not available to other researchers. To be clear, these studies are often the only sources for health effects offered by EPA staff in CAA RIAs, and it is only with the inclusion of these $PM_{2.5}$ -related premature death estimates that many of these rules pass a basic cost-benefit test.

1. Is this practice consistent with:
 - a. E.O. 13563, which requires that regulations “must be based on the best available science”?
 - b. The goals of Public Law 105-277, which sought to require that “all data produced under an award will be made available to the public...”?
 - c. OMB Circular A-4 on Regulatory Analysis, which states that “[a] good analysis is transparent and your results must be reproducible”?
2. You recently cited the President’s approach to data transparency and stated: “In these ways, the President suggested that transparency can serve as a **disinfectant**; provide **data** for citizens to find and use; and ensure that institutions benefit from the **dispersed knowledge** of Americans. Taken as a whole, these points suggest that if regulation is to be empirically informed, it must be in large part because of the knowledge and participation of the American people.” (emphasis in original).

Is EPA’s practice of justifying numerous multi-billion dollar regulations on data that is not publicly available consistent with the President’s approach to data transparency?

3. EPA has failed to respond to Chairman Harris’ September 22 request for data transparency in EPA’s benefits analyses. As OIRA oversees E.O. 13563 (which requires that regulations “must be based on the best available science”) and the enforcement of OMB guidelines resulting from P.L. 105-277, please provide (or require EPA to provide) all original data and analysis for the following studies that are used to justify EPA’s CAA rules:
 - a. The Cancer Prevention Study I compiled by the American Cancer Society.
 - b. The Cancer Prevention Study II compiled by the American Cancer Society.
 - c. The Harvard Six Cities Study.
 - d. The Nurses’ Health Study and Nurses’ Health Study II.

B. Peer Review

As a result of the recently-released report from EPA’s Inspector General, “Procedural Review of EPA’s Greenhouse Gases Endangerment Finding Data Quality Processes,” important questions have been raised about EPA’s approach to peer review and its consistency with both OMB’s Final Information Quality Bulletin for Peer Review (“OMB Bulletin”) and the third edition of EPA’s Peer Review Handbook.

1. Do you agree with the IG conclusion that EPA’s “review did not meet all OMB requirements for peer review”? If not, why not? If so, what guidance, oversight, and enforcement is OIRA providing EPA with respect to its compliance with OMB peer review requirements?
2. The OMB Bulletin requires that “Each agency shall prepare an annual report that summarizes key decisions made pursuant to this Bulletin.” However, EPA has not made public an Annual Peer Review Report since fiscal year 2009. What steps has OIRA taken to ensure timely compliance with the transparency requirements of the OMB Bulletin?
3. The OMB Bulletin “establishes minimum standards for when peer review is required for scientific information” and “covers original data and formal analytic models used by agencies in Regulatory Impact Analyses.” The OMB Bulletin also deems scientific assessments associated with regulations that could have a potential impact of more than \$500 million in any one year as “highly influential” and thus subject to rigorous peer review requirements. However, the

Administration has refused to categorize the scientific assessments associated with its endangerment finding and PM_{2.5}-mortality conclusions—which are directly being used to justify regulations costing into the many billions of dollars—as “influential” or “highly influential.” Please explain how this categorization is compliant with the OMB Bulletin, and describe specific OIRA guidance, oversight, and enforcement efforts in support of its peer review requirements.

4. The IG Report highlighted that “EPA’s guidance for assessing the quality of externally generated information does not provide procedures or steps for assessing outside data or requirements for documenting such analysis.” In light of these concerns about EPA’s inability to incorporate externally-generated information, what peer review guidelines has the Agency followed in utilizing these outside assessments of non-peer reviewed data for PM_{2.5}-mortality associations?

C. Lessons from the Ozone Reconsideration

1. You urged Administrator Jackson to drop her reconsideration of the 2008 ozone NAAQS because the new standard would be “based on evidence that is no longer the most current” and in violation of E.O. 13563.

The data underlying PM_{2.5}-premature mortality associations is primarily based on surveys conducted in the 1980s, while several more recent cohort studies go uncited in EPA’s RIAs. Why have the Utility MACT and other PM_{2.5}-dependent rules not been held to the same interpretation of E.O. 13563 by OIRA?

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
www.science.house.gov

November 4, 2011

The Honorable Lisa Jackson
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Administrator Jackson:

We write today to express our disappointment in the lack of responsiveness by the Environmental Protection Agency (EPA) to Member requests and letters. When President Obama took office in January 2009, he promised that his Administration would be the most transparent in history.

"Information maintained by the Federal Government is a national asset. My Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use."¹

Transparency is necessary in order for Congress to fulfill its oversight responsibilities, therefore requiring Federal agencies to provide requested information as expeditiously as possible is vital. Meaningful and worthwhile oversight requires real cooperation from Federal agencies.

On September 22, 2011 and September 23, 2011, Members of the Science, Space, and Technology Committee sent two letters to Assistant Administrator Gina McCarthy. In the September 22 letter, Energy and Environment Subcommittee Chairman Harris requested the original data sets and analysis for five studies; during a September 15, 2011 hearing, Ms. McCarthy assured the Committee the information was already publicly available and that she would be happy to provide it. Chairman Harris requested the receipt of such information by October 3, 2011. The September 23 letter signed by Chairman Hall and 8 members of the Committee requested information on EPA's development of the Cross-State Air Pollution Rule (CSAPR), including information regarding meetings between EPA and entities affected by CSAPR, information about the cost of electricity to ratepayers, and information regarding the

¹ Memorandum for the Heads of Executive Departments and Agencies: Transparency and Open Government. President Barak Obama, January 26, 2009. FR Doc No: E9-1777.

Integrated Planning Model used as the basis for EPA's analysis for CSAPR. This letter requested information to be provided by October 7, 2011.

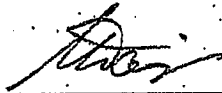
As the authorizing Committee for scientific activities at EPA, we require such information to examine the scientific foundations of EPA regulations and inform our decision making in regard to the Agency's work and resources. This is especially important when regulations have a direct impact on jobs, as we have seen recently in Texas with the announcement of mine closures.

We trust that you will provide the information requested in the aforementioned letters no later than November 7 and that EPA will be more responsive to the requests of this Committee. If you have any questions regarding this matter please contact Ms. Tara Rothschild or Mr. Clint Woods with the Subcommittee on Energy and Environment at (202) 225-8844.

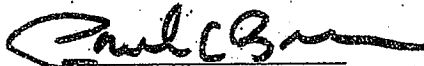
Sincerely,



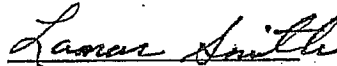
Ralph M. Hall
Chairman



Andy Harris
Chairman
Subcommittee on Energy & Environment



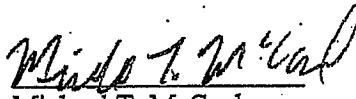
Paul C. Broun
Chairman
Subcommittee on Investigations & Oversight



Lamar S. Smith



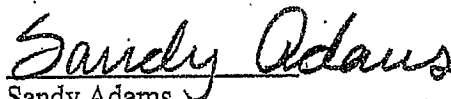
Randy Neugebauer



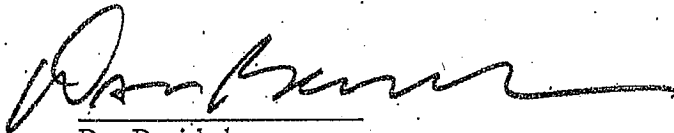
Michael T. McCaul



Dana Rohrabacher



Sandy Adams



Dan Benishek

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
www.science.house.gov

November 15, 2011

The Honorable Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, N.W.
Washington, D.C. 20403

Dear Administrator Sunstein:

As Chairmen of the Energy and Environment and Investigations and Oversight Subcommittees of the Committee on Science, Space, and Technology, we have growing concerns with troubling scientific and economic accounting practices in the Environmental Protection Agency's (EPA) crafting of Regulatory Impact Analyses (RIAs) used to justify numerous Clean Air Act (CAA) rules. In many cases, these required cost-benefit analyses appear designed to provide political cover for a more stringent regulatory agenda rather than to objectively inform policy decisions.

There is further evidence that these RIAs are based on flawed and sometimes nontransparent science, and highly-questionable economics that violate the spirit and letter of (1) executive orders governing regulatory reform, (2) EPA and Office of Management and Budget (OMB) standards for peer review and regulatory analysis, and (3) your own previous recommendations for both Office of Information and Regulatory Affairs (OIRA) and EPA cost-benefit analyses. Our concerns with these issues are exacerbated by several recent baseless and irresponsible statements from senior administration officials that illustrate the "press release science" advanced by EPA, particularly with regard to the overestimation of regulatory health benefits and underestimation of actual economic costs.

Accordingly, with EPA regulatory proposals costing tens of billions of dollars now awaiting your review, we implore you to follow the President's instructions to "give careful scrutiny to all regulations that impose significant costs on the private sector or on state, local, or tribal governments,"¹ and your comment from a recent speech that this scrutiny is "especially important in a period of economic difficulty."²

We fully agree with your statement that scrutiny of regulatory costs and benefits is especially important during a weak economy, and we hope and expect you to apply this scrutiny to EPA RIAs, which serve as the foundation used to justify the myriad of pending EPA rules that threaten to further damage our already weak economy. As you have previously noted, "the most informative document" in the rulemaking

¹ http://www.whitehouse.gov/sites/default/files/ozone_national_ambient_air_quality_standards_letter.pdf.

² Cass Sunstein, "Humanizing Cost-Benefit Analysis," February 17, 2010, http://www.whitehouse.gov/omb/oira_speech_02172010/.

process is the RIA.³ In particular, we are concerned about the tendency of RIAs to understate economic costs and inflate health benefits through double-counting and other means, and we ask your assistance in clarifying and responding to questions associated with these concerns.

Detailed below are troubling examples of questionable scientific and economic assertions involved in EPA's approach to RIAs. We ask you to respond to these specific questions by December 6, 2011:

I. Press Release Science

In an effort to portray its CAA regulations as generating more benefits than costs, EPA has massively inflated health benefit estimates in the last several years without any change in the underlying scientific understanding. There have been numerous examples of EPA officials citing benefit figures that test credibility. To provide a few examples:

- On September 22, EPA Administrator Lisa Jackson stated that "if we could reduce particulate matter to healthy levels, it would have the same impact as finding a cure for cancer."⁴ This claim would mean that reducing fine particulate matter (PM_{2.5}) could prevent nearly 600,000 deaths a year, or roughly 20 percent of all deaths in the U.S. It is baseless and unsupported by science, and ignores dramatic improvements in air quality, including the fact that PM_{2.5} levels have declined almost 30 percent over the last two decades.⁵
- During a recent hearing before our Committee, EPA Assistant Administrator Gina McCarthy presented OMB-approved testimony that the Agency's Cross-State Air Pollution Rule (CSAPR) would prevent "up to 34,000 premature deaths" per year.⁶ Ms. McCarthy could not explain the cause of these premature deaths, did not account for any uncertainty in this and other statements, and has subsequently failed to provide the underlying data behind such claims.⁷
- As you noted in your review of the National Ambient Air Quality Standards (NAAQS) in the late 1990s, at that time EPA found that lowering the PM_{2.5} standard in 1997 would prevent 350 annual mortalities, and that a lower ozone standard would prevent 0 to 80 premature deaths annually.⁸ EPA's current presumption attributes 320,000 deaths in 2005 (roughly 13 percent of all deaths in the U.S.) as "due to PM_{2.5}."⁹ Similarly, EPA's recent proposal to reconsider the 2008 ozone standard claimed that it would prevent up to 12,000 premature deaths (with more than 90 percent of these deaths actually associated with PM_{2.5} and not ozone).
- Based on a single calculating trick devised in 2009, EPA began counting benefits associated with PM_{2.5} down to the lowest measurable level, including well below the ambient standard that had been deemed adequate to protect public health with an adequate margin of safety for susceptible populations. This simple change allowed the Agency to claim that PM_{2.5} levels resulted in 320,000 premature deaths in 2005, compared to the previous total of 88,000 under the old method.¹⁰

³ Sunstein, "Is the Clean Air Act Unconstitutional?" Chicago Public Law and Legal Theory Working Paper No. 03, 1999, pg. 26.

⁴ Video available at: <http://www.c-span.org/Events/EPA-Regulations-Discussed-at-House-Energy-Committee/10737424255/>.

⁵ <http://www.epa.gov/airtrends/aqtrends.html>.

⁶ http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/091511_McCarthy.pdf.

⁷ <http://science.house.gov/press-release/chairman-harris-calls-transparency-epa-health-data>.

⁸ Sunstein, "Clean Air Act," pg. 27.

⁹ Testimony of Dr. Anne Smith, October 4, 2011,

http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/100411_smith_0.pdf.

¹⁰ Ibid.

- In 2009, the National Research Council released an analysis of the underlying price per ton for emissions of PM_{2.5} (including health effects) and found that their mean estimate was \$9,500.¹¹ However, EPA used a figure of \$280,000 benefit per ton for PM_{2.5} in conducting its nitrogen oxide NAAQS RIA.¹²

Repeated Double-Counting of Health Benefits

The Committee recently received testimony noting that EPA has relied almost exclusively on coincidental PM_{2.5} co-benefits to justify a variety of CAA regulations. For example:

- According to testimony on EPA's ozone reconsideration RIA: "...up to 91% of EPA's benefits estimate for its preferred standard was due to EPA's predictions of coincidental PM_{2.5} reductions rather than to reductions in ozone risks that were the target of the rule. Not a single one of EPA's benefits estimates in that RIA exceeded its costs unless PM_{2.5}-mortality co-benefits were added in."¹³
- In analyzing claims that EPA's Maximum Achievable Control Technology Standards for Hazardous Air Pollutants from Electric Utility Generating Units (Utility MACT) would save up to 17,000 lives per year and generate significant health benefits, testimony noted that: "...all of those purported health benefits are due to EPA's predictions of coincidental reductions of PM_{2.5} - which is not an air toxic. Of all the air toxics targeted by this rule, EPA has estimated benefits for only one - mercury - and EPA's highest estimate of those mercury benefits is only \$6 million per year, compared to EPA's estimate of \$10.9 billion in costs per year. In the Utility MACT's RIA, over 99.99% of the benefits that EPA has attributed to the rule are due to PM_{2.5} co-benefits rather than to the air toxics that are its purpose."¹⁴
- Over 90 percent of the benefits from the CSAPR rule come from PM_{2.5}-related estimates.

These examples demonstrate a broader trend in EPA cost-benefit analysis: EPA has justified nearly all CAA rules on the basis of particulate matter co-benefits, raising significant concerns about double-counting of alleged PM_{2.5} benefits as well OIRA's oversight of the RIA process. Even OIRA recognized this phenomenon in its 2011 *Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* ("OIRA Report to Congress"), which stated that, "It is important to emphasize that the large estimated benefits of EPA rules are mostly attributable to the reduction in public exposure to a single air pollutant: fine particulate matter."¹⁵

Appendix A illustrates the extent of this problem in a Congressional Research Service chart showing that, of the 28 CAA RIAs for rules proposed or finalized since 2004 that monetized benefits, 25 of them claimed more than 50 percent of total benefits from PM_{2.5}-related benefits.¹⁶ In nearly all of these cases, fine particulate matter was not being regulated and these benefits are coincidental "co-benefits." Most of these rules would not have passed a basic cost-benefit test if they had not incorporated PM_{2.5} co-benefits. Justifying disparate rules on the basis of these co-benefits compounds issues with the Agency's process of prioritization. As you stated in 2002, "EPA's own studies suggest that it is not devoting resources to the most serious problems and indeed that inadequate priority-setting is a particular problem for clear [sic] air

¹¹ National Research Council, *Hidden Costs of Energy: Unpriced Consequences of Energy Production and Use*, 2009, Washington, DC: National Academies Press.

¹² Arthur G. Fraas and Nathan Richardson, "Public Interest Comment on the Environmental Protection Agency's Proposed Clean Air Transport Rule," EPA-HQ-OAR-2009-0491-2573, September 28, 2010, pg. 38.

¹³ Smith testimony.

¹⁴ *Ibid.*

¹⁵ http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011_cb/2011_cba_report.pdf.

¹⁶ In three cases, this includes rules in which the range of PM_{2.5}-related benefits extend above 50 percent.

regulation.”¹⁷

1. Do you believe it is appropriate, accurate, or intellectually defensible to assert economic benefits already claimed in concurrent and prior rulemakings to justify the economics of an individual regulation?
2. How does relying on coincidental PM_{2.5} co-benefits for non- PM_{2.5} rules meet Executive Order (E.O.) 12866’s requirement that each “agency shall avoid regulations that are...duplicative with its other regulations”?
3. When the PM_{2.5} benefits are removed from the Utility MACT RIA, EPA is asking the American people to pay \$3,600 to \$4.36 million for every one dollar of benefit. Absent benefits derived from PM_{2.5} reductions, does OIRA believe that the cost-benefit ratio for achieving the Utility MACT’s stated purpose – that is, reducing hazardous air pollutants and not fine particulates – satisfies the E.O. 13563 directive to narrowly tailor regulations such that the benefits justify the cost?
4. In 1999, you stated that “If – as seems clear – the risks prevented by the new ozone regulation are far smaller than the risks that would be prevented by more stringent regulation of particulates, EPA should explain the apparent anomaly in terms of statutorily relevant factors. A chief advantage of this approach is that it should ensure inter-regulation consistency, in such a way as to combat, simultaneously, interest-group power, public torpor, and public over-reaction with respect to certain pollutants.”¹⁸ You also stated that “The question is whether EPA can defend apparent interregulation inconsistency in statutorily relevant terms.... If it cannot, it has acted unlawfully.”¹⁹

How does relying on coincidental PM_{2.5} co-benefits for dozens of non-PM_{2.5} rules achieve inter-regulation consistency as you have defined it?

5. The draft OIRA Report to Congress for 2011 discussed revisions to prevent the double-counting of PM_{2.5} benefits, stating that “...to prevent double-counting, the estimates for the PM_{2.5} NAAQS will be adjusted, and estimates associated with the implementing rules promulgated in subsequent years will be used appropriately. The benefit and cost estimates for lead NAAQS and SO₂ NAAQS may also be adjusted in future reports to avoid double-counting....”²⁰
 - a. Why was this language and other references to revising EPA estimates to prevent PM_{2.5} benefit double-counting deleted from the final OIRA Report to Congress?
 - b. Please outline all steps that OIRA has taken to prevent the double-counting of PM_{2.5} benefits for individual CAA rules listed in Appendix A.
 - c. Please also outline the steps that will be taken by OIRA to prevent EPA from taking credit for already-counted PM_{2.5} benefits in upcoming PM_{2.5} NAAQS from the Agency.
6. For the Utility MACT and CSAPR, please quantify the aggregate costs and benefits without double-counting (i.e. ensure that both benefits and costs are unique).

¹⁷ Sunstein, *Risk and Reason: Safety, Law, and the Environment* (Cambridge University Press, 2002), pg. 239.

¹⁸ Sunstein, “Clean Air Act,” pg. 67.

¹⁹ Sunstein, *Risk and Reason*, pg. 247-248.

²⁰ http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/Draft_2011_CBA_Report_AllSections.pdf.

7. You have also stated in the past that “[a] projection of benefits must depend on a baseline about what would have happened without regulation.”²¹

Please provide a list of all examples for EPA CAA RIAs in which the Agency has clearly removed PM_{2.5} benefits that were already counted in providing a baseline for new rules.

8. As noted above, an accounting change in 2009 allowed EPA to inflate health benefit estimates associated with PM_{2.5} reductions by counting benefits down to the lowest measurable level with no change in the underlying science.
- a. Did OIRA approve this change in benefits calculation?
 - b. Has EPA used this same public health benefit assumption in any of the risk analyses regarding its current review of the PM_{2.5} NAAQS? If not, please explain the different treatment of the same air pollutant and why EPA’s approach is not the same.

II. Dismal Science

A. Understating Compliance Costs

In estimating regulatory costs for CAA rules, we are concerned that EPA has adopted practices that are inconsistent with OMB guidelines and prevailing economic accounting practices. An enormous disparity exists between EPA’s compliance cost estimates and those projected by well-respected nongovernmental economists. While the more-sophisticated nongovernmental analyses project the net present value of multi-year cost streams, EPA instead estimates the annual cost for a single year. EPA’s failure to incorporate net present value calculations ignores all up-front capital expenditures that would be needed to comply and allows for another accounting trick to let CAA rules pass a cost-benefit test.²²

However, OMB Circular A-94 (which applies specifically to all RIAs) states: “The standard criterion for deciding whether a government program can be justified on economic principles is net present value.... Programs with negative net present value should generally be avoided.”

How is EPA’s practice of estimating single-year compliance costs instead of net present value consistent with OMB Circular A-94? Why has OIRA approved RIAs and agency communications that do not use net present value? What steps has OIRA taken to revise EPA’s approach to compliance costs?

B. Ignoring Negative Health Impacts of Regulatory Economic Burdens

You have made several statements indicating the need for RIAs to incorporate potential health-related economic costs associated with regulations:

- “In general, it is right to say that agencies should be required to take account of the health problems produced by regulation designed to reduce health problems.”²³
- “Regulations cost money – sometimes a great deal of money – and private expenditures on regulatory compliance may produce less employment and more poverty. People who are unemployed or poor tend to be in worse health and to live shorter lives.”²⁴

²¹ Sunstein, “Clean Air Act,” pg. 68.

²² Garrett Vaughn, “The EPA’s Benefit/Cost Jihad on U.S. Electric Utilities,” October 10, 2011, <http://www.masterresource.org/2011/10/epa-benefit-cost-jihad-utilities/>.

²³ Sunstein, “Clean Air Act,” pg. 78

- “A great deal of evidence suggests the possibility that an expensive regulation can have adverse effects on life and health.”²⁵
- “If poor people are paying a significant amount for modest environmental benefits, their health might be made worse rather than better.”²⁶

As a corollary, you have noted that environmental regulations are more likely to cause economic harm than good: “To be sure, some environmental regulations do increase employment and decrease prices. But as a general rule, there is no reason to believe that regulatory imposition of high costs will benefit workers and consumers; the opposite is more likely to be true.”²⁷

These statements are not merely academic, as you specifically cited the essential role of OIRA in ensuring these regulatory health disbenefits are incorporated in CAA RIAs:

- “OIRA should see, as one of its central assignments, the task of overcoming governmental tunnel vision, by ensuring that aggregate risks are reduced and that agency focus on particular risks does not mean that ancillary risks are ignored or increased.”²⁸
- “The Clean Air Act... is permitted to consider the effects of regulation in causing risks to life and health through poverty and unemployment.”²⁹

1. If, as you have stated, “expensive regulation can have adverse effects on life and health,” why have none of the EPA CAA RIAs listed in Appendix A included a single dollar of cost associated with the health effects from regulatory expenditures and accompanying economic outcomes?
2. Please provide a list of all health disbenefits identified by EPA in the RIAs for the ozone NAAQS reconsideration, the Utility MACT, or CSAPR.
3. In the context of the Utility MACT, please explain how the estimated \$10.9 billion estimate in compliance costs and subsequent increases in electricity rates will not affect the health of a single American.

C. *Failing to Analyze and Communicate Uncertainties*

We are concerned that EPA has failed to adequately report uncertainty in its analysis of costs and benefits for CAA rules, including the Agency displaying RIA health benefits without ranges of potential effects. As you have noted, “...without the range, it is hard to compare the options not chosen.”³⁰ OMB Circular A-94, which governs RIAs, says that because “uncertainty is basic to many analyses, its effects should be analyzed and reported.”

1. Why did OMB approve EPA Assistant Administrator Gina McCarthy’s September 15, 2011 testimony³¹ before the Committee on Science, Space, and Technology in which she stated that CSAPR would avoid “Up to 34,000 premature deaths; 15,000 heart attacks; 400,000 cases of aggravated asthma; 19,000 cases of acute bronchitis; 19,000 hospital and emergency room visits”?

²⁴ Sunstein, “Health-Health Tradeoffs,” University of Chicago Law and Economics Working Paper No. 42, 1996, pg. 7.

²⁵ Sunstein, “Cost-Benefit Analysis and the Environment,” *Ethics*, Vol. 115, No. 2 (January 2005), pg. 366.

²⁶ *Ibid.*, pg. 367.

²⁷ *Ibid.*, pg. 368.

²⁸ Sunstein, “Health- Health Tradeoffs,” pg. 30

²⁹ *Ibid.*, pg. 24.

³⁰ Sunstein, “Clean Air Act,” pg. 29.

³¹ http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/091511_McCarthy.pdf

- a. Is this treatment of uncertainty consistent with OMB Circular A-94?
 - b. What steps does OMB take to ensure that EPA's characterizations of RIAs are consistent with the guidelines for these analyses?
2. Former OIRA Administrator John Graham wrote in a December 2001 letter to then-EPA Administrator Christine Todd Whitman that "it is clear that we need to understand better which sources of PM in our economy are responsible for the PM-related health effects."³² Similarly, you have stated that upon finding the need to lower ambient PM_{2.5} levels, "...EPA will have to decide what, exactly, to regulate; and to do this, it will have to decide what fine particulates consist of."³³

Does OIRA continue to hold this view about PM speciation? If so, why has OIRA approved several regulations that are being justified from associations based on PM mass alone?

3. The OIRA Report to Congress indicates that "[t]he wide range of benefits estimates for particle control does not capture the full extent of the scientific uncertainty in measuring the health effects associated with exposure to fine particulate matter and its constituent elements." The Report further identifies six key assumptions that demonstrate the significant uncertainty in making these associations in RIAs.³⁴

Please explain how EPA's CAA RIAs incorporate an uncertainty analysis that accounts for these six key assumptions.

4. There were also significant changes made to the section on PM_{2.5} uncertainties between the draft and final OIRA Report to Congress for 2011:

The draft reported stated that: "Although biological mechanisms for this effect have not been established definitively yet, the weight of the available epidemiological evidence supports an assumption of causality." (emphasis added)

In the final report, this passage was changed to: "The weight of available epidemiological evidence supports a determination of causality. Biological mechanisms for this effect, while not completely understood, are supportive of this determination." (emphasis added)

Why did OIRA alter this section to reflect more certainty in this association? What was the scientific basis for making this change?

5. EPA has acknowledged that its RIAs assume a causal association between PM_{2.5} exposure and premature mortality and that "[i]f the PM/mortality relationship is not causal, it would lead to a significant overestimation of net benefits."³⁵
 - a. What steps have been taken by EPA in RIAs to reflect uncertainty in making this assumption of causality?

³² http://georgewbush-whitehouse.archives.gov/omb/inforeg/epa_pm_research_prompt120401.html.

³³ Sunstein, *The Cost-Benefit State: The Future of Regulatory Protection* (American Bar Association, 2002), pg. 126.

³⁴ OIRA Report to Congress, see footnote 19 of the report, pg. 16-17.

³⁵ EPA, *The Benefits and Costs of the Clean Air Act from 1990 to 2020*, March 2011, pg. 5-40.

- b. EPA typically relies on only two studies to extrapolate PM_{2.5} -mortality associations,³⁶ ignoring a large body of peer-review literature that indicates different results.³⁷ Is this practice consistent with the President's requirement to develop regulations based on the best available science? In reviewing EPA assertions regarding PM_{2.5} and mortality, does OIRA consider the best available peer-reviewed science? If not, why not? If so, what is this body of science and what does it conclude regarding PM_{2.5} and mortality?
- c. What is the appropriate threshold for an assumption of causality between a pollutant and an individual health outcome?

D. Questionable "Value of a Statistical Life" Assumptions

EPA bases its economic benefit estimates on the "Value of a Statistical Life" (VSL), which is generated from willingness to pay surveys conducted decades ago. You have described these willingness to pay surveys as an "especially crude" proxy for welfare.³⁸

1. Is EPA's VSL identical to the figure used by other federal agencies? If not, how is it different, and why?
2. As commentators on the CSAPR rule noted: "EPA's estimate for the value of a reduction in the risk of premature mortality was developed in the 1990s based on... literature available circa 1990."³⁹ You characterized the proposed reconsideration of the 2008 ozone NAAQS as being "based on evidence that is no longer the most current" in violation of E.O. 13563.⁴⁰ Is EPA's calculation subject to your interpretation of "evidence that is no longer the most current" in violation of E.O. 13563?
3. EPA's VSL has not been updated or discounted in light of our ongoing economic problems. As you noted in 2003, "[w]illingness to pay is dependent on ability to pay,"⁴¹ suggesting that economic issues could substantially diminish EPA's estimated health-based benefits. Has OIRA recommended that EPA or other agencies evaluate VSL in light of economic conditions? If not, why not?
4. You have stated that "it makes a great deal of sense to focus on statistical life-years rather than statistical lives."⁴² In spite of the fact that most mortality associated with PM_{2.5} happens in the population over 65 years of age, EPA puts the same value on mortality for all ages.⁴³ In your view, is this practice appropriate?

³⁶ Laden, et al., "Reduction in Fine Particulate Air Pollution and Mortality," *American Journal of Respiratory and Critical Care Medicine*, 2006; Pope, et al., "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution," *Journal of the American Medical Association*, 2002.

³⁷ See: James Enstrom et al., "Fine particulate matter air pollution and total mortality among elderly Californians, 1973-2002," *Inhalation Toxicology*, 2005; Fred Lipfert et al., "PM_{2.5} constituents and related air quality variables as predictors of survival in a cohort of U.S. military veterans," *Inhalation Toxicology*, 2006; Beelen et al., "Long-term effects of traffic-related air pollution on mortality in a Dutch cohort (NLCS-Air Study)," *Environmental Health Perspectives*, 2008.

³⁸ Sunstein, "Lives, Life-Years, and Willingness to Pay," University of Chicago Law and Economics Working Paper No. 191, July 2003, pg. 13.

³⁹ Fraas, pg. 30.

⁴⁰ http://www.whitehouse.gov/sites/default/files/ozone_national_ambient_air_quality_standards_letter.pdf

⁴¹ Sunstein, "Lives, Life-Years, and Willingness to Pay," pg. 21.

⁴² *Ibid.*, pg. 30.

⁴³ Fraas, pg. 30.

III. Secret Science

A. Lack of Transparency

RIAs for EPA's proposed ozone reconsideration, Utility MACT, CSAPR, and other major CAA rules have relied heavily on two studies to find a correlation between PM_{2.5} and premature death.⁴⁴ In turn, these analyses, which were funded by EPA and the National Institute of Environmental Health Scientists, rely exclusively on data sets that are not transparent and not available to other researchers. To be clear, these studies are often the only sources for health effects offered by EPA staff in CAA RIAs, and it is only with the inclusion of these PM_{2.5}-related premature death estimates that many of these rules pass a basic cost-benefit test.

1. Is this practice consistent with:
 - a. E.O. 13563, which requires that regulations "must be based on the best available science"?
 - b. The goals of Public Law 105-277, which sought to require that "all data produced under an award will be made available to the public...?"
 - c. OMB Circular A-4 on Regulatory Analysis, which states that "[a] good analysis is transparent and your results must be reproducible"?
2. You recently cited the President's approach to data transparency and stated: "In these ways, the President suggested that transparency can serve as a **disinfectant**; provide **data** for citizens to find and use; and ensure that institutions benefit from the **dispersed knowledge** of Americans. Taken as a whole, these points suggest that if regulation is to be empirically informed, it must be in large part because of the knowledge and participation of the American people."⁴⁵ (emphasis in original).

Is EPA's practice of justifying numerous multi-billion dollar regulations on data that is not publicly available consistent with the President's approach to data transparency?
3. EPA has failed to respond to Chairman Harris' September 22 request for data transparency in EPA's benefits analyses. As OIRA oversees E.O. 13563 (which requires that regulations "must be based on the best available science") and the enforcement of OMB guidelines resulting from P.L. 105-277, please provide (or require EPA to provide) all original data and analysis for the following studies that are used to justify EPA's CAA rules:
 - a. The Cancer Prevention Study I compiled by the American Cancer Society.
 - b. The Cancer Prevention Study II compiled by the American Cancer Society.
 - c. The Harvard Six Cities Study.
 - d. The Nurses' Health Study and Nurses' Health Study II.

⁴⁴ See Appendix A for a complete list of recent of CAA rules that rely primarily on PM_{2.5} co-benefits.

⁴⁵ Sunstein, "Humanizing Cost-Benefit Analysis."

B. Peer Review

As a result of the recently-released report from EPA's Inspector General, "Procedural Review of EPA's Greenhouse Gases Endangerment Finding Data Quality Processes,"⁴⁶ important questions have been raised about EPA's approach to peer review and its consistency with both OMB's Final Information Quality Bulletin for Peer Review ("OMB Bulletin")⁴⁷ and the third edition of EPA's Peer Review Handbook.

1. Do you agree with the IG conclusion that EPA's "review did not meet all OMB requirements for peer review"? If not, why not? If so, what guidance, oversight, and enforcement is OIRA providing EPA with respect to its compliance with OMB peer review requirements?
2. The OMB Bulletin requires that "Each agency shall prepare an annual report that summarizes key decisions made pursuant to this Bulletin." However, EPA has not made public an Annual Peer Review Report since fiscal year 2009.⁴⁸ What steps has OIRA taken to ensure timely compliance with the transparency requirements of the OMB Bulletin?
3. The OMB Bulletin "establishes minimum standards for when peer review is required for scientific information" and "covers original data and formal analytic models used by agencies in Regulatory Impact Analyses." The OMB Bulletin also deems scientific assessments associated with regulations that could have a potential impact of more than \$500 million in any one year as "highly influential" and thus subject to rigorous peer review requirements. However, the Administration has refused to categorize the scientific assessments associated with its endangerment finding and PM_{2.5}-mortality conclusions—which are directly being used to justify regulations costing into the many billions of dollars—as "influential" or "highly influential." Please explain how this categorization is compliant with the OMB Bulletin, and describe specific OIRA guidance, oversight, and enforcement efforts in support of its peer review requirements.
4. The IG Report highlighted that "EPA's guidance for assessing the quality of externally generated information does not provide procedures or steps for assessing outside data or requirements for documenting such analysis." In light of these concerns about EPA's inability to incorporate externally-generated information, what peer review guidelines has the Agency followed in utilizing these outside assessments of non-peer reviewed data for PM_{2.5}-mortality associations?

C. Lessons from the Ozone Reconsideration

1. You urged Administrator Jackson to drop her reconsideration of the 2008 ozone NAAQS because the new standard would be "based on evidence that is no longer the most current" and in violation of E.O. 13563.

The data underlying PM_{2.5}-premature mortality associations is primarily based on surveys conducted in the 1980s, while several more recent cohort studies go uncited in EPA's RIAs. Why have the Utility MACT and other PM_{2.5}-dependent rules not been held to the same interpretation of E.O. 13563 by OIRA?

⁴⁶ EPA Inspector General, "Procedural Review of EPA's Greenhouse Gases Endangerment Finding Data Quality Processes," Report No. 11-P-0702, September 26, 2011, <http://www.epa.gov/oig/reports/2011/20110926-11-P-0702.pdf>.

⁴⁷ <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

⁴⁸ Available at: http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

2. In your letter to Administrator Jackson, you also stated that "issuing a final rule in late 2011 would be problematic in view of the fact that a new assessment, and potentially new standards, will be developed in the relatively near future."

CSAPR attempts to achieve existing particulate matter and ozone standards. These standards will soon be changed, resulting in the need for a new transport rule in the relatively near future. Please explain how the final Cross-State rule (which, despite initial compliance requirements on January 1, 2012, is undergoing a series of "technical adjustments" by EPA to state emissions budgets) was not required to meet the same standard that OIRA applied to the ozone reconsideration.

Please provide written responses by December 6, 2011. If you have any questions regarding this request, please contact Clint Woods of the Subcommittee on Energy and Environment staff at (202) 225-8844.

Sincerely,



Rep. Andy Harris, MD
Chairman
Energy & Environment Subcommittee



Rep. Paul Broun, MD
Chairman
Investigations & Oversight Subcommittee

cc: Rep. Ralph Hall
Chairman

Rep. Eddie Bernice Johnson
Ranking Member

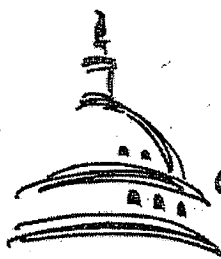
Rep. Brad Miller
Ranking Member
Subcommittee on Energy and Environment

Rep. Paul Tonko
Ranking Member
Subcommittee on Investigations and Oversight

Administrator Lisa Jackson
U.S. Environmental Protection Agency

Enclosure: CRS Memorandum

Appendix A



Congressional
Research
Service

MEMORANDUM

October 5, 2011

To: House Committee on Science, Space, and Technology
Subcommittee on Energy and Environment
Attention: Clint Woods

From: James E. McCarthy
Specialist in Environmental Policy
7-7225, jmccarthy@crs.loc.gov

Subject: Benefits of Clean Air Act Regulations

This memorandum responds to your request that CRS review EPA Clean Air Act regulations proposed or promulgated since 2004. You asked us to provide a list of the rules within that time period for which the Regulatory Impact Analysis claimed that a majority of the monetized benefits were related to health effects or premature mortality associated with reductions of particulate matter.

According to the Office of Management and Budget, EPA proposed or promulgated 75 economically significant Clean Air Act rules from January 2004 through August 2011. Many of these rules were duplicates (e.g., a proposed version and final version of the same rule) or represented procedural steps in implementing rules already promulgated (e.g., the 2004 implementation rule for the 1997 National Ambient Air Quality Standard for ozone). After eliminating such rules, CRS identified 31 distinct Clean Air Act rules that were proposed or promulgated in the relevant period (Table 1). There is still some duplication: as you requested, if a rule promulgated since 2004 was vacated and/or remanded to EPA by a court, we included both the original rule and any subsequent proposal or promulgation of a replacement.

Limitations of the Data

EPA prepared Regulatory Impact Analyses (RIAs) for all of these rules, but often it did not monetize some or any of the benefits. In the 2004 rule setting standards for hazardous air pollutant emissions from the plywood and composite wood products industry, for example, the RIA did not monetize any benefits. The analysis stated: "The Agency is unable to monetize the benefits from the HAP [Hazardous Air Pollutant], VOC [Volatile Organic Compound], and CO [Carbon Monoxide] emissions reductions due to lack of credible data for assigning a benefits value to these reductions."¹

In other cases, the RIAs do monetize some benefits, but often they don't quantify the benefits of controlling the emissions that were the primary target of the regulation. For example, the RIA that

¹ U.S. EPA, Regulatory Impact Analysis for the Plywood and Composite Wood Products NESHAP, Final Report, February 2004, p. ES-2, at <http://www.epa.gov/tmecas1/regdata/RIAs/pcwp-finalruleRIA.pdf>

accompanied the 2004 National Emission Standards for Hazardous Air Pollutants from Industrial, Commercial, and Institutional Boilers and Process Heaters (the "2004 Boiler MACT") estimated that there would be \$16 billion of annual benefits due to reductions in sulfur dioxide and particulate matter. But it also stated:

This analysis does not quantify the benefits associated with reductions in hazardous air pollutants (HAP). The magnitude of the unquantified benefits associated with omitted categories and pollutants, such as avoided cancer cases, damage to ecosystems, or materials damage to industrial equipment and national monuments, is not known.²

There are hundreds of air pollutants regulated by the Clean Air Act. For example, Congress directed EPA to set emission standards for sources of 187 hazardous air pollutants that are listed in the statute. Many of these are categories of pollutants rather than individual substances, so there are more than 187 pollutants to consider. Although there is research indicating that these pollutants are carcinogenic, mutagenic, teratogenic, neurotoxic, cause reproductive dysfunction, or are otherwise acutely or chronically toxic, in most cases, there are not data regarding the concentrations to which populations are exposed, or epidemiological data regarding illness or mortality associated with exposure to the individual pollutant. The agency proceeds with regulation because it was directed by the statute to do so, but it may not be able to quantify or monetize the benefits of regulating emissions of a specific substance.

Why the RIAs Focus on Particulates

The agency does, however, have an established, peer-reviewed methodology for estimating the benefits of reductions in emissions of particulate matter, which have been linked to increased mortality in numerous scientific studies. Most air pollutants are particulates, and most EPA air quality regulations reduce particulate emissions, either as the targeted pollutant, or as a co-benefit of reducing emissions of some other pollutant. As a result, the agency's RIAs have frequently found sizeable benefits associated with reductions in particulate matter emissions.

Defining "Particulates"

Particulate matter (also known as particle pollution, particulates, or PM) is a category of pollutants rather than a specific chemical. EPA identifies PM as "a complex mixture of extremely small particles and liquid droplets. Particle pollution is made up of a number of components, including acids (such as nitrates and sulfates), organic chemicals, metals, and soil or dust particles."³ Hazardous air pollutants, if not particles themselves, often adhere to particles in the emissions. Because PM includes so many different pollutants, many of the regulations targeting hazardous air pollutants rely on technologies that capture PM. Likewise, given the broad nature of particulate emissions, most of the available pollution control technologies

² U.S. EPA, *Regulatory Impact Analysis for the Industrial Boilers and Process Heaters NESHAP*, Final Report, February 2004, p. 10-1, at <http://nepis.epa.gov/Exec/Query.exe?ZyNET.exe/P1003ASI.txt?ZyActionD=ZyDocument&Client=EPA&Index=2000%20Thru%202005&Docs=&Query=452R04002%20or%20epa%20or%20boiler%20or%20neshap%20or%20ria&Time=&EndTime=&SearchMethod=1&ToRestrict=n&ToEntry=&QField=pubnumber%5E%22452R04002%22&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField=pubnumber&IntQFieldOp=1&ExtQFieldOp=1&XmlQuery=&File=D%3A%5CZYFILES%5CINDEX%20DATA%5C00THRU05%5CTXT%5C0000019%5CP1003ASI.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=10&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=-1&ZyEntry=1>.

³ U.S. EPA, Office of Air and Radiation, "Particulate Matter," at <http://www.epa.gov/pm/>.

(scrubbers, fabric filters, electrostatic precipitators, carbon or other sorbent injection, use of catalysts, etc.) capture particulate emissions or PM precursors.⁴

How Benefits Are Monetized

Another reason that particulates play such an important role in RIAs is that they are linked to premature mortality. When premature mortality is avoided, the monetization of that benefit, using what is called "the value of a statistical life," generally overwhelms the value of all other benefits combined.⁵

The value of statistical lives saved is not without controversy. EPA has relied on this method of monetizing benefits for many years. The agency adopted guidelines under President Reagan that, in updated form, have guided its analyses since 1983. The guidelines were most recently updated in September 2000, and have been used in their current form throughout the Bush and Obama Administrations.⁶

Results

Table 1 identifies 31 RIAs conducted by EPA (or its contractors) between January 2004 and September 2011 for rules defined by EPA as economically significant. Of the 31 RIAs, three did not monetize benefits. In 21 of the remaining 28 analyses, reductions in particulate matter or its precursors accounted for more than half the monetized benefits. In four additional RIAs,⁷ EPA produced ranges of benefits that showed PM benefits exceeding 50% of total monetized benefits for some or most, but not all combinations. The table identifies the rules, the dates on which they were proposed or promulgated, the estimated benefits, and whether or not PM accounted for more than 50% of the monetized amount.

I hope this information is useful. If I can be of further assistance, please feel free to call on me.

⁴ The term "precursor" refers to a pollutant that reacts with other substances in the atmosphere to form another air pollutant. Sulfur dioxide (SO₂), for example, is a precursor of sulfate particles and sulfuric acid, both of which are considered particulates.

⁵ Other benefits considered in Regulatory Impact Analyses include health benefits, such as the avoidance of nonfatal heart attacks, hospital and emergency room visits, cases of respiratory symptoms, cases of aggravated asthma, cases of chronic bronchitis, the number of days when people miss work, and the number of days when people must restrict their activities. Environmental effects, including improvements in visibility in national parks, reductions in damage to ecosystems and building materials, and improvements in fishing, agricultural yields, and forest productivity, are also frequently identified as benefits of a rule in RIAs.

⁶ The value of a statistical life used by EPA was nearly \$7.9 million in 2009. For additional information, see CRS Report R41140, *How Agencies Monetize "Statistical Lives" Expected to Be Saved By Regulations*, by Curtis W. Copeland.

⁷ The four RIAs were those for the 2008 Ozone NAAQS Revision, the 2010 proposed reconsideration of that rule, the 2010 Lead NAAQS Revision, and the 2005 Clean Air Mercury Rule.

Table 1. Clean Air Act Rules and Particulate Matter, 2004-2011
(economically significant rules promulgated or proposed)

Date Proposed or Promulgated	Rule	Status	Estimated Benefits (annual unless noted)	PM Benefits > 50% of Total?
September 15, 2011	Greenhouse Gas Emission Standards for Medium- and Heavy-Duty Trucks	Final	\$57 billion over lifetime of vehicles	No
August 23, 2011	Oil and Natural Gas Sector NSPS and NESHAP	Proposed	RIA did not monetize benefits	n.a.
August 8, 2011	Cross-State Air Pollution Rule	Final	\$120-280 billion	Yes
May 3, 2011	Mercury and Air Toxics Standards (Utility MACT)	Proposed	\$59-140 billion	Yes
March 21, 2011	Boiler MACT	Final, but stayed pending reconsideration	\$22-54 billion	Yes
March 21, 2011	Area Source Boiler Rule	Final	\$210-520 million	Yes
March 21, 2011	Commercial and Industrial Solid Waste Incinerator (CISWI) Rule	Final, but stayed pending reconsideration	\$360-870 million	Yes
September 9, 2010	Portland Cement MACT	Final	\$6.7-18 billion	Yes
August 20, 2010	NESHAP for Gasoline-Powered Stationary Engines (RICE Rule)	Final	\$510 million - \$1.2 billion	Yes
June 22, 2010	Sulfur Dioxide NAAQS Revision	Final	\$15-37 billion	Yes
May 7, 2010	Light Duty Motor Vehicle GHG Rule	Final	\$240 billion over lifetime of vehicles	No
April 30, 2010	Large Marine Engine Emission Standards	Final	EPA estimated benefits for a coordinated strategy to reduce ship emissions	Yes
March 26, 2010	Changes to Renewable Fuel Standard Program	Final	\$13 - 26 billion	No
March 3, 2010	NESHAP for Diesel Stationary Engines (RICE Rule)	Final	\$940 million - \$2.3 billion	Yes
January 19, 2010	Ozone NAAQS Revision	Proposed (subsequently withdrawn)	\$19-100 billion	RIA estimated overlapping ranges for ozone benefits and PM co-benefits

Date Proposed or Promulgated	Rule	Status	Estimated Benefits (annual unless noted)	PM Benefits > 50% of Total?
November 12, 2008	Lead NAAQS Revision	Final	\$3.7-6.9 billion	RIA estimated ranges for lead benefits and PM co-benefits. PM benefits would exceed 50% of total benefits in some of the estimated range
October 8, 2008	Nonroad Gasoline Engines and Equipment	Final	\$1.2 - 4.0 billion	Yes
May 6, 2008	Locomotives and Marine Diesel Engines	Final	\$9.2 - 11 billion	Yes
April 30, 2008	NSPS for Petroleum Refineries	Final	\$220 million - \$1.9 billion	Yes
March 12, 2008	Ozone NAAQS Revision	Final	\$2 - 19 billion	RIA estimated a range of 42% to 99% of benefits due to PM
February 26, 2007	Mobile Source Air Toxics	Final	\$6 billion	Yes
September 21, 2006	PM NAAQS Revision	Final	\$9 - 76 billion	Yes
July 11, 2006	Stationary Diesel Engine Standards	Final, but later revised due to court decisions	\$1.36 billion	Yes
July 26, 2005	Clean Air Visibility Rule	Final	\$50 billion	Yes
May 18, 2005	Clean Air Mercury Rule	Final, but later vacated by D.C. Circuit	\$1.5 - 44 million	RIA estimated ranges for mercury benefits and PM co-benefits. PM benefits would exceed 50% of total benefits in most of the estimated range
May 12, 2005	Clean Air Interstate Rule (CAIR)	Final, but later remanded by D.C. Circuit	\$10.1 billion	Yes
September 13, 2004	Boiler MACT	Final, but later vacated	\$16 billion	Yes
July 30, 2004	Plywood and Composite Wood Products	Final	RIA did not monetize benefits	n.a.

Date Proposed or Promulgated	Rule	Status	Estimated Benefits (annual unless noted)	PM Benefits > 50% of Total?
June 29, 2004	Nonroad Diesel Engines and Fuel	Final	\$43 – 81 billion	Yes
June 15, 2004	NESHAP for Stationary Engines	Final, but later revised due to court decisions	\$280 million	Yes
April 26, 2004	NESHAP for Surface Coating of Autos and Light Duty Trucks	Final	RIA did not monetize benefits	n.a.

Source: Compiled by CRS, from *Federal Register* notices, the Office of Information and Regulatory Affairs (OMB) website, and U.S. EPA RIAs. Listing excludes proposed rules if the rules were finalized during the period, as well as rules that implemented or modified rules already promulgated.

Notes: NESHAP = National Emission Standards for Hazardous Air Pollutants (generally MACT); MACT = Maximum Achievable Control Technology; NSPS = New Source Performance Standards; NAAQS = National Ambient Air Quality Standards

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
www.science.house.gov

September 22, 2011

The Honorable Gina McCarthy
Assistant Administrator, Office of Air and Radiation
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 6101A
Washington, DC 20460

Dear Ms. McCarthy:

During your appearance before the Science, Space, and Technology Committee's hearing *Out of Thin Air: EPA's Cross-State Air Pollution Rule* on Thursday, September 15, 2011, there were a number of items I asked for that you stated you would provide to me after the hearing. I am writing to request this information.

I questioned you on how EPA determined that the Cross-State Air Pollution Rule (CSAPR) would avoid "up to" 34,000 premature deaths. Please provide me with the breakdown of the 34,000 premature deaths by disease, the range of the estimate for both the 34,000 figure as well as for each individual disease, and how much quality-adjusted life years (QALY's) these 34,000 people would live as a result of CSAPR. Also, please provide the full data and analysis EPA used in support of this conclusion, including an assessment of downwind National Ambient Air Quality Standards compliance without CSAPR as well as progress made under the Clean Air Interstate Rule. Finally, please provide an explanation of what the term "up to" means and its use in the scientific literature.

I also questioned you about how the number of avoided premature deaths EPA found to justify the CSAPR rule compared with the avoided premature deaths EPA used to justify the ozone reconsideration that was recently pulled back by the White House. Please provide the number of avoided premature deaths attributable to each proposed or finalized Clean Air Act rule issued since January 20, 2009 and a description of the changes from a proposed rule to a finalized rule if the number of avoided premature deaths attributable to the proposed rule changed in the finalized version. Make sure to include the proposed rules since January 20, 2009 that have not yet been finalized. Please distinguish how many of the projected avoided premature deaths result from reductions in each rule's target pollutant and how many resulted from co-benefits from reductions in fine particulate matter. Furthermore, please detail the degree to which each rule contributed to the same avoided premature deaths that would have occurred in the rule's absence.

The Honorable Gina McCarthy

Page 2

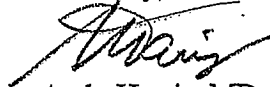
Lastly, I questioned you about the availability of the data that support the death and injury benefits and you assured me that all such data is publicly available and you were willing to provide it. In light of the pivotal role of this publically-funded research in providing a justification for major EPA regulations, it is imperative that associated data and analysis be open and transparent to allow for sufficient scientific and technical review. Accordingly, in the spirit and letter of Public Law 105-277, Executive Order 13563 (which explicitly states that regulations "must be based on the best available science"), EPA's *Peer Review Handbook*, and recently-released Scientific Integrity Policy Draft, please provide all original data and analysis for the following studies that were used in EPA analysis:

1. The Cancer Prevention Study I compiled by the American Cancer Society.
2. The Cancer Prevention Study II compiled by the American Cancer Society.
3. The Harvard Six Cities Study.
4. The Nurses' Health Study and Nurses' Health Study II.

Please provide all this information no later than October 3, 2011.

If you have any questions regarding this request please contact Ms. Tara Rothschild or Mr. Clint Woods with the Subcommittee on Energy and Environment at (202) 225-8844.

Sincerely,



Andy Harris, MD

Chairman

Subcommittee on Energy and Environment