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United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

BETTINA POIRIER, MAJORITY STAFF DIRECTOR
RUTH VAN MARK, MINORITY STAFF DIRECTOR

August 4, 2011

The Honorable Arthur A. Elkins, Jr., Inspector General
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. (2410T)
Washington, D.C. 20460

Re: EPA Management of the Clean Air Act Advisory Committees

Dear Mr. Elkins:

Over the past few weeks I have sent several letters to the Administrator of the Environmental Protection Agency (EPA), Lisa Jackson, raising serious questions about the Agency's handling of scientific information and its decision making process with regard to the National Ambient Air Quality Standards (NAAQS) for ozone. First, on June 30, 2011, Senator Vitter and I sent a letter in which we detailed significant deficiencies in how EPA assesses the science supporting the NAAQS. These weaknesses parallel the valid complaints made by the National Academy of Sciences (NAS) in its recent report, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*. They include systematic policies by the Agency that discount or ignore well conducted studies which show no health effect at air pollutant levels at or below the current standard and instead focus on a subset of studies that show an effect. They also include EPA's policy to assume a causal relationship between PM exposure and health effects down to pristine background levels to the extent that the vast majority of potential health benefits claimed by the Agency for both the ozone and PM2.5 standards occur well below the level the Clean Air Scientific Advisory Committee (CASAC) has advised is within an ample margin of safety. We have yet to receive a response to this letter.

On July 25, 2011, I sent the Administrator a second letter in which I objected to statements made in her July 13, 2011 response to Senator Carper that the 2008 Ozone NAAQS was legally indefensible. This statement cannot be supported by the statute or the 2008 rulemaking record. In my letter I pointed out that CASAC's statutory role in the development of NAAQS is to provide expert *advice* to the Administrator on the public health and environmental effects of air pollutants. Establishing a standard that is "sufficient, but not more than necessary" to protect public health with an adequate margin of safety is a science-based policy decision left exclusively to the Administrator's judgment, which is reviewable by the courts. We also raised several concerns regarding the legality of EPA's decision to reconsider the 2008 ozone standard without seeking public comments on the 2008 standard (0.075 ppm) as part of the reconsideration rulemaking, and without adhering to the statutory requirements for reviewing the standard. Indeed, the decision to lower the standard appears to be a *fait accompli* for which the public had no meaningful input. Given that the final rule is now pending at OMB, we have

asked the Administrator to provide a prompt response to this second letter and the critical questions raised therein.

Today I am requesting that you investigate serious *new* concerns regarding EPA's operation of two key Clean Air Act advisory committees, CASAC and the Advisory Council on Clean Air Compliance Analysis (ACCACA). My review suggests that EPA has managed these committees in ways that are inconsistent with applicable law and Administration policy. Instead of providing forums for impartial, objective advice, the committees appear to be designed and operated in a manner largely to rubberstamp EPA's analyses and decisions. This was not what Congress intended when it created the statutory requirement for external review under the Clean Air Act.

I have attached to this letter my review of a number of key issues surrounding EPA's management of the above noted advisory committees. This document also contains a number of questions I'd like you to explore during the course of your investigation. My review of EPA's operation of the advisory panels shows the following fundamental problems:

- *Lack of Impartiality:* EPA has violated its own *Peer Review Handbook* by selecting members who have publicly taken sides on the issues in question and thus lack the required impartiality. In direct conflict with the recommendations of the National Academies, EPA has also repeatedly asked authors of key studies to opine on their own work by including them on panels that are reviewing reports based on their research.
- *Failure to Balance Perspectives:* EPA has also violated the requirements of the *Federal Advisory Committee Act (FACA)* by failing to assure the resulting panels are balanced in terms of the viewpoints presented. In the two cases examined, no experts with publications supporting a contrary view were selected to balance the 30 to 40 percent of the members included on the panels who have taken public positions.
- *Failure to Rotate Members:* EPA has disregarded Administration policy to rotate membership on standing panels to avoid creating "regulars". On key panels, members are now serving 12 year terms.
- *Financial Conflict of Interest:* EPA has repeatedly selected panel members who are benefiting from millions of dollars in EPA research grants, creating both the appearance and likelihood of a conflict of interest.

EPA will likely make a final decision on its voluntary proposal to revise the 2008 ozone standard within the next few days. Although our inquiry on the impartiality and balance of EPA's clean air advisory panels focused on only two committees, we also have concerns with regard to the objectivity of the current CASAC panel that reviewed the science supporting the 2008 ozone standard. As part of the reconsideration, EPA sought additional advice from the current ozone CASAC panel despite the fact that many members of the panel had publicly opposed the 2008 ozone standard in a letter sent to EPA. This would also appear to violate

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FACA and EPA policy on peer review. I request that you also examine the compliance of the CASAC ozone panel with FACA and EPA peer review policy and report back to me on whether: (1) any members have publicly stated a position on the standard prior to being selected on the panel; (2) the panel is balanced based on their viewpoints and published research; (3) any panel members are authors or co-authors of key studies included in 2008 ozone scientific record; and (4) the amount of funds each member and his organization has received from EPA.

Based on EPA's own estimates, the ozone rule will be one of the most expensive environmental rules ever issued, imposing tens of billions of dollars of new regulatory costs on the American public each year. Given the serious deficiencies in how EPA assesses the scientific evidence and, what we now discover is the lack of objectivity in EPA's Clean Air Act advisory panels, we fear that EPA's most important near-term decisions, including EPA's proposal to reconsider the 2008 ozone NAAQS, are based on flawed science that has not been critically reviewed by an objective external review committee. Because of the significance of the pending ozone rule and the soon to be proposed PM rule, we respectfully request that you undertake an investigation of EPA's management of the CASAC ozone and PM review panels and the ACCACA panel and report back no later than September 19, 2011.

Please contact George Sugiyama on my staff at (202)-224-0146 if you have any questions concerning this letter.

Sincerely,



James M. Inhofe
Ranking Member
Committee on Environment & Public Works

ATTACHMENT

Deficiencies With EPA's Management of the CASAC Advisory Panel¹

In 1999, EPA formed a CASAC panel to provide EPA with advice in the development of the 2006 PM standards. In 2006, EPA promulgated a lower daily PM_{2.5} standard, but retained the annual PM_{2.5} standard, rejecting CASAC's advice on this point.² In response to the new 2006 standard, nine of the 2006 PM NAAQS Review Panel members signed letters to the EPA Administrator objecting to EPA's failure to lower the annual standard and calling for the annual standard to be lowered.³ Notably, one of these members, Dr. Jonathan Samet, also published an editorial in the *American Journal of Respiratory Care Medicine*, claiming that the current annual limit "does not protect the nation's health, as required by the Clean Air Act."⁴ In 2007, EPA formed a new CASAC panel (the 2011 PM NAAQS Review Panel) to advise the Administrator on the scientific issues relating to the development of new PM standards.⁵ EPA selected Dr. Jonathan Samet to chair the 2011 Panel, despite his highly publicized position against the existing standard. In fact, all nine of 2006 CASAC Panel members who had publically criticized EPA and called for a lower annual PM standard were also chosen for the 2011 Panel.⁶ These nine members constitute about 40 percent of that panel. Notably, none of the new members to the 2011 Panel have published research offering a contrary view, despite a rich peer reviewed body of literature questioning aspects of EPA's PM health science. The new 2011 PM standards are expected to be proposed by the end of this year.

¹ This attachment is a review of the available public record on EPA's management of the CASAC and the Agency's compliance with applicable laws and policies. It is EPA's actions that are called into question. It is not intended to characterize or call into question the work product or ethics of any named individuals.

² EPA, National Ambient Air Quality Standards For Particulate Matter, 71 Fed. Reg. 2620 (Jan. 17, 2006).

³ Clean Air Science Advisory Committee Recommendations Concerning the Final National Ambient Air Quality Standards for Particulate Matter (EPA-CASAC-LTR-06-003) (Sept. 29, 2006), available at [http://yosemite.epa.gov/sab/sabproduct.nsf/1C69E987731CB775852571FC00499A10/\\$File/casac-ltr-06-003.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1C69E987731CB775852571FC00499A10/$File/casac-ltr-06-003.pdf).

⁴ William N. Rom and Jonathan M. Samet, "Small Particles with Big Effects," 173 Am. J. Resp. & Crit. Care Med. 365, 366 (2006), available at <http://ajrccm.atsjournals.org/cgi/content/full/173/4/365>.

⁵ Memorandum from Fred Butterfield, Designated Federal Officer for CASAC to Vanessa Vu, Staff Director for the EPA Science Advisory Board, re "Formation of Clean Air Scientific Advisory Committee Particulate Matter Review Panel" (Oct. 23, 2007) available at http://www.epa.gov/science1/pdf/casac_pm_rev_panel_determination_memo_10-23-2007.pdf. NAAQS are to be reviewed and revised every five years based on input from CASAC. See 42 U.S.C. § 7409(d)(1).

⁶ Clean Air Science Advisory Committee (CASAC) Particulate Matter Review Panel's Peer Review of the Agency's Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information (Second Draft PM Staff Paper, January 2005); and Particulate Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report (Second Draft PM Risk Assessment, January 2005) (EPA-SAB-CASAC-05-007) (June 6, 2005), available at [http://yosemite.epa.gov/sab/sabproduct.nsf/E523DD36175EB5AD8525701B007332AE/\\$File/SAB-CASAC-05-007_unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/E523DD36175EB5AD8525701B007332AE/$File/SAB-CASAC-05-007_unsigned.pdf).

EPA's selection of members for the 2011 PM NAAQS review violates the Agency's own *Peer Review Handbook*.⁷ This handbook states: "As a general rule, experts who have made public pronouncements . . . on an issue, those who have clearly 'taken sides,' may have an appearance of a lack of impartiality . . . and should be avoided."⁸ Clearly EPA ignored its own policy guidance on the selection of peer review panels when it reappointed all nine of the 2006 Panel members who publicly voiced their opposition to the 2006 annual standard, including most importantly by appointing as Chair of the new panel, the one member, Dr. Jonathan Samet, who went as far as to publish an editorial against the new standard. Based on these nine individuals' involvement in the 2006 PM NAAQS Panel and their public opposition to EPA retaining the annual PM standard, these panelists have an appearance of a lack of impartiality that should disqualify them for service on the 2011 PM Review Panel. We seek your review of the following questions:

- Did EPA violate its own guidance on peer review by selecting members for the 2011 PM NAAQS Panel who had made public pronouncements against the standard under review?
- Did EPA believe it was acceptable to select Dr. Jonathan Samet as Chair of the review panel when he had personally published an editorial in opposition to the standard?
- Did any official within EPA raise objections to the selection of the Chair or the reappointment of the other panel Members based on their previous public statements?
- Did EPA notify the public in reappointing these members to the 2011 panel of their public comments on the standard? Did EPA notify the public that its decision to reappoint the members violated its own guidance on the selection of peer review panels? Did EPA provide an explanation for doing so?
- Did your office raise any questions with regard to EPA's selection of members for the 2011 panel given many of the members' public stances on the 2006 standard?
- Did OMB or any other agency review EPA's decisions with regard to panel selection to ensure compliance with Administration policy on these key points? In 2009 the EPA IG issued a report "No Violations Found Regarding Removal of Comments from an External Peer Review", Report No. 09-P-0084. Do you believe the current circumstances would require the same outcome as this earlier circumstance?

In addition to violating EPA's *Peer Review Handbook*, the 2011 PM Review Panel also appears to violate the Federal Advisory Committee Act's (FACA) requirement that it be "fairly balanced in terms of the points of view represented."⁹ Nearly 40 percent of the new Panel has taken public positions against the existing standard, while none of the other Panel members appear to have published research offering a contrary view to EPA's PM health science.

- On what basis did EPA select members from the 2006 panel to be reappointed to the 2011 panel?

⁷ EPA, *Peer Review Handbook* (EPA/100/B-06/002) (3d ed. 2006), available at http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf. Pages D-12 to D-14 of the Handbook are an example charge to the CASAC.

⁸ *Id.*

⁹ 5 U.S.C. App., § 5(b)(2) (2006).

- Did EPA reappoint these panel members in part because they publicly opposed the 2006 annual PM standard? What percentage of those reappointed have made public statements opposing or supporting the 2006 annual standard?
- Was the 2011 PM Review Panel balanced in terms of the viewpoints expressed in accordance with the requirements of FACA? Please describe any efforts made by EPA to achieve this balance in order to comply with FACA on this point.
- Did OMB or any external Agency review EPA's decision to assure compliance with FACA?
- Did your office review EPA's compliance with FACA on this key point?
- Does your office conduct periodic reviews to determine whether the Agency is complying with FACA in selecting operation review committees subject to FACA?

The *Peer Review Bulletin* and the *Peer Review Handbook* further encourage agencies to rotate membership on standing panels across the pool of qualified reviewers to avoid creating "regulars" whose independence from the agency may be questioned. The nine 2006 Panel Members who were reappointed to the 2011 PM Panel have presumably now been serving as advisors to EPA on the same set of issues for close to 12 years. More than just "regulars" these panel members appear to have become fixtures in their advisory role on PM science issues.

- Of those members who have been reappointed to the 2011 panel, how long will they have served as advisors on PM related issues?
- Why did EPA believe it was acceptable to reappoint the same members to 2011 PM Panel, such that they would serve 12 years providing advice on the same issue?
- Do you agree that this conflicts with the *Peer Review Bulletin* and *Peer Review Handbook's* admonition against having "regulars" on peer review panels?
- Are there any officials within EPA that monitor the Agency's compliance with the Administration's peer review policy?

Deficiencies With EPA's Management of the Advisory Council on Clean Air Compliance Analysis (ACCACA)

The Advisory Council on Clean Air Compliance Analysis (ACCACA) was tasked by Congress with reviewing EPA reports to Congress on the benefits and costs of compliance with the 1990 Amendments to the Clean Air Act.¹⁰ In 1995, Congress repealed EPA's obligation to file such reports, but EPA has nonetheless maintained ACCACA and has continued to file reports showing very large, if not unrealistic estimates, of the benefits from complying with the 1990 Amendments, driven almost entirely by EPA's claimed benefits from reductions in fine particulate matter. EPA recently completed its "Second Prospective Study" on the costs and benefits of Clean Air Act compliance, and requested the Health Effects Subcommittee (HES) of the ACCACA to review it.¹¹ For this peer review, the five members of the HES were "augmented" by five members of the ACCACA, including three scientists, Drs. Arden Pope, Michelle Bell, and Jonathan Levy, who were lead or coauthors of the key health studies that EPA

¹⁰ 42 U.S.C. § 7612 (f), (g) (2006).

¹¹ EPA, Benefits and Costs of the Clean Air Act: Second Perspective Study 1990 – 2010, <http://www.epa.gov/air/sect812/prospective2-2.html>.

proposed to use, and eventually did use, to estimate the benefits of the Clean Air Act.¹² These scientists ended up opining on the merits of, and recommending the use of, their own studies. This lack of objective and impartial advice may be a major factor in the ballooning benefit estimates that strain credibility.

EPA's selection of the three study authors for the Augmented HES violates Administration policy on peer review and demonstrates a lack of impartiality that should disqualify them for service. OMB's *Peer Review Bulletin* declares: "Peer reviewers shall not have participated in development of the work product [under review]."¹³ The National Academies' policy on this important point is explicit: "[A]n individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work...is the central purpose of the activity. . . ."¹⁴ Selecting the three study authors in a position where they are reviewing a study that is based in large part on their own work undermines the purpose of seeking external review and risks making the review function as a sham unworthy of government funding. We seek your investigation into the following issues:

- Is it permissible or acceptable under current Administration policy to select the authors of the main studies on which EPA relied to participate in the review panel? What were EPA's stated reasons for doing so?
- Are there other examples where EPA has included authors on review panels which are reviewing reports based on their work?
- Does EPA disagree with the National Academies' position that individuals should not serve on a committee that is reviewing and evaluating their own work?
- Did any official within EPA raise objections to including these individuals on the HES?
- Did your office raise concerns?
- Did any Administration office outside EPA review EPA's selection of members for the ACCACA?
- Was the public notified of this inherent conflict of interest when EPA described the panel and its results?

The Second Prospective Study also placed high reliance on the results of an earlier, EPA-sponsored "Expert Elicitation" study to justify its approach to quantifying chronic PM mortality.¹⁵ Similar to the Augmented HES, almost half of the 12 experts on the Expert

¹² Id. at ii-iv.

¹³ OMB, Final Information Quality Act Bulletin for Peer Review, 70 Fed. Reg. 2664, 2675 (Jan. 14, 2005).

¹⁴ National Academies, Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports 5 (May 12, 2003), available at: http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

¹⁵ Industrial Economics Inc., "Expanded Expert Judgment Assessment of the Concentration-Response Relationship Between PM_{2.5} Exposure and Mortality" (Final Report 2006), available at http://www.epa.gov/ttn/ecas/regdata/Uncertainty/pm_ee_report.pdf. EPA contracted for two expert elicitation studies between 2003 and 2006 in response to a recommendation of the National Academy of Sciences that it do so to generate a probability distribution for key sources of uncertainty in its benefits estimates. Id. at 1-1. EPA cited the first, pilot study in support of multiple rulemakings, id. at 1-3, and included the both the pilot study and the peer review version of the second, full-scale study in the Regulatory Impact Analysis for the 2006 PM NAAQS. See

Elicitation panel were again co-authors of the two studies eventually used by the Second Prospective Study to quantify the benefits of PM reductions. This action is in direct conflict with OMB's *Peer Review Bulletin* which states: "Peer reviewers shall not have participated in development of the work product [under review]".¹⁶ While EPA did not organize this "Expert Elicitation," it is difficult to believe that EPA contracting officials were not aware or did not approve the contractor's construction of that panel.

- What role did EPA officials have in identifying potential candidates to serve on the review panel?
- Did EPA approve the selection of experts for this Expert Elicitation panel?
- Did the contractor raise a concern to EPA about the appropriateness of selecting experts for the panel who had also authored the key studies under review?
- Did the contractor inform EPA or discuss with EPA the fact that 50 percent of the members on the review panel were in fact authors or coauthors of studies being reviewed?
- Did EPA at any time discourage the contractor from selecting members who were also authors or co-authors of the studies being reviewed as part of the report?

As with the CASAC 2011 PM Review Panel, EPA's creation of the Augmented HES violates FACA's requirement that federal advisory committees be "fairly balanced in terms of the points of view represented" and similar requirements in the *Peer Review Bulletin* and *Peer Review Handbook* for balanced representation.¹⁷ Similar to the CASAC panel, the Augmented HES does not appear to contain any members with publications supporting a contrary or alternative view of PM health science to balance the 30 percent of its membership whose have expressed publicly a clear view.

- What efforts did EPA undertake to ensure a balance in terms of the points of view presented on the committee on the key risk assessment issues driving the significant benefit claims in the report?

In its March 1, 2011 press release on the report, "EPA Report Underscores Clean Air Act's Successful Public Health Protections/Landmark law saved 160,000 lives in 2010 alone", EPA states that the report is "the third in a series of EPA studies required under the 1990 Clean Air Act amendments that estimate the benefits and costs of the act."¹⁸ This statement, however, appears to be incorrect based on the fact that Congress repealed EPA's requirement to issue these reports in 1995.

Chapter Five, pp. 5-6 & 5-105, available at <http://www.epa.gov/ttn/ecas/regdata/RIAs/Chapter%205--Benefits.pdf>. The full-scale study is the document cited in the Second Prospective Study.

¹⁶ 70 Fed. Reg. 2664, 2675 (Jan. 14, 2005).

¹⁷ 5 U.S.C. App., § 5(b)(2) (2006).

¹⁸ EPA Press Release, "EPA Report Underscores Clean Air Act's Successful Public Health Protections/Landmark law saved 160,000 lives in 2010 alone" (March 1, 2011) ("The report is the third in a series of EPA studies required under the 1990 Clean Air Act amendments that estimate the benefits and costs of the act."), available at <http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/f8ad3485e788be5a8525784600540649!OpenDocument>.

- Did anyone within EPA review the accuracy of this press release?
- Does EPA management incorrectly believe that the statute requires additional reports?
- Does EPA plan to continue issuing these reports?
- What is the full cost to the taxpayer of undertaking the assessment and publishing the report?
- Will EPA correct the statement, now on its website, that the current report is required under the Act?

Financial Conflict of Interest

It should come as no surprise that research in this country is big business and that EPA provides one of the largest sources of funding to assess the public health and environmental effects from exposure to air pollution. Simply acknowledging the income received, which is the current Administration policy, does not correct the problem or ensure objectivity in the panel members when they are: (1) selected by EPA; (2) opining on their own work products funded by EPA; (3) reviewing EPA reports; and (4) receiving millions in dollars in grant funding from EPA. The substantial financial relationships between EPA and the peer review panelists add to the significant concerns over the lack of objectivity in EPA's advisory committees described in this letter. The financial relationships should encourage EPA to act with greater vigilance to assure the objectivity of the review panels. The results of our investigation into the two major advisory committees show that EPA has failed in this important duty.

The following table lists members of the 2011 PM NAAQS Review Panel who have signed letters in support of lowering the annual PM_{2.5} standard. The table shows the amount of EPA funding that each individual, or the research center with which the individual is associated, has received.

Table - EPA Support of 2011 PM NAAQS Review Panel Members¹⁹

Members of 2011 PM NAAQS Review Panel	Individual Grants	Center Grants
Ellis Cowling	-	-
James Crapo	-	\$26.0M – 2 centers
Rogene Henderson	-	\$18.8M – 1 center
Philip Hopke	\$0.9M – 2 grants	\$16.3M – 2 centers
Morton Lippmann	\$1.2M – 1 grant	\$35.1M – 3centers

¹⁹ Information reconstructed from the EPA Grants database. EPA, Grant Awards Database, http://yosemite.epa.gov/oarm/igms_egf.nsf/HomePage?ReadForm.

Richard Poirot	-	-
Jonathan Samet	\$1.5M – 2 grants	\$26.7M – 2 centers
Frank Speizer	\$0.9M – 1 grant	\$11.0M – 2 centers
Sverre Vedal	-	\$8.0M – 1 center

- Please verify that the above figures are correct.
- What role did the funding relationships play in EPA's selection of panel members?
- Does EPA have a policy discouraging the selection of members who are receiving grants from EPA?
- How much grant money do members of EPA's ozone peer review panel receive from EPA?
How much money do their research centers receive from EPA?
- Does EPA's significant funding suggest that a third party, rather than EPA, should select members for review panels?