



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 30 2013

OFFICE OF
AIR AND RADIATION

The Honorable Lamar Smith
Chairman
Committee on Science, Space and Technology
U.S. House of Representatives
Washington, D.C. 20515-6301

Dear Chairman Smith:

Thank you for your letters of June 12, 2013 and July 22, 2013, co-signed by Chairman Chris Stewart, regarding the U.S. Environmental Protection Agency's use of peer-reviewed, scientific studies regarding the health effects of particulate matter (PM) and ozone air pollution that analyze data from the American Cancer Society and Harvard Six Cities cohorts. I write to respond on behalf of the Agency with regard to several of the issues you raise in your letters.

First, the peer-reviewed scientific evidence that particulate matter and ozone are associated with significant public health impacts is robust and well understood. The Clean Air Act requires the EPA to set health-based national ambient air quality standards for these pollutants at a level requisite to protect public health with an adequate margin of safety; the agency must review the best available science every five years and, if appropriate, revise the standards to meet this requirement. In conducting these periodic reviews, the EPA follows a rigorous and open process that examines all available science on these pollutants. The science consistently shows these pollutants are associated with a range of adverse health effects from asthma attacks to heart attacks to premature deaths. This understanding is confirmed by a body of science that includes decades of research documented in thousands of studies. The EPA and a broad range of independent research and public health organizations have identified numerous and serious health risks associated with air pollution. In its most recent review of the science on particulate matter, for example, the American Heart Association found that "the overall evidence is consistent with a causal relationship between PM_{2.5} exposure and cardiovascular morbidity and mortality" and that exposure to PM air pollution is "a modifiable factor that contributes to cardiovascular morbidity and mortality."¹

Your letters request, on the basis of a brief phrase from a 2004 National Research Council (NRC) report on research priorities for particulate matter,² that the EPA refrain from relying on, or even citing, certain studies that analyze the American Cancer Society and Harvard Six Cities cohort data. The NRC report, however, expressly endorses the quality of the American Cancer Society and Harvard Six Cities long-term cohort studies by confirming that they provide critical evidence for health effects and that they are

¹ Brook, et al. American Heart Association Scientific Statement: Particulate Matter Air Pollution and Cardiovascular Disease. May 2010. <http://circ.ahajournals.org/content/121/21/2331.long>

² National Research Council. 2004. "Research Priorities for Airborne Particulate Matter: IV." Board on Environmental Studies and Toxicology.

well-suited for use in risk and health effects estimates. The full relevant sentence in the report reads: "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" (emphasis added). Further, the NRC stated, "Long term studies are likely to remain central, however, in assessing the public health burden caused by air pollution." Consistent with this advice, the EPA considers these peer-reviewed cohort studies as part of the full body of science on air pollution and health in establishing National Ambient Air Quality Standards (NAAQS) and in assessing the health impacts of other major rules.

In the process of establishing a NAAQS, the EPA looks comprehensively at the available science assessing thousands of scientific studies using all of the appropriate peer-review processes and guidance. For example, in the most recent PM NAAQS integrated science assessment the EPA cited approximately 2,000 peer-reviewed studies. The long-term cohort studies you cite in your letter are two of the many studies the EPA considers. During the most recent review of the PM NAAQS, the EPA also examined studies of newer cohorts that confirmed that premature death is associated with fine particle pollution, in some cases at pollution levels lower than those reported in studies of the American Cancer Society and Harvard Six Cities cohorts. Additionally, some of these studies based on newer cohorts showed even greater risks of premature mortality than studies of either the American Cancer Society or Harvard Six Cities cohorts.³

Likewise, in developing methods to use in regulatory impact analyses for major rules, the EPA evaluates a variety of long-term cohort studies, including newer cohort studies. The EPA includes an assessment of the strengths and limitations of each study to determine the most appropriate studies to use in estimating risks and health effects avoided. On balance, studies of the American Cancer Society and Harvard Six Cities cohorts follow groups of participants that are more representative of American populations in terms of age, gender, and geography than other cohorts used in currently available studies. In addition, studies conducted using these cohorts include extended follow-up analyses that capture longer-term health impacts better than other studies without long follow-up periods. These studies also include the most thorough consideration of other factors that affect health, such as smoking and education. For these reasons, studies based on these two cohorts remain more appropriate for estimating the national benefits of reducing pollution than other currently available cohort studies.

Two separate panels of the EPA's independent Science Advisory Board (SAB) recently recommended that the EPA continue to use estimates based on the American Cancer Society and Harvard Six Cities cohorts to quantify PM_{2.5}-related mortality risks and benefits.⁴ The EPA's approach is consistent with

³ U.S. Environmental Protection Agency (U.S. EPA). 2009. Integrated Science Assessment for Particulate Matter (Final Report). See Figure 7-7. EPA-600-R-08-139F. National Center for Environmental Assessment—RTP Division. December. Available on the Internet at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546>.

⁴ U.S. Environmental Protection Agency Science Advisory Board (U.S. EPA-SAB). 2010. *Review of EPA's DRAFT Health Benefits of the Second Section 812 Prospective Study of the Clean Air Act*. EPA-COUNCIL-10-001. June. Available on the Internet at http://yosemite.epa.gov/sab/sabproduct.nsf/9288428b8eeca4c885257242006935a3/59e06b6c5ca66597852575e7006c5d09!OpenDocument&TableRow=2_3#2.

U.S. Environmental Protection Agency Science Advisory Board (U.S. EPA-SAB). 2009. *Review of Risk Assessment to Support the Review of the Particulate Matter (PM) Primary National Ambient Air Quality Standards—External Review Draft (September 2009)*. EPA-CASAC-10-003. Available on the Internet at [http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/BC1ECC5D539EF72385257678006D5754/\\$File/EPA-CASAC-10-003-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/BC1ECC5D539EF72385257678006D5754/$File/EPA-CASAC-10-003-unsigned.pdf).

U.S. Environmental Protection Agency Science Advisory Board (U.S. EPA-SAB). 2010. *CASAC Review of Quantitative Health Risk Assessment for Particulate Matter—Second External Review Draft (February 2010)*. EPA-CASAC-10-008. Available on the Internet at [http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/BC4F6E77B6385155852577070002F09F/\\$File/EPA-CASAC-10-008-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/BC4F6E77B6385155852577070002F09F/$File/EPA-CASAC-10-008-unsigned.pdf).

the advice from the National Academy of Sciences and the SAB. Further, the NRC in the 2004 report cited in your letter specifically endorses the use of long-term cohort studies for quantifying health risks and benefits.

Your letters reiterate a request that the EPA refrain from relying on studies of the American Cancer Society or Harvard Six Cities cohorts because the underlying data are not public. You also request that the EPA provide the underlying data associated with several of those studies. As an initial matter, the data are held by the outside research institutions that conducted these large-scale epidemiological studies, not the EPA, and the Agency already has provided the Committee all of the data that we have received thus far from those institutions.⁵ In response to further requests from Senator Vitter, the EPA has requested from the relevant researchers the research data associated with several additional studies that are required to be provided under the Shelby Amendment, consistent with applicable protections for private medical and similar information.⁶ Additionally, the Agency has sent forward to Dr. Michael Jerrett Senator Vitter's request for the full set of data files relating to his 2009 study entitled "Long-term Ozone Exposure and Mortality" published in the *New England Journal of Medicine*, which is not presently subject to the Shelby Amendment. The letters the EPA has sent to the researchers are enclosed. Finally, the EPA is engaging with relevant research institutions, and other entities with relevant expertise in this area, to get further information about technical options to get access to additional data. Those letters also are enclosed. The EPA will keep you apprised of progress on this front.

I want to emphasize, however, that the fact that some of the data is not public in no way undermines the validity of the studies' results. Nor does it call into question the EPA's reliance on those studies, along with thousands of other peer-reviewed studies, when the agency considers the scientific foundation for NAAQS and similar science-informed determinations, including decisions regarding methods used in risk and benefit assessments. In fact, the original studies based on these cohorts already have been subject to reanalysis and validation by the Health Effects Institute (HEI), a highly respected research institution jointly funded by the EPA and industry. Specifically, HEI entered into confidentiality agreements with the owners of the data to have access to the data in order to conduct a reanalysis of two studies of these cohorts. That re-analysis took 30 researchers more than three years to complete, and confirmed the validity of the findings and methodology. The same methodological approaches were used in the more recent studies of these cohorts, and are therefore similarly validated by the HEI reanalysis.

In closing, the peer-reviewed science consistently shows these pollutants are associated with a range of adverse health effects. This robust body of scientific evidence informs the EPA's actions to ensure public health protection for the American public and assess the impact of the EPA's programs on public health. As has been true for more than 40 years, understanding these issues is of vital importance to this

⁵ On June 7, 2012, and April 10, 2013, the EPA provided the Committee with the data associated with the following studies: Laden, F., J. Schwartz, F.E. Speizer, and D.W. Dockery. 2006. "Reduction in Fine Particulate Air Pollution and Mortality." *American Journal of Respiratory and Critical Care Medicine*. 173: 667-672.

Pope, C.A., III, R.T. Burnett, M.J. Thun, E.E. Calle, D. Krewski, K. Ito, and G.D. Thurston. 2002. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution." *Journal of the American Medical Association* 287:1132-1141.

⁶ The EPA has requested research data associated with the following studies: Krewski D, Jerrett M, Burnett RT, Ma R, Hughes E, Shi, Y, et al. 2009. "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, Boston, MA.

Lepeule J, Laden F, Dockery D, Schwartz J 2012. "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):965-70.

Pope, CA III, E Majid, D Dockery. 2009. "Fine Particle Air Pollution and Life Expectancy in the United States." *New England Journal of Medicine* 360: 376-386.

country. Science is an iterative process, and the EPA will continue to consider any peer-reviewed scientific studies that are published in the future on air pollution and health. The Agency is committed to scientific rigor, transparency and compliance with the Shelby Amendment and will keep you apprised of the responses we receive to the requests described above.

Again, thank you for your letter. If you have any further questions, please contact me or your staff may contact Cheryl Mackay in the EPA's Office of Congressional and Intergovernmental Relations at (202) 564-2023.

Sincerely,



Janet G. McCabe
Acting Assistant Administrator

Enclosure

cc: The Honorable Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology