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STRENGTHENING TRANSPARENCY AND ACCOUNTABILITY WITHIN THE ENVIRONMENTAL PROTECTION AGENCY

HEARING

BEFORE THE

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

NOVEMBER 14, 2013

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STRENGTHENING TRANSPARENCY AND ACCOUNTABILITY WITHIN THE ENVIRONMENTAL PROTECTION AGENCY

TUESDAY, NOVEMBER 14, 2013

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Committee met, pursuant to call, at 10:03 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Lamar Smith [Chairman of the Committee] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

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House of Representatives
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Strengthening Transparency and Accountability within the Environmental Protection Agency

Thursday, November 14, 2013
10:00 a.m. – 1:00 p.m.
2318 Rayburn House Office Building

Witnesses

The Honorable Gina McCarthy, Administrator, Environmental Protection Agency

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

HEARING CHARTER

Strengthening Transparency and Accountability within the Environmental Protection Agency

Thursday, November 14, 2013
10:00 a.m. to 1:00 p.m.
2318 Rayburn House Office Building

PURPOSE

On Thursday, November 14, 2013 at 10:00 a.m. the House Committee on Science, Space, and Technology will hold a hearing to review science and technology activities at the Environmental Protection Agency (EPA) including: agency-wide policies and practices related to the development and use of science in regulatory decisions; the role of independent scientific advisory bodies such as the EPA Science Advisory Board and the EPA Clean Air Scientific Advisory Committee; and the importance of transparency and integrity in the Agency's science activities.

WITNESS LIST

The Honorable Gina McCarthy, Administrator, U.S. Environmental Protection Agency

BACKGROUND

Science has been central to EPA's mission and functions since its establishment in 1970. In his message to Congress regarding the creation of EPA, President Nixon stated that a principal role of the agency should be "[t]he conduct of research on the adverse effects of pollution and on methods and equipment for controlling it, the gathering of information on pollution, and the use of this information in strengthening environmental protection programs and recommending policy changes."[1]

Today, with significantly expanded regulatory authorities and a budget over $8 billion, science remains an important component of the agency's mission and core activities. EPA's policy on scientific integrity states:

> "Science is the backbone of the EPA's decision-making. The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies. The environmental policies, decisions, guidance, and regulations that impact the lives of all Americans every day must be grounded, at a most fundamental level, in sound, high quality science."[2]

[1] http://www.epa.gov/aboutepa/history/org/origins/reorg.html
[2] http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf

EPA Administrator Gina McCarthy echoed this priority in her confirmation hearing, stating that "The rule of law, along with sound science and transparency, is one of EPA's core values and, if I am confirmed, it will continue to guide all EPA actions."[3] Similarly, she stated that, "EPA is committed to transparency with regard to the scientific bases of agency decision making."[4]

Overview of EPA Science Activities and Organization

EPA's science-related authorities and activities are derived from a number of statutes. The Environmental Research, Development, and Demonstration Authorization Act (ERDDA) authorizes agency research and science activities broadly, and created the Office of Research and Development (ORD) and Science Advisory Board (SAB).

In addition to ERDDAA, EPA also derives authority for R&D activities through other major environmental statutes. For example, under the Clean Air Act, the EPA Administrator must issue air quality criteria that "shall accurately reflect the latest scientific knowledge useful in indicating the kind of extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air."[5] Through the Safe Drinking Water Act, EPA sets standards based on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."[6] Similarly, the Clean Water Act requires EPA to publish water quality information "accurately reflecting the latest scientific knowledge."[7]

The science enterprise at EPA is spread across program offices and regions. ORD is organized into three national labs comprised of 18 separate labs and four national centers with 19 divisions. In addition to 18 labs within ORD, there are nine labs split among several program offices and each of EPA's ten regions across the nation has its own lab.

In a 2012 report, the SAB and EPA's Board of Scientific Counselors (BOSC) stated: "Over 6,000 EPA employees are involved in scientific assessments, research, and related activities, with approximately 1,300 full-time scientific staff in the Office of Research and Development (ORD) and approximately 4,700 full-time scientific staff in program and regional offices."[8]

The fragmented, disparate nature of EPA R&D presents a challenge to manage and coordinate, and has complicated efforts to evaluate the effectiveness of these activities. Numerous studies conducted by the Office of Inspector General (OIG), the Government Accountability Office (GAO), the National Academies of Science (NAS) and other outside

[3] http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_id=d71fd4b6-ce77-3a98-46a0-fb02b0cae0ed
[4] Ibid.
[5] 42 U.S.C. §7408 (a)(2) (2000).
[6] 42 U.S.C. §300g-1(b)(3)(A)(i).
[7] 33 U.S.C. §1314 (a)(1).
[8] EPA Science Advisory Board and Board of Scientific Counselors, Science *Integration for Decision Making at the U.S. EPA*, July 6, 2012.

groups over the years have cited significant concerns with the EPA's SAB and the difficulties in evaluating the usefulness of the science to program needs.

ISSUES FOR CONSIDERATION

Through the years, a series of reports have documented problems with science at EPA, including a lack of uniformity of the peer-review process, not evaluating impacts of regulations and a lack of transparency. In 1992, an independent panel stated, "Currently, EPA science is of uneven quality, and the Agency's policies and regulations are frequently perceived as lacking a strong scientific foundation."[9] Beyond the actual science conducted at the Agency, and used to generate regulations, the perception of the public is that EPA does not use science in an effective manner. "A perception exists that regulation based on unsound science have led to unneeded economic and social burdens, and that unsound science has sometimes led to decisions that expose people and ecosystems to avoidable risks."[10]

Regulatory Science

Science plays a foundational but not necessarily determinative role in support of EPA's mission to protect human health and the environment. EPA states that "the role and use of science at EPA are determined by the nature of the scientific information and how it fits with the context of Agency decision-making."[11] This role is further elaborated upon as follows:

> Science does not drive EPA's policy and regulatory decisions, but rather, along with other relevant factors, informs and supports those decisions. Implementation costs and technological feasibility, local autonomy versus federal control, and justice and equity--all of which impact our quality of life and standard of living--are among the considerations that need to be factored into EPA's decisions without compromising scientific integrity, the Agency's mission, or statutory mandates. The impacts or limitations of these non-science factors, as well as the current state-of-the-science, will influence how scientific considerations are brought to bear on a particular environmental problem facing the Agency.[12]

Numerous entities have raised concerns regarding possible shortcomings in the quality and use of science at the agency. The FY2013 Annual Plan of the EPA's OIG raises concerns about science and technology activities at the Agency, stating that "[q]uestions exist as to whether EPA is collecting the right data, of sufficient quality, and is making that data available."[13] In terms of EPA's regulatory process, the OIG further stated that "[m]any policies are out of date or are based on outdated science and technology."[14] More broadly, the chair of a 2009 National Academy of Sciences panel on ways to improve the Agency's risk assessment process told the EPA's SAB and BOSC earlier this year that the "The sleeping giant is that EPA

[9] EPA, *Safeguarding the Future: Credible Science, Credible Decisions,* 1992.
[10] Ibid.
[11] http://www.epa.gov/epahome/science.htm
[12] Ibid.
[13] EPA Inspector General (IG), "FY 2013 Annual Plan," January 2013, http://www.epa.gov/oig/reports/2013/EPA_OIG_FY_2013_Annual_Plan.pdf
[14] Ibid.

science is on the rocks," and that risk assessment process was the Agency's "Achilles heel."[15] Their final report found that, "There is a critical need for more high quality assessments translating existing science on a broad range of topics important to decision making at the EPA," and "narrow interpretations of legislative mandates and the organizational structure of EPA's regulatory programs often have posed barriers to innovation and cross-program solving."[16]

Peer Review and Advisory Panels

EPA's Peer Review Handbook provides guidance to the agency regarding use of peer review to enhance the quality and objectivity of scientific or technical work products. Specifically, EPA's peer review policy "encourages and expects peer review of all scientific and technical information that is intended to inform or support Agency decisions and notes that influential scientific information, including highly influential scientific assessments, should be peer reviewed in accordance with this Handbook."[17]

The EPA OIG released the report "*Procedural Review of EPA's Greenhouse Gases Endangerment Finding Data Quality Processes,*" which raised a number of concerns about how the Agency classifies scientific assessments and information, as well as the quality of peer review that EPA science undergoes. In reviewing EPA's Technical Support Document (TSD) in support of the Endangerment Finding, the OIG found that:

> "EPA's peer review did not meet all OMB [Office of Management and Budget] requirements for such documents. EPA had the TSD reviewed by a panel of 12 federal climate change scientists. However, the panel's findings and EPA's disposition of the findings were not made available to the public as would be required for reviews of highly influential scientific assessments. Also, this panel did not fully meet the independence requirements for reviews of highly influential scientific assessments because one of the panelists was an EPA employee."[18]

With respect to advisory panels, concerns have been raised regarding the make-up, transparency, and rigor provided by EPA advisory panels such as SAB and CASAC. Despite the requirement under the Federal Advisory Committee Act that panels be "fairly balanced in terms of points of view presented and the functions to be performed by the advisory committee,"[19] GAO has found that "[m]any advisory committee members are not appropriately screened for potential conflicts of interest or points of view."[20]

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[15] *Inside EPA*, "Key Adviser Warns EPA to Improve Agency Science Or Face A 'Crisis'," July 6, 2011.
[16] EPA Science Advisory Board and Board of Scientific Counselors, *Science Integration for Decision Making at the U.S. EPA,* July 6, 2012.
[17] http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf
[18] EPA IG, "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.
[19] 5 U.S.C. App
[20] GAO, "Ensuring Sound Science." See also: John Stephenson, GAO, Testimony before the Committee on Environment and Public Works, U.S. Senate, "SCIENTIFIC INTEGRITY: EPA's Efforts to Enhance the Credibility and Transparency of Its Scientific Processes," June 9, 2009, http://www.gao.gov/products/GAO-09-773T.

Cost-Benefit Analysis

EPA regulations are playing a greater role in the overall costs and benefits to the American economy. In its *Draft 2013 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*,[21] the Office of Information and Regulatory Affairs notes the prominence of EPA Clean Air Act rules in the overall regulatory apparatus, saying that EPA rules represent 58 to 80 percent of the agency-estimated monetized benefits and 44 to 54 percent of the monetized costs of all federal regulations.

Risk Assessment and Communication

Another major EPA responsibility within the Science, Space, and Technology Committee's jurisdiction is the conduct of risk assessments. EPA efforts in risk assessment aim to "characterize the nature and magnitude of health risks to humans (e.g., residents, workers, recreational visitors) and ecological receptors (e.g., birds, fish, wildlife) from chemical contaminants and other stressors that may be present in the environment."[22] EPA's primary program for assessing human health risks is known as the Integrated Risk Information System (IRIS).

The National Research Council (NRC) recently noted that as the science of risk assessment has become more complex, "improved analytical techniques have produced more data that lead to question about how to address issues of, for example, multiple chemical exposures, multiple risks and susceptibility in populations."[23] Despite understanding the increasing complexity and greater need for data and information, chemical risk assessment at EPA remains on GAO's High-Risk Program and was targeted for reform in the Consolidated Appropriations Act of 2012. Additionally, a 2011 NRC report made specific recommendations to EPA regarding how best to improve the IRIS process:[24]

[21] http://www.whitehouse.gov/sites/default/files/omb/inforeg/2013_cb/draft_2013_cost_benefit_report.pdf.
[22] http://epa.gov/riskassessment/basicinformation.htm#arisk
[23] NRC, *Science and Decisions: Advancing Risk Assessment*, 2009
[24] http://www.nap.edu/catalog.php?record_id=13142

Chairman SMITH. The Committee on Science, Space, and Technology will come to order. Welcome everyone to today's hearing titled Strengthening Transparency and Accountability Within the Environmental Protection Agency. I am going to recognize myself for five minutes for an opening statement, and then I will recognize the Ranking Member for hers.

The Environmental Protection Agency, like every other governmental institution, should answer to the American people. Everyone agrees that we need to protect the environment, but we should do so in a way that is open and honest. Democracy requires transparency and accountability.

Yet EPA's justifications for its regulations are cloaked in secret science. It appears the EPA bends the law and stretches the science to justify its own objectives.

Americans impacted by the Agency's regulations have a right to see the data and determine for themselves independently if these regulations are based on sound science or a partisan agenda. The EPA's efforts to expand its regulatory reach across the U.S. represent a troubling trend.

For example, take EPA's current attempt to redefine its jurisdiction under the Clean Water Act. It seeks to expand the definition of Waters of the U.S. to give the Agency unprecedented new authority over private property.

According to media reports, this expansion of EPA regulatory power could include almost all man-made and natural streams, lakes and ponds in the U.S. This undermines states' rights and increases Federal control of private property and could lead to the EPA telling us what to do in our own back yard.

The EPA's efforts to demonize hydraulic fracturing are another example of an Agency implementing a partisan agenda before it takes the time to get the facts. The EPA made wild claims of groundwater contamination but was forced to retract those claims when it could produce no evidence. Perhaps the most worrisome examples of the Agency's disregard for transparency and accountability are found in the EPA's Clean Air Program.

We all agree that ensuring clean air is essential, but the EPA has a responsibility to establish rules that balance our environmental concerns and our economic needs.

Nearly all of this Administration's air quality regulations are justified on the basis of hidden data. These regulations cost billions of dollars but the EPA claims that the benefits of these rules justify the costs. These claims can't be verified if the EPA uses secret science.

More than two years ago, before this Committee, then Assistant Administrator McCarthy said this information was available for independent review and verification. And a few months ago, the President's own Science Advisor took the same position. When the EPA failed to live up to those commitments, the Committee issued a subpoena requiring the Agency to produce the data. Three months later, the Agency still hasn't provided the data necessary to verify the Agency's claims.

Let me be clear: It is the EPA's responsibility to ensure that the science it uses is transparent and that its claims can be verified independently.

Recently, the EPA provided us with copies of letters it received from scientists explaining why they believe this data cannot be released to the public. It is unfortunate that it took us two years and a subpoena to get here, but now even the EPA knows the truth: The Agency itself cannot publicly verify its own claims.

So not only do we have a lack of transparency, we have an Agency that is regulating without the facts to back up its claims.

We need to know whether the Agency is telling the truth to the American people. The EPA must either make the data public or commit to no longer use secret science to support its regulations. Without this, Congress will have no choice but to prohibit the EPA's use of secret data moving forward.

I will introduce legislation in the next few weeks that will stop the EPA from basing regulations on undisclosed and unverified information.

We can and should continue to look for ways to protect our environment. But these efforts must be open, transparent and based on sound science. Only then can the American people decide whether the costs of EPA's regulatory agenda is supported by the facts.

[The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF CHAIRMAN LAMAR S. SMITH

The Environmental Protection Agency (EPA), like every other governmental institution, answers to the American people. Everyone agrees that we need to protect the environment, but we should do so in a way that is open and honest. Democracy requires transparency and accountability.

Yet EPA's justifications for its regulations are cloaked in secret science. It appears the EPA bends the law and stretches the science to justify its own objectives.

The Americans impacted by the Agency's regulations have a right to see the data and determine for themselves independently if these regulations are based on sound science or a partisan agenda. The EPA's efforts to expand its regulatory reach across the U.S. represent a troubling trend.

For example, take EPA's current attempt to redefine its jurisdiction under the Clean Water Act. It seeks to expand the definition of "Waters of the U.S." to give the Agency unprecedented new authority over private property.

According to media reports, this expansion of EPA regulatory power could include almost all man-made and natural streams, lakes and ponds in the U.S. This undermines states' rights and increases federal control of private property and could lead to the EPA telling us what to do in our own back yard.

The EPA's efforts to demonize hydraulic fracturing are another example of an Agency implementing a partisan agenda before it takes the time to get the facts. The EPA made wild claims of groundwater contamination, but was forced to retract those claims when it could produce no evidence. Perhaps the most outrageous examples of the Agency's disregard for transparency and accountability are found in the EPA's clean air program.

We all agree that ensuring clean air is essential, but the EPA has a responsibility to establish rules that balance our environmental concerns and our economic needs.

Nearly all of this Administration's air quality regulations are justified on the basis of hidden data.

These regulations cost billions of dollars but the EPA claims that the benefits of these rules justify the costs. These claims can't be verified if the EPA uses secret science.

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Let me be clear: It is the EPA's responsibility to ensure that the science it uses is transparent and that its claims can be verified by the public.

Recently, the EPA provided us with copies of letters it received from scientists explaining why they believe this data cannot be released to the public. It's unfortunate that it took us two years and a subpoena to get here, but now even the EPA knows the truth: the Agency itself cannot publicly verify its own claims.

So not only do we have a lack of transparency, we have an Agency that is regulating with reckless abandon and without the facts to back up its claims.

We need to know whether the Agency is telling the truth to the American people. The EPA must either make the data public, or commit to no longer use secret science to support its regulations. Without this, Congress will have no choice but to prohibit the EPA's use of secret data moving forward.

I will introduce legislation in the next few weeks that will stop the EPA from basing regulations on undisclosed and unverified information.

We can and should continue to look for ways to protect our environment. But these efforts must be open, transparent and based on sound science. Only then can the American people decide whether the costs of EPA's regulatory agenda is supported by the facts.

Chairman SMITH. That concludes my opening statement, and the Ranking Member, the gentlewoman from Texas, is recognized for her opening statement.

Ms. JOHNSON. Thank you very much, and good morning. I am very pleased to welcome Administrator McCarthy to today's hearing. She has had a distinguished record at the Environmental Protection Agency prior to her being selected to be EPA Administrator. And by all accounts, she has been doing an exemplary job since assuming the position.

While I think her record of performance and her integrity speaks for themselves, I thought it was important to review the mission of the Agency. First, the mission of EPA is to protect human health and the environment. As someone who worked in public health before I entered politics, I can think of no mission of the Federal Government that is more important or noble than that. As a Member of Congress, I think I should be doing all I can to encourage EPA as it attempts to carry out a very challenging mission. I think too often EPA is made a target for funding cuts and its leadership subjected to harassment and denigration. Unfortunately, our own Committee has not been immune from employing these tactics.

Mr. Chairman, I am a Texan. From birth to death, I am a Texan, and I am no stranger to the oil and gas industries and the economic benefits they can bring or to the pollution and health and environmental impacts those industries can also bring. I know that EPA's actions have consequences for companies that sometimes are negative. However, I also know that EPA's actions have important consequences for the health of our constituents, especially those who are young, infirmed or elderly. And those consequences have been very positive indeed over the 40 years that EPA has been in existence.

We all want a healthy economy, but we also want a healthy quality of life for our citizenry. And EPA's efforts have played a critical role in achieving both these goals since its inception.

As Members of Congress, I think we should strive to educate our constituents, not scare them. I hope today I can resist the temptation to try for provocative sound bites for my district and instead use today's hearing to better understand what EPA has been tasked to accomplish, how it is doing on those tasks and how we in Congress can help it to do its job more effectively.

Administrator McCarthy, I know you have a very tough job, and I want to commend you for your willingness to take it on in spite

of all the hurdles that you and your Agency face. I look forward to your testimony, and I look forward to working with you to help EPA achieve the goals that the Nation has asked us to carry out.

I thank you and yield back my time.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF RANKING MEMBER EDDIE BERNICE JOHNSON

Good morning. I am very pleased to welcome Administrator McCarthy to today's hearing. She had a distinguished record at the Environmental Protection Agency prior to her being selected to be EPA Administrator, and by all accounts she has been doing an exemplary job since assuming that position.

While I think her record of performance and her integrity speak for themselves, I thought it important to review the mission.

First the mission of the EPA is to "protect human health and the environment." As someone who worked in public health before I entered politics, I can think of no mission of the federal government that is more important or noble than that. As a Member of Congress I think I should be doing all that I can to encourage EPA as it attempts to carry out a very challenging mission. I think, too often EPA is made a target for funding cuts and its leadership subjected to harassment and denigration. Unfortunately, our own Committee has not been immune from employing such tactics.

Mr. Chairman, I am a Texan from birth to death, and I'm no stranger to the oil and gas industries and the economic benefits they can bring—or to the pollution and health and environmental impacts those industries can also bring. I know that EPA's actions have consequences for companies that sometimes are negative. However, I also know that EPA's actions have important consequences for the health of our constituents—especially those who are young, infirm, or elderly. And those consequences have been very positive indeed over the forty-odd years that EPA has been in existence. We all want a healthy economy, but we also want a healthy quality of life for our citizenry—and EPA's efforts have played a critical role in achieving both those goals since its inception.

As Members of Congress, I think we should be strive to educate our constituents, not scare them. I hope today I can resist the temptation to try for provocative "sound bites" for my district, and instead use today's hearing to better understand what EPA has been tasked to accomplish, how it is doing on those tasks, and how we in Congress can help it to do its job more effectively.

Administrator McCarthy, I know you have a very tough job, and I want to commend you for your willingness to take it on in spite of all the hurdles that you and your agency face. I look forward to your testimony, and I look forward to working with you to help EPA achieve the goals that the nation has asked us to carry out.

Chairman SMITH. Thank you, Ms. Johnson. Members who have opening statements can submit them for the record, and they will appear at this point.

[The information follows:]

Chairman SMITH. Our witness today is The Honorable Gina McCarthy, Administrator of the Environmental Protection Agency. Prior to her appointment as Administrator, she was the Assistant Administrator for EPA's Office of Air and Radiation where she advocated to protect public health and the environment. During her career, which spans over 30 years, she has worked at both the state and local levels on environmental issues and helped coordinate policies on economic growth, energy, transportation and the environment.

Administrator McCarthy received a bachelor of arts degree in social anthropology from the University of Massachusetts and a master's of science and environmental health, engineering and planning from Tufts University.

At this time I will yield to the gentlewoman from Connecticut, Ms. Esty, for additional comments.

Ms. ESTY. Thank you, Chairman Smith and Ranking Member Johnson for holding today's hearing on the Environmental Protection Agency. I am very pleased to welcome Administrator Gina McCarthy who served as Commissioner of Connecticut's Department of Environmental Protection and then as Assistant Administrator of the U.S. EPA.

Administrator McCarthy, it is wonderful to see you again. Congratulations on your confirmation. You have an important role and responsibility as head of an agency charged with protecting the environment and the public's health. I appreciate all of your hard work to that end, and we are very proud of you in Connecticut and very pleased to see you here today.

Thank you so much.

Chairman SMITH. Thank you, Ms. Esty. Administrator McCarthy, we welcome your testimony, and please proceed.

TESTIMONY OF THE HONORABLE GINA MCCARTHY, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

Ms. MCCARTHY. Good morning, Chairman Smith, Ranking Member Johnson, and—oh, I am so sorry. Good morning, Chairman Smith and Ranking Member Johnson, other distinguished Members of the Committee. I am pleased to be here to talk about the central role that science plays at the United States Environmental Protection Agency.

Let me begin by stating that science is and always has been the backbone of the EPA's decision-making. The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science upon which it relies. I firmly believe that environmental policies, decisions, guidance, and regulation that impact the lives of all Americans must be grounded, at the most fundamental level, in sound, high quality, transparent, science.

Because we rely so heavily on science to meet our mission on behalf of the American people, it must be conducted in ways that are transparent, that is free from bias and conflict of interest and of the highest quality, integrity, and credibility. These qualities are important not just within our own organization and the Federal Government, but across the scientific community, with its long-established and highly honorable commitment to maintaining strict adherence to ethical investigation and research. That is why the agency has established and embraced a Scientific Integrity Policy that builds upon existing Agency and government-wide policies and guidance documents, explicitly outlining EPA's commitment to the highest standards of scientific integrity. And that commitment extends to any scientist or organization who wishes to contribute to our efforts. All EPA-funded research projects, whether they are conducted by EPA scientists or outside grantees or collaborators, must comply with the Agency's rigorous quality assurance requirements.

To ensure we have the best possible science, we are committed to rigorous, independent peer review of the scientific data, the models and analyses that support our decisions. Peer review can take a number of forms, ranging from external reviews by the National

Academy of Sciences or the EPA's federal advisory committees to contractor-coordinated reviews.

Consistent with OMB's guidance, we require peer review of all EPA research projects and for all influential scientific information and highly influential scientific assessments.

Among the external advisory committees is the EPA's Science Advisory Board. Our SAB reviews are conducted by groups of independent non-EPA scientists with the range of expertise required for that particular advisory topic. We invite the public to nominate experts for the SAB panels and to comment on candidates being considered by the EPA for SAB panels. The EPA evaluates public comments and information submitted about SAB nominees. The EPA's review experts' confidential financial information is available to ensure that there are no conflicts of interest.

SAB peer reviews are conducted in public sessions in compliance with the open-government requirements of the Federal Advisory Committee Act. The public is invited to send and to provide oral and written testimony for consideration by the SAB. Public comments help to ensure that all relevant science and technical issues are available to the SAB as it reviews the science that will support our environmental decisions.

Another example of how well we do science and maintain our integrity is the Clean Air Scientific Advisory Committee which provides independent advice to the EPA Administrator on the science that supports EPA's National Ambient Air Quality Standards. The CASAC reviews the EPA's Integrated Science Assessments which deliver science in support of the Clean Air Act.

Through a transparent and open process, we have also committed to enhancing the Agency's Integrated Risk Information System assessment program. A strong, scientifically rigorous IRIS Program is of critical importance, and the EPA is in the process of enhancing the scientific integrity of assessments, enhancing the productivity of that Program and increasing transparency so that issues are identified and debated early on in the process. In 2009, the EPA made significant enhancements to IRIS by announcing a new 7-step assessment development process. Since that time, the National Research Council has made recommendations related to enhancing the development of the IRIS assessments. The EPA is making changes still to the IRIS program to enhance our ability to respond to those recommendations and to maintain our science integrity. These changes will help the EPA produce more high-quality IRIS assessments each year in a timely and transparent manner to meet the needs of the Agency and the public. A newly released NRC report is largely supportive of the enhanced approach that EPA is now taking to develop the IRIS assessment, in this case, for inorganic arsenic.

As I mentioned in my opening statement, Mr. Chairman, science is the backbone of our decision making, and our work is based on the principles of scientific integrity and transparency that are both expected and deserved by the American people. I am proud of the EPA's research efforts and the sound use of science and technology to fulfill EPA's important mission to protect public health and safeguard the natural environment.

I want to thank you for the opportunity to meet with the Committee for the first time and to provide testimony, and I am happy to answer any questions that you might have.

[The prepared statement of Ms. McCarthy follows:]

TESTIMONY OF
GINA MCCARTHY
ADMINISTRATOR
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

November 14, 2013

Good morning Chairman Smith, Ranking Member Johnson, and other distinguished members of the Committee. I am pleased to be here to talk about the central role science plays at the U.S. Environmental Protection Agency.

Let me begin by stating that science is and has always been the backbone of the EPA's decision-making. The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science upon which it relies. I firmly believe that environmental policies, decisions, guidance, and regulations that impact the lives of all Americans must be grounded, at a most fundamental level, in sound, high quality, transparent, science.

Because we rely so heavily on science to meet our mission on behalf of the American people, it must be conducted in ways that are transparent, free from bias and conflicts of interest, and of the highest quality, integrity, and credibility. These qualities are important not just within our own organization and the federal government, but across the scientific community, with its long established and highly honorable commitment to maintaining strict adherence to ethical investigation and research. That's why the agency has established—and embraced—a Scientific

Integrity Policy[1] that builds upon existing Agency and government-wide policies and guidance documents, explicitly outlining the EPA's commitment to the highest standards of scientific integrity. And that commitment extends to any scientist or organization who wishes to contribute to our efforts. All EPA-funded research projects, whether conducted by EPA scientists or outside grantees and collaborators, must comply with the agency's rigorous quality assurance requirements.

To ensure that we have the best possible science, we are committed to rigorous, independent peer review of the scientific data, models and analyses that support our decisions. Peer review can take a number of forms, ranging from external reviews by the National Academy of Sciences or the EPA's federal advisory committees to contractor-coordinated reviews. Consistent with OMB guidance, we require peer review for all EPA research products and for all influential scientific information and highly influential scientific assessments.

Among the external advisory committees is the EPA Science Advisory Board (SAB). SAB reviews are conducted by groups of independent non-EPA scientists with the range of expertise required for the particular advisory topic. We invite the public to nominate experts for SAB panels and to comment on candidates being considered by the EPA for SAB panels. The EPA evaluates public comments and information submitted about SAB nominees. The EPA reviews experts' confidential financial information to ensure that there are no conflicts of interest.

SAB peer reviews are conducted in public sessions in compliance with the open-government requirements of the Federal Advisory Committee Act. The public is invited to attend and to provide oral and written comments for consideration by the SAB. Public comments help to

[1] http://www.epa.gov/research/htm/scientific-integrity.htm

ensure that all relevant scientific and technical issues are available to the SAB as it reviews the science that will support our environmental decisions.

Another example is the Clean Air Scientific Advisory Committee (CASAC) which provides independent advice to the EPA Administrator on the science that supports the EPA's National Ambient Air Quality Standards. The CASAC reviews the EPA's Integrated Science Assessments which deliver science in support of the Clean Air Act.

Thanks to the science behind the implementation of the Clean Air Act, we have made significant and far-reaching improvements in the health and well-being of the American public. In 2010 alone, EPA estimates that programs implemented pursuant to the Clean Air Act Amendments of 1990 avoided 160,000 premature deaths millions of cases of respiratory problems such as acute bronchitis and asthma attacks; 45,000 cardiovascular hospitalizations; and 41,000 hospital admissions. [2] These improvements have all occurred during a period of economic growth; between1970 and 2012 the Gross Domestic Product increased by 219%.[3]

Through a transparent and open process, we have also committed to enhancing the Agency's Integrated Risk Information System (IRIS) assessment program. A strong, scientifically rigorous IRIS Program is of critical importance, and the EPA is in the process of: 1) enhancing the scientific integrity of assessments; 2) enhancing the productivity of the Program; and 3) increasing transparency so that issues are identified and debated early in the process. In 2009, the EPA made significant enhancements to IRIS by announcing a new 7-step assessment

[2] The Benefits and Costs of the Clean Air Act from 1990 to 2020. Final Report. Prepared by the USEPA Office of Air and Radiation. February 2011. Table 5-6. http://www.epa.gov/air/sect812/prospective2.html

[3] Bureau of Economic Analysis, National Economic Accounts, "Table 1.1.5. Gross Domestic Product," http://bea.gov/national/pdf/dpga.pdf.

development process. Since that time, the National Research Council (NRC) has made recommendations related to enhancing the development of IRIS assessments. The EPA is making changes to the IRIS Program to implement the NRC recommendations. These changes will help the EPA produce more high quality IRIS assessments each year in a timely and transparent manner to meet the needs of the Agency and the public. A newly released NRC report[4] is largely supportive of the enhanced approach the EPA is taking to develop the IRIS assessment for inorganic arsenic.

As I mentioned in my opening statement, science is the backbone of our decision-making and our work is based on the principles of scientific integrity and transparency that are both expected and deserved by the American people. I am proud of the EPA's research efforts and the sound use of science and technology to fulfill the EPA's mission to protect human health and safeguard the natural environment.

Thank you for the opportunity to testify before you today. I am happy to answer any questions you may have at this time.

[4] http://www.nap.edu/catalog.php?record_id=18594

Administrator Gina McCarthy

Gina McCarthy is the Administrator of the U.S. Environmental Protection Agency.

Appointed by President Obama in 2009 as Assistant Administrator for EPA's Office of Air and Radiation, Gina McCarthy has been a leading advocate for common-sense strategies to protect public health and the environment.

Previously, McCarthy served as the Commissioner of the Connecticut Department of Environmental Protection. In her 30-year career, she has worked at both the state and local levels on critical environmental issues and helped coordinate policies on economic growth, energy, transportation and the environment.

McCarthy received a Bachelor of Arts in Social Anthropology from the University of Massachusetts at Boston and a joint Master of Science in Environmental Health Engineering and Planning and Policy from Tufts University.

When she is not in D.C., McCarthy lives in the Greater Boston area with her husband and two dogs, just a short bike ride away from their three children, Daniel, Maggie and Julie.

Chairman SMITH. Thank you, Administrator McCarthy. I will recognize myself for some questions.

The first one is this. When you testified before this Committee in September 2011, you promised to provide the data behind EPA's health benefit claims. And yet, to my knowledge, you have not done that. Yet, the Agency continues to justify major regulations based upon these studies. Now, you have given the Committee some information, but do you agree that the information you have given us so far is insufficient to validate these findings?

Ms. MCCARTHY. Mr. Chairman, my understanding is that we have submitted information that you requested.

Chairman SMITH. I don't deny that, but is the information you have given us sufficient to validate the findings that you have come to?

Ms. MCCARTHY. It is sufficient for you to understand the——

Chairman SMITH. I know. I know it is sufficient to understand, but can we validate it independently? Is the information you have given us sufficient to validate independently the findings that you have concluded?

Ms. MCCARTHY. I believe that it is sufficient for you to understand that we have relied on peer-reviewed science.

Chairman SMITH. Well, let me say that we get a letter from the EPA saying that it was not sufficient, so you might want to check with other individuals within the EPA. We have not gotten sufficient information to validate the findings.

Ms. MCCARTHY. Mr. Chairman, if you are looking to replicate the studies, I would agree with you that all of that information isn't available to the Agency, but we have sought to get that information for you and we have provided that information to you.

Chairman SMITH. Right. The information you have provided—I will just make that statement again—and is validated by a letter we received from the EPA which is not sufficient to validate your findings.

Let me go onto my next question. Next year the EPA is seeking to change its national ozone standards, a move that the Agency admits could be the most expensive regulation in history, I think perhaps exceeding the cost of $100 billion to the American people. Will you specifically commit to not rely on secret science and hidden data in the rule making for the ozone standards? In other words, will you make the underlying data public?

Ms. MCCARTHY. The Clean Air Science Advisory Committee that we rely on as our peer-review entity to take a look at our National Ambient Air Quality Standards ensures that we are public, that we make our information publically available. As far as transparency——

Chairman SMITH. Okay. So the——

Ms. MCCARTHY. —the EPA——

Chairman SMITH. —information will be made publically available that you rely upon to issue the ozone——

Ms. MCCARTHY. In the same way in which we have done it before, Mr. Chairman.

Chairman SMITH. Well——

Ms. MCCARTHY. We are very public——

Chairman SMITH. —the same way——

Ms. McCarthy. —with the information.

Chairman Smith. The same way before wasn't sufficient, so I am kind of wondering if you are saying it will be made public, if it is really going to be made public.

Ms. McCarthy. We rely on thousands of studies. We provide an integrated science assessment that is thoroughly looked at for the peer-review process.

Chairman Smith. Let me take you at your word. You said that the information would be made public, that the data that you rely upon for the issuance of the ozone——

Ms. McCarthy. In the same way we have done it always, Mr. Chairman, yes.

Chairman Smith. Well, okay. We have to disagree on that. I don't think you have always done it, but if you will say you will do it now, I will take you at your word.

Let me ask you this. Have you given the Committee all the subpoenaed data in the EPA's possession?

Ms. McCarthy. If you are referring to the PM data that you have requested from the Agency?

Chairman Smith. No, I am saying——

Ms. McCarthy. I am sorry, Mr. Chairman. What——

Chairman Smith. —have you——

Ms. McCarthy. We have a number of subpoenas.

Chairman Smith. Right.

Ms. McCarthy. I just want to make sure——

Chairman Smith. I am just talking about the one from the Science Committee. Have you given the Committee all the information that we have subpoenaed that is in your possession?

Ms. McCarthy. I believe we have as of September 20.

Chairman Smith. Okay.

Ms. McCarthy. Those were related to some specific studies. One was outstanding until September 20 so we could make sure that we had looked at confidentiality and privacy issues.

Chairman Smith. Okay. Thank you. Will the EPA produce all of its correspondence with outside entities regarding the efforts to comply with the subpoena, and this would include emails, text and other electronic communications?

Ms. McCarthy. I believe we are responding to that request today, Mr. Chairman. If you have further questions after that response or you don't believe it is adequate, we will certainly get staff together——

Chairman Smith. Okay.

Ms. McCarthy. —and we can converse as well.

Chairman Smith. But otherwise you will say it is going to Freedom of Information Act and give us all that correspondence, is that correct?

Ms. McCarthy. We actually respond to a number of Freedom of Information Act requests, Mr. Chairman. If that is your preference, we can do that.

Chairman Smith. No, don't let me confuse the issue. You are going to give us the correspondence that you have engaged in with the third parties to try to get them to comply with the subpoena?

Ms. McCarthy. We are going to respond to your request for that——

Chairman SMITH. Okay.

Ms. MCCARTHY. —I believe today.

Chairman SMITH. Okay. Thank you for that. My last question is this. The EPA has a draft Clean Water Act rule that could give EPA unprecedented authority over private property. The law clearly states that at the time such a proposal is sent to other Federal agencies, it must also be made available to EPA's Science Advisory Board, the SAB, for peer review. In September EPA sent its proposal to OMB for interagency review, but according to your SAB, the draft has not been made available to the Board. Why didn't you comply with this requirement before formally proposing the rule?

Ms. MCCARTHY. Mr. Chairman, I want to assure you that we are going to be and we are complying with our statutory obligations. What you are referring to is a rule that is very, very early in the process of science——

Chairman SMITH. Right, but you submitted it to OMB, and according to the law, when you submit it to OMB, you have got to submit it to your Science Advisory Board, and that hasn't been done yet.

Ms. MCCARTHY. We actually have a process that is established at EPA for how we communicate with the Science Advisory Board on those issues. It is a process that they have agreed to and we have. It is consistent——

Chairman SMITH. The submissions are supposed to be——

Ms. MCCARTHY. —with the law.

Chairman SMITH. The submissions are supposed to be concurrent, and yet you have submitted the rule to OMB but not to the Science Advisory Board. Are you expected to do that immediately?

Ms. MCCARTHY. Again, Mr. Chairman, the Science Advisory Board right now has an opportunity to look at the science that would underpin that rule, but we are very early on in the process and will make sure to comply with the law.

Chairman SMITH. Regardless of where you are in the process, the law says you have to submit it to the advisory board at the same time you give it to other agencies. But you haven't done that, and I am just wondering why.

Ms. MCCARTHY. Well, it is not a question that we haven't done it. It is a question that we have a process in place—

Chairman SMITH. So you have——

Ms. MCCARTHY. —where we work those issues——

Chairman SMITH. So you have submitted the——

Ms. MCCARTHY. —with the Science Advisory Board.

Chairman SMITH. You have submitted the rule to the advisory board and I am just not aware of it?

Ms. MCCARTHY. As far as I know, I don't believe the advisory board has the rule, but we are very early in the process. Unfortunately, you may have it, and they are likely to have it as well because it has been publically released. But it is in a very early stage.

Chairman SMITH. If there is a law that says you are supposed to submit it to them immediately and you haven't done that and that is not following the proper process——

Ms. MCCARTHY. Mr. Chairman, I am happy to supply you with the articulated process that we use to——

Chairman SMITH. No, I understand——

Ms. MCCARTHY. —comply with that.

Chairman SMITH. The process is——

Ms. MCCARTHY. But we believe we are in compliance with the law.

Chairman SMITH. Yeah, the process is very clear because it is the process required by law that you are not following at this point and I hope you will.

That concludes my question, and the Ranking Member is recognized for hers.

Ms. JOHNSON. Thank you very much. I am a little confused myself. I am seeing stacks, huge stacks of materials that have been submitted, and I don't know what is missing that you have access to that has been requested. Do you understand what is being requested or——

Ms. MCCARTHY. We believe that we do, and we believe that we have complied with those requests to the best of our ability. EPA has provided thousands of pages of material that is been requested of us, and we have done it because we agree with this Committee and its mission to ensure that we have sound science and transparency. That is the commitment of this Agency, and we will fulfill that commitment.

Ms. JOHNSON. Well, thank you. I am really trying to follow the line of question of the Chair to understand exactly what the real problem is. How do you interpret what the questions have been for your understanding and what else do you think that can happen, what can be given?

Ms. MCCARTHY. Well, we have provided the information. When we do rule making, like National Ambient Air Quality Standards, we look at the thousands of peer-review studies that are available to us. We also fund studies ourselves, and we conduct studies ourselves. When we fund those studies and the information and the data that we gather to fund those, we have to make sure now under the Shelby Amendment that that underlying data is available to us. We have done that. But there is much information that we look at that is peer-reviewed literature, which is really how science works, Ranking Member, is that we rely on rigorous peer-review data. EPA relooks at that to make sure it is been peer reviewed before we rely on it. But we don't have the wealth of data underneath all of the thousands of studies. But clearly researchers, including EPA, can enter into agreements to gather that data, but much of it ends up being confidential or private and we have obligations under other statutes as well as OMB guidance to protect that privacy. In the case of the National Ambient Air Quality Standards, we have the data on air quality, we have the data on deaths. What we don't have available to us with the full breadth of raw data is the cohort data which really follows individuals. So when we have that data, we have to protect it, but we don't need to see the wealth of raw data under every study to know that it has been rigorously peer reviewed and we can rely on it for our decision making.

Ms. JOHNSON. Has there ever been a time when the Congress has requested raw data that—or is this a unique time?

Ms. MCCARTHY. We did actually face similar questionings, frankly, about the exact same issues, the PM studies, the particulate matter studies, from Harvard University and from American Cancer Society. And we were asked similar questions back in the early '90s is my understanding, and we funded through a contractor 30 researchers to look for three years at all of that underlying data they had available to it because they could enter into a confidential contract with the researchers to access that data so the private information was protected. They did a complete reanalysis of that data and the methodologies used, and they came out with the same types of conclusions. So we have verified even with that underlying data available that these are studies that can be relied on. These are in fact studies that the world relies on, not just EPA. They are well-done, they are credible and they have not changed their methodology substantially since the last time we even looked at the raw data. So we are very confident in the underlying science and that we have done the right thing and paid attention to that, which is what EPA is supposed to do.

Ms. JOHNSON. Thank you very much. I yield.

Chairman SMITH. Thank you, Ms. Johnson. The gentleman from Wisconsin, our former Chairman of this Committee, Mr. Sensenbrenner is recognized for his questions.

Mr. SENSENBRENNER. Thank you very much, Mr. Chairman. Ms. McCarthy, on June 27, 2012, you sent a letter to me relative to the issue of ethanol and the waiver on E–15. And I asked the question, does the EPA remain confident that E–15 will not damage car engines from vehicles of model years 2001 and later. The letter you signed responded the EPA remains confident in the technical basis for the E–15 partial waiver decision. This question can be answered simply yes or no. Do you remain confident in the technical basis for the E–15 decision?

Ms. MCCARTHY. I do.

Mr. SENSENBRENNER. Okay. Now here is what others are saying. Ford says it doesn't support the introduction of E–15 into the marketplace for the legacy fuel. Ford does not approve. In the owner's manual it is considered misfueling and any damage resulting from misfueling is not covered by the warranty. Mercedes-Benz states that any ethanol blend above E–10 including E–15 will harm emission control systems in Mercedes-Benz engines leading to significant problems. Honda states that vehicle engines were not designed or built to accommodate the higher concentrations of ethanol. There appears to be the potential for engine failure. The AAA. AAA's automotive engineering experts have reviewed the available research and believe that additional assessment is warranted to more fully document to what extent the sustained use of E–15 in both newer or older vehicles will cause significant problems such as accelerated engine wear, fuel system damage and false check-engine lights. And the Coast Guard finds that increasing the blend to E–15 can be expected to exacerbate any fuel system deterioration now being reported with E–10 blend gasoline. Fuel leaks cause an unacceptable risk of fire and explosion. My question to you is are the auto manufacturers, the AAA, the small engine makers and the U.S. Coast Guard wrong and how can the EPA continue to ignore these concerns?

Ms. MCCARTHY. Congressman, I am not going to speak to their issues that particularly the car manufacturers might have relative to their liability and warranty considerations. What I can tell you is that EPA with DoE did extensive testing of E–15 on cars. We understand that there are challenges prior to 2001 which is when some new, more robust engines were required in those vehicles. We have done extensive testing. We continue to believe that E–15 is appropriate, and if it were available it would be being used by individuals for vehicles that are 2001 and younger.

Mr. SENSENBRENNER. Well, that is not what the manufacturers say. That is not what the AAA says. They don't make cars. They represent motorists' interest. That is not even what the Coast Guard said because we are dealing with small engines including marine engines, lawn mowers, snow mobiles and things like that.

Ms. MCCARTHY. Congressman, we never——

Mr. SENSENBRENNER. Now, ma'am. Ma'am? I am going to ask you a question.

Ms. MCCARTHY. I am sorry. Go ahead.

Mr. SENSENBRENNER. I am going to ask you a question.

Ms. MCCARTHY. Okay.

Mr. SENSENBRENNER. Because I have a limited amount of time.

Ms. MCCARTHY. All right.

Mr. SENSENBRENNER. You will make a very good senator if you would like to filibuster. I have a bill that this Committee has reported favorably out to require the National Academies of Science to conduct an unbiased assessment of the science surrounding E–15. There seem to be enough questions relating to EPA's conclusions on this. So why don't you support further testing of E–15, and why are you opposed to having an unbiased referee making call on this fuel?

Ms. MCCARTHY. I don't recall, Congressman, that I have spoken to this issue. EPA——

Mr. SENSENBRENNER. Will you support——

Ms. MCCARTHY. Again——

Mr. SENSENBRENNER. —my bill for more testing on this issue?

Ms. MCCARTHY. I am sorry. I have not read the bill but if you are asking me——

Mr. SENSENBRENNER. Well, the bill has been around for a long time because it was sponsored in response to your letter where there's a disagreement on whether the EPA has conducted unbiased research. Now, how about having another look at this before people's engines get wrecked?

Ms. MCCARTHY. Additional research that is done credibly and transparent is also—always welcome, Congressman.

Mr. SENSENBRENNER. Fine. I would appreciate a letter from the EPA and from you supporting my bill, and then maybe we can put it on the floor.

Ms. MCCARTHY. But I do feel that we have sufficiently done our analysis, and I continue to rely on it.

Mr. SENSENBRENNER. Well, then I guess having an unbiased view is something that you won't always support.

Ms. MCCARTHY. Well, I——

Mr. SENSENBRENNER. I yield back the balance of my time.

Chairman SMITH. Thank you, Mr. Sensenbrenner. The gentlewoman from Oregon, Ms. Bonamici, is recognized for questions.

Ms. BONAMICI. Thank you very much, Mr. Chairman, and thank you, Administrator McCarthy for appearing before us today. The work that you do to protect the health of our constituents is very important and very much appreciated.

I want to briefly mention the EPA's work on the Portland Harbor Superfund Site, an issue that's been important for years in the district I represent and in the region but one where I think we could all agree the work has not progressed as expeditiously as it should. And when I met with you in April of this year to discuss the issue, you had yet to be confirmed as administrator, but we still had a very productive conversation and I want to say an encouraging conversation about increased cooperation between the EPA headquarters, the Oregon Congressional delegation, and you also expressed an interest in improving the relationship between the EPA Region 10 and our local stakeholders. And so far I have seen positive signs of that happening, and I wanted to say that I look forward to working with you and the EPA to, we hope, finally take care of that superfund site in the Portland Harbor. So thank you for your work on that.

Ms. MCCARTHY. Thank you.

Ms. BONAMICI. On the topic of EPA protecting public health, in your testimony you focus on how important it is that good science be used to determine when public health is in danger. After all, that is one of EPA's critical missions. And in the first hearing held by the Environment Subcommittee—oh, in a hearing held by the Environment Subcommittee earlier this year, a look at the state of the environment, one witness, Richard Truesbeck, said that looking too closely at a problem can sort of overestimate the need for a solution. He said when one puts anything under a microscope, one necessarily will find something ugly to gawk at.

When considering public health, it is hard to imagine that just because something is small or microscopic, it should not be evaluated to determine its impacts on public health. Surely our constituents can be harmed by pollutants that they cannot see.

So can you talk about the process that EPA goes through to determine when a problem is severe enough to address through Federal action, and then I do want to save time for another question.

Ms. MCCARTHY. We address the science in many different ways depending upon what we are actually focusing on and where authorities lie. EPA doesn't agree with a statement that says that we shouldn't be focused on both our mission as well as appropriately doing our job that Congress gave us. We look at both doing independent reviews of the science. We do that rigorously. We do it through something we call the IRIS process which I mentioned earlier, which is really a health assessment that underpins many of the decisions that we do that helps us understand what the science implications are, what the health implications are for people that are exposed to chemicals and other hazards in the environment. And it is extremely important for us to look at those issues.

Then we look at what authorities Congress has given us, what responsibilities we have and we address those responsibilities in the way in which Congress gave us to address those.

Ms. BONAMICI. Okay.

Ms. MCCARTHY. That is how we make improvements in public health. That is how we have successfully done that for 40-almost 3 years.

Ms. BONAMICI. Thank you. In March of this year the Environment Subcommittee had a hearing on EPA's Science Advisory Board, and since then the committee has passed legislation modifying the makeup of those boards. And throughout the process, some on this Committee have asserted that industry voices are not represented and that academic interests dominate, and others of us acknowledge that the industry perspective should be heard but we are concerned about making sure that we don't have conflicts of interest.

So you discussed this a bit in your opening testimony, but will you please expand on how industry scientists might contribute to the Science Advisory Boards while also avoiding conflicts of interest? And how do you as Administrator ensure that the advice that you are receiving from those bodies are not tainted with policy-related judgments?

Ms. MCCARTHY. For the Science Advisory Board, we believe the EPA meets and exceeds our responsibilities under FACA, our legal requirements, and we are more transparent and we look more closely so that we can make sure that we look at the Ethics in Government Act as well. The Science Advisory Board in our process for doing that is something that we are very proud of. When we do panels and we put them together, we publish our consideration of who the panel members should be. We ask for comments on that. We respond to that. We look at making sure that the panels we put together are well-balanced and that they have all of the range of expertise we are looking for as well as a variety of perspectives.

Ms. BONAMICI. And can you please discuss the conflict of interest issue because I want to make sure you get that in.

Ms. MCCARTHY. We actually look very closely at conflict of interest which we look at both whether or not there are financial problems that are real or the appearance is there, and we make sure that we do a thorough analysis of both any investment opportunities or financial considerations. We just recently established a new process where we are looking at that as well and more rigorously for external contractors as well.

So we look at the issues, whether they are perceived or real. We do them publically, transparently. We take comments every step of the way to ensure that our panel has the expertise as well as the credibility it needs to speak from a sound science and transparency perspective.

Ms. BONAMICI. Thank you very much. I see my time has expired. Thank you, Mr. Chairman.

Chairman SMITH. Okay. Thank you, Ms. Bonamici. The gentleman from California, Mr. Rohrabacher, the Vice Chairman of this Committee, is recognized for his questions.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman, and following up with my colleague from Oregon's line of questioning. I appreciate her setup, and we appreciate you being here with us today.

Ms. MCCARTHY. Thank you.

Mr. ROHRABACHER. About the Science Advisory Boards—and there is serious concern that the EPA's regulatory science has become somewhat of a closed loop that the Agency sets regulatory goals based on whatever motives those goals are based upon and then develops the funds and the science that it needs to justify those goals. The Agency then creates its own regulations and is solely responsible for interpreting those regulations. Making matters even worse, the courts largely defer to the EPA especially when questions involve the analysis of science.

Therefore, the most critical requirement for America to trust this regulatory policy or system and especially the regulations that are set forth by the EPA is scientific integrity. Unfortunately, as I say, there are worries, and at least I believe there seems to be some very serious reasons for being worried about this being a closed loop. A closed loop is not going to give us the type of science that we need. We believe that especially this is evident in a matter that you were just discussing with my colleague from Oregon, the independent peer review of EPA science and we believe, and I would like to ask you a few questions about whether or not this has been compromised.

You are responsible for appointing members of the EPA's Scientific Advisory Boards, and let's take a look at Science Advisory Boards such as, number one, the Science Advisory Board and number two, the Clean Air Science Advisory Committee. And you have called these panels independent review boards.

Ms. MCCARTHY. Um-hum.

Mr. ROHRABACHER. And your predecessor described them as being made up totally of independent expert scientists. And that is pretty well what you still agree with?

Ms. MCCARTHY. Um-hum. Yes.

Mr. ROHRABACHER. You are still acknowledging that that is still what your goal is and what we are trying to do? I would like to put into the record some information prepared by the Congressional Research Service that calls into serious question the independence of the experts that sit on these committees.

Chairman SMITH. Without objection, it will be made a part of the record.

[The information appears in Appendix II]

Mr. ROHRABACHER. According to the CRS, almost 60 percent of the members of these two panels have received EPA grants since 2000. That is totaling taxpayer-funded grants worth roughly $140 million. Perhaps even worse, a majority of the members of the Clean Air Science Advisory Committee, the panel tasked with critically evaluating the EPA's particulate matter standards that was finalized at the end of 2012, a majority had received EPA grants directly related to particulate matter since 2010. So you have someone investigating or passing judgment on things that they themselves have been given grants and been involved in the research they are supposedly overseeing. And Ms. Administrator, in the past we have heard EPA witnesses express the point of view that scientists who have received EPA grants are somewhat immune from any potential conflicts associated with these grants that they are involved with or future grants. Do you consider that the recipient of EPA grants, do you consider that if someone has actually been

involved and had a grant and done study about something they are supposed to now review that that would compromise that person's ability to have an independent judgment?

Ms. MCCARTHY. No, not in and of itself, as long as we have procedures to ensure that they are fair-minded, that they are there because of their expertise.

Mr. ROHRABACHER. Well, fair-minded just means that they don't have any bias. We are talking about a built-in bias here. You are trying to say that somebody who has already been given a grant and has reached conclusions is someone that we can then trust to have an unbiased view, after we have paid them in order to have a biased view?

Ms. MCCARTHY. Mr. Chairman, we understand that there have been concerns expressed about that. We also understand that others have expressed concern about having people who are in the industry that we are discussing that would be impacted.

Mr. ROHRABACHER. That is correct. That is a whole——

Ms. MCCARTHY. That is a——

Mr. ROHRABACHER. That is something someone would be concerned about.

Ms. MCCARTHY. But I would say that we use——

Mr. ROHRABACHER. You think government employees are immune from the same sort of bias that you would find in an——

Ms. MCCARTHY. No, I am not saying they are immune, sir. I am saying that we have a process in which we rigorously pursue those issues to ensure that they are there to represent their expertise and that the panel is balanced, that it is fair, it meets all requirements, ethical requirements——

Mr. ROHRABACHER. The question isn't whether they are——

Ms. MCCARTHY. —and technical requirements.

Mr. ROHRABACHER. —isn't balanced. The question is whether there are members who are involved, sometimes at very high levels, and guiding the direction of those panels who actually have a built-in bias in that they have already been granted grants to make a conclusion before you now are asking them for an unbiased conclusion.

Ms. MCCARTHY. We——

Mr. ROHRABACHER. In fact, sometimes, Administrator, they are asked to give assessments of their own work in other words, we are now paying someone to give an unbiased assessment of something that is his or her work.

Chairman SMITH. The gentleman's time has expired. The gentleman from Washington, Mr. Kilmer, is recognized for his question.

Mr. KILMER. Thank you, Mr. Chairman. I thank you for coming to take our questions today.

Ms. MCCARTHY. It is good to be here, thank you.

Mr. KILMER. I have got a question regarding EPA funding and prioritization. I represent the 6th District of Washington State which is bordered by the Pacific Ocean and Puget Sound and also includes some of the most pristine natural areas in the country. I want to commend the work of your Agency and all of our Federal agencies in the State of Washington for some of the work that has been done to protect our resources. But there is a lot more to be

done. Ocean acidification, storm water runoff, ecosystem restoration are just a few of the issues that we are only beginning to understand, not to mention the effects that these issues have on our marine industries and on the Puget Sound economy.

Faced with this task, myself and Representative Denny Heck along with several of our colleagues created the Puget Sound Recovery Caucus to gather support and try to figure out what we can do on a Federal level to solve these direct problems that we are facing in the Puget Sound and also how to be proactive in issues that are just beginning to emerge.

With a limited Federal budget and sequestration, receiving funding for these types of vital problems is an uphill battle that we are still climbing and we need to continue to climb, not just because it affects our environment but because it affects jobs and our economy. I realize the issues that we face in the Puget Sound are similar to many other issues across the nation, and we want to find ways not only to highlight the Puget Sound but we want to make progress, get projects off the ground and fix the problems we need to ensure the vitality of Puget Sound, not just now but in the future.

So first an invitation and then a few questions. One, I would like to invite your partnership with our caucus. I would love to invite you to meet with our members, and would even love to invite you to come out and meet with the folks who are working on this in our State. And then my question are can you give insights into how we can actually make some progress, particularly in light of this budget environment, how we can fast track and give greater priority to regional efforts like this where the science is clear, the need is clear, and we need to start making some progress.

Ms. MCCARTHY. Well, I do hope that the indiscriminate way that the sequestration has impacted all of the agencies is something that is looked at in the budget, upcoming budget discussions so that everybody can agree on a more sensible and common-sense way to make any reductions that are necessary and to implement the budget effectively.

I do know that we have folks who are working in this area, and you probably know Dennis McLerran. There is nobody in the world that knows or cares more about the issues that you have just identified than he does. I do think there are ways in which we can work together through a variety of shared technical expertise as well as potentially grant funding. We work on those issues together. I have an opportunity over the next three years to make sure we enhance those partnerships. So I would be looking forward to it, and we should have a discussion about how best to do it.

Mr. KILMER. Great. Thank you very much, and I yield back.

Chairman SMITH. Thank you, Mr. Kilmer. The gentleman from Texas, the Chairman Emeritus of this Committee, Mr. Hall is recognized.

Mr. HALL. I thank you, Mr. Chairman. Ms. McCarthy, I thank you for being here today, and the Committee has worked for several years to ensure sound scientific processes and transparency at the EPA. I think we need a study on the EPA's lack of transparency and accountability some time, and you would be one of the witnesses that we would want you back again.

One of the areas that concerns us is the EPA's very poor track record of science relating to hydraulic fracturing. The EPA is zero for three on that. In Parker County, Texas, Dimock, Pennsylvania, and Pavilion, Wyoming, you and the Agency alleged that hydraulic fracturing had been responsible, and three times the agency had to back away from these allegations after proper scientific analysis and review exposed these to be totally unfounded.

We have had a number of regulators and scientists testify where you sit today about hydraulic fracturing, and you have sat there and you testified here and you have also testified in the Energy and Commerce Committee. Nearly all of those that have sat before us have confirmed the safety of these unconventional oil and gas techniques. Not one testified that there has been any incidents of groundwater contamination from fracking, not one of them. We have also received testimony from both the President's Science Advisor as well as the President's Assistant Secretary sitting right where you are under the oath that you have taken for the Department of Energy, said that there has not been a single documented case of groundwater contamination from fracking in this country. You probably won't be surprised that I reference once again in a comment that you made in 2011 that I gave you a chance to take back. I have not seen where you have made any apology for it when you said—and I hope you have backed off of this remark since then. You said I certainly don't want to give the impression that the EPA is in the business to create jobs. A cruel statement I think to those families that can't support their children, can't make a car payment, because according to a 2012 study by the research company IHS Global Insight, hydraulic fracturing, estimated 1.7 million jobs in the United States. That number is projected to go over 3.5 million jobs by 2035. And according to the Energy Information Administration, natural gas production is expected to rise an estimated 44 percent through 2040. Without the use of hydraulic fracturing technology, the nation's energy security and economy would seriously be compromised. Those millions of jobs would be lost.

With that in mind, you stated recently in the interview with The Globe, Boston Globe, I quote, "There's nothing inherently dangerous in fracking that sound engineering practices can't accomplish."

So do you agree that hydraulic fracturing is safe and that there has not been a single documented case of groundwater contamination from fracking? Yes or no.

Ms. McCarthy. I can't answer it that way. I will agree with you——

Mr. Hall. Well, then yes, you have answered it. If you can't answer it that way, you don't know or you refuse to answer it.

Ms. McCarthy. No, I meant I would like to explain it a little bit if I could.

Mr. Hall. I am not asking for your explanation. I just asked you for a yes or no.

Ms. McCarthy. I do not know of a documented case——

Mr. Hall. I will go on.

Ms. McCarthy. —of groundwater contamination.

Mr. HALL. I will take that as you don't know or you don't care because you didn't know and you didn't care about people having jobs back then. That was a terrible statement that you made, and it is of——

Ms. MCCARTHY. Actually, it was taken out of context.

Mr. HALL. —record. It was not taken out of direct context. I read it exactly out of the CR, and you know that. Now why don't you admit it?

Ms. MCCARTHY. Well, it was actually celebrating the fact that we have been successful in reducing environmental pollution while we have grown jobs.

Mr. HALL. Let me go on. So you agree that this hydraulic fracturing is safe. Do you agree to that?

Ms. MCCARTHY. I cannot agree.

Mr. HALL. Okay. You haven't agreed. These experts that have testified before you have also agreed that state regulators have the expertise, competence and experience necessary to oversee hydraulic fracturing. Do you agree that the state regulators are generally quite knowledgeable about local geologic conditions in the drilling operations they oversee? Yes or no.

Ms. MCCARTHY. I believe they are knowledgeable and they often seek EPA's technical advice.

Mr. HALL. I think your answer is led to be yes. Do you think the EPA is better suited to regulate hydraulic fracturing operations than the state regulators who are already doing so? Yes or no.

Ms. MCCARTHY. I believe that with water quality, the state is the line of first defense and EPA is with the state in those——

Mr. HALL. I am not asking you to filibuster anymore. Yes or no.

Ms. MCCARTHY. I am trying to understand how to—in the context of the authority we are given.

Mr. HALL. You are not making me understand. Maybe I can't understand anything you say because——

Ms. MCCARTHY. Okay.

Mr. HALL. —you are hard to believe, ma'am. Do you believe that natural gas prices will remain low if EPA promulgates regulations that restrict production? Yes or no.

Ms. MCCARTHY. I actually think that a large component of the nation's energy security relies on the safe and responsible development of oil and natural gas, sir.

Mr. HALL. Our nation depends on an all-of-the-above energy strategy, and the use of technologies like hydraulic fracturing have been an important role in helping achieve energy security. We need you to support it, not deter it and not deter these efforts.

Ms. MCCARTHY. And I would hope not, sir.

Mr. HALL. I yield back my time, Mr. Chairman.

Chairman SMITH. Thank you, Mr. Hall. The gentlewoman from Connecticut, Ms. Esty, is recognized for her questions.

Ms. ESTY. Thank you, Mr. Chairman, and thank you, Administrator, again. Connecticut, as you know exceptionally well, has been the beneficiary of substantial improvements to health through the Clean Air Act, and so I would like you to talk a little bit about the situation now. Many utilities have already installed pollution control devices on their facilities. If EPA at this time were to pull back on clean air regulations governing these utilities, would they

have and do you believe they would have an incentive to run these pollution control devices and what would be the associated impact on air quality and public health, particularly for those of us, I would have to say, on the Eastern Seaboard who with west-to-east winds are the recipient of what is burned in Indiana, Ohio and elsewhere?

Ms. MCCARTHY. Well, we know even with the control equipment working that the power sector remains the largest single stationary source sector in terms of the amount of pollution that it emits. We have been working hard with them, but there is no question that there is financial incentive to bypass equipment when it is available to be done.

So I would assume that if we were to pull back on our regulations, what you are going to see is increased emission. And that increased emission results directly in public health impacts that are as severe as thousands of premature deaths.

Ms. ESTY. I know in our own State, we have seen those asthma rates rise very substantially in our cities, and those are costs that are borne primarily by state governments who then have to pick up the tab and by insurance companies to——

Ms. MCCARTHY. And many because of pollution, that comes to you from facilities run very far away.

Ms. ESTY. Exactly. If we could turn for a moment to the scientific review process, certainly we have heard some commentary today and elsewhere from Members of Congress who have stated that or suggested that EPA develops regulations based on faulty scientific evidence. Can you explain to us in a little more detail—and I will ask my question and then listen—how the scientific process that underpins EPA regulations is peer reviewed, what you believe to be the importance of peer-review process, and flesh that out a little bit more for us, please.

Ms. MCCARTHY. Yeah. The process that we use is to actually establish peer-review panels. We can do them by seeking advice from the National Academies of Sciences. We can establish it through our Science Advisory Board, and we can use consultants that follow similar processes and establish again transparent, robust, balanced peer review.

The Science Advisory Board is a highly transparent, professional entity. We are—as a FACA, we comply with those regulations. We also comply with ethics requirements. We follow all of the guidance that is given to us in the directives by the Office of Management and Budget in how to do our work. I believe that we are a model for transparent, solid, high-quality science.

The Clean Air Act Science Advisory Committee was mentioned. That advisory committee was just recently looked at by our own IG, our Office of Inspector General, who just issued a report commending us for how solid our panel was in our ability to have that balanced and appropriate. Now we are always working to enhance that, but I am incredibly proud of the science this Agency relies on, and I know the high quality of our science is what is going to keep EPA relevant and make us and allow us to do the right thing in terms of meeting our mission which is public health protection.

Ms. ESTY. And if I may—I am shuttling between hearings, and currently in the Transportation and Infrastructure hearing, we are

talking about the cost of Sandy and the underwater rail lines in the State of Connecticut and Newark, New Jersey, the impacts of the severe weather systems that we see. Can you talk a little bit about how EPA—other than the curbing of greenhouse gas emissions, what other work is EPA doing to look at the scientific but also the very real economic impacts, I have to say, on the Eastern Seaboard we are seeing from climate change and severe weather conditions?

Ms. MCCARTHY. Congresswoman, in 2012 the costs associated with disaster response topped $120 billion. That is not planned expenses. That is what happens. And what we know is that in the face of a changing climate, these types of disasters are going to become more and more prevalent if we don't reduce greenhouse gases.

If you look at the work of this Agency, we have not only been funding efforts at the local level and the state level to look at how you can adapt to a changing climate, we have put out a plan that requires and shows a pathway forward, for EPA to look at how it does its business working with the communities. So we look at a changing climate, and we factor that into our decision making, in our ability to work more carefully and collaboratively with local communities and states moving forward. And my heart goes out to Connecticut. I know it was very hard hit, and it is my home away from home.

Ms. ESTY. Thank you for your service, and I yield back.

Chairman SMITH. Thank you, Ms. Esty. The gentleman from Texas, Mr. Neugebauer, is recognized for his questions.

Mr. NEUGEBAUER. Well, thank you, Mr. Chairman. Administer McCarthy, thank you for appearing before this hearing today.

Ms. MCCARTHY. Thanks for inviting me.

Mr. NEUGEBAUER. I have several questions, and so if you could keep your answers pretty short and direct. First, as you know, setting the levels for the New Source Performance Standards, the Clean Air Act requires you to select the best system of emission reductions for technology that has been adequately demonstrated.

Ms. MCCARTHY. Um-hum.

Mr. NEUGEBAUER. Now, we have had several hearings in this Committee on the new standards where we have heard testimony whether the CCS technology necessary to meet these standards has actually been adequately demonstrated at the full-scale power plants.

I have asked your colleagues from the Department of Energy on a number of occasions if they could give me examples of where full-scale power plants are located, and their testimony is none of them are operating anywhere in the world. If this is true that full-scale power plants operating now are not operating with CCS technology, how can you say that it has been adequately demonstrated?

Ms. MCCARTHY. We believe, sir, that CCS technology has been adequately demonstrated. The technology is proven, it is available. In fact, the coal technologies in facilities that you see being constructed today are actually utilizing CCS.

Mr. NEUGEBAUER. So can you give me, provide me an example of a full-scale power plant that is currently operating with this technology?

Ms. MCCARTHY. I can give you examples of two that are 75 percent completed, and I can give you an example of others that are coming up that are also in the planning stages. So CCS for coal——

Mr. NEUGEBAUER. So what would those be?

Ms. MCCARTHY. —is actually what is being invested in.

Mr. NEUGEBAUER. What would those be?

Ms. MCCARTHY. We have the Kemper facility that is 75 percent complete, and there is another project in Canada that is also utilizing it at levels much higher than the types of reductions that EPA has proposed in its new source data.

Mr. NEUGEBAUER. Are any of those facilities that you mentioned receiving clean coal power initiative funding, excuse me?

Ms. MCCARTHY. It is my understanding that there has been funding supported by DoE. DoE continues to have funding available for these types of projects.

Mr. NEUGEBAUER. So they are receiving clean coal power initiative funding?

Ms. MCCARTHY. Yes, that is my understanding.

Mr. NEUGEBAUER. Well, it is kind of interesting then because the Energy Policy Act of 2005 clearly states that projects receiving funding from this program can't be used to prove technology is adequately demonstrated. So the examples that you are using are receiving funding, and the 2005 act says that you can't use those. So can you explain your logic on that?

Ms. MCCARTHY. Actually, sir, I think we are regulating and proposing this regulation under the Clean Air Act which is very specific in both its intent as well as its history of application. There is no question that CCS technology is available. The components of CCS have been in place and demonstrated for decades. So the question really is, is it reasonable in cost and is it available for this sector? EPA believes it is, but we have proposed that. We are welcome and open to comments. We will be getting to that public comment process shortly. But I think through that public comment process you will see that this technology is well-known, it is available, it is being invested in today and it is going to work and it is going to be a pathway forward for coal into the future.

Mr. NEUGEBAUER. No, but I think to summarize what you have said is, one, there is no full-scale power plants operating with this technology today. Is that correct?

Ms. MCCARTHY. I am aware of—these components being operated in many different applications.

Mr. NEUGEBAUER. I didn't say components, but there is no full-scale power plant operating with these——

Ms. MCCARTHY. No, but the ones being invested in would be operating——

Mr. NEUGEBAUER. No, that is right. Okay.

Ms. MCCARTHY. —at much higher levels than we would be requiring.

Mr. NEUGEBAUER. So and then you are using federally funded CCS projects to argue technology is adequately demonstrated, yet the 2005 act prohibits you from doing that.

Ms. MCCARTHY. Actually, we think it has been adequately demonstrated, but the support——

Mr. NEUGEBAUER. But not on a full-scale basis, right?

Ms. MCCARTHY. —from DoE will help advance the technology.

Mr. NEUGEBAUER. Not on a full-scale basis? We don't have that yet.

Ms. MCCARTHY. We have it on full scale in other applications, sir, other industry sectors.

Mr. NEUGEBAUER. But not on these——

Ms. MCCARTHY. It is only—it is being invested in today and in two facilities are 75 percent complete and on their way.

Mr. NEUGEBAUER. But what you are saying under these new rules is no new coal plants can be built without utilizing this technology, and we don't know that it is adequately demonstrated for these plants because we don't have a full-scale model.

Ms. MCCARTHY. We believe it has been adequately demonstrated.

Mr. NEUGEBAUER. But not on a full-scale model.

Ms. MCCARTHY. It has been fully utilized in other industry sectors.

Mr. NEUGEBAUER. But not on these coal plants, not on a full-scale coal plant.

Ms. MCCARTHY. I have already indicated to you. We know of two that are being constructed today, and they are——

Mr. NEUGEBAUER. That they are being constructed, but we don't have any history that that technology is, one, will accomplish that, but secondly, that it meets any kind of cost-benefit analysis, do we?

Ms. MCCARTHY. The cost-benefit analysis? Is that what we are talking about, sir?

Mr. NEUGEBAUER. No, but that would be a part of that. I mean, you don't know for sure because you don't have a model where this technology is——

Ms. MCCARTHY. No, but we do know that the industry sees CCS technology as a pathway forward. We also see it as one that is available to it and ones that we are hoping with DoE assistance it will continue to progress. It will get less and less expensive. That is how technology gets developed. But in this case, all of the components of CCS as well as those together have been demonstrated over and over as being viable and effective, and we believe that they will be the path forward for coal. Coal is a big part of our energy supply. I know it is going to continue to be a big part of our energy supply. We have tried very hard to make sure that we look at the technologies available to it today so it continues to have a path forward.

Mr. NEUGEBAUER. But we don't tend to use research funds for things that have already been determined adequately demonstrated, do we? And so we are using research funds to try to prove this up, and you are using it as an example that it is adequately demonstrated. It doesn't make sense to me.

Ms. MCCARTHY. Actually, we are coordinating very closely with DoE, and if you have listened and heard from the DoE folks today, you will know that they share our opinion about its availability and that it is been demonstrated. But it is exciting to think that we could make it more cost-effective moving forward and that you could expand the range of sequestration opportunities. So they are actually working very hard with the industry to continue to move that technology forward. That is only good news, sir. That is not bad news.

Chairman SMITH. The gentleman's——

Mr. NEUGEBAUER. But we still don't know whether it is adequately demonstrated.

Chairman SMITH. The gentleman's time has expired. Thank you, Mr. Neugebauer.

Pursuant to the discussion earlier about the sufficiency of the data provided by EPA relating to the Committee's subpoena, I ask unanimous consent to enter into the record a letter from the Texas Commission on Environmental Quality the Committee received just last week that makes clear, "that the data provided to date lacks critical information, making it impossible to replicate the findings" of the EPA. Without objection, that will be made a part of the record.

[The information appears in Appendix II]

Chairman SMITH. We will go now to the gentlewoman from Maryland, Ms. Edwards, for her questions.

Ms. EDWARDS. Thank you, Mr. Chairman, and thank you Madam Administrator. I really appreciate your being here, and I certainly appreciate your patience.

We have heard described on this Committee and throughout the Congress frankly questions about EPA's reliance on faulty and secret science, questions about EPA's transparency and accountability. First of all, I want to thank you for the transparency and accountability the EPA has provided for the volumes of data and correspondence that this Committee has received. And I am just curious that sometimes the correspondence asks for information, sometimes for documents or data as evidenced by testimony, by questions here today. I am a strong supporter of Congressional authority, but I really am concerned about whether we may be overstepping our authority in terms of what we are requiring of the Agency. We are just one committee of many who's making these types of requests to the EPA. And so I wonder if you could just tell me how much time and energy is spent by you and your colleagues at the EPA in responding to these volumes of requests?

Ms. MCCARTHY. Congresswoman, we know how important it is to be transparent, and we will do our very best to respond to any request that Congress brings to us. It is a significant burden in terms of resources. But that is just the amount. I don't mean burden in the negative sense. We want to be open. We want to be responsive. But we receive thousands of these types of requests. We do our best to answer them as expeditiously as we can. I think the times when we have had difficulties is when we have been asked to release data that the EPA doesn't have available to it. Then it becomes an extra effort for us to try to make sure we bridge those gaps with scientists when we fully expect that researchers themselves will access that data as they have always done and work it out that way.

Ms. EDWARDS. Well, let me just ask you this because we have heard some discussion of conflicts of interest. I can understand, and we have heard testimony in this Committee, that when you are forming—when there's peer review done and you are delving into some area of expertise that is a very narrow area, there are only so many folks out there who have the kind of experience that you can draw upon. Some of those may be in industry, some of those may be academics who receive grants. When you assess conflict of

interest and, you know, I am just like a cheap lawyer. And so I always thought that the idea behind conflicts is revealing those conflicts, having them assessed and then making a determination about whether that conflict would prohibit performance, adequate performance, and independence of performance in a peer-review situation. Is that how the EPA looks at conflict of interest?

Ms. MCCARTHY. That is exactly how we do that. You are right. There are opportunities or instances where we have a very narrow expertise that is not represented that is critical to a thorough look at a science question or a technical question. In that case we do a thorough investigation. We post the results of that so that people can know the background and we can make sure that it is a balanced, fair, equitable discussion and as transparent as we possibly can be. And so we do that both for folks who are the scientists as well as folks that bring their history in the industry to the table.

Ms. EDWARDS. And is there anything necessarily exclusionary whether a person receives billions of dollars or a company in profits from an industry or whether a person receives thousands of dollars from the Administration in terms of doing research? Is there anything exclusionary about that that would prohibit service on a scientific advisory panel?

Ms. MCCARTHY. I don't believe so. What it really means is we must have a rigorous and transparent peer-review process and we must rigorously share that information with the public so they can—before the panel is empanelled, they can offer their suggestions and comments and criticisms, and we can make sure that we have the most robust fair, comprehensive science available to us.

Ms. EDWARDS. Thank you. I want to ask you about your work around climate change because there has been a lot of discussion also. Is it your view from the Administration that you have sufficient data to back the work that you are doing around climate change, that in fact it is happening and that there are certain causal effects that would enable you to do rule-making in that area?

Ms. MCCARTHY. I believe that I have a wealth of data that is more than sufficient. I believe that the Supreme Court has agreed with me, which is nice.

Ms. EDWARDS. Great. And so can you tell me about some of the rule-making that you are engaged in going in that direction and then relate that to the mission of EPA protecting our public health and the environment?

Ms. MCCARTHY. Yes, the President's Climate Action Plan identifies mitigation opportunities and reductions in greenhouse gases as well as addressing adaptation and then international issues. EPA is to some extent involved in all three. But I think the most important I want to get at is our opportunity to reduce greenhouse gases so we can try to mitigate significant impacts associated with increased emissions in higher levels of climate change.

And so what we are really looking at is first and foremost regulating greenhouse gas emissions from the power sector, both the new facilities and existing. We have already issued a proposed rule for new facilities, and we are beginning listening sessions and discussions on how we best put out a proposal next June for existing facilities. The reason why we want to do this is that climate change is not an environmental problem. It is a serious public health and

economic problem as well as an environmental challenge. And so what happens with a changing climate is that the weather gets hotter. When the weather gets hotter, the ozone levels increase. When the ozone levels increase, your kids go to the hospital more often with asthma. In this country today, one out of ten children have chronic asthma. We are talking about serious public health challenges. Allergy seasons extend. We are seeing health impacts from different types of mosquitoes and other vector-borne diseases moving north as the weather gets warmer. Things are changing, and things are not changing for the best in terms of public health in a changing climate. It threatens the health, safety and well-being of communities and individuals. It is something we must address and now.

Ms. EDWARDS. Thank you very much for your testimony, and thank you so much for the work that you do to protect all of us.

Ms. MCCARTHY. Thank you.

Chairman SMITH. Thank you, Ms. Edwards. The gentleman from Illinois, Mr. Hultgren, is recognized for his questions.

Mr. HULTGREN. Thank you, Mr. Chairman. Thank you, Administrator McCarthy for coming and testifying today. I do honestly believe that what you are doing is important. That being said, I have a number of problems with how EPA has done its job. Putting forward rules without adequate stakeholder input or a full grasp of the negative impacts proposed rules will have on regular Americans. I think it is important to point out how far we have come, even according to your own data. Since the implementation of the Clean Air Act, aggregate emissions have dropped by 72 percent, all while energy consumption has increased by 47 percent. Vehicle miles traveled has increased by 165 percent, and most importantly, GDP has increased by 219 percent.

That is why I will continue pushing your Agency to base regulations on sound scientific principles and practices, make your data sets open to the public for review and to utilize common-place statistical measures and methods, all of which EPA has seemed adverse to when the facts don't necessitate what often appears to be a politically predetermined regulatory approach.

As you know, Section 316(b) of the Clean Water Act requires the best technology available to minimize harm to aquatic organisms living in water that are withdrawn through cooling water intake structures for power plants. For the last three-and-a-half decades, states and permitting authorities have been setting necessary controls on a site-specific basis. But unfortunately, it now appears that the EPA is again attempting to rewrite the rules to expand your regulatory power. When relying on the science, EPA has not been able to justify this rule-making. This is because the costs always outweigh the benefits. Your agency has recognized that there will be no benefit to human health, and the economic benefits from potential improvements to commercial fisheries and recreation bodies, the use benefits, will not justify the new rules cost, either.

Since the Agency has been unable to justify these rules with their standard methods, I am troubled with the idea of non-use benefits that you are now attempting to put in place. Even more troubling is the way EPA intends to assign values to these benefits through polling. I think every member in this room can attest to

the inaccuracies of polling, and it is troubling to me that the EPA would turn away from science and to a public opinion poll to promulgate regulations. When EPA did their survey asking how much money the public was willing to spend to save a given number of fish, the numbers predictably came back inflated. Then EPA punted the issue to the Science Advisory Board.

Also troubling with the rule is that it could be interpreted to force power plant owners to monetize these non-use benefits and perform willingness to pay surveys for specific control technologies on a site-specific basis.

Although 316(b) is the EPA's first attempt to justify rule-making with this willingness to pay surveys, I am also worried that this controversial methodology will only encroach into other rule-making. If this happens, public opinion polling will become the backbone of many EPA regulations instead of science.

I think it is important that states are allowed to continue exercising permitting discretion. I am asking could you confirm that the EPA's final 316(b) rule will not require states to consider non-use benefits or require plant owners to conduct willingness to pay surveys in the NPDES permitting process?

Ms. MCCARTHY. The final 316(b) is at the Office of Management and Budget, so I am constrained about getting into too much detail. But we have heard similar comments during the public process. The survey that we did was appropriate on the national level to get a handle on people's willingness to pay for the types of improvements that these technologies would bring. We don't expect that to be the way in which states and permittees make case-by-case decisions.

Mr. HULTGREN. Well, again, I think the most important thing is to base this on science, not on public opinion polls.

Ms. MCCARTHY. I understand.

Mr. HULTGREN. You can ask all of us how we feel about public opinion polls and the accuracy of them. Certainly for us to be basing——

Ms. MCCARTHY. I understand.

Mr. HULTGREN. —the scientific decisions and significant costs on them is very troubling. I have another quick question that I hope to get an answer. It is regarding when EPA plans on publishing rules, adjusting the volume requirements for the renewable fuel standard. As you know, with the predictions that were made when designing the RFS not being realized, those predictions have not been realized, your Agency is who are farmers and everyone else downstream must get answers from regarding the early adjustment for this requirement. I think everyone was pleased that the first two adjustments came in a timely manner which helped to bring certainty for all parties involved. The final rule for the 2011 adjustment was published in the beginning of December in 2010, and the 2012 rule came in January of that year.

What is troubling is how long it took EPA to issue their final rule for 2013. It didn't happen until the middle of August. As it is important that our businesses and farmers be able to plan ahead for this, can you give this Committee assurance that you will focus on getting a final rule out in a reasonable amount of time this year

and wonder if you could give a perspective date or timeframe when you expect to have this rule published?

Ms. MCCARTHY. The rule to establish limits for 2014 is soon to be proposed. It will take some time. We did tee this issue up in our 2013 proposal. The only thing I want to make sure that the Committee is aware of is the levels that we are talking about for renewable fuels to get into the system in 2014 are not predictions. They are Congressional mandates that we are dealing with in trying to understand the authority that Congress gave us to——

Mr. HULTGREN. Well, my time is winding down, and I want to be respectful of the 5 minutes.

Ms. MCCARTHY. I apologize. Me, too.

Mr. HULTGREN. So anyhow, the issue is bringing certainty to our businesses and farmers.

Ms. MCCARTHY. I agree with you.

Mr. HULTGREN. The sooner we can get these——

Ms. MCCARTHY. I agree with you.

Mr. HULTGREN. —again, earlier over the last few years, this did happen quickly. I would just ask you for my farmers, for my businesses, to have it as quickly as possible——

Ms. MCCARTHY. I agree with you.

Mr. HULTGREN. —to bring certainty back.

Ms. MCCARTHY. I agree.

Mr. HULTGREN. With that, I yield back, Mr. Chairman. Thank you.

Ms. MCCARTHY. Thank you.

Chairman SMITH. Okay. Thank you, Mr. Hultgren. The gentleman from California, Mr. Takano, is recognized for his questions.

Mr. TAKANO. Thank you, Administrator McCarthy, for your testimony today and your appearance before this Committee.

I have to tell you, it is frustrating to me to sit here and listen to my colleagues on the other side of the aisle beating up on the EPA. My colleagues and I have seen first-hand how the EPA—not my colleagues, my constituents and I have seen first-hand how the EPA and the Clean Air Act have improved air quality and advanced public health in my district. Nationally, the stories are just as compelling. A study by the EPA shows that by 2020 the benefits of the Clean Air Act will outweigh the costs by more than 30 to 1. The Clean Air Act has helped improve public health by cutting down cases of asthma, heart disease and infant mortality, and by 2020, it is expected to prevent 17 million lost work days because people are healthier.

I believe the EPA is a driver of innovation, pushing the industry to adopt new standards that protect the environment, improve public health and create jobs in emerging fields. Administrator McCarthy, could you go into more detail about how the EPA rules have actually created jobs in our country and what new structures have grown because of EPA action?

Ms. MCCARTHY. Actually, thank you for asking that. It helps me to put the job code in a little bit more perspective. I think you would see as we have done a considerable amount of analysis as we do with every rule, about every significant rule looking at job implications, we have been able to make these considerable pollu-

tion reductions at the same time as we have been able to continue to grow the economy here in the U.S.

We are looking at actually a pollution control technology industry that now tops around $2 billion annually. We are leaders internationally in those issues. It is because we have been moving at a concerted pace to get better and better at how we reduce pollution, and we are doing it in a way that is affordable and that is extremely beneficial to the public health. We are talking about saving millions of lives. We are talking about really improving the health of our most vulnerable populations, our children and our elderly. I mean, we are talking about growing jobs, not taking them away, and we can provide you with significant more detail, Congressman. But I appreciate your asking the question because EPA is about public health. But we do it always conscious of how we can reduce economic impacts and actually build the economy at the same time.

Mr. TAKANO. Madam Administrator, I just wanted to clarify something. My colleague, Mr. Rohrabacher, cited a CRS report which indicated an inherent conflict of interest found among members, academic members of its advisory committees. However, this report, which I have right here, made no such conclusion. Rather, it noted that these grants are actually to academic institutions——

Ms. MCCARTHY. Yeah.

Mr. TAKANO. —where the member is employed. And not the member and only a very small proportion of any of the grant may be paid in the form of salary to a member. Is that your understanding as well?

Ms. MCCARTHY. Yes, it is. Yes, it is. Thank you, Congressman, for raising that.

Mr. TAKANO. Yes. With the conclusion, Mr. Chairman, with the discussion of the Committee's subpoena regarding the Harvard and American Cancer Society studies, I would like to enter into the record letters that the Chairman received on October 30 from Harvard, Brigham-Young University, the ACS and the American Cancer Society and the Health Effects Institute. These letters highlight the serious legal, ethical and policy concerns regarding the release of individual health information.

Chairman SMITH. Okay. Without objection, those letters will be made part of the record.

[The information appears in Appendix II]********** COMMITTEE INSERT **********

Chairman SMITH. But just for clarification, those letters were actually addressed to the EPA, not to me.

Mr. TAKANO. Okay. Thank you, Mr. Chairman. Madam Administrator, if I understand these science advisory committees, the industry is—in your opinion, is the industry adequately represented on these committees for a full balance of use?

Ms. MCCARTHY. The members on these panels don't represent specific sectors. They do represent expertise and knowledge and experience. And from my experience in working with these panels is that folks who have worked in the industry usually provide a perspective that is necessary on these panels. So it is a broad and balanced panel when we pull them together. That is required under

law, and we even go above and beyond to ensure that that is the case.

Mr. TAKANO. So in your view there was no such closed loop, that these are open-minded panels that are not contained by a particular ideology?

Ms. MCCARTHY. That is exactly what we are required to do under the law, and I think we do a very good job at ensuring that it is not at all closed. It is very open. We just look for good expertise so we can get the best science.

Mr. TAKANO. Thank you, Mr. Chairman. My time has expired.

Chairman SMITH. Thank you, Mr. Takano. The gentleman from Georgia, Mr. Broun, is recognized for his questions.

Mr. BROUN. Thank you, Mr. Chairman. Administrator McCarthy, I have a very limited amount of time and very many questions, so please answer as quickly as you possibly can so we can get through.

I am a physician, and I want to make sure that we are on the same page about basic principles of toxicology, one of which is that the dose makes the poison. A good example is two aspirins will help relieve the headache, 50 aspirins is a toxic dose. Would you agree with that premise that the dose makes the poison? Yes or no.

Ms. MCCARTHY. I don't want to speak to the science——

Mr. BROUN. Yes or no, please.

Ms. MCCARTHY. —but the dose is very important to us, yes.

Mr. BROUN. So the answer is yes. Even though fine particulate emissions have dropped 55 percent over the last two decades, it is noted on your website, EPA's own website for air quality trends, your Agency has been very concerned with the health effects associated with fairly low dosage, low levels of particulate matter, or PM. It has been the basis of most of your recent Clean Air Act regulations. Agency analysis suggests that hundreds of thousands of Americans die from PM exposure every year. According to your website, "Numerous scientific studies have linked particulate particle pollution exposure to premature death, cancer, non-fatal heart attacks and aggravated asthma." Does the science suggest that PM can cause cancer?

Ms. MCCARTHY. I do not know. I cannot answer that question, sir. I am sorry.

Mr. BROUN. Okay. Well——

Ms. MCCARTHY. I don't know what the word suggests is, and I don't know how the scientists would interpret that. I wait until they tell me.

Mr. BROUN. Well, okay. EPA's most recent assessment of PM stated that there was "strong epidemiological evidence linking short-term exposure to PM as measured in hours, cardiovascular and respiratory mortality and morbidity." Is that still true?

Ms. MCCARTHY. I believe so.

Mr. BROUN. Okay. If the dose makes the poison, as you just indicated you believe that they do and I do, too, and you think that hundreds of thousands of people die from fine particulate levels at the lowest level, why has your Agency conducted a series of human tests in North Carolina that exposes unknowing volunteers, that have no knowledge of the exposure, including those with pre-existing respiratory issues and asthma, to particulate concentrations as

high as 750 micrograms? That is more than 60 times the standard. Would you explain, please?

Ms. MCCARTHY. To my knowledge, we have not done that.

Mr. BROUN. Yes, ma'am, you have. And, in fact, the Inspector General has been investigating this, and we found out about this through the Freedom of Information Act. Were these individuals informed that they were being subjected to a pollutant that EPA thinks causes mortality and cancer, especially since many came from susceptible populations?

Ms. MCCARTHY. It is my understanding that the human studies work that we are doing was recommended by the national academies. It is done with the highest ethical standards. We medically——

Mr. BROUN. Ma'am, I——

Ms. MCCARTHY. —treat every——

Mr. BROUN. —disagree, because these people—according to the knowledge that we have gotten is they were unknowing that they were being exposed to these high levels of exposure of particulate matter. And, as far as I am concerned, as a physician, as a scientist, this is totally unethical, and totally unacceptable. Let me ask you one more question, because my time is running out. Are you signed up for Obamacare?

Ms. MCCARTHY. No, I am not.

Mr. BROUN. Why not?

Ms. MCCARTHY. Well, because I am lucky enough, as a Federal Government, that I have health care available to me, which I have signed up for. In a few years, when that is not the case, I will be happy to have other available——

Mr. BROUN. Well, our President says that——

Ms. MCCARTHY. —health care——

Mr. BROUN. —Obamacare——

Ms. MCCARTHY. —opportunities——

Mr. BROUN. —is much better than forcing most Federal employees to—into Obamacare. And, obviously, if you are not signing up, you don't think it is. Mr. Chairman, I have run out of time. I yield back.

Chairman SMITH. Thank you, Mr. Broun. The gentleman from Massachusetts, Mr. Kennedy, is recognized for questions. We have had some problems with the audio system. How about that one? There we go. Okay, there we go.

Mr. KENNEDY. Thank you. Thank you, Mr. Chairman. Thank you, Madam Administrator, for being here, and I apologize for the raspy voice. It has been going around a bit, so, apologies. I just wanted to start off by saying welcome, and thank you. It is always nice to see another member of Red Sox Nation here today, so—and certainly in front of our committee.

Ms. MCCARTHY. Go Sox.

Mr. KENNEDY. There you go. I want to thank you for all your hard work over the past several months, and I look forward to—very much working with you in the years ahead. I had a couple of questions, if you don't mind, and first is actually an issue that is pertaining to my district a bit. Over the past few decades, the EPA has made really admirable progress in attacking the lingering pollution and contamination issues in local municipalities that, left

unchecked, would have dire long term health and safety consequences, not to mention financial ones.

Back home, in my district, just outside of Boston, the Fourth District of Massachusetts, I hear concerns about the cost of compliance with some of those regulations in almost every city and town I visit. They don't disagree with the importance of these regulations, but the communities struggle to get back on their feet post-recession, and deal with an already crippling loss of state and Federal dollars due to our budget situation here. That price tag of compliance can seem nearly impossible.

In 1992, the city of Fall River was ordered to tackle a combined sewage overflow project that is estimated to cost them $185 million to date, along with 8 million in debt payments every year. This is an old industrial city, with an unemployment rate around 13 percent, median household income that struggles to break $30,000 a year. Similarly, Milford is looking at a $100,000 a year additional spending to meet new regulations for storm water management. They have also included a new pilot program to reduce phosphorus runoff in local rivers and waterways, but the price tag around that is about $111 million up front, a price tag which, if borne by the town, would be felt tremendously by local businesses. The surrounding towns of Franklin and Bellingham are both looking at bills of about 75 million and 35 million respectively through the same pilot program.

When I talk to local officials and businesses, they want—they have a genuine desire to be EPA compliant. They are bringing up their children and grandchildren in these same neighborhoods, and they see the value of clean air and clean water. They are tremendously concerned about the effects of contamination, pollution, and other environmental hazards, and how they wreak havoc on their hometowns, and they know the associated costs of long term savings. But they are stuck, and so I wanted to ask you, in your opinion, is there any assistance that the Federal Government, not just the EPA, but the Federal Government, can give these already strapped municipalities that are struggling with the cost of compliance? And, again, I ask this, of course, given the—understanding the fiscal constraints that our government is under right now, but knowing that, obviously, this is an issue that is important to you as well. So if you could respond for a minute or so, I would be grateful.

Ms. McCarthy. Thank you for raising this, and your voice in this discussion would be really welcome. We are working on these issues pretty diligently, primarily with the conference of mayors, because all of them understand these challenges, why it is important for their public health and their environmental resources that we tackle these more challenging water quality issues. But we are working on this on a number of different fronts, and EPA clearly has funds available to help support this. Is it enough to go around? No, it isn't. It is never expected to be. It will be a challenge. We try to prioritize that, and make sure that we are getting the biggest bang for the buck in helping those most in need.

So we are trying to work on a way to make a—this a much more collaborative process, where we understand the constraints that the cities and towns are in, and we don't expect things that they

cannot deliver, but we work more in partnership to find the least cost opportunities to make continued environmental progress moving forward.

Mr. KENNEDY. Thank you. And then, Madam Administrator, if I can ask, and I apologize, I had to step out for a moment, but, my understanding, there has been two studies that have much discussed today. I can refer shorthand to them as the Harvard study and the ACS, American Cancer Society study, is that right?

Ms. MCCARTHY. Yes.

Mr. KENNEDY. You do understand me? Would you characterize those institutions as reputable?

Ms. MCCARTHY. Yes.

Mr. KENNEDY. Well known?

Ms. MCCARTHY. Yes.

Mr. KENNEDY. Capable, and producing well-regarded and scientific study, other than these past studies?

Ms. MCCARTHY. I would.

Mr. KENNEDY. Have these two studies been peer reviewed?

Ms. MCCARTHY. Many times.

Mr. KENNEDY. By who?

Ms. MCCARTHY. By—through contractors for the agency, through the national community, through EPA.

Mr. KENNEDY. Through EPA? And sometimes through public/private partnerships?

Ms. MCCARTHY. Yes.

Mr. KENNEDY. And so that review, is that all government funded?

Ms. MCCARTHY. No.

Mr. KENNEDY. No? So, in fact, part of that funding was done by a group that was actually funded by automotive industry, is that right?

Ms. MCCARTHY. Yeah, many.

Mr. KENNEDY. Okay. Thank you. I yield back my time.

Chairman SMITH. Thank you, Mr. Kennedy. Mr. Kennedy, you have elicited the shortest answers of the day, so congratulations to you. The gentleman from Indiana, Mr. Bucshon.

Mr. BUCSHON. Thank you. Thank you for being here. I just wanted to give a brief statement about bias. I am a cardiovascular and thoracic surgeon, so I know quite a bit about health, and I recently reviewed the data from the American Lung Association that they put out about particulate matter, and look at the background on the funding for all the studies, and, lo and behold, everything that they used was pretty much very far left leaning global warming activist foundations that privately funded these things. And, in addition to that, the potential health benefits are based on computer modeling, not on actual data, but a computer model projecting their data results into the future, not based on actual factual data, with human studies. And, to make matters worse, the computer modeling was developed by an individual who had a financial stake in the success of the model going forward. In fact, I had the Chief Medical Officer from the American Lung Association come down from New York and discuss this with him in my office, and voiced my disappointment that an organization that is so highly esteemed would be using data which, in my view, was biased.

But my question goes in another direction. In September your agency proposed a rule that represents perhaps the clearest, although not certainly the first, in the administration's war on coal, what I will call war on coal. The Eighth District of Indiana, that I represent, has nine coal mines, every coal mine in the state, our state. 88 percent or so of our power comes from coal. Coal supports the economy, you know, jobs indirect and direct. It helps families put food on the table. In fact, I grew up in Illinois. My dad was a coal miner, so I have known this industry forever. In fact, I wouldn't be here if it wasn't for that.

But the new source—performance stands for new power plants will essentially prevent construction of another coal fired power plant in this country ever, essentially. In the first few pages of the EPA Cost Benefit Analysis, you admit that this policy will, and I quote, "Result in negligible CO_2 emission changes, or quantified benefits, through 2022." In your view, should the federal government regulate coal fired power plants in this manner if there are no clear benefits? That is an up or down.

Ms. MCCARTHY. We should be regulating CO_2 from carbon emissions, yes.

Mr. BUCSHON. Then your statement that you made was incorrect, that there is a benefit through 2022? Because the quote in the first few pages of the Cost Benefit Analysis says, and I quote again, "Result in negligible CO_2 emission changes, or quantified benefits, through 2022."

Ms. MCCARTHY. Which is a reflection of the industry and the market as it sits today.

Mr. BUCSHON. Okay. So what you are saying is they should regulate that, even in light of the fact the EPA admits there is no benefit to it?

Ms. MCCARTHY. The issue is that coal is not being invested in, except in a few instances where carbon capture and sequestration is being invested in, where—when we want to make sure that we take advantage of those new technologies, and make sure that we do what the Clean Air Act says, which is to underpin those reductions——

Mr. BUCSHON. Okay.

Ms. MCCARTHY. —moving forward.

Mr. BUCSHON. And that is fair, and I think the industry would agree that constant innovation and technological advances is something that the industry also——

Ms. MCCARTHY. Uh-huh.

Mr. BUCSHON. —believes in, as—and would—will invest in.

Ms. MCCARTHY. They do.

Mr. BUCSHON. That said, is the technology currently commercially available on a large scale for Indiana and the Midwest to meet the proposed standards?

Ms. MCCARTHY. On a large scale?

Mr. BUCSHON. Yes. I mean, you might quote that the technology is available in——

Ms. MCCARTHY. It is.

Mr. BUCSHON. —in some academic setting, or in an area of the country, say, where things are very close—but specifically, you know, related to CO_2 emission capture, and all, you know, my un-

derstanding is currently there is not the commercially available on a large scale technology to comply, in Indiana, with the regulation. So the regulation is in place, but there is no commercially available technology to comply. Is that true or not true?

Ms. MCCARTHY. We believe that CCS is commercially available. Is it going to be broadly disseminated at this point? No, we don't believe so, because most of the facilities that are being constructed are actually natural gas facilities. They are the most competitive. But where coal is being invested in is being invested in with CCS.

Mr. BUCSHON. Thank you. I yield back.

Chairman SMITH. Thank you, Mr. Bucshon. The gentleman from California, Mr. Peters, is recognized for questions.

Mr. PETERS. Thank you very much, Mr. Chairman. And, Madam Administrator, thank you for being here. I should start by mentioning that the first job I had out of college was at the EPA in Washington, D.C.

Ms. MCCARTHY. Really?

Mr. PETERS. And I left to pursue other interests, and here I am back again with you, but it is nice to see you. And welcome, and thank you for your service. I wanted to ask about hydraulic fracturing, but, for context, I just wanted to call your attention to the work at the Institute for Strategy and Competitiveness at the Harvard Business School. Michael Porter and Jan Rifkin have done a study, what would make the United States the most competitive place to do business in the world? They have identified a lot of things we have heard about, like highly skilled immigration—or highly—immigration of highly skilled individuals, corporate tax reform, overseas profits, international trade, simplifying and streamlining regulation, improving communication and energy infrastructure, creating a sustainable Federal budget, and the responsible development of American shale gas and oil reserves as an important component——

Ms. MCCARTHY. Um-hum.

Mr. PETERS. —of competitiveness worldwide. So, first, I wanted to ask you a little bit about—do you think that it is—that it is possible to develop these reserves responsibly? Is that the EPA's position?

Ms. MCCARTHY. I believe so.

Mr. PETERS. And if so—so, if so, tell me a little bit about what you think the approach should be. And I want to give you a little bit of time, because I feel like I didn't get—you were interrupted sometimes when you were trying to give these answers.

Ms. MCCARTHY. Well, I——

Mr. PETERS. What is the—what should be the approach to the development of this? I would ask you to touch on two things in particular. One is the—obviously water and—water supply and quality, but also the emission of gases, including VOCs and methane, which is a super pollutant, and also how you would avoid double regulation? Because I understand there is other agencies in the Federal Government that may be doing things that are overlapping or inconsistent.

Ms. MCCARTHY. And there is a lot of State Governments working on this issue as well.

Mr. PETERS. Right.

Ms. MCCARTHY. I would, first of all, want to agree with you about the importance of the expanded natural gas availability. It has been a game changer in many ways, and it is important for our national security, as well as our continued ability to have all these energy resources available to us. So I think what EPA has been doing is in two ways. One is the President has been very clear about the fact that natural gas, and its availability, has been incredibly important to the country, but it also needs to be done safe and responsibly.

And I think the committee knows that we are working on a very large project with other agencies of the Federal Government to look at water quality challenges, or implications, associated with hydro fracking, and new unconventional oil and gas exploration. We are in the middle of that study. Again, that is very robust. We have done a lot of outreach, webinars, and we are gathering as much information as we can, doing technical workshops. We expect that a draft will be out for peer review in the end of 2014. So we are tracking those issues, as well as responding to individual states when our technical expertise is being requested.

States are also the first line of responsibility in water quality, so we want to work in partnership with them to make sure that they are able to meet their own needs, and their—and fulfill—and get answers to their own questions, when they arise.

On the air quality side, we have a couple of things happening. We have actually already put out an air quality standard to address methane from emissions related to natural gas facilities—natural gas exploration, in particular fracking, at which time there are a lot of VOCs emitted. We can capture those. With that comes the methane. It can be re-used, and there is an ability to actually move forward in a cost—a very cost-effective, and actually profitable, way to start gathering that methane as we are capturing the volatile organic carbons. We are looking at some other questions that have been raised about what else we should do, and we are looking at those issues, again, working in concert with other agencies, as well as states and local communities.

So while hydro fracking has raised concern about whether it can be done, or is being done, safe and responsibly, EPA is working with states, local governments, and the industry to make sure that we understand how to answer those issues effectively, from a science perspective, and in a way that continues to maintain the availability of inexpensive natural gas that strengthens this economy, as well as helps us reduce air emissions.

Mr. PETERS. And I appreciate that. I think that seems like a reasonable response. The one thing I would ask you, as a—someone who practiced environmental law for a long time——

Ms. MCCARTHY. Yes?

Mr. PETERS. —is please do what you can to work with the administration so we don't have overlapping and potentially inconsistent regulations? Very frustrating for the public, and we want it to be done responsibly. We also want it to be done in a way that people can understand. Again, thank you for being here, and thank you, Mr. Chairman.

Chairman SMITH. Thank you, Mr. Peters. The gentleman from Arizona, Mr. Schweikert, is recognized for his question.

Mr. SCHWEIKERT. Thank you, Mr. Chairman. Madam Administrator, I really only had two things I wanted to walk through, and for everyone that was in a Committee with us here yesterday, I am sorry, you are going to hear part of the same theme again. These large data sets that are used, particularly in things like PM10, which is a big deal for those us out in the desert, southwest, where we actually have this thing called dirt, you know, without grass on it, so it really does affect our lives.

Why is it so controversial, why is it so partisan, to put up the data? And what I mean is down to the individual, because you and I know, with all other types of data—you were a social anthropologist, so when you were being vetted, and doing a review of data, you got down to the line item. If there was something personal there, you do a non-identifier number, you strip the personal data, and put those data sets up on websites, where it is egalitarian, where if a, you know, collectivist group, or a conservative group, or a business group, or a grad student could get it down to the line item data, and say, here is the noise from the data, but at least you have a communal international fight over this is good, this is bad, and who knows, you know, for those of us on the conservative side, it may not yield what we think it will, or the liberal side, but at least there is that purifying effect of lots and lots and lots of people being able to drive their analysis through those data sets. Why is that such a difficult conversation to have around here?

Ms. MCCARTHY. I don't think there is anything political or controversial about making data available.

Mr. SCHWEIKERT. I should show you the tape from this committee from earlier in the year, where that was stunningly a fight.

Ms. MCCARTHY. All the EPA is really trying to do is its responsibility under a number of laws, which is basically—we want to be supporting to the extent we can, openness, transparency, sharing information, sharing data——

Mr. SCHWEIKERT. But——

Ms. MCCARTHY. —meeting our—but——

Mr. SCHWEIKERT. Well——

Ms. MCCARTHY. May I just finish? The one thing I think we just need to have—make sure that there is a clear understanding is we have obligations to protect private information——

Mr. SCHWEIKERT. But there is a——

Ms. MCCARTHY. —and confident——

Mr. SCHWEIKERT. But I will tell you that in many ways that is a bizarre comment, because—do what everyone else does. You strip the personal identifiers, and here is your data set.

Ms. MCCARTHY. We have—and we are actually asking those very same questions, and if you look——

Mr. SCHWEIKERT. Well—but——

Ms. MCCARTHY. —at the——

Mr. SCHWEIKERT. But how do you ask—and then use it as an excuse to not give us the data?

Ms. MCCARTHY. There is no—I am not trying to offer excuses, Congressman. I am trying to be as responsive as I can. But we need to just be careful in how we maintain that confidentiality. And we are working with——

Mr. SCHWEIKERT. But there is all——

Ms. MCCARTHY. —all of the researchers——

Mr. SCHWEIKERT. But there is——

Ms. MCCARTHY. —on this.

Mr. SCHWEIKERT. But, look, there is all sorts of protocols in that. I was involved in a very large project, where we were doing analysis of how much mortgage fraud had happened in our communities. We did random identifiers, and then we put it out, and said, everyone study what happened. It is not hard. It is done every single time it is not that hard. And, if you are also using proprietary data, inappropriate. You are making public decisions, for the public, that affect the public, billions and billions of dollars, maybe for the good, maybe to the bad. To use proprietary data, I believe, is borders on perverse.

I have something else I just want to show real quick, can we put up this slide? And this has sort of been my fixation of how we accumulate data, how we do analysis and study things. In Maricopa County and Gila County, Pinal County, I have a metroplex there with a few million people. We have PM10 and monitoring sites. And instead of putting monitoring sites where my population lives, we have chosen, you have chosen, under the rule sets, and I understand there may be a rule where, once it is there over a couple of years, it is really hard to move, because you lose the baseline data, but take a look at this one, just for the fun of it.

You have put, your predecessor, a monitoring site next to a very large stockyard, next to a railroad track, next to desert agriculture, and next to a series of dirt roads. Could you imagine the data you get from this monitoring site? Yet this is dozens, and dozens, and dozens, and dozens of miles away from where my population base is. How does that not create perverse skewing in your underlying data for trying to really build good quality statistics, particularly in PM10? This is an outlier, and you have two other monitoring stations that have almost the same attributes here. You are getting so much noise in your data, this is where you—for those of us from sort of statistical backgrounds, we are just bouncing off the walls livid.

Ms. MCCARTHY. Well, I am happy to spend some time and bring my folks in, but when we do these rules, we also propose a monitoring plan, and we work with states. We take public comment on those plans as well.

Mr. SCHWEIKERT. My county, and my state, and my communities have been begging for years to put this in a rational spot, and have been ignored.

Ms. MCCARTHY. Well, we should have that conversation. But I do think our obligation is to look at ambient air quality across the country in a way that reflects the——

Mr. SCHWEIKERT. The population basis?

Ms. MCCARTHY. Well, actually, we do the—most of the monitors are done on a population basis.

Mr. SCHWEIKERT. So——

Ms. MCCARTHY. Some of these are not. Clearly this one was not one of them.

Mr. SCHWEIKERT. But this one didn't even hit the trifecta. It hit all four, you know, outliers. So——

Ms. MCCARTHY. But I appreciate your——

Mr. SCHWEIKERT. Madam Administrator——

Ms. MCCARTHY. —raising that point——

Mr. SCHWEIKERT. —sorry——

Ms. MCCARTHY. —and having that——

Mr. SCHWEIKERT. —but this is one that is just been a thorn in our side——

Ms. MCCARTHY. I actually——

Mr. SCHWEIKERT. —for——

Ms. MCCARTHY. —think I have been there before.

Mr. SCHWEIKERT. Well, in that case, I can't believe we didn't move it the next day. Mr. Chairman, I yield back.

Chairman SMITH. Thank you, Mr. Schweikert. The gentleman from Texas, Mr. Weber, is recognized.

Mr. WEBER. Thank you. Thank you, Ms. McCarthy, for being here. The Chairman, in his opening comments, said that he believes the EPA should answer the American people. Do you agree with that?

Ms. MCCARTHY. We work for the American people, yes.

Mr. WEBER. Good. Ms. McCarthy, have you ever run a business?

Ms. MCCARTHY. Have I ever—no.

Mr. WEBER. No? Okay. You said in your comments that you were here to talk about the central role the science plays——

Ms. MCCARTHY. Yes.

Mr. WEBER. —earlier today. And have you ever heard the statement that all scientists are only sure about one thing, and that is that every scientist before them was wrong?

Ms. MCCARTHY. I have not.

Mr. WEBER. You have not heard that? Good. That is, you might learn, does the science ever change, or get proven wrong?

Ms. MCCARTHY. Sure. Yes, it does.

Mr. WEBER. Frequently, doesn't it?

Ms. MCCARTHY. I——

Mr. WEBER. So if you are here to talk about the central role the science plays in the EPA's deliberations, what would you say is the second thing that plays a role in the EPA's deliberations?

Ms. MCCARTHY. There are—if I could say three things?

Mr. WEBER. Quickly, please.

Ms. MCCARTHY. Science, law, and transparency.

Mr. WEBER. Science, law, and transparency. We are off to a good start. You said—and I don't remember who the exchange was with—submitted a rule, was it to OMB?

Ms. MCCARTHY. OMB.

Mr. WEBER. OMB, Office of Management——

Ms. MCCARTHY. Office of Management——

Mr. WEBER. —and Budget. Okay.

Ms. MCCARTHY. Yes.

Mr. WEBER. But not to the Science Advisory Board? And, by law, as you said was the second thing that played a part in you all's deliberations, behind science, or three things, then. So, by law, you are supposed to submit that same rule on the same date—or by that date, is that accurate?

Ms. MCCARTHY. I am not aware that that is specified in the law, but we certainly engage the SAB, and we have a——

Mr. WEBER. And you said you have a process of doing this. But if it is—if you are to submit it at the same time, or the same day, that is a pretty exacting science.

Ms. MCCARTHY. We actually sometimes consult with them even before it goes in the inter-agency——

Mr. WEBER. And you are to be commended. So if you don't submit that at the same time, as the objection was earlier, then, in essence, you are going around that law that you just said you are here to commit science, the American people, and following the law, right? So you are actually going around that law, so that exact science of the date, when you submit the law to OMB and the Science Advisory Panel at the same time, you are circumventing.

Ms. MCCARTHY. No, sir, I believe I am——

Mr. WEBER. You are not—so you are——

Ms. MCCARTHY. —the law.

Mr. WEBER. You are interpreting the law so that as long as you have the process, in effect, you are good?

Ms. MCCARTHY. No, sir, that—that is not what I——

Mr. WEBER. That is not what you said? Well, I misunderstood, I apologize. Let me go on. You said that there are researches that have contracts to verify data, in your earlier comments.

Ms. MCCARTHY. —contact——

Mr. WEBER. You don't recall that? Well, I was taking notes. So you have researches that have contracts to verify data, and my question is do you ever get biased results?

Ms. MCCARTHY. Well, actually, the—our entire peer review process is designed to minimize any possibility——

Mr. WEBER. Right.

Ms. MCCARTHY. —of that, and I think we do a good job at it.

Mr. WEBER. And so Mr. Hall mentioned Parker County earlier, where you had—or the EPA had to retract a statement where they said that fracking has contaminated the water supply. Are you aware of that?

Ms. MCCARTHY. I am aware that the EPA developed data, and has provided that data publicly.

Mr. WEBER. Okay. And when Mr. Sensenbrenner questioned you on the standard for fuel efficiency, you said, pretty much quote, you aren't here to speak to manufacturers' warranties and liabilities.

Ms. MCCARTHY. I can't speak to their——

Mr. WEBER. Right.

Ms. MCCARTHY. —statements about that, no.

Mr. WEBER. So, in essence, if it affects an entire car industry, it doesn't matter——

Ms. MCCARTHY. Very much so it matters. It matters to us, and we——

Mr. WEBER. Okay.

Ms. MCCARTHY. —appropriate testing for that reason. I just can't—I am not—that is not my——

Mr. WEBER. Let me move quickly. Mr. Rohrabacher said, on grant recipients, you said in response to him that you have procedures to ensure that they are fair-minded. Well, let me submit to you, as a business owner, if we are going to put businesspeople on the Science Advisory Panel, can't you apply those same procedures to make sure that they are fair-minded?

Ms. MCCARTHY. We provide the same procedure that is on——

Mr. WEBER. So you would be okay with having more business and industry experts on a panel, as long as they are fair-minded?

Ms. MCCARTHY. Our job is to balance that——

Mr. WEBER. Okay.

Ms. MCCARTHY. —panel out, and make sure they are doing their job correctly.

Mr. WEBER. Very quickly, I have Valero,a plant——

Ms. MCCARTHY. Yeah.

Mr. WEBER. —carbon capture sequestration in my district and I am in the Gulf Coast of Texas, District 14. Four hundress million dollars was the cost of that project. Some 60 percent of that was supplied by the DEO through the—DOE through the ARRA, American Reinvestment and Recovery Act, stimulus. So you said that CCS had been demonstrated to be cost-effective in your exchange with——

Ms. MCCARTHY. No, I am sorry, sir, I said it was a reasonable cost.

Mr. WEBER. It was a reasonable cost? Okay. Well, let us go with that. So out of a $400 million, project, 60 percent of it $240 million, if I have done—my high school math is holding up, is going to have to come from the Federal Government. Do you think it is reasonable to believe that industry can duplicate that, if 60 percent of the money has to come from the American taxpayers?

Ms. MCCARTHY. I think our analysis that has been put out, that we are taking comment on, would indicate that this cost is reasonable for new facilities moving forward.

Mr. WEBER. Okay. So when Congressman Neugebauer asked you if you had a cost benefit analysis, you said no, in essence you have done one, and you made a judgment decision about your analysis that it is reasonable?

Ms. MCCARTHY. Yes. It is a little——

Mr. WEBER. Okay.

Ms. MCCARTHY. —different that what we would look at as a—as being cost——

Mr. WEBER. I got you.

Ms. MCCARTHY. —effective. But——

Mr. WEBER. And then finally, very quickly, I know that you are looking at new projected rules for ozone standards. When are those coming out?

Ms. MCCARTHY. I do not know the exact date, sir. It is in the middle of the process with our Clean Air Act Science Advisory Committee. I know that the next big step in that process is for them to look at a couple of documents that are—we are hoping to provide by the end of the year. We are past our five year time window——

Mr. WEBER. Okay.

Ms. MCCARTHY. —under the law, but we are working as hard as we——

Mr. WEBER. EPA seems to be in the business of mitigating hazards, so this might be a tricky question for you. Would you hazard a guess, will it be before November of 2014 or afterward?

Ms. MCCARTHY. I do not know the——

Mr. WEBER. And go through that?

Ms. MCCARTHY. It needs to be both proposed and finalized, and I haven't even been briefed on that, because we are still looking at the science, and we like to keep the policy and legal questions——

Mr. WEBER. Okay.

Ms. MCCARTHY. —aside and work on the science.

Mr. WEBER. And if I may, Mr. Chairman, very quickly, you did a national survey to see willingness of people to pay?

Ms. MCCARTHY. We are talking about the 316(b)?

Mr. WEBER. Um-hum.

Ms. MCCARTHY. I believe it was a national——

Mr. WEBER. Okay.

Ms. MCCARTHY. —survey.

Mr. WEBER. Did you also survey industry to see if they were willing to pay for the EPA's opinion on whether or not it was cost-effective? And did you also do a survey to see if people were willing to pay for the loss of jobs when jobs are exported offshore because our plants can't compete? Did you do that survey?

Ms. MCCARTHY. I think we are mixing a little bit of apples and oranges, sir, and I don't know if there is time for me to clarify what the survey——

Mr. WEBER. Okay.

Ms. MCCARTHY. —actually was doing, and in what rule it was applying.

Mr. WEBER. We will talk offline.

Ms. MCCARTHY. Okay.

Mr. WEBER. Thank you.

Chairman SMITH. All right. Thank you, Mr. Weber. The gentleman from Utah, Mr. Stewart, is recognized for his questions.

Mr. STEWART. Thank you, Madam Administrator, for being here today. I am sure you have just enjoyed your morning. You have been looking forward to this——

Ms. MCCARTHY. This is——

Mr. STEWART. —for weeks, I hope.

Ms. MCCARTHY. —part of the public process, and I am honored to be here.

Mr. STEWART. Well, thank you, and I am sincere when I say I think we recognize that you have worked hard to serve your country. But there are so many things that you and I disagree with, and that I believe that the EPA is working not for, but actually against the best interest of the American people. And some of those, not all of them, but some of them have been brought up to date in this hearing so far, and let me just list a few of them quickly. Your interpretation of navigable waters, with the Clean Water Act, RFS standards and the new ozone standards that my friend, Mr. Weber, mentioned there very quickly. It is going to affect huge parts of the West.

Hydraulic fracking and clean water, new standards for the human cost of carbon emissions, and standards that—as we have spent some time talking about coal fired power plant generation. All of these things, and there are others, taken together, I believe that these new rules and proposals make life harder for hard-working American families. They take away economic freedom. They take away economic opportunity, I believe, and they have the effect of making Washington D.C. more and more powerful, and

more and more central to Americans' lives. And I think, frankly, that they make the American people less trustful of Washington D.C., and less trustful of the government, and I am sure you have a sense of that as well. And very clearly some of the questions and concerns expressed in this hearing today indicate that to you.

But let me focus on just one of them, if I could, and it is not a particularly partisan issue. It will affect Democratic and Republican districts. It will affect Democratic and Republican states. And I will start with a very simple question, and it is not intended to be a gotcha question at all, but do you think it would be appropriate for the EPA to propose a standard that would be impossible to meet?

Ms. MCCARTHY. If it is a health based standard about what is healthy, and impacts associated with it, we need to rely on the science to say that.

Mr. STEWART. Well, I understand, but, again, would you propose a standard that would be impossible to meet? Would that be appropriate for the EPA to do?

Ms. MCCARTHY. It really depends on what the question is.

Mr. STEWART. Well——

Ms. MCCARTHY. If it is a health based standard, you set the standard based on the health impacts——

Mr. STEWART. But once——

Ms. MCCARTHY. —and then you——

Mr. STEWART. —again, Madam Administrator, if it is impossible to meet, it doesn't matter what your standard might be, if it is impossible. And I think everyone would recognize that.

Ms. MCCARTHY. Well, we would not require the impossible, sir.

Mr. STEWART. Okay, and I appreciate that, and that is what I was hoping you would say. And it wouldn't be appropriate for the EPA to set standards, for example, that are actually below naturally occurring background levels. And if I could call your attention to a slide, and I suppose you have seen this, or something like this before, regarding ozone standards. The areas in red reflect EPA controlled monitor counties where a 60 parts per billion standard would be violated. Areas in orange indicate unmonitored counties that anticipate the violation of the 60 parts per billion.

And, look, I represent parts of Utah. We have got some of the most remote areas, they are very beautiful, but they are some of the most unpopulated areas of our nation. Zion's Canyon, Bryce, canyon lands. You could include Yellowstone National Park in this map as well. And yet, using Yellowstone as an example, naturally occurring ozone, 66 parts per billion, which is above what some of the proposed standards are being considered. And I guess I would just ask you, are you aware that some of the most remote, and in some cases pristine parks and parts of the country will have ozone that exceeds the range of this proposed standard?

Ms. MCCARTHY. There is no proposed standard at this point, Congressman, let us just make sure that people aren't confused by that. But I would also say that I know the Science Advisory Board is looking at this issue with the staff so they can establish some recommendations to me moving forward——

Mr. STEWART. Yeah.

Ms. MCCARTHY. —and we can take a look at these issues.

Mr. STEWART. And I appreciate—okay, maybe there isn't a proposed standard. Maybe this is one of those issues that depends on what the meaning of the word is is, and we could go back to very technical definitions, but there is certainly some consideration of a standard of 60 parts per billion, would you agree with that?

Ms. MCCARTHY. I honestly do not know whether that is part of the consideration——

Mr. STEWART. Okay.

Ms. MCCARTHY. —that the Science Advisory Board will advise me on.

Mr. STEWART. Okay. In hearings that I chaired earlier this spring, we were very clearly told that that was the standard that they were considering. And, in fact, that they were not only considering, it was one that they were leaning towards, and we expected it to be the new proposed standard.

Ms. MCCARTHY. Okay.

Mr. STEWART. I guess I would just conclude with this, my time being ended, and I wish I had more time, but there is nothing that these Western states can do to achieve that kind of standard. It will have great economic cost. By the EPA's own estimate, $90 billion. By some estimates, it may be 10 times that amount. And I would love to talk to you another time about just the wisdom, or the sanity, frankly, forget wisdom, just the sanity of the EPA proposing a standard that is impossible to meet, that would be incredibly expensive. And, once again, coming back to my opening statement, and why that generates so much suspicion——

Ms. MCCARTHY. Yeah.

Mr. STEWART. —and so much ill will in the body politic of the American people. So, with that, thank you, Mr. Chairman, and I yield back my time.

Chairman SMITH. Thank you, Mr. Stewart. The gentleman from Oklahoma, Mr. Bridenstine, is recognized for his questions. Sorry. He is not here. We will go to the gentleman from Texas, Mr. Stockman.

Mr. STOCKMAN. Well, hi, Ms. McCarthy. I am over here.

Ms. MCCARTHY. Thank you.

Mr. STOCKMAN. I know, we are kind of jumping around. I think, though, you earlier gave me my favorite tweet of the day, which is, I am lucky enough—really? The quote is from you, I love it. It says, I am lucky enough not to have to sign up for Obamacare. That is wonderful. I wish my constituents could say the same.

Ms. MCCARTHY. I actually think I was referring to I am lucky enough to have access to good health care, which the——

Mr. STOCKMAN. I still will take your quote——

Ms. MCCARTHY. —Affordable Care Act——

Mr. STOCKMAN. —from the record.

Ms. MCCARTHY. —will expand.

Mr. STOCKMAN. I wrote it down. It is really good. You said also in your testimony there was $2 billion in new jobs from your EPA. I want to point out that one facility alone in my district is a $7 billion—$7 billion in new construction, representing 13,000 jobs, and your administration is saying, because of the two week furlough, that it is going to take many more months to look at the permits. And I would request that, given the circumstances of our poor

economy, and the fact that this needs to be done, it is meeting, I believe, all the EPA requirements, I would ask that you, and I will follow up with you, that you look at this and expedite it. It is 12,000 jobs. That is a lot of jobs.

Ms. MCCARTHY. I am sorry——

Mr. STOCKMAN. And I just——

Ms. MCCARTHY. —what kind of permit are we talking about?

Mr. STOCKMAN. EPA permit. It has been in your office, it has been sitting there. They have followed all the rules and regulations.

Ms. MCCARTHY. I am happy to follow up.

Mr. STOCKMAN. I would appreciate it. There is also another plant that wants to export coal, so it won't be burned here, in my district. Altogether we have $52 billion that is being held up by the EPA, which, by the way, is more than the sequester. I am just saying to you that there is a lot of jobs in my district that is dependent, unfortunately, by your decisions, and I would like to give the information to you so we can facilitate the jobs that I know this President wants. He is the jobs president, and I really want to help him out in doing that.

And this much activity in our district, which, Texas, as you probably know, represents almost 50 percent of all the jobs in the United States that are created. And in my district, we have had 30,000 people move into our district. There has been over a million wells fracked, as you know. There has been a lot of fracking. And there is a general history in this United States of people independently drilling for oil and producing products that this nation relies on. We are going to produce more oil than Saudi Arabia, and I think it is because of the independence and the drive of this American spirit.

I just want the boot off the neck of the Americans so we can see a future where we have independence from the Middle East. This has great implications on our foreign policy, great implications on people's future. And I am real frustrated when I come back to my district, and I have people coming to my town hall meetings and saying, we want the jobs. And I have to tell them, I am sorry, but someone from the EPA is not letting us have the jobs. I am just begging you, please, open your heart up, get these permits done. They have done the work. They have complied with all the regulations. I don't see what it is—for two weeks they said we shut down the government. It shouldn't take months to recuperate the two weeks that is lost.

And, I don't know, I even have a plant, that is not in my district, but a lead plant. Now all the lead plants are closed in the United States. They were willing to spend $100 million upgrading the lead plant. Now the Chinese are going to produce the lead, so now we are not going to have the lead for the Americans to put on their, you know, when you get X-rays, they will come from China. The batteries, the lead will be coming from there.

I am really frustrated that we have so much opportunity in this country, and again, and again, and again, it comes back to your administration, where I hear, okay, it is locked up there, it is locked up there, it is locked up there. And I go to town hall meetings—I would love for you to come with me, and I will invite you to a

town hall meeting where we can share the podium, and hear from the people individually who are losing their jobs because we can't get permits.

And I am troubled that, again, time and time again, I can't get any satisfaction, quoting from The Rolling Stones, of course, from your administration. So if we could work together——

Ms. MCCARTHY. —to sing.

Mr. STOCKMAN. Yeah.

Ms. MCCARTHY. I appreciate it.

Mr. STOCKMAN. Go for it. But if we could work together on this, I would appreciate it. And I will welcome you to any town hall meeting.

Ms. MCCARTHY. You know, this is an issue that, frankly, I just have not heard for a long time. I think we have been trying to do our best to expedite permits as much as we can, knowing the economic implications of that. So if you do have concerns, we really should tackle them together.

Mr. STOCKMAN. I appreciate it. Thank you. I have got one thing I want to add.

Ms. MCCARTHY. Yeah?

Mr. STOCKMAN. This is for my colleague, who wanted to clarify, Dana Rohrabacher. It is my quick clarification on the CRS report, and place this into the record, if I can, Mr. Chairman.

Chairman SMITH. Okay. Without objection.

Mr. STOCKMAN. Okay. Thank you.

Chairman SMITH. Okay. Thank you, Mr. Stockman. The gentleman from Kentucky, Mr. Massie, is recognized.

Mr. MASSIE. Thank you, Mr. Chairman. Madam Administrator, throughout this hearing you have touted the importance of transparency, and I agree. Consistent with your promise of transparency, on September 30, 2013 your agency announced it would hold public listening sessions on reducing carbon emissions from existing power plants to consider the public concerns ahead of development of the EPA rules. But I was disappointed to learn that all of the EPA's 11 announced sessions are in major metropolitan areas, and none of these listening sessions would be in the 10 states most reliant on coal.

In November, our Congressional delegation sent you a letter, informing you that Kentucky's already lost more than 6,200 coal jobs in just the last two years, reducing the state's coal employment to its lowest level since the Commonwealth began keeping statistics in 1927. Unfortunately, these job losses are forecasted to continue, to increase, as additional EPA regulations targeting coal come online. In this letter, we requested that you hold listening sessions in Kentucky for the sake of openness and transparency that you have espoused today. In the eyes of Kentuckians and American people, will you commit to us today that the EPA will hold listening sessions in the Commonwealth of Kentucky, and other similar states, like North Dakota, where my colleague, Mr. Cramer is from, that are reliant on coal production and coal fired electricity as you seek public comment?

Ms. MCCARTHY. Well, Congressman, we received a number of requests for additional listening sessions. I would like to explain to

you, those 11 sites are actually our regional offices, because it is——

Mr. MASSIE. Certainly you——

Ms. MCCARTHY. —helps us——

Mr. MASSIE. We appreciate that, and we appreciate that you have held before listening sessions outside of your offices. I think you should get outside of the office, you know, go out and see the people you are going to affect once in a while. And hopefully you certainly must realize that if you fail to hold these listening sessions on greenhouse gas regulations in the states whose economies most depend on the coal industry and coal fired electricity, this will be perceived as an effort to avoid negative public opinion——

Ms. MCCARTHY. Well, there——

Mr. MASSIE. —or to ignore the adverse effects of these regulations.

Ms. MCCARTHY. I——

Mr. MASSIE. You realize that is going to be perceived that way if you don't hold these hearings?

Ms. MCCARTHY. Well, I think people should recognize that this is even before we are proposing, never mind entering into the rigorous public——

Mr. MASSIE. Can you commit——

Ms. MCCARTHY. —comment process——

Mr. MASSIE. —today——

Ms. MCCARTHY. —without making——

Mr. MASSIE. —to hold this in Kentucky?

Ms. MCCARTHY. There is also opportunities for individuals to——

Mr. MASSIE. Okay, I can't let you take all of my time if you won't answer the question. You know, smog and most other air pollution is a function of urban concentration. In fact, the EPA has recognized 66 of 3,000 counties in the United States as having air quality issues. Those are urban issues, for the most part. So residents of rural areas, like myself, who rely on wood heat as an affordable, abundant, renewable, and you will like this, carbon neutral source of heat energy, are perpetually perplexed by the EPA's fascination with regulating this form of heat, since it is primarily a rural form of heat. And we believe that a one-sized fits all rule on wood heat that comes from Washington D.C., from bureaucrats who have never experienced the warmth of the heat that comes from wood, or maybe even the exercise of collecting it themselves, really aren't qualified to regulate our source of energy, especially when they are taking away our other sources of energy.

Let me read for you from the EPA's website on these new rules that are being proposed. Or maybe this is pre-proposal, but this is certainly from your website. EPA—quote,"EPA is revising the new source performance standards for new residential wood heaters." I will skip some of it. "This action is expected to include the following new residential wood heating appliances, wood heaters, pellet stoves, hydronic heaters", and the list goes on.

Ms. MCCARTHY. Um-hum.

Mr. MASSIE. And then it finishes with this, "These standards would apply only to new residential wood heaters, and not to existing residential wood heating appliances."

Ms. MCCARTHY. Right.

Mr. MASSIE. Is that your impression, that these rules would just apply to new heaters?

Ms. MCCARTHY. That is all they do apply to, yes.

Mr. MASSIE. Okay. So you can promise us——

Ms. MCCARTHY. It would apply to——

Mr. MASSIE. You can promise us today that if Americans like the wood stove they have, they can keep it, period?

Ms. MCCARTHY. This particular part of the Clean Air Act does not address existing for this—these types of pollutants. And the only thing——

Mr. MASSIE. I have one more question, and only 30 seconds to ask, but I am glad that you can assure us we can keep that if we like it, period, and I hope that is a promise you can keep. There is one other issue that affects rural America that just has us scratching our heads. I hope it is an urban legend. Is anybody in the EPA really looking at regulating cow flatulence?

Ms. MCCARTHY. Not that I am aware of.

Mr. MASSIE. Okay. Yeah, because we have heard that on farms, are aware of that, at the USDA?

Chairman SMITH. Pardon me? You have heard it what?

Mr. MASSIE. That the methane emissions from cattle, can you——

Ms. MCCARTHY. Yeah.

Mr. MASSIE. —assure us today that you are not——

Ms. MCCARTHY. I am not looking——

Mr. MASSIE. —investigating that?

Ms. MCCARTHY. —at that.

Mr. MASSIE. Nobody in the EPA is? Thank you very——

Ms. MCCARTHY. Not that I am——

Mr. MASSIE. —much.

Ms. MCCARTHY. —aware of.

Mr. MASSIE. Thank you. And I yield back.

Chairman SMITH. Thank you, Mr. Massie. The gentlewoman from Wyoming, Ms. Lummis, is recognized.

Mrs. LUMMIS. Thank you, Mr. Chairman. Welcome, Administrator.

Ms. MCCARTHY. Thank you.

Mrs. LUMMIS. In your agency's recently re-proposed New Source Performance Standards for power plants——

Ms. MCCARTHY. Yeah.

Mrs. LUMMIS. —you set levels for coal fired plants based on the use of carbon capture and sequestration technologies. You did not require that same technology for gas fired power plants.

Ms. MCCARTHY. Yes.

Mrs. LUMMIS. By requiring CCS for coal units only, aren't you applying a standard that is higher regarding the carbon that is emitted from coal generated power? It just sounds to me like this is not an all of the above energy plan. It singles out coal for punitive treatment. Can this really be defended as a transparent and equitable application of the Clean Air Act? I like the administration, that you have testified, supports opportunities in natural gas. So do I, and I support them also for new coal fired plants, and coal-to-liquid. All the reasons that EPA gives for declining to find CCS technologies to be the best system of emission reduction for gas

fired units apply with equal force to coal fired units. So why require it for coal?

It strikes me that the answer to that question is to set a precedent. EPA is under a consent decree to issue New Source Performance Standards on greenhouse gases for refineries in the near future. Will that rules best system of emission reduction also require implementing technology that is unproven on a commercial scale? That seems to be the new definition of adequately demonstrated. When EPA requires a technology for new coal plants that is not yet in commercial operation, what is to stop it from doing the same for other sources of carbon?

I might add that earlier, in response to Mr. Neugebauer, you said that CCS technology is ready, according to the DOE. But DOE was in front of this committee in the summer, and they couldn't give us a date for the technology to be ready. And then former Secretary of Energy McConnell was here two weeks ago, and he testified that commercial CCS technology currently is not available to meet EPA's proposed rule. So our problem is this committee has received conflicting testimony from the former Secretary of DOE at your sister agency.

I find it interesting that the EPA claims that, regardless of this new rule, no one plans to build traditional coal plants. So does this rule achieve any of the EPA's carbon reduction goals? By its own admission, EPA is requiring carbon reducing technology for plants that will never be built. But, at the same time, it is requiring no reductions from new natural gas plants, even though they are being built in greater numbers than ever before. This doesn't make sense to me, and I just want to ask if it makes sense to you.

Ms. McCARTHY. What—could I address the issues that you have raised?

Mrs. LUMMIS. Yes.

Ms. McCARTHY. Okay. In terms of why we wouldn't be proposing CCS on natural gas, we do not have the kind of wealth of data that we have for the demonstration of CCS on natural gas as we do on coal. We know they run differently. We know the technology is different. We know the—that the gas stream for natural gas is different. We did not have the data available to be able to propose CCS on natural gas. We went with what we knew to be demonstrated technology moving forward. We do have data on the coal side that addresses the requirements we have for being robust. But we will look at comments that come in.

Relative to DOE, I think the DOE employees have been—and staff, as well as the Secretary, have been very supportive of the way we are looking at the data in this industry sector moving forward.

Mrs. LUMMIS. Thanks. I want to squeeze in one more——

Ms. McCARTHY. Okay.

Mrs. LUMMIS. —question before I run out of time.

Ms. McCARTHY. Okay, sorry.

Mrs. LUMMIS. That is okay. Let me ask you—this is kind of a yes or no question. Is it EPA's view that Section 111(d) of the Clean Air Act gives states primacy in the development and implementation of new source performance standards for existing power plants?

Ms. MCCARTHY. Yes, it is state implementation plans that need to be developed.

Mrs. LUMMIS. Thank you. So now you have three seconds to answer my previous question.

Ms. MCCARTHY. Well, the only other one I wanted to hit was this idea that we are not going to be making any progress moving forward because most of them are natural gas. The—what we are trying to do is make sure that new facilities, like power plants, that are around for 60 or 70 years take advantage of the technologies available to them today so that they can be part of the mix moving forward.

Mrs. LUMMIS. Thank you.

Ms. MCCARTHY. Coal is important now. It will be in the future.

Mrs. LUMMIS. Thank you very much.

Chairman SMITH. Thank you, Ms. Lummis. The gentleman from North Carolina, Mr. Cramer, is recognized for questions.

Mr. CRAMER. I am sorry, did you say from North Dakota?

Chairman SMITH. Yes.

Mr. CRAMER. Yeah, I thought you did.

Chairman SMITH. I thought I said North Dakota.

Mr. CRAMER. Thank you, Mister——

Chairman SMITH. I misspoke if I said anything other than North Dakota.

Mr. CRAMER. That is fine. Thank you for being here today, and I want to ask some questions about the hydraulic fracturing study. But before I do that, I want to follow up on Mr. Massie's invitation to—for you to go to Kentucky and hold a listening session on your way to North Dakota to hold a listening session on the new source performance standards. I would like to submit my letter of invitation to you of October 18 into the record, if I could, Mr. Chairman?

And it just seems like, in the spirit of transparency, that having these 11 listening sessions in the cities where you, granted, have regional offices, is okay as far as it goes, but what a wonderful opportunity it would be to add some more listening sessions. And so I would really love to have you commit to considering these other places, including Bismarck, North Dakota.

Ms. MCCARTHY. I appreciate that. And I just want to tell you that that is not the extent of what we are doing. Those are the major listening sessions, but the regional offices and our administrators are really branching out to the individual states.

Mr. CRAMER. And I understand that, but I also understand that, in a place like North Dakota, where there are 17,000 jobs at stake, $3–1/2 billion toward our economy is at stake, and where there are a whole bunch of really wonderful smart experts and scientists who work in this every single day, could provide lots of good information to the EPA, that a better way might be to hold a listening session there in public view, for everybody to participate. So I would appreciate—in fact, I would love it if you would just commit. We will work out the details later as to, you know, what time and what cities, and all of that.

But I also want to get into the hydraulic fracturing study that you are engaged in, because I have some concerns about it, especially the study designed and some of the goals of the study. Because, as we have discussed in this committee previously with

other witnesses, this idea of the EPA searching for what is possible without attention to what is probable is problematic I think from a real scientific standpoint, because one of the primary goals of the study—stated primary goals of the study is to answer questions, like, what are the possible impacts of hydraulic fracturing, fluid surface spills, on—near well pads, on drinking water resources, end quote.

And it appears, in fact, the EPA's independent science advisory board shares this concern as well. One SAB expert comment, "There is no quantitative risk assessment included in EPA's research effort. Thus, the reader has no sense of how risky any operation may be in ultimately impacting drinking water. This is also a significant limitation of the work." Is the mere possibility of an event occurring sufficient to justify regulatory action, in your mind?

Ms. MCCARTHY. I actually think that this is purely a scientific research project so we understand the potential implications. It is not a regulatory decision.

Mr. CRAMER. Sure, but again, the possible versus probable, as what is the standard, then, of probability before you continue with more years and more resources, given the fact that hydraulic fracturing is not exactly a new technology? I mean, it is——

Ms. MCCARTHY. No, it has been around——

Mr. CRAMER. —been around for——

Ms. MCCARTHY. —for a while.

Mr. CRAMER. —over half a——

Ms. MCCARTHY. Yeah.

Mr. CRAMER. —century.

Ms. MCCARTHY. Yeah.

Mr. CRAMER. So, I mean, is there a line—and you certainly can understand why industry and states might be concerned that we are down this path, with the mere possibility as a standard, and the uncertainty that that creates in the investment community as we try to become more energy security in this country.

Ms. MCCARTHY. My understanding is that this is a number of research projects that are looking at the potential for impact on water supplies. It is the first step——

Mr. CRAMER. I understand——

Ms. MCCARTHY. —in looking——

Mr. CRAMER. —but, in fact——

Ms. MCCARTHY. —at this in a more comprehensive way so we can be sure we are doing things safe and——

Mr. CRAMER. While I agree that this is one, and I guess part of something more comprehensive, because your Office of Science Policy director, Dr. Hoffman, in May of last year, stated that the agency was doing "a pretty comprehensive look at all the statutes to determine where holes may allow for additional Federal oversight." So is this study part of that comprehensive look for holes and opportunities to regulate further?

Ms. MCCARTHY. My understanding is, and we can certainly follow up, is that this is purely a research project. It is not, at this point, talking about what laws we might utilize, or what regulations we might want to do.

Mr. CRAMER. Well, have you found any holes, or do you know of any regulatory holes that might present an opportunity for further

regulation by the EPA? Because, you know, that standard is rather frightening in North Dakota.

Ms. MCCARTHY. I—we are purely looking at whether or not there are implications that we need to understand from hydraulic fracturing both—in this case on water quality. That is it.

Mr. CRAMER. All right. Thank you, and my time is expired, Mr. Chairman.

Chairman SMITH. Thank you, Mr. Cramer. The gentleman from Florida, Mr. Posey, is recognized for his questions.

Mr. POSEY. Thank you, Mr. Chairman, and thank you, Madam Administrator, for your testimony today, and it has been largely direct responses, and I really appreciate that.

Ms. MCCARTHY. Thank you.

Mr. POSEY. Following up on some of the questions that we had earlier today concerning science based management, how many Ice Ages have we had on this planet, do you know?

Ms. MCCARTHY. I am sorry, sir, I don't.

Mr. POSEY. Okay. I have read different things. Some say three, some say five. Do you think we have had Ice Ages before?

Ms. MCCARTHY. I am quite sure of reading about those, but I am not a scientist, and I don't want to pretend to be for you, sir. But we can get our scientists to respond, if you want a more direct——

Mr. POSEY. Yeah, I really would like that. You know, normally you can't have seamless Ice Ages. You must have a warming period between the Ice Ages, and I was just wondering if you happen to know what the temperature was here on Earth between the last two Ice Ages.

Ms. MCCARTHY. I am sorry, sir, I can't answer those questions.

Mr. POSEY. Okay. If I told you the Earth was 30 degrees warmer before the last Ice Age, would that surprise you, or——

Ms. MCCARTHY. It would not influence my decision, in terms of listening to the science and the consensus around climate. I leave the science to the scientists.

Mr. POSEY. But don't you think the history of the Earth should have some bearing on science?

Ms. MCCARTHY. I am sure that it does.

Mr. POSEY. But——

Ms. MCCARTHY. I just don't want to pretend that I am a scientist and have that discussion with you, sir, because I am not. I do listen to the scientists, and I look—listen to the consensus that is being drawn.

Mr. POSEY. Well, I listen to scientists too, and I don't claim to be a scientist, but I don't want to put my head in the sand and——

Ms. MCCARTHY. Um-hum.

Mr. POSEY. —ignore what science——

Ms. MCCARTHY. I am not.

Mr. POSEY. —is inconvenient.

Ms. MCCARTHY. I am listening.

Mr. POSEY. And now I was just wondering what impact you thought carbon emissions had on previous global warming between Ice Ages?

Ms. MCCARTHY. The information that I have available to me relates to all of the work that is done by the number of scientists looking at the climate issues. And I pay attention to that, and I

will apply the science in decisions moving forward. I am not either comfortable or qualified to have a science discussion with you on these issues.

Mr. POSEY. Do you see the promulgation of any rules that would enact a carbon tax in the future?

Ms. MCCARTHY. Say that again, sir?

Mr. POSEY. Do you see the promulgation of any rules that would enact a carbon tax for this country in the future?

Ms. MCCARTHY. Only if Congress provides a—provides that mechanism, no.

Mr. POSEY. Okay. Mr. Chairman, I can't get my questions answered, so I guess I am pretty much finished and yield back.

Chairman SMITH. Thank you, Mr. Posey. I don't believe we have any other members with questions, so, Administrator McCarthy, thank you for your presence today. And we may have additional questions that would be submitted to you in writing. We hope you will reply to those in the next couples of weeks.

Ms. MCCARTHY. Mr. Chairman, can I ask you one favor?

Chairman SMITH. Of course.

Ms. MCCARTHY. I know you asked me a lot of information in the front about the subpoena issues.

Chairman SMITH. Yes.

Ms. MCCARTHY. I want to make sure that we both understood one another, so if we could meet afterwards? I want to make sure that I gave perfectly correct answers, and that our expectations are the same on what you are looking for, and whether or not we have complied with that, and what you are looking for next.

Chairman SMITH. Okay.

Ms. MCCARTHY. I want to be very respectful of you, and the wishes of this committee.

Chairman SMITH. Thank you. Well, I am somewhat encouraged by some of your answers today, and I hope you will give us the data that we would like to have, and that we would like to have independently verified. I am not sure it is true or not, but didn't you once tell us, if you like it, you can have it? I am just teasing. Thank you for your appearance today. We stand adjourned.

[Whereupon, at 12:35 p.m., the Committee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by The Honorable Gina McCarthy

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

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Lamar Smith
Chairman
Committee on Science, Space, and Technology
United States House of Representatives
Washington, DC 20515

Dear Chairman Smith:

Thank you for the opportunity to respond to the questions for the record from the House Committee on Science, Space, and Technology's hearing on November 14, 2013 entitled, ***Strengthening Transparency and Accountability within the Environmental Protection Agency.*** Please find our responses in the attached document.

Again, thank you for your letter. If you have further questions, please contact me, or your staff may call Christina J. Moody, in the EPA's Office of Congressional and Intergovernmental Relations, at (202) 564-0260.

Sincerely,

Nichole Distefano
Deputy Associate Administrator

Enclosure

cc: The Honorable Eddie Bernice Johnson
Ranking Member

Questions for the Record
U.S. House of Representatives
Committee on Science, Space and Technology
Strengthening Transparency and Accountability within the Environmental Protection Agency
November 17, 2013

Questions from Lamar Smith

Hydraulic Fracturing Study Questions

Question 1: EPA's Hydraulic Fracturing Study is concerning because EPA is searching for what is possible without paying attention to what [is] probable. For example, the primary goals of the study are to answer questions such "What are the possible impacts of hydraulic fracturing fluid surface spills on or near well pads on drinking water resources?" It appears EPA's independent science advisors share this concern. For example, one SAB expert commented that "There is no quantitative risk assessment included in EPA's research effort. Thus, the reader has no sense of how risky any operation may be in ultimately impacting drinking water. This is also a significant limitation of the work."

Answer: Consistent with the scope defined by Congress in its request, the goal of EPA's report is to provide an assessment of the potential for hydraulic fracturing activities to impact the quality or quantity of drinking water resources in the United States. The goal of this report is to identify factors affecting the frequency and severity of impacts. EPA's report will represent a state of the science synthesis of information concerning the subject and will be national in scope. We did not conduct site specific or national predictive modeling to quantitatively estimate environmental concentrations of contaminants in drinking water resources. The report will not be a human health exposure assessment, it will not identify populations at risk, nor estimate human health impacts. The research approach was reviewed and supported by the EPA's independent Science Advisory Board. The findings from the study's individual research projects will be peer reviewed upon their individual completion. The study's assessment report has been designated a Highly Influential Scientific Assessment (HISA) and EPA is adhering to a rigorous, transparent peer review of the data and conclusions of the study. As a HISA, draft assessment will receive the highest level of peer review in accordance with EPA's Peer Review Handbook. The draft assessment report will be released for external, independent peer review by the Science Advisory Board (see http://www.epa.gov/hfstudy/peer-review.html).

Question 2: The Director of EPA's Office of Science Policy, Dr. Hauchman, stated in May 2012 that the Agency is implementing a "pretty comprehensive look at all the statutes to determine where "holes" may allow for additional federal oversight."
Is this study part of that comprehensive look? What statutes were looked at as part of this effort? What regulatory "holes" has EPA identified?

Answer: Dr. Hauchman was referring to the fact that the EPA is engaged in multiple activities related to hydraulic fracturing, not that the EPA is conducting a formal cross-statutory review. These activities are described on the EPA's web page: http://epa.gov/hydraulicfracturing.

Question 3: Given that there have been no proven instances of groundwater contamination, and that greenhouse gas emissions have actually declined thanks to natural gas, what problems are you seeking to solve?

Answer: The EPA is conducting this study in response to a request from Congress to investigate the potential impacts of hydraulic fracturing for oil and gas on drinking water resources. The study, which benefits from extensive stakeholder input and a scientific peer review by the Science Advisory Board, is designed to evaluate what impacts, if any, may be associated with each stage of the hydraulic fracturing water cycle. EPA is committed to studying and addressing potential concerns related to unconventional oil and gas development so that the public has confidence that it will proceed in a safe and responsible manner. In so doing, we will continue to follow a transparent, science-driven approach with significant stakeholder involvement.

Question 4: What has the Agency done to prevent repeating mistakes made in Parker County, Pavillion, and Dimock regarding fracking? Please include specific policy and protocol changes and actions taken.

Answer: In the three investigations referenced in your question, the EPA took action when the agency became aware of information indicating potential threats to human health. The EPA's actions generally focused on obtaining additional data and information in an effort to better understand and assess potential threats to public health and the environment. The agency consulted with its state and tribal partners prior to taking such measures and shared data and information with homeowners, the relevant state agencies, and where applicable, tribal authorities. In each case, the EPA relied upon sound science as it sought to provide clarity to these stakeholders and ensure that public health was protected, while working closely with individual states which have key regulatory authority relevant to unconventional oil and natural gas extraction. Beyond these instances, the EPA will continue to work with state partners and other stakeholders to study and address potential concerns related to unconventional oil and gas development so that the public has confidence that it will proceed in a safe and responsible manner.

The EPA is currently conducting a study to look at potential impacts of hydraulic fracturing across the nation. The agency's *Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* is being conducted in accordance with the EPA Scientific Integrity Policy[1] and the principles laid out in the request from Congress.

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[1] U.S. EPA Scientific Integrity Policy, http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf

Question 5: Has EPA rescinded the draft Pavilion report and if the draft report has been removed from the hydraulic fracturing drinking water study and Scientific Advisory Board scope?

Answer: As you may be aware from our statement at the time of the State of Wyoming's announcement on June 20, 2013, we believe that the EPA's focus should be on using our resources to support Wyoming's efforts, which will build on the EPA's monitoring results. In light of the State's commitment to further investigation and efforts to provide clean water to Pavillion residents, the EPA does not plan to finalize nor seek peer review of its draft report.

EPA Region 8 maintains a website (http://www2.epa.gov/region8/pavillion) with information about the Pavillion investigation. It includes a chronology of events and hyperlinks to relevant information and reports dating back to August 2009. This chronology includes information regarding the June 2013 announcement that Wyoming would further investigate drinking water quality in the area east of Pavillion. Region 8 will continue to update its website to include additional milestones reached by the State, including a link to the Wyoming Oil and Gas Conservation Commission (WOGCC) website (http://wogcc.state.wy.us/pavillion_wrk_grp.cfm) where the State's August 5, 2014 Well Integrity Review draft report and Appendices can be found.

Question 6: In addition to the retrospective and prospective case studies, it is our understanding that there are 18 additional research projects that EPA had undertaken to help answer the secondary research questions of the study.

- How is EPA conveying the information from these projects to the public?

Answer: The EPA is fully committed to sharing information with the public about our research projects and our findings. The agency has held numerous public information sessions, workshops, roundtables, and webinars to update interested stakeholders about our research activities, and we have posted extensive information on the study website. Externally peer reviewed papers associated with the EPA research projects have been posted and, as papers are peer reviewed and completed, will be posted on the agency's website. Papers that have already undergone peer review can be found at: http://www2.epa.gov/hfstudy/published-scientific-papers.

- Will details be posted on the study website?

Answer: Yes, the website is regularly updated with study updates, meeting materials, published papers, and opportunities for participation.

- What is the plan for peer review of the completed projects?

Answer: Results from individual research projects ndergo peer review prior to publication either as articles in scientific journals or as EPA reports. Each project was reviewed, consistent with OMB's Bulletin on Peer Review, to determine the appropriate level of peer review. Furthermore, articles submitted to journals will be reviewed according to the journals' peer review process, external to the EPA. Projects written up as the EPA reports will undergo contractor-led peer reviews.

- What is the role of the SAB Hydraulic Fracturing Research Advisory Panel with respect to these projects and their final reports?

Answer: The SAB Hydraulic Fracturing Advisory Panel, which is an ad hoc panel of independent experts under the auspices of the SAB, is providing periodic advice and review of the EPA's hydraulic fracturing research. In May 2013, the panel reviewed the study's Progress Report and offered the public an opportunity to provide oral and written comments for consideration by the individual panel members. The EPA is considering the individual panel experts' comments in the development of the draft hydraulic fracturing drinking water assessment report, which will be released for public comment and a formal SAB peer review.

The Panel will review the draft hydraulic fracturing assessment report and will not peer review EPA's separate research projects. EPA's individual research projects will be reviewed consistent with the OMB's Bulletin on Peer Review prior to inclusion in the assessment report, as described in more detail above.

- What is the role of the SAB Hydraulic Fracturing ad hoc panel?

Answer: The answer to the previous question, see above.

The SAB Hydraulic Fracturing ad hoc panel will review the EPA assessment report on the potential impacts of hydraulic fracturing for oil and gas on drinking water resources. This assessment report has been designated as a highly influential scientific assessment (HISA. The Panel will receive an update from ORD on its study of the potential impacts of hydraulic fracturing for oil and gas on drinking water resources during a public teleconference prior to the release of the draft assessment report for formal SAB peer review and public comment.

- What is the ad hoc panel's review schedule for the remainder of the study?

Answer:

The EPA plans to brief the SAB ad hoc panel on the progress of research prior to the release of the draft assessment report for formal SAB peer review and public comment.
The EPA is considering the individual panel experts' comments on the progress report in the

development of the draft hydraulic fracturing drinking water assessment report. Our current timeline for release of the study for public comment and a formal SAB peer review is early 2015.

Question 7: Is EPA planning to release the raw data from the five Retrospective case study sites to the public via the study website? If so, when will that be available and will the needed context be included when released?

Answer:
Yes. The data and the five retrospective case study reports will be posted on the study website following peer review and report completion.

Question 8: Have states been forthcoming with data under current Request for Information on the September 2012 study? If not, how have you reached out to these states, particularly those states where a retrospective case study is located?

Answer: State input has played an important role in the development and execution of the *EPA's Study of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources*. During the development of the study plan, the agency held webinars and in-person public informational meetings in Texas, Colorado, Pennsylvania, and New York to obtain feedback on the EPA's proposed activities. In the execution of the study, the agency coordinated with states on research conducted in the field, including the retrospective case studies, and in the analysis of data obtained from the states. Webinars, technical roundtables and workshops, requests for information through the *Federal Register*, and public comment periods associated with the SAB review of the Progress Report continue to provide states and other stakeholders with information updates and opportunities for input on the agency's hydraulic fracturing research activities. We have recently intensified our state outreach efforts as part of the study. These efforts will ensure that states understand the data sources we used, and will provide them further opportunity to recommend additional sources of information. Moving forward, the EPA will continue to engage with the states.

Question 9: Has the EPA done any testing in real time for sites that are currently being developed? If not, does the agency plan to do testing in real time at any sites?

Answer: We have worked closely with industry partners to try to identify suitable locations for prospective case studies that meet the scientific needs of the study and industry's business needs. We continue to explore opportunities and so far we have not identified a suitable location. For a location to be suitable, it is necessary to gather a minimum of one year of characterization data for ground water and surface water prior to and following unconventional exploration activities in the study area, and for there to be no other hydraulic fracturing activities on adjacent properties during the entire study period, which could last several years.

Question 10: What has been your work with DOE and USGS to date on the study?

Answer: The EPA, DOE, and USGS routinely exchange information regarding ongoing and planned research. Exchanges among principal investigators, in addition to high level discussions, help to assure that information about the research, relevant papers, models, and data are shared and can be used to inform work underway by others. In addition to these consultations, as part of the study's research project on Subsurface Migration Modeling, the EPA is working with DOE's Lawrence Berkeley National Laboratory to explore the potential for hydraulic fracturing fluids to move from the fractured zone to drinking water resources.

Question 11: How are you accounting for fracturing technology innovations as part of the study?

Answer: To ensure that the EPA is up-to-date on evolving hydraulic fracturing practices and technologies, the agency requested relevant data and scientific literature to inform the study through a *Federal Register* Notice. The EPA has solicited relevant information from experts and the public through ongoing stakeholder engagement activities. More than 100 experts participated in a series of technical workshops EPA held in 2013 to engage stakeholders and solicit information regarding technology innovations. In November 2013, the Science Advisory Board held a meeting and specifically requested input regarding technology innovations. The agency is also conducting a comprehensive literature review that will contain the most recent technical information regarding developments in hydraulic fracturing.

Question 12: Do you believe hydraulic fracturing can be performed in a safe and responsible manner?

Answer: Responsible development of America's unconventional oil and natural gas resources offers important economic, energy security, and environmental benefits. The EPA is committed to studying and addressing potential concerns related to unconventional oil and natural gas development so that the public has confidence that it will proceed in a safe and responsible manner. In so doing, we will continue to follow a transparent, science-driven approach with significant stakeholder involvement.

Question 13: Could you tell us what plans the EPA has for addressing methane- particularly in regards to midstream and upstream systems?

Answer: In support of the Administration's Strategy to Reduce Methane Emissions, EPA released a series of five white papers on potentially significant sources of volatile organic compound (VOCs) and methane in the oil and gas sector for input from a panel of independent experts. The white papers focus on technical issues covering emissions and mitigation techniques. EPA will use the papers, along with input from the experts and technical input and data from the public to determine how to best pursue further reductions

from these sources. The papers do not draw policy conclusions.

Question 14: If the EPA sets a lower NAAQS of 60 to 70 parts per billion for ozone, do you believe there will be parts of the country that cannot meet the new standard due to background concentrations of ozone? If so, what would be the economic and regulatory consequences for a state that cannot meet the new standard?

Answer: Our modeling suggests that mean background ozone levels over the U.S. are approximately 25-45 ppb and that the upper end of background levels (i.e., 95th percentile) are less than 55 ppb even at the sites most influenced by background such as high-elevation sites in Western US. We don't expect there to be parts of the country that couldn't attain a lower NAAQS level of 70 or 60 ppb solely due to background. EPA is currently working on the revised ozone standard and has not made a decision yet about what standard it will propose.

By law, the EPA must set the ozone national ambient air quality standards (NAAQS) at a level to protect public health, regardless of where the ozone originates. However, the EPA does not expect states to limit naturally occurring ozone or ozone formed from emissions outside their jurisdiction. The Clean Air Act contains provisions that facilitate excluding high ozone values that meet the definition of exceptional events (section 319), and attainment planning provisions that do not penalize states if attainment is not possible due to international influences (section 179B).

Question 15: Is it fair for the EPA to include Mexican and Canadian emissions in its background estimates when the states will be forced to control for international ozone emissions?

Answer: States will not be forced to control for ozone formed from emissions outside their jurisdiction, including ozone formed from international emissions. The Clean Air Act contains provisions that facilitate excluding high ozone values that meet the definition of exceptional events (section 319), and attainment planning provisions that do not penalize states if attainment is not possible due to international influences (section 179B).

In the current NAAQS review, the EPA will be providing estimates of "U.S. background" which assumes that Canada and Mexico are part of the background and therefore not part of the controllable emissions.

General Air Pollution/NAAQS

Question 16: Considering the limits of science and technology, what is EPA's strategy for working within the framework established by Congress to effectuate the NAAQS?

Answer: As required by the Clean Air Act, the EPA reviews the NAAQS on a 5-year cycle.

After considering the body of scientific evidence on the effects of air pollution on public health and welfare, the agency determines whether the current standards provide an adequate level of protection for public health and welfare or whether the standards should be revised to meet the requirements of the Act. After a standard is set, the EPA works with state, local and tribal partners to implement it.

Question 17: Because of many factors, such as regulatory uncertainty, the funding for and construction of new long-term, base load power is dwindling. How do you balance new regulations that may benefit human health and the environment via decreased emissions against increased energy costs and the possibility of increased blackouts – both of which have a negative impact on human health?

Answer: For 40 years, we have been able to both implement the Clean Air Act and keep the lights on. We don't intend to change that. As you note, the changes in the power sector are driven by several factors. However, many experts, including the Energy Information Administration and Congressional Research Service, agree that the primary driving factor influencing power sector business decisions is low natural gas prices. The EPA works with power sector stakeholders as we develop our policies to identify challenges and provide flexibilities as appropriate to make compliance easier and less expensive. We work with utilities, system operators, state and federal regulators as these stakeholders work together to address local reliability. Although the EPA, as required by the Clean Air Act, does not take costs into account in setting the NAAQS, the EPA does examine the health and environmental benefits and economic impacts of its regulations, including analysis of energy prices and output, changes in electricity generation mix, impacts on reserve margins for reliability, and other energy-related metrics. For example, analyses by the EPA and the DOE on the EPA's Mercury and Air Toxics Standards (MATS) indicate that there will be more than enough electric generating capacity to meet the nation's needs. Meanwhile, the human health benefits from air quality improvements due to MATS implementation totals up to $90 billion each year. Additionally, looking at fossil generation greater than 250 MW that is currently being developed, approximately 6 GW of new capacity is expected to come online in 2015, which is higher than the average for the 2000s (NEEDS 5.13).

Question18: What is your vision to address international transport and what is your plan for equipping states to address these issues?

Answer: The EPA continues to evaluate the international transport of air pollution to ensure that we fully understand and appropriately account for the impacts of this pollution in developing efficient and effective programs for meeting national air quality health standards. To date, science shows that international transport of air pollution can affect air quality in the U.S. at different times and in different locations. However, studies show that domestic sources of emissions are the primary cause of the ambient concentrations of criteria pollutants in the U.S.

The EPA does not expect states to limit naturally occurring ozone or ozone formed from

emissions outside their jurisdiction when implementing the NAAQS. The Clean Air Act contains provisions that facilitate excluding high ozone values that meet the definition of exceptional events (section 319), and attainment planning provisions that do not penalize states if attainment is not possible due to international influences (section 179B).

Question 19: Do you believe EPA has legal authority to require changes from other nations in order to address international transport?

Answer: The EPA does not have legal authority to require changes from other nations in order to address international transport except as provided in international agreements. The EPA has worked successfully with Canada under the U.S.-Canada Air Quality Agreement (1991) and with Mexico under the U.S. – Mexico La Paz agreement (1983) to reduce transboundary air pollution affecting the U.S. In addition, the EPA works with other nations under multilateral environmental agreements that address international air pollution transport including the Convention on Long Range Transboundary Air Pollution, and will do so under the newly established Minamata Convention on Mercury when it enters into force. Another multilateral environmental agreement under which we could work with other nations to address international air pollution is the Stockholm Convention on Persistent Organic Pollutants, signed in 2001, for which implementing legislation and Senate advice and consent is pending. The EPA also works with other nations through Annex VI to the International Convention for the Prevention of Pollution from Ships to address air pollution transport from international shipping. In addition, the EPA has been collaborating with China for over a decade to exchange best practices for understanding and addressing air pollution. This cooperation is giving China technical and policy tools and approaches to help them reduce pollution from power, industrial and transportation sources, thereby reducing pollution that contributes to international transport.

Question 20: What is EPA's plan to address the imbalance created via the adoption of standards and requirements without the tools necessary to demonstrate compliance?

Answer: Although courts have recognized that EPA is not legally required to issue implementation guidance when adopting new or revised standards, EPA customarily evaluates the need for any such additional guidance or implementation rules as a matter of discretion. For example, EPA will often issue an implementation rule and, as appropriate, policy and/or technical guidance that, for example, describes the designations process and schedule, requirements for PSD and NSR programs, and process and schedule for submitting approvable State Implementation Plans. We also provide guidance to address state-specific or source-specific implementation issues that are brought to our attention. Finally, as we did in the 2012 $PM_{2.5}$ NAAQS final rule, we consider whether to include grandfathering provisions to facilitate a smooth transition to any new or revised standards that would apply to permitting for major sources in attainment areas.

Question 21: Is it possible to propose and adopt a new standard and the implementation rule and/or guidance at the same time? If so, can you commit to adopting the new standard and

the implementation rule and/or guidance at the same time? Why or why not?

Answer: In cases where there may be novel issues raised by the adoption of a new or revised national ambient air quality standard, the EPA's goal is to provide timely updates as necessary to address these issues in rules and guidance to implement the new or revised standards. Only certain Clean Air Act requirements demand compliance at the same time as a new standard is adopted (e.g., new source preconstruction permit requirements that apply in attainment areas), and the EPA's goal is to assess what is needed and provide the appropriate updates to rules, tools, and guidance to address those immediate compliance requirements within the same timeframe that the standard is adopted. For Clean Air Act requirements that do not demand compliance for several years after a new standard is adopted, the EPA's goal is to assess and provide any necessary guidance at a reasonable time in advance of the compliance deadline.

Question 22: Does EPA have any plans for addressing methane -particularly in regards to midstream and upstream oil and gas production?

Answer: On March 28, 2014 the Obama Administration released the Climate Action Plan: a Strategy to Reduce Methane Emissions. The strategy summarizes the sources of methane emissions, commits to new steps to cut emissions of this potent greenhouse gas, and outlines the Administration's efforts to improve the measurement of methane emissions. The strategy builds on progress to date and takes steps to further cut methane emissions from several sectors, including the oil and natural gas sector.

As one of those steps, EPA on April 15, 2014 released for external peer review five technical white papers on potentially significant sources of emissions in the oil and gas sector. The white papers focus on technical issues covering emissions and mitigation techniques that target methane and volatile organic compounds (VOCs). The peer review was completed June 16, 2014. As noted in the Obama Administration's Strategy to Reduce Methane Emissions, EPA will use the papers, along with the input we received from the peer reviewers and the public, to determine how to best address emissions from these sources.

This fall, EPA will determine what if any regulatory authorities, including setting standards under section 111 of the Clean Air Act or issuing Control Techniques Guidelines under section 182 of the Act, the agency will apply to emissions from these sources. If EPA determines to follow a regulatory course of action, it will undertake a schedule that will ensure that both rulemaking and any ensuing regulatory requirements for the states are completed by the end of 2016. The white papers as well as the peer review comments are available at: www.epa.gov/airquality/oilandgas/whitepapers.html

Another key step in the Obama Administration's Strategy to Reduce Methane Emissions, is the bolstering of EPA's voluntary Natural Gas STAR Program. The program has already identified more than 50 cost-effective technologies and practices that reduce or avoid methane emissions in the oil and natural gas sectors, by eliciting more robust industry commitments while

enhancing transparency and accountability. In the spring of 2014, EPA began to engage the industry, states, and other key stakeholders on ways to enhance this program, and will formally launch the new partnership by the end of 2014.

Environmental Health Claims

Question 23: EPA estimates that reductions in particulate matter (PM) will prevent 230,000 to 490,000 early deaths making PM exposure between the first to third highest risk factor for mortality in the U.S. in 2020. Will you commit to reviewing these analyses with the CDC and other health agencies to get support for these claims?

Answer: The EPA estimated that the Clean Air Act (CAA) Amendments of 1990 would prevent over 230,000 early deaths in 2020 with a 95th percentile confidence interval of 45,000 to 490,000 early deaths. Most of these early deaths are associated with reduced exposure to fine particles, including precursor pollutants such as sulfur dioxide that form fine particles in the atmosphere. These estimates are relative to a hypothetical baseline scenario without the 1990 Amendments and related programs. The EPA report received extensive review and input from the Council on Clean Air Compliance Analysis, an independent panel of distinguished economists, scientists and public health experts established by Congress in 1991.

The report is the third in a series of the EPA studies required under the 1990 Clean Air Act amendments that estimate the benefits and costs of the act. The reports are intended to provide Congress and the public with comprehensive, up-to-date, peer-reviewed information on the Clean Air Act's social benefits and costs, including improvements in human health, welfare, and ecological resources, as well as the impact of the act's provisions on the U.S. economy. More information and a copy of the report: http://www.epa.gov/air/sect812/prospective2.html

In addition, the peer-reviewed study, *The State of US Health, 1990-2010: Burden of Diseases, Injuries, and Risk Factors* concluded that ambient particulate matter pollution remains one of the top 10 health risk factors in the U.S. The study published in the Journal of the American Medical Association included co-authors from many health agencies. A copy of the study: http://jama.jamanetwork.com/article.aspx?articleid=1710486

New Source Performance Standards for Power Plants

Question 24: In a memo to the broader Science Advisory Board on Nov. 12, the SAB Work Group charged with reviewing the EPA's major rulemaking actions recommended a review of science underpinning the NSPS proposal. Specifically, the Work Group highlighted concerns that the underlying science lacked adequate peer review. Subsequently, at a SAB board meeting Dec. 4-5, the EPA representatives argued against the Work Group's recommendations. In light of these developments, we respectfully request that you make available to the Committee the following information:

- All written communications between those EPA employees the SAB or the SAB Work Group concerning peer review of any studies that the proposed standards relied

on.

Answer: With regard to your request for written communications, EPA staff informs me that the appropriate protocol is to make such a request through a separate letter to the agency. EPA will respond appropriately to any such request.

- A record of all peer review of any studies that the proposed standards relied on.

Answer: The EPA provided some additional information to SAB on the basis of the DOE NETL cost studies that the EPA used in developing the proposed rule and the peer review process followed by DOE NETL for that study. The DOE's robust process included outside input from knowledgeable stakeholders including industry, academia and government experts in the design of the study and a peer review of the final report by a wide range of similar experts. The documents provided to SAB are attached:
"FY05+NETL+Merit+Review+Final+Report+1217.pdf" and
"NETL+Review+comments+on+cost+&+Performance+fossil+EGU.pdf"

- EPA's intentions regarding the need for further peer review of any such studies and whether EPA intends to withdraw its reliance on any of those studies in promulgating the performance standards.

Answer: While the EPA did not conduct additional peer review of the DOE NETL cost studies, the different levels of multi-stakeholder technical input and final review meet the requirements to support the analyses as defined by the EPA Peer Review Handbook.

After consideration of the clarifying information and thorough discussion about the issues during several meetings of the SAB that were open to the public, the workgroup recommended to the full SAB that additional review of the science of sequestration was not necessary in the proposed Carbon Pollution Standard. The full SAB agreed with the workgroup's assessment that the proposed Carbon Pollution Standards rely on existing requirements for sequestration and that peer review of the DOE cost studies was sufficient. In a memo dated January 29, 2014, the SAB informed the EPA that it will not undertake further review of the science supporting this action.

- All records of any SAB or the SAB Work Group review of or input into the proposed standards. If EPA did not solicit this input, please explain why not.

Answer: The SAB convened a Work Group to consider the science supporting actions identified in the Spring 2013 Unified (Regulatory) Agenda and Regulatory Plan and requested the Work Group to provide the SAB with a report on these considerations. As part of that activity the Work Group and the SAB considered whether to review the science supporting any of the planned regulatory actions in that agenda in order to provide advice and comment on the adequacy of the science, as authorized by section (c) of the Environmental Research, Development and Demonstration Authorization Act. This activity included

consideration of the Standards of Performance for Greenhouse Gas Emissions from New Stationary Sources: Electric Utility Generating Units (2060-AQ91).

With regard to your request for records, EPA staff informs me that the appropriate protocol is to make such a request through a separate letter to the agency. EPA will respond appropriately to any such request.

- EPA's intentions regarding future SAB or SAB Work Group input into the proposed standards. If EPA does not intend to solicit this input, please explain why not.

Answer: As noted above, the full SAB agreed with the workgroup's assessment that the proposed Carbon Pollution Standards rely on existing requirements for sequestration and that peer review of the DOE cost studies was sufficient. In a memo dated January 29, 2014, the SAB informed the EPA that it will not undertake further review of the science supporting this action.
With respect to the existing geologic sequestration regulations, the EPA will continue to monitor technological progress on geologic sequestration as those regulations, which contain specific monitoring and operational requirements, are implemented. The EPA also will continue to work with other agencies, researchers, and industry to ensure that our regulations are based on the best available science. The EPA plans to provide a briefing on these activities and periodically update the SAB on the status of its geologic sequestration regulations, ongoing permitting, and collaboration with DOE and other agencies.

- All records of any SAB or SAB Work Group input into EPA's development of regulations under Section 111(d) of the Clean Air Act pertaining to existing fossil- fuel-fired electric generating units or SAB or SAB Work Group consideration of such regulations.

Answer: The SAB did not provide advice or comment to the EPA for the development of a proposed rule for the Greenhouse Gas Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units (2060-AR33). The SAB convened a Work Group to consider the science supporting actions identified in the Spring 2013 Unified (Regulatory) Agenda and Regulatory Plan and provide the SAB with a report on these considerations. As part of that advisory activity the Work Group and the SAB considered whether to review the science supporting any of the planned regulatory actions in that agenda in order to provide advice and comment on the adequacy of the science, as authorized by section (c) of the Environmental Research, Development and Demonstration Authorization Act. This activity included consideration of the Greenhouse Gas Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units (2060-AR33). With regard to your request for records, EPA staff informs me that the appropriate protocol is to make such a request through a separate letter to the agency. EPA will respond appropriately to any such request.

- EPA's intentions regarding future SAB or SAB Work Group input into these existing unit regulations. If EPA does not intend to solicit this input, please explain why not.

Answer: The EPA has engaged in, and continues its engagement with a broad range of stakeholders about the proposed Clean Power Plan to ensure it is informed by a full range of perspectives, technical information and other information relevant to the proposal. . EPA recently informed the SAB of this rule and the Agency's technical approach and the SAB determined that the science supporting this action did not require further peer review.

Question 25: Since EPA claims no one is expected to build a new coal plant in the near future, could EPA wait 8 years until the next review of NSPS to allow greater time for determination as to whether CCS is adequately demonstrated for new coal plants? If so, why does EPA see the need to determine whether CCS is adequately demonstrated before this time, seeing as no NGU's will be built before then?

Answer: The EPA is setting a source category limit as authorized by CAA Sec 111(b). The CAA requires the EPA to identify the "best system of emission reduction ... adequately demonstrated" (BSER) available to limit pollution – and set an emission standard based on that analysis. After analyzing the factors that make up BSER, we proposed to determine that partial CCS is the BSER for new coal-fired EGUs. As discussed in the preamble for the proposed rule, 79 FR at 1462, the Act and subsequent court decisions identify factors for the EPA to consider in a BSER determination including: (1) the technical feasibility, (2) the reasonableness of the costs, (3) the promotion of advanced technology, and (4) the size of emission reductions. After reviewing many reports, studies, projects, and stakeholder input EPA proposed to determined partial capture of CO_2 best meets the requirements for BSER and is consistent with a number of projects currently under development. When finalized, the proposed standards will provide those generators that may choose to build new coal-fired capacity with certainty as to the facilities GHG obligations.

Economic Modeling Commitment

Question 26: Since 1977, section 321 (a) of the Clean Air Act (CAA) has required "the Administrator to conduct continuing evaluations of potential loss of shifts of employment which may result from the administration or enforcement of the provision of [the Clean Air Act] and applicable implementation plans, including where appropriate, investigating threatened plant closures or reductions in employment allegedly resulting from such administration or enforcement." The #321 requirement is different than the requirement from Executive Order 12866 that EPA consider in a Regulatory Impact Analysis (RIA) what impact a single proposed rule will likely have on jobs. For S321, EPA has to consider the impact that existing CAA requirements – taken as a whole- have had on job losses and shifts in employment throughout our economy. RIA's, by contrast, only consider the potential future employment impact that a single proposed rule will have. Therefore, EPA's preparation of RIA's for new rules does not satisfy S321 (a). EPA has never conducted a section 321 (a) study to consider the impact of CAA programs on jobs and shifts in employment.

Why has EPA not conducted a study to consider the impact of CAA programs on job shifts and in employment?

Will EPA commit to conducting such studies in the future?

Answer: The EPA has found no records to indicate that CAA section 321, since its inclusion in the 1977 amendments, has been interpreted by any Administration to require job impacts analysis of rulemakings or job impacts analysis of existing CAA requirements as a whole. Section 321 does provide a mechanism for the EPA investigation of particular claims of job loss related to plant closure or layoffs in response to environmental regulation or enforcement actions. In addition, the EPA performs detailed regulatory impact analyses (RIAs) for each major rule it issues, including cost-benefit analysis, various types of economic impacts analysis, and analysis of any significant small business impacts. Since 2009, the EPA has focused increased attention on consideration and (where data and methods permit) assessment of potential employment effects as part of the detailed RIAs conducted for each major rule. EPA has found that existing methods for assessing employment effects of economically significant regulations have significant limitations and weaknesses, and has been transparent about these limitations and weaknesses as it has explored alternate approaches for better understanding these effects. With this caveat, the EPA analyses, consistent with current literature, have generally found that environmental regulations may have both positive and negative effects on jobs but that these effects tend to be relatively small and difficult to quantify with any precision. This is consistent with data from the Bureau of Labor Statistics that indicate labor markets are primarily influenced by other, larger factors including routine business cycles, changes in production technology, and the state of the overall economy. Nevertheless, the EPA continues to explore and evaluate potential tools, data, and methodologies that could expand and improve assessments of the effects of our programs, including effects on labor markets. We will continue to comply with statutory and administrative requirements for analysis of our programs in a manner consistent with principles of sound science and economics.

Question 27: EPA committed to convene an independent panel of economic experts experienced with "whole-economy" modeling to evaluate whether EPA's current economic modeling adequately measures the employment impacts of rules. Why has the EPA not convened such an independent panel? Does EPA have plans of convening this panel in the future? If so, when?

Answer: Last year, Acting Administrator Perciasepe sent a memo to the EPA's Science Advisory Board (SAB) Office asking it to convene a new expert panel on economy-wide modeling. Following typical procedures for this type of panel, EPA's Office of Policy and Office of Air and Radiation released a set of draft charge questions and an analytic blueprint for public comment in February 2014. The comment period closed on April 7, 2014. The SAB Office recently published a Federal Register Notice soliciting nominations of experts for the panel, which closed on May 21, 2014. The list of candidates was posted on the SAB website on

July 7, 2014 for comment, and EPA expects that the SAB Office will be able to formally convene a panel by Fall of 2014."

Sue and Settle

Question 28: During Senate confirmation as EPA Administrator on July 9, 2013, you agreed to undertake four actions items: (1) improve Freedom of Information Act (FOIA) training for EPA employees, (2) publicly release the scientific information EPA used to set nationwide air quality standards, (3) study whether EPA needs to conduct more through economic analyses of the employment impacts of its regulations, and (4) to publish on two websites the Notices of Intent to Sue (NOIs) and Petitions for Rulemaking (PFRs) received by the agency.

- What steps have you taken since your confirmation to improve the transparency of this process and allow affected parties, including states and industry, to participate in the process, including settlement negotiations, to ensure that all interests are represented?

- As EPA Administrator, what steps are you taking to ensure that the agency does not agree to deadlines through settlements that do not provide sufficient time for EPA to meet its obligations under the Administrative Procedure Act, the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act, OMB Circular A-4, and other requirements that apply to EPA?

Answer: The EPA has made a concerted effort to provide additional information to stakeholders, and to seek input widely on EPA actions. For example, as the Agency works to develop the proposed carbon pollution standards for existing power plants, the process of engagement with states, stakeholders, and the public has been extensive, and stakeholders all over the country have taken advantage of the opportunities provided.

With respect specifically to lawsuits, the EPA has continued to expand its website providing Notices of Intent to Sue, and has begun posting copies of complaints when one associated with a posted notice is filed. http://epa.gov/ogc/noi.html.

Most of the EPA settlements are under the Clean Air Act; most of these agreements are published in the Federal Register for public comment, and all comments are considered before the agreement is finalized.

The EPA does not and will not commit in any settlement agreement to any final, substantive outcome in a rulemaking or other decision-making process. The EPA settlements do not impair notice-and-comment rulemaking rights. In any settlement, it is the EPA's priority to secure enough time to allow for an appropriate decision-making process, including appropriate public input and participation. All interested parties are provided opportunities for comment on proposed rules, and comments submitted are carefully considered and often significantly shape the final rule.

Question 29: In a denial earlier this year of several environmental groups' petition for a rulemaking under the Clean Air Act, Acting Administrator Robert Perciasepe stated that, "[e]ven under the best circumstances, the EPA cannot undertake simultaneously all actions related to clearly determined priorities as well as those requested by the public, and so the agency must afford precedence to certain actions while deferring others... The EPA must prioritize its undertakings to efficiently use its remaining resources."

In your view, do new commitments that EPA agrees to in "sue and settle" agreements with environmental groups, including timetables for rulemaking, have an impact on EPA's priorities as to the rulemakings that it undertakes? Have they had an impact on EPA's budgetary resources?

Answer: The EPA is frequently sued by stakeholders, including industry, environmental groups, and state and local governments. Litigation is adversarial by nature: It is never EPA's preference to be sued, and the Agency is not complicit in such lawsuits. While the EPA litigates most of these suits to final judgment, the EPA, much like its sister agencies throughout the Federal Government, has a longstanding practice of entering into settlements in lieu of resource-intensive litigation where, in the judgment of the Agency and its representatives at the United States Department of Justice (DOJ), it would be in the interest of the Agency and in the interest of the public to pursue settlement. Each settlement agreement is the result of a negotiation between opposing parties, with DOJ representing the EPA and the interests of the United States.

Litigation can certainly be expensive, and as such can have an impact on the EPA's resources. Settlements, however, generally save the Agency (and the taxpayer) money.

The large majority of the EPA settlements occur in cases where the complaint alleges the EPA has failed to meet a mandatory duty it is obligated to perform under federal law. In well-grounded mandatory duty lawsuits, seeking settlement is the most responsible course of action. The alternative would involve engaging in expensive litigation with the expected outcome of a court-ordered schedule likely to require agency action on a less feasible timeline, with an increased risk of higher fees and costs.

Tier 3

Question 30: Did EPA proceed with the Tier 3 rule to satisfy an agreement during the CAFÉ negotiations?

Answer: No.

Integrated Risk Information System

Question 31: IRIS assessments released at the evidence table stage come without context

and the public lacks knowledge regarding EPA thoughts regarding endpoints of concern, modeling and critical literature. As such, within just 60 days, the public must review hundreds of studies to provide comments to EPA on their quality, acceptability and suggested use. This may be placing a heavy burden on stakeholders who wish to engage the EPA. Do you believe changes could be made to this approach that might benefit stakeholders? If so, what changes do you think stakeholders might benefit from most?

Answer: Stakeholder engagement is very important to the IRIS Program, and the EPA was responsive to stakeholder suggestions in designing enhancements to the IRIS Program (announced in July 2013). Small adjustments may become necessary as we move forward to implement the enhancements. For example, in December 2013, we held our first IRIS bimonthly public meeting to discuss: 1) early materials (literature search, evidence tables, and exposure-response figures) for chemicals being assessed through the IRIS Program; and 2) draft assessments and draft peer review charges. In response to comments heard at the December bimonthly public meeting, we are providing information to all stakeholders that will make it possible for anyone to participate early in the assessment development process, prior to IRIS Program decisions regarding hazard identification and dose-response assessment. Some specific changes in our approach, designed to better facilitate participation and discussion, are already occurring through changes to our IRIS bimonthly public meetings and preliminary material releases (e.g., diethyl phthalate and hexabromocyclododecane). These improvements have been recently announced on the IRIS website (www.epa.gov/iris) and include the following additional materials:

- Sections of the assessment on scope and problem formulation that explains why EPA is interested in conducting an assessment and provides some background information on the chemical, its predominant uses, and the pathways through which humans can be exposed.
- The initial literature search strategy and the results of the literature search.
- Evidence tables that summarize key information on the design and results of pertinent scientific studies. Studies with serious flaws according to criteria discussed in the EPA's guidelines (and summarized in the draft Preamble to the IRIS Toxicological Review) are excluded. If additional selection criteria were applied to facilitate a more efficient review of the evidence (for example, to highlight the most informative studies when there are a large number of studies on an effect), these criteria are explained in text accompanying the evidence tables.
- Some key science issues that will be considered in the development of future assessments.

As the IRIS program continues to evolve, the EPA is committed to evaluating how well our approaches promote constructive public discussion with our stakeholders as well as reviewing how our approaches can more effectively facilitate subsequent assessment development.

Question 32: EPA has released a complete draft benzo[a]pyrene assessment for 60 day

peer review. Upon request, EPA did extend the comment period for another 30 days. However, the document and supporting information is over 500 pages and the public did not benefit from any review of evidence tables. There were no earlier discussions with EPA about critical studies. Why didn't EPA share some of the preliminary information with the public before releasing a completed draft assessment?

Answer: When the IRIS Program announced the enhancements in July 2013, there were IRIS assessments in different stages of development. For example, some assessments were in the early stages of development, some were nearly ready to publicly release in draft form, and some were in the latter stages of development. Therefore, the degree to which the enhancements are being applied for a particular assessment varies and depends on the step an assessment was in when the IRIS enhancements were announced. The draft benzo[a]pyrene assessment was nearly complete when we announced the enhancements to the IRIS Program in July 2013 – thus, we released the draft assessment for public comment in August 2013. During the December 2013 IRIS bimonthly public meeting, we had a robust discussion with stakeholders about the draft benzo[a]pyrene assessment. We are revising the draft assessment based on the public comments we received and the discussion we had during the December meeting. We will release a revised draft assessment for peer review in the near future.

Question 33: Will you ensure that as part of the improvements in the IRIS program, the Agency will move away from outdated default assumptions and instead always start with an evaluation of the data and use modern knowledge of mode of action – how chemicals cause toxicity – instead of defaults?

Answer: In developing an IRIS assessment, the EPA looks at all of the available data, including information about mode of action. We look at the entire database of scientific information, and we systematically review that information to develop the assessment. For example, consistent with the Agency's *Guidelines for Carcinogen Risk Assessment*, the EPA considers a critical analysis of all relevant information as the starting point from which a default option may be invoked if needed to address uncertainty or the absence of critical information. Examples of the EPA's other guidelines that include information on default approaches include the Benchmark Dose Technical Guidance (US EPA, 2012) document and the Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (US EPA, 2005). These guidelines and others are available at http://www.epa.gov/iris/backgrd.html. The EPA is committed to using sound science and continues to make significant progress in developing data-derived approaches and mechanistic models that require more detailed databases. While committed to these efforts whenever possible, in the absence of data, the Agency relies on scientifically-based and health protective default approaches, consistent with Agency policies and guidelines.

Question 34: To further improve the IRIS Program, can you commit to revising the way hazard values are presented to the public to ensure that critical science policy assumptions are transparency presented and not comingled with scientific assumptions?

Answer: Yes, the EPA is committed to making sure that the scientific foundation for our decisions reflects the best possible science and that information is communicated in a transparent manner.

Question 35: What are natural environmental chemical levels? What are background, man-made chemical levels? How do you consider these levels in IRIS determinations? How do IRIS hazard values accommodate levels associated with existing natural exposures that are not known to be associated with any adverse effects at these low exposure levels?

Answer: Scientists commonly use the term "background levels" to mean three different things: (1) levels of chemical compounds that are produced within the body ("endogenous" compounds), (2) levels of substances that are in the environment from natural sources and processes (one might call these "naturally-occurring"), and (3) whatever concentrations occur from sources other than the source being considered in a decision, including sources due to human actions.

IRIS assessments are developed to provide information on the health effects associated with exposure to chemicals from sources over which the EPA has regulatory authority, including some chemicals that occur naturally in the environment at some level or are produced endogenously. IRIS values generally already take into account amounts commonly produced by our own bodies ("endogenous exposures"). The fact that a chemical is naturally produced does not make it "safe" at all doses; there are many natural products of metabolism that can have toxic effects at high enough levels. In addition, in the risk assessment paradigm, noncancer hazards and increased cancer risks are generally based on comparisons to unexposed populations. The adverse effects of hazardous agents are not driven by whether or not they are "naturally" occurring. The source of the exposure does not impact the dose at which an adverse effect is observed. Natural occurrence and background levels are more appropriately considered in the risk management strategy.

Question 36: Can you commit to ensuring that a 3rd party, independent of the IRIS Program, is tasked with ensuring that EPA staff have sufficiently considered and responded to peer reviewer and public input before assessments and other documents are finalized?

Answer: Following external peer review, the EPA revises draft assessments to respond to public and peer review comments. The revised draft is then reviewed by Agency scientists who do not work in the IRIS Program; additionally, it is reviewed by scientists from other federal agencies and the Executive Office of the President. The EPA's responses to public and peer review comments are documented in an appendix to each IRIS assessment.

Cross-Cutting Risk Assessment Concerns

Question 37: Some scientists have suggested using a weight of evidence framework that incorporates relevant and reliable data along with knowledge of hypothesized modes of action, so that there is a clear and objective presentation of the extent to which existing data and knowledge do, or do not, support each hypothesis, including the default. Do you support such an approach? If so, can you provide us with a timeline for such an approach that might be adopted within OPPT and IRIS?

Answer: Hazard identification involves integrating evidence from human, animal, and mechanistic studies to draw conclusions about a chemical's hazards. In general, IRIS assessments integrate evidence consistent with a framework developed by Sir Bradford Hill, which outlines aspects (for example, consistency, strength, biological plausibility, etc.) for considering causality in epidemiologic investigations. These were later modified and extended to experimental studies. The IRIS Program currently uses existing methodology (i.e. the 2005 Cancer Guidelines, and the 2002 Technical Report on the RfD/RfC Process) built upon the Hill criteria, to inform assessments. The IRIS Program is working toward adopting systematic review methods (for selecting and analyzing studies) and data integration or weight-of-evidence approaches (to develop overall findings). To move forward in this area, in August 2013, the EPA convened a public scientific workshop focused on approaches for evaluating individual studies, synthesizing evidence within a particular discipline, and integrating evidence across different disciplines to draw scientific conclusions and causality determinations.

The IRIS Program is committed to systematic review and weight of evidence approaches in developing assessments, including consideration of studies with positive and negative findings, and is moving forward in that area.

OPPT supports the IRIS program's approach to weight of evidence, and where available and appropriate incorporates information from IRIS into OPPT assessments. When OPPT does so, the weight-of-the-evidence considerations of the IRIS assessment are brought into the OPPT assessment in a manner consistent with the scoping of the OPPT assessment. OPPT typically assesses chemicals for which there is much less information than exists with chemicals for which IRIS assessments are conducted. As a result, the weight-of-evidence considerations for OPPT assessments that rely on relatively little data are considerably more limited, and case-specific, than those used for IRIS assessments that may have robust data sets.

Question 38: One of the biggest challenges for risk assessment is the insistence by some international regulators to use hazard as a surrogate for risk in regulatory decision-making. When EPA personnel participate in international forums where these issues are being discussed (e.g., OECD, APEC, SAICM, etc.) will you encourage them to advocate that risk be

used as the basis for human health and environmental policy development?

Answer: Yes. For example, the IRIS Program identifies the quantitative dose-response information useful for risk assessment whenever that information exists. As such, it strongly supports the ability of regulatory and other programs to base their decisions upon estimates of risk, not just hazard.
Most of the environmental statutes passed by Congress incorporate the consideration of risk into environmental decision-making within the United States. Given that, I expect that EPA personnel participating in international forums where these issues are being discussed will encourage the use of risk-based decision making.

Question 39: EPA's IRIS program completes no more than 10 assessments per year. Since 1999 the Canadian government has evaluated about 23,000 chemicals as part of its chemical management plan. By 2006, all 23,000 chemicals had been evaluated and about 4,000 chemicals were identified as requiring further review. Since then Canada has been systematically reviewing these 4,000 substances and has thus far identified a list of Priority Substances considered "toxic" under the criteria laid out in legislation for which management plans are to be created.

- Does EPA have the capacity to review the same number of chemicals in the same time period as the Canadian government?
- What did the Canadian government find that disagrees with EPA findings?
- What is EPA doing to streamline the chemical assessment process?
- Would you agree that the IRIS program can do better, and that some fundamental changes are necessary?
- What changes do you believe should be made to the IRIS program?
- Do you support broad discussions with stakeholders to re-think the IRIS framework and approach?

Answer: The efforts of the Canadian government discussed above related to chemical screening and prioritization. To our knowledge Health Canada identified a much smaller subset of the 23,000 chemicals as requiring a full assessment. We are not aware of any disagreements that EPA may have had with the initiatives or findings of the Canadian government. EPA has a number of activities focused on developing new methodologies to screen the large number of chemicals in commerce and the environment. For example, EPA has an active computational toxicology effort in its Office of Research and Development, through the Chemical Safety for Sustainability research program, that uses rapid, automated tests called "high-throughput screening assays." The computational toxicology effort is also developing high-throughput exposure predictions with the goal to generate higher throughput risk-based evaluations. To date, this effort has screened 1,800 chemicals in over 700 high-throughput assays. The EPA's endocrine disruption screening program has already started the scientific review process to use these new high-throughput screening assay data to prioritize chemicals for potential endocrine-related activity.

In September, 2013 the EPA researchers released the draft report *Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology* which begins to address how the EPA can take full advantage of novel data sources in its risk assessments. In the next phase of this effort, the EPA will enter novel data streams generated by ToxCast and related research will be used to enhance and accelerate the EPA's risk-based chemical evaluations.

The EPA ORD now has a research collaboration with Health Canada to determine if the high-throughput chemical data the EPA generates through ToxCast can be used to inform decisions made about the chemicals listed in their Chemical Management Plans. This collaboration as well as others with European chemical and health agencies will help accelerate the EPA's own risk assessments in the coming years.

Regarding your questions about the IRIS Program, in July 2013, after extensive outreach and conversations with Agency partners and external stakeholders, the EPA announced changes to the IRIS Program to: 1) improve the science of assessments; 2) improve the productivity of the Program; and 3) increase transparency so issues are identified and debated early in the process. Since that time the IRIS Program is continuing to evolve, incorporating recommendations from the 2011 and 2014 NRC reports related to IRIS. As part of the changes to the IRIS Program, we are continuing our efforts in stakeholder engagement (including discussion of science and process issues) at bimonthly public science meetings where ongoing assessments are discussed. EPA anticipates that this early engagement will result in identifying issues early in the process so the pace of assessments is not slowed down by scientific controversies later on. We are also strengthening our peer review process through the use of the Science Advisory Board's Chemical Assessment Advisory Committee. We believe that, over time, these changes will increase the efficiency with which the EPA produces the in-depth reviews for which IRIS is known and respected.

Questions Regarding ORD Nominee Thomas Burke

Question 40: Thomas Burke suggested in an NAS report he chaired that information on nonchemical stressors should be incorporated into assessments and EPA should further research dollars into evaluating the interactions between chemical and nonchemical stressors.

- Do you believe that EPA has the staff, with requisite qualifications, and financial capacity to also take on evaluations of nonchemical stressors?
- Should EPA convince Congress, NAS, and all other stakeholders that they can appropriately evaluate chemical stressors before broadening their scope to include evaluation of chemical stressors?

Answer: In 2003, the EPA published the Framework for Cumulative Risk Assessment and where helpful in decision making, the EPA has assessed risks of multiple chemicals. This is an important and evolving area of science, and multiple advisory groups, such as the National

Academy of Sciences and the National Environmental Justice Advisory Committee, have urged the EPA to incorporate information about nonchemical stressors into assessments of chemicals, such as those developed through the Integrated Risk Information System (IRIS) Program. At this point, it would be difficult to routinely incorporate nonchemical stressors into chemical assessments given existing resources. However, because it is an important area of science, the EPA is funding research to increase understanding of the role of nonchemical stressors in cumulative risk assessments, including seven Science to Achieve Results (STAR) grants specifically examining the role of nonchemical stressors in cumulative risk assessment.

In addition to research on methodologies, the EPA has Technical Panels established to develop guidance on how to approach cumulative risk assessments that include chemical and non-chemical stressors. These efforts are directly related to recommendations from multiple reports from the National Academy of Sciences.

Grant Funding – Conflict of Interests

Question 41: In response to questions you stated that you have a process in place to review the eligibility of EPA grant recipients serving on peer review panels. When was this review process put into place?

Answer: The EPA has processes in place to identify potential conflicts of interest for persons (including EPA grant recipients) who may serve on peer review panels. The EPA also monitors its processes for areas of improvement. For example, in March 2013, the EPA strengthened its oversight of contractor-managed peer review panels for influential scientific and technical documents. The new oversight includes additional steps which increase transparency by allowing for a public review and comment period on potential panelists. For more information on the process, you may visit (http://www.epa.gov/osa/pdfs/epa-process-for-contractor.pdf) and http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2012.pdf.

Question 42: Did EPA review in detail the grants that were obtained by current CASAC panel members and consultants to determine if there was a potential conflict?

- If so, who within EPA conducted this review?
- What does the grant review involve?
- Are the grants to the potential member's institution also reviewed?
- Can EPA share the results of this grant review with the Committee?

Answer: Yes, the SAB Ethics Officer conducted an initial review followed by a final review by the SAB Office Director, who is the Deputy Ethics Official. The grants awarded to a candidate are reviewed as part of the full review of the information provided on the confidential financial disclosure form, the EPA Form 3110-48. The SAB Staff follows the approach identified in the OMB Bulletin (p.25): "Research grants that were awarded to the scientist

based on investigator-initiated, competitive, peer reviewed proposals do not generally raise issues of independence. However, significant consulting and contractual relationships with the agency may raise issues of independence or conflict, depending upon the situation." The EPA reviews candidate's grants to ensure that they have no financial conflicts of interest, as defined by 18 U.S.C. §208 and to ensure, consistent with the EPA's Peer Review Policy, that experts will not peer review their own work. Consistent with this latter point, the scope of grants is evaluated to determine whether products developed under any grant are to be peer reviewed by a panel. Grants to a potential member's institution are not reviewed unless the grants are reported on the EPA Form 3110-48 as sources of research or project funding received by the potential member or his or her spouse in the last two years. The EPA cannot share the results of the grant review because the information reported on the confidential financial disclosure form, the EPA Form 3110-48, is deemed confidential under 5 CFR 2634.901(d). Information on recipients of the EPA grant funding are available in the public domain at http://yosemite.epa.gov/oarm/igms_egf.nsf/recipient2?OpenView. Information about the results of the EPA's ethics review is included in the Determination Memoranda posted to the CASAC website (www.epa.gov/casac) for each CASAC panel or committee established by the EPA.

- If EPA has not done the detailed review of the individual grants of CASAC panel members and consultants, why not? When will EPA conduct this review?

Answer: The grants awarded to a candidate are reviewed as part of the full review of the information provided on the confidential financial disclosure form. A review of various factors such as employment, expert testimony, grants and contracts, assets and public comments are considered and reviewed prior to each new advisory activity to determine a candidate's eligibility to participate on a panel. This process was followed for CASAC panel members and consultants.

- Under what specific circumstances would EPA conclude that a grant recipient should not serve on a peer review panel?

Answer: A candidate who has any financial or other interest that conflict with the service of the review panel would not be eligible to participate on that particular review panel. With regard to grants, the scope of grants awarded to a candidate is evaluated to determine whether products developed under any grant are to be peer reviewed by the panel.

Question 43: When EPA appointed Dr. Jonathan Samet to be chair of the CASAC panel reviewing the PM2.5 NAAQS, did EPA review EPA grants to Dr. Samet and his affiliated research institutions for a potential conflict?

Answer: Yes. Grants awarded to candidates for CASAC panels are evaluated to determine whether products developed under such grants include products that will be peer reviewed by the panel. However, as noted in guidance from the Office of Management and Budget, "when an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a

scientist is awarded a government research grant through an investigator-initiated, peer reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects" (OMB's Final Information Quality Bulletin for Peer Review, December 16, 2004).

- How far back did the evaluation go?

Answer: The Confidential Financial Disclosure Form (EPA 3110-48) asks candidates to disclose any source of research or project funding received in the last two years preceding the date of filing.

- What was the total amount of the EPA funding provided to Dr. Samet and his research institutions in the five years leading up to his appointment?

Answer: Prior to his appointment as Chair of the CASAC PM Panel in 2008, Dr. Samet submitted the Confidential Financial Disclosure Form (EPA Form 3110-48). In accordance with instructions on the form, Dr. Samet listed sources of research or project funding received in the last two years preceding the date of filing. The EPA did not develop a total for the EPA funding provided to Dr. Samet or to his research institution in the five years preceding his appointment as Chair of the CASAC.

- If EPA grants were provided, what areas of research did the grant funding cover?

Answer: Dr. Samet reported an EPA grant focused on the physical and chemical characteristics of particulate matter (PM) that determine risk to human health, and EPA funding to support a workshop and report on the use of statistical models for low dose-response data extrapolation in environmental health risk assessments..

- Did any of the grants address PM2.5 or ozone NAAQS related science?

Answer: As noted in the previous response, Dr. Samet reported the EPA grant funding related to the health effects of exposure to fine PM. Dr. Samet was not asked to and did not review the results of any of his research funded by grants from the EPA.

Question 44: EPA's Peer Review Handbook states that experts that have made public pronouncements on an issue may lack impartiality and should be avoided; and that individuals who have "taken sides" should be avoided. According to the recently released IG Report on EPA's management of CASAC, in 2008, EPA selected Jonathan Samet as Chair of CASAC to review the PM2.5 standard even though he had published an article in 2006 opposing EPA's current PM standard. The IG Report stated that Dr. Samet failed to disclose the public statement in the disclosure form that specifically asked if he "made any public statements, written or oral, on the issue that would indicate to an observer that you have taken a position on the issue under consideration." According to the IG Report, CASAC members are also required to update this form annually and to participate in an ethics training course.

- Did the SAB staff review Dr. Samet's publications to see if a public statement had

been made?

Answer: Yes.

- Has anyone at EPA asked Dr. Samet why he omitted this important information despite a direction question on his form?

Answer: Dr. Samet provided disclosure of his public statement. In 2006, the Confidential Financial Disclosure Form (EPA Form 3110-48) did not request information on public statements. However, Dr. Samet did disclose his 2006 editorial in the *American Journal of Respiratory and Critical Care Medicine* in an e-mail to Designated Federal Officer Fred Butterfield dated 1-31-06 in direct response to a question about past public statements.

- Did Dr. Samet submit a new financial disclosure statement annually while Chair? If so, did he continually omit disclosure of his public statements on all his forms?

Answer: Yes, Dr. Samet submitted new financial disclosures on a yearly basis. His disclosures included public statements.

Question 45: Does EPA normally review publications of CASAC members and consultants to determine if public statements have been made?

Answer: Yes, this is part of our standard protocol.

Data Transparency

Question 46: In answering member questions, you stated that in response to the Shelby Amendment on data access, you have assured yourself that you have access to the underlying research data. Does this include the confidential cohort data?

Answer: The EPA has assured that the Agency has received from researchers and transmitted to Congress the research data that the Agency has determined are required to be provided under the Shelby Amendment, consistent with applicable protections for private medical and similar information. The EPA does not have access to much of the underlying data requested by Congress because that information is held solely by the outside research institutions that conducted these large-scale epidemiological studies, not the EPA.

Question 47: Given that the American Cancer Society and Harvard Six City studies were funded by the EPA, does the federal government have the ability to obtain the data that resulted from those grants under 36(c)(1)&(2) of the A-110 Circular?

Answer: The American Cancer Society studies were not funded by the EPA and, accordingly, the Agency does not possess or have access to data held solely by the outside research institution. With respect to the Harvard Six City studies, the EPA has already provided Congress the research data that the Agency has determined are subject to the Shelby Amendment.

Question 48: Can you provide us with a list of all the times EPA has obtained research data to conduct its own analysis?

Answer: The EPA conducts research and analyses on many topics in order to fulfill its mission to protect human health and the environment, and data collection for those studies and analyses occurs continually. Given the many instances of when this occurs, the EPA does not maintain a list of all the times the Agency obtains research data to conduct its own analysis. The EPA follows all applicable laws and regulations to protect private medical and similar information.

Question 49: Are there studies on PM2.5 and ozone studies that rely on publically available data sets? If so, please list those studies.

Answer: There are many studies across the scientific disciplines that use publicly available data sets that are included in the Integrated Science Assessments (ISAs) for ozone and particulate matter (ozone – http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492, and PM – http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546) The EPA maintains a comprehensive list of all studies included in these assessments in its publicly available Health & Environmental Research Online (HERO) database (http://hero.epa.gov/). Ozone (http://hero.epa.gov/index.cfm/project/page/project_id/1628); PM (http://hero.epa.gov/index.cfm/project/page/project_id/15) In many studies, however, scientific protocols require that authors not publicly report underlying data pertaining to personal medical information to protect the privacy of study participants. The EPA understands that it is important to increase transparency and public access to information, but it is also essential to protect the privacy of individuals who have served as subjects in studies along with their personal health information.

Question 50: Will EPA commit to not rely on studies for setting standards that are based on underlying data sets and methodologies that neither EPA nor the public can access and review?

Answer: The EPA is committed to transparency with regard to the scientific bases of agency decision making. The use of personal medical information does not in any way undermine 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.

Questions Relating to the Use of Old Cohort Data

Question 51: The individual cohort data from the American Cancer Society and Harvard University are over 30 years old. Because the data were collected over 30 years ago, the smoking rates of the individuals in the studies have stayed the same despite a dramatic fall in smoking nationally. Similarly, the assumptions about participants' use of heart medicine and cholesterol lowering drugs have not changed over these 30 years, despite

the dramatic increases in their usage nationally.

- Does EPA believe that the outdated nature of the individual cohort data used in studies that rely on the ACS and Harvard Six City cohort data create additional uncertainties and weaknesses that could be corrected if new cohort data were used?

- Does EPA believe that the small but statistically significant decrease in deaths attributed to reduced PM2.5 exposures in these studies are, at least in part, due to reductions in smoking or increased use of medications that the studies are not addressing? If so, how can the EPA know what percent of the decrease in deaths attributed to reduced PM2.5 exposures are actually due to other factors?

Answer: The EPA considers studies based on the American Cancer Society and Harvard Six Cities cohorts 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.

During the most recent review of the PM NAAQS, the EPA 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.

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.

Environmental Research, Development and Demonstration Authorization Act

Question 52: The Environmental Research, Development and Demonstration Authorization Act of 1978, 42USC #4365 (ERDDAA) established the Science Advisory Board (SAB).

a. Please explain in detail how you interpret the provisions ERDDAA.

Answer: The Science Advisory Board (SAB) was established by the EPA Administrator in January 1974. Section 8 of the Environmental Research, Development and Demonstration Authorization Act of 1978 (ERDDAA), 42 USC § 4365, provided statutory authority for the SAB. The SAB is a scientific/technical federal advisory committee, subject to the requirements of the Federal Advisory Committee Act (FACA), 5 USC App. 2. The SAB reports to the EPA Administrator.

b. Explain EPA's interpretation of ERDDA's requirement that the "Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the ...[CWA]... is provided to any other Federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based. Id.

Answer: Under section 4365(c), EPA is required to make proposed criteria documents, standards, limitations, and regulations available to the SAB when it submits such documents to other federal agencies for "formal review and comment." "Formal review and comment" occurs when a statute requires EPA to consult with another federal agency before it can take action.

c. Explain in detail the role and powers ERDDAA gives specific Congressional Committees. Do these powers included the ability to pose charge questions to the SAB? Why or why not? Do these powers include initiating the formation of new SAB panels to provide advice to Congress? Why or why not. Please cite any relevant statutory support for these positions and explanations.

Answer: The SAB is a federal advisory committee established by the EPA Administrator and, as with all EPA federal advisory committees, is subject to "administrative guidelines and management controls" established by the EPA Administrator. (See, FACA section 8(a)). As required by FACA, the EPA DFO calls each meeting and approves the agenda for each meeting.

EPA and staff of the House Science, Space and Technology committee are developing a process for managing questions on which the specific congressional committees would like SAB advice.

d. Does the SAB have the independent power to initiate reviews? Why or why not?

Answer: As stated in ERDDAA, the SAB provides scientific and technical advice as requested by the EPA Administrator. In addition under section 4365(c), the SAB has the authority to provide advice and recommendations on "proposed criteria document[s], standard[s], limitation[s], or regulation[s]" that are "provided to any other Federal agency for formal review and comment."

e. What specifically is requires to initiate review. How were these requirements determined?

Answer: SAB reviews are initiated when an EPA program office contacts the Director of the Science Advisory Board Staff Office.

QUESTIONS FOR THE RECORD
The Honorable Paul Broun (R-GA)
U.S. House Committee on Science, Space and Technology
Strengthening Transparency and Accountability within the Environmental Protection Agency

IRIS Questions

Question 1: You testified on November 14 that "the Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science upon which it relies. I firmly believe that environmental policies, decisions, guidance, and regulations that impact the lives of all Americans must be grounded, at a most fundamental level, in sound, high quality, transparent, science." Additionally, at the September 17, 2012, opening public meeting of the National Research Council (NRC) IRIS Review panel, EPA NCEA Director Dr. Ken Olden stated in his presentation, that "openness and transparency will be the hallmark [of IRIS assessments] going forward." At the same NRC meeting, EPA Acting IRIS Director Vince Cogliano informed the panel that "new [EPA IRIS] initiatives will increase transparency and promote involvement of the scientific community." Finally, in the NRC Formaldehyde Report (2011), the committee noted in its recommendations to EPA for improving the IRIS process overall, "in the judgment of the present and past [NRC] committees, consideration needs to be given to how each step of the [IRIS] process could be improved and gains made in transparency and efficiency." (NRC Formaldehyde Report (2011), p. 164).

In order to understand the scientific underpinnings of many EPA documents, the public has been forced to resort to using FOIA, or other approaches, to try to obtain critical information and data that the EPA has relied upon. As these tools are time consuming and create legal hurdles, the information has not been available to the public in a timely manner to inform review and public comment.

- As part of a commitment to transparency and openness, do you agree that the data and information which underlies the key scientific studies the agency relies upon in important scientific reviews, assessments, and rulemakings (e.g., NAAQS Integrated Science Assessments, IRIS Toxicological Reviews), should be available to the public?

- Can you commit to making this information available in public dockets?

Answer: Transparency and scientific integrity are very important to the agency's work. Transparency is a critical element in the EPA's Scientific Integrity Policy: "To enhance transparency with the Agency, this policy...facilitates the free flow of scientific information. The Agency will continue to expand and promote access to scientific information by making it available online in open formats in a timely manner, including access to data and non-proprietary models underlying Agency policy decisions."

The July 2013 enhancements to the EPA's IRIS program are but one example of the Agency's commitment to this policy.

Question 2: Industry and federal research efforts have invested millions to better understand how chemicals interact with biological systems at human exposure levels in order to ensure development of human health risk assessment prediction models that are as accurate and science-based as possible. However, EPA has a long track record of dismissing these types of scientific biologically-based models and asserting that such approaches cannot prove the defaults are not warranted. Demanding that science proves a negative is an anti-scientific policy and indicates a deep seated prejudice against use of mode of action knowledge to replace defaults. Why shouldn't EPA use the most up to date knowledge on mode of action and dose response at environmentally relevant exposures in lieu of outdated default approaches for hazard identification and dose response throughout the Agency, including in the IRIS Program?

Answer: In developing an IRIS assessment, the EPA looks at all of the available data, including information about mode of action. We look at the entire database of scientific information, and we systematically review that information to develop the assessment. Consistent with the Agency's *Guidelines for Carcinogen Risk Assessment*, the EPA considers a critical analysis of all relevant information as the starting point from which a default option may be invoked if needed to address uncertainty or the absence of critical information. The EPA is committed to using sound science and continues to make significant progress in developing data-derived approaches and mechanistic models that require more detailed databases. While committed to these efforts whenever possible, in the absence of data, the Agency relies on scientifically-based and health protective default approaches.

Question 3: As EPA prepared to conduct a non-cancer toxicity assessment of Libby Amphibole Asbestos, it arranged by contract for development of additional data that EPA describe as "for development of the most accurate RfC for the Libby site." These new data included advanced radiographic imaging and pulmonary function studies of the population from which the RfC would be derived. The new data were collected by the University of Cincinnati as planned, but after several years remain unpublished and undisclosed by the federal government. EPA has neither revealed its assessment of the data nor explained why it chose to prepare its draft toxicity assessment without citation to or disclosure of underlying data that was sought by EPA to ensure the accuracy of the RfC.

- Please explain how EPA reconciles not disclosing the above data with its commitment to transparency and the NRC recommendation as noted above as well as the disclosure directives of FOIA and OMB Circular No. A-130 (Revised) which express the policy that the open and efficient exchange of scientific and technical government information supports the operation of democracy and excellence in scientific research.

Answer: The collection of the pulmonary function data was included as part of the original contract with the University of Cincinnati, but was not funded by the EPA. Accordingly, the Agency does not have the pulmonary function data. With respect to the other requested information, the EPA produced a number of documents in response to a FOIA request, including:

- A spreadsheet of X-ray data from the Marysville full cohort;
- Two files of smoking data corrections made by University of Cincinnati and the EPA;
- A spreadsheet of smoking data from 1980 and 2004;
- Three manuscripts discussing the data;
- A copy of the 2005 contract award to the University of Cincinnati;
- Minutes of meetings and a schedule of deliverables related to this contract;
- A copy of the contract with SRC, Inc.;
- Statements of Work for Task Orders 0003 – Guidance Addendum for Libby Amphibole, 0005 – Libby Human Health Risk Assessment, and 0007 – Libby Operable Unit 3; and
- Monthly reports related to Task Order 0005.

The EPA withheld from production other information consistent with the FOIA and OMB Circular A-130. While the Agency is committed to transparency, the EPA has an obligation to avoid disclosing material that may be confidential business information (CBI), under the Trade Secrets Act and also under Circular A-130, which directs that agencies "[l]imit the sharing of information that ... contains proprietary information to that which is legally authorized." Two of the three documents withheld in response to FOIA request EPA-08-2013-2405 were subject to claims or class determinations of CBI status. In particular, the High Resolution Computed Tomography (HRCT) data was produced by University of Cincinnati researchers and is subject to a confidentiality claim by the University; and the contract documents contain labor rates and similar information that the EPA redacted before release in accordance with CBI Class Determination 1-95. Before releasing the HRCT data or any of the redacted portions of the contract documents, the Agency is required to determine whether any CBI claims are valid and provide notice to the affected businesses.

In addition, the Agency is committed and required to protect citizens' privacy. As noted in Circular A-130, "[t]he individual's right to privacy must be protected in Federal Government information activities involving personal information." One of the withheld documents, the exposure matrix, raised these privacy concerns. It contains medical information that could

directly and indirectly reveal asbestos exposure associated with individual workers. Because the information contains medical or similar files of individuals, including information that could allow exposure data to be traced to specific persons, the disclosure of this document would constitute a clearly unwarranted invasion of personal privacy. Therefore, the EPA withheld this document under Exemption 6.

Finally, as discussed below, we have determined that the HRCT data and the exposure matrix are covered by the deliberative process privilege of FOIA Exemption 5, in addition to the other exemptions from disclosure discussed above.

- If EPA asserts that it does not possess or have access to any portion of the data, for instance because the funding mechanism changed and someone else paid for it, please explain:

    a. In the interests of transparency and sound science, why EPA did not affirmatively obtain for its own use the data during RfC development, especially since EPA had described the data as needed "for development of the most accurate RfC."

Answer: While the EPA included the collection of the pulmonary function and the advanced radiographic imaging data (HRCT data) in the contract with University of Cincinnati, the task for this data collection was not funded by the EPA. Further, the EPA did not affirmatively obtain any portion of this non-EPA-funded data, because the data had not yet been published in a peer-reviewed journal. The Agency uses only peer-reviewed, published data in IRIS toxicity assessments.

    b. Which governmental agencies provided funding for the development of the data

Answer: The Agency for Toxic Substances and Disease Registry provided the funds for these investigations by the University of Cincinnati.

- We understand that EPA received a Freedom of Information Act Request (FOIA) for the above data, and subsequently withheld a portion of the data based upon: the deliberative process privilege. EPA explained by letter of November 1, 2013 that it was withholding the data because:

  The withheld documents, and portions of documents, are protected by the deliberative process privilege because ***they reflect the internal discussions, advice, analysis, and recommendations that were considered in developing the [IRIS] Assessment for Libby Amphibole Asbestos.*** *The records were created prior to the finalization of this IRIS Assessment. Furthermore, withheld records were not circulated outside the Agency.* ***Release of the withheld material would prematurely disclose proposed policies before they are finally adopted*** *and cause public*

confusion by disclosing reasons and rationales that were not in fact ultimately the grounds for EPA's final assessment.

We further understand that the deliberative process privilege does not ordinarily cover scientific information and data, and "government researchers must be willing to expose the underlying data to public scrutiny." Chicago Tribune Co. v. United States Dept of Health and Human Servs., 1997 U.S. Dist. 2308 at *52 (N.D. Ill. Feb. 26, 1997). In light of this, please explain how the deliberative process privilege protects against disclosure of data, and whether the data should be produced to the public under FOIA.

Answer: In response to FOIA request EPA-08-2013-2405, the EPA withheld two documents based in part on deliberative process grounds: an Excel spreadsheet of advanced radiographic imaging data (HRCT data) and an exposure matrix with individual worker exposure calculations. In neither case was deliberative process the only basis for withholding. The Excel spreadsheet of HRCT data was claimed as confidential business information by the University of Cincinnati, while the exposure matrix contained medical information associated with individual workers. Accordingly, the EPA also withheld these documents under Exemptions 4 and 6 as applicable.

The EPA determined that the two withheld documents were also subject to the deliberative process privilege because the records were internal and not disclosed outside the federal government or its contractors; predecisional because the records were created before the finalization of the *IRIS Assessment for Libby Amphibole Asbestos*; and deliberative because the records were intertwined with decisions related to the IRIS assessment. Further, it would tend to reveal the "nascent thoughts" of Agency scientists and would thus "discourage the intellectual risk-taking so essential to technical progress." *Chemical Mfrs. Assoc. v. Consumer Product Safety Com.*, 600 F. Supp. 114, 118 (D.D.C. 1984). Accordingly, the release of this withheld information would prematurely disclose proposed policies before they were finally adopted and could cause public confusion by disclosing reasons and rationales that were not ultimately the grounds for the *IRIS Toxicological Review of Libby Amphibole Asbestos*, which has not yet been finalized.

The EPA does not find the unpublished *Chicago Tribune* opinion quoted above determinative. In that case, the district court made its statement about data not as a general rule of law but as a logical conclusion in light of the specific circumstances, which are different from the facts here. As you are aware, in the *Chicago Tribune* case, the District Court reviewed the appropriateness of asserting Exemption 5's deliberative process privilege on raw data in patient data forms. In contrast, the withheld records contain more than mere facts and raw data. The information included deliberative discussions and preliminary results

For these reasons, the Agency determined the information was exempt from disclosure under Exemption 5's deliberative process privilege.

Question 4: EPA is identifying the non-cancer adverse effect for the draft toxicological assessment of Libby Amphibole Asbestos as pleural plaques, asserting there is an association with certain functional impairment of the lung. It has come to our attention that the question of whether pleural plaques cause any clinically significant impairment is highly disputed and controversial. In light of this information:

- Is EPA considering discarding the assertion that pleural plaques cause lung decrements or any other functionally significant impairment because this initially proposed basis for selecting pleural plaques as the adverse effect lacks the needed scientific support?

a. If so, in the interest of transparency, please explain EPA's current position as to which adverse effect it is using for its non-cancer toxicological assessment, the basis for selecting that adverse effect, and whether the Agency will provide the opportunity for public comment on any change in its position.

Answer: The EPA's draft IRIS assessment of Libby Amphibole Asbestos includes an inhalation reference concentration (RfC) that is based on the presence of localized pleural thickening, an abnormality of the lining of the lung. "Localized pleural thickening" is a more recent term that encompasses what historically was known as "pleural plaques." This draft EPA assessment was reviewed by the Agency's Science Advisory Board (SAB) in 2013, and the question of basing the RfC on "localized pleural thickening" was discussed during this peer review. The SAB, in their peer review report, stated that "localized pleural thickening is an appropriate health endpoint for the derivation of the inhalation reference concentration." They went on to say that it is an "irreversible structural, pathological alteration of the pleura and is generally associated with reduced lung function." The final SAB peer review report is available at:
http://yosemite.epa.gov/sab/sabproduct.nsf/0/4F2A245C7160456B85257B030072E5D3/$File/EPA-SAB-13-001-unsigned.pdf

The EPA is currently revising the assessment to address the peer review and public comments. Following this, the revised draft will be reviewed by Agency scientists and the EPA will lead a science discussion with other federal agencies and the Executive Office of the President. After this, the EPA will move forward to complete the assessment.

Question 5: Do you agree that all studies should be independently judged based on their quality, strength, and relevance regardless of the author affiliation or funding source?

Answer: Author affiliation or funding source does not impact how studies are judged within the IRIS Program. In addition to quality, strength, and relevance, it is important that studies used in IRIS assessments are peer reviewed.

Question 6: Do you agree that chemicals associated with the human body's natural

processes should be addressed specifically and separately in the development of an EPA hazard value or risk assessment?

Answer: IRIS assessments are developed to provide information on the health effects associated with exposure to chemicals from sources over which the EPA has regulatory authority, including some chemicals that occur naturally at some level. There are many natural products of metabolism that can have toxic effects at high enough levels; the fact that a chemical is naturally produced does not make it "safe" at all doses. For noncarcinogens, IRIS typically estimates a concentration that if inhaled, or a dose that if ingested, is expected to be without appreciable risk of deleterious effects during a lifetime. The risk evaluated is typically the risk of increased effect – beyond the effects observed in the "unexposed" group or population. For carcinogens, the EPA typically estimates what additional risk might be caused by additional exposure compared with an "unexposed" population. As such, IRIS values generally already take into account amounts commonly produced by our own bodies ("endogenous exposures") in how they are derived.

Question 7: An analysis presented at the Society of Toxicology meeting showed that 67% of the Hazardous Air Pollutants (HAPs) have no IRIS value.

a. Do you believe that HAPs should be priorities for assessment within the IRIS Program?
b. What are the criteria for selecting chemicals for assessment within the IRIS Program?
c. Can you commit to developing a clearly articulated prioritization process for high priority IRIS assessments that benefits from, and is responsive to, engagement from all stakeholders?

Answer: The EPA recognizes that HAPs are important, and the IRIS Program works with the EPA's program and regional offices, including the Office of Air and Radiation, to develop the IRIS agenda. In the past few years, the IRIS Program has completed assessments for several HAPs, including tetrachloroethylene, trichloroethylene, methanol, and 1,4-dioxane. Additionally, the IRIS Program currently is working on developing assessments for several HAPs; examples include formaldehyde, naphthalene, and stryene.

The EPA periodically solicits nomination of chemicals to be assessed through the IRIS Program. Anyone can nominate chemicals for assessment, including the EPA Program Offices and Regions, other Federal agencies and the Executive Office of the President, as well as any stakeholders and the public. The EPA routinely publishes a Federal Register Notice announcing the opportunity to nominate chemicals for the IRIS agenda, and we also post information on the IRIS website. We use six general criteria for selecting chemicals for the IRIS agenda:

1. Potential public health impact;
2. EPA statutory, regulatory, or program-specific implementation needs;

3. Availability of new scientific information or methodology that might significantly change the current IRIS information;
4. Interest to other governmental agencies or the public;
5. Availability of other scientific assessment documents that could serve as a basis for developing an IRIS assessment; and
6. Other factors, such as widespread exposure.

The EPA has committed to the Government Accountability Office that it will better describe for internal and external stakeholders and the public the nomination and selection process for determining chemicals to be assessed by the IRIS Program, including the rationale for not selecting nominated chemicals.

Utility MACT and Other Air Quality Issues

Question 8: There are many groups that analyze the impacts of the EPA regulations. In particular, most of these groups analyze job losses. These include, for example, job losses due to higher energy prices. How does the EPA determine job losses that are caused by a proposed rule or a final rule? For example, do you use a model to determine job losses? When you analyze the job impacts of a rule that affects power plants-- for example, the Utility MACT rule that will cost $10 billion per year-does the EPA analyze job losses in industries that have to pay higher energy prices?

Answer: The EPA is keenly aware that these are tough economic times and there is particular concern about impacts on employment. That is why we have expanded our discussions of possible employment impacts in our rules. It is important to note that the EPA uses different approaches for employment analysis for different rules (drawing on peer-reviewed research), always takes public comment on those analyses, and has worked with academic researchers to improve our understanding of available tools.

Question 9: In a 2012 letter, you stated that "the best scientific evidence... is that there is no threshold level of fine particle pollution below which health risk reductions are not achieved by reduced exposure." Do you believe that any of the criteria air pollutants under the Clean Air Act (ozone, lead, sulfur dioxide, nitrogen oxides, carbon monoxide, coarse particulate matter) have a threshold below which they are not harmful to human health (or may be beneficial)?

Answer: The EPA's evaluation of scientific evidence in the most recent Integrated Science Assessments for each of the criteria air pollutants did not identify a level of exposure below which these pollutants pose no risk of harm. In the pollutant-specific ISAs, the EPA considered available scientific information from short and/or long-term exposure studies to examine the shape of the concentration – response functions and whether or not a threshold exists. While the EPA recognizes that there likely are biological thresholds for specific health responses for individuals, the PM ISA concluded that the overall evidence from existing epidemiological studies does not support the existence of thresholds for

populations.

Question 10: Last month, the World Health Organization classified outdoor air pollution as carcinogenic to humans. Do you think ambient air in America causes cancer?

Answer: The EPA has not conducted an evaluation of the potential of the collective mixture of outdoor air pollution to cause cancer in humans. However, in its 2009 Integrated Science Assessment for Particulate Matter, the EPA found that "overall, the evidence is suggestive of a causal relationship between relevant PM 2.5 exposures and cancer, with the strongest evidence from the epidemiologic studies of lung cancer mortality."

Question 11: According to the Office of Management and Budget, benefits from reducing particulate matter represent a majority of all benefits for all regulations across the entire federal government. Do you agree?

Answer: Based on recent reports from the Office of Management and Budget (OMB) on the benefits and costs of federal regulations, the EPA regulations have the highest monetized benefits across federal agencies, and a large percentage of these monetized benefits are from air pollution controls that reduce exposure to fine particles. The link between exposure to fine particle and adverse health effects is well-established in the scientific literature, including premature death, cardiovascular effects, and hospital admissions and emergency department visits for heart attacks, strokes, and asthma attacks. As OMB notes, it is not always possible to quantify or to monetize benefits in light of limits in existing information, and these non-monetized benefits can be important.

Question 12: Your predecessor, Lisa Jackson, previously testified that "If we could reduce particulate matter to healthy levels, it would have the same impact as finding a cure for cancer." Cancer kills roughly 600,000 people in this country each year. Do you agree with Administrator Jackson's statement?

Answer: Recent scientific publications are consistent with the findings of EPA's Second Prospective Study, The Benefits and Costs of the Clean Air Act, 1990 to 2020, that particulate matter is associated with thousands of premature deaths each year. Fann et al (2011) found that exposure to recent levels of $PM_{2.5}$ is associated with 120,000 to 320,000 premature deaths each year. A study in the New England Journal of Medicine (Pope et al. 2009) found that reduced levels of fine particles between 1990 and 2000 increased life expectancy at birth by about ½ a year; and, Correia et al. (2013) found that reduced particle levels between 2000 and 2007 further increased life expectancy.

In addition, the peer-reviewed burden of disease study concluded that ambient particulate matter pollution remains one of the top 10 health risk factors in the U.S. The study published in the Journal of the American Medical Association included co-authors from many health agencies. A copy of the study: http://jama.jamanetwork.com/article.aspx?articleid=1710486.

Question 13: Will your Agency propose a new National Ambient Air Quality Standard for ozone before the end of 2014?

Answer: The EPA has not yet reached a decision about what revisions to the ozone standards may be appropriate in light of the current scientific evidence. The EPA intends to issue a proposed decision addressing the question of whether it is appropriate to revise the current primary and secondary ozone NAAQS by December 1, 2014 (as required by court order), and the public will have a chance to review and comment on the proposal before the EPA issues a final rule.

EPA's Second Peer Review on the Bristol Bay Assessment

Question 14: In the development of the Agency's Bristol Bay Assessment, the Agency without soliciting any public input, asked the original twelve peer reviewers to give their opinions on how well the Agency responded to the comments that these peer reviewers made on the first draft of the Bristol Bay Assessment. Will you release the peer reviewers' comments now, before the final Bristol Bay Assessment is released? This will not in any way prejudice the Assessment, and will be in keeping with your commitment to both transparency and sound science.

Answer: On January 15, 2014, the EPA released the final Bristol Bay Watershed Assessment, which is available on EPA's website
at: http://cfpub.epa.gov/ncea/bristolbay/recordisplay.cfm?deid=253500.
Concurrent with release of the final assessment, the EPA posted the agency's response to the peer review comments
at: http://www.epa.gov/ncea/pdfs/bristolbay/EPAs%20Response%20to%20Peer%20Rev%20Comments.pdf. This response includes responses to the 2012 peer review comments as well as the 2013 peer review follow-up evaluations.

The EPA followed a transparent and open public process in developing the Bristol Bay Watershed Assessment, and the Assessment was subjected to rigorous and independent expert peer review. Twelve independent scientists with expertise in mine engineering, salmon fisheries biology, aquatic ecology, aquatic toxicology, hydrology, wildlife ecology, and Alaska Native cultures reviewed the assessment for its scientific quality. The same peer reviewers evaluated the revised draft to determine how well the EPA addressed their comments.

The peer review report from the 2012 peer review is available
at: http://www.epa.gov/ncea/pdfs/bristolbay/Final-Peer-Review-Report-Bristol-Bay.pdf

The peer review report from the follow-up peer review in 2013 is available
at: http://www.epa.gov/ncea/pdfs/bristolbay/PR_Follow-on_Comments.pdf

Climate Regulations

Question 15: When EPA released its regulations on new power plants in September, they were criticized because they would have a negligible impact on climate change. However, you have repeatedly emphasized that if we get enough countries on board we can make a difference, and you have said that a key goal of EPA's rules is to help leverage some kind of international agreement.

With that in mind, will you assure us that EPA will not take unilateral action on climate-which EPA itself acknowledges is not sufficient to make a measurable impact-but rather only proceed with rules if other major emitting countries like China agree to similar binding regulations? If not, why not?

Answer: The President's Climate Action Plan notes that it is imperative for the United States to couple action at home with leadership internationally. As part of this overall strategy, the EPA is contributing to a demonstration of U.S leadership through regulatory and non-regulatory programs that reduce emissions, take advantage of domestic sources of energy, and create jobs. Simultaneously, the Department of State is leading the effort to forge an effective global approach that includes greenhouse gas mitigation contributions from other major emitting countries, such as China.

Question 16: In 2009, President Obama committed to the U.S. to reducing greenhouse gas emissions 17 percent below 2005 levels by 2020. If EPA's power plant regulations are implemented, will the U.S. achieve that goal?

In accordance with the U N Climate Change Conference in Warsaw that concluded on November 23 with an agreement for additional cuts beyond 2020, the U.S. is expected to support additional reductions beyond the President's 2020 goal. What will EPA have to regulate in order to meet those commitments? In other words, does EPA intend to regulate natural gas-fired powered plants in order to meet these new commitments?

Answer: In January 2014, the US government completed its first Biennial Report, which included the latest estimates of historical emissions, and projected future greenhouse gas emissions out to 2020. The Biennial Report concluded that new measures, consistent with the President's Climate Action Plan, will put the United States on a path to reach the U.S. goal of achieving reductions in the range of 17 percent below 2005 levels by 2020. Included in the Climate Action Plan is EPA's Clean Power Plan. This proposed rule, if finalized, would contribute importantly to the achievement of our existing 2020 goal and to offering a robust post-2020 contribution in the context of the new climate agreement that will be concluded in Paris in 2015.

QUESTIONS FOR THE RECORD
The Honorable Larry Bucshon (R-IN)
U.S. House Committee on Science, Space and Technology
Strengthening Transparency and Accountability within the Environmental Protection Agency

Definition of Fill Material

Question 1: The current definition of fill material, finalized in May, 2002, unified the Corps and EPA's prior conflicting definitions to solidify decades of regulatory practice. However, both EPA and the Corps have stated that they are now considering revising the definition of fill material. Ken Kopocis at his nomination hearing pointed to the 2009 Supreme Court decision in Coeur Alaska v. Southeast Alaska Conservation Council as justification, stating that there is "remaining ambiguity regarding circumstances where discharges of fill material (e.g., mine tailings) may also be covered by an Effluent Limitation Guideline." Do you believe that such ambiguity exists, and will EPA be seeking to address that issue?

Answer: The EPA agrees that some confusion remains after the 2002 Fill Rule and subsequent memo discussing implementation issues in the context of Alaska hardrock mining. The Corps and the EPA have at various times discussed actions for both the waste treatment system exclusion and the definition of "fill material" that could provide additional clarity. However, the EPA has no active discussions with the Corps at this time on revising the agencies' definition of "fill material."

Water Quality Criteria- Conductivity

Question 2: While EPA's conductivity "benchmark" that it had applied to Appalachian streams were set aside by the U.S. District Court for the District of Columbia in the case of NMA v. Jackson, EPA recently published several papers supporting its conductivity actions, and announced that it is developing a water quality criteria.

a. Will EPA's new criteria be a regional criteria, or applicable nationwide?

Answer: The EPA is currently working to develop a draft recommended field-based method for states to develop ambient aquatic life water quality criteria for conductivity. The method, if finalized, would provide a method that states and authorized tribes,located in any region of the country, may use to develop field-based conductivity criteria for adoption into water quality standards. It would not impose any binding water quality criteria on any state, but instead would provide recommendations to states as they develop such criteria. The field-based method will allow states to develop science-based conductivity criteria that appropriately reflect ecoregional- or state-specific factors such as background conductivity and ionic and aquatic community composition.

b. As is required by law, will EPA be applying its conductivity criteria to all CWA permits, regardless of industry?

Answer: As described above, the EPA is currently working to develop a draft recommended field-based method for states to develop ambient aquatic life water quality criteria for conductivity. If and when such a criterion is finalized, the EPA would work closely with states to ensure that its scientific recommendations, if adopted, are implemented consistent with the Clean Water Act.

c. In the past, EPA has not addressed scientific critiques that have produced evidence that conductivity is not a good indicator of benthic/aquatic health. Going forward, what plans does EPA have to take this growing number of studies into account?

Answer: Best-available peer-reviewed scientific literature, including literature developed by EPA scientists, identifies a strong causal connection between elevated conductivity levels and harmful effects on downstream aquatic life[1]. The EPA continues to rely on the latest peer-reviewed scientific information to develop its draft recommended national field-based method for conductivity. The EPA anticipates that its draft method will undergo independent external peer review and will be made available to the public to provide scientific views, which the EPA will take into account before finalizing the method.

Selenium Water Quality Criteria

Question 3: EPA is currently involved in a scientific assessment of Selenium that will be used to propose a new national Selenium water quality criterion. Yet, EPA constantly pushes back a potential release date for its proposal, which is causing uncertainty for operations nationwide.

a. What is EPA's proposed release for a selenium water quality criteria?

Answer: In May 2014, the EPA released a draft updated national recommended aquatic life criterion for selenium and requested scientific views on the draft document. The agency received scientific views until July 28, 2014 and is currently reviewing the scientific information it received. As of August 2014, the draft document is undergoing an independent, contractor-led, external expert peer review. After considering public and

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[1] Pond, G.J., M.E. Passmore, F.A. Borsuk, L. Reynolds, and C.J. Rose. 2008. *Downstream Effects of Mountaintop Coal Mining: Comparing Biological Conditions Using Family- and Genus-Level Macroinvertebrate Bioassessment Tools.* J. N. Am. Benthol. Soc. 27(3):717-737.
U.S. Environmental Protection Agency. *A Field-Based Aquatic Life Benchmark for Central Appalachian Streams (Final Report).* 2011. EPA-600-R-10-023F, Appendix C.
U.S. Environmental Protection Agency. *The Effects of Mountaintop Mines and Valley Fills on Aquatic Ecosystems of the Central Appalachian Coalfields* (Final Report). 2011. EPA-600-R-09-138A.

expert peer review feedback, the EPA will revise and publish the draft criterion document and subsequently again request public comment. Once finalized, the EPA's water quality criterion for selenium will provide recommendations to states and tribes authorized to establish water quality standards under the Clean Water Act. The EPA anticipates issuing final water quality criteria for selenium in 2015.

b. What is EPA's strategy for incorporating relevant scientific critiques and comments EPA receives into its final Selenium criteria?

Answer: As described above, the EPA has requested scientific views on its external peer review draft document, and also will be soliciting independent scientific peer-review comments on the document. The EPA will consider both public and peer review comments in revising the document prior to issuing a proposed criterion. The EPA will then again solicit and consider public comments on the proposed criterion, and revise the proposed criteria appropriately, prior to issuing final criteria. The EPA will also develop and publish summaries of how it addressed public and peer review comments it received on the draft criterion.

c. How is EPA taking the site-specific nature of Selenium issues into account when developing the national standard?

Answer: The EPA's draft selenium criterion takes into account a large national data set of measured selenium concentrations in aquatic systems, while also providing guidance on developing site-specific criteria. The draft criterion reflects a large database containing paired environmental measurements of selenium in water, fish, plankton, invertebrate species, and detritus from numerous sites as the basis for the national criterion, based on a peer reviewed, well-accepted model of selenium bioaccumulation developed by U.S. Geological Survey scientists (Presser and Luoma, 2010).[2] The model applied in the EPA's draft also enables development of site-specific selenium criteria through a scientific, rigorous analysis process provided in the text and appendices of the draft document. At the EPA's request, the USGS has provided technical comments on EPA's implementation of the model in this instance, including comments related to procedure, process, and inputs.

Court Cases- *National Mining Association v. Jackson*

Question 4: The U.S. District Court for the District of Columbia in the case of NMA v. Jackson recently struck down several EPA actions- specifically, EPA's Enhanced Coordination Process (ECP) and Multi-Criteria Integrated Resource Assessment (MCIR) for Appalachia surface coal mining, as well as EPA's guidance document, "Improving EPA Review of Appalachian Surface Coal Mining Operations Under the Clean Water Act, National Environmental Policy Act, and the Environmental Justice Executive Order" - as violating the CWA and Administrative

[2] Presser and Luoma, 2010. A Methodology for Ecosystem-Scale Modeling of Selenium. Integrated Environmental Assessment and Management. 6: 685-710.

Procedure Act, as well as, in the case of the guidance document, the Surface Mining Control and Reclamation Act. In your confirmation hearing, you stated that the Agency has directed its field offices not to use the guidance documents affected by the court decision. However, very few mining permits have been issued since the decision.

How does that outcome comport with the District Court's decision, and what additional steps do you think are needed to adhere to the District Court's decision?

Answer: On July 11, 2014, the U.S. Court of Appeals for the District of Columbia Circuit reversed the D.C. District Court's decision that set aside the EPA-Corps Enhanced Coordination Procedures and the EPA's July 21, 2011 final guidance on Appalachian surface coal mining operations.

The EPA is not the permitting authority in Appalachia for either Section 402 or Section 404 of the Clean Water Act. However, the EPA does provide comments on draft Section 402 permits developed by Appalachian States, and on Section 404 public notices issued by the U.S. Army Corps of Engineers. The EPA continues to review draft Clean Water Act permits and public notices and is eager to resolve any issues that arise in order to facilitate timely permitting, consistent with best-available science and the law.

Court Cases -*Mingo Logan Coal Co. v. EPA*

Question 5: In March, 2012, the U.S. District Court for the District of Columbia struck down EPA's retroactive revocation of a mining-related CWA Sec. 404 permit, holding unequivocally that EPA has no authority to retroactively veto CWA Sec. 404 permits issued by the U.S. Army Corps of Engineers. However, EPA appealed that decision and in April of 2013, the U.S. Court of Appeals for the District of Columbia reversed the decision of the District Court.

a. What do you think the practical effect on industry would be of having Sec. 404 permits be subject to EPA's veto even years after permit issuance and even if the permittee is in full compliance with the terms of the permit?

Answer: The EPA takes very seriously the authority provided to the Agency by Congress, pursuant to Section 404(c) of the Clean Water Act (CWA), to determine whether discharges of dredged or fill material into a specified site in waters of the U.S. would result in an unacceptable adverse effect on municipal water supplies, shellfish beds and fishery areas, wildlife, or recreational areas. Indicative of the EPA's thoughtfulness in using this authority is the fact that the Agency has completed 13 Final Determinations since 1972 pursuant to CWA Section 404(c) – only three of which were in connection with projects for which Section 404 permits had issued already. To put this in perspective, over the same period of time, the Corps of Engineers is estimated to have authorized more than two million activities in waters of the U.S. under the CWA Section 404 regulatory program. As these numbers demonstrate, the EPA has worked successfully with the Corps and permit applicants to

resolve concerns without exercising its Section 404(c) authority in all but a miniscule fraction of cases.

As you are aware, this matter remains in litigation, so the EPA is unable to discuss this matter in greater detail.

b. During deliberations on the Clean Water Act in Congress, Senator Muskie noted that there are three essential elements to the Clean Water Act– "uniformity, finality, and enforceability". How do the assertions made by EPA regarding the scope of its authority under Sec. 404 comport with the notion of permit finality? How have you, pursuant to your testimony at your confirmation hearing, worked to implement the CWA to provide uniformity, finality and enforceability?

Answer: Please see response to question 5(a) above.

Bristol Bay Draft Watershed Assessment

Question 6: In response to petitions from environmental organizations to initiate a 404(c) veto process for a potential mine site in Bristol Bay before a permit application was submitted, EPA - pointing to its authority under CWA Sec. 104 - initiated a draft watershed assessment that involved the crafting of a hypothetical mining scenario in Bristol Bay.

a. EPA has stated that the assessment will not have any legal consequences, but also that it is intended to provide a scientific and technical foundation for decision-making. How exactly does EPA intend to utilize this study under your leadership?

Answer: The EPA conducted the Bristol Bay Watershed Assessment to better understand the Bristol Bay watershed and its resources. As a scientific report, the final assessment did not recommend policy or regulatory decisions. The EPA believes the final assessment can serve as a valuable resource for the public and for federal, state, and tribal governments as they consider how best to address the challenges of mining and ecological protection in the watershed.

Separate from the Bristol Bay Assessment but based in part on the results of that assessment, on February 28, the EPA announced that the agency was initiating a process under the Clean Water Act to identify appropriate options to protect the world's largest sockeye salmon fishery in Bristol Bay, Alaska, from the potentially destructive impacts of the proposed Pebble Mine. The EPA based its action on available information, including data collected as part of the agency's Bristol Bay Watershed Assessment as well as mine plans submitted to the U.S. Securities and Exchange Commission. On July 18, EPA Region 10 issued a Proposed Determination pursuant to Section 404(c) of the Clean Water Act and is currently seeking public comments on its proposal. The EPA held seven public hearings from August 12-15 at which the public could provide oral or written comments to the agency. EPA Region 10 will also meet with tribes for formal consultation. Following the close of the public

comment period, EPA Region 10 will review public comments on its proposal and consider next steps in the process, which could include moving toward a Recommended Determination to the EPA Assistant Administrator for Water.

b. EPA has full authority under the well-established Sec. 404 process to review any future permit application submitted to make a determination as to whether or not there will be any of the unacceptable adverse effects listed in CW A Sec. 404(c) at the disposal sites being considered by the U.S. Army Corps of Engineers, including unacceptable impacts to fishery areas and wildlife. Why, then, is EPA using its limited resources to conduct a watershed assessment on a hypothetical mining scenario that even EPA's scientific review panel found did not accurately reflect the conditions of a real mine, rather than allow the companies that have invested millions of dollars to submit their proposal which EPA would then review?

Answer: As described above, the EPA developed the Bristol Bay Watershed Assessment in response to petitions from nine federally recognized tribes and other stakeholders who asked us to take action to protect Bristol Bay's salmon populations. They expressed concern that the Bristol Bay salmon fishery would be at risk from the potential Pebble Mine. We also heard from other tribes and stakeholders who support development in the Bristol Bay watershed and have requested that the EPA take no action and allow a typical permitting process to proceed. In light of the agency's important Tribal Trust and consultation responsibilities and the significant fishery resources of Bristol Bay, the agency decided to conduct a scientific assessment to understand how large-scale mining could potentially affect water quality and salmon ecosystems in the watershed. As described above, the EPA believes that its final assessment is valuable to the public and for federal, state, and tribal governments as they consider how best to address the challenges of mining and ecological protection in the watershed.

c. What impact do you think EPA's actions with respect to Bristol Bay will have on investment in U.S. property and natural resource development?

Answer: As noted above, EPA Region 10 recently issued a Proposed Determination pursuant to Section 404(c) of the Clean Water Act and is currently seeking public comments on its proposal. Through this process, the agency will work to identify appropriate options to protect the world's largest sockeye salmon fishery in Bristol Bay, Alaska, from the potentially destructive impacts of the proposed Pebble Mine. The agency made clear that its action reflects the unique nature of the Bristol Bay watershed as one of the world's last prolific wild salmon resources and the threat posed by the Pebble deposit, a mine unprecedented in scope and scale. The agency also made clear that its action does not reflect any EPA policy change with respect to mine permitting.

d. Has EPA considered the positive environmental justice impacts high-paying jobs and tax revenue will have on the region?

Answer: As part of the EPA's development of the Bristol Bay Watershed Assessment, the agency reviewed existing information on salmon fishery economics, which provided important contextual information about the importance of the salmon fishery. This information is provided in Volume 2, Appendix E of the final Bristol Bay Watershed Assessment.[3] However, the agency's watershed assessment did not represent a cost-benefit analysis of mining or fishing, nor did it present an evaluation of the economic viability or economic impacts of any proposed large-scale mining project.

QUESTIONS FOR THE RECORD
The Honorable Steve Stockman (R-TX)
U.S. House Committee on Science, Space and Technology
Strengthening Transparency and Accountability within the Environmental Protection Agency

Interagency Taskforce on Development of Unconventional Natural Gas Resource

Background Statement on Task Force:

- On April 13, 2013, the President signed an executive order (EO) forming an interagency Task Force to support the safe and responsible development of unconventional natural gas resources.
- In the Policy section of that EO the president states that "it is vital that we take full advantage of our natural gas resources" while doing it safety.
- The EO outlines the function of the Task Force as coordinate agency policy activities, sharing scientific and economic information, long-term research and infrastructure planning and consultation among agencies.
- EPA is a member of that task force at the Deputy level according to the EO.

Question 1: Mrs. McCarthy, who is EPA's representative to this Task Force and how often does it meet?

Answer: The EPA's interim representative to the Task Force is Acting Deputy Administrator Lisa Feldt. An outgrowth of the Task Force meetings was greater support for interagency efforts to coordinate high priority research associated with safely and prudently developing unconventional oil and gas (UOG) resources through the Federal Multiagency Collaboration on Unconventional Oil and Gas Research. The EPA, the Department of the Interior and the Department of Energy have each contributed policy and technical officials to the Collaboration's Steering Committee. Through this team and the creation of a Technical Subcommittee, comprised of DOI, DOE, EPA, and Department of Human Health Services scientists and engineers, the agencies help foster research collaboration and coordination. The collaboration's Steering Committee has been meeting on a weekly basis.

[3] The final assessment and its appendices are available at http://cfpub.epa.gov/ncea/bristolbay/recordisplay.cfm?deid=253500.

Question 2. Have you personally been briefed on the Task Force activities?

Answer: I am regularly briefed on the EPA's research activities, including our collaboration and coordination with fellow federal agencies.

Question 3: Can you provide an update to this Committee today on EPA's activities and focus areas as a member of this Task Force?

Answer: The DOE, DOI and EPA continue to coordinate and collaborate on research devoted to UOG production to conduct timely scientific and technology research. A significant part of this effort involves the overall sharing of information among the agencies. The three agencies have also engaged other Federal partners and stakeholders through a variety of mechanisms. Together the agencies have finalized a strategy document that identifies current and future research needs, and highlights projects that are both underway and could be undertaken to address these needs, available at (http://unconventional.energy.gov).

Question 4: There are a number of Executive Branch departments and agencies engaged in some fashion in unconventional resource development. Can you provide your opinion on the level of coordination on policy activities, sharing of information and, in particular, and your thoughts on long-term research in the area of infrastructure planning?

Answer: As mentioned above, EPA, DOE, and DOI are coordinating their research efforts devoted to high priority research associated with safely and prudently developing UOG resources. A major part of this effort involves the sharing of information among the agencies.

Question 5: Last week, Interior Secretary Jewell said that there is a lot of misinformation about fracking and that quote "Fracking has been done safely for many, many years."

a. Do you agree with Secretary Jewell that fracking has been done safely for many years?

Answer: Responsible development of America's unconventional oil and natural gas resources offers important economic, energy security, and environmental benefits. The EPA is committed to working with states and other stakeholders to understand and address potential concerns with unconventional oil and gas development so the public has confidence that it will proceed in a safe and responsible manner. In so doing, we will continue to follow a transparent, science driven approach with significant stakeholder involvement. The EPA continues to move forward on our national research study on the potential impacts of hydraulic fracturing for oil and gas on drinking-water resources in response to a request from Congress. The agency is working in consultation with a variety of stakeholders and has provided many opportunities for the exchange of information and input on the study design and the research as it progresses.

b. What parts of the fracking process do you feel are being done safely?

Answer: Responsible development of America's unconventional oil and natural gas resources offers important economic, energy security, and environmental benefits. As stated earlier, the EPA is committed to studying and addressing potential concerns related to unconventional oil and gas development so that the public has confidence that it will proceed in a safe and responsible manner. In so doing, we will continue to follow a transparent, science-driven approach with significant stakeholder involvement.

c. Are there any parts of the fracking process that you feel are not safe?

Answer: See (b) above.

Credibility and Ability of EPA Science

Background Statement on EPA Science

- In 2009 legislation, Congress directed EPA to conduct a study on hydraulic fracturing and groundwater.
- Rather than following the statute –how HF affects groundwater-EPA has outlined a sprawling study plan that goes well beyond groundwater issues.
- EPA initially did not recognize this as a "highly influential" study subject to OMB's Peer Review Bulletin, has not been able to garner an industry partner in conducting perhaps the most important aspect of its study plan – the "before and after" prospective study, and also had an EPA science debacle when its scientists independently pursues research in Pavillion, WY.
- Today, at the end of 2013, EPA still has not issues the study and we are told not to expect it until 2016.

Question 1: Can you please describe for us what happened with the study of effects of hydraulic fracturing on Water? Why it got so far off course, and what EPA is doing to get this effort back on track? What do you think this says about the state of EPA's science process and its ability to be timely and relevant?

Answer: EPA is conducting an assessment of the potential impacts of oil and gas hydraulic fracturing activities on drinking water resources in the United States. The study scope was designed to meet Congress' request and was established in November 2011 in the Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources, after public comment and peer review by the Science Advisory Board. The scope has not changed since the release of the final study plan. The assessment will represent the state of the science on this topic as supported by an extensive review of the literature, results from recently completed EPA research projects, and input from states, industry, non-government organizations, the public, and other stakeholders. We remain committed to providing a high quality scientific document.

a. Can you please explain the decision to conduct a sprawling study rather than investigate the narrow question Congress posed?

Answer: The scope of the *EPA's Study of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources*, which was supported by the Science Advisory Board, was designed to be responsive to the request from Congress. There has been no expansion of the scope beyond the original appropriations language.

b. Can you please explain the initial decision not to designate this as a "highly influential" document subject to OMB's Peer Review process?

Answer: The EPA designated the report a Highly Influential Scientific Assessment. There was no initial decision to not designate the report as such.

c. I am concerned that EPA has not been able to get any industry partners for the before-and-after prospective case study. Can you please explain the apparent impasse between EPA and industry stakeholders on the issue? Can you please describe the issues around protocols around the study that we hear is one source of friction between EPA and industry?

Answer: We have worked closely with industry partners to try to identify suitable locations for prospective case studies that meet the scientific needs of the study and industry's business needs. We continue to explore opportunities and, so far we have not identified a suitable location. For a location to be suitable, it is necessary to gather a minimum of one year of characterization data for ground water and surface water prior to and following unconventional exploration activities in the study area, and for there to be no other hydraulic fracturing activities on adjacent properties, during the entire study period, which could last several years.

d. I would note that the University of Texas, EDF and 9 companies partnered for a landmark study to look at emissions from oil and gas operations. That study took about a year. This tells me that industry partnerships are possible and that your agency should be able to find common ground with industry to conduct the study.

EPA's Role in Assuring the Public that Fracking is Safe

Background Statement on EPA's Role in Public Confidence:

- In that same interview last week, Secretary Jewell called on industry to educate the public on safety of hydrofracking
- I agree, and it would seem to me that industry is trying to do just that:
  - Industry is participating with NGO's and academics to confirm the low emission rates of methane
  - Industry is implementing more stringent standards for drill sites, well bores and air emissions

- Industry is working with states to implement more stringent regulatory requirements to further assure the safety of their operations
- Industry has stepped up to the plate to try and educate the public on the safety of their operations

- However, EPA has not been so helpful:
  - You publish ground water contamination studies that are then discredited and withdrawn
  - You don't rebut flawed air emission studies that report methane emissions an order of magnitude higher than EPA's estimates
  - Last week in testimony before the Senate EPW, your Director of Atmospheric Programs (Ms. Sarah Durham) couldn't even make a positive statement about the UT/EDF air emissions study that basically confirmed EPA's estimate of emission from unconventional gas development operations

Question 1: Mrs. McCarthy, what role do you see EPA playing in assuring the public that unconventional oil and gas development, development that President Obama supports, is safe?

Answer: Responsible development of America's unconventional oil and natural gas resources offers important economic, energy security and environmental benefits. The EPA is working with stakeholders to help ensure that oil and gas development is done in a safe and responsible manner. In particular, the EPA is working in partnership with states, which have key regulatory authority relevant to unconventional oil and natural gas extraction. The goal of EPA's drinking water assessment report is to help eliminate any potential impacts to drinking water from unconventional oil and gas development.

Question 2: Do you agree that EPA mis-steps around groundwater contamination can lead to a loss of public confidence?

Answer: In its groundwater investigations, the EPA took action when the agency became aware of information indicating potential threats to human health. The EPA's actions generally focused on obtaining additional data and information in an effort to better understand and assess potential threats to public health and the environment. The agency consulted with its state and tribal partners prior to taking such measures and shared data and information with homeowners, the relevant state agencies and, where applicable, tribal authorities. In each case, the EPA relied upon sound science as it sought to provide clarity to these stakeholders and ensure that public health was protected, while working closely with individual states. The EPA will continue to work with state partners and other stakeholders to help ensure that oil and gas extraction is done in a safe and responsible manner.

Question 3: Do you agree that failure to acknowledge reports confirming your own emission estimates and failure to discredit obviously flawed reports can lead to a loss of public confidence?

Answer: The EPA continues to use the best available data to produce its estimates of GHG emissions in the U.S. Greenhouse Gas Emissions and Sinks Inventory (Inventory). In recent years, the natural gas sector has experienced significant growth and changes in industry practices, and only recently have newer data and studies become available to improve our understanding of emissions for these sources. In the Inventory, the EPA discusses relevant information and data available on emissions from the oil and gas sector from reports that confirm, as well as conflict with the EPA estimates.

Recently, the EPA received new information and data related to the oil and gas sector emission estimates through the annual Inventory preparation process, the formal public notice and comment process of the proposed oil and gas New Source Performance Standards for volatile organic compounds, and through a stakeholder workshop on the natural gas sector emissions estimates. All relevant information provided was carefully evaluated, and updates were made to two key sources: liquids unloading, and completions with hydraulic fracturing and workover with hydraulic fracturing (re-fracturing). The EPA updated its estimates for liquids unloading using new industry data sets, and used data reported to the Greenhouse Gas Reporting Program (GHGRP) to develop a revised method for hydraulically fractured well completions and workovers. As expected, incorporating newly available data has resulted in changes to emissions estimates for the oil and gas sector overall. Updating estimates with newly available data is part of the EPA's standard process for improving the Inventory, and we look forward to receiving feedback on the EPA's approach and use of the data through the Inventory review process.

Question 4: Can you see how EPA's silence on the wide range of hydrofracking issues being debated can lead to a loss of public confidence?

Answer: The EPA is helping build public confidence through several initiatives, first and foremost being the Agency's national research study on the potential impacts of hydraulic fracturing for oil and gas on drinking-water resources. The agency is working in consultation with a variety of stakeholders and has provided many opportunities for the exchange of information and input on the study design and the research as it progresses. Ultimately, the results of this study are expected to inform the public and provide policymakers at all levels with high-quality scientific knowledge.

The EPA is also working to provide regulatory clarity with respect to existing laws and use existing authorities where appropriate to enhance public health and environmental safeguards. For example, in February, the EPA released an interpretive memorandum to clarify requirements under the Safe Drinking Water Act's Underground Injection Control program, for underground injection of diesel fuels in hydraulic fracturing for oil and gas extraction. The agency also released technical guidance containing recommendations for EPA permit writers to consider in implementing these UIC Class II requirements.

In addition, on May 9, 2014, the EPA issued an Advance Notice of Proposed Rulemaking

under Toxic Substances Control Act sections 8(a) and 8(d) seeking public comment on what information should be reported and disclosed for hydraulic fracturing chemicals and mixtures and the approaches for obtaining this information, including non-regulatory approaches. EPA is also soliciting input on incentives and recognition programs that could support the development and use of safer chemicals in hydraulic fracturing. This public process will help inform EPA's efforts to promote the transparency and safety of unconventional oil and gas activities. The public can provide comments through September 18, 2014. The EPA also anticipates moving forward on revisions to existing technology-based wastewater regulations to provide additional controls on discharges to wastewater treatment plans associated with the unconventional oil and gas extraction industry.

In addition, in 2012 the EPA finalized the first federal air regulations for natural gas wells that are hydraulically fractured, along with requirements for several other air emission sources in the oil-and-gas industry that were not regulated at the federal level. A key component of the final rules is expected to yield a nearly 95 percent reduction in volatile organic compounds emitted from more than 11,000 new hydraulically fractured gas wells each year. To help reduce burdens on operators and regulators while achieving environmental benefits, the 2012 rule provides for an alternative to submission of voluminous hard copy well completion records as part of annual compliance reports. Specifically, this "NextGen Compliance" alternatives allows operators to document compliance with the green completion requirements by submitting well identification information and digital photographs (bearing the time, date, and geographic coordinates) of green completion equipment in operation at the well during flowback following hydraulic fracturing.

Question 5: Secretary Jewell, less than 6 months into the job, is trying to instill some confidence with the public on hydrofracking – isn't it time EPA do so as well?

Answer: As detailed in #4, above, the EPA is moving forward on a wide variety of initiatives related to hydraulic fracturing. The agency is seeking to identify innovative approaches that could result in greater environmental benefits and transparency while remaining mindful of the importance of this sector to our country. We are continuing to look at further opportunities for the EPA to support implementation by states and industry of hydraulic fracturing best practices.

Clean Air Science Advisory Committee Transparency and Accountability Issues

Background

- On September 11, the EPA Inspector General released a final report titled *"EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees"*.
- The report raised a number of alarming issues regarding the operation of EPA's Clean

Air Science Advisory Committee (CASAC) and leaves many unanswered questions.

- CASAC is the advisory committee that during the past five years has recommended dramatic reductions in standards for nitrous oxides, sulfur oxides, particulate matter and ozone.
- The current ozone standard is under review again by CASAC and they are expected to make yet another recommendation to dramatically lower the ozone standard.

CASAC Financial Conflicts of Interest and Independence

Background on Financial Conflicts of Interest and Independence:

- CASAC members and contract advisors, or research institutions they are affiliated with, receive substantial grants from EPA for air quality research.
- In one case, Dr. Jonathan Samet, or his affiliated research institutions received almost $30 million dollars in EPA grants for research; Dr. Samet was the chair of the PM CASAC and currently serves on the ozone CASAC.
- In fact, several serving CASAC members have received over $1 million dollars from EPA for research.
- The IG Report confirms that a CASAC member's research grant is a potential area of concern if the Committee plans to address work ·performed under the research grant.
- Despite the millions in grant funding to CASAC members, it is unclear from the Report whether anyone actually investigated to see if those grants compromised their independence.
- The IG also found 9 instances where steps taken to mitigate independence or partiality matters were either not adequately documented or needed additional steps to sufficiently address potential independence or partiality concerns.
    - This included two instances where CASAC members contributed to studies or sections of CASAC reports under review by the CASAC panel creating a situation where they were opining on their own work.

Question 1: Mrs. McCarthy, it's hard to know where to start. EPA is selecting advisors that are receiving millions of dollars from EPA for research. According to the IG Report, some of the selected advisors were also found to be reviewing or opining on elements of their own work; and that the Agency is not following existing agency procedures regarding conflicts of interest, or taking steps to mitigate issues when they are identified. What steps is EPA taking in light of the IG Report to assure that the current CASAC ozone panel is impartial?

Answer: The Inspector General (IG) concluded that the EPA Science Advisory Board Staff Office "has adequate procedures for identifying independence and impartiality concerns," (EPA Office of Inspector General, Report No. 13-P-0387, Sept. 11, 2013) but called for better documentation when members with independence concerns or the appearance of a lack of

impartiality as defined in 5 C.F.R. 2635 are allowed to serve.

For the current ozone panel, the EPA has evaluated and will continue to evaluate experts on the basis of their confidential financial disclosures, responses to the four supplemental ethics questions on the Confidential Financial Disclosure Form (EPA Form 3110-48) and other information gathered by the EPA staff. The EPA Form 3110-48 requests detailed information about candidates' employment, consulting and volunteer work, compensated expert testimony; sources of research or projecting funding, assets and information to determine any loss of impartiality. The form requests experts to respond to four supplemental ethics questions with respect to the review document under consideration:

1. Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the panel/committee/subcommittee or any reason that your impartiality in the matter might be questioned?
2. Have you had any previous involvement with the review document(s) under consideration including authorship, collaboration with the authors, or previous peer review functions? If so, please identify and describe that involvement.
3. Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
4. Have you made any public statements (written or oral) on the issue that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

In its ethics review, the EPA strives to ensure that panel members are fair-minded scientific and technical experts, free from conflicts of interest and the appearance of a loss of impartiality as defined in 5 C.F.R. 2635, and possessing the ability to engage in constructive discussions among scientists with disparate perspectives. The EPA follows required legal procedures and documents any special circumstances when members with conflicts of interest or the appearance of a loss of impartiality as defined in 5 C.F.R. 2635 are allowed to serve on a panel. The EPA also documents its resolution of any question that may be posed related to independence or lack of objectivity of an expert allowed to serve on a panel.

Question 2: Please explain to me why the CASAC recommendation last year to lower the PM standard, a recommendation the EPA took, was not biased or not independent given these serious findings by the IG?

Answer: We could find nothing in the IG report (EPA Office of Inspector General, Report No. 13-P-0387, September 11, 2013) that would call into question the impartiality of the recommendations of the CASAC Particulate Matter Review Panel.

Question 3: Will you commit here today not to select CASAC members and consultants that receive EPA funding for NAAQS related air quality research? There are certainly plenty of qualified individuals out there not on EPA's payroll.

Answer: Consistent with OMB guidance and other federal agency practice, the EPA does not consider the current or past receipt of EPA grants generally to be an appearance of a loss of impartiality, but instead considers information about the EPA grants as they relate to the specific advisory activity. The EPA will continue to follow guidance issued from the Office of Management and Budget that states that "When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects. This contrasts, for example, to a situation in which a scientist has a consulting or contractual arrangement with the agency or office sponsoring a peer review." (Joshua Bolten, Director, Office of Management and Budget, Issuance of OMB's Final Information Quality Bulletin for Peer Review, 12-16-04.)

CASAC Lack of Impartiality

Background:

- Federal ethics regulations require CASAC members to avoid appearances of a lock of impartiality.
- EPA's Peer Review Handbook states that experts that have made public pronouncements on an issue may lack impartiality and should be avoided; and that individuals who have "taken sides" should be avoided.
- In 2008, EPA selected Jonathan Samet as Chair of CASAC even though he had published an article in 2006 opposing EPA's current PM standard.
- As Chair of CASAC, Dr. Samet presided over the review of the PM standard and made recommendations to lower the PM standard.
- Dr. Samet failed to disclose the public statement in the disclosure form that specifically asked if he "made any public statements, written or oral, on the issue that would indicate to an observer that you have taken a position on the issue under consideration. "
- CASAC members are also required to update this form annually and to participate in an ethics training course.

Question 1: Has anyone at EPA asked Dr. Samet why he omitted this important information despite a direction question on his form?

Answer: Dr. Samet provided information about his public statements. In 2006, the Confidential Financial Disclosure Form (EPA Form 3110-48) did not request information on public statements. However, Dr. Samet did disclose his 2006 editorial in the *American Journal of Respiratory and Critical Care Medicine* in an e-mail to Designated Federal Officer Fred Butterfield dated 1-31-06 in direct response to a question about past public statements.

Question 2: Did Dr. Samet submit a new financial disclosure statement annually while Chair? If so, did he continually omit disclosure of his public statements on all his forms?

Answer: Yes, Dr. Samet submitted annual disclosures. He did not omit disclosure of his public statements.

Question 3: Did Dr. Samet participate in all the required ethics training courses?

Answer: Yes

Question 4: Why did the SAB staff not check his publication list to see if a public statement had been made?

Answer: Dr. Samet did disclose his 2006 editorial in the *Am J Respir Crit Care Medicine (Vol 173, pp. 365-369)* in an e-mail dated 1-31-06 to Designated Federal Officer Fred Butterfield.

Question 5: Why aren't the financial disclosure forms (in whole or part) made public to allow the public to assist in reporting financial or potential impartiality conflicts?

Answer: Financial disclosures are deemed confidential under 5 CFR 2634.901(d).

Question 6: If EPA had known, would the SAB staff have avoided Dr. Samet's appointment as Chair of CASAC?

Answer: No. In fact, the EPA was informed of Dr. Samet's 2006 editorial cited above. The EPA considers the full picture of an individual's professional activities, including public statements, as well as the individual's reputation in the field. Given a scientist with a long track record of highly-regarded research and publications, it is reasonable to expect that he would reach conclusions based on his professional activities. Based on the totality of Dr. Samet's scientific credentials and published work, we did not and do not believe his statement is evidence that he is not objective and open-minded. Moreover, the National Academies[4] and other groups have stated that experts who have made public statements should not be excluded experts as long as they can be fair-minded in participating in advisory activities.

Question 7: Should EPA have a clearer policy of not appointing a person to a scientific advisory committee like CASAC if conclusive information has been provided showing a public statement has been made that suggests a clear bias (or removing them, if the evidence emerges after they have been appointed)?

Answer: The EPA's policy is stated above in response to questions 1 and 6.

Question 8: Given that the Chair of CASAC was clearly biased in his opinion prior to serving as Chair of the PM CASAC panel, did his participation undermine the ability of CASAC to provide independent advice during the 2012 PM review? Does that compromise the scientific validity of the resulting NAAQS?

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[4] The National Academies, "Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at http://www.nationalacademies.org/coi/bi-coi_form_0.pdf (Accessed 10/21/13).

Answer: No. The CASAC PM Panel developed scientifically credible and objective advice on the matters brought before it by the EPA.

The Honorable Dan Lipinski (D-IL)
U.S. House Committee on Science, Space and Technology
Strengthening Transparency and Accountability within the Environmental Protection Agency

Question 1: According to the EPA Inspector General, EPA violated Section 1605 of the American Recovery and Reinvestment Act, which plainly requires all public works projects funded by ARRA to use iron, steel, and manufactured goods that are produced in the United States. The IG found that submersible pumps and centrifugal blowers for wastewater treatment plants in Illinois were purchased from foreign companies that control no manufacturing facilities in the U.S. In addition, EPA has claimed that payments to American lawyers and marketing firms made these goods Buy American compliant. This incorrect interpretation of the law was perhaps the most disconcerting part of this incident because it could lead to future similar violations of Buy American laws. Can you tell me what steps the EPA has taken since this incident, and will take in the future, to prevent similar incidents? How will EPA ensure it doesn't spend taxpayer dollars on foreign goods when that money could be spent on American made items?

Answer: The EPA Office of the Inspector General (OIG) issued OIG Report 11-R-0700, "American Recovery and Reinvestment Act Site Visit of Wastewater Treatment Plant-Phase II Improvement Project, City of Ottawa, Ill.," on September 23, 2011. Two specific issues were raised by the report: first, that the wastewater treatment plant in Ottawa, IL, did not comply with the Buy American requirement of the American Recovery and Reinvestment Act (ARRA); and second, that the guidance provided by the Office of Water (OW) for compliance with the Buy American requirement was faulty and should be revised in accordance with OIG recommendations.

After initial discussions between OW and the OIG led to continuing disagreement about the legal requirements of the Buy American requirement, as well as the test described in the OW guidance, the matter was referred to the EPA's Chief Financial Officer for arbitration and resolution. No resolution was reached. The OIG, following resolution procedures, requested final resolution by the Acting Administrator of EPA. Both parties met with the Acting Administrator on April 1, 2013.

The OW guidance required a three-question test to determine whether substantial transformation of a manufactured good took place in the U.S. In order to prove that substantial transformation took place, only one of the three questions needed to be answered affirmatively. The first question addressed situations in which all components of a good were manufactured in the U.S. and assembled into the final product in the U.S. The second question addressed situations in which important processing work was done in the

U.S. prior to assembly. The third question, which addressed situations in which the most significant of the potentially transformative work in the U.S. is assembly of components into the manufactured good, was the only one at issue in this dispute. Under no circumstances would the hiring of American lawyers or marketing firms be a factor in determining whether a manufactured good was substantially transformed in the U.S. The OIG agreed that the use of a substantial transformation test was appropriate, but felt that the third question was not stringent enough.

On May 10, 2013, the Acting Administrator issued his final decision on the matter and concluded that the test as set out by OW was appropriate for use in determining whether manufactured goods were substantially transformed in the US and did not require revision. The decision memo resolved the OIG recommendation concerning the guidance and the alleged noncompliance on the Ottawa project.

In circumstances where a finding of noncompliance with the Buy American requirement was not disputed, the violating community was either required to remove the item in question and replace it with an American-made good, or if removal was impossible or impractical, the community was required to reimburse the State SRF program the cost of the non-U.S. item.

Question 2: A constituent company in my district, Seeler Industries, has had questions about enforcement of regulations made under the General Duty provision of the Clean Air Act. As you know, under the General Duty provision, companies have a general duty to maintain a safe facility preventing and minimizing the effects of releases of extremely hazardous substances. I completely support the principle behind this provision, but in practice this company has found that regional EPA inspectors have a wide authority to enforce the provisions they see fit. In addition, according to the company, the rules under the general duty provision may run counter rules promulgated by DHS for chemical safety. What are you doing to make clear to chemical companies what the requirements are for compliance with the general duty provisions? What are you doing to clarify jurisdictional issues between EPA and DHS on chemical safety?

Answer: The EPA has taken numerous steps to assist sources with complying with the General Duty Clause. For example, the EPA published detailed guidance (*Guidance for Implementation of the General Duty Clause Clean Air Act Section 112(r)(1)*, May 2000) and a fact sheet on the Clean Air Act General Duty Clause (GDC). The guidance is primarily intended to assist the EPA inspectors in promoting compliance with the GDC. However, it is a public document that establishes the agency's expectations for compliance, and is therefore also useful to owners and operators of covered facilities in understanding their obligations under the GDC. The fact sheet provides owners and operators of stationary sources with information on GDC compliance and also refers readers to the guidance for more detailed information. The GDC guidance documents, fact sheets and numerous chemical safety alerts that promote awareness of chemical hazards and provide information on safety measures that facilities can take to control or mitigate hazards can be obtained from the EPA's website: www.epa.gov/emergencies/guidance.htm#rmp.

The EPA has the authority to issue regulations and implement programs intended to prevent accidental chemical releases, and to minimize the consequences of such releases under CAA section 112(r)(7). In addition, many federal agencies have important roles and have specific statutory responsibilities in chemical safety and security that may impact chemical plant security. The EPA is focused on the prevention of and the preparation for chemical accidents arising from natural disasters or technological failure while the Department of Homeland Security (DHS) is focused on addressing acts of terrorism or other security-related concerns. Other agencies, such as the Occupational Safety and Health Administration in the Department of Labor, also have a role in preventing chemical disasters impacting workers. Each agency, in the course of fulfilling its mandates, coordinates its actions when it impacts roles of other agencies so that the policies implemented are complementary as allowed under current law.

The Honorable Mark Takano (D-CA)
U.S. House Committee on Science, Space and Technology
Strengthening Transparency and Accountability within the Environmental Protection Agency

Question 1: Thank you for your testimony before the House Committee on Science, Space and Technology on November 14, 2013. I appreciated learning more about your work at the Environmental Protection Agency, particularly your efforts to protect public health through enforcement of the Clean Air and Clean Water Acts.

On the Subject of clean water, I have additional questions pertaining to the proposed regulations that seek to clarity the bodies of water that should be subject to Clean Water Act jurisdiction. The EPA recently issues a draft scientific report on the connectivity of water, which remains under review by the Science Advisory Board. This report will serve as the scientific foundation for the proposed regulation.

As a member who represents a Southern California district, it is important that the members of the SAB who are putting together this report have an understanding of the water issues in the arid West. As you know, the water challenges and issues we face are vastly different from the Eastern and Midwestern parts of the U.S.

- What steps did the Agency take to ensure that the makeup of the SAB is "regionally" balances and more specifically, includes members who have a working understanding and knowledge of Western water issues?

Answer:

For the SAB Staff Office, a balanced committee or panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific

perspectives, and the collective breadth of experience to adequately address the Panel's charge. In forming the SAB Panel for the Review of the EPA Water Body Connectivity Report, the SAB Staff Office recognized the importance of selecting individuals who had knowledge of the connectivity of aquatic systems in different regions of the U.S. Therefore, a regionally balanced panel was selected. The Panel includes members who have knowledge of the connectivity of western aquatic systems and, in particular, arid west systems. Of the 27 individuals on the Panel, 3 are from the Northeast, 6 are from the South, 6 are from Midwest, and 12 are from the West. The expertise of the 12 members from western states is outlined below.

Dr. Allison Aldous, the Nature Conservancy

Dr. Aldous is a freshwater scientist with The Nature Conservancy in Portland, Oregon. She leads a major partnership between The Nature Conservancy and the U.S. Forest Service with the goal of improving the protection of groundwater-dependent resources on national forests across the U.S.

Dr. Lee Benda, Earth Systems Institute

Dr. Benda is a research geomorphologist at Earth Systems Institute in Mt. Shasta, California. He has been involved with the creation of NetMap, a community based system of tools and digital landscapes that provides consistent analytic stream layers and digital landscapes, coupled to analysis tools, across the western United States.

Dr. Kurt Fausch, Colorado State University

Dr. Fausch is a Professor in the Department of Fish, Wildlife, and Conservation Biology at Colorado State University in Fort Collins, Colorado. His research has focused on the importance of connectivity among critical habitats for fish in river hydroecosystems, and includes studies conducted throughout Colorado and the West, and worldwide.

Dr. Michael Gooseff, Colorado State University

Dr. Gooseff is an Associate Professor in the Department of Civil and Environmental Engineering at Colorado State University in Fort Collins, Colorado. He conducts research on stream-groundwater interactions.

Dr. Charles Hawkins, Utah State University

Dr. Hawkins is the Director of the Western Center for Monitoring and Assessment of Freshwater Ecosystems at Utah State University in Logan, Utah. He conducts research on the physical, chemical, and biotic condition of aquatic and riparian ecosystems.

Dr. Michael Josselyn, Wetlands Research Associates

Dr. Josselyn is a Principal with WRA, Inc. (Wetlands Research Associates) in San Rafael, California. He teaches an annual Wetland Delineator Certification course with a focus on arid west systems. He has completed wetland delineations in arid west systems including desert

dry washes, wet meadows in the Sierra Nevada Mountains, vernal pools in the Central Valley, and inland and coastal marshes.

Dr. Kenneth Kolm, Hydrologic Systems Analysis

Dr. Kolm is President/Senior Hydrogeologist and Hydrologic and Environmental Systems Specialist at Hydrologic Systems Analysis in Golden, Colorado. Dr. Kolm specializes in the fields of hydrogeology, geomorphology, and hydrologic and environmental systems analysis.

Dr. Mark Murphy, Hassayampta Associates

Dr. Murphy is a principal scientist at Hassayampta Associates in Tucson, Arizona. Dr. Murphy's research has focused on the connectivity in arid fluvial systems. He was a Principal Investigator for the Arid West Water Quality Research Project.

Dr. Duncan Patten, Montana State University

Dr. Patten is Director of the Montana Water Center and Research Professor with the Department of Land Resources and Environmental Sciences at Montana State University in Bozeman, Montana. He is also Professor Emeritus in the School of Life Sciences and past director of the Center for Environmental Studies at Arizona State University. His research interests include arid and mountain ecosystems, especially the understanding of ecological processes of riparian, wetland, and riverine ecosystems.

Dr. Jack Stanford, University of Montana

Dr. Stanford is the Director of the Flathead Lake Biological Station in Polson, Montana and is the Jessie M. Bierman Professor of Ecology at the University of Montana. He has conducted long-term studies in the Flathead River-Lake Ecosystem in Montana and British Columbia.

Dr. Maurice Valett, University of Montana

Dr.Valett is Professor of Systems Ecology at the University of Montana in Missoula, Montana. His research focuses on ecosystem ecology and biogeochemistry, nutrient retention in lotic ecosystems, groundwater-surface water exchange, floodplain river interactions, and wetlands and streams as flow-through systems.

Dr. Ellen Wohl, Colorado State University

Dr. Wohl is Professor of Geology in the Department of Geosciences at Colorado State University in Fort Collins, Colorado. Her research focuses on physical process and form in rivers, particularly headwater rivers, as these interact with ecological and human communities. She currently serves on the Grand Canyon Science Advisory Board.

Question 2: Recently, a document surfaces that appears to be the proposed water connectivity regulations that OMB is currently reviewing. If this is the proposed rule that was put forth by EPA and the US Army Corps of Engineers, it would appear that all tributaries will

be considered waters of the U.S. subject to regulations under the Clean Water Act. I have heard concerns that the language of the proposed rule could be broadly interpreted to encompass water conveyance and delivery systems.

- I have heard concerns that under the proposed rule it would be possible that the California Aqueduct and other features of California's vast water delivery system would be considered tributaries to be regulated under the Clean Water. Is that your understanding, how will it affect water delivery for tens of millions of Californians?

Thank you for your attention to my questions. I look forward to your response and continuing to work with you to protect our environment.

Answer: On March 25, the EPA and the U.S. Army Corps of Engineers released a proposed rule in order to provide additional clarity regarding the geographic scope of Clean Water Act jurisdiction and to improve national consistency and predictability. The comment period on the agencies' proposed rule will be open until October 20, 2014.

The agencies do not believe the proposed rule would change the jurisdictional status of water conveyance and delivery systems. However, the agencies look forward to further discussing the proposed rule with states and other stakeholders, including Western water utilities, to ensure that the agencies' rulemaking efforts provide greater clarity, preserve existing exemptions, and improve protections for our nation's waters. The agencies welcome comment on this issue, and the agencies will carefully consider such comments before publishing a final rule.

Appendix II

Additional Material for the Record

SUBMITTED STATEMENT OF REPRESENTATIVE ELIZABETH H. ESTY, MEMBER, COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY

SST Full Committee Hearing
Strengthening Transparency and Accountability
within the Environmental Protection Agency
Congresswoman Elizabeth H. Esty Statement for the Record
November 14, 2013

Thank you Chairman Smith and Ranking Member Johnson for holding today's hearing on the Environmental Protection Agency.

I am also pleased to welcome Administrator Gina McCarthy. Administrator McCarthy served as the Commissioner of the Connecticut Department of Environmental Protection and then as an Assistant Administrator of the United States EPA.

Administrator McCarthy, it is wonderful to see you again. Congratulations on your confirmation. You have an important role and responsibility as the head of the agency charged with protecting the environment and the public, and I appreciate all your hard work to that end.

In Connecticut we have seen firsthand the devastation of climate change. Last year Hurricane Sandy wreaked havoc, killing 285 people. According to FEMA, more than 23,000 people were temporarily displaced from their homes, and more than 8.5 million people lost power. As we continue to recover from the storm, we should be looking for ways to work together on commonsense solutions with the EPA to guard against future harms from superstorms that are becoming all too common in the wake of climate change.

Furthermore, the International Energy Agency announced earlier this week that the United States will become the world's top oil producer by 2015, and our country is estimated to be self-sufficient from an energy perspective in the next two decades. As we work to achieve energy independence, it is important that we work with the EPA to ensure safe and effective oil and gas exploration and production.

I am hopeful that Congress and the Environmental Protection Agency can work together to protect and support our citizens and our environment.

REPORT SUBMITTED BY REPRESENTATIVE DANA ROHRABACHER

MEMORANDUM March 12, 2013

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

From: Linda-Jo Schierow, Specialist in Environmental Policy, 7-7279, lschierow@crs.loc.gov

Subject: **EPA Grants to Members of Selected EPA Advisory Committees**

This memorandum responds to your request for information about current and past grants from the U.S. Environmental Protection Agency (EPA) to members of the following two federal advisory committees that serve the EPA:

- Clean Air Scientific Advisory Committee (CASAC); and
- Science Advisory Board (SAB).

The results were obtained by searching the EPA's National Center for Environmental Research (NCER) Project Database. Members of each committee and the amounts and titles of grants that supported their work are listed in **Table 1**, organized by committee. It is important to note that only EPA research grants are included in Table 1. The table excludes state and local government grants (some of which may ultimately be funded by a federal grant to the state or local entity), as well as grants provided by the private sector, although some committee members have received such grants.

Another key clarification is that while we refer to these grants as being "to" particular committee members, in fact they typically are to the academic institution where the member is employed, and only a very small proportion, if any, of the grant may be paid in the form of salary to the member. Committee members were identified only if they were listed as Principal Investigators or Co-Investigators, whose role generally is to lend expert advice and to oversee work done by graduate students or post-doctoral fellows. In some cases, grants are for major national research centers that house numerous research projects and potentially involve dozens of students and post-doctoral fellows and several professors. Funding for specific projects supported by these centers is not specified in the NCER database and not reported in Table 1. Similarly, some research grants were for projects that are funded through the public-private Health Effects Institute or university consortia known as Hazardous Substance Research Centers. The latter centers were established under the Comprehensive Emergency Response, Compensation, and Liability Act (CERCLA) section 311(d) and are jointly funded by EPA and the National Institute for Environmental Health Sciences. NCER does not provide funding information for these projects, and Table 1 does not include such information.

Finally, it is also important to note that grants may be listed more than once if they were received by several committee members. In addition, some grants are provided by multiple agencies, and the multi-agency total for the project may be stated in the database, although only a portion of the funding derives

from EPA's budget. For this reason it would be inappropriate to sum the grant amounts to obtain a total EPA funding amount across committee members or for any single committee member. Grant amounts are rounded to the nearest $1,000.

I hope that you find this information useful. Please call me if you would like further assistance.

Table 1. EPA Grants to Members of Two EPA Advisory Committees

Member	Affiliation	Grants
Clean Air Scientific Advisory Committee (CASAC)		
Frey, H. Christopher (Chair)	North Carolina State University (NC)	2010-2013, $500,000 - Framework for Context-Sensitive Spatially- and Temporally-Resolved Onroad Mobile Source Emission Inventories
		2008-2011, $893,000 - Spatial temporal analysis of health effects associated with sources and speciation of fine PM
		2004-2009, $680,000 - Advanced Modeling System for Forecasting Regional Development, Travel Behavior, and Spatial Pattern of Emissions
		1998-2001, $553,000 - Development and Demonstration of a Methodology for Characterizing and Managing Uncertainties in Emission Inventories
		1998-1999, $180,000 - Methods for Assessment of Pollution Prevention Technologies
		1998-2001, $329,000 - Probabilistic Modeling of Variability and Uncertainty in Urban Air Toxics Emissions
Allen, George A.	Northeast States for Coordinated Air Use Management (MA)	1998-2003, $3,000,000 - Investigations of Factors Determining the Occurrence of Ozone and Fine Particles in Northeastern USA
		1996-1999, $380,000 - Development and Validation of a Novel Technique to Measure Ambient Particle Properties: Bound Water, Mass Density, and Mean Diameter
		1998-2000, $527,000 - Time-Relevant Communication of Ozone and Particulate Air Pollution Data: A Pilot Project to Raise Public Awareness and Promote Exposure Reduction
Diez-Roux, Ana	University of Michigan (MI)	2011-2012, $556,000 – Center for Integrative Approaches to Health Disparities – Environment Assessment Core
		2006-2009, $576,000 - Heat-related Hospital Admissions Among the Elderly: Community, Socio-economic and Medical Determinants of Vulnerability and Economic Impacts
		2004-2014, $32,999,000 - Prospective Study of Atherosclerosis, Clinical Cardiovascular Disease, and Long-Term Exposure to Ambient Particulate Matter and Other Air Pollutants in a Multi-Ethnic Cohort
		2003-2006, $769,000 - Long-term Exposure to Ambient Particulate Matter and Subclinical Atherosclerosis
Harkema, Jack	Michigan State University	2011-2013, $600,000 – Environmental Transformation and Biological Fate of Fresh and Aged Cerium Oxide Nanoparticles
		2011-2013, $8,000,000 – Great Lakes Air Center for Integrative Environmental Research
		2005-2010, $8,000,000 – Southern California Particle Center
		2004-2007, $748,000 – Estrogen Elicited Gene Expression Network Elucidation in the Rat Uterus
		2001-2004, $855,000 – Effects of Airborne Particles on Allergic

Member	Affiliation	Grants
		Airway Disease
		1999-2005, $8,716,000 – Southern California Particle Center and Supersite
		2000-2005, (Funded by the Health Effects Institute) – Effects of Prolonged Ozone Inhalation on Rats (five specific studies)
Suh, Helen	University of Chicago (IL)	2005-2010, $3,215,000 - Harvard Particle Center
		2003-2006, $934,000 - Chronic Exposure to Particulate Matter and Cardiopulmonary Disease
		1999-2005, $7,747,000 - EPA Harvard Center for Ambient Particle Health Effects
Weathers, Kathleen	Cary Institute of Ecosystem Studies (NY)	None
Wyzga, Ronald	Electric Power Research Institute	None

Science Advisory Board		
Allen, David T. (Chair)	University of Texas (TX)	2012-2015, $500,000 - Analysis of Dynamic, Flexible NO_x and SO_2 Abatement from Power Plants in the Eastern U.S. and Texas
		2012-2015, $750,000 - Response of Regional Air Quality to Severe Drought
		2005-2008, $969,000 - Texas Joint Center for Air Quality
		2005-2007, $350,000 - Benchmarking Sustainability Engineering Education
		2004-2007, $650,000 - Predicting the Relative Impacts of Urban Development Policies and On-Road Vehicle Technologies on Air Quality in the United States: Modeling and Analysis of a Case Study in Austin, Texas
		2004-2005, $10,000 - Systems Approach to Recovery and Reuse of Organic Material Flows in Santa Barbara County to Extract Maximum Value and Eliminate Waste
		2003-2006, $750,000 - Impacts of Climate Change and Land Cover Change on Biogenic Volatile Organic Compounds (BVOCs) Emissions in Texas
		2000-2003, $325,000 - Development of Life Cycle Inventory Modules for Semiconductor Processing
		2000-2004 (Funded by the Gulf Coast Hazardous Substance Research Center) - Engineering of Nanocrystal Based Catalytic Materials for Hydroprocessing of Halogenated Organics
		2000-2004 (Funded by the Gulf Coast Hazardous Substance Research Center) - Catalytic Hydroprocessing of Chlorinated Wastes
		1997-2000 (Funded by the Gulf Coast Hazardous Substance Research Center) - Catalytic Hydroprocessing of Chlorinated Organics
Alexeeff, George	California Environmental Protection Agency (CA)	None
Alvarez, Pedro J.	Rice University (TX)	2009-2011, $400,000 - Interactions of Natural Organic Matter with C60 Fullerene and their Impact on C60 Transport, Bioavailability and Toxicity
		2008-2011, $400,000 - Effects of Quantum Dot on Microbial Communities
		2006-2009, $400,000 - The Effect of Surface Coatings on the Environmental and Microbial Fate of Nanoiron and Feoxide Nanoparticles
		2005-2008, $375,000 - Microbial Impacts of Engineered Nanoparticles
		2000-2002, $195,000 - Effect of the Gasoline Oxygenate Ethanol on the Migration and Natural Attenuation of BTEX Compounds in Contaminated Aquifers
		1995-1998, $246,000 - Biostimulation of BTX Degradation with Environmentally Benign Aromatic Substrates
		1993-2000 (Funded by the Great Plains/Rocky Mountain Hazardous Substances Research Center) – The Role of Metallic Iron in the

		Biotransformation of Chlorinated Xenobiotics
Arvai, Joseph	University of Calgary (Canada)	1999-2001, $228,000 - Understanding Observed Differences in Time-Preference Rates
Burbacher, Thomas	University of Washington	2000-2005 (Funded by the Health Effects Institute) - Effects of Prenatal Exposure to Inhaled Methanol on Nonhuman Primates and Their Infant Offspring
Benitez-Nelson, Claudia	University of South Carolina (SC)	1996-1998, $102,000 - Phosphorus Cycling in the Gulf of Maine: A Multitracer Approach
Burke, Ingrid C.	University of Wyoming (WY)	1996-1999, $1,590,000 - A Regional Assessment of Land Use Effects on Ecosystem Structure and Function in the Central Grasslands
Burke, Thomas A.	Johns Hopkins University (MD)	2008-2011, $500,000 - Longitudinal Indicators of Policy Impact on Pollution, Exposure and Health Risk
Carney, Edward T.	The Dow Chemical Company	None
Daniel, Terry	University of Arizona (AZ)	None
Daston, George	Procter and Gamble (OH)	None
Denson, Costel	Costech Technologies, LLC (DE)	None
Doering III, Otto C.	Purdue University (IN)	1996-1999, $1,394,000 - Integrated Assessment of Economic Adaptation Strategies for Climate Change Impacts on Midwestern Agriculture
Dourson, Michael	Toxicology Excellence for Risk Assessment (OH)	None
Ducoste, Joel	North Carolina State University	2009-2012, $570,000 - An Integrated Approach to Understanding and Reducing Fat, Oil, and Grease (FOG) Deposit Formation for Sustainable Sewer Collection Systems
Dzombak, David A.	Carnegie Mellon University (PA)	1998-2001, $610,000 – Evaluation of Natural Amelioration of Acidic Deep Mine Discharges for Watershed Restoration
		1997-1999, $499,000 - Bioavailability and Biostabilization of PCBs in Soil
Eighmy, T. Taylor	Texas Tech University (TX)	None
Faustman, Elaine	University of Washington (WA)	2009-2015, $5,417,000 (Funded jointly with the National Institutes of Health) - Center for Child Environmental Health Risks Research
		2005-2008, $750,000 - Integrating Innovative Biomarkers of Environmentally Induced Disease for Children in Agricultural Communities
		2003-2008, $3,652,000 - Center for Child Environmental Health Risks Research
		1998-2003, $3,545,000 - Center for Child Environmental Health Risks Research
		1996-1999, $391,000 – Improving Methods for Identifying Noncancer Risks Application of Cell Kinetic Models for Methylmercury Risk Assessment
Field, R. William	University of Iowa	2009-20013, $899,000 - Applying Data Assimilation and Adjoint Sensitivity to Epidemiological and Policy Studies of Airborne Particulate Matter

Frey, H. Christopher	North Carolina State University	2010-1013, $500,000 - Framework for Context-Sensitive Spatially- and Temporally-Resolved Onroad Mobile Source Emission Inventories
		2008-2012, $893,000 - Spatial temporal analysis of health effects associated with sources and speciation of fine PM
		2004-2009, $680,000 - Advanced Modeling System for Forecasting Regional Development, Travel Behavior, and Spatial Pattern of Emissions
		1998-2001, $553,000 - Development and Demonstration of a Methodology for Characterizing and Managing Uncertainties in Emission Inventories
		1998-2001, $329,000 - Probabilistic Modeling of Variability and Uncertainty in Urban Air Toxics Emissions
		1998-1999, $180,000 - New Methods for Assessment of Pollution Prevention Technologies
Giesy, John P.	University of Saskatchewan (Canada)	2004-2007, $750,000 - Chemical Induced Changes in Gene Expression Patterns Along the HPG-axis at Different Organizational Levels Using a Small Animal Model (Japanese medaka)
		1996-1998, $305,000 - Development of a Bioassay for AhR-mediated Toxicity to Rainbow Trout
Harris, Cynthia M.	Florida A & M University	None
Johnston, Robert J.	Clark University	2007-2008, $199,000 - Meta-Analysis and Benefit Transfer at Different Levels of Aggregation: Comparing Group-Averaged and Individual-Level Models Using Hierarchical Bayesian Methods
		2005-2008, $405,000 - Improved Valuation of Ecological Benefits Associated with Aquatic Living Resources: Development and Testing of Indicator-Based Stated Preference Valuation and Transfer
Jones, Kimberly L.	Howard University (DC)	Final report dated 2000, project years unspecified (Funded by the Great Lakes/Mid Atlantic Hazardous Substance Research Center) - Membranes for the Separation, Recovery, and Reuse of Surfactant/Contaminant Solutions
Kahn, Bernd	Georgia Institute of Technology (GA)	None
Karr, Catherine	University of Washington	1999-2004 (Funded by the Research Center for Particulate Air Pollution and Health) - Epidemiologic Study of Particulate Matter and Cardiopulmonary Mortality
Khanna, Madhu	University of Illinois at Urbana-Champaign (IL)	2003-2006, $252,000 - Oregon Business Decisions for Environmental Performance
		2003-2006, $287,000 - Pollution Prevention: The Role of Environmental Management and Information
		1999-2001, $242,000 - Business-led Environmental Management: Economic Incentives and Environmental Implications
Kim, Nancy K.	Health Research, Inc. (NY)	None
Laden, Francine	Harvard University and Brigham and Women's Hospital	2003-2006, $934,000 - Chronic Exposure to Particulate Matter and Cardiopulmonary Disease
		1999-2005, $7,747,000 - EPA Harvard Center for Ambient Particle Health Effects
Lue-Hing, Cecil	Cecil Lue-Hing & Assoc. Inc. (IL)	None

Matsui, Elizabeth	Johns Hopkins University	2009-2014, $4,250,000 - Johns Hopkins Center for Mechanisms of Asthma-Dietary Interventions against Environmental Triggers
		2003-2008, $4,046,000 - Johns Hopkins Center for Childhood Asthma in the Urban Environment
Menon, Surabi	ClimateWorks Foundation	None
Mihelcic, James R.	University of South Florida (FL)	2004-2005, $10,000 - P3 Design Project for an Interdisciplinary Team of Graduate Students: Development of Appropriate, Sustainable Construction Materials
		1997-1999 (Funded by the National Center for Clean Industrial and Treatment Technologies) - Development of Environmental Indices for Green Chemical Production and Use
Moe, Christine	Emory University (GA)	2009-2012, $600,000 - Measures of Distribution System Water Quality and Their Relation to Health Outcomes in Atlanta
		2004-2007, $590,000 - Examining Epidemiologic and Environmental Factors Associated with Microbial Risks from Drinking Water
		2004-2007, $1,223,000 - Drinking Water Quality and Emergency Visits for Gastroenteritis in Atlanta
		2002-2005, $1,821,000 - A Prospective Epidemiological Study of Gastrointestinal Health Effects Associated with Consumption of Conventionally Treated Groundwater
		1998-2001, $588,000 - Studies of the Infectivity of Norwalk and Norwalk-like Viruses
Moo-Young, Horace	California State University (CA)	None
Murphy, Eileen	Rutgers University (NJ)	None
Opaluch, James	University of Rhode Island (RI)	1998-2001, $325,000 - Environmental Policy and Endogenous Technical Change: A Theoretical & Empirical Analysis
		1995-1997, $126,000 - Developing Conjoint Stated Preference Methods for Valuation of Environmental Resources Within Their Ecological Context
Patten, Duncan	Montana State University (MT)	2005-2007, $293,000 - Land Use Land Cover Change Governing Watershed Nitrogen Threshold and Stream Water Quality
		1999-2002, $868,000 - Developing Effective Ecological Indicators for Watershed Analysis
Philbert, Martin	University of Michigan	1998-2003, $2,831,000 - Michigan Center for the Environment and Children's Health
Polasky, Stephen	University of Minnesota (MN)	1998-2001, $810,000 - Developing Methods and Tools for Watershed Restoration: Design, Implementation, and Assessment in the Willamette Basin, Oregon
		1998-2000, $131,000 - Land and Management with Biological and Economic Objectives
		1997-1999, $1,229,000 - Modeling Effects of Alternative Landscape Design and Management on Water Quality and Biodiversity in Midwest Agricultural Watersheds
		1996-1998, $271,000 - Decision-Making under Uncertainty in the Conservation of Biological Diversity
Pope, III, C. Arden	Brigham Young University (UT)	2011-2013, $300,000 - The Effect of Air Pollution Control on Life Expectancy in the United States

		2011-2014, $299,000 – Associations of Short-Term Pollution Exposures with Childhood Autoimmune Disease
		2000-2003, $797,000 – Relationship between PM2.5 Semi-volatile Organic Material, Other PM2.5 Components, and Heart Rate Variability in the Elderly
		2000-2005 (Funded by the Health Effects Institute) - Daily Changes in Oxygen Saturation and Pulse Rate Associated with Particular Air Pollution and Barometric Pressure
Roberts, Stephen M.	University of Florida (FL)	None
Rodewald, Amanda	The Ohio State University (OH)	None
Sanders, James	Skidaway Institute of Oceanography (GA)	None
Schlesinger, William	Cary Institute of Ecosystem Studies	None
Solomon, Gina	Natural Resources Defense Council (CA)	None
Stram, Daniel O.	University of Southern California (CA)	2005-2010, $8,000,000 - Southern California Particle Center
		1999-2005, $8,716,000 - Southern California Particle Center and Supersite
Thorne, Peter S.	University of Iowa (IA)	2004-2007, $335,000 - Impacts of Manufactured Nanomaterials on Human Health and the Environment - A Focus on Nanoparticulate Aerosol and Atmospherically Processed Nanoparticulate Aerosol
		1995-1998, $635,000 - Indoor Air Quality in Large Office Buildings in the Midwest
Tolbert, Paige	Emory University (GA)	2010-2015, $8,000,000 - The Southeastern Center for Air Pollution and Epidemiology: Multiscale Measurements and Modeling of Mixtures
		2009-2012, $599,000 - Measures of Distribution System Water Quality and Their Relation to Health Outcomes in Atlanta
		2008-2012, $900,000 - Improving Particulate Matter Source Apportionment for Health Studies: A Trained Receptor Modeling Approach with Sensitivity, Uncertainty and Spatial Analyses
		2007-2010, $500,000 - Development and Assessment of Environmental Indicators: Application to Mobile Source Impacts on Emissions, Air Quality and Health Outcomes
		2004-2007, $1,223,000 - Drinking Water Quality and Emergency Visits for Gastroenteritis in Atlanta
		2002-2004, $1,239,000 - Multiple Pollutants and Risk of Emergency Department Visits for Cardiorespiratory Outcomes in Atlanta
		1996-1999, $360,000 - The Michigan PBB Cohort 20 Years: Endocrine Disruption?
VanBriesen, Jeanne	Carnegie Mellon University	None
Vena, John	University of Georgia (GA)	2002-2004, $325,000 - Material Selection in Green Design and Environmental Cost Analysis
Zoeller, R. Thomas	University of Massachusetts (MA)	2004-2008, $739,000 - Low-Dose Effects of Thyroid Toxicants on Neurodevelopment

Source: Membership lists are from EPA websites at: "Members of the Advisory Council on Clean Air Compliance Analysis," http://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=COUNCIL&secondname=Advisory%20Council%20on%20Clean%20Air%20Compliance%20Analysis%20; "Board of Scientific Counselors, Executive Committee," http://www.epa.gov/osp/bosc/exec-comm.htm; "Members of the Clean Air Scientific Advisory Committee," http://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=CASAC&secondname=Clean%20Air%20Scientific%20Advisory%20Committee); "Members of the Science Advisory Board," (http://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=BOARD&secondname=Science%20Advisory%20Board); and "Scientific Advisory Panel, Members," http://www.epa.gov/scipoly/sap/members.htm. Grants are from the EPA National Center for Environmental Research (NCER) Project Database at (http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/search.welcome).

Notes: Grants are for projects identified for which the person in question is either a principal investigator or a co-investigator. Grants generally are assigned to the academic institution where the member is employed, and only a very small proportion, if any, of the grant may be paid in the form of salary to the member. In some cases, grants are for major national research centers that house numerous research projects and potentially involve dozens of students and post-doctoral fellows and several professors at several institutions. In some cases, grants are for major national research centers that house numerous research projects and potentially involve dozens of students and post-doctoral fellows and several professors. Funding for specific projects supported by these centers is not specified in the NCER database and not reported in Table 1. Similarly, some research grants were for projects that are funded through the public-private Health Effects Institute or university consortia known as Hazardous Substance Research Centers. The latter centers were established under the Comprehensive Emergency Response, Compensation, and Liability Act (CERCLA) section 311(d) and are jointly funded by EPA and the National Institute for Environmental Health Sciences. NCER does not provide funding information for these projects, and Table 1 does not include such information. Grant amounts are rounded to the nearest $1,000. Project funding amounts also may be listed more than once, because more than one committee member may receive funding from the same grant. In addition, some grants are provided by multiple agencies, and the multi-agency total for the project may be stated in the database, although only a portion of the funding derives from EPA's budget. For this reason it would be inappropriate to sum the grant amounts to obtain a total EPA funding amount across committee members or any single committee member.

LETTER SUBMITTED BY REPRESENTATIVE RANDY NEUGEBAUER

Bryan W. Shaw, Ph.D., P.E., *Chairman*
Toby Baker, *Commissioner*
Zak Covar, *Executive Director*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

November 8, 2013

Chairman Lamar Smith
Committee on Science, Space and Technology
2321 Rayburn House Office Building
Washington, DC 20515

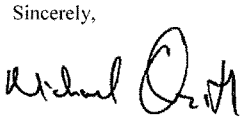
Dear Chairman Smith,

The following statement is based on review of the files your staff submitted to me on August 19th, September 13th and September 30th. The file names are listed in attachment 1.

The subpoena sent by the Committee on Science, Space and Technology to EPA Administrator Gina McCarthy dated August 1, 2031 requested "all analysis and re-analysis of" the Cancer Prevention Study II by the American Cancer Society (ACS) and the Harvard Six Cities (HSC) Studies. The files supplied to date do not fulfill this request. The ACS files do not contain sufficient information on mortality or other variables (age, air conditioning, alcohol use, body mass index, diet, education, employment, income, marital status, race, sex, smoking, and workplace exposure– all included variables in the Pope *et al.* 2002 study as well as the reanalysis by Krewski *et al.* in 2009). The HSC files contain coded data on mortality incidence and air quality, but no information on other variables (age, body mass index, education, race, sex, and smoking – all included variables in the Laden *et al.* 2006 study as well as the reanalysis by Lepeule *et al.* 2012). Furthermore, there is no information regarding the analysis of this data, including critical assumptions or choice of inputs, as would be required for the statistical tests applied (e.g. for Pope *et al.* 2002: Cox proportional hazards modeling with spatial autocorrelation and nonparametric spatial smoothing; for Krewski *et al.* 2009 the Land Use Regression results for industrial, residential, commercial, and agricultural categories are missing; and for Lepeule *et al.* 2012: the "rstrata" variable apparently codes for sex, age, and time period, but the codes are not defined).

In conclusion, the files provided to date lack critical information, making it impossible to replicate the findings of the ACS or HSC studies.

Sincerely,



Michael Honeycutt, Ph.D.
Director, Toxicology Division
Texas Commission on Environmental Quality

Attachment 1

Files Sent by Committee Staff and Reviewed by TCEQ

Sent August 19, 2013:
Copy of Pope etal 2009 NEJM analytic data and dictionary.xls
EPA Response 8-19-2013.pdf

Sent September 13, 2013:
09-13-2013 EPA Response.pdf
acszipec80.sas7bdat
airp_al.sas7bdat
houseincome.sas7bdat
IPm.dat
ipm_mas.ssd01
Krewski 2009 Data Set Descriptions.doc
lazips270.sas7bdat
ny_krige_lur.xls
o3new.sas7bdat
pm_7200.sas.7bdat
pm25_29.sas7bdat
smsa_gas.ssd01
so2_all.sas7bdat
tsp_8081.ssd01
zip267pm25lur.sas7bdat

Sent September 30, 2013:
Lepeule2012_data_0713 Final.xlsx
Lepeule2012_data_0713_datadictionary final.docx

LETTERS SUBMITTED BY REPRESENTATIVE MARK TAKANO

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

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

OCT 30 2013

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

Dear Mr. Chairman:

I am writing today to follow up on the commitments we made in our letter of July 30, 2013, to keep you apprised of certain information related to your interest in research data from certain epidemiological studies.

Enclosed, please find: a letter from Harvard University, dated September 25, 2013; a letter from Brigham Young University, dated August 1, 2013; a letter from the American Cancer Society, dated August 19, 2013; a letter from the Health Effects Institute, dated August 27, 2013; and, a letter from the Harvard School of Public Health, dated September 6, 2013.

Please feel free to contact me if you have any questions, or your staff may contact Tom Dickerson in my office at dickerson.tom@epa.gov or (202) 564-3638.

Sincerely,

Laura Vaught
Associate Administrator

Enclosures

cc: The Honorable Eddie Bernice Johnson
Ranking Member

HARVARD UNIVERSITY
Office for Sponsored Programs

Catherine Breen
Senior Director, Office for Sponsored Programs
catherine_breen@harvard.edu

Holyoke Center, Suite 635
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September 25, 2013

BY FEDERAL EXPRESS

Mr. Lek Kadeli
Principal Deputy Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
Room 41209
1300 Pennsylvania Ave NW
Washington, DC 20004

Dear Mr. Kadeli:

I am writing on behalf of Harvard University in response to the letter that you sent to Professor Francine Laden on July 8, 2013. Your letter transmitted a request that your agency had received from Senator David Vitter relating to several epidemiological studies on the health effects of certain kinds of air pollution, including a 2006 article written by Prof. Laden and other Harvard researchers ("Reduction in Fine Particulate Air Pollution and Mortality," *American Journal of Respiratory and Critical Care Medicine*, 173: 667-672). According to your letter, the EPA has committed to engaging with Prof. Laden and other researchers to understand what information may be available in response to the Senator's request.

As an institution of higher education focused on teaching, research and scholarship, Harvard believes in and advocates for the exchange of data to advance scientific knowledge. At the same time, we have a responsibility to protect not only individual privacy but also our researchers' intellectual property – interests explicitly recognized in both the Freedom of Information Act and the Shelby Amendment. See 5 U.S.C. § 552(b)(4) and (6); 5 U.S.C. § 552(b)(6).2 C.F.R. § 215.36(d)(2)(i).

Large long-term epidemiological studies, like the air pollution research in question, rely on the participation of thousands of human participants. Without assurances that their private medical and other identifying information will be protected, people would not agree to be part of such studies. In this case, Harvard researchers promised to ensure confidentiality not just to the participants themselves, but also to federal and state agencies.

Moreover, for science to flourish, we must recognize and protect researchers' thought processes, innovative ideas, unique approaches and research designs. Under the Shelby Amendment, for example, research data is defined as "the recorded factual material commonly accepted in the scientific community as necessary to validate research findings;" it does not include "preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues." 2 C.F.R. § 215.36(d)(2)(i). Likewise, programs and software that researchers have written are not considered research data.

Your letter recognizes that, in March 2012, after receiving a request pursuant to the Shelby Amendment, Harvard provided to the EPA research data relating to the 2006 article cited by Senator Vitter, and further notes that the EPA subsequently gave a copy of what was provided to Senator Vitter. As required by our confidentiality obligations, this data set did not include individually identifiable information about study participants, nor would Harvard provide such information now.

Moreover, the Krewski report cited in Senator Vitter's request (Krewski, Burnett, et al., 2000. "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") (the "HEI Report") itself contains a comprehensive description of the data collection procedures and an audit of the original data from the Harvard Six Cities study, which was the basis for Prof. Laden's 2006 reanalysis. *See generally* HEI Report Part 1: Replication and Validation at 41-130. For example, the HEI Report specifically describes efforts to review original study protocols (at 42 and 94), describes the data processing and quality control (at 42–64), and provides a detailed review of the death certificate coding protocols (at 47-49). A copy of the questionnaire used in the Harvard Six Cities study is reprinted (at 99-114), along with the questionnaire code book (at 115-16). Thus, Senator Vitter already has access to much of the information he is now requesting.

It is also worth noting that a great deal of time has elapsed since data collection began in these long-term air pollution studies. Existing electronic data from the early years of the Harvard Six Cities study may have deteriorated, or may be stored on media that cannot now be read or deciphered by any available devices or software.

I hope this information is helpful to you. If you have any questions or comments, please do not hesitate to contact me.

Sincerely,

Catherine Breen

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August 1, 2013

Lek Kadeli
Principal Deputy Assistant Administrator
Office of Research and Development
United States Environmental Protection Agency
Washington, D. C. 20460

RE: Requests for data, protocols, methods and related information pertaining to specific epidemiology studies of air pollution and human health.

Dear Lek Kadeli:

I am writing regarding the requests for data, protocols, methods and related information pertaining to specific epidemiology studies on the health effects of particulate matter and ozone air pollution of which I have served as a principle or co-investigator. Details of this request are discussed in your letter dated July 8, 2013 to me and are detailed in the request from Senator Vitter's staff listing the studies and materials requested.

Harvard Six-Cities Cohort Study: Although I was a co-investigator on the initial study of long-term exposure to air pollution and mortality risk (Dockery et al. 1993[1]), data analysis was conducted on site while at Harvard. I have not been a co-investigator on the extended follow-up studies of the Harvard Six-Cities cohort (including Laden et al. 2006[2], Schwartz et al. 2008[3], Lepeule et al. 2012[4]) and I do not currently have copies of or direct access to this study's data files. I note, however, that the Kreski et al. 2000 Health Effects Institute (HEI) reanalysis report[5] and its appendices provide documentation of the Harvard Six-Cities Cohort study that includes an independent data audit, replication of the results of the initial study, copies of the questionnaires and codebook, computer programs and output used in the replication of the original analysis, and related information. The extended follow up studies of the Harvard Six-Cities studies[2-4] provide even further important documentation, replication, and important extensions of the Harvard Six-Cities cohort study.

American Cancer Society Cohort study: The American Cancer Society Cancer Prevention Study II (ACS CPS-II) cohort data were collected by the ACS. The original ACS CPS-II cohort study of long-term exposure to air pollution and mortality (Pope et al. 1995[6]) was a collaborative research effort with ACS researchers. Data analyses occurred on site at the ACS in Atlanta. As

part of the extensive HEI sponsored re-analyses, the ACS made data sharing agreements that allowed separate data access by a large, independent reanalysis team headed by Dr. Dan Krewski at the University of Ottawa to conduct data auditing, replication of originally published results, and substantial sensitivity analyses. For complete documentation, see Krewski et al. 2000.[6] After the re-analysis report was published in 2000, I collaborated on various research projects with researchers from ACS, University of Ottawa, UC Berkeley and elsewhere that was designed to further extend and document the analysis of the original ACS cohort study and the ACS re-analysis. The ACS CPS-II cohort data used in these studies have remained under the ownership of the ACS. Data analyses has been conducted consistent with maintaining the privacy and confidentiality of research participants and data sharing agreements with ASC. As an external co-investigator collaborating with the ACS, I am not authorized nor am I able to provide any ACS CPS-II cohort data files.

With regards to requests for study protocols, statistical methodologies, questionnaires, and related information pertaining to our studies of air pollution and mortality using the ASC CPS-II cohort, we have and continue to provide substantial documentation in various published and peer-reviewed papers and research reports. Most of the publications are journal articles (including Pope et al. 2002[7], Pope et al. 2004[8], Jerrett et al. 2005[9], Jerrett et al. 2009[10], Turner et al. 2011[11], Jerrett et al. 2013[12]) that are necessarily brief (but sometimes include additional documentation in the form of electronic appendices). Others are published as relatively large reports (Krewski et al. 2000[6], Krewski et al. 2009[13], Jerrett et al. 2011[14]) with even more extensive documentation. Various statistical and other methodological approaches developed for and/or used in these analyses have generally been publically documented in multiple publications and are cited in the journal articles and research reports. Copies of the questionnaires and codebook used in the ACS study are published in the Krewski et al. 2000 HEI report[6]. Available on request to the HEI are appendices that include information regarding computer programs and output used in the replication of the original analysis, the quality assurance audit of the data, occupational exposures, flexible modeling of effects of fine particles and sulfate on mortality, alternate air pollution data, selection of ecologic covariates, definition of metro areas, values of the ecologic covariates, spatial analyses, and random effects Cox models. The questionnaires and other documentation for the ACS cohort are also publically available directly on line. (For a general documentation of the American Cancer Society Cancer Prevention Study II see: http://www.cancer.org/research/researchtopreventcancer/currentcancerpreventionstudies/cancer-prevention-study
For the study questionnaires see:
http://www.cancer.org/research/researchtopreventcancer/cancer-prevention-questionnaires).

U.S. Life Expectancy study: The study of reduction in fine particulate air pollution and life expectancy in the U.S. (Pope et al. 2009[15]) utilizes data from public sources. The life expectancy data were generated using publically available data as documented in a published paper (Ezzati et al. 2008[16]) and the complete data set for the generated life expectancy data is directly available on line at
http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0050066#s5 .
The socio-demographic and other variables used in the analysis are also directly available from public sources clearly referenced in the paper. For those who do not want to reconstruct the data from original publicly available data sources, we have also provided an analytic data file (in

Excel Spread Sheet format and with a complete data dictionary) that includes the full data for the 211 counties in the analysis, that can and has been used to reproduce the paper's results using standard statistical software. These data have been provided under separate cover from Harvard University. Additional published papers have provided extended discussion of methodology and protocol (Pope et al. 2012[17]), provided sensitivity analysis regarding potentially influential observations and statistical outliers (Krstic 2012[18], Pope et al. 2013[19]) and have provided some expanded and extended analysis (Correia et al. 2013[20]).

I appreciate the importance of continued efforts to more fully understand the effects of air pollution on human health. I am also fully supportive of open, collaborative, efforts to use data and information in such a way that truly contributes to our scientific understanding, that does not violate the privacy and confidentiality of research participants, that maintains the integrity of the data, and that respects responsible and appropriate sharing of data and replication of results.

Sincerely,

C. Arden Pope III, PhD
Mary Lou Fulton Professor of Economics
Brigham Young University

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Otis W. Brawley, MD, FACP
Chief Medical Officer and
EVP, Research and Cancer Control Science

August 19, 2013

Lek Kadeli
Principal Deputy Assistant Administrator
Office of Research and Development
Environmental Protection Agency
Washington, DC 20460
VIA E-MAIL

Dear Mr. Kadeli:

Thank you for your letter of July 8, inquiring about the permissibility of sharing research data used in certain epidemiological studies focusing on the health effects of particulate matter and ozone pollution. The following is the American Cancer Society's (the Society's) response to your questions.

For 100 years, the Society has worked tirelessly to save lives and create a world without cancer. Along with millions of supporters—over one million of whom volunteered to participate in our research studies—we have committed ourselves to eliminate cancer as a major public health problem. We have been able to lead the way in cancer research by building a foundation of trust with the public and by always placing the public good at the forefront of our mission.

Your inquiry appears to focus on Cancer Prevention Study II (CPS-II) data that were used in four of the studies listed in your letter: Krewski et al (2000),[1] Pope et al (2002),[2] Jerrett et al (2009),[3] and Krewski et al (2009).[4] CPS-II data were not used in the other studies you identified.

What Is CPS-II and
Why Are the Data So Valuable?

The Society established CPS-II in 1982. Over the last 31 years, through the recruitment of nearly 1.2 million male and female participants by approximately 77,000 volunteers in 50 states, the District of Columbia and Puerto Rico, the Society has amassed this data set as a powerful tool to identify the risk factors for cancer and, ultimately, learn how to prevent it. CPS-II data contain comprehensive demographic information as well as health, personal habit history, and economic information. Mortality follow-up of the entire CPS-II cohort continues today with biennial linkage to the National Death Index. The Society has also followed up with subgroups of the larger cohort in a variety of ways, including through repeat questionnaires for assessing cancer incidence and other information and the collection of blood samples and buccal cells for genetic analysis. In addition, Society epidemiologists recently began the retrospective and

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prospective collection of breast, colorectal, hematopoietic and prostate cancer tumor specimens. In short, the CPS-II data set is one the most comprehensive longitudinal data sets in existence.

CPS-II data and corresponding follow-up studies using the data have played a major role in cancer prevention both nationally and internationally over the past several decades. More than 500 scientific articles have been published and the findings have significantly contributed to our understanding of the health effects of tobacco use, obesity, diet, physical activity, hormone use, and various other exposures in relation to cancer and other diseases.

The value to science and the public of the CPS-II data is incalculable. It is a very large snapshot of human information as it existed and evolved over a period of time, and it continues to be extremely relevant to scientific inquiry. It is a medical treasure built with the commitment of our donors, volunteers, staff, and, most importantly, CPS-II participants.

Responses to EPA's Specific Questions

1. **Who owns and/or holds the data necessary to replicate the relevant studies and what are the concerns, if any, associated with making such data publicly available?**

   A. **Control of data**

The Society owns, holds and is entrusted with the stewardship of the individual-level CPS-II data. The Society funded and oversaw the collection of the data, and now directs and controls their dissemination. We obtained some of the mortality data in the CPS-II data set from the Centers for Disease Control and Prevention, which manages the nation's National Death Index (NDI). As we explain below, the Society's use and subsequent disclosure of NDI data is limited to those uses and disclosures permitted under NDI's implementing regulations.

The CPS-II data have since been linked, using participant zip codes or other location information, to ecological information about the area in which the subjects lived (the "Linked Analyses"). These Linked Analyses are conducted by Dr. Daniel Krewski at the R. Samuel McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa, under an agreement with the Society to ensure that he and the University handle our individual level data from CPS-II responsibly and ethically.

   B. **Concerns associated with publicizing data**

The Society has a number of serious legal, ethical, and policy concerns regarding disclosure of both the individual level CPS-II data and the Linked Analyses. At the core of our concern is the Society's ethical obligation as steward of personal and highly confidential information. Accordingly, we follow prevailing privacy norms with respect to the data, and we made assurances to participants, the NIH, and the NDI. To provide identifiable data to Congress under these circumstances would violate these legal obligations and commitments. Moreover, the Society's decades-long investment of resources made the collection of CPS-II data possible, and today the data are priceless.

i. *The Society's duty to maintain confidentiality*

a) Certificate of Confidentiality and the National Death Index

The CPS-II data are protected by a Certificate of Confidentiality issued by the NIH to the Society. Under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the NIH. 42 U.S.C. 241(d). The statute prohibits involuntary disclosure of protected research data:

> Persons authorized by the NIH to protect the privacy of research subjects may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic. 42 U.S.C. 241(d)

If the Society were forced to provide CPS-II data to Congress in direct violation of this statute, the Society would not only breach its Certificate of Confidentiality, but the entire concept of the Certificate and the protection it provides could be in doubt.

Moreover, under these circumstances the Society could not release the information it has received about CPS-II participants' cause of death from the National Death Index, a necessary component of the data to reanalyze the studies in question. The NDI regulations include protections against releasing identifiable information. As we describe in response to Question #2, we are not aware of any way to create a de-identified version of the CPS-II data set sufficient to protect the confidentiality of the participants while at the same time allowing a true replica of the studies.

b) Privacy Policies

The Society is sensitive to and understands the important role of Congress in oversight of environmental policy, but we are concerned that the House of Representatives Committee on Science, Space and Technology's authorization to issue a subpoena for our CPS-II data may put the Society in a position that is inconsistent with prevailing privacy and security standards. Since at least the mid-20th century, confidentiality has been a central tenet of ethical protections for research participants. Individuals share confidential information about themselves to make biomedical and public health research possible and, in exchange, researchers and the public at large assure these volunteers that their confidential data will only be used and disclosed in certain, limited ways. In recent years, these privacy and security protections have become enshrined in various forms, for example in the Health Insurance and Portability and Accountability Act and its implementing regulations, confidentiality protections set forth in the National Death Index regulations, state law, and "privacy by design" principles set forth by the Federal Trade Commission. Although these privacy and security frameworks differ in some respects, core commonalities persist, suggesting a converging set of expectations pertaining to privacy and security.

For example, prevailing privacy norms recognize the need for individuals to be informed about possible permissible uses and disclosures of their data. A closer look at HIPAA is instructive as to legal and public expectations as to privacy. The central tenet of HIPAA is that all uses and disclosures of identifiable data are prohibited, unless they are expressly permitted. Permitted disclosures include those made pursuant to carefully worded authorizations, to *bona fide* researchers under certain, controlled and monitored circumstances, and for public health purposes to health care oversight agencies. HIPAA does not contain any exception to these principles for general congressional curiosity.

Although the Society itself is not directly regulated by HIPAA, most research institutions, such as hospitals and academic medical centers, must comply. The Society is committed to extending the same privacy protections to its research participants as the law would empower institutional providers to extend to their research participants. CPS-II participants deserve no less.

c) Protocols for maintaining confidentiality

Every voluntary participant was assured that their identity and the information they provided, often of a very personal nature, would be kept confidential and used only in connection with research. Volunteers who participated in CPS-II were motivated by a desire to help the fight against cancer and were assured that their commitment and generosity of time and candor would be protected. The confidentiality protections that the Society has in place are vital to the success of research participant recruitment efforts. To balance our promise to the CPS-II participants with our commitment to scientific inquiry, we have a rigorous process to allow outside investigators to request access to CPS-II data subject to confidentiality protections, as explained in our answer to Question #3 below.

ii. *Negative effect on future research*

Violating our legal obligations and breaking the promises we made to participants could damage not only the Society's reputation, but also the next phases of our scientific and public health work. For example, we are currently recruiting participants for our third cancer prevention study ("CPS-3"), and we are concerned that even the threat that Congress might appropriate and possibly make participants' information publicly available could negatively impact our recruitment efforts. More importantly, if research participants believe that confidentiality protections might be limited in circumstances such as these, individuals' willingness to participate in research in all areas may be eroded.

The rationale for the Federal government's acquisition of the CPS-II data appears to be that these underlying data were used in studies that the EPA cited to justify regulatory action. But this sets a dangerous precedent for scientific research: organizations will have reason to fear that any research data cited in connection with a government rulemaking might be subject to confiscation and distribution to the public. This kind of precedent could create a disincentive to researchers to share data, especially if there is a connection to a government rulemaking. Moreover, research entities might limit their own work, choosing to conduct only research that would not be used for government rulemaking to ensure their underlying data are protected. The result could be a breakdown in the collaborative process between scientists necessary to scientific advancement and an impediment to scientific inquiry, particularly in areas of interest for the government. In

addition, this introduces a fundamental disparity in the ethical protections and safeguards for participants in research depending on whether the research is used to inform government policy. What a tragic and ironic disincentive it would be to inform the public that when they give of themselves to support research identified as being of national importance, they must sacrifice basic confidentiality protections.

iii. *Congress cannot properly order EPA to 'take' this data*

The Society's individual level CPS-II data at issue here were funded and collected by the American Cancer Society, and, to the best of our knowledge, without the use of Federal funds. As it is a longitudinal, nationwide study dating from 1982, it is unique and not replicable, and its value cannot be measured. If we were forced by a Committee of the U.S. Congress or by any agency of the executive branch of the federal government to make public this privately created and privately funded resource, it could be akin to taking our property without just compensation in violation of the Fifth Amendment.

iv. *Uncertainty about dissemination caused by Congress is a concern*

Our concerns about confidentiality, the adverse effect on research, and the acquisition of our private property are compounded by statements made about how Congress might disseminate our participants' information. It is our understanding that the House of Representatives Committee on Science, Space and Technology has authorized the Committee Chairman to acquire the CPS-II data by subpoena, if necessary, with the intention of making the data set available "*on the Internet*," as the Chairman stated in an August 1, 2013 public hearing on the subject. The idea that Congress would publish our participants' information online only magnifies our concerns.

2. **What are the technical options for making these data publicly available, taking into account any concerns about the release of confidential personal health information or other confidential data? What are the implications of these options for replicating these studies? What level of effort in terms of time and resources would be required for these options?**

In order to accurately replicate the studies, Congress will need data and statistical programs that the Society does not hold or control in addition to the raw data in CPS-II. First, Congress will need access to the National Death Index to link the CPS-II data to death records, and to do that, Congress would need the Society to provide participants' name, social security number, date of birth, and state of residence. Then, Congress or others would have to link the appropriate ecological variables to our CPS-II data. Otherwise, Congress will need access to the Linked Analyses, which are maintained by Dr. Daniel Krewski at the University of Ottawa, under an agreement with the Society.

With respect to the Linked Analyses, we do not currently have the internal expertise to determine definitively whether it is possible to code or otherwise modify them in such a way as to protect the confidentiality of our CPS-II participants and also allow for true replication of the studies. To determine what might be possible, we would have to engage outside experts, at considerable expense. This is likely to be a time-consuming and long-term effort with uncertain resolution.

Regarding the CPS-II data, it appears impossible to create a public version that would protect the confidentiality of the CPS-II participants while at the same time allowing a true replica of the studies. To enable study replication, we would have to include individual level information, including participants' location, such as zip code or partial zip code, to enable others to link ecological information. The zip code or partial zip, along with updated zip codes for a portion of the participants, would be listed with a wide variety of personal information, including age, race, gender, education, marital status, height, weight, alcohol consumption, smoking history, exposure to environmental tobacco smoke, occupational history and exposures, and, if applicable, cause of death and death date. Using HIPAA as our guide, we note that zip code *alone* is, in some cases, considered an identifier. Accordingly, the residual zip code information, which is necessary to facilitate the linking with ecological data, combined with other information about each participant, such as race, ethnicity and other data points, would heighten the risk of re-identification. In fact, in light of explosion of publicly available data that can be used to re-identify individuals with data otherwise appearing to be de-identified, regulators continue to expand the single data fields that are classified as "identifiers." While the Society might be able, with sufficient time and resources, to remove all of the confidential or identifying information so that individual CPS-II participants could not be identified, such a data set would be so limited and generic that it would not enable a researcher to replicate the studies in question.

3. **If there are no feasible options for making all of the data publicly available, how would a researcher gain access to the full set of underlying data in order to replicate these studies? Please provide any documentation you believe would be helpful in understanding this process.**

The Society recognizes the value of externally-proposed studies that are of general interest and high scientific merit. We welcome outside investigators to request access to our data following our application process, the details of which are available on our website.[5] We only grant access to well-qualified researchers who have demonstrated that their proposed research is well-designed and has the potential to significantly contribute to scientific discourse, and who have the requisite knowledge, qualifications, and experience to conduct the analysis and protect our data.

Once a proposal is accepted, we take various measures to protect our data. Each researcher who is granted access to the data has restrictions on the use and publication of the data and must conduct the research consistent with applicable legal and ethical requirements. Further, a deep understanding of the history of CPS-II and the complexity of the database is needed to conduct scientifically valid research using CPS-II data. Therefore, we require external researchers to work collaboratively with Society investigators, including co-authorship on any resulting publications, and the researchers and their institutions must sign the Society's "Collaboration Agreement," which includes requirements designed to protect the confidentiality of the participants in the research. Moreover, we only give the investigator access to the data that are necessary to conduct the analysis.

The Society may choose to deny requests from individuals sponsored by interest groups who have demonstrated they are not interested in independent and objective scientific research. For example, we have on occasion refused to provide access to scientists who were publicly linked to

sponsorship by tobacco companies. These data are a public trust. We take that responsibility seriously.

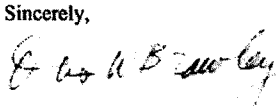
We are currently engaged in more than 30 collaborations with outside investigators. With respect specifically to the CPS-II data used for the studies referenced in your letter, I am sure you are aware that the Krewski (2000) study was a replication of original studies precisely because some were concerned about the objectivity related to the results and conclusions of these original studies. As a result of those concerns, the Society shared the necessary data under a confidentiality agreement to ensure our data were properly protected and the reanalysis was done under the auspices of the Health Effects Institute and conducted by a neutral third party.

In summary, the Society has a number of concerns regarding the potential disclosure of our CPS-II data. To compile the CPS-II data set, we assured the 1.2 million individuals who provided personal information to help us understand what causes and prevents cancer that we would maintain the confidentiality of this information. We also applied for and were awarded a National Institutes of Health-issued Certificate of Confidentiality that protects the entire data set, from the date of its inception from disclosure. At the same time, we value the contributions that outside investigators can make using our CPS-II data, which is why we have a process to allow them to apply to access our data subject to confidentiality protocols. Producing CPS-II data to the Federal government outside of our standard process, when we can be given no assurances of how it will be used, by whom, and how widely it would be disseminated, would cause the Society to betray its own policies, the promises it made to participants, covenants with both the NIH and the National Death Index, and prevailing privacy norms. Moreover, the Society has invested countless resources to collect and analyze the CPS-II data, including three decades of work, tens of millions of dollars, and the dedication of 77,000 volunteers. Leaving aside the Society's critical concerns about confidentiality for the citizens who provided personal data, it would be improper for the Federal government to imply appropriate this privately created data set and make it publicly available.

The Society has engaged outside counsel to assist it in protecting the integrity of our CPS-II data. Please include Mr. Stephen M. Ryan of McDermott Will & Emery, LLP and the Society's General Counsel, Mr. Timothy B. Phillips, on all future correspondence. They are the only persons authorized to respond for the Society to any EPA need for further information.

Thank you for your careful consideration of the issues we have raised.

Sincerely,



Otis Brawley, MD, FACP
Chief Medical and Scientific Officer

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HEI

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August 27, 2013

Mr. Lek Kadeli
Principal Deputy Assistant Administrator
Office of Research and Development
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Washington, DC 20460

Dear Mr. Kadeli:

I am pleased to provide you with the response from the Health Effects Institute (HEI) to your letter of July 8, 2013, seeking HEI's advice and comment on the important questions of sharing the data underlying epidemiologic studies of air pollution and health.

As you know, HEI has a longstanding policy to make data underlying its studies available to the widest possible scientific audience. We accomplish this first by the publication of comprehensive, intensively peer-reviewed reports of all results of research we fund (not just those that investigators might select for publication in a peer-reviewed journal), and by making extensive additional details available on-line. We also endeavor, in cases where we have full ownership of and rights to data produced for our studies, to make those data widely available to other investigators, including publishing entire data sets and analytical programs on the web. While there are legitimate privacy concerns that must be addressed in making epidemiologic data with personal health and other information available to other scientific investigators, HEI has long believed that mechanisms can often be developed for doing so and it is the interest of science, and the public policy informed by such science, to find ways to do that.

It is in this spirit that we respond to your letter. We have both several general comments on the nature of the data, and observations on how data may be shared and results replicated, for the particular studies you cite which rely on the American Cancer Society Cancer Prevention Study II and Harvard Six Cities cohorts. We provide, as well, specific answers to your questions.

General Considerations on the Data

As you note in your letter, air pollution epidemiology studies normally rely on several types of data: air quality data, census-based covariate data (e.g. income levels within a zip code area where the study subject(s) reside), health event data (which in these studies are data from the National Death Index), and individual health and personal characteristics data (e.g. level of education, alcohol consumption, body mass index, and smoking behavior) which are gathered through detailed individual questionnaires and in some cases periodic health examinations. We have several general observations:

- Data sets that have been created from publicly available sources and contain no individual identifying information, such as air quality monitoring data and census-based covariate data, should be able to be made publicly available without tremendous difficulty or cost.

- Data from the National Death Index (NDI) – maintained by the Centers for Disease Control and Prevention – is generally made available to investigators upon certification on their part that they would not advertently or inadvertently release the identity or cause of death or any other identifying information of any individual. The NDI does make provisions for making its data available more broadly, but according to well-specified rules for aggregating the data and removing certain information (e.g. specific date of death), which would keep a third party from using the data to identify an individual.

- Data collected from individual subjects in a study which normally includes detailed personal, health status, and behavioral information, is critical to allowing for these studies to determine whether some other factor than air pollution (e.g. obesity or smoking behavior) may be responsible for any health effects that are observed. This data, which is normally collected through individual questionnaires and/or medical examinations, is collected with the *express commitment to the participants - from the organizations and the original investigators that collect the data - that the participants' personal information and identity will not be divulged.* Studies using this data are also subject to the Common Rule, under which investigators must apply to their respective Institutional Review Boards (IRBs) to ensure the protection of human subjects in biomedical and behavioral research.

Observations on Data Sharing and Full Replication of These Studies

The ACS and Harvard studies, at their root, attempt to determine whether persons living in higher pollution areas are more likely to have higher relative risks of premature mortality than those living in lower pollution areas, while attempting to control for a host of personal-level and community-level covariates that may also differ between the individuals and the communities. This by its nature requires knowing where the person lives, which can pose challenges for protecting the identity of an individual if s/he lives in a smaller or sparsely populated area. This challenge has been long recognized, and there are a number of protections in federal rules and scientific practice that address this (e.g. the Census Bureau will not release certain data at the block or even zip code level if they believe that would allow identification).

Since the goal should be to find ways to share data which enables full replication and sensitivity analysis of original studies, it is valuable to consider two aspects of these particular studies that have moved them towards using data at smaller spatial scales:

- First, in response to valid criticisms that the earlier versions of these studies relied only on central air quality monitoring data to estimate exposure, investigators have increasingly sought to better estimate exposure employing land use regression models and other methods that can account for the distance of a subject's home from roadways, industrial facilities, and other sources of air pollution. They have also applied increasingly finer-grained community-level covariates (e.g. at the zip code level). While in the largest locations the application of these finer-grained data would likely not allow

for identification of individual subjects, the national analyses in some of these studies include subjects from a wide range of community sizes, including smaller communities where identification could be possible.

It should be possible to produce a data set which uses techniques like land use regression to assign exposure levels to each subject in a study and to provide only that exposure value in a dataset made available to others. This would avoid the possibility of identification of an individual subject, and would allow for replication of the original results for a study that was analyzing a range of exposure across a specific metropolitan area, for example. But such a data set, absent location information for each participant, would not allow for sensitivity analyses applying different forms of exposure modeling nor full testing of the validity of the original study's exposure estimates.

- Second, as these studies have been reviewed intensively by the HEI Review Committee, the Committee has identified two potentially significant sources of uncertainty in their results: so-called "ecological confounding"[1] and "spatial autocorrelation."[2] This is detailed in the HEI Review Committee's Commentary on the most recent HEI Research Report of Extended Analyses in the American Cancer Society cohort (pp. 128-129 in Krewski 2009). To address both of these issues, one of the first steps that investigators have taken has been to use data at smaller scales, e.g. at the zip code level, which while enhancing their ability to test for these two sources of uncertainties, also poses the potential in smaller communities for individuals and their personal information to be identified.

Taken together, these characteristics – which have in general enhanced the quality and the sensitivity of the studies – increase the difficulty of providing a fully "de-identified" data set while *also* enabling a different investigator to conduct a full replication and sensitivity analysis of the original study results.

Options for Making Data Available – Answers to your Specific Questions
With these considerations in mind, we attempt to answer your specific questions below:

1) Who owns and/or holds the data necessary to replicate the relevant studies and what are the concerns, if any, associated with making such data publicly available?

The publicly available air quality and census covariate data are of course collected and owned by the government and are freely available. The air quality and census data sets created specifically by investigators for a particular study are generally the property of the investigators, but should be capable of being made available, especially in the case where they were created using public funds.

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[1] Ecological confounding arises when some community-level variables, which are themselves risk factors for mortality, are also associated with air pollution levels

[2] Spatial autocorrelation is the tendency for variables to have similar values for people or areas that are geographically close, which can suggest that there are other mortality causes which are unaccounted for in the analysis, or can distort the precision of risk estimates.

As to the ownership of the detailed participant data in the ACS and Harvard Six Cities cohort studies, HEI will leave the answers to the other two recipients of your letter – Harvard University and the American Cancer Society – who created these data sets, maintain them, and would have the most current information on others who may be holding these datasets in whole or in part. Those organizations also provided study participants with express commitments that their personal identity and information would not be divulged and have the responsibility to ensure that this commitment is not compromised during any data sharing.

2) What are the technical options for making these data publicly available, taking into account any concerns about the release of confidential personal health information or other confidential data? What are the implications of these options for replicating these studies? What level of effort in terms of time and resources would be required for these options?

3) If there are no feasible options for making all of the data publicly available, how would a researcher gain access to the full set of underlying data in order to replicate these studies? Please provide any documentation you believe would be helpful in understanding this process.

We see a range of options for making such data available, in different formats and with different procedures, so we are answering the questions jointly. In our view, it is feasible to share data in one of three ways (which have been used in many instances) and to do so while protecting the privacy of the individual subjects. The options range, however, from those that offer the most detailed access to study data to those that offer significantly less access:

A. **Collaboration with original investigators to obtain full access to data in order to conduct joint analyses**

This process is the most common practice in the scientific community for sharing personal data. It normally involves either formal or informal application processes for a scientific researcher to ask the original organizations and investigators who created the data set to gain access to the data to allow for collaborative analyses of an important research question. The American Cancer Society, for example, provides explicit instructions on their website on how to collaborate with them, and many other investigators have conducted more informal collaborations of a similar type. Such collaborations have, of course, to be conducted in full compliance with the Common Rule and any federal or other requirements for protecting the privacy of the participants.

The *advantage* of this process is that it can provide investigators with the fullest access to the data sets and with the benefits of regular consultation with the original investigators whenever there are questions about data structure or content. The *disadvantages* include that the original investigators may not choose to collaborate with all who request access, and a fully independent replication and sensitivity analysis of the original studies may not be possible or broadly accepted, given the collaborative relationship.

B. **Application to obtain independent access to analytic data sets sufficient to allow for replication and sensitivity analysis of the original results**

This process involves the request by a researcher to the original investigators, or to agencies and organizations, who created the data set to gain access to the data sets underlying a particular study. This normally would involve the development of a protocol for such analysis by the researcher, the review and approval of the protocol by the submitting scientists' IRB, explicit signed commitments by the researchers that they will not disclose personal information (on pain of penalty in the case of federally owned data sets), and usually other protections (e.g. prohibition of the publication of any results presenting data for groups of fewer than a certain number of subjects, and review by the original investigators before publication to ensure that no such information is inadvertently disclosed). Such a process is currently used within the US Department of Health and Human Services.

One relevant example of such data sharing is the detailed data sharing procedures established for the Multi-Ethnic Study of Atherosclerosis (MESA) which can be viewed at https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?view_pdf&stacc=phs000403.v1.p3. In addition, MESA has created several "Limited Access Data Sets" in which personal identifying information has been removed and which can be accessed more readily, but which would not allow for full replication of original studies (see https://biolincc.nhlbi.nih.gov/studies/mesa/?q=MESA).

The *advantage* to this approach is that it can provide access to a substantial portion of the relevant data and allow for fully independent replication and sensitivity analyses of the original results. The major *disadvantage* is that this approach normally does not provide access to the full data set, but rather only to the detailed analytic data set or summary tables used in specific studies, thus precluding full replication.

A similar albeit much more intensive process enabled HEI and its independent investigators to gain access to the full data which we reanalyzed from the Harvard Six Cities Study and the American Cancer Society Study (HEI 2000). This process was structured to allow intensive efforts to replicate and test the robustness and sensitivity of the originally reported results. It was undertaken with the full agreement of, but not collaboration with, the original investigators, and provided full access to the data in accordance with a specifically developed data use agreement which ensured protection of privacy. The analyses were also informed by expert advisors from industry, academia, and other stakeholders.

C. **Provision of a "de-identified" disk (or other electronic medium) to provide a more limited data set that would not under any circumstances allow for identification of individuals**

In some cases, the simplest mechanism for providing access to study data would be through the provision of a fully de-identified data set in electronic form that can be readily shared with all parties without the possibility of an individual and his or her personal characteristics to be divulged. This has the *advantage* that it may allow independent replication and sensitivity analyses of some of the results of the original investigators. The most significant *disadvantage* is that, as noted above, the most recent analyses in the ACS populations have applied increasingly finer-grained community level data analysis; the release of a fully "de-identified" dataset will not allow full replication and sensitivity analysis of these most recent results, e.g. the testing of

alternative models for estimating exposure among the study subjects, and the inability to test whether ecological confounding and spatial autocorrelation could be affecting the results.

Overall, HEI believes that the opportunity for other scientific investigators to have access to and conduct additional analyses in these epidemiologic data sets is of tremendous scientific value, and can provide additional understanding of important scientific questions that can in turn inform air quality policy decisions. As we have described, there are well-established processes for making such data available; however, not all processes provide the fullest access to the data required while still protecting the privacy of individual information that is essential to the studies.

We would be pleased to provide additional consultation on these important questions and to answer any questions you might have. Please let us know if you have further questions or need additional assistance in this effort. You may feel free to contact me or HEI Science Director Dr. Rashid Shaikh at rshaikh@healtheffects.org or (617) 488-2301 for any follow-up questions

Sincerely,

Daniel S. Greenbaum
President

cc: Dr. Rashid Shaikh
Dr. Susan Gapstur, American Cancer Society
Dr. Douglas Dockery, Harvard University

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September 6, 2013

Mr. Lek Kadeli
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Dear Mr. Kadeli:

I am pleased to respond to your letter of July 8, 2013, seeking advice and comment on sharing the data underlying epidemiologic studies of air pollution and health. Let me address each of your three questions specifically.

1. Who owns and/or holds the data necessary to replicate studies and what are concerns, if any, associated with making such data publicly available?

This question makes several assumptions which must first be clarified.

WHAT IS MEANT BY REPLICATION?

Replication is the standard for scientific investigations. Replication implies independent data, analytic methods, laboratories, and methods (Greenbaum, Bachmann et al. 2001; Peng, Dominici et al. 2006). While replication is the standard in physical and biological (experimental) sciences, replication can be difficult in epidemiology (observational) sciences where it may be hard to find comparable data from independent populations.

True replication of long-term observational (epidemiologic) studies is time-consuming and costly. Nevertheless, there has been replication of the original air pollution mortality associations reported in the Six Cities study reported in 1993 (Dockery et al., 1993). Indeed, the subsequent analysis of air pollution associations in the American Cancer Society CPS II cohort (Pope et al., 1995) was undertaken explicitly as an independent replication of the observations in the Six Cities study of mortality associations with fine and sulfate particulate matter air pollution (Greenbaum, Bachmann et al. 2001). Since these original observational studies two decades ago, there have been numerous reported replications of the original findings in independent studies from the United States and Europe (see Table below abstracted from a recent review of these studies (Hoek, Krishnan et al. 2013)). The EPA particulate national ambient air quality standard is based on a review of all of this body of evidence and not solely on the Six Cities and ACS studies. The EPA benefit analyses used exposure response functions from these two studies because they represent the range of exposure response reported in the scientific literature.

Reproducing results implies that independent investigators subject the original dataset to their own analyses and interpretation (Peng, Dominici et al. 2006). Reproducing results does not provide the same level of independent replication, but at times can be the only feasible approach.

Several authors have advocated that data and analytic code should be routinely made publically available for epidemiology studies to allow for reproduction of published results (Peng, Dominici et al. 2006; Hernan and Wilcox 2009; Samet 2009).

In 1997, following calls for release of original data for the Six Cities and ACS analyses (Greenbaum, Bachmann et al. 2001), the Harvard and ACS investigators agreed to provide a copy of the analytic datasets and access to the original records to independent investigators selected by the Health Effects Institute, with appropriate assurances and oversight to ensure protection of participants' confidentiality. These data were subjected to validation of the data records, an attempt to reproduce the original results by independent analyses, and testing the sensitivity of the original published results to alternative assumptions, methods, and adjustment for additional potential confounders. This quality assurance check and reanalysis found the data to be of high quality, the results to be reproducible, and the findings to be insensitive to alternative analytic approaches and control of confounders. These results were published in a 293 page peer-reviewed HEI report (Krewski, Burnett et al. 2000), and published in the peer-reviewed scientific literature (Krewski, Burnett et al. 2003; Krewski, Burnett et al. 2005; Krewski, Burnett et al. 2005).

TABLE 1: Long-term cohort studies of the effects of particulate air pollution ($PM_{2.5}$, PM_{10}, and TSP) on mortality. Abstracted from Hoek, Krishnan et al (2013).

Study	Study population	Follow-up period	Pollutant	Authors	Publication Year
Harvard Six Cities	8111 adults in six US cities	1976 - 1989	$PM_{2.5}$	Dockery et al	1993
American Cancer Society (ACS) Study	552, 800 adults from 51 US cities	1982 - 1989	$PM_{2.5}$	Pope et al	1995
ACS Study	500,000 adults from 51 US cities	1982 -1998	$PM_{2.5}$	Pope et al	2002
ACS Sub-Cohort Study	22,905 subjects in Los Angeles area	1982 - 2000	$PM_{2.5}$	Jerrett et al	2005
Harvard Six Cities	8096 adults in six US cities	1979 -1998	$PM_{2.5}$	Laden et al	2006
German Cohort	4752 women in Ruhr area	1985 – 2003	PM_{10}	Gehring et al	2006
Women's Health Initiative Observational Study	65,893 postmenopausal women from 36 US metropolitan areas	1994-1998	$PM_{2.5}$	Miller et al	2007
Netherlands Cohort Study	120, 852 subjects from Netherlands	1987 -1996	$PM_{2.5}$	Beelen et al	2008
Nurses' Health Study	66,250 women from the US north eastern metropolitan areas	1992-2002	PM_{10}	Puett et al	2008

Medicare National Cohort	13.2 million elderly Medicare recipients across the USA	2000 - 2005	$PM_{2.5}$	Zeeger et al	2008
Nurses' Health Study	66,250 women from the US north eastern metropolitan areas	1992-2002	$PM_{2.5}$	Puett et al	2009
Swiss National Cohort	National census data linked with mortality	2000 - 2005	PM_{10}	Huss et al	2010
California Teachers Study	45,000 female teachers	2002 -2007	$PM_{2.5}$	Ostro et al	2010
US Trucking Industry Cohort	53,814 men in the US trucking industry	1985 -2000	$PM_{2.5}$	Hart et al	2011
Health Professionals Follow-Up Study	17,545 highly educated men in the midwestern and northeastern US	1989 – 2003	$PM_{2.5}$	Puett et al	2011
China National Hypertension Survey	70,497 men and women	1991 - 2000	TSP	Cao et al	2011
California Teachers Study	101,784 female teachers	1997- 2005	$PM_{2.5}$	Lipsett et al	2011
Chinese Retrospective Cohort Study	9,941 adults from five districts of Shenyang city	1998 -2009	PM_{10}	Zhang et al	2011
Vancouver Cohort	452,735 Vancouver residents 45–85 yr	1999 – 2002	$PM_{2.5}$	Gan et al	2011
Harvard Six Cities	8096 adults in six US cities	1974 - 2009	$PM_{2.5}$	Lepeule et al	2012
Nippon Data Cohort	7,250 adults > 30 yr throughout Japan	1980 - 2004	PM_{10}	Ueda et al	2012
Canadian National Cohort	2.1 million nonimmigrant Canadians . > 25 yr	1991 - 2001	$PM_{2.5}$	Crouse et al	2012
New Zealand Census Mortality Study	1.06 million adults in urban areas from 1996 census	1996 -1999	PM_{10}	Hales et al	2012
German Cohort	4752 women in Ruhr and surrounding area	1985 - 2008	PM_{10}	Heinrich et al	2013
Rome Longitudinal Study	1,265,058 adults from Rome	2001 - 2010	$PM_{2.5}$	Cesaroni et al	2013

WHO OWNS AND/OR HOLDS THE DATA?

Under the terms of the NIEHS grants and EPA contracts, the Six Cities data are owned and held by the President and Fellows of Harvard College. This ownership of the data by Harvard is well established legally.

WHAT ARE CONCERNS WITH MAKING SUCH DATA PUBLICALLY AVAILABLE?

Harvard has supported free exchange of data for reproducing and advancing scientific knowledge whenever individual privacy is not compromised.

A recent example was the release of lung function measurements of children in the Six Cities study collected between 1974 and 1989, for a multinational pooled analysis of normal values for children (Quanjer, Hall et al. 2012; Quanjer, Stanojevic et al. 2012). In this case, individual data including sex, race/ethnicity, age, height, weight, and lung function were released. Individual identifiers were not included and the characteristics released were not alone sufficient to allow identification of individual children.

In asking potential subjects to participate, we assured all participants that their individual data would not be released to anyone other than the study investigators (see below).

In the case of mortality records, there are a variety of standards. Individual death records are compiled by each state, and forwarded to the National Center for Health Statistics (NCHS). Death records are made available to researchers in several forms. Surveillance data of deaths have previously been available by county and death date from the National Center for Health Statistics. While these data sets did not include individual identifiers prior to 1989, they did include sex, age, race/ethnicity, date of death, county of death, and primary cause of death. However, concerns with privacy of death data have led to increasing restrictions on the identifiable data (Centers for Disease Control and Prevention 2013).

Over the years, confidentiality standards have changed for the public release of geographic and date details on vital statistics micro-data files (Centers for Disease Control and Prevention 2013). These changes are reflected in the data available in successive time periods, as follows:

- Prior to 1989, NCHS public-use death micro-data files contained all counties and exact dates (year, month, and date) of deaths.
- Between 1989 and 2004, public-use death micro-data files contained only geographic identifiers of counties and cities with a population of 100,000 or greater, and no exact dates of death (year, month, and day of week, e.g. Monday, only).
- Beginning in 2005, public-use death micro-data files contained individual-level vital event data at the national level only, that is, with no geographic identifiers (no state, county, or city identifiers), and no exact dates of death (year, month, and day of week, e.g. Monday, only).

Thus, since the study was published in 1993 there has been a substantial shift in the standards for confidentiality of death records, as reflected by the practices of the National Center for Health Statistics of the Centers for Disease Control and Prevention.

Since 1979, individual death records have been compiled into the National Death Index, a national resource for follow-up studies. Investigators may apply to the NDI to search for deaths of study participants. NDI requires informed consent of the study participants, institutional review board oversight, and assurances that identifiable data are not released. Standards for release of death data vary between states. In some states, death records are considered public and are readily available. In other states, death records are considered private, and are available only to next of kin (immediate family).

Prior to the creation of the National Death Index, the Six Cities Study investigators had to apply to each state to obtain copies of death certificates. Cause of death was coded by a certified nosologist from the original death certificate. Release of death data was then dictated by the most restrictive state privacy requirements.

EXAMPLES OF REPRODUCTION

In the case of non-identifiable mortality data, Harvard investigators have worked with interested independent investigators to replicate published findings. For example, the 1996 study entitled "*Is daily mortality specifically associated with fine particulate air pollution*" examined the effect of acute air pollution exposures on counts of daily mortality in the Six Cities Study communities (Schwartz, Dockery et al. 1996). In a replication/reanalysis exercise sponsored by the Electric Power Research Institute, independent investigators at Klemm Associations were provided with copies of the original data. They attempted to reproduce the original mortality data, replicate the original analyses, and assess the sensitivity of the analyses to alternative methods and control of covariates. This led to joint (Klemm, Mason et al. 2000) and independent (Klemm, Mason et al. 2000) peer-reviewed publications.

A more recent study examined the association of changes in county-specific life-expectancy with changes in fine particle air pollution in 211 counties in the United States between 1980 and 2000 (Pope et al., 2009). These data were compiled from publically available datasets and included no individual death records. Copies of these data were provided to interested individual investigators including Dr. Goran Krstić of Fraser Health in British Columbia, Dr. James Enstrom of the Scientific Integrity Institute, and Dr. Stanley Young of the National Institute for Statistical Sciences (a private, nonprofit organization in Research Triangle Park, NC). These re-analyses have led to a lively debate in scientific literature. Dr. Krstić published a critique in 2012 (Krstic 2012). Dr. Enstrom presented his reanalysis at a symposium (Enstrom 2010). Dr. Young has presented his results orally (Young 2010) and more recently in the peer-reviewed literature (Young and Xia 2013). The original authors published responses to these critiques in peer-reviewed journals (Pope, Ezzati et al. 2013), as is normal practice in scientific debate.

As these re-analyses illustrate, there has not been a question of availability of mortality/air pollution data when individual death records are not involved.

2. What are the technical options for making these data publicly available, taking into account any concerns about release of confidential personal health information or confidential data? What are the implications of these options for replicating these results? What level of effort in terms of time and resources would be required for these options?

Release of identifiable individual data would violate the assurances of confidentiality required by the Harvard Human Studies Committee (Institutional Review Board) and given to each study participant upon their enrollment into the Six Cities Study. As participants were enrolled into the study, they signed the following "*Assurance of Confidentiality,*" also signed by Benjamin G. Ferris, Jr., the Principal Investigator of the study, and by a witness:

> *Harvard University School of Public Health hereby gives the assurance that your identity and your relationship to any information obtained by reason of your participation in this study of respiratory symptoms will be kept confidential and will not otherwise be*

disclosed except as specifically authorized by you. The data from individuals will be pooled and used as group data in scientific studies.

As custodians of these data, we consider that we are obligated to maintain the commitment to maintain this Assurance of Confidentiality made with each participant in the study.

In addition, release of identifiable individual death records would violate the agreements with the National Death Index and with the individual state agencies to obtain copies of the individual death records. For example, the original application requesting data from the National Death Index includes the following *Applicant Assurance*:

> *The identifiable data obtained from the National Death Index will be used only for research and statistical purposes. With the exception of requests for death record information made to the appropriate State vital statistics office, no data will be published or released in any form if a particular individual or establishment supplying the information or described in it is identifiable.*

In addition, we had to apply to each state vital statistics division to obtain copies of death records. In each case, we had to provide assurances of confidentiality of these vital records. For example, the Missouri Division of Health required:

> *The request will be approved only if adequate assurances are provided to protect the confidentiality of the records requested. This includes limiting access to the records only to members of the research staff, not releasing records to other agencies, publishing data so individuals cannot be identified, destroying the records upon completion of the study, and not contacting family members or acquaintances of decedents or infants without written permission from the Director of the Missouri Division of Health.*

Thus we also have made very explicit institutional commitments to protect the confidentiality of the death information of participants in the study.

DATA REQUIRED FOR REPRODUCING RESULTS

What data are required to reproduce the results of the 1993 mortality analyses (Dockery, Pope et al. 1993), the 2006 mortality follow-up (Laden, Schwartz et al. 2006), or the most recent mortality follow-up (Lepeule, Laden et al. 2012)? There are three classes of data required for these analyses: exposures, health outcomes, and the covariates (or confounders). Let us consider each of these separately starting with exposures.

For these analyses, the exposures are community level air pollution concentrations. Air pollution concentrations are publically available. This study included annual mean air pollution concentrations collected specifically for this study at a centrally located site in each community. There is no issue with making these air pollution data publically available. However, to conduct the analysis, the residency of each research participant must be linked to the exposure data, resulting in the identification of the subjects' city of residency.

The health outcome is time to death (or cause-specific death) from the start of the study for each individual. This requires knowing when a person was enrolled in the study, when they died and cause of death, and if they did not die or were lost to follow-up, the date of last contact.

The covariates that need to be considered for reproducing the results are other predictors of death. In this analysis, the covariates included age, sex, race, smoking (indicators of current

and former smoking, number of pack-years smoked), education (indicator of less than high school), and body-mass-index. Defining exposure required knowing city of residence at enrollment into the study. Knowing their individual characteristics alone would not be sufficient to identify an individual in the study. As noted above, these types of non-identifiable data have been released to other researchers. The difficulty arises when these individual characteristics (covariates) are combined with death records (date of death) and exposure information (place of residence).

De-identification is not simply the process of removing names and addresses. To illustrate the difficulty of ensuring privacy with respect to death records, consider a study participant in Watertown, Massachusetts, the first city enrolled in the study. The 1990 census population of Watertown was 33,284. Assuming a national average death rate of 799.5/100,000 per year (Centers for Disease Control and Prevention 2013), we would expect less than one (0.73) death per day. Knowing a participant from Watertown died on a specific date would almost certainly allow identification of that individual from published obituaries, and hence is considered identifiable information. Knowing the person's age, sex, and race as required to reproduce the analyses would leave no doubt of their identity. The table below presents the 1990 census population for each of the Six Cities and estimated numbers of deaths per day.

TABLE 2: 1990 census population in each of communities in the Harvard Six Cities Study, and expected number of deaths per day based on US average death rates (Centers for Disease Control and Prevention 2013)

Study Community	1990 Population	Expected Deaths/Day†
Portage/Pardeeville/Wyocena, WI	10,890	0.24
Kingston/Harriman, TN	11,671	0.26
Steubenville, OH	22,125	0.48
Watertown, MA	33,284	0.73
Topeka, KS	119,883	2.63
St. Louis, MO*	396,685	8.69

† *Assuming US average of 799.5 deaths/100,000/year*

**Note: St. Louis sample only included residents of the Carondelet section of St. Louis. Census is for entire city.*

Thus knowing the date of death plus the essential individual characteristics for these analyses – sex, age, and city of residence, is sufficient to identify individual study participants. Furthermore, even knowing the year of death, in combination with sex, age and city of residence would be sufficient to identify most participants.

For comparison, as noted earlier, prior to 1989 the National Center of Health Statistics only released public use data specifying date of death and county of residence. This was subsequently changed to specify only counties with population greater than 100,000, and date was reported only as year, month, and day of the week. Currently, public-use death data are only

available without specification of county of residence and no exact dates of death are provided (year, month, and day of week only).

3. If there are no feasible options for making all the data publically available, how would a researcher gain access to the full set of underlying data in order to replicate these studies? Please provide any documentation you believe would be helpful in understanding this process.

First, we would like to note that as indicated above, the results of the Six City Study have been both replicated and reproduced. More broadly, we have struggled with the competing demands of providing full access to policy-relevant observational public health data while maintaining the confidentiality of personal data for more than 15 years. As illustrated in the previous sections, these issues have been the subject of vigorous debate. Based on this experience, we would suggest that there are two approaches to allow independent researchers to gain access to the full set of underlying data.

The first approach would to provide access to all the data as we did in response to the EPA request in 1997. On January 31, 1997, Mary Nichols, EPA Assistant Administrator for Air and radiation wrote to Dr. Dockery stating in part:

> *"As you know, there has been considerable interest in your research on the health effects of air pollution, including requests by members of Congress, governors of several states, and other for the raw data underlying your published research. ... (G)iven the strong interest in your research, EPA would encourage reasonable accommodations with the scientific and governmental community that would permit other interested scientists and agencies to understand fully the basis for your work. We therefor request that you make data associated with your published studies available to interested parties as rapidly as possible."*

After thoughtful consideration of this request, in April 1997 we asked an outside, independent agency, the Health Effects Institute (HEI), to provide an independent, comprehensive review and re-evaluation of the study data. We agreed to turn over a complete copy of all the data and provide access to all original records to HEI. There were no constraints on analyses or questions that the HEI investigators could explore. However, the HEI investigators were required to apply for and receive approval from the same agencies and institutional review boards that approved the original Harvard study that generated these data. In addition, the data were kept on a secure computer, not connected to the web or network, to ensure data security.

HEI assembled an Expert Panel to provide scientific oversight of the reanalysis project. The HEI Expert Panel had an open competition for a team of investigators to conduct the reanalyses. Harvard had no input into the process of selecting the independent scientific review team. A team from the University of Ottawa was selected.

HEI also established an Advisory Board to provide stakeholder participation (Health Effects Institute 2000). HEI solicited and compiled questions broadly through open solicitation and public meetings.

In 2000 the independent investigators produced a report which was peer-reviewed and then reviewed by the Expert Panel. The Harvard investigators were given an opportunity to comment on the report but not to edit it. The report, Expert Panel review, and original investigator comments then were published by HEI (Krewski, Burnett et al. 2000). In addition,

the results have been published in the peer-reviewed scientific literature (Krewski, Burnett et al. 2003; Krewski, Burnett et al. 2005).

This complete access approach provided a transparent review of the quality of the data, reproduction of the original results, and analyses of the sensitivity of the findings to alternative methods and control for alternative explanations. While this process was comprehensive and successful, it was also long and expensive, making it less than an ideal model (Greenbaum, Bachmann et al. 2001). Moreover, since the data integrity and findings of the Six Cities study already has been reproduced, the argument for repeating this process seems weak.

The alternative approach is to allow specific, restricted access to interested investigators. As a groundbreaking study and as a valuable data resource, the Six Cities Study remains a potential resource for additional analyses. The Harvard investigators have been and continue to be open to collaborating with interested, qualified investigators to fully explore the use of these observational data for discovery and better understanding.

Interested investigators may apply to use specific data to address specific questions. This approach has been used in several similar large observational studies.

For example, the American Cancer Society (ACS) has a well-defined procedure for outside investigators to propose questions that could be addressed using the Cancer Prevention Studies (American Cancer Society 2013). Similarly, at Harvard, the Nurses' Health Studies have established procedures for proposing use of the data sets (Nurses' Health Study 2013).

Following the model of the procedures for the American Cancer Society and the Nurses' Health studies, we could create a formal procedure for requesting and monitoring access to data from the Six Cities Study, managing and monitoring analyses, and monitoring dissemination of results.

The first step would be to establish an independent expert panel to establish procedures, review applications, and monitor the process. One option would be to ask the existing *External Advisory Committee* of the Harvard Clean Air Research Center to take on this task.

Requests for access to data would require a formal application to the *External Advisory Committee*. Following the examples of the ACS and Nurses' Health studies, such an application could include the following elements:

- Specific hypothesis of the proposed analysis
- Scientific significance of the project
- Data variables required and analysis plan
- Reasons for proposing use of these data, rather than another source
- Sources of funding
- Qualifications of external investigator
- Identification and agreement of collaborating Harvard investigator

Upon approval of the *External Advisory Committee*, the external and Harvard investigators would enter into a formal agreement, which, again based on ACS and Nurses' studies examples, could include the following elements:

- All primary data, computer programs, and analysis results would be maintained on the Harvard computer servers, and all data analyses will be conducted on Harvard computers.

- Agreement on the role of Harvard collaborator(s) on the project, and authorship for specific publications arising from the work using the Harvard data.
- At least one member of the Harvard investigative team would be a coauthor on any manuscript resulting from this collaboration and, as such, would need to approve any manuscript prior to its submission for publication.
- Certification of Human Subject training for each investigator and approval from the Harvard School of Public Health Human Subjects Committee (Institutional Review Board).
- Prohibited use of the material for any purpose other than that explicitly stated in the proposal.
- Guarantee of the confidentiality of any data arising from the study, and agreement not to release data to any other person or group for any purpose, except with the explicit permission of Harvard investigators.
- Specification of terms for payment for time and effort by Harvard investigators.

As noted above, these procedures have been commonly applied in providing access of interested investigators to similar population based studies, while protecting confidential individual information. Given others' successful experience with this approach, Harvard stands ready to work on such a process with interested investigators.

I hope you find these comments helpful, and I would be pleased to provide additional consultation on these important questions. Please let us know if I can be of further assistance in this effort.

Best regards,

Douglas W. Dockery, ScD

xc: Michael Grusby, Catherine Breen

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